Should we stop telling well pregnant women to monitor fetal movements? How to use and interpret guidelines

The confusion articulated in the commentary by Hill-Smith is interesting on several levels. Is this an example of the mess that evidence-based medicine (EBM) can get us into? It certainly raises the thorny issue of how research conducted in one place and time could usefully assist us in clinical practice in another setting. It also calls into question what good guidelines should look like.

Hill-Smith wonders whether we should ask women to routinely keep a fetal movement diary (‘kick chart’). The NICE (National Institute of Clinical Excellence) guidelines suggest not — kick charts make no difference to infant mortality. But there is a rider: one baby may be saved for every 1250 women routinely using kick charts. These two statements appear contradictory.

To understand them we have to go back past the NICE guidelines and read the original trial on which they are based, published in The Lancet 15 years ago. It was a well conducted multicentre study in the United Kingdom (UK), United States (US), Ireland, Sweden, and Belgium of 68 654 women in a cluster randomised trial in which 33 clusters (a total of 31 993 women) were randomised to keep routine kick charts, and 33 clusters (of 36 661 women) were not. The principal outcome was unexplained late fetal death. There were 59 fetal deaths in the kick chart groups compared with 58 in the controls, which can be expressed as 2.9 per 1000 births for the formal counting compared with 2.7 for the controls. No differences were significant. So far it seems pretty clear that formal movement charts confer no benefit.

So where does the 1:1250 babies saved come from? It comes from the lower 95% confidence interval for the estimate of odds for the intervention groups compared with the control. The explanation between these apparently incompatible statements represents the gap between ‘no evidence of effect’ and ‘evidence of no effect’ — not the same thing by any means.

There are other considerations. Would pregnant women agree that it is worth undertaking a non-invasive test if it saved one baby in 1250? This is a question of values, a ‘what is it worth?’ question. We suspect that most women would say they would willingly invest the time. But not necessarily all. How many would in practice? The Lancet trial partly answers this: only about 50% of those women whose babies died had made use of the kick charts.

But then, what should be done if women report decreased fetal movements even if not asked to do so? The NICE guidelines suggest that they should report to their midwife or hospital (another apparent contradiction). What then? Of the 17 clusters randomised to kick charts who did sound the alarm for fetal wellbeing (including biophysical profile and Doppler ultrasound of umbilical arterial flow) although even these have not been helpful in the low-risk population. Perhaps the intervention failed not because of the insensitivity of women to decreased fetal movements, but because of inadequacies in the next stage of the clinical pathway. If this is the case, then we might expect things to improve if and when effective tests for fetal wellbeing are developed — presumably the hope on which this NICE recommendation is based.

Hill-Smith’s careful analysis of the NICE guidelines show how hard they are to use. In particular, the apparent contradictions are likely to confuse clinicians. What would make them easier? Perhaps guidelines should adhere better to the definition ‘systematised review of the evidence’ (rather than to inconsistent recipe-like instruction), enabling us to decide how good the information is, and giving us the flexibility to adapt the information for an individual patient — even at the cost of making us have to work it out.

Finally, how is the world reacting to this information? Are fetal wellbeing kick charts being abandoned wholesale for uncomplicated pregnancy across the globe? A quick look at the repository at The National Guideline Clearinghouse in the US (www.guideline.gov) yielded 19 hits for ‘fetal movements’, of which two guidelines were still recommending them for normal pregnancy. Clearly — as the trial was published so long ago — the information can be interpreted very differently!

And for the future, although the intervention might be helpful one day, the problem area is with finding the appropriate mode to further evaluate the fetus. Perhaps a Cochrane protocol under development might throw further light on the current situation by evaluating any newer studies. Or perhaps it is timely to review all the current methods developed to assess fetal wellbeing. Perhaps a fresh new study is required.

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Republic of Ireland’s indoor workplace smoking ban

On 29 March, in accordance with Article 8 of the World Health Assembly’s Framework Convention on Tobacco Control, a ban on smoking in all enclosed places of work, including pubs and restaurants, was introduced in the Republic of Ireland. After 1 month, the Office of Tobacco Control found that 97% of premises inspected nationally were compliant with the smoke-free law. This compliance rate is similar to, or higher than, that achieved in California and New York. How has this come about — in anachronistic Ireland of all places?

Firstly, a high level of knowledge and understanding about the reasons for the ban were critical to ensuring compliance. The year of often heated debate — in newspapers, on television, on national and local radio, through expert discussions and phone-ins — meant that no one in the Republic of Ireland remained ignorant of the impending ban, that everyone had an opinion, and that popular support strengthened over the course of the debate as people began to perceive the self-serving nature of the hospitality industry’s economic arguments. The strident arguments of the hospitality industry were partially responsible for driving the debate. But the debate was also driven by a carefully managed communications campaign. Non-governmental organisations and government departments used the same few, simple, consistent messages: passive smoking causes serious harm to health, workplace smoking is a health and safety issue, and ventilation does not work.

The high level of knowledge achieved by the communications campaign was indicated by a poll in December 2003, 11 months after the announcement of the ban (and 3 months before the ban came into force). Some 84% of the population knew not only that the ban was coming in, but also that it was for health and safety reasons. Public support has remained strong. A survey commissioned by the Department of Health and Children showed that 4 months after the ban, 82% supported the Smoke-Free at Work measure, 95% agreed that the ban is a positive health measure, and 90% agreed that going smoke-free is of benefit to workers. Most reported that the new legislation improved their experience in pubs (70%) and restaurants (78%).

But this has not been a short-term communication process. It has taken many years of advocacy led by non-governmental organisations — such as ASH (Action on Smoking and Health) Ireland, the Irish Cancer Society, the Irish Heart Foundation — and by public health to raise awareness in trade union and government circles. Eventually there was sufficient concern to lead to the commissioning of an independent scientific working group to assess the degree of consensus that existed among leading scientific authorities on the risk posed to human health by environmental tobacco smoke in the workplace. The Minister of Health and Children considered the findings of this report so stark that he felt he had no option but to bring in the smoking ban.

Meanwhile, ongoing work at community level was critical to ensuring compliance once the ban was implemented. Polls had shown, in Ireland as elsewhere, that as well as non-smokers, many smokers would be supportive of a ban. Most smokers want to stop smoking and most have tried, usually more than once. Smokers know better than anyone that non-smoking environments help them to stop or at least to cut down. Cessation supports are required to help smokers make the best of such opportunities. A platform of smoking cessation structures had been evolving and these have supported the successful implementation of the ban. One important measure was that nicotine replacement therapy has been available since 2001 free of charge to medical card holders, that is, the poorest third of the Irish population, who also have the highest smoking rates. Quitlines and health board cessation clinics had been developed across the country and cessation training offered to GPs, practice nurses, and pharmacists. Links between health boards and environmental health officers and restaurants, pubs and other workplaces had been developed for various health and safety initiatives, which could then be used to support and monitor the new smoking legislation. These and various other measures, such as price increases and advertising bans, had led to declines in adult smoking prevalence in the Republic of Ireland from 30% in the late 1990s to close to 25% prior to the ban. Equivalent declines had occurred earlier in the United Kingdom (UK): adult smoking prevalence was 30% in 1990, 27% in 1994, and 26% in 2002.2,3

The most widely trumpeted negative effect of the ban is on the profits of the hospitality industry. However, reports to date in Ireland are varied. Some publicans are claiming 20% declines in business due to a combination of the smoking ban and a new watershed time limit of 9 pm for under-18s; other publicans and many restaurateurs say that business is either up or unchanged. But reviews of objective data in other countries have indicated that although some sectors may suffer, particularly in the short term, overall there are unlikely to be long-term adverse economic effects.4,5 Preliminary evidence from the Republic of Ireland indicates a small downturn, but this should be viewed in light of the downward trends that were evident prior to the ban. However, given the seriousness of the health consequences of exposure to passive smoke, the economic argument is hardly relevant. For example, would any-

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