Technology In Healthcare: Evaluating Technological Innovation In Musculoskeletal Care, Advancement In Delivery And Treatment Options

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ABSTRACT

Musculoskeletal health has a widespread impact on patients and the public health sector as a whole. Musculoskeletal pathology is ubiquitous, affecting one in two adult Americans. As a result, it is one of the largest contributors to patient and payer burden, with estimated direct costs of over \$50B in 2019. Healthcare technology innovation has been growing rapidly over the years. The integration of these new technologies can provide vast benefits to patients, payers, and research for the future of the field.

The purpose of this paper is to explore the impact of technology integration in the field of musculoskeletal health and how this innovation will influence and advance the field's delivery and treatment options in the years to come. This essay is supported through a literature review to examine the ideation of these integrations and progress to date along with interviews from industry experts and a program evaluation from an aspect of the author's residency, Hospital for Special Surgery Innovation Institute.

The development of musculoskeletal innovation revolutionizes clinical integration, medical device, care delivery, patient accessibility, and more. By improving outcomes, providing better quality care at lower cost, and better diagnostics and prevention, musculoskeletal innovation drives improved efficiencies for patients and providers. Digital healthcare is proving to be pivotal for the advancement of patient experience and empowerment throughout the care

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continuum, also leading to improved clinical outcomes. For organizations in this space, best practices include emphasizing the impact on patients and on industry and highlighting the cross-collaborative synergies between field experts.

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PREFACE

The ideation of this thesis stems from my internship experience at Hospital for Special Surgery supporting their Innovation Institute. Throughout my internship, I was exposed to proposals of new technological advancements and their potential impact on the field of musculoskeletal healthcare. In a specialty that affects so many patients worldwide, I found it inspiring that industries outside of traditional healthcare are finding ways to integrate and advance healthcare delivery and treatment options. This essay explores the development of technology into the field of musculoskeletal healthcare, how and where the future of technological integration may lead musculoskeletal care delivery and treatment, potential impacts on patients and payers, and finally, evaluating a program that focuses specifically on musculoskeletal innovation.

I would like to thank the many dedicated professors from the University of Pittsburgh Graduate School of Public Health in the Health Policy & Management department, as well as the dedicated professors from the University of Pittsburgh Katz Graduate School of Business. I would also like to thank my essay committee, Dr. Evan Cole, Professor Andrew Hannah, and Sandra Bossi, MCM, for challenging me and supporting me. Further, I would like to thank the Innovation Institute team at Hospital for Special Surgery, who welcomed me to their team and exposed me to facets of healthcare that I was previously unfamiliar with. Finally, I would like to thank my fiancé, my family, and my friends for supporting me.

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1.0 INTRODUCTION

Musculoskeletal healthcare has a widespread impact on patients and the public health sector as a whole. Impacting over 130M patients in the U.S., musculoskeletal conditions are the second leading cause of global morbidity-related burden of disease and the cause of over 260M lost workdays per year in the U.S. (Musculoskeletal Key, 2017). In 2014, the annual average direct cost for patients with a direct musculoskeletal disease and for patients with a musculoskeletal disease in addition to other health issues combined was estimated to be up to a staggering \$980.1B (Yelin et al., 2016). In 2019, musculoskeletal conditions accounted for onethird of workers compensation cost, nearly 400K injuries per year, and an estimated \$54B in direct costs—with indirect costs estimated to by five times the direct costs (Middlesworth, 2020). Efficient and innovative musculoskeletal healthcare delivery and treatment options are proving critical to the advancement of the field (WHO, 2019). Candidates to trailblaze this advancement are stemming from industries outside of traditional healthcare, such as digital-technology start ups and video game developers. More and more technology-enhanced companies are breaking into the foreground, as technological innovations are seeing benefits to improve healthcarerelated models of care. Further, companies are seeing an opportunity to leverage their technologies, motivating them to capture first dollars of new markets.

As we shift to a more technologically advanced world, traditional models of care are becoming outdated. For generations, the healthcare industry has been battling between risk avoidance—as new innovations tend to be high risk—and "advancement aspiration," i.e., investing in innovation to advance healthcare management, delivery, and research. 2020 health technology companies are at an all-time high in valuation, seeing valuations nearly twice as high

as 2019 and seeing "a combined market cap of \$9.8B at IPO" (Reuter, 2021). These companies are competing in a fast-paced market to revolutionize how the healthcare industry views and utilizes technological integration. Research across the industry suggests that a failure to adopt technology transformation will prove to be fatal for healthcare organizations.

Through an internship with Hospital for Special Surgery working with their Innovation Institute, the author was made aware of the vast opportunities that exist to merge technology with the field of musculoskeletal (MSK) healthcare. In the forefront of this advancement, the field of musculoskeletal health is collaborating with tools to advance treatment and care delivery options through the integrated use of machine learning, artificial intelligence (AI), robotics, medical devices, remote monitoring, and more.

The aim of this essay is to examine the development and integration of technology in musculoskeletal healthcare delivery and treatment to date. The author will use literature review, interviews, and program evaluation to explore and evaluate how these integrations will influence and advance the field. Through this examination, the author will discuss integrative disruptors that may change the future of musculoskeletal healthcare delivery.

1.1 MUSCULOSKELETAL CONDITIONS DEFINITION & IMPACT

Musculoskeletal conditions encompass more than 150 diagnoses affecting the locomotor system, i.e., "muscles, bones, joints, and associated tissues such as tendons and ligaments" (WHO, 2021). Often characterized by persistent pain and "limitations in mobility, dexterity and functional ability," musculoskeletal conditions significantly inhibit individuals' quality of life.

These patients have a limited capability to work, to enjoy personal-social activities, and have been found to have associated impacts on mental health and wellbeing (WHO, 2021).

Musculoskeletal conditions may be impermanent or chronic and affect patients from adolescence through elderly years. Contributors of musculoskeletal burden include low back pain, fractures, osteoarthritis, neck pain, amputations, rheumatoid arthritis, and other injuries (WHO, 2021). According to the 2017 Global Burden of Disease (GBD) study, musculoskeletal conditions accounted for 16% of all "years lived with disability" and were the highest contributor to global burden of disability. This study also found that between 20-33% of people globally live with the burden of a musculoskeletal condition; however, while there is evidence to prove significant burden of musculoskeletal conditions, there is widespread belief that the burden and pain is being underestimated globally (Blyth et al., 2019).

Within the United States of America, more than 1 in 2 Americans over the age of 18 reportedly live with a musculoskeletal condition, exceeding the combined number of Americans with cardiovascular or chronic respiratory conditions (Impact on Americans Exec Summary, Bone & Joint, 2016). In addition to the personal impact on patients, the social and economic implications of musculoskeletal conditions are staggering. Musculoskeletal disorders generated the highest healthcare-related expenditures in aggregate, exceeding \$380B in 2016 (see Table 1) (Dieleman et al., 2020).

			Estimate, %*												
Aggregated		Health Care Spending	Aggreg	ated Age Gr	oup, y	Type of Pa	yer		Type of Care						Government Administration
Health Category	Category Code	2016 \$Billion (95% CI)	<20	20-64	≥65	Public Insurance	Private Insurance	Out-of-Pocket Payments	Ambulatory	Inpatient	Prescribed Pharmaceuticals	Nursing Care Facility	ED	Dental	of Insurance Programs
Musculoskeletal disorders	A	380.9 (360.0-405.4)	3.6	61.3	35.2	37.3	54.0	8.7	49.0	21.5	13.1	4.0	2.4	0	10.0
Diabetes, urogenital, blood, and endocrine diseases	В	309.1 (292.4-328.4)	4.5	57.5	38.0	45.8	47.0	7.1	35.5	18.6	25.7	4.9	5.4	0	10.0
Cardiovascular diseases	c	255.1 (233.4-282.6)	1.7	38.8	59.5	56.5	37.7	5.8	19.0	49.2	6.0	11.7	4.1	0	10.0
Communicable diseases ^b	D	241.7 (226.5-258.6)	29.3	47.7	23.0	46.0	48.0	6.0	15.0	55.2	9.9	3.6	6.2	0	10.1
Other noncommunicable diseases	E	240.2 (231.3-249.5)	17.1	48.8	34.1	31.2	50.2	18.6	39.9	10.4	7.6	1.8	3.1	28.2	8.9
Injuries	F	231.1 (211.7-250.7)	9.9	57.8	32.3	37.2	53.5	9.3	30.9	36.0	1.0	8.5	13.7	0	9.9
Mental and behavioral disorders	G	180.7 (172.8-189.7)	14.7	71.8	13.5	57.4	34.4	8.2	46.1	18.8	20.2	3.0	2.2	0	9.7
Neurological disorders	н	173.9 (161.2-186.9)	4.7	36.4	58.9	49.2	34.9	15.9	23.7	10.1	14.4	39.0	3.9	0	8.9
Well care	1	167.0 (158.0-175.4)	28.3	64.0	7.7	18.8	65.1	16.1	25.0	29.3	2.4	0	0.2	33.6	9.5
Digestive diseases	1	135.6 (127.9-144.3)	7.8	60.6	31.5	42.3	52.4	5.3	19.8	41.3	9.2	4.6	14.8	0	10.3
Neoplasms	К	123.8 (114.9-132.8)	6.7	53.7	39.6	38.2	53.2	8.6	36.0	38.8	13.1	1.9	0.3	0	10.0
Chronic respiratory diseases	L	117.0 (110.8-123.2)	15.6	50.8	33.5	44,4	48.5	7.1	38.1	14.1	26.0	4.3	7.5	0	10.0
Treatment of risk factors	м	117.0 (109.3-125.7)	0.8	52.1	47.1	52.9	40.5	6.6	49.1	12.0	18.6	6.3	4.1	0	9.9
Cirrhosis	N	32.5 (27.0-40.4)	3.6	67.9	28.4	39.9	56.2	3.9	17.4	62.9	2.6	2.3	4.3	0	10.5
All categories (total)		2705.6 (2705.6-2705.6)	10.7	54.2	35.1	42.6	48.0	9.4	33.0	28.2	12.4	7.0	5.0	4.6	9.8

Table 1. Total Estimated Spending and Aggregated Health Categories for 2016.

* The 95% CIs appear in eTable 12.1 in the Supplement.

^b Includes maternal, neonatal, and nutritional disorders.

Source: Dieleman JL, Cao J, Chapin A, et al. US Health Care Spending by Payer and Health Condition, 1996-2016. JAMA. 2020;323(9):863–884. doi:10.1001/jama.2020.0734.

1.2 AUTHOR'S ROLE

The author's role for the purposes of this paper were that of 1) a student performing literature review and 2) a previous Business Intern at Hospital for Special Surgery. While at Hospital for Special Surgery, the author supported the Innovation Institute's 2-person Care Delivery team. In this role, the author supported future virtual care offerings and potential partnerships with external companies. She completed preliminary research of potential partners, drafted discussion documents, and assisted with deal structure to support new collaborative partnerships.

2.0 BACKGROUND

This section includes information to further explain technology development and advancement in the field of musculoskeletal healthcare, as well as the organization and its key functional department that was evaluated to better understand the topic discussed in this paper.

2.1 DEVELOPMENT OF TECHNOLOGICAL INNOVATION IN HEALTHCARE AND MUSCULOSKELETAL HEALTH

Broadly defined as "invention + adoption + diffusion," healthcare innovation spans novel ideas, products, services, or care pathways (Kelly & Young, 2017). The incorporation of technology in these innovations, both from within and outside the medical field, further drives useable and desireable advances that enhance the benefits of current processes and standards. Technological innovation has been slowly integrating into healthcare over the past 50-60 years. Beginning with artificial pacemakers, magnetic resonance imaging (MRI) machines, and blood cell separators, technology in healthcare stemmed from clinical advancement in the '60s and '70s. The development of the MRI in 1977 was an early and impactful technological integration into healthcare and was particularly valuable in the musculoskeletal field to allow physicians to distinguish between soft tissues in the body, aiding in musculoskeletal diagnostics.

Fast forward 20 years, there were significant improvements to clinical uses of technology, with the da Vinci surgical system, digital hearing aids, and much more. In addition, the computerization of management systems and administration functions became a popular solution to reduce the profusion of identified medical errors (MDID, 2009).

Today, two more decades later in our current landscape, healthcare technology is almost vital to incorporate in various functions of the healthcare industry, including vast clinical integration, financial operations and performance improvement, technology-enabled patient engagement tools, digital care offerings, and digital transformation and interoperability. Other current advancements are looking at how to utilize artificial intelligence (AI), machine learning, and additional technology systems to aid in clinical decision making and consumer preference alignment. Specific to musculoskeletal healthcare, current innovations are aimed at improving patient outcomes while enabling greater cost-effectiveness. Some examples include AI-enabled medical devices, digital health apps aimed at MSK prevention, and biofeedback wearables for mobility monitoring and rehabilitation.

In 2020, there were an estimated 3,000+ health tech startups, all aiming to transform the future of healthcare (Venture Scanner, 2020). Deloitte projects an annual growth rate of 5% to the healthcare market from 2019-2023 (Allen, 2020). This growth projection presents a significiant opportunity to bring impact to the prevalent and costly specialty of musculoskeletal care. This paper will be exploring the technological integration specifically in musculoskeletal care delivery and treatment.

2.2 HOSPITAL FOR SPECIAL SURGERY

Hospital for Special Surgery (HSS) is a 205-bed specialty hospital focused on orthopedics, rheumatologic conditions, and overall musculoskeletal treatment. HSS has locations in New York, New Jersey, Connecticut, and Florida, and services patients from around the world. HSS has been ranked No. 1 for orthopedics for 11 consecutive years by U.S. News &

World Report (2010-2021) and was the Guardian of Excellence Award winner for the 7th consecutive year for outstanding patient experience. HSS is staffed by 389 active medical staff, 280 advanced practice providers, over 100 training students, and over 4,900 staff members and performs more than 33,000 surgical procedures annually. Hospital for Special Surgery's Innovation Institute has managed and supported a pipeline of technology & innovation projects since the 1970's and continues to collaborate and support innovation in the field of musculoskeletal health today.

2.3 KEY FUNCTIONAL DEPARTMENTS

2.3.1 INNOVATION INSTITUTE

The HSS Innovation Institute was created to manage and enhance the pipeline of technology projects that HSS has been involved in since 1979. Focused entirely on advancing the field of musculoskeletal care, the Innovation Institute collaborates with physicians, researchers, surgeons, and scientists to improve clinical outcomes, enhance patient experience, and lower the cost of care delivery. The Innovation Institute supports internal and external advancements, particularly early-stage life sciences and care delivery innovations.

3.0 LITERATURE REVIEW

The following section includes a compilation of studies and articles, organized by themes to better provide a framework for this essay.

3.1 THE INTEGRATION AND PROGRESSION OF TECHNOLOGY IN MUSCULOSKELETAL HEALTHCARE

3.1.1 MEDICAL DEVICE

The World Health Organization defines medical devices as any "instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s)" (n.d.). Medical devices are widely utilized for musculoskeletal healthcare diagnosis and treatment. New innovative technologies in the medical device field span from technological advancements to product innovation to the use of 3D printing and manufacturing and machine learning and AI. Many medical devices are being integrated with diagnostic data collection, machine learning, and artificial intelligence to enhance the efficiencies of musculoskeletal care.

Diagnostics innovation has brought significant impact to musculoskeleltal conditions such as cerebral palsy. Gait analysis pairs motion analysis and video capture with physical exams to help accurately diagnose patients with cerebral palsy. Through the use of video capture on infrared cameras and motion analysis through surface electrode sensors, patient mobility can be tracked, recorded, and analyzed in 3D (CerebralPalsy.org, 2021). Analysis of bone and joint

motion is crucial for diagnosis as well, and traditional measuring included the use of anglers or de-adhesion markers on patients, which could cause poor accuracy and poor reproducibility. Healthcare technology companies have been developing measuring devices specific to musculoskeletal care that utilize image processing technology through 3D cameras and AI to analyze data (HealthcareDive, 2019). These diagnostic innovations help improve diagnostic accuracy and efficiency for musculoskeletal conditions.

The development of medical device wearables has been monumental in the integration of the Internet of Things (IoT) and healthcare. Through the use of biosensors, machine learning, and analytics, wearables allow for diagnostic data collection, tracking, and assessment. Wearables have been highly regarded to giving patients the agency to advocate and better understand their health, in the comfort of their home. Research from 2020 is projecting that the Internet of Medical Things (IoMT) will balloon with a growth rate of 27.2% from 2020-2027 and projects that the market value will top \$155.8B by 2027 (Acumen Research and Consulting, 2020). With both patient impact and financial opportunity, many researchers expect to see more investment in the IoMT space, whether to wearables or other integrations. Regardless of how technology is incorporated in medical devices, there are many different pathways to innovate medical device in musculoskeletal care.

3.1.2 DIGITAL HEALTH APPLICATIONS

Digital health adoption has been trending upward over the years, but recent public health events, specifically the COVID-19 global pandemic, have created an even larger surge of digital health adoption. Digital health spans categories such as "mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine" (FDA, 2020). Digital health applications utilize computing platforms, software, connectivity, and sensors to develop patient-facing platforms that range from general wellness to "companion" medical device applications, and more.

There is a large opportunity for musculoskeletal-focused digital apps (MDAs) to evolve patient care through physical therapy and rehabilitation, pain management, and behavioral health. Digital health intervention can include patient-provider communication tools, health tracking, information services, and more. These digital health applications increase access to providers for patients who were previously unable to see their care provider regularly. The opportunity for this innovation is evident, as the market of global mobile health is expected to grow to over \$110B by 2025 (Kwo, 2020).

Digital health applications are being adopted by employers, payers, and individual entrepreneurial health-tech companies, with a majority focus on preventative care and injury reduction. Many of the applications aim to reduce the use of opioids and unnecessary surgery through encouraging physical therapy and other recovery treatments. These applications utilize different approaches to musculoskeletal-induced pain management, including treatment programs, mental health programs, and the use of complementary treatment such as using external sensors to monitor the affected area or hardware applications such as ECG to track movement.

There is an abundant supply of health-related apps, with over 50,000 mobile health apps listed in the Apple App Store in Q4 of 2020 (Statista, 2021). With the upsurge in these apps, there are concerns that not all are created equal in terms of effectiveness and safety. In the MDA community, there is widespan recommendation that MDAs should be reviewed and cleared by

trained care providers and instructed to patients with ample education to correctly utilize the MDA. Further, when assessing MDAs, an evaluation should be conducted covering "usability, technical content, health content, security and transparency" (Kwo, 2020). Once appropriately vetted, digital health applications can provide patients with more autonomy for their care and more tools and resources to educate and support them throughout the musculoskeletal care continuum.

3.1.3 COMPUTER-AIDED NAVIGATION

Computer-aided navigation and imaging analysis has become popular in the treatment of musculoskeletal conditions. Computer-aided navigation (CAN) during orthopedic surgery is the "use of computer-enabled tracking systems to facilitate alignment in a variety of surgical procedures, including fixation of fractures, ligament reconstruction, osteotomy, tumor resection, preparation of the bone for joint arthroplasty (knee and hip), and verification of intended implant placement" (UHC, 2021). CAN provides surgeons with technology-enabled support during procedures to assist with accuracy and efficiency.

CAN integrates data acquisition, registration, and tracking with patient care. Data acquisition is incorporated through fluoroscopic, guided MRI, or imageless systems. Registration aides in matching the anatomical position of the field with the accompanying data, such as imaging or 3D anatomy. Data and accuracy tracking is integrated through the use of sensors and measurement devices that provide "feedback during surgery regarding the orientation and relative position of tools to bone anatomy." CAN may be imaged-based or non-image-based, and the utilization of CAN during orthopedic procedures has been suggested to increase surgical accuracy, bone alignment, and reduce misplacement and malposition during surgery. Although some form of computer-assisted navigation during orthopedic surgery has been implemented since the 1990's, there is still active research to confirm if CAN surgeries deliver improved clinical outcomes and long-term improvement for musculoskeletal patients. Some studies suggest computer-aided navigation may lower revision rates, but this research is ongoing and the technology development remains active.

3.2 IMPACT ON PATIENTS

The impact that musculoskeletal innovation has on patients is extensive. By way of providing patients the tools and resources to gain education about their condition and treatment options, to improving accessibility, to hopeful clinical outcome improvement, healthcare technology bridges a gap that musculoskeletal patients face.

3.2.1 PATIENT EDUCATION AND EMPOWERMENT

Due to integration of technological innovation in the healthcare field, patients are presented with more data-backed information about treatments and outcomes. This can empower patients to make more informed decisions about their care pathway. In a previous healthcare environment where patients had to solely rely on surgeons' opinions, technological innovation enables precision medicine while supporting patient-centric care to account for patient preference and expectations (Bossi, 2021).

Using virtual care models, patients can receive education to help better manage their conditions, track and assess their progress, and be guided in rehabilitation movements tailored to their specific musculoskeletal condition. These care offerings can be offered to patients at their

convenience and comfort, providing support to patients who previously may have had access issues. A study published in June 2020 showed that there is evidence supporting the efficacy of digital health interventions in reducing patient burden of musculoskeletal conditions, including improving pain, improving functional disability, and coping strategies (Hewitt et al., 2020).

3.2.2 IMPROVED ACCESS

Healthcare innovation "looks to reduce cost, provide better treatment, and have more accessibility so more patients can have access to same high-quality care" (Bossi, 2021). Technological integration with healthcare improves patient accessibility through continuous care monitoring for more comprehensive diagnosis and treatment, digital health applications that can tailor unique patient needs, real-time access to care through telehealth offerings, and more. Providing patients with better access to care, particularly through mobile health platforms, further empowers patients to manage their own conditions.

An example of improved access is patient utilization of virtual physical therapy solutions to improve symptoms from musculoskeletal disorders. Traditionally, there are limitations to the number of physical therapy sessions covered by insurance, and many times these covered sessions cease before the patient is fully recovered. New virtual care models can prolong patient access to care sessions and access to providers throughout the patients' recovery (Olson, 2020).

3.2.3 CLINICAL OUTCOME IMPROVEMENT

Technological integration in healthcare allows healthcare providers to collect and analyze more data than before, enabling forecasting models to determine more effective treatment

interventions. Integrating digital solutions into musculoskeletal models of care are widely thought to help close "innovation-adoption gaps" in the field, leading to improved clinical outcomes.

As will be discussed in more depth later in this essay, technology has vastly improved research, testing, diagnostics, and treatment of gait abnormalities. The use of biofeedback markers and motion analysis have improved the diagnostic accuracy and capabilities of gait analyses. Different gait-analysis technologies are "constantly being refined to provide reliable measures of improvement from disease" (Lewis et al., 2019).

Hinge Health, a leading musculoskeletal digital clinic startup, utilizes the combination of wearable sensors and remote delivery software to enable virtual physical therapy and behavioral health offerings for chronic musculoskeletal conditions. In 2017, Hinge Health had data from over 1,000 patients that "demonstrated a 55% improvement in both chronic low back pain and knee pain, while avoiding 60% of surgeries" (Hinge Health, 2017). The incorporation of technological advances and digital offerings presents significant improved outcomes for patients with musculoskeletal conditions.

3.3 IMPACT ON PAYERS

3.3.1 COST OF MSK CONDITIONS TO PAYERS

Musculoskeletal conditions are major drivers of expenses to health insurance payers. Costing payers over \$260B in 2016, the impact of musculoskeletal conditions is significant. Low back and neck pain accounted for over \$133B paid by private insurance, public insurance, and by individuals out-of-pocket. Other musculoskeletal disorders cost over \$128B paid by the three

payer categories in 2016 (Dieleman et al., 2020). Musculoskeletal disorders including low back and neck pain, joint and limb pain, myalgia, and osteoporosis received majority of funding from private insurance (see Figure 1). Secondary to private insurance, public insurance funded over \$90B to these disorders and out-of-pocket payments came in third, covering over \$20B of funding for musculoskeletal disorders.

A 2019 white paper by healthcare company Optum found that pharmaceutical expense is a significant contributor to musculoskeltal payer spending. Costing \$130B in direct medical costs across all payers, musculoskeletal conditions did see a slight decrease in spending as care shifted to an outpatient model. However, the per-case spending is still increasing. Annual musucloskeletal per-case average spend was measured to grow by 15.4% in 2019. This growth rate, in addition to other projections for the rise in other musculoskeletal conditions, are expected to "contribute to a \$73B increase in MSK spending by 2024" (Friedman, 2019).



Figure 1. Estimated Health Care Spending by Payer and Type of Care in 2016.

Source: Dieleman JL, Cao J, Chapin A, et al. US Health Care Spending by Payer and Health Condition, 1996-2016. JAMA. 2020;323(9):863–884. doi:10.1001/jama.2020.0734.

3.3.2 REGULATORY IMPACT OF DIGITAL HEALTH OFFERINGS

In the current age of the COVID-19 global pandemic, the government and healthcare payers have moved swiftly to change provisions and reimbursements for different virtual healthcare offerings. Centers for Medicare and Medicaid Services (CMS) relaxed regulations on telehealth services to ensure patients had access to care. Moving into a digital age has presented both challenges and opportunities for payers.

Payers and providers have been adopting digital health applications and services over the past few years, as these technologies have proven to be beneficial and convenient for consumers. In 2011, a study found that private payers were relying on external health technology assessment (HTA) data in making coverage decisions for personalized medicine (Trosman et al., 2011). This newfound partnership that is developing between payers and providers, where payers can support covering digital health in exchange for payer benefits such as "initial capital investments, gainsharing arrangements, incentives for the payer's members to participate, and fee structures for services offered" presents an interesting task for regulators (Friesdorf et al., 2019). Dr. Liz Kwo, MD, MBA, MPH from Harvard University found that FDA-approved medical applications are currently reimbursed by payers in varying amounts. Before the COVID-19 pandemic, 25% of integrated health networks were providing coverage for digital therapies and an additional 45% were interested in providing this coverage (Kwo, 2020). The continuous development of digital healthcare services and the partnerships between providers and payers to exchange data for coverage and reimbursement may complicate the landscape for regulators. When taking into consideration the "back end" negotiation that happens to reach reimbursement decisions, it is curious if regulators will create policies creating guidelines and rules around these partnerships. Technology in healthcare is presenting new considerations for regulators and it will be

interesting to see how the regulatory environment develops as healthcare technology and patientfacing services become more commonplace.

3.4 MARKET ANALYSIS

This section includes a market analysis of various contributors that drive healthcare technology innovation. A report from Silicon Valley Bank found that healthcare technology companies raised a record \$15B+ in funding in 2020 and surpassed biopharma in the number of deals for the first time (Reuter, 2021). Digital health companies in particular saw a surge in 2020, raising a total of over \$3.7B in funding (Reuter, 2021). For the purposes of this essay, the main contributors specifically related to musculoskeletal health innovation include musculoskeletal health start-up organizations and medical device innovation. Medical device was chosen for the comparison of HSS medical device innovative work. Universities were included in this market analysis as these institutions have been making meaningful strides toward healthcare innovation.

3.4.1 MEDICAL DEVICE INNOVATION

3.4.1.1 ZIMMER BIOMET

Zimmer Biomet is a medical device manufacturer that was founded in 1927 and headquartered in Warsaw, Indiana. Zimmer Biomet focuses on innovative orthopedics and has developed and integrated the use of digital health offerings across diagnostics, surgical intervention, biologics, sports medicine, and various musculoskeletal subspecialties. Innovation is a core value of Zimmer Biomet, even sponsoring a Connected Health Innovation Award in 2018, which was open to any digital health start-up interested in improving outcomes and lower costs in musculoskeletal health (Zimmer Biomet, 2021).

3.4.1.2 DEPUY SYNTHES | J&J MEDICAL DEVICES

DePuy Synthes is a medical device solution company within the Johnson & Johnson Medical Devices group. Founded in 1895 and headquarted in Raynham, Massachusetts, DePuy specializes in joint reconstruction, trauma, craniomaxillofacial, spinal surgery, and sports medicine. With focuses in orthopedics and spine innovations, DePuy utilizes robotic-assisted clinical solutions, material innovation through the use of 3D bioprinting, digital surgery integration, and more (DePuy, 2021).

3.4.1.3 MEDTRONIC

Medtronic is a medical device company that holds a strong emphasis on innovation. Founded in 1949 in Minneapolis, Minnesota, the company has a number of product inventions in the spinal and orthopedic space and use technology innovation such as algorithms and AI, biosensors, augmented reality, and material science. The Medtronic Innovation Lab combines human-centered design and technology to create innovations geared to alleviate pain, restore health, and extend life. Medtronic also encourages invention submissions to be evaluated by Medtronic for potential partnership through their Meaningful Innovation vertical. Medtronic's innovation team has been recognized with a handful of awards honoring tech insights and innovation leader impact (Medtronic, 2021).

3.4.2 MSK HEALTH TECH START UPS

3.4.2.1 HINGE HEALTH

Hinge Health is a healthcare technology startup founded in 2015 that offers a digital solution to treat chronic musculoskeletal conditions. Hinge Health focuses on the continuum of musculoskeletal care, from prevention through to post-surgery. The digital platform offers virtual sessions with physical therapists and clinicians, one-on-one health coaching, and sensor technology that provides feedback and tracking to patients in real-time. Hinge conducted the world's largest digital MSK cohort study to support their digital solution's benefits outcomes (Hinge Health, 2021).

3.4.2.2 SPARTA SCIENCE

Sparta Science Force Plate Machine Learning (FPML) utilizes machine learning and predictive analytics through force plate data to emphasize musculoskeletal health. Founded in 2007, Sparta Science uses collected data to identify patient movements and provide training plans based on patient need. Utilized in healthcare and rehabilitation, professional and collegiate sports, and the military, Sparta's FPML helps treat preexisting conditions, reduce future injuries, and optimize performance. Results from Sparta analyses are integrated with a user platform to track performance and movements and to receive recommended exercises to holistically improve musculoskeletal health (Sparta Science, 2021).

3.4.3 UNIVERSITIES

Universities play a significant role in research and development that contributes to new innovation. With the Bayh-Dole Act signed into law in 1980, academic institutions gained the rights to the titles and licensing revenue that resulted from university research (NIH, n.d.). This Act fundamentally changed the extent that universities contributed to and benefitted from innovations, and stimulated innovation in the life sciences sector. Universities specialize in technology transfer (also called "tech transfer"), which includes research and inventions that are transformative to daily life. Further, it is the commercialization of these innovations created by institutions (AUTM, n.d.). In 2015, U.S. academic institutions accounted for 5.5% of all U.S. investment in the medical and health research sector, investing nearly \$9B (Ezell, 2019).

In 2018, over 17K new technology transfer patent applications were completed and over 7,500 tech transfer patents were issued (Nag et al., 2020). This figure rose over 250% from patents issued in 2008 (National Science Board, 2018). Over \$70B was spent on federally sponsored research at U.S. universities in 2018, generating almost \$3B in licensing revenue (Nag et al., 2020). Universities are expected to continue research and innovation in the healthcare sector. Educational institutions have a plethora of healthcare data and medical knowledge, and the advancement of AI and computing power that universities hold will enable research and development in this meaningful and lucrative industry (Nag et al., 2020).

3.5 BARRIERS

Barriers regarding the adoption of technology by health systems and other healthcarerelated organizations span across organizational culture, capital spending, and lack of necessary

personnel. A significant barrier may include the capital required to continuously invest in innovative healthcare technology. Economists estimate that 40-50% of annual healthcare cost increases are related technological advances to expand medical capabilities (Baker et al., 2008). To illustrate, diagnostic imaging, which is frequently used in musculoskeletal healthcare, often presents initial cost efficiencies; however, "improvements in quality and rapid growth in the use of these techniques ... led to higher total spending on diagnostic services" (Baker et al., 2008). Further, the advancements in diagnostic capabilities led patients to utilize more healthcare services than before, indirectly increasing spending.

Authors from the healthcare journal Health Affairs found that novel innovations with low productivity are an excessive cost driver, and that "novel procedures tend to incompletely replace traditional procedures," leaving expense from inefficient utilization of new and old procedures (Cahan et al., 2020). Despite these considerations, many studies and sources strongly suggest that healthcare technology enables sustainable, cost-effective care.

New healthcare innovations can pose significant risk to developers and providers. Large moves into an unknown territory can be quite intimidating for healthcare organizations. However, these risks are proving to be necessary for providers to stay competitive and current in today's healthcare climate. Risk averse organizations may be slower to adopt these technologies, which may result in a competitive, operational, and efficiency lag. As an example, early adopters of MRI machines in the 1980s found competitive advantage through factors such as more accurate diagnostics leading to increased demand and revenue. While there was cost and risk associated with adopting this technology initially, the early adopting healthcare providers saw

roughly five years of competitive gain before the market became concentrated (Bhidé et al., 2019).

Lack of expertise and understanding needed of the "complex ecosystem and interactions that underpin healthcare" when leveraging digital technologies can be futile to a successful implementation and serve as a barrier as well (Chehade et al., 2020). Along with a lack of needed expertise, companies that cannot effectively direct the necessary change management and culture realignment that a shift toward innovation requires may find themselves at a cross with their organization. Another barrier related to organizational culture includes a health system which maintains a siloed outlook, where transformation can be hindered due to the lack of cross-collaboration. This perspective may lead to a failed adoption of new technological innovations geared to improve patient outcomes and achieve greater cost-effectiveness, potentially limiting a health system's capacity for fully integrative medicine and will limit the patient continuum of care (Bansal, 2018).

4.0 PROGRAM EVALUATION: HSS INNOVATION INSTITUTE

This section will discuss the organization that the author got significant first-hand exposure to over the course of a summer internship June 2020 – September 2020. Through working with a musculoskeletal innovation institute directly, the author was able to gain a deeper understanding of how innovations are approached, developed, and operationalized.

4.1 TEAM AND CHARGE

The Hospital for Special Surgery Innovation Institute is focused on developing the innovative landscape of musculoskeletal care to improve clinical outcomes, patient experience, and cost of care delivery. Through a commitment to being a leader in the industry, HSS Innovation Institute aims to be at the forefront of new innovations that will change the musculoskeletal industry as a whole.

The HSS Innovation Institute team has 11 different professionals with backgrounds ranging from life sciences, medicine, and engineering to business development and intellectual property management. The Innovation Institute is comprised of three focus areas: care delivery, life sciences, and medical devices. Through collaboration and commercialization of novel concepts and inventions, the Innovation Institute develops, markets, and licenses innovative technologies to enable the use of these technologies to patients who could benefit from them.

4.2 INNOVATIONS FROM HSS

HSS engages in collaborative partnerships with industry, investors, and entrepreneurs to commercialize a portfolio of technologies and co-develop new offerings in musculoskeletal care. HSS shares its expertise, know-how, and network of resources when developing these new ventures and care models/offerings. This section highlights some of the innovations that the HSS Innovation Institute is working to bring to market or has already brought to market in collaboration with its partners.

4.2.1 HSS AND ZIMMER BIOMET: mymobility® with Apple Watch® Remote Care Management System

HSS collaborated with Zimmer Biomet to enhace their patient-facing digital platform. Zimmer Biomet's Mymobility platform in conjunction with Apple Watch facilitates communication between patients and their clinicians/care teams throughout their surgical journey. This platform "acts as a virtual care team member by providing patients with support and guidance at the direction of their healthcare professional as they prepare for and recover from orthopedic procedures from the comfort of their home." Through this partnership, healthcare systems and clinicians nationwide will be able to access HSS Orthopedic Care Pathways through the mymobility platform, commercially available in 2021.

4.2.2 HSS AND SCIENTIFIC ANALYTICS INC.: DARI Motion Platform

HSS and Scientific Analytics Inc. (SAI) collaborated on a care delivery technology that uses computer vision technology to measure human movement patterns. SAI uses its proprietary, FDA-cleared, markerless motion capture technology to analyze and inform movement quality, including generating clinical insights. The DARI Motion platform was validated through HSS beta testing at the HSS Motion Analysis Lab, and is integrated with HSS by the use of HSS knowledge and know-how (see Appendix A).

4.2.3 HSS AND MATHYS EUROPEAN ORTHOPEDICS: BalanSysTM UNI

HSS surgeons and Mathys Medical LTD collaborated to develop the BalanSys[™] UNI medical device, which was "designed to recreate normal kinematics of the knee joint while reducing stresses in the polyethylene insert." Aimed to be utilized on singular condyle arthritis patients, indicated treatment may suggest unicondylar knee replacement. Unicondylar implants uncover the affected section while keeping the healthy cavity intact. The use of mobile-bearing technology allows "an ultra-high molecular weight polyethylene insert to articulate with both the femoral and tibial components" (HSS Innovation Porfolio, 2020). This collaboration reduces stresses and wear on the replacement due to its large contact areas at femoral and tibial interfaces.

4.3 INTERVIEWS

The purposes of these interviews was to better understand best practices and challenges that innovators in this space may be experiencing. The interviews were also an opportunity for the student to learn how success was measured in different innovative environments. All interviews were conducted within one month of each other to ensure that the information collected would reflect the interviewees' current views of the organization and industry as a whole. Interviewees were chosen from the key functional area, HSS Innovation Institute. The

main themes for each interview were the interviewees' perceptions about the development of technological integration in musculoskeletal care, impact of innovation to the musculoskeletal industry at large, best practices, challenges, and measuring success. Interviewees were informed that the interview was being conducted for academic purposes, related to the author's project. Below are key themes and points drawn from the interviews.

4.3.1 DEVELOPMENT OF INNOVATION IN MSK HEALTHCARE

When speaking with leaders in musculoskeletal innovation at Hospital for Special Surgery, there was consensus that development in this medical specialty will realize significant benefits to patients; however that it is still lagging comparatively. From innovations to new implants to new care pathways for patients, "innovation has always existed, just at different rates and speeds. We are now in an era where innovations are more transformative to the industry and empowering to patients" (Bossi, 2021). Further, the Chief Innovation Officer and Senior Vice President of Innovation and Development at HSS added that given the burden of these conditions, "musculoskeletal innovations have the opportunity to be highly impactful, as there has been little dedication to innovate in this space compared to other disease categories" (Achan, 2021). The Director of Innovation and Technology Commercialization concluded that a contributor to the rate of this innovation is that "industry partnerships have grown significantly over the past few years to drive innovation in this field, specifically in the care delivery and digital space" (Vijayan, 2021).

4.3.2 IMPACT OF INNOVATION ON MSK HEALTHCARE

Innovation in this space is having an impact on the industry at large as it relates to musculoskeletal healthcare. Regarding the advancement of treatment options, Associate Director of Care Delivery, Sandra Bossi, remarked that "innovations are permitting the collection and analysis of more data than before, enabling us to build forecasting models to determine efficacy of different treatment options" (Bossi, 2021). These predictive and prescriptive models can impact treatment options by providing more data-backed decision making that will educate care providers in making the best decision for the patient. Impact to the industry comes in the form of bringing value to payers. "In leveraging and using innovative technologies, high-quality outcomes and value-based conversations can be achieved" (Achan, 2021). Another impact identified in the interviews was that of research and development brought on by academic innovation. Following the Bayh-Dole Act, "university innovation has been accelerated. Tech transfer is presenting vast opportunities and innovations that will further the advancement of musculoskeletal condition treatment" (Vijayan, 2021).

4.3.3 BEST PRACTICES

When it comes to the success that HSS has found, the intervewiees all shared the sentiments of highlighting the impact and the importance of the people. Leonard Achan remarked how emphasizing organizational mission and the impact to patients is necessary to drive advancement to the industry as a whole. Further, he stressed the need to strive for adding knowledge and value to the industry and to patients, as opposed to focusing on the profits. This sentiment is humbling and emulates the genuineness of Hospital for Special Surgery, as there is

lucrative opportunity in this space but the focal point for the Hospital is on the impact they can bring to patients and to the industry as a whole.

Beyond the altrutic motivation for innovating, the interviewees also stressed the importance of identifying the right stakeholders and achieving buy-in. Against organizational and cultural barriers, buy-in from all necessary perspectives is crucial to push an innovation to fruition. Stakeholders can come from medical, technology, and entrepreneurial fields and all must emphasize building synergies. Sandra Bossi also stressed that expertise in one field alone will never be sufficient: "It is crucial to emphasize cross-functional collaboration, to find true believers in the innovation, and to be thoughtful about when to present/implement a new idea for it to be a success" (Bossi, 2021). All of these factors, in tandem, enable successful innovation from ideation to industry.

4.3.4 CHALLENGES TO ORGANIZATIONS WANTING TO INNOVATE

The interviewees also discussed challenges that both HSS and other organizations face when striving to be a leader in musculoskeletal innovation. These challenges span across organizational culture, the market and competitive space, and regulatory barriers. Cultural issues include but are not limited to: organizational complacency, resistance to change, organizational misalignment, and discouraged workforce due to failed attempts. When talking with Sandra Bossi, she stressed the importance of timing when presenting new innovation development, as rejection rates can be high in the innovative landscape with "likely only one to two projects out of ten being successful" (Bossi, 2021). Teams that face this rejection may lose motivation, so the leaders of innovation must be persistant to counterbalance this challenge of burnout. The interviewees also reflected on the overall market, and many commented on the ballooning of

innovation over the years, saturating the competitive landscape in an already high-risk setting. Another significant consideration is the extensive regulatory, legal, and compliance barriers, including the need for a large budget for legal work. Through the influx of these external partnerships, the HSS legal team is inundated, which can slow the timeline and process to initiate the collaboration. Further, there are many rules around how patient data can be utilized, inhibiting certain advancement. Sandra Bossi specifically remarked on the lack of a national database, which inhibits development of certain algorithms and models. The complex regulatory environment requires a team that is dedicated to navigating this space in pursuit of bringing improved innovations to patients and to the industry.

4.3.5 DEFINING SUCCESS

Success is measured in a variety of ways depending on the perspective of medical innovation. In my interviews, I gained three different perspectives of how success is measured in the environment of musculoskeletal technological innovation. These perspectives are not inclusive of all potential measurements of success for this complex field.

When speaking to the Chief Innovation Officer at HSS, it was communicated that their success is measured by the "mission, charge, community, and move into the market" (Achan, 2021). There are more tangible measurements of success such as sales and inventions; however, as an industry leader, HSS values measuring success through accountability and accessibility, ensuring new innovations can reach various communities.

Tech transfer innovations measure success using a variety of metrics. An inexhaustive list of these metrics include invention disclosures, filed patent applications, patent issuances, number of licenses, patent cost reimbursement, revenues, or number of startup organizations coming

from your institution. Due to the nature of tech transfer innovations, these metrics of success have more standardization to measure across competitors.

When it comes to care delivery, success is often measured on providing better value: lowering cost and offering more accessible and higher quality care (Bossi, 2021). Other metrics to measure success may include scaling HSS standards of care nationwide through collaborative partnerships, often with technology driven companies that HSS may have an equity stake in. This feeds into other metrics such as how successful the partnerships are and the commercialization success of these inventions/partnerships.

5.0 **DISCUSSION**

Healthcare innovation is coming from many different perspectives and can be applied to various aspects of musculoskeletal treatment, delivery, and care models. Ranging from organizations that emphasize medical device innovation or digital health intervention to ones that are open to all kinds of innovation that may impact musculoskeletal care, the market is growing both in competition and in merit. Through innovative technological integrations, healthcare technology is helping revolutionize the way patients get access to care and the quality of that care.

There has been a long history of the integration of technology into healthcare over the past 50 years. Beginning with devices to aid in diagnostics and clinical interventions, we are currently seeing the versatility in healthcare technology through digital health applications, wearables, use of artificial intelligence, and much more. There's no telling where health-tech innovation may be in another 50 years.

It is important to note that some research was not entirely convinced of the clinical outcome benefits that musculoskeletal technology suggests (Cahan et al., 2020). Although musculoskeletal technologies have been on the rise over the years, clinical outcomes should be measured carefully when technologies have been utilized. This will aid in giving a fuller picture to the benefits these technologies provide, although often at a considerable cost.

The Innovation Institute at Hospital for Special Surgery emphasized best practices in the commitment to innovate, in stressing adding value to both the industry and to patients over

financial incentive, in encouraging cross-collaboration, and in engaging all necessary stakeholders and attaining buy-in for ultimate success.

The collaboration and trust required on many parties dedicated to innovating care and treatment of musculoskeletal conditions is obvious. It is through hard work, commitment to growth, and a drive to innovate that HSS and other organizations like it are able to invest in pursuing novelties that may change the future of musculoskeletal care forever. Musculoskeletal health has a widespread impact on public health, affecting roughly 1 in 2 adult Americans. Considering the pace that healthcare innovation is moving, new technologies that are geared to prevent and treat chronic musculoskeletal conditions bring substantial impact to patients.

6.0 CONCLUSION

The chase for innovation in musculoskeletal care remains tenacious, as there are many different applications of healthcare technology in this specialty. There are different subsets of technologies to be integrated with the treatment of musculoskeletal conditions; these subgroups appear to self-categorize into prevention-focused, which often include digital platforms, and intervention-focused, including medical device and computer-aided navigation. Regardless of the integration, the aim resides to make musculoskeletal care more efficient, accurate, and cost-effective.

Musculoskeletal conditions continue to be a driver in patient burden of disease and in cost to the U.S.'s annual healthcare spend and payer burden. Focusing on ways to improve the efficiencies of treating these conditions, which impacts so many and costs the U.S. so much, may help bring widespread value to the industry. When looking to the future, there is an excitement and hunger amongst those innovative companies who internalize this effort.

APPENDIX A: DARI Motion Platform Materials by Scientific Analytics Inc.



HSS has been the #1 hospital for orthopedics for over a decade. With their insights, DARI has built a clinical tool like no other on the market.

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Clinical documentation for reimbursement made easy.

Clinical Insights

FDA Tool

DARI : The 5 Step Process

Step 1: Capture Collect Full Body Movement Data



Step 2: Map Identify Joint Vulnerability



Step 3: Prioritize Focus Areas And Action Steps



Step 4: Plan Confirm And Objectively Track



Step 5: Deliver Send Your Roadmap For Progression

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APPENDIX B: Gait Motion Analysis Examples





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