# Quali-quantitative analysis: a new model for evaluation of unusual cases in hospital performance?

# Erica Bell

### Abstract

This paper aims to provide hospital administrators and others making decisions about hospital error funding, as well as researchers, with information about what good hospital error research looks like. It offers a selective review of how the error literature has approached hospital error, which is used to develop five criteria for sound hospital error research. It also explores the potential for better hospital error research of quali-quantitative analysis (QQA), an innovative social sciences research method. In a context in which other methodologies all have their shortcomings, QQA appears to go some way toward meeting the five criteria for sound hospital error research. Ideally, QQA would be used in combination with other approaches to answer the kinds of questions that are important to hospital administrators when they are faced with high-stakes error evaluation situations.

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**CONSIDERABLE MEDIA AND POLICY** attention is given to the high stakes "unusual cases" (such as error and/or professional misconduct) in hospital service delivery. But how can hospital administrators and policy decision makers prevent such cases from happening in the first place? This paper describes the research methods that have been used to understand hospital error. It also explores the potential of a transdisciplinary research method (quali-quantitative analysis

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### What is known about the topic?

Hospital error research is a burgeoning field characterised by many different approaches, each with their own strengths and limitations for error management. Some of the most celebrated and resource-intensive investigations of hospital error have failed to meet basic research quality standards.

#### What does this paper add?

This paper defines five criteria for distinguishing sound hospital error research. It also explores the potential of an innovative transdisciplinary method (quali-quantitative analysis) for hospital error research.

#### What are the implications for practitioners?

Being able to commission good error research is a critical skill in hospital error management. This paper offers information and a tool in the form of the five criteria that hospital administrators can use together with other information about research standards and their own contexts, to make decisions about what research will meet their needs. It also describes a new information-rich research method (QQA) that hospital administrators can ask to be included in their hospital error research.

Research teams investigating errors in hospitals can also use this paper to explore research design possibilities.

[QQA]) for understanding hospital error and its causes, particularly in small-*N* studies.

Without sound practices for investigating and preventing errors, the most accurate and full error reporting systems are meaningless. Knowledge about what works and what doesn't in error research methodology is critical to managing error. Accordingly, this paper aims to provide information and criteria for deciding on the kind of study of hospital error likely to deliver sound evidence for policy and practice. The paper should also be of interest to researchers of hospital error interested in questions of research technique.

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This paper does not provide a systematic review of the hospital error literature, but identifies papers that are illustrative of the methodological issues. This is why there is not an extensive discussion of the content of the hospital error literature, including the admirable work on error modelling and error management in Reason's writings, except insofar as it illustrates the methodological practices of this particular research field.

# Methods

The paper has two parts: a consideration of methodological issues in hospital error research; and an exploration of QQA, an innovative research method. The first part uses discussion of methodological issues in the error literature to develop a set of criteria for quality hospital error research. This section explores the broad strengths and limitations for error analysis of common research approaches. For this part of the paper two kinds of PubMed searches were conducted on publications dated 2001–2006 using the search terms "hospital error", ie, searches of:

- 1160 abstracts and titles of publications to identify 210 possibly relevant papers
- 65 abstracts and titles of systematic reviews to identify 25 possibly relevant papers.

Bibliographies of all such possibly relevant papers were scanned to identify any other publications of interest. The contents pages of relevant journals were also scrutinised. The aim of these searches was not to offer an exhaustive formal review of hospital error research but rather to identify the "big" methodological issues characterising this literature, as a basis for defining what quality error research should be able to do.

The inclusion and exclusion of papers was informed by a broad definition of hospital error as "the failure of a planned action to be completed as intended ... or the use of a wrong plan to achieve an aim"; as well as "an unintended act, either of omission or commission, or an act that does not achieve its intended outcome"<sup>1,2</sup> in a hospital service setting. That is, the literature examined included both planned and unplanned acts. Since

this is a paper about research methodology in a particular area of research practice, the matter of definition was important only insofar as it allowed the researcher to include papers illustrative of the hospital error research. Accordingly, no attempt was made to argue for any particular definition of error, or canvass the range of distinctions relevant to understanding the anatomy of error, found most notably in Reason's work.<sup>3-6</sup> Publications outside this broad definition of hospital error but in the larger family to which hospital error belongs (hospital performance and quality assurance) were only included if they offered useful insights into methodological issues in hospital error research.

For the second part of the paper, a synthesis was made of the literature associated with the global research movement quali-quantitative analysis, more commonly called "qualitative comparative analysis". The former term is used in this paper because it emphasises for health audiences the fact that this is an approach that draws on both qualitative and quantitative techniques. The key elements of the QQA approach are explained in ways that suggest what a QQA-based study of hospital error would look like, and why it might go some way towards meeting the criteria developed for sound hospital error research. This discussion draws on aspects of papers taken from Charles Ragin's website at http://www.u.arizona.edu/~cragin/cragin/ as well as the linked website for methodologies for cross-case analysis and small-N studies: http://www.compasss.org.

# Findings

Five criteria were identified to distinguish sound hospital error research.

### Captures complex causality

The first criterion for hospital error research is that it engages complex causality. The analysis of hospital error is, by definition, the analysis of complex causality: each error exhibits its own complex array or configuration of client–service– environment elements. The need to examine all the circumstances surrounding the error has ethi-

cal, clinical, and policy imperatives. What is often expected of the analysis of hospital error is "the complete answer" to why that error occured.<sup>7</sup> In particular, for policy and practice, what is expected is identification of the fundamental underlying mechanism at work in producing the error. However, as Reason has demonstrated. errors at "the sharp end" involve both human fallibility and organisational failings, with the former being hard to predict, and the latter usually being present beforehand.<sup>1</sup> In short, some components of an error may not have a fundamental underlying, diagnosable, manageable mechanism as such, although there is much to be gained from studying human error, including associated cognitive mechanisms.<sup>8,9</sup> Reason's work also suggests that the more features present in a task, the more likely an omission; the greater the combinatorial complexity of a situation, the greater the likelihood of error.<sup>10</sup> Research practices can only seek to offer explanations that engage with such complexities. A key question then, in contracting research into hospital error, is: Will the research design atomise and simplify the causes of hospital error, or will it engage with its holistic, multifactoral, configurational nature?

## Appropriate for real-world cases

The second criterion for quality hospital error might be that it remains close to the "real-world" complexity of the cases being considered. This is one reason incident-based studies have had such currency in this field; mostly imported from nonhealth industry quality and safety approaches. Anaesthesia error research, beginning with the work of Cooper<sup>11</sup> using first hand interview data about safety-related incidents, has led the way. Team-based critical incidents analysis using workplace observations and interviews along with flow diagramming, scoring matrices, and decision trees for studying health care processes is the basis of prospective, qualitative analysis tools such as failure mode effects analysis (FMEA).<sup>12,13</sup> Root cause analysis (RCA) has also been used retrospectively to qualitatively analyse processes and identify events that led to an adverse client event.14 RCA has been used to engage clinicians

in structured information gathering focused on critical incident analysis identifying systemic causes of adverse events; these have had mixed success, especially if they are conducted on reductive scientific assumptions.<sup>15,16</sup> There have also been innovative applications of another industrial safety management prospective tool: sociotechnical probabilistic risk assessment (ST-PRA), which models combinations (unlike FMEA) of equipment failures, human error, atrisk behavioural norms, and recovery opportunities to proactively identify and prevent patent safety risk, using probabilistic, team-based information.14,17 Other applications and variants of such approaches characterise the error literature,<sup>18,19</sup> and Reason's work also includes a strong emphasis on task analysis in theorising and managing error.<sup>10</sup> However, this literature is still in search of an authentic, "universally applicable method"7 that will engage with the real-world complexity of error to identify multifactoral patterns or combinations of error conditions, including latent conditions.

# Evidence-based theorisation useful to policy and practice

The definition and classification of error and other safety-related events is linked to the capacity of hospitals to learn from, and prevent, such events.<sup>20</sup> Research into hospital error must be able to generate theoretically sophisticated distinctions between not only those errors with various clinical outcomes, but also "near misses" for which there may be no sequelae,<sup>12</sup> offering insights into these "potential errors" that are also a part of quality and safety practices.<sup>21,22</sup> It must also be able to handle situations where clients with multiple complicated conditions requiring risky procedures make the notion of preventable error highly problematic.<sup>23</sup>

This is not to argue for a single taxonomy of error. It is by way of agreeing with Reason that different error classification systems must serve different needs.<sup>1</sup> Accordingly, error research ought to generate theoretical constructs useful to particular contexts. We cannot afford to be complacent about the performance of hospital error

research in relation to this criterion. Studies of medication error are by far the biggest focus of the hospital error literature and the area where one would expect to see commensurate attention to useful theorisation. Studies of medication history "discrepancies", which include errors of considerable clinical importance, most often involve analyses of diverse qualitative records: the hospital doctor's admission chart notes versus the pharmacist's chart notes, as well as interviews, standardised semi-structured data collection forms, results of inspections of medication vials, records of observational studies, results of expert panelling, and so on. Systematic review of such studies suggests that they too often suffer from a lack of precision in the classification of cases: for example, a failure to distinguish between unintentional discrepancies and intentional therapeutic changes that arise from discussions with ordering doctors.24

Yet the error literature includes taxonomies of error such as the National Quality Forumendorsed Joint Commission on Accreditation of Healthcare Organizations Patient Safety Net Taxonomy,<sup>25</sup> intended for use across different contexts. There are also taxonomies for particular aspects of practice such as medication error<sup>26,27</sup> or particular kinds of errors within particular areas of practice such as anaesthetic human errors.28 The work of Reason provides a sound theoretical base for conceptualising and managing error.<sup>1,6,7,9,10,29-36</sup> However, the need remains for research that can better contribute to the theorisation of hospital error in ways that are useful to policy and practice. The results of The Royal College of Anaesthetists' analyses of critical incidents demonstrates that categorising is not the same as identifying causation.<sup>7</sup> An issue for error research is when pre-set categories for the analysis of error drive the study of events, rather than the events driving the categories for analysis.

Learning from medical error, actual or potential, is by its nature a task of translation of concrete in situ detail into larger concepts to do with systems development. That is, organisational-managerial directions based on notions of what are the correct and incorrect ways of performing clinical tasks need to be developed from analysis of the specifics of in-situ clinical and other events - no simple task. Accounts of the use of such techniques as RCA<sup>16</sup> suggest that hospital administrators need better evaluation approaches for including clinicians in the task of theorising hospital error, that is, evaluation methods that help make collaborative, openended, non-reductive, but also systematic, evidence-based translations from the detail of cases to the abstraction of rules and procedures. Poor theorisation of error creates a vicious circle: without theorisation of error research can be hard to do, but good research also helps theorise error. Hospital administrators and those contracting error research can ask researchers to demonstrate how their research designs are conducive to making theoretical distinctions in ways that are useful to policy and practice.

### Contextual authenticity

This is about having information that reflects the synergistic, combinatorial nature of error conditions. Its importance can be seen in the evaluation of interventions to prevent error, many of which are multifaceted and multidisciplinary:<sup>37</sup> They include interacting combinations of error reporting tools, education and training interventions aimed at changing cultures, and any number and manner of systems redesign elements.38,39 Accordingly, any number and combination of changes in staffing, training, equipment, supervision, or latent environmental factors may be at work synergistically to produce the effects being observed.<sup>25</sup> Evaluations of the efficacy of error detection systems<sup>40</sup> and error recovery strategies<sup>41</sup> form another important but often neglected area of enquiry. These involve evaluation of complex interacting components of systems that have synergistic effects, including between the type of error detected and the error detection mode.<sup>40</sup> Some kinds of interventions, such as the use of barcode technology in preventing medication dispensing errors, may ostensibly be suited to quantitative variable-oriented approaches to capture intervention effects on specific error rates.<sup>42</sup> However, they have their

limits for more holistic small-*N* studies involving complex interventions.

Often the synergistic, combinatorial information needed from error research must also be longitudinal, because quality and safety practices are about learning from a complex past. For example, the trauma error literature includes longitudinal, institution-based analyses of errors using a range of written information — such as daily and annual trauma registry abstracts and reports, morbidity and mortality reports, and hospital quality assurance reports.<sup>25</sup> Such research calls for methodologies that document the history of particular configurations of error conditions and outcomes.

Another aspect of contextual authenticity in error research is the idea that such research should engage systematically with diversity. Heterogeneous, as opposed to homogenising, information relevant to settings, or groups, or even individual cases is required. Without diversityoriented research information there are problems for policy and practice follow-on. Whatever else it is, good error research is diversity-oriented. For example, research into medication errors involving particular groups such as HIV-infected clients,<sup>43</sup> or paediatric inpatients,<sup>44</sup> suggests the urgent need for more nuanced, multidisciplinary, case-based analyses that better capture the related theoretical and practical complexities.

Diversity-oriented hospital error research also needs to capture the roles of institutional setting and culture. There has been some important work, particularly by Reason and colleagues, in defining "team errors", "organisational pathologies", and "the vulnerable system syndrome": the different kinds of organisational characteristics, learnings, and strategies that make such vulnerabilitities more or less likely, and related safety paradoxes.<sup>9,29,34,35,45-48</sup> However, analysis of what represents an error-prone organisation is very much in its infancy in the hospital error literature. The role of "organisational culture" and variously termed forms of "cultural censorship" in the obscuration of error is given some attention in the literature.49 Reason has pointed out that some organisations can anticipate the worst and be

equipped to deal with it; organisational culture has an important role to help individuals remember to be uneasy.9 Accordingly, hospital error research needs to capture relationships between knowledge, attitudes and beliefs of different professions, and procedures, as well as other features of the institutional setting, and disclosure and reporting behaviours.<sup>50-52</sup> It must also provide information about what disclosure procedures would work best in what particular settings, such as emergency settings.<sup>53</sup> A safe organisational culture requires that we develop an effective reporting culture.<sup>33</sup> The hospital error literature has often used qualitative approaches to explore such matters<sup>54</sup> and to develop practical and theoretical understandings of, for example, error recovery strategies in use in emergency settings,<sup>55</sup> or physicians' reactions to "medical mishaps"56 which quantitative research might position as suffering from a lack of generalisability and empirical rigour. Mixed method approaches using aspects of both qualitative and quantitative data collection techniques, with multivariate data analyses to produce the findings, are common in error disclosure literature. 52,53,55-57 The diversity demands of error research into hospital "error acknowledgement" have prompted calls to supplement quantitative macro studies with smallscale qualitative studies.58

It seems that "big Q" quantitative analyses work well with large datasets: in analyses of the accuracy of computerised medication error reporting systems in big hospitals,<sup>59</sup> in drawing inferences from large cross-hospital databases of error reports provided by standardised computerised error reporting systems;<sup>60</sup> or in developing inferences about medication error and organisational characteristics (such as facility bed capacity) from large-*N* longitudinal databases of reporting errors.<sup>27</sup> It is only when hospital "error acknowledgement" research has to engage with small-*N* populations that its limitations become obvious, as, for example, in the neglected area of research into error in rural and remote hospital settings.

Organisational setting can be about features defined by culture or geography: but in hospital error research it is also defined by clinical

practice. Hospital error research methodologies need to be diversity-oriented in the sense that they can engage with the clinical features of different error contexts. The ophthalmic error literature includes analyses of clinical notes to identify "near miss" errors that involve confusing left with right eyes,<sup>61</sup> with potentially serious implications such as wrong-site surgery, but many errors have a clinical anatomy beyond the ken of laypersons. For example, the surgery error literature includes analyses of arterial switch operations that involve multivariable baseline models to analyse the role of human factors after adjustment for patient-specific variables.<sup>62</sup> The study of errors and near misses in cardiac operations involves sophisticated integration of the human, patient, clinical procedural and other factors.<sup>63</sup> The point about the importance of clinical context is an obvious one that has subtle implications for error research methodology and error management. For example, approaches to paediatric surgical errors often rely on approaches to quality assurance and error reduction similar to those used in general surgical pathology, though they present very specific diagnostic challenges - one big reason they suffer from a lack of theoretical clarity about the nature of clinical diagnostic errors 64

### Information for decision making

The fifth and final criterion for hospital error research is that it should produce information in a form close to the practical judgements about error management that must be made. There are calls for studies that produce information in a form that does not focus on individual error but on systems development.65-67 However, very little research has been done modelling the form of information that would be useful to error management. Information can be relevant but it may not be useable if it requires too great an effort of translation into the real-world contexts of hospital error management. In the absence of systematic investigations of this issue, it seems likely, from the previous discussion, that hospital error management requires information in a form that reflects combinations of client–service–environment error conditions and outcomes, and the judgments about these that must be made.

We live in times that may see mandatory state-based error reporting systems that would permit ever more quantitative, variable-driven approaches involving large databases.<sup>68</sup> Editorials in prestigious American medical journals suggest that the American system has not moved far enough since the watershed 1999 report To err is human by the US Institute of Medicine, pointing to events in America that facilitate the aggregation of large cross-institutional databases.<sup>69</sup> Yet it seems not enough questions are being asked about the methodological engine room of the health error titanic. One fundamental question is: Can we have confidence that traditional quantitative measurement approaches will deliver what error management needs?

Pawson and Tilley have argued that much research has disappointed policy decision makers in the late 20th century.<sup>70</sup> Some have argued that this problem of social relevance is related to the valorisation of traditional quantitative methods and the rise of a new measurement culture.71 Traditional quantitative methods suffer from weaknesses that may limit their usefulness for holistic understandings of hospital error and for studying systems generally: "somatic reductionism", an "exaggerated search for certainty", atomisation of the research subject, narrow and often "inflexible criteria for truth", and a host of errors to do with restricting "ways of searching for truth"72-75 that may be important to understanding the kind of paradoxes of safety identified by Reason.<sup>34</sup> As Runciman has noted, "... values must often be reduced to numbers using measurement techniques which may only capture one facet of a multi-faceted phenomenon."<sup>76</sup> (p. 146)

Traditional quantitative methods rest on having many more cases than there are variables — Good and Hardin suggest that if m observations are needed to determine a univariate regression then at least mn observations are needed to appropriately observe and represent a model with n variables.<sup>77</sup> As we have seen, hospital error is complex and multifaceted — there will be many variables to consider. Some of the fundamental assumptions required by statistical studies are not sound in risk reduction approaches. For example, Brady and Seawright have discussed the potential failure of a key assumption required by controlled or randomised experiments, one which implies that each supposedly identical treatment actually is identical and that each unit is a separate, isolated possible world unaffected by what is happening to the other units.<sup>78</sup>

It is not the purpose of this paper to enter into a polemic for and against quantitative or qualitative research. This polemic is already well represented in the health literature. Quantitative techniques may have good internal validity but often lack external validity for complex service settings. Qualitative techniques may capture the ecological complexity of services but are often criticised for lacking reliability and generalisability, especially in health research cultures enamoured of randomised controlled treatment studies.<sup>79-81</sup>

The foregoing review suggests that, while hospital error research appears as one of the more methodologically innovative areas of health research, it has been innovative in taking scientific reductionist techniques from the industrial quality and safety literature and applying them to health contexts. There is evidence of qualitative "thematic" studies and traditional content analysis, but these are generally uninformed by even traditional research techniques from the social sciences and humanities designed to explore complex social and cultural phenomena. That is, there is a general lack of application of wellknown techniques such as ethnography (the use of simple observational techniques in error studies has been taken to mean that study is therefore "ethnographic"), hermeneutics, social reproduction, or critical discourse theory - though a study by Iedema et al shows how important discourse analysis can be to critiquing industrybased techniques such as RCA.<sup>15</sup> Ensuring the quality of qualitative methodology is a problem for hospital error research, not least because of its high-stakes nature. Even the most celebrated enquiries into "suboptimal clinical practice" have

failed to conform to basic standards of sound qualitative research.<sup>82</sup>

Reason and colleagues, in making their strong contribution as error theorists and error management analysts rather than research methodologists, have emphasised the value of both quantitative and qualitative research techniques.<sup>63</sup> As Runciman has noted, many incident reporting studies typically use complementary techniques from both these traditions.<sup>76</sup> However, mixed effects approaches can suffer from the limitations of both traditions without transcending them. What about the more innovative transdisciplinary social sciences methodologies that haven't yet been applied to hospital error? The second part of this paper explores one of the more promising of these.

# Quali-quantitative analysis and its potential for hospital error research

This section suggests the potential of QQA for hospital error research. It avoids a technical discussion of the method, and instead focuses on what a QQA-based investigation of hospital error might look like, and why such an approach might meet the criteria for sound hospital error research developed previously.

The term QQA refers to a global research movement that is often dated from the 1987 publication of a seminal work on cross-case analysis, *The comparative method*, by Charles Ragin.<sup>83</sup> The methods of this approach are given in a large body of writings by Ragin and his colleagues,<sup>83-88</sup> though his 2000 book *Fuzzy-set social science* represents the fullest and latest statement of the approach.<sup>86</sup> Ragin's transdisciplinary method has been applied across many different disciplines, yet has scarcely been used to meet health challenges, and cannot be found in hospital error research.

A QQA study of hospital error would not prevent researchers from using a combination of data collection methods to assemble information about cases, including any kind of sampling technique, provided these were defensible. What QQA offers is a systematic tool for case-based

analysis: comparing information about cases considered as configurations to identify their similarities and differences.<sup>86</sup> QQA is about enriching explanations of causal complexity; the generalisability of such explanations can be built into the research design through appropriate sampling techniques. For Ragin, traditional quantitative methods of analysis are homogenising, with the focus on dependent and independent variables obscuring the diversity that is only apparent through consideration of cases as configurations.<sup>86,89,90</sup> The actual research information produced by QQA is in the form of set-theoretic relationships or a form of verbal causal argument expressing set relationships between things. In a hospital error application of Ragin's methods, such information could be developed by focussing on combinations of client-service-environment elements to deliver systemic causal information.

# QQA stages

The three basic stages in a QQA-based hospital error study are described below. Imagine that a team has been assembled at a hospital to retrospectively investigate the errors that have occurred in that hospital over the past year. What follows is a thumbnail sketch of the QQA-based approach, and the related research outcomes.

The first stage would involve selection of cases (through chosen methods), and the creation of "property spaces" that define these cases as types according to their different characteristics. Any kind of chosen error classifications system and error conceptual system could be applied to the development of these characteristics, in the context of a lack of industry standards for error categorisations. Put simply, the error investigation team would develop a "truth table" or crosstabulation of the characteristics of cases in terms of the presence or absence of their attributes. Later "fuzzy set" versions of Ragin's method involve tabulation of degrees of membership of cases to particular categories (causal conditions and outcomes).<sup>90</sup> The cases so tabulated are then minimised to shorthand expressions of the occurrence of combinations, ie, a "logical equation" for the outcome being considered, with more than one logical equation quite possible for the same outcome.<sup>84</sup> Software developed specifically for applications of the QQA method<sup>91</sup> would be used at this and subsequent stages.

The outcome of this first stage would be classifications of types of error and their possibly causally-related conditions, built through iterative processes of checking and cross-checking the tabulation of cases. These would be highly consensual and team-based to make the research process rigorous and open to scrutiny. They would also be informed by available research and procedural literature offering error classifications.

The second stage would be conducting tests of "necessity" and "sufficiency" of possible causal conditions. In a QQA-based error study, a cause is necessary if all instances of the outcome occur with the cause, and a cause is sufficient if all instances of the cause occur with the outcome. Under the later "fuzzy set" version of QQA, this stage would involve use of probabilistic criteria underpinned by Bayesian probability theory,<sup>86</sup> and would also be developed consensually by the error research team. The outcome would be information about which causes are necessary for particular errors, and which are sufficient.

The third stage of a QQA error study is evaluation of the results of these tests, in ways that interrogate any homogenising assumptions. Again, this would be done consensually, and might involve examination of findings of the study with those set-theoretic relationships that can be generated from a literature review, ie, subjecting published literature to QQA analysis to develop set-theoretic statements that can be compared with the study results. Alternatively, the error research team might examine a random sample of cases at the hospital where the outcomes (errors) have not been observed, subjecting these cases to a QQA analysis to see what configurations of conditions do or don't typify such cases, and whether they support or do not support the conclusions drawn from the primary study.

The outcome of this third stage of a QQA-based error study would be testing the truth of the

findings by seeking out opportunities for their falsification, and consequent development of deeper theoretical and in-practice understandings of errors at that hospital (at least).

These stages model a retrospective study, but QQA could also be used prospectively, to model kinds of errors and their causal relationships; it offers a structured, systematic approach to gathering clinical and other judgments about the nature and likelihood of potential errors. That is, the critical point about QQA for hospital error research is that it is a systematic approach to transdisciplinary research practice that does not make assumptions about how error works. In contrast, such methods as FMEA (failure modes and effects analysis) and ST-PRA (sociotechnical probabilistic risk assessment) are industrialdriven risk evaluation methods that are not valuefree in the sense that they are informed by error philosophies that drive, for example in ST-PRA, the construction of "fault trees". This is one major reason such tools have had their problems in health care contexts.92

A QQA approach seems to go some way towards meeting the criteria for sound error research methodologies described earlier. That is, it would:

- engage with complex causality through the consideration of cases as configurations, retaining the multifactoral nature of hospital error;
- keep the research team close to the "real-world" complexity of cases through iterative techniques for classifying cases, developing conclusions, and testing of homogenising assumptions that require researchers to look at the data rather than generate *P* values using "point and click" quantitative recipes;
- theorise cases from systematic classifications of them built from consensual and accountable judgements about their features, tested and retested using diverse potentially falsifying techniques to add new dimensions to theoretical and in-practice learnings;
- capture contextual authenticity through an emphasis on the synergistic, combinatorial nature of error, that is, its non-linearity, synergy, and equifinality (multiple configurations);<sup>93</sup>

and engage with diversity, not only by taking case configurations as the unit of analysis (thereby capturing setting or practice specific information), but also by offering a method for intensive study of small-*N* situations;

produce useable information for policy and practice by delivering verified shorthand statements about different types of error conditions and outcomes.

# **Discussion and conclusions**

This paper has referred to many useful, high quality studies in the error literature. However, it has also suggested that large-*N*, variable-driven research that emphasises linearity, additive effects, and unifinality (one configuration) in understanding causality in hospital events often fails to capture the non-linearity, synergy, and equifinality (multiple configurations)<sup>93</sup> important to understanding and learning from hospital error. Qualitative studies have difficulty laying claim to generalisability and empirical rigour. Mixed methods studies seem bound by the limitations of both traditions, and lack a systematic base for integrating them.

Analysis of hospital error requires new transdisciplinary research methods. Quali-quantitative analysis has potential as a research approach for exploring the complex multi-dimensional nature of causality in small-N situations. It offers potential as a means of addressing areas of neglect in the literature, such as error management in rural and remote hospitals. This paper has suggested that QQA goes some way towards meeting a set of criteria for sound hospital error research. In fact, it is likely that QQA in combination with other techniques of analysis would satisfy these criteria more fully; Ragin emphasises the value of a complementary mind-set.<sup>83,94</sup>

Although QQA has limitations, as a small-*N* method it offers a novel blend of quantitative and qualitative techniques that can begin to answer the kinds of questions that are important to hospital administrators when they are faced with high-stakes error evaluation situations: What were the full range of pre-conditions present in

the error case? Do those pre-conditions still exist in this hospital? What can be learnt from errors to help me better identify and manage high-risk configurations of client, service, and environmental elements?

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# **Competing interests**

The author declares that she has no competing interests.

## References

- 1 Reason J. Safety in the operating theatre Part 2: Human error and organisational failure. *Qual Saf Health Care* 2005; 14: 56-60.
- 2 Medstat Group. Implementation Planning Study for the Integration of Medical Event Reporting Input and Data Structure for Reporting to AHRQ, CDC, CMS, and FDA. Santa Barbara: Centre for Quality Improvement and Patient Safety and Agency for Healthcare Research and Quality, 2002.
- 3 National Patient Safety Agency. Building a memory: preventing harm, reducing risks and improving patient safety. London: National Patient Safety Agency, 2005.
- 4 Runciman W, Merry A, Tito F. Error, blame and the law in health care - an antipodean perspective. *Ann Int Med* 2003; 138: 974-9.
- 5 Auditor General Victoria. Managing patient safety in public hospitals. Melbourne: Department of Human Services Victoria, 2005.
- 6 Reason J. Understanding adverse events: human factors. *Qual Health Care* 1995; 4: 80-9.
- 7 Arnstein F. Catalogue of human error. *Br J Anaesth* 1997; 79: 645-56.
- 8 Takano K, Reason J. Psychological biases affecting human cognitive performance in dynamic operational environments. *J Nucl Sci Technol* 1999; 36: 1041-51.
- 9 Reason J. Human error: models and management *BMJ* 2000; 320: 768-70.
- 10 Reason J. Combating omission errors through task analysis and good reminders. *Qual Saf Health Care* 2002; 11: 40-44.
- 11 Cooper JB, Newbower RS, Long CD, McPeek B. Preventable anesthesia mishaps: a study of human factors. 1978. *Qual Saf Health Care* 2002; 11: 277-82.
- 12 Day S, Dalto J, Fox J, Turpin M. Failure mode and effects analysis as a performance improvement tool in trauma. *J Trauma Nurs* 2006; 13: 111-17.

- 13 Tilburg C, Leistikow I, Rademaker C, et al. A health care failure mode and effect analysis: a useful proactive risk analysis in a pediatric oncology ward. *Qual Saf Health Care* 2006; 15: 58-64.
- 14 Marx DA, Slonim AD. Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modelling in health care. *Qual Saf Health Care* 2003; 12 Suppl 2: ii33-8.
- 15 ledema RAM, Jorm C, Long D, et al. Turning the medical gaze in upon itself: root cause analysis and the investigation of clinical error. *Soc Sci Med* 2006; 62: 1605-15.
- 16 ledema RAM, Jorm C, Braithwaite J. A root cause analysis of clinical error: confronting the disjunction between formal rules and situated clinical activity. *Soc Sci Med* 2006; 63: 1201-12.
- 17 Lane R, Stanton NA, Harrison D. Applying hierarchical task analysis to medication administration errors. *Applied Ergonomics* 2006; 37: 669-79.
- 18 Lyons M, Adams S, Woloshynowych M, Vincent C. Human reliability analysis in healthcare: a review of techniques. *Int J Risk Saf Med* 2004; 16: 223-37.
- 19 Horsky J, Kuperman GJ, Patel VL. Comprehensive analysis of a medication dosing error related to CPOE. J Am Med Inform Assoc 2005; 12: 377-82.
- 20 Tamuz M, Thomas EJ, Franchois KE. Defining and classifying medical error: lessons for patient safety reporting systems. *Qual Saf Health Care* 2004; 13: 13-20.
- 21 Stump L. Re-engineering the medication error-reporting process: removing the blame and improving the system. *Am J Health Syst Pharm* 2000; 57(suppl 4): S10-17.
- 22 Balas MC, Scott LD, Rogers AE. Frequency and type of errors and near errors reported by critical care nurses. *Can J Nurs Res* 2006; 38: 24-41.
- 23 Hofer TP, Hayward RA. Are bad outcomes from questionable clinical decisions preventable medical errors? A case of cascade iatrogenesis. *Ann Intern Med* 2002; 137(5 Part 1): 327-33.
- 24 Tam VC, Knowles SR, Cornish PL, et al. Frequency, type and clinical importance of medication history errors at admission to hospital: a systematic review. *CMAJ* 2005; 173: 510-5.
- 25 Gruen R, Jurkovich G, McIntyre L, et al. Patterns of errors contributing to trauma mortality: lessons learned from 2,594 deaths. *Ann Surg* 2006; 244: 371-80.
- 26 Phillips J, Beam S, Brinker A, et al. Retrospective analysis of mortalities associated with medication errors. *Am J Health Syst Pharm* 2001; 58: 1835-41.
- 27 Goeckner B, Gladu M, Bradley J. Differences in perioperative medication errors with regard to organization characteristics. *Aorn J* 2006; 83: 351-2, 355-62, 365-8.

- 28 Marcus R. Human factors in pediatric anesthesia incidents. *Paediatr Anaesth* 2006; 16: 242-50.
- 29 Reason J. Human error. Cambridge, UK: Cambridge University Press, 1990.
- 30 Reason J. Understanding adverse effects: the human factor. In: Vincent C, editor. Clinical risk management: enhancing patient safety. London: BMJ Books, 2001: 6-30.
- 31 Reason J. The contribution of latent human failures to the breakdown of complex systems. *Philos Trans R Soc Lond B Biol Sci* 1990; 327: 475-84.
- 32 Reason J. A systems approach to organizational error. *Ergonomics* 1995; 38: 1708-21.
- 33 Reason J. Achieving a safe culture: theory and practice. Work Stress 1998; 12: 293-306.
- 34 Reason J. Safety paradoxes and safety culture. *Inj Control Saf Promot* 2000; 7: 3-14.
- 35 Reason J. Beyond the organisational accident: the need for "error wisdom" on the frontline. *Qual Saf Health Care* 2004; 13(suppl 2): ii28-33.
- 36 Reason J, Carthey J, Leval M. Diagnosing "vulnerable system syndrome": an essential prerequisite to effective risk management. *Qual Health Care* 2001; 10(Suppl II): ii21-ii25.
- 37 Sim T, Joyner J. A multidisciplinary team approach to reducing medication variance. *Jt Comm J Qual Improv* 2002; 28: 403-9.
- 38 McFadden KL, Stock GN, Gowen CR, 3rd. Exploring strategies for reducing hospital errors. J Healthc Manag 2006; 51: 123-35; discussion 136.
- 39 Barber N, Rawlins M, Dean Franklin B. Reducing prescribing error: competence, control, and culture. *Qual Saf Health Care* 2003; 12 Suppl 1: i29-32.
- 40 Nyssen AS, Blavier A. Error detection: a study in anaesthesia. *Ergonomics* 2006; 49(5-6): 517-25.
- 41 Kanse L, van der Schaaf TW, Vrijland ND, van Mierlo H. Error recovery in a hospital pharmacy. *Ergonomics* 2006; 49(5-6): 503-16.
- 42 Poon EG, Cina JL, Churchill W, Patel N, et al. Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy. *Ann Intern Med* 2006; 145: 426-434.
- 43 Rastegar DA, Knight AM, Monolakis JS. Antiretroviral medication errors among hospitalized patients with HIV infection. *Clin Infect Dis* 2006; 43: 933-8.
- 44 Kaushal R, Bates DW, Landrigan C, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA* 2001; 285: 2114-20.
- 45 Reason JT, Carthey J, de Leval MR. Diagnosing "vulnerable system syndrome": an essential prerequisite to effective risk management. *Qual Health Care* 2001; 10 Suppl 2: ii21-5.

- 46 Spear SJ, Schmidhofer M. Ambiguity and workarounds as contributors to medical error. *Ann Intern Med* 2005; 142: 627-30.
- 47 Carthey J, de Leval MR, Reason JT. Institutional resilience in healthcare systems. *Qual Health Care* 2001; 10: 29-32.
- 48 Sasou K, Reason T. Team errors: definition and taxonomy. *Reliability Engineering and System Safety* 1999; 65: 1-9.
- 49 Hart E, Hazelgrove J. Understanding the organisational context for adverse events in the health services: the role of cultural censorship. *Qual Health Care* 2001; 10: 257-62.
- 50 Handler SM, Nace DA, Studenski SA, Fridsma DB. Medication error reporting in long term care. *Am J Geriatr Pharmacother* 2004; 2: 190-6.
- 51 Potylycki M, Kimmel S, Ritter M, et al. Non punitive medication error reporting: 3-year findings from one hospital's primum non nocere initiative. *J Nurs Adm* 2006; 36: 370-6.
- 52 Hobgood C, Weiner B, Tamayo-Sarver JH. Medical error identification, disclosure, and reporting: do emergency medicine provider groups differ? *Acad Emerg Med* 2006; 13: 443-51.
- 53 Stokes SL, Wu AW, Pronovost PJ. Ethical and practical aspects of disclosing adverse events in the Emergency Department. *Emergency Medicine Clinics of North America* 2006; 24: 703-14.
- 54 Armitage G. Drug errors, qualitative research and some reflections on ethics. *J Clin Nurs* 2005; 14(7): 869-75.
- 55 Henneman EA, Blank FS, Gawlinski A, Henneman PL. Strategies used by nurses to recover medical errors in an academic emergency department setting. *Appl Nurs Res* 2006; 19(2): 70-7.
- 56 Engel KG, Rosenthal M, Sutcliffe KM. Residents' responses to medical error: coping, learning, and change. *Acad Med* 2006; 81(1): 86-93.
- 57 Cleopas A, Villaveces A, Charvet A, et al. Patient assessments of a hypothetical medical error: effects of health outcome, disclosure, and staff responsiveness. *Qual Saf Health Care* 2006; 15: 136-41.
- 58 Rosenthal MM, Cornett PL, Sutcliffe KM, Lewton E. Beyond the medical record: other modes of error acknowledgement. J Gen Intern Med 2005; 20: 404-9.
- 59 Miller MR, Clark JS, Lehmann CU. Computer based medication error reporting: insights and implications. *Qual Saf Health Care* 2006; 15: 208-13.
- 60 Milch CE, Salem DN, Pauker SG, et al. Voluntary electronic reporting of medical errors and adverse events. An analysis of 92,547 reports from 26 acute care hospitals. *J Gen Intern Med* 2006; 21: 165-70.

- 61 Elghrably I, Fraser SG. An observational study of laterality errors in a sample of clinical records. *Eye* 2006 Sep 15; [Epub ahead of print].
- 62 de Leval MR, Carthey J, Wright DJ, et al. Human factors and cardic surgery: a multicenter study. *J Thorac Cardiovasc Surg* 2000; 119: 661-72.
- 63 Carthey J, de Leval MR, Reason JT. The human factor in cardiac surgery: errors and near misses in a high technology medical domain. *Ann Thorac Surg* 2001; 72: 300-05.
- 64 Coffin CM. Pediatric surgical pathology: pitfalls and strategies for error prevention. *Arch Pathol Lab Med* 2006; 130: 610-2.
- 65 Conlon P, Gartner G. A jury of our PEERS. *Health Prog* 2006; 87: 39-42.
- 66 Force MV, Deering L, Hubbe J, et al. Effective strategies to increase reporting of medication errors in hospitals. *J Nurs Adm* 2006; 36: 34-41.
- 67 Crone KG, Muraski MB, Skeel JD, et al. Between a rock and a hard place: disclosing medical errors. *Clin Chem* 2006; 52: 1809-14.
- 68 Wood KE, Nash DB. Mandatory state-based errorreporting systems: current and future prospects. *Am J Med Qual* 2005; 20: 297-303.
- 69 Minogue WF. Error reporting: patient safety's weakest link. *Am J Med Qual* 2005; 20: 295-6.
- 70 Pawson R, Tilley N. Realistic evaluation. London: Sage Publications, 1997.
- 71 Porter T. Trust in numbers: the pursuit of objectivity in science and public life. Princeton: Princeton University Press, 1995.
- 72 Alonso Y. The biopsychosocial model in medical research: the evolution of the health concept over the last two decades. *Patient Educ Couns* 2004; 53: 239-44.
- 73 Skurvydas A. New methodology in biomedical science: methodological errors in classical science. *Medicina (Kaunas)* 2005; 41: 7-16.
- 74 Tarlier D. Mediating the meaning of evidence through epistemological diversity. *Nurs Ing* 2005; 12: 126-34.
- 75 Hyman MA. The evolution of research: meeting the needs of systems medicine, part 1. *Altern Ther Health Med* 2006; 12: 10-1.
- 76 Runciman WB. Qualitative versus quantitative research balancing cost, yield and feasibility. *Qual Saf Health Care* 2002; 11: 146-7.
- 77 Good P, Hardin J. Common errors in statistics (and how to avoid them). Hoboken, New Jersey: Wiley, 2003.
- 78 Brady H, Seawright J. Framing social enquiry: from models of causation to statistically based causal inference. Annual Meeting of the American Political Science Association; 2004 Aug 28. American Political Science Association.

- 79 Benson K, Hartz A. A comparison of observational studies and randomised, controlled trials. N Engl J Med 2000: 1878-86.
- 80 Concato J, Shah N, Horwitz R. Randomized, controlled trials, observational studies, and the hierarchy of research designs. *N Engl J Med* 2006; 342: 1887-92.
- 81 Pocock S, Elbourne D. Randomized trials or observational tribulations? N Engl J Med 2000; 342: 1907-09.
- 82 Faunce TA, Bolsin SN. Three Australian whistleblowing sagas: lessons for internal and external regulation. *Med J Aust* 2004; 181: 44-7.
- 83 Ragin C. The comparative method. Los Angeles: University of California Press, 1987.
- 84 Ragin C. Using qualitative comparative analysis to study configurations. In: Kelle U, editor. Computeraided qualitative data analysis: theory, methods and practice. London: Sage Publications, 1995.
- 85 Ragin C. Turning the tables: how case-oriented research challenges variable-oriented research. *Comparative Social Research* 1997; 16: 27-42.
- 86 Ragin C. Fuzzy-set social science. Chicago: The University of Chicago Press, 2000.
- 87 Ragin CC. Using qualitative comparative analysis to study causal complexity. *Health Serv Res* 1999; 34(5 Part II): 1225-1239.
- 88 Ragin CC. Fuzzy-set analysis of necessary conditions. In: Goertz G, Starr H, editors. Necessary conditions: theory, methodology and applications. Lanham, Maryland: Rowman and Littleford, 2002.
- 89 Ragin C. Set relations in social research: evaluating their consistency and coverage. *Political Analysis* 2006; 14: 291-310.
- 90 Ragin C. The limitations of net effects in thinking. In: Grimm H, Rihoux B, editors. Innovative comparative methods for policy analysis. New York: Springer, 2006: 13-41.
- 91 Ragin C, Drass K, Davey S. Fuzzy-set/qualitative comparative analysis 2.0. Tucson, Arizona: Department of Sociology, University of Arizona, 2006. Available at: http://www.u.arizona.edu/~cragin/fsQCA/ software.shtml (accessed Feb 2007).
- 92 Marx DA, Slonim AD. Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modelling in health care. *Qual Saf Health Care* 2003; 12 Suppl 2: 33ii-38.
- 93 Fiss PC. Towards a set-theoretic approach for studying organisational configurations. Kingston, Canada: Queen's University, 2005.
- 94 Ragin CC. Introduction to qualitative comparative analysis. In: Janoski T, Hicks AM, editors. The comparative political economy of the welfare state. Cambridge: Cambridge University Press, 1994.
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