# THE SORCERER'S APPRENTICE

**A Newsletter Dedicated to International Communication and Cooperation Concerning the Assessment of Medical Technology and Health Policymaking.**

**Clyde Behney, *Editor***

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CHARTER ISSUE


Welcome to the inaugural issue of The Sorcerer's Apprentice, a newsletter on resource allocation and health technology assessment. The idea for the newsletter arose at the last day's discussions at the Bellagio Conference. It's purpose, as you remember, is simply to serve as one method of continuing the cooperation and sharing of information that took place at the conference. It is not an Office of Technology Assessment newsletter, nor is it a United States newsletter. But to ensure that it does not become either of those, you have to take an interest and sometimes an active role in its content. We will edit and distribute the newsletter -- if it appears to be a useful method for fulfilling its purpose -- but its frequency, size, and most especially its content will depend on contributions from the readers.

We should mention the title of the newsletter. By calling it The Sorcerer's Apprentice, we are of course implying several things: The immense, often seemingly magical, power that technology can possess; the fearful attraction that can develop around a technology or the technologists; and, most importantly, that the wizardry and power of technology can only be appropriately used with as full as possible an understanding of its effects and workings. Thus, another way of stating the purpose of the newsletter is that we hope it will help, if only to a small extent, in moving us all -- health professionals, researchers, public and private officials, consumers -- a bit further along in our efforts to become full masters of technology.

This first issue contains, of necessity, pieces by two members of the OTA Health Program staff. Dr. Banta, the Program Manager, you know well. Dr. Mick Riddiough is a Senior Analyst who directed OTA's study of vaccine and immunization

policies, focusing on the case of the pneumococcal pneumonia vaccine. As his piece indicates, this report is an example of a policy analysis that led to legislative change, with implications for resource allocation. David Banta's piece describes some of the activities he observed or took part in during trips to South America and France following the conference in Bellagio.

On Bellagio, we were very pleased with the conference. Your reactions to the format or the substance of the meeting would make good contributions to the newsletter. So, too, would be ideas for other methods of sharing information and keeping each other up to date on methods of assessment, techniques or rationales for allocating resources, ways of using assessment information in decisions, and so on. We feel that terms such as assessment, technology, and resources should be defined, for the newsletter, quite broadly, at least until a better common understanding of what we each mean by them develops. And that can be one of the purposes of this newsletter.

Photo of Lake Como by Egon Jonsson. Apologies to Egon: The xerox is bad, but his photo is beautiful.

We are very aware of the failure rate of newsletters. We are also aware of the other demands on your (and our) time. We are determined, however, that this newsletter will not fail for lack of attention to its production on our part. Energy, though, is not enough. We need ideas and direction. The features and articles should be ones that serve your needs. Let us know what they are. Following the pieces by David and Mick are some of our initial thoughts on features or columns. We are interested in your reactions and in any other thoughts you have about the newsletter. We also need contributions, either articles or feature items.

# A TRAVELOGUE

by David Banta

After the Bellagio conference: A traveling seminar in medical technology assessment by D.B., Clyde Behney, Egon Jonsson, and Pia Maria (a Finnish medical student, friend of E.J., interested in T.A.). We journeyed together to Florence and then to Rome. Clyde and I then pushed on south to Sorrento, visiting Pompeii and Herculaneum, missing the earthquake by 24 hours. Audiences for the seminars were small (We neglected to advertise), so we had ample time to examine local appropriate technology. After I recovered from the Bellagio bug (sometimes called the Russell rush), all was fine.

The next week, intense work began again when I flew to Argentina to participate in a week-long course in health services research. The Argentine government has granted a sum of money to the Catholic University of Buenos Aires to develop a health services research program. The Director of the program, Dr. Aquiles Lanza, decided to inaugurate the program with the course (or seminario). I was asked to present on technology assessment. Other outside participants were Dr. Roy Acheson from Cambridge, England, who presented on medical record linkage; Dr. Robin Badgley from Toronto, Canada, who described developments in Canada, focusing on changes in the health system; Dr. Sakari Härö from Finland, who discussed health planning, focusing on the Finnish model; and Dr. Evert Reerink from Utrecht, Netherlands, who presented on quality assurance. In addition, Dr. Abraam Sonis, an Argentine who is now director of the Regional Medical Library for the Americas (BIREME) in Sao Paulo, made a presentation on information development and dissemination. My lecture on technology assessment was the opening talk, and seemed to be well received. I was nervous about the applicability of ideas developed almost entirely in the industrialized world to a country like Argentina, but the similarities were astounding. One day at lunch, I sat next to a gastroenterologist who told me that all of his younger colleagues are passing endoscopes into the stomach at great rates and that he is concerned both about unnecessary services and about the fact that the fee system encourages such services. OTA has a case study, developed in California, on gastrointestinal endoscopy, that discusses the same concern. Other similarities were apparent, perhaps even heightened, by the relative limitation of resources and by abortive attempts of the government to control expenditures. So private medicine is flourishing, for example. It was a fascinating experience, and made me feel that we must recruit

Argentine members to our international club.

The next Monday, I stopped in Sao Paulo to visit BIREME. I learned that the major international retrieval mechanism for medical literature is the U.S. National Library of Medicine, which has a number of cooperating libraries in other countries. BIREME is the Latin American library and also publishes the Latin American Index Medicus. Dr. Sonis has decided to publish some sort of newsletter on medical technology and asked my advice on sources of information. I offered the cooperation of OTA and my help in getting access to other U.S. government sources. If others have ideas or offers, I will pass them along to Dr. Sonis.

I then returned home, but the next Saturday (December 6) I flew to Paris for a three day meeting sponsored by the Organisation for Economic Cooperation and Development (OECD). OECD has decided that medical technology assessment is an important issue, and so convened a small group of experts for in-depth discussions. Egon Jonsson and Barbara Stocking were there, as was Dr. Lacronique, who had intended to be with us in Bellagio. It became clear in the meeting that Dr. Lacronique would like to expand technology assessment activities in France. I also spent a day discussing the issues less formally with OECD staff. OECD intends to write a report, discussing medical technology assessment from a policy perspective, that will go to all member nations.

In addition to the OECD meeting itself, Dr. Seymour Perry, the Director of the National Center for Health Care Technology, and I made a presentation to French health policymakers on activities in the United States related to medical technology.

At the end of the Bellagio meeting, a number of participants said that they felt OTA had some responsibility to continue to build a network of people interested in these issues. Clyde and I thought that the above evidence of an expanding network would be interesting to you. For myself, I hope that this newsletter will begin to formalize a relationship between the many people doing analytic work related to the benefits, risks, and costs of medical technology.

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# OTA'S REPORT ON FEDERAL VACCINE POLICIES

By Michael A. Riddiough, Pharm. D., M.P.H.

In September 1979, OTA released a report that addressed four areas of Federal vaccine policy:

A. Vaccine Research and Development. The Federal government is the single most important determinant of the extent of vaccine research, development, and use in the United States. Federal actions having a positive effect include the financing of vaccine research and development and of major public immunization programs. Federal policies that may be contributing to a decline in the private sector's commitment to vaccine development include an unwillingness to resolve certain liability issues. The nation depends heavily on vaccines to prevent several childhood diseases. For that and other reasons, decisive government efforts are needed to help stimulate the creation of new vaccines and to ensure the continued supply and use of existing safe and efficacious vaccines.

B. Vaccine Safety and Efficacy. The U.S. Food and Drug Administration (FDA) is responsible for assessing the safety and efficacy of vaccines in this country. FDA's primary evaluative tool is data from clinical trials. Limitations of the premarketing vaccine testing procedures required by the FDA may permit some vaccines to be marketed without clinical testing in targeted populations and without awareness of rare adverse vaccine reactions. Furthermore, the government does not require vaccine manufacturers, health professionals, or any Federal agency to collect data regarding the safety and efficacy or effectiveness of licensed vaccines.

C. Federal Reimbursement for Adult Vaccinations. Medicare (the Federally financed health insurance program for the aged) pays for the treatment of infectious diseases, but not for vaccinations to prevent them. Consequently, even though the Federal government 1) spent $6.5 million to help develop a vaccine to prevent pneumococcal pneumonia, and 2) deemed that vaccine to be safe and effective enough to license it for general use (especially among those 65 years old and over), Federal law prohibited reimbursement for the new vaccine among Medicare beneficiaries. OTA's analysis indicated that pneumococcal vaccination was a cost-effective method of yielding years of healthy life, especially among the elderly.

D. Liability and Compensation for Vaccine-Related Injury. Stemming primarily from injuries incurred by vaccinees in the 1976 so-called "swine flu" immunization program, liability and compensation for a small number of unavoidable

injuries (caused by nondefective and properly administered vaccines) may be eroding the commitment of vaccine manufacturers, Congress, and State health departments to public immunization programs. Some courts have ruled that vaccine manufacturers must warn people about possible unavoidable side effects and must compensate injured vaccinees for unavoidable harm if a warning was not given. When vaccine producers sell their products to the Federal government, their contracts specify that the government is responsible for the "duty to warn" those vaccinated about possible side effects. The legality of the transfer of the "duty to warn" responsibility has never been tested in court. The seriousness of this unresolved situation is underscored by the fact that some vaccinations are mandated by law. Most children, for example, must receive certain vaccines before starting school.

This report stimulated a successful piece of legislation and two follow-up studies by OTA on vaccine-related issues.

Changing the Medicare Law

Within one month after this report's release, legislation was introduced in both chambers of Congress to permit Medicare reimbursement for pneumococcal vaccinations. (Note: Although the report addressed issues of perhaps greater significance, Medicare reimbursement for pneumococcal vaccination was a highly visible and relatively straightforward legislative task to tackle.)

Advocates of this legislation quickly formed a coalition including: The two manufacturers of pneumococcal vaccine, certain State health officers, various public health associations, selected Members of Congress and their staffs, and (unobtrusively) a few executive branch employees.

The legislation encountered several obstacles as it moved through the two chambers of Congress, the largest of which was concern over its budget impact. Some staff members were blatently opposed to paying for a preventive medicine measure, fearing such a move would "open the flood gates" to other but more expensive and questionably effective preventive measures.

In the final week of the 96th Congress, the legislation was finally passed by both chambers of Congress. It was signed into law by President Carter on December 28, 1980.

Throughout the Congressional debates on this issue, OTA's cost-effectiveness analysis of pneumococcal vaccination, supplemented by a similar analysis conducted by the Congressional Budget Office (another Congressional research agency), was used to illustrate the merits of pneumococcal vaccine.

Two Follow-Up Studies

OTA's vaccine policy report generated Congressional requests for two follow-up reports concerning vaccine-related issues. The first request was for an analysis of the Congressional options available to create a Federal compensation program for victims of vaccine-related injuries. That report has just been released: Compensation for Vaccine-Related Injuries, Office of Technology Assessment, U.S. Congress, Washington, D.C., Government Printing ffice (No. 052-003-00788-6), November 1980.

The second request was for a cost-effectiveness analysis of influenza vaccination. The role of the Federal government in promoting influenza vaccinations has been debated virtually annually for at least ten years. Such a Federal role has ranged from no support to complete financing of a mass influenza vaccination program (i.e., the 1976 "swine flu" program). This report quantifies the health effects (in terms of disability days and deaths), socio-economic effects (e.g., days of work, school, and housekeeping lost), and costs (e.g., hospitalization, physician visits, vaccine purchases) associated with influenza and influenza vaccination. The purpose of the report is to help clarify for legislators the benefits and costs of influenza vaccination. It will be released in spring of 1981.

In summary, OTA's vaccine policy report illustrates how an objective medical technology assessment, when properly introduced into a governmental decisionmaking arena, can create and contribute to public debate and legislative actions concerning an important public health issue.

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Editor's Note: Any reader who wishes to receive a copy of any of the reports described by Mick should write him at: Office of Technology Assessment, U.S. Congress, Washington, D.C. 20510, United States of America. If you are writing the newsletter editor on some other matter (with a contribution, I hope!), you can also mention your request and I'll pass it on to Mick. All OTA reports are also available through the U.S. Government Printing Office and, usually, the National Technical Information Service. If you wish to call Mick, he's on the same telephone number as the rest of the Health Program here at OTA: (202) 226-2070.

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## IDEAS ON POSSIBLE FEATURES

By "features" we mean sections of the newsletter that would appear in each issue. By having defined features (or "columns") we hope to encourage the submission of contributions of a brief nature. They are simply discrete forums for the exchange of a particular type of information. Below we list some of our ideas on possible features. We would like your comments on these. We would also like your ideas on additional ones and your contributions to any of these.

### RECENT PUBLICATIONS

Self-explanatory. If you learn of or publish a document that you feel would be of interest to the other readers, send a brief description of it, along with a complete citation and information on how to order it.

### STUDIES IN PROGRESS

Similar to above, but obviously not yet complete or published. Could also include studies or projects that will not result in a publication (or one that would not be accessible to most readers).

### CALLS FOR INFORMATION

If you are interested in a particular topic, let us know and we'll put out a call for information to the readers. (We'll also try to let you know what information we have or know of on the topic.) When requesting information, be as descriptive as possible in terms of the topic and the types of information needed.

### NEW NETWORK MEMBERS

We will publish the names, affiliations, and addresses of new members. You can help by suggesting new members to us or by telling interested potential members how to get in touch with us. The ubiquitous Blank Form is provided below for suggesting people.

### CALLS FOR POTENTIAL REVIEWERS

Many of us publish studies that are sent for review to numerous organizations and individuals. And, we're always interested in learning of other reviewers who we should be asking to help us. If you are in such a position, and the need for additional potential reviewers can be anticipated sufficiently in advance, let us

know and we'll publish your request. Again, be explicit about the nature of the document to be reviewed, its approximate length, the timing, and the type of comments or review you need, including the points-of-view you feel are especially important.

TERMS/DEFINITIONS

As mentioned above, terminology is a constant source of confusion and miscommunication. We encourage suggestions for terms that should be discussed. We also would be pleased if you sent a brief analysis of such a term. Some possible terms that might be spotlighted are "efficacy versus effectiveness," "disability," or "quality-adjusted life years."

FOCUS ON COUNTRIES/AGENCIES/PEOPLE

We believe that it would be interesting and informative to have a brief write-up on a different country, agency, or individual in each issue of the newsletter. The editor personally encourages submissions on Ethiopia and the Sudan. We may also run a piece on the National Center for Health Care Technology and perhaps the Medical Research Council of the U.K.

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THE PEP TALK

We need your ideas, reactions, and contributions. Please send these to:

Clyde Behney
Office of Technology Assessment
U.S. Congress
Washington, D.C. 20510
U.S.A.

My phone number is (202) 226-2070. Feel free to call. We are especially interested in hearing of ideas on additional methods of following up on the Bellagio meeting.

The blank form for suggesting new network members is attached. Please send these to the above address.

To suggest additional people who should receive The Sorcerer's Apprentice and be added to the list of network members, please fill out the below form and mail it to the address below.

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NAME _____

MAILING ADDRESS _____

_____

_____

(Country) _____

AFFILIATION _____

POSITION _____

TELEPHONE NUMBER _____

AREAS OF INTEREST _____

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COMMENTS (By Nominator) _____

_____

NOMINATED BY _____

MAIL TO: Clyde Behney
Office of Technology Assessment
U.S. Congress
Washington, D.C. 20510
U.S.A.