

A CONSUMER VIEWPOINT

“Spin Doctoring” the Research

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Things are seldom what they seem. Skim milk masquerades as cream.

Gilbert & Sullivan, *HMS Pinafore*

A funny thing happened on the way to practicing evidence-based obstetric care. Obstetricians hijacked some of the research. In the late 1970s and 1980s advocates for change could say either that the evidence did not exist to support typical obstetric management or that it existed and discredited it. Enough people made this point that governmental agencies, third-party payers, and consumers began pressuring obstetricians to mend their ways. To cite one example, the Healthy People goals set in 1990 mandated a reduction in the cesarean delivery rate to 15 percent by 2000 (1). (It is worth noting that the National Institutes of Health convened a consensus conference in 1980 to strategize on how to lower a cesarean rate that had reached the alarming *heights* of 15 percent [2].)

Mainstream obstetricians reacted, not by bringing their practices into line with what the research showed to be safe and effective care, but by fighting change. In a variation of the old saw “If it looks like a duck and sounds like a duck and walks like a duck, it’s a duck,” they discovered that if a study read like a well-done study—it was laid out as such, used the right terminology and concepts, and was published in a peer-reviewed journal—it would be accepted into the canon of evidence-based care and could be

used to shape policy, even if it was junk. And as medical organizations grew more sophisticated about press releases and public relations, the obstetric powers-that-be also realized that even if the study did not produce the results they had hoped, it didn’t matter. If it was accompanied by an editorial, the commenter could make any claims he or she liked for the study, and almost no one—few obstetricians and certainly no one in the media—would notice the discrepancy.

This exercise pulled the rug out from under birth activists. It was hard enough trying to explain to an unsophisticated public and clinicians that expert opinion was insufficient without science to back it up. Convincing them that research published in respected medical journals might be fatally flawed or that claims for it were not justified is well-nigh impossible. Once misinformation is widely disseminated, a well-crafted rebuttal has little effect. The damage is done, and the fact that the falsehood aligns with the cultural zeitgeist, whereas the correction does not, ensures that it cannot be undone. Some examples follow.

Induction Studies

1. Hannah et al’s 1992 multicenter randomized controlled trial concluded only that induction of labor at 41 weeks’ gestation decreased the cesarean rate from 25 to 21 percent compared with expectant management (3). This trial was actually one of elective induction, since pregnancy was not considered postterm at that time until 42 weeks. Its conclusion, however, contradicted the finding of other studies of elective induction, all of which reported substantial increases in the cesarean rate in nulliparous women (4). Since two-thirds of Hannah et al’s population had no prior births, why the difference? Answer: One-third of the expectant management group was induced, and one-third of the induction group began labor spontaneously, which

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would flatten out the differences between groups. A follow-up analysis revealed that, in fact, 42 percent of induced nulliparas had cesareans compared with 25 percent of nulliparas laboring spontaneously (5). The Hannah et al trial found no differences in perinatal morbidity or mortality.

Result: This trial fueled a headlong rush to induce labor routinely at 41 weeks' gestation or even earlier on the grounds of improved perinatal outcomes. This practice particularly hurts nulliparous women because 41 weeks is the median length of pregnancy in healthy nulliparas, who are at high risk for cesarean section when induced (6).

2. Misoprostol (Cytotec) to induce labor: After the drug's manufacturer, Searle, wrote a letter to all obstetricians repudiating the off-label use of Cytotec and the U.S. Food and Drug Administration (FDA) banned its use, a review of the literature argued that misoprostol was safe (at least in women with unscarred uteruses) and effective, and that no other drug could substitute (7). An accompanying editorial chastised the FDA for banning it (8). Contradicting its own conclusion, the review acknowledged that misoprostol resulted in more cases of uterine hyperstimulation and accompanying fetal distress and that it produced similar cesarean rates compared with oxytocin or prostaglandin E2 inductions. The review also omits mention of case reports of uterine rupture in women with no uterine scar.

Result: The FDA rescinded the ban, not on the grounds of misoprostol's efficacy and safety, but because it was in such common use (9). The drug's package insert continues to state a long list of serious and life-threatening complications attributed to it (10). In fact, misoprostol's only virtues are its extremely low cost—pennies per dose—and its tendency to throw women into short, violent labors, which allows obstetricians to practice “daylight obstetrics,” a clear case of sacrificing the best interests of women and babies to economics and convenience.

VBAC versus Elective Repeat Cesarean Studies

Dozens of studies, comprising tens of thousands of women, and meta-analyses of those studies have conclusively demonstrated that VBAC is less hazardous for the mother and equally safe for the baby (11–14). Because 70 percent or more of women can give birth vaginally, a policy of routine VBAC spares women and babies exposure to the risks of cesarean section in subsequent pregnancies. Obstetricians have

long opposed VBAC, however, and starting in 1996, they began producing studies purporting to support, or which editorials claim support, elective cesarean. Four examples to wit:

1. McMahon et al's study concluded that, “Major complications were nearly twice as likely among women undergoing a trial of labor” (15, p 689). However, the authors coded wound infections and hemorrhage requiring transfusion as “minor complications” (16). These would normally be considered major complications, and coding them as such would have wiped out the difference. Even so, “nearly twice” the major complication rate amounted to a little less than 1 percent in the elective cesarean group, a little more than 1 percent in the VBAC group.

2. Mozurkewich and Hutton conducted a meta-analysis and concluded that a trial of labor “may” result in an increase in fetal and neonatal mortality compared with elective repeat cesarean, despite finding no statistically significant difference (12).

They reached this conclusion despite stacking the deck against trial of labor by including deaths unrelated to birth route. The combined fetal and neonatal mortality rates in 11 studies totaled 136 per 23,486 (or 6/1000) for trial of labor versus 56 per 16,239 (or 3/1000) for elective repeat cesarean for an absolute difference of 3 per 1000. All but 8 deaths in the former group and 3 deaths in the latter group came from 3 studies. A closer examination of those 3 studies reveals that when the numbers are corrected by subtracting deaths unrelated to birth route, the numbers fall to 43 in the trial of labor group and 13 in the elective group for a corrected mortality rate of 2 per 1000 versus 1 per 1000 and an absolute difference of 1 per 1000.

3. Lydon-Rochelle et al's study was accompanied by an editorial, in which Greene asserted that the investigators had proved that elective cesarean section was safer for babies than VBAC (17). The study itself only showed the dangers of induction with prostaglandin E2 (18). The uterine rupture rate was 1.6 per 1000 with elective repeat cesarean, 5.2 per 1000 with spontaneous labor onset—only slightly more than with planned cesarean and the same as that found in other large studies, 7.7 per 1000 with oxytocin induction, but a whopping 24.5 per 1000 with prostaglandin E2. The study did not report comparative neonatal mortality rates, but they can be calculated from the reported 5.5 percent death rate after uterine rupture: 1 per 10,000 with elective repeat cesarean, 3 per 10,000 with spontaneous labor, 4 per 10,000 with oxytocin induction, but 13 per 10,000 with prostaglandin E2. The accuracy of the data must

also be questioned, since 311 VBAC women had breech presentations or placenta previa, conditions that would surely disqualify them from VBAC (19).

4. Smith et al recommended elective cesarean at 39 weeks on the basis of finding an 11-fold increase in perinatal mortality with trial of labor (20). But the study defined any vaginal birth or emergency cesarean after 37 weeks' gestation as a trial of labor. Thus, any woman who had a uterine rupture or placental abruption after 37 weeks and had an emergency cesarean would be classified as a trial of labor. The perinatal mortality in such cases would likely be high. Investigators in a large Swiss study reported that the odds of uterine rupture in pregnancy in women with a uterine scar were 2 per 1000, the odds of placental abruption 3 per 1000 (13). Although not every baby would die, and some cases would occur earlier than 37 weeks, still, this means that, several, if not many, of the 20 infant deaths in Smith et al's so-called "trial of labor group" were not trials of labor. In any case, the absolute difference in mortality between planned cesarean and planned vaginal birth was 1 per 1000, and did not differ significantly from the mortality rate in primiparous births. To put these mortality rates in perspective, the chance of losing the pregnancy as a result of amniocentesis is 1 in 200 to 1 in 400 (21). Yet no one is suggesting abandoning amniocentesis.

The study by McMahon et al is the sole one cited in support of the American College of Obstetricians and Gynecologists' (ACOG's) about face on VBAC. These latest guidelines emphasize the risks of VBAC, say nothing about the risks of repeat cesarean, and set standards of care for VBAC labors that many community hospitals cannot meet—standards of care that the guidelines themselves acknowledge are not backed by research (22). That ACOG singles out VBAC labors, even though emergencies occur in non-VBAC labors at higher rates, suggests that the intent is to eradicate VBAC, not protect the well-being of mothers and babies (23).

Result: Between the new ACOG guidelines and these studies, the VBAC rate has plunged from a high of 28 percent in 1996 to a low of 16.4 percent in 2001 (24). Thousands of women have been refused VBACs, including women who have already had one or more (25), a policy that not only contravenes an ACOG Committee Opinion guaranteeing women the right to refuse any treatment, test, or procedure, but the right of any patient to decline surgery (26).

Home Birth versus Hospital Studies

Contradicting the consistent findings of a large body of research affirming the safety of planned home

birth with a trained attendant, Pang et al claimed that Washington state birth certificate data showed that such births increased the risk of neonatal death and other adverse outcomes (27). The study's many flaws included failure to exclude unplanned home births or planned home births with no qualified attendant; failure to exclude preterm births; failure to determine whether the choice to birth at home was at fault in neonatal deaths; failure to establish truly comparable populations; and failure to report on adverse outcomes strongly associated with hospital birth in low-risk women, such as greatly increased cesarean and vaginal instrumental delivery rates (28,29).

Result: This study will almost certainly be used to justify the ongoing persecution of home birth midwives and to put pressure on those physicians willing to provide backup care.

Cochrane Systematic Reviews

Problems even infest the Cochrane systematic reviews, long the gold standard of evidence-based care. They have crept in as the Cochrane evolved from a small band of upstart, radical physicians and midwives challenging established practice into a mainstream institution itself. A disturbing number of reviews conform to the Cochrane guidelines but reach erroneous conclusions and misrepresent the true state of affairs. This is especially problematic because these reviews have the power to effect sweeping changes in management. Some examples follow.

1. The review *Interventions for Preventing or Improving the Outcome of Delivery at or Beyond Term* concludes that routine induction of labor at 41 weeks will reduce the perinatal mortality rate without increasing the cesarean rate (30). Among the 19 studies, 9 per 3800 babies died perinatally in the expectant management group versus 1 per 4125 babies in the routine induction group (2.3/1000 vs 0.2/1000). But 2 of the 9 deaths in the await-labor group occurred before 41 weeks' gestation. A policy of routine induction at 41 weeks would not have prevented them. Another 2 deaths occurred in a 1969 study of only 110 women. This study and those deaths can be eliminated on the grounds that the obstetrics of that era and the perinatal death rates simply do not apply to modern-day care. That leaves 5 perinatal deaths in 3750 women versus 1 in 4050 women, or 1.3 per 1000 in the expectant management group versus 0.2 per 1000 in the routine induction group, or a difference of 1 per 1000 between groups. A difference this small seems likely to be due to chance.

The reviewer also fails to find a difference in cesarean rates even among nulliparous women, but this is almost certainly because the reviewer failed to address crossover. Typically, 20 percent or more of participants assigned to induction began labor spontaneously and vice versa. In the Hannah et al trial, one-third in each group received the other treatment, which is especially problematic because the size of this trial in relation to the other trials makes it the “500 lb gorilla” in the weighted meta-analysis (3). Such a degree of crossover will greatly flatten out differences in outcomes between groups.

2. Crossover also afflicts the Cochrane reviews of epidurals, early amniotomy, and episiotomy. To illustrate, the Cochrane review of episiotomy finds no statistical difference in severe posterior or vaginal trauma with routine versus selective use of episiotomy, even with midline episiotomy (31). Every study that has ever been done has concluded that midline episiotomy predisposes to anal tears, but in the sole randomized controlled trial of midline episiotomy, 57 percent of primiparas and 31 percent of multiparas had episiotomies in the “restrict episiotomy” group (32). In point of fact, 52 of 53 anal tears were episiotomy extensions.

3. The review *Vaginal Misoprostol for Cervical Ripening and Induction of Labour* notes “reduced failure to achieve vaginal delivery within 24 hours” as an advantage of the drug in the abstract, but readers must delve into the review’s text to find that misoprostol resulted in no difference in cesarean section rate overall when compared with prostaglandin E2 (33). This is a serious omission, given the review’s ominous findings that misoprostol increases the incidence of uterine hyperstimulation compared with other induction agents, that it increases the likelihood of abnormal fetal heart rate and meconium staining compared with intracervical prostaglandin E2, and the authors’ acknowledgment of case reports of uterine rupture with and without uterine scars. The abstract gives the misimpression that misoprostol is a superior induction agent, when, in fact, it is not, but it is more dangerous than others.

These errors are not subtle. Experienced researchers should know better, or failing that, peer review committees, who also should know better, should have caught the errors. That these “experts” did not raises the possibility that the errors may have been intentional.

Conflicts of Interest?

Why would supposed experts pass off badly done studies as sound research? The inbred biases of some

researchers, peer reviewers, and editorialists assuredly play a role. Mary Hannah, principal author of large multicenter randomized controlled trials of postdates pregnancy, prelabor rupture of membranes, and vaginal breech delivery, recently convened and chaired a conference entitled “Choosing Delivery by Caesarean: Has Its Time Come?” (34) Michael Greene, assistant editor of the *New England Journal of Medicine*, who wrote the editorial damning VBAC that accompanied Lydon-Rochelle et al’s study, said of elective primary cesareans, “The in-laws get to use supersaver fares” (35). James Scott, who shaped ACOG’s current guidelines and is editor of *Obstetrics and Gynecology*, which published Pang et al’s home birth study, is on record opposing VBAC in 1991 (36).

That obstetricians should be prejudiced in favor of intervention in general and surgery in particular is scarcely surprising for physicians who are, after all, surgeons and specialists in the pathology of women’s reproductive organs. Obstetric management rests on the erroneous premise that pregnancy and childbirth are events fraught with peril, and require the services of just such specialists to avert the disasters that would otherwise frequently ensue. It follows that these who believe this will tend to exaggerate the dangers of the natural process and overlook the harm done by injudicious intervention. Belief is not amenable to change by science, logic, or even common sense. “My mind is made up; don’t confuse me with the facts” will do quite as well to compromise research, reviews, and commentaries as financial incentives to get the “right” result.

ACOG and its spokespeople sometimes also have less innocent motives than self-deception. A prominent obstetrician and the ACOG guidelines for VBAC openly admit that avoiding malpractice litigation motivates the discouragement of VBAC (22,37), despite the ACOG “Code of Professional Ethics,” which enjoins obstetricians to resolve conflicts of interest in favor of what is best for the patient (38). Given misoprostol’s potential for disasters and the availability of an equally efficacious and less risky drug, this motive also appears to be the only logical reason for pressuring the FDA to rescind the ban on Cytotec. The ability to claim that misoprostol induction meets the community standard of care protects obstetricians in misoprostol-related lawsuits. Another strong motivator is preserving the hegemony of obstetric management and the power, prestige, and economic reward that go with it.

As scandals elsewhere have taught us, in the absence of outside oversight or restraint, the danger always exists that members of any occupation will act in their own self-interest at the expense of those they

profess to serve when the two conflict. Practitioners and the public trust that the scientific method and peer review will protect against exactly this potential and ensure that, insofar as it is possible, results reflect the truth. When those involved co-opt the process and present propaganda as research, they break that covenant.

In the end, motivation doesn't matter. The damage is done regardless. As it stands now, reformers of obstetric management have effectively been silenced. Indeed, those daring to publish criticism of the research may even be accused of libel or threatened with legal action (39). The concept of evidence-based care has been suborned. Those who rely on the research or interpreters of the research to guide practice or assist women in making informed choices cannot trust that what they read or hear is disinterested, but few of them know it. Reporters and editors who disseminate research findings in the media unwittingly spread untruths. They do not exercise journalistic skepticism or fact checking, because obstetric researchers, pundits, and ACOG itself continue to carry credibility, authority, and influence that too often they do not deserve.

The consequences of the breakdown are not trivial. The financial cost is enormous, and the toll on the physical and emotional health and well-being of women and babies is appalling. Millions of women and thousands of babies have suffered permanent injury. Some of them have died.

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