

Yet there were hidden costs of extending local review so widely. The OHRP reports that more than 4000 IRBs are now registered, and two National Academy of Sciences panels on human-subjects research regulations have documented that the local-review requirement has created redundant work for IRBs in multisite studies. It has also fueled frustration among researchers, since different IRBs interpret the rules differently, for both good reasons (such as local context) and poorer ones (including local politics and specific pet peeves of influential members).

By revising the Common Rule, the OHRP aims to fix many of the problems that the local review system created when it was scaled up from Bethesda to research sites worldwide, even as RCTs were increasing in size and acceptability. Yet the OHRP's proposed revisions have generated at least as much controversy as they have resolved, as a recent report from the National Academy of Sciences makes clear.⁵

For example, the revisions would require most multisite, cooperative studies to use a single IRB. Under this centralized sys-

tem, either one research site would take on review responsibilities for all sites involved or research teams would all agree to use an IRB unaffiliated with any of the sites. Although this proposal is intended to streamline and accelerate review, critics worry that sites would lose the ability to adapt protocols and consent materials to their local context. The history of ethics review suggests that resistance to centralized review may stem from concern about who holds liability as well as from the desire to protect the distinct needs of specific populations. The best of the models that NIH and universities are developing for centralized review are anticipating this obstacle, but more work is needed to clarify how liability would shift.

The local review model was created to manage the ethics of clinical research undertaken at one site, on a small scale, with participants different from those enrolled in today's RCTs. Yet forms of scientific collaboration, standards of research, and political sensibilities change over time, and unfortunately, the proposed revisions include no requirement

that policymakers systematically update the regulations in the future. We may not be able to predict the new forms that medical research will take, but we can build a regulatory structure flexible enough to accommodate inevitable change — without waiting another 40 years.

Disclosure forms provided by the authors are available at NEJM.org.

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Rethinking the Primary Care Workforce — An Expanded Role for Nurses

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The adult population of the United States will soon have a different primary care experience than we've been used to. In the primary care practice of the future, the physician's role will increasingly be played by nurse practitioners (NPs). In addition, the 150 million adults with one

or more chronic conditions will receive some of their care from registered nurses (RNs) functioning as care managers.

Workforce experts agree on the growing gap between the population's demand for primary care and the number of primary care physicians available to meet that

demand. About 8000 primary care physicians (including doctors of osteopathy and international medical graduates) entered the workforce in 2015, up only slightly from 7500 in 2005. And in fact, the number of yearly entrants is expected to plateau at around 8000. But the number of primary

care physicians who retire each year is projected to reach 8500 in 2020 — in other words, the number of retirees may exceed that of new entrants. And the size of the primary care physician workforce will be declining even as the U.S. population grows, ages, and becomes more adequately insured.¹

In contrast, the number of NPs entering the workforce each year has mushroomed from 6600 in 2003 to 18,000 in 2014. The number of primary care NPs is projected to increase by 84% between 2010 and 2025. The number of physician assistants (PAs) entering the workforce is also growing, though not as rapidly. If these trends continue, the proportion of primary care practitioners who are physicians will drop from 71% in 2010 to 60% in 2025 and will continue to decline thereafter. The proportion of practitioners who are NPs will jump from 19% to 29% during those years and will continue to rise.² In rural communities, this trend is even more pronounced, since NPs are considerably more likely than physicians to settle in rural America.

Clearly, more and more patients will see an NP or a PA as their primary care practitioner. Physicians will probably focus on diagnostic conundrums and lead teams caring for patients with complex health care needs. A large and growing body of research demonstrates that care delivered by NPs is at least as high quality as that delivered by physicians. In addition, patient-satisfaction scores are similar for NPs and physicians.³ Moreover, care may cost less when it's provided by NPs rather than physicians: Medicare beneficiaries assigned to an NP had primary care costs that

were 29% lower and office-visit and inpatient costs that were 11 to 18% lower than those of beneficiaries assigned to a primary care physician.

Even with the increased numbers of NP and PA graduates, the ratio of primary care practitioners to population will decline, because only 50% of NPs and 32% of PAs choose primary care careers. Thus, other professionals will be needed to care for the growing number of U.S. adults with chronic conditions and geriatric syndromes. Enter the enhanced role of the RN.

While the NP role begins to approximate that of the physician, RNs are assuming three important emerging primary care functions: managing the care of patients with chronic disease by helping them with behavior change and adjusting their medications (e.g., for hypertension and diabetes) according to physician-written protocols; leading complex care management teams to help improve care and reduce the cost of care for patients with multiple diagnoses who are high users of health care services; and coordinating care between the primary care home and providers of other health care services — in particular, assisting with transitions among hospital, primary care settings, and home.⁴

RNs are well on their way to filling the gap. In 2015, a total of 43% of U.S. physicians worked with nurse care managers for patients with chronic conditions. The 3.1 million RNs in the United States represent the country's largest health profession, and its numbers are projected to grow by an astonishing 33% between 2012 and 2025. Government data show that the number of RN graduates per year has increased from 69,000

in 2001 to 155,000 in 2013 (see graph); a separate analysis put the number of RN graduates at 200,000 in 2014. Thus, primary care practices are likely to benefit from a pool of RNs who could be hired to serve as chronic care managers.

Several studies indicate that RNs are qualified to perform these enhanced roles. For example, in a randomized, controlled trial, patients with diabetes and elevated blood pressure who received care from RN care managers (including initiation of medications and titration of doses) were more likely to reach their blood-pressure goals than patients whose care was managed by physicians alone.⁵ Some state boards of registered nursing have created a mechanism by which RNs can change medication doses using standardized procedures authorized by their physician leadership.⁴ Using these procedures, RNs who've been trained as health coaches could provide most of the care for patients with uncomplicated diabetes, hypertension, and hyperlipidemia, thereby adding considerable primary care capacity. And RN coordination of transitions from hospital to home has resulted in improved patient self-management and reduced hospital readmissions.

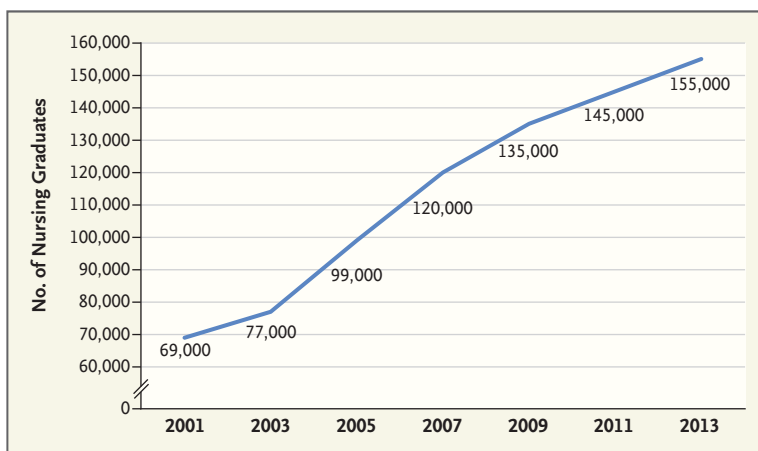
Although NPs and RNs are increasingly central to primary care, there are still obstacles to their performing these roles that need to be overcome. Physicians report that new NP graduates are not initially comfortable taking responsibility for a panel of patients. To address this problem, intensive 1-year primary care NP residencies are springing up. Thus far, 37 such programs exist. Doctor of Nursing Practice degree

programs were designed to supplant master's level NP programs, but they are growing more slowly than expected.

As for an enhanced role for RNs, one barrier is that public and private insurers rarely pay for RN services, but that barrier is beginning to crumble. Even under the fee-for-service payment model, practices can receive payment for Medicare wellness visits and chronic care management encounters, both of which can be conducted entirely by RNs. As alternative payment models gradually expand, primary care payment will become less visit-based, which will allow practices to reallocate more and more responsibilities to RNs and other team members.

The inadequacy of primary care training in nursing schools presents another obstacle to RNs' becoming chronic care managers. The focus of nursing education on inpatient care skills has left some primary care RNs unprepared for the care manager role. The American Academy of Ambulatory Care Nursing and nursing leaders are addressing this problem with new curricula and training programs.

Finally, although RNs may be attracted to primary care's regular work hours, its focus on pre-



Numbers of Nursing Graduates, 2001–2013.

Data are from the U.S. Bureau of Health Workforce.

vention, and long-term relationships with patients, the fact that salaries are lower in primary care than in hospitals could also be a barrier.

Despite these challenges, the shortage of primary care physicians and the increasing prevalence of chronic diseases are powerful forces pushing primary care toward stronger NP and RN participation. It's fortunate that the growth in the supply of NPs and RNs enables us to rethink who does what in primary care.


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