

## Ethics oversight of quality campaign institutions

When are quality improvement initiatives 'research' and how can institutions assure that those that are not, are conducted in an ethically sound manner? A systematic assessment of current ethics review committee (Institutional Review Board) practices was conducted by a survey of a random sample of the 3000 US institutions that participated in the IHI 100 000 Lives initiative. While 83% indicated that their institutions conducted oversight review, these were predominantly administrative in nature. As 69% indicated that the oversight mechanisms considered ethical issues, only 16% indicated their ethics review committee was involved in formal review. Finally, while two-thirds indicated some sort of ethical review was part of the formal oversight, it was unsystematic in nature. These data offer an overview of the current ethics oversight of QI initiatives in the US and indicate that, in this example, QI initiatives are not conducted by colleagues who are independent of the initiative or have formal research ethics training. (See page 271).

## Natural history of erosion of a safety policy

The Rasmussen/Amalberti model of violations of safety rules has been tested in several environments but the mechanisms of erosion of system compliance over time are incompletely understood. This study explored the gradual erosion of compliance with a new safety rule over the 12 months after its introduction in an anaesthesia setting, in order to explore the individual, social and organisational factors that may influence rule compliance and how healthcare systems may migrate from operating within safety boundaries to a state where they may pose a danger to patients. Study of 717 patient records showed initial compliance of up to 86% for some items, but reduction began within 6 months and

returned almost to initial levels within a year. Even initially compliant doctors demonstrated reduction. A major trigger of erosion seemed to be lack of continued compliance by a senior member of staff. The authors conclude that rules and procedures constitute fragile safety barriers, and it may be better to forgo introduction of a new safety rule if it is not considered a priority by staff, and is therefore vulnerable to sacrifice when in conflict with competitive demands. (See page 327).

## A 40-year patient safety story

Study of the Madagascar periwinkle in the 1950s resulted in the use of the vinca alkaloid, vincristine sulphate, as a therapeutic agent for certain blood cancers. While intravenous administration of vincristine is the appropriate route of administration, intrathecal administration, which causes death, is one of the most enduring of patient safety stories. This article traces the history of this error back to the first death in 1968. In spite of FDA, WHO and other policy initiatives, and the use of various forcing function techniques, this error still occurs. An analysis of every death tells a classic story of recurring system error. The elimination of rare yet catastrophic errors like this remains one of the litmus tests of whether healthcare can be made safer. The authors offer five areas for potential solutions to ineffective systems learning. (See page 323).

## Finding common language for evaluation of QI interventions

Finding common useful ingredients in the stew of QI evaluation strategies remains a challenge. A structured literature review by investigators at the NHS Institute for Innovation and Improvement demonstrated that, although many evaluation guides are available, the language is varied and complex and, in itself, poses a potential barrier. Nevertheless, four frameworks with diverse methodological perspectives

were identified and substantial common ground was identified. A second report from RAND Corporation in the US, reported by investigators from the US and UK, tested the ability of QI experts to agree on empirical evaluations of QI reports. They showed only moderate agreement. Raters identified three controversial article selection issues: first, no data on patient health, provider behaviour or process of care outcomes; second, no evidence for adaptation of an intervention to a local context; and third, a design using only observational methods as correlational analyses, with no comparison group. An accompanying commentary suggests the need for a new discipline of 'evaluation ecology,' a proposal that will surely further stir the pot. (See pages 266, 279, 264).

## Microsystems metrics for improvement interventions

Microsystems theory was used to study how microsystem characteristics shaped the development and implementation of an evidence-based diabetes prevention intervention in a low-resource US health care setting. Five characteristics of high-performing microsystems were reflected, but not fully achieved. First, there was no universally shared definition of the desired purpose of the intervention. Second, investment in quality improvement was strong yet sustainability remained a concern since efforts were dependent upon external grant support. Third, lack of cohesiveness between the initiative planning team and the rest of the organisation served to both facilitate and constrain implementation. Fourth, institutional administrators showed support for new initiatives but lacked a strategic vision for quality improvement. Fifth, this initiative substantially strained already expanded role definitions. Understanding how a microsystem can facilitate or hinder the translation of evidence into practice may be a valuable assessment mechanism for efforts to accelerate implementation. (See page 290).