

Diagnostic Informatics: Its Role in Enhancing Clinical Excellence, Patient Safety and the Value of Care

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Abstract

Diagnostic informatics encompasses the role of information technology in key areas of the diagnostic testing (pathology and medical imaging) process, including the selection of appropriate tests and interpretation and follow-up of test results. We present three case studies employing diagnostic informatics methodologies to demonstrate their potential use and value in health services research: (1) Data analytics applied to diagnostic data linked with patient outcome data as a means of enhancing the monitoring of the quality and appropriateness of diagnostic test choices; (2) Business process modelling which can help to highlight healthcare processes in the diagnostic pathway as a means of improving safety and performance, and (3) Consumer involvement in the diagnostic research process to assist in the establishment of person-centred test result management systems. The case studies provide evidence of the role that diagnostic informatics can have in improving the quality and safety of patient care.

Keywords:

Diagnosis; Quality; Safety.

Introduction

Diagnostic testing, (laboratory medicine, anatomic pathology and medical imaging), is an essential part of healthcare systems. Diagnostic testing generates information that is crucial to the prevention, diagnosis, prognosis, stratification of risk, and treatment of disease [19]. Whilst diagnostic testing may account for a small (less than 5%) proportion of most hospital budgets, there is evidence to show that laboratory services influence 66% of clinical decision making [8]. Despite the importance of laboratory and medical imaging in clinical care, diagnostic testing and its impact on healthcare processes has been an overlooked area of health services research [2].

Diagnostic error involves the failure to either establish an accurate and timely explanation of a patient's diagnosis, or communicate the explanation to the patient [15]. Diagnostic error poses a serious risk to patient safety, with major studies showing that it contributes to approximately 10% of patient deaths and 6-17% of hospital adverse events [15].

Factors which can contribute to diagnostic error include: problems with collaboration and communication among clinicians, patients and their families; lack of infrastructure to support the diagnostic process; and inadequate attention to understanding the problem and its causes. [15]. Failures can occur across a number of areas in the diagnostic process beginning with a failure to engage with a patient, to order the

correct or appropriate test, follow up test results with the patient, or gather, integrate or interpret the necessary information, which can result in diagnostic errors [5]. Existing evidence has shown that over 40% of patients leave the hospital before all test results are finalised, 9.4% of which were deemed actionable by independent review [18]. The failure to follow-up test results can lead to missed diagnoses, delayed treatments, unnecessary healthcare utilisation and preventable harm [4]. Effective solutions must engage all stakeholders to arrive at decisions about who needs to receive the test results, how and when the results are communicated, and how they are acknowledged and acted upon [10].

We use the term *diagnostic informatics* to define the role that information technology plays in generating, gathering, integrating, interpreting, and communicating clinical test data and information. The diagnostic informatics landscape encompasses key areas of the diagnostic process, starting with the selection of the appropriate test/referral to address a clinical question, the quality and efficiency of the analytical process, and finally the interpretation, communication and follow-up of test results (including engagement with patients) and their impact on enhancing the value of care and patient outcomes (see Figure 1).

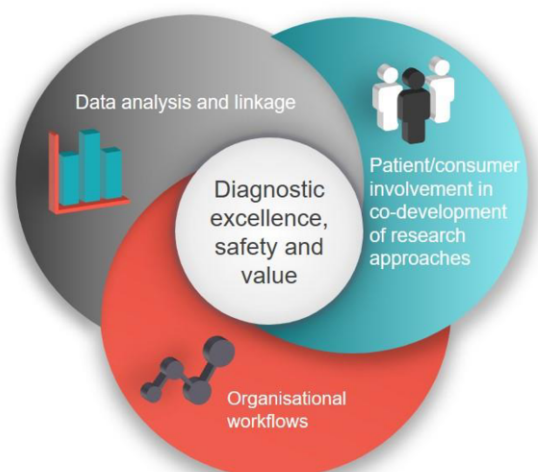


Figure 1. Diagnostic informatics landscape

Major areas of diagnostic informatics research can thus include the study of the choice of the appropriate laboratory/medical imaging request, the quality and efficiency of the analytical process, and the interpretation and follow-up of test results and their impact on patient care outcomes. Information and communication are a key component of the whole diagnostic process. The aim of this paper is to demonstrate how diagnostic informatics research can be used to inform decision-making and improve health outcomes. We outline three case studies to illustrate the application of diagnostic informatics research to the effectiveness of healthcare:

1. **Data analysis and linkage**, the impact of electronic ordering on the rate of potentially unnecessary repeat tests for older hospital inpatients.
2. **Organisational workflows**, the use of Business Process Model and Notation (BPMN) techniques to model and simulate crucial test result management and communication workflows in the diagnostic process.
3. **Patient/consumer involvement in the co-development of research approaches**, where consumers are partners in the development of the research process.

Case studies

Case study 1: Using data linkage to study repeat testing amongst older hospital patients

Aim

The aim of this study was to determine whether electronic provider ordering of laboratory could contribute to a reduction in potentially unnecessary repeat tests.

Methods

A retrospective study investigated 1,367,015 laboratory tests from 55,979 admissions of inpatients aged 80 years and over across three metropolitan hospitals from New South Wales, Australia, between 2014 and 2016. Data from the pathology service laboratory information system (Omnilab v9.4.2 SR10 updated to v11.1.1 SR23 in 2016), containing laboratory test information, and the patient administration system (Cerner PowerChart v2010.02.16), containing admission information, were linked by matching de-identified patient medical record number, gender, date of birth, hospital, and date-times of laboratory tests and admissions-discharges. The linked dataset was used in the analyses. The five most frequently utilised laboratory tests were identified and used to investigate repeat testing. The proportion of repeats were reported for electronic and paper-based test orders.

Results

The most frequently utilised laboratory tests for older inpatients aged 80 years and over were Electrolytes-Urea-Creatinine (EUC), Full Blood Count (FBC), Calcium-Magnesium-Phosphate (CaMgPhos), C-Reactive Protein (CRP), and Liver Function Test (LFT). The total number of tests by the ordering method (paper or electronic) are shown in Table 1. Among EUC, FBC, and LFT tests, there were more repeat tests among paper-based orders compared to electronic orders. The reverse was true for CaMgPhos and CRP tests. (Table 1).

Table 1. Proportion of tests which are repeats of a previously conducted test during a patient's admission, shown by paper-based or electronic ordering of tests

Test		Repeat Tests (%)	Total (n)
EUC	Paper	82.1	7,474
	Electronic	78.3	236,883
FBC	Paper	80.6	6,662
	Electronic	77.6	231,170
CaMgPhos	Paper	68.5	5,070
	Electronic	70.6	121,125
CRP	Paper	67.2	4,460
	Electronic	72.0	85,915
LFT	Paper	63.5	4,085

The repeat test interval (i.e., the time between successive repeat tests) was shorter for paper-based orders (examples of two of these tests, FBC and CRP, are shown in Figure 2). The difference in the cumulative proportions of repeat-tests between electronic and paper ordering became progressively smaller with increasing time between the repeat tests. Similar time-trends were observed for all of the top five tests.

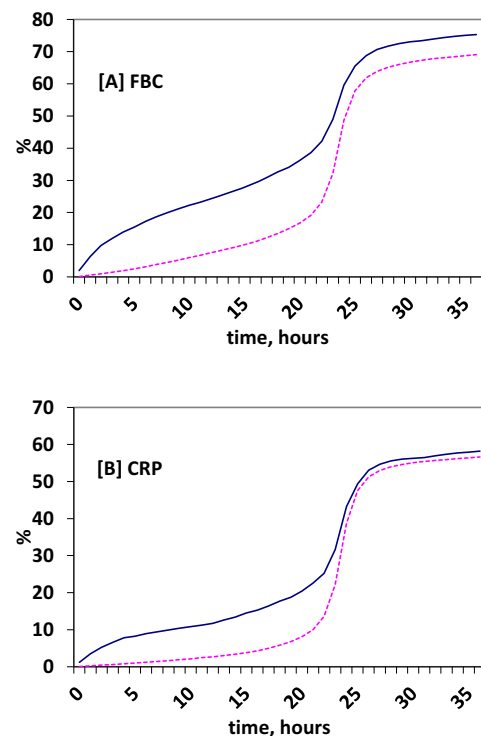


Figure 2. Cumulative proportions of repeat testing (horizontal axis) as a proportion of all test orders, by time (vertical axis; hours) for two analytes. Time intervals up to 36 hours shown. (A) Full blood count (FBC) (B) C-reactive protein (CRP) (Solid line=paper, dashed line=electronic)

Discussion

This study showed that paper-based orders were repeated with shorter time between tests when compared to electronic orders. This observation is similar to the study by Li *et al.* [14], which also found shorter time between repeat tests in paper-based test orders among paediatric intensive-care unit patients. Guidelines outline the minimum repeat testing intervals for a meaningful change to be observed as: 12 hours for EUC and FBC tests, 36 hours for LFT and CaMgPhos tests, and 24 hours for CRP tests [13]. Although repeats before the suggested minimum retest interval were observed for all tests, paper-based orders had a

Methods

In order to form an in-depth understanding of the context in which a system (e.g. electronic test result management) operates, we created a generic high-level process model for test-results management. The model was developed using the Business Process Model and Notation (BPMN) standard [16], a technique which uses structured analysis to diagrammatically represent business processes using standard symbols to provide insights into the complexity of healthcare processes. Models were created with the Bizagi Modeller freeware application.

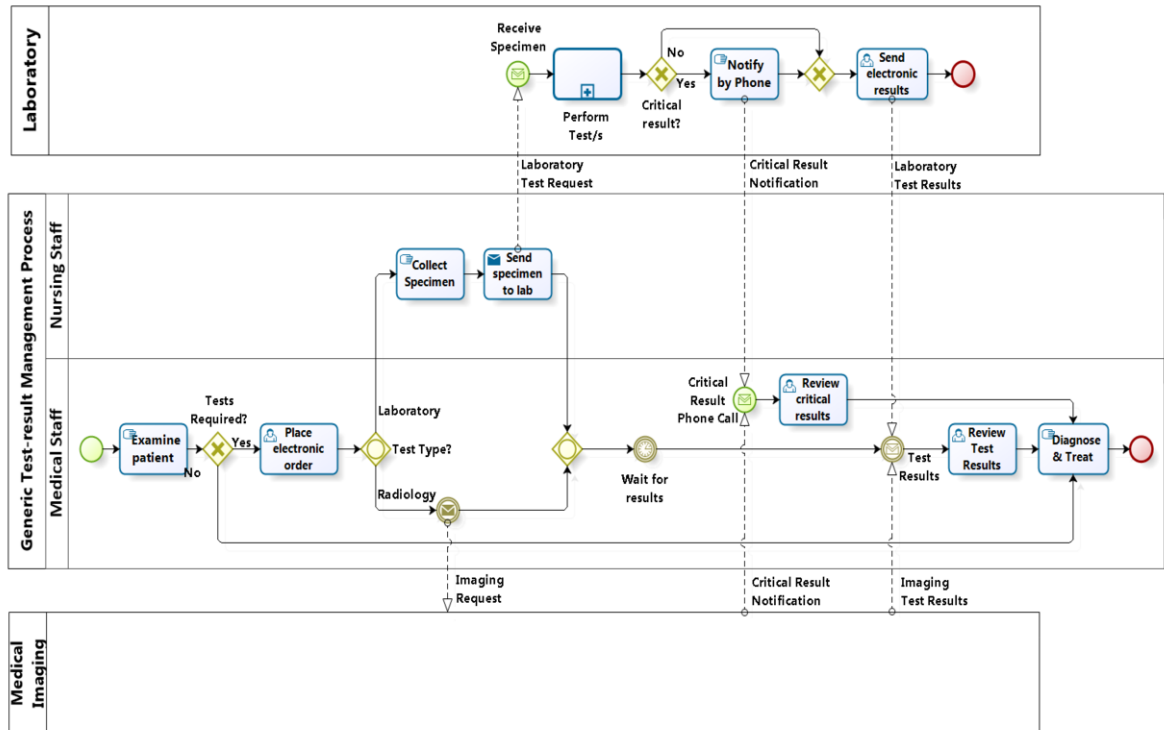


Figure 3. High-level process model for test results management developed using the Business Process Model and Notation (BPMN) standard

higher proportion of repeats with shorter intervals between tests when compared to electronic orders. Potential reasons for this difference as proposed by Li *et al.* included: (1) duplicate order alerts were provided in the electronic ordering system, notifying clinicians that an identical test had already been ordered within 24 hours for the same patient; and (2) clinicians could more easily see existing test orders and results in the electronic ordering system, thus leading to better self-regulation of ordering decisions [14]. This study provides valuable information on the differences between electronic and paper-based laboratory test orders on repeat tests. The findings suggest that electronic ordering can potentially reduce potentially unnecessary short-interval repetitions of tests.

Case study 2: Using Business Process Model and Notation (BPMN) techniques to model communication workflows in the diagnostic process

Aim

The aim of this study was to model communication workflows in the diagnostic process.

Results

The BPMN 2.0 standard allows processes to be represented using 'pools' (which can be divided into multiple 'lanes') to clearly identify which participants perform each 'activity'. This is demonstrated in Figure 3 as a high level process model. Three 'pools' are represented, namely the laboratory, medical imaging and a clinical department (represented by a medical staff 'lane' and a nursing staff 'lane'). Medical imaging is represented as a 'black box' i.e. only the message flows into and out of the pool are represented. In contrast, the laboratory and clinical department are modelled as 'white boxes' where all activities related to the process are visible. Following the arrows from the start (green circle event) of the process shows the sequence flow of activities (blue rectangles). The process pathway deviates based on the decision outcomes of questions posed at each gateway (yellow diamond).

The model in Figure 3 depicts the interaction between the pool containing the process of test result management by medical and nursing staff in a hospital test setting, with the pools of laboratory and medical imaging processes. Diamond shaped 'gateways' depict decisions in a process where one or more

alternative paths may be taken (e.g. is a test required, or is a result critical). Circular shaped 'events' (e.g. receiving a specimen, waiting on results, or calling through a critical result) can be used to indicate pertinent events in the process including (but not limited to) the start or end of a process, time related events or instances where messages are sent/received.

Discussion

The BPMN model highlights the value of using structured analysis to visualise healthcare processes. The technique allows proposed changes to processes to be modelled to determine their impact on existing workflows. As more data are collected, it will be possible to use BPMN to run theoretical process simulations.

BPMN enables business processes to be visually represented for ease of understanding and analysis. It can thus aid in enhancing the design and evaluation of evidence-based interventions, such as test result management tools/interventions (including electronic decision support aids) to consider how they impact on existing communication processes. This is particularly important for the laboratory notification of high-risk test results to the appropriate and responsible clinician, for immediate clinical action. Other clinical scenarios that have applied BPMN techniques include modelling clinical pathways [17; 20], for process improvement [1; 6; 20], for pre/post implementation workflows [9] and in genetic testing processes [6].

Case study 3: Engaging consumers in the analysis of diagnostic studies

Aim

The aim of this study is to involve consumers in the diagnostic informatics research process to assist in the establishment of person-centred test result management systems.

Methods

Consumer-focused research is a critical element in the development of person-focused care and shared decision making, which can contribute to improvements in the safety and quality of care. Health consumers can be defined as previous, current, or potential patients and their carers accessing healthcare services [11].

A core component of our research strategy was the establishment of a Consumer Reference Group which engaged consumers as partners in the research process. The value of research increases when consumer participants are familiar with how research is designed and undertaken [12]. Meaningful engagement of patients as partners in the research team requires the provision of adequate preparation and training for their research roles [3], which are achieved through capacity building activities and workshops. These hands-on learning activities ensure that the patient/consumer is involved in all phases of the research project.

Consumer representative organisations provided input during the development of our research proposal. We held a stakeholder forum to launch the project, where key recommendations were identified to address threats to patient safety resulting from failure to follow up test-results.

Informed by the stakeholder forum, we conducted semi-structured interviews with a diverse purposive sample of clinicians, radiology and laboratory staff, and patients within three NSW Emergency Departments in Australia. Consumer (including through interviews with patients) and clinician perspectives positively shaped the direction of the research study [7]. Interview results were used to compare current work

processes and gauge patients experience of the test-result management cycle. Re-iterative qualitative thematic analysis was conducted.

Results

Ten consumers formed a Consumer Reference Group (CRG) and ranked themes (previously identified in interview analysis) according to their chosen order of importance. The CRG then analysed (in an interactive qualitative data analysis workshop with members of our research team) the two topics with the highest ranking: 1) 'Transitions of care' (how and if results move from one healthcare setting to another including procedures related to patient discharge); and 2) 'Access' (whether and how a person can have access to their results).

Discussion

This innovative, consumer-driven approach engaged consumers/patients in inclusive research which provided rich insights into consumer experience and expectations in test-result management. Moving forward, consumers will be invited to contribute to the preparation of research publications, including contributions of intellectual content and critical revisions of the manuscript. Dissemination of the study findings via academic and policy publications will inform future directions for research in this area.



Figure 4. Consumer reference group and research team

Enhancing consumer contribution through inclusive research has required, and continues to necessitate, a rigorous, open, negotiated, and interactive process. Ensuring consumer/patient involvement during all phases of the project, including the inclusion of consumers in data analysis, represents a step towards research that is co-produced with consumers. Our consumer engagement strategy helps build capacity by assisting consumers in developing relevant research skills which will enable them to effectively navigate and inform outcomes-based research.

Conclusions

Diagnostic informatics requires an innovative and interdisciplinary approach to enhancing clinical excellence and quality care through the incorporation of outcomes-based approaches to monitoring and measuring diagnostic quality. These approaches include the building of robust communication workflows and evidence-based electronic decision support systems, and the establishment of shared decision-making through consumer/patient involvement.

The three case studies outlined above demonstrate how diagnostic informatics can be used to answer key research questions. In Case 1, linking diagnostic data with patient outcomes uncovered valuable information on differences

between electronic and paper-based laboratory test orders and the impact of electronic ordering on repeat tests. This evidence can contribute to the development of decision support tools to promote appropriate and safe test ordering. Case 2 demonstrated how business process modelling can be used to visualise healthcare processes in the diagnostic pathway, helping to optimise design through the identification of potential problem areas and the modelling (and simulation) of interventions. The ability to identify and explicate health care processes provides a valuable means of enhancing the design and implementation of digital systems, thus providing a valuable connection for the development of research tools identified in Case 1. Finally, Case 3 showcased the importance of consumer-driven analysis and interpretation of study findings, which allowed us to identify consumer-perceived barriers, leading to the development of person-centred, safe and effective test result management systems. A better understanding of diagnostic informatics as an integral part of the diagnostic process is crucial to the future quality and safety of patient care.

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