# BMJ Open Quality Content analysis of 50 clinical negligence claims involving test results management systems in general practice

Diane Baylis,<sup>1</sup> Julie Price,<sup>1</sup> Paul Bowie<sup>2</sup>

Background and aims Laboratory test results

to the management of test results.

statistical analysis.

management systems are a complex safety issue in

primary care settings worldwide. Related failures lead

to avoidable patient harm, medicolegal action, patient

complaints and additional workload to problem solve

Methods The Medical Protection Society database

was searched and a convenience sample of 50 claims

identified from a 3-year period covering 2014-2016. A

content analysis of documentation was undertaken to

quantify and theme data, aided by a Risk Assessment

Quantitative data were subjected to simple descriptive

or treatment of a patient with cancer. 15 cases were

48%), while 18 cases (36%) involved a test result not

contributory factors (n=30, 60%) were related to local

working conditions, for example, unclear professional

Conclusion This small study highlights why test result

management systems fail and contribute to future litigation, providing new insights in this area. Most claims

involved avoidable harm to patients and preventable

design of practice systems and the need for proactive

strategies to improve the management of test results in

organisational risks. The findings point to the inadequate

up or lack of patient care continuity.

Matrix and the Yorkshire Contributory Factors Framework.

Results 14/50 cases (28%) involved a delay in diagnosis

judged to be 'never events' (30%) and 85 distinct system

issues were identified. Just under half of cases involved a failure to notify patients of an abnormal test result (n=24,

being actioned by a doctor. The most frequently occurring

responsibilities with regards to test result review or follow-

identified issues. We aimed to review and learn from 50

clinical negligence cases involving system failures related

## ABSTRACT

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<sup>1</sup>Medical Protection Society Leeds, Leeds, UK <sup>2</sup>Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK

Correspondence to Prof Paul Bowie;

Prof Paul Bowie; paul.bowie@nes.scot.nhs.uk

#### INTRODUCTION

order to reduce patient harm.

Recent research has clearly demonstrated a multitude of interacting issues with the safety and functioning of laboratory test results management systems in primary care settings worldwide.<sup>1-4</sup> The scale and frequency of patient safety incidents for this high-volume complex activity are currently unknown. However, they are known to occur at most stages of the process including the ordering of test investigations, reconciling tests ordered with results received, actioning test

results and communicating the outcomes to patients.<sup>56</sup>

The implications of these failures can have multiple impacts on human well-being and often highlight system design inadequacies. For patients, this can include avoidable physical and psychological harm, frustration, irritation and inconvenience.<sup>7-9</sup> For general practitioners (GPs), this may impact on timely clinical decision making, diagnoses and management, while safety-related incidents may also have medicolegal consequences.<sup>10–13</sup> For administrative support staff, inadequate system designs can contribute to daily work hassles and impact negatively on how they comprehend and communicate test result outcomes with clinicians and patients.<sup>14</sup> For practice managers, this will involve additional workload and reallocation of resources to problem solve and dealing administratively with related complaints from patients and carers.<sup>6 13 15</sup>

This study reports the results of the analysis of 50 cases from the Medical Protection Society's (MPS; box 1) database, which involved general practices and where the functioning of the test results management system was judged to be a significant contributory factor in the patient outcome and subsequent claim made. A typical (fictional) case example is described in box 2 to provide background context. Previous research in the field has reported related data from patients,89 incident reporting systems,<sup>2 3 16</sup> clinicians and support staff,<sup>13</sup> ethnographic observations,<sup>17</sup> external risk assessments of practice systems<sup>15</sup> and the review of significant event analysis documentation.<sup>25</sup> However, a research and knowledge gap appears to exist at arguably the more serious end of the patient safety spectrum, in terms of reported evidence related to analysis of clinical negligence claims where the system-based management and communication of test results played a key role and contributed to patient harm and poor care experiences.

## Box 1 About Medical Protection Society (MPS)

- > The MPS is a leading mutual, not-for-profit membership organisation.
- It protects and supports the professional interests of more than 300 000 medical, dental and healthcare professionals around the world.
- Membership provides access to expert advice and support together with the right to request indemnity for complaints or claims arising from professional practice.
- In the UK, MPS manages claims for clinical negligence brought against members who are general practitioners and private doctors, while National Health Service (NHS) Resolution (in England only) manages claims arising in the NHS hospital sector.

The main aim of this study, therefore, was to review and learn from the selected clinical negligence cases in question, many of which by their nature are likely to have extreme consequences for patients and professional impacts for the doctors involved. In doing this, it is expected that new knowledge will be generated about the effectiveness of general practice safety management systems governing this clinically important area of patient care. This will provide insights into how system controls and safeguards could be strengthened to reduce and manage risks.

# **METHODS**

#### Study sampling

A search of the MPS database of general practice cases opened in the UK and Ireland during a 3-year period between January 2014 and December 2016 was conducted. A researcher systematically scrolled through each database entry and read the 'headline summary' of each claim to identify if the systems-based management of test results

## Box 2 Typical case example of a test result system failure

- Mr X visited his general practitioner with various health concerns. Dr Y decided to undertake a series of blood tests, including a prostate specific antigen (PSA) test after discussing with Mr X.
- Mr X made an appointment to have the blood tests taken at the practice. He attended the appointment and had a number of samples taken by the practice nurse. However, she inadvertently failed to send a sample for the PSA test as requested.
- Mr X contacted the practice, as directed, to obtain his test results and was informed that they were all normal. He wrongly assumed that the PSA result was also normal. Dr G failed to notice that the PSA test was not included in the list of tests that he reviewed, as he relied on the computer system to 'flag up' any abnormal results.
- Mr X did not return to see Dr Y for 12 months. Dr Y then discovered that the PSA test had not been done previously and was very concerned about the patient and made an urgent specialist referral due to the severity of his symptoms. Unfortunately, Mr X was diagnosed with prostate cancer.
- Mr X then decided to make a claim against Dr Y for medical negligence as he felt that the diagnosis of cancer was delayed leading to a more invasive treatment for the cancer, which could have been avoided had the diagnosis been made at an earlier stage.

featured as a potential factor contributing to the claim. Where this was confirmed, the case number was recorded to provide access to the full case documentation. This process was repeated until 50 claims in total had been identified. The sample number of 50 was agreed for feasibility and pragmatic reasons of time and resource.

## Data collection and analysis

We undertook a content analysis<sup>18</sup> of all claims documentation related to each medicolegal case. Content analysis is a flexible qualitative and quantitative research method that can be used to systematically analyse textual information such as that contained in organisational documents (eg, medical correspondence and written legal reports). This enables the quantification and theming of important patterns and categories of data that are useful to the study purpose. The research team were a mix of highly experienced clinicians with significant risk management expertise and a human factors and safety science researcher.

All documentation was read and reread on an iterative basis and extracted data to a predesigned proforma that were uploaded to an Excel spreadsheet to enable more detailed analyses. To add validity to this process, two other authors checked one in three proforma against the claims documentation to ensure accuracy. Identified disagreements were resolved through the authors' meeting to discuss these issues, which were resolved through further analysis until consensus on the outcomes was achieved. Data were collected on the personal characteristics of patients; clinical conditions and patient outcomes; year of case and setting; and whether the case involved a 'never event' as defined using criteria published in a recent UK study that defined and validated a list of 10 'never events' for that setting (two events are of potential study relevance as they are concerned with missed referral of cancer and failure to action abnormal test results).<sup>19</sup> A general practice-based 'never event' was defined as a serious patient safety incident that should 'never' occur if all preventative safety controls are in place.

Specific data were extracted and coded using the following previously published conceptual frameworks:

- 1. The National Patient Safety Agency (NPSA) Risk Assessment Matrix<sup>20</sup> to categorise the risk consequence (catastrophic, major, moderate, minor and negligible) and risk likelihood (almost certain, likely, possible, unlikely and rare) of individual claims.
- The 'process stages' (n=4) of the test result system implicated as an issue in the claim documentation ((1) preanalytical stage, (2) specimen processing stage, (3) postanalytical stage and (4) communication outcome issue).<sup>15</sup>
- 3. The Yorkshire Contributory Factors Framework<sup>21</sup> to categorise the different system elements judged to be factors in underlying why the claim occurred (individual factors, task characteristic factors, team factors, patient factors, local working conditions, organisational factors and external factors).

Data were then quantified and categorised and subjected to simple descriptive statistical analysis to generate frequency counts and calculate percentages and means (with ranges).

## RESULTS

#### **Demographic variables**

The mean age of patients was 50.5 years (range: 17–82 years), and 27 were men (54%). A total of 45 cases (90%) involved one or more GPs, with three cases involving the practice nurse/nurse practitioner (6.0%) and a further two cases (4.0%) involving a healthcare assistant. In 14 of 50 cases, the main issue was a delay in diagnosis or delay in treatment of a patient with cancer (28.0%). Five of those cases related specifically to missed diagnoses or delay in treatment for patients with prostate cancer (36.0%). Three cases related to missed diagnosis or delay in the treatment of patients with lung cancer (21.0%). Other missed cancer cases included bladder cancer (n=1), ovarian cancer (n=1), skin cancer (n=2), myeloma (n=1) and cervical cancer (n=1).

#### NPSA risk assessment and 'never event' classifications

All 50 cases were considered 'likely' using the NPSA risk matrix (100.0%), an indication of how probable it is that the adverse consequence will occur. The risk consequences were classified as follows: catastrophic, that is, death (n=5, 10.0%); major (n=9, 18.0%); moderate (n=19, 38.0%); and minor (n=17, 34.0%) (table 1). Typical examples based on 'real-life' scenarios are outlined in box 3 for these selected categories. A total of 15 cases (30.0%) were judged to be 'never events'. All cases related to the following two 'never events': (1) a planned referral of a patient, prompted by clinical suspicion of cancer, is not sent and (2) an abnormal investigation result is received by a practice but is not reviewed by a clinician.

Table 1 Classification of claims by NPSA risk assessment and risk likelihood categories (n=50) % Factor n **Risk consequence** 0.00 Negligible 0 Minor 17 34 Moderate 19 38 Major 9 18 Catastrophic 5 10 Risk likelihood Rare 0 0.00 Unlikely 0.00 0 0.00 Possible 0 50 100 Likely Almost certain 0 0

NPSA, National Patient Safety Agency.

Box 3 Examples of claims categorised as 'catastrophic', 'major' and 'moderate' using the National Patient Safety Agency Risk Assessment Matrix

#### Catastrophic

Elderly female patient seen by general practitioner (GP) complaining of shoulder pain. GP referred the patient for a chest X-ray. Chest X-ray result was abnormal and advised specialist referral. The report was reviewed by the GP, but he failed to act on the report and did not refer the patient. The patient was seen by the practice nurse 12 months later who made an urgent referral. Unfortunately, the patient was diagnosed with carcinoma of the lung and subsequently died.

#### Major

Middle-aged women who was on warfarin following an aortic valve replacement. The patient had an INR (international normalised ratio) monitoring machine at home so she did not attend the practice for blood tests. However, the practice was issuing prescriptions for warfarin without any recorded INRs from the patient and continued to do so for 8 months. The patient collapsed and died from a thrombosed prosthetic aortic valve.

#### Moderate

Middle-aged woman with a family history of ovarian cancer. GP sent blood test for CA125, which came back elevated. GP documented in notes that patient needs a scan but failed to contact the patient to advise this or inform her of the elevated CA125. Patient did not followup the test results herself. Eight months later, the patient returned and was seen by another GP who made an urgent referral. The patient was found to have a large pelvic mass requiring extensive surgery.

## High-level system process stages

A total of 85 system issues across each of the four stages were uncovered in the 50 cases reviewed. Almost half of cases involved a communication outcome issue in terms of a practice system failure to notify the patient of an abnormal laboratory test result (n=24, 48.0%). Eighteen cases involved a system failure in terms of a test result not being reviewed and actioned by a practice GP (36.0%). A minority of cases involved a system issue related to the need to order a test after a decision was made that this was clinically necessary (n=8, 16.0%).

## Systems-wide factors contributing to cases

In the majority of cases (n=30, 60.0%), the most frequently occurring factors contributing to why specific incidents happened related to a range of local working conditions such as unclear professional responsibilities with regards to review or follow-up of test results or lack of continuity in patient care (table 2). Organisational factors such as lack of formal practice systems for reviews and follow-ups, or reliance on the patient to contact the practice for test results, were uncovered in 19 cases (38.0%).

## DISCUSSION

In this small study, clinical negligence cases that involved the suboptimal management of laboratory test ordering and results handling were analysed. A range of systemwide information was uncovered pinpointing where and

Table 2Proportion of system level factors contributing to claims (n=50)			
Yorkshire Contributory Factors Framework Categories	n	%	
<ul> <li>Local working conditions, for example:</li> <li>Unclear responsibilities with regards to review or follow-up of test results.</li> <li>Lack of system to ensure test results are reviewed by the requesting clinician.</li> <li>Lack of continuity in patient care resulting in confusion over whose responsibility to ensure patient follow-up.</li> </ul>	30	60.0	
<ul> <li>Organisational factors, for example:</li> <li>Lack of a consistent system to announce urgent action.</li> <li>Lack of practice systems for reviews or follow-ups; no annual recall system.</li> <li>Practice reliance on the patient to contact the practice for test results.</li> <li>Practice process of allocating the senior GP to review all the test results of patients whom they have not personally seen.</li> <li>No test result audit.</li> </ul>	19	38.0	
<ul> <li>Individual factors, for example:</li> <li>Inexperienced practice nurse who failed to undertake the blood tests requested by the GP and misinformed the patient that their test results were normal.</li> <li>GP overlooked the abnormal test result by relying solely on the computer system.</li> <li>Locum GP may lack the knowledge of that particular practice's system.</li> </ul>	15	30.0	
<ul> <li>Patient factors, for example:</li> <li>Patient did not fully understand the process due to having learning difficulties.</li> <li>Patient did not follow-up with their test results.</li> <li>Patient with multiple medical conditions.</li> <li>Patient who frequently failed to attend appointments.</li> </ul>	13	26.0	
<ul> <li>Task characteristic factors, for example:</li> <li>Data input error in computer system.</li> <li>Incorrectly picking the wrong drop-down box on the computer software. Thus, the patient was informed that their test was normal when they should have been directed to consult their GP.</li> <li>Complete reliance on the computer software to highlight abnormal results.</li> <li>Poor documentation.</li> </ul>	10	20.0	
<ul> <li>External factors</li> <li>Ambiguity about who was responsible for ordering a test, when the patient was under the care of both GP and the hospital.</li> <li>Ambiguity in referral guidelines for a specific condition.</li> <li>No clear system for sharing test results between primary and secondary care.</li> <li>Test results were sent to the wrong practice, in a shared building perhaps due</li> </ul>	5	10	

Table 2 Continued		
Yorkshire Contributory Factors Framework		
Categories	n	%
Team factors, for example:	2	4.0
<ul> <li>Inappropriate task delegation.</li> </ul>		

GP, general practitioner.

why practice processes fail and ultimately contribute to future litigation. The majority of cases highlighted incidents of avoidable harm to patients (mainly involving the clinical management of cancer and other serious illness) and preventable risks to practices. A minority of cases were also categorised as very serious 'never events', which was the first reported test results data for this category of patient safety incident. In summary, the findings highlighted the inadequate design of the practice systems concerned and point to the need for proactive improvement to strengthen the controls and safeguards in these systems to minimise the risk of harm to patients and related reputational and financial risks to healthcare professionals and practices.

In many cases involving communication issues, it was documented that the GP intended to advise the patient to make an appointment, but this was not conveyed to the patient, and therefore the abnormal result was not acted on resulting in a failure or delay in referring the patient for specialist medical treatment. Typical contributory factors identified included: failure to forward the test result to the appropriate clinician; not acting on results that require actions; test results being filed without being clinically reviewed; suboptimal management of multiple results for a single patient, that is, the patient is informed that their test results were 'normal' when not all test results ordered had been received from the laboratory and collated by the practice; and lack of a 'buddy system'; for example, if a GP is on annual leave, the management of their awaited test results was not assigned to another GP. Other factors uncovered included failure to order the test as part of annual screening or to follow-up or order blood tests requested by secondary care specialists. Sociotechnical system issues were also identified, for example: locum GPs' lacking knowledge of local practice IT systems; over reliance on the IT systems to highlight abnormal results; patients' frequently failing to attend appointments; no clear system for sharing test results between primary and secondary care settings; and ambiguity in referral guidelines for specific clinical conditions.

It is interesting to note that our findings with regards to contributory factors concur with previous non-claims patient safety research, particularly in demonstrating that communication issues were at the heart of many cases studies. This is similar to the findings of a recent review of the reported incidents to the UK National Reporting and Learning System relating to test results management, which highlighted communication failure as a contributory factor in approximately one-third of incidents.<sup>22</sup>

Continued

to similar-named GP.

Similarly, Elder and Dovey in their study of the barriers in the testing process in family medicine identified communication and inadequate systems as a contributory factor to test result 'errors'.<sup>3</sup> Poon *et al*<sup>10</sup> identified similar contributory factors and concluded that the improvement of workflow and tracking of test orders to completion are required in order to improve the process and time spent managing test results.<sup>10</sup> The majority of previous studies tended to focus on contributory factors rather than patient outcomes. However, although Callen *et al* also reviewed the impact on patient outcomes, including missed cancer diagnosis, our research appears to be the first study of this kind that reviewed medical negligence cases.<sup>4</sup>

The contributory factors leading to system failures in the management of tests results in general practice appear to be a common occurrence and may lead to a 'near miss', complaint or adverse event. Although perhaps the majority of outcomes are less serious and practices may seem to 'get away with it' and escape undesirable consequences most of the time, however, a small proportion that has the same or similar system-based contributory factors do lead to a serious outcome for the patient, families and practice teams members.<sup>15</sup> From a system complexity perspective, it can be argued that the source of system 'success' (where things go well most of the time) and 'failure' (where things go wrong sometimes) is the same, that is, how everyday work is typically organised and enacted, for example, to cope with patient demand and high-volume activities and managing conflicting practice goals such trading-off efficiency with thoroughness.<sup>23</sup>

A key strength of the study is gaining access to medicolegal case documentation to analyse the role of test results management systems in serious patient harm incidents, which provided novel insights into this under-researched area. While all the data were collected and analysed by the lead author, steps were taken for the other authors to cross-check and validate this work so that group consensus was achieved on interpretation of results. The main limitations were the small-scale pragmatic nature of the study due to the time and resource required to collect and analyse data. Some of the content of the documentation was also missing or limited in some respects in terms of providing an in-depth system-wide understanding of the issues contributing to why things went wrong.

This study has served to improve knowledge in terms of empirical evidence reported from analysis of clinical negligence claims directly involving the management and communication of test results in general practice. For general practices and primary care organisations concerned about local test results handling systems, guidance on what can go wrong and how multiple risks can be managed to 'as low as reasonably practicable' has been published. However, this remains a highly complex sociotechnical and cultural problem given the heterogeneity of general practices and the multiple steps involved in this high-volume activity.<sup>17</sup> While formal guidance suggested procedures and improvement tools are welcome,<sup>5 24</sup> they

are likely to have a limited impact where practice teams do not seek to better understand the complex intricacies of their local systems and contexts. Taking a system approach to shedding light on, for example, the 'informal dimensions' of practice related to this activity while seeking the perspectives of all team members and exploring everyday work and efficiency–thoroughness trade-offs, would be essential to this process.<sup>23</sup> However, given that the implementation of patient safety improvement interventions is at a nascent stage in most primary care organisations worldwide,<sup>12</sup> this type of approach is highly likely to be a significant learning need for the great majority of practice teams.

Future research could focus on a larger sample of similar clinical negligence cases in an attempt to generalise about the scale and nature of serious failures related to test results handling systems, where this information is available. This approach of reviewing clinical negligence cases has merit in researching other areas of general practice that are known to be high risk such as medication incidents and communication failures at the interface between primary and secondary care. It would also be of interest to explore the possibility of reviewing and comparing related claims data in different international contexts. A further possibility is to follow-up with doctors' subject to claims to investigate the extent to which robust support systems for staff well-being were in place, particularly as this is known to cause work-related stress and contribute to physician burnout (as well as unsafe patient care).<sup>25</sup> The primary goal of such support mechanisms should focus on overall system improvements, rather than person-level interventions, to enhance their effectiveness.<sup>26</sup>

## **CONCLUSION**

The suboptimal management of test results in general practice has been reported in previous research in many modern healthcare systems, although this has tended to focus on care processes rather than outcomes. This appears to be the first study that reviews clinical negligence cases from serious test results-related safety incidents in general practice that have significant impacts for patients, professionals and practices. Patients have expectations that their healthcare will be delivered to a high standard. Irrespective of the skill and dedication of practice teams, the design and operation of local care systems are equally important in minimising risks. Practices can begin to reduce test results-related incidents where there is an open, learning culture and team members are engaged and can freely raise potential safety risks and promote improvements to enhance the reliability of systems. Risks can also be better managed by ensuring regular reviews of the system of managing and reconciling test results and having a system that tracks and reconciles tests requested against results received. Inadequate or poor communication of test results to referrers and inadequate arrangements for a follow-up after the test results

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are nationally acknowledged patient safety issues. Better communication between healthcare professionals and patients is vital to improve the test result system, thereby improving patient safety outcomes. Where the functioning of these practice systems are improved, there is a likelihood of a further benefit in reducing the risk of burnout or stress to clinicians and staff.<sup>26</sup>

#### **ETHICAL REVIEW**

Under UK 'Governance Arrangements for Research Ethics Committees', an ethical research committee review is not required for service evaluation or research which, for example, seeks to elicit the views, experiences and knowledge of healthcare professionals on a given subject area.<sup>27</sup>

**Contributors** All authors conceptualised and designed the study. DB collected, analysed and interpreted data with support from PB. All authors checked the interpretation of data results. DB and PB drafted initial versions of the manuscript, and all authors contributed to drafting and approving the final version.

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