Original Scholarship

Patient Identification of Diagnostic Safety Blindspots and Participation in "Good Catches" Through Shared Visit Notes

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Policy Points:

- Patients and families can identify clinically relevant errors, including "blindspots"—safety hazards that are difficult for clinicians or organizations to see.
- Health information transparency, including patient access to electronic visit notes, now federally mandated in the US and the subject of policy debate worldwide, creates a new opportunity to engage patients in diagnostic safety. However, not all patients access notes.
- Patient identification of blindspots in their notes underscores the need to systematically and equitably engage willing patients in safety, promote patient "good catches," and establish routine systems for patient feedback to help avoid preventable diagnostic errors and delays.

Context: Policy shifts toward health information transparency provide a new opportunity for patients to contribute to diagnostic safety. We investigated whether sharing clinical notes with patients can support identification of "diagnostic safety blindspots"—potentially consequential

breakdowns in the diagnostic process that may be difficult for clinical staff to observe.

Method: We used mixed methods to analyze patient-reported ambulatory documentation errors among 22,889 patients at three US health care centers who read $\geq$ 1 visit note(s). We identified blindspots by tailoring a previously established taxonomy. We used multiple regression analysis to identify factors associated with blindspot identification.

Findings: 774 patients reported a total of 962 blindspots in 4 categories: (1) diagnostic misalignments (n = 421, 43.8%), including inaccurate symptoms or histories and failures or delay in diagnosis; (2) errors of omission (38.1%) including missed main concerns or next steps, and failure to listen to patients; (3) problems occurring outside visits (14.3%) such as tests, referrals, or appointment access; and (4) multiple low-level problems (3.7%) cascading into diagnostic breakdowns. Many patients acted on the blindspots they identified, resulting in "good catches" that may prevent potential negative consequences. Older, female, sicker, unemployed or disabled patients, or those who work in health care were more likely to identify a blindspot. Individuals reporting less formal education; those self-identifying as Black, Asian, other, or multiple races; and participants who deferred decision-making to providers were less likely to report a blindspot.

Conclusion: Patients who read notes have unique insight about potential errors in their medical records that could impact diagnostic reasoning but may not be known to clinicians—underscoring a critical role for patients in diagnostic safety and organizational learning. From a policy standpoint, organizations should encourage patient review of visit notes, build systems to track patient-reported blindspots, and promote equity in note access and blindspot reporting.

Keywords: patient engagement, patient portal, patient advocacy, patient safety.

I NCLUSION OF PATIENTS AND FAMILIES IN HEALTH CARE processes such as diagnosis, clinical decision-making, and safety incident detection can contribute to improvement in quality of care and the reduction of medical errors.[1–7] Patients and families have alternative perspectives on health care delivery when receiving care and observing clinical staff, and privileged knowledge of their medical histories. They are, at times, the only connecting thread between various encounters with different providers or health care systems. As a result, they are in the unique position to detect "blindspots"[8]—safety

problems that are difficult for clinical staff to observe and address. Patients and families who report blindspots, such as complications arising outside the organization, communication errors among care team members, or missing test results, can enable clinicians and systems to become aware of safety problems that would likely otherwise be hidden, thereby reducing the risk of medical errors.

Psychological research on the concept of "shared mental models" shows that safety outcomes in organizations are improved when critical knowledge for decision-making is shared and updated within a team, and informational asymmetries between team members are avoided.[9,10] Crucially, this research recognizes that for a team to develop a shared mental model, members must have insight on one another's understanding of a shared task, such as arriving at a patient's diagnosis,[11] so that knowledge gaps or misunderstandings can be recognized and addressed.

Resonating with shared mental models and the idea that patients are a central part of the health care team, social cognitive "situativity theory" recognizes that clinical reasoning does not rely solely on the provider, but rather the complex interactions between the provider, patient, and contextual factors.[12,13] Situativity theory is especially relevant to the diagnostic process because patients and providers each hold "distributed cognition"—unique information and actions necessary to arrive at a correct and timely diagnosis.[12,14,15] During key clinical activities such as making a diagnosis, each party holds "parts of the puzzle" (e.g., unique information on symptoms, histories, tests) but none holds it all.

Accordingly, optimizing patient safety relies on bidirectional information flow between clinicians or organizations and patients. In addition to the *organization* collecting patient feedback about hospital safety, patient and family contributions to health care safety may be most useful when *patients*, too, have access to the knowledge held by clinical staff about their conditions and treatments in order to provide the context needed to identify potential information gaps. For example, by accessing their own health information, patients can see the clinician's perspective and thus identify and correct missing or inaccurate information that may be important for preventing errors and managing risk—yet is only known to them. An apparent route through which this can be achieved is by enabling patients and families to read their clinical notes[16] and inviting feedback on potential errors.

The idea that patients and families might be supported to actively observe and address blindspots in health care delivery is significant for health care policy, especially in the global context of increased health information sharing.[17,18] Initially, it suggests that interventions to improve patient safety may benefit from recognizing and focusing on intentional knowledge-sharing between patients and clinicians to help reduce blindspots during diagnostic processes and outcomes—a key mechanism through which errors may be avoided. More fundamentally, the conceptualization of blindspots indicates that the role of patients and families in preventing medical error, although actively debated,[19–22] is more substantive and important than generally recognized.[1,4,22–24] Patient-identified blindspots, originally conceived from patient complaints in the UK,[8] have now been applied to patient complaints in general practice in Ireland,[25] and to compensation claims in Danish emergency care.[26] In both cases, breakdowns in the diagnosis stage (including evaluation, listening, and tests) were common.[25,26]

Patient and Family Involvement in Preventing Diagnostic Errors

Diagnostic errors (where a clinical diagnosis is wrong, missed, or delayed) are a global safety priority. Estimated to occur in 5% of ambulatory visits and affecting 12 million patients in the United States annually, these errors are a leading cause of US ambulatory malpractice claims.[1,27,28] The landmark 2015 National Academies of Medicine report on improving diagnosis urged engagement of patients and families to improve safety and quality of care, and implicit in this recommendation is the idea that patients and families hold unique knowledge related to the diagnostic process and safe delivery of care.[1,29] The report defines diagnostic error as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient," underscoring the significance of the patient's viewpoint.[1] The emphasis on engagement reflects, perhaps more than any other aspect of patient safety, the extent to which accurate and timely diagnosis relies on patients/families and clinicians working together. Accordingly, coproduction of diagnosis is a focus of civic engagement.[30] However, theorization as to how patients might specifically contribute to reducing diagnostic errors is lacking, and there are

few, if any, proven strategies for achieving this aim.[1,31] In addition, organizational reporting and characterization of diagnostic errors often lack the patient and family perspective, and may therefore miss important events.[16,32–34]

Drawing on the concept of blindspots, we suggest that patients and families can support the delivery of safe diagnoses through identifying diagnostic process-related safety breakdowns (e.g., gaps in patient histories, miscommunications, missing diagnostic tests and referrals,) that may not be captured by traditional safety data, such as clinician adverse event reporting, surveys, or electronic health record (EHR) triggers.[35–37] Where these blindspots emerge, the likelihood of error is increased, due to the clinician missing critical information about a patient's history or timely completion of the diagnostic evaluation. A "360 degree" view of the diagnostic process and its potential breakdowns that is derived from integrating multiple perspectives including patients' and clinicians', may help ensure blindspots in clinical decision-making are captured and avoided.[6] However, patients and families need access to their health information in order to engage in this process. Without it, they may be unaware of gaps or misunderstandings in clinician knowledge.

Learning from medical errors and near misses has long been the focus of policymaking for patient safety. Patient safety "good catches," a subset of near misses,[38] describe a condition or situation that had the potential to cause harm but did not because the safety threat was identified and proactively prevented.[39,40] Efforts to encourage "good catches" have been promoted at many health care systems to encourage staff reporting,[41] but to date have not been routinely applied to patient and family engagement efforts. Despite the tremendous potential of leveraging unique patient knowledge to uncover blindspots, act on good catches, and improve diagnostic safety,[32,35,42] studies focused on patient-identified blindspots in the diagnostic process—which, by definition, are invisible to clinicians—have not yet been explored.

Health Information Transparency as a Mechanism for Patient Blindspot Detection

The practice of sharing electronic visit notes with patients through the patient portal ("open notes") has grown dramatically over the past

decade. Beginning with 20,000 patients in a proof-of-concept study in 2010, more than 54 million US patients had easy access to electronic notes roughly a decade later. The 21st century Cures Act Final Rule, implemented in April 2021 in the United States now federally mandates that patients have easy access to their electronic health records, including visit notes. Shared notes are therefore a new, broad, and underutilized resource for patient engagement and diagnostic error prevention. In our prior research we found that about one in five patients reported a perceived error in ambulatory visit notes, including breakdowns in virtually every step of the diagnostic process.[16,35] Yet practice lags behind policy, and there are currently few approaches to elicit and act on this unique patient knowledge.

Current Study

To determine whether patients and families can identify safety blindspots, we investigated their ability to identify vulnerabilities in the diagnostic process that might otherwise go undetected by clinicians or organizations. Specifically, we examined the extent to which patients can identify incorrect or missing information in outpatient clinical notes, that represent a threat to diagnostic safety and cannot be easily captured or addressed by health care staff alone. With the possibility of broad-scale patient and family engagement through shared medical notes on the horizon through the US Cures Act and further momentum toward health information transparency internationally, we recognized the vast potential of this new, but currently underutilized, platform for patient engagement in safety.

We focused our exploration on the field of ambulatory diagnosis, using survey data from three US health centers that have shared visit notes with patients for more than seven years. We anticipated that blindspots may play a critical role in ambulatory diagnostic error because these safety events occur not only during the office visit, but also before, after, or between visits, where they are difficult for anyone but the patient or family to see. We envisioned that patient-identified blindspots would have the potential to prevent harm and promote organizational learning, thereby enabling *patient good catches*. Given the risk of inequities in health information access and use, we also examined whether there is variability in the characteristics of patients who identify blindspots in

notes, to better equip policymakers in understanding potential barriers to equitable patient participation. Specifically, we aimed to: 1) characterize the types and frequencies of diagnostic safety blindspots reported by patients who read visit notes; and 2) explore patient factors associated with identification of blindspots.

We hypothesized that sharing notes between clinicians and patients can help patients identify unrecognized safety threats that emerge during diagnostic processes. In addition, we anticipated that some sociodemographic factors placing patients at greater risk for diagnostic error, harm, or health care inequity, such as race, education, language preference, or health status, might also differentially affect blindspot detection. The contribution of the study is to show how health care policies on open access to clinical notes can support health care organizations to reduce diagnostic breakdowns through informed development of stronger shared mental models of diagnosis and care between patients and clinicians. By further exploring factors associated with patient blindspot identification, we also contribute to equity-informed policy deliberation on the requirement and methods for including patients in efforts to improve patient safety through the resource of shared notes.

Methods

Participants

Patients at three US healthcare systems were invited to participate in an online survey about their experiences with open notes. Each site had open notes available for up to seven years, including notes from primary care and both medical and surgical specialty clinics. The sites included one urban academic health system in the Boston area; one large rural integrated health system in Pennsylvania, and an urban safety net hospital with both private and community-funded practices in Washington. Participants were those aged 18 or older, who logged in to their portal account at least once over the preceding 12 months and had at least one ambulatory visit note available during that time. As previously described,[16] of 136,815 patients who received survey invitations, 29,656 (21.7%) responded and 22,889 patients read one or more note in the past 12 months and completed survey questions about perceived note errors. Of these, 4,830 (21%) reported a perceived error in the notes

and 2,043 (42%) reported it was somewhat or very serious. A total of 1,749 (86%) of participants reporting a somewhat or very serious error provided free text responses describing the perceived error.

Survey

The open notes survey was adapted from the initial open notes questionnaire including both closed and open-ended (free text) items.[43] We used a mixed-methods approach for this study. Participants were asked "Have you ever found anything in your visit notes you thought was a mistake (not counting misspellings or typographical errors)?" Response categories were no, yes, or don't know/not sure. Those who answered yes were asked, "How important was the most serious mistake you found?" Response categories were not at all serious, somewhat serious, or very serious. At the two largest sites, (representing 26,732 (93%) of patients), those who described the mistake as somewhat or very serious were asked, "Please describe the most serious mistake" (free text), which was used for qualitative analysis. Sociodemographic data included respondents' self-identified gender, race, ethnicity, education, physical health, employment status, health care-related work, and primary language spoken at home. Additional survey details have been published, and the questionnaire is available on request.[44]

Analysis

Diagnostic Safety Blindspots . Gillespie and Reader have previously defined *blindspots* as "A domain of individual or organizational functioning that is either unobservable or incorrectly observed."[8] In other words, the patient knows something that the clinician or organization does not and that may otherwise go undetected. We applied the idea to potential *diagnostic safety blindspots* and defined these as "breakdowns in diagnostic processes and outcomes that represent a threat to diagnostic safety and cannot be easily captured or addressed by health care staff alone."

We identified diagnostic safety blindspots in a two-step process. First, we identified and categorized patient-reported diagnostic process-related breakdowns (PRDBs) from all patient-reported errors in visit notes using the Framework for PRDBs in ambulatory care.[35] The framework was developed by a multidisciplinary team including patients and families and was derived from qualitative analysis of patient-reported

ambulatory errors in two large US datasets. We defined a PRDB as a problem or delay reported by patients that could map to any part of the diagnostic process, as outlined in the National Academies of Medicine conceptual model,[1] including missing or inaccurate symptoms or medical history, delays in diagnostic tests or referrals, and communication breakdowns, such as patients who did not feel heard. The framework for PRDBs includes seven types of breakdowns that are further characterized by 40 subcategories. These provide granular information regarding what went wrong in each step of the diagnostic process from the patient and family perspective. Further details about development and performance of the framework can be found elsewhere.[35]

Two coders—one internal medicine physician (SB) and one pediatrician (FB)— used the Framework for PRDBs[35] to code free text responses describing patient-reported errors in the survey using standard procedures for the content analysis,[45] whereby a coding framework was used to identify and classify patient comments relating to concepts of interest, and then these data were inductively analyzed to interpret and explain how patients recognized and addressed breakdowns related to the diagnostic process. The two coders each participated in at least five hours of training related to framework use and had access to a detailed framework with definitions and examples of each type of patient-reported breakdown. Coders independently applied the framework to the patient reports, coding only empirically identifiable text (not inferences), and assigning as many breakdown categories as appropriate to each patient report.[8] We tested inter-coder reliability using Gwet's AC1 statistic, a test used for categorical data with a skewed distribution, because some categories in the Framework for PRDBs were used at a much higher rate than others, similar to the coding frequencies and distributions in the original blindspot study.[8] We also calculated the kappa statistic since this test is widely recognized and a more conservative measure of reliability.[8] We evaluated complete matches; in other words, we counted as disagreement any time one reviewer coded a category that the other did not. We compared patient-reported breakdown category coding between the two coders using a random selection of 10% (180) of patient reports. Given the good reliability between coders (AC1 [95% CI]: 0.93 [0.92,0.94] and kappa [95% CI]: 0.77 [0.73,0.81],[35] one physician (SB)] coded the remainder of all the patient reports.

Next, we determined the subset of PRDBs that reflected diagnostic safety blindspots, focusing on patient-reported information that might

affect clinicians' diagnostic reasoning and subsequent care decisions. We began our analysis using the same three blindspot categories in organizational patient safety established by Gillespie and Reader: 1) events occurring outside the organization; 2) multiple problems that may cascade into more serious events; and 3) omissions (things that were not done).[8] Guided by the original inclusion criteria in each category, we mapped PRDB categories to each of these blindspots, as follows.

To examine *events occurring outside the organization* (i.e. before, after, or between visits["outside the visit"] for our ambulatory care study) we focused on problems described by patients with access to care and breakdowns related to tests and referrals (which typically occur before or after the index visit). We assessed the *multiple problems* blindspot by identifying patient reports that included three or more PRDBs. Finally, we examined *omissions* using similar criteria to those established by Gillespie and Reader, examining quality, communication, and listening problems, and focusing on something that was not done or was missing (Table 1).[8]

To address the particularity of breakdowns in diagnostic safety, we added a fourth blindspot, termed "*diagnostic misalignment*." Following the literature on unique patient contributions to the diagnostic process,[1,16,32,35] the importance of shared mental models of diagnosis,[46] and the potential effect of misalignment between patients and clinicians on diagnostic delay,[47] we focused on instances where patients and clinicians differed in their understanding of the clinical history, processes, and outcomes of diagnoses, because these could lead to significant errors (Table 1). For example, misalignment between patients and clinicians about the main clinical concern may lead to inaccurate capture of symptoms, a crucial step in the diagnostic process. These misalignments are blindspots because patients have knowledge about a problem related to the diagnostic process that may be difficult for health care providers to see or know and can negatively impact diagnostic safety if left uncorrected.

Three multi-disciplinary researchers—two psychologists (AG, TR) and one physician (SB)—reviewed patient comments coded in each of the four blindspot categories to examine the face validity of the data; such that, overall, the comments captured events where patients and families reported their clinical notes as having an error or missing information potentially related to the diagnostic process and relevant to each specific blindspot category.[48] After confirming the existing categories of blindspots, we conducted an in-depth review of patient comments

Table 1. Categories and Descriptions of the Four Types of Diagnostic Safety Blindspots

Blindspot	Category	Description
Between visits	Access to care	Not being able to schedule or get to an appointment, often due to something the organization may not know about such as a missing diagnosis (i.e., an incorrect diagnosis is listed) that is required for a referral
	Tests/referrals	Breakdown in scheduling, completing, interpreting, or communicating about tests or referrals
Multiple/cascade		≥ 3 patient-reported diagnosis-related breakdowns
Omission	Something important missing from history, next steps, or physical exam	Patient knows important missing information
	Diagnosis or next steps not effectively communicated to patient	Missing or ineffective communication about diagnosis or next steps, such as situations where a patient learns of a diagnosis by reading a note or does not know what to do next
	Patient not listened to/not heard	Patient knowledge or questions that are ignored by provider(s); or no response to patient outreach, including patient attempts to correct a perceived error

Continued

Table 1. (Continued)

Blindspot	Category	Description
Diagnostic misalignment: lacking shared mental model	Inaccurate symptoms/relevant history	Documentation of symptoms is not aligned with patient experience/knowledge of symptoms or clinical course, such as inaccurate or misinterpreted symptoms
	Documentation on wrong patient	Information in medical record pertains to the wrong patient
	Failure or delay of diagnosis or treatment	Inadequate work up, diagnosis not consistent with existing evidence (such as test results), or correct diagnosis made elsewhere; disagreements between clinicians about diagnosis or next steps, sometimes resulting in patients resolving the disagreement themselves; or other instances where the patient knows something the clinician or health care system doesn't know about diagnosis and/or treatment related to diagnosis

to develop the boundaries of what would be included and excluded in the novel literature-informed category of diagnostic misalignments. We iteratively reviewed patient comments with potential blindspots, discussed the content, and developed a list of exemplars related to the definition of the diagnostic misalignment blindspot. We then applied these criteria and again reviewed all qualifying patient comments for overall face validity. We included all potential blindspots identified by patients, recognizing that a single patient comment may have more than one blindspot (for example, an omission and a diagnostic misalignment).

Multiple Regression. To assess the relationship between patient identification of at least one blindspot and sociodemographic factors including age, gender, race, ethnicity, education, self-reported health, employment status, work in health care, and primary language spoken at home, we conducted multiple logistic regression. Because relatively few participants self-identified as Black or African American, Asian, American Indian or Pacific Native, Native Hawaiian or Pacific Islander, other race or multiple races; we created a binary variable for race, combining these participants into one group and comparing their responses to those who self-identified as White. Given prior debate about patient interest or ability to engage in safety, and based on Levinson's demonstration of variability in patient preference to engage in care,[49] we also included in the regression model a previously tested item ("I prefer to leave decisions about my medical care up to my provider") with the original six point agree vs disagree response categories,[49] dichotomized at agree vs disagree.

Ethics

Analysis of previously collected anonymized survey data was reviewed by the IRB at Beth Israel Deaconess Medical Center and determined to be exempt (Protocol 2019P000970).

Results

Table 2 describes the characteristics of the study population and the 1,466 participants who described at least one PRDB in their ambulatory notes. Compared with their counterparts, individuals reporting a PRDB were more likely to be female, white, more educated,

Table 2. Characteristics of the Study Population (N = 22,889) and Individuals Who Identified at Least One Patient-Reported Diagnostic Process-Related Breakdown (PRDB) Compared With Those Who Did Not

Variable	Total (N = 22,889)	At least 1 PRDB (N = 1,466)	No PRDB (N = 21,423)
	N (%)	N (%)	N (%)
Age			
18–24	774 (3.4)	21 (1.4)	753 (3.5)
25–44	5,090 (22.2)	293 (20.0)	4,797 (22.4)
45–64	9,494 (41.5)	691 (47.1)	8,803 (41.1)
65+	7,531 (32.9)	461 (31.5)	7,070 (33.0)
Gender			
Female	14,447 (63.1)	1,106 (75.4)	13341 (62.3)
Male	8,442 (36.9)	360 (24.6)	8082 (37.7)
Race			
White	18,301 (84.9)	1,179 (85.8)	17,122 (84.8)
Black or African American	570 (2.6)	37 (2.7)	533 (2.6)
Asian	1,175 (5.5)	41 (3.0)	1,134 (5.6)
Other[a] or multiple races	1,515 (7.0)	118 (8.6)	1397 (6.9)
Ethnicity			
Non-Hispanic	20,855 (96.2)	1,343 (96.6)	19,512 (96.2)
Hispanic	816 (3.8)	48 (3.5)	768 (3.8)

Continued

Table 2. (Continued)

Variable	Total (N = 22,889)	At least 1 PRDB (N = 1,466)	No PRDB (N = 21,423)
Education			
High school or less	1,456 (6.7)	43 (3.1)	1,413 (6.9)
Some college or technical school	4,814 (22.0)	263 (18.7)	4,551 (22.2)
College graduate, or some graduate school	7,464 (34.1)	434 (30.9)	7,030 (34.3)
Masters or Doctoral degree	8,145 (37.2)	667 (47.4)	7,478 (36.5)
Health			
Excellent	3,001 (13.8)	125 (8.9)	2,876 (14.1)
Very good/good	15,436 (70.7)	922 (65.4)	14,514 (71.1)
Fair & Poor	3,388 (15.5)	363 (25.7)	3,025 (14.8)
Employment			
Employed/Self-employed/Homemaker	13,099 (60.1)	765 (54.5)	12,334 (60.5)
Unemployed or disabled	1,881 (8.6)	223 (15.9)	1,658 (8.1)
Retired	6,828 (31.3)	415 (29.6)	6,413 (31.4)
Primary language spoken at home			
English	19,966 (92.0)	1308(93.8)	18658(91.8)
Other than English	1,746 (8.0)	86(6.2)	1660(8.2)
Health care professional			
No	18,571 (85.3)	1,082 (77.2)	17,489 (85.8)
Yes	3,204 (14.7)	320 (22.8)	2,884 (14.2)

[a] "Other" race included: American Indian or Pacific Native, Native Hawaiian or Pacific Islander, or other race.

English-speaking, and work as health care professionals. Patients self-reporting poorer health, unemployed or disabled status, and an age of 45–64 were also more likely to report a PRDB.

Patient-Reported Diagnostic Process-Related Breakdowns

Table 3 shows the types and frequencies of PRDBs. The overall frequency of PRDB identification was 1,466/22,889 (6.4%). These 1,466 patients reported 1,884 PRDBs, with an average of 1.29 PRDBs/individual. The most common category of PRDB was medical history (59%) followed by communication (34%), explanation/plan (15%), and tests/referrals (9%). Among patients with fair or poor self-reported health, the PRDB frequency was 363/3,388 (10.7%). Among patients with high school education or less it was 43/1,456 (3.0%) and among those who spoke a language other than English at home it was 86/1,756 (4.9%).

Blindspots

Among the 1,466 participants reporting a PDBR, 774 (52.8%) individuals reported at least one diagnostic safety blindspot. At the event level, we identified 962 (51.1%) diagnostic safety blindspots among the 1,884 PRDBs. Table 4 shows the types and frequencies of the four blindspots, which are further detailed below.

Factors Associated With Identifying a Blindspot

In multiple regression analysis, individuals who were older, identified as female, had fair/poor health, were unemployed or disabled, or worked in health care were more likely to identify a blindspot. Those who self-identified as Black or African American, Asian, "other" or "multiple races;" who reported less formal education, or who deferred decision-making to their provider were less likely to report a blindspot (Table 5). The greatest effect sizes were demonstrated for self-reported health and education. Patients with fair or poor health were significantly more likely to identify a blindspot than those with excellent health: OR 3.4 (95% CI 2.5, 4.7); and those with high school education or less were

Table 3. Frequency and Types of Patient-Reported Diagnostic Process-Related Breakdowns (PRDBs) in Visit Notes

PRDB Category	All Participants With at Least 1 PRDB: N = 1,466		Patients With Fair or Poor Physical Health and at Least 1 PRDB N = 363		Patients With Education ≤ High School and at Least 1 PRDB N = 43		Patients Who Speak a Primary Language Other Than English at Home and at Least 1 PRDB N = 86	
	N	%	N	%	N	%	N	%
Access	4	0.3%	2	0.6%	0	0.0%	0	0.0%
Medical history	862	58.8%	198	54.6%	16	37.2%	47	54.7%
Physical exam	100	6.8%	20	5.5%	3	7.0%	6	7.0%
Tests/Referrals	134	9.1%	19	5.2%	4	9.3%	13	15.1%
Explanation/Plan	227	15.5%	70	19.3%	7	16.3%	16	18.6%
Communication and Respect	498	34.0%	170	46.8%	19	44.2%	33	38.4%
Other	59	4.0%	12	3.3%	0	0.0%	3	3.5%

Table 4. Patient-Identified Diagnostic Safety Blindspots

Blindspot	Number of Blindspots N = 962 (%)	Examples
Events Occurring Outside the Visit		
Access	138 (14.3%)	A family history was not correctly reported in a note, which affected ability to get an appointment with genetic counselors.
Tests and referrals		During my primary care office visit it was determined that I had a heart murmur and should have it followed up with an echo. My visit note did not mention it or say that a test should be planned. I pointed that out to the Dr. and he responded with a note correction.
		My results indicated that I did test positive for Chlamydia but I was told by my provider that I didn't (which was a mistake). If I didn't have these visit notes, I most likely would not have gotten the medication I needed.
		I was told my bone density test came back showing I had lost more bone mass, but based on the notes from two years prior, I saw I had actually GAINED bone mass.
		After a yearly physical, my PCP reported that I had no history of abnormal PAP smears. I had just had an abnormal pap 2 months prior and had to have a colposcopy. My PCP never asked about this at our appointment and must have just assumed there were no issues.

Table 4. (Continued)

Blindspot	Number of Blindspots N = 962 (%)	Examples
Multiple/Cascade >/= 3 PRDBs	36 (3.7%)	The HPI as written made little sense, reported that I had been hypothyroid when I had been hyperthyroid, reported that my symptoms were well controlled with current conservative therapy (which was untrue, and which is why I was seeking a second opinion), and failed to document an extra-ocular movement exam, when one of my primary problems is double vision. In fact, as far as I could tell, there were no salient parts of an exam documented at all.
Omission Missing important symptoms/history, physical exam, or next steps	367 (38.1%)	A doctor mentioned that I had NOT been febrile, when I mentioned that I had, and he said my lymph nodes were not enlarged, when he never palpated them. "[The] provider wrote that I did not have shortness of breath when I did indeed and had said so. It made me wonder if I had been misdiagnosed. [Note] said no diarrhea, which is not true. It is a big problem, I always complained about it. I recently found out I had IBS [Irritable Bowel Syndrome]. I didn't tell the doctor I had had a hysterectomy. The notes said my uterus was normal. I called her office to correct that.

Table 4. (Continued)

Blindspot	Number of Blindspots N = 962 (%)	Examples
Not listening to patients		Doctors (plural) not recording my explanation of reason for visits completely accurate which makes a difference. Which means they weren't listening to me.
		I repeatedly (three times) asked the doctor what were the risks of my discontinuing treatment for my condition and he never answered me, but in the report states that he advised me of these risks and named them.
		When at a follow up visit and doctor asks question like: do you have discharge?
		I say yes but yet I read in my Chart notes where it is marked no. This frustrates me when they do not mark right answers. This will affect medical decisions made for me.
		Reported that I had gall bladder removed when I didn't and it was impossible to correct.

Table 4. (Continued)

Blindspot	Number of Blindspots N = 962 (%)	Examples
Diagnostic Misalignment Erroneous symptoms or history	421 (43.8%)	It is mistake in regards to a certain type of migraine that I have. It stated clearly that I do not have migraine with aura. I in fact do have migraine with aura and that can create confusion that can alter another physician's perception of my situation later on particularly being that I am also epileptic.
		[The note] indicated that I had a metastasis from the wrong cancer episode. That mistake affected my current condition inaccurately.
		[The note said] I had post-menopausal bleeding and that was what led doctors to find a uterine abnormality. The fact is that I never had post-menopausal bleeding. A swelling in my leg led to searching for abdominal abnormalities and finding the one in my uterus.
		I was listed as having congestive heart failure, which was a surprise and untrue.
		Injury was at work so [it affected a] workman's company claim. Notes stated [the injury] happened elsewhere vs work so claim rejected. Have had to appeal, hire an attorney.

Continued

Table 4. (Continued)

Blindspot	Number of Blindspots N = 962 (%)	Examples
Wrong patient		Conditions have been listed that do not apply to me. Test results have been published for tests I never took! I have brought this to my PCP's attention and the appropriate changes were made.
		Someone else's notes were in my report, a different person with same name.
Breakdowns in diagnosis or next steps		The consulting surgeon…had not mentioned a rotator cuff tear in the right shoulder, which had undergone rotator cuff surgery in the past for adhesive capsulitis… when I went to P[hysical] T[herapy], expecting to receive help for serious rotator cuff pain, the therapist was completely unaware of the diagnosis. Eventually I was required to submit a written request for a correction to the visit notes, in order to have any level of attention paid to the shoulder. A lot of time went by and I was in considerable distress.
		Nurse practitioner prescribed antivirals for a rash she assumed to be a herpes (it wasn't). I never filled the prescription and the test came back negative for herpes, but the mistake was never corrected and the medication was (maybe still is?) listed as a medication I'm taking.

Table 5. Multiple logistic regression of identifying at least one blindspot and socio-demographic factors (N = 22,889)

Variable	Odds Ratio	95% CI		P value
Age				0.007
18-24 (reference)				
25-44	2.6	1.3	5.4	
45-64	3.0	1.5	6.2	
65+	2.5	1.2	5.3	
Gender				<.0001
Male (reference)				
Female	2.0	1.6	2.3	
Race				0.017
White (reference)				
Asian	0.5	0.3	0.8	
Black	0.8	0.5	1.3	
Other race	0.7	0.4	1.1	
Multiple races	1.1	0.8	1.6	
Ethnicity				0.243
Non-Hispanic (reference)				
Hispanic	1.3	0.8	1.9	
Education				<.0001
Masters or Doctoral degree (reference)				
College graduate or some graduate school	0.7	0.6	0.9	
Some college or technical school	0.5	0.4	0.6	
High school or less	0.2	0.1	0.3	

Continued

Table 5. (Continued)

Variable	Odds Ratio	95% CI		P value
Health				<.0001
Excellent (reference)				
Very good or good	1.9	1.4	2.5	
Fair or Poor	3.4	2.5	4.7	
Employment				<.0001
Employed/Self-employed/homemaker (reference)				
Unemployed or disabled	2.2	1.7	2.7	
Retired	1.2	1.0	1.6	
Preferred language spoken at home				0.606
English (reference)				
Other than English	0.9	0.7	1.3	
Health Care Professional				<.0001
No (reference)				
Yes	1.5	1.2	1.8	
Prefer to leave medical decisions to providers				<.0001
Disagree (reference)				
Agree	0.5	0.4	0.6	

significantly less likely to identify a blindspot compared to those with masters or doctoral level education: OR 0.2 (95% CI 0.1, 0.3). Detailed data for all factors are shown in Table 5.

Types of Diagnostic Safety Blindspots

Diagnostic Misalignment

Misalignments between patients and clinicians about perception of the clinical history or its significance, or about the diagnosis or next steps, comprised 421 (43.8%) of blindspots, and often set the diagnostic process or treatment off track. Misalignments included failure to capture the patient's symptoms or story correctly, such as a "completely wrong description of presenting symptoms and type of seizures." By reading notes, patients picked up on misalignments between patients and clinicians that led to missteps in diagnostic reasoning. Patients often held privileged, specific information that could help sharpen the diagnostic process. For example, one patient reported: "The doctor referred to my concern as dizziness. Actually, I had come in due to sudden incoordination when walking which turned out to be due to M[ultiple] S[clerosis]."

Another patient recognized the potential for a missed diagnosis: "The notes regarding sinus pain were not accurate as to the area of my upper jaw being affected… It mattered to me because I had recently had dental work in the actual area of the pain." In this blindspot category, several patients again commented that note access was key to discovering the error: "The notes described the symptoms as pain when in fact it was related to syncopal/fainting symptoms…Without open notes I would never have known about the mistake."

Patients perceived that inaccurate descriptions of their symptoms may be the result of copy and paste of information from old notes: "I was seeing someone about my knee and some of the notes talked about my shoulder which led me to believe some of the notes may have been canned." Patients specifically commented about concerns related to misinterpretation or misdiagnosis by the future clinicians reading the note; inaccurate documentation leading to waste or inefficiency, such as repeat appointments; or delays in appropriate treatment as a result of erroneous information. One patient noted: "MD described disease etiology

incorrectly, which resulted in a change in medication protocol ordered. Contacted her immediately, situation resolved in less than a day. [Open] records were essential in resolving the problem."

Patients noted errors stemming from diagnostic misalignments that were carried forward in the medical record and taken as "truth." These often required ongoing effort on the patient's part to correct propagated errors:

> "I was prescribed penicillin for strep throat when I also had mono (which is contraindicated). I got a rash because of this, and now my medical record reads that I am allergic to penicillin (I am not, I just had a bad reaction when it was erroneously prescribed). I have had two doctors mention that I am allergic to penicillin when in the office for other reasons."

In extreme cases, the wrong symptoms or clinical course resulted from documentation on the wrong patient:

> "The fellow had made what appeared to be an error copying and pasting, because the medical history that was allegedly mine was a very specific description of someone else's condition. There were enough discrepancies to make it clear that it was just someone else altogether. I told {the} providers…{who} acknowledged the error and amended the notes."

Occasionally wrong patient mistakes triggered a plan to change treatment, such as test results from another patient. At other times, patients receiving the erroneous information worried the correct patient was overlooked, potentially resulting in two errors: "I was listed as a patient and received a call for an appointment regarding cancer treatment. I am not being treated for cancer and was concerned that the correct patient was not being attended to properly."

Finally, patients discovered in their notes disagreements between providers about diagnosis, treatment, or interpretation of results, such as, "Primary care physician recommended medication that my cardiologist didn't agree with." In some instances, patients themselves became proactive to resolve the disagreement between providers, for example:

> "I requested Theraflu because I had come down with pneumonia a month before. The nurse on the phone had written down that I was tested a month ago for pneumonia but was cleared (which was the first radiologist reading and was true based on my urgent care discharge notes, but the second radiologist a few hours later reviewed the X-ray and decided that it did indicate pneumonia). I totally understood the confusion and was able to correct the misunderstanding the next day ."

Omissions

Omissions were reported in 367 (38.1%) of blindspots and occurred when patients identified a main concern that was missed by providers or something important that was absent in the notes, most commonly involving the history, physical exam, or next steps. For example, "Notes said I had no chest pain, when, in fact, chest pressure/pain was a major presenting factor several times." Patients noted omissions affecting screening decisions, such as: "I read a line that said 'no family history of colon cancer,' but I was never asked… and do have a family history of it."

Occasionally, patients reported omissions related to not being told about a specific diagnosis, next steps, or contingency planning (as related to next steps). Some patients learned about the diagnosis or plan for the first time from reading the visit note. For example: "[Notes] said I had a heart and kidney problem and nothing was ever said to me about it." Recognizing inherent uncertainty in diagnosis, and recent data indicating that patients reported they didn't know what to do if/when their clinical course changed,[35] we also noted situations in which patients perceived that guidance reported in notes did not occur at the visit, such as: "Notes routinely stated that they had reviewed topics with me that they had not reviewed. For example, [the] note would say something like 'reviewed signs of early labor, discussed when to go to hospital' and in reality neither thing had been mentioned to me at all."

Finally, omission blindspots reflected reports of patients who felt they were not listened to by providers. Because feeling heard is a subjective experience, we took at face value patient accounts such as "Doctor totally omitted some of my concerns as though they had not existed." Accurate and timely diagnosis relies on careful listening to the patient's story, and the patient has privileged access to its evaluation. In any one case the absence of listening may or may not represent a true hazard, however, this type of blindspot flags an organizational vulnerability in terms of patient safety, quality of care, and patient experience. For example:

"My … [electrophysiology] doctor, failed to note that I told him I was in heart failure. He said I was fine. I had a second cardiac arrest and he failed to note I told him I was having [atrial fibrillation], which was confirmed when my new pacemaker was read."

Not listening, not responding, or failure to correct a perceived error identified by patients even after they pointed it out, sometimes repeatedly, often led to frustration, feeling disrespected, or leaving care with that clinician. For example:

> *"A physical therapist who did not provide written take home instructions for home exercises, consistently claimed that he did. Yet when I asked him for it, he said the process would cut into my physical therapy time with him. Since I found it difficult to remember most of the rather difficult instructions, I stopped my P{hysical} T{herapy} sessions."*

Events Occurring Outside the Visit

Participants reported a total of 138 (14.3%) blindspots related to events occurring before, after, or between visits, such as access to subsequent appointments or breakdowns with tests or referrals. Some patients described difficulty accessing needed appointments due to erroneous documentation or lack of response from the health care system (Table 4). The majority of before, after, or between visit blindspots pertained to tests and referrals. For example, by reading notes, patients detected tests that were planned by the clinician as part of the diagnostic work up, but not ordered.

Other patients detected errors related to test results such as the incorrect blood type or radiology reports discussing the wrong breast, wrong lung, or the presence of pacemaker and defibrillator in a patient who did not have any such devices. Patients noted repeated errors such as ongoing notation of the gallbladder on an MRI despite its removal and the patient's notification to the radiology team; or test results from a specialist visit repeatedly sent to the wrong primary care doctor at a different hospital. Some blindspots related to faulty test interpretation by clinicians reflected specific clinical knowledge known by the patient about their own condition.

> *"My last pregnancy was very difficult. I had a placental abruption. There was a recording error at my 20 week ultrasound that stated I had {had} placenta previa in addition to the placental abruption - something that would have made the pregnancy even more high risk with completely different care protocols. I did not have placenta previa."*

In some instances, the test result itself was correct, but patients held unique information that could potentially explain the results. For

example: "Hemoglobin level was low on test result. Dr. recommended follow-up test. I wrote a message back revealing that I had donated blood 2 days before the visit and he said that would explain the low Hematocrit level."

Finally, patients also identified discrepancies between reports and clinician interpretation of results, or instances where the clinician was using outdated data such as inaccurate CD4+ lymphocyte counts in their clinical assessment. Several patients detected blindspots related to either unnecessary planned test duplication or delayed cancer screening due to inaccurate dates of a prior test or lack of clinician knowledge about a prior test or abnormal result. In many of these instances, patients notified the provider about the accurate date and averted duplication or delay.

Multiple Breakdowns

Multiple breakdowns, comprised of three or more PRDBs, occurred in 36 (3.7%) of patient-reported blindspots, and most commonly involved breakdowns related to different aspects of the medical history, often coupled with communication and listening breakdowns (Table 4). In the latter case, the problem was compounded when patients tried to report the perceived error but were dismissed or belittled. For example: "Notes about an exam that did not take place, along with results reported that were not mine. I called the doctor to report this, and received a call back from an office assistant who dismissed my concern as 'just a transcription error.'"

One common pattern in multiple/cascading blindspots was an error that propagated forward, leading to delay in diagnosis or treatment, such as:

"I was in an automobile accident and needed my injury evaluated for future care (i.e., physical therapy). This visit needed to be billed to an insurance company at a separate address, which I provided in writing on letterhead in a note to be placed in my file. The diagnosis for the visit was incorrect, so that although I did receive a referral for physical therapy, it was for the wrong body part. This necessitated two more visits to the clinic (I had switched doctors at this point) and a significant delay in the treatment of my injury. Additionally, the visit was billed incorrectly, causing confusion with the insurance company... the delay in treatment has been both painful and frustrating."

Discussion

Patients' evaluation of their clinical notes, in the context of their own privileged knowledge about their health can help patients and clinicians build stronger shared mental models of the diagnostic process, identify unrecognized errors, and fix safety blindspots that lead to good catches. It may further improve the quality of notes since patients picked up on "copy and paste" behaviors with outdated or erroneous data, or use of templates documenting exams, review of systems, or contingency planning and counseling that they perceive did not occur in the visit. In effect, interventions such as open notes may better align patients and clinicians during clinical work-ups and treatments, with the opportunity to identify and correct misunderstandings and mistakes before they result in clinical harm. Our findings have five timely policy implications.

Patient Involvement in Diagnostic Safety is Essential to Optimize Safety

Diagnostic safety blindspots are a call to action to routinely involve patients and families in patient safety and diagnosis. The results suggest that the inclusion of patients in patient safety can no longer be considered optional for policymakers. By capturing safety blindspots that might otherwise go undetected and potentially lead to harm, the study shows that greater patient involvement is necessary for addressing a range of safety concerns. Arguably, this shifts the debate on patient involvement in patient safety from one of "whether they should be involved" to "how they should be involved." Interventions such as open notes promote patient involvement that is highly context-driven and focused, standardized, and potentially accessible to most patients.

There has long been debate about the role of patients and families in safety. Some raise legitimate concerns regarding unfair burden on sick patients, negative consequences for patients who speak up in environments that do not fully support patient involvement, loss of patient trust in physicians after discovering mistakes, and a potential inappropriate shift of responsibility from clinicians and organizations to patients.[20] However, as seen in this study and others, a substantial

proportion of patients want to help clinicians get it right, and bring relevant information to the health care system.[2,3,50] In addition, studies suggest that patient satisfaction and trust increase when organizations share information transparently, acknowledge errors and take proactive corrective action.[51–54] Clinical environments need adjustment in order to leverage the essential knowledge held by patients and families on safety blindspots, and the onus is on organizations to engage those patients who are able and willing.

Patient Good Catches Should Be Invited, Supported, and Celebrated

In our study, many patients who identified a blindspot were primarily concerned with fixing the breakdown. Some patients proactively took action on blindspots that could have had negative consequences, had they not intervened. To date, such good catches have largely been attributed to health care staff. Their capacity to improve patient safety is recognized and rewarded among staff through "good catch programs" because "they occur up to 100 times more frequently than sentinel events but often go underreported."[55] The Pennsylvania Patient Safety Authority has developed a "Good Catch Comparison report" enabling hospitals to compare their rates to peers, in order to identify specific event types or care area targets for improvement. Other organizations routinely share good catches through weekly emails or safety huddles, and celebrate "good catch heroes" in cases where good catches not only prevented patient harm but also resulted in lasting change preventing future harm for other patients.[56]

Our findings demonstrate that patients too can make "good catches," such as patient detection of intended diagnostic tests that were not ordered, misinterpretation of tests or missing knowledge regarding more recent results at other centers that patients know about but clinicians do not, and erroneous diagnostic decisions based on the results of other patients—each of which could have clear negative consequences on accurate or timely diagnosis. In some cases, patients, because they were on the receiving end of errors that cascade downstream, such as to another health care encounter, were uniquely capable of linking the secondary error to the initial error (because they were at both health care encounters or part of both incidents). This unique perspective can help

provide context and continuity in understanding contributing factors to the error that may not have been visible to any single provider in the chain of events, thus enhancing the potential for deeper organizational learning.

The opportunity for diagnostic safety improvements may be vastly expanded by systematically partnering with patients, as demonstrated by the patients in this study who reached out to clinicians, resolved conflicts, and corrected errors. Broadscale patient good catches could be institutionalized, particularly if bolstered by education, support, formalized procedures for patient feedback, and a culture that encourages and celebrates patients and families as safety partners and good catch heroes.

Open Notes Provide a New Scalable Platform for Patient Engagement in Safety

Patient-identified documentation errors demonstrate the value of sharing notes as a broad and scalable mechanism to engage patients in safety. Sharing visit notes provides the context and information that can enable patients to identify blindspots, since the gap in care or clinician knowledge is revealed upon review of the note. Indeed, some blindspots would have been unknown to patients themselves had they not read their notes. For example, a common characteristic in many "omission" blindspots is that the patient becomes aware of what was omitted only because the patient is able to view the notes on the encounter—underscoring the value of note access—particularly since errors of omission are otherwise rarely detected.[25]

Roughly one in five patients have reported an error in the EHR,[57] and the note may uniquely provide synthesis and interpretation of all the discrete data available to patients through the patient portal. Sharing notes recognizes that patients and families can have substantive and privileged insights on the safety of their health care, and creates a mechanism through which these insights can be leveraged to support clinicians in identifying and preventing error. Significantly, this expands the inclusion of patients to improve health care safety beyond their valuable participation in focus groups or committees to broadly scalable and actionable patient involvement at the frontlines of their own care.

The implementation of the 21 Century Cures Act Final Rule in the United States offers significant opportunities for health care organizations to increase the likelihood that patients will identify these important safety risks. Further, organizations should work to ensure that all patients understand that notes are available, how to find them, why they should access them, and how to report potential errors. Without these efforts, organizations run the risk of squandering the opportunity that this new transparency provides.

Leveraging unique patient knowledge through information transparency is particularly relevant to emerging global discussions regarding patient access to electronic visit notes.[58] Our data come from three health care systems, and thus are not nationally representative and are likely affected by response bias of more activated patients. However, they may provide the basis for a useful thought experiment and a first "ballpark" estimate of the potential impact of universal note-reading by patients on identification of potential blindspots. In our research, 6.4% of individuals reported PRDBs in ambulatory visit notes. Based on the US Centers for Disease Control and Prevention estimates of 860.4 million annual physician office visits[59] (with an average of 267 visits per 100 persons), up to 21 million patients in the United States may find a PRDB in their doctor's notes. Because 53% of these individuals identified blindspots, up to 10.5 million individuals may identify at least one diagnostic safety blindspot in their notes. Participant error detection was not annualized and currently not all patients read notes, so these broad estimates of *potential* impact should not be taken at face value. Nonetheless, since 12 million Americans are estimated to experience ambulatory care diagnostic errors annually in the United States,[27] detection of even just a fraction of these blindspots would still represent a substantial contribution to preventing one of the most prevalent, harmful, costly and vexing problems in patient safety—ambulatory diagnostic error.[1]

Routine Systems for Patient Feedback are Needed to Harness Unique Patient Safety Knowledge

Beyond providing patient access to open notes, organizations need new routine mechanisms to solicit and act on patient feedback on visit

notes, not only at the individual level but also in aggregate analysis, to drive organizational learning.[8] A centralized system would benefit organizations by streamlining workflows to prevent clinician overload from repeated "one off" messaging from patients to their provider about individual concerns. Because most health care systems are not yet resourced with such centralized structures, responding to patient feedback has been seen more as a burden than an opportunity for learning and improvement. Encouraging patient reports without developing such systems risks unintended consequences, particularly at the clinical interface, where clinicians feel most time-compressed and patients may be deeply discouraged by lack of response to their partnership efforts.[60]

We are at the very beginning stages of understanding how to engineer systems that thoughtfully use patient feedback to better support providers' diagnostic reasoning. If diagnostic accuracy relies on some factors beyond the clinician—as delineated by the situativity model—we need systems that bring relevant information that is outside the health care provider's view to the clinical interface.[61,62] Patients themselves have innovative suggestions for how to do so.[63]

Partnership with clinician leaders, experts in user-centered design, and EHR vendors to match functionality and workflows with patient recommendations could stimulate testing of some patient-centered approaches. In addition to user-centered design (involving both patients and clinicians), success of a system for patient feedback to improve note accuracy will require thoughtful triage strategies, patient and provider education, patient encouragement from clinicians, rapid and meaningful responses to patient reports, support for clinicians, and cultural shifts in the value of patient feedback—each known barriers to effective patient engagement, patient speaking up,[60,63–65] and patient-centered change.[66]

A leading concern among clinicians is that patient-reported breakdowns may not be clinically relevant or may not imply risk of harm. Capture of important events missed by clinicians may come at the expense of some "false positives" in patient reporting.[6] However, mounting evidence suggests that the majority of patient-reported breakdowns that are deemed serious by patients are relevant,[2,3,67,68] and examples in this study and others carry substantive face value regarding potential harm prevention.[16,32,69] Even those events that are discovered from patient engagement and deemed to have lesser clinical

relevance from the clinician perspective may carry significant patient experience impact.[6,70] Nonetheless further research that characterizes the proportion of meaningful contributions (averting safety risks or patient experience problems) compared to false positives could help address these concerns, and cost/benefit analyses that compare the resource burden to solicit and respond to patient reports to the costs of undetected blindspots and their impacts on patients and families are needed.

Policy and Resources to Diversify Patient Participation are Needed to Avoid Safety Disparities

Engaging patients and families to detect blindspots and participate in good catches through shared visit notes has specific policy implication for equity.[71] Simply providing access to notes and other data such as reports and test results will not ensure that patients will read them. Only four in ten Americans have a patient portal account,[72] and there are significant disparities in even inviting patients to use the patient portal, as well as registration and use by race, ethnicity, health literacy, language preference, education, and age.[73–76] Low portal use among minoritized populations could worsen inequities, as well-intentioned innovations disproportionately result in safety improvements for better resourced patients.[77-79] Even among portal users, we observed differences in engagement with health information. In our study and others, patients who reported less formal education or self-identified as Black or African American, Asian, or "other race" were less likely to identify breakdowns or speak up about perceived errors,[63] although effect sizes varied. We did not observe notable differences between participants who primarily spoke English compared with another language at home, although the latter group was small.

While early data suggest that patients who self-identify as Black or Hispanic, those who report less formal education, and those who primarily speak a language other than English at home report the same or greater benefits from reading notes as their counterparts, larger studies are needed.[44,80] In addition, in a recent study, patients with limited English-language health literacy who reported a diagnostic error were more likely than their counterparts to report contributing factors related

to access, coordination, or inaccurate medical records,[81] suggesting that access to notes could improve record accuracy. Developing, implementing, and evaluating strategies to reduce disparities in portal offering, registration, and use, as well as innovations that leverage mobile technologies, are critical to ensure portals benefit all populations. Because blindspots can only lead to safety improvements if they are reported, tackling barriers to speaking up about care concerns or perceived documentation errors—especially among populations more vulnerable to error or harm—must gain urgency, to avoid exacerbation of health inequalities by selective patient participation.[60,63]

Despite the importance of equal access to health information and opportunities for blindspot reporting, not all patients will welcome the idea of blindspot identification. Some patients will prefer to leave safety surveillance to their providers. As demonstrated by Levinson and colleagues, and echoed in our findings, variability in patient preference for making care decisions is a factor likely to be associated with blindspot identification.[49] Organizations should develop systematic ways to engage those patients and family members who are willing and able to be involved in diagnostic safety as a default pathway, accounting for patient preference. Organizations should also recognize that patient preference regarding degree of engagement is not static, since it may be influenced by illness severity, fear or anxiety related to possible diagnoses, other life stressors and responsibilities, patient confidence, psychological safety to speak up, and perceived belief that reported issues will be acted upon. Systems to elicit patient preference should therefore be welcoming and supportive and enable fluid changes or opportunities for preference changes. As patient portals evolve, this kind of personalization can help optimize individual patient experience and use.

Strengths and Limitations

Our study on diagnostic safety blindspots stems from a large dataset of patient-reported errors in notes at three US organizations. Compared to the initial study of blindspots identified from patient complaints in the UK, our study setting makes the current findings more generalizable. Although a patient population that reads notes is likely more activated, submitting a formal complaint is generally considered a "higher bar" for participation. However, portal registration was a prerequisite for reading

visit notes, and while patient portal use is increasing across the United States and elsewhere, there are still important limitations related to patient portal registration and use among more diverse patient groups.[73–76] Further affecting potential reporting bias, our study participants were predominantly White, employed, reported more formal education, and spoke primarily English at home. Surveys were conducted in English; the experiences of patients with limited English proficiency and a more representative patient sample in general requires further study. In addition, our results are further limited by a low response rate, although it is similar to other online surveys.[82–84] Finally, while patient-reported errors are important in their own right, clinician verification or chart review was beyond the scope of this study. However, one hallmark of blindspots is that patients hold information that clinicians or medical records may not, therefore such verification processes may be inherently limited in reliability.

Conclusions

Greater inclusion of patients and families in health care processes is recognized as a potential way to improve safety, but has proven difficult to implement routinely, despite over a decade of research. Our study of more than 22,000 patients found that providing patients with access to their clinical notes enabled them to consistently identify safety blindspots in essentially all aspects of the diagnostic process. Drawing on theory relating to shared mental models, situativity, and distributed cognition, we demonstrate that patients and families can identify otherwise unrecognized knowledge gaps amongst clinicians, thereby potentially preventing unintended harm. Organizations have the opportunity to use open notes as a new and broad, albeit currently underutilized, platform for engaging patients and families in diagnostic safety. With broad-scale access to electronic health information in the United States and global discussions on information transparency, the policy implications for diagnostic safety are critical. Patients will soon (if not already) hold substantial information about diagnostic safety blindspots and potential good catches to prevent harm that may be invisible to clinicians, urging policy to promote routine patient involvement in diagnostic safety.

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