The impact for patient outcomes of failure to follow up on test results. How can we do better?

Joanne Callen, Andrew Georgiou, Julie Li, Johanna I Westbrook

Centre for Health Systems and Safety Research, Australian Institute of Health Innovation, Macquarie University, Sydney, Australia

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Corresponding author:
Joanne Callen
Associate Professor, Centre for Health Systems and Safety Research
Australian Institute of Health Innovation
Macquarie University
Level 6, 75 Talavera Road
Sydney, 2109
Australia
E-mail: Joanne.Callen@mq.edu.au

ABSTRACT

Background: The World Health Organization–World Alliance for Patient Safety has identified test result management as a priority area. Poor test result follow-up can have major consequences for the quality of care, including missed diagnoses and suboptimal patient outcomes. Over the last three decades there has been considerable growth in the number of requests for pathology and radiology services which has added to the complexity of how patient care is delivered and test results are managed. This can contribute to a lack of clarity about where and with whom responsibility for test follow-up should reside: a problem that is compounded by a lack of clear definitions about what are critical, unexpected or significantly abnormal results.

Aim of this paper: This paper will present a narrative review highlighting key issues related to the problem of failure to follow up laboratory test results, and outline potential solutions.

Conclusions: Information technology (IT) has the potential to enhance the performance and safety of test result management processes. Effective solutions must engage all stakeholders, including consumers, in arriving at decisions about who needs to receive results, how and when they are communicated, and how they are acknowledged and acted upon and the documentation of these actions.

Meeting these challenges requires the establishment and maintenance of resilient governance approaches and a culture dedicated to ensuring the reliability and safety of patient care.

INTRODUCTION

The World Health Organization–World Alliance for Patient Safety has identified poor test result management as a priority patient safety area (1). Poor test result follow-up can have major consequences for the quality of care, including missed diagnoses and suboptimal patient outcomes. A root cause analysis of aggregated information from a national Australian incident management information system showed that 11% (3/27) of clinical incidents resulting in a serious outcome (e.g., patient death), and 32% (24/75) of clinical incidents with major patient-related consequences, were related to problems with test follow-up (2). Clinicians themselves acknowledge that their test management practices are inefficient (3). The urgency of the problem was underscored by the US Emergency Care Research Institute's (ECRI) 2014 report on patient safety concerns for health care organizations (4). The report listed data integrity failures associated with health information systems, poor care coordination across levels of care and test result reporting problems as the leading three items of their top 10 patient safety concerns (4). Each of these problems is intrinsically connected to the issue of poor test result follow-up.

A systematic review published in 2011 (5) identified 12 studies over a 20 year period which investigated the extent of failure to follow up laboratory and radiology results for hospital patients. The review reported the lack of follow-up of test results for hospitalized inpatients ranged from 20.04% to 61.6%, and 1.0% to 75% for patients treated in the Emergency Department (ED), when calculated

as a proportion of tests. The consequences of missed test results for patient care included delayed diagnoses such as malignancies, hypothyroidism, hyperthyroidism, and osteoporosis, reinforcing the urgent need to address the problem. In situations involving missed microbiological results consequences included failure to commence or change antibiotic therapy. The review also highlighted that there were cases of missed positive serological test results for *Helicobacter pylori* and *Chlamydia* and in the latter the patient subsequently developed pelvic inflammatory disease (5). Another systematic review which quantified the extent of failure to follow up test results in ambulatory care settings (6) identified 19 studies and reported wide variation in the proportions of tests not followed up: 6.8% to 62% for laboratory test results and 1.0% to 35.7% for radiology (6). These failings included missed cancer diagnoses in four of the seven studies reporting on the impact on patient outcomes (6). Increased hospital presentations resulting from hyperkalaemia related to missed abnormal serum potassium levels and adverse drug events related to insufficient supplementation with levothyroxine due to missed follow-up of abnormal TSH results were examples of other reported negative patient outcomes.

Results pending at discharge was identified as an area of particular concern for hospitalized patients (5). A 2012 study of test orders in an Australian hospital revealed that 47% of missed results stemmed from tests ordered on the day of discharge, which raises concerns about the appropriateness of those tests where results are not followed up (7). The systematic review of missed test results for hospital patients also flagged follow-up of critical results as a problem area (5). Despite practice guidelines requiring critical values to be telephoned to the clinical team, compliance remains an issue and information may

not always reach the clinician involved in the patient's care. Several studies report the absence of guidelines regarding responsibility for patient notification, and documentation of actions related to test follow-up (8-12). The management of test results involves communication between many individuals, including physicians, nurses, clerical and laboratory staff and patients, across a variety of settings using a range of manual and electronic systems. The systematic reviews (5, 6) identified varying test management practices between care settings and the information systems used in the process included paper-based, electronic, and a combination of paper and electronic systems. Information technology (IT) has a key role to play in supporting the management of test results in terms of ordering, reporting, accessing and tracking follow-up with documentation of actions. However, evidence of the effectiveness of IT is limited although studies show a general trend towards improved test follow-up when electronic systems are used (5, 6). New models of test management supported by IT can only succeed when a systems approach is adopted which recognises the complex clinical governance challenges associated with safe test management (13). The two systematic reviews on test follow-up for hospitalized and ambulatory patients identified evidence that failure to follow up test results is a substantial problem, but with only 31 studies conducted across a span of 20 years (5, 6) the evidence base is not substantial. What is particularly lacking is evidence of potential interventions to support clinicians and patients to reduce the rates and thus risks associated with failure to follow up test results. Further studies are urgently needed to evaluate solutions such as on-line endorsement/acknowledgment of test results and particular attention must be paid to the integration of solutions with work

practices of clinicians and laboratories and the needs of consumers.

ENHANCING THE QUALITY AND SAFETY OF TEST RESULT MANAGEMENT

Harmonization of test result management

Pathology and medical imaging services perform a major role in the delivery of patient care by ensuring that reliable and accurate results are delivered in a timely fashion to inform clinical management decisions (1). One of the main errors associated with delayed follow-up of pathology and medical imaging results originates in the post-analytic phase of the testing process, or once a report or test result has been issued to the requesting (or referring) doctor. Failures in this phase are linked to a lack of clarity about where and with whom responsibility for test result follow-up should reside (14), and clear definitions about what are critical, unexpected or significantly abnormal results. There is also no consensus regarding the reporting timeframe for these abnormal results between laboratories, medical imaging departments, hospitals and other health care settings (15). A 2012 survey of test result management in Australasian laboratories, conducted by Campbell and Horvath (16), revealed large variations in how critical results are managed and the failure of laboratories to uniformly follow internationally-recognised guidelines. Out of a total of 58 participating laboratories across Australia, New Zealand, and Hong Kong, 97% included critical results and 81% incorporated significantly abnormal results in their critical limit list. Only 41% of laboratories stated that they compiled their list in consultation with doctors, even though this is an accreditation requirement specified by the ISO 15189 quality management system standard for medical laboratories. In this paper the authors also stated that there was a

subjective element in the compilation of critical limit lists and this was a factor in the substantial variation in range of values between institutions(16). Inconsistent policies also existed between laboratories regarding critical result notification procedures, including the identification of critical results, timeliness of reporting critical results, how critical results are notified, to whom the result is notified, and the acknowledgement of results receipt (16).

Evidence-based recommendations in this area (15-18) emphasise the importance of clear definitions of key terms and the need for agreed alert thresholds and timeframes and specified procedures for fail-safe communication of test results that pose critical or significant risk to patient safety. Many doctors describe existing test result management systems as inefficient and chaotic (3, 19). It is an important issue faced by pathology and medical imaging departments world-wide (15), and requires establishment of standardized pathology information structures and terminologies to improve recording, decision support and communication of laboratory information (18).

Information technology initiatives

IT offers solutions to enhance the performance and safety of test result management processes. The process of identifying missing test results can involve time-consuming and cumbersome audits involving paper (and electronic) records (20). In such cases, the identification of missed test results may be too late to have any positive effect on patient safety (5). IT systems can be used to track pending test results at hospital discharge (21), deliver result alerts and document test result acknowledgement and subsequent clinical actions (22). An on-line test result endorsement function provides an auditable trail of test follow-up actions and as such provides a continuous quality audit

capability which can be used by clinicians and management (5).

The existence of hospital data silos and poor integration of electronic systems remains a well-documented problem and major patient safety hazard in Australia and internationally (23). The establishment of integrated electronic data sources is a key component for safely monitoring, identifying and acting upon any instances of failure to follow up test results, to ensure that appropriate treatment is delivered (24). The use of hybrid medical records, that is paper and electronic systems, has been shown to be associated with errors and duplications compared to complete electronic systems (25, 26). In relation to test follow-up, the use of a partial electronic medical record (eMR; paper based progress notes and electronic test results or vice versa) was shown to be associated with higher rates of failure to inform patients of clinically significant results compared to using a complete manual or electronic system (8).

Successful implementation of IT must recognise the dynamic between the technology and the complex social environment in which healthcare is delivered (27). Management of test results needs to ensure that the requirements of clinicians in different clinical settings need to be taken into account. Sittig and Singh (28) have made recommendations which aim to reconcile the social (personal, workflow, organizational) and technical (hardware/software, clinical content, user interface) elements of test result follow-up in the clinical environment to facilitate correct use of eMR-based IT initiatives and realization of potential benefits. These recommendations include: the provision of standardized clear definitions of test result categories to facilitate prioritization (flagging of significantly abnormal test results) and electronic reporting; that physicians be trained to process test result notifications in

a timely manner and consistently document all follow-up actions in the eMR, as multiple sources of documentation may lead to a break-down in communication of test results and follow-up failure; and that responsibility for test result follow-up and communication under all clinical circumstances should be clear, formally documented and regularly reviewed, and understood by all professional parties concerned (28). The Safer Self-Assessment Guides (29) also recommend that automated result alerts should be limited to those that are clinically relevant to avoid information overload or "alert fatigue", and all test ordering should be completed using Computerized Provider Order Entry systems to allow access to tests electronically and avoid the creation of hybrid information environments.

Establishment of a safety and quality governance structure and culture

Tackling the issue of test result follow-up requires the establishment and maintenance of integrated governance systems and a culture dedicated to ensuring the reliability and safety of patient care. Effective clinical governance systems require integration across all parts of an organization. This involves the clear delineation of responsibilities and workforce accountability, along with systems to monitor progress and deal with any risks or impediments (30). The US Joint Commission Journal on Quality and Patient Safety, "Safe Practice Recommendations for Communicating Critical Test Results," outlines this process as starting with the identification of the ordering or responsible provider as the person who should receive results, followed by the person the result is directed to if the ordering provider is not available, to ensure that patients receive timely clinical attention (17).

A 2014 study investigated the successful implementation of an electronic test management system at a major Australian hospital (24). The system provided an electronic safety net based upon a test management governance model. This system ensures that, if the responsible medical officer who ordered a test does not acknowledge the receipt of a test result within 3 days, a notification-escalation process is set in motion so that as each day passes, email or pager alerts are sent to increasingly senior members of the hospital staff. This process begins with the clinical unit's designated medical officer (day 4), and then escalates to the clinical unit support supervisor (administration or medical) (day 5), clinical unit director (day 7) and division director (day 10). This process enabled the ongoing monitoring of test results and allowed delays in test result follow-up to be identified and remedied in a timely fashion. Evaluation of the system identified that over a period of one year *all* test results had been acknowledged, with 60% of laboratory and 44% of medical imaging results acknowledged within 24 hours of result availability (24).

Enhancing the role of consumers in test result access

The engagement of consumers in their health care is an important trend in Australia and internationally. It is increasingly acknowledged that the benefits of increased consumer engagement encompass better quality and safer health care practice (31, 32). Consumer involvement is particularly relevant to test result management, where failure to inform patients of test results has been described as legally indefensible in malpractice claims (33). Hospital eMRs can be used to provide consumers with access to information on-line using a secure electronic patient portal, which in addition to allowing access to appointment and personal clinical information, including test results, also facilitates communication with health professionals (34, 35).

Patients have regularly expressed interest in being involved in medical decision making and in being notified of their test results, both abnormal and normal (36). It has also been argued that sharing information and engaging patients to take responsibility for follow-up lead to improvements in the efficiency and effectiveness of the laboratory test process (e.g. decrease in test redundancy) (37). However, there are major obstacles which hinder the active involvement of consumers in test follow-up, including a lack of access to both clinical information and tools and checklists that help consumers understand and engage in their own care (33). Clinicians do not agree on the level and timing for consumers to have access to their test results (38); clinical unease may also be related to the impact that direct patient access to test results has on the traditional physician role and authority as the information gatekeeper (36). Concerns about patient anxiety, confusion and lack of expertise to appropriately interpret their test results have also divided physicians in their attitudes toward direct patient notification of test results (39, 40). This contrasts with the findings of a quasi-experimental pilot of a patient portal (41) in primary care practices across three regions in the United States which found that only a very small proportion of patients (1% to 8%) experienced confusion or worry when directly accessing their electronic notes, and 77% to 87% across the three sites reported that *Open Notes* helped them feel more in control of their care. All participating physicians also expressed a willingness to continue use of the portal. However, generalizability of the study was limited by sampling bias as all participants were volunteers who responded positively in their attitudes and expectations of the patient portal administered pre-study (41).

Evidence of patient portal use and impact has been, in general, limited and inconclusive (34, 35, 42, 43), as patient portals are relatively new technology and the health care community has only begun to understand how they can engage with this innovation to optimize care delivery, outcomes and patient engagement (44). A recent systematic review examining the effect of patient portals on clinical care concluded that there was insufficient evidence to determine whether patient portals had a positive, negative or neutral impact, although patient outcomes and satisfaction appeared positive when portals were integrated within a larger case management program (42). The review highlighted important gaps in the literature, advocating studies that look at context and implementation factors. Patient race and ethnicity, education level or literacy, and degree of comorbid conditions may influence portal use. The review identified disparities between patients who access portals and those who do not, and described instances of suboptimal patient attitudes of their worth. It suggests that increased acceptance will require attention to overcoming these disparities and addressing usability and patient-perceived value to engage certain populations that are not readily embracing personal health record systems (42).

CONCLUSION

Failure to follow up laboratory test results is a significant concern and a priority patient safety area. The issue of missed test results is multi-dimensional, and involves a number of interconnected issues encompassing both test result management practices and the systems involved in the process. An examination of existing research has revealed a lack of consistency in how test results are managed in the post-analytic laboratory testing phase,

including variations and ambiguity in policies regarding result notification procedures, identification of critical results, timeliness of results reporting, and acknowledgement of result receipt. Evidence of the impact of IT on improving the safety of the test result management process has also been inconsistent with few published evaluations to date. Electronic systems have yet to overcome issues with integration and hospital information silos, whilst partial uptake of the eMR has resulted in hybrid paper and electronic systems which may add to the risk of missed test results. Improving the safety of test result management through IT initiatives involves the establishment of a fully integrated electronic system that is implemented as a component of the solution alongside appropriate clinical and organizational governance elements. The success of IT interventions is intrinsically linked to resilient management arrangements, attention to clinical governance and commitment to robust evaluation practices which address issues with laboratory test management work practices and guidelines at the post-analytic testing phase. The empowerment and engagement of consumers in the management of their own healthcare data will further the move towards a culture which delivers reliable and safe patient care (32).

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