# Editorials

## Assessing A Technology: What Constitutes Enough?

For researchers who consider well-conducted experimental trials the final word on a clinical question, the article by Cauthen and colleagues in this issue regarding the Cytobrush™ is essential reading.[1]

The story of the Cytobrush™ is an instructive example of technology assessment. Using a brush-tipped collector of cytologic material for the Papanicolaou smear has an impressive research pedigree and has achieved rapid acceptance by practitioners. It is a simple new technology offering a common-sense solution to the problem of not collecting adequate cellular material for the Papanicolaou smear. More than once have I heard a practitioner comment, "Why didn't I think of that?"

Several studies, both experimental and quasi-experimental, have shown that the Cytobrush™ is more effective than other methods at obtaining endocervical cells, and some of the best such research has been generated from family practice settings.[2] If ever a technology seems on its way to becoming standard practice, the Cytobrush™ is it.

What, then, are we to make of the finding by Cauthen, et al. that cellular material was (probably) better, but that the Cytobrush™ overall did not change the proportion of abnormal smears? The first question is whether the study itself was competently performed (internal validity): are the results as they appear? The design was disarmingly simple, a one-group pre-test–post-test design. This design is not a strong one in that there was no concurrent control group (randomized or not), and it is possible that something else might have happened to account for the disappointing showing of the Cytobrush,™ e.g., a concurrent change in preservative or handling of the specimen, a change in cytotechnologists' reading habits or criteria, or a change in physicians or patients (any epidemiologist can suggest many such potential biases). The authors briefly discuss several concerns in the discussion section, but either the authors are concealing something, or we are left with the impression that all of these potential biases are justly far-fetched.

Indeed, some of the weaknesses of the study design might be reclassified as strengths when measured against the criterion of whether an innovation proves useful in routine practice. The authors conducted the study to assess the impact of the Cytobrush™ on their practice much as any reasonable group might, and it is this high "reasonableness factor" that challenges those wishing to dismiss the results of the study as insufficiently rigorous. The finding strikes too close to home. The average reader might ask, "If these physicians with their 14,000 Pap smears couldn't show that the Cytobrush™ made a difference, what is the chance that I will?" A fair question.

This brings me to the choice of title for this editorial: when does technology assessment end? In my view, medicine's history is cluttered with research that stopped too soon. Too many research programs fold their tents after demonstrating biologic efficacy, without showing that whatever it is actually works in practice, with all its variables in patient satisfaction, compliance, physician acceptance, and cost. I find myself confronted by many treatments that my patients will not take, or do not like, or cannot afford, or that otherwise fall short of the promise heralded in the randomized controlled trials that have brought them to notice.

We in family medicine research need to select outcomes that tell. Biologic efficacy is not enough. The term *effectiveness* is used to cover the phase of research that follows demonstration of biologic efficacy, but the term is usually applied narrowly to patient acceptance. With a given intervention, there are many other outcomes of clinical interest ranging from the purely biological to the quasiphilosophical.

The resulting question of external validity is, "What do these findings mean in the real world?"

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Do similar percentages of abnormal smears with and without the Cytobrush™ mean that the Cytobrush™ is no better than a wooden spatula? Not necessarily. In reading this study, we must ask whether the outcome chosen — the proportion of abnormal smears — is the decisive one. Certainly ease of reading smears (implied by the cytotechnologists' impressions that more cells were available) is an important positive outcome, as might be confidence that the smears are valid, satisfaction of the physician, acceptance by patients (in minimizing second visits because of an inadequate smear the first time), and others.

The selection of outcomes is not value-free. The factors that we (and patients) choose for study are selected because we value them, but our values differ. Mainstream medical research has placed most of its emphasis on biologic outcomes measured in carefully controlled settings. Our curiosity should not end with publication of a "definitive" randomized controlled trial focusing on biologic outcomes.

The Cytobrush™ study takes us a step forward in providing a biologic outcome measured in a more realistic setting. Yet ahead in this and other areas of clinical research should be an even broader range of outcomes examined in actual practice.

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**References**

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2. Murata PJ, Johnson RA, McNicoll KE. Controlled evaluation of implementing Cytobrush technique to improve Papanicolaou smear quality. Obstet Gynecol 1990; 75:690-5.

# Family Physicians Performing Obstetrics: Is Malpractice Liability The Only Obstacle?

The medical malpractice liability problem is one of the most complicated issues facing health policy makers in the 1990s. Its solution is inextricably linked with improvements in health care access and the cost of medical care. The problem is not difficult to describe. Between 1982 and 1985 obstetrician-gynecologists saw their malpractice insurance premiums more than double compared with an 81 percent increase for all physicians. Premiums in 1986 were increased by 46.5 percent from their levels in 1984. In 1987 premiums rose another 21 percent![1]

Family physicians represent two-thirds of all obstetric providers in rural areas.[1] Premium increases have been far greater for family physicians than for obstetrician-gynecologists. Family physicians performing obstetrics are paying premiums two to three times higher than their colleagues who do not perform obstetrics. While professional liability insurance premiums for family physicians are much lower per physician than for obstetrician-gynecologists, the latter experience considerably lower malpractice costs per delivery, because the average obstetrician-gynecologist performs four to five times more deliveries each year than the average family physician who provides obstetrical care.[1] In rural areas, where fees for services tend to be lower and care is largely provided by family physicians, this premium discrepancy becomes even more important. Rural areas have a higher proportion of uninsured deliveries. In a 1987 survey the Oregon Medical Association found that 34 percent of family physician-attended deliveries were covered by only partial or no payment because of patients' inability to pay.

## Malpractice and Obstetric Care in Rural America: Defining the Problem

### *Loss of Obstetric Providers in Rural Areas*

It has been estimated that currently only 29 percent of family physicians practice obstetrics, a 25 percent decline in rural family practice participation in obstetric care since 1980.[2] Twenty percent of rural providers discontinued obstetric care in the last 5 years alone![3] A 1990 survey

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