

Diagnostic errors and harms in primary care: insights to action

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In this issue we are presented with two novel and important studies in English primary care addressing the epidemiology of patient safety. The first study, by Reeves and colleagues, retrospectively reviewed 2057 randomly selected consultations in 21 general practices to identify missed diagnostic opportunities, in order to estimate their incidence, origins and potential harms.¹ They conclude that diagnostic errors occur in up to 4% of consultations, are multifactorial, and that 40% of them have the potential to result in moderate or severe patient harm. The second study recruited 12 randomly selected general practices and reviewed the case notes of an ‘enhanced’ sample of 14 407 patients with significant health problems.² In this second study, Avery and colleagues were interested in actual harms that could be considered avoidable, in order to estimate their incidence and to quantify and classify the context from which they arose. They identified 74 cases of avoidable significant harm, a rate of 36/100 000 patient years, with diagnosis problems accounting for the majority (61%).

Although the field of patient safety research goes back to the 1980s, much of it was initially focused on specialist care and hospital settings, where rates of adverse events as high as 10% were reported.^{3,4} In contrast, studies in primary care found that rates of adverse events were much lower, but the potential for harm, notably from prescribing errors, was significant.⁵ This led to developments such as PINCER, a pharmacist-led intervention to reduce clinically important medication errors that has since been widely adopted in England,⁶ and in the USA to a focus on preventing ‘Never Events’ or serious, preventable medical errors.⁷ More recently, the importance of diagnostic error in patient safety has come to the fore, with a landmark report from the US Institute of Medicine

(IoM)⁸ and recognition that this aspect of patient safety is distinct from errors in the management of patients with a diagnosis and that it represents a global concern.^{9,10} The latter has been driven by early diagnosis being a policy focus in many high-income countries, particularly in relation to cancer, with misdiagnosis one of the most common reasons for malpractice claims¹¹ and evidence that early cancer diagnosis leads to better outcomes.

Diagnostic error was defined in the IoM report *Improving Diagnosis in Healthcare* as the ‘failure to make an accurate and timely explanation of the patient’s health problem, or to communicate that explanation to the patient’.⁸ The concept of ‘missed diagnostic opportunities’, proposed by Singh and colleagues and applied in the study by Reeves and colleagues, is one that works well for primary care, since it takes account of the evolving course of a patient’s presenting problem, sometimes over multiple consultations.¹²

Preventable or avoidable harm is by definition attributable to medical error, although many errors do not lead to harm. Harm can also be a broad concept, ranging from transient anxiety through to death. Avery and colleagues have been particularly diligent in their definitions of avoidability and significant harm, deriving the latter from that provided by WHO,¹³ which in turn lies between the definitions of moderate and severe harm described by England’s National Patient Safety Agency and by Panesar and colleagues.¹⁴

By drawing our attention to the extent to which errors and avoidable harms occur, these two studies also prompt us to consider ways in which we might take action to improve diagnostic safety in primary care. One is to identify errors as soon as, or right after, they are made, which then provides an opportunity to forestall any ensuing harm or reduce

its severity. Safety-netting is a well-established if ill-defined consultation technique where the patient is advised on the anticipated course of events and the action(s) to take if these do not follow within a specified timeframe.¹⁵ It is specifically advocated in English national guidance on management and referral of suspected cancer.¹⁶ A more systematic and technical approach is the use of e-triggers, signals of a likely error or adverse event, generated by the systematic mining of electronic patient data. These can prompt clinicians to the correct actions or can generate reminders when the correct actions are not performed in a timely way.¹⁷ Singh and others have also proposed the SaferDx e-Trigger Tool Framework for the future development of tools that monitor diagnostic errors and intervene for specific patients when needed.¹⁷

Another way to take action to improve diagnostic safety is to use retrospective clinical record review to identify the circumstances and types of events that might threaten patient safety during the diagnostic process, in order to address these circumstances in the future. Examples include a Danish study that found 'quality deviations' in 30% of the 5711 patients presenting with symptoms subsequently found to be due to cancer,¹⁸ and an English national audit of 14259 patients with cancer where GPs reported avoidable delays in 24% of the sample.¹⁹ 'Quality deviations' and other avoidable delays can potentially be prevented, but only with a strong professional culture that values identifying them in the first place. A culture of identifying and reflecting on safety incidents is well established in many countries where strong primary care systems pertain. In the UK, significant event audit is widely practised and is part of the Royal College of General Practitioners' patient safety toolkit. Changes in clinical practice or quality of care are often reported although not easily verified.²⁰ However, qualitative analysis of multiple significant event audits has been used to identify opportunities for quality improvement in the diagnostic process for lung cancer.²¹ On the other hand, reporting of patient safety incidents to a central body, such as the National Reporting and Learning System in England has not been widely adopted in primary care, in contrast to secondary care, which accounts for more than 99% of patient safety incident reports. Incident reporting has also not generally been as successful as it could be in the USA, despite strong models of its importance for improvement in other fields, such as aviation.²²

These various approaches to identifying errors and harms that occur in primary care can all inform the design of safer systems and/or safer diagnosticians, to reduce the risk of error in the first place. By learning about which processes lead to errors, one can try to improve those processes and prevent errors occurring. In this way, e-triggers, for example, could provide the information needed for a healthcare system to identify targets for diagnostic safety, as suggested in the

SaferDx framework. For example, if triggers identified frequent failures in a particular healthcare system in the follow-up on abnormal test results, a system re-design could be put in place to prevent these. Alternatively, one might provide clinicians with tools that enhance their diagnostic capabilities. These could include better access to diagnostic tests or the provision of electronic clinical decision support systems; a recent systematic review confirmed that these have the capacity to improve diagnostic decision making for cancer in primary care.²³ The two studies in this issue of the journal clearly describe the problems; action is now needed to address them in a concerted and systematic way.

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REFERENCES

- 1 Cheraghi-Sohi S, Holland F, Singh H, *et al*. The incidence and associated potential harm of diagnostic errors in English primary care: a retrospective electronic health record review study. *BMJ Qual Saf* 2021;30:977–85.
- 2 Avery AJ, Sheehan C, Bell B, *et al*. Incidence, nature and causes of avoidable significant harm in primary care in England: retrospective case note review. *BMJ Qual Saf* 2021;30:961–76.
- 3 Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;322:517–9.
- 4 Wilson RM, Runciman WB, Gibberd RW, *et al*. The quality in Australian health care study. *Med J Aust* 1995;163:458–71.
- 5 The Health Foundation. *Evidence scan: levels of harm in primary care*. The Health Foundation, 2011.
- 6 Avery AJ, Rodgers S, Cantrill JA, *et al*. A pharmacist-led information technology intervention for medication errors (pincer): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. *Lancet* 2012;379:1310–9.
- 7 National Quality Forum (NQF). *Serious reportable events in Healthcare—2011 update: a consensus report*. Washington, DC: NQF, 2011.
- 8 Institute of Medicine. *Improving diagnosis in health care*. Washington, DC: National Academies of Sciences, Engineering, and Medicine, 2015.
- 9 Singh H, Schiff GD, Graber ML, *et al*. The global burden of diagnostic errors in primary care. *BMJ Qual Saf* 2017;26:484–94.
- 10 World Health Organization. *Safer Primary Care - a Global Challenge*. Geneva: WHO, 2012.

- 11 Wallace E, Lowry J, Smith SM, *et al.* The epidemiology of malpractice claims in primary care: a systematic review. *BMJ Open* 2013;3:e002929.
- 12 Lyratzopoulos G, Vedsted P, Singh H. Understanding missed opportunities for more timely diagnosis of cancer in symptomatic patients after presentation. *Br J Cancer* 2015;112(Suppl 1):S84–91.
- 13 World Health Organisation. *The conceptual framework for the International classification FPR patient safety*. Geneva: World Health Organisation, 2009.
- 14 Panesar SS, deSilva D, Carson-Stevens A, *et al.* How safe is primary care? A systematic review. *BMJ Qual Saf* 2016;25:544–53.
- 15 Nicholson BD, Mant D, Bankhead C. Can safety-netting improve cancer detection in patients with vague symptoms? *BMJ* 2016;355:i5515.
- 16 National Institute for Health and Care Excellence. Suspected cancer: recognition and referral (NICE guideline 12), 2015. Available: www.nice.org.uk/guidance/ng12
- 17 Murphy DR, Meyer AN, Sittig DF, *et al.* Application of electronic trigger tools to identify targets for improving diagnostic safety. *BMJ Qual Saf* 2019;28:151–9.
- 18 Jensen H, Nissen A, Vedsted P. Quality deviations in cancer diagnosis: prevalence and time to diagnosis in general practice. *Br J Gen Pract* 2014;64:e92–8.
- 19 Swann R, Lyratzopoulos G, Rubin G, *et al.* The frequency, nature and impact of GP-assessed avoidable delays in a population-based cohort of cancer patients. *Cancer Epidemiol* 2020;64:101617.
- 20 Bowie P, Pope L, Lough M. A review of the current evidence base for significant event analysis. *J Eval Clin Pract* 2008;14:520–36.
- 21 Mitchell ED, Rubin G, Macleod U. Understanding diagnosis of lung cancer in primary care: qualitative synthesis of significant event audit reports. *Br J Gen Pract* 2013;63:e37–46.
- 22 Mitchell I, Schuster A, Smith K, *et al.* Patient safety incident reporting: a qualitative study of thoughts and perceptions of experts 15 years after 'To Err is Human'. *BMJ Qual Saf* 2016;25:92–9.
- 23 Chima S, Reece JC, Milley K, *et al.* Decision support tools to improve cancer diagnostic decision making in primary care: a systematic review. *Br J Gen Pract* 2019;69:e809–18.