# The process of updating the National List of Health Services in Israel: Is it legitimate? Is it fair?

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**Objective:** The Israeli National Health Insurance Law stipulates a National List of Health Services (NLHS) to which all residents are entitled from their HMOs. This list has been updated annually for almost a decade using a structured review and decision-making process. Although this process has been described in detail in previous papers, none of these have fully addressed legitimacy and fairness. We examine the legitimacy and fairness of the process of updating the NLHS in Israel.

**Methods:** We assessed the priority-setting process for compliance with the four conditions of accountability for reasonableness outlined by Daniels and Sabin (relevance, publicity, appeals, and enforcement). These conditions emphasize transparency and stakeholder engagement in democratic deliberation.

**Results:** Our analysis suggests that the Israeli process for updating the NLHS does not fulfill the appeals and enforcement conditions, and only partially follows the publicity and relevance conditions, outlined in the accountability for reasonableness framework. The main obstacles for achieving these goals may relate to the large number of technologies assessed each year within a short time frame, the lack of personnel engaged in health technology assessment, and the desire for early adoption of new technologies. **Conclusions:** The process of updating the NLHS in Israel is unique and not without merit. Changes in the priority-setting process should be made to increase its acceptability among the different stakeholders.

**Keywords:** Resource allocation, Accountability for reasonableness, Technology assessment, Decision making, Fairness

The rapid increase in healthcare costs coupled with the limited resources allocated to healthcare systems make priority setting or rationing inevitable. There are numerous contributing factors to rising healthcare costs, but costly new medical technologies have been identified as the leading cause of increasing healthcare expenditures in almost every Western healthcare system. As a result, the need for evidence-based, transparent approaches for setting priorities in public funding of new technologies has emerged, and several Western countries have established an explicit priority-setting decisionmaking process. To date, no country has come up with an optimal solution for resource allocation in healthcare. The key principles guiding a fair priority-setting process are straightforward and a rationing mechanism requires a scientifically rigorous and transparent process, based on clear and standard criteria. Traditional approaches to priority setting have focused on evidence-based medicine and health technology assessment, as well as cost-effectiveness analyses, but recent theories of healthcare priority setting have emphasized the importance of ethical processes to ensure fairness of the decision-making process (3–5).

Condition	
Relevance	The rationale for priority-setting decisions should provide a reasonable explanation of how the organization seeks to provide "value for money" in meeting the varied healthcare needs of a defined population under budget constraints. In this regard, resource allocation decisions are based on principles that fair-minded people can agree are relevant to deciding how to meet the healthcare needs of the populations under budget constraints.
Publicity	Decisions regarding both direct and indirect limits to care (resource allocation) and their rationales should be publicly accessible.
Revision and appeals	Every process must incorporate a mechanism for challenging and disputing resolutions regarding resource allocation decisions and, more broadly, opportunities for revision and improvement of policies in light of new evidence or arguments.
Regulative or enforcement condition	There should be either voluntary or public regulation of the process to ensure that the first three conditions are met.

Previous studies have examined priority-setting practices at the national level for the rigor of their clinical and pharmacoeconomic evidence. Others have focused on the final recommendations and decisions made by the agencies responsible for this process and compared technology diffusion and adoption rates in different healthcare systems (23). However, only recently have an increasing number of researchers begun to outline the need and importance of ensuring the fairness of the decision-making process at the national level (10,11;13–15;18;22). Accountability for Reasonableness is a framework for legitimate and fair priority-setting in health care that was initially developed in the context of managed care in the United States (2;3). It provides four conditions that emphasize transparency and stakeholder engagement in democratic deliberation. A priority-setting decision may be considered legitimate and fair if it satisfies four conditions or principles: relevance, publicity, appeals, and enforcement (Table 1).

In this study, we first outline the process of updating the National List of Health Services in Israel, and then assess this process for compliance with the four conditions of accountability for reasonableness. Although this process has been described and scrutinized in detail in previous studies (8;12;25;26;28;30), none of these have fully addressed its legitimacy and fairness.

## THE PROCESS OF UPDATING THE NATIONAL LIST OF HEALTH SERVICES

The Israeli National Health Insurance Law, enacted in January 1995, stipulates a National List of Health Services (NLHS) that all residents are entitled to receive from their health plans (HMOs). Every year, as part of the annual budgeting process, the government determines the additional budget that will be available to fund new technologies. Because the budget allocated is far from being sufficient to keep up with the pressures from the growing healthcare market, rationing of health care is inevitable. In 1998, Israel established a formal priority-setting process for the addition of new technologies to the NLHS. This process is based on two main elements: (i) A health technology assessment process in which each candidate technology is evaluated using a set of predefined criteria that include clinical, epidemiological and economic data, and legal, societal, cultural, and ethical aspects. (ii) A decision-making process that is undertaken within a Public National Advisory Committee (PNAC) and the prespecified budget constraint (28). The process of updating the NLHS is comprised of six main stages that are outlined in Table 2.

## Is the Priority-Setting Process Legitimate? Is it Fair?

The Relevance Condition. According to the relevance condition, priority-setting decisions have to be made by a committee of fair-minded people that represent a broad spectrum of professionals as well as members of the public. The PNAC, which is appointed by the Ministers of Health and Finance, is composed of twenty representatives from the Ministry of Health (MoH), Ministry of Finance, HMOs, experts in health economics, and representatives of the public at large. The choice of the committee members is designed to ensure that different stakeholder opinions will be heard and considered (12). One may argue that selection of PNAC members may serve the government to dictate its policy. However, because the vast majority of the committee decisions are reached using a consensus process and are made unanimously (12;30), the impact of a particular committee member on its recommendations is limited. Among stakeholders, members of the public have an important role in ensuring that decisions reflect community values and needs. Participation of lay people in the decision-making process does not always guarantee that community views are fully reflected; compared with other professionals, they may not have enough knowledge or power to influence decisions, and they may not speak for the entire community (18). Indeed, one of the critics of the priority-setting process in Israel suggests that: "not enough has been done to incorporate the priorities, values, views, and preferences of the general public"

Stage	Main activities
Call for proposals and technologies suggested for inclusion in the NLHS	Call by the Ministry of Health (MoH) for proposals for new medical technologies to be added to the NLHS.
	□ Technology applications are accepted from industry, HMOs, patient interest groups, and individuals (usually physicians), with the vast majority of technologies being proposed by the industry. Additional technologies may be identified and suggested by the Medical Technology Administration (MTA) and other units of the MoH.
	□ Stakeholders suggesting a technology, prepare a dossier that adheres to the guidelines published by the MoH. The dossier should include the following information: indication and potential use of the technology; proof of its safety, efficacy, effectiveness, its advantage over a technology already included in the NLHS for the same indication; and a budget impact analysis. As of 2007, inclusion of an economic evaluation is also required.
Screening and initial assessment of submitted technologies	<ul> <li>The MTA at the MoH performs a rapid assessment and screening of the new proposed technologies.</li> <li>Only technologies that are registered or in the process of registration in Israel, whose safety and efficacy have been scientifically and/or clinically established, are considered eligible for the NLHS updating process.</li> </ul>
Comprehensive evaluation	<ul> <li>□ The list of proposed technologies is presented to the Medical Technology Forum at the MoH.</li> <li>□ A comprehensive evaluation is performed to integrate clinical, epidemiologic, economic, and ethical</li> </ul>
	considerations, aiming to demonstrate the added value of each submitted technology. The forum also considers the scope of the health problem (i.e., burden of disease), the expected number of patients to benefit from the new technology, and existing treatment alternatives.
	□ Recommendations from professional medical societies and technology assessment agencies in other countries are solicited, and a summary of data and recommendations for each technology is compiled into one uniform format. Each summary contains a recommendation for the appropriate use of the technology, the target population, and the annual projected cost.
	<ul> <li>A governmental resolution (Israeli Government, August 9, 2005), allowed for the appointment of a subcommittee that provides the PNAC with the anticipated overall cost of adding each technology to the NLHS. Members of the subcommittee include representatives from the Ministry of Finance, MoH, and the four HMOs (30). In order to clarify and deliver expert opinions on certain controversial technologies, medical specialists are invited to participate in the meetings.</li> </ul>
Priority setting	□ The Medical Technology Forum recommends to the PNAC a prioritized list of new technologies. The priorities are determined according to established criteria that include the effect on mortality and longevity, morbidity, quality of life, the added value of the suggested technology, and so on.
	□ Each recommended technology is placed in one of three major groups, with the technologies graded on a scale from one to ten: Group A consists of high priority technologies (grades 8–10), Group B consist of intermediate priority technologies (grades 4–7), and Group C consists of low priority technologies (grades 1–3). Thus, according to this scoring system, the highest priority is given to a technology graded "A10" and the lowest to a technology graded "C1." To date, the vast majority of technologies that received public funding were graded "A10" or "A9" (28).
The PNAC and the decision-making process	<ul> <li>The final recommendation on the new technologies to be added to the NLHS is made by the PNAC, which is comprised by different stakeholders (e.g., representatives of the MoH, HMOs, and members of the public at large).</li> <li>The committee concludes its mission by recommending the list of new technologies that should be</li> </ul>
	added to the NLHS, according to the allocated budget.
Government approval and legislation	<ul> <li>The list of prioritized technologies is approved by the Minister of Health, the National Health Council the Minister of Finance and the government.</li> <li>The final list of technologies receives formal validity as an act of government and is published on the</li> </ul>
	<ul> <li>The final list of technologies receives formal validity as an act of government and is published on the MoH Web site, and in the major daily newspapers.</li> <li>Following governmental approval, all HMOs are required by law to provide the new technologies</li> </ul>
	added to the NLHS, as an integral part of services offered to their insurees.

Table 2. The Process of Updating the National List of Health Services (NLHS)

(21). However, what are the views and preferences of the general public? Does the public prefer, for a given budget, interventions that help a few people to gain much health? Shall we give priorities to treatments that provide a lower health gain, but to a larger population? Or should we cover treatments for vulnerable populations first? Some scholars suggest that public recommendations are crucial when making difficult decisions that affect healthcare services for public consumption. A pioneering attempt to incorporate the public preferences was initiated in Israel in 2003. A public consultation in the form of a "Health Parliament" consisting of six focus groups, was held throughout the country and topics relating to equity, provision of private health services in public hospitals, co-payments in health care, and healthcare rationing have been discussed (7). Participants in the Health Parliament agreed that classifying a new technology as "life saving" and deciding to include it in the NLHS should be based on three criteria: the efficacy of the treatment determined by the number of patients whose lives will be saved, the gain in life expectancy in those patients, and the patients' quality of life after the treatment. Whereas the regional parliament disagreed on the relative weights to be given to each criterion, all of them agreed that the final score for the inclusion of a life-saving technology should be based on the combination of the three. Health Parliament participants were also asked to address the dilemma of funding an expensive intervention that only a small number of individuals benefit from, versus an intervention that provides relatively small health gains to a substantially larger population. It was generally perceived that priority should be given to those interventions that serve a relatively large population and at the same time pose a relatively high financial burden on patients if not included in the NLHS. Unfortunately, despite a statement of official endorsement of the Health Parliament initiative, by the Health Council in Israel, this public consultation was discontinued and the process was not integrated in the health policy and decision-making process, mainly due to lack of funding (7). Priority setting processes in other countries have benefited from consulting the public. For example, appraisal committees at the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom include at least two lay members, and patients or their representatives can appear as expert witnesses before the committee. Moreover, the NICE Citizens Council was established in 2002. Composed of thirty members of the general public, it serves to assist in the development of social value judgments that underpin NICE guidance to the National Health Service (NHS) (1).

A careful examination of the technologies added to the NLHS in Israel through 2009, reveals that many were characterized as "life-saving" technologies. Israel is considered an "early adopter" of many technologies, granting public funding before their coverage in other healthcare systems. Several technologies have been adopted when the clinical or the economic evidence was partial, and insufficient evidence was gathered on the safety and effectiveness of the technology as observed in clinical practice. This suggests that decision makers in Israel tend to use the "rule of rescue" to guide their decisions. The "rule of rescue," describes the imperative that people tend to rescue identifiable individuals facing avoidable death even when the same limited budget can be more efficiently used to prevent deaths in a larger population. It suggests that more funds should be allocated to save lives of identifiable versus unidentifiable individuals. This rule, which has basis in the Jewish tradition, and its relevance to resource allocation decisions, was previously discussed in Israel (7;28). In a survey conducted among 2,030 adults, Shmueli (27) found that the "rule of rescue" was predominant for more than a quarter of the population, even when death was only marginally postponed. Nevertheless, some scholars have recently argued that this rule should not be necessarily used, and being an "identifiable" patient is not sufficient grounds for discrimination against other patients. In one of the latest deliberations of the PNAC in Israel, one of the committee members suggested that any forum that is assigned the responsibility of allocating public resources must overcome the natural inclination of identifying with actual people that seem to be in imminent danger, and must adhere to an overall optimal use of resources. Consequently, classifying technologies as "life saving," "life extending," "preventing illness," and so on, can form the basis for preferences among the categories. The value of the classification is in its ability to compare technologies within each category. As suggested by Daniels and Sabin (3) in their definition of the relevance condition, the ultimate objective of the PNAC should be to inform decision makers on technologies that both maximize health outcomes and provide "good value for money" under a prespecified budget constraint and the varied health needs of the Israeli population. It should, therefore, consider the clinical evidence (i.e., safety, efficacy and effectiveness), epidemiologic data (incidence and prevalence of the disease, and the population in need of the new technology), economic evidence (the cost of the technology, cost-effectiveness and budget impact analysis), and ethical considerations. Whereas the most up-to-date clinical evidence is used in the prioritysetting process, this is not the case when the relationship between costs and clinical outcomes is considered. To date, the only economic criterion considered is the estimated budget impact of each new technology added to the NLHS, because full economic analyses are usually not available (19). Even the Israeli Supreme Court has recently hinted at the need to consider costs and effectiveness in deciding health technology priorities. In a court decision regarding Victoria Israeli who sued for coverage of a cochlear implant, the court concluded: "Beyond the human-medical need at the basis of this issue, the PNAC will evaluate, as they need to address these issues, also issues of cost and effectiveness, i.e., if the improvement in quality of life of those receiving the implant is not at a level that will allow them to continue their work without imposing an economic burden on the shoulders of the public, beyond the feeling of human dignity that will be preserved for them, and thus saving other public funds" (31).

The Publicity Condition. The publicity condition stipulates that decisions regarding both direct and indirect limits to care (i.e., resource allocation) and their rationales must be publicly accessible. The importance of the publicity or transparency condition is emphasized in theoretical frameworks and has been presented in several studies (3;5). In a study conducting semistructured interviews with stakeholders in Australia, Canada, New Zealand, and the United Kingdom, participants identified transparency as crucial to ensuring accountability and decreasing potential controversy around formulary listing recommendations (14). Indeed, accountability and political defensibility of a coverage decision are increased when the various stakeholders (e.g., manufacturers, patients, and the general public) understand the reasons for these decisions. Morgan et al. (15) quoted an expert informant that stated: "I understand how they reached that decision. I can see the process, I followed the methods. I may not necessarily have made exactly the same judgment, but they've made a judgment, which in the circumstances can be justified." A careful examination of the rationing process in Israel suggests that the *publicity* condition is only partially met. The coverage decisions and the list of the new technologies added to the NLHS and the indications for which they are to be used are published on the MoH Web site and are frequently cited by the media. However, the relevant criteria used in the priority-setting process and their relative contributions are not disclosed to the public, nor are proponents of technologies or the general public informed about the reasons and rationales for the rejection of the technologies proposed.

Transparency is a crucial element in gaining public support for the new health technology approval process. Therefore, specific deliberations and the bases for decisions should be publicly accessible. Until recently, the PNAC meetings were not open to media and transcripts from the PNAC deliberations and decisions were not available to the public. This situation generated accusations and speculations about committee members' judgments and interests in recommending one technology or another. In an attempt to increase the transparency of the process and improve the level of information provided to the patients, the medical community and the general public, journalists were recently allowed to participate in the PNAC deliberations and summaries of the PNAC deliberations and decisions were posted on the MoH Web site (http://www.health.gov.il/). However, the subcommittee responsible for determining the budgetary impact of each technology continues to convene in closed meetings, and the industry, one of the most important stakeholders, has no access to this process. Although the PNAC meetings are open to the media, PNAC members, however, may not be quoted verbatim. This decision was made to protect the committee members' ability to speak freely without fear of public or legal consequences. One way to circumvent this is to publish the considerations and rationale for each technology at the end of the process. While the *publicity* condition is only partially met in the resource allocation process in Israel, other countries and health technology assessment agencies have made efforts to increase the transparency of their process by posting final decisions and their rationales. In the United Kingdom, the technology assessment committee's initial assessments and final appraisal determinations are posted on the NICE Web site (www.nice.org.uk). The published documents include cost, clinical, and economic data. These documents do not include confidential data submitted by the manufacturers. As of 2005, Australia posts its final coverage decisions and their rationale on the internet (15). Despite efforts to achieve a level of acceptable transparency, final committee decisions are posted in only a brief outline format (17). Additional efforts for ensuring the transparency of decisions is noted in other countries as well: in the United States, the Center for Medicare and Medicaid Services (CMS) posts its National Coverage Decisions for medical technologies, and the

rationale underlying them on its Web site (16). In Canada, the Canadian Expert Drug Advisory Committee (CEDAC), the advisory boards of the Common Drug Review (CDR), posts its recommendation for drug reimbursement, as well as the reason for the recommendation, an overview of the CDR clinical and pharmacoeconomic report and a summary of the CEDAC discussion on its Web site (20).

Revision and Appeals Condition. Daniels and Sabin (3) suggest that there must be a mechanism for challenging and disputing resolutions regarding resource allocation decisions and, more broadly, opportunities for revision and improvement of policies in light of new evidence or arguments. Before using an appeal process, one must ensure that all criteria under the relevance condition have been considered and that the reasons involved in the original decision are publicly accessible. However, as we have previously mentioned, these two conditions are not fully met in the Israeli healthcare system. Stakeholders in Israel are not allowed to appeal PNAC decisions and there is no formal dispute resolution mechanism. Parties interested in acquiring public funding for a new technology have to reapply in the subsequent update cycle, adding the new supporting evidence, if applicable. Other countries have set-up a formal appeal process. In the United Kingdom, for example, groups such as manufacturers and professional or patient organizations may appeal NICE recommendation through an internal process. Indeed, recent data suggest that more than one-third of NICE decisions between the years 2000 and 2008 have been appealed (29).

Regulative Condition. Daniels and Sabin suggest that there should be a voluntary or public regulation of the process to ensure that the first three conditions are met (3). In Israel, there is no mechanism or central body responsible for decision making to enforce the conditions of accountability for reasonableness or equivalent concept. Although the priority-setting process in Israel is related to the National Health Insurance Law, the PNAC, appointed by the Ministries of Health and Finance, has no legitimate independent mandate and it works under the auspices of the National Health Council. The process of updating the NLHS was subject to audits performed by the Israeli State Controller and Ombudsman (9), and was also challenged in courts. To date, the Supreme Court did not interfere with the recommendations of the PNAC and with the adoption of the technologies proposed. Israeli courts acknowledged budgetary constraints and accepted standards of evidence-based medicine as benchmarks for public funding (24).

### CONCLUSIONS AND POLICY IMPLICATIONS

The process of updating the NLHS in Israel is unique and not without its merits. The need for priority setting in health care has been recently addressed in a resolution of the Israeli Supreme Court stating that: "In a world which is typified by rapid changes in science and medicine, when the cost of drugs and technologies is very high, the process of priority-setting is imperative." Moreover, the Court stated that regarding the process of updating the NLHS, "there is no doubt that the decision making process is well organized, and secondly, rationing is imperative under the circumstances of the NLHS" (31).

Notwithstanding the merits, we suggest that the prioritysetting process does not fulfill the appeals and enforcement conditions, and only partially follows the transparency and relevance conditions, outlined in the accountability for reasonableness framework.

To fulfill the relevance condition, we suggest using results from cost-effectiveness analyses to inform the decisionmaking process. The importance of using economic evaluations for informing priority-setting in Israel was recently acknowledged. According to the recent guidelines drafted by the MoH, each technology proposed for inclusion in the NLHS should be accompanied by a cost-effectiveness analysis presenting a cost per quality-adjusted life-year (QALY), which is an incremental cost-effectiveness ratio. However, this request was not enforced and only a very few of the technologies submitted in the recent two updating cycles adhered to these guidelines and included sufficient economic evidence. In the absence of relevant economic evaluations for the vast majority of technologies, determining the "value for money" will remain limited in coming years. We, therefore, suggest that the MoH enforce these guidelines and that no technology be considered for inclusion in the NLHS without submission of proper economic evaluation. Moreover, the committee should focus on the reasonableness of the rationales for each technology coverage decision. To this end, it is essential that committee members receive training in the principles of priority setting to ensure that members have ownership of the process (18).

An appeal process on resource allocation decisions may be feasible only when a relatively small number of technologies are assessed. Given the large number of technologies assessed every year for inclusion in the NLHS in Israel (400–500 technologies), implementing a formal appeal process would be very difficult, if not unrealistic, as without predetermined conditions of appeal, there would be no deterrent to the appeal of all new technologies that were not approved in any given year.

It is important to note that to date, no technology has been removed from the NLHS. The National Health Insurance Law in Israel established a clear mechanism for amending the NLHS; according to statute a technology can only be removed from the list upon approval of the parliamentary committee on health and social welfare (24). However, currently there is no mechanism for revision and removal of technologies that have been adopted in the past. Removal of technologies from the NLHS does not occur even when a new technology included in the list is believed to be more effective, as compared with an old treatment for the same indication that may be obsolete or ineffective, even if the new technology is cost-efficient in comparison. An attempt to stipulate temporary or conditional inclusion for some technologies with a predetermined date for reconsideration was denied by the Ministry's legal advisors.

The process of updating the NLHS has been recently scrutinized by the Israeli Medical Association, who has initiated a parallel process, known as the "Public Forum" for prioritizing the adoption and reimbursement of new technologies. More recently, Golan (6) presented a model to help decision makers in Israel reach fair and transparent decisions and minimize ethical dilemmas inherent in the process of updating the NLHS under a strict budget framework. However, major advances in the current priority-setting process toward improving its legitimacy and fairness can be achieved only by consensus of the major stakeholders: the Ministry of Finance, the MoH, and the four HMOs.

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