New plan proposed to help resolve conflicting medical advice

Imagine for a moment that you're a dedicated doctor confronting a thorny problem in a patient with high blood pressure who previously suffered a stroke. Unsure what medication to prescribe, you turn to the National Guideline Clearinghouse (www.guidelines.gov), a US government–sponsored website that compiles clinical practice guidelines intended to help doctors like you. There, you find no fewer than 471 different guidelines related to high blood pressure and another 276 that are relevant to stroke.

"We have a proliferation of clinical practice guidelines being written by any number of organizations all over the map," explains Merrill Goozner, director of the Integrity in Science project at the Center for Science in the Public Interest in Washington, DC. "Which ones are right?"

The best medicine? Experts propose a program to help decide.

Enter the Institute of Medicine (IOM), an independent scientific advisory body established by the US government. In late January, the institute issued a report, titled "Knowing What Works in Health Care: A Roadmap for the Nation," that recommended US lawmakers establish and fund a new national program to set quality standards for clinical guidelines, which today rely on different forms of medical evidence and analysis. The ultimate aim is for doctors, insurers, patients and anyone else trying to sort wheat from chaff to use only clinical recommendations that meet these standards.

"We need some mechanism of pulling the information together in a way that will provide a roadmap to physicians, and perhaps to patients," says Barbara McNeil, who heads the department of health care policy at Harvard Medical School in Boston. The new program, acting on advice from a committee of external advisers, would identify the most urgent questions about the treatment of specific medical conditions, and then assess existing evidence concerning the efficacy of these treatments. The aim is to clarify "what has passed muster and is considered to clearly provide a health benefit, what hasn't, and what is in a grey zone," adds McNeil, who chaired the 16-member committee that wrote the IOM report.

McNeil and the committee envision a staffed organization—either within the government or a public-private partnership—that could respond readily to pressing questions, such as "Are artificial discs effective for people with crumbling backbones?" (Recently, the health insurance giant Aetna determined such discs are "medically necessary" in some cases, whereas Medicare called them "not reasonable and necessary.")

Critics, however, say that the project is misguided. "The danger is that the attempt to set rigorous national clinical practice guidelines through prolonged analysis and review— even with the best of intentions—will slow the advance of new medical technologies and deny patients timely access to new therapeutic options," says Paul Howard, a health care analyst at the Center for Medical Progress, a branch of the conservative Manhattan Institute for Policy Research in New York.

Howard points to a 2005 study by Sweden's Karolinska Institute, titled "A pan-European comparison regarding patient access to cancer drugs." The study found that reviews by the UK's National Institute for Health and Clinical Excellence (NICE)—which appraises treatments for the country's universal healthcare system—delayed UK cancer patients' access to new therapies compared to those in the US, France and Switzerland.

In the meantime, with the US Congress preoccupied with presidential elections, a teetering economy and a major ongoing war, it may be a while before lawmakers weigh in on whether the IOM's recommendations are the right prescription for change.

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Despite potential side effects, two drugs make a comeback

The discovery of a possible fatal side effect typically spells the death of a drug. But the return of two medications previously taken off the shelf for safety concerns represents a notable exception to this rule.

One such drug, Tysabri (natalizumab), had originally received approval from the US Food and Drug Administration (FDA) in 2004 for multiple sclerosis. However, the medication was withdrawn the next year after researchers linked it to a rare and potentially fatal viral infection that affects the brain. (In 2006, Tysabri was reintroduced, under restrictions, for the treatment of multiple sclerosis.) Evidence from recent clinical trials has suggested that Tysabri could ease the symptoms of Crohn's disease, an autoimmune disease that affects the gastric system. In light of these findings, on 14 January 2008, the FDA reapproved the drug for the treatment of this gastric disorder.

Another drug, thalidomide, is also undergoing a revival. In the late 1950s and early 1960s, doctors in Europe, Canada and Japan used it to treat ailments such as morning sickness until they realized that the drug caused horrific birth defects and subsequently banned it. After reviewing new research, the European Medicines Agency recommended it for approval on 24 January to treat multiple myeloma, the second most common cancer of the blood.

According to the FDA, any manufacturer wanting to use a withdrawn or banned drug to treat a disease faces the same obstacles of proving safety and efficacy that any new drug would. But Nora Hansen, director of the Lynn Sage Comprehensive Breast Center in Chicago, notes that it's not easy to convince the medical community that a formerly banned or unapproved drug is acceptable for a new purpose. Fears of litigation over dangerous side effects run high, especially in hospitals.

Still, she adds that "most physicians are open to new uses of drugs with questionable safety records if there is good evidence that it works and safety concerns can be adequately addressed," such as those regarding pregnancy in women taking thalidomide

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