Project Title: Learning from Primary Care EHR Exemplars About HIT Safety

Principal Investigator: Steven Mark Ornstein, MD

Team members: Cara B. Litvin, MD, MS; Lynne S. Nemeth, PhD, RN; Andrea Wessell, PharmD

Organization: Medical University of South Carolina

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Federal Project Officer: Christine Dymek

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1. Structured Abstract:

Purpose: Nearly ubiquitous use of EHR systems by office-based physicians has raised concerns that use of these systems, while assumed to improve patient safety, may have unintended consequences and harm. SAFER guides have been developed to improve EHR safety in health care settings, but physician perspectives on the recommendations in these guides are unknown.
Scope: Primary care practices using EHRs who were deemed exemplars based on high performance on a summary of 62 clinical quality measures.
Methods: Three focus groups with a total of 19 primary care physicians from exemplar practices were conducted. The groups discussed 12 recommendations from 4 SAFER guides. Findings from these groups were shared with five EHR vendor executives who were then interviewed by telephone.
Results: Despite no familiarity with the SAFER guides, participants widely agreed with most of the recommendations studied and used a variety of pragmatic approaches to adopt them. Challenges related to their EHR system, cost and logistical issues, and incomplete agreement with some specifics in the recommendations were barriers to complete adoption. Vendor executives found the focus group findings unsurprising and cited regulatory requirements as barriers to development of better EHR systems.
Discussion: Experienced primary care physicians using EHRs view selected SAFER guides as relevant and important and offer practical approaches to their adoption in small primary care practices.
Key Words: Electronic health records, SAFER guides, primary care,

2. Purpose

The 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act was intended to improve the quality of healthcare provided to the American public by incentivizing the meaningful use of electronic health records (EHRs), defined as their use by providers to achieve significant improvements in care. (1) EHR use by office based physicians has nearly doubled under HITECH, and reached 87% by 2015.(2)

Concurrent with this rapid increase in EHR use, concerns have been raised that health information technology (HIT) may potentially lead to new types of errors in health care. EHR safety risks related to technical features, users and their workflow, and the rules and regulations relevant to their use may lead to unintended consequences such as errors in dosing, diagnoses and delays in treatment that cause serious injuries and death.(3-5)

In response to these concerns, the Office of the National Coordinator of HIT (ONC) has initiated programs to facilitate reporting and surveillance of HIT safety events, incorporated safety into the certification criteria for HIT products, and developed Safety Assurance Factors for EHR Resilience (SAFER) guides to enable EHR users to evaluate and improve safety issues within their own organizations.(6-9) Since their initial release in 2014 and update in 2016 (10) there have been no published studies on physician perspectives about or use of the SAFER guides.

This study assessed perspectives about a curated set of the SAFER recommendations and explored approaches taken to adopt them in a group of exemplar clinicians largely practicing in small, independent primary care practices across the U.S. Studies in these settings are critical because small practices, unlike large groups and hospital-based clinicians, have limited resources to devote to HIT and may be more susceptible to safety issues. (11, 12) The study used a multi-method approach used in a previous study by the co-authors. (13)

3. Scope:

The study was conducted in PPRNet, an innovative national EHR-based primary care practice-based research network (PBRN), and an AHRQ Center for Primary Care Practice-Based Research and Learning.(14) PPRNet, founded in 1995, links interested primary care practices using EHRs across the United States. Most PPRNet practices are community-based, about one-third have one or two providers, and more than two-thirds have five or fewer providers. The study design was multi-method, combining a quantitative assessment to identify exemplar practices in EHR safety with focus group interviews among physicians in these practices to explore their perspective about and adoption of SAFER recommendations.

Exemplar practices were defined as those, among the 59 PPRNet practices who submitted data for the third quarter of 2016, who performed in the top half on a summary clinical quality measure (CQM) (15). The summary measure aggregated data on 62 CQMs, 18 of which directly reflect patient safety relevant to medication prescribing and monitoring. Most of the remainder (CQMs relevant to cardiovascular disease, diabetes, preventive services, and other conditions) require safe EHR use as described in the SAFER guides.

4. Methods

Exemplar practices were contacted in November 2016 and asked to send a physician representative most knowledgeable about their EHR to represent the practice at one of three

focus groups in geographically dispersed sites on Saturdays in April 2017. We chose the focus group method because of its advantages over individual interviews to produce data and insights based upon the synergy of the group interaction. Focus group scripts were based on recommendations from four of the nine SAFER guides (6) most relevant to community-based primary care practices. These guides were: "High Priority Practices," "Computerized Provider Order Entry with Decision Support (CPOE CDS)," "Test Results Reporting and Follow-Up," and "Clinician Communication." We tentatively chose 24 recommendations from these guides, which was narrowed to 12 recommendations after a pilot test in March 2017 (Table 1).

Table 1: SAFER guides and specific recommendations addressed in focus groups.

SAFER Guide	**Recommendation**
High Priority Practices	Data and application configurations are backed up and hardware systems are redundant.
	Evidence-based order sets and charting templates are available for common clinical conditions, procedures, and services.
	Clinical knowledge, rules, and logic embedded in the EHR are reviewed and addressed regularly.
	The status of orders is tracked in the system.
CPOE CDS	Coded allergen and reaction information (or NKA) are entered and updated in the EHR prior to any order entry. Drug allergy interaction checking occurs during the entry of new medication.
	Drug condition checking occurs for important interactions between drugs and selected conditions.
	Dose range checking occurs before medication orders are submitted.
	A process is in place to review interactions so that only the most significant interaction related alerts, as determined by the organization, are presented to clinicians.
	Users can access authoritative clinical reference materials directly from the EHR, including organization specific information when available.
Test Result Reporting and Follow Up	Test names, values, and interpretations for labs are stored in the EHR as structured data using standardized nomenclature. Text-based test reports have a coded interpretation.
	Workflows vulnerable to mishandling of test results, especially critical ones, are identified, and back up procedures ensure results are received by someone responsible for the patient's care.
Clinician communication	The EHR contains a copy of clinician-to-clinician communications.

Each focus group was led by two of the co-authors (SO, LN) and observed by one or two of the other co-authors (CL, AW). Verbal consent was obtained from each participant to record the discussion and to ask that the recording be turned off at any time. During a 20-30-minute introduction in each group, the study design, HIT safety, and the SAFER guides were presented in a didactic fashion to assure participants had a basic common understanding. Each SAFER recommendation (Table 1) was then discussed in turn, with the participants asked to address four specific questions for each recommendation. The questions addressed the perceived relevance of the recommendation, approaches taken by the practice to adopt it, safety issues that occurred prior to adoption, and impact of its adoption on patient safety. As much as

possible the moderators asked each participant to respond to all four questions for each SAFER recommendation and endeavored to keep the discussion focused on the topic. Focus groups lasted for 3-4 hours, with a mid-session break.

A process of intensive immersion and crystallization(16) was used for analysis of digital audio recordings from the focus groups. The four coauthors met for seven listening sessions of the recordings to develop detailed themes relevant to the 12 SAFER recommendations. During these sessions, the recording was stopped and replayed, as needed, to discuss key segments of the recordings to identify and exemplify themes from the perspective of relevance, observed safety issues, and implementation. As each focus group recording was reviewed, comparisons to the other groups were made to assess convergence or divergence from the themes that evolved. Detailed notes of the process were captured in text, including relevant quotes from participants.

To supplement the findings from the focus groups, we shared our findings in writing and conducted telephone interviews with five high-level EHR vendor representatives. Their perspectives were transcribed by one of the co-authors and used to triangulate the perspectives of the physicians.

5. Results

Physicians representing 17 of the 21 participating practices attended in person one of the three focus groups held during April 2017 in Charleston SC, Nashville TN, and Las Vegas NV. Due to illness, a physician from an 18th practice participated in one of the groups by teleconference and due to travel disruptions a 19th responded to the study topics in writing. Interestingly, although all participants had years of expertise working with their EHR and most had personally worked to configure and refine it with the goal of optimal patient care, none had heard of the SAFER guidelines. A summary of the discussion of each of the 12 SAFER recommendations follows.

High Priority Practices

1) Data and application configurations are backed up and hardware systems are redundant.

Relevance and Observed Safety Issues:
Agreement with the importance of data backups was unanimous, with lesser consensus on the importance and feasibility of application software and hardware redundancy. Although not universal, several participants recalled incidents where hardware and/or software issues caused lost data and the lack of redundancy created ongoing problems.

"We were down for 4 hours and lost all data captured during that time, including appointments scheduled. For six months, patients were showing up for appointments that we did not know had been made."

"In 2014 our server crashed and we discovered our IT support was NOT backing up any of our scanned files such as X-rays, consult notes, hospital notes etc. 8 years' worth of data gone!"

A few participants had experiences with viruses and other malware that caused practice interruptions and data loss. However, while agreeing with the importance of data backups, most participants agreed that data loss was uncommon and orders of magnitude less frequent than with paper-based records.

"We've been using EHRs for 24 years and have been down for only three days during that time."

Implementation Themes:
All practices had some approach to data backup, though the approaches varied widely among the participants. A common theme was that some expertise was necessary to implement and maintain a feasible approach. In most practices, the individual or group responsible for data backup was responsible for other areas of hardware and EHR software support for the practice. In some practices, the expertise resided within a practice physician or office manager who had prior IT experience though most participants expressed the belief that their expertise was in medicine, not HIT. In another, a family member of a physician provided this expertise and in another practice, a patient who was a friend of the physician did so. In others, the EHR software valued added reseller (VAR) provided this service. A few participants noted that having EHR support from an individual experienced with maintaining the same software in other settings, e.g., an academic health system, was extremely valuable.

The technological approach to data backup varied among practices and changed over time in response to advances in the field. Several participants referred to "tape backups" although upon further questioning none were still using this archaic technology. Some participants used portable magnetic or solid-state drives which were stored off site on a regular rotation, e.g., weekly. Others used internet based server technologies, through their VAR or another third-party. Although more expensive (more than $800 a month for a one full-time equivalent physician practice), the advantage of their host being able to both monitor their backups and quickly restore missing data was deemed to be worth the cost. Other participants stated that this cost was prohibitive for their small practice. At least one practice used both internet-based server backups and on-site backup drives.

Approaches to hardware redundancy also varied widely, as did the perception of the feasibility and need for having this capability. Some participants ran their EHR software on a server with a single hard drive and relied on their ability to quickly purchase and configure a new server. Others had mirrored or RAID drives for redundancy, while others relied on the ability of their VAR to mount their data on a remote server in the event of local hardware failure. Few had performed a disaster recovery test, noting that the time and/or expense to do so was prohibitive.

A consensus among the participants was that better guidance from their EHR vendor, a national organization, or a federal agency to vet and recommend approaches for their practices would be valuable.

2) Evidence-based order sets and charting templates are available for common clinical conditions, procedures, and services.

Relevance and Observed Safety Issues:
Perspectives varied widely on the relevance and wisdom of this recommendation for primary care. Advantages acknowledged were the impact of order sets and charting templates on avoiding care omissions (e.g., urine albumin in patients with diabetes or hypertension; vision screening in patients with a red eye, orthostatic blood pressure in patients with dizziness); the ability to standardize care in setting where there were learners, less experienced or new clinicians, or a lot of ancillary staff initiated care.

"A really good doctor, if there are 10 things on the list, will remember 6 things."

"We found out if we give nurses something to do, they work off checklists and you get better care."

Other participants noted the advantage of including diagnostic criteria in charting templates to help assure accurate diagnoses were being made based on the history and clinical findings, e.g., the diagnostic criteria for pneumonia from the American Thoracic Society.

Disadvantages centered around concerns related to loss of physician autonomy, the ability to customize care for individual patients, clinician censure for not following established protocols; and potential overuse through duplication of tests that had recently been completed.

Participants noted the differences between primary care and emergency care, where standardized processes are frequently followed, noting that primary care patients may more often have undifferentiated problems (e.g., chest pain due to grief) which do not easily fit a templated approach to care.

"I'm afraid of cook-booking."

"You click it, it does it and then you don't think about why you've done it."

Despite concerns, the ability of order sets and templates to help prevent errors was acknowledged, with several participants citing errors that occurred prior to their adoption. One noted a common theme of later identification of hypokalemia in patients on diuretics whose metabolic panel had not recently been checked.

Implementation Themes:

All participants acknowledged the time commitment required to develop order sets and charting templates, despite many using an EHR that was easy to adapt without interaction with the vendor and that was shipped with a basic set of templates. One problem was the need to adapt at least two sections of the EHR (order sets, charting templates) when guidelines or procedures changed or when new procedures were developed. The other major time concern related to the need to curate clinical updates and choose which updates mandated a change in order sets and/or templates. Practices approached the curation and modification process in several ways. In one practice with five physicians, two led the curation process and advised the others of changes at monthly meetings. In another the practice relied upon updates in their PPRNet CQM reports to adjust their order sets and clinical templates. A third assigned this responsibility to a trusted registered nurse, particularly for well child care. Some participants noted the trade-off between the advantage and disadvantage of practicing in a larger system, where updates were done for providers, who had no control of the choice of the clinical evidence chosen to guide the updates.

An interesting contrast was observed between participants who thought that order sets and clinical templates were most relevant for conditions that they did not commonly encounter, e.g., Hepatitis C. Others believed that such conditions could be handled as "one-offs" by consulting reference materials and that order sets and templates were more useful for commonly seen conditions, e.g., diabetes mellitus and general wellness examinations.

Some practices that did not commonly use EHR-based order sets or clinical templates adopted other strategies to affect the same end. One physician used a complex flow sheet to view

multiple types of data in one place instead of a single order set; another used a commercially available patient history program that uses patient symptoms and responses to prior questions to guide the "interview", and other participants noted that the prior note for complex patients was often the best "template" for their care.

3) Clinical knowledge, rules, and logic embedded in the EHR are reviewed and addressed regularly.

Relevance and Observed Safety Issues:
This recommendation met with universal agreement and many participants viewed their ability to maintain current clinical knowledge in their EHR as a key to better and safer care. Physicians deemed up-to-date health maintenance reminders as crucial components of these functions.
"The health maintenance has made me tend more closely to all of the requirements that are needed for each patient. "I have way fewer patients in the hospital than my peers do."

"When Dr. "X" and I started doing the health maintenance and really doing PPRNet [referring to practice improvement approaches], our hospitalization rate went down and we knew it because we actually started making less money."

Implementation Themes:
Practices adopted different approaches to the concept of "reviewed and updated regularly." A few did so on a fixed scheduled (e.g., every 6-12 months they would review United States Preventive Services Task Force (USPSTF) recommendations and incorporate updates. Another practice did so more regularly, spending two hours weekly to update the EHR and update providers and ancillary staff on new information and approaches. Another reported implementing updates as frequently as daily, based on reading high quality publications such as *JAMA* and the *Annals of Internal Medicine* or after listening to audio digests of journals while running, reading *Journal Watch,* or other email summaries. Some practices had no systematic process to update these information in the EHR, citing time constraints. A number based their updates on PPRNet CQM report updates or academic detailing delivered at research project related site visits or webinars. Whereas some practices used small teams of clinicians and ancillary staff to update their EHR, at least one designated one physician to do so, and allocated protected time for this activity.

The consensus of the group was that the work involved to update their EHR with clinical content depended on the specifics of the update. For example, removing medications from the electronic formulary when a safety issue was published was straightforward. In contrast, updating certain preventive service (cervical cancer screening) or immunization recommendations (e.g. adult pneumococcal) with complex logic was more difficult. Also viewed as difficult was the need to update multiple components of the EHR (reminder template and rules, note templates, and patient education) when a recommendation changed. Many wished that theirs had the capacity to automatically update these components when new evidence was available, particularly if the practice could choose which updates to incorporate.

"It would be nice if we had a central person who would do all that and send it out to us."

Others, however, doubted whether EHR vendors wanted to provide such functionality for their clients.

"I think one of the things we're coming back to is that these systems are not actually designed with a lot of this in mind. What we're hearing and what I'm observing is that to keep it current, to make it safe, to make it work for you, all of us in our own individual offices have to put the crampons on and climb up the ice and say this is what we need to do…"

Given this perspective, some participants reported using tools outside their EHR for up to date clinical content and patient education, a subject that will be discussed in more detail in a later section.

4) The status of orders is tracked in the system.

Relevance and Observed Safety Issues:
Many participants agreed that using EHR-based tracking helped assure completion of ordered tests and procedures. Also noted were opportunities to generate revenue through chronic care management fees from Medicare and to satisfy Patient Centered Medical Home and the advancing care information component of the Merit-based Incentive Payment System (MIPS) through order tracking and patient outreach. However, one vocal participant was adamant that order completion was a patient's responsibility alone, a second thought the process was too complex for a small practice, and all agreed that significant human involvement was required to optimize order completion.

"Tracking is easy and that's lovely but human beings still need to be involved…my nurses go through and take care of 80% of the orders…some of the orders haven't been done and they're not sure if it's really that important or not. And then I have to review and say follow-up with it or don't worry about it, I'll get it the next time they come in."

Several participants acknowledged safety issues prior to establishing EHR-based order tracking processes. One specific example was of a patient on anticoagulant therapy who did not complete an ordered international normalized ratio (INR) and presented with hematuria six weeks later.

Implementation Themes:
Unlike other functions in the EHRs used by participants, the discussions indicated that order tracking features were less familiar. Many noted that the features needed to be configured at the level of the individual practice. Full functionality of order tracking required interfaces not only with laboratories, which most practices have, but with facilities conducting procedures, imaging, and referrals, which were less common. Not surprisingly participants noted that order tracking worked well for lab tests; less well for other orders.

The approaches used to track and follow uncompleted orders varied widely among the participants. Some have hired nurses to conduct this work or designate a specific nurse to do so. Others use their medical assistants for this function. Another has their front desk review overdue orders, and confirm with clinicians which require follow-up. The frequency of order review varied as well, with some doing so monthly and others every few months; as did the extent to which practices endeavored to encourage patients to complete ordered tests and procedures.

"We will make one phone call or letter communication and if still a few months later is not done we cancel the order, since patients should take some responsibility for their health."

Most participants doing order tracking and follow-up agreed that the volume of uncompleted orders could be overwhelming, that not all orders are of equal importance to track and follow-up, and make specific decisions about which types of orders to monitor. For example, one practice has chosen to do so only for pap smears, mammograms, and colonoscopies.

Some participants who had not implemented their EHR order tracking functions used other functionality as substitutes. Some send forward dated messages to themselves or their nurses as reminders to ascertain whether important tests or procedures were completed. Another used the health maintenance section of their EHR, querying it for noncompleted procedures. Others used registries provided by PPRNet to identify patients overdue for high priority orders

A consensus among the participants was that patients themselves were critical agents in the order tracking practices and asked them to check back with the practice if they have not received a test result. Several cited the common quote: *"no new is no news!"*

Computerized Physician Order Entry with CDS

1) Coded allergen and reaction information (or NKA) are entered and updated in the EHR prior to any order entry. Drug allergy interaction checking occurs during the entry of new medication.

Relevance and Observed Safety Issues:
Participants widely agreed that these recommendations were an important component of safe medical care and a major benefit of using an EHR. Most also agreed that it was important to document the specific allergic or other reaction that had affected the patient. Also noted were the positive impacts of following these recommendations on malpractice rates and satisfying requirements for the CMS "Meaningful Use" program.

Several participants recalled medication safety issues that had occurred prior to their use of an EHR. Some said that issues happened "all the time" before implementing their EHR. More specifically, one participant described an avoidable hospitalization that occurred due to an unrecognized medication allergy. Another described an incident of an allergic reaction to celecoxib in a patient with sulfa allergy.

Implementation Themes:
Participant practices had adopted different approaches to allergy documentation and updating. Some left the responsibility to physicians, suggesting that look alike-sound alike medications could confuse staff members and result in erroneous recording of allergies. Also expressed as a concern was the ability of staff members to make the distinction between a medication allergy and intolerance. In other practices, nursing staff members record allergies, but leave edits or deletions to these information as clinician responsibilities. In others nursing staff had the prerogative to edit allergy information with oversight by physicians.

Additionally, practices had adopted clear protocols for regular gathering and review of allergies; most reported doing so at most office visits. The importance of pharmacies providing duplicate allergy checking was also emphasized, as was the fact that errors can occur despite the use of EHR-based allergy checking.

"Even with automated allergy checking, I have had a nurse practitioner prescribe Augmentin for someone with a penicillin allergy…. you get the flag but you have flag fatigue and she just clicked through it. The patient developed a rash."

2) Drug condition checking occurs for important interactions between drugs and selected conditions.

Relevance and Observed Safety Issues:
Most participants agreed that this recommendation was important and a strength of EHRs, although most also felt that some of the alerts were either wrong or irrelevant.

"These have many more false positives, so I don't act on these as commonly as I act on other alerts."

Some pointed out that drug-condition checking was particularly important for patients with multi-morbidity. Several participants had observed medication safety problems prior to using their EHR or implementing drug-condition checking. Examples included using quinolones in patients with cardiomyopathy or QT segment prolongation, pioglitazone in patients with congestive heart failure, and non-steroidal anti-inflammatory agents with patients with chronic kidney disease.

Implementation Themes:
Participants noted that use of drug-condition checking advanced patient safety for the care they delivered and improved the care delivered by outside consultants whose records regarding a patient's medical problems might be incomplete. One example was of an outside physician prescribing bupropion to a patient, not knowing of the patient's alcohol disorder; a medication safety issue that was recognized when the primary care physician entered this medication into the EHR.

Most however, expressed disappointment with the number of alerts that were incorrect, e.g., avoiding use of angiotensin converting enzyme inhibitors in patient with diabetes mellitus or chronic kidney disease, and avoiding aspirin in all patients with influenza.

"A big hassle for a little bit of help" was a sentiment expressed by one participant.

Alert fatigue was a commonly expressed concern and participants wanted the ability to edit the drug-condition alerts embedded in their EHR, a function not available in the EHRs they used.

3) Dose range checking occurs before medication orders are submitted.

Relevance and Observed Safety Issues:
Although participants agreed with the importance of this recommendation, particularly for children and patients with renal impairment, not all were aware that the functionality to do so was available in their EHR.

"The main [feature] that I find valuable is the renal impairment flag, since I have indeed altered prescriptions due to [these alerts]."

Examples described of medication safety issues that had occurred absent use of this functionality included: high dose ranitidine in a 90-year old patient, under-dosing of an antibiotic

for a pediatric patient, and inappropriate prescribing of alendronate in a patient with renal impairment.

Implementation Themes:
In the EHRs used by many participants, dose range checking must be invoked by the prescriber, using a non-intuitive command; appropriate medication dosage is not automatically calculated. Given this required extra step, some participants were not aware of the functionality and used tools external to the EHR for dosage checking (e.g., the Epocrates app on their mobile phone.) When used, however, some participants found the functionality helpful for their own prescribing and to adjust dosages of medications prescribed by outside clinicians, who either did not use an EHR, lacked this functionality in their EHR, or chose not to use it. Adjusting apixaban dosage in patients with renal impairment and histamine H2-receptor antagonist dosages in elderly patients were two specific examples described.

4) A process is in place to review interactions so that only the most significant interaction related alerts, as determined by the organization, are presented to clinicians.

Relevance and Observed Safety Issues:
Most participants strongly agreed with the importance of setting the drug-drug interaction alert level based on agreement within the practice.

"I agree with this wholeheartedly because you do get that alert fatigue and you just ignore them."

A significant health IT safety issue observed by some of the participants, whose practices were unaware that the interaction level could be adjusted or had set it to alert for any possibly interaction, was ignoring all alerts, even important ones, given the large number that were displayed.

Implementation Themes:
Most of the participants reported that their practice had adjusted the drug-drug interaction alert level, though several expressed confusion about the meaning of the different setting levels, how many there were, and whether evidence-based recommendations were presented to guide the setting used. Participants whose practices adjusted the level to report only moderate to severe interactions consistently seemed to describe the alerts as more useful than prior to the adjustment. Some participants using one EHR noted that it only initially displayed one potential alert, and that the interface unintuitively required the user to request display of other alerts. Such a design was deemed much less helpful than one in which all were initially presented on one screen. Another recommendation for improvement of this functionality was the ability to suppress specific alerts on the patient level, based on the view that once the interaction was considered by the clinician it would not be helpful for the alert to be displayed repeatedly.

5) Users can access authoritative clinical reference materials directly from the EHR, including organization specific information when available.

Relevance and Observed Safety Issues:
While acknowledging the great importance of their point-of-care use of authoritative clinical references, most participants disagreed that these materials needed to be directly accessible

from the EHR. Most commented that in 2017 there was nearly ubiquitous internet access and mobile based apps with access to these reference materials.

"It's nice but this is somewhat old school."

Another concern noted about this recommendation was its possible impact on EHR response time.

"It takes up too many resources within the EHR program itself and therefore slowing down the EHR."

Another perspective was that clinicians valued multiple clinical reference sources and it would be unlikely for an EHR to be configured to link to all of them.

"I know that I'll go to different references based on what I'm trying to look up, because I know the best place to go to."

Finally, one participant, who had access to UpToDate® directly through his EHR and mobile phone noted:

"*The UpToDate® app on my phone is often faster and allows me to keep the patient chart open and in full view while accessing it*."

In contrast, participants agreed with the importance of links from the EHR to organization-specific information (e.g., consent, do not resuscitate, and prior authorization forms; medication formularies, and the like).

Test Result Reporting and Follow Up

1) Test names, values, and interpretations for labs are stored in the EHR as structured data using standardized nomenclature. Text-based test reports (e.g. radiology) have a coded (e.g., abnormal/normal at a minimum) interpretation.

Relevance and Observed Safety Issues:
While participants largely appreciated the value of this recommendation for laboratory data and in certain circumstances for radiology and other procedures, their consensus was that the entirety of the recommendation was not feasible. For example, many radiology tests and procedures have several findings which can only be assessed as abnormal or normal in the context of the clinical situation.

Implementation Themes:
Most participants reported only routinely getting lab results as structured data and noted that their EHR highlighted abnormal values using different colors or fonts. Several reported having clinician or staff codify data even if it was received from the service provider in text form. Examples included use of the Breast Imaging Reporting and Data System (BI-RADS) for mammography results and Bethesda system for pap smears. Some recorded these codes in laboratory tables to better visualize the results over time; some used diagnostic codes. None reported using anything but coded laboratory tests for clinical f decision support.

2) Workflows vulnerable to mishandling of test results, especially critical ones, are identified, and back up procedures ensure results are received by someone responsible for the patient's care.

Relevance and Observed Safety Issues:
Participants all agreed that these recommendations were critical for clinical and liability reasons, noting that HIT safety issues in this area were *"too numerous to count"*. A specific example included a patient presenting in a myxedema coma after her thyroid laboratory tests were mishandled. Although all agreed with the importance of these recommendations, at least one participant acknowledged only developing explicit approaches to adopt them in response to the requirements of a patient centered medical home application.

Implementation Themes:
Approaches to preventing safety issues from mishandling test results included technical, workflow, and patient activation strategies. Technical approaches included using the EHR feature that flagged abnormal values in laboratory tables in red, setting the laboratory interface to send critical results to multiple staff members including a physician and a nursing staff member, and adapting the EHR so that abnormal results were highlighted in a larger font in progress notes.

Workflow approaches with outside service providers included developing agreements so that laboratory and radiology providers called physicians directly with critical findings. In the office, some had adopted procedures whereby staff members hand abnormal results sent via fax directly to a physician, and for more complex procedures such as CT scans, directly handing the report to a physician if the result does not clearly indicate that the procedure was normal. To adapt to times when the physician is not in the office for any reason, practices have developed explicit agreements as to whether the physician will check results remotely, another physician will do so, or a nursing staff member will do so and notify the on-call provider about abnormal findings.

Some practices also used patient activation strategies to avoid mishandling of test results. Some asked patients to call for results after a set time, telling them that *"no news is no news,"* not an indication that their tests were normal. Others used the EHR patient portal to share results, but acknowledged the problems with this approach, given the inability of many patients to understand the implication of minor abnormalities and the subsequent disruption to patients, staff, and physicians.

"The next patient phone call that they take me out of the room for a hepatic hemangioma, I'm going to kill someone!"

Clinician communication

1) The EHR contains a copy of clinician-to-clinician communications.

Relevance and Observed Safety Issues:
Participants largely agreed with the concept underlying this recommendation, but also largely disagreed with how the recommendation has been implemented, emphasizing their current EHR system contained both too much and not enough data. Too much referred to their observation that their consultants' EHR, largely due to its templates, generated multiple pages of unimportant information for each consult.

"The information is important but a copy of the direct clinician-to-clinician communication is not important."

Indeed, participants noted that long emergency room or other consultation notes without clearly highlighted plans created safety issues. While noting that the length of notes was due to regulatory/billing requirements, participants wished that they could instead facilitate communication.

"Some of the ERs will send you 18 pages of garbage."

"In an [widely used EHR], good luck finding what your consultant recommended."
"These template-driven systems, they create a note that makes no sense."

"When I'm seeing a note back from the ER or from anyone, is just checking boxes but not being factual. This patient is a long-time smoker and they have in there "non-smoker."

Too little data referred to salient communications, which historically had occurred in the hospital doctors' lounge, now transpiring via non EHR embedded emails or texts.
Some participants also noted that they sometimes do not receive consultation notes, and many that they do arrive by fax, due to sparse adoption of direct secure email by their consultants.

"It would be great if it works. This was a part of Meaningful Use. We couldn't find anyone to communicate with."

Implementation Themes:
Few participants reported developing approaches to overcome these problems with clinician to clinician communication. One participant did observe that his practice was receiving reimbursement for recording information from consultants in structured fields in the EHR from Medicare using Chronic Care Management codes. Others reported doing similar work without compensation, with clinicians "digesting" long communications by summarizing in the EHR relevant information from each consultation or hospitalization.

Other health IT safety issues:
In open discussion, participants noted several other HIT related patient safety issues not related to the 12 SAFER recommendations addressed. Some were related to documentation requirements for billing and from the EHR Meaningful Use Incentive program itself. One observation was that extensive documentation requirements could distract clinicians from patient care and in and of themselves create safety problems. Another pointed to workforce problems, noting that physician burnout that happens *"because of all the documentation"* is also a safety issue. A third noted that these requirements adversely impacted their EHR functionality in population management, due to lack of focus by the vendor.

Other patient safety issues related to over-reliance on HIT, particularly with care transition processes. An example was incomplete medication reconciliation between hospital discharge medication lists, ambulatory EHR medication lists, and what the patient is actually taking after discharge. Another example was the inability to send discontinue orders through electronic prescribing systems, creating problems with therapeutic duplication, additional cost, and other potential harms.

A broader issue was the concern that the EHR Meaningful Use incentive program, given the large scope of its requirements, missed the opportunity to improve patient safety by not focusing on a few high priority requirements.

"When Meaningful Use first started, if they had just said: you must have an accurate active problem list, medication list, allergy list, and you have to have up to date health maintenance based on the U.S. Preventive Services Task Force. If they had said 4 things but made sure we did all 4 of those things with veracity and it was across all interfaces, from nursing home to hospital, that would've been so rich."

Despite the numerous concerns expressed by participants, their overall perspective about the impact of their EHR on patient safety was positive.

"It's a real pain to do a lot of this, to deal with an EHR and all of the different workarounds we have to do, but I feel that my patients are safer and healthier because I have these tools."

Summary of Findings:
Based on the results presented above, we developed a taxonomy of key strategies and best practices for safe EHR use in small primary care practices (Table 2).

Table 2. Taxonomy of Key Strategies and Best Practices for Safe EHR Use in Small Primary Care Practices

SAFER Guide	Key Strategies and Best Practices
High Priority Practices	**Data backups** are important, although the approach taken for backups may vary based on a practice's resources. Primary care practices should **designate a person with HIT expertise** to assist with implementing and maintaining a feasible approach.
	Use of EHR-based order sets, charting templates, flow charts, and health maintenance reminders should be implemented to prevent omissions of care for both common and uncommon conditions. A **designated clinician** (i.e. physician, registered nurse) or group of clinicians should **curate clinical updates** and **modify** these tools at least every 6 months or as frequently as the day after a new publication or guideline. Practices should consider joining a practice-based research or learning network to help them keep up with evidence-based care. EHR vendors should consider providing clinical updates for their clients.
	Prioritize orders to be tracked. Given the volume of orders in a primary care practice, better HIT systems are needed to improve the feasibility of tracking all orders. Primary care practices should consider prioritizing essential orders to track.

SAFER Guide	Key Strategies and Best Practices
CPOE CDS	**Allergen** and reaction information should be reviewed and updated at all office visits. A protocol should be in place for either physicians or nursing staff members to assume this responsibility, although if designated to nursing staff, physicians should oversee them.
	Review and edit drug-condition alerts embedded in an EHR to advance patient safety, by a physician designee.
	Dose-range checking is important, although the EHR functionality to do so should be intuitive and part of prescribing workflow.
	Configure drug-drug interaction alert levels by the practice. The EHR functionality to configure these alerts should be intuitive. All alerts should be presented on one screen.
	The **EHR should contain links to organization-specific protocols** (e.g., consents, do not resuscitate, medication formularies). Clinical reference materials do not need to be accessible directly from the EHR.
Test Result Reporting and Follow Up	**Implement technical, workflow, and patient activation strategies to prevent mishandling test results**. Abnormal results should be flagged in the EHR, critical results should be sent to multiple staff members, and agreements should be developed with outside providers (i.e. laboratory, radiology) to call physicians directly with critical findings. When the ordering physician is not available, a protocol should be in place to direct the result to another physician (i.e. partner, on-call physician). Patients should also be told, **"No news is no news"** and instructed to call for results (whether normal or abnormal) after a specified amount of time.

Vendor Perspectives:

The five EHR vendor representatives (VR) interviewed were affiliated with each of the EHRs used by focus group participants. One was a former EHR company founder and chief executive officer, another a current chief operating officer, and the others either current or former chief medical officers or medical directors of one or more EHR companies.

Three of the five VR were clearly familiar with the SAFER guides and largely thought that we had selected appropriate recommendation for discussions. The consensus was that our findings were reasonable, expected, and relevant to all EHR systems, not just those used by focus group participants.

Most VR responses related to the High Priority Practices recommendations. For data and application backups, VR agreed that the process was smoother in larger practices and that while vendors could offer backup services and consistent recommendations, it remained the practice's responsibility to adopt an effective solution in a client-server environment or choose a hosted EHR solution.

With respect to evidence-based order sets and charting templates, VR addressed five issues: trust, content updates, user diversity, specificity, and competing obligations. Trust related to the provenance and timeliness of the recommendations. One VR suggested that transparency about the source of the recommendations and dates they were updated would enhance trust.

VR agreed with both the importance and challenges implicit with content updates. One noted that our focus group participants, because they were early adopters of EHR systems were more likely to be willing to adapt their order sets and templates; while mid-stage and late adopters would most likely be less willing to do so. Another, whose company had recently purchased the EHR used by most of the focus group participants, noted that order sets and templates modified by the user were difficult for the vendor to update and maintain, causing later problems with updating data fields needed for regulatory reporting and value-based payment. All VR mentioned the extensive work required for order set and charting template updates.

User diversity was best summarized by one VR who noted: "A template satisfies one provider." He added that a template library was essential for sales, but that few clinicians like to use templates developed by others. Diversity was seen not only as an issue between different practices, but within practices. One VR reflected that in a group of five physicians, all could practice differently and want different order sets and templates and noted: "we can't build 50 systems for 50 different docs." He also noted that different payers, including Medicaid in different states, had different interpretations of evidence and different rules that affected order sets and templates.

Specificity related to the challenge of digitizing an analogue world, applying yes or no choices in ambiguous situations. It also reflected trade-offs—one VR noted that to minimize EHR clicks increased the likelihood that inaccurate data were recorded, but that to assure greater accuracy required more clicks, a problem for most clinicians.

Competing obligations were widely cited as barriers to creating and maintaining evidence-based order sets and charting templates. The major competing obligation cited was the EHR certification and recertification process. One VR noted that "in our company we are buried in certification." Another noted that each certification cycle takes their development, quality assurance, and product team offline for 3-6 months and pulls them out of other activities. He explained that to sell product and maintain their revenue stream, their company was required to have a certified product, because their clients expected it, but "that is not what keeps customers happy; that stuff has nothing to do with certification." A third VR observed that it was a huge business challenge to balance innovation with certification and thought that this challenge was a big reason small EHR companies were merging or being acquired by others.

Some content updates were viewed as less problematic. VR pointed to drug dictionaries, drug-drug interaction, and preventive service recommendations as domains where reliable third parties maintained content that could be readily incorporated in EHR update.

VR offered some perspectives on CPOE CDS recommendations. Alert fatigue was acknowledged as a major concern, particularly for drug-condition and drug-drug interactions. The importance of finding an appropriate balance between providing alerts that are important and avoiding alerts that will frequently be ignored while causing both screen clutter and alert fatigue was emphasized. One VR also noted the importance of making alerts user friendly, e.g., brief with embedded links to additional information, and actionable, not simply leaving it up to the clinician to identify appropriate responses. A final VR reflection was on the ongoing need for consistent clinician training, so that clinicians do not criticize their EHR for the absence of features that actually are present.

Discussion:

In this study of EHR-experienced and high quality primary care physicians there was widespread agreement with most of the SAFER recommendations discussed, despite the observation that none of the participants had any prior familiarity with them. Participants cited numerous examples of safety issues that had occurred prior to their use of EHRs or adoption of related SAFER recommendation. In adopting strategies to adopt the SAFER recommendations, practices used a variety of approaches. Variation was due to limitations of their EHR, participants' understanding of their EHR functionality, office staffing, and extent of their agreement with the recommendation. Widely expressed were sentiments that it is expensive and time-consuming to maintain and update their EHR and its knowledge bases, that clinical judgement was often required to supplement EHR recommendations, and that greater assistance with optimal EHR use and maintenance from their vendor, value-added reseller (VAR), or another group was needed. The consensus, however, was that these difficulties were outweighed by the quality of care that their EHR use provided.

Vendor representatives largely agreed with the findings from the focus groups and added useful perspectives about the challenges they face meeting some of the SAFER recommendations discussed. They also strongly concurred with the physicians' view that it would be desirable to be able to focus on product updates that help clinicians and patients, rather than the regulatory requirements that require many of their resources.

To our knowledge this study is the first assessing how primary care practices have employed recommendations within the SAFER guides, despite not knowing of their existence. Such adoption provides support for the validity of the guides, particularly given that the study participants were exemplars who demonstrated their ability to use EHRs to achieve high quality care.

Some caveats are in order. The 12 recommendations chosen for study addressed only 14% of 83 recommendations in the "High Priority Practices," "CPOE CDS," "Test Results Reporting and Follow-Up," and "Clinician Communication" SAFER guides. The study team, who, in the aggregate have more than 65 years of experience using and studying EHRs in primary care, chose these recommendations as those most relevant to the study participants. Clearly, however, findings might have differed if other recommendations were chosen. Also, although PPRNet has members using different EHRs, most use or previously used a product from one vendor as did all study participants. Findings might have been different from participants using different EHRs, although most of the VR reported that they viewed the findings as product agnostic. Finally, all participants were from practices that are high performers on a broad set of CQMs and most participants had at least ten years of experience using their EHRs; largely in a manner that facilitated high quality. Finding from less experienced practices might well be different.

The field of HIT safety is young and complex and our study addresses a small component of it. Better software and regulatory mechanisms (17) and a more robust safety framework (18) are needed to advance the field. As the field develops it will also be important to continue to assess the relevance of HIT safety recommendations and their pragmatic implementation in "real-world" practice.

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6. **List of Publications and Products:** None