Evaluation of Young Adults' Preferences, Needs, and the Understandability of the Personal Health Record Data Contents

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This research study examines Personal Health Records (PHRs), focusing on the issues of data contents from the end users' perspectives. The study evaluates the understandability of the Continuity of Care Record (CCR) standard terminology currently used in PHR system and explores users' preferences and needs for data contents.

PHRs are becoming an increasingly important and popular means of enabling individuals to have more direct and stronger ownership and management of their health information. One of the potential barriers to the PHRs adoption is the usability of the system, particularly the fact that PHR data contents contain difficult terminology and does not meet the users' needs and preferences.

A review of currently available PHR systems shows that vendors are trying to design a comprehensive PHRs primarily based on data contents from the health providers' perspectives, especially the CCR standard. However, this comprehensive data set may be neither suitable nor appealing to most individuals with a busy schedule. Therefore, this research aims at identifying the needs and preferences of the primary users of PHRs with the ultimate goal of designing a user-friendly PHR system that caters to the specific and individual needs of a healthy young adult population.

A mixed-method of qualitative and quantitative research in the form of an exploratory-descriptive study was conducted to examine the individual's needs in terms of PHR contents and terminology. Data was collected through an in-depth, semi-structured interview.

Furthermore, a qualitative review study was conducted to identify each data element in the currently available free and for-purchase PHR systems and compare those with the CCR. The PHR included in this study were randomly chosen from the list of PHR tools and services available at www.myphr.com.

The results of this research provide insight for PHR developers, enabling them to better design and tailor PHR technology in order to fulfill the needs and desires of each specific individual group and subgroup. A PHR system tailored to the user's individualized needs will serve to make the user feel more comfortable using and maintaining it, and then could lead to wider adoption of PHR within the population.

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1.0 INTRODUCTION

1.1 BACKGROUND

The Personal Health Record (PHR) is rapidly emerging and evolving as a means to enable individuals to have easier access to their own health information (Appendix A). Unlike the traditional medical record, the PHR focuses on the individual as a person who wants to maintain his/her own health, not just as a patient. In fact, the PHR's ultimate goal is to keep a person from succumbing to a state of disease by promoting that individual's health and well-being (Munnecke & Kolodner, 2005). The PHR system, which allows individuals to control, maintain, and update their own health history, can be either paper-based or electronic (American Health Information Management Association, 2006; Clarke, Meiris, & Nash, 2006; Endsley, Kibbe, Linares, & Colorafi, 2006; Fahrenholz, Chery, Buck, & Staci, 2007; Markle Foundation, 2004; Waegemann, 2005). Due to limited accessibility of the paper-based PHR and difficulty controlling, maintaining, and updating it, it is a less desirable option than the electronic PHR. Moreover, Hurricane Katrina in 2005 proves the vulnerability of such paper-based health records. Once floods damaged medical records and prescriptions, thousands of people endured improper treatment or medical complications (Endsley et al., 2006; Lowes, 2006; Medical Software Companies, Pharmacy Benefit Managers, Chain Pharmacies, local & National Foundation, 2005; Tang, Ash, Bates, Overhage, Sands, 2006). Therefore, the government and

private organizations are focusing their efforts on development of the electronic health records and personal health records to ensure the continuity of care, enhance patient safety, and improve the quality of healthcare.

The study of the PHR system as an information technology has become an important aspect of healthcare transformation strategies in the government, public, and private sectors. For instance, the former President George W. Bush, who acknowledges the significance of computerized health records to prevent medical mistakes and to increase efficiency of care, envisions an electronic health record for every American by the year 2014 (Bush, 2004; Clarke et al., 2006; Ford, Menachemi, & Phillips, 2006; iHealthBeat, 2004; Lowes, 2006; Sprague, 2006). In addition, the former Secretary of Health and Human Services, Michael Leavitt, created the American Health Information Committee in order to coordinate efforts and expedite the process of shifting nationally from paper to electronic health records. Leavitt's initiative demonstrates the government's commitment to and enthusiasm for the transformation of healthcare in the US to an electronic environment (e-Health Initiative, 2007; Featheringham, 2005; Markle Foundation, 2006; Sprague, 2006). Other examples of those organizations committed to transforming into electronic health records are the American Health Information Management Association (AHIMA), American Medical Informatics Association (AMIA), American Health Information Community (AHIC), Agency for Health Care Research and Quality, and the Robert Wood Johnson Foundation.

Many studies and reports suggest that those individuals who maintain personal records of their health history bring more comprehensive information to points of care. By taking more ownership and control of their health information, they also have the potential to play a more active role in their health management (American Health Information Management Association,

2006; Clarke et al., 2006; Endsley et al., 2006; Featheringham, 2005; Lowes, 2006; Markle Foundation, 2004; Taylor, Bower, Girosi, Bigelow, Fonkych, & Hillestad, 2005; Waegemann, 2005). Knowledge enables people to notice any mistakes in their health information and to correct them accordingly. Furthermore, being in charge of their medical decisions empowers people to improve their overall health status and leads to a higher quality of healthcare services (American Health Information Management Association & American Medical Informatics Association, 2007; Mueller, Teslow, & Hallyburton, 2007).

Different types of consumers utilize PHRs based on their own specific health and family needs (Heubusch, 2007b). These consumers, distinguished as being "patients" or "healthy individuals", can be further divided into many subgroups. For example, the patient group could include those with chronic diseases, acute diseases, or specific conditions like pregnancy; it could also include families with children and elderly parents. The healthy group, on the other hand, could include the health-conscious individual as well as the average person. While health-conscious individuals closely monitor their diet, regularly exercise, and avoid negative habits like smoking and excessive alcohol consumption, the average person may either not pay attention to such matters or, in the best-case scenario, embrace them on an intermittent basis.

The author has conducted a qualitative investigation review study of currently available free electronic-based PHR systems. The results show that vendors are trying to design comprehensive PHRs primarily based on the health providers' perspectives and the Continuity of Care Record (CCR) (e-HIM Personal Health Record Work Group, 2005; Fahrenholz et al., 2007; Rodriguez, Casper, & Brennan, 2007). Appendix D provides a summary of the current ASTM CCR standard. The National Committee on Vital and Health Statistics (NCVHS) cites that because PHRs are still in their early stages, more time is needed to develop a unified and

conclusive standard of data elements (e-HIM Personal Health Record Work Group, 2005; Endsley et al., 2006; Fahrenholz et al., 2007; Rodriguez et al., 2007). NCVHS has pointed out that "there is no uniform definition of PHRs in industry or government, and the concept continues to evolve" (National Committee on Vital and Health Statistics, 2006). Therefore, for the purpose of this study we have adopted the American Health Information Management Association (AHIMA) definition of the PHR as "an electronic universally available, lifelong resource of health information needed by individuals to make health decisions. Individuals own and manage the information in the PHR, which comes from healthcare providers and the individual. The PHR is maintained in a secure and private environment, with the individual determining the right of access. The PHR is separate from and does not replace the legal record of any provider" (e-HIM Personal Health Record Work Group, 2005).

In order to create a PHR system that the end user, whether a patient or healthy individual, finds appealing and useful, consumers must be included in the early stage of design (Heubusch, 2007b; Rodriguez et al., 2007). Currently, the PHR development rarely adopts a user-centered design approach even though it is costly to incorporate the user's point of view once the design of the PHR is complete (Rodriguez et al., 2007). Failing to address the issue of what and how much the individual desires to know has become obstacle to the wide adoption of the PHR (Ariely, 2000). Therefore, a pressing need exists to examine and identify what data elements each group of consumers prefers to have in his/her PHR system (Heubusch, 2007b; Rodriguez et al., 2007). Research must also evaluate users' understanding of the CCR data elements terminology and acknowledge how individuals would like their PHR formatted in order to best display information with specific significance and relevance to them. Appendix E illustrates the

current standard specifications for CCR, which developers use as a reference to design the currently available PHRs.

This research aims to help fulfill this need by taking the opinion of consumers, the primary users of the PHR, into consideration in order to design a friendly PHR that caters to the specific and individual needs of a diverse population. Participants in this study consisted of a sample of healthy young adults at the University of Pittsburgh (ages 18-25) who, as shown by some studies, can be considered "early adopters" to PHR technology (for more details, refer to the methodology section). First, they were oriented to the research study; then, their level of understanding of the CCR terms was evaluated; finally, they were interviewed to identify their preferred PHR data elements.

1.2 RESEARCH MOTIVATION

Providing healthcare staff with accurate and complete health information about the right person at the right time is the key to successful medical decision making during a medical encounter. Lacking access to individual health information can lead to medical errors, inaccurate decision-making, and increased cost.

The American Health Information Management Association (AHIMA), as part of its electronic health information management (e-HIM) strategy for 2003 and beyond, aims to "promote the migration from paper to an electronic health information infrastructure" (American Medical Informatics Association, 2006; e-HIM Personal Health Record Work Group, 2005). In a step towards empowering patients, the Association developed myPHR, a component of an education campaign that encourages patients to have more control over their healthcare

(Abdelhak, 2005). In addition, one of the AHIMA efforts to promote the PHR is AHIMA's public service announcement (PSA), which has reached more than 700,000 viewers since its initial broadcast in the Albuquerque market on February 5, 2008.

While today's healthcare industry explores Personal Health Record (PHR) systems and examines the advantages to the adoption and utilization of the system, such as cost reduction, lessening of fragmentation in current healthcare delivery systems, improvement of the patient-physician relationship, empowerment of patients and other individuals caring for loved ones, enhancement of patient safety, and an increase in quality of care, the PHR remains in its infancy and needs time to be fully developed (Clarke et al., 2006; Endsley et al., 2006; Lowes, 2006; Markle Foundation, 2004; Ventres, Kooienga, Vuckovic, Marlin, Nygren, & Stewart, 2006).

Preliminary implementations show that the PHR is a helpful tool that provides patients with a better comprehension of and more control over their health issues and conditions, resulting in empowered patients (American Health Information Management Association, 2006; American Health Information Management Association & American Medical Informatics Association, 2007; Clarke et al., 2006; Endsley et al., 2006; Markle Foundation, 2004; Ventres et al., 2006; Waegemann, 2005). However, more research is needed to adequately understand and address all issues related to the PHR (American Health Information Management Association & American Medical Informatics Association, 2007; Armijo, Mark, Chin, John, Allison, Kneale et al., 2006; Civan, Skeels, Stolyar, & Pratt, 2006; Conemaugh Health System, 2007; Cronin, Lober, Esterhay, & Dimitropoulos, 2007; Gearon, 2007; Heubusch, 2007b; Kukafka, 2007). Necessary research includes study in the following areas: confidentiality of patient information, web security, reimbursement and incentives for physicians who use electronic consultations, liability concerns, attitudes of individuals toward owning, accessing, and managing their health

information using the PHR system, and consumer preferences and needs with respect to specific content of the PHR.

This study addresses this last issue. To evaluate the level of user's understandability of CCR terms, and to investigate the preferences and needs of healthy young individuals with regards to the PHR system. It explores what information-specific data elements users want to include in their PHR. With individuals having different expectations and needs concerning the use of the PHR system, there is an urgency to examine the specific demands of different types of users and to enable tailoring of a PHR system more suited to each individual. Designing an ideal PHR which fits the specific criteria of the user(s) will undoubtedly have a positive impact on the development, utilization, and maintenance of the PHR system.

This study included healthy young adults for the following reasons. First, none of the current studies on design of PHR and evaluation of users' satisfaction with the PHR system acknowledged this group of individuals, which constitutes a large segment of the population. While the Agency for Healthcare Research and Quality and the Robert Wood Johnson Foundation have funded many large projects involving design of PHR systems for non-healthy groups, such as diabetic patients and women with breast cancer, they have not funded studies examining designs for healthy young adults. Second, this study determined the inclusion criteria based on the characteristics of the "early adopters" of the PHR system. These attributes are individuals who are young (age 18-25), are usually healthy, more educated, motivated, enthusiastic, and technologically savvy—having reasonable competency in using computers and accessing the Internet—(Fowles et al., 2004, Lake research partners & American view point, 2006, Munir& Boaden, 2001; Williams et al., 2001, Munir& Boaden, 2001, Leonard, 2004). Third, with limited funding, the personal and organizational costs to gather information from

non-healthy individuals would be prohibitive, especially when the main method of collecting data would be in-depth interviews that last approximately ninety minutes. Since the PHR's ultimate purpose is to prevent disease and promote health and well-being by enabling individuals to manage their own health information, it should be accessible to all competent adults regardless of the presence or absence of any kind of disease. Moreover, since PHRs have a diverse user base, it is difficult to obtain meaningful feedback from all potential users at once. Therefore, for the purpose of this study, we targeted a sample of young, healthy individuals to obtain a deeper understanding of their expectations and needs, which will then form a foundation to expand the body of knowledge to another population in the future.

As a result, upon completion, this research will yield a better understanding of the type of information that is most relevant to individual users. Also, gaining knowledge of individuals' reasons for using or not using the PHR and determining participants' understanding of the commonly used PHR vocabulary and healthcare provider terminology will enable policy makers, private organizations, healthcare providers, and advocates of the PHR to explore and identify new approaches that can encourage the widespread acceptance of the PHR by all individuals.

1.3 SPECIFIC AIMS AND RESEARCH QUESTIONS

The specific aims of this research study are:

1. To measure the young adults' level of understandability of Continuity of Care Record (CCR) data items.
2. To discover end-users' needs, expectations, and PHR preference in terms of information included and vocabulary used for specific data elements.
3. To determine how the data elements of PHRs differ for the needs of end-users and healthcare providers.
4. To review the existing PHR systems to validate the usefulness of current PHR systems based on the minimum data set recommended by the ASTM CCR standard.
5. To establish the differences in PHR data elements across existing PHR systems, in order to identify areas of improvement for the future revision of the PHR standard.

In order to reach these specific aims**,** this research study will answer the following three research questions:

1. How easy is it for a young adult user to understand the Continuity of Care Record (CCR) data items?
2. To what extent do healthcare providers and users have different needs regarding the data elements of the personal health record system?
3. How do the data elements of the currently available PHR systems differ from the Continuity of Care Record (CCR) standard?

1.4 PROBLEM STATEMENT

Different providers at several locations gather patient health information (Appendix B) that spans a large period, often from birth to death. These healthcare providers may make their medical decisions (diagnosis, choice of therapy, plan of treatment/care, prognosis, etc.) based on incomplete, inaccurate, and scattered data; some of these decisions are intuitive and not rooted in evidence-based practice (Rohrer, 2006). This leads to instances of inaccurate decision-making, increased costs, and medical errors, which result in a significant number of avoidable deaths. For example, some reports show up to 98,000 deaths annually are a result of preventable medical errors, one-fifth of these errors being related to the lack of immediate access to accurate and complete patient health information (Benjamin, 2000; Institute of Medicine's (IOM), 1999; Starfield, 2000; The Cance Cure Foundation, 2000). One study ranks this as the eighth leading cause of deaths in the United States, and another lists it as the third (IOM's Committee on the Quality of Health Care in America, 2001; Starfield, 2000; The Cance Cure Foundation, 2000). With access to Personal Health Record (PHR), healthcare providers should have a clearer understanding of each case and to more reliably make the appropriate decisions for each patient. This would increase patient safety and prevent unnecessary medical errors (Markle Foundation, 2004).

Although individuals have been using the PHR, especially the paper format, for a long time, professionals still consider it to be in its early stage of development (Bush, 1945; Cimino, Elkin, & Barnett, 1992; Clarke et al., 2006; Endsley et al., 2006; Lowes, 2006; Markle Foundation, 2004; Ventres et al., 2006). A fairly limited number of studies of the PHR system has been conducted and published to date (Delbanco & Sands, 2004; Tang et al., 2006; Wang, Lau, Matsen, & Kim, 2004). Nonetheless, many studies by such leading organizations and agencies as the American Health Information Management Association (AHIMA), the American Medical Informatics Association (AMIA), the Markle Foundation, California HealthCare Foundation, and the Agency for Healthcare Research and Quality, as well as other public or private agencies, scholars, and researchers, have concluded that Americans favor the use of the PHR. However, the overall PHR adoption rate in the US is a mere 10% to 15% and its adoption rate among patients who actively managing chronic conditions is only 30% to 40% (Heubusch, 2007a; Sprague, 2006; Ventres et al., 2006).

Once individuals understand the full potential of the PHR, they can be proactive in taking the responsibility to create, complete, and maintain their own health information by adopting a PHR system. In fact, many studies found that 72% of the public favor the PHR as a new technology with only 23% opposing it (Delbanco & Sands, 2004; Heubusch, 2007a, 2007b; Kane & Sands, 1998; Markle Foundation, 2005; Ventres et al., 2006). However, a study by Manhattan Research shows that only 1% of the public actually uses PHRs (Heubusch, 2007a). Rodriguez et al. (2007) argue that the main reason for PHR systems low utilization is that most of the commercial and non-commercial PHRs are: 1) traditional, i.e. provider-centered, with a design based almost entirely on the health providers' perspective and the Continuity of Care Record (CCR). 2) give little attention to involving users in the design stage; and 3) fail to address the

needs and preferences of end users (Bonander, Crawford, Kukafka, Daniel, & Mandl, 2007; Heubusch, 2007a, 2007b). These studies show that user involvement and participation in the early stage of the design process of PHR system is crucial for their adoption and utilization as a part of users' daily life. That is, they suggest that obtaining users' viewpoint and incorporating this in the design, could enable users to have more control over the PHR contents and personalized data elements to better fit their needs, will result in higher usage. In addition, because the average user usually will not have the medical knowledge and background of a healthcare provider, simple, clear, and understandable vocabulary and terminology must be provided for a lay person to use the system easily (Armijo et al., 2006; Sherrilynne, 2007; Sittig, Masys, Brennan, Chute, & Oberle, 2007; Smith, Treitler, keselman, & Zielstorff, 2007; Zeng & Tse, 2006).

In order to have a PHR that is both appealing and helpful to the end users, whether patients or healthy individuals, developers must include these users in the early stage of design (Bonander et al., 2007; Bosworth, 2007; Rodriguez et al., 2007; Sherrilynne, 2007). In fact, Vera Rulon, MS, RHIT, CCS, presented her opinion at a seminar at the AHIMA's 2007 convention, saying, "Anytime you need to effect a change, it is really about the people, not so much the technology." She also said, "Technology can do anything, but just because we build technology that is useful doesn't mean people are going to use it" (Rulon, 2007). Therefore, developers have to design technology with users in mind. Currently, PHR development rarely adopts a patient-centered design approach (Rodriguez et al., 2007). Failing to address the issue of what type of information and how much of it each individual desires impedes the wide utilization of the PHR (Ariely, 2000). Therefore, a pressing need exists to examine and identify what data elements and terminology each group of users prefers in a PHR system (Heubusch,

2007b; Rodriguez et al., 2007). In addition, research must identify how consumers prefer their PHR to be formatted in terms of specific significance and relevance to them.

Little research currently focuses on the perspectives of the product's primary user, an important key for a widespread use of the PHR (Bosworth, 2007; Cronin et al., 2007; Heubusch, 2007a, 2007b; Rodriguez et al., 2007).

1.5 SIGNIFICANCE OF THE STUDY

The results of this study will be valuable in many ways. First, they will provide insight for personal health record systems (PHR) vendors and developers as to how to better design and tailor PHR to fulfill the widely varied health needs and desires of the potential end users. Individuals can then feel more comfortable using PHR designed for their own individualized needs. Second, the data gathered from the participants in the in-depth interview will be used to answer the research questions in an effort to further expand the existing body of knowledge on different target populations of either healthy or non-healthy individuals in different age groups. The published results will provide a basis for further research and investigation by eliciting users' needs and expectations, with which designers can generate new ideas regarding strategies for overcoming barriers to use of the PHR. Third, the findings will provide valuable information to healthcare policy makers, research-funding agencies, PHR users, and stakeholders about what changes are necessary to promote PHR. Fourth, the results will address the concerns of the Health Information Management Research Team, School of Health and Rehabilitation Sciences, University of Pittsburgh, about the needs of the users to aid in development of the optimal MyHealthBits Advance Personal Health Information Management. Finally, the study's results

will yield a better understanding of the level of users' knowledge, of how to assist individuals in the establishment and maintenance of the PHR system, and how to satisfy the specific preferences and needs of users.

2.0 RELATED WORK

2.1 PERSONAL INFORMATION MANAGEMENT SYSTEM

Personal Information Management System (PIMS) technology is becoming increasingly significant in both the work and home environments. This technology includes any information system owned and controlled by an individual, such as decision support systems, resource and people management applications, project management, or database retrieval applications. This type of system can be developed for personal use—employing and supporting the processes of acquisition, organization, maintenance, retrieval and presentation of information in a meaningful manner. Therefore, this technology must be designed based on end users' needs and preferences. This includes precise data contents that are relevant to end-users and understandable terminology and vocabulary. Ideally, a system tailored to the user's individualized needs will serve to make the user feel more comfortable using and maintaining it. This tailoring, then, could lead to the expediting of the adoption of that system among individuals, which is essential for the usability of PIMS (Barreau, 1995; Bellotti & Smith, 2000; Boardman & Sasse, 2004). The focus of this research is on one type of PIMS—Evaluation of Young Adults' Preferences, Needs, and the Understandability of the Personal Health Record Data Contents.

Many studies have concentrated on the organization, management, and retrieval of paper and electronic documents such as files, emails, bookmarks, appointments, reminders, and contacts, and shown the importance of PIMS in increasing productivity, and reducing time and effort while increasing accuracy with sharing of information (Barreau, 1995; Boardman & Sasse, 2004; Fertig, Freeman, Gelernter, & 1996; Ofer, Ruth, & Rafi, 2003). Many other studies also have shown that empowering individuals by giving them the ownership of their health information has a significant positive impact on their health (Patterson, Luckmann, Sherman, & Vidal, 2007; Wolter & Friedman, 2005).

Barreau and Nardi (1995) investigate the similarities and differences in electronic filing and finding methods among users of different operating systems to identify the types of documents used and to determine "the factors affecting individual decisions to acquire, organize, maintain, and retrieve information" (p.39). They point out that regardless of what operating system they used, users employed similar finding location-based techniques and that users considered archived files not as important as other files. However, one interesting finding was the difference in the use of subdirectories between the DOS/Windows users and Macintosh users: DOS/Window users did not employ subdirectories while Macintosh users used them often because they are flexible and easy to understand. The authors claim that people often feel frustrated by the high amount of collected information both in the work and home environments making people feel unorganized and vulnerable. They also report that people have difficulty in deciding which information is important and relevant and which is not, so they usually have a fear of deleting any kind of information stored in their computer, even if they have not used it for a long time.

Efficient and effective organizing, storing, recalling, and retrieving mechanisms have been widely investigated. According to Bergman et al. (2003), there are three principles for effectively organizing PIMS, drawn from the User-Subjective Approach. First, the Subjective Classification Principle suggests that all different types of information (notes, to-do-lists, electronic documents, e-mails, pictures, graphs, bookmarks of Web pages, etc.) that are related to the same theme should be classified, grouped, labeled, and stored according to personal cognitive schemes under a labeled root folder. This root folder makes sense to the user to recall and retrieve specific pieces of information easily. The second principle, the Subjective Importance Principle, concludes that most information important and relevant to users should be located and stored in a visible, noticeable, and easy-to-access location to eliminate any dissatisfaction, distraction, and interruption from low-importance items. Finally, the Subjective Context Principle demonstrates the importance of retrieving and viewing the information in the context encountered during the process of the first interaction with it.

Barreau (1995) discovers that there is a relationship between content of information and classification decisions. He asserts that each person has his/her unique way to personalize and classify information in a way that is convenient, accessible, and understandable in order to facilitate the retrieving and recalling process (in reasonable time) of the right information at the right time, especially in critical situations. Fertig et al. (1996); however, argue that users employ a categorization mechanism when organizing different type of information and consider that a location-based technique as a foundation for organizing and retrieving personal information is not practical because of its disadvantages.

In addition, Barreau and Nardi (1995) believe that old information is perceived to be unimportant and rarely used. Fertig et al. (1996), on the other hand, report that archived information may be needed sometime in the future, and it is important to be able to retrieve this information in a convenient and easy way. Healthcare professionals agree with Fertig et al. (1996) in believing that storing, organizing, and retrieving archived information is crucial, because most health information, such as x-rays, immunizations, past surgeries, and annual physical examinations, is archived. In fact, Fertig et al. (1996) have developed a life stream system that enables users to perform a logical search of archived information, and provides a reminder, meeting schedule, and to-do-list capability. They recommend further studies to examine users' preferences in order to develop a richer and more functional interaction environment.

In Jones et al.'s research study (2006) "Planning personal projects and organizing personal information," researchers examine participants' daily activities and discover different methods employed to organize personal information with the use of a variety of personal information management (PIM) tools, such as a personal computer, personal digital assistant (PDA), and smart phones. They discover information fragmentation problems are common due to the large and overlapping amount of information the participants encounter daily at work and home. They report that participants are usually involved in many projects at the same time, which includes dealing with paper and e-documents, e-mails, and Web pages. Participants generally employ a folder hierarchy structure (folder-subfolders-sub-sub folders, etc.) as a strategy to organize and manage their personal information (Jones, Bruce, Foxley, & Munat, 2006); however, participants considered PIM tools to be too sophisticated and not user-friendly.

Similarly, in the project "Keeping Found Things Found", Bruce et al. (2004) investigate the leaving and keeping behavior that is associated with personal information collection with the intention to reuse the information at a certain point in time. Authors observe different strategies employed by librarians, managers, researchers, and students to manage and organize different types of information that they encounter on the Internet. For example, they "make a bookmark or favorite; do nothing to save but search again to re-access; do nothing to save but enter the URL directly; send e-mail to others; do nothing to save but access another website; print out the Web page; and send e-mail to oneself" as the most popular methods for keeping important information to re-use. More importantly, each person has his/her unique way of organizing and managing their personal information, and the use of folder hierarchies to organize and represent this information is common among different occupational groups (Bruce, William, & Dumais, 2004).

Obviously, people will be willing to use a new technology if they are convinced that it is what they need to make their life easier, especially if that technology is affordable, has a friendly user interface, and is accessible and useful to them. There are many available methods for retrieving and presenting such information, for instance, retrieval of a certain piece of information can be organized according to type, time, or event. The researchers of the study "LifeLines: Using Visualization to Enhance Navigation and Analysis of Patient Records" analyze the ability of an online LifeLines visualization technique to present the comprehensive data of a computerized patient and healthy individuals' medical records including data, such as problems, allergies, diagnosis, labs, imaging, medications, and immunizations. They report that the LifeLines display has a positive impact on the usability of electronic medical records because

it gives the overall data of an individual on a one-screen display (Plaisant, Mushlin, Snyder, Li, Heller, Shneiderman et al., 1998).

2.2 DEFINITIONS OF PERSONAL HEALTH RECORDS

Professional organizations and foundations each offer definitions of Personal Health Records (PHRs) with the goal being to generate the most comprehensive and agreed upon definition. For example, the American Health Information Management Association (AHIMA) defines the PHR as "an electronic universally available, lifelong resource of health information needed by individuals to make health decisions. Individuals own and manage the information in the PHR, which comes from healthcare providers and the individual. The PHR is maintained in a secure and private environment, with the individual determining the right of access. The PHR is separate from and does not replace the legal record of any provider" (e-HIM Personal Health Record Work Group, 2005). The American Medical Informatics Association (AMIA) describes the PHR as "an electronic application through which individuals can access, manage, and share their health information, in a private, secure, and confidential environment; personal data created, developed, and/or provided by individuals about themselves" (American Medical Informatics Association, 2006). The Markle Foundation's committee, representing the private and public sector, suggests that a PHR is "an electronic application through which individuals can access, manage and share their health information in a secure and confidential environment. It allows people to access and coordinate their lifelong health information, and make appropriate parts of it available to those who need it" (Markle Foundation, 2004).

For the last few years, PHR advocates have attempted to create a universal definition of the PHR for widespread use. Despite their efforts, it seems there is little agreement among scholars on a unified definition of this technology. The National Committee on Vital and Health Statistics (NCVHS) states that it is difficult and undesirable to come up with a unified definition of PHRs at the present time. It cites that because PHRs are still in an early stage of development, more time is needed to come up with a unified, conclusive definition (National Committee on Vital and Health Statistics, 2006). Similarly, Sprague (2006) raises a critical question regarding the nature of the PHR. She argues that not only is a specific and meaningful definition of the PHR to all parties still lacking, but it is also not clear what constitutes PHRs (Sprague, 2006). Her study further reports that clarification is needed to determine whether the PHR is the data contained in PHRs, the process which facilitates data accessibility, the applications used by the individual to use the data, or all of these (Clarke et al., 2006; Endsley et al., 2006).

2.3 STAKEHOLDERS OF PERSONAL HEALTH RECORDS

The two distinct groups who have the greatest interest in creating and maintaining Personal Health Records (PHRs) are consumers (patients and their caregivers or healthy individuals) and healthcare providers (physicians or hospitals). Other stakeholders who have a stake in PHRs may include payers, employers, organizations, government, and health insurance companies (Delbanco & Sands, 2004; Fahrenholz et al., 2007; Kane & Sands, 1998; Markle Foundation, 2004; National Committee on Vital and Health Statistics, 2006; Ventres et al., 2006). While many studies and reports have suggested that consumers and healthcare providers favor PHRs as a general concept, these two groups of stakeholders have different opinions regarding the PHR

and its applications based on the stakeholders' needs and uses (Fahrenholz et al., 2007; Ferris, 2007). For example, consumers may be more interested in the ease and convenience of recording particular data contents, such as tracking their daily physical exercise (jogging, walking, etc.) by using wearable health monitoring devices, such as BodyMedia, GlobalSat Personal GPS Sport Watch With Heart Monitor, or a pedometer to continuously record individual heartbeat, calorie intake, etc. Others may be more interested in electronically requesting a consultation with a healthcare provider without the need of being physically present in the doctor's office through the use of e-mails, instant messaging, or videoconferencing (Markle Foundation, 2004). On the other hand, physicians may emphasize knowing detailed data contents, such as the allergies of the patient, the history of the patient's previous illnesses, conditions, and surgeries in order to reach an accurate diagnosis and to avoid any possible negative drug interactions (Bush, 2004; iHealthBeat, 2004; Lowes, 2006; Markle Foundation, 2004).

Each group has different views concerning whether or not to maintain PHRs and which applications are the most useful and beneficial (Rodriguez et al., 2007). Patients with a family history of hereditary diseases may prefer a PHR system whose applications will help them deal with a specific genetic health issue. Patients with multiple chronic diseases may have other types of concerns so that applications used by the former group do not fit their specific health needs. Furthermore, pregnant women or families with small children will have totally different issues and needs than the previous two populations (Gary, 2006; Heubusch, 2007b). They may be interested in having a PHR system whose applications archive ultra sound images, keep records for immunizations, and update weight charts for growing babies. Another group of consumers constitutes the healthy individuals, singles or couples, who do not have a family history of

disease, a chronic illness, or children. This group tends to focus on living and maintaining a healthy life style. Such individuals will have an interest in applications that keep track of their healthy eating habits, nutrition supplement intake such as herbs and vitamins, cholesterol level, exercise regimen, weight, and body mass index among other related PHR data elements (Gary, 2006; iHealthBeat, 2004; Markle Foundation, 2004).

It is obvious, then, that different types of consumers utilize PHRs based on their own specific health and family needs (Heubusch, 2007b). These consumers, broadly distinguished as either "patients" or "healthy individuals," can be further divided into many subgroups. For example, the patient group could include those with chronic diseases, acute diseases, or a specific condition like pregnancy; it could also include families with children and elderly parents. The healthy group, on the other hand, could include the proactive, health-conscious individual as well as the average person. While health-conscious individuals closely monitor their diet, regularly exercise, and avoid negative habits like smoking and excessive alcohol consumption, the average person may either not pay attention to such things or, in the best-case scenario, embrace them on an intermittent basis.

2.4 RELATIONSHIP BETWEEN ELECTRONIC HEALTH RECORDS AND PERSONAL HEALTH RECORDS

As envisioned by the American Health Information Management Association (AHIMA), American Medical Informatics Association (AMIA), the Markle Foundation, and similar organizations and foundations, Personal Health Records (PHRs) should ideally comprise health information derived and imported from patients' Electronic Health Records (EHRs). While the EHR, also known as a Computer-based Patient Record (CPR), Electronic Medical Record (EMR), or Electronic Patient Record (EPR), and PHR may share common and overlapping health information about patients, they are two different entities (Appendix C). EHRs, designed for use by healthcare providers and clinicians, are defined as "personal data created, developed, maintained and/or provided by providers, clinicians, and allied health providers in direct patient care; or it is an electronic application containing health information about individuals that is used by clinicians, providers, and allied health professionals to provide direct care for the individuals." (American Medical Informatics Association, 2006; Tang et al., 2006). A well-developed and accurately implemented EHR is a key element in the success of PHRs, because the latter heavily depends on the former. The electronic format of PHRs is the optimal one because its absence makes it difficult to have paper-based PHRs that are comprehensive and responsive to changes in individuals' health. In fact, paper-based PHRs are a less desirable option than the electronic PHRs due to their limited accessibility and difficulty in being controlled, maintained, and updated. Hurricane Katrina in 2005 proves the vulnerability of such paper-based PHRs. Once floods damaged medical records and prescriptions, thousands of people endured improper treatment or medical complications (Endsley et al., 2006; Lowes, 2006; Medical Software Companies et al., 2005; Tang et al., 2006).

Both EHRs and PHRs have similar functions and complement each other (Markle Foundation, 2004). When both are properly implemented, they will ensure an exchange of patients health information among healthcare providers that better coordinates the healthcare provided to patients, especially those 100 million Americans with multiple chronic conditions (Burton, Anderson, & Kues, 2004). Also, the integrated EHR/PHR will prevent medication errors, provide a basis for avoiding drug interactions, duplicate prescriptions, and reduce redundant laboratory testing. Moreover, future applications should empower patients to participate in managing their own health. For example, patient could use the CCR, as a part of their PHRs, on their home computer to review medications, to identify drug-drug interactions, and/or to synchronize their healthcare schedule with their cell phone, PDA, smart phones (iphone, Black Berry, Android) or iPods (Ferranti, Musser et al., 2006; Markle Foundation, 2004; Records For Living, 2006). Consequently, the PHR will have a strong, positive impact on individual's healthcare quality and patient safety.

2.5 CONTENTS OF PERSONAL HEALTH RECORDS

The American Health Information Management Association (AHIMA), American Medical Informatics Association (AMIA), and Markle Foundation suggest that ideal Personal Health Records (PHRs) should be a comprehensive one that contains minimum data contents and be based on the CCR (Appendix D). Ideal PHRs include all the relevant information concerning the health of an individual or of a family member, such as an ailing spouse, an elderly parent, or a dependent child for whom the individual cares. For example, patients with multiple chronic conditions might have reports that are not present in a healthy individual's PHRs. Their forms may include information about renal dialysis, EEG, range of movement for knee conditions, and relevant consultation reports from other specialists. In any case, a typical PHRs should contain the following forms and data: identification information, next of kin information, health insurance information, living will and advance directives, organ donor authorization, history and physical, progress notes, physician's orders, medications, immunization records, allergies, drug reactions, family illness history, recent physical exams, specialists' consultations, X-rays and lab results, eye and dental records, correspondences with physicians and other healthcare providers, release of information form and other consents, and any other information of relevance, such as food regimen, reminders or e-mail notification of appointments, live data exchange with healthcare providers, and daily living habits, such as smoking, diet, and exercise habits (American Health Information Management Association, 2006; Endsley et al., 2006; Markle Foundation, 2004; Matthew & Johnson 2002).

While not wrong, this comprehensive or ideal view of the PHR contents can create some problems. First, a PHR system that includes a snapshot of the individual's entire personal health and healthcare history might be acceptable for patients with a chronic disease; however, it is not suitable for all types of patients (Heubusch, 2007b). This "ideal" version of a PHR system, for example, might not be appropriate for the younger population that tends to be healthier. Second, unified and lengthy PHRs for all types of individuals pose a real barrier to the widespread utilization of PHRs endorsed by promoters and advocates. Third, a vast amount of information, which seems beneficial, can also cause confusion, making it difficult for an individual to make sound decisions (Ariely, 2000; Edgman & Cleary, 1996). In fact, people already often feeling frustrated from information overload both in work and home environments and have difficulty in deciding which information is important and relevant—the same feelings could result from complicated PHRs (Barreau & Nardi, 1995). Fourth, patients with chronic diseases might have an edge when it comes to medical terminology in comparison with a lay person, who would no doubt find such medical terms to be foreign, with no significant value to their health status (Heubusch, 2007b). This approach of "one size fits all" might not be the right answer when it comes to PHRs. Because people have dynamic, changing lifestyles and habits, a static, inflexible, or unresponsive PHR system does not serve their needs (Munnecke & Kolodner, 2005). Specially tailored PHR systems that cater to the specific demands of users are key to the success and implementation of PHRs among all types of people, including patients, people with special situations, and healthy individuals (Heubusch, 2007b; Rodriguez et al., 2007).

2.6 TYPES OF PERSONAL HEALTH RECORDS

In the past few years, personal health records (PHRs) have become more acceptable as a way to store and share the health information of individuals, whether patients or healthy people, with authorized users (Munnecke & Kolodner, 2005). The PHR complements and is considered to be an element of the electronic health record used by healthcare professionals and providers (Sprague, 2006). It is also more comprehensive than the EHR as it includes information added by individuals such as diet and exercise routine. The healthcare industry embraces these PHRs for two main reasons. First, the PHR can overcome the national lack of interoperability among health information systems. Second, individuals/patients are becoming more familiar and comfortable with using the Internet on which the PHR is primarily based. In general, information in personal health records comes from two main sources. The first is the individual/ patient or the person acting as a caregiver. Healthcare providers and clinicians, including physicians, nurses, pharmacists, and insurance companies are the second source of information (Markle Foundation, 2004).

Regardless of the source of information, personal health records can be categorized in the following five ways (American Health Information Management Association, 2006; Clarke et al., 2006; e-HIM Personal Health Record Work Group, 2005; Endsley et al., 2006; Gearon, 2007; Markle Foundation, 2004; Sittig, 2002; Sprague, 2006; Waegemann, 2005):

1. Paper-based PHRs: Like those kept in file folders, these may include insurance claims and immunization records. Individuals or personal caregivers usually create and maintain this simple type of PHR.
2. Web-based commercial/organizational PHR: As the name implies, this type of PHR stores the health information on the Internet. This allows flexible accessibility to

different individuals in different places. The individual may either access his/her health information on a website or authorize a specific physician or healthcare provider of choice to access and view the entire PHR or certain segments on a secured web site. This service may be provided in four different ways:

A. As a free-based service in which a commercial organization supports the free service and generates revenue through data mining or use of sponsors.

B. As a fee-based service, where users are charged for the provision and maintenance of an individual's health information.

C. As a member benefit service by a professional managed care organization for a fee or free of charge, as in the case with consumers of health plans or health providers. Health plans or an employer create, maintain, and make this type of PHR available to more than 70 million Americans. This widely available form of the personal health record, referred to as "tethered," is handicapped by its lack of portability and loss of access due to employment or insurance changes (Sprague, 2006). A more sophisticated form of the personal health record is provided either by a single provider such as a solo physician or by an organization such as a hospital as part of an electronic health record. This comprehensive form of the PHR, which stores the patient's clinical information, is designed to accept data from different sources.

D. As a free service provided to a specific population by a local, regional, or national health authority (e.g. public health service).

3. PC-based PHR: The individual personal computer stores the health information. This format lacks an exchange capability since no direct Internet access enables a

flexible sharing of information among providers. Further, it does not allow healthcare providers to access and update the individual's health information.

4. Hybrid desktop/Web-based: This mixed format allows the person to maintain the PHR on his/her personal computer and provides an upload facility to a secure Web server.
5. Portable devices: In this format, the individual can store health information on a variety of storage media including smart cards, personal digital assistants (PDAs), mobile phones, and memory flash cards. The portable devices can be used either separately or as complements or back-ups for the desktop, web, or hybrid-based PHR. Portable devices like smart cards have many advantages, including easy portability and access for sharing. Still, they possess major disadvantages: they are vulnerable to being lost or stolen and they have read-only access for patients, which allows only health professionals to update information (Aubert & Hamel, 2001).

2.7 CONTINUITY OF CARE RECORD (CCR)

Different organizations, foundations, and associations that are interested in both the electronic and personal health record technologies have attempted to define, explain, and develop a health record standard, such as the Continuity of Care Record (CCR) to ensure interoperability and interchangeability among different healthcare systems. Despite their efforts, there is little agreement on the definition of this concept among researchers. For example, the American Academy of Family Physicians (AAFP), defines the CCR as "a way to create flexible documents that contain the most relevant and timely core of health information about a patient, and to send these electronically from one care giver to another" (Kibbe, 2008). The American Society for Testing and Materials (ASTM) International, on the other hand, defines the CCR as a ''summary of the patient's health status (e.g., problems, medications, allergies) and basic information about insurance, advance directives, care documentation, and care plan recommendations" (The American Society for Testing and Materials (ASTM International, 2008). While Claudia Tessier, CAE, RHIA, co-chair ASTM, suggests that the CCR is "A snapshot in time: A core dataset of the most relevant facts about a patient's healthcare, organized and transportable, prepared by a practitioner at the conclusion of a healthcare encounter; to enable the next practitioner to readily access such information, which may be prepared, displayed, and transmitted on paper or electronically" (Tessier, 2004).

Generally speaking, the CCR is a unique standard that has resulted from an extraordinary effort by various sponsors and volunteers, such as ASTM International, Massachusetts Medical Society, Health Information Management and Systems Society (HIMSS), American Academy of Family Physicians (AAFP), American Academy of Pediatrics, American Medical Association, Patient Safety Institute, American Health Care Association, patients, and patient advocates. All of these groups have agreed on the minimum data contents and characteristics of the CCR standard.

Unfortunately, with the current healthcare system, all patient health information is scattered among different healthcare providers in various locations. The CCR standard can bridge the information gap between them, hence enhancing patient safety and improving the continuity and quality of healthcare. Therefore, the CCR should contain the recommended minimum data set that will communicate and support both the electronic and personal health records. This minimum data set includes the following items: identification information, next of kin information, health insurance information, living will and advance directives, organ donor authorization, history and physical information, progress notes, physician's orders, medications, immunization records, allergies, drug reactions, family illness history, recent physical exam information, specialists' consultations information, X-rays and lab results, eye and dental records, correspondence with physicians and other healthcare providers, release of information forms and other consents, and will also include data from specific aspects such as long-term care, disease management, acute care, and personal health records that may contain any other information of relevance such as food regimen, reminders or e-mail notification of appointments, live data exchange with healthcare providers, and daily living habits, such as smoking, diet, and exercise (Tessier, 2004).

The CCR is unique in that it has the ability to communicate with other electronic systems through the use of the World Wide Web Consortium standard of Extensible Markup Language (XML), which is readable by both machine and humans. This is important when an emergency occurs, a referral needs to be completed, a transfer of information is necessary, a discharge is taking place, or in case information is needed to improve epidemiological research or to develop Personal Health Records (PHRs). Its data items may be displayed or printed using a variety of tools and software such as a web browser, PDF reader, or word processor. Also, with the Health Level 7 (HL7), Clinical Document Architecture (CDA), and CCR standard, health data can be easily prepared, transmitted, exchanged, and displayed between other compatible systems (browser, HL7 CDA-compliant document, secure email, etc.).

This information must be complete, accurate, clear, and up-to-date about patient health status to avoid any unnecessary medical errors and delay in providing healthcare.

Healthcare providers and support staff (physicians, nurses, social workers, and physical therapists) are responsible for keeping the patient information in the CCR updated and ready for access by any future healthcare providers at a new point of care. There are many applications for the CCR. First, it will be a vehicle that provides a reliable, efficient, and effective communication channel among all healthcare providers, whether they are in the same facility or at different organizations. It can provide comprehensive and up-to-date health information, patient's allergies, medications, current and recent past diagnoses, and other pertinent information, about the right patient at the right time, patient's most recent healthcare assessment and services and recommendations of the caregiver who last treated the patient, which is crucial in any medical encounter because it enable caregivers to make accurate medical decisions. This, in turn, leads to high quality and efficiency of care, improvement in patient safety, a reduction in

medical errors and supports continuity of patient care and high patient satisfaction (U.S. Department of Health and Human Services, 2006). Second, the CCR helps reduce or eliminate duplicate tests and allows patients to receive faster, safer treatment and care in an emergency, which may save patients' lives. Also, it saves time, effort, and minimizes the workflow disruption for healthcare providers, which leads to increase productivity (Ferranti et al., 2006), as various caregivers do not have to repeatedly ask a patient for demographic information in detail. Rather, this information can be quickly and easily verified. Third, the CCR empowers individuals, enabling them to improve their self–efficacy, i.e. the availability of their individual health information will help them to be more active and involved, in their own healthcare, giving them a greater stake in the outcome. Also they gain a broader understanding of the issues regarding their health, leading to more informed care decisions and better health choices as well as experience improved relationships with their healthcare provider. Fourth, because the CCR is interoperable (deals with electronic communication and documentation); it helps to expedite the adoption of both Electronic Health Record (EHR) and PHR. In other words, it facilitates the exchange of clinical and administration data between incompatible systems by importing and exporting the CCR data.

The relationship between the ASTM standard and EHR and PHR has been investigated by many researchers (Chheda, 2005). For example, the study of the awareness, use, and validity of the minimum contents recommended in the ASTM standards for content and structure of electronic health records concludes that the majority of respondents (75%) have little or no awareness of the existing standard. Also, among respondents there was shown to be a need for differing specific minimum data elements to be included in the electronic health records (Watzlaf, Zeng, Jarymowycz, & Firouzan, 2004).

The development of a standard has become an important aspect of PHR systems. Currently available PHR systems to date have been designed almost exclusively from the perspective of healthcare providers. These systems fail to address the needs, expectations, preferences, skills (level of understandability of CCR terms) of potential system users. In addition, PHR developers and vendors have a great flexibility in the amount and type of data items included in their system, structuring the specific minimum data set recommended by the CCR as a reference. The absence of PHR standards negatively impacts the interoperability between the two powerful technologies (EHRs and PHRs) (U.S. Department of Health and Human Services, 2006). In fact, the US Department of Health and Human Services reports "Comparability requires that the meaning of data is consistent when shared among different parties. Lack of comparable data can directly impact patient care. A simple example is the use by physical therapists of a pain scale that ranges from 1 to 4, and another used by nurses that ranges from 1 to 10. Obviously, pain designated 'level 3' carries vastly different meanings to these professionals. Standard healthcare vocabularies would assure that data shared across systems are comparable at the most detailed level. Further, this lack of standard vocabularies makes it difficult to study best practices and develop clinical decision support." (U.S. Department of Health and Human Services, 2006). Therefore, there is an urgent need for development of PHR standards to incorporate both the users' and healthcare providers' needs. For instance, America's Health Insurance Plans (AHIP) and Blue Cross Blue Shield Association (BCBSA) have decided to develop a standardization of the data contents of electronic health plan based PHRs and to make PHRs information portable across health insurance plans; that is, to record and present health and clinical data in a manner accessible and useful to both users and healthcare providers, which is the key role of PHR systems (Medical News Today, 2006).

2.8 PERSONAL HEALTH RECORDS AND THEIR APPLICATIONS IN THE LITERATURE

Personal Health Records (PHRs) have many useful applications and functions. These applications vary in significance according to each individual's preferences and needs. For example, a national survey conducted by the Markle Foundation ranked a patient-physician secure messaging communication system as the most useful and desired priority among all PHR functions, followed by tracking immunizations, noting mistakes in health records, transferring information to new providers, and receiving and viewing test results (Markle Foundation, 2003, 2004). This finding is not surprising; it is also consistent with a prior report about Internet use which estimated that 90% of online users consider e-mails to be their primary means of communication (PEW Internet and American Life Project, 2003). Other researchers noted that patients who used e-mail messages as a tool of communication with their doctors said it was a fast, convenient, and efficient method of contact (Delbanco & Sands, 2004; Hopkins, 2004; Kane & Sands, 1998). However, it must be emphasized that e-mails only handle routine encounters between patients and doctors: prescription refills, lab results, appointment reminders, insurance inquires, and other basic follow-up questions (Kane & Sands, 1998; Markle Foundation, 2004). While the Markle Foundation used a panel representing multiple disciplines, including public and private sector electronic medical records professionals, consumer advocates, medical groups and health systems, and other healthcare clinicians to select the choices in their national survey instrument, it left little or no room for participants to express their own set of preferences.

Another study conducted to examine patients' attitudes toward the use of e-mail with their providers found that the majority of those surveyed (85%) were active e-mail users (sent one or more e-mail a day) (Sittig, King, & Hazlehurst, 2001). Sixty-five percent answered yes to "have you ever wanted to send an e-mail to your healthcare provider?" However, only 6% had actually sent an e-mail to their primary care physician. This low percentage of patient-provider electronic communication clearly confirms what previous studies have reported: personal health records are still in their early stages and need time to fully proliferate among consumers. This is especially true since the personal health record considers e-mail messaging to be the main channel of the patient-physician communication system. The data also suggest that patients' enthusiasm for a new trend, which in this case is the PHR, does not always translate into high utilization rates.

A study by Sittig et al. (2001) found that the higher the number of e-mails an individual sent, the greater the chance that this individual had actually sent an e-mail to a physician or had an interest in sending one (Sittig et al., 2001). In general, surveyed patients expressed optimistic feelings toward an e-mail messaging system with their providers as a way to further enhance the communication process. Physicians, on the other hand, fear that by allowing patients to communicate with them via e-mail, they will have to deal with a huge number of messages. The study, which did not collect any socio-demographic information, could not provide any relationship between or understanding of those characteristics and the individuals' perceptions.

Denton (2001) addressed PHRs by conducting a study regarding patients' use of electronic personal health records (Denton, 2001). The results of his study confirmed what advocates of PHRs found in patients' perceptions toward the use of PHRs: patients have high praise and enthusiasm about the future use of PHRs. However, one worthy finding is the

percentage of actual patients who elect to use the freely provided electronic PHR. Denton offered an electronic PHR program to 1,000 active patients. Among those approached, only 330 patients (33%) agreed to participate in the program. While those 330 patients received a survey ten months after their approval of participation, only 136 responded. Of those, 50 patients (37%) had used the PHR during the ten-month period. When comparing this number to the total sample initially invited, the result was very low: only 5% of the patients offered the free trial of electronic personal health records agreed to participate and continue the program for the ten-month period. Interestingly, 68 patients said they would recommend the electronic PHR to friends; a number exceeding the actual number (50) of respondents who used the proposed program. Furthermore, 46 stated that they would use the program "when the time comes." This study's findings suggest that patients are more likely to recommend the electronic personal health records to a friend than use it themselves. According to Denton, the sample studied can be generalized to the entire population of his practice.

Similarly, Sprague (2006) reported that the America's Health Insurance Plans (AHIP) conducted a research study in which they estimated that health plans provide more than 70 million Americans with access to a PHR (Sprague, 2006). However, this large number does not necessarily translate into actual and active users of the PHR. Assuming that all of the sampled population, or even the majority, are active users of the PHR will increase the previously reported figure of active PHR users twenty-three fold. These findings coincide with what "Connecting for Health" reported: In 2003, individuals in a focus group expressed "a strong desire to have total control of their personal health information through the use of the PHR, however the usability rate among them was absolutely low" (Markle Foundation, 2003). In fact, research has found that only one percent of the population currently uses and maintains an online

PHR (Heubusch, 2007a). Still, a critical question remains: will the person's strong desire translate into a high percentage of PHR utilization? To date, more research and evidence are needed to answer this question (Markle Foundation, 2004).

Kleiner et al. conducted a study to examine the attitudes of parents and pediatricians regarding electronic communication. The study concluded that the majority (74%) of parents surveyed indicated their willingness to use e-mail to contact their child's doctor. Parents cited a number of reasons for the electronic contact, including obtaining information or test results, scheduling an appointment, and/or discussing a specific symptom. Pediatricians, however, expressed their objection toward the use of e-mail, stating that it would burden them with additional non-reimbursable work (Kleiner, Akers, Burke, & Werner, 2002).

In a Canadian study that evaluated the factors affecting the adoption of smart cards, one type of PHR, the researchers found many variables that predict how well physicians and pharmacists will accept and use PHRs. Ease of use, compatibility, quality of support, and willingness all positively correlated with the professional usage of PHRs. In other words, the easier the technology, the higher the probability that consumers will utilize it (Aubert & Hamel, 2001).

Many studies have concentrated on the organization, management, and retrieval of paper and electronic documents such as files, e-mails, bookmarks, appointments, reminders, and contacts and shown the importance of personal information management systems in increasing productivity and reducing time and effort while increasing accuracy with the sharing of information (Barreau, 1995; Boardman & Sasse, 2004; Fertig et al., 1996; Ofer et al., 2003).

Despite the many reports that note individuals' high satisfaction ratings with the early implementations of personal health records and the associated advantages and uses of PHRs, Tang et al. argue that the available literature offers limited evidence supporting these hypothetical benefits (Tang et al., 2006). Thus, more research is needed to validate the findings of these provisional implementations. Likewise, Matthew and Johnson (2002) report that the available web-based personal health records "demonstrated limited functionality and serve as static repositories for personal medical information" (Matthew & Johnson 2002), while others point out that further study is required to validate the benefits of PHRs (Markle Foundation, 2004).

2.9 ADVANTAGES OF THE PERSONAL HEALTH RECORD

The advantages of the Personal Health Record (PHR) including, but not limited to, the following:

1. Creates Cost Reduction: For years, healthcare policy makers have been trying to curb the continuous increase in healthcare expenditures. The introduction of the Prospective Payment System, the Diagnosis-Related Group (DRG), and Managed Care somewhat reduced this escalation; however, the increase continues without a comprehensive solution. Many factors, including new and costly health technology, the aging of the population, and the use of an inefficient paper-based medical record format which leads to unnecessary paper work and unneeded tests and repeated expensive exams such as magnetic resonance imaging (MRI) and computed tomography (CT scan), all contribute to this cost escalation. While approximately $30-293 billion of current spending results from extraneous paper work, patients and physicians still are dissatisfied with this ineffective communication system (Markle Foundation, 2003,

2004). It seems that the personal health record might be the solution that health policy makers need to cap health expenditure. PHRs can save money in a variety of ways (American Health Information Management Association, 2006; Markle Foundation, 2003, 2004; Taylor et al., 2005), such as by minimizing the number of unnecessary or redundant tests and procedures ordered by different physicians working in different locations or on different shifts (American Health Information Management Association, 2006; Clarke et al., 2006; Markle Foundation, 2004). Further, the PHR can decrease each physician's cost of malpractice insurance by enabling all physicians to have access to patients' personal health records, which list prior conditions, allergies, and medications (American Health Information Management Association, 2006; Markle Foundation, 2004), knowledge of which can prevent mistakes.

The PHRs can also prevent the patient from wasting time in the physician's office inquiring about insurance claims, requesting prescription refills, or acquiring copies of already conducted tests (Tang et al., 2006). Physicians could save $29 billion by using the electronic prescription system; $27 billion would result from fewer duplicate prescriptions; and $2 billion from lowering prescriptions errors (Hopkins, 2004). Clinicians and administrators can also benefit from a patient's utilization of the PHR for routine procedures or inquiries (American Health Information Management Association, 2006; Markle Foundation, 2004; Tang et al., 2006). More importantly, the PHR can improve care for patients suffering from multiple chronic conditions by better coordinating healthcare plans between different physicians who simultaneously provide care (Burton et al., 2004; Clarke et al., 2006). The implementation and utilization of a personal health record, then, could easily reduce the overall cost of healthcare.

This financial benefit is especially necessary in the United States, which now spends a higher percentage of its GDP on healthcare (16% in 2006) than any other industrial country

(International Trade Administration, 2007). Electronic communication, mainly e-mails facilitated by the PHR as a means of communication between patients and clinicians, can reduce the annual number of clinical and administrative office visits, estimated at 880 million, that occur each year (Markle Foundation, 2004; Taylor et al., 2005).

2. Improves Patient-Physician Relationship: One of the main advantages of the PHR is its ability to improve the patient-physician relationship (Tang et al., 2006; Tang & Newcomb, 1998). By using e-mail and other messaging systems, patients will be able to more easily communicate with their physician from the convenience of their homes without the need to go to the physician's office. E-mail lets the patient request a prescription refill, consult about a specific symptom and ask for lab test results to be electronically sent (Clarke et al., 2006; Markle Foundation, 2004;Tang et al., 2006). From their end, physicians can save time in authorizing the prescription refills and then automatically forwarding them to the pharmacy of the patient’s choice. Furthermore, physicians can use e-mail to handle basic procedures such as reviewing lab results, sending appointment reminders, addressing insurance inquiries, and responding to common follow-up questions (Kane & Sands, 1998; Markle Foundation, 2004; Tang et al., 2006). This will improve a situation in which physicians must spend an inordinate amount of time on routine procedures that do not require the patient’s presence in the physician's office, while administrative personnel also must squander time playing phone tag with patients regarding scheduling or other minor issues. An implementation of a secure electronic communication system confirmed that this is indeed the current situation and concluded that the use of e-mails increased the level of trust between patients and physicians, personalized office visits, and improved efficiency of office visits (Delbanco & Sands, 2004).

3. Empowers Patients and Other Individuals Caring for Loved Ones: By being able to continuously monitor their personal health records, patients will be able to ensure the accuracy of their information (Clarke et al., 2006). They can also make sure that their PHRs are complete and up-to-date. As a result, patients will feel that they have better control of their medical records and the maintenance of their health. Patients, as well as caregivers of older or disabled individuals, will gain a broader understanding of the issues regarding their health or the health of their loved ones, leading to more informed care decisions.

Research shows that adult Americans increasingly search the Internet whenever faced with a specific disease or medical problem about which they do not have adequate information. Approximately 80% of adult Internet users (about 93 million Americans) have searched the Internet for at least one of 16 major health topics (Fox & Fallows, 2003). In the same fashion, many other studies also have shown that empowering individuals by giving them the ownership of their health information has a significant impact on their health (Bosworth, 2007; Conemaugh Health System, 2007; Gearon, 2007; Patterson et al., 2007; Wolter & Friedman, 2005).

4. Enhances Patient Safety: When an individual is in control of his/her own personal health record, that individual continuously monitors the health record to ensure the accuracy and completeness of their information. The information supplied by individuals can be used to alert the physician and other caregivers to possible adverse drug interactions, contraindications, and allergies (Clarke et al., 2006; Kaushal, Shojania, & Bates, 2003). At present, only 23% of physicians in the United States are able to receive computerized warnings for possible drug adverse effects compared with 93, 91, 87, and 80% in the Netherlands, the United Kingdom, New Zealand and Australia, respectively (Featheringham, 2007). In addition, the patient could also use his/her PHR to direct the physician's attention to test results that might be missing or

misfiled because the absence of such data might have a severe consequence in the treatment plan (Markle Foundation, 2004).

PHR systems solve the fragmentation of the current healthcare delivery system by filling the information gap between individual & healthcare providers. Also, PHR allows the individual to provide doctors with valuable information that can help improve the quality of care received, especially in critical situations such as when visiting the ER, traveling, moving, or changing physicians. The PHR helps reduce or eliminate duplicate tests and allows the individual to receive faster, safer treatment and care in an emergency, which may save that person's life. For example, an 83-year-old woman acknowledged the usefulness of the PHR when she said, "When I had a serious heart attack and (was) rushed to the hospital, the only means of working out my past health problems and present medications was my PHR, it proved very useful" (Liaw, Radford, & Maddocks, 1998).

5. Increases the Quality of Care: When the patient supplies all the information relevant to his/her health and well-being, the physician will have a more comprehensive picture of the history of the patient. This results in better diagnosis and treatment (Markle Foundation, 2004; Tang et al., 2006). In a study that surveyed patients regarding the use of smart cards, the majority of the respondents indicated that smart cards will yield in an improvement in healthcare service (Aubert & Hamel, 2001). Furthermore, patients with chronic conditions can better manage their health with their physicians when they have electronic access to their health information, especially when this information is shared by all the physicians providing care to them (Burton et al., 2004). When physicians and healthcare providers use electronic health records, the coordination of care becomes seamless, allowing the patient's health information to be transferred from one system to another with the patient's consent. This is especially true if the physicians who are

users of the electronic medical records convince non-users that a secure information system connecting all physicians' offices, laboratories, radiology offices, and hospitals will lead to an effective exchange of patients' information (Loomis, Ries, Saywell, & Thakker, 2002).

2.10 BARRIERS AND ISSUES OF CONCERN TO THE IMPLEMENTATION OF THE ELECTRONIC AND PERSONAL HEALTH RECORD

PHR advocates report that the EHR is the foundation for a usable and useful PHR system, i.e., a successful, effective, and ideal PHR system is contingent on the full implementation of an EHR. Therefore the general formula is "PHR= EHR+ personally generated data"; thus, the two powerful technologies have the same barriers and issues of concern with respect to their implementation.

2.10.1 Barriers to the Implementation of the Electronic Health Record and Adoption of Personal Health Record

Despite the great potential of electronic and personal health records, many concerns and barriers impede their wide adoption and broad implementation, thus preventing an effective and efficient exchange of patients' health information among providers (Burton et al., 2004; Clarke et al., 2006). These concerns and barriers including, but not limited, to the following:

1. Record Architecture Standard: the agreed structure that can accommodate all types of data, support different views, and at the same time preserve the meaning and the context.

2. Terminology Standard: necessary to preserve the meaning for proper coding of diseases and classification of medical procedures. Also, a terminology standard is essential for any possibility of multilingualism and to connecting and updating other information sources. The development of terminology is long lasting, difficult, and requires a concerted effort by many disciplines and countries (American Academy of Pediatrics, 2009).

3. Lack of Health Information Standards: In order to reap its full array of benefits such as an increase in patient safety, improved quality and efficiency of care, and individual empowerment, the PHR must be accessible to different authorized users. However, without the PHR having standards for data field definitions, a common core data set, and guidelines for electronic transmission, it is impossible for the personal health record to receive and accept data from different sources (Sprague, 2006). The public and the private sectors must collaborate to achieve a consensus for a standard of health information. Patients' health information is currently scattered in different locations among multiple healthcare providers. An integrated personal health record must be able to interface with an electronic health record in which patient health information resides (Clarke et al., 2006; Tang et al., 2006) to ensure the interoperability for exchanging clinical data.

4. High Cost of Shifting to and Maintaining the Electronic Format (Burton et al., 2004; Clarke et al., 2006): The transfer from a paper –based medical record to an electronic health information system is a major shift which affects the flow of work, the search and selection of a reliable vendor, the creation of a budget for buying the hardware and software and, most importantly, the training of manpower (Burton et al., 2004). Without the full adoption and implementation of electronic health records, personal health records will primarily depend

upon the input of the patients, which is in turn contingent on their level of knowledge. Medicare estimates it would cost a billion dollars per year to reimburse each physician $5 to transmit one EHR for a single patient visit. In 2003, Wang et al. conducted a study to measure the cost-benefit analysis of electronic medical records in a primary care setting. The authors found that a primary care physician would need about $13,100 to establish and maintain an electronic health record in the first year of switching from the traditional paper-based records (Wang, Middleton, Prosse, Bardon, Spurr, Carchidi et al., 2003). This cost includes the purchase of hardware and the software as well as their implementation, support, and maintenance. Induced costs, the initial transitional productivity loss, could add approximately $11,000 to the initial estimate. Physicians who presently use the paper-based medical records and potential users worry about the high cost of EHRs (Loomis et al., 2002).

Healthcare providers favoring the widely accepted, easy to use, and low-cost paper-based medical records need to be convinced about the advantages of electronic health records (Bates, Ebell, Gotlieb, Zapp, & Mullins, 2003). They need to understand the financial benefits they will reap from the use of PHRs facilitated by the adoption of electronic health records. These considerable financial benefits vary from provider to provider, depending on the types and number of features implemented by the computerized medical records system. According to Wang et al. (2003), physicians could annually accrue a 34% reduction in adverse drug events, 15% in drug usage, and 14% in radiology utilization (Wang et al., 2003). The same authors estimate that financial benefits of up to $331,000 per provider over a five-year period should offset any initial cost resulting from the switch to EHRs. Beyond financial concerns, physicians also express doubts about EHRs improving the quality of healthcare or reducing medical errors (Loomis et al., 2002).

5. Unclear Financial Incentive for Sharing Patient Health Information Among Providers: Without physicians realizing the financial benefits of shifting toward the electronic format of health information, it would be difficult to convince them to make this costly move (Burton et al., 2004; Clarke et al., 2006; Parmanto, 2005; Taylor et al., 2005).

6. Privacy Concerns for Patients: Physicians and patients alike have concerns about the confidentiality and safety of patients' health records (Loomis et al., 2002). In this new era of digital information, patients are growing increasingly wary about their personal privacy, including the data in their health record. However, a nationwide telephone survey conducted by Public Opinion Strategies in Alexandria, Virginia reported that nearly 80% of the individuals contacted agreed to share their health record, contingent upon their first granting permission to do so (Markle Foundation, 2004). Burton et al. found that patients are unwilling to let all healthcare providers view their medical information; the authors consider this a major barrier to the implementation of the electronic health record (Burton et al., 2004). The same authors also note that patients are reluctant to share sensitive health information, including details about mental conditions, substance abuse, or sexually transmitted diseases, with different providers. Another study concluded that respondents have privacy concerns which prevented one-fifth of the sample surveyed from sending e-mails to their providers; thirty-three percent expressed concern that someone other than the doctor might screen their e-mail message (Sittig et al., 2001). In another study conducted in pediatric settings, the majority (74%) of the parents surveyed, showed an interest in communicating through e-mails with the pediatrician. However, both parents and physicians in the study feared a lack of confidentiality regarding the children's medical information (Kleiner et al., 2002).

In a study conducted by Fridsma et al., the researchers found that patients have confidentiality reservations when e-mail messages are used as a means of communication with their physicians (Fridsma, Ford, & Altman, 1994). In fact, Delbanco & Sands (2004) claim that the widely used conventional e-mail is not suitable with such applications of personal health records as prescription refills and consultations because it is too susceptible to interception by intruders (Delbanco & Sands, 2004).

While electronic messaging between patients and physicians holds great potential for improving effectiveness in communication and for promoting personal relationships, both patients and physicians continue to have concerns. Patients and healthcare providers need to have a clear and mutual understanding about what type of consultations are considered routine and could be handled through an electronic messaging system, and what conditions are considered urgent and require prompt professional care and interventions (Kane & Sands, 1998).

Patients, individuals caring for others, and physicians must recognize that an electronic messaging system such as e-mail cannot and should not handle consultations of an urgent or life threatening nature. The security of the messaging system also raises privacy questions. Using encryption and decryption measures to safeguard the electronic messaging system is paramount to securing and protecting the patient's health and personal information. Further, the use of an electronic signature is crucial when protecting health information from any tampering by unauthorized users. All of these measures, including fire walls or any new technological advances, will result in higher data integrity (American Health Information Management Association, 2006). For example, the Health Information Technology for Economic and Clinical Health (HITECH) Act enforces the security and privacy regulations under the Health Information Portability and Accountability Act (HIPAA) for generally improving healthcare

quality, safety, and efficiency (HIMSS Analytics Report, 2009). HITECH requires hospitals and healthcare providers to restrict the use and disclosure of protected health information (PHI) as follows (http://www.nixonpeabody.com):

- Covered entities including hospitals, health care providers, health plans, business associates, vendors, health information exchanges (HIEs), and Regional Health Information Organizations (RHIOs) and PHRs must honor a patient's request to withhold PHI from a health plan if the patient paid for the medical care;
- covered entities must limit use or disclosure of PHI to a "limited data set" or, if needed, to the minimum necessary to accomplish an intended purpose;
- when requested, covered entities must provide patients with an audit trail of all disclosures of PHI made within the past three years;
- covered entities may not receive payment for communicating with patients for marketing purposes without the specific authorization of the patient (including fundraising solicitations);
- employees of covered entities or other individuals who knowingly access, use, or disclose PHI for improper purposes will be subject to criminal penalties; and
- civil penalties for violations under HIPAA are increased, depending on the conduct. The federal government must impose penalties if the violation of the conduct was willful. State attorneys general (most of whom already have the jurisdiction to prosecute under state privacy laws) are authorized to prosecute and seek civil penalties. The penalties are tiered according to conduct, from $100 per violation with a maximum of $25,000 per year, to the maximum penalty of $50,000 per occurrence and $1.5 million per year.

7. Liability Concerns for Physicians: Another problematic issue for both patients and physicians focuses on access to sensitive personal medical information such as sexually transmitted diseases, mental illnesses, and substance abuse. Patients fear that their personal information could be shared with or revealed by unauthorized personnel, such as triage nurses who might screen physician e-mails. Physicians have similar fears; worrying about liability should they inadvertently disclose a patient's sensitive health and personal information to unauthorized users. More importantly, clarification is needed to determine whether patients' e-mail messages are legally considered part of the patient medical records (Blumenthal, 2002). While some may argue that physicians alone should handle all electronic messaging from patients, regardless of the legality issues, the reality of the situation questions whether physicians can do this without the help of other administrative and clinical staff in their office.

Another issue of liability for physicians deals with the information sharing process. It is not yet clear whether information provided by another physician without a request will have any legal implications for the physician office receiving the information (Burton et al., 2004). How physicians should react to information provided by other sources, such as the patient, a caregiver, or another physician or healthcare provider, must also be addressed. Physicians are still grappling with accepting or questioning the validity of information provided by others, especially if that input differs from the verbal reports of patients (Sprague, 2006).

8. Lack of Sponsorship to pay for the PHR Cost: The adoption and implementation of personal health records most benefits the patients. Although healthcare payers and purchasers will also enjoy the financial profits, these two factions seem reluctant to bear the cost of establishing PHRs. A successful and effective personal health record is contingent on the full

implementation of an electronic health record, which most healthcare providers still lack (American Health Information Management Association, 2006; Burton et al., 2004).

2.10.2 Issues of Concern to the Implementation of the Electronic and Personal Health Record

This section focuses on significant but less major issues that raise challenging questions concerning the Personal Health Record (PHR). These unresolved areas involve the PHR, patients, and physicians. As previously mentioned, the optimum PHR is one that derives health information from the patient's electronic health record. The patient then reads the imported information and adds other data, like exercise and eating habits, relevant to his/her health. While this sounds ideal, such a PHR does not address issues related to the patient's level of education or the patient's knowledge of specific medical terminology (Chapman, Abraham, Jenkins, & Fallowfield, 2003; Pearson, Parten, & Hipskind, 2007; Rodriguez et al., 2007; Sherrilynne, 2007; Sittig et al., 2007). Not all patients are equally prepared in terms of medical awareness or level of knowledge. Patients coming from different socioeconomic backgrounds, educational levels, and technological competencies have diverse attitudes towards or awareness of the PHR. Before committing patients to personal health records, these serious issues must be closely examined and carefully addressed.

Most PHR advocates assume that patients possess a fair knowledge about personal computers, health-related information, and medical terminology including medical conditions, symptoms, and test results. While this might be true for some individuals, it does not apply to the vast majority. Previous findings show that most patients do have difficulty in understanding medical terminology (Chapman et al., 2003; Pearson et al., 2007; Rodriguez et al., 2007;

Sherrilynne, 2007; Sittig et al., 2007). This leads to an important question: Do patients understand what they read in their PHR and, based on this understanding, will they use their knowledge in a positive or negative way in terms of their health? (Lowes, 2006). In a Markle Foundation telephone survey targeting the older population and the less technologically-savvy, the researchers concluded that almost one-third of the sample surveyed selected "none of the above" or "I don't know" as their answer when asked about naming two choices from a list of electronic capabilities that would most likely inspire them to try a new online PHR service (Markle Foundation, 2004).

Furthermore, as patients become more involved in searching for information related to their health and well-being and thus assume more responsibility and control over their healthcare matters, the terminology gap between patients and healthcare providers becomes a greater concern. Healthcare providers must adopt a medical terminology that is medically acceptable yet simple enough for the layperson to understand. Physicians and other healthcare providers must also note that specific technical terms that do not accurately represent what the physician actually means may confuse the average individual. Using "sadness" to describe the psychological state of depression illustrates this issue (Bosworth, 2007; Conemaugh Health System, 2007; Cronin et al., 2007; Fahrenholz et al., 2007; Smith et al., 2007; Zeng & Tse, 2006).

Another unclear issue is whether physicians will be paid for their online and e-mail consultations, or whether these are considered part of their regular responsibilities once they implement the personal health record (Clarke et al., 2006). Delbanco and Sands reported that the American Medical Association (AMA) and the American College of Physicians, insurers and health plans are trying to find ways to compensate doctors for the use of e-mails (Delbanco & Sands, 2004). It seems that patients and doctors have conflicting opinions when it comes to

charging for e-mail messages. One study found that almost half of the patients surveyed indicated that they will not pay for e-mail consultations (Sittig et al., 2001). Another reported that despite the high percentage (80%) of parents surveyed who stated that all pediatricians should communicate through e-mails, sixty-three percent said they would not pay for such access (Anand, Feldman, Geller, Bisbee, & Bauchner, 2005). A third study, however, found that two-thirds of physicians indicated that their use of e-mail messages is conditional upon being paid for the time they spend online (Delbanco & Sands, 2004). Another group of physicians surveyed expressed their objections toward exchanging e-mails with parents, fearing the time burden resulting from such communication (Kleiner et al., 2002).

3.0 METHODOLOGY

The research measured the level of understandability and explored healthy young adults' needs, preferences, and expectations of Personal Health Record (PHR) contents. As a first step, the study was advertised and flyers were posted at different locations on the University of Pittsburgh campus, Carnegie Mellon University, and Duquesne University. Then eligible participants were interviewed. The study determined individuals' 1) level of physical activity, 2) knowledge of or the use of technology, and 3) interest in maintaining health information. Researching these dimensions provide insights that allows PHR vendors and developers to better design and tailor PHR systems to satisfy the widely varied health needs and desires of potential end users. Individuals can then feel more comfortable with PHRs designed for their own individualized needs.

In addition, this research conducted a qualitative review study to investigate the data elements in the currently available free and for-purchase PHR systems and compare them with the Continuity of Care Record (CCR) standard.

Five pilot studies were conducted in the form of face-to-face, semi-structured interviews. The primary goals were to identify core data elements for future use in this research on PHR data contents to meet patient-consumer needs and expectations. The specific purposes for these pilot studies were: 1) to explore and select data items that are not CCR items for the use of participants' needs assessment; 2) to validate the interview instrument for clarity and ease of use;

3) to decide on the inclusion criteria for the study participants; and 4) to get a better understanding of the participants' point of view regarding maintaining their health information though the use of PHRs.

After obtaining IRB approval and prior to the actual interviews, five pilot studies were conducted and any required changes or improvements were incorporated.

The first pilot study explores the preferences of individuals as healthcare consumers with PHR familiarity with respect to PHR data contents and understanding of Continuity of Care Record (CCR) items. Accordingly, forty Health Information Management (HIM) professionals were queried during face-to-face, semi-structured interviews.

This study's target population was American Health Information Management Association (AHIMA) members with HIM backgrounds working in different sectors in the US. Subjects included: HIM directors, Health Informatics and Information Management program faculty, Health Information Technology program coordinators, and HIM coding specialists. The majority (90%) of participants held Registered Health Information Administrators (RHIA) credentials. Participants had no work or personal experience with PHRs.

The sample (n=40, 35 females and five males) reflected the gender distribution of HIM professionals. All participants were 40+ years of age and in good health. Although participants did not sign an informed consent, as no identifying information was collected, they were assured that study information gathered would be strictly confidential.

Study results suggest that PHR adoption, even among HIM professionals, still faces significant barriers, including individuals' unwillingness to be burdened with the responsibility of entering, updating, and managing their own health information. Participants preferred core data elements composed of simpler versions of CCR data items and the inclusion of additional

data items not currently included in CCR standards that were relevant to their needs (Appendix J). Results from this study are of interest as they were incorporated into large-scale studies and ultimately into PHR template development.

The second pilot study consisted of seventeen healthcare providers (n=17, ten females and seven males) within the University of Pittsburgh Medical Center (UPMC). Participants included: nurses (n=5), physical therapists (n=4), radiologists (n=5), and lab technicians (n=3). Participants were generally healthy, physically active, technologically savvy (had reasonable knowledge of computers and access to the Internet), enthusiastic, motivated, and interested in the research topic. No incentive, financial or otherwise, was offered to participants.

The third pilot study consisted of ten members of the Health Information Management Research Team (HIMRT) who are experts in PHRs (n=10, three females and seven males). Participants were asked to brainstorm and provide a wish list of data items that they would like to include in the future PHR. After providing a long list of data items, they were asked to categorize the items according to theme, then to organize and to label each of the items to be incorporated into large-scale studies.

In the fourth pilot study, ten college students in different fields at the University of Pittsburgh and Duquesne University aged 18 to 25 years participated (seven females, three males; seven native English speakers, three non-native English speakers; seven participants are from a non-health field, three are from the health field). Participants were generally healthy, physically active, technologically savvy (had reasonable knowledge of computers and access to the Internet), enthusiastic, motivated, and interested in the research topic. No incentive, financial or otherwise, was offered to participants. Participants were generally educated and orientated towards PHRs using the AHIMA PHR education tool (e-mail communication between Haya

Alkhatlan, primary investigator, and Karen Czirr, MS, RHIA, CHP, HIM Community Education Coordinator for Pennsylvania) (Alkhatlan, 2006).

Based on the large amount of feedback from this pilot study, participants were extremely motivated to participate in the study. In addition, they were seriously involved with the organization and categorization of each data element that were not CCR items and believed that PHR technology offers a solution for all their problems and frustrations with scattered important health information. They seriously considered this task and asked for more explanation and clarification of some unclear data elements in the lists provided in order to logically categorize and label them (Appendix J).

Moreover, based on the results from the face-to-face, semi-structured interviews of these ten undergraduate students, the primary investigator decided on the inclusion criteria for participants to be 1) generally healthy young adults (age 18-25) who are able to communicate with the researcher to provide necessary information (for further information about the subjects, refer to the inclusion criteria section), 2) students from non-health fields to avoid any familiarity bias with the PHR contents and vocabulary, and 3) native English speakers in an effort to reduce any language barriers.

The fifth pilot study consisted of thirty participants from Carnegie Mellon University and Duquesne University (n=30, 15 females and 15 males). The data collection method was conducted in the same format as the previous studies in order to develop a reliable and valid instrument and to develop the list of data items for the needs assessment (Appendix F, Section D).

3.1 RESEARCH DESIGN

This research consisted of two studies; the first study used a mixed-method approach, including both qualitative and quantitative methods, in the form of an exploratory-descriptive study while the second study used a qualitative review study. Qualitative research helped the investigator to focus attention on users' needs and preferences and identify factors that satisfy users' expectations concerning a PHR design, a critical component in the system development process and User-Centered Design (UCD), to help developers and designers to produce a usable product**.**

The first study, qualitative exploratory-descriptive, was conducted to evaluate participants' level of understandability of the Continuity of Care Record (CCR) terms and to examine individuals' needs and preferences in terms of PHR contents. Data was collected through face-to-face, in-depth semi-structured interviews. The format remained semi-structured by giving the participant a chance to freely talk without any constraints. This research used the in-depth semi-structured interview for a number of reasons (Rubinstein, 2006). Unlike a focus group format, it is ideal for investigating personal behavior, attitudes, beliefs and values, and sensitive or confidential information. Second, the in-depth semi-structured interview better fits the lifestyle of young adults whose busy school schedule and social life prevent them from attending a focus group. This approach provided participants the opportunity to choose a convenient time and place for the interview. Finally, this study's design is the most appropriate research technique to use in situations where the area under investigation is new, with little known facts (Rubinstein, 2006; Watzlaf, 2005).

The second study, qualitative review, was conducted to identify each data element in the currently available, free and for-purchase PHR systems and compare those with the CCR data elements to determine any similarities and differences. Another goal of this study was to

determine the minimum essential data set that should be included in the design of the future PHR systems. PHR systems to be included in the qualitative review study were randomly chosen from the list of PHR tools and services available at www.myPHR.com.

3.2 RESEARCH METHODS

The in-depth, semi-structured interviews were used as the primary data collection method for the qualitative exploratory-descriptive study. This study was advertised in different schools, buildings, and activity centers within the University of Pittsburgh, Carnegie Mellon University, and Duquesne University (Appendix H). Each interview was approximately ninety minutes. Participants were greeted and introduced to the rules, objectives, and structure of the interview, as well as the privacy statement, at which time each participant was required to sign an informed consent to participate in the study (Appendix G). The questions utilized for the interviews (Appendix F) had a number of goals, including the following:

1. To measure the young adults' level of understandability of the Continuity of Care Record (CCR) data items.
2. To discover end-users' needs, expectations, and Personal Health Records (PHRs) preference in terms of information included and vocabulary used for specific data elements.
3. To determine how the data elements of PHRs differ for the needs of end-users and healthcare providers.
4. To provide assessment of the consumers' physical activity level, interests, needs, experience, level of awareness, and concerns regarding the PHR contents.

5. To demonstrate to participants the advantages to using PHRs to store and maintain health information and to applying it to everyday life.
6. To determine participants' familiarity and comfort with using different types of technology (e.g., cell phones, PDA, computers) and how this may influence the use of an electronic PHR.
7. To give primary users the opportunity to participate in the design process of PHRs system.

The interview consisted of three parts. The first goal measured for each participant was the level of understandability of the CCR items. These items are "payers/payment sources," "advance directives," "support sources," "functional status," "problems," "family history," "social history," "health status," "alerts," "medications," "medical equipment," "immunizations," "vital signs," "plan of care," "healthcare providers," "procedures/surgeries," and "encounters/consultations." A scale was developed to evaluate participants' understandability level of the seventeen CCR items, which range from zero to three as follows:

1. If a participant understood a data item completely by giving an example to the investigator, the score given was a three.
2. If a participant understood a data item with a short definition given only by the investigator based on the operational definition in the CCR, the score given was a two (Table 1 provides the operational definitions of the seventeen data items).
3. If a participant understood a data item with a long definition given only by the investigator based on the operational definition in the CCR, the score given was a one.
4. If a participant did not understand a data item even after being given a long definition, the score given was a zero.

Then the average score of the level of understandability of each CCR data item was computed and labeled based on the following scale:

1. If the average level of understandability ranged between 2.50-3.00, then the item was labeled "Easy To Understand."

2. If the average level of understandability ranged between 1.50-2.49, then the item was labeled "Understandable with Short Definition."

3. If the average level of understandability ranged between 0.50-1.49, then the item was labeled "Understandable with Long Definition."

4. If the average level of understandability ranged between 0.00-0.49, then the item was labeled "Difficult To Understand."

The second part of the interview, participants responded to interview questions that had three variables (level of physical activity, level of technology, and level of interest in maintaining health information). For the third part, participants were asked to select seventeen items that they feel are most important to include in PHRs from the data items list provided (Appendix F, Section D, total of 32 items, including the 17 CCR items and the 15 hypothetical items that were collected from literature and feedback from the five pilot studies). Finally, participants were asked to provide any information not on the list that they feel should be included in PHRs.

Since few studies dealt with differing expectations on the part of PHR users with regards to their needs and preferences (Boutin, 2007; Kukafka, 2007; Massoudi, 2007; Pearson, 2007; Rodriguez, 2007), this study developed a new instrument that was piloted for clarity and ease of use on a small group of participants who resemble the sample under study. The HIMRT, peers review, HIM professionals, PHRs experts and advocates, and the Office of Measurement and Evaluation were consulted for review and approval of the interview questions and the methodology.

The qualitative review study was conducted in three phases. The first phase was to choose the baseline for comparison. Because there is no standard for PHR data contents and for the purpose of this study, the CCR was utilized as a "consensus" record that represents PHR complete data contents to ensure interoperability, comprehensiveness, effectiveness, quality, and user satisfaction (Table 2). As mentioned previously, the CCR should not be understood as a gold standard for PHRs. It is simply a representative of the minimum data set of individuals' health information that can be shared among various practitioners to ensure high quality of care.

In the second phase, 20 web-based PHRs were randomly selected from www.myphr.com for the comparison. The ten free PHRs included were AboutMyHealth, Dr.I-Net, Ivalley, WorldMedcard, VIA, iHealthRecord, Google Health Records, Microsoft HealthVault, Patient Power, and Telemedical.com, while the other ten for-purchase PHRs included were A Smart PHR, AccessMyRecords, ActivePHR, Health Records Online, HealthString, CrisisID, MedicalSummary, LifeOnKey, VitalChart, and Your Health Record.

In the third phase of this study, the Primary Investigator (PI) attempted to identify each data element of the CCR in each of the PHRs compared in the sample. It is important to note that the PI only measured the presence or absence of each CCR data category and data elements within each category (Table 3). For each data category in the CCR, the PI first checked whether a corresponding data element with the same label could be identified in the PHR being compared. If that was not the case, then the PI searched for a label that was either a synonym of the CCR data category label (e.g., “immunizations” and “vaccinations”) or easily understood as having the same meaning (e.g., “medications” and “drugs and supplements”). If one of those conditions was satisfied, the PI marked the CCR data category/elements as “present,” otherwise as “absent.”

Table 1: Short and Long Definitions of the Seventeen CCR Items

CCR Item	Short Definition	Long Definition
Payers/payment source	Who is responsible to pay your service bill? Self-pay, insurance, others.	Contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination of payers and is used to define which entity is the responsible fiduciary for the financial aspects of a patient's care.
Advance Directives	Living will, durable power of attorney that allow someone else to act on your behalf on matters that you specify.	Contains data defining the patient's advance directives and any reference to any existing supporting documentation and the physical location of that documentation, such as a durable power of attorney for healthcare.
Support sources	whoever provides support to you incase of seeking healthcare and services.	Lists the patient's support providers and contacts (family, next of kin, legal guardian, durable power for healthcare, clergy, caregivers, support organizations, etc.)
Functional Status	Ability to care for your self, activities of daily living.	Lists and describes the patient's functional status, e.g. competency, ambulatory status, ability to care for self, activities of daily living.

Table 1 continued

Problems	Any complaints, conditions, diagnoses, symptoms, and findings.	Contains data defining the patient's relevant current and historical clinical problems, conditions, diagnoses, symptoms, findings, and complaints.
Family History	Any one in the family with high blood pressure, cancer, or any other hereditary diseases.	Contains data defining the patient's blood or genetic relatives in terms of possible or relevant health risk factors.
Social History	Lifestyle, smoking, marital status, race, ethnicity, religious affiliation.	Contains data defining the patient's occupational, personal (for example, lifestyle), social, and environmental history and health risk factors, as well as administrative data (ADT), such as marital status, race, ethnicity, and religious affiliation.
Health Status	How would you describe your current health (Ill, healthy, hospitalized, long term facility care, etc.).	Description of the symptom, disease, data about births and prenatal care, deaths and infant mortality, childhood and adult immunizations, smoking and overweight/obesity rates, mental health, diseases such as heart disease, cancer, strokes, data and information related to HIV/AIDS.
Alerts	Allergies to certain type of medications or adverse reaction.	Lists and describes any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history.

Table 1 continued

Medications	Type of prescribed medications, supplements, herbs, or over the counter medications.	Defines a patient's current active medications& pertinent medication history. Also, an entire medication history.
Medical Equipment	Artificial leg, hand, or any other organ in your body.	Defines a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history. This section is also used to itemize any pertinent current or historical durable medical equipment (DME) used to help maintain the patient's health status.
Immunizations	Any type of vaccine (flu shot).	Defines a patient's current immunization status and pertinent immunization history.
Vital Signs	Blood pressure, pulse, respiratory rate, height, weight.	Defines the patient's current and historically relevant vital signs, for example, blood pressure, pulse, respiratory rate, height, weight, body mass index, head circumference, and pulmonary function tests.

Table 1 continued

Plan of Care	What healthcare providers recommend for you to improve your health, such as medication, surgery, rehabilitation, physical therapy, etc.	Contains data defining all pending orders, interventions, encounters, services, and procedures for a patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. *(1)* All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient should be listed, unless constrained due to issues of privacy. *(2)* Clinical reminders should also be placed here for purposes of providing prompts that may be used for disease prevention, disease management, patient safety, and healthcare quality improvements, including widely accepted performance measures.

Table 1 continued

Healthcare Providers	Complete information about any healthcare provider that provides care during your visit for future reference. Such as full name, contact information, specialty, facility location.	Contains data defining all healthcare providers involved in the current or pertinent historical care of the patient. At a minimum, the patient's key healthcare providers should be listed, particularly the patient's primary physician and any active consulting physicians, therapists, and counselors.
Procedures/surgeries	List of all previous operations.	Defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically.
Encounters/consultations	Hospitalizations, office visits, home health visits, long-term care stays, or any other pertinent encounters.	Contains data defining all healthcare encounters pertinent to the patient's current health status or health history. Encounters can be hospitalizations, office visits, home health visits, long-term care stays, or any other pertinent encounters.

Table 2: The CCR Data Categories and its Data Elements

CCR Items	Sub-Category	Sub-Sub Category
Payers/Payment Source(s)		
	Type of Payment Source	
	Payment Provider	
		Payer Name
		Role
	Date/Time	
		Effective Date
		End Date
		Termination Date
	Subscriber ID	
	Authorizations available	
	Reference(s)	
	Comment	
Advance Directive(s)		
	Date/Time	
		Recorded Time
	Status	
	Directive Type	
	Description	
	Reference(s)	
Support Sources		
	Type of support source	
	Description	
Functional Status		
	Date/Time	
	Type of functional status	
	Description	
	Status	
	Source of information	
	Reference(s)	
	Comments	

Table 2 Continued

CCR Items	Sub-Category	Sub-Sub Category
Problems		
	Date/Time	
	Type	
	Description	
	Status	
	Episodes	
		Episode
		Frequency
		Duration
	Patient Knowledge	
		Patient is aware
		Reason
	Source of information	
	Reference(s)	
	Comments	
Family History		
	Date/Time	
	Type	
	Description	
	Status	
	Family Member	
	Source of information	
	Reference(s)	
	Comments	
Social History		
	Date/Time	
	Type	
	Description	
	Status	
	Episodes	
		Description
	Source of information	
	Reference(s)	

Table 2 Continued

CCR Items	Sub-Category	Sub-Sub Category
Health Status		
	Description	
	Cause of Death	
Alerts		
	Date/Time	
	Type	
	Description	
	Status	
	Agent	
	Reaction	
		Description
		Severity
		Intervention
		Status
	Source of information	
	Reference(s)	
	Comments	

Table 2 Continued

CCR Items	Sub-Category	Sub-Sub Category
Medications		
	Date/Time	
	Type	
	Product Name	
	Brand Name	
	Description	
	Status	
	Manufacturer	
	Strength	
		Value
		Unit
	Form	
	Concentration	
		Value
		Unit
	Size	
	Quantity	
	Directions	
	Delivery Method	
	Vehicle	
	Site	
	Administration Time	
	Duration of use	
	Dose restriction	
	Indication	
	Stop Indicator	
	Patient Instructions	
	Additional Instructions	
	Refill	
		Quantity
		Date/Time of refill
		Constraints of refill
		Comments
	Follow-up Reaction	
	Fulfillment History	

Table 2 Continued

CCR Items	Sub-Category	Sub-Sub Category
Medical Equipment		
	Date/Time	
	Type of medical equipment	
	Product Name	
	Brand Name	
	Description	
	Status	
	Manufacturer	
	Directions	
	Vehicle	
	Site	
	Duration of use	
	Source of information	
	Reference(s)	
	Comments	

Table 2 Continued

CCR Items	Sub-Category	Sub-Sub Category
Immunizations		
	Date/Time	
	Type of immunization	
	Product Name	
	Brand Name	
	Description	
	Status	
	Manufacturer	
	Strength	
		Value
		Unit
	Form	
	Concentration	
		Value
		Unit
	Size	
	Quantity	
	Directions	
	Delivery Method	
	Vehicle	
	Site	
	Patient Instructions	
	Additional Instructions	
	Follow-up Reaction	
	Fulfillment History	
		Date/Time
		Provider
		Location
		Fulfillment Method
	Source of information	
	Reference(s)	
	Comments	

Table 2 Continued

CCR Items	Sub-Category	Sub-Sub Category
Vital Signs/Results		
	Date/Time	
	Type	
	Description	
	Procedure	
	Substance	
	Test	
		Date/Time
		Type of test
		Description
		Status
		Method
		Agent
		Test Result
		Normal Result
		Flag
		Confidence Value
	Source of information	
	Reference(s)	
	Comments	
Procedures		
	Date/Time	
	Type	
	Description	
	Status	
	Location	
	Practitioner	
	Frequency	
	Duration	
	Indication	
	Products	
	Substance	
	Method	
	Site	
	Position	

Table 2 Continued

CCR Items	Sub-Category	Sub-Sub Category
Encounters		
	Date/Time	
	Type	
	Description	
	Location	
	Practitioner	
	Frequency	
	Duration	
	Indication	
	Instructions	
	Consent	
	Source of information	
	Reference(s)	
	Comments	
Plan of Care		
	Date/Time	
	Type	
	Description	
	Status	
	Order/Request	
		Date/Time
		Type
		Description
		Status
	Goals	
	Source of information	
	Reference(s)	
	Comments	

Table 2 Continued

CCR Items	Sub-Category	Sub-Sub Category
Healthcare Providers		
	Name	
		Birth name
		Additional name
		Current name
		Display name
	Date of birth	
	Gender	
	Organization	
	Relation	
	Specialty	
	Address	
	Telephone	
	Email	
	URL	
	Status	
	Source of information	
	Reference(s)	
	Comments	

Table 3: Summary of 17 Data Categories in the CCR, Number of Corresponding Data Elements, and Sample of Data Elements

CCR Items	Number of Data Elements	Sample of Data Elements
Payer/ payment	10	Payment source/effective date, end/termination/subscriber id
Advance directives	5	Recorded date/status/directive type/description/reference
Support sources	2	Type of support source/ descriptive
Functional status	7	Date, type, description, status, source, references
Problem	12	Date of onset/type/description
Family history	8	Date of onset/type/family member
Social history	8	Date of onset/type
Health status	2	Description/ cause of death
Alerts	12	Date/type/description/status
Medications	37	Product name/strength/size/quantity/direction/delivery method/duration of use/refill
Medical equipment	14	Date, time, type, product name, brand name
Immunization	28	Type of immunization/product name/brand name/form/concentration/size/quantity
Vital signs	18	Height/ temperature/ weight
Plan of care	12	Date, time, goal, comments
Healthcare providers	17	Name/gender/organization/specialty/address/phone/email/URL
Procedures/ surgeries	17	Type/date/description/location/method/duration/frequency
Encounters	13	Date/type/description/location
Total	222	

3.3 SAMPLE SIZE

In general, mixed method, qualitative and quantitative, research designs that seek insight and deeper understanding of the topic of the investigator's interest and gain more information and meaningful feedback from participants, require a small sample size (Gay, 2006). This kind of study generates insights to improve the design of a system with the power of quantifiable measurements. Therefore, for the purpose of the qualitative exploratory-descriptive study, the sample size was thirty participants. While the sample size for the qualitative review study was twenty PHRs. Simple random sampling was used in selecting the available free and for-purchase PHRs from PHR tools and services list available at myPHR.com.

3.4 INCLUSION CRITERIA

Generally healthy young adults (age 18-25) who are native English speakers and able to communicate with the researcher to provide necessary information and whose field of study was non-health related were eligible. The study chose healthy young adults as a convenient sample based on previous research studies' findings. For instance, a study finding by Conemaugh Health System (CHS) reported that the majority of the system respondents who use Internet-based technologies and information tools to empower the consumer to make wise and better health decisions were between the ages of 18- 25 (Conemaugh Health System, 2007). Other studies concluded that the first adopters and potential users of PHRs are 18 to 25 year-olds who are technologically savvy, want to maintain their health, and frequently use e-health to search health information (Forrester Research, 2006; Leonard, 2004; Markle Foundation, 2003, 2004;

Munir & Boaden, 2001). California HealthCare Foundation and Fowles et al. found that many early adopters of PHRs were either people who manage their own chronic condition or that of their loved ones, or healthy individuals who want to give care providers instant access to their medical information in an emergency as well as maintain their health, and those are usually young, physically active adults (California HealthCare Foundation, 2005; Fowles, Kind, Craft, Kind, Mandel, & Adlis, 2004). California HealthCare Foundation also reported the necessity of expanding health literacy education, adding that the greater economic payoff of PHRs would be for healthy people (California HealthCare Foundation, 2005). The Department of Biomedical Informatics, Columbia University, asserted that family is the most influential factor for introducing PHRs technology. If this young generation buys into PHRs, then a widespread utilization of PHRs will occur, based on the significant influence of this age group on partners, parents, children, siblings, and friends, (i.e. circles of influence: individual-family-clinical expertise-work-community) (Kukafka, 2007). The Environmental Scan of PHRs Market Study suggested that the significant degree of internal communication is among healthy young groups. For instance, recommendations from someone enthusiastic about PHRs are likely to result in additional users from the similar group (Armijo et al., 2006). People in this age group are interested in maintaining their health through exercise and a proper diet. In addition, young adults have high levels of interaction with personal computers and the Internet, which make them ideal subjects for this study (Leonard, 2004; Munir & Boaden, 2001). Moreover, while each age group has its own unique needs, they may also have needs in common with other age groups.

This research focused on the healthy young adult age group and an understanding of their needs and expectations due to the convenience of recruiting them; however, in the future the HIMRT, School of Health and Rehabilitation Sciences, The University of Pittsburgh, will expand the study to different groups.

3.5 DATA ANALYSIS

The quantitative data, computed from the level of understandability questions, was statistically analyzed using descriptive statistics, such as measures of central tendency (mean) and measures of variability (standard deviation) within SPSS and Excel. In addition, appropriate types of graphs, such as bar graphs, were created.

Descriptive statistics was chosen because it is the typical method of analysis for quantitative variables (Friedman & Wyatt, 2006; Rosner, 2006; Rubinstein, 2006; Watzlaf, 2005; Watzlaf & Abdelhak, 1989). For example, to answer the first research question: How easy is it for a lay person to understand the CCR items? Each participant was evaluated for his/her understandability of each of the CCR item based on the following scale:

Easy to understand= 3 (with no clarifications)

Understandable with a short definition= 2 (Table 1)

Understandable with a long definition= 1 (Table 1)

Difficult to understand= 0 (could not be understood even after providing a long definition)

Then the average level of understandability of each CCR item was computed and labeled as follows:

1. If the average level of understandability of CCR item was: 2.50-3.00, then it was labeled Easy To Understand.
2. If the average level of understandability of CCR item was: 1.50-2.49, then it was labeled Understandable with a Short Definition.
3. If the average level of understandability of CCR item was: 0.50-1.49, then it was labeled Understandable with a Long Definition.
4. If the average level of understandability of CCR item was: 0.00-0.49, then it was labeled Difficult To Understand.

To answer the second research question: To what extent do healthcare providers and users have different needs regarding the data elements of the personal health record system? The percentage of each data item selected as important and needed by participants out of the 17 items from the CCR standard was computed. If participants select at least 10 items from the CCR list with 50% or more, then the results concluded that both healthcare providers and users have the same needs with respect to data items of PHRs.

Finally, the data analysis for the third research question: How do the data elements of the currently available PHR systems differ from the CCR standard? was based on the results of the qualitative review study, which used the Standard Specification for the Continuity of Care Record (CCR) as a comparison base with each PHR system included in this study; Appendix E provides the specific data elements.

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4.0 RESULTS

4.1 RESULTS OF THE EXPLORATORY DESCRIPTIVE STUDY

4.1.1 General Description of the Sample

The study sample consisted of 30 participants (15 Female, 15 Male). Participants were generally healthy, young adults (age 18-25) who are native English speakers and able to communicate with the researcher to provide necessary information. All participants (100%) were students at the University of Pittsburgh whose field of study was non-health related, such as Engineering, Law, Arts and Sciences, etc. All participants (100%) were single and had private health insurance under their parents' health plan. Table 9 summarizes the demographic characteristics of the sample, such as Age, Gender, Marital Status, Nationality, and Race.

Table 4: Demographic Characteristics of the Sample (Age, Gender, Marital Status, Nationality, Race)

	N	%
Age		
18-19	5	16.66
20-21	10	33.33
22-23	11	36.66
24-25	4	13.33
Gender		
Male	15	50
Female	15	50
Marital Status		
Married	0	0
Single	30	100
Divorced	0	0
Widowed	0	0
Nationality		
American	30	100
Non-American	0	0
Race		
Caucasian	15	50
African American	15	50
Total	**30**	**100**

4.1.2 Level of Understandability of the Continuity of Care Record (CCR) Terms

A scale was determined to evaluate the level of understandability of the CCR terms. Any term with a score between 2.50 and 3.00 ($2.50 \geq 3.00$) has a level of understandability of "Easy to Understand." If the score is 1.50 to 2.49 ($1.50 \geq 2.49$), the term's level of understandability is "Understandable with Short Definition." If the score is 0.50 to 1.49 ($0.50 \geq 1.49$), the term's level of understandability is "Understandable with Long Definition." If the score is less than or

equal to 0.49 (≤ 0.49), then the term's level of understandability is "Difficult to Understand." Table 10 shows the average level of understandability of the CCR terms among the participants. The terms included seventeen items: "payers/payment sources," "advance directives," "support sources," "functional status," "problems," "family history," "social history," "health status," "alerts," "medications," "medical equipment," "immunizations," "vital signs," "plan of care," "healthcare provider information," "procedures/surgeries," "encounters/consultations." As can be seen, participants reported different levels of understandability of the CCR data items. Generally, participants fully understood some of the CCR data items that are common, popular, and widely used by the public, such as "family history," "medications," "immunizations," "procedures/surgeries," and "payers/payment source." The average score of understandability of these terms was 2.63 to 3.00, which indicates that the terms are "easy to understand" by lay people who do not have the same health background as healthcare providers. On the other hand, with an average score of understandability range of 1.50 to 1.93, "vital signs," "encounters/consultations," "healthcare provider information," "plan of care," and "social history" were understandable only when short definitions were provided to participants. The remaining CCR data items were "health status," "problems," "medical equipment," "support sources," "functional status," and "alerts"; these terms, with an average score of understandability range of 0.60 to 1.20, were understandable when long definitions were provided to participants. The only CCR term that was "difficult to understand," with an average score of understandability equal to 0.27, was "advance directives."

Table 5: Level of Understandability of the Continuity of Care Record (CCR) Terms

Item	Average	Level of Understandability
Family history	3.00	Easy to understand
Medications	3.00	Easy to understand
Immunizations	3.00	Easy to understand
Procedures/ surgeries	2.97	Easy to understand
Payers / payment sources	2.63	Easy to understand
Vital signs	1.93	Understandable with a short definition
Encounters / consultations	1.90	Understandable with a short definition
Healthcare provider information	1.63	Understandable with a short definition
Plan of care	1.57	Understandable with a short definition
Social history	1.50	Understandable with a short definition
Health status	1.20	understandable with a long definition
Problems	1.17	Understandable with a long definition
Medical equipment	1.03	Understandable with a long definition
Support sources	0.90	Understandable with a long definition
Functional status	0.77	Understandable with a long definition
Alerts	0.60	Understandable with a long definition
Advance directives	0.27	Difficult to understand

As can be seen from Table 9, out of the 17 CCR terms, only five were "easy to understand" by lay people. That is, 29.4% of the CCR terms were easy to understand, with the average score of understandability between 2.63 and 3.00 and a standard deviation of 0.00 to 0.72. On the other hand, only one term (5.88%), advance directives, was "difficult to understand," with an average score of understandability of 0.27. The majority of the CCR terms (35.29%) —such as "support sources," "functional status," "problems," "health status," "alerts," "medical equipment" were "understandable with long definitions," and the standard deviation range was between 0.83 and 1.25. However, the remainder of the CCR terms (29%) were "understandable with short definitions"—for example, "social history," "vital signs," "plan of care," "healthcare provider information," "procedures/surgeries," and "encounters/consultations,"—and the standard deviation range was between 0.82 and1.25. The difficulty of understanding some specific CCR terms was due to the following reasons:

participants tended to guess the meaning of unfamiliar terms by associating them with a common meaning. For example, 22 participants out of 30 found the term “alert” “difficult to understand.” This is because they assumed that the CCR term “alert” was associated with a red flag to indicate serious medical problems, symptoms, signs, or reminders. In addition, more than half of the participants had a score of zero for the term “medical equipment,” which indicates it was “difficult to understand.” Moreover, they thought of the term as meaning any tool or physical equipment that the healthcare staff uses to diagnose or treat a disease, such as ECG machine, MRI machine, and blood analyzers. Table 11 illustrates some of the CCR terms and the participants’ anticipations of their meanings.

Table 6: Definitions of the CCR Terms from Participants' Understandability vs. CCR Operational Definitions

CCR Terms	Participants Understandability of Each Term	CCR Definition of Each Term
Payers/payment source	Insurance company, whoever pays for any health service received, out of pocket, services for a fee.	Contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination of payers and is used to define which entity is the responsible fiduciary for the financial aspects of a patient's care.
Advance Directives	Healthcare providers directions, first aid information in case of emergency	Contains data defining the patient's advance directives and any reference to any existing supporting documentation and the physical location of that documentation, such as a durable power of attorney for healthcare.
Support sources	Financial support, medical support, nurses, healthcare staff, physicians.	Lists the patient's support providers and contacts (family, next of kin, legal guardian, durable power for healthcare, clergy, caregivers, support organizations, etc.)

Table 10 Continued

CCR Terms	Participants Understandability of Each Term	CCR Definition of Each Term
Functional Status	What is your job, what do you do for living?	Lists and describes the patient's functional status, for example, competency, ambulatory status, ability to care for self, activities of daily living.
Problems	Financial, social , emotional, educational, family problems	Contains data defining the patient's relevant current and historical clinical problems, conditions, diagnoses, symptoms, findings, and complaints.
Family History	History of disease that runs in the family, genetic diseases	Contains data defining the patient's blood or genetic relatives in terms of possible or relevant health risk factors.
Social History	Smoking, drinking alcohol, who are your friends, where do you live?	Contains data defining the patient's occupational, personal (for example, lifestyle), social, environmental history and health risk factors, as well as administrative data, such as marital status, race, ethnicity, and religious affiliation.

Table 10 Continued

CCR Terms	Participants Understandability of Each Term	CCR Definition of Each Term
Health Status	How do you currently describe your health, are you ill?	Description of the symptoms, disease, data about births and prenatal care, deaths and infant mortality, childhood and adult immunizations, smoking and overweight/obesity rates, mental health, diseases such as heart disease, cancer, strokes, data, and information related to HIV/AIDS.
Alerts	Red flag, abnormal signs of disease, bad symptoms, warning, directions.	Lists and describes any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history.
Medications	Prescribed medication, over the counter, herbs, supplements.	Defines a patient's current active medications and pertinent medication history. Also, an entire medication history (supplements, vitamins, herbs, prescribed, over the counter).
Medical Equipment	Tools used by health staff for diagnosis, treatment, x-ray equipment.	Defines a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history. This section is also used to itemize any pertinent, current, or historical durable medical equipment (DME) used to help maintain the patient's health status.

Table 10 Continued

CCR Terms	Participants Understandability of Each Term	CCR Definition of Each Term
Immunizations	Vaccine, shots	Defines a patient's current immunization status and pertinent immunization history.
Vital Signs	Basic body measurements such as height, weight, temperature, or the measurements that identify whether a person is alive or dead, such as heart rate, pulse	Defines the patient's current and historically relevant vital signs, for example, blood pressure, pulse. Respiratory rate, height, weight, body mass index, head circumference, and pulmonary function tests.
Healthcare Providers	Health staff, physicians, nurses, technicians, therapists, health insurance, whoever pays for your health service.	Contains data defining all healthcare providers involved in the current or pertinent historical care of the patient. At a minimum, the patient's key healthcare providers should be listed, particularly the patient's primary physician and any active consulting physicians, therapists, and counselors.
Procedures/ surgeries	Any type of minor or major surgeries such as outpatient and inpatient	Defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically.

Table 10 Continued

CCR Terms	Participants Understandability of Each Term	CCR Definition of Each Term
Plan of Care	What you plan to do to be well and healthy, what healthcare staff recommend for you to do to avoid getting sick, what you are supposed to take to get well.	Contains data defining all pending orders, interventions, encounters, services, and procedures for a patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. (1) All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient should be listed, unless constrained due to issues of privacy. (2) Clinical reminders should also be placed here for purposes of providing prompts that may be used for disease prevention, disease management, patient safety, and healthcare quality improvements, including widely accepted performance measures.

Table 10 Continued

CCR Terms	Participants Understandability of Each Term	CCR Definition of Each Term
Encounters/ consultations	Every time you meet with any healthcare staff at the hospital, Dr.'s office.	Contains data defining all healthcare encounters pertinent to the patient's current health status or health history. Encounters can be hospitalizations, office visits, home health visits, long-term care stays, or any other pertinent encounters.

The graph in Figure 1 has the different levels of understandability of the CCR terms among participants. It can be noted that the level of understandability decreases as the term becomes more technical, unusual, or unfamiliar; has multiple meanings; or is not publicly used.

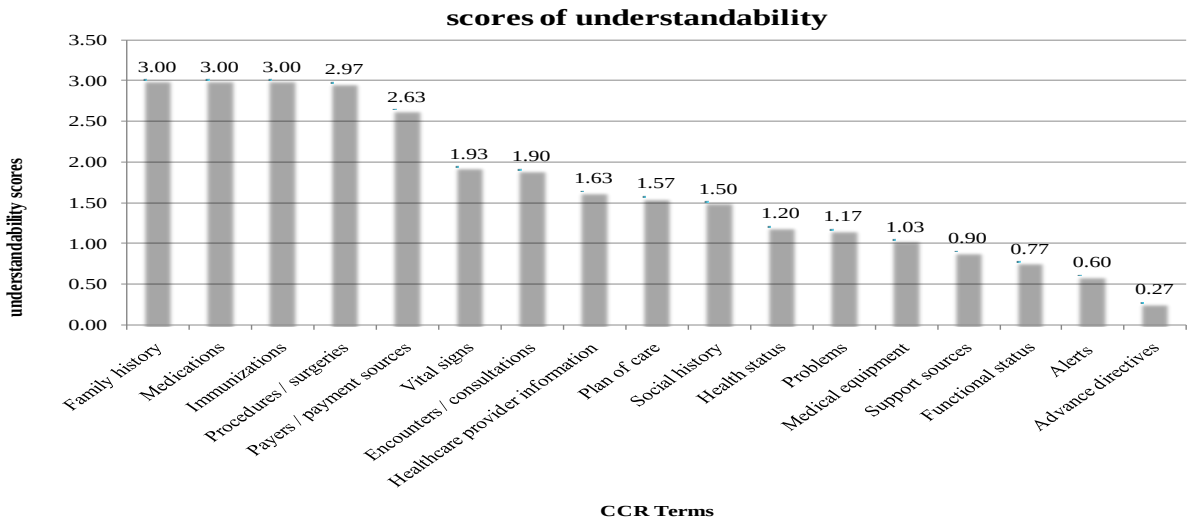


Figure 1: Descending Order of the Score of Understandability of the CCR Terms

Table 12 summarizes the descriptive statistics for the CCR terms based on the research sample of thirty participants. In summary, out of the seventeen CCR terms, as can be seen in

Figures 2-6 only five terms (29%) were straightforward and completely "Easy to Understand"—"family history," "medications," "immunizations," "procedures/surgeries," and "payers/payment source." Slightly more than a quarter of the CCR terms (29%) were understandable by lay people to a certain degree only, that is, when short definitions were provided for each term—"social history," "vital signs," "plan of care," "healthcare providers," and "encounters/consultations." Figures 7-11 display the number of participants who understood the terms with short definitions. On the other hand, the majority of the CCR terms (35 %) were understandable when long definitions were provided, which indicates the natural level of understandability of the specific technical terms by lay people: for example, "health status," "problems," "medical equipment," "support sources," "functional status," and "alerts." Figures 12-17 show the level of understandability of these terms. Finally, as can be seen from Figure 18, only one term (6%) "advance directives" appeared to be difficult to understand by lay individuals according to the predetermined scale of the level of understandability. The low percentage (6%) of the most difficult CCR terms was somewhat unexpected. This phenomenon probably reflects the level of understandability of CCR terms among participants who are educated healthy young adults. Nevertheless, all findings need to be treated with some caution because they were based on what participants said, rather than on direct observation of their using PHRs. Table 13 displays the frequency of each level of understandability of the CCR terms.

Table 7: Descriptive Statistics of the CCR Terms (CCR data items sorted according to their means arranged from highest to lowest)

CCR Terms	N	Minimum	Maximum	Mean	Standard Deviation
Family History	30	3	3	3	0
Medications	30	3	3	3	0
Immunizations	30	3	3	3	0
Procedures/Surgeries	30	2	3	2.97	0.18
Payers / Payment Sources	30	0	3	2.63	0.72
Vital Signs	30	0	3	1.93	1.2
Encounters/Consultations	30	0	3	1.9	0.84
Healthcare Provider Information	30	0	3	1.63	1.25
Plan of Care	30	0	3	1.57	0.97
Social History	30	0	3	1.5	0.82
Health Status	30	0	3	1.2	0.96
Problems	30	0	3	1.17	0.83
Medical Equipment	30	0	3	1.03	1.25
Support Sources	30	0	3	0.9	1.03
Functional Status	30	0	3	0.77	1.01
Alerts	30	0	3	0.6	1.1
Advance Directives	30	0	3	0.27	0.83

Table 8: Level of Understandability of the CCR Terms

CCR data items	Score 3		Score 2		Score 1		Score 0	
	#	%	#	%	#	%	#	%
Family history	30	100	0	0.00	0	0.00	0	0.00
Medications	30	100	0	0.00	0	0.00	0	0.00
Immunizations	30	100	0	0.00	0	0.00	0	0.00
Procedures/surgeries	29	96.6	1	3.3	0	0.00	0	0.00
Payers /payment sources	22	73.3	6	20.0	1	3.33	1	3.33
Vital signs	14	46.6	6	20.0	4	13.3	6	20.0
Encounters/consultations	7	23.3	15	50.0	6	20	2	6.66
Healthcare providers	11	36.6	5	16.6	6	20	8	26.6
Plan of care	4	13.3	15	50.0	5	16.6	6	20.0
Social history	2	6.66	15	50.0	9	30.0	4	13.3
Health status	2	6.66	11	36.6	8	26.6	9	30.0
Problems	1	3.33	10	33.3	12	40.0	7	23.3
Medical equipment	6	20.0	5	16.6	3	10.0	16	53.3
Support sources	2	6.66	8	26.6	5	16.6	15	50.0
Functional status	2	6.66	6	20.0	5	16.6	17	56.6
Alerts	4	13.3	2	6.66	2	6.66	22	73.3
Advance directives	2	6.66	1	3.33	0	0.00	27	70

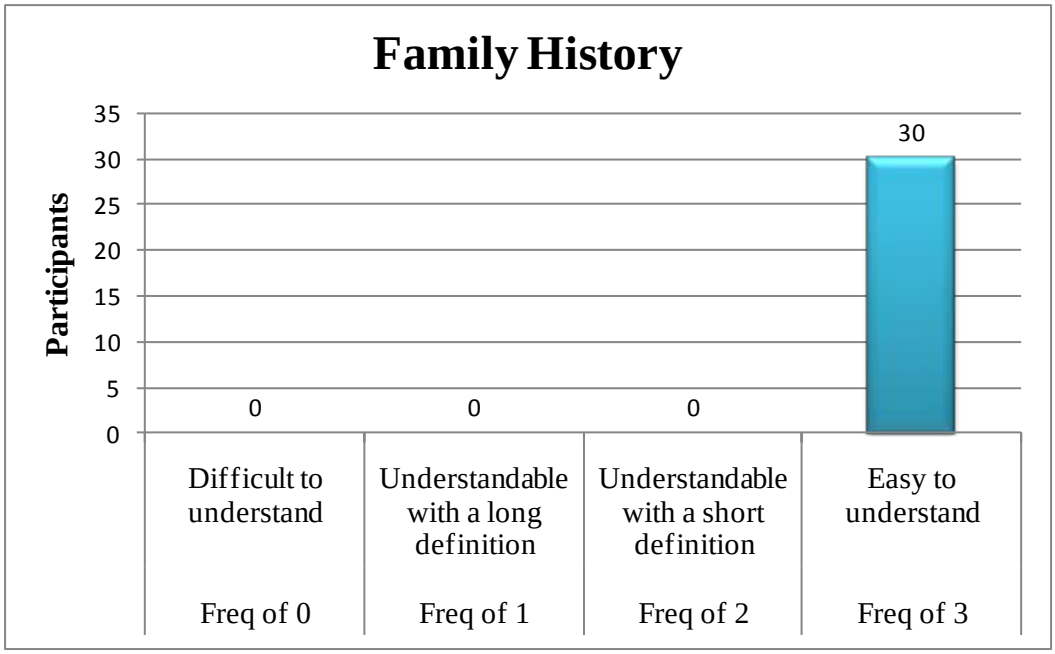


Figure 2: CCR Term which is "Easy to Understand"

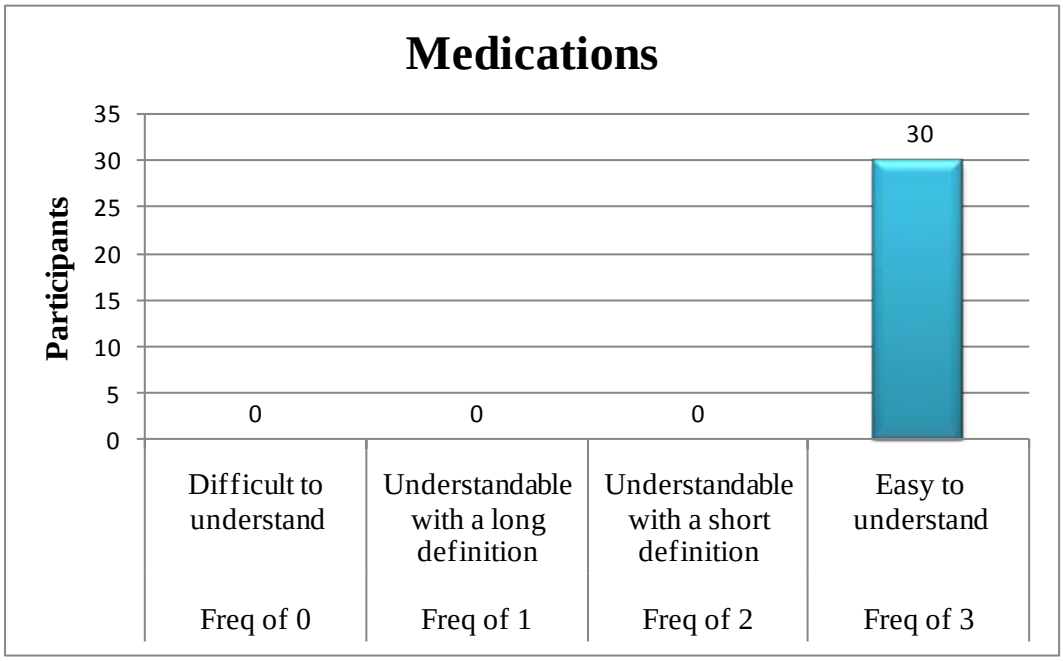
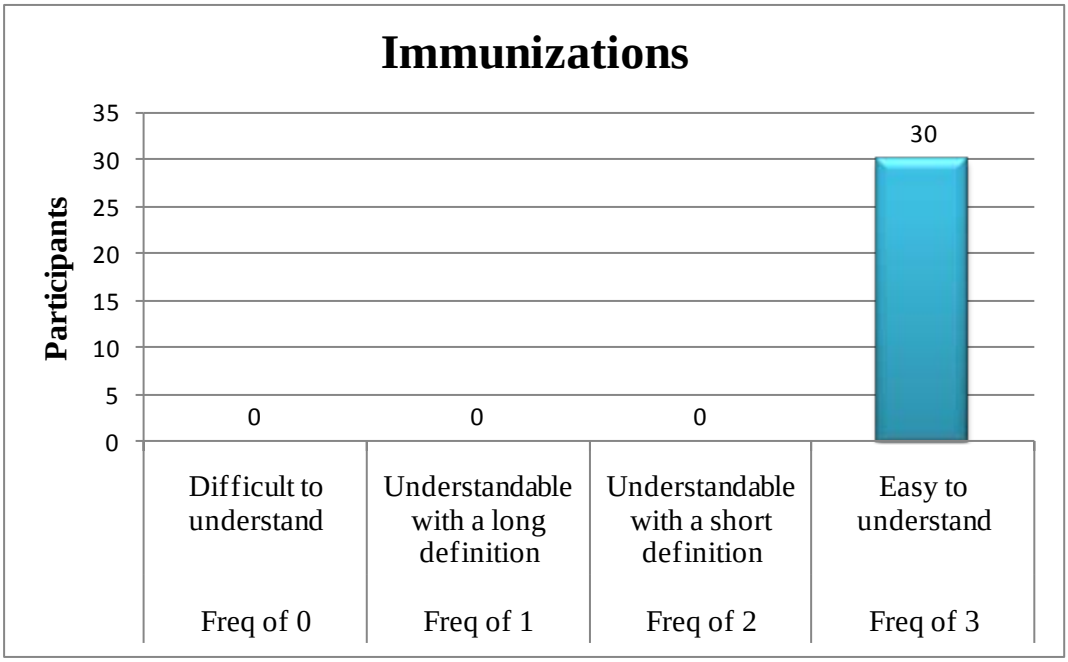


Figure 3: CCR Term which is "Easy to Understand"



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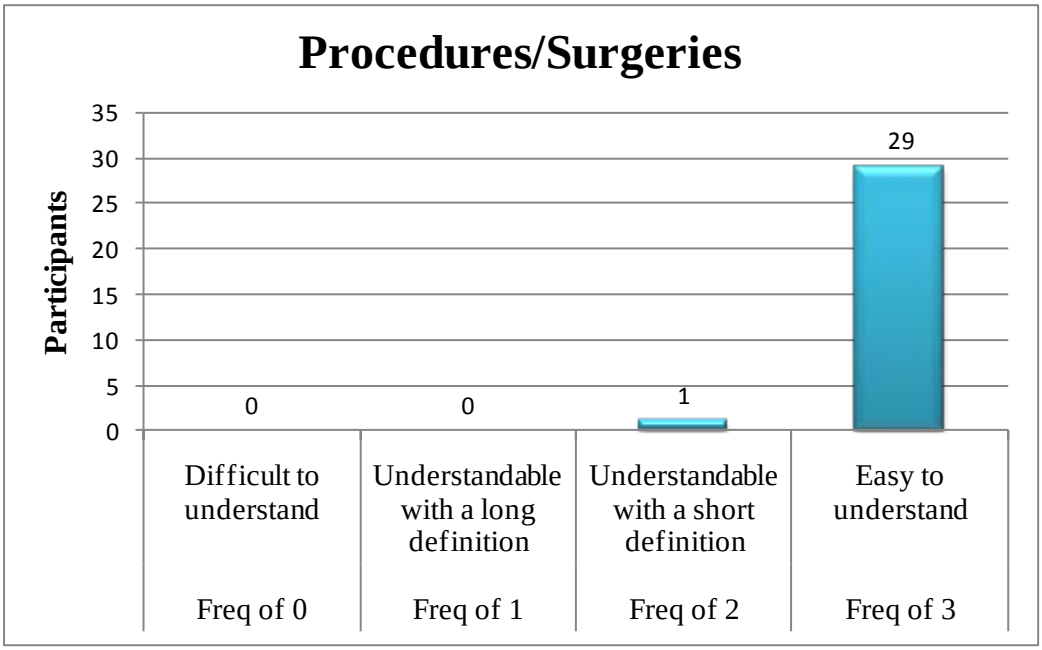

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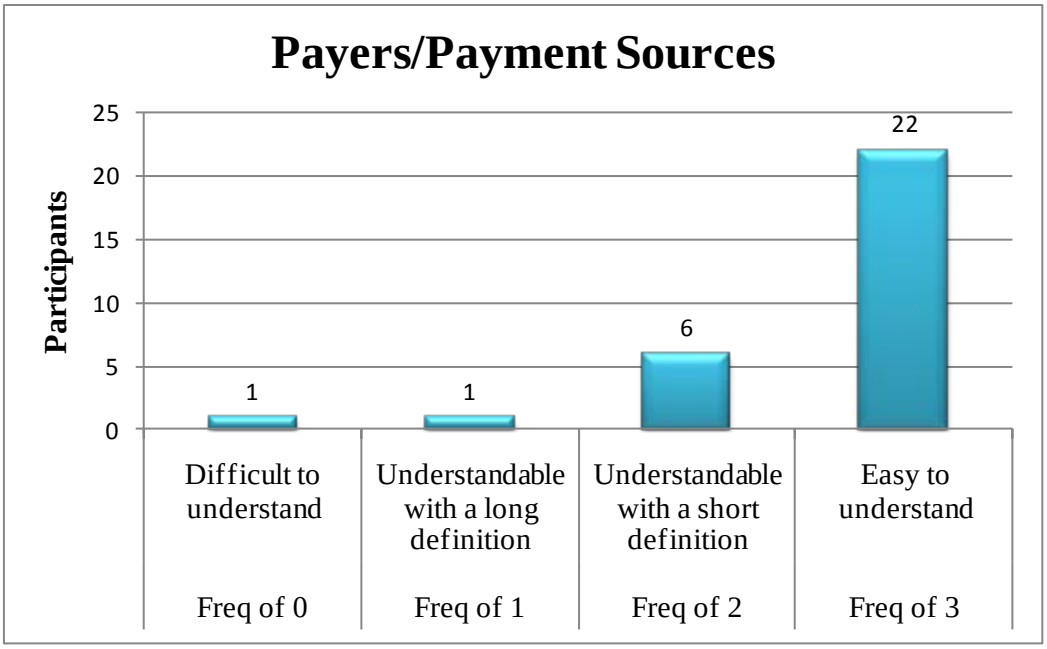

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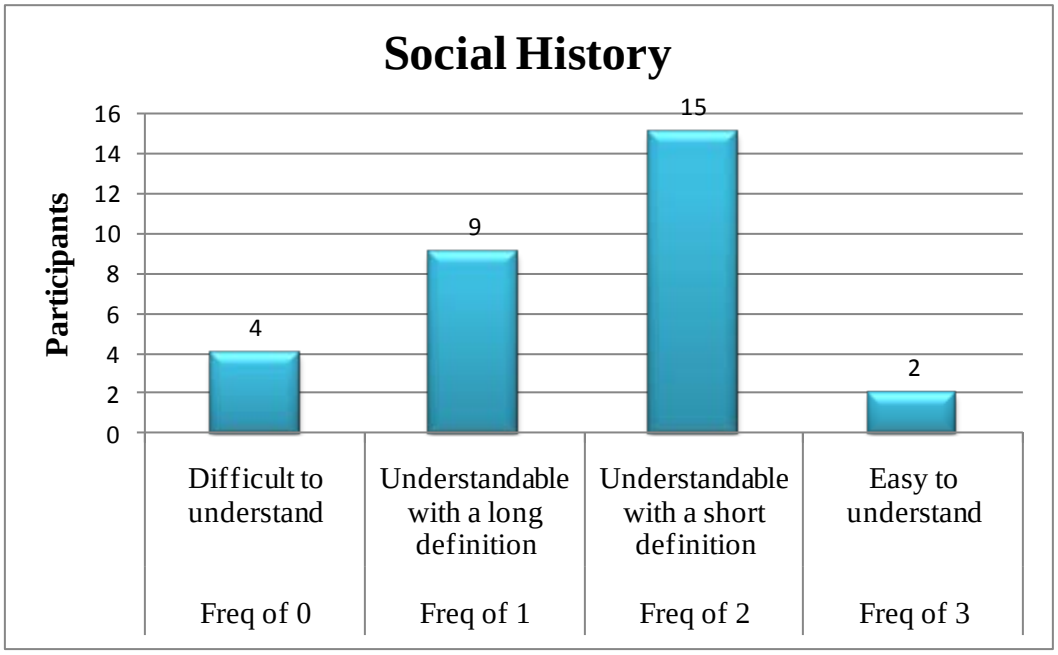

Figure 7: CCR Term which is "Understandable with Short Definitions"

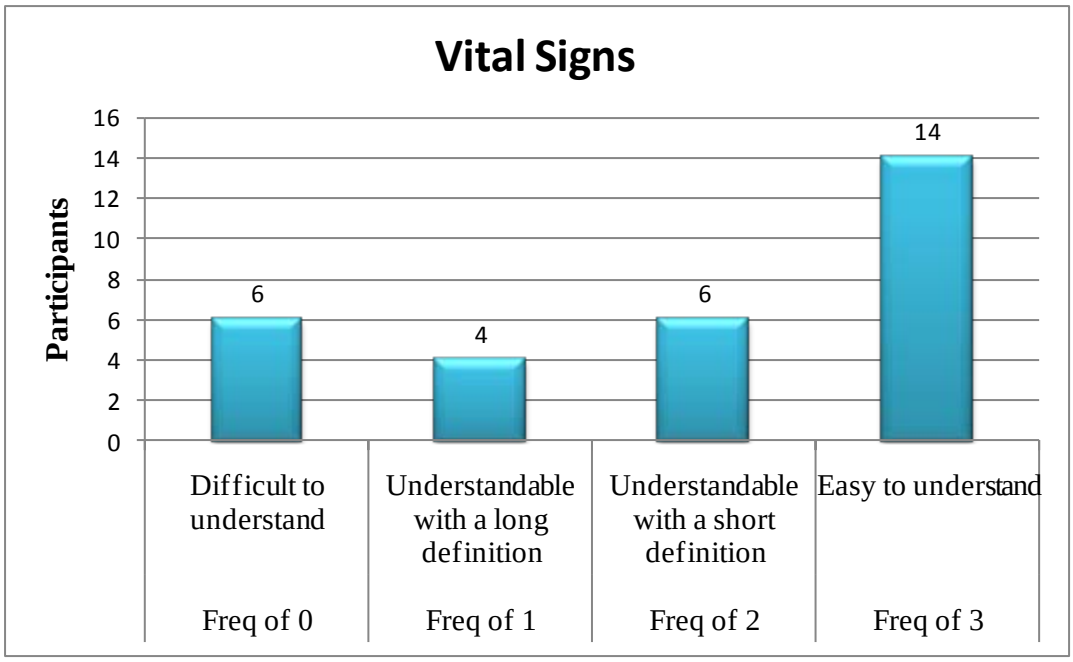

Figure 8: CCR Term which is "Understandable with Short Definitions"

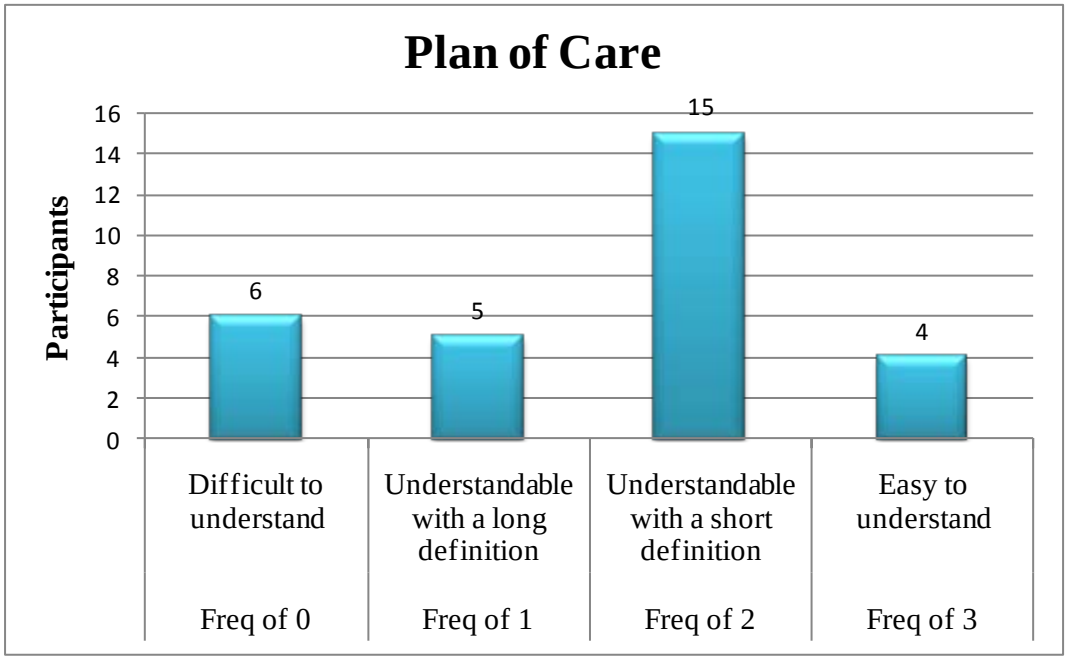

Figure 9: CCR Term which is "Understandable with Short Definitions"

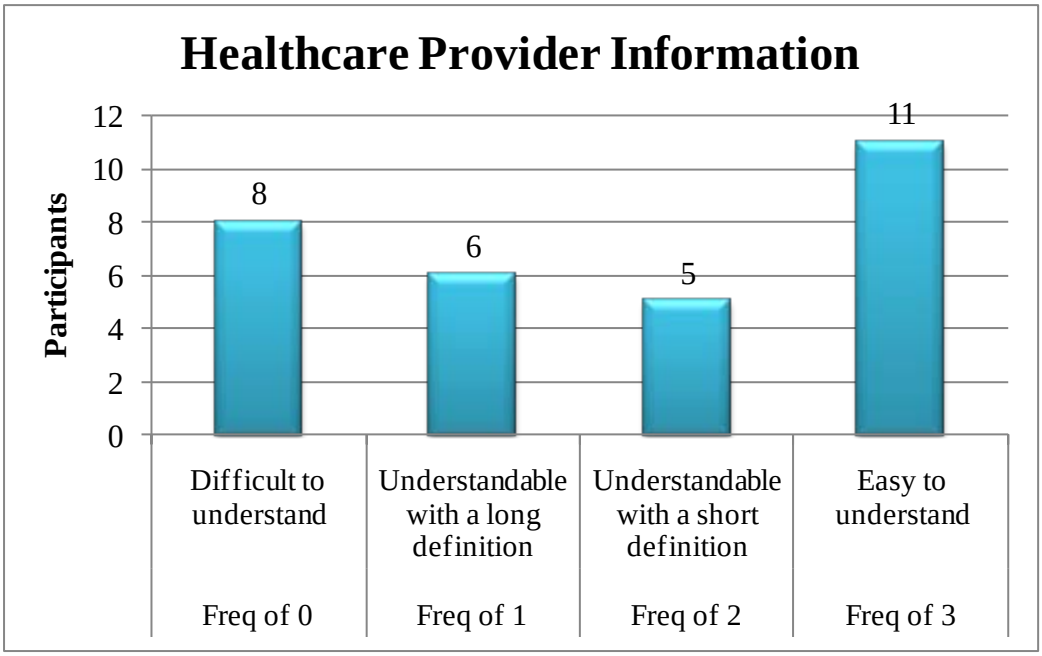

Figure 10: CCR Term which is "Understandable with Short Definitions"

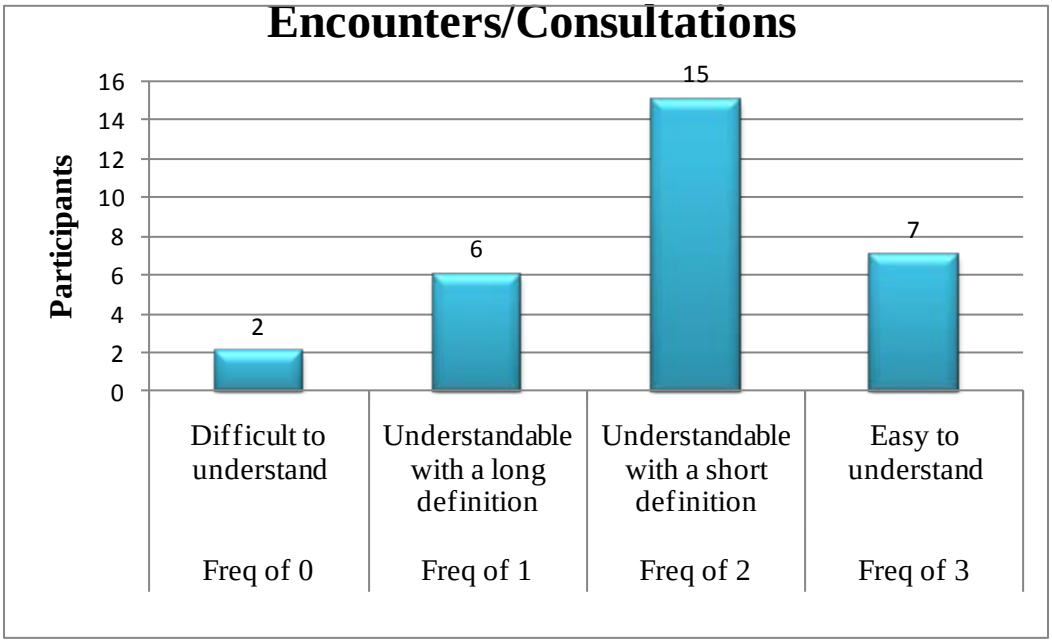

Figure 11: CCR Term which is "Understandable with Short Definitions"

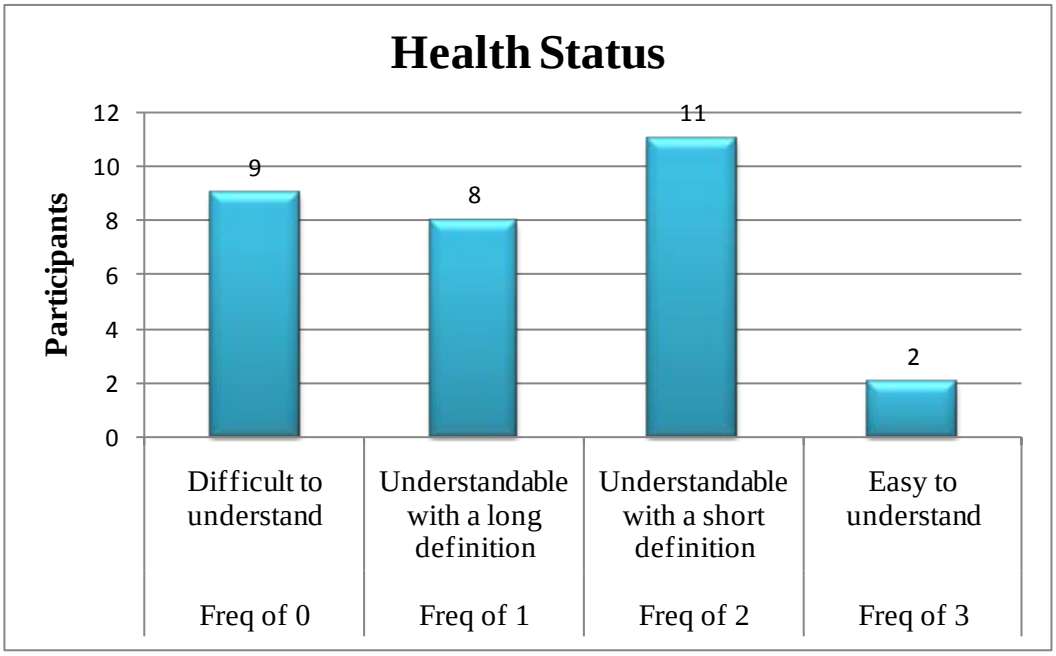

Figure 12: CCR Term which is "Understandable with Long Definitions"

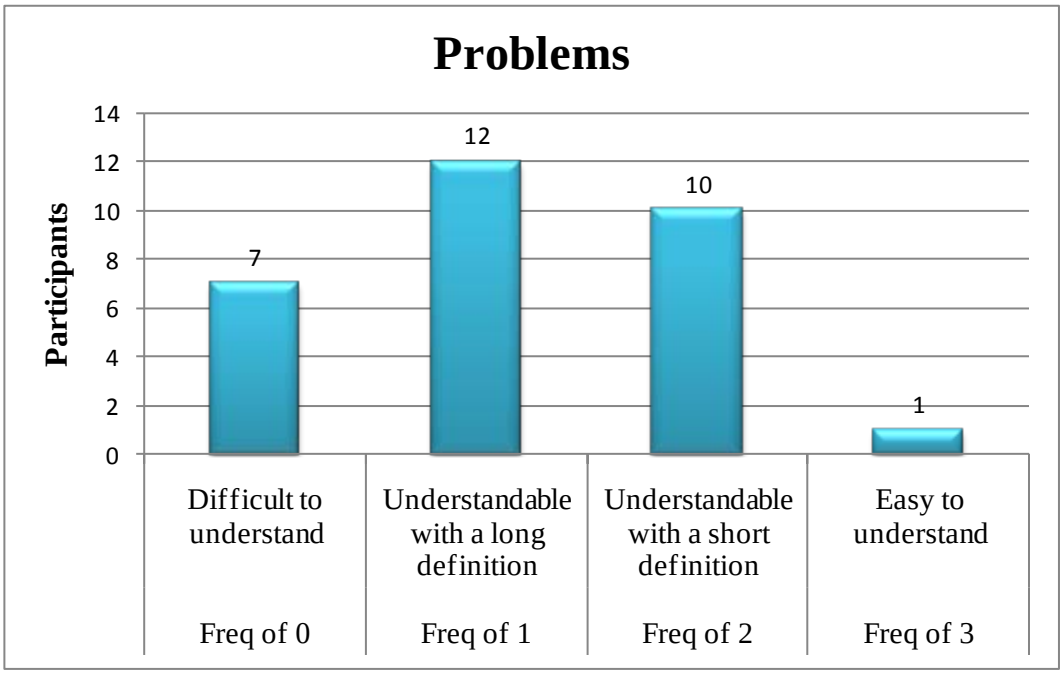

Figure 13: CCR Term which is "Understandable with Long Definitions"

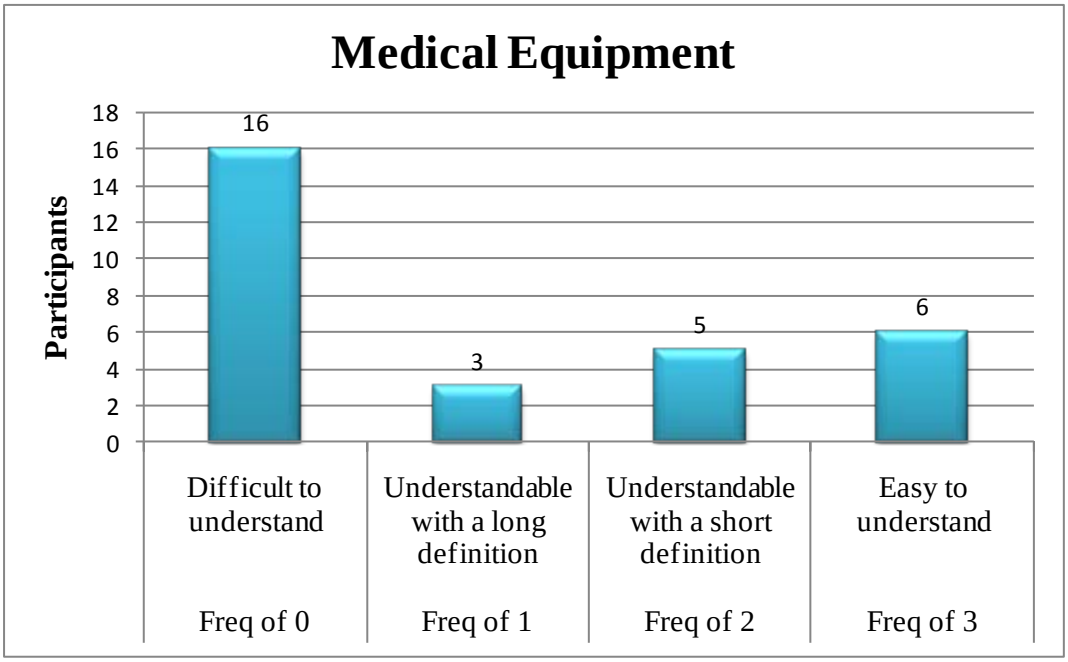

Figure 14: CCR Term which is "Understandable with Long Definitions"

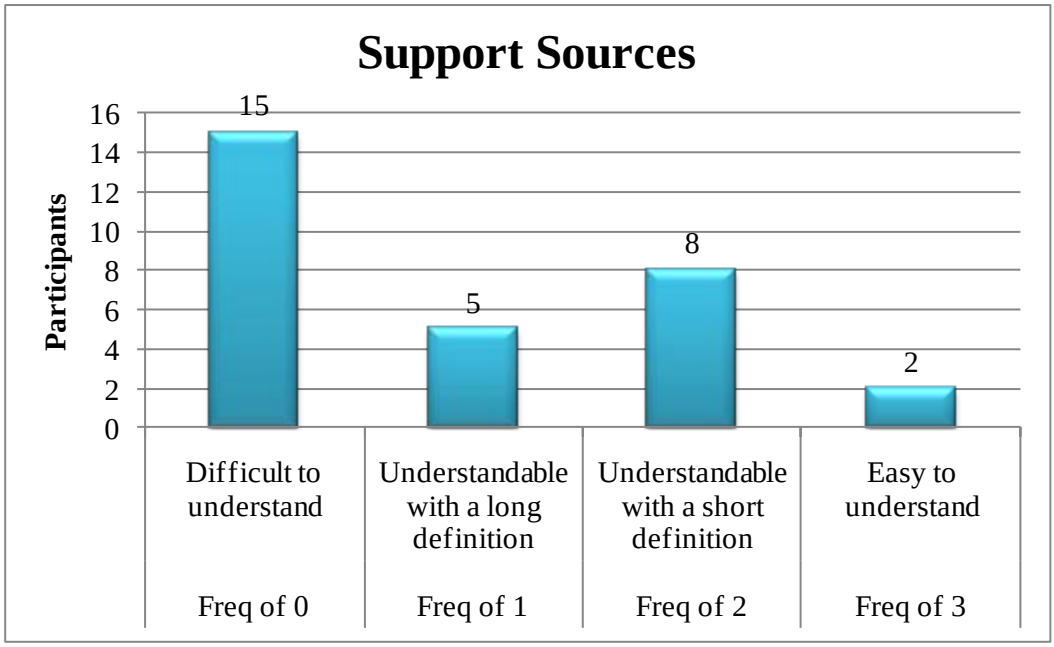

Figure 15: Term which is "Understandable with Long Definitions"

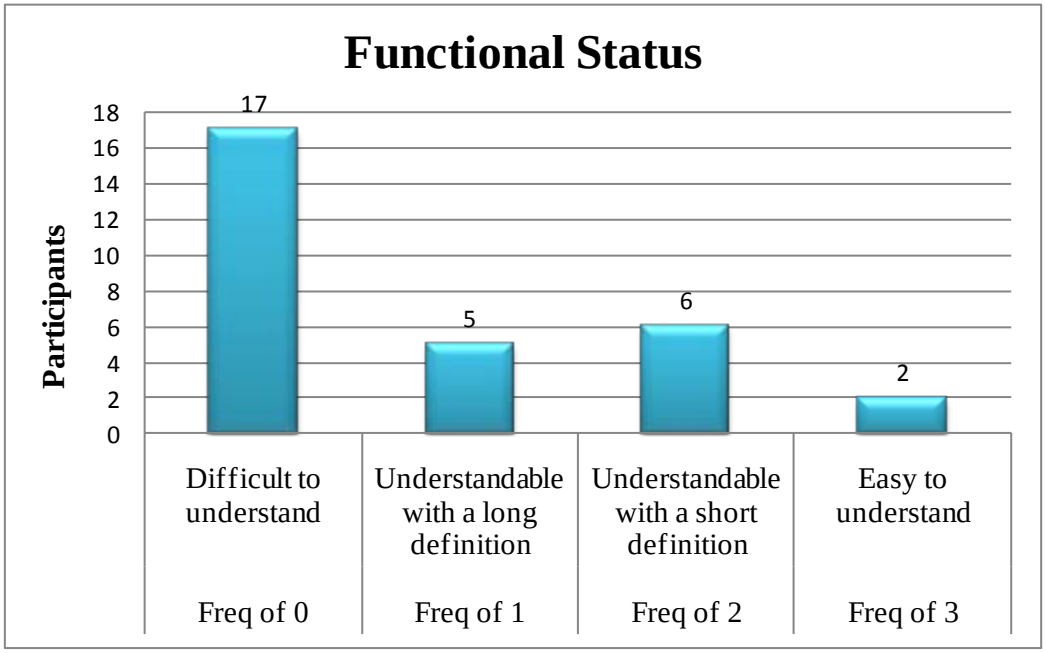

Figure 16: CCR Term which is "Understandable with Long Definitions"

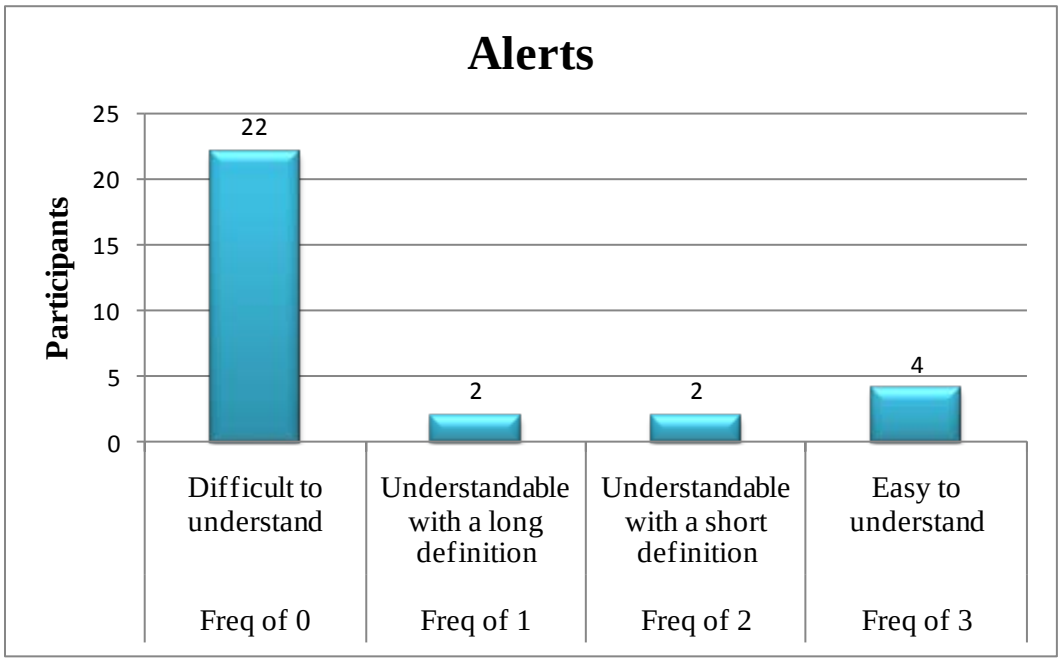

Figure 17: CCR Term which is "Understandable with Long Definitions"

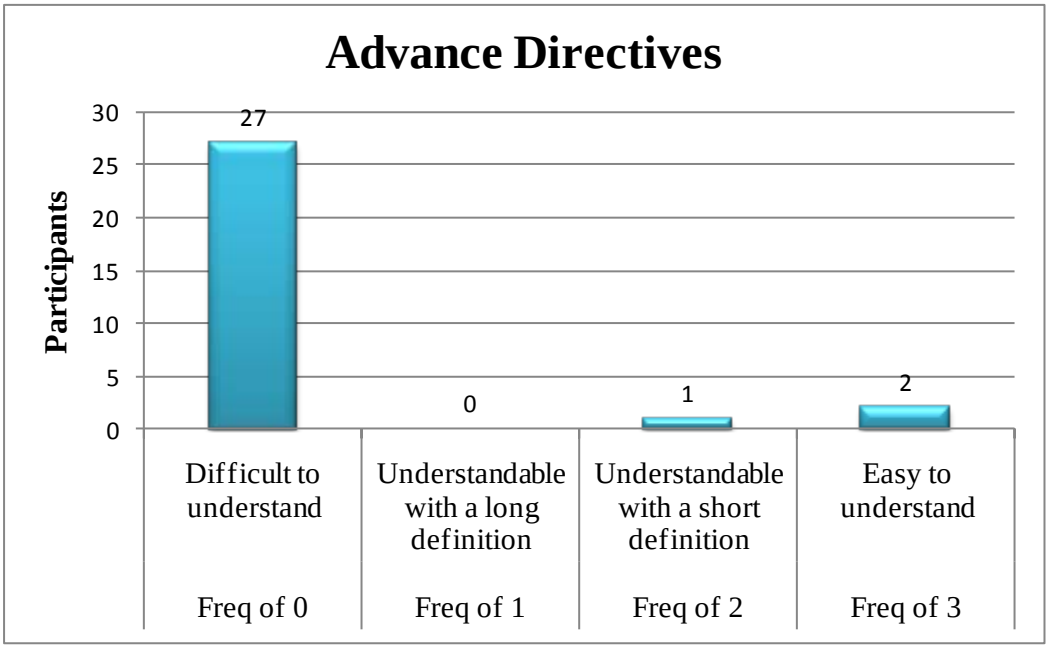

Figure 18: CCR Term which is "Difficult to Understand"

Table 13 demonstrates that participants had difficulty understanding some of the technical CCR terms because society does not have the same health background as healthcare professionals. Therefore, lay people prefer the use of understandable, common, and popular terms in PHRs; because they can easily determine the meaning of each term and provide the relevant information accordingly. For example, "medical equipment" is defined as internal or external devices used by a patient to enhance his health, such as pacemakers or oxygen tanks. An individual may consider an x-ray machine as "medical equipment"; however, this is incorrect. Consequently, they would provide inaccurate information. Participants suggested changing some of the technical and difficult to understand terms to simple ones. For example, the CCR term "payers/payment source" could be listed as "insurance information." Table 14 displays some CCR terms and simple alternative terms suggested by participants.

Table 9: Participants' Expectation of the Meaning of Some of the CCR Terms

CCR Terms	Participants' Expectation of the Meaning of CCR Terms
Alert	• Symptoms • Reminders • Signs • Indications of serious medical conditions • Database search alert
Problem	• Financial problems • Social problems • Personal problems • Any kind of problem but not related to health
Healthcare provider information	• Medical staff • Insurance companies • Employer • Whoever pays for health services
Medical equipment	• Equipment used for diagnosis or treatment • Physical equipment in hospital or Dr.'s office • Tools • X-rays
Encounters/consultations	• Whoever gives advice • Parents • Caregivers • Pharmacists • Friends
Advance Directives	• Instructions from health insurance companies • Recommendations from healthcare professionals • Help with payment plan • Preauthorization from health insurance companies

Table 10: CCR Terms vs. Participants' Suggested Simple Terms

CCR Terms	Terms Suggested by Participants
Payers/payment	• Insurance information
Alerts	• Allergies
Advance directives	• Legal documents • Living will • Power of attorney
Support sources	• Emergency contact information
Functional status	• Functional ability
Social history	• Life style • Social habits
Problems	• Major medical problems • Health problems • Health problem history • Current/past medical problems
Plan of care	• Treatment plan
Medical equipment	• Personalized medical devices • Internal or external medical devices used
Healthcare provider information	• Healthcare practitioners • Healthcare professionals • Healthcare personnel
Health status	• Description of current health
Encounters/consultations	• Appointments • Dr. visits • Healthcare professional visits

In determining participants' 1) level of physical activity, 2) knowledge of or use of the technology, and 3) interest in maintaining health information, the results indicated that the majority of the participants interviewed had a good self-perception of their overall health status. Roughly 96.7% of the sample described their overall health as "healthy" and rated their health status to be between "good" and "excellent."

All participants (100%) had a positive attitude regarding physical activity. For example, they exercised to promote their health, enjoyment and relaxation, and to maintain well-being. The majority of participants (96%) were physically active and involved in various types of workouts an average of 3 to 5 times per week: such as aerobic exercise, dance, swimming, jogging, basketball, biking, hiking, skating, boxing, jumping rope, rock climbing, and weightlifting. They also reported some negative associations and concerns with exercising, such as soreness, pain, tension, and injuries. Only 17% of the participants stored their physical data from exercising, such as distance, duration, calories burned, etc., in a paper format.

As far as evaluating participants' knowledge of or use of technology, all of them (100%) had positive associations with technology and the use of the Internet. Participants showed their full satisfaction with all types of technology because they could use it for communication, socialization, entertainment, education, enjoyment, etc. They also explained their negative associations and concerns regarding security and privacy issues. In addition, participants expressed concerns regarding being very dependent on technology, lack of communication with people, and being impersonal. Participants were technologically savvy and familiar with searching/googling personal health-related topics. The majority of participants, nearly 97%, had used WebMD (http://www.webmd.com) as a reliable, trustworthy, and professional source of

health information. Participants were familiar with this specific site as being very popular from TV commercials and wide-spread advertisements.

Responses to the questions involving the participants' attitudes toward creating Personal Health Records (PHRs), and thus owning their health information, revealed that a surprisingly high number of the participants (96.7%) displayed a positive attitude and response to the idea of owning and maintaining their own personal health information. They were supportive of PHRs (Delbanco & Sands, 2004; Heubusch, 2007a, 2007b; Kane & Sands, 1998; Markle Foundation, 2005; Ventres et al., 2006). They explained that such a system would help them keep track of their own health information, share important information with their healthcare providers, fill the gaps among healthcare specialists (primary physicians, dentists, ophthalmologists), and save their time and effort trying to communicate with multiple healthcare providers. PHRs would also make them feel more secure and comfortable because healthcare providers would have instantaneous access to their health information and treat them based on reliable, complete, accurate, and up-to-date health information (California HealthCare Foundation, 2010). This high percentage was somewhat unexpected, because the participants had never heard of PHRs before the interview. Participants agreed to be advocators, supporters, and educators of PHRs technology. Additionally, they would recommend PHRs to their family and friends (Denton, 2001). As a result, these participants provided valuable information on the value of PHRs and its data contents during the in-depth interviews. This information also included the drawbacks of PHRs and what needs to be addressed in future PHR design.

Although participants were in favor of PHRs and were interested in owning their health information, they were not ready at this time to be "early adopters" and take full responsibility for updating and managing their health information using such a system (California HealthCare

Foundation, 2010). This high percentage (96.7%) was somewhat unexpected, as one would assume that young, highly educated individuals who are technologically savvy would be advocators, supporters, educators, and "early adopters" of PHR technology. However, even when participants were not in favor of PHRs at this time of their lives, they said that they would consider PHRs in the near future, especially when they have a family (spouse and children) to take care of. Participants also reported that if they were to become totally independent from their family, they would consider PHRs. Participants maintained that entering data into PHRs is cumbersome and they did not have any spare time to take the responsibility to maintain and manage their own health information (Munir & Boaden, 2001). One participant specifically said, "It is time consuming and I have no time to add any more things to my life. I am a full-time student and work 20 hours a week." In addition, participants explained that they did not need such technology because they are healthy young adults and have no health problems to be managed through multiple healthcare providers. Another reason for their rejection of creating PHRs at the time of the interviews was that they depended on their parents to take care of their health records. Also, they assumed that healthcare providers would have all the necessary health information about them and would be able to retrieve all of their health data in case of emergency. Participants discussed the importance of PHRs with respect to empowering patients and their families. They stated that PHRs provide users with better tools for managing health information and better communicates with their physicians, especially when they are away from home. They also explained during the interview how PHRs could make them active participants in their health, such as providing their complete health history to new healthcare providers while they are in college. They expressed that an ideal and valuable PHRs would include all the important information about them, such as "identification information," "medication," "family

history," and "surgeries." It would further upload health information from the original source (healthcare providers) through connecting with an electronic health record; therefore, participants would not be required to enter the data manually (California HealthCare Foundation, 2010). Moreover, participants indicated that healthcare providers would not trust any information entered by a lay person. Therefore, healthcare providers, physicians in particular, will not pay attention to what a patient provides to them during any visit. For example, one participant described his experience as follows: "Do you think that any physician will trust any information entered by you?"; "Physicians will not take the time to read what you bring during a visit. They will rather question you till you forget what you came for."

More than half of the participants (60%) expressed their concern with the privacy and security of the system. However, the remainder of the participants (40%) were mildly concerned about this issue. They were very confident and trusted the terms and regulations that govern each site. The privacy and security issues involved with online personal health information is not a concern to them (California HealthCare Foundation, 2010).

Generally, all participants were concerned about the privacy and security of PHR systems, which they considered to be problematic. Overall, participants would like to own their health information; however, they are unwilling to manually enter, manage, and update their data on the system (Heubusch, 2007a; California HealthCare Foundation, 2010).

4.1.3 Needs Assessments from Participants' Perspectives

In response to the question which dealt with the participants' attitudes toward owning their health information by creating Personal Health Records (PHRs), a surprisingly high number of the participants (96.7%) displayed a positive response to the ideas of owning and maintaining their own personal health information and were in favor of PHRs (California HealthCare Foundation, 2010). However, since none of the participants had ever heard of PHRs before the interviews, such a high percentage was somewhat unexpected. Nevertheless, the participants assured the investigator that they would be educators, advocators, and supporters of PHR technology. Because of their positive responses to owning and maintaining their health information and their being in favor of PHRs, these participants provided not only valuable information on the value of PHRs and its data contents, but also information about the drawbacks of PHRs and what needs to be addressed in future PHR design.

Participants tended to want to include data contents in PHRs that are useful and helpful to both them and their healthcare providers. That is, make PHR contents speak for them by assisting healthcare providers in making correct medical decisions based on valid, accurate, complete, and up-to-date health information in case of an emergency to save their life and in avoiding any unnecessary medical mistakes, such as negative drug interactions. They also reported that they would like PHRs to consist of the initial data contents that healthcare providers usually ask for during each visit, such as "What medications are you currently taking?"; "Are you allergic to any medications?"; "Is there any family history of high blood pressure, diabetes, cancer?"; "Do you smoke?" Table 15 illustrates participants' needs with respect to PHRs data contents. It is worth mentioning at this point that healthcare providers' needs are what the CCR contains (the 17 CCR data items previously mentioned).

Table 11: Participants' Needs with Respect to PHRs Data Contents

Item	%	>50
Medications	100.00	Y
Family history	96.67	Y
Alerts	93.33	Y
Problems	90.00	Y
Immunizations	90.00	Y
Personal identification information	90.00	Y
Healthcare provider information	83.33	Y
Procedures/surgeries	83.33	Y
Imaging data	80.00	Y
Lab test results	76.67	Y
Social history	73.33	Y
Payers/payment sources	70.00	Y
Vital signs	66.67	Y
Plan of care	66.67	Y
Appointment Records	63.33	Y
Advance directives	56.67	Y
Health status	56.67	Y
Medical equipment	53.33	Y
Support sources	46.67	N
Encounters/consultations	46.67	N
Diet & weight records	43.33	N
Expense records	36.67	N
Functional status	33.33	N
Referral request records	23.33	N
Personal calendar/Reminders (as contents/information)	23.33	N
First aid information	20.00	N
Records of exercise habits/physical activity records	13.33	N
Identification of health goals/progress notes	10.00	N
Free text notes/personal diaries	6.67	N
Chat Records	3.33	N
E-mail Archive	3.33	N
Related educational materials (personal library)	3.33	N

As can be seen from Table 15, “medications” is the most preferred data item to 100% of the participants. The CCR data items that were selected for inclusion by almost all of the participants (90% to 97%) were “family history,” alerts,” “problems,” and “immunizations.” In addition, 90% of the participants wanted to include “personal identification information,” which is not a CCR item. The majority of participants (70% to 83%) pointed out the importance of including the following CCR items in PHRs “healthcare provider information,” “procedures/surgeries,” “social history,” “payers/payment sources.” The same percentage of participants suggested that additional items, which are not CCR items, be included in PHRs, such as imaging data and lab test results. Some of the CCR items were not important to participants; however, they were essential to healthcare providers. These items were selected by more than half of the participants: “vital signs,” “plan of care,” “advance directives,” “health status,” and “medical equipment.” The results reported that there is a set of CCR items that were not favored by the participants for inclusion in PHRs. Less than half of the participants recommended “support sources,” and “encounters /consultations.” Additionally, only a very low percentage of the participants suggested including some data items that are relevant to their needs, but which are not included in the CCR standards and thus are not relevant to healthcare providers’ needs. These items included “diet & weight records,” “expense records,” “referral request records,” “personal calendar/reminders (as contents/information),” “first aid information,” “records of exercise” “habits/ physical activity records,” “ identification of health goals/progress notes,” “free text notes/personal diaries,” “chat records,” “e-mail archive,” and “related educational materials (personal library).”

Furthermore, participants designed a structure for the most needed data contents that would serve them best to manage their health and share their health information with multiple healthcare providers. The results of the most relevant data contents and their structure from these users' perspectives are summarized in Appendix I.

4.1.4 Review of the Existing PHR Systems to Validate the Usefulness of Current PHR Systems Based on the Minimum Data Set Recommended by the ASTM CCR Standard.

The results of the qualitative review study showed that all PHR tools selected were designed to be user-friendly, enabling lay people regardless of their educational level to store, retrieve, and transmit key medical data, health information, and images electronically and enabling information to be easily accessed instantly 24/7 from any place in the world with Internet access. Generally, the ultimate goal of these applications is to enable individuals to manage and control their health information and provide them a snapshot of crucial information when needed. In addition, these PHR applications aim to give individuals more power over their own health information in order to help them achieve better health outcomes. Because PHRs deal with personal health information, they have explicit security and privacy policies. For example, they do not require any personal information such as Social Security Number as part of the log-in process. Vendors are trying to encourage individuals to share their PHRs experience with friends, family, patients, and colleagues, and let them know this service is available for all to use with no or at an affordable cost. When there is a fee, costs range from $30 to $150. For example, HealthString PHR charges are as follows:

Plan Name	Initial Cost	Renewal Cost
Individual Year-long Subscription	$30.00	$30.00
Family Year-long Package for Two	$55.00	$55.00
Each Additional Family Member	$10.00	$10.00
Lifetime Individual	$75.00	
Lifetime Couple	$150.00	

Moreover, PHRs have various purposes; the majority aim to store the most up-to-date snapshot health information for individuals. This is where information such as "medications," "allergies," "health history," "care plans," etc. is stored. Some PHRs are dedicated to promoting cancer screenings, immunizations, other preventive measures, and overall wellness. Vendors make PHR applications fast and easy for lay individuals to track their healthy habits and preventive health compliance over time. Others provide a place to shop for services, products, and easily track healthcare expenses.

Based on the literature review and the feedback from the pilot study, the PI expected significant differences between the CCR and PHRs contents; however, after thoroughly comparing the data category/elements of the ten free and ten for-purchase PHRs to the CCR, the results show otherwise. Table 18 reports the percentage of data categories in both free and for-purchase PHRs that match the CCR category.

It is apparent that both free and for-purchase PHRs contain the majority of the CCR data elements (15 out of 17 CCR items) that would be found on a waiting-room clipboard summary, such as “payers/payment sources,” “problems,” “family history,” “alerts,” “medications,” “procedures.” However, the web-based for-purchase PHRs include almost all the CCR categories/elements (50%-100%) in more detail than the free web-based PHRs.

Given the facts mentioned above, it is clear that available PHRs are personal, private, and an effective way to provide a complete panoramic picture of a person’s health, reducing the stress, which comes from having to remember critical health issues, which might have a negative impact on individual’s health. Providing healthcare providers with the most up-to-date, complete, and accurate key information at the right time for the right person will help them to accurately diagnose patients’ conditions and treat them accordingly to avoid any preventable medical errors. The results of the qualitative review study showed that all PHR applications that are currently available include simple terms and vocabulary to simplify communication and provide healthcare providers with the key information they need to best help patients. Results also proved that PHRs are an easy way to communicate with doctors and family regarding health conditions. For example, some of them are connected to Social Networking, such as Facebook, Twitter, MySpace, LinkedIn group. Also, some are connected to many hospitals’ and providers’ electronic health records systems. With the complexity of medical care and increase in baby boomers, PHR systems are growing, providing a new generation of tools and resources to simplify for healthcare consumers the complexities of healthcare information based on the CCR data categories/elements (California HealthCare Foundation, 2010).

Table 12: Mapping of Data Category in Both Free and For-Purchase PHRs to the CCR Categories

CCR data category	% of Free Web-based PHRs	% of For-Purchase Web-based PHR
Payers/Payment Source(s)	100	100
Advance Directive(s)	30	100
Support Sources	80	100
Functional Status	10	50
Problems	80	100
Family History	80	100
Social History	40	90
Health Status	20	100
Alerts	80	100
Medications	90	90
Medical Equipment	0	70
Immunizations	80	100
Vital Signs (See Results)	40	100
Procedures	70	100
Encounters	60	100
Plan of Care	0	100
Healthcare Providers	70	100

5.0 DISCUSSION

This section describes the shared care setting in which PHRs are functioning and benefiting all of the possible users, namely physicians, specialists, general practitioners, nurses, healthcare managers/authorities, epidemiologists, researchers, healthcare policy makers, research funding agencies, and ultimately healthcare consumers (Ball & Gold, 2006). This shared care setting may seem an ideal or futuristic situation; however, some parts have already been implemented in some European countries, while others are being implemented in today's national, or regional strategies for development of healthcare information networks (Neame, 2000).

It can be assumed that any desirable healthcare system ensures the continuity of care through all the stages of care delivery, including prevention, diagnosis, treatment and rehabilitation, as well as continuity across all the points of care such as: primary care centers, general hospitals, speciality hospitals, rehabilitation institutions, laboratories, pharmacies, and homes (Ball & Gold, 2006). This ultimate goal of continuity of care can be achieved by "shared care." This allows health professionals of all the stages to share vital and non-redundant patient information, thus contributing to better quality and efficacy of care delivery, improvement of their own efficiency and satisfaction in work, and ultimately, to the satisfaction of the patient–customer. This patient-centered shared care builds on health telematics networks and services, linking primary care centers, hospitals, laboratories, pharmacies, and social centers (Neame, 2000).

The main objectives of this study have been to evaluate the level of understandability of the Continuity of Care Record (CCR) data items for young healthy adults and to explore their needs and preferences toward PHR data elements.

5.1 HOW EASY IS IT FOR A YOUNG ADULT USER TO UNDERSTAND THE CONTINUITY OF CARE RECORD (CCR) DATA ITEMS?

The first research question is: How easy is it for a young adult user to understand the Continuity of Care Record (CCR) data items?

The results indicate that, generally speaking, participants have some difficulty with and below average level of knowledge of the CCR data items when compared to healthcare providers. The results are consistent with an earlier study conducted by Markle Foundation (Markle Foundation, 2003). It is apparent that the respondents have different levels of understanding of those items based on their background and experiences with utilizing healthcare services. The overall results suggest that participants understand the CCR terms easily or with short definitions under the following conditions: 1) interaction with family members already in the health field who discuss specific health conditions, 2) experience as a caregiver for family member with chronic disease or special needs, 3) coverage by health insurance and frequent utilization of health services, or 4) familiarity with medical Internet sites, such as Mayo Clinic and WebMD, or Google health-related topics/issues. Results confirm that there are four levels of understandability of the CCR data items. In the first category, respondents were able to understand completely the meaning of a data item without any explanation. They were able to provide an example of that data item to the investigator. These items were labeled as “Easy to

Understand" with no clarifications; the score for level of understandability for these items was 2.50 to 3.00.

In the second category, however, respondents were able to understand the data items only after short definitions based on the operational definition in the CCR given by the investigator. Items in this category were labeled as "Understandable with Short Definitions," with the score for level of understandability being 1.50 to 2.49.

In the third category, respondents were able to understand the data items only after receiving long definitions and explanations. Items in this category were labeled as "Understandable with Long Definitions." Their score for level of understandability is between 0.50 and 1.49.

The last category of level of understandability was "Difficult to Understand," meaning that participants had difficulty to easily understand this item even after being provided with long definitions; the score for level of understandability of items in this category was between 0.00 and 0.49. In other words, according to respondents' understandability, the CCR data items can be arranged into four levels in terms of difficulty for respondents. These levels vary from very easy or not difficult to understand, to somewhat easy or fairly difficult, to not easy or quite difficult, and lastly to not easy or very difficult.

In general, the first category includes five data items which are: "payers/payment source," "family history," "medications," "immunizations," and "procedures/surgeries." It is apparent that respondents were able to easily recognize and understand terms that might be considered common, familiar, popular, and widely utilized in everyday life by the lay people who do not have the same health background as healthcare providers. Also, these items do not include any confusing words or vague language that could lead to misunderstanding the terms.

For instance, “payers/payments source” was easily understood by the majority of respondents (74%) with an average level of understandability being 2.63. Because “payment” might be easier to understand when compared to “payers,” “payers” might require short explanations and definitions. “Payment” is self explanatory for the study sample that consists of native English speakers and is widely used by the public. In addition, it is worth mentioning here that the entire sample had health insurance through their parents and had widely utilized health services, which made them more familiar with some terms than those who do not have health insurance, and hence a lack of experience utilizing healthcare services.

Another example from the “Easy to Understand” category was “family history.” All participants fully understood the concept with an average level of understandability being 3.00. This might be due to the fact that the concept is unanimously used by all providers and care givers to list all hereditary conditions in the family.

Another fully “Easy to Understand” item was “medications” with an average level of understandability being 3.00. This term is obvious and is used widely by the public, hence cannot be confused with another term.

The fourth item that was completely recognized by respondents with the same score of understandability as the above is “immunization.” This term may be considered both technical and lay languages. For the same reasons as the above, this term is widely used and it is difficult to find someone who is lacking knowledge about this concept since it is used from childhood throughout the life span of individuals. In fact, participants were able to give “vaccination” as a synonym to the term “immunization,” thus indicating that participants are very familiar and comfortable with the term.

The fifth almost fully understood CCR data item was “procedure/surgeries” with an average level of understandability being 2.97. Similar to some of the other terms in the “easy to understand” catogory, “procedure/surgeries” is commonly used and easy to understand by the general population. However, it is worth mentioning that one participant among the thirty needed short explanations for this item.

The next level of understandability consists of five CCR data items. These were not understood by respondents right away; rather, they were understandable after providing short definitions. These items were referred to as “Understandable with Short Definitions,” with an average score of understandability that ranged from 1.50 to 2.49. This category included the following: “vital signs,” “encounters/consultations,” “healthcare providers,” “plan of care,” and “social history.” Due to the participants’ tendency to have health insurance and regularly utilize healthcare services, they have different levels of understandability of the CCR data items. For example, “vital signs” were recognized easily by less than half (47%) of the participants with an average score of understandability equivalent to 1.93. Although this term might be simple and easy to understand to those in the healthcare field, it seems respondents with no healthcare background struggled with this term. More than half of the participants (54%) were not sure what was actually meant by “vital signs.” This may indicate that the more technical the term is, the harder it is to be understood by lay people.

The second item in this category was “encounters/consultations” in which half of the respondents were able to understand the term after being provided short definitions. This may be due to the confusion associated with the word “encounter,” which might have different meanings for different respondents. This term includes different possible meanings, such as it may be related to encountring any of the healthcare providers including physicians, nurses, allied health

professionals, or something totally different like encountering a specific type of disease or even treatment. Some participants assumed "encounter" was related to parents, caregivers, friends, or any person who gives advice.

The third item in the "Understandable with Short Definitions" category was "healthcare provider information" which was recognized by some of the participants after being provided short explanations, with an average score of understandability being 1.63. It is clear that this data item is too broad for an average young adult to fully understand. "Healthcare providers" have multiple meanings for the participants because they associate it with some terms, such as "insurance companies," "employment," or "whoever pays for received health services." The word "information" may also have a number of possible meanings, such as "financial information," "address," "name," "billing information," or "type of service information."

"Plan of care," also in this category, received an average score of understandability equivalent to 1.57. Participants seemed to be unsure of what was meant by the word "plan" and what this "plan" actually includes. An average person is usually familiar with having a "medication" after seeing a doctor; however, to have a "plan of care" seems to be puzzling to the young adults who participated in the study. The "plan of care" term might be better understood by older patients or patients with multiple chronic conditions and have multiple healthcare providers and specialists; and consequently, have a "plan of care" for those multiple chronic conditions.

"Social history" was the last data item in the "Understandable with Short Definitions" category, with the respondents' level of knowledge equivalent to 1.50. This CCR data item was understood when half of the respondents were provided with short definitions. Although the word "history" was well known to all participants, the majority of the participants struggled with

the word “social.” This word seems to be too general because participants did not understand what specific “social information” could be classified under it.

The third level of knowledge included six of the CCR data items. This category consisted of data items that were not understandable to average healthcare consumers, such as “health status,” “problems,” “medical equipment,” “support sources,” “functional status,” and “alerts.” Respondents had difficulty understanding these terms without being provided long definitions. The average score of understandability of these items ranged between 0.60 and 1.20.

The most widely understood CCR data item in this level was “health status,” with an average score of understandability equivalent to 1.20. Although it was expected that this data item should have been fairly easy to understand by most participants, the results indicated otherwise. More than half of the young adults failed to understand this term without being provided long definitions or explanations. Participants incorrectly associated the term with “the past history of one’s health,” “history of diagnosis or health problems” or “ family history of certain conditions.” That is, they associated “health status” with any hereditary diseases that run in a family. However, according to the CCR, the correct definition of “health status” is “how an individual describes his/her current health (ill, any specific health issue, healthy, hospitalized, long term facility care, etc.), including a description of the symptom, disease, data about births and prenatal care, deaths and infant mortality, childhood and adult immunizations, smoking and overweight/obesity rates, mental health, diseases, such as heart disease, cancer, strokes, data and information related to HIV/AIDS.” It should be noted that “health status” is very specific, technical, and precise. Therefore, participants recommended using simple terms more easily

understood by average healthcare consumers correspondent to an Eighth grade reading level, such as “current health status” (HIMSS, 2007).

The next data item was “problems,” which constitutes an imprecise term that might encompass an array of problems to the participants (Bates, 2006). This item was identified with an average score of understandability equivalent to 1.17. Participants had difficulty understanding this term because they associated it with different types of problems, such as “family problems,” “financial problems,” “social problems,” “academic problems,” “friendship problems,” etc. However, they did not think of the term as related to “health problems.” According to the CCR, the definition of “problem” is “any complaints, conditions, diagnoses, symptoms, findings, and complaints that contains data defining the patient’s relevant, current, and historical clinical problems, conditions, diagnoses, symptoms, findings, and complaints.” The overall results reported that almost all participants (97%) had difficulty understanding “problem” without being provided short or long definitions. It is obvious that having the word “problem” by itself is not an adequate data item for a young adult to comprehend. Participants suggested making this term easier to understand for their generation by simply renaming it “health problem.”

“Medical equipment” was the next data item. It had a low average score of understandability equivalent to 1.17. Participants were able to comprehend the term only after being provided long definitions. They had confusion with the term because they incorrectly associated it to “physical equipment,” which is used by healthcare providers at any healthcare facility for the purpose of diagnosis, treatment, evaluation, surgery, etc. For example, “medical equipment” could be as basic as small tools such as a stethoscope, a blood pressure cuff, a oxygen monitor, or any tool that is used to conduct research and perform tests. Participants

defined “Medical equipment” as big machines for radiological films such as a computerized tomography scanner (CT scan) machine. However, the CCR definition for this term is far from what the participants had expected. According to the CCR, the definition of “Medical equipment” is “a patient’s implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history. It is also used to itemize any pertinent current or historical durable medical equipment (DME) used to help maintain the patient’s health status.” Participants pointed out that the use of easy vocabulary could help an average person to easily understand the meaning without confusion (Heubusch, 2007b; Rodriguez et al., 2007). For example, the use of the term “internal/external medical equipment used by a patient” rather than “medical equipment” would be easier to understand not only for health professionals, but also for the public.

The next CCR term was “support sources,” with an average score of understandability less than one (0.90). The results revealed that this data item was vague to the majority of respondents (94%). It must be noted that half of the participants found this term to be difficult to understand. Only two respondents (7%) understood the term easily, and the rest (44%) were in need of either short or long definitions. The word “support” seemed to be what most interviewees struggled with. They were unsure of which type of support: “medical support,” “social support,” “financial support,” “legal support,” “emotional support,” etc. The CCR defines this term as, “anyone that provides support to individuals in cases of seeking healthcare and services such as lists the patient’s support providers and contacts (family, next of kin, legal guardian, durable power for healthcare, clergy, caregivers, support organizations, etc.”

Less understood, with a score of 0.77, was “functional status” data item. It is discernible that this item was difficult to understand by more than half of the participants (57%), as with “support sources,” “functional status” had only two respondents (7%) who understood the term easily.

The “alert” data item was recognized even less by participants, with an average score of understandability equivalent to 0.60. Participants associated “alerts” with a red-flag, which indicate serious problems such as fever or rash. They also thought it might be related to reminders of an appointment or medication.

The last and the least understood CCR data item in the “Difficult to Understand” category was “advance directives,” with only an average score of understandability equivelant to 0.32. Young adults included in the study sample were not aware of “advance directives,” because this term mainly deals with issues that concern older people or those with multiple serious chronic diseases (HIMSS, 2007). Being young and healthy, in general, does not require the knowledge of this unfamiliar term. Living with or caring for older family members, or having a fair amount of medical legal experience might also make this young group more informed.

Based on the above discussion, it is clear that out of the 17 CCR data items, the participants were able to easily understand only five data items without any intervention. Eleven data items required some type of explanation to be provided with either short or long definitions. In other words, the majority of the data items are unfamiliar to young adults (Armijo et al., 2006; Sherrilynne, 2007; Sittig, Masys, Brennan, Chute, & Oberle, 2007; Smith, Treitler, Keselman, & Zielstorff, 2007; Zeng & Tse, 2006). It is apparent that some of the popular terms used in daily life or media are among the well known data items, while those that were not used on a daily basis are difficult and foreign to young adults. Also, we could conclude that those data items

understood with short definitions might be somewhat recognizable to participants, but not fully understood.

In summary, participants could understand some of the CCR data items. It is very cricial that PHR users fully understand the CCR items in order to provide an accurate, complete, and up-to-date health information to avoid any possible medical errors. The CCR standard is a patient health summary standard. It is a way to create flexible documents that contain the most relevant and timely core health information about a patient, and to send these electronically from one care giver to another. It contains various sections such as: patient demographics, insurance information, diagnosis, problem list, medications, allergies, and plan of care. These represent a "snapshot" of a patient's health data that can be useful or possibly life saving, if available at the time of clinical encounter. The ASTM CCR standard is designed to permit easy communication by a physician using an Electronic Health Record (EHR) system at the end of an encounter (Hassol et al, 2004). Because it is expressed in the standard data interchange language known as Extensible Markup Language (XML), the CCR can potentially be created, read, and interpreted by any PHR or EHR systems. The CCR can also be exported in other formats, such as PDF and Microsoft Word 2007 format. Data in healthcare, especially patient-based clinical data, have long been entered and stored on paper. Paper records usually allow practitioners to record information in a semi-structured, free-text format. One weakness of paper records is that the information documented can be accessed by only one person at a time at one location. Sharing paper records is cumbersome and cost-inefficient (Cimino, Patel, & Kushniruk, 2002). More importantly, it presents a challenge to aggregate all the data from different sources in order to find patterns which are often used in health policy analysis (Hassol et al, 2004).

The national priority is to establish a networked PHR system that shares the integrated information of each individual at the point of care. To achieve this goal, a totally automated PHR system is needed at each healthcare institution. More importantly, these institutions should have the capacity to share information with others (Cimino, Patel, & Kushniruk, 2002).

5.2 PERSONAL HEALTH RECORD AND END-USER NEEDS

Research question two: To what extent do healthcare providers and users have different needs regarding the data elements of the personal health record system?

When comparing participants' needs to healthcare providers' needs, we can safely draw the following conclusions. Healthcare providers and users demonstrate substantially similar needs and desires regarding their preferred Personal Health Record (PHR) contents. For example, healthcare providers focus on data that might be helpful in the case of an encounter with potential PHR users. Health information such as "problems," "family history," "social history," "medications," and previous "procedures and surgeries" is what matters most for healthcare providers (Bonander, Crawford, Kukafka, Daniel, & Mandl, 2007; Heubusch, 2007a, 2007b). Such information is critical to physicians in aiding them to reach an accurate diagnosis. Similarly, results support that the participants have the same interests in data items that the CCR provides—fourteen data items out of the seventeen CCR data items were chosen by the participants as the most important items to be included in any PHR. This leads us to conclude that the CCR is a fair representation at this time of PHR history for both healthcare providers and users. One explanation is that the PHR is a new concept and is not widely used.

Thus, the public's lack of experience and knowledge about the value and benefits of the PHR, leads them to be satisfied with what data contents are currently offered in the PHR based on the healthcare providers' perspective and the CCR (Bosworth, 2007; Cronin et al., 2007; Heubusch, 2007a, 2007b; Rodriguez et al., 2007). Therefore, more education and training to both healthcare providers and consumers might contribute to a wider use of the PHR (Tang et al., 2006).

For the purposes of this paper, the PHR is defined as "digitally stored healthcare information about an individual's lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times" (Cimino, Patel, & Kushniruk, 2002). The PHR is not a goal in of itself; rather, it is a tool for supporting the continuity of care and consequently the quality, access and efficiency of health care services. In other words, the enabling factor of the patient-centred shared care is the availability of both clinical as well as administrative patient data through the PHR that are accessible, secure and highly usable in the European multilingual environment (Neame, 2000).

It is worth making a clear distinction between the PHR and the PHR system. The PHR system functions on the PHR in order to manage and provide information to authorized stakeholders in a user-friendly manner. The system can be small group of computers, a hospital information system, or a group of hospital and primary care systems in a regional network. Ideally, PHR systems help users to retrieve information in a fast and user-friendly manner (interfaces), communicate easily with others, and make user's work more effective. PHR systems ensure confidentiality at all times by meeting security and HIPPA requirements.

Furthermore, from this definition we can immediately differentiate PHR systems from the medical record systems that are normally stand-alone. The administrative systems, departmental clinical systems, or even stand-alone general practitioner's systems are not examples of PHR systems but rather limited scope electronic medical systems, computerized medical systems, or EHR. Thus, PHR supports the decentralized network of health care delivery institutions that will ideally slowly replace hospitals as centers of care delivery. The experts in the field of medical informatics and telematics have been trying for decades to describe the ideal PHR on both sides of the Atlantic. In 1991, the Institute of Medicine in the US published a report called "The Computer-Based Patient Record: An Essential Technology for Health Care" describing the requirements of the PHR and making recommendations for the future design. In the same year in Europe, the requirements of a PHR were formulated in the work-programmed of the European Union R&D programmed called Advanced Informatics in Medicine (AIM), which is now called "Telematics Applications for Health." Further recommendations were agreed in the AIM/CEN workshop on medical records in 1993 and its follow up, the EU/CEN workshop in 1997 (Cimino, Patel, & Kushniruk, 2002).

5.3 USEFULNESS OF PERSONAL HEALTH RECORD SYSTEMS

In order for a Personal Health Record (PHR) system to be useful and beneficial to all stakeholders, it should include at least some functional requirenments that can be categorized as: 1) accessibility and availability—continuous access to patient data and timely access to other information resources; 2) reliability—ensures data integrity and permanence of original information in agreed format and for given time; 3) usability and flexibility—supports multiple users' views and user-friendly interactions, such as input and output of data; 4) integration—enables the integration of different administrative and clinical systems; 5) performance—provides information normally within a few seconds; 6) confidentiality and audit ability—provides an audit trail that documents the interactions and authentication of information using user identification, e.g. digital signatures (Markle Foundation, 2004).

There are many other attributes of PHR systems that could be discussed, such as the facilitation of clinical reasoning, support in measuring and managing costs, linkage to knowledge bases, and support for monitoring and outcomes, etc. The requirements and the beneficial features list will continue to grow as healthcare providers and consumers realize the potential of the PHR. In fact, it is not difficult for any healthcare professional to notice the direct benefits of using the PHR and having both administrative as well as clinical data that are accurate, complete, up-to-date, accessible, comparable, communicable, and confidential (Markle Foundation, 2004).

The significance of computerizing medical records in the form of EHR and PHR has been reported in the literature (Markle Foundation, 2003, 2004) for many areas include, but are not limited to, the following:

1) the area of preventive care, information is provided to both healthcare consumers and health professionals through automated reminders and alerts (e.g., immunizations, screenings) that could reduce medication errors, adverse drug reactions, and ultimately promote overall wellness (http://www.mehima.org). Also, regarding preventive care, data is made available about a population's health status, allowing for monitoring and decision making.

2) the area of diagnosis, previous patient encounters and summary information, such as medical history (previous illnesses, conditions, surgeries), laboratory tests, or images are quickly available not only within the hospitals, but also to general practitioners and other centers of care (Endsley et al., 2006). This information linked to knowledge in the form of research papers or clinical databases will support decision making and clinical research.

3) the area of treatment, the PHR's link to knowledge could provide internationally agreed guidelines, outcomes can be better monitored and assessed, and a multi-disciplinary environment for treatment and rehabilitation can be supported. The benefits are also obvious for healthcare managers and authorities. For example, better data is available for resource management; for automation in the referral process and better use of specialists; for quality assurance and financial forecasting; and for support to regional or national decision making, such as decisions on reimbursement of medical procedures. There are several studies that indicate direct financial benefits of using electronic medical records in an outpatient setting as well, such as reduction of labor costs for coding, billing, and reduction in cost for repetitive tests (Wang et al., 2003). For general practitioners, savings come from better management of their practice, and simply, less time spent searching for critical information translates into spending more quality time with patients. Of course, one should not forget the initial costs and the extra expenses for support personnel and operation of such systems. There are too few PHR systems with the

above mentioned requirements implemented to have concrete data on improvement of quality of practice or return-on-investment analysis (Wang et al., 2003). How many PHRs have been installed and are functioning around the world? Very few, if any, as we have defined them with all the beneficial attributes (Heubusch, 2007a).

5.4 TO ESTABLISH THE DIFFERENCES IN PHR DATA ELEMENTS ACROSS EXISTING PHR SYSTEMS

Some projects like SYNAPSES and HANSA encounter technical diffuculties in integrating multiple health information systems (Matthew& Johnson, 2002). However, there is more to these difficulties than interfacing the existing system and setting up intranets in a hospital. There is a great need for conceptual work on the architecture of the PHR systems, which will give the possibility of accommodating ever-increasing amounts of patients' data that can be shared and viewed by all healthcare professionals within and outside of any healthcare facility (Kupchunas, 2007).

In general, the few hospitals that have good examples of PHR systems are usually pilot projects that have been running for many years with strongly committed leaders and users and with enough resources. As technology evolves and some standards emerge, the installation of PHR systems in hospitals in Europe will increase. Many European countries, such as Denmark, Finland, and Sweden support national projects and strategies for regional health telematics networks and in that way, they are addressing the issue of standardized PHR that can be shared within hospitals, among multiple hospitals, and primary care centers (Bakker, 2004). Personal Medical Record Systems (PMRS) in addition to practice management systems for a general

practitioner have the highest penetration so far—both are very popular in countries with a strong tradition of primary care, such as the United Kindom, Ireland, Netherlands, and Denmark.

A study performed by the Community Association Management Group (CAM) in 1996 indicates the percentage of physicians using computers in their medical practice in eleven European countries (Fig. 19) (Bakker, 2004).

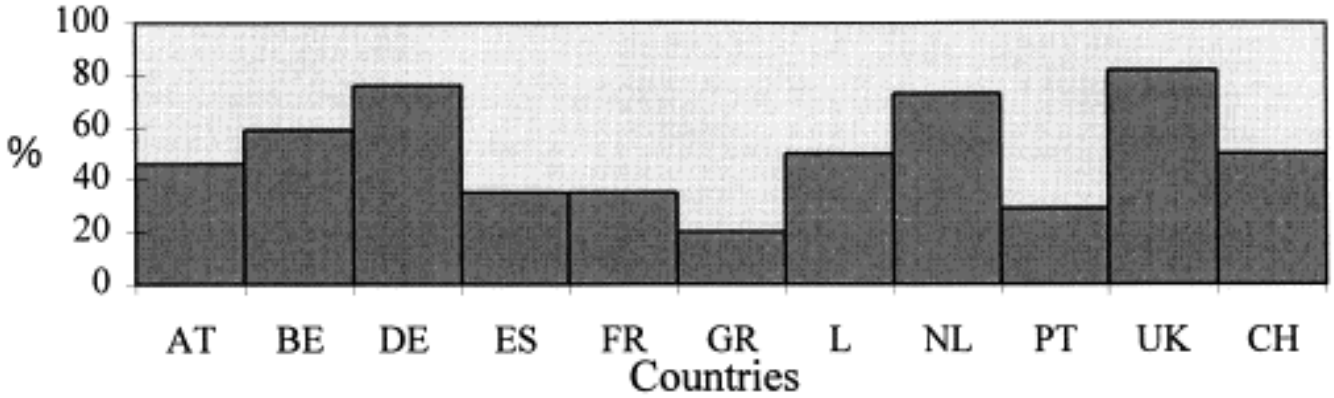

Figure 19: Percentage of physicians using a computer in their practice (National Committee on Vital and Health Statistics, 2006)

The figure indicates that more than 90% of General Practitioners (GP) in the UK are computerized. It must be noted that having a computer does not automatically mean that the physician uses the computer to store clinical data regarding patients. Therefore, the percentages of physicians that use PMRS are normally much lower. It is worth mentioning that this section is refering to PMRS and not to PHR systems as defined in the first chapter, since these GP systems are normally stand-alone (recall the first stage of use of informatics in healthcare). Further study in the UK shows that the use of the software by GPs in the UK is mainly for patient registration (98%) and repeat prescribing (94%). Only 29% keep full clinical records electronically and only 14% have a ‘paperless’ office (Bakker, 2004).

The computerization and use of electronic medical systems is rapidly growing in some European countries, either because the GPs act as gatekeepers working alone or in small groups, thereby making it easier to manage the systems (e.g., UK and The Netherlands), or because of regulations and policies that require the physicians to submit reimbursement claims electronically (e.g., France). Moreover, some countries' decision to distribute patient-health cards requires the physicians to buy a card reader and computer (e.g., Germany). Finally, the use of electronic medical records in primary care is much higher in Europe compared to anywhere else in the world, including Canada and the US, mainly due to the European governments' reimbursement schemes for the purchase of hardware and software (Markle Foundation, 2004).

5.5 IMPLEMENTATION CHALLENGES

Why are there so few Personal Health Record Systems (PHRS) available and even fewer implemented around the world? The market seems to be booming and many Health Information Management professionals are contributing to the PHR in many ways, such as participating on the Personal Health Information Practice Council. In addtition, publications on the subject are rising, and the conferences on the PHR are attracting hundreds and in some conferences, thousands of users and providers. In fact, a simple Internet search will yield hundreds of references to PHR. It is a mystery then that after 30 years of research and development, PHR are still so rare (Clarke et al., 2006; Endsley et al., 2006; Lowes, 2006; Markle Foundation, 2004; Ventres, Kooienga, Vuckovic, Marlin, Nygren, & Stewart, 2006). I attempt to explain the problems and challenges of implementation of PHR systems via the following six categories:

organizational and cultural, technology and standards, legal requirenments, industrial and market factors , lack of vision and leadership, and acceptabilitiy and usability of PHR.

1) Organizational and Cultural Issues Relating to Healthcare Delivery:

This applies to countries or regions where the organization of the care delivery cannot ensure continuity of care with or without information systems. Many cultures do not support the idea of sharing patient information. Each professional is trained to trust no one and is even penalized for relying on information from other colleagues. Often, old conflicts and mistrust between different specialists, or between physicians and nurses, prevent the efficient sharing of information in any form. Most of these countries are currently considering some form of health reform to introduce some degree of shared care and exchange of information, primarily in order to control the rising cost of healthcare (Clarke, Meiris, & Nash, 2006).

2) Technology and Standards:

The main challenges from the technological point of view, which may be geographically distributed, refer to the storage, maintenance, communication, and retrieval of multimedia information in different technological platforms and heterogeneous database systems (Kupchunas, 2007). Research and development projects have recently focused on integration and interface of multivendor platforms, as well as the development of health sector specific middleware and applications. As previously mentioned, there are projects such as SYNAPSES, HANSA, and SYNEX. Also, large companies have many problems keeping the initial "legacy" systems running in hospitals and interfacing them with new departmental systems and updating to new technologies. This integration effort is critical because the number of different single-purpose systems (administrative, insurance, clinical, nursing, etc.) is rising. It is not uncommon

to see within one hospital department three computers, each for one specific aspect of patient care and management.

In this area, the new intranet networks have proven to be the solution to many integration and communication problems. The standardization of the PHR parameters has a large impact on the development of the PHR systems and the market in general. The standardization issues can be grouped into the following categories:

- Record Architecture Standard: the agreed structure that can accommodate all types of data, support different views, and at the same time preserve the meaning and the context.
- Terminology Standard: necessary to preserve the meaning for proper coding of diseases and classification of medical procedures. Also, a terminology standard is essential for any possibility of multilingualism and to connecting and updating other information sources. The development of terminology is long lasting, difficult, and requires a concerted effort by many disciplines and countries (American Academy of Pediatrics, 2009).
- Communication Standard: communication standard of the records among different users, which is the fundamental feature of the PHR. The standardization of the exchange format substantially depends on the previous two categories because access to the PHR and the "virtual" display of requested information needs a dictionary of terms and objects related to the structure in the health records (American Academy of pediatrics, 2009). In the future, there is an expected increase of those using the Intranet approach for institutions and an expected increase in the Internet based communications for regions. There is also a large effort by the projects and standardization bodies in the area of Electronic Data Interchange (EDI) to standardize some particular health data—for

example, laboratory input–output, discharge summary, and communication between hospitals and General Practitioners (GP).

- Security Feature Standards: For example, digital signature, digital keys, and other authentication systems. Most of the security applications and technologies are not health-sector specific, and development is mainly controlled by large financial or military institutions. The issue of security is closely related to the requirements of confidentiality, which are inherent in the definition of the PHR by American Health Information Management Association (AHIMA) and will also be legally required by national legislation (Markle Foundation, 2004). In Europe, the standardization organization is called the Committee European de Normalisation (CEN), which includes the technical sub-committee TC 251, responsible for medical informatics. The TC 251 committee gathers experts from all over Europe to propose standards. The first working group is responsible for the standardization of the above issues for the last few years, resulting in some pre-standards. Slow procedures and lack of funding are the major obstacles in the adoption of these standards (Clarke, Meiris, & Nash, 2006). In the US, however, the approach to standardization is quite different. It is more industry controlled, and the responsibilities for medical informatics are spread out over many groups, organizations, and committees (Kardas & Tunali, 2007).

3) Legal Requirements:

This concerns the confidentiality of personal data and requirements with respect to storage and authentication of patient-related data. It is clear that unless a law provides the possibility for patient records to be kept only in digital form, there will be no wide implementation of PHR systems; and it will be used only in small pilots—"digital islands,"—or specialized departmental

and organizations systems—such as the Cardiovascular Organization, the American Lung Association, dialysis organizations, and cancer organizations (The Personal Health Records Council Practice, 2009). Thus, the legal framework has to address the issues of confidentiality and privacy; permanence of data; digital signatures; and authentication of systems. The issue of a patient identifier (the necessary link between all the distributed patient health data) is explicitly the responsibillity of the Member States. From the principles relating to data collection, it is important to note that "Notification Authorities" will be established in each Member State, which will authorize any collection and further processing of personal data. Therefore, if the health-sector does not get a comprehensive deal with these authorities, the laws pertaining to the collection and communication of patient data will remain ambiguous. Consequently, the wide implementation of PHR systems will go through a turbulent period in the near future (Kardas & Tunali, 2007).

4) Industrial and Market Factors:

These issues are determined by the demand for the PHR systems and the willingness of the industry to invest in quality records. In general, the healthcare market is seen by the industry as large. However, it is not highly profitable, mainly due to the lack of standards (mentioned above) for the PHR systems and related applications (Kardas & Tunali, 2007). The overall percentage of the healthcare budget spent on information and telecommunication technologies is relatively low in healthcare ($400 per employee) compared to other sectors, such as manufacturing ($1,500 per employee) or finance ($5,000 per employee). On the other hand, expenditure is expected to grow due to the new policies and strategies of Member States, or due to structural funds provided to some Member States for computerization of healthcare. Different

legal requirements, different languages, and specificity of work processes of each country or region have led to the high cost of development and customization (Kupchunas, 2007).

In Europe, the situation is very fragmented. Most of the countries have a few dozen providers of mostly electronic medical records, which have very few installations and are not interoperable with other systems. Exceptions are countries like Norway, Iceland, and The Netherlands where the market has consolidated. The companies are not willing to cooperate, resulting in each company having to reinvent the wheel, which is very costly. Finally, it is important to point out that the laws governing the healthcare market are not competitive, for-profit laws, but slow public decision/procurement laws.

5) Lack of Vision and Leadership:

Lack of vision and leadership of healthcare managers and health authorities, and the lack of willingness to re-engineer the healthcare processes for the benefit of the quality and efficiency of care delivery has delayed the adoption of PHR and PHR systems. In the last few years, some European countries, such as Denmark and Sweden, have initiated strategies for the implementation of the PHR under the Telematics Applications for Health Sector of the European Commission projects. It is also understood, from the exposition above, that successful implementation goes hand in hand with re-engineering the healthcare processes, which is a time and effort consuming process. Other countries still lack vision and initiative in this direction. Managers are usually squeezed between the demands of the healthcare-sector related to direct care and cost-containment pressure from the authorities. As a result, decisions about authorieties adopt information systems or the PHR systems concern mostly short-term needs and costs, or ”wait and see” policy for the final solution. The need for leadership and standards has long been recognized in the US (Kardas & Tunali, 2007).

As previously mentioned, many public and private sectors— such as the American Health Information Management Association (AHIMA), the American Medical Informatics Association (AMIA), the Markle Foundation, and similar organizations—have advised staff, volunteers, and the industry on personal health information policy, advocacy, and standards. Also they have developed and promoted AHIMA's vision of personal health information management, including PHR record keeping, PHR systems usage by consumers, and PHR/EHR interoperability.

6) Issues of Acceptability and Usability:

Issues of acceptability and usability of the PHR pertaining to human-related factors and the issues of education and training. Even in the places with the latest technology and the best intranets, users complain about the non-friendliness and speed of the system. Some examples of the complaints regarding the usability of the system are: "lost" time going to the computer rooms; the time spent of retrieving the data (waiting for data more than 3–5 second is usually unacceptable); the non-intuitive data input (structured data entry is still unacceptable by most physicians); the security procedures (login taking too much time); and the inability for mobile interaction with the system while in the corridors or outside of the hospital (Kardas & Tunali, 2007).

The above problems lead to a series of challenges from the Human–Computer Interaction (HCI) perspective related to the capturing and input of data in the PHR, as well as the presentation of recorded data in a variety of forms, such as media and output systems. In particular, specific technological areas that need to be addressed involve input and output devices (e.g., pen-based input, speech recognition input), 2D and 3D interaction techniques, intuitive interface metaphors, mobile systems, multimodal interfaces, tailor able and adaptable interfaces,

more natural access procedures (e.g. speech interfaces), computer-supported co-operative work intelligent interfaces, user identification procedures, and user interfaces for mobile services (Albright, 2007). Finally, it is important to remember that the acceptance of the new systems by users is dependent, to a large degree, on the expectations that the users have and the training they receive (Rulon, 2007).

During the installation of a new system, training is often one of the most costly items. In this situation, the medical informatics education of medical students and nurses is very important because it gives the idea of what is to be expected in the early stage, gives more opportunities to users to express their needs, and reduces future expenditure on redesigning and training (Heubusch, 2007b; Rodriguez et al., 2007). Medical informatics and telematics classes should be part of the basic training of all healthcare professionals (Kardas & Tunali, 2007).

It is encouraging to see that the number of medical informatics departments is growing every year all over the world. There are many stakeholders in the field of medical informatics: for instance, healthcare professionals will certify and agree to work with new technology for their benefit and the benefit of patients; the health authorities will adopt the legal framework to understand the vision and make decisions for re-engineering; researchers will use technology to provide new solutions to the problems mentioned above; and industry will adopt standards and provide inexpensive and interoperable solutions. Only a concerted effort of all the players and groups can succeed. No isolated initiative by any of the relevant groups—i.e. healthcare professionals, healthcare managers, health authorities, researchers, or industry—will lead to successful and widely accepted PHR and PHR systems. The immediate question that can be raised is: Who cares about the big picture? The healthcare professionals care for the part that improves their work, managers only care for the data that they need, and industry aims to

maximize profit, etc. Thus, the challenge is posed to national, regional and non-profit organizations to bring all parties to work towards the PHR that supports the continuity of care and benefits all stakeholders (payers, employers, organizations, government, healthcare providers, healthcare consumers, and health insurance companies) (Halamka, Mandl, & Tang, 2008).

5.6 THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH (HITECH) ACT

The US government considers Personal Health Record (PHR) systems as one of the strategic plans for healthcare reform and the consumer health Information Technology (IT) solutions. The government believes that the health IT is the solution to improve health outcomes; enhance medical and healthcare quality; help achieve the goal of patient-centered healthcare by better involving healthcare consumers to play an important role in their health decisions; promote access to health information; and ultimately reduce overall healthcare costs across the nation. As a result, the federal government has recently promised $29 billion to support healthcare providers in adopting online health records through the Health Information Technology for Economic and Clinical Health (HITECH) Act, which also known as the economic stimulus bill. HITECH is a part of the American Recovery and Reinvestment (ARRA) Act of 2009, also known as the Economic Stimulus Package, signed by the President Barack Obama on February 17, 2009. This legislation has four important objectives:

1. Require the government to take a leadership role to develop standards by 2010 that allow for the nationwide electronic exchange and use of health information to improve the quality and coordination of care.
2. Invest $20 billion in Health Information Technology (HIT) infrastructure and Medicare and Medicaid incentives to encourage doctors and hospitals to use HIT to electronically exchange patients' health information.
3. Save the government $10 billion and generate additional savings throughout the health sector, through improvements in quality of care and care coordination, and reductions in medical errors and duplicative care.
4. Increase federal privacy and security law to protect identifiable health information from misuse as the healthcare sector increases the use of Health IT.

These objectives are to be accomplished by assigning a specific budget through HITECH funds, the major spending areas are as follows:

- **$18 billion** through the Medicare and Medicaid reimbursement systems as incentives for hospitals and physicians who are "meaningful users" of EHR systems.
- **$2 billion** to the Office of the National Coordinator for infrastructure necessary to allow for, and promote, the electronic exchange and use of health information for each individual in the US; updating the Department of Health & Human Services' technologies to allow for the electronic flow of information; integrating health IT education into the training of healthcare professionals; and promoting interoperable clinical data repositories.

- **$1 billion** to be made available for the renovation and repair of health centers and for the acquisition of health IT systems.
- **$550 million** for the purchase of equipment and services including, but not limited to, health IT within Indian Health Service facilities.
- **$400 million** for comparative effectiveness research on how the use of electronic data impacts healthcare treatments and strategies.
- **$300 million** to support regional and sub-national efforts towards health information exchange.

In addition to the above funds, HITECH provides incentives and funding for hospitals and physicians to promote the widespread adoption of Health Information Technology (HIT) and encourage the meaningful use of Electronic Health Records (EHRs) and ultimately Personal Health Records (PHRs) (http://www.boisestate.edu/research/recovery/HITECHlegislation.pdf). The incentive payments for practitioners and hospitals to promote the adoption and use of certified EHRs technology will commence in 2011 and phase out through 2015. (http://democrats.science.house.gov). Eligible healthcare professionals, who become "meaningful" EHR users quickly, by 2010 or 2011, will receive the maximum payment of $44,000. On the other hand, those who adopt an EHR later will receive $24,000. Eligible professionals in designated shortage areas will receive a 10% increase in their bonus payment as follows:

	Estimated Payment Amount Received Each Year						
Year they first file	2011	2012	2013	2014	2015	2016	TOTAL
2011 (system in place before 2011)	$18,000	$12,000	$8,000	$4,000	$2,000	$0	$44,000
2012	$0	$18,000	$12,000	$8,000	$4,000	$2,000	$44,000
2013	$0	$0	$15,000	$12,000	$8,000	$4,000	$39,000
2014	$0	$0	$0	$12,000	$8,000	$4,000	$24,000
2015 or later	$0	$0	$0	$0	$0	$0	$0

However, these incentives will be replaced by financial penalties for physicians and hospitals that are not using certified EHRs. Those who are not in compliance will face reductions in their Medicare Part B payments of 1% in 2015, 2% in 2016 and 3% thereafter. Furthermore, if by 2018 75% of eligible professionals are not using EHR, the Secretary of the US Department of Health and Human Services (HHS) can continue reducing Medicare payments up to 5%. Consequently, the Congressional Budget Office (CBO) predicts that about 45% of hospitals and 65% of physicians will have adopted HIT by 2019. In addition, the CBO estimates that the incentive mechanisms in the HITECH Act will increase the adoption rates to about 70% for hospitals and about 90% for physicians. The CBO also estimates that the adoption of certified EHR and the provisions of the HITECH Act will reduce Medicare spending by 4.4 billion and will save the government approximately $12 billon on direct spending in the Medicare, Medicaid, and Federal Employee Health Benefits programs over the 2011-2019 time periods (http://www.hipaasurvivalguide.com/hitech-act-text.php).

This law enforces the security and privacy regulations under the Health Information Portability and Accountability Act (HIPAA) for generally improving healthcare quality, safety, and efficiency (HIMSS Analytics Report, 2009). HITECH requires hospitals and healthcare providers to restrict the use and disclosure of protected health information (PHI) as follows (http://www.nixonpeabody.com):

- Covered entities including hospitals, health care providers, health plans, business associates, vendors, health information exchanges (HIEs), and Regional Health Information Organizations (RHIOs) and PHRs must honor a patient's request to withhold PHI from a health plan if the patient paid for the medical care;
- covered entities must limit the use or disclosure of PHI to a "limited data set" or, if needed, to the minimum authorized personnel necessary to accomplish an intended purpose;
- when requested, covered entities must provide patients with an audit trail of all disclosures of PHI made within the past three years;
- covered entities may not receive payment for communicating with patients for marketing purposes (including fundraising solicitations) without the specific authorization of the patient;
- employees of covered entities or other individuals who knowingly access, use, or disclose PHI for improper purposes will be subject to criminal penalties; and
- civil penalties for violations under HIPAA are increased, depending on the conduct. The federal government must impose penalties if the violation of the conduct was willful. State attorneys general (most of whom already have the jurisdiction to prosecute under state privacy laws) are authorized to prosecute and seek civil penalties. The penalties are tiered according to conduct, from $100 per violation with a maximum of $25,000 per year, to the maximum penalty of $50,000 per occurrence and $1.5 million per year.

6.0 CONCLUSION

6.1 FUTURE RESEARCH

As a consequence, of the US government's healthcare reform strategy and developments in technology, more than ever, medical informatics is needed for efficient development and strategic management of new Health Information Systems (HIS). Having the possibility of doing research and education in this field or to contribute to its practice is a great opportunity and responsibility, as it gives the chance to contribute to the quality and efficiency of healthcare services (Hassol et al, 2004).

Twenty years after Peter Reichertz's talk, we may redefine the aim of HIS as to contribute to high-quality and efficient healthcare for both patients and healthcare consumers through development of medical research. HIS have to be developed and explored in order to enhance opportunities for global access to health services and medical knowledge. Informatics methodology and technology is expected to facilitate continuous quality of care in aging societies. Ubiquitously available computing resources and networks existing worldwide for the transmission of all varieties of data will allow us to consider new types of information systems for healthcare, including new kinds of health monitoring and also new opportunities for the analysis of biomedical and health data (Cimino, Patel, & Kushniruk, 2002). These trans-institutional information system architectures and infrastructures, once appropriately designed

and adequately strategically managed, will provide new opportunities for the whole field of biomedical and health informatics as well as of biomedical statistics and epidemiology.

As in most areas of the sciences, let us remember that we need high-quality evaluation studies to learn what we really have achieved and what we can do better (Rodriguez, Casper, & Brennan, 2007). Last but not least, these new opportunities for the systematic processing of data, information and knowledge in medicine and healthcare may considerably contribute to the progress of medicine and the health sciences as well as to the progress of informatics in general. Remember, (bio-) medical informatics, health informatics, as well as statistics and epidemiology, aim not only for more advanced technology, but also for more and better care, care that is affordable in aging and highly uninsured societies. In the end, only the health and well-being of individuals is what count (Cimino, Patel, & Kushniruk, 2002).

PHR systems are a key application of bioinformatics. Historically, many terms have been used for the concept of the PHR system. The Electronic Medical Record (EMR) is a term often used interchangeably with PHR. The key conceptual differences between EMRs and PHRs are the owner and location of the record. EMRs are usually included in a local clinical data repository used to support clinical operations. They are usually owned by an individual healthcare provider and are often accessible to the patients who are the customers of that healthcare provider. On the other hand, PHR refers specifically to an overarching system based on information shared by individual care practitioners regardless of practitioner specialty, type of care (inpatient, ambulatory), or location of care. EMRs are often practitioner-oriented while PHRs are patient-centric and support coordinated care (Rodriguez, Casper, & Brennan, 2007).

More prominently, the concept of PHRs goes beyond episodic care in healthcare facilities by providing not only a comprehensive medical history (when patients interact with practitioners) but also including patients' own records of their health status (when patients don't interact with practitioners), such as physical activity, diet, over-the-counter medications. Therefore, even an EMR system in an integrated delivery system is not equivalent to a PHR system because it does not contain the entire picture of a patient's health status (Rodriguez, Casper, & Brennan, 2007). However, EMRs and PHRs are interrelated. Successful PHRs rely on EMRs as an accurate and complete source enabling healthcare providers to construct different segments of the individual's health history. The key for the success of patient-centric PHR systems is for each EMR system to have the capability to share data in an automated and error-proof way. Because a patient may have different records located in different EMRs, accurately and efficiently linking all these records together is a challenge because there is no existing centralized patient index. Such sharing is called "Health Information Exchange" (HIE).

To undertake the task of HIE, two strategies are being implemented by the Office of the National Coordinator of Health Information Technology. One strategy is the building of a national health information network, which enables providers to access critical patient-related information at the time of encounter (Cimino, Patel, & Kushniruk, 2002). The US government is currently promoting a bottom-up, market-oriented approach by advocating Regional Health Information Organizations (RHIOs) as the foundation of a national health information network. Stakeholders within each RHIO will share data with their own preference of network and information architecture. For example, the North Carolina Healthcare Information and Communications Alliance (NCHICA) is coordinating an effort to create a regional health information organization in North Carolina. Sharing of data among regional health information

organizations will complete the national health information network. Fully functional regional health information organizations and national health information networks rely on the development of interoperability, which still has a long way to go.

The other strategy to facilitate HIE is to let patients manage their own personal health information using tools like PHR based on the American Health Information Management Association (AHIMA). The AHIMA defines a PHR as "a collection of important information about your health or the health of someone you are caring for (such as a parent or child) that you actively maintain and update. The information comes from your healthcare provider and from you." It is not necessary to have only the encounter data stored in a PHR. Ideally, patients also will record data related to their health status such as weight, diet, and exercise routines. A successful PHR system should have interfaces to all the EMR systems in which patients have data footprints. As an example, Microsoft has recentley launched a Web-based PHR called "Microsoft Health Vault" that allows consumers to store their health information records online and share them with their designated providers. Similarly, Google has introduced "Google Health."

6.2 PERSONAL HEALTH RECORD AND HEALTH POLICY

The advocates of Personal Health Records (PHRs) believe that they are integral to controlling the cost, improving the quality, and increasing the efficiency of healthcare. These benefits are largely at the direct patient care level. There also are important benefits to health policy makers at the system level. As Sandra Greene asserted in her issue brief, "health policy provides the direction, specifications, and building blocks that define our health care system" (Green, 2007).

Hence, PHRs could systematically be used for quick data collection and policy dissemination in health care.

6.3 PERSONAL HEALTH RECORD AS A DATA SOURCE FOR HEALTH POLICY

The Personal Health Record (PHR) has primary and secondary uses. Examples of primary uses of PHRs include informing and supporting direct patient care, management support, financial and administrative processes, and patient self-management. Secondary uses of PHRs, on the other hand, include education, regulation, research, public health policy, homeland security, and policy support. The medical or clinical encounter record, whether in paper or electronic format, is the primary data source in healthcare because it contains specific data pertaining to a specific patient. Primary data sources, after de-identification and aggregation, provide the raw input to the secondary data sources that are used in healthcare policy-making. For example, a cancer registry is a secondary data source that collects data related to cancer diagnosis and uses it for monitoring patterns of cancer cases in the US (http://www.cdc.gov/cancer/npcr). After a patient is diagnosed with cancer, demographic data, occupational history, and administrative and pathological data will be recorded into a facility's cancer registry. The information is then sent to state and national registries.

The process of data collection historically relied on manual chart review and reporting due to the paper-based record environment. In PHR systems, data collection is simplified by querying a well-structured database. The PHR accelerates data transmission from an individual facility to a state or national registry.

An effort at the Centers for Disease Control and Prevention, the National Program of Cancer Registries Modeling Electronic Reporting Project (NPCR-MERP) aims to enable cancer registries to obtain most cancer data electronically and to produce more complete, timely, and accurate cancer surveillance data (http://www.cdc.gov/cancer/npcr). PHRs may not necessarily reduce the burden of data entry; however, they will largely facilitate data retrieval and analysis. For example, drug recalls in the past required nurses to manually review patient charts at one facility to find all patients who had a certain drug on their medications list. In contrast, in the electronic health record environment, it takes a fraction of the time to query a database in order to identify these same patients. Because PHRs and PHR systems contain data from both individuals and multiple healthcare providers, they make it easy to collect data that would be difficult to collect from paper records. For example, the Behavioral Risk Factor Surveillance System (BRFSS) collects data from telephone surveys. However, if the BRFSS survey were implemented as data elements in PHRs or PHR system, the data could be easily collected electronically.

On the other hand, Ball and Gold (Ball & Gold, 2006) propose a Health Record Bank model that provides patients with the power to share their health data with researchers. This would expand the scope of health policy data collection from clinical care to health status. The other implication of PHRs for health policy is that healthcare providers can be informed of important policies by the integration of health policies with PHR systems by policy makers. In addition, the Institute of Medicine of the National Academies has reported eight core functions of PHRs, such as: (1) health information and data, (2) results management, (3) order entry/management, (4) decision supports, (5) electronic communication and connectivity, (6) patient supports, (7) administrative process, and (8) reporting and managing population health.

The functions of administrative process and of reporting and managing population health could be used as the leverage points for implementing health policy at the practitioner's level (Rodriguez, Casper, & Brennan, 2007).

In case of health events affecting a large population, a key activity of health policy is to notify practitioners and patients about available actions to prevent a disease or reduce its impact on individual and community levels. Notifiying practitioners and patients with regards to health improvement is important as well. This type of information needs to be disseminated quickly to individual practitioners to be effective, especially at the point of care. Generally, reminders are generated from guidelines related to preventive public health interventions. Again, the PHR is beneficial because integrated reminders in PHR could increase the level of compliance with accepted healthcare guidelines or policies. Moreover, alerts could include important information about disease outbreaks or important medication updates. When available, information could be extended to providers on applicable public health interventions, preventive medicine, or disease management. PHRs can provide decision support that enables the implementation of public health intervention directly to the patient at the point of care. Additionally, they can be a means to informing clinicians of health policy updates. Ultimately, they can provide necessary education to both practitioners and patients (Rodriguez, Casper, & Brennan, 2007).

As mentioned above, PHRs also offer the opportunity to improve policy compliance by incorporating policies and rules into the PHR system. Because each PHR system ideally includes decision support capability, transforming health policies—particularly those for disease prevention and management—to unambiguous knowledge representation modules will systematically standardize treatment of consumers at the point of care. For example, the use of reminders in an PHR system increases the number of mammograms, blood tests, and

immunizations. However, many barriers remain on the way to having a universal PHR system by year 2014, as envisioned by the former president George W. Bush. Some of these barriers are lack of initial financial support, misaligned incentives, and missing business models for sustainable HIE (Tang, 2006). In order to have a greater patient engagement in the PHR campaign, healthcare payers and purchasers must provide some financial assistance in helping patients establish and maintain the cost of their PHR (Tang et al., 2006). Furthermore, the federal government must take a leading and more active role in providing the necessary public funds for a national adoption of electronic health records, as the law of the Health Information Technology for Economic and Clinical Health (HITECH) Act, which also known as the economic stimulus bill. HITECH is a part of the American Recovery and Reinvestment (ARRA) Act of 2009, also known as the Economic Stimulus Package, signed by the President Barack Obama on February 17, 2009. These records, considered a cornerstone in the coordination of healthcare among physicians, will promote quality and cost effectiveness in the medical field (Bates et al., 2003; Burton et al., 2004; Wang et al., 2003). The US Department of Health and Human Services has recently started a 5-year project to encourage small and medium-size medical practices to adopt PHR systems by providing incentive to participating practices that adopt certified PHRs. There is still a long way to go before there is a PHR system that can store the entire health history of a patient and provide instant access to those who need the information. Until then, the benefits of PHR to health policy will not be fully realized (Foxhall, 2007).

6.4 FUTURE OF PERSONAL HEALTH RECORD

Susannah Fox testified at a meeting organized by the National Committee on Vital Health Statistics and the US Department of Health and Human Services to discover privacy, security, and confidentiality issues regarding Personal Health Record (PHR), social media, and the future of medicine. She asserted that there are pockets of people who remain offline; however, the advent of smartphones with Internet access may change that. Our understanding of what the "Internet" can do will change over the next few years as more people access it on small screens such as Android, IPhone, or Black Berry wherever they are, not necessarily on desktop screens at home or at work. In the political arena, 2008, more adults than ever before used the Internet to read or watch "unfiltered" campaign material, such as candidate debates, announcements, position papers, and speech transcripts. In the health arena, e-patients are reading medical journal articles, viewing photos or video of other people with similar conditions, and uploading details of their symptoms and treatments (http://www.pewinternet.org).

What if personal health records could be designed to be part of the naturally-occurring network we see in the Pew Internet Project's survey data? What if personal health records could take account of the primary relationship between a patient and a health professional, but not make it an exclusive relationship? What if instead of a health information exchange being one-to-one, a personal health record allowed it to be many-to-many? What if a personal health record gave people access to what the doctors, allied health providers, nurses, and insurance companies have: that is, the industrial-strength information? Finally, is it meaningful if a patient can't use it? (Foxhall, 2007).

6.5 LIMITATIONS OF THE STUDY

The majority of the limitations for this study stem from the sample selected for the study in terms of size and inclusion criteria. The small sample size, 30 participants, might be considered as relatively small and not highly representative of the general population under study. However, a number of factors dictated the small sample size, such as time limitations, funding resources, the lengthy nature of the in-depth interview method, and the focus and scope of this research, which was primarily intended to collect provisional data regarding the level of CCR knowledge as follows:

1. To measure young adults' level of understandability of CCR data items.
2. To discover end-users' needs, expectations, and PHR preference in terms of information included and vocabulary used for specific data elements.
3. To determine how the data elements of the PHR differ for the needs of end-users and healthcare providers.

Another limitation was the specific inclusion criteria. The current study included only healthy young adults with an age span ranging between 18-25 years old. While this segment represents a significant and possibly the most active portion of the general population, it does not represent the entire population of PHR users. Again, these inclusion criteria were selected due to a number of factors, including funding resources as well as time constraints and the primary goals of the study, which were aimed at collecting provisional data about the level of knowledge and the CCR familiarity among the sample studied. Furthermore, this study was limited to college students, which are not necessarily representative of the general population. The sample study was limited to

this group of people to compensate for time constraints because college students are widely available and willing to participate in research studies, especially when monetary incentive is provided. The sample study revealed that all participants were coming from middle-class income families and all had health insurance through their parents. This might have played a role in their high level of familiarity with CCR terms since they frequently utilize healthcare services. Another limitation in the inclusion criteria is the condition of requiring only native speakers of English. This language factor might also have resulted in yielding a relatively high percentage of CCR familiarity.

6.6 SUMMARY

Healthcare reform in the US can be studied from many viewpoints. Recently, national healthcare policy has included research on Health Information Systems on its agenda. Physicians need to process large amounts of data into valuable information to make clinical decisions. In addition, public health practitioners need to aggregate data at population levels to prevent and detect epidemics. Moreover, healthcare policy makers need to use a variety of secondary databases as a source of information and evidence for policy making. How can we ensure the right healthcare information is accessible to the right person at the right point in a timely manner? At this moment, the only answer to this question is to digitalize the information and share it on a secure, networked information system (Foxhall, 2007).

6.7 CONCLUSION

Electronic Personal Health Record Systems (EPHRS) are a tool necessary to support the person (citizen) centered shared care. It is not a stand-alone, static system in a physician's office or in a hospital, or a clinic, rather it is a collection of health data about an individual's life from both individuals and healthcare providers that is stored at the point of care. Access to this information by authorized professionals and storage of this information in a standardized way are the main technological challenges to the implementation of these distributed systems. There are many other challenges to ensuring a wide use of EPHRS that can be categorized as follows: organizational and cultural issues, legal issues, market and industrial issues, issues regarding leadership and vision of decision-makers, and user acceptance issues. Presently, widely implemented systems include hospital administrative systems, electronic medical systems in use in primary care, and clinical information systems in hospitals that are normally stand-alone and do not communicate with other systems. Moreover, the structure of the established clinical databases and the terminology used for clinical data is still not standardized. Currently, there are several research and development projects that are tackling these challenges, such as those of the telematics application for the health-sector of the European Commission (Foxhall, 2007).

Future trends indicate stronger involvement of people in the process of prevention, care, and awareness, which together with a person's rights to his/her personal health data, will lead to direct interaction of the person with his/her personal health record, including the input of data from home, work, and leisure places. This trend will change the nature of the EPHRS, which is now primarily used only during care episodes, to a comprehensive system, supporting not only care, but also prevention, monitoring, awareness, and education of the persons–citizens. The European Commission is promoting the trend towards citizen-centered care through the 5th

Framework Program, which supports the research and development of new systems and services allowing citizens to assume greater participation in and responsibility for their own health (http://ec.europa.eu/research/fp5.html). Given the benefits this kind of EPHRS can provide, it is only appropriate that it continue to receive attention from the government and public or private health organizations in the US as well.

6.8 RECOMMENDATIONS FOR FUTURE RESEARCH

The current study provides significant insight into the area of Continuity of Care Record (CCR) familiarity among young healthy adults. However, due to the limited number of subjects interviewed and the specific inclusion criteria, these results might not be representative of the entire population and hence cannot be generalized. Therefore, future research with the same focus should increase the sample size to reflect the make-up of the entire population. In addition, the inclusion criteria should be expanded to include all potential users of the PHR. These may include individuals in all age groups, in underserved communities, at different educational levels, of different socioeconomic backgrounds, with single or multiple chronic diseases or their caregivers, and finally people from different ethnicities.

Currently, healthcare consumers' involvement and satisfaction have become an important aspect of healthcare transformation strategies in the US government, public, and private sectors. "Consumer satisfaction" is of growing importance not only in the privately managed care delivery systems, but also in public systems. In the Europe directive mentioned previously, patients are given the right to be informed about the use of their health data, the right of access to their records, and the right to object to some data. Both the tendency of people to want to know

more and to actively participate in health promotion, prevention, and healthcare, together with the rights that will become standard legislation, guide the development of informatics systems that support these tendencies (Albright, 2007). Thus, the trend is towards more involvement of people (both sick and healthy) in receiving and owning their health information, and in making decisions. Here, we mention people and not patients since we would like to stress the focus of future healthcare on health promotion and prevention and on the fact that a person will have a personal health record even if he does not get sick (Halamka, Mandl, & Tang, 2008). In fact, the prime features of this trend are a shift from healthcare-institution-centered care to indvidual-centered care, with emphasis on continuity of care from prevention to rehabilitation (Albright, 2007).

As mentioned earlier in Chapter Five, this vision can be achieved through shared care, which builds on health telematics networks and services, linking hospitals, pharmacies, primary care centers, and social centers and offering to individuals "virtual health information" with a single point of entry. Furthermore, this vision implies the provision of new innovative health services to homes, such as personal health monitoring and support systems and user-friendly information systems for supporting health education and awareness. People are 'thirsty' for health-related information. As the Healthcare Information Management and Systems Society (HIMSS) study reports, the most significant healthcare-related computer development affecting the average consumer is access to on-line health information and services from home and in particular via the Internet. The PHR will not only be accessible to patients, but it will also allow them to incorporate their views and notes resulting from self-monitoring of chronic illness, to make dietary notes, to track sport and exercise performance, to monitor behavioral activities and moods, etc. (Halamka, Mandl, & Tang, 2008). We could see in the near future the development

of personal health status monitoring and support systems at home that interact with PHR and complete the picture of the continuity of care scenario.

It has also been suggested that a possible risk that may result from breaching confidentiality when using personal information is discrimination. Indviduals who have particular health problems or certain characteristics that increase the risk of disease may suffer some type of discrimination in obtaining and/or keeping a job, or some type of health or life insurance. Some authors believe the risk is even greater with genetic information, which offers even more scope for discrimination due to the sensative data it contains (Halamka, Mandl, & Tang, 2008). However, we cannot for this reason relinquish the possibility of collecting and using this information. In fact, society already sometimes accepts the use of personal data without informed consent if it is for the benefit of the population in general. For example, the distribution of income in developed countries with a so-called Welfare State system requires a suitable system of taxes that will minimize fraud. In such a state, the government has access to different sources containing personal information about each citizen's income so that administrative and legal action can be taken against those who do not adhere to the rules and regulations. Likewise, an up-to-date electoral census with a minimum set of personal data is a basic requirement for a democratic society (Halamka, Mandl, & Tang, 2008). In most countries, political parties taking part in elections have access to these personal data in order to distribute their electoral program to each citizen. In a similar way, in the case of an epidemic of some communicable disease, health authorities can use personal data without the informed consent of subjects to identify characteristics of the epidemic that will make it possible to develop intervention measures to impede its spread. Discrimination due to the inappropriate use of any kind of personal information does not depend on the existence of stored personal data, but on the

lack of the necessary mechanisms to protect confidentiality and on the absence of sanctions when this type of information is accessed or revealed for ends other than those which society believes are ethical (Albright, 2007).

APPENDIX A

PERSONAL HEALTH RECORD SUMMARY

Term	Personal Health Record (PHR)
Purpose	"Enable[s] people electronically to manage their health information and that of others for whom they are authorized."
Owner (who enters information)	Patient or institutions associated with patient (e.g., payer or employer)

Information included	• Personal information • Family medical history • Immunization history and planner • Allergies to food and drugs • History of personal illnesses or past procedures • Medications and supplements • Contact information for other healthcare practitioners, clinics, etc. ***Additional optional or possible information:*** • Vital signs recording • Graphing and trending of health data • Visit information • Lab and radiology results • Medical record security audit • Mental illness history • Discharge summaries • Daily living habits (smoking, diet, exercise, etc.) • Drug interaction checks • Health goals and planning • Reputable medical education sources • Links to other healthcare services • Medical information resources (such as a medical test handbook that provides a listing and description of different medical tests) • Listings of healthcare providers in local areas • Scheduling functions and appointment requests • Reminders or e-mail notification of appointments • Live data exchange with healthcare practitioners • Online communities and chat rooms • Event listings • Product shopping • Emergency card or member card IDs
Interoperability	Depends on the particular product
Accessibility	Depends on the particular product

APPENDIX B

TERMS AND DEFINITION OF PATIENT HEALTH INFORMATION

Term	Definition
ASTM Continuity of Care Record (CCR)	"The ASTM CCR standard is a patient health summary standard, a way to create flexible documents that contain the most relevant and timely core health information about a patient, and to send these electronically from one care giver to another. It contains various sections—such as patient demographics, insurance information, diagnosis and problem list, medications, allergies, care plan, etc.—that represent a 'snapshot' of a patient's health data that can be useful, even lifesaving, if available when patients have their next clinical encounter. The ASTM CCR standard is designed to permit easy creation by a physician using an electronic health record software program (EHR) at the end of an encounter."
HL7 Clinical Document Architecture (CDA)	"The HL7 Clinical Document Architecture (CDA) is a document architecture standard designed to represent medical legal health care encounter documents in a standardized format. CDA r2 (Release 2) was balloted and approved in June 2005."

HL7 EHR System Functional Model	"The HL7 EHR System Functional Model and Standard Draft Standard for Trial Use (DSTU) is intended to provide a summary understanding of functions that may be present in an Electronic Health Record System (EHR-S), from a user perspective, to enable consistent expression of system functionality. This EHR-S Model describes the behavior of a system from a functional perspective and provides a common basis upon which EHR-S functions are communicated. The DSTU can help vendors describe the functions their systems offer, and help those planning new purchases or upgrades to describe the functions they need."
Computer-based Patient Record (CPR)	"Computer-based Patient Record is a compilation in electronic form of individual patient information that resides in a system designed to provide access to complete and accurate patient data, alerts, reminders, clinical decision support systems, links to medical knowledge, and other aids."

APPENDIX C

CPR, EHR, EMR, EPR SUMMRY

Terms	Computer-based Patient Record (CPR), Electronic Health Record (EHR), Electronic Medical Record (EMR), Electronic Patient Record (EPR).
Purpose	"Provides secure, reliable, real-time access to patient health record information where and when it is needed to support care. Captures and manages episodic and longitudinal electronic health record information. Functions as clinicians' primary information resource during the provision of patient care. Assists with the work of planning and delivering evidence-based care to individual and groups of patients. Captures data used for continuous quality improvement, utilization review, risk management, resource planning, and performance management. Captures the patient health-related information needed for medical records and reimbursement. Provides longitudinal, appropriately masked information to support clinical research, public health reporting, and population health initiatives. Supports clinical trials and evidence-based research."
Owner (who enters information)	Authorized clinicians and healthcare personnel

Information included	"Captures and manages episodic and longitudinal electronic health record information." "Data [are] used for continuous quality improvement, utilization review, risk management, resource planning, and performance management."
Interoperability	There are some standards (CCR, HL7) required for full interoperability between different systems; or, for multi-providers, multispecialty, and multisystem interoperability, a concept patient identifier is required.
Accessibility	The accessibility of patient health information depends on the product and the healthcare organization.

APPENDIX D

ASTM CONTINUITY OF CARE RECORD (CCR) SUMMARY

Term	ASTM Continuity of Care Record (CCR)
Purpose	"The goal is to create a CCR that will enable the next provider to easily access the information . . . at the beginning of a first encounter and easily update the information when the patient goes on to another provider, in order to support the safety, quality, and continuity of patient care. The CCR may be used as a vehicle to exchange clinical information among providers, institutions, or other entities. It may also be used by the patient as a brief summary of recent care."
Owner (who enters information)	"The CCR will be completed by physicians, nurses, and ancillary providers (e.g., social work, physical therapy, occupational therapy) upon referral or transfer or other transition of a patient from one caregiver to another, whether it is outpatient, inpatient, or community based."
Information included	Provider information Patient identifying information Patient insurance and financial information Health status of the patient • Diagnoses, problems, conditions • Adverse reactions, alerts • Current medications • Immunizations • Vital signs • Laboratory results • Procedures/assessments • Optional extensions • Care documentation • Care plan recommendations

Interoperability	The CCR supports full semantic and computational interoperability (object-oriented data model using an XML-defined data object-attribute approach).
Accessibility	XML coding is required when the CCR is created in a structured electronic format. The XML coding "provides flexibility that will allow users to prepare, transmit, and view the CCR in multiple ways, for example, in a browser, as an element in a Health Level 7 (HL7) message or CDA compliant document, in a secure email, as a PDF file, as an HTML file, or as a word processing document. It will further permit users to display the fields of the CCR in multiple formats."

APPENDIX E

STANDARD SPECIFICATION FOR CONTINUITY OF CARE RECORD

Designation: E 2369 – 05

Standard Specification for Continuity of Care Record (CCR)[1]

This standard is issued under the fixed designation E 2369; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 The Continuity of Care Record (CCR) is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters.[2] It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care.

1.1.1 The CCR data set includes a summary of the patient's health status (for example, problems, medications, allergies) and basic information about insurance, advance directives, care documentation, and the patient's care plan. It also includes identifying information and the purpose of the CCR. (See 5.1 for a description of the CCR's components and sections, and Annex A1 for the detailed data fields of the CCR.)

1.1.2 The CCR may be prepared, displayed, and transmitted on paper or electronically, provided the information required by this specification is included. When prepared in a structured electronic format, strict adherence to an XML schema and an accompanying implementation guide is required to support standards-compliant interoperability. The Adjunct[3] to this specification contains a W3C XML schema and Annex A2 contains an Implementation Guide for such representation.

1.2 The primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient.

1.2.1 This specification does not speak to other use cases or to workflows, but is intended to facilitate the implementation of use cases and workflows. Any examples offered in this specification are not to be considered normative.[4]

1.3 To ensure interchangeability of electronic CCRs, this specification specifies XML coding that is required when the CCR is created in a structured electronic format.[5] This specified XML coding provides flexibility that will allow users to prepare, transmit, and view the CCR in multiple ways, for example, in a browser, as an element in a Health Level 7 (HL7) message or CDA compliant document, in a secure email, as a PDF file, as an HTML file, or as a word processing document. It will further permit users to display the fields of the CCR in multiple formats.

1.3.1 The CCR XML schema or .xsd (see the Adjunct to this specification) is defined as a data object that represents a snapshot of a patient's relevant administrative, demographic, and clinical information at a specific moment in time. The CCR XML is not a persistent document, and it is not a messaging standard.

NOTE 1—The CCR XML schema can also be used to define an XML representation for the CCR data elements, subject to the constraints specified in the accompanying Implementation Guide (see Annex A2).

1.3.2 Using the required XML schema in the Adjunct to this specification or other XML schemas that may be authorized through joints efforts of ASTM and other standards development organizations, properly designed electronic healthcare record (EHR) systems will be able to import and export all CCR data to enable automated healthcare information transmission with minimal workflow disruption for practitioners. Equally important, it will allow the interchange of the CCR data between otherwise incompatible EHR systems.

1.4 *Security*—The data contained within the CCR are patient data and, if those data are identifiable, then end-to-end

[1] This specification is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.25 on Healthcare Data Management, Security, Confidentiality, and Privacy.

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[2] A CCR is not intended to be a medical-legal clinical or administrative document entered into a patient's record, but may in specific use cases be used in such a manner, provided that accepted policies and procedures in adding such data to a patient's record are followed. A personal health record, with the information under the control of the patient or their designated representative, would be an example of such a use case, as would be importation into an electronic health record system, a data repository, or a registry.

[3] Available from ASTM International Headquarters. Order Adjunct No. ADJE2369.

[4] Since the CCR is a core data set of selected, relevant information, it is not a discharge summary, that is, it does not include all of a patient's health information that would be routinely recorded at the time of discharge, nor is it the transfer of an entire patient record.

[5] The required XML may be as represented in the Adjunct to this specification or Annex A2 or other XML representation made possible through joint efforts of ASTM and other standards development organizations.

CCR document integrity and confidentiality must be provided while conforming to regulations or other security, confidentiality, or privacy protections as applicable within the scope of this specification.

1.4.1 Conditions of security and privacy for a CCR instance must be established in a way that allows only properly authenticated and authorized access to the CCR document instance or its elements. The CCR document instance must be self-protecting when possible, and carry sufficient data embedded in the document instance to permit access decisions to be made based upon confidentiality constraints or limitations specific to that instance.

1.4.2 Additional Subcommittee E31.20 on Security and Privacy guides, practices, and specifications will be published in support of the security and privacy needs of specific CCR use cases. When a specification is necessary to assure interoperability or other required functionality, the CCR core schema will be extended to meet the profile requirements of the underlying use case, building upon existing standards and specifications whenever possible.

1.4.2.1 For profiles that require digital signatures, W3C's XML digital signature standard (http://www.w3.org/TR/xmldsig-core) will be used with digital certificates. Encryption will be provided using W3C's XML encryption standard (http://www.w3.org/TR/xmlenc-core).

1.5 The CCR is an outgrowth of the Patient Care Referral Form (PCRF) designed and mandated by the Massachusetts Department of Public Health for use primarily in inpatient settings.

1.5.1 Unlike the PCRF, the CCR is designed for use in all clinical care settings.

1.6 It is assumed that information contained in a CCR will be confirmed as appropriate in clinical practice. For example, the CCR insurance fields should not be construed to address all reimbursement, authorization, or eligibility issues, and current medications and other critical data should be validated.

1.7 Committee E31 gratefully acknowledges the Massachusetts Medical Society, HIMSS (Health Information Management and Systems Society), the American Academy of Family Physicians, the American Academy of Pediatrics, the American Medical Association, the Patient Safety Institute, the American Health Care Association, the National Association for the Support of Long Term Care, the Mobile Healthcare Alliance (MoHCA), the Medical Group Management Association (MGMA) and the American College of Osteopathic Family Physicians (ACOFP) as co-leaders with ASTM in the standard's development and adoption, and joins them in inviting the collaboration of all stakeholders, including other clinical specialty societies, other professional organizations, insurers, vendors, other healthcare institutions, departments of public health, and other government agencies.

1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:* [6]

E 1382 Test Methods for Determining Average Grain Size Using Semiautomatic and Automatic Image Analysis

E 1384 Practice for Content and Structure of the Electronic Health Record (EHR)

E 1762 Guide for Electronic Authentication of Health Care Information

E 1869 Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Electronic Health Records

E 1985 Guide for User Authentication and Authorization

E 1986 Guide for Information Access Privileges to Health Information

E 2084 Specification for Authentication of Healthcare Information Using Digital Signatures

E 2085 Guide on Security Framework for Healthcare Information

E 2086 Guide for Internet and Intranet Healthcare Security

E 2147 Specification for Audit and Disclosure Logs for Use in Health Information Systems

E 2182 Specification for Clinical XML DTDs in Healthcare

E 2183 Guide for XML DTD Design, Architecture, and Implementation

E 2184 Specification for Healthcare Document Formats

E 2211 Specification for Relationship Between a Person (Consumer) and a Supplier of an Electronic Personal (Consumer) Health Record

E 2212 Specification for Health Certificate Policy

2.2 *Other References:*

Health Information Portability and Accountability Act, U.S. Congress, 1996

ICD-9-CM (http://www.cdc.gov/nchs/about/otheract/icd9/abticd9.htm)

LOINC (http://www.loinc.org/)

Massachusetts Department of Health Patient Care Referral Form

NDC (http://www.fda.gov/cder/ndc/)

RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm_main.html)

SNOMED (http://www.snomed.org/)

W3C XML Digital Signature Standard (http://www.w3.org/TR/xmldsig-core/)

W3C XML Encryption Standard (http://www.w3.org/TR/xmlenc-core)

3. Terminology

3.1 *Definitions of Terms Specific to This Standard*—These terms also include the common terms seen in many documents related to the CCR. See also Annex A1 for definitions of additional terms specific to this specification.

3.1.1 *actors*—all the individuals, organizations, locations, and systems associated with the data in the CCR.

[6] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

3.1.2 *attribute*—for the purposes of this specification, an attribute is a characteristic of data, representing one or more aspects, descriptors, or elements of the data. In object-oriented systems, attributes are characteristics of objects. In XML, attributes are characteristics of tags.

3.1.3 *CCR body*—contains the core patient-specific data in a CCR, for example, Insurance, Medications, Problems, Procedures, and the like.

3.1.4 *CCR components*—CCR Header, CCR Body, CCR Footer; each component is made of sections, which in turn are made up of data fields.

3.1.5 *CCR footer*—contains data defining all of the actors, as well as information about external references, all text comments, and signatures associated with any data within the CCR.

3.1.6 *CCR header*—defines the document parameters, including its unique identifier, language, version, date/time, the patient whose data it contains, who or what has generated the CCR, to whom or what the CCR is directed, and the CCR's purpose.

3.1.7 *comments*—all text comments associated with any data within the CCR not containing core relevant, clinical, or administrative data, and not containing pointers to references external to the CCR.

3.1.8 *CDA*—the HL7 CDA (Clinical Document Architecture) is a document markup standard for the structure and semantics of exchanged clinical documents. **E 2182**

3.1.9 *complex data type or a group*—concepts used more than once; defined by adding the post-fix 'Type.'

3.1.10 *continuity of care record (CCR)*—a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. See Section 5 for a summary of CCR contents, and Annex A1 for a detailed list of data fields.

3.1.11 *current procedural terminology (CPT)*—an annual reference published by the American Medical Association that lists descriptive terms and identifying codes for reporting medical services and procedures performed by physicians.

3.1.12 *data fields*—required or optional data within a section. Data fields may be repeated as often as necessary (see Annex A1).

3.1.13 *data objects*—discrete patient-specific data (Medications, Problems, Procedures, and the like).

3.1.14 *DERF*—NCPDP's Data Element Request Form used to request an addition or modification to NCPDP's current or new standards. **www.ncpdp.org**

3.1.15 *digital signature*—data associated with, or a cryptographic transformation of, a data unit that allows a recipient of the data unit to prove the source and integrity of the data unit and protect against forgery, for example, by the recipient. **E 2084**

3.1.16 *DMR*—durable medical equipment

3.1.17 *document object*—the CCR as an XML document, consisting of a header, a body, and a footer, each built from a set of discrete XML building blocks.

3.1.18 *domain-specific applications*—additional, optional sets of CCR data elements specific to such areas as clinical specialties, institutions or enterprises, payers, disease management, and personal health records. Data sets for optional CCR domain-specific applications will be developed and balloted separately from this specification.

3.1.19 *element and attribute names*—the literal names of the XML tags (elements) and attributes of the XML tags (attributes).

3.1.20 *encounter*—*(1)* an interaction, regardless of the setting, between a patient and a practitioner who is vested with primary responsibility for diagnosing, evaluating, or treating the patient's condition. It may include visits, appointments, as well as non face-to-face interactions; and *(2)* a contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment. **E 1384**

3.1.21 *enumeration*—the process of limiting the allowed data values within a defined set of XML tags to a defined and constrained list, an enumerated list.

3.1.22 *electronic health record (EHR)*—any information related to the physical or mental health/condition of an individual that resides in electronic system(s) used to capture, transmit, receive, store, retrieve, link, and manipulate data for the primary purpose of providing health care and health-related services. The EHR is meant to be a much more comprehensive collection of information than the CCR. **E 1384**

3.1.23 *extensible markup language (XML)*—a standard from the World Wide Web Consortium (W3C) that provides for tagging of information content within documents, offering a means for representation of content in a format which is both human and machine readable. Through the use of customizable style sheets and schemas, information can be represented in a uniform way, allowing for interchange of both content (data) and format (metadata). **E 1382**

3.1.24 *fields*—see *data fields*.

3.1.25 *Health Level 7*—also known as HL7, a standards organization traditionally focused on message-oriented standards for healthcare. HL7 messages are the dominant standard for peer-to-peer exchange of clinical, text-based information. **E 2182**

3.1.26 *HIPAA*—Health Information Portability and Accountability Act adopted by U.S. Congress in 1996.

3.1.27 *HL7*—see *Health Level 7*.

3.1.28 *ICD9-CM*—The International Classification of Diseases, Ninth Revision, Clinical Modification, is based on the World Health Organization's Ninth Revision, International Classification of Diseases (ICD-9). ICD-9-CM is the official system of assigning codes to diagnoses and procedures associated with hospital utilization in the United States. Source: National Center for Health Statistics.

3.1.29 *ICD-10*—the International Classification of Diseases, Tenth Revision, the World Health Organization.

3.1.30 *integrity*—property that data has not been altered or destroyed in an unauthorized manner. **E 2084**

3.1.31 *language*—Refers to the language in which the CCR is expressed.

3.1.32 *LOINC*—Logical Observation Identifiers Names and Codes (LOINC) is a database to facilitate exchange and pooling of results, such as hemoglobin, serum potassium, or vital signs, for clinical care, outcomes, management, and research. **http://www.loinc.org/**

3.1.33 *messaging standard*—a method of electronic data exchange offered by HL7.

3.1.34 *NCPDP*—National Council for Prescription Drug Programs. Creates and promotes standards for transfer of data to and from the pharmacy services sector of the healthcare industry. **www.ncpdp.org**

3.1.35 *NCPDP SCRIPT*—A standard created by NCPDP to facilitate the electronic transfer of prescription data between pharmacies and prescribers. **www.ncpdp.org**

3.1.36 *NDC*—National Drug Code; originally established as an essential part of an out-of-hospital drug reimbursement program under Medicare. The NDC serves as a universal drug identifier for human drugs. The current edition of the National Drug Code Directory is limited to prescription drugs and a few selected OTC products. **http://www.fda.gov/cder/ndc/**

3.1.37 *normalization*—the process of listing data only once within a data object (XML document) or database and then referring to that data through a link, reference, or pointer.

3.1.38 *optional field*—a CCR data field that is not required but should be completed when there is relevant information about the patient available (see Annex A1).

3.1.39 *optionality*—defining whether or not something is optional or not.

3.1.40 *patient health record*—the primary legal record documenting the healthcare services provided to a person in any aspect of healthcare delivery. This term is synonymous with: medical record, health record, patient care record (primary patient record), client record, and resident record. The term includes routine clinical or office records, records of care in any health-related setting, preventive care, life style evaluation, research protocols, special study records, and various clinical databases. **E 1384**

3.1.41 *persistent document*—a document that remains as a document within a data structure or file system once it has been used for its original intended use.

3.1.42 *personal health record (PHR)*—an electronic application where individuals can maintain and manage their health information or that of others for whom they are authorized in a private, secure, and confidential environment that allows the individual or other authorized persons to access and share such information. **E 2211**

3.1.43 *practitioner*—an individual who is qualified to practice a healthcare profession, for example, physician, nurse, or physical therapist. Practitioners are often required to be licensed as defined by law. **E 2184**

3.1.44 *purpose*—the specific reason for which a specific CCR is generated, such as patient admission, transfer, consult/referral, or inpatient discharge.

3.1.45 *referral*—the process of transferring all or a portion of a patient's care from one setting or practitioner to another.

3.1.46 *references*—data sources/locations that are outside the CCR, for example, URLs, diagnostic images, clinical documents.

3.1.47 *required field*—a field that must be completed within the CCR (see Annex A1). *None* or *unknown* is an acceptable entry.

3.1.48 *role*—defines the healthcare or support role of the <Actor> relative to the patient. <Role> does not define, in itself, an explicit role relative to data security, confidentiality, privacy, or access control.

3.1.49 *RxNorm*—a clinical drug nomenclature produced by the National Library of Medicine, in consultation with the Food and Drug Administration, the Department of Veterans Affairs, and HL7. RxNorm provides standard names for clinical drugs and for dose forms as administered. **http://www.nlm.nih.gov/research/umls/rxnorm_main.html**

3.1.50 *section*—a group of data fields within each component of the CCR (see Annex A1).

3.1.51 *SIG*—the use or administration instructions for a medication.

3.1.52 *SNOMED CT*—SNOMED Clinical Terms is the universal healthcare terminology that makes healthcare knowledge usable and accessible wherever and whenever it is needed. **http://www.snomed.org/**

3.1.53 *transfer*—referral of a patient that results in the physical movement of the patient from one location to another.

3.1.54 *vendor configurable fields*—fields where a vendor can define their use or content, or both.

3.1.55 *version*—refers to the version of the CCR as defined by the release of the standard used.

3.1.56 *W3C XML schema*—defines the elements that may appear within the XML document and the attributes that may be associated with an element. An element that has no content must not be present in the CCR XML. It also defines the structure of the XML document: which elements are children of others, the sequence in which the child elements may appear, and the number of child elements. It defines whether an element is empty or can include text. The schema can also define default values for attributes. **E 2183**

3.1.57 *XSLT*—extensible style language transformation; a standard from the W3C that is a language for transforming XML documents into other XML documents and with extensions into other formats. **http://www.w3.org/TR/xslt**

3.1.58 *Xpath*—a standard from the W3C that is a language for addressing parts of an XML document, designed to be used by XSLT and other XML technologies. **http://www.w3.org/TR/xpath**

3.1.59 *XML*—extensible markup language; a standard from the World Wide Web Consortium (W3C) that provides for tagging of information content within documents, offering a means for representation of content in a format which is both human and machine readable. Through the use of customizable style sheets and schemas, information can be represented in a uniform way, allowing for interchange of both content (data) and format (metadata). **E 2182**

3.1.60 *XML codes*—descriptors used to define the fields of the CCR when it is prepared in a structured electronic format.

3.1.61 *XML document*—a document constructed of XML tags and data.

3.1.62 *XML encryption*—a W3C standard for encrypting XML.

3.1.63 *XML signature*—a signature to an XML document that is similar in intent to a signature for paper-based document. In actual use within XML, these tend to be digital signatures.

3.1.64 *XML tag attributes*—attributes that apply to a specific XML tag and its data.

3.1.65 *xsd*—the XML schema.

3.1.66 *xsl*—extensible style language; used to format and transform XML documents into other XML formats or to non-XML data or print formats.

3.1.67 *W3C*—the World Wide Web Consortium develops interoperable technologies (specifications, guidelines, software, and tools) to lead the Web to its full potential as a forum for information, commerce, communication, and collective understanding. **E 2182**

4. Significance and Use

4.1 Standardizing patient care information transfer through the CCR will greatly benefit the healthcare process. It addresses the lack of appropriate, succinct, and up-to-date patient health information for practitioners at a new point of care, and it can improve continuity of patient care by providing a method for easily communicating the most relevant clinical information about a patient among practitioners, institutions, and other entities. It enables a practitioner to readily access information about a patient's healthcare at any point in an encounter and to easily update the information at any time, particularly at the end of an encounter or when the patient goes from one provider to another.

4.2 The intent of the CCR is to enhance patient safety, reduce medical errors, reduce costs, enhance efficiency of health information exchange, and assure at least a minimum standard of health information transportability when a patient is referred, transferred, or is otherwise seen by, another practitioner.

4.2.1 The information included in the CCR is essential to good patient care and thus serves as a necessary bridge to a different environment, often with new practitioners who know little about the patient. By using the CCR, the next healthcare practitioner may:

4.2.1.1 Be informed about a patient's allergies, medications, current and recent past diagnoses, most recent healthcare assessments and services, advance directives, and the recommendations of practitioners who last treated the patient.

4.2.1.2 More quickly and easily verify patient demographics and insurance status, saving time and effort by not having to repeatedly ask a patient for this information in detail.

4.2.1.3 Minimize the effort required to update the patient's most essential and relevant information in an EHR.

4.2.1.4 Reduce costs associated with the patient's care, for example, through avoiding repetitive tests and basic information gathering.

4.3 The CCR will be completed by practitioners, such as physicians, nurses, and ancillary practitioners (for example, social work, physical therapy, occupational therapy), for example, in the following instances, which are non-normative.

4.3.1 *Referral (inpatient or outpatient) or Transfer (from an inpatient or institutional setting)*—The referring practitioner should transmit the CCR to the receiving practitioner and new care setting where the patient is being sent so that it arrives before or with the patient.

4.3.2 *Discharge without a Referral or Transfer*—The CCR should be provided to the patient for future use, including visits to an urgent care or emergency department, and to whomever the patient designates as the primary care practitioner who will be responsible for follow-up care, if needed.

4.3.3 *Personal Health Record*—A person may keep copies of his/her CCRs and supplement them, for example, with alternative medicine information and other personal health information. It should be noted, as well, that a person may also generate their own CCR.

4.4 Subsequently, the CCR may provide additional content and support for the EHR through domain-specific applications,[7] including the following non-normative examples:

4.4.1 *Enterprise- and Institution-specific Information*—particularly regarding discharge or transfer, for example, hospital to nursing and rehabilitation facilities or to home care agencies, and vice versa.

4.4.2 *Clinical Specialty Information*, for example, Pediatrics, Surgery, OB-GYN, Cardiology, Orthopedics, and so forth

4.4.3 *Disease Management Information*, to accommodate the recording of disease-specific management information, performance measures, or guidelines, for example, for diabetes, congestive heart failure, asthma, and so forth. This extension may be utilized by health plans, pharmaceutical companies, patient advocacy groups, and others interested in promoting "best practices".

4.4.4 *Payer-related Information*, including additional financial and care documentation.[8]

4.4.5 *Patient-entered Personal Health Record Information*, for example, complementary and alternative medicine care documentation or other patient considerations, such as private or sensitive health information a patient may be reluctant to share with certain practitioners or spouses. Expanded family history information is another potential use.

4.4.6 With appropriate modifications for confidentiality, the CCR may also be useful to researchers and others not directly involved in a patient's treatment.

5. Specifications

5.1 The CCR consists of three core components: the CCR Header, the CCR Body, and the CCR Footer.

5.1.1 *CCR Header* consists of the following CCR Sections:

5.1.1.1 *Unique Identifier* of the CCR, generated by the originating entity/system uniquely identifies each explicit instance of a CCR.

[7] Where representation of data for such additional content cannot be achieved through the current CCR structure, it shall be addressed through the ballot process. Variability of data expression will be limited in order to support interoperability.

[8] The CCR is not intended for use as a claims attachment. Claims attachments are standardized (U.S. Realm) under the ASC X12N standard ASC X12N 275 (004050X15) 275 – Additional Information to Support a Health Care Claim or Attachment.

(1) The uniqueness of the ID is defined within the generating system and must be unique to and within each CCR and ideally is unique across the universe of CCRs.[9]

5.1.1.2 *Language* refers to the language in which the CCR is expressed.

5.1.1.3 *Version* refers to the version of the CCR Implementation Guide that is used to create a given instance of a CCR.

5.1.1.4 *Date/Time* refers to the exact time the data on a specific patient were aggregated to create a CCR, which is not necessarily the time the CCR was transmitted, printed, or sent.

5.1.1.5 *Patient* identifies the person to which the CCR refers.

(1) Patient identification is not based on a centralized system or a national patient identifier. Rather, it is based on a distributed identification system that links various practitioners and contains the core data set of identifying information that could be used by any record system to assign the individual their own identifier.

(2) A CCR can be about only one patient with the rare exception of Siamese Twins, where it contains data on two patients. Other than within that rare exception, the CCR is a snapshot in time of the clinical, demographic, and administrative data of a unique patient.

5.1.1.6 *From* identifies who or what has generated the CCR and also defines the healthcare role that entity is playing when generating the CCR.[10]

5.1.1.7 *To* identifies to whom or to what the CCR is targeted and that recipient's role in relationship to the patient.

5.1.1.8 *Purpose* defines the specific reason that a CCR is generated, such as patient admission, transfer, consult/referral, or inpatient discharge.

5.1.2 *CCR Body* includes the following patient administrative and clinical sections.

5.1.2.1 *Payers* contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination of payers and is used to define which entity is the responsible fiduciary for the financial aspects of a patient's care.

(1) This CCR section defines each unique instance of a payer and all the pertinent data needed to contact, bill to, and collect from that payer.

(2) Also contained within the Payers section is authorization information that can be used to define pertinent referral, authorization tracking number, procedure, therapy, intervention, device, or similar authorizations for the patient or provider, or both.

5.1.2.2 *Advance Directives* contains data defining the patient's advance directives and any reference to any existing supporting documentation and the physical location of that documentation, such as a durable power of attorney for healthcare.

5.1.2.3 *Support* lists the patient's support providers and contacts (family, next of kin, legal guardian, durable power for healthcare, clergy, caregivers, support organizations, etc.) at the time the CCR is generated.

(1) The patient's healthcare providers are not listed in this section. They are listed under the Practitioners Section in the CCR.

5.1.2.4 *Functional Status* lists and describes the patient's functional status, for example, competency, ambulatory status, ability to care for self, activities of daily living, at the time the CCR is generated.

5.1.2.5 *Problems* contains data defining the patient's relevant current and historical clinical problems, conditions, diagnoses, symptoms, findings, and complaints at the time the CCR is generated. If the CCR is being created for a referral, they should be ranked in order of importance for the referral purpose. Otherwise, reverse chronological order of onset should prevail.

5.1.2.6 *Family History* contains data defining the patient's blood or genetic relatives in terms of possible or relevant health risk factors.

5.1.2.7 *Social History* contains data defining the patient's occupational, personal (for example, lifestyle), social, and environmental history and health risk factors, as well as administrative data (ADT) such as marital status, race, ethnicity, and religious affiliation.

5.1.2.8 *Alerts* lists and describes any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history.

(1) Alerts data represent critically important variations from the norm that have temporal relevance in the near term or long term to the patient's condition and therapeutic options.

(2) Alerts are prompts or warnings related to patient safety.

5.1.2.9 *Medications* defines a patient's current medications and pertinent medication history.

(1) At a minimum, the currently active medications should be listed, with an entire medication history as an option, particularly when the CCR is used for comprehensive data export.

5.1.2.10 *Medical Equipment* defines a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history. This section is also used to itemize any pertinent current or historical durable medical equipment (DME) used to help maintain the patient's health status.

5.1.2.11 *Immunizations* defines a patient's current immunization status and pertinent immunization history.

5.1.2.12 *Vital Signs* defines the patient's current and historically relevant vital signs, for example, blood pressure, pulse. respiratory rate, height, weight, body mass index, head circumference, crown-to-rump length, pulse oximetry, and pulmonary function tests.

(1) At a minimum, pertinent vital signs, such as the most recent, maximum or minimum, or both, baseline, or relevant trends should be listed.

5.1.2.13 *Results* captures detailed pertinent and most recent laboratory, diagnostic, and therapeutic results data.

5.1.2.14 *Procedures* defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically and at the time the CCR is generated.

[9] The use of a universally unique ID representation is recommended, such as a UUID or OID.

[10] The intent of <From> is for validity of origin of the CCR not validity of data.

(1) The preferred controlled vocabulary here is SNOMED CT, as well as the current CPT Codeset for the procedure and LOINC for any result,

5.1.2.15 *Encounters* contains data defining all healthcare encounters pertinent to the patient's current health status or health history.

(1) Encounters can be hospitalizations, office visits, home health visits, long-term care stays, or any other pertinent encounters.

5.1.2.16 *Plan of Care* contains data defining all pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only.

(1) All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient should be listed, unless constrained due to issues of privacy.

(2) Clinical reminders should also be placed here for purposes of providing prompts that may be used for disease prevention, disease management, patient safety, and healthcare quality improvements, including widely accepted performance measures.

5.1.2.17 *Healthcare Providers* contains data defining all healthcare providers involved in the current or pertinent historical care of the patient. At a minimum, the patient's key healthcare providers should be listed, particularly the patient's primary physician and any active consulting physicians, therapists, and counselors.

5.1.3 *CCR Footer* contains the following sections:

5.1.3.1 *Actors* contains data defining all of the individuals, organizations, locations, and systems associated with the data in the CCR.

5.1.3.2 *References* contains details concerning all references within the CCR to external data sources.

(1) External reference data can be URLs, references articles, clinical documents, paper or electronic patient records, diagnostic or document images, or any other data that would be of value to the providers using the CCR data for patient care.

5.1.3.3 *Comments* contains all text or structured comments associated with any data within the CCR.

(1) Comments are text or structured comments that are not intended to contain core relevant clinical or administrative data.

(2) Comments are not to be used to contain any data that correctly belong under <Description>, <Type>, <Status>, <Source>, or <ReferenceID>.

(3) Comments should also not contain pointers to references or other data external to the CCR that apply to a CCR section.

5.1.3.4 *Signatures* contains all signatures associated with any data within the CCR.

5.2 Annex A1 provides a detailed list of the CCR sections contained within the CCR Header, Body, and Footer, as well as all data fields within each section. Each field within a section includes: an XML code; a definition; explanations, descriptions, requirements, and restrictions; comments and examples; and specification of whether the field is required or optional.

5.3 The Adjunct to this standard provides the W3C XML schema derived from the XML codes in Annex A1. When the CCR is prepared in a structured electronic format, this XML schema in conjunction with Annex A2, the Implementation Guide, or other XML xsd and its related implementation guide that may be authorized through joint efforts of ASTM and other standards development organizations, must be used to assure interoperability.

5.4 Annex A2 provides the Implementation Guide, which contains instructions for using the XML schema (provided in the Adjunct to this specification) for generation of a standards-compliant, interoperable CCR.

5.5 Detailed coding is recommended whenever practical within the CCR. In all instances, the coding system and version must be specified.[11] Specific coding recommendations (for the U.S.) include the following. (note that these are coding suggestions and are non-normative).

5.5.1 Problems should be coded at the highest level using SNOMED CT and the most recent ICD-9 CM codes at the time the CCR is generated to accommodate the need for the various healthcare entities that will be interacting with the CCR data to have accurate coding for reimbursement purposes. These and other controlled vocabularies are integral to the enhancement of data contained within the CCR to support intelligent clinical decision support. It is recommended that problems be categorized with SNOMED CT codes to as granular a level as possible.

5.5.2 Procedures should be coded at the highest level using SNOMED CT, LOINC, and the most recent CPT codes at the time the CCR is generated to accommodate the need for the various healthcare entities that will be interacting with the CCR data to have accurate coding for reimbursement purposes as well as potential utilization for clinical decision support functions. It is recommended that procedures be coded with SNOMED CT and LOINC codes to as granular a level as possible.

5.5.3 Products and agents should be coded with RxNorm to as granular a level as possible. In addition, they may be coded with another standard as applicable (NDC, for example) or proprietary code, with the type of code and the source and version clearly defined. If any coding system is used, however, an RxNorm code must be included, if legally required.

5.5.4 Procedures generating results should be coded with the most recent CPT codes at the time the CCR is generated for procedures and with LOINC for <Result> and <Test>.

6. Keywords

6.1 actor; advance directives; adverse reactions; alerts; allergies; attribute; care documentation; CCR; CCR Body; CCR components; CCR Footer; CCR Header; coding; comment; complex data type or group; condition; Continuity of Care Record; core data set; data field; data object; date/time; diagnosis; digital signature; discharge; disease management; document object; electronic health record; EHR; encounter;

[11] While it is recognized that there is no clear method to interpret the relationship between coded elements, it is outside the scope of this specification to resolve this difficulty.

encryption; enumeration; external CCR link; family history; field; from; functional status; health risk factors; health status; healthcare provider; HIPAA-compliant; immunization; insurance; integrity; internal CCR link; laboratory results; language; medical equipment; medication; normalization; optionality; patient; patient health record; patient health status; patient identifying information; payer; personal health record; PHR; physiological measurements; plan of care; practitioner; problem; procedure; purpose; referral; reference; required data; result; sections; security; SIG; signature; social history; source; status; support; to; transfer; unique identifier; vendor configurable fields; version; vital signs; W3C; XML; XML code; XML document; XML schema; XML signature; .xsd; .xsl

ANNEXES

(Mandatory Information)

A1. CCR DATA FIELDS SPREADSHEET

A1.1 Table A1.1 lists and describes the data set attributes of the three core components of the CCR: the Header, the Body, and the Footer. The following information is included for each document object attribute:

A1.1.1 An XML code (see the Adjunct for the corresponding W3C XML schema derived from these XML codes);

A1.1.2 A definition;

A1.1.3 Explanations, descriptions, requirements, and restrictions;

A1.1.4 Comments and examples; and

A1.1.5 Required or optional status.

TABLE A1.1 CCR Data Fields Spreadsheet

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
CCR Document Object Attributes					
CCR HEADER					
CCR Unique Identifier	<CCRDocumentObjectID>	The CCR and all Data Objects contained within the CCR must have ObjectIDs. The CCR Document Object ID is generated by the originating entity/system to uniquely identify each explicit instance of a CCR. The uniqueness of this ObjectID is defined within the generating system and must be unique to and within each CCR and ideally should be unique across the universe of all CCRs.	The <CCRDocumentObjectID> is of type xs:string. Ideally it is a UUID or OID.	Any numeric or alphanumeric string.	Required
Language	<Language>	The Language in which the CCR is expressed.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	English	Required
Version	<Version>	The Version of the CCR Implementation Guide that is used to create a given instance of a CCR.	<Version> is expressed as type xs:string. For this <Version> of the CCR it must state "V1.0."	V1.0	Required
CCR Creation Date/Time	<DateTime>	This is the exact clock time that this CCR was created/generated. This DateTime refers to the exact time the data on a specific patient were aggregated to create a CCR, which is not necessarily the time the CCR was transmitted, printed, or sent.	CCR Creation DateTime must be expressed in ISO-8601 date-time format, with precision to include seconds. All date times expressed in Hours, Minutes, and/or Seconds in the CCR must express a time zone offset, either using Z [universal coordinated time, or Zulu time], or an offset in hours and minutes. The CCR further requires that the time zone offset be a legal time zone. This latter constraint cannot be expressed in the schema, as time zones are determined by political entities [for example, Nations or States]. There presently exist time zones in the form ##:15 and ##:30. CCR Creation DateTime time should ideally come from a net-based atomic time service and not from an individual computing device's internal clock.	The ISO-8601 standard defines the time string as CCYY-MM-DDThh:mm:ss-hh:mm. 2005-01-25-T12:15:37-09:00 represents January 25, 2005 12:15:37 PST (Pacific Standard Time), which is minus (-) 9 hours from universal coordinated time (Zulu). This exact time can also be expressed as Zulu time as 2005-01-25-T21:15:37Z, which represents January 25, 2005 21:15:37 Zulu.	Required
Patient	<Patient>	Identifies the patient to which the CCR refers. This is a link to <Actor> through an <ActorID> of type xs:string. This should equal one of the <ActorObjectID> in <Actors>. Detailed data on each <Actor> is maintained in the <Actors> Section in the CCR Footer.	The CCR can only be about one patient with the extreme exception of Siamese Twins, where it can contain data on two patients. Therefore, patient cardinality must be at least 1, and at most 2, in the rare case of Siamese Twins. Other than within that extreme exception, the CCR is a snapshot in time of the clinical and administrative data of a unique patient.		Required

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
From	<From>	Identifies who or what has generated the CCR. This is a link to an Actor <ActorID> and also defines the healthcare role <ActorRole> that the actor is playing when generating the CCR.	An Actor and their Role must be specified under <From>. An <ActorLink> and <ActorID> are REQUIRED.	Originating practitioner(s), other healthcare provider, healthcare organization, or healthcare information system (in the use case where the CCR is generated by a computer system for data exchange or export, for example).	Required
To	<To>	Identifies to whom or what the CCR is targeted. This is a link to an Actor <ActorID> and also defines the healthcare role <ActorRole> that the Actor plays in receiving the CCR.	An Actor and their Role must be specified under <To> if the <To> object is used in the CCR. An <ActorLink> and <ActorID> are REQUIRED.	Receiving/target practitioner(s), other healthcare provider, healthcare organization, or healthcare information system (in the use case where the CCR is generated by one computer system for data exchange or export to another computer system, for example).	Optional
Purpose	<Purpose>	Defines the specific reason for which the CCR was generated.	The general use case does not require a <Purpose>. <Purpose> should be utilized when the CCR has a specific purpose such as patient admission, transfer, consult/ referral, or inpatient discharge.		Optional
	<DateTime>	An optional data attribute used to define DateTimes relevant to the <Purpose> of the CCR.	Exact DateTime, age, approximate DateTime, or DateTime range are permitted.	For a CCR with a <Purpose> defined as a request for consult, a range of time (e.g., within two weeks) may be specified, or ASAP, or Today, or a specific date or specific date and time. The same would hold true for a request for procedure, request for follow-up, request for authorization, etc.	Optional
	<Description>	Used to express the <Purpose> of the CCR. One or more purposes are allowed.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Request For Consult, Request For Procedure, Request for Service, Request for Encounter, Request for Authorization, Request for Medical Device Or Product, Request for Medication, Request for Immunization, For Patient Use.	Required if Purpose Section/ Object is included
	<OrderRequest>	Used to define a specific Procedure, Device/ Product, Medication, Immunization, Service, Encounter, and/or Authorization that is the <Purpose> of this CCR.	See <OrderRequest> under <PlanOfCare>.	See <OrderRequest> under <PlanOfCare>.	Optional
	<Indications>	Defines a specific <Indication> that supports the <Purpose> of this CCR.	See <Indication>.	See <Indication>.	Optional
	<ReferenceID>	Used to link the <Purpose> to an external data source or location.	This is a link to <Reference>.	See References.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <Purpose>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under <Description>, <OrderRequest>, or <Indication>. This is a link to <Comment>.	See Comments.	Optional
CCR BODY					

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
Payers	<Payers>	This CCR DataObject contains data on the patient's payers, whether insurance, self-pay, other payer, or some combination of payers.	At a minimum, the patient's pertinent current payment sources should be listed.		Optional
	<Payer>	Defines each unique instance of a payer - insurance or self-pay or other, and all the pertinent data needed to contact, bill to and collect from that payer.			Required if Insurance Section/Object is included
	<CCRDataObjectID>	All CCR data objects must have a unique data object ID.	The <CCRDataObjectID> is of type xs:string.	Any numeric or alphanumeric string.	Required if Insurance Section/Object is included
	<PaymentProvider>	Identifies the <PaymentProvider>. This is a link to an Actor <ActorID> and also defines the healthcare role <ActorRole> that the actor plays.			<ActorID> is Required, <ActorRole> is Optional.
	<DateTime>	Used to define dates and times relevant to the payer and patient relationship.	This is restricted to an ExactTime and requires <Type> and <ExactDateTime>, which should be specified to at least the Year/Month/Day. <ExactDateTime> must be expressed as an ISO8601 DateTime.	For healthcare insurance: Effective Date, End Date, Termination Date	Optional
	<Type>	Used to define the <Payer> <Type>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Self-Pay, Primary Health Insurance, Supplemental Health Insurance, Prescription Drug Benefit, Mental Health Benefit, Long Term Care Benefit, Worker's Compensation, Auto Insurance, Dental Insurance, Other.	Optional
	<Subscriber>	Identifies the <Subscriber>. This is a link to an Actor through <ActorID> and also defines the role through <ActorRole> that the <Subscriber> plays.			<ActorID> is required, <ActorRole> is optional.
	<IDNumber>	Used to list all of the relevant IDs for this patient relative to the defined payer.	If an <ID> is listed, then <Type> is also required in this instance.	Subscriber Number, Group Number, Employer Number, Plan Code, Worker's Comp Claim Number, Etc.	Optional but required if <ID> is listed
	<Authorizations>	Used to define any authorizations/pre-authorizations that are currently active for this patient and payer.		Authorization for service, encounter, product/device, medication, immunization, procedure.	Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <Insurance> data.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of all CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to the patient or patient's parent, child, relative, guardian, durable power, primary physician, practice management system, etc.	Required if Insurance Section/Object is included

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID	Pharmacy benefit plan to cover medications. <Authorization> to a specific procedure, etc.	Optional
	<ReferenceID>	Used to link the <Payer> to a <Reference>.	This is a link to <Reference>. <Reference> under <AdvanceDirective> must be a child of <Source>.	A <Reference> to an insurance card on file, etc.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <AdvanceDirective>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under <Description>, <Type>, <Status>, <Source>, or <Reference>. This is a link to <Comment>.	See Comments.	Optional
Advance Directives	<AdvanceDirective>	This CCRDataObject contains data defining the patient's advance directives and any reference to any existing supporting documentation and the physical location of that documentation —such as a durable power of attorney for healthcare.	The most recent and up-to-date Advance Directives are required in the general use case, if known,, in as much detail as possible. Otherwise, optionality is use-case specific.		Required if known in general use case, otherwise use-case specific.
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required if known in general use case, otherwise use-case specific
	<DateTime>	Used to define dates and times relevant to the patient's advance directives.	This is restricted to an ExactTime and requires <Type> and <ExactDateTime>. <ExactDateTime> should be specified to at least the Year/Month/Day. <ExactDateTime> must be expressed as an ISO8601 DateTime.	This should list the DateTime that the Advance Directive was last recorded and/or verified and any relevant applicable dates or ranges (applicable from Date A____ to Date B____). DateTime <Type> should express Last Recorded, Verified With Patient, Verified With Parent, Verified With Guardian, Verified With Family, Verified With Durable Power Of Attorney for Healthcare, Verified With Treating Physician, Start Date, End Date.	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Defines the <AdvanceDirective> <Type>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Resuscitation Status, Intubation Status, IV Fluid and Support Status, CPR Status, Antibiotic Status, Life Support Status, Tube Feedings, Other.	Required if Advance Directives Section/Object is included

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Description>	Used to express the <AdvanceDirective>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Full Code, No Code, No CPR, Cardioversion Only, CPR Drugs Only, No Intubation, IV Fluids Only, No IV Fluids, Antibiotics Only, No Antibiotics, Tube Feedings, No Feeding Tube, No Prolonged Life Support.	Required if Advance Directives Section/Object is included
	<Status>	Used to define the <Status> of the <AdvanceDirective>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Current and Verified, Supported By Healthcare Will, Supported By Durable Power of Attorney for Healthcare, Verified With Family Only, Verified By Medical Record Only.	Required if Advance Directives Section/Object is included
	<Source>	Used to define the person, system, or institution that is the <Source> of the <AdvanceDirective> data.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of all CCRDataObjects so that any data within the CCR can be validated as to its origin/source.	Link to the patient, or the patient's parent, child, relative, guardian, durable power, primary physician, etc.	Required if Advance Directives Section/Object is included
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	Advance Directive may be linked to a specific problem/diagnosis such as COPD or metastatic CA, etc.	Optional
	<ReferenceID>	Used to link the <AdvanceDirective> to a <Reference>.	This is a link to <Reference>. <Reference> under <AdvanceDirective> must be a child of <Source>.	A <Reference> to a durable power of attorney for healthcare or other documents or healthcare records that support the <AdvanceDirective>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <AdvanceDirective>.	This is restricted to legitimate free text comments only. It is NOT to be used to contain any data that correctly belong under <Description>, <Type>, <Status>, <Source>, or <ReferenceID>. This is a link to <Comment>.	See Comments.	Optional
Support	<SupportProvider>	Used to list the patient's sources of support such as immediate family, relatives, guardian, durable power, spiritual advisory/clergy, and the like.	This is a link to an <Actor> with an <ActorRole>. This data object is *not* used for listing a patient's healthcare providers, which are listed under the <HealthCareProviders> Section of the CCR, with the exception that 'Care Giver' should be listed under <Support>. At a minimum, the patient's key support contacts relative to healthcare decisions, including next of kin, should be listed here.	Parent, immediate family, next of kin, relative, guardian, durable power, care giver, priest, minister, rabbi, iman, etc.	Optional
Functional Status	<Function>	This CCRDataObject is used to list and describe the patient's current functional status including ambulatory status, activities of daily living, mental status, home/living situation, ability to care for self, etc.	At a minimum, any functional limitations that affect the patient's ability to care for self, ambulate, follow diagnostic, therapeutic, or treatment advice, follow-up for care, or which in any way limit or compromise the patient's ability to function normally should be listed.		Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required if Functional Status Section/Object is included
	<DateTime>	Used to define dates and times relevant to the patient's <FunctionalStatus>.	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Date of Onset, From Date A___ To Date B____, Since Age___, etc.	Optional
	<Type>	Defines the <FunctionalStatus> <Type>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Ambulatory Status, Mental Status, Activities of Daily Living, Home/Living Situation, Ability to Care for Self.	Required if Functional Status Section/Object is included
	<Problem>	Used when the <FunctionalStatus> is a problem, such as a clinical condition.	See Problems.		Optional
	<Result>	Used when the <FunctionalStatus> is a result such as a mini-mental status exam or functional assessment.	See Results.		Optional
	<Description>	Used to express the <FunctionalStatus> *if and only if* the <FunctionalStatus> described is not a <Problem> or a <Result>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	To be used only in the rare case where <FunctionalStatus> is not more appropriately described as a <Problem> or <Result>.	Optional
	<Status>	Defines the <Status> of the <FunctionalStatus>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Active, Chronic, Temporary, Resolved.	Required if Functional Status Section/Object is included
	<Source>	Used to define the person, system, or institution that is the <Source> of the <FunctionalStatus> data.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of *all* CCRDataObjects so that any data within the CCR can be validated as to its origin/source.	Link to a healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required if Functional Status Section/Object is included
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	<Function> to a specific <Problem>.	Optional
	<ReferenceID>	Used to link the <FunctionalStatus> to a <Reference>.	This is a link to <Reference>. <Reference> under <FunctionalStatus> *must* be a child of <Source>.	A link to a reference such as a healthcare document, assessment tool, or healthcare record that is a <Reference> for the <FunctionalStatus>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <FunctionalStatus>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under <Description>, <Type>, <Status>, <Problem>, <Result>, <Source>, or <ReferenceID>. This is a link to <Comment>.	See Comments.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
Problems	<Problem>	This CCRDataObject lists and describes all relevant clinical problems, conditions, diagnoses, symptoms, findings, and complaints at the time the CCR is generated.	At a minimum, all pertinent current and historical problems should be listed. In the special case that the CCR is being created for a referral, each <Problem> should be ranked in order of importance for the referral purpose. Otherwise, reverse chronological order of onset should prevail.		Optional
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required if Problem Section/ Object is included
	<DateTime>	Used to define dates and times relevant to the patient's <Problem>.	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Date of Onset, From Date A___ To Date B____, Since Age___, etc.	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Defines the <Problem> <Type>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Problem, Condition, Diagnosis, Symptom, Finding, Complaint, Functional Limitation	Optional
	<Description>	Used to express the <Problem>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. It is recommended that, when possible, all problems be coded (ICD-9CM, ICD-10, and/or SNOMED).	Myocardial Infarction, Nausea, Headache, Parkinson's Disease, etc.	Optional
	<Status>	Defines the <Status> of the <Problem>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Active, Inactive, Chronic, Intermittent, Recurrent, Rule Out, Ruled Out, Resolved.	Optional
	<Episodes>	Used to define one or more occurrences of a problem.	Episodes should be listed for recurrent or repetitive problems, conditions, diagnoses, or symptoms, rather than listing a problem multiple times in the problem list. <Episodes> has children <Number>, <Frequency>, <Episode>, and <Duration>.		Optional
	<HealthStatus>	Used to define the <HealthStatus> of the Actor to whom the problem applies (used more commonly in <Family History>).	<HealthStatus> has children <DateTime>, <Description>, <CauseOfDeath>. <DateTime> can be an Exact DateTime, an age, an approximate DateTime, or a DateTime range. <Description> and <CauseOfDeath> are instances of Coded DescriptionType with restricted content that must be one of the defined structured text values.	<Description> Alive And Well, In Remission, Symptom Free, Chronically Ill, Severely Ill, Disabled, Severely Disabled, Deceased; <CauseOfDeath> Yes, No, Unknown. Note that under <HealthStatus> the CCR can record the current health status relative to this problem as well as if the problem was or was not the <CauseOfDeath> and a Time Of Death as a <Type> under <DateTime>.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<PatientKnowledge>	Used to define whether or not the patient is aware of a <Problem> and the <Reason> why they are or are not aware.	<PatientAware> restricted to Yes, No, Unknown. <Reason> is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	<PatientAware> Yes, No, Unknown. <Reason> Patient Request Not To Know, Family Request For Patient Not To Know, Durable Power Request For Patient Not To Know.	Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <Problem> data.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of all CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to a healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required if Problem Section/ Object is included
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	Problem to a specific <History>, <Procedure>, <Product>, or <Encounter>, etc.	Optional
	<ReferenceID>	Used to link the <Problem> to a <Reference>.	This is a link to <Reference>. <Reference> under <Problem> *must* be a child of <Source>.	A <Reference> to a clinical note, discharge summary, or other documents or healthcare records that support the <Problem>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <Problem>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under <Description>, <Type>, <Status>, <Episodes>, <CurrentHealthStatus>, <PatientKnowledge>, <Source>, or <ReferenceID>. This is a link to <Comment>.	See Comments.	Optional
Family History	<FamilyProblemHistory>	This CCRDataObject contains data defining the patient's blood or genetic relatives in terms of possible or relevant risk factors.	At a minimum, all family history that has a potential impact on the patient's healthcare risk profile should be listed. Family history is a key risk factor of high predictive value in diagnosis and treatment for many healthcare conditions, and is often difficult to collect at each encounter and maintain between encounters. Inclusion of family <History> data in the CCR is important.		Optional
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required if Family History Section/ Object is included
	<DateTime>	Used to define dates and times relevant to the patient's family <History>.	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Date of Onset, From Date A___ to Date B____, Since Age___, etc.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Defines the family <History> <Type>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Condition, Diagnosis, Problem, Symptom	Optional
	<Description>	Used to express the <History> if and only if the <History> described is not a <Problem>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	To be used only in the rare case where <History> is not more appropriately described as a <Problem>.	Optional
	<Status>	Defines the <Status> of the family <History>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Active, Inactive, Chronic, Intermittent, Recurrent, Rule Out, Ruled Out, Resolved.	Optional
	<Problem>	Defines the <Problem>.	If only the <Problem> is known but not which <FamilyMember> or members have or have had that <Problem>, then only the <Problem> need be listed. If the affected <FamilyMember> is known, then <FamilyMember> must be listed and all problems must be constrained and listed discretely by Family Member.	See <Problem>, above.	Optional
	<FamilyMember>	Defines the <FamilyMember> to whom the <Problem> or in the exceptional case <Description> applies.	This is an <ActorRole> and comes from the <ActorRole> restricted values set. If the family member is listed under the <Actors> section, then this also includes a link to an <ActorID>.	See <ActorRole>.	Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <History> data..	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of *all* CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to a healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required if Family History Section/ Object is included
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	<History> to a specific <Problem>.	Optional
	<ReferenceID>	Used to link the <History> to a <Reference>.	This is a link to <Reference>. <Reference> under <History> *must* be a child of <Source>.	A <Reference> to a clinical note, discharge summary, personal health record, or other documents, system, or healthcare records that support the <History>.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <History>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under <Description>, <Type>, <Status>, <Problem>, <FamilyMember>, <Source>, or <ReferenceID>. This is a link to <Comment>.	See Comments.	Optional
Social History	<SocialHistoryElement>	This CCRDataObject is used to define the patient's occupational, personal (for example, lifestyle), social, and environmental history and health risk factors. Included are administrative data (ADT) such as marital status, ethnicity, nationality, and religious preference.	At a minimum, all pertinent social history and risk factors should be included, with respect to the high sensitivity and privacy concerns surrounding some of these data for patients.		Optional
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required if Social History Section/ Object is included
	<DateTime>	Used to define dates and times relevant to the patient's social <History>.	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Start Date, Stop Date, From Date A___To Date B____, Since Age___, Stop Age/Age of Last Use, Exposure, etc.	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Defines the social <History> <Type>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values. <Type> defines each discrete data object within <SocialHistory> and each time a new data object is generated a new instance of <RiskFactorHistory> must be initiated.	Marital Status, Religion, Ethnicity, Race, Language, Smoking, Exercise, Diet, Employment, Toxic Exposure, ETOH Use, Drug Use, Etc.	Optional
	<Description>	Defines the specific attributes of the Social History defined under <Type>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.		Optional
	<Status>	Defines the <Status> of the social <History>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Active, Prior History No Longer Active, Unknown	Optional
	<Episodes>	Used to define one more occurrences of a social history item.	Episodes should be listed for social history items that have an episodic component or character, such as changing Marital Status, Tobacco Use, ETOH Use, Employment, etc.		Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <History> data.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of *all* CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to a healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required if Social History Section/ Object is included
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	<History> to a specific <Problem>.	Optional
	<ReferenceID>	Used to link the <History> to a <Reference>.	This is a link to <Reference>. <Reference> under <History> *must* be a child of <Source>.	A <Reference> to a clinical note, discharge summary, personal health record, or other documents, system, or healthcare records that support the <History>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <History>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under <Description>, <Type>, <Status>, <Source>, or <ReferenceID>. This is a link to <Comment>.	See Comments.	Optional
Alerts	<Alert>	This CCRDataObject is used to list and describe any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history.	At a minimum, currently active and any relevant historical allergies, adverse reactions, and alerts should be listed.		Optional
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required if Alerts Section/Object is included
	<DateTime>	Used to define dates and times relevant to the patient's <Alert>.	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Start Date, Stop Date, From Date A___ To Date B____, Since Age___, Stop Age/Age of Occurrence, Exposure, etc.	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Defines the <Alert> <Type>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Allergy, Adverse Reaction, Alert	Optional
	<Description>	Defines the specific attributes of the Alert defined under <Type>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.		Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Status>	Defines the <Status> of the <Alert>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Active, Prior History No Longer Active	Optional
	<Agent>	Defines the <Agent> that is the cause of the allergy, adverse reaction, or alert.	Can be <EnvironmentalAgent>, <Product>, <Problem>, or <Procedure>. <EnvironmentAgent> is a CodedDescriptionType. <Product>, <Problem>, and <Procedure> follow the explicit rules defined for each of these data types in this spreadsheet.	Product (including medications and immunizations), environmental agent, Problem/Diagnosis (G6PD deficiency, for example), or Procedure (claustrophobia with MRI, for example).	Optional. <Unknown> is required content.
	<Reaction>	Describes the <Reaction> that the <Alert> addresses.	Contains <Description> and <Severity> as CodedDescriptionTypes, and <Intervention>, which can be used to define any <Intervention> that has been successful in treating the <Reaction>. For multiple reactions <ReactionSequencePosition> and <MultiplereactionModifier> are used and <Status> is used to define pertinent positive or pertinent negative reactions.	Pertinent Positive: <Description><Text>Anaphylaxis<Severity>Life Threatening<Intervention>Intubation; Pertinent Negative: <Description> <Text>Anaphylaxis<Status>Not Present	Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <Alert> data.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of all CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to a healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required if Alerts Section/Object is included
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	<Alert> to a specific <Product>, <Problem>, or <Procedure>.	Optional
	<ReferenceID>	Used to link the <Alert> to a <Reference>.	This is a link to <Reference>. <Reference> under <Alert> must be a child of <Source>.	A <Reference> to a clinical note, discharge summary, personal health record, or other documents, system, or healthcare records that support the <Alert>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <Alert>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under <Description>, <Type>, <Status>, <Agent>, <Reaction>, <Source>, or <ReferenceID>. This is a link to <Comment>.	See Comments.	Optional
Medications	<Medication>	This CCRDataObject is used to list and describe the patient's current medications and pertinent medication history.	At a minimum, the currently active medications should be listed, with an entire Medication History as an option, particularly when the CCR is used for comprehensive data export.		Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required if Medications Section/Object is included
	<DateTime>	Used to define dates and times relevant to the patient and the <Product>.	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Start Date, Stop Date, From Date A___ To Date B____, Since Age___, Stop Age, Etc.	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Defines the <Product> <Type>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Medication, IV Fluid, Parental Nutrition, Supplemental Nutrition, Immunization, Disposable, Supplies, Device, Implantable Device, Durable Medical Equipment	Optional
	<Description>	An instance of a CodedDescriptionType. <Text> under <Description> is used as a text string container for those systems that cannot generate a structured description of a product. The structured and coded portions of <Description> are used to define the name and overall characteristics of any complex product made up of one or more structured products as defined below.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Amoxicillin	Optional
	<Status>	Defines the <Status> of the <Product>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Active, On Hold, Prior History No Longer Active	Optional
	<Product>	Used as a container for the core descriptive attributes of a <Product>.	<Product> is used within the CCR for <Medication>, <Immunization> and for medical devices and durable medical equipment (DME). A product can be a simple <Product> or can repeat to define a combination product made up of two or more individual products.		Required if Medications Section/Object is included
	<ProductName>	Defines the generic name for prescriptions and over-the-counter medications and nonproprietary name for non-medication products.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. An NCD Code or RxNorm Code (preferred) should be used when <Product> is used to describe a medication.	Amoxicillin	Required if <Product> is used
	<BrandName>	Defines the <BrandName> of the <Product>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Amoxil	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Manufacturer>	Defines the <Manufacturer> of the <Product>.	This is a link to <Actor>.	Eli Lilly, Pfizer, etc.	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Strength>	Defines the predefined strength of the <Product>.	MeasureType with <Value>, <Units>, and <Code>. <Units> has children <Unit> and <Code>.	250mg	Optional
	<Form>	Defines the <Form> of the <Product>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Capsule, tablet, etc.	Optional
	<Concentration>	Defines the <Concentration> of the <Product>.	MeasureType with <Value>, <Units>, and <Code>. <Units> has children <Unit> and <Code>.	250mg/5mL	Optional
	<Size>	Defines the <Size> of the <Product>.	Can be a text string, structured text, or defined by <Dimensions>.	Small, Medium, Large, 6, 6.5, 7, 7.5, 2 cm by 15 cm, 24 mm diameter.	Optional
	<Quantity>	Defines the <Quantity> of the <Product>.	MeasureType with <Value>, <Units>, and <Code>. <Units> has children <Unit> and <Code>.	30	Optional
	<Directions>	<Directions> is the instructions (SIG) component describing the intended patient use of the <Product>. <Directions> contains an XML string defined as follows below:	Can be used to map a single SIG or a complex recurring SIG like a tapered dose or sliding scale. Recurring SIG segments are represented by repeating the <Directions> tag and its children.	1 po tid x 10 days, Prednisone taper, Insulin sliding scale	Optional
	<DoseIndicator>	Indicates the action to be taken on the <Description>/SIG. This is a direct map to the NCPDP Script SIG standard.	CodedDescriptionType - codes and content to follow NCPCP Script SIG standard.	1 = Specified - remaining fields populated. 2 = As needed - skip rest of Dose Segment. 3 = As directed - skip rest of Dose Segment. 4 = Unspecified - see free text <Description>.	Optional
	<DeliveryMethod>	The textual representation of the Dose Delivery Method. This is the method in which the dose is delivered (describes how the dose is administered/consumed).	CodedDescriptionType - codes and content to follow NCPCP Script SIG standard.	Defines the method: take, apply, swish, swallow, inject, insert, chew, use, give, sprinkle, mix, dissolve…	Optional
	<Dose>	This is the dose portion of the SIG which can define a fixed dose or can repeat to define a variable dose, dose range, or dose options. This is the dose to be administered, not the dispensed dose. Dispensed dose is found under <Strength>, above.	MeasureType with <Value>, <Units>, and <Code>. <Units> has children <Unit> and <Code>. Also contains <Rate> and for multiple or variable doses <DoseSequencePosition> and <MultipleDoseModifier>.	This is the numeric or text expression of the dose. A simple does example would be '250mg' where the value in this field would be '250'.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<DoseCalculation>	This segment is used to express a dose as a calculation, such as '40mg/kg/day divided into 3 doses'. This segment is used in conjunction with <Dose> to allow the expression of a dose as a calculation. Also used to express doses to be calculated by nurses based on physiological parameters, such as Dopamine, Nipride, etc.	Includes <Dose><Value> and <Units> as well as a <Variable> and a <DoseCalculation>. Also contains <Rate> and for multiple calculations <CalculationSequencePosition> and <MultipleCalculationModifier>.	Amoxicillin for a child is dosed at approximately 40mg/kg/day/2 to 3 doses. For a 9kg child, an appropriate dose would be 125mg tid. To express this, the prescribing physician would put '125mg' in the <Dose> (and 'tid' in <Frequency>) and '40mg/kg/day/3 doses' in <DoseCalculation>. This allows the pharmacist to look at the dose (125mg tid) and do a secondary patient safety check against the desired dosing of '40mg/kg/day/3 doses'.	Optional
	<Vehicle>	Used to define a <Vehicle> used to deliver the <Product> such as an IV solution.	Vehicle can be expressed as a CodedDescriptionType (<Description>) or as an <InternalCCRLink> to another <Product>. For mulitple vehicles, includes <VehicleSequencePosition> and <MultipleVehicleModifier>.	D5W, normal saline, etc.	Optional
	<Route>	Used to define the <Route> of administration.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. For multiple routes it contains <RouteSequencePosition> and <MultipleRouteModifier>.	po, pr, sl, etc.	Optional
	<Site>	Used to define the physical location on the patient for use, implantation, or administration, where specified.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. For multiple sites it contains <SiteSequencePosition> and <MultipleSiteModifier>.	Right gluteus, left deltoid, Hickman catheter, etc.	Optional
	<AdministrationTiming>	This is used to define a specific administration or use time. Can repeat for more than one administration time.	An instance of DateTimeType. For multiple or variable timings it includes <TimingSequencePosition> and <MultipleTimingModifier>.	Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.	Optional
	<Frequency>	Used to define a <Product> frequency of use/ administration.	This can be expressed as a <Description> (CodedDescriptionType) or a <Value> and <Units>. For multiple or variable frequencies it includes <FrequencySequencePosition> and <MultipleFrequencyModifier>.	qd, bid, tid, qid, qod, etc.	Optional
	<Interval>	Used to define a <Product> interval of use/ administration.	This can be expressed as a <Description> (CodedDescriptionType) or a <Value> and <Units>. For multiple or intervals timings it includes <IntervalSequencePosition> and <MultipleintervalModifier>.	q15m, q2h, q4h, q12h	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Duration>	Used to define the <Duration> of use or administration of a product.	This can be expressed as a <Description> (CodedDescriptionType) or a <FixedDuration> or a <DurationRange>. For multiple or variable durations it includes <Duration SequencePosition> and <MultipleTimingModifier>.	x 10 days	Optional
	<DoseRestriction>	This is the dose restriction segment of the SIG which defines a maximum or dose limit. This segment can repeat for more than one dose restriction.	An instance of DoseCalculationType - identical to <DoseCalculation> above.	'Not to exceed 10 Tablets in 24 Hours' or '1000 mg/kg/hr'.	Optional
	<Indication>	Defines the <Indications> for the use of the <Product>.	This can be a <Description> or a <Problem> or a link to a <Problem> within the CCR, or one or more <PhysiologicalParameter>. It also includes a PRN designator.	Strep pharyngitis	Optional
	<StopIndicator>	Used to express a hard stop, such as the last SIG sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.	An instance of CodedDescriptionType. Can have the value Yes or the tags will not exist and there will be no content (the null instance of a <StopIndicator>).		Optional
	<DirectionSequencePosition>	Used when the <Direction> repeats (multiple SIGs) such as with an insulin sliding scale or tapering dose, etc.	Expressed as an Integer from 1-n. Signifies the order of the directions. Tag is not used if there is no repeat.	1, 2, 3,…	Optional
	<MultipleDirectionModifier>	Defines the relationship between multiple directions (SIGs).	Used with the values AND, OR, or THEN to express when there is more than one SIG as to whether all the SIGs must apply (AND) or if any of the SIGs can apply (OR) or if the SIGs are sequential (THEN), in the sequence defined by <DirectionSequencePosition>.	AND, OR, THEN	Optional
	<PatientInstructions>	Defines the <PatientInstructions> for the <Product> that are not covered under <Directions> - in other words <PatientInstructions> that are not traditionally part of the SIG.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Take with water.	Optional
	<FulfillmentInstructions>	Defines the <FulfillmentInstructions> for the <Product>, which in the case of medications are the instructions to the dispensing pharmacist or nurse.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Label In Spanish, Dispense As Written	Optional
	<Refill>	Defines the number of <Refills> and any constraints on <Refills>.	Includes <Number>, <Quantity>, <DateTime>, to define 'Last Refill", for example, and <Comment> for any specific <Refill> alerts or comments.	None, 2 refills of 25 capsules, etc.	Optional
	<SeriesNumber>	Defines the <SeriesNumber> of the <Product>, for use when there is a series of medication administrations.	This is a simple integer 1-x.	Enoxaparin, chemotherapy, etc.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Consent>	Used to catalog any <Consents> obtained relative to the administration of this <Product>. Also used to catalog patient, family, guardian, or other mechanism of refusal.	Must contain a <DateTime>, a <Description>, and <Source>. <ReferenceID> and <CommentID> are optional. May link to <Actor> or <Reference>.	<Description><Text>Consent Obtained ,Source>Mother	Optional
	<Reaction>	Defines any follow-up <Reaction> to the <Product>.	This is used only to track routine follow-up reactions to the administration of a medication, but is not to be used for allergic or adverse reactions, which belong under <Alerts> in the CCR.	No adverse reaction 30 minutes post administration	Optional
	<FulfillmentHistory>	Defines the fulfillment history of the <Product>.	Under <Fulfillment> contains <DateTime>, <Description>, <Provider>, <Location>,and <FulfillmentMethod>.	DateTime, Provider, Location and Method as to how and where dispensed/fulfilled.	Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <Product> order or prescription or administration or fulfillment.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of all CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to a healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required if Medications, Medical Equipment, or Immunization Section/Object is included
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	<Product> to a specific <Encounter>, and/or as a link under <Indication> to a specific <Problem>.	Optional
	<ReferenceID>	Used to link the <Product> to a <Reference>.	This is a link to <Reference>.	A <Reference> to a prescription, order, clinical note, discharge summary, personal health record, or other documents, system, or healthcare records that support the <Alert>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <Product>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under the appropriate explicit tags.	See Comments.	Optional
Medical Equipment	<Equipment>	This CCRDataObject is used to define the patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history. It also itemizes any pertinent current or historical Durable Medical Equipment (DME) used to help maintain the patient's health status.	This is a specific use for <Product> and uses the same tagging as defined under <Medication>, above, with the tag content to be specific for implanted or external medical devices or durable medical equipment (DME). All pertinent equipment relevant to the diagnosis, care, and treatment of a patient should be included.	Pacemaker/defibrillator, artificial joint, implanted or external prosthetic, home nebulizer, ventilator, hospital bed, oxygen, wheelchair, walker, etc.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
Immunizations	<Immunization>	This CCRDataObject is used to define the patient's current immunization status and pertinent immunization history.	This is a specific use for <Product> and uses the same tagging as defined under <Medication>, above, with the tag content to be specific for immunizations. At a minimum, the latest immunization in an immunization series should be listed, with an entire Immunization History as an option, particularly when the CCR is used for comprehensive data export.	Hepatitis A, B, MMR, DPT, etc.	Optional
Vital Signs	<Result>	This CCRDataObject is used to list pertinent vital signs.	This is a specific use for <Result> as defined below (Results). Vital Signs is defined within the CCR as a Section in order to follow clinical convention, even though Vital Signs are technically Results (″Observations″). At a minimum, pertinent vital signs, such as the most recent, maximum and/or minimum, baseline, or relevant trends should be listed.	Blood pressure (systolic/diastolic, mean), pulse, respiratory rate, height, weight, body mass index (BMI), head circumference, crown-to-rump length, pulse oximetry. pulmonary function tests, etc.	Optional
Results	<Result>	This CCRDataObject is used to provide detailed laboratory, diagnostic, and therapeutic results data.	Pertinent results, such as the most recent, maximum, average, mean, and/or minimum, baseline, or relevant trends should be listed at a minimum. Due to the importance of establishing normal or stable trends as well as abnormal, comprehensive results should be considered, particularly when the CCR is used for comprehensive data export.	Hematology, chemistry, serology, virology, microbiology, imaging - X-ray, ultrasound, CT, MRI, angio, nuclear medicine, pathology, etc.	Optional
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required If Vital Signs or Results Section/Object is included
	<DateTime>	Used to define dates and times relevant to the patient and the <VitalSign> or <Result>.	For a <Result> this should be restricted to an exact DateTime, or a DateTime range if a collection was done over a specific time period. At a minimum, the DateTime of collection or physiological measurement should be included. Additional times such as when the <Result> was run, sent, or recorded can be included if and when pertinent.	Collection date time, collection start date, collection stop date, measurement time, measurement start date, measurement stop date	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Used to define the <VitalSign> or <Result> <Type>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Hematology, Chemistry, Serology, Virology, Toxicology, Microbiology, Imaging - X-ray, Ultrasound, CT, MRI, Angiography, Cardiac Echo, Nuclear Medicine, Pathology, Procedure.	Required If Vital Signs or Results Section/Object is included

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Description>	Used to describe a <VitalSign> or <Result> set when there are more than one <Test> in a <VitalSign> or <Result>, such as a panel or battery.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. <Description> should be coded with CPT and LOINC codes, when applicable.	CBC, Lytes, Hepatitis Panel, Thyroid Panel, Diabetes Panel, Etc.	Optional
	<Procedure>	Used to define the procedure used to obtain the <Result>.	This is a specific use of <Procedure> as defined, below (Procedures). The use of <Procedure> under <Result> should be reserved for instances where listing the <Procedure> has direct clinical relevance to the <Result> or when the <Procedure> used to obtain the <Result> is not obvious or is atypical or specialized. When the <Procedure> is listed in the <Procedures> section of the CCR, <Procedure> under <Result> should be an <InternalCCRLink>.	Punch Biopsy Left Shoulder Skin Lesion, Cath Urinalysis	Optional
	<Substance>	Used to define the substance that the <Result> is obtained from.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Arterial blood, venous blood, urine, spinal fluid, joint fluid, aspirate, etc.	Optional
	<Test>	<Test> contains the actual result data XML string defined as follows below:	Each <Test> is a potential CCRDataObject in its own right, if a specific test result will be referred to as an InternalCCRLink.		Optional
	<DateTime>	Used to define dates and times relevant to the patient and the <Test>.			Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes “external” IDs such as a driver’s license number, Social Security number, product ID number, serial number, or “internal” IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Defines the <Test> <Type> as an Observation or a Result.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Observation, Result.	Required
	<Description>	The actual name of the <Test>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. <Description> should be coded with CPT and LOINC codes, when applicable.	Hematocrit, hemoglobin, cell count, specific gravity, micro or path description, etc.	Optional
	<Status>	Defines the <Status> of the <Test>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Pending, In Process Preliminary Results, Final Results, Corrected Results	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Method>	Used when a <Description> modifier is needed.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Manual Differential, Buffy Coat, KOH, etc.	Optional
	<Agent>	Used to define a specific agent in relation to a <Test>, such as a drug name for microbiology/culture sensitivities.	An instance of Complex Data Type AgentType. Has children <Products>, <EnvironmentalAgents>, <Problems>, <Procedures>, <Results>.	Ciprofloxacin, Penicillin, etc.	Optional
	<TestResult>	The actual <TestResult>, recorded at the individual, discrete <Test> level.	<TestResult> can be a <Value>, <Value> and <Units>, and/or a <Description>, which is a CodedDescriptionType supporting a free text string, a structured text string or strings, or a structured and coded text string or strings.	HCT as a value with the units %, Urine culture as a text string with coded organisms and detailed susceptibilities, etc.	Required if Results Section/ Object is included
	<NormalResult>	The benchmark <NormalResult> or range for the <TestResult>.	This is not to be used to express a normal <TestResult>, rather it is to be used to express the benchmark 'normal'. <NormalResult> can be expressed as a <Description> (CodedDescriptionType), or as a <Value> or <Value><Units> pair. Ranges are expressed within <Value> with a "-" (dash) as a separator. This also applies to <Units> as ranges. <Units> as concentrations are expressed with a "/" (backslash) as a separator.	Any normal test result value.	Optional
	<Flag>	Used to express a warning or "flagged" <TestResult>. There can be zero-to-many flags per <TestResult>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Abnormal Value, Critical Value, Hemolyzed Sample, Mis-Labeled Sample, Etc.	Optional
	<ConfidenceValue>	Used to express a <TestResult> <ConfidenceValue>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Varies by lab/test result.	Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <Result> data.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of all CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to a laboratory, healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required if Results Section/ Object is included
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	<Result> or <TestResult> to a specific <Problem> or <Encounter>.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<ReferenceID>	Used to link the <Result> to a <Reference>.	This is a link to <Reference>.	A <Reference> to a prescription, order, clinical note, discharge summary, personal health record, or other documents, system, or healthcare records that support the <Result>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <Result>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under the appropriate explicit tags, such as <Flag>. This is critical to avoid clinical errors when data are not in their assigned and explicitly allocated positions in the CCR. <Flag> not <Comment> is specifically used in <Result> to point out warnings.	See Comments.	Optional
Procedures	<Procedure>	This CCRDataObject is used to define all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient's health status at the time the CCR is generated.	At a minimum, any recent or historically relevant <Procedure> should be listed. The intent is to list major diagnostic and/or therapeutic procedures that have a current or historical impact on the patient's current or future health. The preferred controlled vocabulary is SNOMED CT, as well as the current CPT Codeset for the <Procedure> and LOINC for any <Result>.		Optional
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required if Procedures Section/Object is included
	<DateTime>	Used to define dates and times relevant to the patient and the <Procedure>	For a <Procedure>, <DateTime> should express the <DateTime> the <Procedure> occurred, as accurately as possible, but due to the fact that historical <Procedure> data may be collected retrospectively, exact DateTime, an age, an approximate DateTime, or a DateTime range are all valid.	Procedure DateTime	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Defines the <Procedure> <Type>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Cardiac, Surgical, Imaging, etc.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Description>	Used to describe the actual <Procedure>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. <Procedure> should be coded with SNOMED, CPT, and LOINC codes, when applicable.	Cardiac catheterization, transfusion, echocardiogram, exercise stress test, appendectomy, cholecystectomy, endoscopy, etc.	Optional
	<Status>	Defines the <Status> of the <Procedure>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Cancelled, On Hold, In Progress, Not Completed, Completed	Optional
	<Location>	Defines the geographic location where the procedure was done. Physical location on the patient is defined as <Site>.	This can be expressed as a <Description> (CodedDescriptionType) or as a link to an <Actor>.	Charity Hospital	Optional
	<Practitioner>	Used to describe the <Practitioner>(s) who did the <Procedure>.	This is a link to <Actor> and includes an <ActorRole>.	John Q. Doe, MD, Consulting Cardiologist	Optional
	<Frequency>	Used when more than one occurrence of the same <Procedure> are related (a series of treatments, for example).	This can be expressed as a <Description> (CodedDescriptionType) or as a <FixedFrequency> or a <FrequencyRange>.	Chemotherapy or radiation treatments, physical therapy	Optional
	<Duration>	Used when a <Procedure> involves a <Duration>.	This can be expressed as a <Description> (CodedDescriptionType) or as a <FixedDuration> or a <DurationRange>.	Chemotherapy or radiation treatments, physical therapy, bariatric chamber times, etc.	Optional
	<Indication>	Used to describe the <Indication>(s) for the <Procedure>.	This can be a <Description> or a <Problem> or a link to a <Problem> within the CCR.	Chest pain, myocardial infarction, malignant melanoma, etc.	Optional
	<Product>	Used to describe any <Product>(s) associated with the <Procedure>.	This is a specific use of <Product>, described above. It can either list the <Product> or link to a <Product> in the CCR through an <InternalCCRLink>.	Pacemaker/defibrillator, artificial joint, implanted prosthetic, etc.	Optional
	<Substance>	Used to describe any <Substance>(s) associated with the <Procedure>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Packed red blood cells (PRBC), fresh frozen plasma (FFP), etc.	Optional
	<Method>	Used to describe a specific procedural technique.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Anterior approach, punch biopsy, etc.	Optional
	<Position>	Used to describe a specific anatomical position relative to the <Procedure>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Supine, left lateral decubitus, etc.	Optional
	<Site>	Used to describe a specific anatomical location relative to the <Procedure>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Left shoulder, anterior chest, etc.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <Procedure> history.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of all CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to a healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required if Procedure Section/Object is included
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	<Procedure> to a specific <Problem>.	Optional
	<ReferenceID>	Used to link the <Procedure> to a <Reference>.	This is a link to <Reference>.	A <Reference> to a prescription, order, clinical note, discharge summary, personal health record, or other documents, system, or healthcare records that support the <Alert>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <Procedure>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under the appropriate explicit tags.	See Comments.	Optional
Encounters	<Encounter>	This CCRDataObject is used to list and describe any healthcare encounters pertinent to the patient's current health status or historical health history. An Encounter is an interaction, regardless of the setting, between a patient and a practitioner who is vested with primary responsibility for diagnosing, evaluating, or treating the patient's condition. It may include visits, appointments, as well as non face-to-face interactions. It is also a contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment.	At a minimum, the most recent and all pertinent recent and historical healthcare encounters should be included, particularly any that apply to Problems and significant clinical events.	An <Encounter> can be a hospitalization (acute, rehab, nursing facility, or longterm care), office or clinic visit, emergency room visit, home health visit, or any treatment or therapy (physical, occupational, respiratory, or other), or any interaction, even non face-to-face, between the patient and the healthcare system or a healthcare provider.	Optional
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required if Encounters Section/Object is included
	<DateTime>	Used to define dates and times relevant to the patient and the <Procedure>	For a <Encounter>, <DateTime> should express the <DateTime> the <Encounter> occurred as accurately as possible, but due to the fact that historical <Encounter> data may be collected retrospectively, exact DateTime, an age, an approximate DateTime, or a DateTime range are all valid.	Encounter DateTime	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Defines the <Encounter> <Type>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Inpatient Hospitalization, Emergency Room Visit, Physician Office Visit, Rehabilitation, Nursing Facility Stay, Long Term Care Facility, Physical Therapy, etc.	Optional
	<Description>	Used to describe the actual <Encounter>, if <Encounter> cannot be more appropriately expressed with <Location> and <Practitioner>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.		Required
	<Location>	Used to describe the <Location>(s) of the <Encounter>.	This can be expressed as a <Description> (CodedDescriptionType) or as a link to an <Actor>.	Charity Hospital	Optional
	<Practitioner>	Used to describe the <Practitioner>(s) with whom the patient had the <Encounter>.	This is a link to <Actor> and includes an <ActorRole>.	Jane Q. Doe, MD, Admitting Physician	Optional
	<Frequency>	Used when more than one occurrence of the same <Encounter> are related (a series of visits/admissions, for example).	This can be expressed as a <Description> (CodedDescriptionType) or as a <FixedFrequency> or a <FrequencyRange>.	Chemotherapy or radiation treatments, physical therapy	Optional
	<Duration>	Used when a <Encounter> involves a <Duration>.	This can be expressed as a <Description> (CodedDescriptionType) or as a <FixedDuration> or a <DurationRange>.	Chemotherapy or radiation treatments, physical therapy	Optional
	<Indication>	Used to describe the <Indication>(s) for the <Encounter>.	This can be a <Description> or a <Problem> or a link to a <Problem> within the CCR.	Chest pain, myocardial infarction, malignant melanoma, etc.	Optional
	<Instructions>	Used to define <Instructions> for a <Encounter>. Used primarily when a <Encounter> is an <OrderRequest>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	NPO after midnight, Hold Beta Blockers for one week prior to procedure, No Aspirin or Non-Steroidal Anti-Inflamatory agents 7 days prior to procedure.	
	<Consent>	This is used to document that consent was obtained and documented for the encounter or procedure.			Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <Encounter> history.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of all CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to a healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required if Encounters Section/Object is included

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	Link of an <Encounter> to a specific <Problem>.	Optional
	<ReferenceID>	Used to link the <Encounter> to a <Reference>.	This is a link to <Reference>.	A <Reference> to a prescription, order, clinical note, discharge summary, personal health record, or other documents, system, or healthcare records that support the <Alert>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <Encounter>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under the appropriate explicit tags.	See Comments.	Optional
Plan of Care	<Plan>	This CCRDataObject is used to list and describe any prospective, that is, active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient. Plan of care does not include past orders, appointments, etc.	All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient should be listed, unless constrained due to issues of privacy. Clinical reminders should also be placed here for purposes of providing prompts that may be used for disease prevention, disease management, patient safety and healthcare quality improvement. This allows any receiving, consulting, admitting provider, system, or healthcare institution to understand the current and pending clinical care for this patient to avoid conflict, assure patient safety, to optimize care and convenience for the patient and their family, and to allow any changes to be communicated appropriately and in a timely manner to all affected providers and organizations.		Optional
	<CCRDataObjectID>	Defined above.	Required of all CCRDataObjects.		Required if Plan of Care Section/ Object is included
	<DateTime>	Used to define dates and times relevant to the patient and the <Plan>.	A <Plan> <DateTime> should be expressed as an <ExactDateTime> or a <DateTimeRange>.	Plan Start DateTime, Plan Completion DateTime	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes “external” IDs such as a driver’s license number, Social Security number, product ID number, serial number, or “internal” IDs such as EHR or system-specific IDs for discrete data objects.		Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Type>	Used to define what <Type> the <Plan> item is.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Reminder, Order, Prescription, Request For Authorization, Authorization, Referral, Request For Consultation, Treatment Recommendation	
	<Description>	Used to describe a <Plan> set when there are more than one <OrderRequest>s in a <Plan> such as a detailed Care <Plan> or pre-procedure <Plan>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Postoperative rehabilitation, stroke rehabilitation, pre-procedure work-up and evaluation, etc.	Optional
	<Status>	Used to define the <Plan> <Status>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Pending, In Process, On Hold, Cancelled	Optional
	<OrderRequest>	<OrderRequest> contains the actual <OrderRequest> data XML string defined as follows below:	Each <Test> is a potential CCRDataObject in its own right, if a specific test result will be referred to as an InternalCCRLink.		Optional
	<DateTime>	Used to define dates and times relevant to the patient and each specific <OrderRequest>.	An <OrderRequest> <DateTime> should be expressed as an <ExactDateTime>.	Procedure DateTime, Encounter DateTime, Appointment DateTime, etc.	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Type>	Defines the <OrderRequest> <Type>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Order, Encounter, Procedure, Service, Product, Immunization, Medication, Authorization, Referral, Consultation.	Optional
	<Description>	Used to describe an <OrderRequest> that is not a <Procedure>, <Product>, <Medication>, <Immunization>, <Service>, <Encounter>, or <Authorization> request.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.		Optional
	<Status>	Defines the <OrderRequest> <Status>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Ordered, Requested, Pending, On Hold, Repeat, No Show, Cancelled	Optional
	<Procedure>	Used to describe a specific <Procedure> <OrderRequest>.	This is a specific use of <Procedure> as defined, above. The tag <Instructions> can be used to contain specific patient instructions.	CT scan, ultrasound, CBC, biopsy, cholecystectomy, ECG, pulmonary function tests, stress echocardiogram, etc.	Optional
	<Product>	Used to describe a specific <Product> <OrderRequest>.	This is a specific use of <Product> as defined, above.	Wheelchair, home nebulizer, prosthesis, etc.	Optional
	<Medication>	Used to describe a specific <Medication> <OrderRequest>.	This is a specific use of <Product> (Medication) as defined, above.	Enoxaparin, chemotherapy, etc.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Immunization>	Used to describe a specific <Immunization> <OrderRequest>.	This is a specific use of <Product> (Immunization) as defined, above.	Hepatitis A, B, MMR, DPT, etc.	Optional
	<Service>	Used to describe a specific <Service> <OrderRequest>.	<Service> is a special use case of EncounterType. The tag <Instructions> can be used to contain specific patient instructions.	Physical therapy, occupational therapy, home health evaluation, social service evaluation, family counseling, financial counseling, etc.	Optional
	<Encounter>	Used to describe a specific <Encounter> <OrderRequest>.	This is a specific use of <Encounter> as defined, above. The tag <Instructions> can be used to contain specific patient instructions.	Appointment, Admission	Optional
	<Authorization>	Used to describe a specific <Authorization> <OrderRequest>.	This is a specific use of <Authorization> as defined, above. It is to be used only for pending authorization requests. Authorizations that have already been approved should be contained under <Insurance>.	Authorization for treatment, procedure, immunization, brand name medication, etc.	Optional
	<Goals>	Use to describe a specific <Goal>(s) for the patient.	<Goal> can be discretely tagged or defined as a CodedDescriptionType under <Description>.	Ambulation without assistance, ability to care for self, custodial care training, etc.	Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <Plan> or <OrderRequest> data.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of all CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to a healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required if Plan of Care Section/ Object is included
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	<OrderRequest> to a specific <Problem> or <Encounter>.	Optional
	<ReferenceID>	Used to link the <Plan> or <OrderRequest> to a <Reference>.	This is a link to <Reference>.	A <Reference> to a prescription, order, clinical note, discharge summary, personal health record, or other documents, system, or healthcare records that support the <Alert>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <Plan> or <OrderRequest>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under the appropriate explicit tags.	See Comments.	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
Healthcare Providers	<Providers>	Used to define all healthcare providers involved in the current or pertinent historical care of the patient.	This is a link to an <Actor> with an <ActorRole>. This data object is not used for listing a patient's non-healthcare <Support> providers. <Support> providers are listed under the <Support> section of the CCR. At a minimum, the patient's key healthcare providers should be listed, particularly their primary physician and any active consulting physicians, therapists, and counselors.	Physicians, PAs, NPs, nurses, therapists, counselors, etc.	Optional
CCR FOOTER					
Actors	<Actor>	This CCRDataObject is used as a container to define all of the individuals, organizations, locations, and systems associated with the data in the CCR.	<ActorID> in the CCR Header and Body link to the details in this CCR Footer Section. Note that the details of the <Patient>, <From>, and <To> are all contained in this CCR Footer Section as are all <Actors>.		Required
	<ActorObjectID>	This is the CCR Object ID for the <Actor>.	This is the ID that each <ActorID> will link to and is expressed as xs:ID. The <ActorObjectID> must be made up of characters in the set A-Z, a-z, 0-9, dash(-), underscore (_) and period (.). The first character must be from the set A-Z, a-z, 0-9. It can be of any character length.		Required
	<Person>	Defines the details about a <Person> as an <Actor>.			Optional
	<Name>	A container for patient name(s) as follows below:			Optional
	<BirthName>	The name the patient was legally given at birth.	Consists of <Given>, <Middle>, <Family>, <Suffix>, <Title>, <NickName>.	<Given>John <Middle>Quincy <Family>Doe <Suffix>III <Title>MD <Title>PhD <NickName> Jack	Optional
	<AdditionalName>	Any prior legal or assumed name set.	Consists of <Given>, <Middle>, <Family>, <Suffix>, <Title>, <NickName>.	See example above.	Optional
	<CurrentName>	The patient's current legal name or assumed name set.	Consists of <Given>, <Middle>, <Family>, <Suffix>, <Title>, <NickName>.	See example above.	Optional
	<DisplayName>	A text string that represents the <Actor> name as it should be displayed as a simple, untagged, and unparsed string.	A display string for full name representation.	John Q. Doe, III, MD, PhD	Optional
	<DateOfBirth>	Defines <DateOfBirth>.	<DateOfBirth> should be as accurate as possible and should use <ExactDateTime>.		Optional
	<Gender>	Defines <Gender>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Male, Female, Other, Unknown	Optional
	<Organization>	Defines the details about an <Organization> as an <Actor>.	Expressed by a text string under <Name>.	Southfork Community Clinic	Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<InformationSystem>	Defines the details about an <InformationSystem> as an <Actor>.	Expressed by a text string under <Name> with optional <Type> and <Version>.	Acme EHR Version 2.3	Optional
	<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.		Optional
	<Relation>	Defines the <Relation> of the <Actor> to the <Patient>, when applicable.	This primarily applies to family members. This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Parent, child, husband, wife, significant other, etc.	Optional
	<Specialty>	Defines the medical or healthcare <Specialty> of the <Actor> when applicable.	This primarily applies to healthcare providers. This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. Ideally, this should be matched to the AMA list of medical and surgical specialties.	Cardiology, primary care, general surgery, etc.	Optional
	<Address>	Used to express the <Address> of the <Actor>. Can specify a type (home, office) or priority (primary, preferred), and a status (active, temporary).	<Address> contains <Type>, <Line1>, <Line2>, <City>, <County>, <StateProvince>, <Country>, <PostalCode>, <Priority>, and <Status>.	1234 Smith Road, Suite 22, San Diego, San Diego County, California, United States, 92013	Optional
	<Telephone>	Used to express the <Telephone> of the <Actor>.	<Telephone> contains <Value>, <Type>, <Priority>, and <Status>.	555-555-5555 x555	Optional
	<Email>	Used to express the <EMail> of the <Actor>.	<EMail> contains <Value>, <Type>, <Priority>, and <Status>.	jdoe@xxx.com	Optional
	<URL>	Used to express the <URL> of the <Actor>.	<URL> contains <Value>, <Type>, <Priority>, and <Status>.	www.xxx.com	Optional
	<Status>	Used to express the <Status> of the <Actor> relative to the <Patient>.	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values.	Active, Prior History No Longer Active, Unknown	Optional
	<Source>	Used to define the person, system, or institution that is the <Source> of the <Actor> data.	Source can be a link to an <Actor> with an <ActorRole> or a <Reference>. <Source> also has children <DateTime> and <Comment>. <Source> is required of all CCRDataObjects. This is so that any data within the CCR can be validated as to its origin/source.	Link to a healthcare provider, the patient, their parent, child, relative, guardian, durable power, a healthcare record, etc.	Required

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<InternalCCRLink>	Used to link one CCRDataObject to another CCRDataObject.	This defines internal CCR links and uses a <LinkID> to refer/link to a CCRDataObjectID, which is of type xs:string. <LinkRelationship> defines the relationship to the CCRDataObjectID.	Links <Actor> to a specific <Problem> or <Encounter>.	Optional
	<ReferenceID>	Used to link the <Actor> to a <Reference>.	This is a link to <Reference>.	A <Reference> to more detailed information about the <Actor>.	Optional
	<CommentID>	Used to link to and support a free text or structured <Comment> for the <Actor>.	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under the appropriate explicit tags.	See Comments.	Optional
References	<Reference>	This CCRDataObject is used as a container to list the details concerning all references within the CCR to external data sources.	All <ReferenceID>s from the CCR Header, Body, and Footer are pointers to a <Reference>, the details of which are defined in this CCR Footer.	Articles, clinical documents, paper or EPR, document images, etc.	Optional
	<ReferenceObjectID>	This is the CCR Object ID for the <Reference>.	This is the ID that each <ReferenceID> will link to and is expressed as xs:ID. The <ReferenceObjectID> must be made up of characters in the set A-Z, a-z, 0-9, dash(-), underscore (_) and period (.). The first character must be from the set A-Z, a-z, 0-9. It can be of any character length.		Required if References Section/Object is included
	<DateTime>	This is the <Reference> <DateTime>.	<Reference><DateTime> should be as accurate as possible and should refer to the date of origin of the <Reference>. It should be expressed as an <ExactDateTime>.	Reference DateTime	Optional
	<Description>	This is a <Description> of the <Reference>.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Admission H&P	Optional
	<Source>	This is the <Source> of the <Reference>.	This is an <Actor> reference with <ActorID> and <ActorRole>.		Optional
	<Locations>	This is a pointer to one or more <Locations>(s) where the <Reference> can be accessed or where it is stored.	This can be expressed as a <Description> (CodedDescriptionType) or as a link to an <Actor>.		Optional
Comments	<Comment>	This CCRDataObject contains all text <Comments> associated with any data within the CCR. <Comments> are free text or structured comments that are intended to provide a 'comment' to a CCR data object but are not intended to contain core relevant clinical or administration data that are more appropriately contained within the CCR data object itself.	All <CommentID>s from the CCR Header, Body, and Footer are pointers to a <Comment>, the details of which are defined in this CCR Footer Section.		Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<CommentObjectID>	This is the CCR Object ID for the <Comment>.	This is the ID that each <CommentID> will link to and is expressed as xs:ID. The <CommentObjectID> must be made up of characters in the set A-Z, a-z, 0-9, dash(-), underscore (_) and period (.). The first character must be from the set A-Z, a-z, 0-9. It can be of any character length.		Required if Comments Section/Object is included
	<DateTime>	This is the <Comment> <DateTime>.	<Comment><DateTime> should be as accurate as possible and should refer to the data of origin of the <Comment>. It should be expressed as an <ExactDateTime>.	Comment DateTime	Optional
	<Description>	<Description> contains the actual Comment.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. Most <Comments> will be simple text strings that would be placed under <Description><Text>.	Patient's father is an unreliable historian.	Required
	<Source>	This is the <Source> of the <Comment> content.	This is an <Actor> reference with <ActorID> and <ActorRole>.		Optional
	<ReferenceID>	Used to link the <Comment> to a <Reference>.	This is a link to <Reference>.	A <Reference> to more detailed information about or referred to in the <Comment>.	Optional
Signatures	<CCRSignature>	This is the container for all <Signatures> associated with any data within the CCR.	If <Signatures> are used within the CCR, they must be digital signatures that meet the W3C's XML digital signature standard.		Optional
	<SignatureObjectID>	This is the CCR Object ID for the <Signature>.	This ID is expressed as xs:ID. The <CCRSignatureID> must be made up of characters in the set A-Z, a-z, 0-9, dash(-), underscore (_) and period (.). The first character must be from the set A-Z, a-z, 0-9. It can be of any character length.		Required if Signatures Section/Object is included
	<ExactDateTime>	This is the <Signature> time.	CCR Signature DateTime must be expressed in ISO-8601 date-time format, with precision to include seconds. CCR Signature DateTime must express a timezone offset, either using Z [universal coordinated time, or Zulu time], or an offset in hours and minutes. The CCR further requires that the Timezone offset be a legal time zone. This latter constraint cannot be expressed in the schema, as timezones are determined by political entities [e.g., Nations or States]. There presently exist time zones in the form ##:15 and ##:30. CCR Creation DateTime time should ideally come from a net-based atomic time service and not from an individual computing device's internal clock.		Optional

TABLE A1.1 *Continued*

CCR Attributes and Data Objects	XML	Definition	Explanations, Descriptions, Requirements, and Restrictions	Comments and Examples	Required or Optional
	<Type>	This defines the <Signature> <Type>, which in all cases must be W3C XML Digital Signature.	This is a CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	W3C Digital Signature.	Optional
	<IDs>	This expresses an external <Signature> IDs. This is a bucket to allow any external system that wants ot affix an institutional or other ID to the <Signature> that is external to the W3C XML Digital Signature within <Signature>.	<IDs> contains <DateTime>, <Type>, <ID>, and <IssuedBy>.		Optional
	<Source>	This is the <Source> of the <Signature>.	This is an <Actor> reference with <ActorID> and <ActorRole>.		Optional
	<Signature>	This is a container for a W3C Digital Signature.	Until the release of the CCR Security Standard from ASTM, this tag/container can be used for a proprietary digital signature.		Optional

A2. IMPLEMENTATION GUIDE FOR THE CONTINUITY OF CARE RECORD V1.0

INTRODUCTION

The Implementation Guide contains instructions for using the CCR XML schema (see the Adjunct to this standard) for generation of a standards-compliant CCR. The Implementation Guide is extremely strict regarding requirements on the use and formatting of the CCR XML and extremely strict regarding the content allowed within each field/XML tag. This is an interoperability standard for data expression and exchange, on paper as well as between healthcare information systems. Note that the XML schema (the Adjunct to this standard) that accompanies this Implementation Guide (Annex A2) must be used with the Implementation Guide for validation of a CCR under this version of the CCR standard. Other XML expressions of the CCR and related implementation guides may be authorized through joint efforts of ASTM and other standards development organizations.

This Implementation Guide represents a generalized use case and constraints across all instances of the CCR. Use-case specific Implementation Guides may be defined for specific domains that may incorporate further constraints, as appropriate, provided they are derived from and are a part of the formal ASTM CCR ballot process. A generalized use-case and constraints are required due to the explicit fact that the originator of a CCR in the general use-case may not and is not required to know the exact end-use case to which a CCR might be applied.

The constraints in the Implementation Guide are currently not formally expressed as XML constraints. ASTM E31 Committee on Healthcare or others may provide sample XSLT/XPath expressions expressing these constraints as well as sample patient data for use in testing CCR implementations, but it is the responsibility of the entity doing the implementation to assure compliance with the CCR standard, with this Implementation Guide, and with the CCR XMLschema, or with other schemas and related implementation guides that may be authorized through joint efforts of ASTM and other standards development organizations.

The core patient-specific data in the CCR are contained within the Body of the CCR Document Object, as illustrated in Fig. A2.1.

A2.1 Scope

A2.1.1 This Implementation Guide contains instructions for generating a standards-compliant Continuity of Care Record (CCR) XML document. This Implementation Guide (IG) is extremely strict regarding requirements on the use and formatting of the CCR XML and extremely strict regarding the data content allowed within each field/XML tag.

A2.1.2 The CCR is an interoperability content standard for data expression and exchange, on paper as well as between healthcare information systems, and strict adherence to this Implementation Guide and the accompanying CCR W3C XML Schema (or with other XML Schema and related implementation guides that may be authorized through joint efforts of ASTM and other standards development organizations) are required to support efficient interoperability. Unlike many other standards in use in healthcare, there are no end-user or vendor configurable fields in the CCR. Data optionality, cardinality, enumeration, and specificity of mapping are tightly controlled. Data content, their expression, and where exactly they must be placed are explicitly defined. In many instances the exact, enumerated allowed and required content is also explicitly spelled out. A data element that has no content is not permitted in the CCR XML.

NOTE A2.1—Adherence only to the CCR XML schema is necessary, but not sufficient to support interoperability.

A2.1.3 The implementation guide includes explicit requirements for implementation using specific XML tags, some of which represent changes to the content from the first CCR standard. The CCR Implementation Guide is not a messaging standard and does not allow configurable fields and latitude in implementation. The benefit of current messaging standards in healthcare is that in their abstract original form, they allow a certain amount of latitude so that trading partners and institutions can work out specific implementations relative to concrete use cases and environments. In actual, real world usage, these tend to be static and point-to-point instances of data exchange for a specific use case between or within controlled networks.

A2.1.4 The CCR, on the other hand, is an open, interoperable, content-specific standard for a patient health record summary. It allows data from any entity to be exchanged securely with any other authorized entity that supports the CCR structure and function as outlined within the Implementation Guide. There is no requirement that one entity have any prior knowledge of or about the other, as long as the appropriate security rules and policies are followed, so the CCR must be

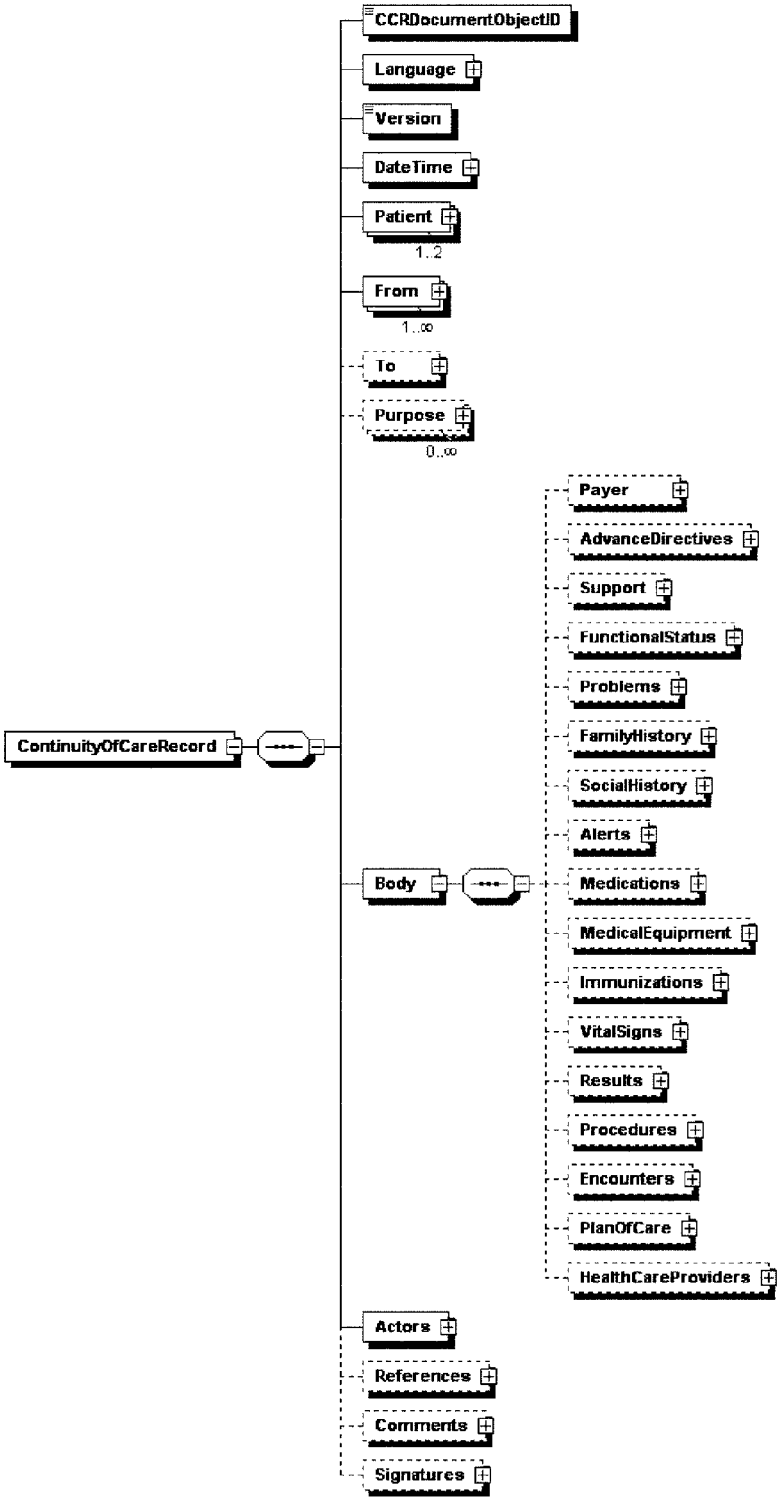

FIG. A2.1 Core Patient-specific Data are Contained within the Body of the CCR Document Object

implemented exactly as outlined in this Implementation Guide. To reiterate, there are no end-user or vendor configurable fields in the CCR.

A2.1.5 This point cannot be made strongly enough: A CCR from one entity must be readable by another entity with no knowledge of how the originating entity created the CCR other than this Implementation Guide and the accompanying XML Schema. Any entity receiving a CCR should be able to follow this Implementation Guide to the letter and be able to parse and display a CCR from any other entity and vice versa.

A2.1.6 *Important Note Regarding Compliance With This Standard*—The Implementation Guide is to be used with the CCR XML Schema that is presented in Annex A2 of this standard specification. A CCR instance must be valid against

the accompanying schema and the Implementation Guide (or against other XML Schema and related implementation guides that may be development through joint efforts of ASTM and other standards development organizations) in order to conform to this specification. The CCR uses a condensed and partially normalized XML Schema in order to constrain the length and complexity of the XML Schema. This normalization also simplifies versioning of the XML Schema to facilitate the management of the CCR Standard. This means that certain reusable tag and object strings and descriptions are normalized for the general use case, but may be constrained in actual use cases. All compliance validation must be done against both the Implementation Guide and the XML Schema, not against the XML Schema alone. This Implementation Guide was developed to be rigid in order to avoid the endless customization and variation that have plagued prior attempts to achieve widespread, error-free clinical data exchange. The CCR represents standardized core data about a patient at any given point in time.

A2.1.7 It is the responsibility of the entity doing the implementation to assure compliance with the CCR standard, with this Implementation Guide, and with the CCR XML schema or with other XML Schemas and related implementation guides that may be authorized through joint efforts of ASTM and other standards development organizations.

A2.1.8 In the future, compliance with this implementation guide may be facilitated through XSLT transforms using XPath expressions, Schematron schemas, RelaxNg schemas, and/or other industry-standard mechanisms.

A2.1.9 *Table of Contents*:

A2.2 CCR Principles and Structure

A2.2.1 The CCR is defined as a data object that represents a "snapshot" of a patient's relevant administrative, demographic, and clinical information at a specific moment in time. The format of the CCR is XML. It must be well-formed XML, and it must conform to the CCR XML Schema and this Implementation Guide or with other XML Schemas and related implementation guides that may be authorized through joint efforts of ASTM and other standards development organizations. The CCR is an XML document, but the use of the word 'document' refers to the XML as a document, not to the CCR as a clinical document – such as a Clinical Note, Encounter Note, History & Physical, or Discharge Summary. To reiterate, the CCR represents a summary of the patient's relevant health record at a specific point in time. In the electronic health record (EHR) world, the CCR represents the patient summary, which for many EHRs is called the 'Overview' of the patient or the 'Patient Summary.'

A2.2.2 The CCR XML is defined using a set of core principles:

A2.2.2.1 *Structure*:

(1) The CCR is an XML document that is defined within this Implementation Guide as a Document Object.

(2) The CCR Document Object is constructed from a set of discrete XML building blocks, which are defined as Data Objects.

(3) The Data Objects are contained within Sections, such as Medications, Immunizations, Problems, and Procedures, in the CCR Document Object.

(4) Each discrete Medication, Immunization, Problem, Procedure represents a discrete data object within the CCR.

(5) A Medication List or Problem List, therefore, represents a list of discrete Data Objects, within a specific Section and within the CCR Document Object (the CCR itself).

A2.2.2.2 All data within the CCR must be contained within XML tagged elements.

A2.2.2.3 An element that has no content is not permitted in the CCR XML.

A2.2.2.4 No data are allowed in the CCR to be contained within XML tag attributes.

A2.2.2.5 Concepts used more than once are defined as a Complex Data Type, Groups, or Global Elements. Complex Data Types are defined by adding the post-fix 'Type.' Examples: ProblemType; CodedDescriptionType. All efforts have been made to simplify and keep the XML Schema compact, but not at the expense of detailed and explicit data expression. This approach enhances human readability, particularly for clinicians and patients.

A2.2.2.6 Element and attribute names use the Pascal Notation where the first letter of each word is capitalized – example <DateTime>.

A2.2.2.7 Normalization is provided through the use of internal links for all discrete data objects that can potentially be referred to more than once within the document, including Individuals, Organizations, and Information Systems <Actor>, References <Reference>, Comments <Comments>, and Signatures <Signatures>.

A2.2.3 The CCR essentially consists of three core components:

A2.2.3.1 A Set of Header Sections,

A2.2.3.2 A Set of Body Sections, and

A2.2.3.3 A Set of Footer Sections.

A2.2.4 The Header Sections define:

<CCRDocumentObjectID>
<Language>
<Version>
<DateTime>
<Patient>
<From>
<To>
<Purpose>

A2.2.5 The Body Sections contain the <Patient> data, within the following Sections:

<Payers>
<AdvanceDirectives>
<Support>
<FunctionalStatus>
<Problems>
<FamilyHistory>
<SocialHistory>
<Alerts>
<Medications>
<MedicalEquipment>
<Immunizations>
<VitalSigns>
<Results>
<Procedures>
<Encounters>
<PlanOfCare>
<HealthCareProvider>

A2.2.6 The Footer Sections contain the normalized links within the CCR for:

<Actors>
<References>
<Comments>
<Signatures>

A2.2.7 The CCR core structure is represented in Fig. A2.2.

NOTE A2.2—Within this version of the CCR Implementation Guide all figures/diagrams are derived from the proprietary commercial XML tool XMLSpy (© 1998-2005 Altova GmbH & Altova, Inc.) from Altova (www.altova.com). This is for the sole purpose of illustrating the concepts, hierarchy, and object inheritance within the CCR. This is not an endorsement of any product as any number of commercial and proprietary products could have been used to generate the Figures in this Implementation Guide.

A2.2.8 In all Figures and Tables in this Implementation Guide, whether or not a given tag is optional or required is defined as its cardinality. Cardinality is expressed as follows in all Figures and Tables:

Required and Bounded To One Instance	1..1
Required and Bounded To *x* Instances	1..*x*
Required and UnBounded	1..∞
Optional and Bounded To One Instance	0..1
Optional and Bounded To x Instances	0..*x*
Optional and UnBounded	0..∞

A2.3 Data Representation in the CCR

A2.3.1 The Implementation Guide defines the expression of patient-specific healthcare data within the core CCR XML framework in Fig. A2.3. The core structure illustrated in Fig. A2.3 represents the essential categories of data that make up the CCR. These are the 'sections' that are data containers for comprehensive patient data.

A2.3.1.1 Within these sections/content containers, data within the CCR should be expressed in as much detail as possible. The CCR is designed to promote highly structured and coded information to support not only data exchange, but also to support complex data expression as well as both human and automated clinical decision support, through the use of alerts, reminders, performance measures and sophisticated data analysis.

A2.3.1.2 In an ideal world all data expression in healthcare would be to a level of detail and standardization such that data from any system representing a specific concept would be identical to data from another disparate system representing the exact same concept. At the time of publication of this Implementation Guide, that is not the case in healthcare. Therefore the CCR XML has been defined to allow a range of expression of data and data complexity. This standard strongly recommends the use of controlled vocabularies, but these are non-normative suggestions, and the standard has provided a small number of 'escape hatches' for free text where deemed absolutely necessary for those systems that cannot support discretely structured, tagged, and coded data.

A2.3.1.3 As noted earlier, the CCR is set up as a Document Object that is a container for Data Objects. That Document Object is the CCR, and the Data Objects are the medications, problems, procedures, encounters, immunizations, and the like that are contained within the sections illustrated in Fig. A2.3. The CCR supports the detailed parsing of any specific data object into its detailed structured components.

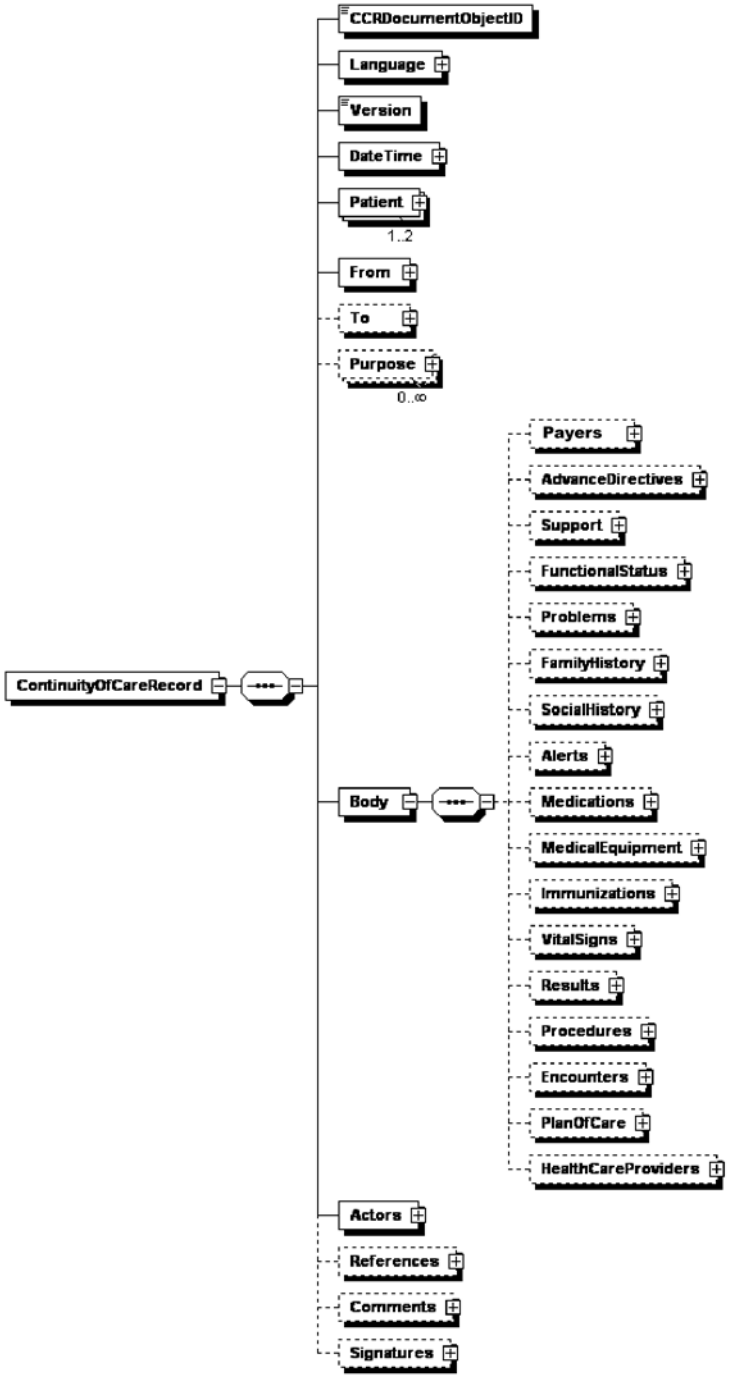

FIG. A2.2 Overall Structure of CCR

A2.3.1.4 The medication Amoxicillin for example, would represent a data object in the CCR. Its attributes within the CCR are expressed with discrete specificity as attributes of that data object, displayed as tagged data elements in XML. Amoxicillin, therefore, has discrete tags for <BrandName>, <Strength>, <Form>, <Quantity>, <Dose>, <Route>, <Site>, <Indication>, <Instructions>, etc., and each of these is sub-classed with a set of tags to promote detailed data specificity. <Dose>, for example, is expressed as a <DoseCalculation> and as <FixedDose> or a <DoseRange> and is further sub-classed to express a <Value> and <Units>, any <Variable>, and an optional <DoseCalculation>. The CCR medication data object is structured to comprehensively support all prescriptions. This includes inpatient as well as ambulatory or office-based medication administration, IV admixtures, home health and outpatient administration and infusions, and all instances and ways in which a medication/drug can be delivered to a patient. It also covers medication administration and dosing from the youngest neonatal patients to the oldest in our geriatric population.

A2.3.1.5 Similar levels of detail are supported for all data objects in the CCR, tailored to the specificity needed to express complex clinical and administrative concepts. In addition, the

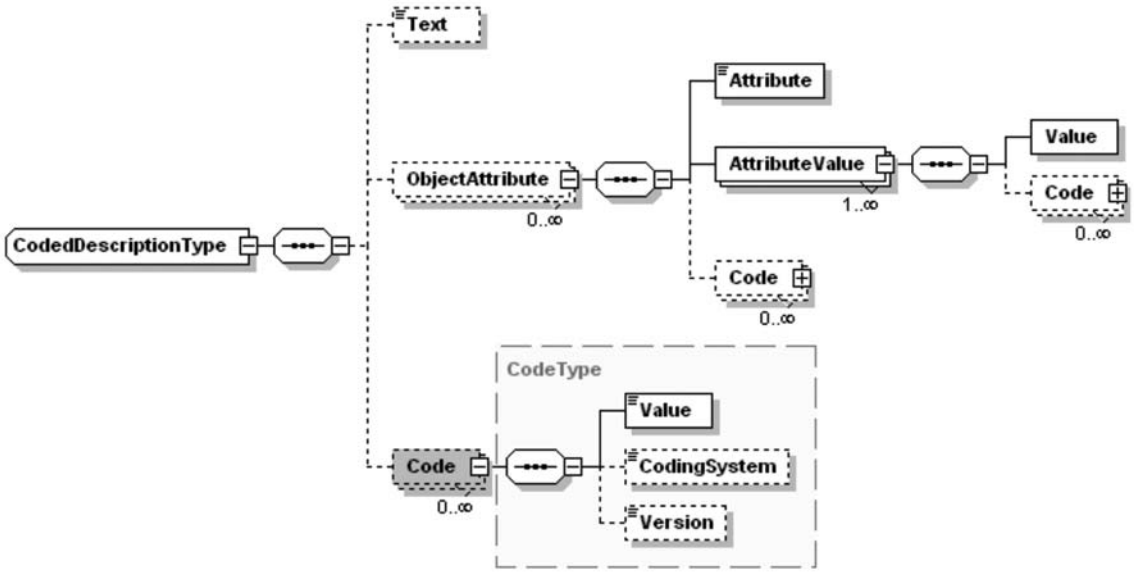

FIG. A2.3 Complex Data Type CodedDescriptionType

CCR supports detailed coding of data and detailed data attributes with standardized coding methodologies such as SNOMED CT, ICD-9 CM, ICD-10, CPT, LOINC, RxNorm, and the like. Although explicitly constrained terms, term sets, controlled vocabularies, and code sets are not completely defined within this Implementation Guide, future Implementation Guides will contain explicit constraints relative to terms, term sets, controlled vocabularies, and code sets as quickly as these can be defined by the ASTM E31.28 CCR Subcommittee.

NOTE A2.3—The following XML elements are currently defined as xs:string, but should not contain arbitrary text strings: Within CodedDescriptionType: ObjectAtribute/Attribute.

A2.3.1.6 In other words, the CCR is a comprehensive tool for the detailed and encoded expression of patient-centric, summarized clinical data. XML is the object-description language used by the CCR to express data objects and their attributes. Ideally all systems using the CCR for interoperable exchange would express data using XML and would conform to the standardized content detail that the CCR is capable of supporting. Unfortunately, due to the lack of any comprehensive and widely used clinical content standards for patient summaries in healthcare, most systems have not been either standardized or are not interoperable, and their capabilities relative to structuring data vary widely.

A2.3.1.7 The emerging use of the IHE Integration Profiles (Integrating the Healthcare Enterprise) created though the collaboration with several standards bodies (HL7, DICOM, ASTM, ISO, OASIS, IETF, etc.) has made great strides in moving the industry towards a structured approach to data. There is marked variability within the industry, however, and in order to deal with this reality, the CCR XML has been designed to allow an expression of data in a range of modalities, as follows:

(1) Non-specific text strings,

(2) Coded text strings,

(3) Coded or un-coded text strings with an arbitrary level of structure, and

(4) Fully structured and coded data expression.

A2.3.1.8 A significant amount of thought and effort has gone into mapping the CCR to string-based and other XML healthcare messaging standards and architectures such as NCPDP and NCPDP Script, HL7 2.x and 3.0, HL7 CDA, and X12 (specifically X12 standards such as the 837 claims standard). In general, the CCR Implementation Guide, as noted above, contains greater data specificity than some of these string-based and XML standards, but care has been taken to assure that the data needed to generate a message or document using one of these standards is supported within the CCR. The intent is that the CCR would be fed by data coming from messages and documents expressed in these standards and that a system could generate a message or document consistent with these standards from a CCR. In addition, ASTM International and HL7 have a Memorandum of Understanding, for each organization to work with the other toward the goal of harmonizing HL7 and CCR content. Additional cooperative work is ongoing with IHE, NCPDP, and X12.

A2.3.1.9 To support the continuum of data expression encompassing text strings to fully coded and structured data, the CCR uses an XML data container defined as a CodedDescriptionType. All expressions of data within the CCR where text strings are allowed utilize the CodedDescriptionType or follow the rules defined for the CodedDescriptionType, so it will be defined in detail here, as will other key overarching CCR concepts such as CodingSystem, ObjectIDs, and the expression of date/time within the CCR.

A2.3.2 *CodedDescriptionType*:

A2.3.2.1 All data within the CCR must be the content of an XML tag. As defined earlier, no data are allowed as XML tag attributes. Most data within the CCR are explicitly tagged, and it is recommended that all implementations fully tag data to their maximum granularity and specificity so that complex concepts can be accurately and explicitly represented. It is understood, however, that some systems can only express complex concepts as text strings and cannot parse and express

data as discretely tagged and coded data. The Complex Data Type CodedDescriptionType is used within the CCR to support the use of either simple text strings or complete, detailed tagging and coding of discrete data.

NOTE A2.4— <Type> is not intended to be explicitly linked to codes under <Description>. Its intent is for sorting and filtering and will in the future have its own defined controlled vocabulary source terminology.

A2.3.2.2 The CCR CodedDescriptionType is illustrated in Fig. A2.3.

A2.3.2.3 If a system generating a CCR can only generate a text string, then that text string must be placed in its entirety as content of the tag <Text>.

A2.3.2.4 A text 'diagnosis' can be used as an example:

Example 1 – CodedDescriptionType
(Simple Text String)

```
<Text>Acute Antereoseptal Myocardial Infarction</Text>
```

A2.3.2.5 This same text string as a coded diagnosis would be expressed as follows:

Example 2 – CodedDescriptionType
(Coded Simple Text String)

```
<Text>Acute Antereoseptal Myocardial Infarction</Text>
<Code>
  <Value>410.1</Value>
  <CodingSystem>ICD-9 CM</CodingSystem>
  <Version>2004</Version>
</Code>
```

A2.3.2.6 The same text string coded in both ICD-9 CM and SNOMED CT would be expressed as follows:

Example 3 – CodedDescriptionType
(Simple Text String Coded in Two Different Coding Schemes)

```
<Text>Acute Antereoseptal Myocardial Infarction</Text>
<Code>
  <Value>410.1</Value>
  <CodingSystem>ICD-9 CM</CodingSystem>
  <Version>2004</Version>
</Code>
<Code>
  <Value>62695002</Value>
  <CodingSystem>SNOMED CT</CodingSystem>
  <Version>20050131</Version>
</Code>
```

A2.3.2.7 The same diagnosis represented as both a text string and fully tagged and coded data object with ICD-9 CM and SNOMED CT coding would be expressed as follows:

Example 4 – CodedDescriptionType
(Coded Simple Text String + Structured Representation)

```
<Text>Acute Antereoseptal Myocardial Infarction</Text>
<Code>
  <Value>410.1</Value>
  <CodingSystem>ICD-9 CM</CodingSystem>
  <Version>2004</Version>
</Code>
<Code>
  <Value>62695002</Value>
  <CodingSystem>SNOMED CT</CodingSystem>
  <Version>20050131</Version>
</Code>
<ObjectAttribute>
  <Attribute>Diagnosis</Attribute>
  <AttributeValue>
    <Value>Myocardial Infarction</Value>
    <Code>
      <Value>22298006</Value>
      <CodingSystem>SNOMED CT</CodingSystem>
      <Version>20050131</Version>
    </Code>
  </AttributeValue>
</ObjectAttribute>
<ObjectAttribute>
  <Attribute>Acuity</Attribute>
  <AttributeValue>
    <Value>Acute</Value>
    <Code>
      <Value>53737009</Value>
      <CodingSystem>SNOMED CT</CodingSystem>
      <Version>20050131</Version>
    </Code>
  </AttributeValue>
</ObjectAttribute>
<ObjectAttribute>
  <Attribute>Site</Attribute>
  <AttributeValue>
    <Value>Antereoseptal</Value>
    <Code>
      <Value>20706007</Value>
      <CodingSystem>SNOMED CT</CodingSystem>
      <Version>20050131</Version>
    </Code>
  </AttributeValue>
```

A2.3.2.8 In Example 4, there is no explicit equivalence between coded structures and narratives/text. It is important to note that within <ObjectAttribute> even though the value of the <Attribute> tag is defined of type xs:string in the schema, it cannot contain arbitrary text strings. <Attribute> must be part of a specific vocabulary or code set that although not defined in this Implementation Guide, will be specified in future implementation guides as controlled vocabularies are explicitly defined for the CCR.

A2.3.2.9 Note that qualifiers should only be used according to well-defined rules of controlled vocabularies and post-coordination. A value of type CodedDescriptionType should only have qualifiers if its code system defines the use of such qualifiers or if there is a third code system that specifies how other code systems may be combined.

A2.3.2.10 This diagnosis in the CCR can also be represented as structured, tagged, and coded data object, using only structured and coded data as follows:

Example 5 – CodedDescriptionType
(Structured XML Data Object Representation)

```
<ObjectAttribute>
  <Attribute>Diagnosis</Attribute>
  <AttributeValue>
    <Value>Myocardial Infarction</Value>
    <Code>
      <Value>22298006</Value>
      <CodingSystem>SNOMED CT</CodingSystem>
      <Version>20050131</Version>
    </Code>
  </AttributeValue>
</ObjectAttribute>
<ObjectAttribute>
  <Attribute>Acuity</Attribute>
  <AttributeValue>
    <Value>Acute</Value>
    <Code>
      <Value>53737009</Value>
      <CodingSystem>SNOMED CT</CodingSystem>
      <Version>20050131</Version>
    </Code>
  </AttributeValue>
</ObjectAttribute>
<ObjectAttribute>
  <Attribute>Site</Attribute>
```

```
<AttributeValue>
 <Value>Antereoseptal</Value>
  <Code>
   <Value>20706007</Value>
   <CodingSystem>SNOMED CT</CodingSystem>
   <Version>20050131</Version>
  </Code>
 </AttributeValue>
</ObjectAttribute>
```

A2.3.2.11 Example 5 represents data representation and granular encoding that is explicit. Note that the text string 'Acute Antereoseptal Myocardial Infarction' can be reconstructed using an XSLT script in XML from the detailed discrete representation in Example 5.

A2.3.2.12 One problem with encoding data in healthcare is the variability and inexactitude of many widely used coding schemes. ICD, CPT, and NDC codes are non-specific in many instances of use, whereas SNOMED CT, LOINC, and RxNorm codes are more granular, specific, and clinically meaningful. The problem in healthcare is that ICD, CPT, and NDC codes are often required for healthcare claims processing and reimbursement (in the United States), and due to these widespread uses and requirements their inclusion and representation in the CCR must be supported.

A2.3.2.13 The CodedDescriptionType provides support for detailed discretely encoded data representation, while also supporting the use of a less specific code—a code such as an ICD-9 CM code in the diagnosis example, as follows:

Example 6 – CodedDescriptionType
(Structured XML Data Object Representation + Roll-Up Code)

```
<ObjectAttribute>
 <Attribute>Diagnosis</Attribute>
 <AttributeValue>
  <Value>Myocardial Infarction</Value>
  <Code>
   <Value>22298006</Value>
   <CodingSystem>SNOMED CT</CodingSystem>
   <Version>20050131</Version>
  </Code>
 </AttributeValue>
</ObjectAttribute>
<ObjectAttribute>
 <Attribute>Acuity</Attribute>
 <AttributeValue>
  <Value>Acute</Value>
  <Code>
   <Value>53737009</Value>
   <CodingSystem>SNOMED CT</CodingSystem>
   <Version>20050131</Version>
  </Code>
 </AttributeValue>
</ObjectAttribute>
<ObjectAttribute>
 <Attribute>Site</Attribute>
 <AttributeValue>
  <Value>Antereoseptal</Value>
  <Code>
   <Value>20706007</Value>
   <CodingSystem>SNOMED CT</CodingSystem>
   <Version>20050131</Version>
  </Code>
 </AttributeValue>
</ObjectAttribute>
<Code>
 <Value>410.1</Value>
 <CodingSystem>ICD-9 CM</CodingSystem>
 <Version>2004</Version>
</Code>
```

A2.3.2.14 This supports structuring the data as a discretely tagged XML data object, coded in SNOMED CT, with a roll-up code in ICD-9 CM for billing purposes.

A2.3.2.15 As a condensed XML string, Example 6 would look as follows:

Example 7 – CodedDescriptionType
(Example 6 As An XML Text Block)

```
<ObjectAttribute><Attribute>Diagnosis</
Attribute><AttributeValue><Value>Myocardial Infarction</
Value><Code><Value>22298006</Value><CodingSystem>SNOMED CT</
CodeType><Version>20050131</Version></Code></AttributeValue></
ObjectAttribute><ObjectAttribute><Attribute>Acuity</
Attribute><AttributeValue><Value>Acute</
Value><Code><Value>53737009</Value><CodingSystem>SNOMED CT</
CodingSystem><Version>20050131</Version></Code></AttributeValue></
ObjectAttribute><Attribute>Site</
Attribute><AttributeValue><Value>Antereoseptal</
Value><Code><Value>20706007</Value><CodingSystem>SNOMED CT</
CodingSystem><Version>20050131</Version></Code></AttributeValue></
ObjectAttribute><Code><Value>410.1</Value><CodingSystem>ICD-9 CM</
CodingSystem><Version>2004</Version></Code>
```

A2.3.2.16 The Definitions for the key XML tags in the CodedDescriptionType are displayed in Table A2.1.

A2.3.3 *CodingSystem*:

A2.3.3.1 The Complex Data Type CodingSystem is used to express codes within the CCR. It is recommended that wherever possible, all data be discretely coded in implementations of the CCR.

A2.3.3.2 CodingSystem is illustrated in Fig. A2.4.

A2.3.3.3 In all instances where a Code is used in the CCR, the Complex Data Type CodingSystem is required. The key XML tags for CodingSystem are defined in Table A2.2.

A2.3.4 *Coding*—Detailed coding is recommended whenever practical within the CCR. The following are specific

TABLE A2.1 CodedDescriptionType Definition Table

CodedDescriptionType	Accepted Values/Formatting	Optionality/Cardinality	Description
<Text>	Text String	Optional and Bounded To One Instance (0..1)	This is the text description as a string and can only be used to represent unstructured data.
<Attribute>	Child of <ObjectAttribute>	Required if data are structured and <ObjectAttribute> is used, Bounded (1..1)	This is the container for structured data object-attribute descriptors – 'Diagnosis', 'Acuity', 'Site', 'Severity', 'Laterality', 'Acuity', etc.
<Value>	Child of <AttributeValue>	Required if data are structured and <AttributeValue> is used, Bounded (1..1)	This is a container for object attribute values – 'Myocardial Infarction', 'Acute', 'Antereoseptal', 'Mild', 'Left', 'Acute', etc.
<Code>	See CodingSystem	Optional UnBounded (0..∞)	<Code> is a Complex Data Type – CodingSystem. It is to be used whenever codes are defined for a given data element.

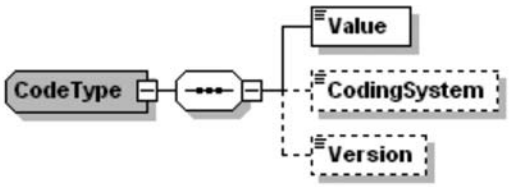

FIG. A2.4 Complex Data Type CodingSystem

TABLE A2.2 CodingSystem Definition Table

CodingSystem	Accepted Values/Formatting	Optionality/Cardinality	Description
<Value>	String	Required and Bounded To One Instance (1..1).	This is the Code – numeric or alphanumeric.
<CodingSystem>	String	Optional and Bounded To One Instance (0..1).	This defines the coding system – such as ICD-9CM, ICD-10, SNOMED, LOINC, NCPDP, X12, CPT.
<Version>	String	Optional and Bounded To One Instance (0..1).	This defines the version – for example if the <CodingSystem> is ICD-9CM, the <Version> might be 2004.

coding recommendations for the U.S. Note that these are coding suggestions and are nonnormative.

A2.3.4.1 *Problems*—Problems should be coded at the highest level using SNOMED CT and the most recent ICD-9 CM codes at the time the CCR is generated to accommodate the need for the various healthcare entities that will be interacting with the CCR data to have accurate coding for reimbursement purposes. These and other controlled vocabularies are integral to the enhancement of data contained within the CCR to support intelligent clinical decision support. It is recommended that problems be categorized with SNOMED CT codes to as granular a level as possible.

A2.3.4.2 *Procedures*—Procedures should be coded at the highest level using SNOMED CT, LOINC, and the most recent CPT codes at the time the CCR is generated to accommodate the need for the various healthcare entities that will be interacting with the CCR data to have accurate coding for reimbursement purposes as well as potential utilization for clinical decision support functions It is recommended that procedures be coded with SNOMED CT and LOINC codes to as granular a level as possible.

A2.3.4.3 *Products and Agents*—Products and agents should be coded with RxNorm to as granular a level as possible. In addition, they may be coded with another standard as applicable (NDC, for example) or proprietary code, with the type of code and the source and version clearly defined. If any coding system is used, however, an RxNorm code must be included, if legally required.

A2.3.4.4 *Results*—Procedures generating results should be coded with the most recent CPT codes at the time the CCR is generated for procedures and with LOINC for <Result> and <Test>.

A2.3.5 *Object IDs*:

A2.3.5.1 The CCR and all Data Objects contained within the CCR must have ObjectIDs.

A2.3.5.2 The CCR has an ObjectID:

<CCRDocumentObjectID> – a unique ID for the CCR Document Object

A2.3.5.3 All CCR Data Objects have ObjectIDs:

<CCRDataObjectID> – a unique ID for all CCR Data Objects.
<ActorObjectID> – a unique ID for all Actors.
<ReferenceObjectID> – a unique ID for all References.
<CommentObjectID> – a unique ID for all Comments.
<SignatureObjectID> – a unique ID for all Signatures.

A2.3.5.4 CCR Document and Data ObjectIDs are unique IDs used by the generating entity/system to uniquely identify each explicit instance of a CCR and each explicit Data Object. The uniqueness of these ObjectIDs is defined within the generating system. The </CCRDocumentObjectID> should ideally be unique across all CCRs through the use of a UUID or OID or other generally accepted universal unique ID mechanism. Data Object IDs must be unique to and within each CCR, but are not considered unique across the universe of all CCRs. A universal unique ID mechanism such as UUID, OID, or other generally accepted universal unique ID mechanism can be used for data object IDs, but is not required.

Example 8 – <CCRDataObjectID>

<CCRDataObjectID>**AA0001**</CCRDataObjectID>

A2.3.6 *Links Between CCR Data Objects With <InternalCCRLink>*:

A2.3.6.1 <InternalCCRLink> is used to link internal references between CCR Data Objects within the CCR, defined by <CCRDataObjectID> and xs:string.

A2.3.6.2 Links are used to reference data contained within other parts of the document, such as a <Problem> under <Problems> being the <Indication> for a <Procedure> or <Medication>.

A2.3.6.3 Links are made using the Complex Data Type InternalCCRLinkType, which is illustrated in Fig. A2.5.

A2.3.6.4 There is no 'bucket' or section for InternalCCRLinks. They are referentially self-contained, since they are pointers from one data object to another data object.

A2.3.6.5 The Definition Table for InternalCCRLinkType is Table A2.3.

A2.3.7 *Sequentially Repeating Object Attributes*:

A2.3.7.1 XML provides an ideal platform for repeating object attributes, with the default explicit order of repetition defined within XML as the order with which they are listed within the XML string.

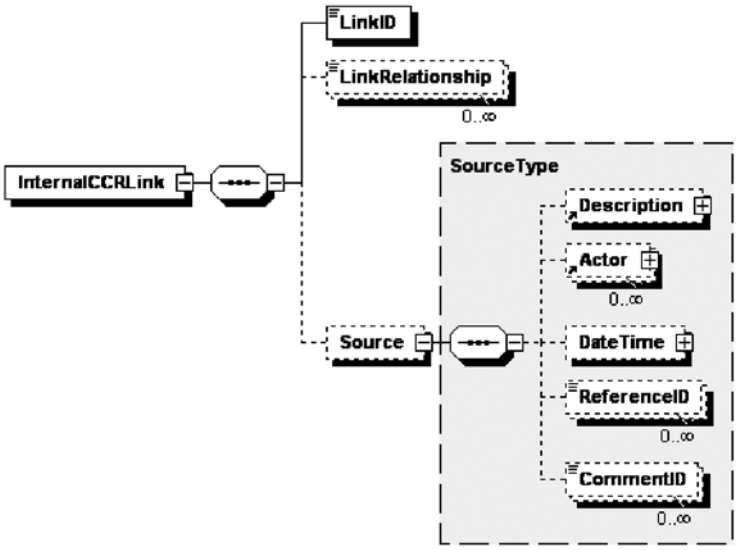

FIG. A2.5 Complex Data Type InternalCCRLinkType

TABLE A2.3 InternalCCRLinkType Definition Table

InternalCCRLinkType	Accepted Values/Formatting	Optionality/0 - ∞	Description
<LinkID>	Internal CCR ObjectIDs Only – xs:string	Required and Bounded To One Instance (1..1).	This must be an internal CCR ObjectID.
<LinkRelationship>	Instance of type xs:string that allows enumerated values only.	Optional and UnBounded (0..∞)	Links are internal references within the CCR that link a specific Data Object to another. Enumerated values are not yet defined for Links but will include: "Indication" "Etiology" "Associated With" "Must Occur Before" "Must Occur After"

A2.3.7.2 To ensure exact order, and to facilitate mapping to string-based messaging standards, such as NCPDPScript 8.0, HL7 2.x, and X12 837, the CCR provides for a <SequencePosition> tag and a <SequenceModifier> tag.

A2.3.7.3 If there is no repeat of an attribute, then these tags are not used. If there are one or more repeats, then the <SequencePosition> of the first attribute in order is the integer '1' and that attribute does not use a <SequenceModifier>. For the second and subsequent attribute repeats their <SequencePosition> is an integer '2' or higher in increments of '1', and they each have a <SequenceModifier>.

A2.3.7.4 The <SequenceModifier> is a regular expression, such as AND, OR, TO, THEN, which connects the attributes as follows:

Attribute 1	AND	Attribute 2	(Inclusive)
Attribute 1	OR	Attribute 2	(Either/Or)
Attribute 1	TO	Attribute 2	(Expression of a Range)
Attribute 1	THEN	Attribute 2	(Sequential)

A2.3.7.5 <SequencePosition> and <SequenceModifier> are defined by an explicit naming of the tag relative to the attribute to which they apply, for example <FrequencySequencePosition> and <VariableFrequencyModifier>. <SequencePosition> and <SequenceModifier> are used whenever attribute order must be maintained or when there are multiple segment repeats or object repeats within other objects.

A2.3.8 *Representation of Dates and Times in the CCR with DateTimeType*—The CCR provides a mechanism to represent dates and times with exact precision to accommodate the requirements for medical-legal documentation. The CCR also supports inexact clinical dates and times where relative times are all that are available, e.g., 'a few years ago' or 'as a child', such as when representing after-the-fact historical recollections of clinical events. Time is expressed in the CCR with <DateTime> which is an exact expression of date and time or a Complex Data Type used to delineate an exact (precise) or inexact date or date time, an age, an approximate date, or a timeframe or time range. The Complex Data Type DateTimeType is illustrated in Fig. A2.6. An expanded representation of the DateTimeType, to illustrate its comprehensive approach to the expression of clinically and administratively relevant times in healthcare, is illustrated in Fig. A2.7. The key XML tags for DateTimeType are defined in Table A2.4.

A2.3.8.1 *<ExactDateTime>*

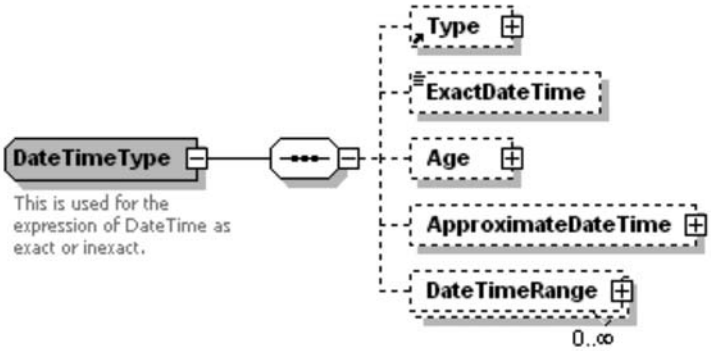

FIG. A2.6 Complex Data Type DateTimeType

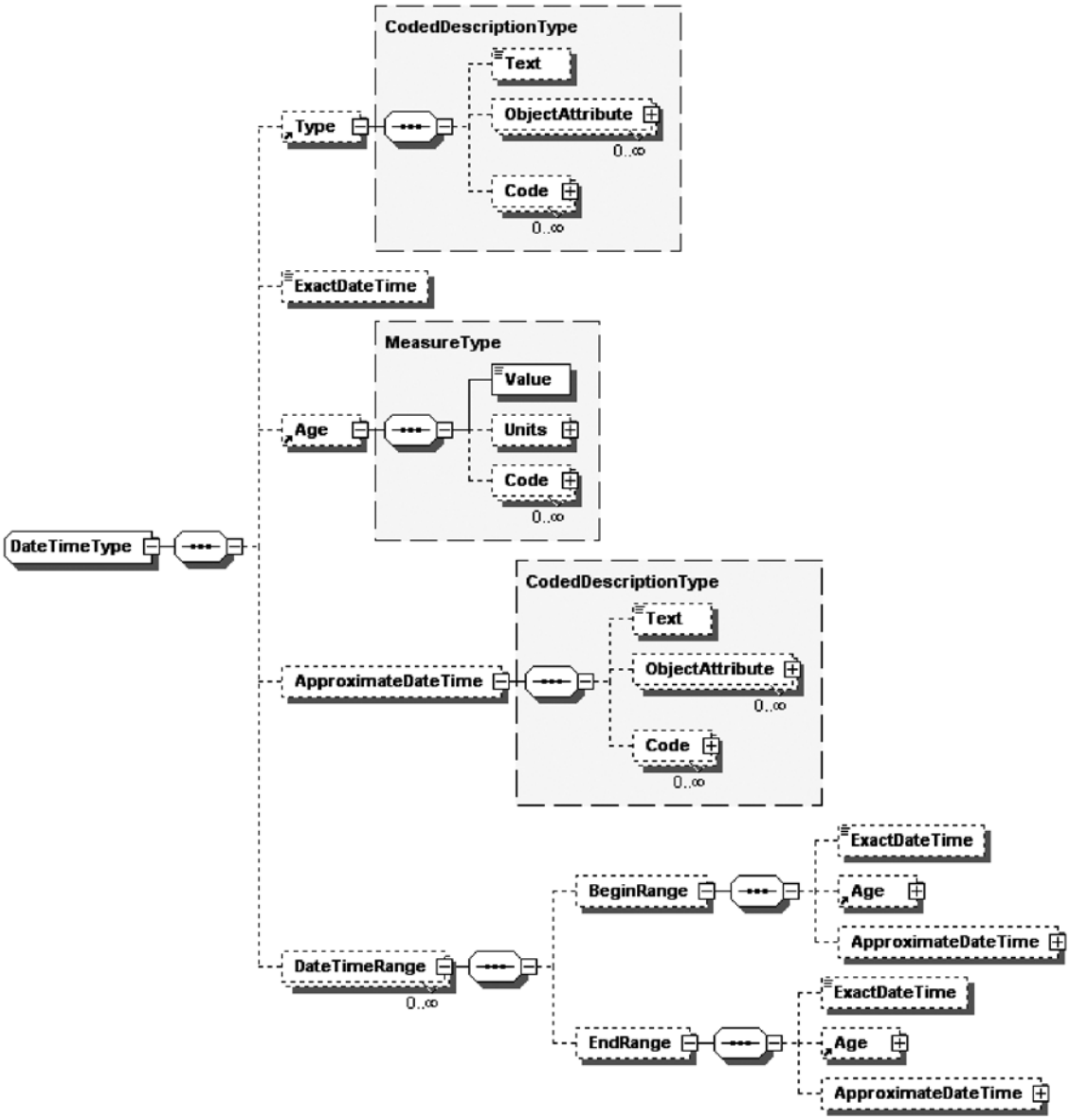

FIG. A2.7 Partially Expanded Data Type DateTimeType

(1) <ExactDateTime> must conform to the ISO 8601 Date-Time Standard described at http://www.iso.org/iso/en/prods-services/popstds/datesandtime.html#three and available from ISO (www.iso.org).

TABLE A2.4 DateTimeType Definition Table

DateTimeType	Accepted Values/Formatting	Optionality/Cardinality	Description
<DateTimeType>	Restricted – acceptable values are to be defined for each instance of use.	Optional and Bounded To One Instance (0..1).	<DateTimeType> defines the type of date/time and is required anytime a DateTimeType is used. Acceptable values are restricted. Specific Types may be required in a particular instance.
<ExactDateTime>	Must be in ISO-8601 Date-Time Format – yyyy-mm-ddThh:mm:ss-hh(GMT):mm(GMT)	Optional and Bounded To One Instance (0..1).	A specific Date and Time is the preferred usage of DateTimeType. It can be Year Only; Year and Month; Year, Month, Day; Year, Month, Day, Hour; Year, Month, Day, Hour, Minutes; Year, Month, Day, Hour, Minutes, Seconds. It is required that time have its offset from UDT, when available, (stated as Z or ± GMT/UDT). An example is 2004-01-12T13:30:00-05:00.
<Age>	Defined with <Value> and <Units>.	Optional and Bounded To One Instance (0..1).	<Age> is allowed only when appropriate and is defined as a <Value>/<Units> pair. Representations can be exact or approximate.
<ApproximateDateTime>	CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Optional and Bounded To One Instance (0..1).	<ApproximateDateTime> is allowed only when appropriate. Examples of Approximate Time are: One Week Ago; As A Child; When 30 Years Old; In 30s.
<DateTimeRange>	No content – must contain either one or both <BeginRange> and/or <EndRange>, which in turn must contain a tagged DateTime representation, using one of the DateTime formats defined above.	Optional and Bounded To One Instance (0..1).	Used to represent imprecise or precise date/time ranges.

(2) <ExactDateTime> within the CCR must be defined by a standard time reference to support interoperability of the CCR between systems and across time zones. The clock at Greenwich, England is traditionally used as the standard clock for international reference of time. This time was originally referred to as Greenwich Mean Time or GMT, but the official name is now Coordinated Universal Time or UTC. The letter designator for this clock is Z. Times in UTC are written in military time or 24-hour format such as 1830Z. UTC is the standardized reference time used in the CCR.

(3) The required format for <ExactDateTime> to represent a specific time on a specified day within the CCR is the calendar date and time representation as follows, with the capital letter T used to separate the date and time components:

YYYY-MM-DDThh:mm:ss

(4) This representation must be immediately followed by a "Z" to indicate that the time is Coordinated Universal Time (UTC) or by a sign, + or -, followed by the difference from UTC represented as hh:mm. For example, to indicate 1:25:34 pm on September 1, 2004, for Eastern Standard Time, which is 5 hours behind Coordinated Universal Time (UTC), the CCR <ExactDateTime> must be represented as:

2004-09-01T13:25:34-05:00.

(5) See http://www.iso.org/iso/en/prods-services/popstds/datesandtime.html for more information on UTC formats and examples.

(6) Note that <ExactDateTime> is used to express exact dates and times, but these times are not required, depending on their relevance and use in the CCR, to be precise to the seconds. Depending on use, <ExactDateTime> can express time as:

(a) Year only [2004].

(b) Year and month only [2004-09].

(c) Year, month, and day only [2004-09-01].

(d) Year, month, day, and hours only [2004-09-01T13:00:00-05:00].

(e) Year, month, day, hours, and minutes only [2004-09-01T13:25:00-05:00].

(f) Year, month, day, hours, minutes, and seconds only [2004-09-01T13:25:34-05:00].

(7) Note that in instances 4 through 6 an offset from UTC is required.

A2.3.8.2 *<Age>*

(1) <Age> in the CCR must be represented with a <Value> and <Units>. In addition, <Units> under <Age> are restricted to Days, Weeks, Months, and Years. The expression of <Age> for patients less than 2 years of age must be as follows:

Age <2 Weeks must be expressed in days [__ Days].
Age 2 Weeks – 2 Months must be expressed in weeks [__ Weeks].
Age 2 Months – 2 Years must be expressed in months [__ Months].
Age >2 Years must be expressed in years [__ Years].

(2) Examples are as follows:

Example 9 – <Age>

```
<Age><Value>5</Value><Units><Unit>Days</Unit></Units></Age>
<Age><Value>3</Value><Units><Unit>Weeks</Unit></Units></Age>
<Age><Value>18</Value><Units><Unit>Months</Unit></Units></Age>
<Age><Value>45</Value><Units></Unit>Years</Unit></Units></Age>
```

A2.3.8.3 *<ApproximateDateTime>*

(1) <ApproximateDateTime> is expressed as a text string using CodedDescriptionType. Since there are no currently encoded values to express <ApproximateDateTime>, CodedDescriptionType is used as a text string container only as illustrated in the following examples:

Example 10 – <ApproximateDateTime>

```
<ApproximateDateTime><Text>One Week Ago</Text></Approximate
 DateTime>
```

```
<ApproximateDateTime><Text>As A Child</Text></Approximate
 DateTime>
<ApproximateDateTime><Text>Thirty Years Ago</Text></Approximate
 DateTime>
<ApproximateDateTime><Text>In 30s</Text></Approximate
 DateTime>
```

A2.3.8.4 *<DateTimeRange>*

(1) <DateTimeRange> must be expressed using <BeginRange> and <EndRange>. <BeginRange> and <EndRange> can be expressed as an <ExactDateTime>, <Age>, or <ApproximateDateTime> following the rules defined above.

A2.3.8.5 *<Source>*

(1) <Source> is required in all instances of data objects in the CCR. <Source> is defined by the Complex Data Type SourceType. SourceType includes a link to <Actor> and a <SourceDateTime>, which is an <ExactDateTime>.

A2.4 Security and Privacy

A2.4.1 The primary use case for the CCR is for the CCR document instance to provide a snapshot in time containing the relevant clinical, demographic and administrative data for a specific patient. The data contained within the CCR are patient data and, if those data are identifiable, then end-to-end CCR document integrity and confidentiality must be provided while conforming to regulations or other security, confidentiality, or privacy protections as applicable within the scope of this standard.

A2.4.2 Conditions of security and privacy for a CCR instance must be established in a way that allows only properly authenticated and authorized access to the CCR document instance or its elements. The CCR document instance must be self protecting when possible and carry sufficient data embedded in the document instance to permit access decisions to be made based upon confidentiality constraints or limitations specific to that instance.

A2.4.3 Additional ASTM E31.20 Subcommittee on Security and Privacy guides, practices, and specifications will be published in support of the security and privacy needs of specific use cases. When a specification is necessary to assure interoperability or other required functionality, the CCR core schema will be extended to meet the profile requirements of the underlying use case—building upon existing standards and specifications whenever possible. For profiles that require digital signatures, W3C's XML digital signature standard (http://www.w3.org/TR/xmldsig-core) will be used. Encryption will be provided using W3C's XML encryption standard (http://www.w3.org/TR/xmlenc-core).

A2.4.4 Until detailed security, confidentiality, and privacy standards can be published by ASTM to support the CCR, the following procedures should be followed in all instances where a CCR will be considered for security purposes 'in-the-clear':

A2.4.4.1 The CCR should have a checksum calculated against the entire document and a W3C XML digital signature applied.

A2.4.4.2 The CCR Body and Footer as well as the Patient section should be encrypted with W3C XML encryption.

A2.4.4.3 The only allowed unencrypted data should be the <CCRDocumentObjectID>, CCR document <DateTime>, <From> containing the minimum data required to define whom the CCR is from, and <To> containing the minimum data to define to whom the CCR is intended.

A2.4.5 The CCR is an interoperability standard and requires a standardized security approach by all parties. As stated earlier in this Implementation Guide, the receiving party should not need to have any prior knowledge of the originating party. This is more difficult to accomplish seamlessly with security and encryption, but until interoperable CCR security standards are finalized, all parties using the CCR should adopt the above-defined methodologies and assist in the standardization process through cooperative agreements between sender and receiver. There are many alternative models and approaches available to provide for secure management and transmission of data, but the above-defined methodologies are the result of significant work in the field and represent the best consensus in the general computer industry on how to handle XML security and non-repudiation. The above methods are compliant with existing ASTM healthcare security standards.

A2.5 CCR Implementation

A2.5.1 Implementation of the CCR described within this Implementation Guide will be defined in the discrete order in which the XML appears within the CCR, starting at the top of the document (CCR Header), then through the body (CCR Body,) and then to the normalized footer (CCR Footer) – see Fig. A2.2 for reference.

A2.5.2 *The CCR Header*—The CCR Header consists of the CCR XML Document Header, and the following CCR Sections:

```
<CCRDocumentObjectID>
<Language>
<Version>
<DateTime>
<Patient>
<From>
<To>
<Purpose>
```

NOTE A2.5—The CCR Header consists of tags, as defined above, but is not contained within a <Header> tag.

A2.5.2.1 *CCR XML Document Header*:

(1) The CCR XML Document Header exists within the tag attributes of the tag <ContinuityOfCareRecord>. CCR XML Document Header expression is illustrated in Example 11.

Example 11 – CCR XML Document Header

```
<ContinuityOfCareRecord xmlns="urn:astm-org:CCR"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:astm-org:CCR CCR1.0.xsd">
```

(2) The Header Tag Attributes are:

(a) xmlns—This defines the XML namespace.

(b) xmlns:xsi—This defines the xsi and must state "http://www.w3.org/2001/XMLSchema-instance."

A2.5.2.2 *<CCRDocumentObjectID>*

(1) <CCRDocumentObjectID> is required and is the unique ID that applies to the entire CCR. The <CCRDocumentObjectID> is generated by the originating entity/system (aka an <Actor>) to uniquely identify each explicit instance of a CCR. The uniqueness of this ObjectID is defined within the generating system and must be unique to a CCR and should

ideally be unique across the universe of all CCRs through the use of a UUID, OID, or other generally accepted unique ID mechanism.

(2) The uniqueness of a CCR in the universe of CCRs is enhanced through the combination of the <CCRDocumentObjectID>, the CCR <DateTime>, and the <Patient>. However, to make the CCR truly and irrevocably unique, a digital signature and hash should be incorporated within the footer section <Signatures>. In combination with the <CCRDocumentObjectID>, the CCR <DateTime>, and the <Patient> identifiers a digital signature will make any CCR instance truly unique.

Example 12 – <CCRDocumentObjectID>

<CCRDocumentObjectID>**19099377737**</CCRDocumentObjectID>

A2.5.2.3 *<Language>*

(1) <Language> is required and refers to the actual language used to generate the CCR and which the CCR is expressed in. <Language> is a CodedDescriptionType and the language should ideally be expressed in a controlled and encoded vocabulary. At a minimum it must express the language as a text string, as in Example 12a, although this usage is discouraged. ASTM will define explicit vocabulary pointers to use in future versions of the CCR Standard.

Example 12a – <Language>

<Language><Text>**English**</Text></Language>

A2.5.2.4 *<Version>*

(1) <Version> is required and refers to the version of the CCR Implementation Guide that is used to create a given instance of a CCR. <Version> is of type xs:string and for this version of the CCR must be expressed as "V1.0", as in Example 12b.

NOTE A2.6—One may think that this tag is redundant due to subsequent versions of the CCR having a different XSD and therefore the SchemaLocation would suffice for versions. This is not the case because future versions may add additional constraints in the implementation guide but not change the XSD.

Example 12b – <Version>

<Version>**V1.0**</Version>

A2.5.2.5 *<DateTime>*

(1) <DateTime> is required and refers to the exact time the data on a specific patient were aggregated to create a CCR, which is not necessarily the time the CCR was transmitted, printed, or sent. This CCR Document <DateTime> applies to the entire CCR and is the exact <DateTime> the data within the CCR were collected and aggregated.

(2) CCR Document <DateTime> must be expressed in ISO-8601 date-time format, with precision to include seconds and must include a UTC offset. All date times expressed in Hours, Minutes, and/or Seconds in the CCR must express a time zone offset, either using Z [Universal Coordinated Time], or an offset in hours and minutes. The CCR further requires that the time zone offset be a legal time zone. This latter constraint cannot be expressed in the schema, as time zones are determined by political entities [e.g., Nations or States]. There presently exist time zones in the form ##:15 and ##:30. CCR <DateTime> time should ideally come from a net-based atomic time service and not from an individual computing device's internal clock.

(3) The ISO-8601 standard defines the time string as CCYY-MM-DDThh:mm:ss-hh:mm. 2005-01-25-T12:15:37-09:00 represents January 25, 2005 12:15:37 PST (Pacific Standard Time), which is minus (-) 9 hours from Universal Coordinated Time). This exact time can also be expressed as Universal Coordinated Time as 2005-01-25-T21:15:37Z, which represents January 25, 2005 21:15:37 Universal Coordinated Time.

Example 13 – CCR Document <DateTime>

<DateTime><ExactDateTime>**2005-01-25-T12:15:37-09:00**
</ExactDateTime></DateTime>

A2.5.2.6 *<Patient>*

(1) <Patient> is required and identifies the patient to which the CCR refers. This is a link to <Actor> through an <ActorID> of type xs:string. The actual name and detailed data about this patient are not contained under <Patient>.

(2) Detailed data on each <Actor> is maintained in the <Actors> Section in the CCR Footer. The corresponding <Actor> in the <Actors> section of the CCR Footer is identified by an <ActorObjectID>, which is of type xs:string.

(3) The CCR can be about only one patient with the rare exception of Siamese Twins, where it can contain data on two patients. Patient cardinality, therefore, must be at least 1, and at most 2, in the rare case of Siamese Twins. Other than within that rare exception, the CCR is a snapshot in time of the clinical, demographic, and administrative data of a unique patient.

Example 14 – <Patient>

```
<Patient>
  <ActorID>________</ActorID>
</Patient>
```

A2.5.2.7 *<From>*

(1) <From> is required and bounded to one instance (1..1) to represent one or multiple sources for the CCR. <From> identifies who or what has generated the CCR. This is an ID link to an Actor through <ActorID> of type xs:string and also defines the healthcare role <ActorRole> that the actor is playing when generating the CCR. An Actor and the Role must be specified under <From>. An <ActorLink> with an <ActorID> and <ActorRole> is required and multiple <Actorlink> tags can be used to represent multiple sources for the CCR. <ActorLink> is unbounded (1..∞).

(2) <ActorRole> is a CodedDescriptionType. This Implementation Guide does not currently specify a code set for <ActorRole>, so the CodedDescriptionType in this case is used as a free text container with the text string under <Text> defining the actual <ActorRole>. All efforts will be made to specify an appropriate code set and set of coded values to use for <ActorRole> in future releases of the CCR Standard.

(3) The following example illustrates a CCR generated by (<From>) the patient's primary care provider's EHR system. Note that both the originating healthcare provider and EHR are referenced in this use case.

Example 15 – <From>

```
<From>
  <ActorLink>
    <ActorID>________</ActorID>
    <ActorRole><Text>Primary
Care Provider</
Text></ActorRole>
  </ActorLink>
  <ActorLink>
    <ActorID>________</ActorID>
<ActorRole><Text>Care
Facility</Text></
ActorRole>
</ActorLink>
<ActorLink>
  <ActorID>________</ActorID>
    <ActorRole><Text>EHR
System</Text></
ActorRole>
  </ActorLink>
</From>
```

A2.5.2.8 *<To>*

(1) <To> is optional and bounded to one instance (0..1). It identifies to whom or what the CCR is targeted, and it is an ID link to an <Actor> through an <ActorID>. In addition to <ActorID> the role played in the patient's care should be defined for <To> using <ActorRole>. Multiple <ActorLink> tags can be used to represent multiple recipients for the CCR. <ActorLink> is required and unbound (1..∞).

Example 16 – <To>

```
<To>
  <ActorLink>
    <ActorID>________</ActorID>
    <ActorRole><Text>Long Term Care Facility</Text></ActorRole>
  </ActorLink>
<ActorLink>
<ActorID>________</ActorID>
<ActorRole><Text>Primary Care Provider</Text></ActorRole>
</ActorLink>
</To>
```

(2) It should also be noted that the <Patient> in some cases may be the <Actor> who is either sending <From> or receiving <To> the CCR when the patient wishes to use the CCR as the basis for a Personal Health Record (PHR).

A2.5.2.9 *<Purpose>*

(1) <Purpose> is optional and unbounded. It is a Complex Data Type of PurposeType and is illustrated in Fig. A2.8.

(2) <Purpose> defines a specific reason that a CCR is generated. Note that the general use case of the CCR does not require a <Purpose>. <Purpose> should be utilized, however, when the CCR has a specific purpose such as patient admission, transfer, consult/referral, or inpatient discharge. <Purpose> is defined in Table A2.5.

(3) Note that if the system generating the CCR can only create a text string as the <Purpose>, and that text string must be placed under <Description><Text> and cannot be placed under <Comment>. To reiterate <Comment> is for legitimate comments and cannot be used for data that belong in structured tags.

Example 17 – <Purpose>

```
<Purpose>
  <DateTime>
    <DateTimeRange>
      <BeginRange>
        <ExactDateTime>2005-01-25</ExactDateTime>
      </BeginRange>
      <EndRange>
        <ExactDateTime>2005-02-25</ExactDateTime>
      </EndRange>
    </DateTimeRange>
  </DateTime>
  <Description>
    <Text>Cardiology Follow-Up</Text>
  </Description>
</Purpose>
```

A2.5.3 *CCR Body and Data Objects*—The core patient-specific data contained within the CCR is within the Body of the CCR Document Object. A CCR without a <Body> is invalid. The patient-specific data objects within the CCR Document Object are contained within the tag <Body>. <Body> is comprised of sections, which contain the discrete data objects that make up the core elements and content of the CCR. All of the data objects are contained within an appropriate CCR <Body> section tag. The tags for the data objects

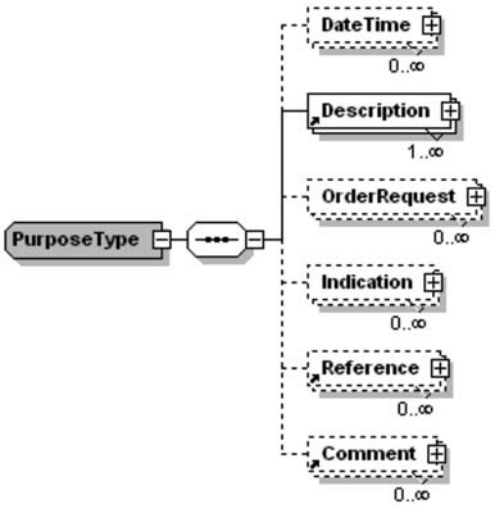

FIG. A2.8 Complex Data Type PurposeType

TABLE A2.5 PurposeType Definition Table

PurposeType	Accepted Values/Formatting	Optionality/Cardinality	Description
<DateTime>	DateTimeType	Optional and Bounded To One Instance (0..1).	Defines a DateTime, if applicable, when the <Purpose> is intended to occur. For a CCR with a <Purpose> defined as a request for consult, a range of time (e.g., within two weeks) may be specified, or ASAP, or Today, or a specific date or specific date and time. The same would hold true for a request for procedure, request for follow-up, request for authorization, etc.
<Description>	CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings.	Required and Unbounded (1.. ∞).	Used to provide a text string or structured and coded <Description> of the <Purpose>. Examples: Request For Consult, Request For Procedure, Request for Service, Request for Encounter, Request for Authorization, Request for Medical Device or Product, Request for Medication, Request for Immunization, For Patient Use (e.g. a PHR).
<OrderRequest>	See <OrderRequest> under <PlanOfCare>.	Optional and Unbounded (0.. ∞).	Used to define a specific <OrderRequest> as the <Purpose> of the CCR.
<Indication>	IndicationType, see <Indication> under <Medications>/<Product>.	Optional and Unbounded (0.. ∞).	Used to define a specific <Indication> as the <Purpose> of the CCR, usually a diagnosis or problem.
<ReferenceID>	This is a link to a <Reference>.	Optional and Unbounded (0.. ∞).	Used to link the <Purpose> to an outside document or record.
<CommentID>	This is a link to a <Comment>.	Optional and Unbounded (0.. ∞).	This is restricted to legitimate comments only. It is NOT to be used to contain any data that correctly belong under <Description>, <OrderRequest>, or <Indication>.

(data items) within the CCR <Body> are defined in Table A2.6. Each one of these sections is optional and bound to one instance (0..1). Sections are required only when they contain data. The CCR XML Schema is normalized and uses a number of generalized tags and tag sets to simplify and shorten the XML Schema and simplify its maintenance and management as a standard. These will be defined before the discrete data objects are described.

A2.5.3.1 *CCRCodedDataObjectType*—All CCR data objects share a set of common characteristics, most of which are defined in the CCR XML Schema as a base type CCRCodedDataObjectType, which is illustrated in Fig. A2.9. The elements that make up a CCRCodedDataObjectType are defined below.

(1) <CCRDataObjectID>

(a) <CCRDataObjectID> is required. All data objects in the CCR must have a unique object ID.

(b) The ObjectIDs must be unique within the CCR but do not require any uniqueness in the universe outside a specific instance of the CCR.

(c) <CCRDataObjectID> is of type xs:string.

TABLE A2.6 CCR <Body> Data Objects

Data Object Tag	Description
<Payer>	Contains Payer information and basic eligibility data
<AdvanceDirectives>	Contains Advance Directives and resuscitation data
<Support>	Contains support persons and organizations relevant to patient
<FunctionalStatus>	Contains information relating to the patient's functional status and activities of daily living (ADL)
<Problems>	Contains Problems
<FamilyHistory>	Contains a pertinent or relevant Family Health History
<SocialHistory>	Contains a pertinent Social History, such as occupation, marital status, smoking history and other social history and risk factors
<Alerts>	Contains the patient's allergies, adverse reactions, and other alerts (for example, enzyme or metabolic pathway deficiencies, pertinent clinical warnings and precautions, and critical lab or result values)
<Medications>	Contains the patient's current medications and pertinent medication history
<MedicalEquipment>	Contains the patient's medical devices and durable medical equipment (DME)
<Immunizations>	Contains the patient's Immunization status/history
<VitalSigns>	Contains the patient's pertinent Vital Signs
<Results>	Contains the patient's pertinent Results (lab, imaging, interventional)
<Procedures>	Contains a history of the patient's pertinent clinical procedures
<Encounters>	Contains a history of the patient's pertinent healthcare encounters and pending appointments
<PlanOfCare>	Contains all pending orders or other pertinent pending Plan Of Care items including 'Reminders' designed for systems that utilize clinical decision support; it is limited to prospective plans and may not include those from the past
<HealthCareProviders>	Contains the patient's relevant healthcare providers (primary provider(s), specialist(s))

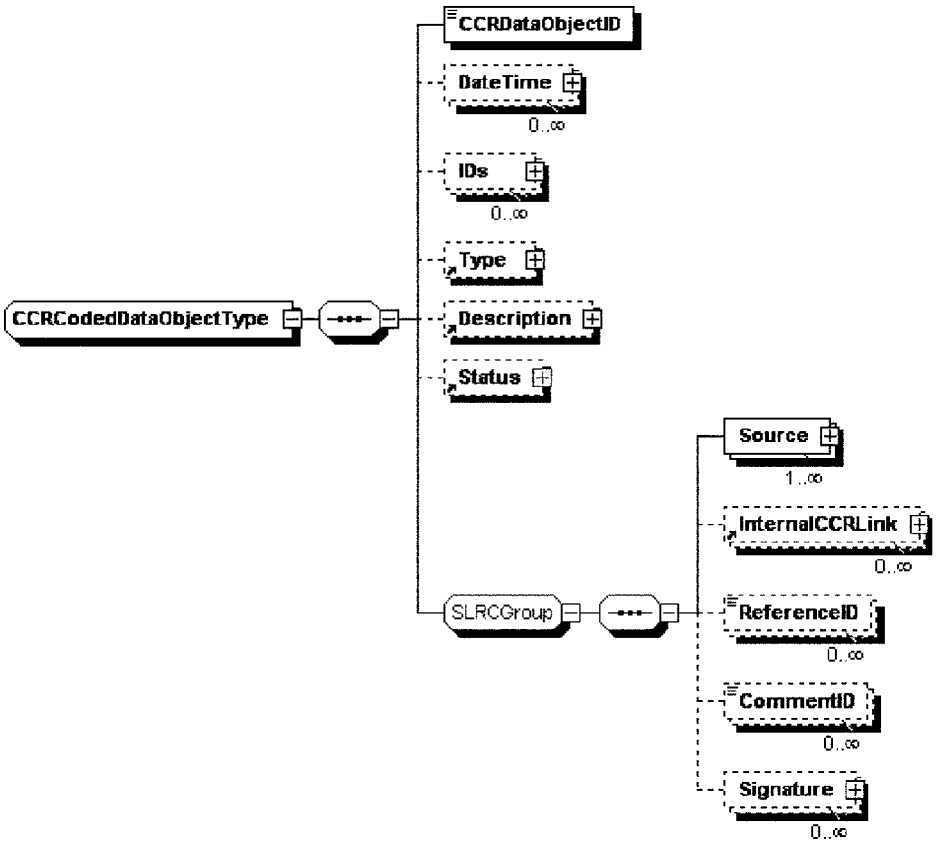

FIG. A2.9 CCRCodedDataObjectType

Example 18 – <CCRDataObjectID>

```
<CCRDataObjectID>5bK74635Hy-.9_uu7K</CCRDataObjectID>
```

(2) <DateTime>

(a) <DateTime> is optional and unbound. It is a DateTimeType and is used to express one or more dates/times relevant to the data object.

Example 19 – Data Object <DateTime>

```
<DateTime>
  <Type>
    <Text>Age At Onset</Text>
  </Type>
  <Age>
    <Value>35</Value>
    <Units><Unit>Years</Unit></Units>
  </Age>
</DateTime>
```

(3) <Type>

(a) <Type> is optional and is a CodedDescriptionType used to express a <Type> relevant to the data object.

Note—<Type> is not intended to be explicitly linked to codes under <Description>. Its intent is for sorting and filtering, and it will in the future have its own defined controlled vocabulary source terminology.

Example 20 – Data Object <Type>

```
<Type>
  <Text>Diagnosis</Text>
</Type>
```

(4) <Description>

(a) <Description> is optional and is a CodedDescriptionType used to describe the concept in the data object as a text string or (preferred) as structured and encoded object-oriented data.

Example 21 – Data Object <Description>

```
<Description>
  <ObjectAttribute>
    <Attribute>Diagnosis</Attribute>
      <AttributeValue>
        <Value>Myocardial Infarction</Value>
        <Code>
          <Value>22298006</Value>
          <CodingSystem>SNOMED CT</CodingSystem>
          <Version>20050131</Version>
        </Code>
      </AttributeValue>
  </ObjectAttribute>
  <ObjectAttribute>
    <Attribute>Acuity</Attribute>
      <AttributeValue>
        <Value>Acute</Value>
        <Code>
        <Value>53737009</Value>
        <CodingSystem>SNOMED CT</CodingSystem>
        <Version>20050131</Version>
      </Code>
    </AttributeValue>
  </ObjectAttribute>
  <ObjectAttribute>
    <Attribute>Site</Attribute>
    <AttributeValue>
      <Value>Antereoseptal</Value>
```

```
      <Code>
        <Value>20706007</Value>
        <CodingSystem>SNOMED CT</CodingSystem>
      <Version>20050131</Version>
    </Code>
    </AttributeValue>
  </ObjectAttribute>
  <Code>
    <Value>410.1</Value>
    <CodingSystem>ICD-9 CM</CodingSystem>
    <Version>2004</Version>
  </Code>
</Description>
```

(5) <Status>

(a) <Status> is optional and is a CodedDescriptionType used to express a <Status> relevant to the data object.

Example 22 – Data Object <Status>

```
<Status>
  <Text>Active</Text>
</Status>
```

(6) <Source>

(a) <Source> is unbound and required of all CCRDataObjects so that any data within the CCR can be validated as to its origin/source. It is used to define one or more sources for the data object. It is illustrated in Fig. A2.10 and must be a link to one or more <Actor>, <Reference>, or <Comment>, or it must state under <Description><Text> that the <Source> is 'Unknown' as illustrated in the following example:

Example 23 – <Source> Unknown

```
<Source>
  <Description><Text>Unknown</Text></Description>
</Source>
```

(b) <DateTime> under <Source> is optional and is used to define an <ExactDateTime> that the <Source> generated the data object. This is recommended to be included with <Source> as it provides critical clinical knowledge assistance as to how current or recent historically a given data object is.

(7) <InternalCCRLink>

(a) <InternalCCRLink> is optional and is used to link one CCR data object to another CCR data object. Note that this link is internal within the CCR and is not from one CCR to another CCR. External links, that is, outside the CCR, are defined under <Reference>.

(b) <InternalCCRLink> consists of <LinkID>, which is required and is of type xs:string. <LinkID> points to a <CCRDataObjectID> of type xs:string as defined in A2.5.3.1(1). <LinkRelationship> is optional and defines the relationship between the two data objects relative to this link. <Source> is optional, is of type SourceType, and defines the <Source> of the <InternalCCRLink>. It is used to define whom/what established that there was an <InternalCCRLink> between these two data items and what the <LinkRelationship> is. <InternalCCRLink> is defined in detail at the end of this Implementation Guide.

(8) <ReferenceID>

(a) <ReferenceID> is optional and consists of a link, which is an xs:string to a <ReferenceObjectID> in the <References> section in the CCR Footer. <Reference> is a link to a source external to the CCR and is not to be confused with the <InternalCCRLink>. <Reference> is defined in detail under the CCR Footer section of this Implementation Guide.

(9) <CommentID>

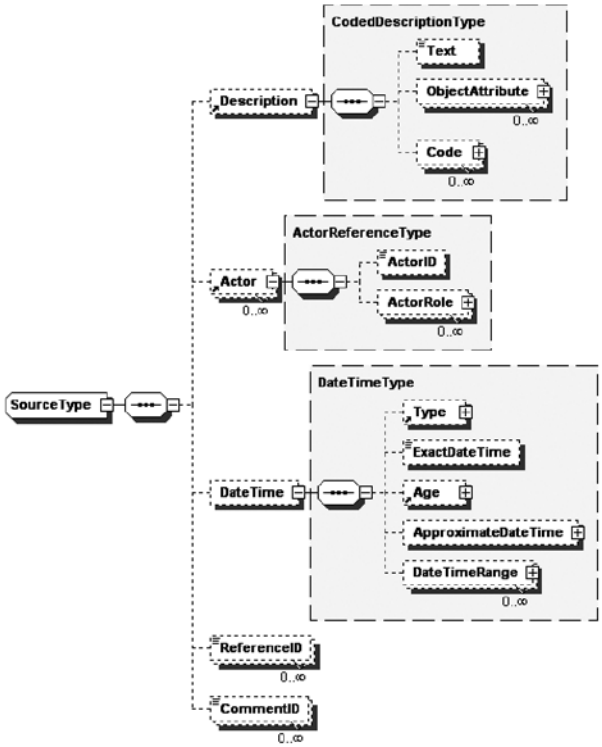

FIG. A2.10 SourceType

(a) <CommentID> is optional and consists of a link, which is an xs:string to a <CommentObjectID> in the <Comments> section in the CCR Footer. <Comment> is defined in detail under the CCR Footer section of this Implementation Guide.

A2.5.4 *CCR <Body> Sections*:

A2.5.4.1 *<Payers>*

(1) <Payers> contains data on the patient's payer, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination of payers. <Payers> is used to define which entity is the responsible fiduciary for the financial aspects of a patient's care. A patient may have one health plan or many, may have no insurance and be self-pay, or may have a Health Savings Account (HSA) with catastrophic insurance and is otherwise insured or self-pay for the balance.

(2) <Payer> is required and unbound (1..∞) and can be used for one or more health plans, worker's compensation, auto insurance, pharmacy benefit manager (PBM), or other pertinent benefit plans, or to list self-pay. At a minimum, the patient's pertinent current payment sources should be listed. <Payers> is illustrated in Fig. A2.11.

(3) Also contained within the <Payer> data object is <Authorizations>, which can be used to define pertinent referral, authorization tracking number, procedure, therapy, intervention, device, or similar authorizations for the patient or provider, or both. Authorizations are particularly pertinent to the referral, long-term care, inpatient, and procedure-based/surgical uses for the CCR. <Authorizations> within <Payer> are approved <Authorizations>, not requests for <Authorization>. Requests for <Authorizations> are contained within the <PlanOfCare> section in the CCR Body. The data fields in this CCR Data Object map to the appropriate eligibility and related electronic standards incorporated as the 'Final Rule' in the Codes and Transactions Rules promulgated by the federal HIPAA initiatives under 'Administrative Simplification.'[12]

[12] The most recent modifications were published in the Federal Register on 2/20/2003.

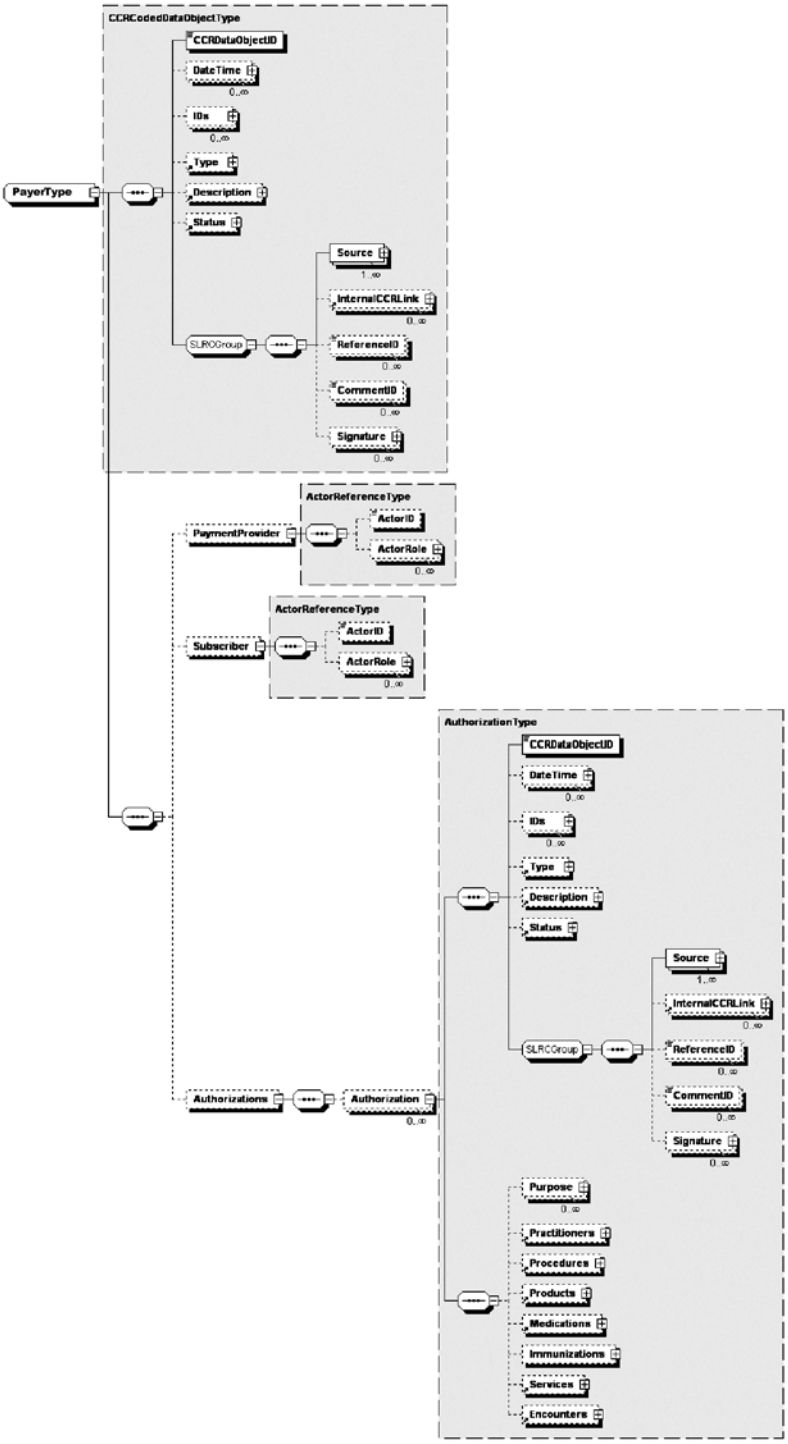

FIG. A2.11 <Payers> Data Object

(4) <Payers> is defined in Table A2.7:

TABLE A2.7 <Payers> Object Type Definition Table

<Payers>	Accepted Values/Formatting	Optionality/Cardinality	Description
<PaymentProvider>	A link to an <Actor> through <ActorID> of type xs:string with <ActorRole> as 'Payer'	Optional and Bounded to one instance (0..1)	Defines each unique instance of a payer: insurance or self-pay or other, and all the pertinent data needed to contact, bill to, and collect from that payer
<DateTime>	Instance of DateType that is restricted to an ExactTime and requires <Type> and <ExactDateTime>, which should be specified to at least the Year/Month/Day. <ExactDateTime> must be expressed as an ISO8601 DateTime	Optional and Unbounded (0.. ∞)	Used to define dates and times relevant to the payer and patient relationship; examples of <DateTimeType> are Benefit Start Date and Benefit Stop Date, used to define the Effective Period or Effective Date, Termination Date, or Renewal Date
<Type>	Instance of CodedDescriptionType	Optional and Bounded to one instance (0..1)	This is the type of payer: Healthcare HMO, Healthcare PPO, Healthcare Indemnity, Auto, Worker's Compensation
<Subscriber>	This is a link to an Actor through <ActorID> of type xs:string and also defines the role as <ActorRole> that the <Subscriber> plays	Optional and Bounded to one instance (0..1)	Defines the subscriber of the health plan or benefit
<IDNumber>	Instance of IDType – see IDType under <Actors>	Optional and Unbounded (0.. ∞)	Examples are Subscriber Number, Member Number (if patient is not subscriber), Plan Number, Group Number, Plan Code, and the like
<Authorization>	Instance of AuthorizationType	Optional and Unbounded (0.. ∞)	Can contain all of the specific data regarding an authorization as well as regarding what is authorized or a link to an internal CCR data object that is 'authorized' through this <Authorization>

Example 24 – Data Object <Payers>

```
<Payers>
<Payer>
 <CCRDataObjectID>___________</CCRDataObjectID>
 <DateTime>
  <Type>
   <Text>Effective Date</Text>
  </Type>
  <ExactDateTime>2005-01-01</ExactDateTime>
 </DateTime>
 <IDs>
   <Type><Text>Subscriber Number</Text></Type>
   <ID>555-55-5555</ID>
<Source>
 <Actor>
  <ActorID>75871</ActorID>
  <ActorRole><Text>Patient</Text></ActorRole>
 </Actor>
</Source>
 </IDs>
 <IDs>
   <Type><Text>Group Number</Text></Type>
   <ID>H7X8A5</ID>
<Source>
 <Actor>
  <ActorID>75871</ActorID>
  <ActorRole><Text>Patient</Text></ActorRole>
 </Actor>
</Source>
 </IDs>
 <IDs>
   <Type><Text>Plan Code</Text></Type>
   <ID>520</ID>
<Source>
 <Actor>
  <ActorID>75871</ActorID>
  <ActorRole><Text>Patient</Text></ActorRole>
 </Actor>
</Source>
 </IDs>
 <Type>
  <Text>Supplemental Health Insurance</Text>
 </Type>
<Source>
 <Actor>
  <ActorID>75871</ActorID>
  <ActorRole><Text>Patient</Text></ActorRole>
 </Actor>
</Source>
 <PaymentProvider>
  <ActorID>__________<</ActorID>
 </PaymentProvider>
 <Subscriber>
  <ActorID>__________</ActorID>
  <ActorRole><Text>Spouse</Text></ActorRole>
 </Subscriber>
 <Authorizations>
  <Authorization>
<CCRDataObjectID>___________</CCRDataObjectID>
   <DateTime>
    <Type>
     <Text>Approval Date</Text>
    </Type>
    <ExactDateTime>2004-12-16</ExactDateTime>
   </DateTime>
 <IDs>
   <Type><Text>Plan Code</Text></Type>
   <ID>520</ID>
<Source>
 <Actor>
  <ActorID>75871</ActorID>
  <ActorRole><Text>Patient</Text></ActorRole>
 </Actor>
</Source>
</IDs>
  <Type><Text>Referral</Text></Type>
 <Status>
  <Text>Approved</Text>
 </Status>
<Source>
 <Actor>
  <ActorID>75871</ActorID>
  <ActorRole><Text>Patient</Text></ActorRole>
 </Actor>
</Source>
 <Encounters>
  <Encounter>
<CCRDataObjectID>___________</CCRDataObjectID>
<Status>
  <Text>Approved</Text>
 </Status>
<Source>
 <Actor>
  <ActorID>75871</ActorID>
  <ActorRole><Text>Patient</Text></ActorRole>
 </Actor>
</Source>
  <Practitioners>
   <Practitioner>
    <ActorID>__________</ActorID>
    <ActorRole><Text>Physical Therapy</Text></ActorRole>
   </Practitioner>
  </Practitioners>
   <Frequency>
     <Value>5</Value>
     <Units><Unit>Visits</Unit></Units>
   </Frequency>
   <Indications>
    <Indication>
<Source>
 <Actor>
  <ActorID>75871</ActorID>
  <ActorRole><Text>Patient</Text></ActorRole>
 </Actor>
</Source>
     <InternalCCRLink>___________</InternalCCRLink>
    </Indication>
   </Indications>
 </Encounter>
</Encounters>
  </Authorization>
 </Authorizations>
</Payer>
</Payers>
```

A2.5.4.2 *<AdvanceDirectives>*

(1) <AdvanceDirectives> is required (if known) in the general use case (requirement is otherwise use-case specific) and bound to one instance (0..1). The <AdvanceDirective> child element is required and unbound (1..∞) and contains data defining the patient's advance directive and any reference to any existing supporting documentation and the physical location of that documentation, such as a durable power of attorney for healthcare. The most recent and up-to-date Advance Directives should be listed in as much detail as possible, and if advance directives are available, they must be included. This section contains data such as the existence of living wills, healthcare proxies, CPR and resuscitation status, etc.

(2) <AdvanceDirective> is a CCRCodedDataObjectType as illustrated in Fig. A2.12.

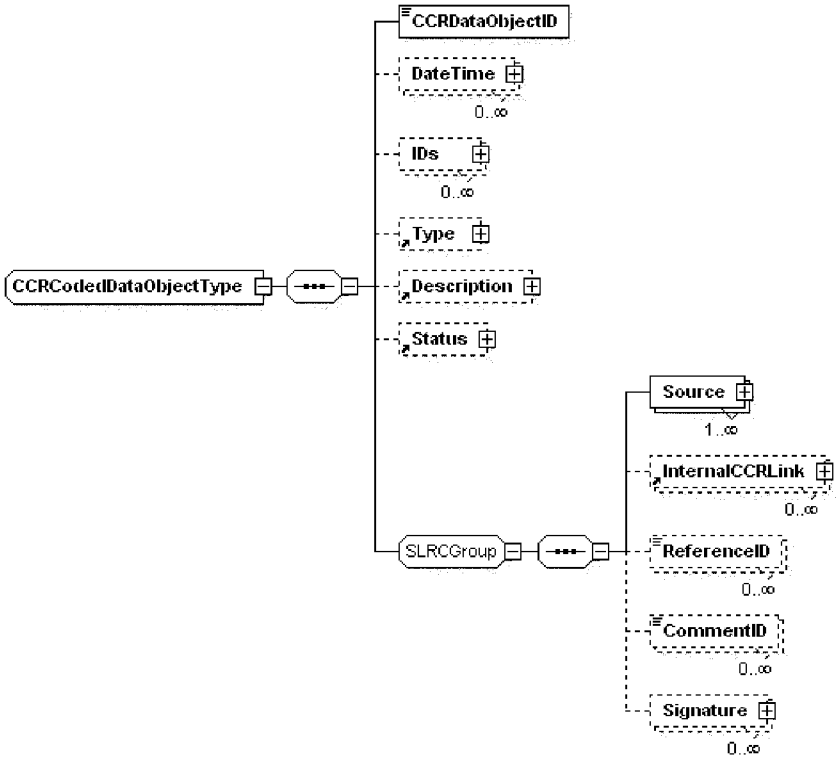

FIG. A2.12 <AdvanceDirective> Data Object

(3) <AdvanceDirectives> is defined in Table A2.8.

TABLE A2.8 <AdvanceDirective> Object Type Definition Table

<Advance Directives>	Accepted Values/Formatting	Optionality/ Cardinality	Description
<DateTime>	Instance of DateType that is restricted to an ExactTime and requires <Type> and <ExactDateTime>. <ExactDateTime> should be specified to at least the Year/Month/Day. <ExactDateTime> must be expressed as an ISO8601 DateTime.	0..∞	This should list the DateTime that the Advance Directive was last recorded or verified, or both, and any relevant applicable dates or ranges (applicable from Date A____ to Date B____). DateTime <Type> should express Last Recorded, Verified With Patient, Verified With Parent, Verified With Guardian, Verified With Family, Verified With Durable Power Of Attorney for Healthcare, Verified With Treating Physician, Start Date, End Date.
<Type>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Resuscitation Status, Intubation Status, IV Fluid and Support Status, CPR Status, Antibiotic Status, Life Support Status, Tube Feedings, Other.	0..1	Defines the <AdvanceDirective><Type>.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	0..∞	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Description>	An instance of CodedDescriptionType	0..1	Used to describe the <AdvanceDirective>. Full Code, No Code, No CPR, Cardioversion Only, CPR Drugs Only, No Intubation, IV Fluids Only, No IV Fluids, Antibiotics Only, No Antibiotics, Tube Feedings, No Feeding Tube, No Prolonged Life Support.
<Status>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Current and Verified, Supported By Healthcare Will, Supported By Durable Power of Attorney for Healthcare, Verified With Patient, Verified With Family Only, Verified By Medical Record Only.	0..1	This defines the status of the Advance Directive.

Example 25 – Data Object <AdvanceDirective>

```
<AdvanceDirective>
 <CCRDataObjectID>___________</CCRDataObjectID>
 <DateTime>
  <Type>
   <Text>Verification Date</Text>
  </Type>
  <ExactDateTime>2004-09-01T13:25:34-05:00</ExactDateTime>
 </DateTime>
 <Type>
  <Text>Resuscitation Status</Text>
 </Type>
 <Description>
  <Text>Full Code</Text>
 </Description>
 <Status>
  <Text>Verified With Patient</Text>
 </Status>
</AdvanceDirective>
```

A2.5.4.3 *<Support>*

(1) <Support> is optional and bound to one instance (0..1). The child element <SupportProvider> is required and unbounded (1..∞) and contains data defining the patient's support providers and contacts – family, 'next of kin,' legal guardian, durable power for healthcare, clergy, caregivers, support organizations – at the time the CCR is generated.

(2) This is a link to an Actor through <ActorID> of type xs:string and also defines the role <ActorRole> that the actor is playing when generating the CCR. An Actor and their Role must be specified under <Support>.

(3) This data object is not used for listing a patient's healthcare providers, which are listed under the <HealthCareProviders> Section within the CCR Body, with the exception that 'Care Giver' should be listed under <Support>. At a minimum, the patient's key support contacts relative to healthcare decisions, including next of kin, and direct care and patient transport should be listed here.

(4) <Support> is illustrated in Fig. A2.13.

Example 26 – Data Object <Support>

```
<Support>
  <SupportProvider>
    <ActorID>________</ActorID>
    <ActorRole><Text>Mother</Text></ActorRole>
</SupportProvider>
</Support>
```

A2.5.4.4 *<FunctionalStatus>*

(1) <FunctionalStatus> is optional and bound to one instance (0..1). The child element <Function> is required and unbounded (1..∞) and contains data defining the patient's functional status—competency, ambulatory status, ability to care for self, activities of daily living—at the time the CCR is generated. Function is essentially a subset of ProblemType (see <Problem> in A2.5.4.5(1)), in that functional problems are essentially clinical problems for the patient. They are specifically defined within the CCR <FunctionalStatus> section, as separate from other clinical problems.

(2) <Function> is illustrated in Fig. A2.14.

Example 27 – Data Object <Function>

```
<FunctionalStatus>
 <Function>
 <CCRDataObjectID>___________</CCRDataObjectID>
 <DateTime>
  <Type>
   <Text>Date Of Onset</Text>
  </Type>
  <Age>
   <Value>83</Value>
   <Units><Unit>Years</Unit></Units>
  </Age>
 </DateTime>
  <Type><Text>Mental Status</Text></Type>
 <Description>
  <Text>Does Not Respond To Command</Text>
 </Description>
 <Status><Text>Chronic</Text></Status>
<Source>
 <Actor>
  <ActorID>75307</ActorID>
  <ActorRole><Text>Primary Care Provider</Text></ActorRole>
 </Actor>
</Source>
</Function>
</FunctionalStatus>
```

A2.5.4.5 *<Problems>*

(1) <Problem> is optional and bound to one instance (0..1). The child element <Problem> is required and unbounded (1..∞). It contains data defining the patient's relevant clinical problems, conditions, diagnoses, symptoms, findings, and complaints at the time the CCR is generated. At a minimum, a CCR should contain all pertinent current and historical problems relevant to that patient at the point in time a CCR is generated and relative to the <Purpose> of that instance of a CCR. In the special case that the CCR is being created for a referral, each <Problem> should be listed in order of importance for the referral purpose. Otherwise, reverse chronological order of onset should prevail.

(2) Problem is an instance of the Complex Data Type ProblemType, which, for example, is also used within <FunctionalStatus>, <FamilyHistory>, <Indication>, and other pertinent data objects in the CCR.

(3) <Problem> is illustrated in Fig. A2.15.

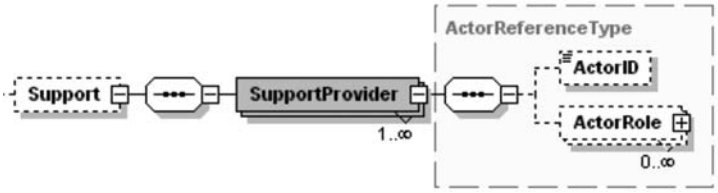

FIG. A2.13 Data Object <Support>

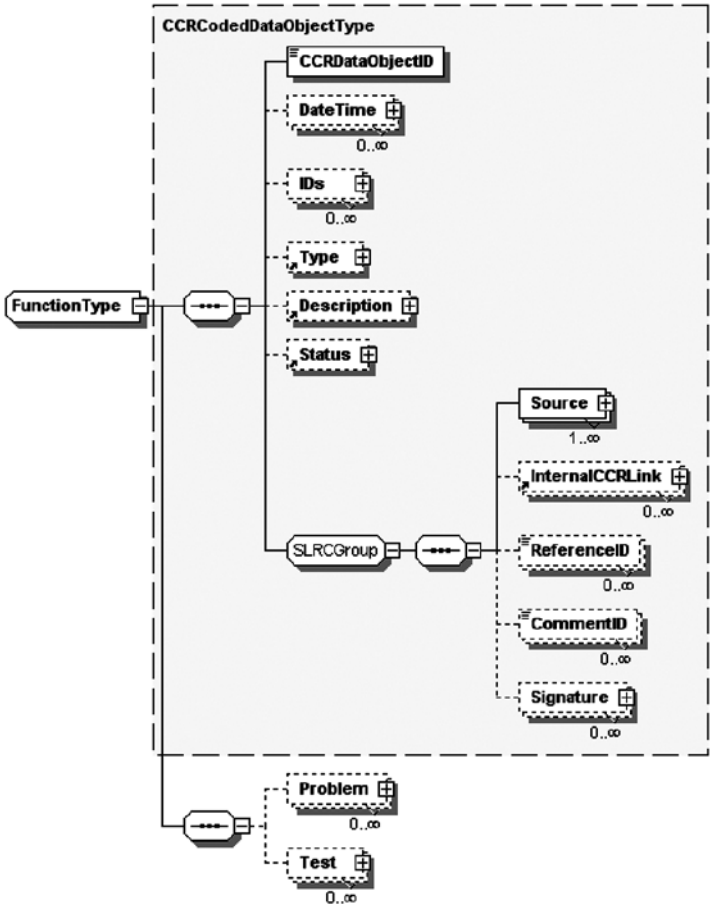

FIG. A2.14 Data Object <Function>

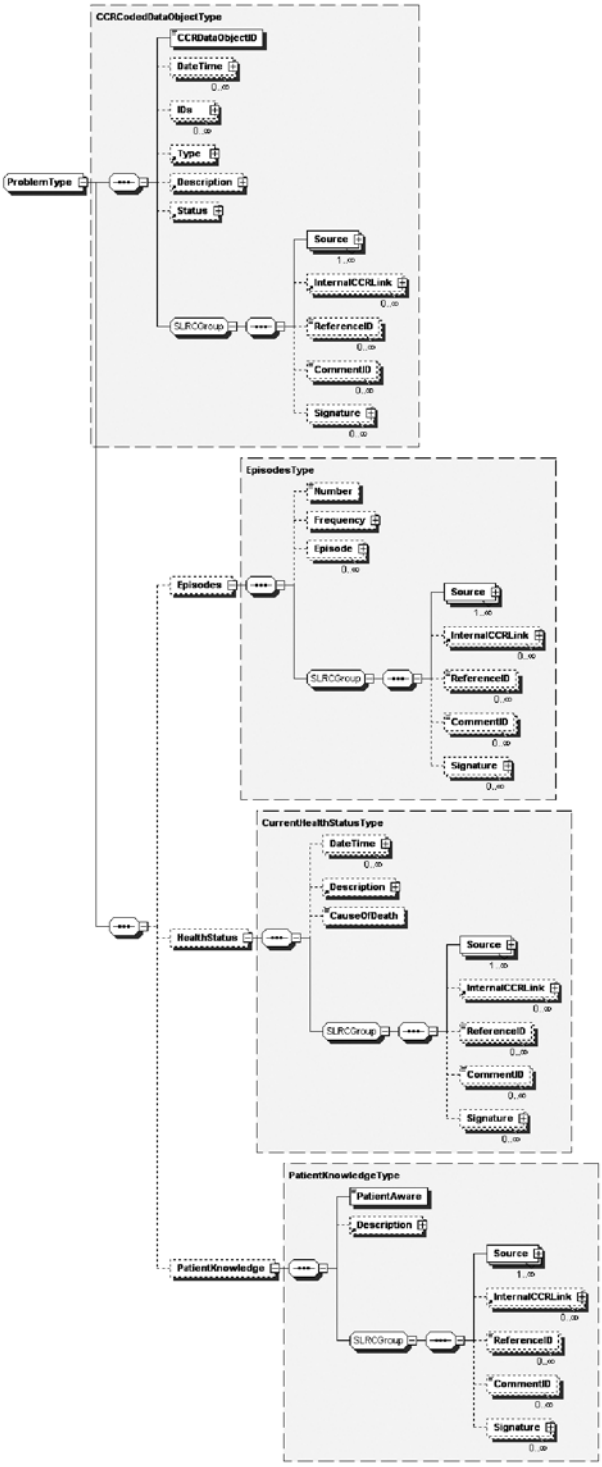

FIG. A2.15 Data Object <Problem>

(4) <Problem> is defined in Table A2.9.

TABLE A2.9 <Problem> Object Type Definition Table

<Problem>	Accepted Values/Formatting	Optionality/Cardinality	Description
<DateTime>	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Optional and Unbounded (0..∞).	Used to define dates and times relevant to the patient's <Problem>. Date of Onset, From Date A___ To Date B____, Since Age___, etc.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Type>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Problem, Condition, Diagnosis, Symptom, Finding, Complaint, Functional Limitation.	Optional and Bounded to one instance (0..1).	Defines the <Problem><Type>.
<Description>	An instance of CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. It is recommended that, when possible, all problems be coded (ICD-9CM, ICD-10, or SNOMED, or both).	Optional and Bounded to one instance (0..1).	Myocardial Infarction, Nausea, Headache, Parkinson's Disease, etc.
<Status>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Active, Inactive, Chronic, Intermittent, Recurrent, Rule Out, Ruled Out, Resolved.	Optional and Bounded to one instance (0..1).	Defines the <Status> of the <Problem>.
<Episodes>	<Episodes> has children <Number> (0..1), <Frequency> (0..1), <Episode> (0..∞), and <Duration> (0..1).	Optional and Bound to one instance (0..1).	Used to define one or more occurrences of a problem. Episodes should be listed for recurrent or repetitive problems, conditions, diagnoses, or symptoms, rather than listing a problem multiple times in the problem list.
<HealthStatus>	Has children <DateTime> (0..∞), <Description> (0..1), <CauseOfDeath> (0..1). <DateTime> can be an Exact DateTime, an age, an approximate DateTime, or a DateTime range. <Description> and <CauseOfDeath> are instances of Coded DescriptionType with restricted content that must be one of the defined structured text values.	Optional and Bound to one instance (0..1).	Used to define the health status of the Actor whom the problem applies to (used more commonly in Family History). <Description> is an instance of a CodedDescriptionType and is confined to the values: Alive And Well, In Remission, Symptom Free, Ill, Chronically Ill, Severely Ill, Critical, Terminal, Disabled, Severely Disabled, Deceased; <CauseOfDeath> defines if this condition was the cause of death of the Actor whom the problem applies to – values are Yes, No, Unknown; <DateTime> is an instance of DateType and could be an exact date or date/time, an age, or an approximate date. <DateTime> is used to set the <DateTime> that applies to the <HealthStatus> and is also used to record the 'Time of Death' for problems that are a <CauseOfDeath>.
<PatientKnowledge>	<PatientKnowledge> has children <PatientAware> (0..1) and <Description> (0..1).	Optional and Unbounded (0..1).	Used to define whether or not the patient is aware of a <Problem> and any reason why they are not aware. <PatientAware> restricted to Yes, No, Unknown. <Description> is a CodedDescriptionType with restricted content that must be one of the defined structured text values: Patient Request Not To Know, Family Request For Patient Not To Know, Durable Power Request For Patient Not To Know.

Example 28 – Data Object <Problem>


```
<Problem>
 <CCRDataObjectID>___________</CCRDataObjectID>
 <DateTime>
  <Type>
   <Text>Date of Onset</Text>
  </Type>
  <ExactDateTime>2004-09-01T13:25:34-05:00</ExactDateTime>
 </DateTime>
 <Type>
  <Text>Diagnosis</Text>
 </Type>
 <Description>
  <ObjectAttribute>
  <Attribute>Diagnosis</Attribute>
  <AttributeValue>
   <Value>Myocardial Infarction</Value>
   <Code>
    <Value>22298006</Value>
    <CodingSystem>SNOMED CT</CodingSystem>
    <Version>20050131</Version>
   </Code>
  </AttributeValue>
 </ObjectAttribute>
 <ObjectAttribute>
  <Attribute>Acuity</Attribute>
  <AttributeValue>
   <Value>Acute</Value>
   <Code>
    <Value>53737009</Value>
    <CodingSystem>SNOMED CT</CodingSystem>
    <Version>20050131</Version>
   </Code>
    </AttributeValue>
 </ObjectAttribute>
 <ObjectAttribute>
    <Attribute>Site</Attribute>
    <AttributeValue>
     <Value>Antereoseptal</Value>
     <Code>
      <Value>20706007</Value>
      <CodingSystem>SNOMED CT</CodingSystem>
      <Version>20050131</Version>
     </Code>
    </AttributeValue>
   </ObjectAttribute>
  <Code>
   <Value>410.1</Value>
   <CodingSystem>ICD-9 CM</CodingSystem>
   <Version>2004</Version>
  </Code>
 </Description>
 <Status>
  <Text>Resolved</Text>
 </Status>
<Source>
 <Actor>
  <ActorID>75307</ActorID>
<ActorRole><Text>Primary Care Provider</Text></ActorRole>
 </Actor>
</Source>
 <Episodes>
  <Number>2</Number>
  <Episode>
 <CCRDataObjectID>___________</CCRDataObjectID>
   <DateTime>
    <Type>
     <Text>Age At Onset</Text>
    </Type>
    <Age>
     <Value>35</Value>
     <Units><Unit>Years</Unit></Units>
    </Age>
   </DateTime>
   <Status>
    <Text>Resolved</Text>
   </Status>
 <Source>
  <Actor>
   <ActorID>75307</ActorID>
<ActorRole><Text>Primary Care Provider</Text></ActorRole>
 </Actor>
</Source>
  </Episode>
 <Source>
  <Actor>
   <ActorID>75307</ActorID>
<ActorRole><Text>Primary Care Provider</Text></ActorRole>
 </Actor>
</Source>
 </Episodes>
</Problem>
```


A2.5.4.6 *<FamilyHistory>*

(1) <FamilyHistory> is optional and bound to one instance (0..1). The child element <FamilyProblemHistory> is required and unbounded (1..∞) and contains data defining the patient's blood or genetic relatives in terms of possible or relevant risk factors. At a minimum, all family history that has a potential impact on the patient's healthcare risk profile should be listed. Family history is a key risk factor of high predictive value in diagnosis and treatment for many healthcare conditions, and is often difficult to collect at each encounter and maintain between encounters. Therefore, inclusion of <FamilyHistory> data in the CCR is extremely important.

(2) <FamilyProblemHistory> includes an instance of the Complex Data Type ProblemType derived by Restriction, which is a variation of <Problem>. If only the <Problem> is known but not which <FamilyMember> or members have or have had that <Problem>, then only the <Problem> need be listed. If the affected <FamilyMember> is known, then <FamilyMember> must be listed and all problems must be constrained and listed discretely by Family Member. In addition to <Problem>, <FamilyHistory> contains the element <FamilyMember>. Essentially the <FamilyHistory> section of the CCR is designed to contain a <FamilyHistory> of diagnoses, conditions, and problems as well as the current health status of family members as well as what diagnoses, conditions, or problems, or combinations thereof, were the causes of death for a deceased relative. Risk factors relevant to family members, such as a family member's smoking, ETOH, dietary, BMI, activity, toxic exposure, or other risks relative to the family member's own health should also be itemized in <FamilyHistory>.

(3) <FamilyProblemHistory> is an instance of the Complex Data Type FamilyHistoryType illustrated in Fig. A2.16.

(4) <FamilyProblemHistory> consists of two key elements <Problem> and <FamilyMember>. Note that a single <Problem> can affect one or more <FamilyMember>, and a single <FamilyMember> can have more than one <Problem>. As noted in A2.5.4.6(2), in <FamilyProblemHistory>, all problems must be constrained and listed discretely by Family Member.

(5) <FamilyMember> is a link to an <Actor> through an <ActorID> of type xs:string. <FamilyMember> must include an <ActorRole>. Each <FamilyMember> <ActorRole> should

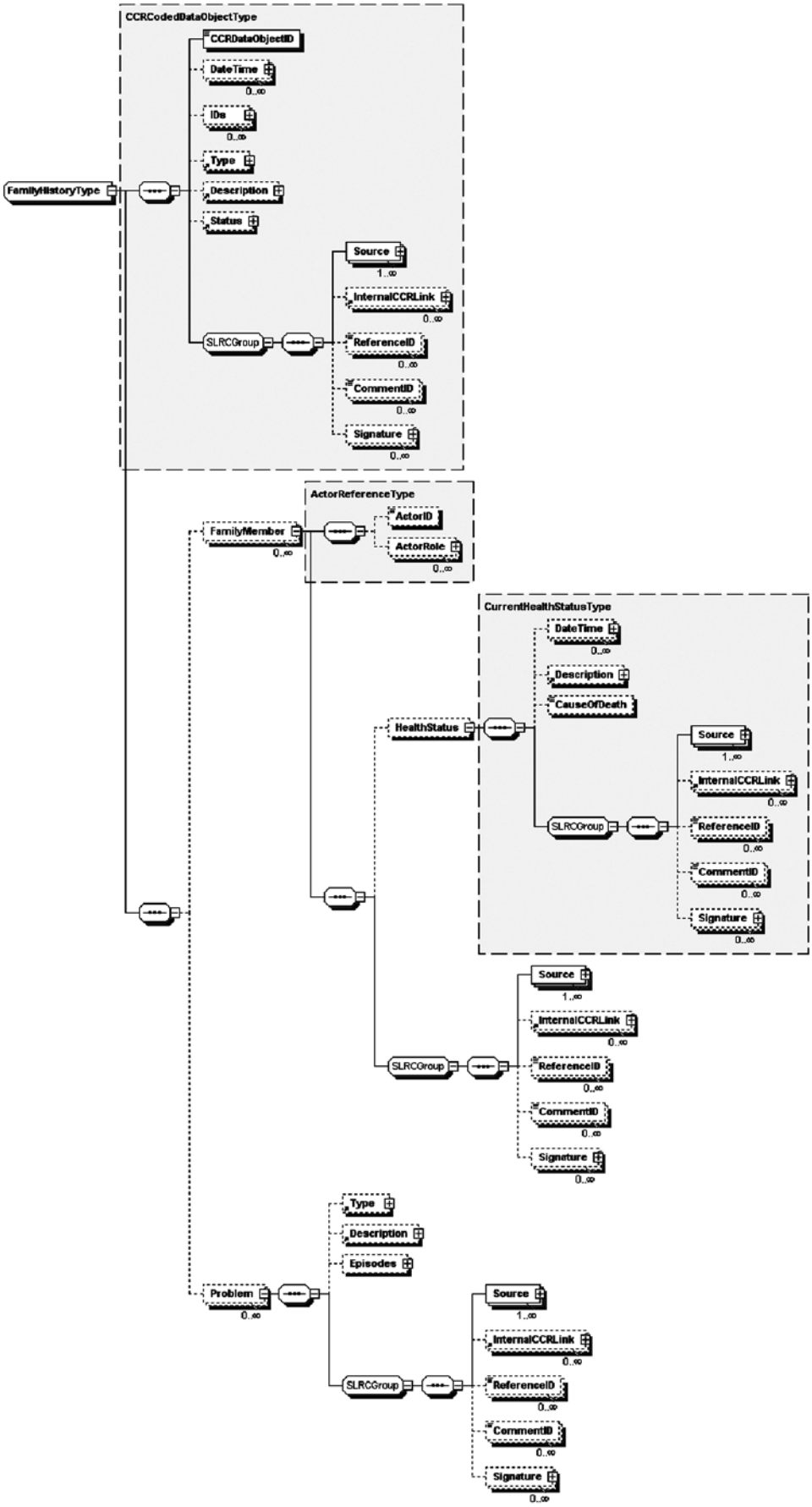

FIG. A2.16 FamilyHistoryType Data Object

reflect the <Relation> of that <FamilyMember> to the <Patient>. <FamilyHistory> is illustrated in Example 29.

Example 29 – Data Object <FamilyHistory>

```
<FamilyHistory>
 <FamilyProblemHistory>
  <CCRDataObjectID>___________</CCRDataObjectID>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source>
  <FamilyMember>
    <ActorID>________</ActorID>
    <ActorRole>
      <Text>Father</Text>
    </ActorRole>
   <HealthStatus>
    <Description>
      <Text>Deceased</Text>
    </Description>
    <CauseOfDeath>Yes</CauseOfDeath>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source>
   </HealthStatus>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source>
  </FamilyMember>
  <Problem>
   <Type>
    <Text>Diagnosis</Text>
   </Type>
   <Description>
    <ObjectAttribute>
     <Attribute>Diagnosis</Attribute>
      <AttributeValue>
       <Value>Myocardial Infarction</Value>
       <Code>
        <Value>22298006</Value>
        <CodingSystem>SNOMED CT</CodingSystem>
        <Version>20050131</Version>
       </Code>
      </AttributeValue>
    </ObjectAttribute>
   </Description>
   <Episodes>
    <Number>1</Number>
    <Episode>
  <CCRDataObjectID>___________</CCRDataObjectID>
     <DateTime>
      <Type>
       <Text>Age At Onset</Text>
      </Type>
      <Age>
       <Value>57</Value>
       <Units><Unit>Years</Unit></Units>
      </Age>
     </DateTime>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source
    </Episode>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source
   </Episodes>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source
</Problem>
 </FamilyProblemHistory>
</FamilyHistory>
```

A2.5.4.7 *<SocialHistory>*

(1) <SocialHistory> is optional and bound to one instance (0..1). The child element <SocialHistoryElement> is required and unbounded (1..∞) and contains data defining the patient's occupational, personal (for example, lifestyle), social, and environmental history and health risk factors. Within the CCR, items commonly grouped under administrative data (ADT) in other healthcare systems and standards are included in <SocialHistory>, such as Marital Status, Race, Ethnicity, and Religious Affiliation, as all of these have relevance to healthcare and possible preferences, optimization, or restrictions on healthcare interventions, or combinations thereof, and therapeutic options for a specific patient. In addition, these ADT data are all highly confidential and private data attributes about a patient and require the identical protections afforded all patient healthcare data.

(2) <Type> under <SocialHistoryElement> within <SocialHistory> is a CodedDescriptionType with restricted content that must be one of the defined structured text values. <Type> defines each discrete data object within <SocialHistory>, and each time a new data object is generated, a new instance of <SocialHistoryElement> must be initiated.

(3) SocialHistoryType is illustrated in Fig. A2.17.

(4) <SocialHistoryElement> is defined in Table A2.10.

Example 30 – Data Object <SocialHistory>

```
<SocialHistory>
 <SocialHistoryElement>
 <CCRDataObjectID>___________</CCRDataObjectID>
 <DateTimeRange>
  <BeginRange>
   <Age>
    <Value>17</Value>
    <Units>
     <Unit>Year</Unit>
    </Units>
   </Age>
  </BeginRange>
  <EndRange>
   <Age>
    <Value>67</Value>
    <Units>
     <Unit>Year</Unit>
    </Units>
   </Age>
  </EndRange>
 </DateTimeRange>
</DateTime>
<Type>
 <Text>Tobacco Use</Text>
</Type>
<Description>
 <Object Attribute>
  <Attribute>Type</Attribute>
  <AttributeValue>
    <Value>Cigarettes</Value>
    <Code>
     <Value>___________</Value>
     <CodingSystem>SNOMED CT</CodingSystem>
     <Version>20050131</Version>
    </Code>
  </AttributeValue>
 </Object Attribute>
 <Object Attribute>
  <Attribute>Packs Per Day</Attribute>
  <AttributeValue>
    <Value>1.5</Value>
    <Code>
     <Value>___________</Value>
     <CodingSystem>SNOMED CT</CodingSystem>
     <Version>20050131</Version>
    </Code>
  </AttributeValue>
 </Object Attribute>
</Description>
 <Status>
  <Text>Historical</Text>
 </Status>
 </Source>
</SocialHistoryElement>
```

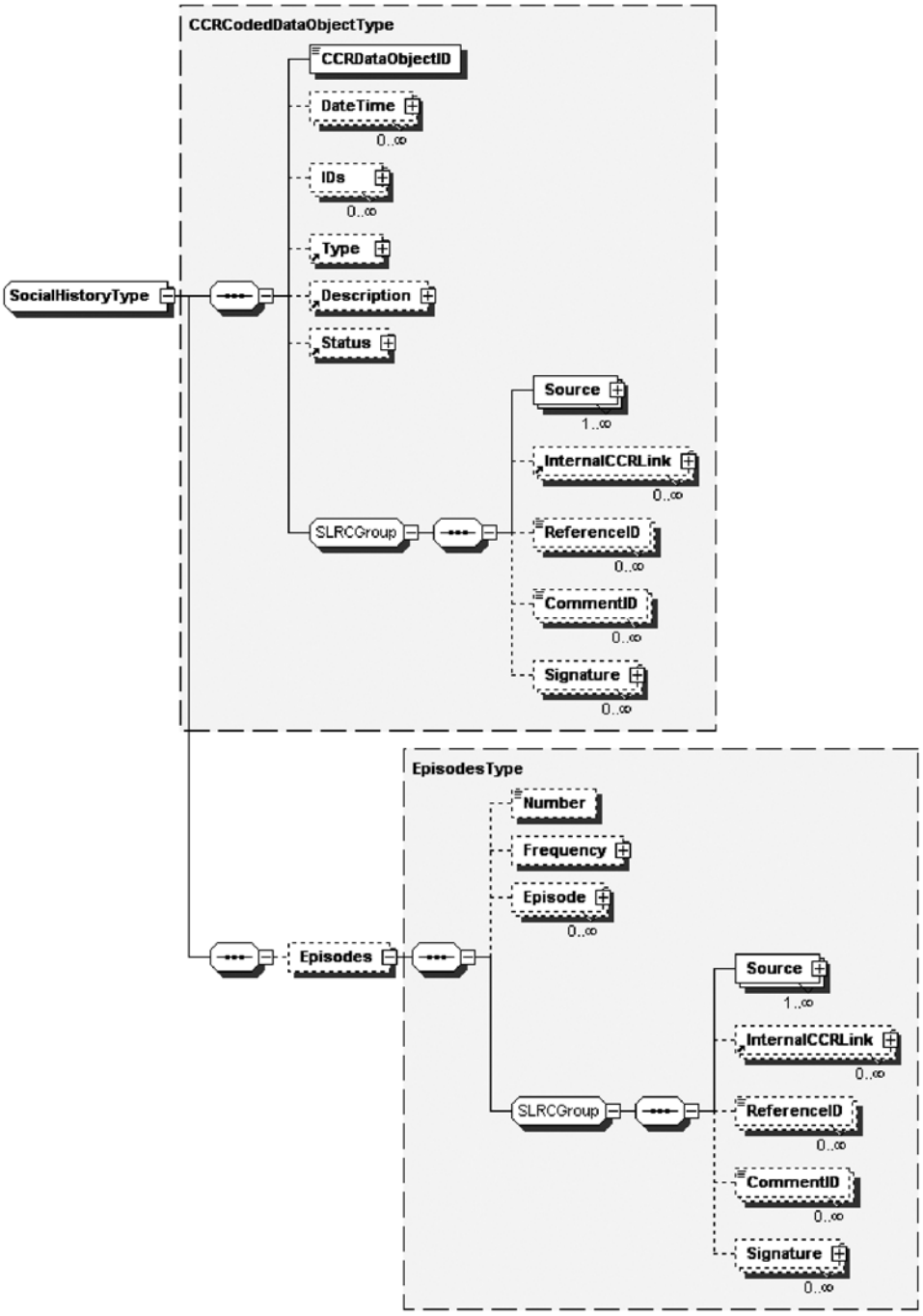

FIG. A2.17 Data Object <SocialHistoryType>

A2.5.4.8 *<Alerts>*

(1) <Alerts> is optional and bound to one instance (0..1). The child element <Alert> is required and unbounded (1..∞) and contains data used to define a patient's warnings such as allergies, adverse reactions, and other alerts (for example, enzyme or metabolic pathway deficiencies and critical lab or result values). In the CCR, <Alerts> should be used to highlight severe or critical issues, such as a history of an anaphylactic reaction to a bee sting (a severe form of allergy with a life-threatening adverse reaction) or a critical lab value such as potassium level of 6.6 mEQ/l. Other examples of <Alerts> could be the report of a very abnormal Pap smear or a mammogram generated through routine screening.

(2) <Alerts> is a data container for data that represent critically important variations from the norm that have temporal relevance in the near term or long term to the patient's condition and therapeutic options. They are prompts for near-term action or consideration of action or for warnings relative to therapeutic options to which the patient could have a potentially harmful outcome. <Alerts> in the CCR are, in other words, prompts or warnings related to patient safety. The presence of an <Alert> in the CCR is a conscious effort to

TABLE A2.10 <SocialHistoryType> Object Type Definition Table

<SocialHistory>	Accepted Values/Formatting	Optionality/Cardinality	Description
<DateTime>	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Optional and Unbounded (0..∞).	Used to define dates and times relevant to the patient's <SocialHistory>. Date of Onset, From Date A___ To Date B____, At Age ____, Since Age___, etc.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Type>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Marital Status, Race, Ethnicity, Religious Preference, Living Situation, Employment, Tobacco Use, ETOH Use, Recreational Drug Use, Toxic Exposure, Treatment Restrictions.	Optional and Bounded to one instance (0..1).	Defines what <Type> of social history is being defined (Tobacco Use, Living Situation, Marital Status, etc.) <Type> defines each discrete data object within <SocialHistory>, and each time a new data object is generated, a new instance of <RiskFactorHistory> must be initiated.
<Description>	An instance of CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. It is recommended that, when possible, all social history entries be coded with SNOMED CT.	Optional and Bounded to one instance (0..1).	Defines the specific attributes of the social history defined under <Type>.
<Status>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Current, Historical.	Optional and Bounded to one instance (0..1).	Defines the <Status> of the <SocialHistory><Description>.
<Episodes>	<Episodes> has children <Number> (0..1), <Frequency> (0..1), <Episode> (0..∞), and <Duration> (0..1).	Optional and Bounded to one instance (0..1).	Used to define one or more occurrences of a social history item. Episodes should be listed for social history items that have an episodic component or character, such as changing Marital Status, Tobacco Use, ETOH Use, Employment, etc.

emphasize safety even though it may be redundant with data in another section of the CCR. For example, an abnormally elevated potassium level would be a <Result> in the patient's CCR <Results> section. An Alert may have significant historical value, but it is up to the discretion of the author of the CCR to determine the relevance of a specific alert in the context of the <Purpose> for which a specific instance of the CCR is being created. <Alerts> are not to be confused with 'Reminders' that are defined under the <PlanOfCare> section of this Implementation Guide. However, both <Alerts> and 'Reminders' are examples of the types of specific content data fields found within the CCR that support clinical decision support.

(3) <Alert> is illustrated in Fig. A2.18.

(4) <Alert> is defined in Table A2.11.

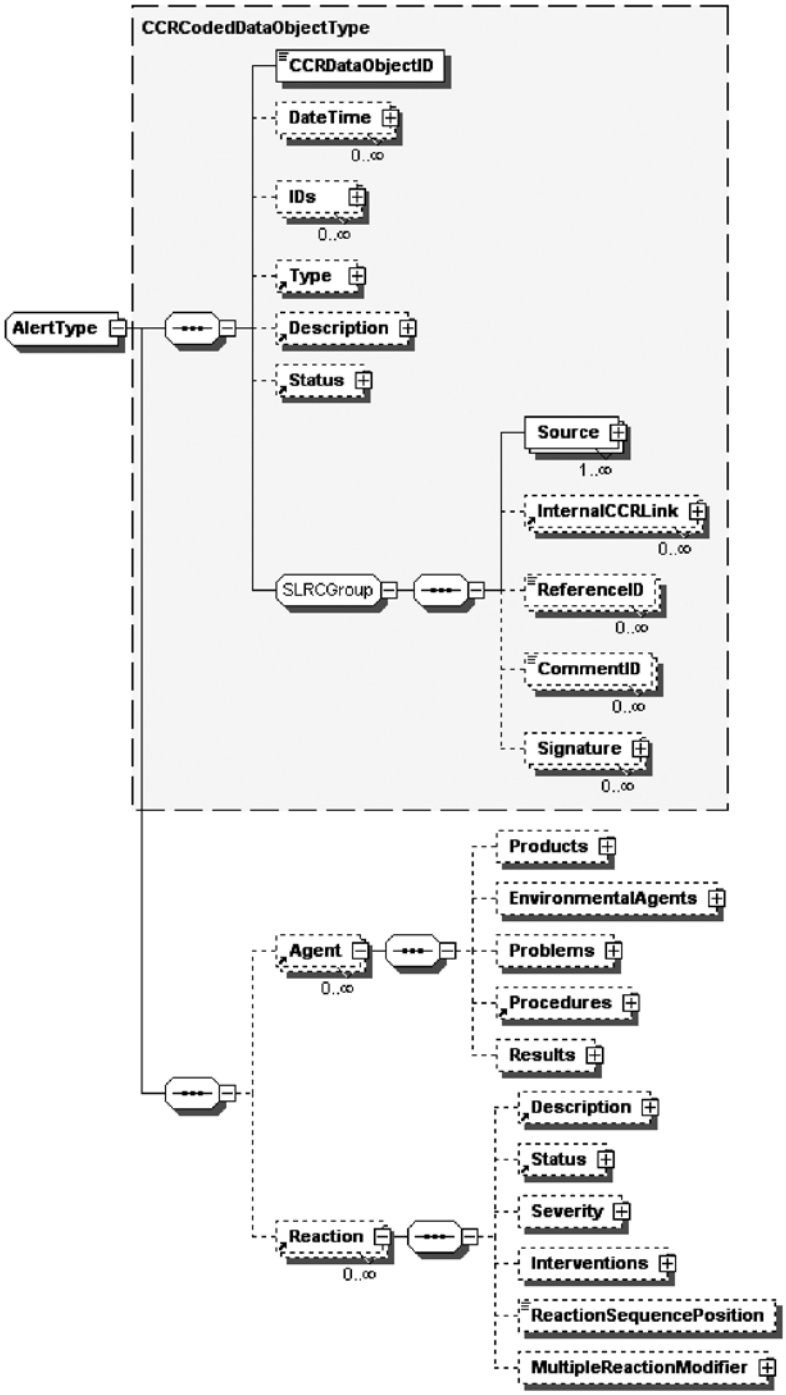

FIG. A2.18 <Alert> Data Object

TABLE A2.11 <Alert> Object Type Definition Table

<Alert>	Accepted Values/Formatting	Optionality/Cardinality	Description
<DateTime>	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Optional and Unbounded (0..∞).	Used to define dates and times relevant to the patient's <Alert>. Date of Onset, From Date A___ To Date B____, At Age ____, Since Age___, and so forth.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Type>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Allergy, Adverse Reaction, Alert, Critical Result.	Optional and Bounded to one instance (0..1).	Defines what <Type> of <Alert> is being itemized.
<Description>	An instance of CodedDescriptionType that supports a free text string, a structured text string or strings, or a structured and coded text string or strings. It is recommended that, when possible, all instances of <Alert> be coded with SNOMED CT.	Optional and Bounded to one instance (0..1).	Defines the specific attributes of the <Alert> defined under<Type>.
<Status>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Current, Historical, Unknown.	Optional and Bounded to one instance (0..1).	Defines the <Status> of the <Alert><Description>.
<Agent>	<Agent> has children <Products>, <EnvironmentalAgents>, <Problems>, <Procedures>, and <Results>.	Optional and Unbounded (0..∞). If an <Agent> is unknown, then "Unknown" is required content for <Agent>,	Defines an <Agent> that caused an <Alert>, specifically a <Product> (Penicillin), an <EnvironmentalAgent> (dust, bee stings), a <Problem> (G6PD Deficiency), a <Procedure> (IVP, Endoscopy), or a , <Result> (K+, Na+, Dig Level, Mammogram, PAP, Pathology, Cytology).
<Reaction>	<Reaction> has children <Description>, <Severity>, and <Interventions>.	Optional and Unbounded (0..∞).	<Description> is used to describe the <Reaction>, if any, that the <Alert> addresses – Rash, Angioedema, Anaphylaxis, Nausea, and so forth <Description> can be a string or can be used to encode the reaction (recommended/preferred).
<Status>	An instance of CodedDescriptionType, <Status> is used to define pertinent positive or pertinent negative reactions.	Optional and Bounded to one instance (0..1).	Pertinent Positive: <Description><Text>Anaphylaxis<Severity>Life Threatening<Intervention>Intubation Pertinent Negative: <Description><Text>Anaphylaxis<Status>Not Present
<Severity>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Minimal, Mild, Moderate, Severe, Life Threatening, Critical.	Optional and Bounded to one instance (0..1).	Defines the <Severity> of the <Reaction>.
<Interventions>	<Interventions> has child <Intervention> to support one or more <Interventions> used to respond to a <Reaction>. <Intervention> has children <Procedures>, <Products>, <Medications>, <Immunizations>, <Services>, and <Encounters>	<Interventions> is Optional and Bounded to one instance (0..1). <Intervention> is Required if <Interventions> is used and is Unbounded (0..∞).	Defines any<Intervention>used to treat a <Reaction>.
<Reaction Sequence Position>	Type xs:integer.	Optional and Bounded to one instance (0..1).	Used only to define sequence order when there is more than one <Reaction>. <ReactionSequencePosition> must be an integer starting a 1. If there is only one (1) reaction, then this tag is not used.
<Mulitple Reaction Modifier>	CodedDescriptionType	Optional and Bounded to one instance (0..1).	Used to define the relationship between reactions when there is more than one <Reaction>. Can contain the values AND, OR, or THEN to denote if for an instance of more than one <Reaction> if all reactions were present together (AND), or if each of the listed reactions might have occurred (OR), or if the reactions were sequential (THEN).

Example 31 – <Alert> Data Object

```
<Alert>
 <CCRDataObjectID>___________</CCRDataObjectID>
 <DateTime>
  <Type>
   <Text>Onset Date</Text>
  </Type>
  <ApproximateDateTime>
   <Text>As A Child</Text>
  </ApproximateDateTime>
 </DateTime>
 <Type>
  <Text>Allergy</Text>
 </Type>
 <Status>
  <Text>Current</Text>
 </Status>
<Source><Actor><ActorID>___________</ActorID></Actor></Source>
 <Agent>
  <Products>
   <Product>
```

```
<CCRDataObjectID>___________</CCRDataObjectID>
      <Description>
        <Text>Penicillin</Text>
        <Code>
          <Value>__________</Value>
          <CodingSystem>RxNorm</CodingSystem>
          <Version>________</Version>
        </Code>
      </Description>
<Source><Actor><ActorID>___________</ActorID></Actor></Source>
<Product><ProductName><Text>PenVK</Text></ProductName></
Product>
    </Product>
  </Products>
 </Agent>
 <Reaction>
  <Description>
   <ObjectAttribute>
    <Attribute>Reaction</Attribute>
    <AttributeValue>
     <Value>Anyphylaxis</Value>
     <Code>
      <Value>__________</Value>
      <CodingSystem>SNOMED CT</CodingSystem>
      <Version>20050131</Version>
     </Code>
    </AttributeValue>
    </ObjectAttribute>
   </Description>
   <Severity>
     <ObjectAttribute>
      <Attribute>Severity</Attribute>
     <AttributeValue>
      <Value>Life Threatening</Value>
      <Code>
        <Value>__________</Value>
        <CodingSystem>SNOMED CT</CodingSystem>
        <Version>20050131</Version>
      </Code>
     </AttributeValue>
    </ObjectAttribute>
    </Severity>
    <Interventions>
     <Intervention>
 <CCRDataObjectID>___________</CCRDataObjectID>
<Source><Actor><ActorID>___________</ActorID></Actor></Source>
 <CCRDataObjectID>___________</CCRDataObjectID>
          <Description>
           <Text>Cardiopulmonary Resuscitation</Text>
           <Code>
            <Value>__________</Value>
            <CodingSystem>RxNorm</CodingSystem>
            <Version>________</Version>
           </Code>
          </Description>
<Source><Actor><ActorID>___________</ActorID></Actor></Source>
         </Procedure>
       </Procedures>
     </Intervention>
    </Interventions>
  </Reaction>
</Alert>
```

A2.5.4.9 *<Medications>, <MedicalEquipment>, and <Immunizations>*

(1) <Medications>, <MedicalEquipment>, and <Immunizations> are optional and bound to one instance (0..1). Their respective child elements <Medication>, <Equipment>, and <Immunization> are required and unbounded (1..∞) and contain data defining the patient's current and historical <Medications>, <MedicalEquipment>, and <Immunizations>. Each of these categories exist as separate sections in the CCR, but their child elements utilize the same XML data object definition and tagging. They are all instances of the Complex Data Type StructuredProductType.

(2) <Medications> is used to define a patient's current medications and pertinent medication history. <MedicalEquipment> is used to define a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history. In addition, <MedicalEquipment> is used to itemize any pertinent current or historical durable medical equipment (DME) used to help maintain the patient's health status. <Immunizations> is used to define a patient's current <Immunization> status and pertinent <Immunization> history.

(3) To reiterate, all medications, immunizations, implanted and external medical devices, as well as all DME, are defined within the CCR as <Products> and are defined by the Complex Data Type StructuredProductType. They are stored within the CCR and intended for display as separate sections. They are defined discretely by <Type>, which is constrained to the values: Medication, IV Fluid, Parental Nutrition, Supplemental Nutrition, Immunization, Disposable, Supplies, Device, Implantable Device, Durable Medical Equipment.

(4) Careful consideration has gone to make StructuredProductType within the CCR map explicitly to and support:

(a) NCPDP Script and the ongoing cooperative work on SIG definitions for medication prescriptions and orders with NCPDP, HL7, and ASTM.

Note—The <Directions> under <Product> within this Implementation Guide maps explicitly to the latest available version of NCPCP Script SIG submitted (DERF) by the SIG Workgroup October 7, 2005.

(b) Immunization reporting requirements of State and Federal agencies and immunization registries, particularly to support the data needs of the Centers for Disease Control and Prevention (CDC).

(c) Product and manufacturer identification and tracking of implanted medical devices.

(d) Home oxygen and all other DME tracking, reporting, authorization, and clinical validation/justification under Medicare/Medicaid and X12 837.

(5) The Complex Data Type StructuredProductType as illustrated in Fig. A2.19.

(6) The Complex Data Type StructuredProductType are defined in Table A2.12.

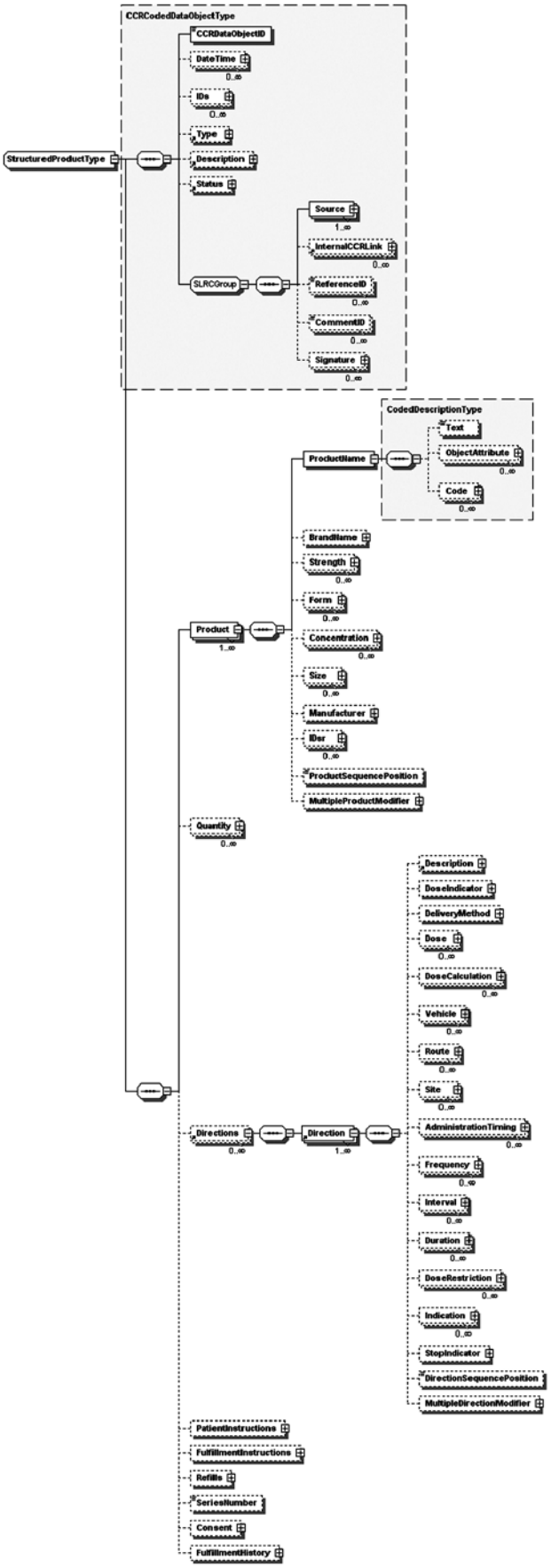

FIG. A2.19 Complex Data Type StructuredProductType

TABLE A2.12 <Product> Object Type (StructuredProductType) Definition Table

<Product>	Accepted Values/Formatting	Optionality/Cardinality	Description
<DateTime>	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Optional and Unbounded (0..∞).	Used to define dates and times relevant to the patient's <Alert>. Date of Onset, From Date A___ To Date B____, At Age ____, Since Age___, and so forth.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Type>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Medication, Immunization, Disposable, Supplies, Device, Implantable Device, Durable Medical Equipment	Optional and Bounded to one instance (0..1).	Defines the <Product><Type>.
<Description>	CodedDescriptionType	Optional and Bounded to one instance (0..1).	An instance of a CodedDescriptionType. <Text> under <Description> is used as a text string container for those systems that cannot generate a structured description of a product. The structured and coded portions of <Description> are used to define the name and overall characteristics of any complex product made up of one or more structured products, such as a GI Cocktail, an Insulin Sliding Scale, or the like.
<Status>	Instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Active, On Hold, Prior History No Longer Active	Optional and Bounded to one instance (0..1).	Defines the <Status> of the <Product>.
<Product>	Used as a container for the core descriptive attributes of a <Product>.	Required and Unbounded (0..∞).	Used to define a <Product>.
<ProductName>	Instance of CodedDescriptionType.	Required and Bounded to one instance (0..1).	The generic, non-proprietary, name of the product.
<BrandName>	Instance of CodedDescriptionType.	Optional and Bounded to one instance (0..1).	The Brand Name.
<Manufacturer>	A link to <Actor>.	Optional and Bounded to one instance (0..1).	Links to an <Actor>.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Strength>	Child of Product and instance of MeasureType	Optional and Unbounded (0..∞).	The predefined strength that the medication comes in – 500mg tablets, for example.
<Form>	Child of Product and instance of CodedDescriptionType.	Optional and Unbounded (0..∞).	The Form – Tablet, Capsule, Elixir, Suspension, Crème, Powder, Box, Syringe, and so forth.
<Concentration>	Child of Product and instance of MeasureType.	Optional and Unbounded (0..∞).	Used to define product concentration, when applicable – 250 mg/ml, for example.
<Size>	Child of Product. Can be a text string, structured text, or defined by <Dimensions>.	Optional and Unbounded (0..∞).	Used to define a <Product> <Size>.
<Quantity>	Instance of MeasureType.	Optional and Unbounded (0..∞).	Defines the quantity – to be ordered, dispensed, or used, for example.
<Directions>	Container for the <Directions>/SIG. This maps explicitly to NCPDP Script SIG as submitted (DERF) October 7, 2005.	Optional and Unbounded (0..∞).	Contains the directions for use. This is the 'SIG' component of the Prescription, for example, or is the use or administration instructions for a <Product>. <Description> can contain a text string or complex, coded data object.
<DoseIndicator>	Indicates the action to be taken on the <Description>/SIG. This is a direct map to the NCPDP Script SIG standard.	Optional and Bounded to one instance (0..1).	1 = Specified - remaining fields populated. 2 = As needed - skip rest of Dose Segment. 3 = As directed - skip rest of Dose Segment. 4 = Unspecified - see free text <Description>.
<DeliveryMethod>	The textual representation of the Dose Delivery Method. This is the method in which the dose is delivered (describes how the dose is administered/consumed).	Optional and Bounded to one instance (0..1).	Defines the method: take, apply, swish, swallow, inject, insert, chew, use, give, sprinkle, mix, dissolve…
<Dose>	A Child of <Direction>. It is of MeasureType with <Value>, <Units>, and <Code>. Dose also contains <Rate>.	Optional and Unbounded (0..∞).	Defines the dose parameter 125, 250, 500; units mg, mcg, g, U; rate per minute, per hour; and can repeat for multiple doses to support sliding scales, pulse dosing, tapering doses, dose ranges, variable doses.
<DoseCalculation>	A Child of <Direction> and instance of DoseCalculationType.	Optional and Unbounded (0..∞).	Used to provide a dose calculation. <Dose> defines the dose parameter 125, 250, 500; <Unit> and <Rate> define the unit parameters mg/kg/hr, for example <Variables> defines dosing variables, which can be more than one. <Calculation> defines the calculation.

TABLE A2.12 *Continued*

<Product>	Accepted Values/Formatting	Optionality/Cardinality	Description
<Vehicle>	A Child of <Direction> and can be expressed as a CodedDescriptionType. (<Description>) or as an <InternalCCRLink> to another <Product>.	Optional and Unbounded (0..∞).	Defines a product that is a vehicle for this product, such as an IV admixture, or vehicle/suspension.
<Route>	A Child of <Direction> and instance of CodedDescriptionType.	Optional and Unbounded (0..∞).	This defines the Route of administration – po, pr, sl, in either plain English or Latin abbreviation.
<Site>	A Child of <Direction> and instance of CodedDescriptionType.	Optional and Unbounded (0..∞).	Physical location on the patient of use, implantation, or administration, when specified (commonly used in IM, IV, and immunizations, and implantable devices).
<AdministrationTiming>	A Child of <Direction> and instance of DateTimeType	Optional and Unbounded (0..∞).	This is used to define a specific administration or use time. Can repeat for more than one administration time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.
<Frequency>	A Child of <Direction> and can be expressed as a <Description> (CodedDescriptionType) or a <Value> and <Units>.	Optional and Unbounded (0..∞).	Defines the frequency of administration – qd, bid, tid, qid, 5x/d…
<Interval>	A Child of <Direction> and can be expressed as a <Description> (CodedDescriptionType) or a <Value> and <Units>.	Optional and Unbounded (0..∞).	Defines an interval q15m, q2h, q4h, q12h.
<Duration>	A Child of <Direction> and can be expressed as a <Description> (CodedDescriptionType) or a <Value> and <Units>.	Optional and Unbounded (0..∞).	Defines the duration of use/administration.
<DoseRestriction>	A Child of <Direction> and instance of DoseCalculationType.	Optional and Unbounded (0..∞).	Used to provide a dose restriction. Otherwise, the same as above.
<Indication>	A Child of <Direction> and can be a <Description> or a <Problem> or a link to a <Problem> within the CCR, or one or more <PhysiologicalParameter>. Also includes a PRN designator.	Optional and Unbounded (0..∞).	Indication for a product.
<StopIndicator>	A Child of <Direction> and an instance of CodedDescriptionType.	Optional and Bounded to one instance (0..1).	Used to express a hard stop, such as the last SIG sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment.
<DirectionSequencePosition>	Used when the <Direction> repeats (multiple SIGs) such as with an Insulin sliding scale or tapering dose, etc.	Optional and Bounded to one instance (0..1).	Expressed as an Integer from 1-n. Signifies the order of the directions. Tag is not used if there is no repeat.
<MultipleDirectionModifier>	Defines the relationship between multiple directions (SIGs).	Optional and Bounded to one instance (0..1).	Used with the values AND, OR, or THEN to express when there is more than one SIG as to whether all the SIGs must apply (AND) or if any of the SIGs can apply (OR) or if the SIGs are sequential (THEN), in the sequence defined by <DirectionSequencePosition>.
<PatientInstructions>	An instance of CodedDescriptionType.	Optional and Unbounded (0..1).	Patient instructions that are not part of the traditional <Directions>/SIG.
<FulfillmentInstructions>	An instance of CodedDescriptionType.	Optional and Unbounded (0..1).	Instructions to the dispensing pharmacist or administering provider.
<Refill>	A Child of <Refills> and includes <Number>, <Quantity>, <DateTime>, to define 'Last Refill", for example, and <Comment> for any specific <Refill> alerts or comments.	Optional and Unbounded (1..∞).	Number of allowed refills per prescription.
<SeriesNumber>	String.	Optional and Bound to one instance (0..1).	Defines number in series, such as a series of immunizations.
<Consent>	Must contain a <DateTime>, a <Description>, and <Source>. <Reference> and <Comment> are option.	Optional and Bound to one instance (0..1).	Allows <Description> of consent as well as link to <Actor> or <ExternalReference>.
<FulfillmentHistory>	Under <Fulfillment> contains <DateTime>, <Description>, <Provider>, <Location>, and <FulfillmentMethod>.	Optional and Bound to one instance (0..1)	Product fulfillment history – tags as for <OrderRxHistory> above, but applied to fulfillment/dispensing.
Various "SequencePosition' and "Modifier"		Optional	Used when more than one sequence in a product repeats. These fields map discretely and explicitly to NCPDP Script, as proposed in June 2005 through joint work between NCPDP and ASTM.

Example 32 – <Medication>/<Product>

```
<Medication>
 <CCRDataObjectID>___________</CCRDataObjectID>
 <DateTime>
  <Type>
   <Text>Prescription Date</Text>
  </Type>
  <ExactDateTime>2004-09-01T13:25:34-05:00</ExactDateTime>
 </DateTime>
 <Type>
  <Text>Medication</Text>
 </Type>
<Source>
 <Actor>
  <ActorID>75307</ActorID>
  <ActorRole><Text>Primary Care Provider</Text></ActorRole>
 </Actor>
```

```
</Source>
 <Product>
  <ProductName>
    <Test>Amoxicillin</Text>
     <Code>
      <Value>_______</Value>
      <CodingSystem>RxNorm</CodingSystem>
      <Version>________</Version>
     </Code>
  </ProductName>
  <BrandName>
    <Test>Amoxil</Text>
    <Code>
     <Value>_______</Value>
     <CodingSystem>RxNorm</CodingSystem>
     <Version>________</Version>
    </Code>
  </BrandName>
  <Strength>
   <Value>250</Value>
   <Units>
   <Unit>mg</Unit>
   </Units>
  </Strength>
 </Product>
 <Quantity>
  <Value>30</Value
   <Units>
  <Unit>Capsules</Unit>
   </Units>
 </Quantity>
 <Directions>
 <Direction>
  <Dose>
   <Value>1</Value>
  </Dose>
  <Route>
    <Text>po</Text>
  </Route>
  <Frequency>
   <Value>tid</Value>
  </Frequency>
  <Duration>
   <Value>10</Value>
   <Units><Unit>Days</Unit></Units>
  </Duration>
 </Direction>
 </Directions>
</Medication>
```

A2.5.4.10 *<VitalSigns> and <Results>*

(1) <VitalSigns> and <Results> are optional and bound to one instance (0..1). Their respective child elements, each named <Result>, are required and unbounded (1..∞) and contain data defining the patient's current and historically relevant <VitalSigns> and <Results>. Vital Signs are technically Results ('Observations'), but <VitalSigns> and <Results> exist as separate sections in the CCR, although they utilize the same XML data object definition and tagging. They are both instances of the Complex Data Type ResultType.

(2) Vital Signs are defined within the CCR as a section in order to follow clinical convention. At a minimum, pertinent vital signs, such as the most recent, maximum or minimum, or both, baseline, or relevant trends should be listed. For <Results>, all pertinent as well as the most recent results should be included in the CCR.

(3) ResultType has been carefully constructed within the CCR to support numeric test result values as well as text-based test result values. ResultType also supports numeric test results with associated text. Particular care has been given to the ResultType data object to support microbiology, imaging, procedure, and pathology results as well as laboratory results. ResultType supports comprehensive structured result reporting as well as structured coding with any code set. It is recommended that all results be coded within the CCR with LOINC and SNOMED CT.

(4) ResultType is illustrated in Fig. A2.20.

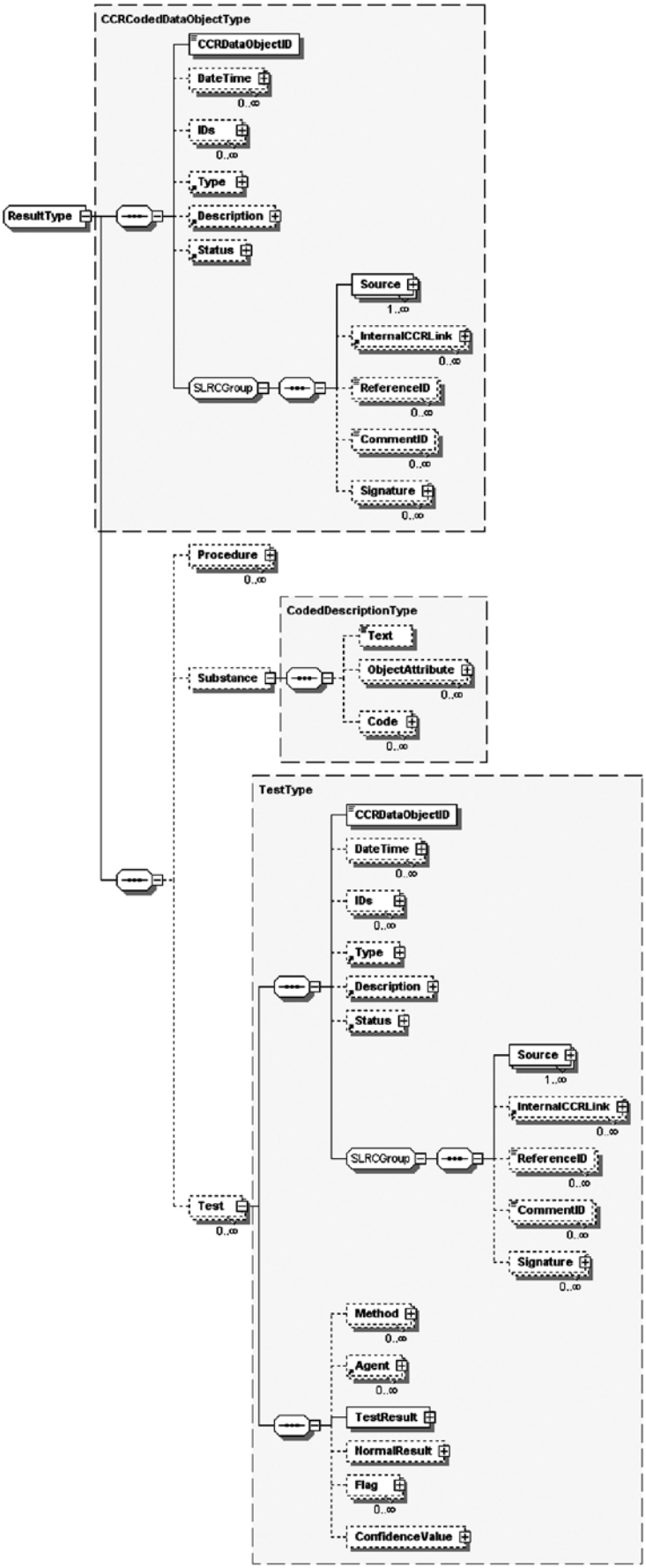

FIG. A2.20 Data Object ResultType

(5) ResultType defines discrete values as a <Result> with one or more instances of <Test> with an instance of a <TestResult>. <Test> is a Complex Data Type TestType. The elements of ResultType are defined in Table A2.13 followed by the definition of TestType in Table A2.14.

TABLE A2.13 <Result> Object Type Definition Table

ResultType	Accepted Values/Formatting	Optionality/Cardinality	Description
<DateTime>	For a <Result> this should be restricted to an exact DateTime, or a DateTime range if a collection was done over a specific time period. At a minimum, the DateTime of collection or physiological measurement should be included. Additional times such as when the <Result> was run, sent, or recorded can be included if and when pertinent.	Optional and Unbounded (0..∞).	Used to define dates and times relevant to the patient and the <Result>. Collection date time, collection start date, collection stop date, measurement time, measurement start date, measurement stop date.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Type>	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values. Hematology, Chemistry, Serology, Virology, Toxicology, Microbiology, Imaging - X-ray, Ultrasound, CT, MRI, Angiography, Cardiac Echo, Nuclear Medicine, Pathology, Procedure.	Optional and Bounded to one instance (0..1).	Defines the <Result> <Type>.
<Description>	An instance of CodedDescriptionType. <Description> should be coded with SNOMED CT, CPT, and LOINC codes, when applicable.	Optional and Bounded to one instance (0..1).	<Description> of the result – Blood Pressure, Heart Rate, Complete Blood Count (CBC), Urine Culture, Urinalysis. Specifically used to describe a<Result>set when there are more than one <Test> in a <Result>, such as a panel or battery.
<Status>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Current, Historical, Unknown.	Optional and Bounded to one instance (0..1).	Defines the <Status> of the <Result>.
<Procedure>	This is a specific use of <Procedure> as defined, below (Procedures). The use of <Procedure> under <Result> should be reserved for instances where listing the <Procedure> has direct clinical relevance to the <Result> or when the <Procedure> used to obtain the <Result> is not obvious or is atypical or specialized. When the <Procedure> is listed in the <Procedures> section of the CCR, <Procedure> under <Result> should be an <InternalCCRLink>.	Optional and Unbounded (0..∞).	This is an instance of a procedure or a link. This is the procedure for which there is the <Result>, or a procedure done to get the <Result>, or both.
<Substance>	An instance of CodedDescriptionType	Optional and Bounded to single use (0..1).	Used to define the substance that the <Result> is obtained from. Arterial blood, venous blood, urine, spinal fluid, joint fluid, aspirate, and so forth.
<Test>	An instance of the Complex Data Type TestType. <Test> contains the actual result data XML string.	Optional and Unbounded (0..∞).	TestType – defined in the following Table.

TABLE A2.14 TestType Definition Table

TestType	Accepted Values/Formatting	Optionality/0 - ∞	Description
<DateTime>	This can be an exact DateTime, an age, an approximate DateTime, or a DateTime range.	Optional and Unbounded (0..∞).	Used to define dates and times relevant to the patient's <Alert>. Date of Onset, From Date A___ To Date B____, At Age ____, Since Age___, and so forth.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Type>	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values. Observation or Result.	Required and Bounded to single use (1..1).	Defines the <TestResult> as an Observation or Result.
<Description>	Instance of CodedDescriptionType.	Optional and Bounded to one instance (0..1).	<Description> of the test – Systolic Blood Pressure, Diastolic Blood Pressure, Hct, Hgb, Na, K, BUN, Cr, Urine Specific Gravity, and so forth.
<Status>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Current, Historical, Unknown.	Optional and Bounded to one instance (0..1).	Defines the <Status> of the <Result>.
<Method>	Instance of CodedDescriptionType	Optional and Unbounded (0..∞).	Used when a <Description> modifier is needed – currently not used.
<Agent>	An instance of Complex Data Type AgentType. Has children <Products>, <EnvironmentalAgents>, <Problems>, <Procedures>, <Results>.	Optional and Unbounded (0..∞).	Allows inclusion of or link to <Agent>, such as a drug name for microbiology/culture sensitivities.
<TestResult>	<TestResult> can be a <Value>, <Value> and <Units>, or a <Description> or combinations thereof, which is a CodedDescriptionType supporting a free text string, a structured text string or strings, or a structured and coded text string or strings.	Required and Bounded to single use (0..1).	Contains the Test Result.
<NormalResult>	An instance of NormalType. <Normal> can be text, a value/units, and can repeat as a range or variable.	<Normal> under <NormalResult> is Optional and Unbounded (0..∞).	Defines the benchmark normal result or range for the <TestResult>.
<Flag>	An instance of CodedDescriptionType	Optional and Unbounded (0..∞).	Defines an abnormal flag for the Test Result – Low, High, Abnormal, Out of Range, Panic Value.
<ConfidenceValue>	An instance of CodedDescriptionType	Optional and Bounded to single use (0..1).	Defines a <ConfidenceValue> for the <TestResult>.

Example 33 – <Result>

```
<Results>
<Result>
 <CCRDataObjectID>_____</CCRDataObjectID>
 <DateTime>
  <Type>
   <Text>Collection Date</Text>
  </Type>
  <ExactDateTime>2004-09-01T13:25:34-05:00</ExactDateTime>
 </DateTime>
 <Type>
  <Text>Hematology</Text>
 </Type>
 <Description>
  <Text>Spun Hematocrit</Text>
  <Code>
   <Value>_______</Value>
   <CodingSystem>SNOMED CT</CodingSystem>
   <Version>________</Version>
  </Code>
  <Code>
   <Value>_______</Value>
   <CodingSystem>CPT-4</CodingSystem>
   <Version>________</Version>
  </Code>
  <Code>
   <Value>_______</Value>
   <CodingSystem>LOINC</CodingSystem>
   <Version>________</Version>
  </Code>
 </Description>
<Source>
 <Actor>
  <ActorID>75307</ActorID>
  <ActorRole><Text>Primary Care Provider</Text></ActorRole>
 </Actor>
</Source>
 <Substance>
   <Text>Venous Blood</Text>
   <Code>
    <Value>_______</Value>
    <CodingSystem>SNOMED CT</CodingSystem>
    <Version>________</Version>
   </Code>
 </Substance>
 <Test>
 <CCRDataObjectID>_____</CCRDataObjectID>
  <Description>
   <Text>HCT</Text>
   <Code>
    <Value>_______</Value>
    <CodingSystem>LOINC</CodingSystem>
    <Version>________</Version>
```

```
      </Code>
    </Description>
  <Source>
   <Actor>
    <ActorID>75307</ActorID>
    <ActorRole><Text>Primary Care Provider</Text></ActorRole>
   </Actor>
  </Source>
    <TestResult>
      <Value>9.2</Value>
      <Units><Unit>%</Unit></Units>
    </TestResult>
    <NormalResult>
      <Normal>
        <Value>14.0</Value>
        <Units><Unit>%</Unit></Units>
        <ValueSequencePosition>1</ValueSequencePosition>
  <Source>
   <Actor>
    <ActorID>75307</ActorID>
    <ActorRole><Text>Primary Care Provider</Text></ActorRole>
   </Actor>
  </Source>
      </Normal>
      <Normal>
        <Value>18.0</Value>
        <Units>%</Units>
        <ValueSequencePosition>2</ValueSequencePosition>
        <VariableNormalModifier>TO</VariableNormalModifier>
  <Source>
   <Actor>
    <ActorID>75307</ActorID>
    <ActorRole><Text>Primary Care Provider</Text></ActorRole>
   </Actor>
  </Source>
      </Normal>
    </NormalResult>
    <Flag>
        <Test>Critical</Text>
      </Description>
    </Flag>
   </Test>
  </Result>
```

A2.5.4.11 *<Procedures>*

(1) <Procedures> is optional and bound to one instance (0..1). The child element <Procedure> is required and unbounded (1..∞). and defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically and at the time the CCR is generated. The preferred controlled vocabulary here is SNOMED CT, as well as the current CPT Codeset for the <Procedure> and LOINC for any <Result>, although revisions to LOINC are recommended to make object definition and standardization more uniform.

(2) At a minimum, any recent or historically relevant <Procedure> should be listed. The intent is to list major diagnostic or therapeutic procedures, or both, that have a current or historical impact on the patient's current or future health.

(3) <Procedure> is defined by the Complex Data Type ProcedureType, which is illustrated in Fig. A2.21.

(4) <Procedure> is defined in Table A2.15.

Example 34 – <Procedure>

```
<Procedure>
 <CCRDataObjectID>___________</CCRDataObjectID>
 <DateTime>
  <Type>
   <Text>Procedure Date</Text>
  </Type>
  <ExactDateTime>2004-09-01T13:25:34-05:00</ExactDateTime>
 </DateTime>
 <Type>
  <Text>Surgery</Text>
 </Type>
 <Description>
  <Text>Appendectomy</Text>
  <Code>
   <Value>_______</Value>
   <CodingSystem>SNOMED CT</CodingSystem>
   <Version>________</Version>
  </Code>
  <Code>
   <Value>_______</Value>
   <CodingSystem>CPT-4</CodingSystem>
   <Version>________</Version>
  </Code>
 </Description>
</Procedure>
```

A2.5.4.12 *<Encounters>*

(1) <Encounters> is optional and bound to one instance (0..1). The child element <Encounter> is required and unbounded (1..∞) and contains data defining all pertinent healthcare encounters as well as pending healthcare appointments of the patient at the time the CCR is generated. An encounter is an interaction, regardless of the setting, between a patient and a practitioner who is vested with primary responsibility for diagnosing, evaluating, or treating the patient's condition. It may include visits, appointments, as well as non face-to-face interactions. It is also a contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment.

(2) <Encounter> is illustrated in Fig. A2.22.

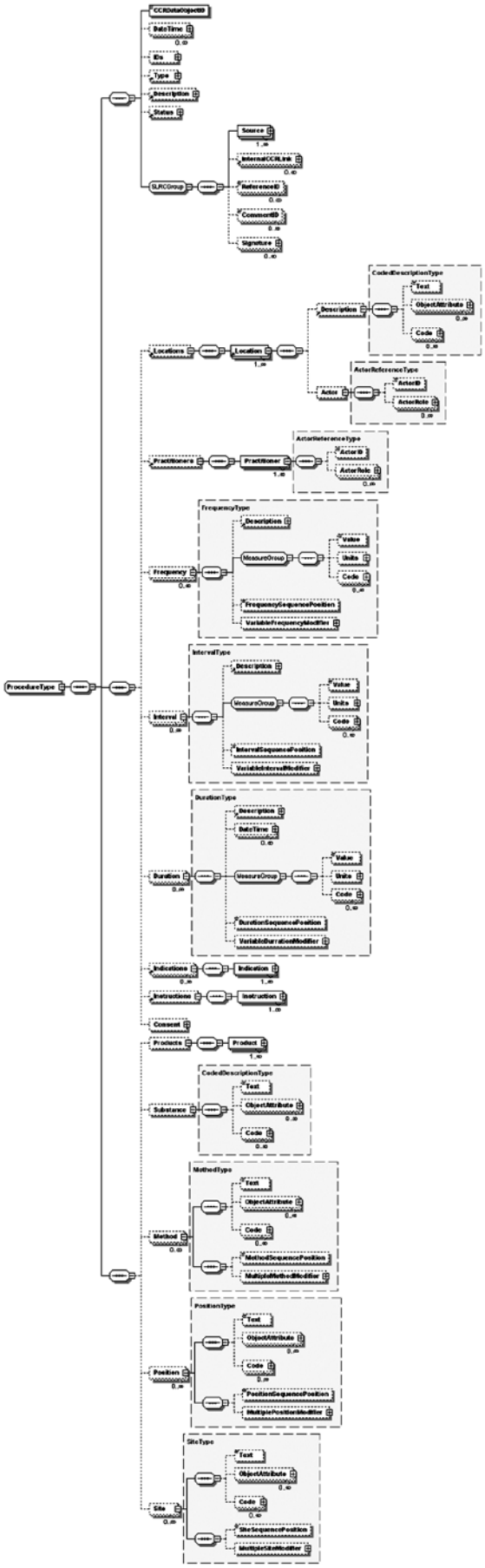

FIG. A2.21 Data Object <Procedure>

TABLE A2.15 <Procedure> Object Type Definition Table

<Problem>	Accepted Values/Formatting	Optionality/ Cardinality	Description
<DateTime>	An instance of DateTimeType.	Optional and Unbounded (0..∞).	Used to define dates and times relevant to the patient and the<Procedure>. For a <Procedure>, <DateTime> should express the <DateTime> the <Procedure> occurred, as accurately as possible, but due to the fact that historical <Procedure> data may be collected retrospectively, exact DateTime, an age, an approximate DateTime, or a DateTime range are all valid.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Type>	An instance of CodedDescriptionType.	Optional and Bound to one instance (0..1).	Defines the <Procedure><Type>, Surgical, Cardiac, Imaging, etc.
<Description>	An instance of CodedDescriptionType. <Procedure> should be coded with SNOMED, CPT, and LOINC codes, when applicable.	Required and Bounded to one instance (1..1).	<Description> of the Procedure – Cardiac catheterization, transfusion, echocardiogram, exercise stress test, appendectomy, cholecystectomy, endoscopy, etc.
<Status>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Cancelled, On Hold, In Progress, Not Completed, Completed.	Optional and Bounded to one instance (0..1).	Defines the current <Status> of the <Procedure>.
<Location>	A child of <Locations> (0..1) and expressed as a <Description> (CodedDescriptionType) or as a link to an <Actor>.	Optional and Unbounded (0..∞).	Defines the <Location>. Location is a physical geographic location *not* a physical location on the patient. Physical location on the patient is defined as <Site>.
<Practitioner>	A child of <Practitioners> (0..1). This is a link to <Actor> and includes an <ActorRole>.	Optional and Unbounded (0..∞).	Defines the <Practitioner> who did the procedure.
<Frequency>	An instance of FreqDurGroup.	Optional and Unbounded (0..∞).	Defines the <Frequency> of the <Procedure>.
<Interval>	Is an instance of IntervalType. It can be expressed as <Description> which is a CodedDescriptionType and as <Value><Unit> or both.	Optional and Unbounded (0..∞).	Defines an interval q15m, q2h, q4h, q12h.
<Duration>	An instance of FreqDurGroup.	Optional and Unbounded (0..∞).	Defines the <Duration> of the <Procedure>.
<Indication>	Can be a <Description> or a <Problem> or a link to a <Problem> within the CCR, or one or more <PhysiologicalParameter>. Also includes a PRN designator.	Optional and Unbounded (0..∞).	Indication for a <Procedure>.
<Instruction>	A child of <Instructions> (0..1) and an instance of InstructionType.	Required and Unbounded (1..∞).	Used to define <Instructions> for a <Procedure>. Used primarily when a <Procedure> is an <OrderRequest>.
<Product>	A child of <Products> (0..1) and an instance of StructuredProductType	Required and Unbounded (1..∞).	Defines any <Product> associated with the<Procedure>.
<Substance>	An instance of CodedDescriptionType	Optional and Bound to one instance (0..1).	Used to define the substance upon which the <Procedure> was done. Arterial blood, venous blood, urine, spinal fluid, joint fluid, aspirate, etc.
<Method>	Instance of CodedDescriptionType.	Optional and Unbounded (0..∞).	<Procedure><Method>.
<Position>	Instance of CodedDescriptionType.	Optional and Unbounded (0..∞).	Patient position for/during the <Procedure>.
<Site>	Instance of CodedDescriptionType.	Optional and Unbounded (0..∞).	Physical location on the patient of<Procedure>.

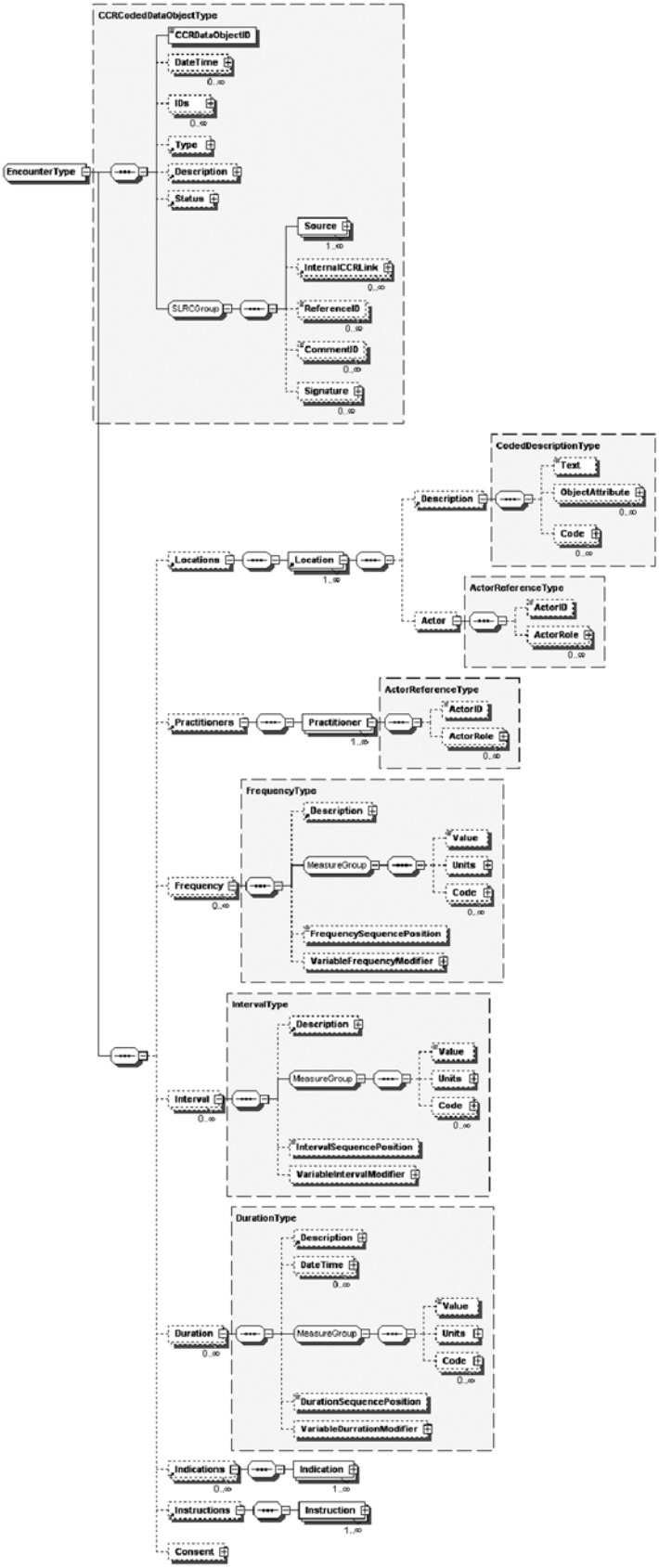

FIG. A2.22 <Encounter> Data Object

(3) <Encounter> is defined in Table A2.16.

Example 35 – <Encounter>

```
<Encounters>
<Encounter>
 <CCRDataObjectID>___________</CCRDataObjectID>
 <DateTime>
  <Type>
   <Text>Encounter Date</Text>
  </Type>
   <ExactDateTime>2003-07</ExactDateTime>
  </DateTime>
  <Type>
   <Text>Inpatient Hospitalization</Text>
  </Type>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source>
  <Locations>
  <Location>
   <Description>
    <Text>Jackson County Hospital</Text>
   </Description>
  </Location>
  </Locations>
  <Indications>
  <Indication>
   <Problem>
 <CCRDataObjectID>___________</CCRDataObjectID>
     <Description>
      <Text>Pneumonia</Text>
     </Description>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source>
    </Problem>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source>
  </Indication>
  </Indications>
</Encounter>
```

A2.5.4.13 *<PlanOfCare>*

(1) <PlanOfCare> is optional and bound to one instance. The child element <Plan> is required and unbounded (1..∞) and contains data defining all pending orders, interventions, encounters, services, and procedures for the patient. It defines what is 'planned' or expected for the care of the patient. It is for prospective, unfulfilled, or incomplete orders and requests only. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient should be listed, unless constrained due to issues of privacy. 'Clinical Reminders' should also be placed here for purposes of providing prompts that may be used for disease prevention, disease management, patient safety (generic), and healthcare quality improvement, including widely accepted performance measures. Clinical Reminders are clinical decision support prompts that are closely related to quality issues or continuous quality improvement (CQI). They have temporal relevance of a longer-term nature than <Alerts> explained earlier in this guide. Consider <Alerts> as specific, patient safety related, near-term warnings and Clinical Reminders as patient quality related, longer term prompts. One example of a Clinical Reminder is the performance measurement set derived from widely accepted guidelines that have been vetted and disseminated through the AMA convened, Physician Consortium for Performance Improvement (PCPI). These measures were chosen by CMS for the DOQ-IT national pilot project. An illustration of the combination of the CCR's Clinical Reminders within the <PlanOfCare> section and related <Reference>

TABLE A2.16 <Encounter> Object Type Definition Table

<Encounter>	Accepted Values/Formatting	Optionality/ Cardinality	Description
<DateTime>	An instance of DateTimeType.	Optional and Unbounded (0..∞).	Used to define dates and times relevant to the patient and the <Encounter>. For a <Encounter>, <DateTime> should express the <DateTime> the <Encounter> occurred, as accurately as possible, but due to the fact that historical <Encounter> data may be collected retrospectively, exact DateTime, an age, an approximate DateTime, or a DateTime range are all valid.
<Type>	An instance of CodedDescriptionType.	Optional and Unbounded (0..∞).	Defines the <Encounter><Type>, Hospitalization, Rehabilitation, Nursing Facility, Emergency Room, Clinic Visit, etc.
<Description>	An instance of CodedDescriptionType. <Procedure> should be coded with SNOMED, CPT, and LOINC codes, when applicable.	Required and Bounded to single use (1..1).	Used to describe the actual <Encounter>, if <Encounter> cannot be more appropriately expressed with <Location> and <Practitioner>.
<Location>	Expressed as a <Description> (CodedDescriptionType) or as a link to an <Actor>.	Optional and Unbounded (0..∞).	Defines the <Location>. Location is a physical geographic location *not* a physical location on the patient. Physical location on the patient is defined as <Site>.
<Practitioner>	This is a link to <Actor> and includes an <ActorRole>.	Optional and Unbounded (0..∞).	Defines the <Practitioner> with whom the <Encounter>occurred.
<Frequency>	An instance of FreqDurGroup.	Optional and Unbounded (0..∞).	Defines the <Frequency> of the <Encounter>.
<Duration>	An instance of FreqDurGroup.	Optional and Unbounded (0..∞).	Defines the <Duration> of the <Encounter>.
<Indication>	Can be a <Description> or a <Problem> or a link to a <Problem> within the CCR, or one or more <PhysiologicalParameter>. Also includes a PRN designator.	Optional and Unbounded (0..∞).	Indication for an <Encounter>.
<Instructions>	Instance of InstructionType.	Optional and Bound to one instance (0..1).	Used to define <Instructions> for a <Encounter>. Used primarily when a <Encounter> is an <OrderRequest>.
<Consent>	An instance of CCRCodedDateObjectType	Optional and Bound to one instance (0..1).	This is used to document that consent was obtained and documented for the encounter or procedure. The SLRC Group could be used to point to the location of the actual consent.

section would be the capacity to embed a link to the PCPI webpage (or another reputable clinical web source) that contains the specific performance measures relevant to the patient's care plan, e.g., diabetes care measures are concisely summarized at: http://www.ama-assn.org/ama1/pub/upload/mm/370/diabetesset.pdf.

(2) Thus, the CCR Clinical Reminders in the <PlanOfCare> section can be used as a powerful tool to promote CQI and evidence based medicine (EBM), within the patient's summary and <PlanofCare>. Including Clinical Reminders as one or more data items in <PlanofCare> allows any receiving, consulting, admitting provider, system, or healthcare institution to understand the current and pending clinical care plans for this patient at a specific moment in time. This should help to avoid conflict, assure patient safety, to optimize care and convenience for the patient and their family. This section allows any changes to be communicated appropriately and in a timely manner to all affected providers and organizations. Finally, the <PlanofCare> section is designed to be of great relevance to nursing, particularly in transfers to home care, convalescent and rehab settings after an acute care hospitalization. The intent is that all providers caring for the patient should be aware at all times what is currently planned, scheduled, or recommended to care for the patient and maximize their clinical outcomes.

(3) <Plan> is illustrated in Fig. A2.23.

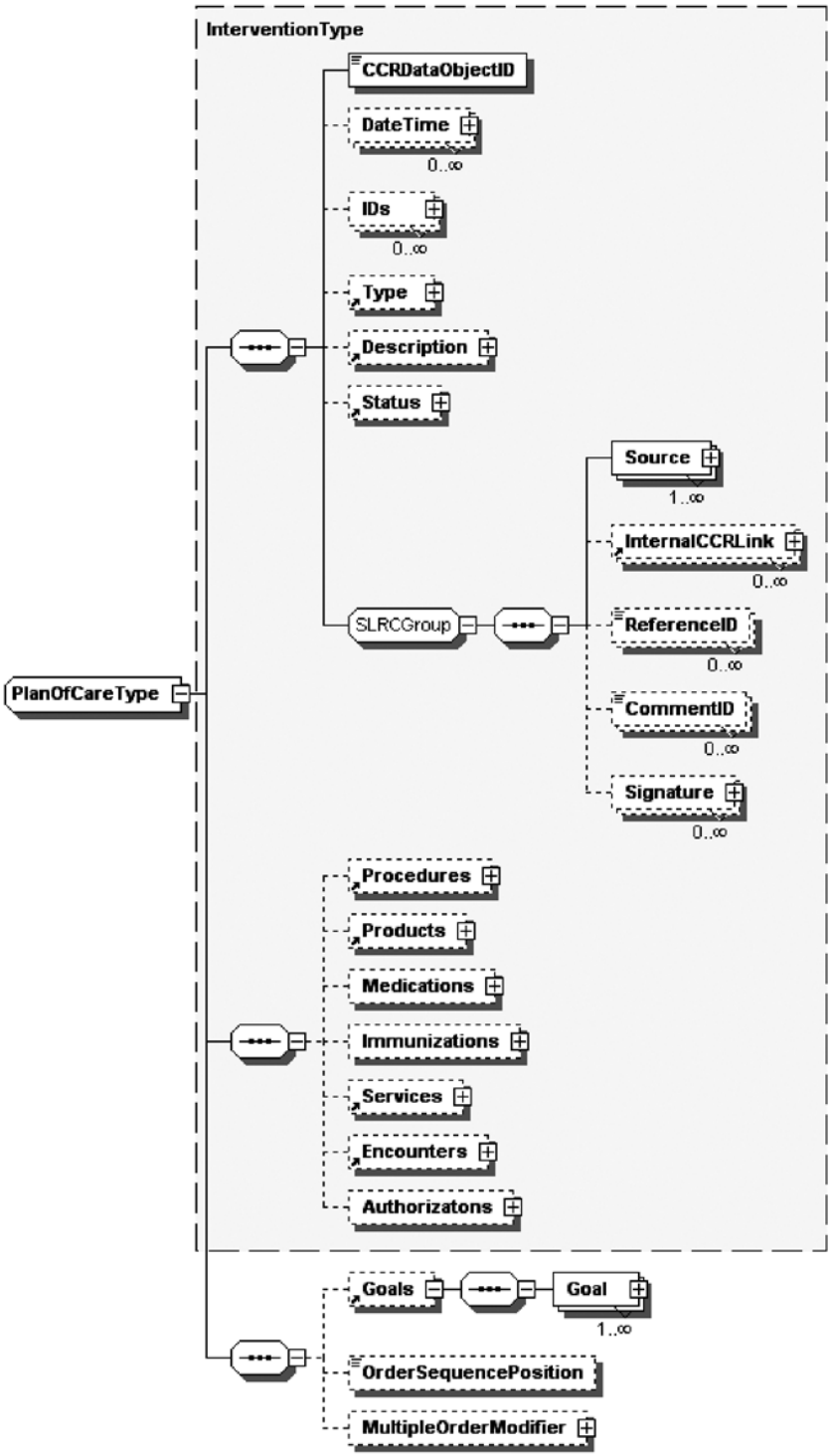

FIG. A2.23 Data Object <Plan>

(4) <Plan> is defined in Table A2.17.

Example 36 – <PlanOfCare> (<Source> not included to simplify example)

```
<PlanOfCare>
<Plan>
<CCRDataObjectID>___________</CCRDataObjectID>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source>
<OrderRequest>
 <CCRDataObjectID>___________</CCRDataObjectID>
 <DateTime>
  <Type>
   <Text>Request Date</Text>
  </Type>
  <ExactDateTime>2004-09-01T13:25:34-05:00</
ExactDateTime>
 </DateTime>
 <Type>
  <Text>Procedure</Text>
 </Type>
 <Status>
  <Text>Ordered</Text>
 </Status>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source>
 <Procedures>
  <Procedure>
<CCRDataObjectID>___________</CCRDataObjectID>
    <Description>
     <Text>CBC With Differential</Text>
      <Code>
       <Value>_______</Value>
       <CodingSystem>SNOMED CT</CodingSystem>
       <Version>________</Version>
      </Code>
      <Code>
       <Value>_______</Value>
       <CodingSystem>CPT-4</CodingSystem>
       <Version>________</Version>
      </Code>
      <Code>
       <Value>_______</Value>
       <CodingSystem>LOINC</CodingSystem>
       <Version>________</Version>
      </Code>
    </Description>
<Source><Actor><ActorID>___________</ActorID></Actor></
Source>
    <Substance>
     <Text>Venous Blood</Text>
    </Substance>
  </Procedure>
 </Procedures>
</OrderRequest>
</Plan>
<PlanOfCare>
```

A2.5.4.14 *<HealthCareProviders>*

(1) <HealthCareProviders> is optional and bound to one instance (0..1). The child element <Provider> is required and unbounded (1..∞) and contains data defining all healthcare providers involved in the current or pertinent historical care of the patient. <Provider> is an ActorReferenceType that links to an <Actor> within the CCR through xs:string.

(2) <Provider> is a link to an <Actor> with an <ActorRole>. This data object is not used for listing a patient's non-healthcare <Support> providers. <Support> providers are listed under the <Support> section of the CCR. At a minimum, the patient's key healthcare providers should be listed, particularly the patient's primary physician and any active consulting physicians, therapists, and counselors.

(3) <HealthCareProviders> is illustrated in Fig. A2.24.

A2.5.5 *CCR Footer Sections*—Note that the CCR Footer consists of the following sections, but is not contained within a <Footer> tag.

A2.5.5.1 *<Actors> – Persons, Organizations, Locations, Systems*—<Actors> is required and bounded to one instance (1..1) and contains data defining all of the individuals, organizations, locations, and systems associated with the data in the CCR. Individuals (Patients, Family, Support, Healthcare Providers), organizations, locations, and systems (IT systems, EHRs, and the like) are *normalized* within the CCR. *Normalized* means that everything about each individual, organization, location, or system is listed once, and only once, in the CCR and any data that are from, about, or in reference to that individual, organization, location, or system are then linked within the CCR to that one listing. Within the CCR, each individual, organization, location, or system is listed separately as an <Actor> in the <Actors> section of the CCR. Actors (<Actor>), are expressed within the CCR by the Complex Data Type ActorType. The specific and detailed information about that individual person, organization, location, or system are fully itemized and tagged under <Actor> within the CCR <Actors> Section and given a CCRDataObjectID (<ActorID>) of type xs:string. Wherever an <Actor> is referred to within the CCR, it is referenced through the complex data type ActorReferenceType with an <ActorID> of type xs:string . This allows the details about an <Actor> to be listed once (normalized), while an <Actor> can be referenced as many times as necessary within the CCR. ActorReferenceType also contains <ActorRole>, which is used to define the specific role of that <Actor> in relation to the data at that specific point of reference within the CCR. <ActorRole> defines the healthcare or support role of the <Actor> relative to the patient. <Role> does not define, in itself, an explicit role relative to data security, confidentiality, privacy, or access control. Each time an <Actor> is referenced within the CCR, an <ActorID> is required. <ActorRole> is optional or required, depending on the use, but its use is encouraged in all instances due to the significant value of knowing the specific role the <Actor> plays in each reference to data. ActorReferenceType is illustrated in Fig. A2.25. Each <ActorID> in the CCR Header, Body, or Footer sections points to an <Actor> listed in the CCR Footer section <Actors>. Within the <Actors> section, each <Actor> is represented by a subset of tagged data elements consistent with the representation of them as a <Person>, <Organization> (which includes locations), or <InformationSystem>.

(1) ActorType—The overall XML structure of <Actor> is as illustrated in Fig. A2.26. ActorType is defined in Table A2.18. Further definition of the XML within ActorType is as follows:

(2) <Person> — <Person> defines the individual as an <Actor>. Its elements are defined in Table A2.19. Other traditionally 'demographic' data on the patient such as Marital Status, Race, Ethnicity, Religious Affiliation/Preference, are all contained in the CCR within <SocialHistory>.

(3) <Organization> — <Organization> defines an Organization as an ActorType as in Table A2.20.

TABLE A2.17 <Plan> Object Type Definition Table

<Plan>	Accepted Values/Formatting	Optionality/ Cardinality	Description
<DateTime>	An instance of DateTimeType. For <Plan> this should be an exact DateTime, or a DateTime range if an order/request is scheduled or intended to be scheduled. <Age> would be appropriate for clinical reminders, although more exact datetime and/or range calculated against the patient's date of birth would be more helpful and informative to continuity of care providers.	Optional and Unbounded (0..∞).	Used to define dates and times relevant to the patient and the <Plan>. Plan Start DateTime, Plan Completion DateTime. Dates and times of explicit orders/requests are defined under <OrderRequest><DateTime>.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Type>	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values. Reminder, Order, Prescription, Request For Authorization, Authorization, Referral, Request For Consultation, Treatment Recommendation.	Optional and Bounded to one instance (0..1).	Defines the <Plan><Type>.
<Description>	An instance of CodedDescriptionType. <Description> should be coded with SNOMED CT, CPT, and LOINC codes, when applicable.	Optional and Bounded to one instance (0..1).	Used to describe a <Plan> set when there are more than one <OrderRequest>s in a <Plan> such as a detailed Care <Plan> or pre-procedure <Plan>. Postoperative rehabilitation, stroke rehabilitation, pre-procedure work-up and evaluation, etc.
<Status>	An instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Pending, In Process, On Hold, Cancelled.	Optional and Bounded to one instance (0..1).	Defines the <Plan><Status>.
<OrderRequest>	Contains the actual <OrderRequest> XML string.	Required and Unbounded (1..∞).	The actual order/request. This XML object string can repeat within a <Plan>.
<DateTime>	An instance of DateTimeType. For <OrderRequest> this should be an exact DateTime, or a DateTime range if an order/ request is scheduled or intended to be scheduled. <Age> would be appropriate for clinical reminders, although more exact datetime and/or range calculated against the patient's date of birth would be more helpful and informative to continuity of care providers.	Optional and Unbounded (0..∞).	Used to define dates and times relevant to the patient and the <OrderRequest>. Procedure DateTime, Encounter DateTIme, Appointment DateTime, etc.
<Type>	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values. Order, Encounter, Procedure, Service, Product, Immunization, Medication, Authorization, Referral, Consultation.	Optional and Bounded to one instance (0..1).	Defines the <OrderRequest><Type>.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Description>	An instance of CodedDescriptionType	Optional and Bounded to one instance (0..∞).	Used to describe an <OrderRequest> that is not a <Procedure>, <Product>, <Medication>, <Immunization>, <Service>, <Encounter>, or <Authorization> request.
<Status>	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values. Ordered, Requested, Pending, On Hold, Repeat, No Show, Cancelled.	Optional and Bounded to one instance (0..1).	Defines the <OrderRequest><Status>.
<Procedures>	The child <Procedure> (1..∞) is an instance of ProcedureType.	Optional and Bounded to one instance (0..1).	CT scan, ultrasound, CBC, biopsy, cholecystectomy, ECG, pulmonary function tests, stress echocardiogram, etc.

TABLE A2.17 *Continued*

<Plan>	Accepted Values/Formatting	Optionality/ Cardinality	Description
<Products>	The child <Product> (1..∞) is an instance of StructuredProductType.	Optional and Bounded to one instance (0..1).	Wheelchair, home nebulizer, prosthesis, etc.
<Medications>	The child <Medication> (1..∞) is an instance of StructuredProductType.	Optional and Bounded to one instance (0..1).	Enoxaparin, chemotherapy, etc.
<Immunizations>	The child <Immunization> (1..∞) is an instance of StructuredProductType.	Optional and Bounded to one instance (0..1).	Hepatitis A, B, MMR, DPT, etc.
<Services>	The child <Services> (1..∞) is an instance of EncounterType. Supports description of <Service> with <Description> (CodedDescriptionType), as well as <Provider> and <Location>.	Optional and Bounded to one instance (0..1).	Physical therapy, occupational therapy, home health evaluation, social service evaluation, family counseling, financial counseling, etc.
<Encounters>	The child <Encounter> (1..∞) is an instance of EncounterType. Supports description of <Encounter> with <Description> (CodedDescriptionType), as well as <Provider> and <Location>.	Optional and Bounded to one instance (0..1).	Appointment, Admission
<Authorizations>	The child <Authorization> (1..∞) is an instance of AuthorizationType. It is to be used only for pending authorization requests. Authorizations that have already been approved should be contained under <Insurance>.	Optional and Bounded to one instance (0..1).	Authorization for Procedure Requested
<Goals>	The child <Goal> (1..∞) is an instance of GoalType – supports text description of <Goal> with <Description> (CodedDescriptionType).	Optional and Bounded to one instance (0..1).	Authorization for treatment, procedure, immunization, brand name medication, etc.

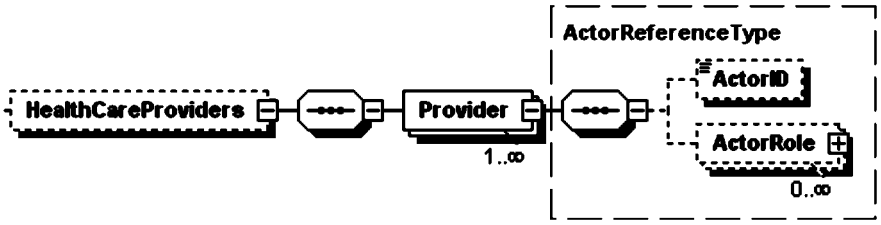

FIG. A2.24 <HealthCareProviders> Data Object

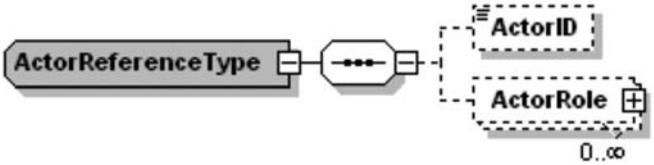

FIG. A2.25 Data Object ActorReferenceType

(4) <InformationSystem> — <InformationSystem> defines an Information System as an ActorType as in Table A2.21.

(5) Samples of <Actors> are illustrated in Examples 37 and 38 for the <Actor> Patient and Referring Physician.

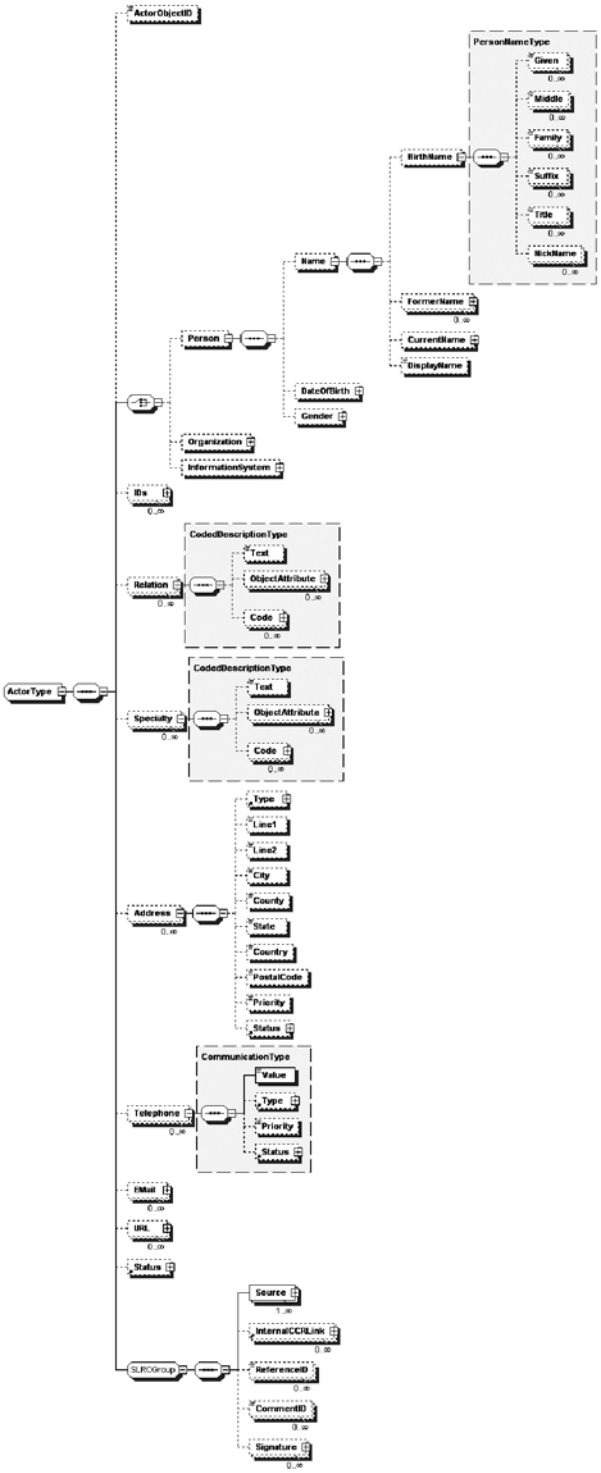

FIG. A2.26 Complex Data Type ActorType

TABLE A2.18 ActorType Definition Table

ActorType	Accepted Values/Formatting	Optionality/0 - ∞	Description
<ActorObjectID>	The ID must be made up of characters in the set A-Z, a-z, 0-9, dash (-), underscore (_) and period (.). The first character must be from the set A-Z, a-z. It can be of any character length.	Required and Bounded to one instance. (1..1).	This is the ObjectID of the <Actor>.
<Person>	Defines the details about a <Person> as an <Actor>.	Optional and Bounded to one instance. (0..1).	Used when the <Actor> is a <Person>.
<Organization>	Defines the details about a <Organization> as an <Actor>.	Optional and Bounded to one instance. (0..1).	Used when the <Actor> is an <Organization>.
<InformationSystem>	Defines the details about a <InformationSystem> as an <Actor>.	Optional and Bounded to one instance. (0..1).	Used when the <Actor> is an <InformationSystem> – example: when the Source of the CCR is an Information System.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	<IDs> is a container for any <ID> that applies to a data object but is not the <CCRDataObjectID>. This includes "external" IDs such as a driver's license number, Social Security number, product ID number, serial number, or "internal" IDs such as EHR or system-specific IDs for discrete data objects.
<Relation>	An instance of CodedDescriptionType.	Optional and Unbounded (0..∞).	Defines the <Relation> of the <Actor> to the <Patient>, when applicable. Parent, Child, Significant Other, etc.
<Specialty>	An instance of CodedDescriptionType.	Optional and Unbounded (0..∞).	Defines the Medical or Healthcare Specialty of the Person or Organization. Ideally, for Medical Specialties, this should be matched to the AMA list of medical and surgical specialties.
<Address>	<Address>contains <Type>, <Line1>, <Line2>, <City>, <County>, <StateProvince>, <Country>, <PostalCode>, <Priority>, and <Status>.	Optional and Unbounded (0..∞).	Defines an address of a Person or Organization. Each address can specify a type (Home, Office…), a Priority for contacting (Primary – Preferred, Secondary), and a Status (Active, Temporary…).
<Telephone> <Email> <URL>	Contain <Value>, <Type>, <Priority>, and <Status>.	Each one is Optional and Unbounded (0..∞).	These are each represented by the Complex Data Type – CommunicationType. They are used to define phone number, email, or url for contacting the Actor. Each can specify a <Type> (Home, Office…). a <Priority> for contacting (Primary – Preferred, Secondary), and a <Status> (Active, Temporary…).
<Status>	This is a CodedDescriptionType with restricted content that must be one of the defined structured text values. Active, Prior History No Longer Active, Unknown.	Optional and Bounded to one instance. (0..1).	Defines the current <Status> of the <Actor>.

TABLE A2.19 <Person> Definition Table

<Person>	Accepted Values/Formatting	Optionality/Cardinality	Description
<Name>	Container for all the different names for the person.	Optional and Bounded to one instance (0..1).	Holds <BirthName>, <FormerName>, <CurrentName>, or <DisplayName> or a combination thereof.
<BirthName>	Consists of <Given>, <Middle>, <Family>, <Suffix>, <Title>, <NickName>.	Optional and Bounded to one instance (0..1).	The name the patient was legally given at birth. <Given>John<Middle>Quincy<Family>Doe<Suffix>III<Title> MD<Title>PhD<NickName>Jack
<AdditionalName>	Consists of <Given>, <Middle>, <Family>, <Suffix>, <Title>, <NickName>.	Optional and Unbounded (0.. ∞)	Any prior legal or assumed name set.
<CurrentName>	Consists of <Given>, <Middle>, <Family>, <Suffix>, <Title>, <NickName>.	Optional and Bounded to one instance (0..1).	The patient's current legal name or assumed name set.
<DisplayName>	A text string that represents the<Actor>name as it should be displayed as a simple, untagged, and unparsed string.	Optional and Bounded to one instance (0..1).	John Q. Doe, III, MD, PhD
<DateOfBirth>	Instance of DateTimeType.	Optional and Bounded to one instance (0..1).	Defines <DateOfBirth> and should be as accurate as possible, preferably using <ExactDateTime>.
<Gender>	Instance of CodedDescriptionType with restricted content that must be one of the defined structured text values. Male, Female, Other, Unknown.	Optional and Bounded to one instance (0..1).	Defines<Gender>.

TABLE A2.20 <Organization> Definition Table

<Organization>	Accepted Values/Formatting	Optionality/Cardinality	Description
<Name>	String	Optional and Bounded to one instance (0..1).	This is the <Name> of the <Organization>.

TABLE A2.21 <InformationSystem> Definition Table

<InformationSystem>	Accepted Values/Formatting	Optionality/Cardinality	Description
<Name>	String	Optional and Bounded to one instance (0..1).	This is the <Name> of the <InformationSystem>.
<Type>	String	Optional and Bounded to one instance (0..1).	This defines the <Type> of <InformationSystem>.
<Version>	String	Optional and Bounded to one instance (0..1).	This defines the <Version> of the <InformationSystem>.

Example 37 – Patient as <Actor>

```
<Actor>
 <ActorObjectID>AA0001</ActorObjectID>
 <Person>
  <Name>
   <BirthName>
    <Given>Harriet</Given>
    <Middle>Mary</Middle>
    <Family>Kellogg</Family>
   </BirthName>
   <CurrentName>
    <Given>Harriet</Given>
    <Middle>Kellogg</Middle>
    <Family>Parker</Family>
    <Title>Esq.</Title>
   </CurrentName>
  </Name>
  <DateOfBirth>
    <ExactDateTime>1917-01-16</ExactDateTime>
  </DateOfBirth>
  <Gender>
<Text>Female</Text>
</Gender>
 </Person>
 <IDs>
<Type>
<Text>SecurityNumber</Text>
</Type>
  <ID>000-00-0000</ID>
<Source>
 <Actor>
 <ActorID>___________</ActorID>
 </Actor>
</Source>
 </IDs>
 <Address>
  <Type>
<Text>Home</Text>
</Type>
  <Line1>1010 Morris Road</Line1>
  <City>San Francisco</City>
  <State>CA</State>
  <Country>USA</Country>
  <PostalCode>94304</PostalCode>
 </Address>
 <Telephone>
  <Value>555-555-5555</Value>
  <Type>
<Text>Home</Text>
</Type>
  <Priority>Primary – Preferred</Priority>
 </Telephone>
 <Telephone>
  <Value>555-555-5555</Value>
  <Type>
<Text>Mobile</Text>
</Type>
  <Priority>Secondary</Priority>
 </Telephone>
 <EMail>
  <Value>hparker@whatevermail.com</Value>
 </Email>
<Source>
 <Actor>
 <ActorID>___________</ActorID>
 </Actor>
</Source>
</Actor>
```

Example 38 – Referring Physician as <Actor>

```
<Actor>
 <ActorObjectID>AA0017</ActorObjectID>
 <Person>
  <Name>
   <CurrentName>
    <Given>John</Given>
    <Middle>Q</Middle>
    <Family>Doe</Family>
    <Suffix>Jr.</Suffix>
    <Title>MD</Title>
    <Title>PhD.</Title>
   </CurrentName>
  </Name>
 </Person>
 <IDs>
  <Type><Text>Physician Number</Text></Type>
  <ID>120001</ID>
<Source>
 <Actor>
 <ActorID>___________</ActorID>
 </Actor>
</Source>
</IDs>
 <Specialty>
  <Text>Emergency Medicine</Text>
 </Specialty>
 <Address>
  <Type><Text>Office</Text></Type>
  <Line1>94044 Link Road</Line1>
  <City>San Francisco</City>
  <State>CA</State>
  <Country>USA</Country>
  <PostalCode>94304</PostalCode>
 </Address>
 <Telephone>
  <Value>555-555-5555</Value>
  <Type><Text>Office Phone</Text></Type>
  <Priority>Primary – Preferred</Priority>
  <Status><Text>Active</Text></Status>
 </Telephone>
 <EMail>
  <Value>jqdoe@pacifichealthclinic.org</Value>
 </Email>
 <URL>
  <Value>www.pacifichealthclinic.org</Value>
 </URL>
<Source>
 <Actor>
 <ActorID>___________</ActorID>
 </Actor>
```

```
</Source>
 <InternalCCRLink>
  <LinkID>BB0004</LinkID>
  <LinkRelationship>Employer</LinkRelationship>
 </InternalCCRLink>
</Actor>
```

A2.5.5.2 *<References>*

(1) <References> is optional and bound to one instance (0..1). The child element <Reference> is required and unbounded (0..∞) and contains information about external references. External references are data sources/locations that are outside the CCR. External reference data can be URLs, reference articles, clinical documents, paper or electronic patient records, diagnostic or document images, or any other data that would be of value to the providers using the CCR data for patient care. As with <Actors>, all <References> in the CCR are *normalized*. All defining attributes are listed under a unique instance of <Reference> within the <References> section of the CCR, for each reference. Each <Reference> is defined by a CCRDataObjectID (<ReferenceObjectID>) of type xs:string. Each link to a <Reference> from any other data object within the CCR is through a <ReferenceID> which is of type xs:string.

(2) Each <Reference> is a Complex Data Type ReferenceType as illustrated in Fig. A2.27.

(3) The Definition Table for ReferenceType is Table A2.22.

A2.5.5.3 *<Comments>*

(1) <Comments> is optional and bound to one instance (0..1). The child element <Comment> is required and unbounded (1..∞) and contains all text <Comments> associated with any data within the CCR. As with <Actors> and <References>, all <Comments> in the CCR are *normalized*. All defining attributes are listed under a unique instance of <Comment> within the <Comments> section of the CCR, for each reference. Each <Comment> is defined by a CCRDataObjectID (<CommentObjectID>) of type xs:string. Each link to a

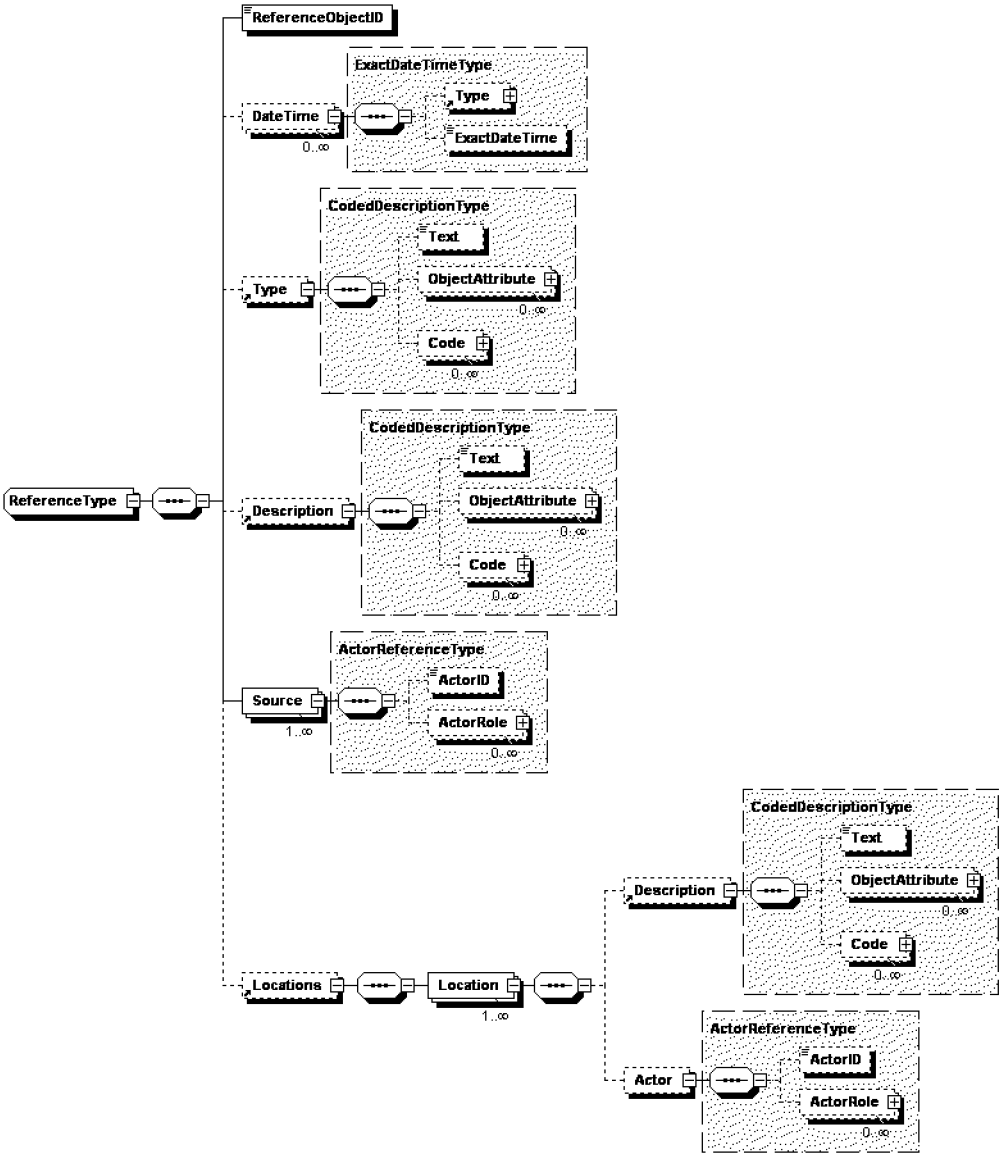

FIG. A2.27 Complex Data Type ReferenceType

TABLE A2.22 ReferenceType Definition Table

ReferenceType	Accepted Values/Formatting	Optionality/Cardinality	Description
<ReferenceObjectID>	xs:string AA0000-ZZ9999	Required and Bounded to one instance (1..1).	This is the <Reference> ObjectID.
<DateTime>	Instance of DateTimeType.	Optional and Unbounded (0..∞).	<Reference><DateTime> should be as accurate as possible and should refer to the date of origin of the <Reference>. It should be expressed as an <ExactDateTime>.
<Description>	Instance of CodedDescriptionType.	Optional and Bounded to one instance (0..1).	This is a <Description> of the <Reference>. Admission H&P
<Source>	This is an <Actor> reference with <ActorID> and <ActorRole>.	Required and Unbounded (1..∞).	This is the <Source> of the <Reference>.
<Locations>	This can be expressed as a <Description> (CodedDescriptionType) or as a link to an <Actor>.	Optional and Unbounded (0..∞).	This is a pointer to one or more <Locations>(s) where the <Reference> can be accessed or where it is stored.

<Comment> from any other data object within the CCR is through a <CommentID> which is of type xs:string.

(2) <Comments> are intended to provide a 'comment' to a CCR data object but are not intended to contain core relevant clinical or administrative data. All core relevant clinical and administrative data should be mapped to the appropriate data objects within the CCR and contained within that data object within the Body or appropriate Header or Footer sections of the CCR. <Comments> should also not contain pointers to references or other data external to the CCR that applies to a CCR data object. Pointers to references should be contained within the <References> section within the CCR Footer and not in <Comments>.

(3) To reiterate, <Comments> is for non-essential comments relevant to a CCR data object, but not containing core data or links that are more appropriately contained within the CCR data object itself.

(4) <Comments> are defined within the CCR by the Complex Data Type CommentType as illustrated in Fig. A2.28.

(5) The Definition Table for CommentType is Table A2.23.

A2.5.5.4 *<Signatures>*

(1) <Signatures> is optional and bound to one instance (0..1). The child element <CCRSignature> is required and unbounded (1..∞) and contains all <Signatures> associated with any data within the CCR. As with <Actors>, <References>, and <Comments>, all <Signatures> within the CCR are *normalized*. All defining attributes are listed under a unique instance of <CCRSignature> within the <Signatures> section of the CCR, for each signature. Each <CCRSignature> is defined by a CCRDataObjectID (<SignatureObjectID>) of type xs:string. Each link to a <CCRSignature> from any other data object within the CCR is through a <SignatureID> that is of type xs:string.

(2) If <Signatures> are used within the CCR, they must be digital signatures that meet the W3C's XML digital signature standard (http://www.w3.org/TR/xmldsig-core).

(3) It is recommended that, at a minimum, the entire CCR have a checksum calculated at the time of generation and a digital signature applied to the entire document to assure non-repudiation. Additional uses of digital signature for validation of origin, as well as validation of origin and non-repudiation of individual data objects within the CCR, is at the discretion of the originating entity.

(4) <Signatures> within the CCR are defined by the Complex Data Type SignatureType as illustrated in Fig. A2.29.

(5) The Definition Table for SignatureType is Table A2.24.

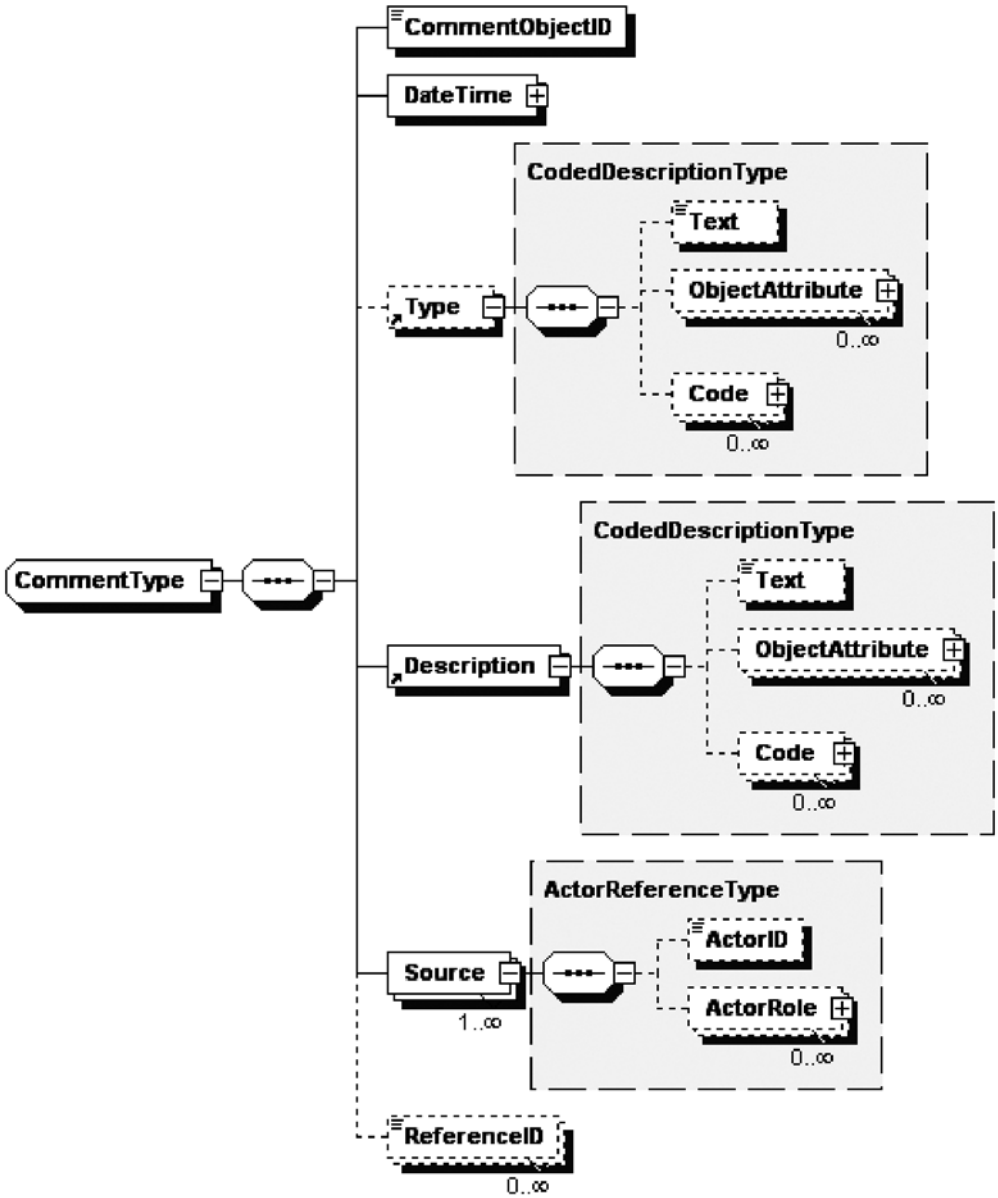

FIG. A2.28 Complex Data Type CommentType

TABLE A2.23 CommentType Definition Table

CommentType	Accepted Values/Formatting	Optionality/Cardinality	Description
<CommentObjectID>	This is the ID that each <CommentID> will link to and is expressed as xs:string.	Required and Bounded to one instance (1..1).	This is the CCR Object ID for the <Comment>.
<DateTime>	Instance of DateTimeType.	Required and Bounded to one instance (1..1).	This is the <Comment><DateTime>. <Comment><DateTime> should be as accurate as possible and should refer to the data of origin of the <Reference>. It should be expressed as an <ExactDateTime>.
<Description>	Instance of CodedDescriptionType.	Required and Bounded to one instance (1..1).	<Description> contains the actual Comment. Example: Patient's father is an unreliable historian.
<Source>	This is an <Actor> reference with <ActorID> and <ActorRole>.	Required and Unbounded (1..∞).	This is the <Source> of the <Comment> content.
<ReferenceID>	This is a link to <Reference>.	Optional and Unbounded (0..∞).	Used to link the <Comment> to a <Reference> to more detailed information about or referred to in the <Comment>.

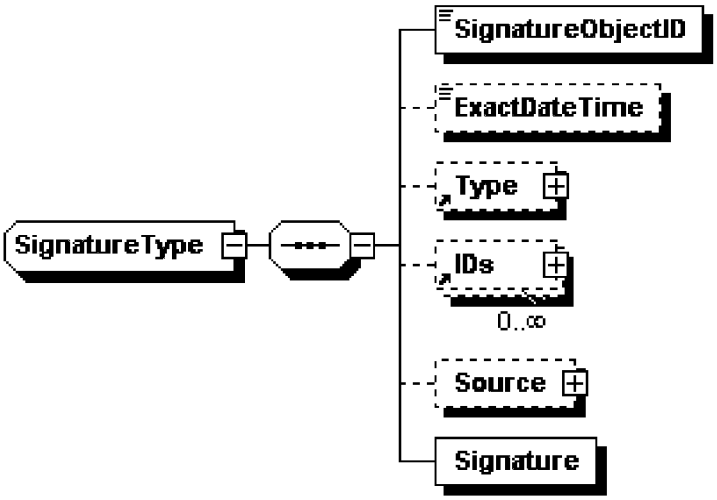

FIG. A2.29 Complex Data Type SignatureType

TABLE A2.24 SignatureType Definition Table

SignatureType	Accepted Values/Formatting	Optionality/Cardinality	Description
<SignatureObjectID>	Instance of type xs:string.	Required and Bounded to one instance (1..1).	This is the CCR Object ID for the <Signature>.
<ExactDateTime>	Instance of ExactDateTimeType.	Optional and Bounded to one instance (0..1).	This is the <Signature> time.
<Type>	Instance of CodedDescriptionType.	Optional and Bounded to one instance (0..1).	This defines the <Signature><Type>, which in all cases must be W3C XML Digital Signature.
<IDs>	Instance of IDType, which includes child elements <Type>, <ID>, and <IssuedBy>.	Optional and Unbounded (0..∞).	This is a bucket to allow any external system that wants to affix an institutional or other ID to the <Signature> that is external to the W3C XML Digital Signature within <Signature>.
<Source>	This is an <Actor> reference with <ActorID> and <ActorRole>.	Optional and Bounded to one instance (0..1).	This is the <Source> of the <Signature>.
<Signature>	<Signature> is a tag reserved for the expression of a W3C XML Digital Signature.	Required and Bounded to one instance (1..1).	This is a container for an W3C XML Digital Signature.

A3. Adjunct TO STANDARD—REQUIRED W3C XML SCHEMA FOR THE CCR

A3.1 The schema represents how the CCR should be represented in XML. When prepared in a structured electronic format, XML must be used. This .xsd is derived from the XML codes in Annex A1. Strict adherence to this schema, or other schema that may be authorized through joint efforts of ASTM and other standards development organizations, is required to support standards-compliant interoperability.

A3.2 Fig. A3.1 represents the CCR general schema structure.

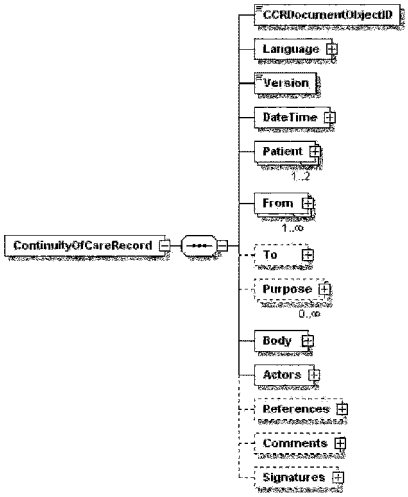

FIG. A3.1 General Structure of the CCR.xsd

BIBLIOGRAPHY

(**1**) Bates, D. W., et al, *Annals of Internal Medicine*, 2/4/2003.

(**2**) *Crossing the Quality Chasm: A New Health System for the 21st Century*, Institute of Medicine 2001.

(**3**) *The Future of the Public's Health in the 21st Century*, Institute of Medicine, 2002.

(**4**) Health Information Portability and Accountability Act (HIPAA), U.S. Congress, 1996.

(**5**) ICD-9-CM (http://www.cdc.gov/nchs/about/otheract/icd9/abticd9.htm).

(**6**) LOINC (http://www.loinc.org/).

(**7**) Multum (www.multum.com/).

(**8**) Bates, D. W., and Gawande, A. A., *The New England Journal of Medicine*, 6/19/2003.

(**9**) NDC (http://www.fda.gov/cder/ndc/).

(**10**) RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm_main.html).

(**11**) SNOMED CT (http://www.snomed.org/).

(**12**) *To Err Is Human: Building a Safer Health System*, Institute of Medicine, 2000.

(**13**) W3C XML digital signature standard (http://www.w3.org/TR/xmldsig-core/).

(**14**) W3C XML encryption standard (http://www.w3.org/TR/xmlenc-core).

APPENDIX F

INTERVIEW QUESTIONS

Welcome and Ground Rules

Script:

Welcome and thank you very much for coming to this interview about "Evaluation of Young Adults' Preferences, Needs, and the Understandability of the Personal Health Record Data Contents." Your ideas and opinions are very important in determining users' needs and preferences in the Personal Health Record System.

I am Haya Alkhatlan, and I will be conducting the interview today. That means I have a set of questions and discussion topics that I will be guiding you through this (morning/ afternoon/ evening).

Interview Objectives

My goal today is to get your ideas and opinions concerning personal health records so that you will be encouraged to use the personal health record to store and maintain your health information and apply it to your everyday life.

This interview will last about ninety-minutes.

Here are some ground rules that will help us work together this (morning/ afternoon/ evening):

1. First, I want you to know there are no right or wrong answers. I only want to know your honest ideas and opinions. I am here to learn from you, and I want to hear and learn what you think about the issues we will be discussing.
2. If you do not understand a question that I ask, please let me know. I will try to rephrase the question or better explain its point.
3. Should you need to go to the restroom during the interview, please feel free to do so.

Privacy Statement

Your participation today is voluntary. If you feel uncomfortable with any of the questions asked, you do not have to answer the question or you can simply refuse to participate. I will write a summary report of the findings from all the interviews I conduct. Your names will not be used in any way in the report.

Please read the copy of the informed consent form and sign it.

Any questions before I start?

First: determine the level of understandability of each data item from the CCR

(Payers / payment sources, Advance directives, Support sources, Functional status, Problems, Family history, Social history, Health status, Alerts (allergies, adverse reactions), Medications, Medical equipment, Immunizations, Vital signs, Plan of care, Healthcare providers, Procedures/surgeries, Encounters/consultations)**;** participants will be evaluated based on the following:

Easy to understand= 3

Understandable with short definition= 2

Understandable with long definition= 1

Difficult to understand= 0

Note: Appendix E provides the short and long definitions of the CCR data items.

CCR data Item	Short definition	Long definition
Payers/payment source	Who is responsible to pay your service bill? Self-pay, insurance, other.	Contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination of payers and is used to define which entity is the responsible fiduciary for the financial aspects of a patient's care.
Advance Directives	Living will, durable power of attorney that allow someone else to act on your behalf on matters that you specify.	Contains data defining the patient's advance directives and any reference to any existing supporting documentation and the physical location of that documentation, such as a durable power of attorney for healthcare.

Support sources	Any one that provides support to you incase of seeking healthcare and services	Lists the patient's support providers and contacts (family, next of kin, legal guardian, durable power for healthcare, clergy, caregivers, support organizations, etc.
Functional Status	Ability to care for self, activities of daily living bathing, cooking, driving, writing, etc.).	Lists and describes the patient's functional status, for example, competency, ambulatory status, ability to care for self, activities of daily living.
Problems	Any complaints, conditions, diagnoses, symptoms, findings.	Contains data defining the patient's relevant current and historical clinical problems, conditions, diagnoses, symptoms, findings, and complaints.
Family History	Any one in the family with high blood pressure, diabetic, cancer, or any other hereditary diseases.	Contains data defining the patient's blood or genetic relatives in terms of possible or relevant health risk factors.
Social History	Lifestyle, smoking, marital status, race, ethnicity, religious affiliation.	Contains data defining the patient's occupational, personal (for example, lifestyle), social, and environmental history and health risk factors, as well as administrative data (ADT) such as marital status, race, ethnicity, and religious affiliation.

Health Status	How you describe your current health (Ill, any specific health issue, healthy, hospitalized, long term facility care, etc.).	Description of the symptom, disease, data about births and prenatal care, deaths and infant mortality, childhood and adult immunizations, smoking and overweight/obesity rates, mental health, diseases such as heart disease, cancer, strokes, data and information related to HIV/AIDS.
Alerts	Allergies to certain type of medications or adverse reaction.	Lists and describes any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history.
Medications	Type of prescribed medication or over the counter medication.	Defines a patient's current active medications and pertinent medication history. Also, an entire medication history (supplement, vitamins, herbs, prescribed, over the counter).
Medical Equipment	Artificial leg, hand, or any other organ in your body.	Defines a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history. This section is also used to itemize any pertinent current or historical durable medical equipment (DME) used to help maintain the patient's health status.

Immunizations	Any type of vaccine or shots to prevent you from getting sick.	Defines a patient's current immunization status and pertinent immunization history.
Vital Signs	Blood pressure, pulse. respiratory rate, height, weight, body mass index, head circumference.	Defines the patient's current and historically relevant vital signs, for example, blood pressure, pulse, respiratory rate, height, weight, body mass index, head circumference, and pulmonary function tests.
Plan of Care	What healthcare providers recommend for you to improve your health such as medication, surgery, rehabilitation, physical therapy, etc.	Contains data defining all pending orders, interventions, encounters, services, and procedures for a patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. *(1)* All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient should be listed, unless constrained due to issues of privacy. *(2)* Clinical reminders should also be placed here for purposes of providing prompts that may be used for disease prevention, disease management, patient safety, and healthcare quality improvements, including widely accepted performance measures.

Healthcare Providers	Complete information about any healthcare provider that provides care during your visit for future reference.	Contains data defining all healthcare providers involved in the current or pertinent historical care of the patient. At a minimum, the patient's key healthcare providers should be listed, particularly the patient's primary physician and any active consulting physicians, therapists, and counselors.
Procedures/surgeries	Any kind of operation that you did	Defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically.
Encounters/consultations	Hospitalizations, office visits, home health visits, long-term care stays, or any other pertinent encounters.	Contains data defining all healthcare encounters pertinent to the patient's current health status or health history. Encounters can be hospitalizations, office visits, home health visits, long-term care stays, or any other pertinent encounters.

Second: Semi-Structured Interview

The semi- structured interview is separated into three parts that include a set of questions and discussion topics to determine the level of physical activity, knowledge of or proficiency with technology, and interest in maintaining health information and needs assessment; after discussion, participants will be asked to select seventeen items that are the most important to them to have in the PHR from the list of data items (including the 17 items from the CCR and the hypothetical ones that were collected from the feedback of the informal pilot study). Finally, participants will be asked to provide a "wish list" of any information not on the provided list that they feel should be included in a PHR., and then the investigator conclude the interview.

A: Physical Activity

1. What do you think about physical activity?
    a. What positive associations does physical activity bring to mind?
    b. What negative associations or concerns come to mind?
2. Do you currently engage in any type of physical activity?
    a. What are these activities?
    b. How often?
    c. Are any of these activities done with the intention of promoting your health?
    d. Have you ever stored your physical data?
        i. In what format?

B: Technology

3. Tell me about your use of technology in everyday life
    a. What positive associations does technology bring to mind?
    b. What negative associations or concerns come to mind?

4. Do you use a cell phone?
    a. Is your cell phone Internet capable?
    b. Do you ever use the Internet on this device? If so, for what purposes? (Check e-mail, bank accounts, credit card accounts, bills; shop online; make reservations; search and/or store health information).
5. Do you use a PDA or other portable hand-held device?
    a. Is your PDA internet -capable?
    b. Do you ever use the Internet on this device? If so, for what purposes? (Check e-mail, bank accounts, credit card accounts, bills; shop online; make reservations; search and/or store health information).
6. Tell me about your use of computers and the Internet.
    a. Do you use your computer to access health information or learn about health-related topics?
    b. How often?
    c. What types of information do you look up?

C: Interest in maintaining health information using PHR

7. Do you currently keep track of your health information?
8. What would you do with a PHR?
9. Tell me about your attitudes toward technology in managing your personal health information.
    a. What positives do you see?
    b. What negative aspects or concerns come to mind?

10. Do you think the PHR, like the ATM, cell phone online reservation, online shopping, etc., can fit into your daily life?

11. What should we consider in order to make the PHR more beneficial for you?

D: Needs assessment

Please select 17 items that you consider the most relevant to your needs and most important to have in the PHR

Item number	Data item (suggested PHR data contents)	Type of suggested PHR data contents	Structure (data elements)
1	Alerts	Simplified CCR data item	Allergies (drug, medication, material, food, other), adverse reactions.
2	Social history	Simplified CCR data item	Lifestyle, habits, smoking, alcohol consumption, etc.
3	Expenses records	Non-CCR data item	Medical bills and receipts.
4	Referral request records	Non-CCR data item	Name of specialty, address, contact information, reason for visit, medical report for referring condition from primary physician, date of appointment.
5	Identification of health goals/ Progress notes	Non-CCR data item	Free text to contain information related to specific goals and accomplishments.
6	Functional status	Simplified CCR data item	Ability to care for yourself such as (Activities of daily living (ADLs) are "the things we normally do in daily living including any daily activity we perform for self-care (such as feeding ourselves, bathing, dressing, grooming), restrictions for any reason.
7	Payers/payment sources	Simplified CCR data item	Insurance coverage name/ address/ phone number, type of coverage, effective and expiration date, policy number, group number, ID number.

Item number	Data item (suggested PHR data contents)	Type of suggested PHR data contents	Structure (data elements)
8	Personal identification information	Non-CCR data item	Name, DOB, unique number, address, numbers (home phone, work, cellular, fax), first and second emergency contact information, blood type, marital status, race, ethnicity, religion affiliation.
9	Medical equipment (ME)	Simplified CCR data item	Name of ME, description, date of implantation, location, Dr. responsible for implant, special instructions in case of emergency, reason, and restrictions.
10	Support sources	Simplified CCR data item	Name/ address/ email address/ phone number of (family member, next of kin, caregiver, legal guardian).
11	Vital signs	Simplified CCR data item	Temperature, blood pressure, height, weight.
12	Appointment Records	Non-CCR data item	Date/ time/ location of the appointment, Dr. name and contact information, reason, report of the visit.
13	Family history	Simplified CCR data item	Choose from lists the type of disease, relationship of the person in the family who has/had it.
14	Problems	Simplified CCR data item	Major medical conditions, diagnoses, symptoms, date of onset of each medical condition, provider treating each condition, treatment prescribed for each condition.

Item number	Data item (suggested PHR data contents)	Type of suggested PHR data contents	Structure (data elements)
15	Diet & weight records	Non-CCR data item	Consumption/ burning of calories, records of type of food, weight calculation daily, weekly, monthly, and other).
16	Chat Records	Non-CCR data item	Instant live messages e.g. msn, videoconferencing, date, time, subject, reason, detailed identification information for participants such as name of a physician/ technician/nurse/therapist.
17	Immunizations	Simplified CCR data item	Select from lists name of immunization, type, date, dose, reason.
18	E-mail Archive	Non-CCR data item	Date, time, sender name, receiver name, digital signature of responding healthcare providers, subject, reason for message, and context of the message.
19	Encounters/ consultations	Simplified CCR data item	Date, reason, Dr. responsible, dictated consult report.
20	Imaging data	Non-CCR data item	Type (MRI, CT scan, X-ray), date, reason (diagnostic, therapeutic, other), results reports, attached image, provider information responsible for ordering each test.
21	Advance directives	Simplified CCR data item	Legal documents of living will, durable power of attorney, dates, detailed information, and authorization name for person to act on your behalf.
22	Free text notes/ Personal diaries	Non-CCR data item	Feedback about your experience with specific Dr. or healthcare providers, facility, to-do-list, etc.
23	Records of exercise habits/ Physical activity records	Non-CCR data item	Manually or automatically capturing data from wearable devices such as pedometers or data from fitness equipment such as a treadmill.

Item number	Data item (suggested PHR data contents)	Type of suggested PHR data contents	Structure (data elements)
24	Plan of care	Simplified CCR data item	Dr. responsible for treatment plan, start/end date, instruction, detailed information such as medication, surgery, rehabilitation, physical therapy, disease management information.
25	Related educational material (personal library)	Non-CCR data item	Saving web pages related to health, educational materials on health related to individual health needs such as how some medications reduce heart rate, how some exercises reduce stress level, how some diets reduce weight, Encyclopedia (health, drug), etc.
26	First aid information	Non-CCR data item	First aid information in case of emergency (e.g. burns, foot injuries, nose bleeds, etc.)
27	Health status	Simplified CCR data item	Condition (e.g. ill, well, chronic disease, hospitalized, long term facility, nursing home), description (date, reason)
28	Procedures/surgeries	Simplified CCR data item	Date, Dr. responsible, reason, description (in/out patient), results after the operation, dictated operative report.
29	Personal calendar/ Reminders(as contents/information)	Non-CCR data item	Appointment with healthcare providers or taking of medication/therapy, to-do-list, etc.
30	Healthcare provider	Simplified CCR data item	Primary physician name, other physicians, specialty, office address (location), phone number, email address.

Item number	Data item (suggested PHR data contents)	Type of suggested PHR data contents	Structure (data elements)
31	Medications	Simplified CCR data item	Select prescribed medication from lists, current/past medication, dose, frequency, start/end day, duration, instructions, Dr. prescribing medication, pharmacy information that issued medication, free text entry for over the counter medication (supplement, herbs, vitamins, etc.), medications prescribed by pharmacist, drug reaction, drug interactions information, restriction.
32	Lab test results	Non-CCR data item	Select lab test from lists, import results from source, date of test, reason for test, interpretation of test results, lab report, and provider information responsible for ordering each test.

Concluding Questions

Script:

Have I missed anything that you feel is important, or is there anything else you would like to add before we finish this (morning/afternoon/evening) session?

Closing

We are done for today. Thank you so much for your time this (morning/afternoon/evening). I really appreciate your coming here to meet with me for this discussion. Your comments and insights have been very helpful!

APPENDIX G

INFORMED CONSENT FORM

Dear Participant:

IRB # PRO08060161

You have decided to participate in this research study entitled

"Evaluation of Young Adults' Preferences, Needs, and the Understandability of the Personal Health Record Data Contents"

Your participation in this study is extremely important since your response could provide crucial information regarding preferred Personal Health Record data elements.

The results of this study will yield valuable information to personal health record developers, vendors, and policy makers as they design and promote the personal health record system.

Please understand that your participation is completely voluntary. Should you agree to take part, you will receive $30 in compensation upon completion of the entire ninety-minutes session. You may choose to stop your participation at any time if you feel uncomfortable or for any other reason, but you will forfeit the $30.

The information gathered in this study will be kept strictly confidential; no personal identification information will be released.

Sincerely,

Haya Alkhatlan, M.S.

Ph.D. Candidate, School of Health and Rehabilitation Sciences, University of Pittsburgh

APPENDIX H

THE STUDY FLYER

Needed: Young Adults, Ages 18-25

The Department of Health Information Management, School of Health and Rehabilitation Sciences, University of Pittsburgh, is conducting a research study to evaluate preferences, needs, and the level of understandability of the personal health record data contents.

If you are a healthy male or female 18-25 years old and a native English speaker, and your major is not in any kind of health field, you might be eligible for this study. No prior knowledge about the subject of the research is necessary for participation.

The interview, which takes approximately ninety-minutes, consists of a brief orientation about the subject of the study and an in-depth interview.

Upon completion of the entire interview, participants will immediately receive a check for the amount of $30 compensation.

The American Health Information Management Association funds this research study.

For further information, please contact the principal investigator, Haya Alkhatlan at: **hma6@pitt.edu**, hmast12@gmail.com, or 412-576-3892

APPENDIX I

THE MOST RELEVANT DATA CONTENTS AND THEIR STRUCTURE FROM PARTICIPANTS' PERSPECTIVES

1. "Payers / payment sources" (insurance coverage name, address, phone number, type of coverage, effective and expiration date, policy, group, ID number).

2. "Advance directives" (living will, durable power of attorney, date, detail information, authorization name for person to act on your behalf).

3. Support sources (name, address, email address phone number of family member, next of kin, caregiver, legal guardian)

4. Functional status (ability to care for yourself, activity of daily living, restrictions for any reason)

5. Problems (major medical conditions, diagnosis, symptoms, date of onset of each medical condition, provider treated each condition, treatment prescribed for each condition)

6. Family history (choose from lists the type of disease, relationship of the person in the family)

7. Social history (life style, smoking, alcohol consumption, occupation, hobby)

8. Health status (ill, well, chronic disease, hospitalized, long-term facility, nursing home)

9. Alerts (allergies, adverse reactions)

10. Medications (select prescribed medication from lists, current/past medication, dose, frequency, start/end day, duration, instructions, Dr. prescribed medication, pharmacy information that issued medication) free text entry for over the counter medication, pharmacist prescribed, supplement, herbs, vitamins, etc.), drug reaction, drug interactions information, restriction)

11. Medical equipment (description, date of implanted, location, Dr. responsible for implant, special instruction in case of emergency, reason, restrictions)

12. Immunizations (select from lists, type, date, dose, reason)

13. Vital signs (temperature, blood pressure, height, weight)

14. Plan of care (dr. responsible for treatment plan, start/end date, instruction, detailed information such as medication, surgery, rehabilitation, physical therapy, disease management information)

15. Healthcare provider information (primary physician name, other physicians, specialty, office address, phone number, email address)

16. Procedures/surgeries (date, Dr. responsible, reason, description, results after the operation, dictated operative report)

17. Encounters/consultations (date, reason, Dr. responsible, dictated consult report)

18. Personal identification information (unique hospital number, name, DOB, address, numbers (home phone, work, cellular, fax, next of kin, first and second emergency contact information, blood type, marital status, race, ethnicity, religion affiliation)

19. Related educational materials {Encyclopedia (health, drug); Facility Directory (department, physicians, locations, phone numbers, services); Healthy lifestyle programs (weight management information, smoking cessation information, depression control information, health classes, health calculators for healthy weight, pregnancy due date calculator, Calcium intake, Number of calories burned, Stress level, Cost of smoking, Calorie intake, Asthma triggers, Recipes for healthy food and weight watchers, etc.)}

20. Chat Records (date, time, sender information, receiver information, content of a massage, subject)

21. E-mail Archive (date, time, sender information, receiver information, content of a massage, subject)

22. Appointment Records (date, time, Dr. information, facility information, reason, visit report)

23. Diet & weight records (date/time of a meal, number of meal, number of snacks, type of food, calories intake, and weight)

24. Imaging data (date, reason, type, radiology report, imaging diagnostic and results reports)

25. Lab test results (select lab test from lists, import results from source, date of test, reason of test, interpretation of test result, lab report, and provider responsible for ordering each test)

26. Library (saving web pages related to health, educational materials on health related to individual health needs such as how some medications reduce heart rate, how some exercises reduce stress level, how some diets reduce weight, etc.)

27. Free text notes entry/ Personal diaries (feedback about your experience with specific Dr. or healthcare providers, facility, etc.)

28. Referral request records (referral letter, reason, specialist contact information, appointment date/time, appointment location)

29. Identification of health goals/ Progress notes reviewing goals/ Automated system providing feedback/encouragement

30. Personal calendar/reminder (appointment with healthcare providers or taking medication/therapy)

31. First aid information (what you can do in case of broken leg, bloody noise, burn)

32. Expenses records (medical bills and receipts)

33. Records of exercise habits/ Physical activity records (manually or automatically capturing data from wearable devices such as pedometers

APPENDIX J

USERS' NEEDS FROM FIVE PILOT STUDIES

1. Payers / payment sources
2. Advance directives
3. Support sources
4. Functional status
5. Problems
6. Family history
7. Social history
8. Health status
9. Alerts (allergies, adverse reactions)
10. Medications
11. Medical equipment
12. Identification information
13. Next of kin information
14. Health insurance information
15. Living will and advance directives
16. Organ donor authorization

17. History and physical reports
18. Progress notes
19. Physician's orders
20. Drug reactions
21. Family illness history
22. Specialists' consultations
23. Eye and dental records
24. Recent physical exam
25. X-rays
26. Lab reports
27. Correspondences with physicians and other healthcare providers
28. Release of information form and other consents
29. Sharing health concerns and conditions via Social Networking (Facebook, Twitter, MySpace, LinkedIn group)
30. Immunizations
31. Vital signs
32. Plan of care
33. Healthcare provider information
34. Procedures / surgeries
35. Encounters / consultations
36. Health classes
37. Health encyclopedia
38. Facility directory

39. Health lifestyle programs

40. Weight management information

41. Smoking cessation information

42. Depression control information

43. Connection to your health / medical record

44. Drug encyclopedia

45. Contact a professional by e-mail, instant messaging, live video

46. E-mail your doctor capability

47. Featured health topics (online discussion such as e-consulting, diet, exercise advice; consumers sharing their experiences with others whose medical situations are similar and answering other questions in real time; health plan explanation of benefits and services; help with insurance claims)

48. Health calculators

    i. Healthy weight
    ii. Pregnancy due date calculator
    iii. Calcium intake
    iv. Number of calories burned
    v. Stress level
    vi. Cost of smoking
    vii. Calorie intake
    viii. Asthma triggers
    ix. Recipes for healthy food
    x. Weight Watchers

49. Appointment scheduling with your physician

50. Prescription refill information and capability

51. Lab test results review

52. Diet tracking

53. Weight recording

54. Wearable devices capturing data (pedometers)

55. Saving web pages related to health

56. Free text notes

57. Referral request form or referral request record

58. Identification of health goals

59. Progress notes reviewing goals

60. Automated system providing feedback/encouragement

61. Pertinent information uploaded? to healthcare providers

62. Personal calendar of any appointment with healthcare providers or taking medication

63. First aid information

64. Personal Diaries

65. Medication self-care logs

66. Educational materials on health related to individual health needs

67. Reminders (taking medications, doctors appointments)

68. Care management guidance

69. Medical bills and receipts

70. Population health

71. Climate and environmental conditions

72. Monitoring of exercise habits
73. Decision support/graphical display from row data (how some medications reduce heart rate, how some exercises reduce stress level, how some diets reduce weight)
74. Ability to print critical health information in case of emergency
75. Advanced search/retrieval tools for individual health information
76. Physical activity tracking (manually or automatically)
77. Operational definition of the PHR contents

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