Diagnosing diagnostic errors: it's time to evolve the patient safety research paradigm

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Optimising patient safety in the hospital setting remains a significant challenge for modern healthcare. Substantial efforts have been made to eradicate patient harm events since the 1999 publication of *To Err is Human: Building a Safer Health System*.[1] Nevertheless, a recent meta-analysis of 94 adult inpatient studies concluded that 8.6 hospital harm events occur for every 100 patient admissions, with over half (52.6%) judged to be preventable.[2] Estimates in high-risk paediatric settings suggest a rate as high as 40 patient harm events per 100 admissions.[3–5] Although patient harms within the subset known as hospital-acquired conditions in the USA have declined in the adult and paediatric populations,[6 7] multicentred, longitudinal studies of adult[2 8] and paediatric inpatients[9] have shown no significant improvement in overall harm rates over the past 20 years.

As highlighted in the study by Lam *et al*,[10] in this edition of *BMJ Q&S*, the subtype of harm events resulting from diagnostic errors has recently garnered a great deal of attention in patient safety efforts. Diagnostic errors have been studied with several methods and in many settings, including primary care sites,[11] paediatric intensive care units[12 13] and paediatric emergency departments (EDs).[14] The methods used to identify diagnostic errors range from basic chart review to focused chart reviews with a trigger-based approach. The trigger approach relies on use of certain data elements (eg, administration of naloxone) within the medical record to 'trigger' a more in-depth review for patient safety events. The trigger approach has emerged as a reliable and more encompassing method than voluntary reporting (incident reporting or occurrence reporting), unstructured chart review and AHRQ PSI calculations in identifying harm events.[2 15 16] Therefore, it stands to reason that the trigger method would also be valuable for identifying the subset of patient safety events and harms caused by diagnostic error.

Lam *et al*[10] present a well-designed and executed single-trigger investigation meant to identify cases of diagnostic error and establish the performance characteristics of this trigger. The trigger identified paediatric patients admitted within 14 days of a previous paediatric ED visit over a 2-year period. Once a patient meeting these criteria was identified, one study author reviewed the patient's chart to determine if the patient's original ED visit and admission diagnoses were different yet possibly related. Patients were excluded if their subsequent ED visit and admission diagnoses were unrelated to the index condition or represented the same condition with either progression or recurrence of the correctly diagnosed condition. After this screening, the subset of patients remaining ('screened in') underwent detailed physician chart review using the SaferDx tool for identification of possible diagnostic errors.

Of the 24 849 total inpatient admissions, 7.7% (1915 patients) met the original trigger criteria and 1.8% (453 patients), representing 23.7% of the triggered patients, were screened in for further review. After the detailed screening, the authors used the SaferDx process to conclude that 0.4% (94 patients) of the entire admitted cohort had 'likely diagnostic errors'.

There is much to be admired about the Lam *et al* study.[10] First, the authors use the electronic health record and

certain data elements relevant for this trigger to narrow the large number of ED admissions that were potentially associated with a diagnostic error. Second, the authors enhance the rigour of the study by formally evaluating the inter-rater reliability of the screening component of the process, and then using the SaferDx tool to confirm that a diagnostic error had occurred. The kappa value of 0.65 signifies moderate concordance between the two independent reviewers in the SaferDx stage of the case review. Finally, this work represents foundational efforts to identify paediatric diagnostic error in the ED setting. Diagnostic errors have been identified as a significant and growing cause of paediatric patient harms yet are challenging to identify and minimally studied with this level of rigour.

Despite these strengths, this study leaves a few areas of opportunity unexplored. First, the authors chose not to analyse the charts of admitted patients who did not meet the trigger criteria. Such analysis is necessary to establish the sensitivity and specificity of the trigger being studied. The absence of these data limits our ability to determine the effectiveness of this trigger. Second, the authors did not describe the time necessary to identify these cases, limiting our ability to conclude if the proposed process is efficient enough to warrant global implementation. The trigger methodology is time intensive, expensive and requires substantial training to optimise. Third, while well intended, single-trigger studies such as this study are limited in their ability to accelerate the advancement of the patient safety field. In this study and others like it, investigators establish the performance characteristics of a single or small number of triggers, missing opportunities to identify additional safety events and diagnostic errors that may have been uncovered had other triggers been grouped together and tested simultaneously. Given the relatively uncommon occurrence of errors identified by the single trigger in the current study, there would be little reason to recommend its widespread adoption in our view.

Despite these limitations, this study provides an excellent example of the value of leveraging electronic record in identifying harm events. Of the almost 25 000 records, the use of an electronic medical record-driven trigger narrowed the need for human review to less than 2000 records. While reviewing 2000 charts remains a significant expenditure of human capital, the electronic-driven trigger approach decreases the need for human chart review which will move us closer to being able to practically translate the predominantly research-focused trigger methodology into efficient general hospital operations. We applaud the authors' recognition of the impractical approach of using human resources to identify harms via non-electronic chart review and encourage future safety researchers to partner with operational safety leaders, hospital executives, and even regulators to improve both our detection and management systems.

In summary, we applaud the rigorous approach to diagnostic error detection reflected in the Lam *et al* article,[10] combining the trigger approach to event detection with the effective SaferDx tool. Expanding and automating electronic driven triggers is likely to be the most accurate and feasible approach to doing so. Reliably pairing researchers with patient safety operations leaders will be crucial to embarking on the ultimate reasons for efficiently and comprehensively identifying patient harms, namely implementing data-driven interventions that decrease diagnostic errors and overall harms in the patients whom we serve.

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