

case has the hallmarks of a gap that arises through change and, undetected and unappreciated, participates in catastrophe. To plan effective change, it is essential to know how people detect and understand the new gaps produced by change.

### Gaps as tools for research

The enormous complexity of health care is a daunting obstacle to those trying to study safety systematically. Everything, it seems, is connected to everything else, and every thread of action and cause is wound into a great Gordian knot. The pursuit of gaps as a research target is a means of cutting through the knot. Gaps themselves mark the areas of vulnerability and show the mechanism by which complexity flows through health care to individual patients. Pursuing gaps is a method that allows technical work to guide both research into and improvement in safety.

Future work on gaps might be approached in three different ways. Firstly, a catalogue of gaps would yield a map of many of the complexities and hazards in work at the sharp end of systems. Secondly, tracing out the details of how practitioners anticipate, detect, and bridge gaps within the context of actual practice would provide the outlines of what constitutes practitioners' expertise. Thirdly, discovering how gaps are created by organisational and institutional change would link the processes of management to the real demands confronting practitioners. Together, these explorations of gaps can provide a coherent, usable view of patient

safety, a kind of landscape that can be used to identify future safety problems, anticipate the impact of change, and measure progress.

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## Detecting and reporting medical errors: why the dilemma?

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Errors in medicine are a major cause of harm to patients. Though there is little controversy among clinicians about the importance of accurate and reliable clinical data and the imperative of correct diagnosis, that commitment to exactitude dissolves when errors happen. Then, clinicians and managers may behave in a way that limits investigation. We often use the subjectivity and complexity of medicine to rationalise and justify error.

Many factors explain this reluctance to investigate and to accept error. If we are to design effective systems to prevent errors from affecting patients, we must understand these factors. The following case study illustrates the concerns, fears, and practical problems that we faced in conducting an evaluation of misinterpreted prostate biopsies.

### The problem and the decision

In February 1999 a urologist at the Sturdy Memorial Hospital in Attleboro, Massachusetts, requested a retrospective review of a 1996 biopsy result because of the patient's clinical course and the results of a biopsy in 1999. The review revealed that the 1996 report was incorrect. The urologist and pathologist (neither of whom was responsible for the 1996 reading) implemented appropriate management for the affected patient.

### Summary points

Detection and prevention of errors are obvious goals for any organisation

In reality, however, medicine's approach to error has been limited and inadequate

Motivational factors, both real and perceived, that influence how errors in medicine are handled must be identified, discussed, and changed if the "patient safety movement" is to succeed

Our experience with misread prostate biopsies illustrates the concerns, fears, and practical problems encountered when dealing with the discovery of medical errors

When they discovered a second misread prostate biopsy from the same period the urologist and pathologist became concerned that the frequency of these errors was higher than "expected." Fears about malpractice suits and damaged reputations emerged. The potential of a bigger problem meant risk to more patients but also greater risk to the physicians whether

they confronted or ignored the problem. Were more patients at risk because of errors? If this was not addressed now but discovered later, would the risk of lawsuits and dishonour be greater? The clinicians sought the advice of the medical director.

As a clinician, the medical director's instincts were to place the patients first and investigate the problem. As an administrator, he worried that even the suggestion of errors would damage the reputations of those involved before any investigation was completed. Those risks would be magnified if the media inflamed the story, and regulatory agencies had histories of being highly accusatory. The hospital board of managers might not support an investigation because of the bad publicity. An investigation might result in a colleague being disciplined for findings that might be controversial or even within the normal range.

Ultimately, the medical director thought that all the prostate biopsies performed during 1995-7, the period of tenure of the clinicians associated with the two errors, should be reviewed. For this, the support of the hospital president was critical. The president also recognised the importance of addressing this issue for patients, physicians, hospital staff, and the community. Not being emotionally burdened by a belief in medical infallibility, the president felt less conflict than the clinicians about how to proceed: she worried about the impact of negative publicity, not least on the hospital's financial performance, but for her the only option was to ensure that no other patients were at risk.

## The review

The current chief of pathology reviewed specimens from all 279 prostate biopsies performed in 1995-7 and identified 18 additional misread cases. Our fears of a larger problem had been confirmed. During the review we wondered about any requirements to report to regulatory agencies. Our lawyers told us we had no obligation to report this kind of error. The involvement of the agencies at other hospitals often resulted in media attention, and both the agencies and the media often seemed accusatory, putting the hospital on the defensive and requiring diversion of time and resources to managing the adverse publicity. On the other hand, in all the cases of which we were aware, the hostile attitudes of regulators and media seemed to stem from hospitals not admitting their error and the agencies learning about the problems from others. We decided to report our initial findings to the Department of Public Health and the Board of Registration in Medicine. We thought we were taking the correct action to protect patients and that we would be at less risk and possibly in more control if we initiated this action.

In total 20 of the 279 prostate biopsies from 1995-7 were in error. The urologists caring for these 20 patients were told of the changes in the biopsy interpretations, and it was agreed that the urologists would contact each patient and recommend appropriate evaluation and treatment. Although they agreed with this plan, the urologists were worried about potential lawsuits, damage to their reputations, and the stress of difficult meetings with the patients and their families. Several meetings occurred between the medical director and the urologists to ensure that the follow-

up was occurring and to support the urologists. The medical director attended some of the meetings with patients.

When the process of notifying the patients started, the hospital president realised that questions about the validity of other biopsies would be raised even though there was no clinical evidence to raise such concern. She thought that all should be reviewed. There was no precedent for such an extensive review. Moreover, in considering it, all the earlier dilemmas resurfaced. We weighed the risk of further negative publicity, the lack of standards for "acceptable rates of error," costs, time required to complete the review, and lack of clinical indications to justify such a review. Finally, we decided to do the review to ensure no more patients were at risk, to maintain professional and public confidence in our department of pathology, and to affirm our commitment to patients.

About 6000 biopsies would have to be reread, and we needed help. Inquiries to the professional pathology bodies were disappointing: not only did we receive little assistance, but we were routinely asked why we wanted

to expose more errors. Were we really interested in protecting patients or just exposing physicians? To do the review we wanted pathologists who were board certified and had extensive clinical experience, and we wanted to limit the number of reviewers to only a few. We eventually contracted with two pathologists, who were willing to help us only if they remained anonymous. Our project was apparently so controversial in pathology circles that they would not openly acknowledge that they were helping us.

### Communicating with our community

In the meantime the president and other senior managers were communicating with the medical staff, hospital staff, the board of managers, and the community at large. The public relations “nightmare” began when a potential plaintiff’s attorney called the local newspaper. That resulted in an intense flurry of newspaper and television coverage. Much of the coverage in the electronic media was inaccurate and inflammatory, and it became difficult to work with the electronic media. Reporters without medical expertise often unintentionally misled the public because of the complexities of the issues and the lack of time to understand and explain. Moreover, they seemed to believe wholeheartedly in the mythology of infallibility that professionals have promoted.

We discovered that communicating directly with our community was our best communications strategy. We sent several written updates to the hospital family (medical, administrative, and other staff of the hospital and hospital corporation members) and mailed 88 000 letters to patients explaining what was happening. The public respected us for this effort and maintained their confidence in the hospital and physicians.

After the review of the prostate biopsies was complete and the rereading of the 6000 other biopsies had started, officials from the Department of Public Health and Healthcare Financing Administration visited us. Their initial statements were clearly critical and potentially punitive. The officials spent more than four days reviewing not only the amended pathology

reports but also our quality assurance programmes, minutes of meetings, laboratory certifications, technical procedures in the laboratory, equipment repair logs, and the methods of reporting variance and incidents. In all discussions our wish to be clear and honest and to provide the required information was tempered by the need to protect patient confidentiality and confidential information from peer review of physicians’ performance (such information is protected by law from disclosure for legal purposes).

Initially, our refusal to divulge confidential information was interpreted by the officials as reluctance to cooperate. Yet our lawyers were clear on the importance of protecting confidential information from peer review. Eventually, after many hours’ discussion, attitudes on both sides adjusted, and we were able to respect each other’s needs. The officials found no deficiencies in our pathology and laboratory operations.

Throughout this process, there was no measurable negative impact on the hospital’s workload or financial performance. Nor were the urologists adversely affected. Our openness reaffirmed our reputation for putting our patients first. Our patients were much more accepting of the inevitability of human error than we were, and they were impressed that we were doing something about it. Our experience suggests that putting patients first is also a good business strategy when addressing errors.

### A positive experience

Why are we so reluctant to own up to errors in medicine? If we expect perfection, error is humiliating and potentially costly. But expecting perfection is foolish; we must move away from this false and unattainable standard. If we don’t accept the inevitability of our own errors and those of everyone on the healthcare team we cannot honestly put patients first. We also risk becoming the villains in the growing “patient safety movement” instead of leaders in it. Our experience of admitting errors at Sturdy has taught us how positive an experience it can be.

#### *A memorable patient*

##### Realising why

Thud th-thud thud. I was awake—4 30 am Saturday morning—great. The shells were landing closer than normal and the ground was vibrating in sympathy. The intensity rose and fell like a good symphony and finally ceased, the ground exhausted. All was quiet; I finally rolled over to resume my slumber.

“Hurry hurry, you come quick.” I ran—the casualties, delayed by a three hour tractor ride, were slowly arriving. Most had died along the way, but one young lad, his arm and leg completely shattered by shrapnel, was conscious and groaning. Adrenaline pumping, trauma protocols whizzing around, lines going in, rushing to theatre, and the smell of fear everywhere. This was exciting; this was why I was here wasn’t it?

The rest of the day was predictably busy with more injured people dribbling in, but as late afternoon arrived tranquillity descended, interrupted only by distant shells landing like rumbling thunder. We wandered back for an overdue breakfast and began to see the chaos emerging. Streets busy with displaced people, possessions laden onto carts, bicycles and backs—nobody

would be troubling the hospital—there were more important things to do than be ill.

The calm remained; the night, exhausted by its previous endeavours, was silent. Morning came and I anticipated a quieter day with some relish. “Hurry hurry, you come quick.” I ran—more casualties, I wondered. That didn’t make sense—but no, instead a 2 year old boy just about to arrest, dehydrated, with a respiratory rate of 75. We worked hard and fast but the enormity of his problems and the inadequate facilities combined fatally. As he died I found myself looking at his anguished mother almost in anger. Why had she delayed so long?

The reason slowly emerged as the truth distilled from yesterday’s excitement. Twenty four hours of fraught fleeing with an already sick child, a night under a tree, too scared to leave until dawn, torrential rains, a further journey on foot, and now a mother’s grief. Only then did I begin to learn why I was really there.

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