A plea for professional independence

When "should not" becomes "must not" — how mandatory compliance with guidelines can threaten professional independence

Hans Peter Dietz
MD, PhD, FRANZCOG, Professor of Obstetrics and Gynaecology[1]

Barrie J Stokes
BSc, MMath, Senior Research Scientist[2]

1 Sydney Medical School Nepean, University of Sydney, Sydney, NSW.
2 Discipline of Clinical Pharmacology, University of Newcastle, Newcastle, NSW.

hpdietz@bigpond.com

doi: 10.5694/mja11.11064

There is a proliferation of rules and red tape at all levels of society. In New South Wales, for example, the Department of Health has been generating around 70–100 policy directives a year. Among other things, such directives tell obstetricians when and how to deliver babies — compliance is mandatory, under threat of disciplinary action and loss of indemnity cover.

One of the most prominent recent directives, PD2010_045 (*Maternity — towards normal birth in NSW*), requires a reduction in caesarean section rates to 20% by 2015,[1] a target that is illusory and possibly dangerous. Others are worse. Policy directive PD2007_024 (*Maternity — timing of elective or pre-labour caesarean section*) states:

> The risk of respiratory morbidity is increased in babies born by caesarean section before labour, but this risk decreases after 39 completed weeks. Therefore elective or pre-labour caesarean section must not routinely be carried out before 39 completed weeks. These findings are supported by recent studies.[2]

This text is taken almost verbatim from a guideline of the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom[3] and, at the time, accorded with the relevant Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) guideline on the timing of elective caesarean section, the wording of which has since been softened slightly.[4] However, there is one very substantial difference: the "should not" of NICE and RANZCOG became a "must not".

The NICE guideline was produced by a committee of 16 members, two of whom were obstetricians. Nicholas Fisk, then chairman of the Royal College of Obstetricians and Gynaecologists (RCOG) Scientific Advisory Committee, strongly criticised the outcome and stated that the committee "selectively interpreted" the facts to suit its case.[5]

Timing of elective caesarean delivery is a complex issue. There are factors (mainly related to pulmonary maturity) suggesting delay until 39 weeks' gestation, and others (mainly related to unexplained stillbirth[6,7]) supporting the traditional timing between 38 weeks and 38 weeks and 6 days. A large randomised controlled trial (RCT) or a carefully conducted observational study employing propensity scoring would be required to provide a solid evidence base. For the moment it remains a matter of opinion, and RCOG, NICE and RANZCOG can, and should, express expert opinion and review the available evidence. Guideline committees and their products make an important contribution to improving clinical practice, and the voluntary work of countless individuals in this regard should not be denigrated.

> "Evidence-based medicine ... is a tool to inform clinicians, not an excuse to switch off one's brain"

However, the situation may be altered completely once bureaucrats become involved. Changing the "should" of a College guideline to a "must" in a NSW Health policy directive has major implications. PD2007_024 effectively forbids doctors in NSW public hospitals to schedule routine elective caesarean section before 39 weeks. Anyone doing so risks disciplinary action and may forfeit their indemnity cover.

PD2007_024 is not currently supported by high-level evidence, and even if there were solid data from a large RCT or a meta-analysis, it would be inappropriate to stipulate "mandatory compliance". Evidence-based medicine has great potential to improve patient care, but it is a tool to inform clinicians, not an excuse to switch off one's brain. As recently argued in the case of mesh use in pelvic reconstructive surgery,[8] guidelines derived from a large RCT (or a valid meta-analysis of appropriate trials) are of limited use as a guide to the care of an individual patient if that patient is far off the trial sample mean in predictors of outcome. The Term Breech Trial[9] is an excellent example. If there is a very high likelihood of an uncomplicated birth for an individual woman (eg, fast progress, small baby, previous normal births), a clinician may want to ignore the findings of the Term Breech Trial when deciding how to advise her.

The process of starting with some initial information (probabilities of events of interest) and combining it with data related to an individual case or circumstance has been mathematically formalised by statisticians as "Bayesian updating".[10-13] Information from a clinical guideline, prevalence study or meta-analysis provides the "prior probability", the data related to the individual case at hand are embodied in the "likelihood", and the application of Bayes' theorem[13,14] gives the updated "posterior probability" on which a decisionmaker can act. This implies that even the best evidence in literature and guidelines can provide only prior probabilities. It is our job to adapt these to the clinical management of the individual patient, generating posterior probabilities that have been updated by the relevant particulars of the patient and processed by clinical intuition and common sense.

However, in a trend that is encouraged by guidelines and policy directives, clinicians increasingly omit this updating process. Once a document — a seminal paper, a guideline, a policy directive — is published, it is likely to be interpreted cautiously (ie, as widely as possible) because of the litigious, risk-averse nature of our society. We do not particularise to the individual patient because our work environment strongly discourages doing so.

Finally, even if a guideline is produced after an optimally diligent process and published so rapidly that it is up to date at its launch, it still freezes current best practice. Inevitably, today's best practice will be obsolete tomorrow. Practice guidelines therefore have the potential to slow down progress, and unthinking adherence to such documents is unlikely to deliver the best outcomes to the

greatest number of individuals. The expert system of our brains, employed in the assessment and treatment of the individual patient — and using relevant prior information from evidence-based sources — is a potentially superior tool when compared with the replication of a course of action outlined in a document issued by a government agency or professional body. It is time to reassert our professional independence.

Competing interests: No relevant disclosures.

Provenance: Not commissioned; externally peer reviewed.

1 New South Wales Health. Maternity — towards normal birth in NSW. Policy directive PD2010_045. Sydney: NSW Health, 2010. http://www.health.nsw.gov.au/policies/pd/2010/PD2010_045.html (accessed Sep 2011).
2 New South Wales Health. Maternity — timing of elective or pre-labour caesarean section. Policy directive PD2007_024. Sydney: NSW Health, 2007. http://www.health.nsw.gov.au/policies/pd/2007/PD2007_024.html (accessed Sep 2011).
3 National Institute for Health and Clinical Excellence. Caesarean section: quick reference guide. London: NICE, 2004. http://guidance.nice.org.uk/CG13/QuickRefGuide/pdf/English (accessed Sep 2011; no longer available).
4 Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Timing of elective caesarean section. College statement C-Obs 23. Melbourne: RANZCOG, 2009. http://www.ranzcog.edu.au/component/content/article/503-c-obs/436-timing-of-elective-caesarean-section-c-obs-23.html (accessed Sep 2011).
5 Fisk N, Paterson Brown S. The safest method of birth is by caesarean. *The Observer* (London) 2004; 1 May: 18. http://www.guardian.co.uk/society/2004/may/02/health.politics1 (accessed Jan 2012).
6 Vashevnik S, Walker S, Permezel M. Stillbirths and neonatal deaths in appropriate, small and large birthweight for gestational age fetuses. *Aust N Z J Obstet Gynaecol* 2007; 47: 302-306.
7 Cotzias CS, Paterson-Brown S, Fisk NM. Prospective risk of unexplained stillbirth in singleton pregnancies at term: population based analysis. *BMJ* 1999; 319: 287-288.
8 Dietz HP. To mesh or not to mesh. *Aust N Z J Obstet Gynaecol* 2009; 49: 344-345.
9 Hannah ME, Hannah, WJ, Hewson SA, et al; Term Breech Trial Collaborative Group. Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial. *Lancet* 2000; 356: 1375-1383.
10 Jaynes ET. Probability theory: the logic of science. Cambridge: Cambridge University Press, 2003: 86-90.
11 Taper ML, Lele SR, editors. The nature of scientific evidence. Chicago: University of Chicago Press, 2004: 12.
12 Pearl J. Probabilistic reasoning in intelligent systems: networks of plausible inference. San Francisco: Morgan Kaufman, 1988: 33.
13 Ghosh JK, Delampady M, Samanta T. An introduction to Bayesian analysis: theory and methods. New York: Springer Science and Business Media, 2006: 31.
14 McGrayne SB. The theory that would not die: how Bayes' rule cracked the enigma code, hunted down Russian submarines, and emerged triumphant from two centuries of controversy. New Haven, Conn: Yale University Press, 2011. ❑