Consensus Conference as a Tool for National Health Services Policy: the Case for Osteoporosis

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Key words: osteoporosis, consensus conference, national health policy

IMAJ 2000;2:375–376

The National Health Services Basket in Israel is publicly funded according to the stipulations of the National Health Insurance Law [1], which is based on principles of justice, equality and mutual assistance. This 1994 law determined rules for introducing possible changes in the composition of the basket and the manner of updating the costs of its various components. In order to facilitate the inclusion of new technologies (namely drugs, medical devices and medical procedures) in the health services basket, it is necessary to formulate a precise medical assessment process and policy on a national level. It follows that the inclusion of new technologies in the NHSB requires a clearly defined budget.

The initial stage of this technology assessment process includes examinations of safety and efficacy. These are universally accepted principles and are mandatory for economic evaluations that embody local components relevant to each particular country. A final stage of this process involves the difficult issue of predicting the needs assessment of the population for a specific technology.

During the past two years, a new method has evolved for examining new technologies that are candidates for inclusion in the NHSB. This method stresses medical, epidemiological and economic examination of new technologies according to clearly expressed priority guidelines (submitted for publication).

In 1998, a public committee was appointed by the Minister of Health to determine which medications would be included in the NHSB. By the year 2000, this committee had received requests for the adoption of approximately 450 new medical technologies totaling $400 million. The amount designated by the Government for this purpose amounted to only $65 million (1.5% of the total budget for general health services in Israel provided by the four sick funds according to the NHSB). One of the major issues in the committee discussions centered on the treatment for osteoporosis.

Osteoporosis is a chronic progressive metabolic bone disease that can affect almost the entire skeleton [2]. It has been defined as "a disease characterized by low bone mass and micro-architectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk" [3,4].

Research conducted over recent years has given birth to a new generation of medications (such as alendronate, raloxifen and others) for the treatment of osteoporosis. However, despite the high level of their "proven" efficiency, these drugs involve extremely high costs that are to be covered by government funding. During the past years, both physicians and patients exerted pressure on the government to include these new medications as top priorities in the NHSB.

Introducing the new generation of medications required an accurate utilization prediction. This necessitated a needs assessment of the population, specifying information on pharmacoepidemiology, compliance and consensus on good medical practice.

This mission encompasses a number of major components and important questions to be addressed. These include: a) determining the size of the population involved – in this particular case, the target female population in Israel in 1999 was approximately 150,000 women (based on a national survey conducted in 1998 on women's health); b) defining medical indications for treatment; c) specifying compliance; d) determining whether the issue in question is prevention or treatment; e) ascertaining age groups for early detection; and f) estimating the funding required – regarding osteoporosis, the national annual budget for these drugs has been estimated to range from $6.5 million to $60 million.

In discussions held in 1998, the national council failed to reach a full consensus on the above issues and the medications were therefore not included in the NHSB. Thereupon, the need arose for a broad national consensus that would consider the clinical indications, public opinion, patients' demands expressed through organizations representing their health interests, political pressure, the viewpoint of insurers and the requests of clinicians, and finally an economic evaluation of all the medical technologies for the prevention and treatment of osteoporosis in terms of cost-effectiveness and cost-benefit analysis.

In order to address this need, prior to the decision to expand the NHSB, the Ministry of Health, in collaboration with the Israel Center for Technology Assessment in Health

NHSB = national health services basket

Care and the Israel Medical Association, organized working groups in 1999 to discuss the relevant issues. A consensus conference followed, which included experts in multidisciplinary fields — specialists, clinicians, medical administrators, ministerial and sick fund representatives, economists, representatives of the public, and members of the Knesset. The Osteoporosis Consensus Conference dealt with the following questions:

- What is the epidemiology of osteoporosis in Israel?
- What are the target populations for primary and secondary prevention of osteoporosis?
- What are the different techniques available to diagnose osteoporosis?
- Should population screening for osteoporosis be recommended?
- How should the prevention of osteoporosis be approached in the presence of osteopenia?
- What treatments are available for established osteoporosis?
- What is the target population for treatment?
- How effective are these therapies?
- What is the therapeutic approach for patients suffering from osteoporosis due to glucocorticoid therapy?
- How should male osteoporosis be treated?
- What is the economic impact (cost-utility, cost-benefit) of programs for the prevention and treatment of osteoporosis?
- What are the possible alternatives available to the health system in 2000 for the prevention and treatment of osteoporosis?

The results of this consensus conference are presented in this edition of *IMAJ* [5]. The decisions of the consensus conference contributed both to the adoption of these new drugs through public funding, and to the acceptance of all the other recommendations for the prevention, detection and treatment of the disease. Following discussions, the national committee adopted all the recommendations of this consensus conference; since January 2000 the new generation of drugs are included in the NHSB.

This consensus conference was the second of a series initiated by the Ministry of Health, the Israel Center for Technology Assessment in Health Care and the Israel Medical Association, and funded by the National Health Council as an effective cost-contained mechanism. The first consensus conference held in 1999 was a vital step in the systematic process to formulate national policy on osteoporosis. It addressed the treatment and rehabilitation of hip fracture in the elderly, presented the extent of the problem, and proposed recommendations to improve clinical processes, rehabilitation, service organization, data collection and economic aspects [6].

The notion of the consensus development conference originated in the National Institutes of Health in 1977 to serve as a catalyst for activities, bringing "together various concerned parties in order to seek general agreement on the safety, efficacy and appropriate conditions for the use of various medical procedures, drugs, and devices" [7]. To be sure, active participation of all concerned parties in open discussion and public debate helps clarify findings, issues and points of view, thereby promoting the acceptance and application of recommendations. A crystallized presentation of these activities appears in two momentous articles written by Dr. Seymour Perry, founder of the NIH consensus conferences, in the *New England Journal of Medicine* [7,8]. Other countries, such as the UK, Switzerland, Sweden, Norway, Netherlands, France, Australia and Canada, have taken this path during the last two decades and hold consensus conferences on major health issues. It must be noted, however, that the decisions of consensus conferences in other countries cannot be adopted automatically. Each nation has unique characteristics that must be taken into consideration, such as differences in epidemiology, public opinion, medical standpoint, patients' attitudes, ethical and cultural values, political atmosphere, and national priorities.

The Israeli experience demonstrates that the national consensus development conference is an important tool for the assessment of medical technologies under debate. Certain conditions in medicine and particularly in administrative policy are essential to facilitate the determination of national policy, as exemplified in the inclusion of new medical technologies.

An additional article on osteoporosis in this issue of *IMAJ* [9] epitomizes the importance of providing clear guidelines and expanding knowledge to enhance the decision-making process.

In conclusion, the national consensus conference is an excellent tool for the decision makers to help them in their task of promoting and adopting new medical technologies. It is a cost-effective method that facilitates accuracy and appropriateness.

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