An Examination of SEP-1: The Effectiveness of the Severe Sepsis and Septic Shock Management Bundle Measure

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Abstract

In 2023 the Centers for Medicare and Medicaid decided the Severe Sepsis and Septic Shock Management Bundle, SEP-1, will be a pay-for-performance quality measure. This decision is the result of two decades of sepsis care being protocolized. As SEP-1 becomes a pay-for-performance measure the effectiveness of the policy can be viewed with higher scrutiny. This paper will address the effectiveness of the policy through a literature review. In addition, SEP-1 effects for healthcare organizations will also be explored through a PEST (Political, Economic, Social, Technological) Analysis. The public health significance starts with sepsis being a leading cause of death in the United States. The public health relevance is the SEP-1 policy aims to reduce the burden of disease attributed to sepsis. The role of evidence and ethics on policymaking as well as measure and evaluate the impact of a health policy on population health will be discussed.

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1.0 Introduction

According to the Centers for Disease Control and Prevention (CDC) at least 1.7 million adults develop sepsis and around 270,000 of those adults die in the United States every year (U.S. Department of Health and Human Services, 2023). Sepsis is a leading cause of death nationally and among the most expensive conditions to treat (Rhee, 2020). It is also a main reason people are readmitted to the hospital in the United States (U.S. Department of Health and Human Services, 2023).

1.1 Relevant Concepts

1.1.1 Sepsis

Sepsis is a clinical condition with the potential for serious medical complications, including long-term disability and death. Sepsis occurs when a person's whole-body immune response is triggered by an infection or injury (U.S. Department of Health and Human Services, 2023). Sepsis can progress unpredictably and rapidly. In extreme cases, a person's blood pressure drops and heart weakens which leads to septic shock (U.S. Department of Health and Human Services, 2023). Once septic shock happens organs - including the liver, lungs, and kidneys- can fail quickly and lead to death.

The most common cause of sepsis is bacterial infections. However, viral, and fungal infections and noninfectious causes can also lead to sepsis. To fight infection, the body releases

chemical or protein immune mediators. However, if the immune mediators are overactive, they can trigger widespread inflammation, blood clots and leaky blood vessels (U.S. Department of Health and Human Services, 2023). This can lead to impaired blood flow which deprives organs of oxygen and nutrients which leads to organ damage (U.S. Department of Health and Human Services, 2023).

This paper will use the definition of sepsis that CMS employs. Sepsis is defined by having a source infection, and two or more systemic inflammatory response syndrome (SIRS) criteria. The SIRS criteria include a temperature above 38° or under 36° Celsius, heart rate above 90, respiratory rate under 20 and PaCO2<32mm Hg, white blood cell count > 12,000/mm^3 or <4,000mm^3 or >10% bands (Alexander, 2022).

1.1.1.1 Severe Sepsis

CMS defines severe sepsis as sepsis compounded by organ dysfunction. It can be demonstrated through a serum lactic acid above the upper limit of normal or systolic blood pressure under 90mm Hg or a drop of more than 40mm Hg compared to normal (Alexander, 2022).

1.1.1.2 Septic Shock

Septic shock occurs when severe sepsis is compounded with low blood pressure even after adequate fluid resuscitation (Alexander, 2022).

1.1.2 Hospital Value-Based Purchasing Program

CMS's Hospital Value-Based Purchasing (VBP) Program rewards acute care hospitals through incentive payments for the quality of care provided. Based on the quality of care delivered,

the VBP program adjusts payments to hospitals (Centers for Medicare and Medicaid, 2024). The Hospital VBP Program was created to improve the quality of care for inpatient services. According to CMS, the Hospital VBP Program encourages hospitals to work to increase quality, efficiency, patient experience, and safety of care for Medicare enrollees (Centers for Medicare and Medicaid, 2024). The Hospital VBP Program does this by reducing adverse events, adopting evidence-based care standards and protocols to obtain the best outcomes (Centers for Medicare and Medicaid, 2024). Additionally, CMS encourages desired results through incentivizing hospitals to improve patient experience, increase transparency, and recognizing hospitals that provide high-quality care at a lower cost to Medicare (Centers for Medicare and Medicaid, 2024).

The VBP program works through rewarding hospitals based on quality rather than quantity of care. If a hospital chooses to participate in the VBP program, 2% of the hospital's Medicare payments are withheld (Centers for Medicare and Medicaid, 2024). These reserves are pooled to fund the value-based incentive payments for hospitals that perform well. This incentivizes hospitals to be attentive to CMS's policy and comply to receive the maximum reward possible.

1.1.2.1 The SEP-1 Bundle

Within CMS Hospital VBP Program, sepsis is targeted through the "Early Management Bundle, Severe Sepsis/Septic Shock Measure," better known as SEP-1. The target population is inpatient adults- 18 years and older- with a diagnosis of septic shock or severe sepsis (Alexander, 2022).

A 'bundle' is an umbrella term to encompass the grouping of all the metrics measured. The two bundles in the SEP-1 measure are severe sepsis bundle and septic shock bundle. The severe sepsis bundle requirements include lactate measurements, blood cultures, and broad-spectrum

antibiotic administration within 3 hours of sepsis identification. If the initial lactate level is elevated, a repeat lactate measurement is needed within 6 hours (Alexander, 2022).

The septic shock bundle requires all the severe sepsis bundle requirements, and an additional 3 requirements. They include 30 mL/kg of IV fluids within three hours, vasopressors within five hours for persistent hypertension, and a repeat volume assessment within six hours (Alexander, 2022). All these interventions in the bundle need to be completed in the time allotted for a case to be considered compliant with SEP-1. This means it is an "all-or-nothing" quality measure which can pose challenges for healthcare facilities and providers.

1.1.2.2 Pay-for-Reporting Measure

A pay-for-reporting measure is a Hospital VBP Program measure where healthcare organizations are awarded based on whether they report their compliance. Even if their organization is not compliant, it is not penalized. Rather it is a measure to encourage organizations to share information with CMS. This is a method that CMS employs to increase transparency of healthcare systems. Since 2018 SEP-1 compliance rates by hospital are publicly available on CMS' Care Compare website (*Hospital Quality Initiative Public Reporting,* 2024).

1.1.2.3 Pay-for-Performance Measure

A pay-for-performance measure is a Hospital VBP Program measure where healthcare organizations are awarded based on how compliant their organization was with the parameters of the measure. This means an organization can be penalized if they are not up to the standards CMS sets.

2.0 Aim of Analysis

The aim of this analysis is to examine the policymaking process through a public health lens. Evidence and ethics can play a large role in shaping policy. By reviewing and judging the quality of evidence supporting the basis of a policy, it can demonstrate whether a policy is evidence-based. Also, measuring and evaluating the impact of health policies on population health is a critical public health function. This essay is an effort to understand the impact that CMS's VBP Program measure SEP-1 has on population health.

2.1 Public Health Significance

Sepsis is a serious public health concern (Rhee, 2023). Due to the human as well as economic toll sepsis takes on the United States every year, controlling and treating sepsis is critical to population health. Early detection of sepsis is important to reduce the risks of complications. A goal of the SEP-1 measure is to increase the detection of sepsis. SEP-1's inclusion in CMS quality guidelines means it has a high potential to impact public health as it is the standard in the U.S. for treating potential sepsis. Studying the SEP-1 measure can help provide information on how policies can impact health on the population level in the United States. In addition, the creation and adoption of the SEP-1 bundle can highlight the role of advocacy groups on politics. The trajectory of this policy can demonstrate larger trends in how the quality of care is incentivized by CMS.

2.2 Scope and Methods

2.2.1 Literature Review

A review of the literature on SEP-1 was conducted to ascertain the current evidence and beliefs surrounding the measure. A concerted effort was taken to review relevant sources from varying viewpoints. While there is research on sepsis treatment worldwide, this literature search was contained to the United States. The literature review contained 25 sources. Key words used to find the studies included: sepsis/septic/shock/severe, SEP-1 bundle/measure, compliance, non-compliance, evidence-based, protocolized medicine, quality measure, improvement, protocol. Systematic reviews and comprehensive, large studies were prioritized. The following sections 3.0-5.0 was informed by the review of the literature.

2.2.2 PEST Analysis

Conducting a PEST analysis is a method to examine the political, economic, social, and technological implications that a policy has on an organization. A PEST analysis in section 6.0 will be used to examine how the shift to a pay-for-performance measure will impact U.S. health systems.

3.0 History of Sepsis Treatment

3.1 Role of Protocolized Medicine

Treating sepsis can pose challenges for care teams because the symptoms can present suddenly and progress rapidly. At the turn of the 21st century, there was a push to create protocols that would standardize sepsis care and improve outcomes. Protocolized medicine is the approach where protocols are defined through detailed plans for a treatment or procedure.

3.2 Changes to SEP-1 Guidelines Over Time

SEP-1 is a protocol that aims to standardize care for possible sepsis to reduce morbidity and mortality from sepsis. The development of the protocol for sepsis was contentious (Rhee, 2023). The first edition of the Surviving Sepsis Campaign, SSC, was originally published in 2004 by the Society of Critical Care Medicine (SCCM). The guidelines were focused on the principles of Early Goal-Directed Therapy (EGDT). EGDT is a protocol for providers to follow when a patient presents with potential sepsis. EGDT was supported by "a then landmark, though subsequently nonreproducible, study by Rivers and colleagues, a small, single-center study that found mortality benefit in patients who received a protocol of therapies targeting measured goals for central venous pressure (CVP), mean arterial pressure, and ScvO2" (Spiegel, 2022). There were multiple international large, robust studies that followed Rivers' study that failed to reach the

same conclusions that EGDT was effective. Yet, the nonreproducible of EGDT model for sepsis did not hinder it from being the basis of the current policy.

Despite the nonreproducible nature of results that were shown in multiple subsequent large-scale studies, the National Quality Forum endorsed SEP-1 (Spiegel, 2022). It was subsequently formally adopted by CMS in 2015 (Spiegel, 2022). The adoption of SEP-1 connected hospital reimbursement, through the Hospital VBP Program, to the implementation of the 3- and 6-hour target bundles (Spiegel, 2022).

The initial SSC guidelines were funded by pharmaceutical company Eli Lily to promote a drug. SEP-1, "is a performance measure initially developed by a number of SCCM members, modeled closely after the SSC guidelines and was similarly muddied by industry ties" (Spiegel, 2022). The policy was promoted first by sources that have incentives to include favorable treatment options into a protocol.

Additionally, the number of tasks during the onset of SEP-1 were exhaustive. "By 2017, this required reporting of up to 7 unproven hemodynamic interventions and potential completion of up to 141 tasks within 3 hours for one patient" (Spiegel, 2022). This increased the burden on providers to not only complete the tasks, but also document them appropriately.

There was an outcry by providers who pointed to the intensive processes of the SEP-1 measure. So, "an examination of the evidence supporting the hemodynamic interventions mandated by SEP-1 found that the CMS guidelines relied on low-quality studies without proven mortality benefit. In 2018, the SCC updated their recommendations, dissolving the 3- and 6-hour bundles that many hospitals have struggled to implement in favor of a 1- hour bundle." (Spiegel, 2022). Despite this update, the SEP-1 is still based on the 3- and 6-hour bundles.

4.0 Evidence-Based Policymaking

Discussing the policy-making process, including the roles that ethics and evidence play is a necessary step to understanding how the SEP-1 policy affects public health practice. There are ethical standards when applying policy. Ethics can be infused into every aspect of the policymaking process, from defining the problem, to decision making, to implementation, and evaluation (Boston, 2010). Policymakers' values underpin policies through beliefs around what is considered good" and "right." CMS touts promoting evidence-based policies that improve health outcomes (Centers for Medicare and Medicaid, 2024). So, an exploration of SEP-1 will be completed to understand if CMS is satisfying its values.

To better understand the SEP-1 measure, addressing what it means for a policy to be evidence-based is needed. The subsequent sections will address include the following questions. Does the evidence support the magnitude of the policy? Is this policy based on the "right" evidence? If there are questions about the validity of the evidence, does it harm the quality of the policy?

4.1 Defining an Evidence-Based Policy

When determining whether a policy is an Evidence-Based Health Policy (EBHP), a framework can be a helpful tool. The EBHP framework is 3-pronged. First, policies should be well-specified, meaning it is specific and implementable (Baicker, 2017). Second, it is necessary to distinguish between policies and goals. Third, EBPH requires evidence that equals the

magnitude of the policy. According to the framework, introspection and theory should not sustain a policy (Baicker, 2017).

4.2 Applying Framework on SEP-1

This section will apply the EBHP framework on SEP-1. As for the first requirement, SEP-1 clears the hurdle. It is very well defined, and it can be implemented in health systems. The ease of implementation may be challenging considering technological and personnel requirements, but it can be achieved with investments.

For the second requirement, there are clear policies that are in place to reach the goals set forth. For CMS, the goal is to reduce the burden of sepsis morbidity and mortality through its Hospital VBP Program. CMS aims to reduce adverse events and incentivize hospitals to be more transparent (Centers for Medicare and Medicaid, 2024). In addition, CMS's goal when developing SEP-1 as a treatment guideline was to increase quality and cost-effective care across the U.S. (Wang, 2020). SEP-1, the corresponding policy, has specific implementation plans and is a pay-for-performance measure.

Third requirement of whether SEP-1 has the evidential support to match the magnitude of the policy will be explored the following section 5.0.

5.0 Current Evidence on SEP-1's Effectiveness

To begin with addressing whether SEP-1 is based on the "right evidence" in the literature, there are two main outlooks. Those who believe the SEP-1 measure is appropriate and those who do not. Those that believe the evidence is appropriate to support the policy point to studies that have "shown that hospitals demonstrating compliance with SEP-1 have superior process measures (e.g., serum lactate measurement) or have positive patient outcomes including lower mortality, length of stay and readmission rates" (Marius et al., 2022). Compliance with SEP-1 being connected to superior process measures is logical, as being compliant with the bundle requires strong attention to completing process measures. The latter point is more valuable to understand the quality of evidence as it points to improved outcome measures. If the improved outcome measures are accurate, it demonstrates the value of SEP-1 in reducing sepsis morbidity and mortality. This shows the value of the policy on public health outcomes.

However, multiple systematics reviews demonstrated that low-quality evidence supports most of SEP-1's interventions (Wang, 2020), (Rhee, 2023). Since its introduction in 2015, CMS has removed some of the unproven components, yet others remain (Wang, 2020). Experts have continued to raise concerns that SEP-1 remains overly prescriptive, lacks a sound scientific foundation, and presents risks to population health (Wang, 2020), (Rhee 2023). Some experts believe "SEP-1 should be based on high quality reproducible evidence from randomized controlled trials (RCT) demonstrating its benefit and thereby safety. Otherwise, we risk not only doing harm but standardizing it" (Wang, 2020).

According to a joint position paper from multiple prominent medical societies that conducted a metanalysis, "multiple studies indicate that SEP-1 implementation was associated

with increased broad-spectrum antibiotic use, lactate measurements, and aggressive fluid resuscitation for patients with suspected sepsis but not with decreased mortality rates" (Rhee, 2023). Studies that examined upwards of 50,000 patient records found that SEP-1 implementation led to an increase in lactate testing but not a subsequent improvement in sepsis morbidity or mortality (Barbash, 2021).

According to the experts from six healthcare societies, "increased focus on SEP-1 risks further diverting attention and resources from more effective measures and comprehensive sepsis care" (Rhee, 2023). The position paper posits it would be better to retire SEP-1 than make it a pay-for-performance measure.

In the joint position paper, the retrospective studies that find lower 30-day mortality rates with SEP-1 compliance are confounded (Rhee, 2023). The retrospective study was unreliable, because "patients who receive bundle-compliant care tend to be different compared to patients who receive non-compliant care. For example, patients with sepsis without shock have a much lower risk of death compared to patients with septic shock but are also more likely to receive bundle-compliant care because fewer steps are required to pass the measure for patients without shock" (Rhee, 2023). This means compliance is easier when the case has fewer complications. This makes sense as more resources are needed to handle complicated and advanced cases. The review of literature points to SEP-1 not having the evidential support to match the magnitude of the policy.

According to a study compliance rates for SEP-1 show high variability (Barbash, 2019). Overall bundle compliance was generally low and varied widely between hospitals (Barbash, 2019). In April 2024, the national average was 60% for percentage of patients who received appropriate care for sever sepsis and/or septic shock (*Hospital Quality Initiative Public Reporting,*

2024). This is important as the measure shifts to pay-for-performance, as currently non-compliant healthcare centers will need to invest considerably more resources to reach compliance.

The administration of antibiotics in a timely fashion is a critical intervention to reduce sepsis mortality (Im, 2022). Long recognition delays and administration delays are associated with increased hospital mortality (Taylor, 2021). The administration of antibiotics within the set time frame for all patients suspected with sepsis requires huge amount of effort and resources (Im, 2022). In addition, it may increase the risk for in patients without infection to be unintentionally exposure to broad-spectrum antibiotics (Im, 2022). The results of Taylor's study suggest the administration of antibiotics can improve outcomes for patients with suspected sepsis, but the analysis does not support a target of 1 hour (Taylor, 2021). This means that clinicians are weighing these considerations when considering whether following the SEP-1 bundle would benefit their patients.

The robustness of the study designs that support the measure are not as robust as the studies that demonstrate it does not have the desired effects. Specifically, the studies that have looked at whether the implementation of SEP-1 has improved care for sepsis have not demonstrated improved clinical outcomes. According to experts, SEP-1 is not the optimal policy to achieve the goals of reducing sepsis morbidity and mortality.

According to experts, SEP-1 lacks the evidential support to match the magnitude of the policy. It is useful to consider the questions; if issues are raised about the validity of the evidence, and whether it harms the quality of the policy. In the case of SEP-1, while experts provide conflicting information, the policy is highly informed by those who believe in its effectiveness. This means the quality of the policy could be harmed by not taking different perspectives into account. In order to build trust and support in a policy, a consensus needs to be reached and

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currently there is not a consensus on SEP-1. In the case of SEP-1, policymakers have accepted that the validity of evidence is high enough to craft policy around it. The impact of SEP-1 is set to be further magnified in coming years.

6.0 PEST Analysis

Health systems across the nation are facing decisions on how to approach SEP-1 compliance as it transitions to a pay-for-performance measure. One of the main questions revolves around whether to invest additional resources to increase compliance with the SEP-1. A healthcare facility needs to demonstrate compliance with all metrics in each category within the bundle to be considered compliant with SEP-1 which can be difficult. Individual health care providers or a system may want to make informed decisions based on whether the SEP-1 bundle helps their patient population. This makes sense as sepsis is a serious concern, and treating it as effectively is critical to ensure quality of care.

Yet, CMS incentivizes compliance regardless of whether an individual health system or provider concludes the SEP-1 bundle would improve clinical outcomes through saving lives. So, this PEST analysis will explore an organization decision to invest resources into compliance, regardless of belief in its ability to improve mortality outcomes. While a health system can conduct studies to determine if SEP-1 compliance increases quality and/or length of life for their patients to aid in decision-making, this PEST analysis will assume the clinical outcomes are similar between compliance and non-compliance. This exploration is for an organization that is open-minded to increasing compliance. This is for an organization that considers SEP-1 as the standard of care and generally wants to improve the quality of care.

Table 1: PEST Analysis

Political	• CMS is the largest insurer for most hospital systems, which means it is important to follow guidelines and expectations set by CMS to ensure the highest reimbursement possible. Compliance can be influenced by CMS healthcare policies that prioritize sepsis management; the pay-for-performance mechanism that will penal those that do not meet benchmarks. If a health system is seen to intentionally not following quality guidelines put into place by CMS it could imply the health system is not committed to ensuring quality. • In addition, increasing compliance with SEP-1 is aligned with current regulatory standards and could improve a hospital's standing with accreditation bodies and regulators.
Economic	• A health system should conduct a cost-effectiveness analysis for their facility to determine whether increasing SEP-1 compliance is worth it for them. Implementing SEP-1 bundle protocols incurs costs to the health system as it needs to have a set of procedures completed within short turn-around times. There must be adequate staff to perform the procedures with appropriate equipment. • In addition, a health system needs the correct technology and administrative support to ensure compliance recorded properly which could increase costs.

	• Major healthcare payers, namely Medicare and Medicaid, will offer higher reimbursement rates for hospitals that show high compliance with SEP-1.
Social	• Patient outcomes and satisfaction are important considerations when considering SEP-1 compliance. There is a growing public awareness of patient safety and quality improvement, with quality and compliance being publicly available on the CMS Care Compare website. If a health system is falling short of its peers, it could lead to lower patient satisfaction and admissions.
Technological	• A health system needs to make a considerable investment in technology to be compliant with SEP-1. Investing in data analytics and real-time monitoring can help to identify sepsis early and track compliance. In addition, integrating SEP-1 protocols into a health system's Electronic Health Records (EHR) system can streamline the process. These technological investments could make it easier for healthcare providers to follow procedures and document compliance.

The PEST analysis table demonstrates that making efforts to increase SEP-1 compliance may be beneficial to a health system. Despite additional investments in technology and staffing, the benefits of compliance outweigh the costs on the health system level. The benefits include maintaining or increasing reimbursement rates from CMS. In addition, increasing compliance

could improve a health system's reputation for patient safety and quality. So, from the perspective

of a health system's leadership team, SEP-1 is worthy of investment.

7.0 Discussion

There is a need for a concerted effort to curtail the effects of a leading cause of death. The SEP-1 protocol is the United States' response to that need. It has the support of the government and patient safety advocacy groups. SEP-1 is consistently supported by major health authorities and is now codified into CMS guidelines. As the PEST analysis demonstrates, a health system should invest in SEP-1 compliance to maintain status. Yet, the literature review highlighted how researchers and medical associations contest the assertion that SEP-1 is the appropriate mechanism to curtail sepsis mortality and morbidity.

What motivates policymakers' decisions? The Hospital VBP Program can state they aim to reduce adverse events by adopting evidence-based care standards and protocols to obtain the best outcomes (Centers for Medicare and Medicaid, 2024). Yet, in the lead up to the SEP-1 bundle becoming a pay-for-performance measure, many experts shared their robust data that the policy did not have the desired effect (Rhee, 2023). Despite the evidence presented from credible experts, the National Quality Forum continued to unanimously uphold their endorsement of SEP-1 (NQF releases, 2022). This indicates there are other factors than solely promoting evidence-based care at play when adopting standards.

Like all other policy decisions, there are political implications to consider. There has been significant political momentum driving policy on sepsis mandates. The first regulation, *Rory's Regulation*, was issued by New York State Department of Health in 2013 (Kahn, 2019). The policy was championed by the family Rory Staunton, a 12-year-old who died of sepsis (Kahn, 2019). Advocacy groups have immensely powerful stories of the medical harm that mistreatment and delayed treatment of sepsis causes. Sepsis is a serious public health concern and deserves to be a

priority focus of CMS' efforts. Yet, the politics of sepsis mandates as a strategy to enforce sepsis protocols remains controversial (Kahn, 2019). To address a leading cause of death that is multifaceted, policy makers have turned to regulatory mechanisms. The mechanisms are designed to mandate sepsis performance improvement through care protocols (Kahn, 2019). Yet, as the literature review demonstrates, there is a lack of resounding evidence to support the conclusion that sepsis mandates improve outcomes.

For CMS policymakers, the options in 2023 were either to move SEP-1 to a pay-for-performance measure or to retire it and effectively have no sepsis measure. The latter would have been politically unthinkable due to the enormous toll sepsis takes. It would have been shocking to advocacy groups if a policy was retired and there was not a new and improved policy in place immediately to replace it. Unfortunately, there are no plausible alternatives to SEP-1 that CMS could adopt at this current time.

At this current juncture, it appears the SEP-1 policy is the best option that CMS has in its arsenal to handle sepsis. It has political support, and no alternative has mounted a successful campaign to alter CMS' decision yet. Creating evidence-based policies pose challenges for policymakers when faced with a multi-faceted problem with no easy answers. SEP-1 demonstrates the difficulty of deciding what policies to promote. The evidence so far does not demonstrate that SEP-1 will improve population health. This demands ongoing evaluation of the SEP-1 policy. There needs to be continued efforts to improve upon current policies and create new policies that are effective in improving sepsis outcomes on the population level.

8.0 Conclusion

Ensuring and delivering care that is safe and effective presents ongoing challenges for providers and policymakers. This paper looks to examine how evidence informs policy. The need for early detection of sepsis is paramount. The SEP-1 measure attempts to give a protocol for sepsis that is useable and effective. The literature demonstrates it is a step in the right direction but lacks the outcomes to inform a pay-for-performance measure. The quality of evidence that policy is based on can influence outcomes.

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