the culprits of extravagant costs, excessive testing, inhumaneness, and other forms of exploitation. On the other hand, we have not yet practiced in a system of care that depends for its economic viability on maximizing, standardizing, and monitoring these virtues. As a practical, unspectacular specialty, we have not been in the spotlight of public accountability in the way we might become under the Clinton reforms. We will lose our charms if we forget our roots, take on airs, and see reform as our chance to grab for power.

Brody calls attention to two potential conflicts, which are part of the same thing, namely, better utilization of expensive and scarce resources. One is the shifting of funds toward primary outpatient care and away from expensive tertiary and subspecialty care. The other is gatekeeping. In both instances the moral task is to divest secondary personal gain from individual clinical decisions. Whatever gains accrue from better utilization must be used to improve services and enhance the functional integrity of the system. I cannot imagine this happening in a climate of conflict and suspicion among family physicians, consultants, and patients, so our commitment to reform ought to include transparency of financial arrangements at all levels of care.

Gatekeeping is like walking a gymnast's balance beam; it's much harder when the beam is elevated. Brody draws a fine distinction between protecting patients from the potential harm of overtreatment and denying them potential beneficial treatment. Because iatrogenic harm is already built into the present system of care, and only a fraction of it ever comes to litigation, my guess is that denying potentially beneficial treatment will continue to be felt by physicians as the greater risk.

There is a third element of gatekeeping that might become more important in a reformed system; that is, when the primary physician goes to bat as an advocate for a patient to get what is needed from the system. My recent conversations with about 50 family physicians working in one of the established managed care systems suggest that the advocate role takes on more importance as the managed care entity "matures."

Already the shape of opposition to the Clinton reforms is becoming visible. Some will deny the reality of the crisis; that position has already reached the "letter-to-the-editor" stage in Alabama. The major opponents, however, will concede the injustice of the uninsured, avow that they have always favored universal coverage, then oppose the changes that could remedy the problem. They will fight a skillful retreat under the banner of "freedom of choice" and conjure visions of long lines of sick people waiting interminably to be treated.

What feels different to me now than when Medicare and Medicaid were debated in the mid-1960s is that the old "socialized medicine" rhetoric has become hollow. There is nothing left to be feared from big government than has already been experienced from big business. It's way past time for a change, and I, for one, support Brody's call.

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Family Physicians As Researchers In Their Own Practices

The resurgence of interest in practice-based research[1] provides special impetus to consider carefully the report in this issue of *JABFP* by Slatkoff, Curtis, and Coker.[2] Beginning with the apparently innocent request to provide a control group for an investigation that required only an additional cervical specimen to be taken at the time of the Papanicolaou smear and a willingness of the patient to talk with an investigator, they report unanticipated difficulties that emerged, affecting both providers and patients. This article is not about theoretical possibilities; it is about the practical consequences of fear, distrust, additional unplanned work, and unnecessary interventions that resulted from their efforts to improve medicine through research about problems important

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to their patients. The authors point out and discuss important ethical considerations, including informed consent, confidentiality, clinicians as liaisons, timely feedback, and when to interrupt a study. We want to call further attention to a previously recognized problem that could have special importance to family physicians conducting research in their own practices.

The dilemma or problem for which there seems to be no fully satisfactory solution is that of the physician-researcher with the dual ethical obligations to enhance the well-being of individual patients while uncovering relevant knowledge for the general good. This dilemma is not news, of course, as noted in references accompanying the Slatkoff, et al. article, such as the thoughtful discussion by Levine.[3] There has been general agreement that the dual role of physician-researcher should be permitted, and this viewpoint is a necessary precondition for the advancement of family medicine and primary care through collaborative practice-based research. Although data are lacking, our experiences suggest that involvement of practicing physicians in all aspects of research done in their practices probably minimizes research risks to patients, their physicians, and their shared relationships. Although participating in the formulation of research questions and study design might blur the roles of physicians and researchers, this process also permits during study development an explicit discussion of implications for the physician-patient relationships that might be affected by a study. No matter how committed to a particular research effort, we have never observed physicians in practice-based research networks placing higher value on their research than on their patients' well-being. These observations notwithstanding, the nature of family practice and practice-based research merits further explicit consideration to confirm the ethical requirements of family practice research.

There is a special imperative, now well recognized, to cope with referral and selection biases to avoid misinterpreting the medical literature into family practice and perpetuating "false science."[4] This effort necessitates research into the phenomena of family practice and primary care that can realistically be done only by family physicians at the interface between free-living persons and the rest of the health care system. In other words, it is no longer acceptable for family physicians to leave research to other scientists and assume that their results will be of relevance and do more good than harm when implemented with patients in family practice.

Simultaneously, it is widely accepted that the physician-patient relationship is central to effective family practice.[5] It is striking that the research reported by Slatkoff, et al. was reviewed and approved by two institutional review boards, and yet the project negatively impacted patients and providers and could have jeopardized their relationships with each other. Perhaps this outcome was partly a consequence of the formal ethical reviewers not addressing the question, "How will this project affect the physician-patient relationship, if at all?" For much of our medical research, the physician-patient relationship does not exist; if it does, it is often restricted in focus or in time. Obviously, the same is not true for research done by family physicians in their own practices, where the typical assumption is that care will be ongoing, beyond the concerns of a particular problem or research project. Indeed, practice-based research in family practice has special advantages and opportunities because of this circumstance, but have we adequately assessed the special requirements this situation imposes on conducting research in a manner that protects the relationships between patients and their family physicians? Have we determined which, if any, of the usual requirements and procedures of institutional review boards are not needed?

There are other attributes of family practice and the rest of primary care that might also require explicit consideration in the evaluation of the ethical appropriateness of practice-based research. For instance, doing nothing is often very useful in primary care. Time spent in watchful waiting without any intervention is often essential to excellent care. Some research designs might not permit "no intervention."

Alternatively, doing something, however clinically benign, can have substantial impact in primary care, creating effects that are neither desired nor harmless. As shown in the report by Slatkoff, et al., an unanticipated telephone call initiated by the clinician is not likely to be viewed as a neutral or negligible event by the patient who receives such a call.

Feedback in the primary care clinical setting is relatively immediate, occurring often within

hours or days instead of the months that can intervene between starting and concluding a research project. The desirable habit of follow-up with a preparedness to react to interval developments in behalf of a patient perhaps sets the stage for what Slatkoff, et al. eventually recognized was a mistaken decision to intervene with patients serving as controls in their study.

Ambiguity and uncertainty are inherent to the nature of primary care, and much of the research that is needed will of necessity grapple with this ambiguity. It seems likely that no amount of anticipation can predict all the variance and unexpected events that will occur during a well-conceived investigation executed in family practice settings. These unexpected events might require responses that readily can be made in the context of a known past and an anticipated future involving patient, clinician, and staff.

So far, much practice-based research has been done without alteration of care and without identification of physician or patient. Data that would have been collected anyway form the substrate for investigation, with the assumption that the consent patients give by seeking care is sufficient and exempts such research from further special procedures. Inevitably, probing beyond descriptions leads to a need for prospective data collection linked to individuals, and more intervention research is needed in family practices. It seems the time has arrived for careful consideration to be given to the mechanisms that should be used to assure research done "among friends" in ongoing relationships is promoted by practical and achievable methods that protect patients who depend upon practices, which are also laboratories.

We suggest that there is a need for further attention to the establishment of standards for the ethical conduct of practice-based research. Not being expert in this area, we suspect such standards will almost certainly replicate much of what has evolved for the rest of medical research. It is possible that on careful reflection, nothing additional will be required. It seems to us, however, that research occurring within the context of an ongoing physician-patient relationship will require some special consideration.

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Planning For The Unknown In Research: Ethical Dilemmas Confronting The Clinician-Investigator

Medical history is replete with examples of ways in which concern about risks and respect for the patient-subject have been allowed to erode in the name of science.[1,2] The recent revelation by the federal government regarding questionable experiments with plutonium on unsuspecting and unconsenting human subjects, particularly in cases where the subjects were considered a captive or disadvantaged class, demonstrates the fragile nature of the moral safeguards supposedly in place for the protection of patients and research subjects. In this issue of *JABFP*, Slatkoff, Curtis, and Coker's thoughtful article highlights at least two difficult problems facing clinician-investigators who enroll their patients in a research study.[3] The first problem focuses on the content of informed consent and the level of knowledge a clinician-investigator should attain about a research project in order to inform the prospective patient-subject fully about uncertainties

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