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An organisational approach to improving diagnostic safety

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ABSTRACT

Diagnostic error affects up to 10% of clinical encounters and is a major contributing factor to 1 in 100 hospital deaths. Most errors involve cognitive failures from clinicians but organisational shortcomings also act as predisposing factors. There has been considerable focus on profiling causes for incorrect reasoning intrinsic to individual clinicians and identifying strategies that may help to prevent such errors. Much less focus has been given to what healthcare organisations can do to improve diagnostic safety. A framework modelled on the US Safer Diagnosis approach and adapted for the Australian context is proposed, which includes practical strategies actionable within individual clinical departments. Organisations adopting this framework could become centres of diagnostic excellence. This framework could act as a starting point for formulating standards of diagnostic performance that may be considered as part of accreditation programs for hospitals and other healthcare organisations.

Keywords: diagnosis, errors, framework, organisation, performance, program, safety, standards.

Introduction

Diagnostic errors (i.e. missed, delayed, or wrong diagnoses, over-diagnosis, or failure to communicate diagnoses to patients[1]) afflict up to 1 in 10 clinical encounters,[2] cause serious harm or death in 1% of adult inpatients, and account for over a third of serious harm claims with hospital medical indemnity bodies.[3]

The integrity of clinician diagnostic reasoning processes can be compromised by system vulnerabilities (limited diagnostic services, laboratory errors, test result miscommunication).[4] Consequently, diagnostic errors prove more difficult to measure and evaluate than many other safety events, such as wrong-site surgery and obstetric mishaps. Among multiple existing quality and safety measures, few focus on diagnostic performance.[5] While remediation of reasoning error of individual clinicians has received attention,[6] organisational strategies for improving diagnostic safety have been overlooked.[7]

The organisational challenge

Given the complex interplay between system-, patient-, and team-related factors and individual clinician cognitive processes, identifying root causes of diagnostic failures retrospectively requires substantial inference with risk of hindsight bias. Although system factors are suspected as 'contributing,' definitive causal links remain elusive, and actionable analyses that account for system effects on clinician reasoning are difficult to generate.[8] Furthermore, many diagnoses are made by clinical teams, which makes attribution and ownership of errors difficult, such that identifying target audiences for delivering useful feedback becomes problematic.

These analytical limitations cause healthcare organisations to under-appreciate the scale of diagnostic failures and perceive them as difficult to address given the multiple, intertwined causative factors. Diagnostic safety programs are not progressed because of

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Table 1. Measures of diagnostic safety.[14,19,22,23]

Data sources	Methods of data collection	Potential insights
Routinely recorded quality and safety events	Peer review meetings	Awareness of the impact and harm of diagnostic safety events
	Morbidity and mortality meetings	Emerging patterns that may suggest high-risk situations
	Adverse event or incident reports	
	Risk management reports	
	Medicolegal claims	
	Autopsy results	
Solicited clinician reports	Web-based, telephone-based, written, and in-person mechanisms to report suspected safety breakdowns	Understanding of system-related and cognitive factors that affect diagnostic safety
	Follow-up interviews with clinicians	
Solicited patient reports	Surveys and interviews	Understanding of system-related, patient-related, and communication factors that affect diagnostic safety
	Follow-up of patient feedback to institutions, professional boards, and accrediting organisations	
	Real-time reporting (e.g. inpatient hotline)	
Administrative data	ICD-based indicators applied to administrative datasets to select cases for further review (e.g. populations with specific ICD diagnostic codes demonstrating higher than expected mortality, length of stay, complications or procedures, or re-admissions)	Detection of diagnostic safety-related patterns and events within patient cohorts demonstrating outlier outcome rates
Medical records	Review of randomly selected records of patients seen in high-risk settings (e.g. emergency department)	Detection of diagnostic safety events which suggest settings and patient populations more vulnerable to diagnostic failure
	Review of records selected from high-risk cohorts (e.g. patients with cancer or cardiovascular events)	
	Review of records flagged by use of electronic triggers[A] (e.g. patients with unplanned re-admission within 7 days of discharge)	
Advanced data science methods, including natural language processing of EMR data	Application of machine learning algorithms to structured or unstructured EMR data to search for language indicating possible safety concerns (e.g. discordance between initial diagnosis on admission and discharge diagnosis or between pre-operative and post-operative diagnosis; clinician expressions of diagnostic uncertainty)	Detection of possible diagnostic safety events or risks ascertained retrospectively or in real time

ICD, International Classification of Diseases; EMR, electronic medical record.
[A]e-triggers: pre-specified algorithms applied to electronic discharge summaries or administrative data that detect cases more likely to be associated with diagnostic safety events.

insufficient organisational capacity due to competing priorities,[9] and few accreditation or financial incentives exist, in contrast to efforts directed at meeting explicit standards for infection control or medication safety.[10] Open discussions about diagnostic failures challenges professional norms[11] and systematic feedback loops, including autopsies and clinic-pathological conferences that calibrate clinician diagnostic performance, are not well established.[12] Patients and families are much less involved in diagnostic discussions, compared to treatment and prognosis discussions.[13] Furthermore, regular interactions between referring clinicians and radiologists and pathologists compete with other tasks, systems for following up are not well established and interpreting and communicating test results can fail.[14] Clinical handovers, ward rounds and clinic consultations are pushed for time, limiting discussion and communication of diagnostic uncertainty.

Multiple other factors contribute: lack of same clinician continuity of patient care; delayed access to specialist expertise and diagnostic services; over-reliance on automated order sets and excessive copying and pasting of out-of-date, potentially incorrect diagnostic information in electronic medical records (EMRs);[15] and marginal yields from, or limited clinical application of, decision aids (such as diagnostic checklists and computerised decision support systems).[16,17]

In addressing diagnostic error, institutions have had no clearly articulated framework on best measures, standards or practices for achieving diagnostic excellence, and no clear

signal from funders, regulators or accreditors that diagnostic safety should be a priority.

Proposing an organisational framework for improving diagnostic safety

In first gauging the extent of diagnostic error, measurement should focus on conditions commonly misdiagnosed (e.g. cardiovascular events, infections, cancers),[18] as well as cross-cutting measures focused on high-risk processes (e.g. care transitions, patient follow-up), high-risk settings (e.g. emergency departments) and high-risk populations (e.g. people with mental illness, intellectual disability or limited English). Standardised tools for analysing large administrative datasets at scale in identifying misdiagnosis-related harms,[19] such as the Symptom-Pair Analysis of Diagnostic Error method,[20] should be trialled. This data can inform open, non-punitive discussions about both cognitive failures and system-level processes requiring re-engineering (e.g. insufficient staff, disrupted workflows, slow turnaround of test results).[21]

Several guidance statements for improving hospital diagnostic performance from the US Agency for Healthcare Research and Quality[22,23] and the Leapfrog Group[24] are predicated on the Safer Diagnosis (SaferDx) framework.[14] This depicts a work system comprised of structural factors, both technical (e.g. digital infrastructure) and non-technical (workflows, communication channels, internal procedures). Process factors comprise five interacting elements: patient-clinician encounter; performance and interpretation of diagnostic tests; follow-up and tracking of diagnostic information over time; referral-specific and patient factors. Deconstructing diagnostic failures according to these domains informs clinical and governance teams about potential organisational reforms.[25] Methods for identifying and quantifying diagnostic failures derived from the literature[14,19,22,23] and the authors' experience are listed in Table 1. In Table 2, we map these events to errors in diagnostic processes often implicated as contributory causes, serving as targets for remedial intervention.[14,22,23]

Since 2015, the SaferDx framework has evolved into a more comprehensive, evidence-informed, consensus-based checklist of high-priority practices which emphasise multiple stakeholder engagement, systematic feedback loops, and clearly defined organisational accountability.[26] In Table 3, we have adapted this checklist with a hospital focus and

Table 2. Mapping of potential safety events to diagnostic processes.[14,22,23]

Diagnostic process	Examples	Potential diagnostic failure
Patient-provider encounter (history, examination, investigation requests)	Emergency department (ED) or primary care (PC) visit followed by unplanned hospitalisation	Missed red flag findings or incorrect diagnosis or inappropriate or omitted investigations during initial visit or admission
	ED/PC visit within 72 h after ED or hospital discharge	
	Unexpected transfer from hospital general ward to intensive care unit within 24 h of ED presentation	
Performance and interpretation of diagnostic tests or procedures	Imaging report subject to major amendment of diagnostic interpretation	Missed findings on initial reading of the image or lack of communication of amended report to treating teams
	Pathology or diagnostic imaging investigations not performed within the expected turnaround time	Limitations in diagnostic service capacity
	Adenoma detection rates on colonoscopies lower than accepted benchmarks	Deficiencies in operator competence, bowel preparation, patient selection
Follow-up and tracking of diagnostic information	Abnormal test result with no timely follow-up action	Abnormal test result missed
Referral-related factors	Urgent referral to a specialist for a diagnostic opinion which was subsequently cancelled before the scheduled appointment date	Diagnosis delayed due to lack of timely request for, or access to, specialty expertise or procedures
	Diagnostic procedure (e.g. colonoscopy, bronchoscopy) performed outside recommended time window	
	No second opinion or review requested on patients with diagnostic dilemmas	
Patient-related factors	Patient feedback or poor ratings on patient experience scores following first presentation to ED or PC	Communication failures related to missed diagnosis
	Patients with no-shows for diagnostic procedures or test result follow-up	Absence of recall and reminder systems for patient follow-up

Table 3. Adapted SaferDx checklist[26] with example scenarios.

High priority practices	Example scenarios at organisational level	Example scenarios at departmental level
1. Organisation leadership builds a 'board-to-bedside' accountability framework that includes structure, capacity, transparency, time, and resources to measure and improve diagnostic safety.	• Establish a 'diagnostic safety' multidisciplinary team or committee or hub charged with identifying and co-ordinating activities for improving diagnostic safety. The team should include departmental directors (including diagnostic services) and clinical champions. • Define a set of measures of diagnostic safety and undertake a risk assessment of system vulnerabilities to diagnostic error. • Share data from the diagnostic safety team consistently with hospital executive, quality and safety committees, and individual departments, embodying the concept of learning health systems.	• Place diagnostic safety events and instances of diagnostic excellence ('good saves') as agenda items on departmental quality and safety meetings. • Analyse incident reports, mortality and morbidity reviews, rapid response team calls for instances of diagnostic error or near misses, and reframe them as learning opportunities. • Identify clinical champions with expertise in improving diagnostic reasoning and let them train others to recognise and minimise cognitive errors. • Develop department-specific diagnostic pathways, guidelines and checklists for high volume, high risk clinical presentations known to be associated with increased risk of diagnostic error and harm. • Request trainees and consultants to keep a log book of their diagnostic dilemmas and errors, as well as their good saves. • Implement a research program that explores department-specific diagnostic pitfalls and develops evidence-based strategies to improve diagnosis.
2. Organisation promotes a just culture and a psychologically safe environment that encourages clinicians and staff to share opportunities to improve diagnostic safety.	• Create non-punitive environments that encourage clinical and non-clinical staff to report and share missed opportunities, harms, 'good catches' or 'near misses,' as well as tips and lessons related to prevent errors.	• Institute a weekly diagnostic conundrums session in which all staff can present, discuss and resolve diagnostically challenging cases that may involve both cognitive and system factors. • Ensure junior staff can easily contact consultants at all hours for advice in dealing with diagnostically challenging scenarios. • Ensure access to appropriate decision support in high-volume, high-risk clinical settings.
3. Organisation establishes mechanisms for capturing, measuring, and providing feedback to the diagnostic team about patients' subsequent final diagnosis and clinical outcomes.	• Implement systems that enable clinicians, both internal and external to the organisation (e.g. general practitioners, emergency physicians, ambulance paramedics, community nurse practitioners) to efficiently and reliably follow-up on patients they have cared for to see if their provisional diagnoses have changed or evolved.	• Reconcile provisional diagnoses made on admission with final diagnoses specified in discharge summaries, and analyse discrepant cases for diagnostic error. • Identify and analyse diagnostic errors relating to inpatient care that become apparent at follow-up visits to outpatient clinics. • Establish cross-departmental review meetings for discussing cases of diagnostic error that have occurred at the care interfaces between departments. • Include a statement in discharge summaries inviting patients and receiving clinicians to notify treating teams of any concerns they have as to the accuracy of discharge diagnoses.
4. Organisation considers perspectives of other disciplines in understanding and addressing contributory factors when analysing diagnostic safety events (human factors, information technology system design, cognitive elements).	• Diagnostic safety teams work with clinicians and non-clinicians from other disciplines to engage in analyses which may identify work-system/environmental factors that place a cognitive or process burden on clinicians.	• Consider diagnostic safety issues within departmental meetings that stem from poorly configured workflows, admission/discharge procedures, testing protocols, teamwork, communication modalities, and EMR templates. • Empower all disciplines (medical, nursing, allied health, volunteers, administrative staff) to notify treating teams of any concerns they have around diagnostic safety.
5. Organisation actively seeks patient and family feedback to identify and understand diagnostic safety concerns and involves them in co-designing solutions.	• Create mechanisms to encourage and educate patients/family to report diagnostic concerns, including escalation procedures that mandate independent review of a patient's case. • Involve patient representatives in root cause analyses and engage consumer representatives in co-designing solutions.	• Develop and provide, at first point of contact with hospital or clinics, literature for patient and family that explains their role and opportunities in improving diagnostic safety (e.g. being empowered to ask 'What else could this be?'). • Review relevant case records of any patient complaint that implies possible diagnostic error.

(*Continued on next page*)

Table 3. (*Continued*)

High priority practices	Example scenarios at organisational level	Example scenarios at departmental level
6. Organisation allows patients to review their health records and has mechanisms in place to help patients understand, interpret, and/or act upon diagnostic information.	• Encourage patients to be proactive in ensuring the post-discharge diagnostic evaluation is reviewed by outpatient clinicians in a timely manner. • Engage patients in understanding that 'no news is not necessarily good news' when it comes to following up test results. • Enable patients to challenge diagnostic labels that they feel were always, or have become, inaccurate.	• Inform patients they have a right to fully understand, and participate in, diagnostic decisions and need for further investigations. • Discuss diagnoses with patients in language they can understand and gauge their level of agreement. • Provide patients with copies of discharge summaries and clinic letters and allow them to check their understanding of diagnostic decisions and the accuracy of diagnostic information.
7. Organisation prioritises equity in diagnostic safety and implements strategies to address and narrow equity gaps.	• Segment and analyse diagnostic safety data according to specific patient characteristics to uncover inequities. • Assess whether the means for obtaining diagnostic information (history, examination, past clinical encounters) are culturally appropriate and likely to provide accurate and relevant information.	• Analyse identified cases of diagnostic error according to patient characteristics associated with higher risk of error (e.g. intellectual or physical disability, mental health condition or substance abuse, older patients, non-English speaking patients, First Nations people) and assess whether bias exists in diagnostic processes, test ordering and specialist referrals.
8. Organisation has in place systems and processes to encourage direct, collaborative interactions between clinical teams and diagnostic specialties in cases that pose diagnostic challenges.	• Collaborate with pathologists and radiologists in developing appropriate investigational strategies for common diagnostic scenarios, including instances of overdiagnosis arising from incidental findings. • Undertake regular review of diagnostic errors and instances of diagnostic excellence jointly with diagnostic specialties and treating teams.	• Consult diagnostic services in real time (face-to-face or virtual) to discuss problematic cases relating to choice, sequencing, timing and interpretation of diagnostic investigations. • Perform a diagnostic reconciliation in response to investigation results that challenge past or present diagnostic labels or differential diagnoses. • Exercise stewardship of diagnostic resources by avoiding unwarranted overuse of investigations.
9. Organisation has in place standardised systems and processes to ensure reliable communication of diagnostic information between care providers and with patients and families during handovers and transitions of care.	• Implement evidence-based tools and resources to improve both verbal (e.g. SBAR, TeamSTEPPS) and electronic communication (e.g. ONC SAFER Guide for Clinical Communication [available at: Clinician Communication (healthit.gov)]).	• Conduct clinical handover procedures, especially morning handover, in ways that promote diagnostic safety (e.g. using diagnostic cross-checking, role modelling, deliberative practice, cognitive debiasing). • Communicate clear management and follow-up instructions to patients discharged with an uncertain diagnosis. • Inform patients and family (and provide relevant contact details) of their ability to contact a member of their treating team to follow-up on impending test results following discharge, or to report changes in clinical course or events that challenge the diagnostic plan. • Organise clinic reviews so that follow-up is provided by the same clinicians who provided inpatient care.
10. Organisation has in place standardised systems and processes to close the loop on communication and follow up of abnormal test results and referrals.	• Clarify responsibilities and processes for following up on abnormal test results at the time of the request. • Implement evidence-based tools and resources to improve follow-up on test results, including incidental findings (e.g. ONC SAFER Guide for Test Results Reporting and Follow-up [available at: Test Results Reporting and Follow-up (healthit.gov)]). • Implement strategies to close the loop on referrals using evidence-based guidance (e.g. Closing the Loop: A Guide to Safer Ambulatory Referrals in the EHR era [available at: Closing the Loop: A Guide to Safer Ambulatory Referrals in the EHR Era | IHI – Institute for Healthcare Improvement]).	• Ensure all investigations ordered for patients at morning rounds are checked at end of shift, preferably by two members (a senior and junior) of the treating team who can cross-check and verify results and subsequent action plans, and use the interaction as a learning exercise. • Mandate regular checking of personal message centres in electronic medical records for outstanding test results that require endorsement or actioning. • Include outstanding test results in discharge summaries and provide receiving clinicians with contact details of a treating team member with whom they can discuss, or chase up, test results.

EHR, electronic health record; SBAR, Situation, Background, Assessment, Recommendation; TeamSTEPPS, Team Strategies and Tools to Enhance Performance and Patient Safety; ONC SAFER, Office of the National Coordinator for Health Information Technology Safety Assurance Factors for EHR Resilience.

added specific department-level strategies more actionable by front-line clinical teams. While having face validity, only some of these strategies to date have been empirically validated in routine care.[27] These include voluntary error reporting,[28] EMR-embedded e-triggers for identifying errors,[29] feedback loops at clinical handovers,[30] electronic

Table 4. Proposed first steps in establishing diagnostic safety programs.

1. Develop and apply standardised definitions of diagnostic safety events.
2. Implement administrative data analytic systems that identify these events and, where possible, ascertain their underlying causes.
3. Establish routine operational metrics that quantify event rates and causative factors.
4. Institute clinician- and system-level preventive interventions targeting high-risk clinical scenarios, processes, settings and patient populations.
5. Engage patients in all stages of program development.

surveillance for detecting missed test follow-up,[31] and e-autopsy/e-biopsy methods for errors involving specific patient poputations.[32]

Incentivising organisations to develop and implement diagnosis safety programs

Diagnostic safety programs may benefit organisations in several ways. First, patients will appreciate organisations making diagnostic error prevention a priority. Second, as media reports of egregiously harmful errors are often portrayed as clinician failures within dysfunctional organisations, preventing such errors avoids severe mental harm to clinicians involved, reputational damage to the organisation, and protracted litigation. Third, as diagnostic errors often incur compensation payouts and avoidable downstream costs from knock-on interventions and prolonged hospital stays, financial benefits may accrue. Actions need to be taken to balance underdiagnosis of serious illness with wasteful, harmful overdiagnosis and over-investigation of conditions likely to never cause harm.[33] Fourth, health service standards will likely come to include specific diagnostic safety standards, with some state bodies already providing on-line educational resources and audit tools.[34] Finally, US hospitals[35] and health maintenance organisations[7] are aspiring to become diagnosis safety centres of excellence. In Table 4, we outline first steps to be considered in establishing diagnostic safety programs in Australia.

Conclusion

Healthcare organisations must play a role in designing operational environments that enable clinicians and patients to improve diagnostic performance.

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