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In the Literature

CENTRALIZED DRUG REVIEW PROCESSES IN AUSTRALIA, CANADA, NEW ZEALAND, AND THE UNITED KINGDOM

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As new drugs come to market and more limits are set on health care costs, policymakers in government and industry must make tough decisions regarding which medicines will be covered by health plans. To help with such judgments, many countries have centralized programs that perform clinical and economic assessments of drugs based on the best scientific and financial evidence available.

According to a Commonwealth Fund–supported study in *Health Affairs,* the success of these programs depends on the scientific rigor of the review process, the separation of the analysis into distinct phases—an initial assessment and then a subsequent appraisal of the evidence—and the ability of the public to understand the decision-making rationale.

In "Centralized Drug Review Processes in Australia, Canada, New Zealand, and the United Kingdom" (*Health Affairs*, Mar./Apr. 2006), former Harkness Fellow Steven G. Morgan, M.A., Ph.D., a health economist at the University of British Columbia, joins colleagues in surveying coverage assessment processes in Australia, Canada, New Zealand, and the United Kingdom. The authors discuss the different program approaches, the differences in resulting drug coverage and costs, and successful components of each program.

About Centralized Drug Review

The researchers report that the drug review processes in the four countries have two stages: an initial assessment and a subsequent appraisal of the evidence. The initial assessment involves expert evaluation of the scientific evidence from manufacturers and the literature. Reviewers determine the probable impact of the product on the patient's health, on costs, and on the overall health care system. In the second phase, reviewers propose which drugs should be funded, for whom, and under what circumstances. Appraisals require choices; given limited resources, all effective medicines cannot be funded. Typically, to reduce the chance for bias, different members serve on the committees performing the assessment and appraisal phases of the process.

Reviews are conducted to create formularies—lists of medicines covered under a given program and the subsidy level and conditions under which each medicine is offered. Drugs not on such a formulary—called a "positive" formulary—are generally not covered. The United Kingdom, however, has a "negative" formulary, where virtually all medicines are covered unless listed or restricted locally.

During the decision-making process, there are opportunities for exchange and feedback among the reviewing agency, the manufacturer, and the public. Once decisions are made public, stakeholders can file appeals.

Decisions and Impact

To compare the systems, the research team selected 17 top-selling, high-volume drugs in 2003 for each of the four countries and the United States. Several were new entrants into long-established drug classes, while others were intensely marketed "breakthrough" drugs. While the listing

decisions varied by country, the researchers did find a common trend: public listings have an influence on usage. Rates of use tend to be highest among countries offering some form of national coverage and lowest among those without coverage. In general, spending levels closely followed usage levels in all countries.

But in those cases where Australia and New Zealand had higher-than-average usage levels, they often had lower-than-average spending levels. This finding, the authors say, most likely reflects the fact that these two countries tie national coverage decisions to price negotiations—similar to what large U.S. insurers do. Because of relatively high per-unit costs, the United States tended to be a greater outlier in per capita spending than in per capita usage, although this may not reflect all price discounts provided directly to insurers.

Components of Successful Review Programs

After reviewing the drug processes, the researchers interviewed expert informants in each country. The following factors, they say, are key to success:

- *Rigor of the process*. The scientific assessment of evidence must have high standards. A "hierarchy of evidence" should be used to determine the merits of a study's design, which ideally should be a blinded, randomized, and controlled trial. But reviewers also should use a "hierarchy of outcomes," that would, for example, place the greatest emphasis on mortality measures.
- *Clarity of roles*. Participants in the different stages of the review should have their roles and responsibilities clearly defined. Just as conflicts of interest with manufacturers can discredit the process, people involved in the scientific review should not be responsible for appraising evidence and making coverage recommendations.
- *Transparency of rationale*. Providing stakeholders, such as manufacturers and the public, with information about the decision-making process increases political accountability. One major obstacle to transparency is commercial confidentiality often imposed by manufacturers.

In order to help policymakers make tough, evidence-based choices in the health care sector, centralized review processes must be transparent and rigorous. Ultimately, say the authors, the public must be able to follow the process and methods and understand how decisions are reached.

Facts and Figures

- The Australian government provides virtually all residents with a subsidy for drugs listed on a national, positive formulary.
- In Canada, approximately half of prescription drug purchases are funded through a patchwork of 16 federal, provincial, and territorial drug plans.
- In the United Kingdom, the National Health Service (NHS) does not have a national list of drug benefits; rather, it has a "negative" list of drugs excluded from the NHS subsidy.
- In the United States, the Drug Effectiveness Review Project conducts regular systematic reviews of evidence for private and public drug plans to compare drugs within leading therapeutic drug classes.