SCIENTIFIC PUBLISHING

Pressure for quick release

Washington

IN the wake of yet another round of accusations that US health officials have delayed informing the public of a promising AIDS treatment, the National Institutes of Health (NIH) are moving to establish a set of standards for the quick release of important health-related research findings before they are published in a scientific journal.

Faced with epidemics such as that of AIDS, with its vocal and scientifically literate advocacy groups, NIH officials have been under increasing pressure to short-circuit the traditional journal-based process of disseminating scientific information and instead issue immediate warnings to physicians and the public.

Although a procedure for such release was set up in the mid-1980s to cover advances in cancer research, it has been used sparingly and has been opposed by some researchers, who fear that their chances of publication in a leading journal will be imperilled by early release of their data.

Last week, the sensitivity of the issue was made painfully clear when the *New York Times*, in a front-page article, accused NIH of delaying for five months the release of the results of a study showing that steroids appear to be effective in treating *Pneumocystis carinii* pneumonia, a common and often fatal infection of people with AIDS.

The article said that members of an expert panel had decided that a public announcement should be made, but had spent from May to October of this year negotiating the wording and timing of that announcement so as not to preclude publication in the *New England Journal of Medicine* (NEJM).

NIH quickly contradicted much of the *New York Times* article. Among other things, a NIH statement noted that the results of the steroid trial had already been widely reported, and had even appeared in a front-page *Los Angeles Times* article in June and that NEJM had agreed to allow an early release of the data. But NIH officials also admit that the controversy points to an unresolved problem in reporting key clinical trials.

Clinical alerts

Samuel Broder, director of NIH's National Cancer Institute (NCI), says that although NCI has a procedure for early notification, known as clinical alerts or updates, it has been used only twice in two years, in part because of criticism from the scientific community.

"When [former NCI director Vincent] DeVita issued the first alert [a breast cancer therapy notice in May 1988], he caught unshirted hell", Broder recalls. When Broder himself decided last year that a new colon cancer treatment called for another early announcement, scientists reacted nearly as badly. "Shirted hell", Broder says, may have been an improvement, but not much of one.

The problem, Broder says, is that many researchers are uncomfortable both with the idea of science by press-release, and the idea of "central bureaucratic authority dictating the release of their work".

NIH officials also accept that there are risks in the circulation of clinical alerts. Broder notes the sobering possibility that the information may be wrong. With an official NIH notice in hand, physicians may well turn immediately to the new treatment, even though nuances that would be clear in a journal article might not be obvious in an abbreviated clinical alert. If further investigation reveals error in the research, "you've got a disaster", he says. "With a government stamp on the information, people tend to view it more uncritically than they would a journal article", says Anthony Fauci, director of the NIH National Institute of Allergy and Infectious Diseases.

Despite these risks, NIH have decided that early release is unavoidable in cases of significant advances that have broad implications for public health. Fauci says the risks can best be reduced by making important data public under the supervision of scientists, health officials and scientific journals. A meeting between these groups has been arranged for 15 January at NIH to establish a procedure for such releases. A critical element, Fauci says, will be to establish a consensus on the issue, both among scientists and the journals.

A sampling of the opinions of top journals suggests this may be easier said than done. Policies on early release of data vary (see below), ranging from absolute prohibition to guaranteed leniency.

Electronic solution

NCI already has the means to make primary data on which an alert is based available to physicians in an on-line electronic database (the PDQ system). But NIH officials acknowledge that many doctors are still unfamiliar with computer telecommunications. They have also suggested that journals maintain on-line databases of their own, to make data available in the period between the acceptance of research articles and their publication. That, too, is likely to find some resistance. Although several journals are considering electronic versions, few have found a way to make on-line access pay for itself.

The need for a uniform policy on eventual publication is also plain. As things are, researchers can rarely predict what might happen to their papers should NIH decide on a clinical alert.

Jerome Groopman, a Harvard University AIDS researcher, says a clear policy is essential, but insists that the direction has to come from the scientific community, not just journal editors and NIH officials. "It's our responsibility to establish our own ethical norms." January's NIH meeting may be a good opportunity to put that to the test.

Christopher Anderson

What the journals are saying

ARNOLD Relman, editor of the *New England Journal of Medicine*, says he will always consider allowing the early release of results with important public health implications. His journal also permits the discussion of results at scientific meetings, and even if it is then "picked up by the press, we would not let that get in the way of publication". But Relman says that "we warn researchers to be cautious at press conferences lest they give away more details than they gave at the meeting, or turn over their manuscript", which could affect eventual publication.

At the other end of the spectrum is *Cell*, which publishes mostly basic, rather than clinical, research. The editor, Benjamin Lewin, says *Cell* has "an absolute ban on any release prior to the release date of the journal". But he says that, with a 'fast-track' review process, *Cell* can publish an article in as little as two weeks after submission. "If there is a threat of a leak — anything that may disturb the natural order of [scientific publishing] — we may consent to speed up the review process", he says.

This journal and *Science* occupy something of a middle ground. *Nature* will consider allowing researchers to release results once an article has been accepted for publication, but only after negotiation with the authors, according to the editor, John Maddox. Daniel Koshland, the editor of *Science*, takes the same view and recalls several occasions when *Science* has agreed to the early release of papers of medical importance.

It seems that the more clinical a journal, the more tolerant it is of early release. But journals earn their reputations by publishing more new and interesting work than their competitors. Few would tolerate regularly losing their thunder to NIH alerts and press conferences. Fauci suggests that a solution may lie in an independent panel that would review results and, with the agreement of editors, select for early release only those findings most likely to save lives immediately. C.A.