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Patient complaints as predictors of patient safety incidents

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Abstract

Patients remain an underused resource in efforts to improve quality and safety in healthcare, despite evidence that they can provide valuable insights into the care they receive. This study aimed to establish whether high-level patient safety incidents (HLIs) were predictable from preceding complaints, enabling complaints to be used to prevent HLIs. For this study complaints received from November 2011 through June 2012 and HLI incident reports from April through September 2012 were examined. Complaints and HLIs were categorised according to location or specialty and the themes they included. Data were analysed to look for correlations between number of complaints and HLIs in a given area. A qualitative analysis was carried out to determine whether any complaints contained information that, if acted upon earlier, could have prevented later HLIs. In the data a total of 52 complaints and 16 HLIs were included. No correlation was established between location of HLIs and complaints. Complaints commonly focused on staff attitude, diagnostic problems and delayed treatment. HLIs most often arose from failure to recognise a patient's deterioration and escalate appropriately or incorrect patient identification. Most HLIs were not preceded by similar complaints. However, in two instances complaints did signpost future HLIs. Patient complaints can highlight specific risks to patient safety and act as an early warning system. There is a need to devise reliable means of identifying the minority of complaints that do precede serious incidents.

Keywords

Patient experience, patient safety, communication, consumer engagement

Introduction

It is now nearly 15 years since the modern patient safety movement began in earnest with the publication of the Institute of Medicine's *To Err is Human*,¹ and more than a decade since calls were made to better involve the patient in safety efforts.² Despite this, patients and their families remain an underused resource in patient safety improvement. Patients and their families are present throughout an episode of care, unlike individual members of staff who go on and off shift. A lack of medical training means that patients and relatives have a different perception of events from hospital staff. This constancy coupled with an alternative perspective offers fresh insight into how care is delivered and a potentially rich source of information on safety issues. This information may be delivered in several ways, formally or informally, such as through complaints and compliments.

The importance of patients' and their families' perception of the care they receive in gauging quality and safety is being increasingly recognised³⁻⁵. In the English National Health System, several recent reports have called for more extensive use of patient complaints in safety improvement efforts,⁶ and patients' willingness to recommend a hospital

is now used in monitoring hospital performance through the "friends and family" test.⁷

Others have looked at patient complaints and their relationship to patient safety issues. It is clear that there is a relationship between the volume of complaints received and the quality and safety of care provided, both at the level of an organisation and of an individual provider.⁸⁻⁹ It is clear that members of the public can identify safety issues in health care¹⁰, including the ability to identify issues missed by other methods such as incident reports. Several researchers have already established a positive association between patient experience, clinical effectiveness and patient safety, presenting a sound case for the use of patients' feedback for the monitoring of quality in healthcare settings.¹¹ More recently published is a systematic review attempting to produce a "coding taxonomy" to standardise analysis and interpretation of patient complaints.¹² In response to a lack of standardisation of complaint coding, the authors propose a taxonomy based on multiple subcategories under seven headings grouped into three important domains (namely safety and quality of clinical care, management of healthcare organisations and problems in healthcare staff-

patient relationships including communication, caring and patient rights).

Despite recognition of a relationship between safety and quality of care, it remains unclear how complaints could be used prospectively in safety improvement. Previous studies have examined complaints *following* rather than *preceding* safety incidents. However, if patient safety incidents are preceded by complaints that warn about the issues leading to such incidents, then there is potential for the use of systematic analysis and monitoring of complaints as a form of early warning system to improve patient safety.

The objective of this study was therefore to determine whether high-level patient safety incidents (events occurring in a healthcare organisation that either cause or have the potential to cause harm) are predictable from preceding patient complaints and whether there is the potential to use complaints to prevent the occurrence of high-level patient safety incidents (HLIs).

Methods

Setting

The study took place in a publically funded specialist children's hospital in the English National Health Service. The hospital has 370 beds and provides both general and specialist medical and surgical pediatric services to the local and regional population with some national level super-specialist services.

Identification of Complaints

The hospital has a dedicated complaints department that receives and collates complaints from patients and their families. All complaints are recorded on a database and are categorised according to the hospital location or department in which the complaint originated and the nature of the complaint. The hospital also uses an electronic incident reporting system as a portal for hospital staff to report adverse events or near misses. Reports are received in a risk management department and recorded on a database according to the severity of the incident reported and the service area involved.¹³ Severity is scored on a scale from 1-5 as below:

Level 1 – low – minimal adverse effects requiring no or minimal intervention or unsatisfactory patient experience which can be resolved locally

Level 2 – minor – minor injury / illness requiring minor intervention or unsatisfactory patient experience with minimal short-term patient safety risk

Level 3 – moderate – moderate injury requiring professional intervention or mismanagement of patient care with short-term consequences

Level 4 – major – major injury resulting in long-term incapacity or disability of mismanagement of patient

care leading to long-term effects (potential or actual significant harm, e.g. admission to critical care unit)

Level 5 – catastrophic – leading to unexpected death or multiple permanent injuries or irreversible effects or totally unacceptable patient experience with potential impact on large number of patients (potential or actual serious harm, e.g. permanent disability or death)

The two databases were used to identify all complaints received from November 2011 through June 2012 and all level 4 (potential or actual significant harm, e.g. admission to a critical care area) and level 5 (potential or actual serious harm, e.g. permanent disability or death) safety incidents reported from April 2012 through September 2012. These time periods were chosen to give a significant but manageable number of complaints and HLIs and only include complaints and HLIs that had been fully investigated by the time of data collection (January 2013). A six month lead-in period for complaints and a three month run-out period for HLIs were used in order to identify incidents that were preceded by a related complaint. Only level 4 and 5 incidents were included in the study as lower level incidents, although more numerous, were not investigated by the organisation in detail. This meant that reports of these less significant incidents usually lacked sufficient detail to allow thematic analysis. Conversely, all level 4 and 5 incidents had been subjected to a detailed investigation, revealing the underlying causes and circumstances, making a thematic analysis and comparison to the content of complaints feasible. The study therefore focused its attention on the most serious of safety incidents: those leading to serious harm or even death.

Complaints and incident reports were read in detail by two authors (IY and HK) to check that their initial categorisation of level of harm and the location of the incident was correct. Complaints and HLIs were grouped according to the locations or department of the hospital in which they originated and compared to look for correlations between volume of complaints received and number of HLIs reported in a given location or department.

Qualitative Analysis

Two authors then independently coded the narrative sections of both complaints and incident reports (IY and HK), noting the apparent themes. Themes identified included staffing levels, communication issues and medication errors. The researchers then reviewed all reports together and agreement was reached on the themes present where there had been dispute.

Complaints within a certain area or service preceding an incident in the same area or service with the same or a

similar theme were examined in more detail to see if the complaint contained information that, if acted upon at the time of the complaint, could have prevented the incident from occurring. Incident reports were scrutinised in detail to search for potentially preventable or reversible problems that were also contained in a preceding complaint.

Results

Complaints and High-Level Patient Safety Incidents

A total of 16 HLIs (ten level 4 and six level 5) and 52 complaints were identified in the time periods studied. There was no correlation between the location of HLIs reported and the number of complaints lodged (Figure 1). Although the greatest number of HLIs (five) occurred in the Pediatric Intensive Care Unit, this department received only two complaints. Conversely, the most complaints were generated by the Trauma and Orthopedic (ten), Emergency (six) and Respiratory (five) departments; however, these clinical areas were associated with none, one and one HLI report, respectively.

Complaint Themes

The themes involved in complaints are shown in Table 1. The total number of themes is greater than the number of complaints, as several complaints covered more than one theme. There was a high level of agreement between the

two researchers coding the reports, with only two cases involving disagreement in the codes allocated. In both cases agreement was reached that the report contained multiple themes, and both researchers' codes were included.

Three themes were mentioned in over half of all complaints. The most common category was "staff attitude", mentioned in 15 complaints. These involved doctors on eight occasions, nurses in three and administrative staff in the other two. The next commonest theme in complaints was "diagnostic problems". These included missed and delayed diagnoses, sometimes where a secondary condition, such as an undescended testicle, was not picked up while the primary condition was being treated; in other cases there were delays in the investigation of the presenting complaint, usually whilst waiting for radiological investigations such as CT or MR scans. "Delays in treatment" was the third commonest theme, the vast majority of these being surgical cases where the operation was either delayed or postponed.

Clinical outcomes were only mentioned in five complaints, although some of these indicated serious events, including the potentially avoidable loss of a kidney and transfers to critical care areas. The remainder of the complaints related to the standard of nursing care (usually inadequate numbers of staff), the care environment (chiefly

Figure 1. Number of Complaints and High-Level Incidents by Department (CAMHS, Child and Adolescent Mental Health Service)

Table 1. Themes Included in Complaints (total 65, as some complaints contained multiple themes)

Theme of Complaint	Total No.
Attitude of staff	15
Diagnostic problems	13
Treatment delay	12
Administrative problems	6
Standard of nursing care	6
Care environment	6
Clinical outcome	5
Failure to coordinate care	2

dissatisfaction with catering and car parking facilities), administrative issues (such as difficulty contacting clinical teams or letters sent to incorrect addresses) and a failure to coordinate care between the acute and community sectors.

High-level Patient Safety Incident Themes

The themes of the HLIs reported are shown in Table 2. There was again a high level of agreement between researchers on the codes allocated. Each HLI was considered to contain only one theme, the only adjustments required on joint review being an agreed nomenclature for the themes.

Failure to recognise a deteriorating patient and escalate care appropriately was the commonest theme in HLIs, usually related to excessive workloads of the nursing staff.

This was followed by patient identification errors relating to patients having incorrect or missing wristbands or pathology samples being incorrectly labeled. Intra-operative errors included wrong site surgery and a retained swab. Delays in care either related to delays in arranging investigations or in coordinating care between sectors, for example the acute hospital setting and the community.

Relationship between Complaints and High-level Patient Safety Incidents

For the majority of HLIs, there were no preceding complaints on a similar theme, which might have been used to predict the later HLI. There were, however, two instances in which complaints highlighted issues which could have heralded later HLIs.

Table 2. Themes Included in High-Level Incidents (HLIs)

Theme of HLI	Total number
Failure of care escalation	5
Patient/sample identification failure	4
Prescribing errors	2
Intra-operative errors	2
Delays in care	2
Diagnostic error	1

One of these HLIs was reported following a member of the radiology department's administrative staff going on prolonged leave without a replacement. When a delay in a patient undergoing a CT scan was investigated, a total of 43 radiological investigation requests (mostly MRI scans) were found not to have been actioned. Although no actual patient harm occurred in this instance, it was classed as a level 4 HLI due to the potential for significant harm. This HLI was reported in August 2012. On examining complaints relating to delays in diagnosis or treatment, the HLI had been preceded by five complaints over the previous six months which were based on delayed or missed appointments for scans, prolonged actioning of results and missed or delayed follow-up. Three of these were investigation requests that should have been actioned by the member of staff on leave. Had the cause of these preceding complaints been investigated and acted upon at the time they were received, further delays and consequent risk could have been prevented.

Another instance where complaints preceded HLIs pertained to the monitoring of patients. In October 2011 and March 2012 complaints were received from parents who were concerned that the observation of their children during their inpatient stay had been sub-optimal due to inadequate numbers of nursing staff. This had contributed to delays in the escalation of care despite deterioration in the child's condition. Both complaints related to the same ward and to children with acute severe asthma. One led to admission to the intensive care unit. In April, July and August of 2012 (all after the two complaints described above), three level 5 HLIs were reported where the severity of a child's illness had not been recognised and acted on in a timely manner. Two of these cases occurred on the same ward as the preceding complaints. It is possible that, had the issues included in the complaints been acted upon more robustly, for example by increasing the availability of nursing staff on that ward and better implementation of the Early Warning Score system, the later HLIs and the harm they represent could have been prevented.

No other HLIs were preceded by complaints containing themes relating to the safety incident. However, a number of complaints clearly describe a significant patient safety incident, which did not lead to a staff-generated formal incident report. Examples of this include the complaints mentioned above describing the failure to monitor children with asthma. Another was a complaint about the failure to organise surgical intervention for a tumour in a timely fashion, which led to more extensive surgery than might otherwise have been necessary. Conversely, several HLIs involved factors that could not be realistically expected to be either noticed or reported by patients or their families. Examples of this include mislabeled blood sample bottles, failure to identify a non-accidental injury,

and prescribing errors that were identified before they impacted on the patient.

Discussion

Our study has demonstrated that some complaints received from patients and (in the context of a children's hospital) their families accurately predict future high-level patient safety incidents, all of which had the potential to cause harm, and some of which did cause harm. If these complaints had been identified when they were received, they would have alerted the hospital to issues which, if dealt with, may have prevented the later safety incident from occurring. However, these complaints were in the minority, and most complaints did not presage a serious incident. This makes it difficult for an organisation to know which complaints are the ones upon which they must act. We found no clear way to identify these critical complaints, although in each case where later harm arose, there were recurrent complaints from the same clinical area on the same theme, which may provide a starting point for devising ways to identify complaints requiring prompt remedial action.

Previous studies have found a correlation between the volume of complaints received by a care provider and the quality of care delivered.^{8,9} This is true at both the level of the institution and the individual provider.¹⁴ Other authors have also found that complaints, internal incident reports, and litigation can be used to triangulate information on quality and safety in a complementary way, with each information source providing different perspectives on the same issue and highlighting different areas of concern.¹⁵ Several studies suggest a correlation between complaints and serious adverse events, and there has been evidence demonstrating that information from complaints systems and health care litigation are greatly underexploited as a learning resource.^{5, 16, 17}

Our study adds a demonstration of the ability of complaints to *forewarn* of specific risks to patient safety and thus act as an early warning system rather than simply as a general marker of quality. This should not be surprising, given the constant presence of the patient and their family throughout their journey through the hospital system. This enables them to detect problems that may not be apparent to staff, for example at points of transition of care and in delays in care, particularly when the patient is not in hospital, for example waiting for an outpatient investigation.

Our study does have some limitations: it only covers a relatively short period of time and, despite the lead-in and run-out periods being included for data collection purposes, some connections between complaints and HLIs may not yet have happened and therefore might have been missed. It also uses only one source to identify

safety incidents, namely staff reporting. We know that staff reporting of safety incidents is subject to many limitations in terms of what is reported and by whom.¹⁸ The variation in numbers of incidents reported between departments is more likely to represent varying levels of risk awareness and different safety cultures in the departments than true differences in the numbers of incidents occurring. This makes it probable that other significant adverse events were not included. Indeed it is clear from the study that not all serious incidents end up being classified as HLIs. These factors make it likely that we are underestimating the potential for complaints to predict HLIs.

Using complaints prospectively as a form of early warning is not without its difficulties. The major problem is the volume of complaints received in comparison to the small proportion that do highlight issues leading to future safety incidents. In our retrospective study, only seven of 52 (13%) complaints could have been used to predict a later safety incident: the majority could not. It is possible that complaints might be deemed to have a stronger correlation with incidents if all incidents, including those of a less serious nature, were to be studied. Further work is needed to clarify the potential for complaints to act as an early warning system for patient safety at all levels.

In addition to this, there was no correlation between the number of complaints received and HLIs reported in a given service or area of the hospital, so simply concentrating attention on areas generating high levels of complaints is unlikely to help identify specific risks. Receiving, classifying and recording complaints is a labour intensive activity, making the use of a common taxonomy invaluable in these efforts.¹² Investigating and carrying out root-cause analysis for all complaints would be a major undertaking. Furthermore, choosing which complaints to investigate and act on is not necessarily straightforward, particularly as it is not easy to filter out which complaints are significant enough to warrant further actions or even a change in practice. A cluster of complaints on the same theme from the same clinical area should raise concerns. This is particularly true when the area in question is known to be under pressure, for example with understaffing or higher than expected numbers of minor incidents being reported. Complaints probably have the best chance of functioning effectively in improving patient safety when used alongside a number of other factors to triangulate on areas of increased risk needing urgent attention.

Other limitations to the use of complaints are the multiple steps involved in the process of complaining.¹⁹⁻²¹ A formal complaint tends to follow more than one negative experience and is often the final step in a patient or their family's attempts to communicate with a hospital system. There will likely have been opportunities to intervene before a complaint is lodged. Departments will also take different approaches to families raising concerns. Some

will seek to resolve issues as soon as possible in an attempt to avoid a formal complaint whereas others will advise and encourage families to complain formally. If opportunities to resolve issues are taken, a formal complaint will never arise and the episode will not have been detected by our study.

Furthermore, there are various reasons why patients might be motivated to put in a complaint, and some individuals may be more inclined to do so than others. Limiting factors include low literacy and numeracy, poor understanding of healthcare issues and medical conditions as well as sociodemographic factors such as culture, gender, age and education.²² Some patients will complain because they are anxious that another patient should not experience the same difficulties that they have, whilst others will complain out of anger or frustration.²³ Added to this is the difficulty some patients have in complaining, perhaps owing to communication problems or lack of knowledge surrounding the process of lodging a complaint. Patients might fear being labeled as "difficult" or have concerns that their future care will be compromised if they complain, or they might be unwilling to complain about a service that ultimately saved their life or that of a loved one, despite there being problems during their care.²⁴ Conversely, other confounding factors might include patients' disregard for or personal feelings towards a particular healthcare professional, leading them to be more likely to put in a complaint, regardless of whether it has any foundation. Whilst not wishing to promote stereotyping of different medical specialties, these factors may go some way to explaining the widely differing rates of complaints in different clinical areas. Finally, there is also variation in healthcare professionals' interest in promoting patient involvement which may determine which patients take on a more active role or make a complaint.²⁵ Organisational barriers such as a department or hospital's desire to avoid complaints or reluctance to be open might also present problems for potential future use of complaints to help reduce the number and severity of adverse incidents.

It has taken many years for the true value and potential of patient complaints to be recognised.²⁶ However, if we are to maximise their potential to improve patient safety, we need to change the way in which complaints are viewed. Instead of regarding a complaint as an undesirable event, hospitals need to welcome complaints and the information they can provide. This requires efforts to encourage feedback from patients and their families,²⁷⁻³⁰ making it easier for them to provide this, for example using electronic means and social media.³¹⁻³³ It will also necessitate changes to the way that complaints are examined, recorded and acted on.³⁴⁻³⁵ In our hospital, efforts have been made to become more responsive to the concerns raised by patients and their families. The Patient Advice and Liaison Service (PALS) acts as the patient's

advocate in supporting them to find resolutions for problems they have experienced. PALS works to bring patients and their families together with clinical and managerial staff in a constructive manner to resolve issues without the need for formal complaints.

It is difficult when faced with a large number of complaints to identify those in need of further investigation. However, in our study the complaints that did offer opportunities to intervene did have some common factors. Firstly, the departments concerned were known to be operating under a great deal of pressure during the period studied, with the loss of senior clinical staff. Secondly, the two issues involved (delays to investigations and ward monitoring) were both mentioned in multiple complaints. *Recurrent or repeated* complaints about the same theme from areas with other known risks for safety would thus seem to be the most reliable method of identifying the complaints that require further scrutiny and action to prevent an HLI.

Each complaint should not be viewed in isolation but in the context of other complaints or known issues. Using taxonomy when recording complaints would make such analysis and pattern recognition easier. If recurring themes in the same service area are identified, then this should prompt an investigation to be carried out and remedial actions to be undertaken as needed. Perhaps consideration should be given to restructuring institutions already in place in order to ensure that someone with the appropriate background, experience and authority can explore relevant issues raised by complaints so that escalation to adverse incidents can be actively pre-empted by dealing with any underlying reversible problems at source. Obviously, this will require additional resources, but if safety can be improved this should be seen as an investment rather than an expense as it has the potential to reduce future costs as well as improve the quality and safety of care.

Complaints should also be viewed in the context of other sources of information about potential safety issues and these sources could be used to focus attention on areas in need. Despite organisational barriers such as logistical and financial considerations or effects on public relations, the health service needs to be more receptive to complaints voiced by patients and relatives and willing to look into relevant issues raised, particularly if they are highlighting major problems which could escalate towards potentially preventable significant adverse incidents. Instead of merely discussing the need for openness and changes in attitude, there needs to be a shift in how hospitals deal with complaints and adverse incidents – not just in theory, but also in practice.

Conclusion

The complaints that hospitals receive from patients and their families have the potential to provide a form of early warning system that, if acted upon, could prevent serious safety incidents from occurring. Further work is required to identify complaints that may predict future incidents.

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