Guest Editorial

The Ethics of Changing Practice: Do We Cross the Line?

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In 1971 Barrat-Boyes, Simpson, and Neutze reported the use of deep hypothermia with surface cooling and limited cardio-pulmonary bypass in 41 infants with congenital heart disease less than 2 years of age and 10 kg in weight (1). The first of these patients was operated on in July 1969, following a 1967 report from Koyoto University in Japan. Professor Shirotani and his registrar Dr. Atsumi Mori from Koyoto, had visited the Green Lane Hospital Cardiothoracic Surgical Unit (CTSU) to learn about the use of aortic valve homografts, and had presented information on their approach to pediatric congenital heart surgery. The Koyoto group used ether (which is flammable) and administered fatty acids preoperatively in the belief that this improved cardiac function (2). The Green Lane group used halothane, and omitted the fatty acids. Their series was not only a dramatic change in local practice—it led to changes around the world. Other world leading events associated with Green Lane included the first descriptions of supra-aortic stenosis (3), underdeveloped right ventricle with pulmonary stenosis (4), and isolated atrial inversion (5), as well as the pioneering use of homografts for aortic valve replacement (6) and the primary repair of ventricular septal defects (7).

In parallel with this formally reported research, many refinements occurred to clinical practice in a more informal manner, often building progressively on previous innovations. The introduction of phenoxybenzamine (the late Carl Moller, an anesthesiologist, used to teach, “Dilate or die early”) and the steady and progressive improvement of monitoring both intraoperatively and during transfer from the operating room to the intensive care are examples.

Many changes have been made in perfusion, mostly on the basis of implementing steady gains in technology and knowledge over time, but also on the basis of local groundbreaking research (8–11).

Since the first deep hypothermic arrest in 1969, practice in cardiac surgery, anesthesia, and perfusion has changed almost beyond recognition; many of the lessons learned during this period have been captured in (arguably) the definitive text “Cardiac Surgery” edited by Kirklin and Barratt-Boyes (12). There are many children today, who would simply have died before 1970 and have received palliative treatment at considerable risk in the following decade or so, who can now expect definitive correction of their congenital heart disease in relative safety. In 2007, 312 open heart operations were undertaken in pediatric patients at the pediatric unit at Auckland City Hospital with an overall early mortality of 1.9%. Over this period, this process of continuous improvement through progressive changes in practice underpinned by research and audit seems to have been working.

But has it been ethical? From my knowledge of the clinicians concerned (and personal communications with some of them), and of the culture of the unit, I am relatively certain that detailed discussions would have taken place with the patients’ families, including a thorough explanation of the risks and the alternatives. However, the really striking thing from today’s perspective is that in 1971, major journals did not see it as necessary to establish the ethical basis of innovative work such as this. Regular changes in the manner now described as continuous quality improvement with the aim of achieving better patient outcomes was integral to clinical practice and seen as ethical per se: In fact it would have been thought unethical to accept the status quo.

It is relevant that these changes in practice were carried out in an environment committed to research and audit and to the publication of results. This research dealt with
surgical technique (13), included reports relevant to perfusion (8) and relevant to physiology and pathology (14,15), but there was a strong emphasis on tracking the results of clinical practice (16,17). This was audit, and I suggest that the combination of research into the principles underlying one’s practice combined with the tracking of results is the key to managing change. The innovation in this era of the Green Lane CTSU is very different from idiosyncratic changes in practice by individuals in the absence of underpinning research or audit.

It is not always obvious when formal research methods are required before change should be made, or when change might be justifiable on simple considerations of first principles and common sense. The point has been made previously that certain aspects of practice warrant adoption without the need for level 1 evidence (18,19), and it could be argued that there is no need to involve ethics committees or obtain informed consent for straightforward quality improvement (QI) initiatives. Recent responses to the Keystone project are therefore very interesting. Peter Pronovost’s group at Johns Hopkins demonstrated in 108 participating intensive care units in the state of Michigan that a simple intervention to ensure proper attention to sterile principles in the insertion of central venous lines could virtually eliminate central venous catheter-related blood stream infections (20). The study was approved by the institutional review board (IRB) of Johns Hopkins University School of Medicine. Informed consent was waived because the study was considered exempt from review. Soon after the publication of this paper, the Office for Human Research Protections launched an investigation, which culminated in the suspension of the Keystone project for a period of time, citing failure to obtain IRB approval from the participating hospitals or informed consent from participating patients. Interestingly, this investigation was a response to an anonymous complaint (21). The fundamental question was whether the Keystone project constituted QI or human subjects research. After some months, the investigators concluded that the project was not human subjects research, so IRB oversight and informed consent were not required. On the whole, commentary has supported this outcome; strong argument has been advanced emphasizing the benefits of QI (in a general sense) and suggesting that both patients and clinicians have a responsibility to partake in QI (22), but more conservative views have also been expressed (23).

The contrast is stark between the ethics environment that pervaded in the early days of the CTSU and this level of angst over the rights and wrongs of instituting change that is supported not only by evidence but also by common sense and which furthermore is exceptionally unlikely to cause harm.

Irony is added to this debate by the obvious but often overlooked fact that medicine in general is characterized by variation based on practitioner preferences rather than on differences between patients or inequalities in resources. The Dartmouth group has demonstrated extraordinary variance in the rates at which various operations are carried out (24–26), and this can be seen in such things as approaches to the management of lung cancer and to the adoption of evolving stent technologies. In light of this information it is perhaps not surprising, for example, that in at least one well known institution, there are several protocols for the postoperative management of atrial fibrillation: The one to use depends on the responsible consultant surgeon rather than on any particular feature of each individual patient’s condition. A suggestion that ethics committee oversight or informed consent should be obtained before an individual practitioner elected to change from one of these established protocols to another would make for interesting debate. Nevertheless, standardization is widely accepted as important in promoting safety, and disregard of this point is itself, arguably, of ethical relevance. It seems clear that an ideal approach would be for any unit to standardize its practices, monitor its results, and make changes through consensus on the best available evidence as it emerges: This is in fact how evidence based medicine ought to work (27).

Sadly things are not so simple. A lack of standardization in the absence of clear evidence one way or another is one thing. It is rather more disconcerting to note that, in the United States, compliance with many accepted best practice standards is less than 50% (28). However the real challenge lies in assessing the reliability of the peer reviewed research on which one would expect to base such standards, and to make decisions on changes in practice.

At Perfusion Downunder in 2006, I discussed the ethical framework in which research might be assessed, in the context of a case study involving the retraction of certain COX-2 inhibitors from the market place (29). Traditional non-steroidal anti-inflammatory drugs, which have gained great popularity for post-operative pain management, are often contra-indicated in the context of the major physiological challenges associated with cardiac surgery; the newer COX-2 inhibitors, by contrast, were promoted as much safer. Unfortunately it has now emerged that these newer drugs are associated with an increased risk of myocardial infarction. This information was slow to emerge, and we cited the Celecoxib Long-term Arthritis Safety Study (30), and commentary on the standards of transparency in this publication (31,32). It is encouraging to note that the PRECISION trial has now been set up to reinvestigate the cardiovascular risks of celecoxib, but with explicit measures to avoid conflicts of interest on the part of the investigators (33). In concluding, we optimistically endorsed Miller and Brody’s call for high standards of ethical conduct on the part of investigators and warning against too great an emphasis on regulation (34).
It is, therefore, dismaying to discover that 21 studies of postoperative analgesics (including celecoxib) by the well-known investigator Dr. Scott Reuben have recently been retracted on the grounds of data fabrication (35). A Medline search for Reuben SS identified over 80 publications. What are we to make of the 60 or so that have not been retracted? What of the various opinion articles and presentations based in good faith on what we now know to be unreliable work? These will undoubtedly have promoted changes in practice. How long will it take to differentiate completely misleading information from established fact in this field? And how are we to make sensible decision in this area of practice in the interim? Reuben’s various co-authors (of which there are quite a number) have been exonerated, but one can’t help wondering about the system in which they worked: for one or two people to be taken in is understandable, but surely someone involved in his publications ought to have suspected that something was amiss?

At Green Lane Hospital, the commitment to research and audit as the cornerstone of excellence in practice persisted, and Sir Brian eventually contributed to at least 123 papers. Furthermore, the emphasis on the team is clearly reflected in the authorships, which included representatives from anaesthesiology, pediatrics, pathology, physiology, and notably perfusion (8,36). Outcome data continue to be monitored and published (37–39).

In the year 2009 there is a much greater emphasis on regulations than in 1969, and few journals would publish reports of research or innovative practice without including explicit information on informed consent and appropriate ethics review, but perhaps this apparent change relates primarily to documentation: It was ethical to pursue excellence in practice in 1969, and it remains ethical to do so today. The ongoing pursuit of excellence does imply a commitment to an iterative process of well considered change. It is unsatisfactory that, as things stand today, there seems to be no easy answer to the question of how any particular source of evidence should be evaluated with a view to guiding such changes in practice, but groups of people working closely together as teams in a tradition of enquiry and openness seem likely to make reasonable decisions in this regard. Like the Green Lane Hospital CTSU, Perfusion Downunder provides an excellent model for this approach.

REFERENCES


