Utilization of health technologies—Do not look where there is a light; shine your light where there is a need to look!
Relating national health goals with resource allocation decision-making: illustration through examining the Israeli healthcare system

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\begin{abstract}
Innovative health technologies are often the focus of attention. However, in the allocation of public resources for improving health, the focus should be on the health needs of the population. It is the need that should be analyzed first, and decision makers should then evaluate the full range of interventions available, whether new or old, to meet this need. This is in contrast to analyzing the technology first and then characterizing the need it meets, which is the current practice in reimbursement decision-making in several countries. The identified health need should define national health goals, and these goals should be proactively assimilated into the reimbursement decision-making process. Differential reimbursement rates could reflect the relative contribution of the technology to the unmet health need.
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1. Introduction

It is health that people desire; and healthcare services and technologies are but the means for producing it [1]. Therefore, decision-making regarding allocation of public resources in order to increase health utility could be expected to stem from evaluation of the population’s health needs and health-related welfare (comprising clinical matters as well as equity, equality, morality, current and projected well being, and other relevant societal matters [2]). This is expected to be followed by evaluation of potential beneficial interventions across the whole range of available technologies, whether new or old. A differential reimbursement rate could then reflect the potential contribution (the marginal effect) of the health technology to the unmet health need.

However, it appears that in countries where national reimbursement schemes are applied, as in Israel, the setoff point for reimbursement decision-making is the reverse of this: First, the health technologies (most of which are new) are evaluated, and the health state they are intended to achieve, is characterized at a later stage. A wide gap might result between the health policy goals and their actual implementation [3–5]. In addition, an apparent informal tendency to focus on innovative health technologies and “life saving” interventions (e.g., for cancer, HIV/AIDS treatment, etc.), generated at least to some extent by the pharmaceutical industry, might lead to marginalization of less “attractive” measures, including preventive interventions [6,7]. The discrepancy described above, might

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resemble the famous metaphor of searching for a coin lost in the dark under a street light because this is where the light is, and the need to switch to proactively shining the light where there is a need to search.

In Israel, following the 1994 National Health Insurance Law, a formal priority-setting process was established in 1997 to update the national benefits package (the National Health Basket) annually [8]. Each year, the government determines the sum of money that will be available for updating the Basket [8]. The priority setting process consists of five stages, starting in February with a call for applications, progressing via evaluation of the applications within the Ministry of Health during April–September, and ending with prioritization of the top-ranking technologies under the budgetary constraints by a public committee during October–December of the same year [5,9]. In January 2009, the annual budget for update of the National Health Basket was NIS 415 million (approximately US$100 million). Of this amount, 94% was allocated to medications, and the rest to devices, pediatric nutrition supplements and laboratory tests. Among the medications, only one vaccine was included—Pneumococcal vaccine for ataxia telangiectasia patients. Likewise, services such as pharmaceutical care (for optimization of individual-level medication treatment), reduction of patients’ co-payment for selected populations or for preventive medications, and compensation for primary physicians for dedicating more time to elderly patients were not discussed. In addition, preventive measures advocated by Israel’s ratification of the WHO’s “Health For All” program did not gain funding necessary for their implementation or monitoring [10].

2. The current state: parallel tracks for innovation/novelty evaluation oriented reimbursement decision-making, and for characterization of health goals—an asymmetrical competition over scarce resources

2.1. Current reimbursement mechanism and the dazzling effect of innovative health technologies

Innovative health technologies attract much attention as they encompass a promise for better health, which is highlighted by their manufacturers [11–13]: sick people are likely to cling to the chance of improving their condition; healthy people are not only keen to assist the ill, but also are afraid of becoming ill [6,14], and probably are impressed by the glow that is projected over the promising technology; healthcare professionals might be impressed by the chance to improve their patients’ state of health, together with boosting their own prestige and income that follow adoption of the apparent scientific innovation [11]. All of these factors could potentially affect decision makers, who face the tremendous challenge of allocating scarce resources for health technologies, to provide better health for a reasonable price.

In addition, when decision makers evaluate technologies submitted to them, they are prone to be exposed to unwarranted external pressure: lobbyists, media coverage and patient groups operate in the foreground, while pharmaceutical companies and other commercial bodies operate in the background to apply considerable influence and pressure, with the goal of maneuvering the decision-making towards allocating resources to “life-saving” new technologies [6,7].

Older, less “attractive” health technologies that are not promoted by the heavily funded health industry might be left behind in the battle to “innovation” and “novelty”, even if they provide similar or even greater health benefits. An example could be seen in the increased rate of sales of innovative antihypertensive drugs (i.e., ACE inhibitors) even though a large-scale study has shown that older (and much cheaper) medications (i.e., Thiazide diuretics) probably provide similar benefit [6]. Examples of services that might have been put aside in Israel due to lack of commercial incentive could include support of national vaccination programs through school nursing services; pharmaceutical care services intended for guidance and monitoring of rational use of medication among chronically ill and special populations (e.g., elderly, pediatric, etc.); free preventive dental care for children of school age; exclusion of patients’ co-payment from preventive therapies such as vaccinations; etc. If a mechanism for evaluation of health technologies with respect to national health goals, as suggested in this manuscript, was implemented, these “old” technologies would be given the same attention as the new ones.

The key role of innovative health technologies in improving health should not, however, be underestimated [1,12,13]. Even if the technology per se does not offer the maximal expected benefit, the innovation process behind it is imperative to the study of health improvement, as is shown by the early history of medicine [11,15]. As in a cycle, resource allocation to innovative interventions provides an incentive for further innovation [12]. Likewise, innovation as a component of the economy might bear utility in addition to its projected direct health benefit. However, when considering the resource allocation of health-assigned public funds, the objective of improving the population’s health at a reasonable cost, should not be forgotten. It should be kept in mind that what people want is to be healthy, and that utilization of health technologies is but a means to reach this goal [1]. In addition, it should be remembered that innovation also bears a risk encompassed within its inherently unknown aspects. As described in the book “Hope or Hype” by Deyo and Patrick, advanced technologies could actually lead to reduced health utility and cause harm to patients [6]. This phenomenon could be traced back to Hippocrates and his students, who used their most advanced technology to aid the sick, but, in many cases, appear to have caused more harm than good [15]. Therefore, promotion of the benefits of innovation in itself should be considered separately from evaluation of the health benefits provided by that innovation. Decision-making regarding allocation of health-assigned resources to health technologies and services should be about evaluation of the health needs of the population, followed by evaluation of potential solutions, whether new or old. Innovation support through other funding mechanisms should also be sought, in order to provide incentive to derive other potential benefits.
2.2. National health goals—active programs

In 1977 the World Health Organization (WHO) issued a call for all governments to aim towards a goal of enabling all of the world’s citizens to enjoy a level of health that would enable them to lead a socially and economically productive life by 2000. This call and vision has become known as “Health for All” [4]. This vision was followed by a 1978 declaration in Alma-Ata defining the basic way to strive towards that goal through “acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and the country can afford” [4]. “Health for All” was not intended to be a model, or a guideline; rather it aimed to serve as an inspiring framework for individual countries’ health policies [4]. The European region of the WHO adopted its “Health for All” strategy in 1984, adding a list of 65 indicators, linked to state, with regard to disparities among sub-populations and among countries. Some have adopted WHO’s “Health for All” framework (“as is” or as a concept to be locally adjusted), whereas others have created their own frameworks [4,10,16–18]. In addition, Health Technology Assessments/Appraisals (HTA) are becoming a prominent step in reimbursement decision-making [19]. Nevertheless, there appears to be a discrepancy between policy concepts and actual decision-making regarding resource allocation [4,16].

Another program is the US “Healthy People” initiative, which was first introduced in 1979 and has two broad goals: “to increase quality and years of healthy life, and to eliminate health disparities”, which are supported by specific objectives in 28 areas [16]. The focus areas were determined by an alliance of over 350 national membership organizations and 250 state health, mental health, substance abuse, and environmental agencies, as well as by a series of national meetings and the utilization of web-based interaction with the general public [16]. The midcourse review of “Healthy People 2010” reveals that merely 10% of the 281 objectives that could be measured (out of a total of 467 objectives) were met or exceeded the target. 49% showed progress towards the target and 20% moved further away from the target [16].

In Israel, the current national health goals program, entitled “For a Healthy Future 2020”, was launched in 2005 [10]. This initiative is aimed at creating a framework for prevention and health promotion to be adopted by the Israeli Government as a health road map for future years. Three main focus fields were determined: morbidity prevention, reduction of age-related problems (e.g., maternity, adolescence, and geriatric health problems), and reduction of risk factors (e.g., environmental hazards, work safety, etc.). Hundreds of professionals, representing a broad range of health organizations in the country, volunteer in 19 committees that comprise the initiative workforce. The objectives are being defined and prioritized within each committee and among all committees, in accordance with the evidence base, the contribution to equity, expected public support, and feasibility using current means. Feasibility is evaluated by using cost-effectiveness analysis and evaluating expected compliance of both healthcare providers and the public with suggested interventions.

These health goals initiatives show that health policy makers worldwide favor similar objectives, but there appears to be a difference between their approval and actual acceptance of these goals, when public funds are at stake. There appears to be a gap between the statements and the decision-making, with regard to allocation of public funds to health technologies and services.

3. The proposed model for national health-goals based reimbursement decision-making utilizing differential reimbursement rates

3.1. National health goals, innovation and differential reimbursement rates

Policy makers have acknowledged the approach of defining national health goals to match the national health state, with regard to disparities among sub-populations and among countries. Some have adopted WHO’s “Health for All” framework (“as is” or as a concept to be locally adjusted), whereas others have created their own frameworks [4,10,16–18]. In addition, Health Technology Assessments/Appraisals (HTA) are becoming a prominent step in reimbursement decision-making [19]. Nevertheless, there appears to be a discrepancy between policy concepts and actual decision-making regarding resource allocation [4,16].

Several countries, including Israel, have separate schemes for health-goals characterization and for reimbursement decision-making [4,10,18]. Whereas health goals appear to reflect health prospects of policy makers, they still appear to be somewhat detached from the actual allocation of resources to health technologies [4,5,9,10].

When allocation of public funds for maximization of health utility is discussed, health should be regarded as one entity rather than a compilation of self-standing clinical states. In addition, maximization of health utility would better be viewed from the societal perspective rather than from the more limited perspective of budgetary impact on the healthcare provider or payer [20]. Evaluation of health technologies as a means of achieving maximization of the population’s health utility should not be mistakenly regarded as a competition among alternatives submitted to the decision makers, with regard to novelty or innovation. This evaluation process (and the decision-making derived from it) should be based on a predefined national health strategy that comprises national health goals (Fig. 1). For the design of a national health strategy, an analysis of morbidity, mortality and risk factors should first be conducted in order to characterize health gaps, i.e., disparities between the current health state and the desired one, with regard to the country’s population, its sub-populations (stratified by age, gender, education level, income level, residency, etc.), and to international data and international policies (i.e., the WHO’s framework: “Health for All” [4]). A national research institute with full access to all data sources (hospital records, HMOs’ databases, pathological institutes, etc.) should be responsible for this analysis. Characterized health gaps should then be used to develop well-defined and practically measurable national health goals. Introducing societal considerations (e.g., equity, equality, morality,
and ethics) should yield a prioritized list of national health goals, to construct the “National Health-Utility Strategy” (NHUS). Once the NHUS is described, systematic evaluations (i.e., cost-effectiveness analyses) of technologies (including services) that might assist in achieving the defined goals should be conducted. Decision makers should evaluate all available information and use it to determine the reimbursement status for these technologies. A differential reimbursement rate that projected the incremental contribution of each technology to achieving the desired goal could serve as an incentive and a weighing tool for assimilation of required technologies. Health technologies that were denied public funding, but were found to be suitable for utilization (i.e., technologies that met quality, safety and efficacy criteria) might still be accessible to individuals, depending on their own preferences and economic capabilities. These technologies could be re-evaluated in the future when additional information is available, and/or if amendments to the NHUS justify it. Technologies approved for reimbursement should be monitored in order to evaluate their health benefits and costs in real life practice and in light of new information (e.g., additional trials). If it appears that these technologies exceed their expectations or if they do not meet their expectations, their reimbursement status should be re-evaluated.

3.2. A dynamic, continuous model

An essential component of this scheme is its dynamism. The process should be continuous and self-generating: as health interventions take place in light of the NHUS, they make an impact that modifies the NHUS: health goals that were fulfilled (either completely or partially) move down the priority list, and others move up. Thus, a cycle of events
is initiated that comprises: health-need analysis – setting health goals – evaluating health technologies to meet the goals – assimilating these technologies – evaluating their contribution to meeting the goal – and coming back to an updated health-need analysis. Technologies are monitored and their reimbursement status is re-evaluated in light of their performance and of accumulated information. This dynamic circular process is in line with the observation made by Gafni and Birch that the “opportunity cost of marginal healthcare resources is a dynamic concept and its value will change as new programs are funded and/or resource constraints change” [21].

With a dynamic goal attainment and varying scopes, one could assume that a variable professional mix could be required. The National Research Institute should comprise multidisciplinary teams that analyze health needs and also evaluate the cost-effectiveness of potential interventions. This should be relatively easy to achieve. However, training of healthcare professionals takes time and planning, and might not be as dynamic as the model might seem to indicate. This emphasizes the importance of multidisciplinary healthcare team working. When these teams become the essential form of care provision, then much greater flexibility could be achieved in meeting the dynamic process at the provision level as well. Further discussion of multidisciplinary teams is beyond the scope of this paper.

3.3. Disinvestment

Another implication of the dynamic model, as mentioned above, is the removal of reimbursement or reduction of its rate for technologies that revision showed to be less beneficial than expected. This complete or partial withdrawal of technologies from the publicly funded scheme because an updated evaluation indicates that they deliver less health gain relative to their cost is referred to as disinvestment [22]. The process of disinvestment should assist in enhancing accessibility to beneficial treatments by utilizing resources saved through discarding non-beneficial ones. This approach gained support by the National Institute for Health and Clinical Excellence (NICE) in the UK [23,24]. One of the known barriers to disinvestment is the associated political concern regarding denial of support for health technologies because of lack of evidence [22]. However, if disinvestment were based on accumulated data and revised evaluations by multidisciplinary teams that addressed clinical as well as societal aspects, as proposed in the model, rather than on lack of data and uncertainty, the political barrier to this approach might be alleviated, thereby facilitating its implementation [22].

The proposed dynamic process should contribute to increasing accessibility of the population to health technologies that meet their needs, and thus maximize its health utility.

3.4. Utilizing innovation: collaboration with manufacturers and horizon scanning

Nevertheless, the association between innovation and reimbursement should not be neglected. Reimbursement is a key incentive for innovation, and forms a consider-
It could be argued that an investment in education might yield greater health utilities in the long run in comparison to an investment in a life-extending medication for colorectal cancer patients, for example. Thus, it could be expected that expenditure for an intervention aimed at achieving a national health goal could be shared among all relevant ministries. For example, an education program that aimed to introduce better diet habits to children could be shared by the Ministry of Health and the Ministry of Education; a program to reduce co-payments for lower socioeconomic populations could be shared with the Ministry of Welfare. It could also be argued that increasing the police budget to better supervise driving within cities should be shared with the Ministry of Health, as it could reduce number of road-accident casualties and hence reduce emergency department burden. Alas, this approach, though it does show significant advantages, appears to be impracticable under current political environment operated by ministerial budgetary systems. It is beyond the scope of this paper to discuss alternatives. Therefore, the underlying assumption for the proposed model is that the funding for health technologies is constrained by the budget allocated to the Ministry of Health alone.

3.6. Health goals—defining and measuring

In order to define health gaps, as mentioned above, health indicators should be defined and selected. There are several health indicators that serve as a basis for the international statistical comparison of health [32]. These can be divided into health status, health-care resources, and health-care utilization. They include, among others:

- **Health status**: life expectancy, mortality causes, maternal and infant mortality, years of life lost because of illness, subjective perception of health status, infant birth weight, birth defects, dental health, communicable diseases, injuries (e.g., road accidents, work accidents), and missed work-days because of illness.
- **Health-care resources**: number of employees in the healthcare system, classified by sector (private/public, primary/secondary/tertiary, etc.), and by profession (doctors, pharmacists, nurses, etc.), number of hospital beds, availability of medical technology (e.g., CT scans, MRI units, etc.).
- **Health-care utilization**: administration of immunizations, screening, physician visits, dentist visits, length of in-patient stay, stratified by institution type and by disease, discharge rate, surgical procedures, transplants and dialysis, and numbers of medications used, stratified by clinical category and by pharmacological class.

In addition to these indicators, it might be useful to include the following:

- **The percentage of the population avoiding utilization of health technologies because of their price, even though these technologies (services) are reimbursed.**
- **The percentage of the population that utilizes non-reimbursed health technologies, stratified by illness and payment source (i.e., private insurer, out of pocket, etc.).**
- **Prevalence of orphan illnesses, stratified by illness and number of patients.**
- **Clinical problems associated with the main burden of hospitalization.**
- **Clinical problems associated with major expenditures for the payer.**
- **Number of malpractice lawsuits found justified, stratified by diagnosis and institutions.**
- **Number of off-label uses of health technologies.**
- **Number of patients seeking treatment abroad.**

3.7. Transforming the National Health-Utility Strategy into a practical and efficient decision-making process

An effective data analysis for evaluation of the Israeli population’s health status requires a National Institute populated by qualified researchers who would avoid any possibilities of conflict of interests. Relevant players and bodies of interests such as the sick funds, the ministry of health, the ministry of treasury, the innovative industry, and patients’ organizations should play primary role in consulting the institute and supplying data. However, unlike current situation, they should not be involved in the actual decision-making process. The national institute should be granted – by law – accessibility to all data sources. Analyzing the developing national database would enable a strategic national view of mortality, morbidity and resource utilization under current practice. This, in turn, would enable mapping of health gaps in the Israeli population, and formation of the NHUS. Cost effectiveness analyses of technologies (including health services and other health interventions) that met the goals of the NHUS would direct updating of clinical practice guidelines and assist in resource-allocation decision-making. The potential contribution (qualitative and quantitative) of a national center for evaluation of health technologies has been presented [33,34]. Relating this function with the construction of a NHUS should significantly increase its projected benefit. A differential reimbursement rate would act as an incentive to meet the goals and as a filtering tool to enable introduction of technologies through reduction of inequalities. By applying a differential reimbursement rate at the provider level, the anticipated hurdles of differential rationing at the consumer level could be alleviated [35]. A permanently established institute (as opposed to the ad hoc nominated public committee) would enable evaluations to be conducted year round. There would no longer be competition over a “new technologies budget”. Instead, decisions would be made according to the budget allocated for each goal and to the incremental cost-effectiveness ratio threshold. This, in turn, would be expected to contribute to increased equity in accessibility to healthcare services by the various patient groups.

Conducting cost-effectiveness analyses involves intense consumption of resources. Therefore, only technologies that were expected to generate a significant budget impact would undergo a full cost-effectiveness analysis by the proposed National Institute. The economic evaluation of other technologies would be “out-sourced” (to academic institutions, either in Israel or abroad, according to the nature of
the technology, the health status and the estimated differences in healthcare systems and behavior among countries) or waived entirely (e.g., where the budget impact was minimal and the projected health consequences of making a wrong decision were minor).

Financing for the evaluation process could arise from a combination of national resources (governmental budget), non-specific research funds, and a fee paid by those submitting technologies for approval. In order to enable individuals and small groups or companies to submit technologies for reimbursement, the fee would be progressive, according to financial characteristics of the submitter. If the submitted technology were found to meet the national health goals, the fee might then be rebated. In order to avoid situations where institutes “hide” behind individuals to save the submission fees, the right to be involved in the decision-making process (e.g., by presenting the request prior to decision-making and by appealing a decision) would be available only to the formal submitter.

4. Summary

Innovation plays a key role in medical progress, and contributes significantly to public health. Reimbursement provides a significant incentive for innovation, with the two forming a feedback cycle. Nevertheless, it should be kept in mind that it is health that people desire, and health technology utilization is merely the means to achieve it. Therefore, the reimbursement mechanism should reflect the population’s health needs and should be closely related to them. This could be achieved by ensuring that the reimbursement decision-making forms an integral part of a National Health-Utility Strategy. This strategy is based on evaluation of health gaps: among subpopulations within the country; between the current national health status and the desired one; and in comparison with other countries.

Then, decision-making would be based on first analyzing the need and then evaluating the whole scope of alternative solutions, rather than first evaluating competing health technologies (comprising mainly new technologies) and then characterizing the need they might meet. Health technologies would be reimbursed differentially according to the extent to which they meet designated health goals, and to the placing of their goals in the hierarchy of those defined by the National Health-Utility Strategy.

Setting well-defined, measurable health goals a priori, using horizon scanning to identify matching health technologies, and having a constructive dialogue with the innovative industry in order to guide its development efforts, might reduce unwarranted external pressure on decision makers, set the stage for older and "less attractive" interventions to be considered for resource allocation, and link health policy with actual reimbursement decision-making.

Thus, allocation of public fund resources could be associated with maximization of health utility of the population according to current practice, as well as to considerations of equity, equality, fairness and social well-being.

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