Editorial

Clinical incidents and risk management—a public health issue

The rail, plane and ferry disasters during the final months of 1999 accompanied by many fatalities and injuries are tragic reminders of the risky nature of human endeavour (railway accidents in Paddington, London October; Sydney, Australia, December; aircraft accident Nantucket, New York, November; and ferry disaster Norway, November 1999). Such tragedies are examples of recurring worldwide but rare accidents in diverse industrial settings. They may have multiple causes involving many people at different levels within their respective organisations.[1] Are accidents of this scale and impact a feature of the health care industry? The answer is yes. Recognition that such large scale accidents may occur is a fairly recent phenomenon, although their occurrence is not always obvious. Two important and substantive epidemiological studies indicate that the prevalence of iatrogenic harm (injury from care itself recorded as an adverse event) may range between 3.7% (the Harvard Medical Practice Study in the United States (US))[2] to almost 16% (the Quality in Australian Health Care Study)[3] in hospitalised patients. In the absence of data from other countries including the United Kingdom it may be assumed that similar rates apply to other Western health systems. However, it is unusual for a health care service to generate in a single time limited event large numbers of iatrogenically harmed hospitalised patients. Typically a number of patients may be affected over a longer time period but remain unrecognised for many months or years. The recent Bristol Royal Infirmary tragedy involving paediatric cardiac surgery is exemplar.[4]

Despite the lack of a simple explanation for such wide difference in rates between the two studies they are indicative of the enormous scale of iatrogenic harm in secondary care services. There is weak evidence of similar but perhaps less frequent occurrences in the primary and community services.[5] Extrapolation of the above rates to whole populations suggests a significant burden is placed on their respective healthcare systems, and that the direct healthcare cost burden of dealing with such injury is equal to all other forms of injury put together.[6 7] Furthermore, half of these events are preventable and one quarter associated with expensive litigation itself placing a further cost burden on limited healthcare resources.[2] For example recent awards for brain damaged patients are achieving record settlements in the UK in excess of £4 million.[8] Most high settlement cases arising in the hospital sector occur within the field of obstetrics. The level of injury highlighted by the above studies cannot be ignored. Its occurrence, preventability and cost to individual patient and their relatives and to both commissioners and providers of health care constitutes a major public health and societal concern in Western health care systems. What must be done?

These concerns have spurred the health care sector both in the UK and elsewhere to manage this risk. Risk management activities are being introduced. An example is the introduction of critical (or clinical) incident reporting where practitioners are expected to report occurrences that resulted or almost result (near miss) in patient injury. Evidence suggests that 96% of UK National Health Service (NHS) Trusts have systems for reporting clinical incidents, though there are great variations in what they expect to be reported and how they use the data.[9] Ideally such activity should be evidence based and cost effective. Unfortunately this has not been clearly established in respect of critical incident reporting.

Incident reporting has its origins within the aviation industry where it has been seen to be successful in reducing the number of aviation incidents.[7] To date its transference to the health care sector has been less obviously successful. Indeed studies of implementation in US and UK hospitals have shown poor levels of reporting.[10 11]

Anonymous reporting to an independent body at a regional or national level may encourage reporting in the short-term.[12] Such an approach may be comparatively cheap, universally applicable and a medico-legally safe source of relevant and specific information particularly of rarer causes of iatrogenic harm, and should also be of value educationally.[13] National registers will have their place.[14] However, analysis of small samples of incidents obtained through incomplete reporting may overlook problems pertaining to local circumstances. On the other hand complete coverage especially of more common and perhaps less serious events would overwhelm a national or regional scheme. I would suggest that trusts still require the establishment of local schemes to detect and investigate such incidents.

The desire to apportion blame and the threat of litigation, which itself helps underpin a blame culture, are reasons given for failure to implement critical incident reporting.[15] Unfortunately the blame culture will continue to dog implementation in the NHS while there is a climate of fear of dismissal and suspension among both managers and doctors at all levels should adverse events lead directly to scrutiny by the Department of Health and or the General Medical Council. A fear that I think results from the deep seated blame culture that pervades our social systems. If progress is to be made this state of affairs must be tackled. Anecdotal evidence suggests that a blame free culture in a hospital setting and successful implementation of critical incident reporting is achievable.[16]

Reporting incidents alone is not enough. They have to be investigated so that lessons may be learnt and appropriate preventive action identified and implemented. Subsequent review of the steps taken should form part of a trust's audit cycle and good clinical governance. The best and most cost effective methods of investigating critical incidents whether in an individual Trust or at a regional or national level have yet to be identified. The current vogue in investigating incidents generally is to look at the whole organisation using system failure analysis accompanied by a standard in depth interview of all the parties involved.[17] Valuable lessons on how to investigate incidents may also be gleaned from the experience of national confidential enquiries such as CEPOD and other enquiries into large scale disasters including the current Bristol inquiry although such enquiries can be both relatively slow and expensive.

Despite these difficulties critical incident reporting ought to be implemented not least because it is both a pragmatic and an intuitively acceptable approach. It makes sense in the absence of clear alternative and cost effective systems for identifying adverse events. Or at least until there are comprehensive means of electronic surveillance based on electronic patient records available in all trusts. Critical incident reporting can provide good qualitative

research data that complement other evidence and would be useful in effecting improvements in health care delivery and organisation.[18] Alone however it is unlikely to provide a sound quantitative basis to assess the incidence or trends in adverse clinical events or the impact of preventive steps. The two epidemiological studies of adverse events reported above were both costly and time consuming and appear beyond the resources of UK research funding bodies. However, without baseline prevalence or incidence data it is difficult to assess whether intervention or preventive activities are being successful. Strategies such as building a concurrent programme of research and evaluation alongside implementation and service development that engages clinicians and managers and operates across several Trusts should help these processes.

The research agenda in this area is potentially vast. Many international and national research commentators active in this field perceive a need for much more quantitative, qualitative and collaborative research. Common national or even international definitions and classification systems for clinical incidents would be advantageous. There is a need at both national and regional level to focus on areas of priority and establish carefully designed multi-centre studies.[18] There may be a number of ways of identifying priority areas. A focus on medical negligence claims would highlight obstetric claims. However a focus on clinical incidents could shift the emphasis to adverse drug events.[19] Attention in the UK on clinical indicators may shift the focus to wound infections for example.

Studies should extend across health regions and be collaborative in nature. Research(ers) should be contracted to give something back to the service if it receives the necessary funding and support. Otherwise non-teaching Trusts will continue to struggle to implement these schemes if they are not encouraged to play a part in the research. Evidence based change in my view is more likely if those expected to change are engaged early in the research activity. Research programmes should be built around willing Trusts across the country. The way forward may be for each Region to lead on a specific topic for research as part of an agreed nationwide agenda for collaborative research in this field. Regions should be part of the development of a national research agenda. NHS regions have a responsibility to lead, encourage and support such activity not withstanding the national priorities for research. Indeed the prevention of iatrogenic harm ought to be a priority, especially as resources are deflected from other priorities because of a failure to carry out such prevention adequately.

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