EARLY AWARENESS AND ALERT SYSTEMS FOR MEDICAL TECHNOLOGIES IN ISRAEL

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Background: Throughout the world, decision makers face the need to plan on the basis of uncertainty. Prospective updates on future trends of medical technology usage are tools to improve national health status. In Israel, this challenge is met by several steps taken to promote insight into the realm of emerging technologies. Israel's unique horizon strategy refers to three time spans: the immediate to short-term (for the coming year) updating the National List of Health Services (NLHS) and quarterly scanning; the medium-term (3 years to a decade) revitalizing hospital devices and infrastructure; and long-term planning (over a decade), such as the "Health Israel 2020 Project".

Methods: A description of the Israeli setup of different time spans and tiers.

Results: The matrix of players, loci, interests, population groups, and incentives creates a complex situation and the Ministry of Health has to regulate the different suppliers and tiers of insurance (obligatory, supplementary, and private), balancing need, equity, and cost containment in preparing for future health care. However, preparedness is not a sterile laboratory and is pervaded by numerous dilemmas and the search for adequate evidence for new less mature technologies is an on-going challenge.

Conclusion: Bridging the forecasting chasm for the future requires analyzing needs, reinforcing evidence and seeing "around the corner" when synergizing between all the "actors" in the national arena. Expert consultation and international cooperation with similar horizon organizations can assist in paving the way for more successful planning efforts for future medical technology implementation.

Keywords: Horizon scanning, Medical technologies, Dilemmas in health policy, Health policy

The continual evolution of new technologies requires on-going surveillance to improve health care. Countries around the world have established a range of early awareness and alert (EAA) systems implementing various methodologies to identify innovations and filter according to potential value and benefits (1).

There are innumerable sources of information to consider when identifying new technologies. Journal articles, internet scanning, news reports, expert opinion, inventors, and registries of clinical trials and patents are some of the most common sources of knowledge, as well as the industry (12).

Planning the future usage of medical technologies is a challenge for decision makers worldwide (19). Since characteristics of health systems differ, as do values, the weight of criteria used to filter beneficial technologies is adjusted according to national and local needs (11). The developing EAA systems reflect these regional principles.

In Israel, there is obligatory universal coverage with a basic positive list of health services provided to all citizens without any discrimination in line with the National Health Insurance Law (NHIL) of 1994 (9). This law highlights principles of justice, equity, and solidarity. According to the NHIL, each new technology implemented requires an additional targeted budget, which in turn becomes an integral part of the overall budget for

the National List of Health Services (NLHS) (13). All publicly funded health services are registered in this positive list (NLHS). Primary care is provided by four insurers - health funds (health management organizations (HMOs). Other health services are provided by hospitals.

Hospitals in Israel are free to compete and adopt many new and emerging technologies, devices, procedures, and drugs (that are not available in community health services) even in the experimental stage, using their own resources. In comparison, pharmaceuticals and health services in the community are restricted within the NLHS. The insurers supplying services in the community have the option to adopt additional new technologies, but this is not often done due to budget limitations and rigid regulations. The most convenient mechanism for insurers to add such innovations is the supplementary insurance tier. New technologies can also be purchased by the individual through private insurance or directly out of pocket.

OBJECTIVES

This article aims to (i) describe the Israeli strategy for identifying new technologies worthy of adoption on a national level and (ii) raise dilemmas in decision making toward planning policy for innovations in different insurance layers.

Time Span

We would like to focus on three basic time spans in our emerging technology process. When relating to future planning, we can

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Table 1. Analyzing the Time Spans for Adopting New Health Technologies in Israel

Horizon scanning	Short term	Medium term	Long term
Type of adoption	The annual update of the NLHS	Purchase of advanced technologies for hospitals and clinics	National projects such as "Health Israel 2020" National Project
Time span	1 year	3-5 years may extend to a decade	A decade or more
Unique feature	Balancing need with budget allocation	Quality of care, professional competition, regulation	Complexity and uncertainty
Participants involved	MOH and the Public Committee	MOH, specialists, professional organizations, providers (hospitals and clinics), insurers.	MOH, professional organizations, national councils, universities, researchers, insurers, Treasury, parliament committees
Fiscal allowance	Specific annual budget allocation	Hospital and community clinic planning	National strategy (undefined amount)
Technology stage experimental stage	New but must be registered in Israel	Emerging	Futuristic trends
Type of technology	Mostly pharmaceutical, procedures, medical devices for individual use	Expensive/ complex medical devices, infrastructure, medical units and hospitals	Health plans, vaccinations, screening tests, experimental technologies
Examples	Elaprase for Hunter's disease	Da Vinci surgical robot, telemedicine, imaging devices, CVA units	Preventive medicine, genetic therapy stem cells

describe our scope relevant to different time periods: short-, medium-, and long-term.

The first time span is immediate to short-term (for the coming year); the second is a medium-term (a period of approximately 3 to 5 years that can be extended to a decade); and the third is long-term planning, 10–20 years or more.

Methodologies used by EAA systems are dynamic and may vary according to time spans and domestic health policy in different countries.

In Israel, the Department of Medical Technology Policy (DMTP, see Supplementary Table, which can be viewed online at www.journals.cambridge.org/thc2012039) at the Ministry of Health (MOH) and the Israeli Center for Technology Assessment in Health Care (ICTAHC) collaborate on horizon scanning to enhance insight into prospective health services for the future. Forecasting activities are conducted simultaneously on national, regional, local, and individual scopes for the three different time spans-short, medium, and longterm, each with unique features, and impact on future planning. Other countries such as England (10) and Austria (8) focus on short-term EAA up to 3 years. In Israel, different approaches have been applied to operate and regulate these varying time span mechanisms (Table 1). These time-related forecasting pathways vary according to the type of adoption, participants' involvement, fiscal allowance and the stage of technology lifecycle.

Short-term Planning - Balancing Need With Budget Allocation

In the short-term, two different approaches are used side by side: extraction of emerging technologies from candidate health services presented to the MOH for updating of the NLHS (see appendix) and quarterly health scanning of publications and news on health innovations.

The predominant approach is enacted during the updating process of the NLHS. Immature technologies, which constitute the emerging phase, are identified and examined using criteria on issues of safety, clinical effectiveness, alternatives, pricing, social and ethical values, and national policy (3) to wisely support future implementation within budget limitations.

During evaluation it is often found that scientific evidence needs reinforcement, diminishing the uncertainty parameter, and we therefore, wait another year to present the candidateship of this technology, while gathering additional information. This was the case for the drug eluting stent in 2002, Lucentis (Ranibizumab) for age-related macular degeneration in 2005, spinal neurostimulator for urinary incontinence in 2008, Yervoy (Ipilimumab) for melanoma in 2010, and bone marrow drill for elongation of bone as part of fracture repair (Fitbone) in 2011.

Different filtration criteria and scales are used for filtering beneficial technologies in the different time frames. Grading scale A is used in the short-term frame, and reflects the added value in clinical terms (e.g., life-saving, prolongation of life, improving quality of life) combined with the level of evidence (Table 2).

In cases of less mature candidate technologies, they will remain under the umbrella of pending entities, channeled for follow-up and future re-ranking (2;5).

The second approach in the short-term relates to the scanning process conducted at ICTAHC, using key Internet sources and according to the guidelines as proposed in the EuroScan toolkit (16). Findings from this scanning are integrated in the NLHS update process.

Clinical criteria	Evidence	Major grading	Secondary grading	Score	Further action
Life-saving	High (A)	А	10	A10	To be raised for discussion
,	Medium-low	А	9-10	A9, A9*	
Prolongation of life	High (A)	А	9	A9	
5	Medium-low	А	8	A8, A8—9	
Improving quality of life	Reasonable	А	8	8	
Improving health (survival or quality of life)	Medium	В	7	B7	For further follow-up
	Low, very low or absent	В	6-4	B6, B5, B4 respectively	I
New technology	No evidence or no experience	C	3-1	C3, C2, C1 respectively	Not recommended at this time

Table 2. Grading Criteria: Short Time Span (Scale A)

Table 3. Grading Criteria ("added value") for Medium Time Span for Candidate Technologies (Scales B & C)

Innovativeness	Scalea	Major comparative parameter	Investment in training or costs	Further action
High (breakthrough)	В	No alternative	High	To be raised for discussion
			Low	Prioritized for adoption
		Few alternatives	High	For further follow-up
			Low	To be raised for discussion
	C	Patient-centered individual use	High - Low	Prioritized for adoption
Medium (new)	В	Few alternatives	High	To be raised for discussion
			Low	Prioritized for adoption
		Many alternatives	High	Not currently recommended
			Low	To be raised for discussion
	C	Patient-centered individual use	Low	To be raised for discussion
Low or only a minor medical improvement	В	Many alternatives	High Low	Not currently recommended For further follow-up
	С	Patient-centered individual use	High - Low	Not recommended at this time

^a Scale B indicates technologies involving infrastructure (e.g., MRI). Scale C indicates devices for individual use (patient-centered) vs. technologies that are part of the equipment located in the clinic available to all patients (clinic-centered) (e.g. glucometer vs. glucose monitoring halter).

Medium-term Planning: Quality of Care, Professional Competition, and Regulation

Leading professionals identify promising innovations that may be future breakthroughs, and usually aspire to swiftly promote such advanced technologies. The MOH is involved in forecasting and regulating these technologies (especially devices or procedures) due to the economic burden entailed and preparedness required, because they are often dependent on intensive training and costly infrastructure. Other players collaborating in the medium-term process are specialist and professional organizations, providers of health services (such as hospitals and clinics), as well as insurers.

When analyzing medium-term adoption of emerging technologies the MOH has to consider morbidity and mortality trends, demographic changes (population size and characteristics such as age and socioeconomic status), and geographic parameters (that reflect accessibility) (18). Examples of technologies analyzed using this preparedness strategy include planning for cerebral vascular accident (CVA) units in highly professional intensive care departments, the need for PET-CT in a medical center with specific expertise, and operating and locating an electron-beam center for cancer treatment. All of these assessments must take into account considerations of professional skills, performance ability, cost, and accessibility.

Grading scale B uses the added value of a new technology in comparison to current alternatives, (uniqueness, or complementary or add-on features) combined with costs or the need to invest in infrastructure or training of personnel. Grading scale C uses the added value for the individual (patient-centered technology) versus the benefit to the clinical community as a whole or the medical organization (clinic-centered), combined with cost (Table 3).

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Table 4. Tiers of Potential Loci for Identification of Medical Innovations

Loci	Tier	% of population	Mechanism	Frequency of action	Mode of action	Contribution to EAA system	Comments
MOH DMTP	National	100%	Established systematic	Annual	Filtering comprehensive assessment	High	Updating NLHS, based on NHIL
MOH ICTAHC	National	100%	EAA	Quarterly	Identification	High	
Insurers (HMOs)	1 st tier	HM01-55% HM02-25% HM03-11% HM04-9%	Systematic	ND	Adoption-geared assessment (AGA)	Medium-high	Following updating NLHS
Insurers (HMOs)	2 nd tier ^a	78 % ^c	NE/ NS	ND	AGA	Medium- high	Limited by governmental regulation
Insurers (HMOs & other)	3 rd tier ^b	30% ^c	NE/ NS	ND	AGA	Medium- high	Limited by governmental regulation
Hospital (public sector)	Regional	${\sim}5\%$ each	NE/ NS	ND	AGA	High	Limited by governmental regulation
Providers (private sector)	Local (custom oriented)	individual	NÉ/ NS	ND	AGA	Low	•••

^a Supplementary insurance.

^b Private or additional insurance.

^c Note that in some cases, citizens may purchase three different kinds of health insurance simultaneously – the basic health basket + supplementary insurances by the HMO and additional private insurance to top it all up.

NE/ NS, not established/not systematic; ND, non defined; AGA, adoption-geared assessment.

Long-term Planning: Complexity of the Process and Uncertainty on the Horizon

Long-term planning of promising medical technologies was engineered in the "Health Israel 2020 Project", as a part of the WHO agenda for preventive medicine for 2020. This national publicly funded project was created to cover twenty-three spectrums of health care for the entire population focusing on preventive medicine (including anti-hypertensive drugs, statins, etc.), vaccinations, combating obesity, and screening programs (17). Many stakeholders were involved in this process, headed by the MOH and including the four health funds, professional organizations, national councils, university departments of public health, and health research bodies accompanied by the Treasury (for potential future financial backing and control) and parliament committees (for legal aspects).

Tiers of Potential Loci for Identification of Medical Innovations:

The key features and tiers present in the identification and assessment of innovative technologies in Israel are presented in Table 4. The updating process of the NLHS in Israel is only the first point of intersection in the short-term phase. Other points of intersection in the early recognition of new technologies are the insurers, hospitals and the private sector. The perspectives of the different "actors" in the health scene can be divided into tiers representing the different levels of insurance. They differ in the proportion of the population encompassed, mechanism and frequency of update, mode of action, and contribution to the overall EAA system.

The first tier, based on the annual updating process focuses on identifying, filtering, and comprehensively assessing candidate technologies, and is relevant for the entire population (5).

Insurers operate on behalf of members of their fund and operate on three levels. The first is part of the MOH updates; the second is the supplementary insurance; and the third is an additional insurance to supply promising emerging technologies that were not yet adopted through the MOH mechanism. These supplementary technologies may be promoted by each insurer on their own initiative (second and third tiers based on age and risk, respectively).

Hospitals operate on a regional basis. Their inspiration to promote new technologies is only partially directed by the MOH, and they are free to innovate within their budgets. They are positively encouraged to compete on quality and innovativeness on the healthcare market. Private healthcare providers have even more opportunities for innovation for their clients. Naturally, their scope is profit-based and customer oriented.

Further filtering scales are warranted to classify the innovativeness and importance (added value) of the technologies investigated at each tier, referring to the different tiers, budget limitations and time perspectives.

DISCUSSION

One of the most important variables in evaluating emerging technologies is timing. There are many points during the development of an innovation when decision makers may become aware of its potential value. An analysis of the EuroScan International Network (www.euroscan.org.uk) database indicates that over a third of the technologies in the database were identified at the investigational phase III stage (6). A quarter of them were identified when they were already established, with another fifth being identified when they were nearly established. This indicates that most innovations in the database are recognized later in the technology's lifecycle, showing that uncertainty leads us to focus on more mature technologies. In this registry, the actual time gap between identification and potential implementation of many of the technologies is relatively short.

The three time spans presented in this article merge into the more distant future, although naturally highlighting the shorterterm perspective.

Identifying and filtering the most beneficial health technologies is critical in planning improvements in health services on a national level. We are confronted by public pressure to provide more advanced health services and caution is needed to overcome uncertainty in the early warning (EAA) process. We, therefore, need to be wise in using the scales mentioned in striving to filter relevantly, reducing uncertainty, and preparing the platform for identifying promising technologies.

In the medium-term, hospitals are leaders in the promotion of advanced devices and procedures. The EAA system aims to assist the government in balancing between two major roles: encouraging the adoption of highly expensive medical devices in hospitals while safeguarding accountability for promoting equity in accessibility to health services for populations residing in geographically peripheral areas and low socioeconomic groups.

Long-term planning is in general a complex feat in all fields. Prophecy was given to the simple "Ever since the fall of the holy temple, it has come to be that prophecy was taken away from the prophets, and given to the infants and the fools" (Talmud, Baba Batra chap. 12, line 2).

Uncertainty is a frail foundation for future decision making. General global trends must be taken into account but carefully adjusted according to Israeli data. For example, adjustments to general Western trends need to be amended due to the fact that the proportion of young people in Israel is higher than in many European countries. Notably, in Israel there are clusters of disease that are ethnic, genetic and specific, requiring unique focused attention by EAA system (20). The shortage of healthcare personnel (nurses and physicians) may also influence the choice of technology for broad future usage.

As in other Western countries, priority setting for budget allocation is a constant source of turmoil. Budget conflicts prevail, challenging policy makers in attempts to divide funds between defense needs, education, health and national infrastructure and also within the realm of individual needs. There is conflict between social and health needs, although they are interrelated. In 2009, the national expenditure allocated for health issues was 7.9 percent of GDP, while for social affairs it was 16.3 percent of GDP (21).

In long-term planning all stakeholders share the burden, responsibility, and accountability. The dilemma entails the bal-

ance of influence in the roles of the different participants. Empowering patients and the public as well as private insurers in this process will change the equilibrium. Involvement of the public will integrate values, culture, and habits, and may influence compliance and dissemination (4). These are all concepts that must be considered in EAA activities.

CONCLUSION AND THE FUTURE

Health planning in Israel matches world trends in the field, while being unique in certain aspects. In the Israeli health system the adoption of medical technologies is considered in the short-, medium-, and long-term and incorporates a variety of perspectives and stakeholders. Several different players have an interest in various innovations in different implementation loci (hospitals, community care), for different populations (national, regional, local, individual) and in different tiers of insurance (obligatory, supplementary, private).

Furthermore, the MOH has to deal with regulatory aspects and harmonize dilemmas of need, equity and cost containment. In the long-run, the horizon is cloudy, inhibiting focused decision making and budget tugs-of-war between different sectors of the economy—education, defense, welfare, and health continue. An increased number of stakeholders are involved, each swaying the balance of power in their direction.

An effective EAA system should identify innovations that are likely to have a significant impact (7). To adequately evaluate information, the EAA system needs to establish consistent methodology (1). Ideally, this would help to ensure that important technologies are not overlooked and, conversely, that time is not wasted evaluating unimportant technologies. This methodology should take into account maintaining the system's objectivity while encouraging the flow of information, the feasibility of implementation and sufficient funding (9;14;15). Moving forward, global collaboration between EAA systems would be useful for streamlining processes.

Our crystal ball is immersed with uncertainty. Israel should highlight this subject of preparedness for future needs, initiating comprehensive action toward identifying emerging technologies, prioritizing and filtering on the basis of national values and policy. Caution is needed to balance regulatory control while monitoring quality of care versus the freedom to seek and adopt beneficial innovations. Another possible pathway open to us is enhancing the impact of international collaborations among specialists in the field deliberating on these issues.

SUPPLEMENTARY MATERIAL

Supplementary Table 1: www.journals.cambridge.org/ thc2012039

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CONFLICTS OF INTEREST

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APPENDIX

Health Funds – Health services in Israel are delivered by the four healthcare insurance companies (the health funds, also called Health Management Organizations - HMOs) according to reasonable medical judgment, within a feasible time span ensured by reasonable accessibility and within the framework of a restricted budget.

The updating process of the National List of Health Services

The annual appraisal of approximately 400–600 new candidate technologies submitted for public funding by manufacturers, healthcare professionals and organizations, patients and patient organizations, and the general public is performed at the MOH. A professional team of physicians, nurses, pharmacists, and medical engineers supported by a legal advisor and economists, ranks the evidence, and filters each technology, on the basis of safety, effectiveness, and appropriateness according to national needs and values. Grading criteria are detailed in Table 1.

There is an annual timeline for the prioritization process beginning with filtering, grading, and ranking added value, gathering epidemiological data and pricing with final deliberations and recommendations by the Public Committee for legal implementation and funding.

The Public Committee is composed of sixteen to twenty-one members appointed by the Ministers of Health and Finance. The members include at least: four physicians, four economists, the four medical managers of the insurers (HMOs), and four representatives of the public including an ethicist and a cleric. Other representatives may be added such as the medical professional union and the ombudsman. The Committee uses clinical, economic, social, legal and ethical principles in a transparent consensus process. Clinical aspects involve life-saving, prolonging life, or improving quality of life; economic parameters reflect the added value for investment; social aspects include preferences in consideration of large populations or low socioeconomic groups; while ethical dilemmas relate to allocation of resources according to solidarity and equity.

The final recommendations of the Public Committee are approved by the government at the end of the fiscal year, matched to specific budget appropriations and scheduled to be implemented early in the following year.