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1. WHAT PROBLEMS CAUSED YOUR COUNTRY TO BEGIN A DEBATE ON EXPLICIT PRIORITY SETTING? WHEN DID THE DEBATE TAKE PLACE? WHO WAS INVOLVED?

a) Generally — the increasingly high cost of providing quality medical care and the impossibility that the state budget would provide funding for all the services and drugs that the health care system wished to introduce;
b) Specifically — the public outcry at the non-inclusion of certain new drugs and therapies in the basket of drugs and therapies provided by the national health care system.
c) Who was involved? The Ministry of Health, the Ministry of Finance, the health management organizations (HMOs), senior physicians, patient groups and their advocacy associations, drug manufacturers, the daily press, researchers.
d) When? The issue arose during the passing of the National Health Insurance Act in 1995. Explicit priority setting began in 1998.

1A. WHAT KIND OF HEALTH CARE STRUCTURE EXISTED AT THE TIME?

In 1995 the National Health Insurance Act was passed, making health care insurance coverage compulsory and universal. The Act set out a list of health care services and drugs to which all residents were entitled (the NLHS). The government is responsible for funding those services and drugs and that funding comes in approximately equal proportions from a universal Health Tax (as a percentage of wages) and a direct allocation from the state budget. This funding is then distributed by capitation among the four large health management organizations (one of which every resident must join). The HMOs are the main actual service providers (the government remains responsible for some direct service provision) and each HMO must provide its members all the services and drugs listed in the NLHS (the “health basket”). This ‘basket’ was composed of all the drugs and services provided in 1994 by Israel’s largest HMO.

Since all the HMOs are in financial deficit and one cannot expect new services to be funded by increased efficiencies, the National Health Insurance Act determines that the NLHS can be updated only when additional funding is provided. During the first three years after the Act was passed (1995-97), no budget was allocated for the purpose of updating the NLHS. Therefore, no new medical technologies were added to the NLHS (except for one drug included in response to a specific court order).

2. WHICH HEALTH CARE SERVICES OR SERVICE AREAS ARE TO BE PROVIDED AS A PRIORITY?
Basically, it is mandatory to provide all services that are included in the NLHS and therefore, all these services have the same priority. It should be noted that the range of health services provided by the NLHS is broad, including a comprehensive range of health technologies (drugs, devices, procedures etc.).

ARE THERE GROUPS OF PEOPLE OR DISEASES WHICH ARE GIVEN HIGH/LOW PRIORITY?
No.

ARE THEIR PARTICULAR HEALTH CARE GOALS WHICH HAVE HIGH PRIORITY?
According to the values of the Israeli society, saving lives, prolonging life and improving quality of life are the principle goals of our national health system. The practical implementation of these goals is complex and raises numerous ethical and social dilemmas.
For example, what is the borderline between saving life and prolonging life? Another instance: what precedence should be given to improving the quality of life of a large population, as opposed to extending life for a limited period for a small group of patients?

3. ON THE BASIS OF WHICH ETHICAL VALUES AND CRITERIA ARE PRIORITIES SET IN ISRAEL?
See Question 6.

4. WHAT INSTITUTIONS AND GROUPS DEAL WITH PRIORITY SETTING?
In 1999 the Ministry of Health appointed the Medical Technologies Administration (MTA) at the Ministry responsible for managing and updating the NLHS by prioritizing new health technologies.
To assist the MTA in this mission, a National Public Advisory Committee was established of 24 members, including public representatives and representatives of different health organizations - HMOs, hospitals, the Israel Medical Association, etc.
The Public Committee recommends to the Ministry of Health which prioritized technologies are to be included in the updated NLHS, according to the yearly budget allocations.

HOW ARE THESE ACTORS LEGITIMIZED?
The major participants in the national priority setting process are the members of the Public Committee appointed by the Ministry of Health (as mentioned above).

Health organizations as well as the public, the media and others have largely accepted that the Committee possesses a broad vision on scientific, medical and social matters and is, as such, qualified to set national priorities.

WHAT ROLE DOES PUBLIC INVOLVEMENT PLAY?
The role of public involvement in this process is as follows:
1. In the Call for proposals: Any person in Israel is entitled to submit proposals for updating the NLHS.
Each proposal is reviewed equally by an initial Health Technology Assessment process, with no preferential regard to the person or group submitting the proposal.
2. In the Final Prioritization Process: a substantial part of the Public Committee that prepares the national prioritization of health technologies for updating the NLHS consists of public representatives.

5. IN WHAT WAYS IS PRIORITY SETTING TO BE INTRODUCED AND IMPLEMENTED?

The Medical Technologies Administration (MTA) has devised a 7-stage process based on Health Technology Assessment. The 7 stages of the prioritization process are:

1. Call for proposals
2. Quick assessment and screening of proposals
3. Data collection and initial evaluation
4. Comprehensive evaluation
5. Priority setting
6. Decision-making
7. Government approval and legislation

The process can be described briefly as follows: health care teams are established to evaluate the clinical safety, efficacy and effectiveness of all the proposed technologies (approximately 400 per year), and conduct needs assessment and economic analyses.
Priority setting is conducted by the Public Committee, which prepares a list of recommendations to the Minister of Health and the Israeli government. Following approval by the Minister of Finance and the government, the updating of the NLHS is mandatory.

6. WHAT VALUES AND CRITERIA ARE APPLIED IN PRIORITIZATION?

At the initial evaluation and comprehensive evaluation stages the proposals that had passed the Quick Assessment stage underwent clinical, epidemiological and economic evaluations. The clinical evaluations focus on evidence-based data, including post-marketing effectiveness data. Special attention is paid to identifying the specific patient groups that would benefit most from each new technology, given the likelihood that it will not be possible to treat all the indicated patient population.
Key issues in the comprehensive evaluations are:

a. The scope of the problem — assessed by prevalence and incidence indices;
b. The disease's burden on the health care system — in terms of mortality, morbidity, services utilization and/or functional disability;
c. The available alternatives;
d. The cost of the disease — in terms of the resources required for it and for alternative treatments;
e. Clinical and economic aspects of the new treatment.

Other criteria that are considered during the prioritization process include:

1. Life-saving technology with full recovery;
2. The technology's potential for preventing mortality/morbidity;
3. The number of patients who would benefit;
4. The financial burden on society and the individual patient;
5. New technology for mild diseases, for which no treatment alternative exists;
6. New technology for serious diseases, for which no treatment alternative exists;
7. The technology increases longevity and/or quality of life;
8. The benefit from reducing morbidity versus the benefit from improving quality of life;
9. The net gain to the health care system or society is higher than the technology's short-term/ long-term cost;
10. Mutual assistance for publicly funding a technology of proven efficacy that is very expensive to the individual but of reasonable cost to society.

An additional group of technologies is also considered:
technologies identified as imposing no extra cost as compared with existing technologies in the NLHS. These are included without prioritization for two reasons:

a. To expand treatment possibilities
b. To increase competition between manufacturers, thereby possibly leading to price reductions.

HOW ARE THE VALUES AND CRITERIA OPERATIONALIZED?
Each one of the technologies that comes through the comprehensive 3-part evaluation (clinical, epidemiological and economic) is then placed by the members of the Medical Technology Forum into one of 3 major groups, High, Intermediate and Low priority. These prioritizations are then presented to the National Public Advisory Committee, which makes the final decisions and recommendations to the Ministry of Health and government.

WHAT FACTORS ARE NOT CRITERIA IN PRIORITY SETTING?
See the details above.

7. WHO IMPLEMENTS PRIORITIZATION DECISIONS? AT WHAT LEVELS? HOW BINDING ARE THE DECISIONS?
Following government and finance approval, the implementation process is conducted by the Ministry of Health. By law, the 4 HMOs must provide the updated services.

8. WHAT MECHANISMS ARE BEST SUITED TO IDENTIFYING AND REALIZING PRIORITIES? HOW SIGNIFICANT ARE THE CONCEPT AND METHODS OF EVIDENCE-BASED MEDICINE?

An essential condition for incorporating new technologies in the updating process is the basic requirement that the technology has undergone registration and official regulatory approval.

Evidence-based medicine (EBM) plays a central role in the prioritization process (see question 6, Clinical Evaluations). During the prioritization process a balance is created between the need for EBM and the desire to introduce new emerging technologies.

WHAT CONFLICTS HAVE COME TO LIGHT IN THE PRIORITIZATION PROCESS?

There is a dilemma between the priorities of saving patients' lives, prolonging life and improving the quality of life. Other dilemmas include: providing expensive treatment for few patients as opposed to less expensive treatment for a broad population? How to save lives? Prioritization of treatment for chronic disease as opposed to major acute conditions.

9. HOW IS PRIORITY SETTING EVALUATED, ADJUSTED?

The national prioritization process began 5 years ago. Hence, this is an appropriate time period to assess the diffusion of the technologies that were included in the national health basket.

The mechanisms for evaluating the prioritization decisions are ready and data has been collected (checking how new technologies are performing, how they are being used, etc.). Analysis of the data is planned to be conducted during the coming year 2005.

10. HAS THE PRIORITY SETTING PROCEDURE TAKEN ROOT?

There is no automatic mechanism for providing funds to update the NLHS. Each year the government decides on financial allocations to government ministries on the basis of national needs in all sectors of the economy. The government also decides what portion of the funds dedicated to the Ministry of Health will be set aside for updating the NLHS.

It should be mentioned that there is a current legislative proposal to change this situation and enable an annual automatic mechanism for updating the budget for new health technologies.

11. WHICH APPROACHES HAVE PROVEN USEFUL, WHICH DISCARDED?

12. WHAT LONG-TERM EFFORTS EXIST TO MEET THE CHALLENGE OF ALLOCATING RESOURCES FAIRLY?

In Israel we have established a systematic mechanism to identify, evaluate and prioritize technologies within the framework of a specific budget. This model has been in operation for the past 5 years and has been well-accepted by the public, policy-makers and health officials.

During these past few years we have improved technical aspects of the process, enhancing the measures implemented. The outcome is that the

update meets the needs of different fields of medicine (specialties) and different patient groups.
We are currently in the process of assessing the outcomes of this methodology and its national implications.

13. WHAT RECOMMENDATIONS CAN YOU GIVE GERMANY AS REGARDS EXPLICIT PRIORITY SETTING IN HEALTH CARE?

The Israeli model includes references to a broad range of parameters – medical, economic, ethical, social etc. We can provide you with recommendations considering the professional parameters and scales that we found to be adequate and appropriate for the process.

However, the innovation of the Israeli model lies in combining a budget and prioritization – our process uniquely prioritizes new technologies **within the framework of a specifically allocated budget.**

To the best of our knowledge, in other countries such as England, the technology assessment process conducted by NICE, is not subject to the restrictions of a specific budget.