IMPACT OF ELECTRONIC HEALTH RECORD SYSTEMS ON INFORMATION INTEGRITY: QUALITY AND SAFETY IMPLICATIONS

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Abstract

While the adoption of electronic health record (EHR) systems promises a number of substantial benefits, including better care and decreased healthcare costs, serious unintended consequences from the implementation of these systems have emerged. Poor EHR system design and improper use can cause EHR-related errors that jeopardize the integrity of the information in the EHR, leading to errors that endanger patient safety or decrease the quality of care. These unintended consequences also may increase fraud and abuse and can have serious legal implications. This literature review examines the impact of unintended consequences of the use of EHR systems on the quality of care and proposed solutions to address EHR-related errors. This analysis of the literature on EHR risks is intended to serve as an impetus for further research on the prevalence of these risks, their impact on quality and safety of patient care, and strategies for reducing them.

Keywords: electronic health records; health information technology; data integrity

Introduction

US health spending far surpasses that of other countries, yet our healthcare system fails to regularly deliver high-quality healthcare.¹ The quality of healthcare across the continuum depends on the integrity, reliability, and accuracy of health information.² Adoption of health information technology (HIT), including electronic health records (EHRs), is essential for the transformation of the current US healthcare system into one that is more efficient, is safer, and consistently delivers high-quality care.³ (In this article, the terms HIT and EHR are used interchangeably and include electronic prescribing and clinical decision support.)

Adoption of HIT has failed to achieve projected benefits and cost savings because of shortcomings in the design and implementation of HIT systems, including safe and effective use of these systems.⁴ Despite the promise of EHRs’ improving quality of care and patient safety, a growing body of evidence has found potential safety hazards associated with their use, sometimes referred to as “e-iatrogenesis.”⁵ The emergence of EHR-related errors results in data being lost or incorrectly entered, displayed, or transmitted, leading to loss of information integrity.⁶ Although little published evidence quantifying the magnitude of HIT-associated risks exists,⁷ as HIT products have become more intimately involved in the delivery of care, the potential for HIT-induced medical error, harm, or death has increased significantly.⁸
Although EHR-related errors, and their actual and potential impact on the quality and usefulness of EHR documentation, quality of care, and patient safety, have been documented for years, much work still needs to be done to measure the occurrence of these errors, determine the causes, and implement solutions. Currently there are no regulatory requirements to evaluate EHR system efficacy and safety. EHR certification does not guarantee that EHRs will be implemented and that they will work as planned. Policies, usability principles, and best practices for proper EHR system use have not been widely and consistently adopted. There is no sense of shared accountability between system developers and users for product functioning. Adverse outcomes associated with EHRs are not being systematically and consistently tracked.

**EHR Risks Adversely Impacting Information Integrity**

It has been suggested that the introduction of HIT, rather than leading to improvements in the quality of data being recorded, has led to the recording of a greater quantity of bad data. Although some of the studies cited in this article are several years old, recent literature continues to cite these studies. While a primary goal of EHR implementation is the reduction of medical errors, reports of new types of errors directly related to EHR implementation that can compromise quality of care and patient safety have emerged. For example, a patient’s treatment for cancer was delayed by several years because a setting in her physician’s EHR system defaulted to an old normal Pap test result instead of the more recent abnormal results. In another case, a baby died from a massive drug overdose as a result of a transcription error that occurred when a handwritten order was entered into the computer system. This medical error could have been prevented if automated alerts had been activated.

Since there is no regulatory framework to monitor EHR system safety, these systems may

- Have been developed from erroneous or incomplete design specifications;
- Be dependent on unreliable hardware or software platforms;
- Have programming errors or bugs;
- Work well in one context or organization, but be unsafe or fail in another; and
- Change how clinicians do their daily work, thus introducing new potential failure modes.

The increasing scope and complexity of tasks clinicians can perform using EHRs, in conjunction with unprecedented pressure to rapidly adopt these systems (as a result of the incentives created by the Health Information Technology for Economic and Clinical Health Act), increase the potential for EHR-related patient safety hazards. In a complex healthcare environment, in which interactions
with other computer systems and provider workflow impact how the systems work, it is challenging for users to anticipate potential problems or understand how a particular failure occurred. Also, once providers have invested money in system implementation and training, they are likely to retain a system even if they discover it is flawed rather than incur the high cost of replacement.

For at least 10 years, a great deal of information has been published on the deterioration in the quality of clinical documentation captured electronically, such as the prevalence of mindlessly or repetitively copied and pasted text and outdated or erroneous information. However, research studies to date have been limited in scope. No comprehensive study has been conducted to determine the industrywide incidence of EHR-related errors or adverse clinical events resulting from these errors. To complicate matters, there is no consensus as to the quality of electronic clinical documentation or even agreement as to what “data quality” means in the context of EHRs. There are also no clear standards for defining, measuring, or analyzing EHR-related errors.

Types of EHR risks identified in the literature are described in the remainder of this section.

### EHR System Design Flaws

The expanding capabilities of EHR systems require increasingly complex software, which heightens the likelihood of software failures that may harm patients. A software flaw in an EHR system containing hundreds or thousands of medical records, such as a glitch that causes an inaccurate recording of patients’ allergies or medications, could adversely affect a large number of patients. Software bugs may jumble data, deleting information or depositing it in the wrong place. Software bugs may jumble data, deleting information or depositing it in the wrong place. Computers may spew forth a slew of disorganized data, such that physicians are unable to quickly find critical patient information. Data may be missing or corrupted (e.g., a laboratory value may come back with an extra character inadvertently inserted). System interface problems can lead to poor decisions, delays, data loss, errors, unnecessary testing, and system downtime.

### Poor System Usability and Improper System Use

In addition to EHR design features and functions that can potentially contribute to suboptimal healthcare quality, errors can result from improper system use. Usability errors occur as a result of system complexity, lack of user-friendly functionality (e.g., confusing user interfaces), workflow incompatibility, or limitations of the user. Faulty functionality could mislead clinicians where there is a confusing screen display or when incorrect values result from a programming error that
incorrectly converts from one measurement system to another (e.g., pounds to kilograms or Celsius to Fahrenheit). A new kind of error occurring in EHRs that is not an issue with paper-based records is an “adjacency error,” in which a provider selects an item next to the intended one in a drop-down menu, such as the wrong patient or medication.

Discrepancies between data fields can cause errors, such as when a structured data field (a list of choices that cannot be altered) and free-text field are inconsistent. For example, a structured data field may indicate that one pill should be taken twice a day, while the free-text instruction field says to take two pills in the morning and one pill in the evening. Other errors can be caused by inconsistent drug dosing and missing information.

Clinicians increasingly share control of complex processes with computers; in some instances, they assume a higher-level oversight role and allow computers to make routine decisions and carry out appropriate actions (e.g., the computer automatically generates a laboratory order when certain medications are ordered). Although EHR systems do not directly impact patient care without human intervention, this technology is often so complicated that users are unable to analyze or understand its computations and therefore cannot exercise competent human intervention. For example, clinicians may rely on computer-generated diagnoses and treatment recommendations without fully understanding how the algorithm was developed or that the algorithm did not take into account certain medical conditions or clinical factors that are relevant to the patient at hand. Also, competent human intervention depends on users having the time, motivation, and ability to reflect on and challenge computer-generated data and recommendations, which may not be true in the midst of surgery or in the intensive care unit.

Workarounds are often employed by users when systems are not flexible enough to support real-life clinical practice and workflow patterns. However, these workarounds can further undermine patient safety. For example, when a medication system does not allow administration of a drug until the order has been entered in the system by the physician, even in urgent situations, documentation of the order may occur after it has been administered, which could result in the medication being administered again. Disabling functions such as alerts because they are distracting or disruptive can result in a critical safety feature not being deployed when needed.

Inappropriate Documentation Capture

EHR system vendors often add functionalities to assist with documentation, such as copy and paste, templates, use of standard phrases and paragraphs, and automatic object insertion (e.g., clinical...
values brought in from other parts of the electronic record).\textsuperscript{45} Benefits of these features include improved efficiency of data capture, timeliness and legibility, and consistency and completeness of documentation.\textsuperscript{47,48} However, when used inappropriately, without proper education and controls, these features can lead to inaccurate documentation and potentially result in medical errors or allegations of fraud.\textsuperscript{49} Errors related to copy/paste functionality and templates, described in further detail below, represent two of the most common EHR risks associated with inappropriate documentation capture. Additional types of user-related errors resulting from improper documentation capture can be found in Appendix A.

A study of records in the Veterans Health Administration’s EHR system found that 84 percent of progress notes contained at least one documentation error, with an average of 7.8 documentation errors per patient.\textsuperscript{50} Types of errors included copied text, incomplete or inaccurate templates, documentation entered in the wrong patient’s medical record, inconsistent text, and outdated embedded objects.\textsuperscript{51} Although this study was published 10 years ago, more recent studies are consistent with these findings. Current literature suggests there has been little or no improvement in the prevalence of EHR-related errors, which is not surprising since little has been done to identify the root causes and address them. Also, patient harm resulting from EHR-associated errors is likely underrecognized and underreported.\textsuperscript{52}

**Copy/Paste**

The growth of copying and pasting (also referred to as cloning, copying forward, and carrying forward)\textsuperscript{53} text from various locations in the health record, either from the same encounter or previous encounters, is a significant problem in EHRs,\textsuperscript{54} and this problem is worsening as EHR use expands.\textsuperscript{55} Risks to documentation integrity resulting from incorrect use of copy/paste functionality include:

- Inaccurate or outdated information;
- Redundant information, which causes the inability to identify the current information;
- Inability to identify the author or intent of documentation;
- Inability to identify when the documentation was first created;
- Propagation of false information;
- Internally inconsistent progress notes; and
- Unnecessarily lengthy progress notes.\textsuperscript{55}

Ultimately, the trustworthiness and integrity of the health record are damaged,\textsuperscript{57} and patient harm is
a real possibility. For example, in a case study published in the Agency for Healthcare Research and Quality’s webM&M, copied and pasted text led to a failure to administer heparin to prevent venous thromboembolism, resulting in the patient being readmitted for a pulmonary embolism. In another reported case, copying and pasting the same note for several days in a row nearly resulted in a patient’s antibiotic regimen unnecessarily being changed because the note had not been updated to reflect the fact that the patient’s abscess had been drained.

The ease with which documentation can be copied and pasted has resulted in clinician complaints that EHRs are often cluttered with redundant or irrelevant information, making it difficult to read the record and to locate important details. Once the EHR has become a vast warehouse of disorganized, irrelevant, or erroneous data, the story of the patient and the patient’s illness (the narrative) is no longer easy to read, which has implications for clinical decision-making as well as medical malpractice litigation.

Recent studies on the prevalence of copying and pasting in EHRs support the results of earlier studies, indicating that this practice continues to be common. A study published in 2013 in Critical Care Medicine found that 82 percent of residents’ progress notes and 74 percent of attending physicians’ notes in intensive care unit EHRs contained 20 percent or more copied text. Another study, published in 2010 in the Journal of the American Medical Informatics Association, found that 78 percent of sign-out notes and 54 percent of progress notes contained copied text. In a 2008 survey of physicians at two affiliated academic medical centers, 90 percent of physicians used the copy/paste functionality in daily electronic progress notes, and 71 percent felt that inconsistencies and outdated information were more common in copied and pasted notes.

Text that has been inappropriately copied and pasted may not be readily detected. For example, in Hussain v. Principi, an employment discrimination lawsuit, a physician’s pattern of copying and pasting other physicians’ assessments without any evidence that the physician had actually seen the patient prior to, during, or after treatment was only found as a result of close monitoring of the physician’s patient encounters.

**Templates**

Templates can guide documentation so that elements essential to demonstrating appropriate care are not ignored. If health record content is produced as a result of physicians’ “point-and-click” choices from a template, many records may end up containing similar or identical content. Use of templates can also result in events being documented before they actually occur. In some cases, templates automatically fill in data elements based on certain patient characteristics or other data
entries, even though this default information is not an accurate representation of that particular patient encounter. For example, an amputee’s EHR noted that his extremities were “normal.” In addition to the risk of reduced quality of care or increased liability exposure, automatic population of template data fields or completion of templates in advance increases the risk of fraud due to “overdocumentation” that causes a higher-level service than was actually provided to be billed.

Errors Related to Use of Clinical Decision Support Systems

The use of clinical decision support applications results in errors due to software design flaws, system performance issues, poor decision support rules, inadequate user training, human error, disruption of system use because of interruptions by colleagues, or use of the system in ways not intended by the system developer. Use of decision support systems may lead to errors of omission, whereby individuals miss important data because the system does not prompt them to notice the information, or errors of commission, whereby individuals do what the system tells or allows them to do, even when it contradicts their training and other available information. This latter type of error is known as “automation bias.” When individuals understand that they will be held personally accountable for their clinical decisions, automation bias is reduced because people take the time to verify the accuracy of the actions recommended by the decision support system. Clinicians should decide when it is appropriate to heed decision support system advice and when this advice should be overridden. The clinical environment can contribute to the occurrence of a clinical decision support system error. For example, user distraction might cause data entry errors or inattentiveness to the information being presented by the decision support system.

A clinical decision support system that is designed and implemented according to high-quality standards, and is working as intended, can still give wrong clinical advice. It is inherently difficult for EHR systems to accurately handle or anticipate the highly flexible and fluid ways in which healthcare is provided in real life. Decision support system recommendations do not fit every clinical scenario. Atypical circumstances, such as unusual combinations of conditions or local lack of resources, are not always taken into consideration. Systems are unable to handle all possible exceptions, so at some point, the number of decision tree options becomes too great and the system becomes impossible to maintain and use. Also, data entry errors that result in incomplete or incorrect information in the EHR can lead to inappropriate decision support recommendations, or failure of an alert to be issued altogether.

A study assessing the effect that computer interpretation of electrocardiograms (EKGs) had on the
The accuracy of internal medicine residents’ EKG interpretations demonstrated that physicians are significantly influenced by incorrect computer interpretations. The residents documented an incorrect EKG interpretation almost twice as often when they were provided with an incorrect computer interpretation than when they received no computer assistance. The results of this study are a clear example of automation bias, whereby physicians tended to follow the computer’s advice even when it was incorrect. Because another study demonstrated no negative impact on the accuracy of EKG interpretations when cardiologists were presented with an incorrect computer interpretation, the tendency toward overreliance on computer decision support may be greater if clinicians are less skilled in the task involving computer assistance or less confident in their skills.

An ongoing challenge with EHR systems is alerting users to clinically significant errors or potential adverse events without overwhelming the prescriber with alerts of little practical significance and causing “alert fatigue.” Studies have found that decision support recommendations are frequently disregarded. In many instances, decision support prompts and alerts can be excessive and disruptive, and thus justifiably overridden. Researchers have found that physicians accept fewer than 20 percent of drug allergy alerts, and almost all of the overrides are medically appropriate.

There is no standardized method for presenting safety alerts according to severity and/or clinical importance. Many systems lack intelligent mechanisms for relating patient-specific data to allowable overrides, such as those associated with a particular patient and drug allergy alert or duplicate therapy request. A clinically appropriate alert may also fail to be generated, possibly because of a decision support knowledge base that is inaccurate or out of date.

**Recommendations for Reducing EHR Risks and Improving Information Integrity**

EHR systems offer opportunities to transform healthcare, but only if the systems are properly designed and used and the data in the systems are accurate. Although HIT-associated risks have been reported in the literature for at least a decade and research over the past several decades supports HIT usability guidelines and principles to improve safety, these guidelines and principles have not been put into widespread practice. Nor has little other action been taken to address these risks. A 2008 study noted that a number of reports had documented the potential of EHRs to contribute to healthcare system flaws and patient harm, but few EHR risk management strategies had been published. A dynamic tension exists between the need for design standards and vendors’ competitive differentiation, resulting in restraint of the dissemination of best practices for EHR
Safer implementation and use of HIT is a complex, dynamic process requiring a shared responsibility between vendors and healthcare organizations. Policy makers, EHR vendors, and healthcare providers must all work together to ensure that EHR systems prevent, rather than cause, medical errors and lead to better patient care. To achieve the high-level quality of care and improved patient safety anticipated from the use of HIT, the problems with EHR design and use that hinder achievement of these benefits need to be addressed. The need for more rigorous data quality governance, stewardship, management, and measurement is greater than ever.

The remainder of this section provides suggested strategies for reducing EHR risks and improving information integrity.

**Reduce EHR System Design Flaws**

Currently, EHR products are held to few standards with respect to both design and development. Greater focus should be placed on improving EHR design. By identifying EHR features that users believe present new opportunities for error and the tactics that physicians employ to work around them, EHR system developers can enhance current functionalities and create new tools to minimize new EHR-associated errors. To reduce EHR system design flaws and other unintended consequences, the following changes in how EHR systems are regulated, approved, and monitored have been recommended:

- Federal regulations should be promulgated that establish approval and monitoring processes and EHR system standards and implementation specifications.
- Federal regulations should mandate that EHR system vendors employ design and usability standards that optimize system safety, efficacy, and information integrity.
- EHR systems should not be able to be marketed without being scrutinized, approved, and subject to ongoing oversight to assess their safety, effectiveness, and accuracy.
- An industry standard should be established for quality principles and processes for EHR design, and EHR system developers should be required to adopt these principles and processes.
- An industry standard is needed to ensure that comprehensive quality management principles and processes are adopted throughout the EHR industry to provide assurance that EHR products meet a minimum level of safety, reliability, and usability.
Improve System Usability and Proper Use

To prevent medical errors (including errors that stem from flawed or erroneous information), it is not merely the design of the EHR system that is important, but also its implementation, or how it is incorporated into clinical processes and workflow and how users actually use it in routine clinical care. The risk of patient harm associated with a specific application should be systematically assessed, and quality and safety procedures that are proportional in stringency to the identified clinical risk should be adopted.

The current approach to EHR standardization and certification does not address system implementation, usability by clinicians (including integration with workflows), or information integrity. Certification criteria used to establish eligibility for use in the Centers for Medicare and Medicaid Services EHR Incentive Program, while slowly starting to address EHR safety and usability issues, are not yet sufficient to ensure EHR-related safety and improve information integrity. Strategies to address EHR usability problems and reduce improper system use include the following:

- EHR usability should be included in the EHR certification process.
- EHR certification requirements should define what a vendor’s product is not allowed to do in addition to what it must do.
- Healthcare organizations and other providers should develop and implement policies and procedures pertaining to appropriate EHR use.
- Healthcare organizations should ensure that all users receive thorough training on system use, including the organization’s expectations regarding the use of the system.
- For each application, quality and safety procedures that are consistent with the degree of safety risk associated with that application should be adopted.
- An internal reporting system to identify problems using the EHR, EHR-related errors, and any other EHR-related issues should be established.

Improve Documentation Capture Processes

Recommendations for improving EHR documentation creation include the following:

- EHR content standards should be defined, which would enhance efficiency, reduce redundancy, alleviate the documentation burden, and improve integrity.
- Guidelines should be developed for both vendors and users of EHR systems regarding the
appropriate use of documentation techniques to ensure complete, accurate, and quality documentation.\textsuperscript{118} 
- Policies and procedures should be developed and implemented pertaining to appropriate EHR use.
  - Organizational policies should promote ethical documentation practices.\textsuperscript{119} 
  - Policies should be designed to minimize insertion of patient data available elsewhere in the record and discourage copying as a way of improving clinician productivity.\textsuperscript{120} 
  - Organizational policies should address the limits on what type of information can be copied, outline the provider’s responsibility for copied information and notification of errors, and specify corresponding sanctions or disciplinary actions.\textsuperscript{121} 
  - Source attribution for copied text should be required.\textsuperscript{122} 
  - A “zero tolerance” policy on unethical copying practices should be adopted.\textsuperscript{123} 
  - Error-prone EHR documentation practices, such as copying and pasting text, should be monitored to ensure they are appropriate. Corrective action should be taken if a pattern of inappropriate documentation practices is identified.

\textbf{Minimize Errors Resulting from Clinical Decision Support Systems}

As noted above, in order to promote the quality and safety of clinical decision support systems, the risk of patient harm associated with a specific application should be systematically assessed, and quality and safety procedures that are proportional in stringency to the identified clinical risk should be adopted.\textsuperscript{124} Since risks cannot be eliminated entirely, the goal should be to implement processes that minimize avoidable patient harm and manage known but unavoidable safety hazards.\textsuperscript{125} For example, safe organizational practices and cultures should be established,\textsuperscript{126} including training users properly, establishing a working environment that is conducive to safe practices, and ensuring that the decision support system is appropriate for the clinical tasks for which it is being used.\textsuperscript{127}

\textbf{Report EHR-related Adverse Events and System Concerns}

To understand the array of EHR-related adverse events and implement effective corrections and improvements (whether design concerns, unintended consequences, documentation or information integrity concerns, or others), the Institute of Medicine recommended that an EHR-related adverse event reporting system be instituted, with a clear, standardized process that includes the following:

- Reporting of HIT-related adverse events should be mandatory for vendors.\textsuperscript{128} 
- Reporting of HIT-related adverse events by users should be voluntary, confidential, and
nonpunitive.\textsuperscript{120}  
- Impartial investigations should be conducted by an independent, federal entity, and in the spirit of transparency, investigative reports and results should be made public.\textsuperscript{130}  
- EHR system vendors should support the free exchange of information about EHR-related adverse events and not prohibit information sharing among EHR system users.\textsuperscript{131}

The Institute of Medicine suggested that one mechanism to facilitate user reporting of EHR-related problems to the vendor would be for EHR products to include a “report here now” button.\textsuperscript{132}

**Conduct Additional Research on EHR-related Information Integrity and Adverse Events**

Research is needed on the industrywide prevalence of each type of EHR risk and the impact on health record integrity, patient safety, and quality of care. Further research is also needed on the causes of EHR-related errors and on effective strategies for preventing and correcting them. This research should:

- Explore specific system characteristics that are associated with increased or decreased error rates;\textsuperscript{133}
- Identify characteristics of safe EHR systems;\textsuperscript{134} and
- Investigate the development of “use cases” and tools for evaluating EHR implementations for adherence to usability principles and best practices.\textsuperscript{135}

**Advance Information Governance in Healthcare**

The improvements envisioned in healthcare with EHR systems depend on high-quality information to reform the way healthcare services are delivered, safety is improved, patients are engaged in their care, and healthcare costs are reimbursed. Accountability for the accuracy, reliability, availability, compliance, and protection of health information has not been well defined in healthcare organizations, leading to siloed decision-making and limited value for healthcare enterprises in their HIT investment. As discussed previously, concerns with the integrity of information in EHRs continue to rise. Simultaneously, organizations recognize the need for high-quality information for “big data” and analytics that support decision-making and improve quality. Strategies are needed to identify and address the challenges to information integrity.

To manage information assets and ensure appropriate decision-making, healthcare organizations (including providers, policy makers, and vendors) should deploy information governance concepts and programs. With an effective information governance program, healthcare organizations can
move from a reactive position to one that is built on controlling information assets, formalizing enterprise information management, and optimizing the use of HIT.136

**Conclusion**

EHR systems can transform the way healthcare is delivered when these technologies are designed, implemented, and used appropriately. Designed and used inappropriately, EHRs add a layer of complexity to the already complex delivery of healthcare, leading to unintended adverse consequences such as dosing errors, failure to detect serious illnesses, and delays in treatment due to poor human-computer interactions or loss of data.137

While much has been written about EHR-associated risks impacting information integrity, and the subsequent actual and potential impacts on quality of care and safety over at least the past decade, little has been done to systematically measure and analyze these risks, identify the root causes, and universally implement strategies (such as system design modifications and adoption of usability principles) to reduce risks. However, attention to the potential unintended consequences of electronic documentation is growing.138 In addition to the risks to the quality and safety of patient care, apprehension about EHR-associated errors may be a barrier to EHR adoption and use.139

Although many system developers and policy makers believe that the risks of EHRs are minor and easily manageable, that is not the case.140 Patient safety and quality of care are seriously compromised by flawed EHR system design or functionality or improper use.141 Failure to address information integrity issues in EHR systems will lead to spiraling, rather than declining, healthcare costs and medical errors as a result of the proliferation of new types of patient safety hazards.

A combination of federal government oversight and industry action is necessary to avert unintended consequences from EHR use. Federal leadership, in the form of regulation and oversight (and legislation if appropriate), is needed to ensure the development, implementation, and enforcement of comprehensive national standards for the design, performance, and use of EHR systems that reduce serious EHR-related errors. However, federal oversight alone is insufficient to eliminate EHR-related adverse events. EHR system vendors should adopt design and usability standards that optimize system safety and information integrity. Healthcare providers should implement policies and procedures that address proper EHR training and use, in order to prevent errors related to system use (rather than system design) and identify errors in the EHR before patient care is affected.

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