How to drive early diagnosis of cancer: improving our ability to detect and promptly act on diagnostic delays
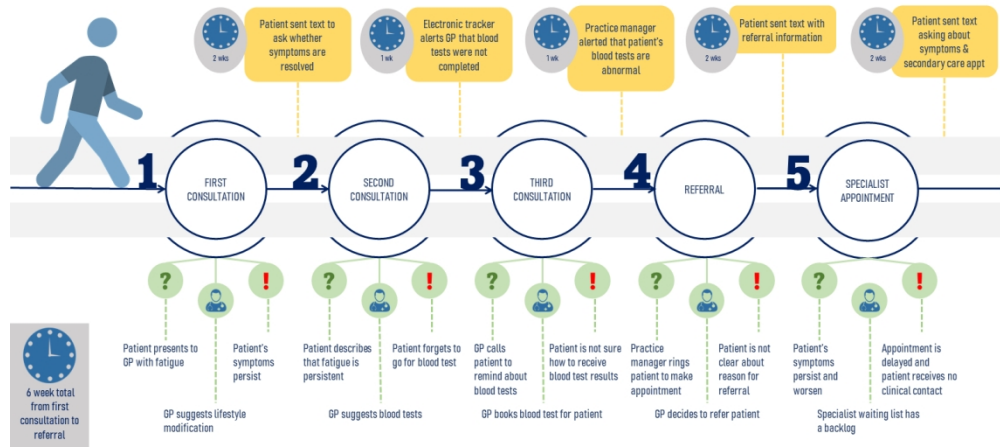
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How to drive early diagnosis of cancer: improving our ability to detect and promptly act on diagnostic delays

Georgia B. Black[1]

Georgios Lyratzopoulos[2]

Charles A. Vincent[3]

Naomi J. Fulop[1]

Brian D. Nicholson[4]

1. Department of Applied Health Research, University College London, UK.
2. ECHO (Epidemiology of Cancer Healthcare & Outcomes), Department of Behavioural Science and Health, University College London, UK.
3. Department of Experimental Psychology, University of Oxford, UK.
4. Nuffield Department of Primary Care Health Sciences, University of Oxford, UK.

KEY MESSAGES

- Non-specific presenting symptoms make the timely diagnostic suspicion of cancer challenging due to wide range of possible causes
- Initial misattribution of symptoms to other diseases is common, leading to prolonged diagnostic intervals and worse outcomes in some patients
- 'Systems' approaches can help to enhance diagnostic processes and mitigate unnecessary risks to timely cancer diagnosis
- This could include automated processes to support proactive information sharing, monitoring of symptoms and investigations, detection of missed or incomplete actions, and transparent mechanisms to attribute and share responsibility.

Contributors and sources

Georgia Black is a current THIS Institute postdoctoral fellow, and social psychologist whose research has two main foci: (1) patient safety in diagnostic pathways and (2) the effect of socioeconomic inequalities and specifically exclusion from healthcare. Georgios Lyratzopoulos is an epidemiologist, specialising in cancer healthcare and early diagnosis research. Charles Vincent is a clinical psychologist who has conducted extensive research on the causes of harm to patients, the consequences for patients and staff and methods of improving the safety of healthcare. Naomi Fulop is social scientist and health services

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researcher with expertise in qualitative and mixed methods studies of change and improvement at the interfaces between health policy and service delivery, management and organisation of health care. Brian Nicholson is an academic general practitioner, with a research portfolio centred on improving diagnosis for patients with non-specific or vague symptoms of cancer. GBB conceptualised the article and drafted the narrative. All authors developed components of the article and identified exemplars from clinical practice and research to support the conceptualisation.

Acknowledgements

Patient involvement

Members of the public were consulted about their views and priorities for research about diagnosis in primary care in a stakeholder event in December 2018. They highlighted the importance of continuity and 'system thinking' based on their experiences as patients. For example, members of the public highlighted that it can be frustrating to return to primary care for a second or third consultation, and to be unsure about who to contact for test results.

Conflicts of Interest

No competing interests.

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Introduction

People with symptoms that may indicate cancer fall into two groups: (1) patients with (relatively few) alarm symptoms, for whom guidelines recommend urgent referral for specialist assessment, and (2) patients who present initially with non-specific symptoms with a low predictive value for cancer for whom there is a scarcity of evidence-based guidelines and who may be managed for long periods by a variety of primary and secondary care services. Cancer patients in the latter group typically require multiple consultations before being diagnosed either through GP urgent or "routine" referral, or through emergency diagnosis. While some diagnoses are made during a single healthcare encounter, the diagnostic process is often dynamic and distributed in space and time, involving many different healthcare professionals, often at different locations and times. Most attempts to improve diagnosis focus on enhancing the initial consultation. However, in this paper we advocate a 'systems' approach to reducing diagnostic delays, where the 'system' includes interconnected components of healthcare such as multiple healthcare professionals and organisations, technology, equipment and workplace culture.[1,2] This approach requires early detection of when things go wrong in the diagnostic process through proactive monitoring by healthcare teams.

Challenges of relying on symptom interpretation to drive early diagnosis of cancer

Cancer pathways rely on the patient choosing to seek medical help and presenting their symptoms in such a way that their clinician suspects cancer sufficiently to make a referral. The interpretation of symptoms will vary between clinicians based on their attitudes, knowledge and experience and will provoke different actions.

As cancer diagnosis in primary care is uncommon, with a full-time GP diagnosing around one patient with cancer each month, referral guidelines are designed to facilitate the diagnostic process.[3] Referral recommendations have traditionally been based on specific 'red flag' symptoms with relatively strong associations with a specific cancer (e.g. a breast lump in breast cancer, or rectal bleeding in colorectal cancer). In recent years, new pathways have been developed for non-specific symptoms that may be associated with several cancers (e.g. abdominal pain which may indicate colorectal, gastric, ovarian, pancreatic, or renal cancer) as well as benign and serious diseases.[4] Guidelines need not always be followed, especially in cases where knowledge of the patient overrides simplistic referral criteria. However, undiagnosed cancer is later detected in some patients who met guideline criteria and were not referred, or who did not meet guideline criteria.[5]

Prolonged delays in the diagnostic pathway

Most investigations for cancer start with a series of investigations over weeks or months, offering many opportunities for failures and problems (Table 1).[6] Even in 'state-of-the-art'

and guideline-concordant clinical management, some such incidents are inevitable due to limitations of existing guidelines and the inherent epistemic uncertainty involved in the diagnostic process.[7]

Table 1. Diagnostic process errors identified retrospectively

Prior to consultation
➔ Lack of access to diagnostic procedures ➔ Waiting for (single or multiple) specialist consultations
During consultation
➔ Missed information during history taking ➔ Undetected signs during clinical examination ➔ Appropriate tests omitted from investigation requests ➔ Insufficient or ambiguous referral information
Between consultations
➔ Failures in the testing process ➔ Misinterpretation of diagnostic test results ➔ Missed communication of diagnostic information to patient ➔ Forgotten or missed follow up actions by clinicians ➔ Lack of multidisciplinary team assessment ➔ Patients' notes or clinical letters getting lost between healthcare settings.

Patients who experience such problems or failures tend to have difficulties in navigating the diagnostic process, such as wondering how they will receive their test results, and may experience heightened anxiety. This may delay the diagnostic process due to reluctance to seek or re-seek healthcare advice, failure to follow the doctor's prescribed advice, non-attendance at appointments, communication breakdown between patient and healthcare team and inappropriate use of unplanned healthcare. [8,9]

A 'calibration gap' (where confidence in one's own accuracy is not aligned with actual accuracy) may exist between what the clinician thinks about the effectiveness of their management approach and what the patient considers effective as clinicians do not regularly receive feedback from their patients.[10] It is especially difficult to learn about diagnostic delays from patients who do not receive a cancer diagnosis, as there is no audit of whether the chosen approach to symptom management or communication was effective.[11]

Interventions to improve safety in early diagnosis of cancer

Interventions have been designed to reduce risks at different stages of the diagnostic pathway (see Table 2). These are mostly aimed at encouraging patients to consult and optimising the consultation, rather than addressing the entire diagnostic pathway.

Table 2. Types of interventions that have been designed to improve safety in early diagnosis of cancer

Prior to consultation	
Educational	**For the public:** Education interventions are based on the assumption that risks occur due to low knowledge of symptoms that could be predictive of cancer. For example, patients taking a long time to seek help for symptoms because they do not associate them with cancer. Educational interventions for the public are often in the form of symptom awareness materials and campaigns, led by cancer charities and public health bodies. Population symptom awareness continues to be low in all but the most common cancer symptoms. **For healthcare professionals:** Educational interventions are also aimed at GPs and other primary care practitioners around developing their decision-making strategies for referral.
During consultation	
Guidelines	The National Institute for Clinical Excellence (NICE) has a guideline to support GPs in referring patients with suspected cancers. It contains specific advice for each cancer type, based on evidence from primary care, to help GPs identify patients with a 3% risk of cancer or higher.[12]
Decision aids	Decision aids are designed to reduce errors in diagnostic processes by supporting GPs in accurately assessing cancer risk. The tools are used in consultation, and produce a risk score as well as potential advice about actions (e.g. blood tests). The tools are presented in a software package that is integrated into the primary care electronic record in a significant minority of primary care practices.
Safety netting	Safety netting is a term used to describe measures taken by the clinician to promote timely follow up of a patient that they have seen in consultation. This could include giving advice about the expected duration of symptoms, symptoms that would indicate serious disease, suggesting follow up consultations (either actively or passively), and may be supported by electronic trigger tools.[13] The logic of the intervention is that differential diagnosis and diagnostic processes will become easier to determine after a test of time; either the patient will discover a new symptom, or the natural course of a benign differential will elapse, or the persistence of a low-risk symptom will indicate a higher risk of cancer than initially inferred.
Communication tools	Specific tools have been developed to help GPs communicate optimally. For example, to encourage patients to disclose a greater number of symptoms, or communicate more effectively with patients that have lower health literacy. These tools have been evaluated through research but are not implemented as standard practice.

Post-consultation	
Feedback from clinical audits	National clinical audits (e.g. the National Cancer Diagnosis Audit) are part of professional education for healthcare professionals, along with participation in quality improvement projects focussed on early diagnosis of cancer. Feedback about delays in cancer diagnosis, the use of diagnostic investigations and referrals can help healthcare professionals individually or collectively to make improvements to practice.

Evaluating current interventions with respect to impact on early diagnosis

There is moderate evidence to suggest that interventions to drive earlier diagnosis of cancer are working. The proportion of all cancers diagnosed at an early stage is increasing slowly, yet the results for individual cancers (and particularly those presenting with non-specific symptoms) are less encouraging.[14] In this section we consider the limitations of current interventions to drive further improvements in early diagnosis.

Too much reliance on individuals and their communication during consultations to manage patient progress

With the exception of national and local audits, all the interventions above are focussed on the (initial) consultation between clinician and patient, putting pressure on clinicians to deliver a 'perfect consultation'. Few interventions that acknowledge the reality that the primary healthcare professional will probably not suspect cancer at the first consultation at all. The clinician and patient are the sole carriers of responsibility for tracking and following up on patient progress, which is unpredictable and error-prone given the high volumes of complex patients with communication difficulties and low-risk symptoms that transpire to be self-limiting disease. The uncertainty and variability of the diagnostic process is harder to manage in deprived areas due to reduced capacity and resources, exacerbated by the current severe and growing shortage of both primary and secondary healthcare staff in the UK.

Over-reliance on increasing knowledge through educational interventions

Patient health literacy: Educational campaigns to increase public awareness of symptoms increase primary care consultations and urgent referrals; however, there is little impact on stage at diagnosis and no measurable impact on cancer survival.[15] This may be because a substantial proportion of patients with known cancer symptoms (such as coughing up blood) will not seek help for other reasons, such as normalising symptoms and self-management in

the first instance.[16] Furthermore, campaigns and education programmes may unwittingly change public perceptions of what is and is not a cause for concern by focussing on particular symptoms, and typically do not address non-specific symptoms.

Implementation of evidence-based interventions in practice: Interventions such as diagnostic decision-aids, risk prediction tools and safety netting rely on clinician suspicion of cancer. They require burdensome steps to calculate and mitigate low-risk events within the timeframe of the consultation and to have an appreciable impact, would need to be used consistently for all patients including those where cancer is *not* suspected. This type of intervention is vulnerable to time pressure, increased patient complexity/need and inadequate resourcing e.g. local access to imaging.

Lack of active monitoring during the diagnostic process

Most cancer patients with non-specific symptoms will experience periods of unmonitored delay in their diagnostic pathway.[17] Relatively few interventions are targeted at mitigating delays caused by psychological barriers such as over-reassurance from a benign explanation for their symptoms,[18] misunderstanding of a 'watch and wait' strategy,[19] or fear of bothering the doctor. Furthermore, there are few interventions that target those patients who are most likely to experience delays in cancer diagnosis, such as patients with comorbidities, lower socioeconomic status and older adults.

The alternative: improving the resilience of diagnostic processes to prevent consequential delays

We propose that the safe management of patients who are not immediately referred would be made easier with the design of interventions that consider the entire diagnostic process. These interventions would anticipate that, in the absence of guidance-concordant symptomatology that will prompt an urgent referral, the first (and/or second) consultation may contain diagnostic process errors that could potentially derail a cancer diagnosis. We believe that thinking should extend beyond the consultation and the actions of individual clinicians, and envision the healthcare system in which cancer can be detected. These interventions should happen automatically, whether or not a clinician suspects cancer or another serious disease.

Figure 1 includes a number of principles which would demonstrate a system capable of mitigating delays and errors in the context of a potential cancer diagnosis. We might consider that 4-6 weeks was the maximum time for a primary healthcare professional to gather enough information to refer a patient, with minimal impact on the progression of disease.

-----insert Figure 1 here--------------
Figure 1. Schematic for an alternative approach to safe management of a patient who is not immediately referred for cancer-related investigations

Supporting patients to monitor symptom progression

Asynchronous methods of follow up and automated call/recall methods could be used to help patients monitor their symptoms at home, including encouraging them to reconsult if symptoms persist or worsen. These tools could include text messaging linked to the electronic patient record that would be automatically triggered by a symptom monitoring code. Patients could also be supported by symptom-monitoring apps, wearables and other telemedicine or e-health tools that have been evaluated for accessibility and ease of use. Patients who cannot use smartphone or electronic devices should be supported by the use of validated paper-based tools, delivered at the point of consultation to avoid deepening health inequalities.[20]

Detecting missed diagnoses or incomplete diagnostic processes

Systems should be designed with a 'no fail' protocol for the management of diagnostic processes such as blood tests or prescription fulfilment. This may include several measures such as improving patient access with different sites for phlebotomy and pharmacy, issuing automated reminders (e.g. text message or telephone call), linking results to the correct patient record, automated identification of errors from the electronic health record (e.g. missed prescriptions, missed or delayed blood, imaging or endoscopy tests) with a clear protocol for who is responsible for following up.[21]

Clearly attributed responsibility for actions between clinicians, patients, and administrators

A clear protocol for healthcare actions following the consultation should be communicated to the patient both verbally and via letter or text message, as well as added to the medical record. Protocols should not be solely reliant on patients contacting the surgery, nor use communication "by omission" i.e. both negative *and* positive blood or imaging results should be communicated in the same way. Clinicians should also not be solely responsible for monitoring patient progress, particularly in an era when patients often visit multiple clinicians at subsequent consultations and may be seen by locum or trainee practitioners. Automated safeguards should be implemented to detect missed actions or communications , and a default action should be initiated (e.g. a reminder or prompt, or transfer of responsibility to someone else).

Information sharing

Sharing information about agreed actions, investigations and referrals should be done proactively for *every* patient, either in paper form (writing down) or by sending it in a text message or email.[22] This acts as precaution that the patient might either (1) not have understood the information given in the consultation (2) not remember the information (3) want to share the information accurately with someone else (e.g. family member or carer).

Implications for research and clinical practice

A common language relating to diagnostic process management and error could drive active quality improvement activity including regional and national audits with a shared purpose. We envisage that a systems approach would result in the expansion of clinical capacity (particularly in primary care) with decreased cognitive and administrative burden, particularly in more deprived areas and for patients with more complex health conditions.

We urge researchers and quality improvement professionals to focus on research at the system level, which anticipates that errors and failures may occur in any consultation. This is particularly relevant to diagnosing cancers with non-specific low-risk symptoms; fruitful research directions may therefore include barriers to technology use, the capacity of organisations and clinicians to integrate interventions into practice, with a reduced focus on entirely new interventions.

Longer term, we would expect research and investment in new and existing technologies ('eHealth') that support system safety, underpinned by sociotechnical models that acknowledge the complex relationships between humans, technology and organisational cultures [23]. Technologies should also redress the potential for increased disparities rather than exacerbating them, and maintain the essential 'humanness' of clinical practice in primary and specialist care.

Conclusions

We aspire to better quality patient interactions and experiences regardless of cancer risk, with more reliability and explicit expectations during the diagnostic process in line with patient preferences. Errors and failures in diagnostic pathways are inevitable, and earlier diagnosis of cancer can only be achieved by designing a system which increases the resilience of the diagnostic process, by proactively monitoring, detecting and resolving problems as they occur.

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