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A note from the editor

Welcome to issue 7 of the EuroScan newsletter. The period since issue 6 has been an exciting one for EuroScan, with the launch of a new and improved website www.euroscan.org.uk. The site has some additional features including a news section, and access to information on new and emerging health technologies for public users has been improved. The new website helps to address one of EuroScan's objectives

of sharing more of the work of the collaboration with non-members. Feedback from members and public users has been very positive, so if you haven't yet visited take a look for yourself.

Many of our members attended HTAi in Singapore. Members contributed to the conference with oral presentations on sources for identification of new and emerging technologies,

stages of identification and answering the question "What is an innovative public health intervention?".

In this issue you will have a chance to read about the work of five EuroScan members, with articles on both processes and specific new and emerging health technologies, and the issues they pose for decision makers.

Sue Simpson

EuroScan Newsletter Editor

Dilemmas for the Adoption of New Health Technologies in 2010

Orna Tal & Nina Hakak, Ministry of Health, Israel.

This year's process of informing the National Public Committee for the Updating of the National List of Health Services (health basket) in Israel has raised further dilemmas:

- public funding for biologic agents, which are very expensive;
- the allocation of budgets for orphan diseases,

some of which are weight-dependent for these life-extending technologies since costs rise as the child grows;

- investing in palliative treatment;
- debates on the threshold of public funding for treatments extending life for less than 3 months;
- allocations for gender-related technologies; and
- public funding for technologies that are preventive as opposed to technologies for treatment of acute disease.

During the months October – December 2009, the National Public Committee for the Updating of the National List of Health Services (health basket) in Israel, convenes to determine the recommendations for a list of new health technologies to be added within the framework of public funding.

Over 400 technologies are candidates for inclusion within the budgetary allocation of only NIS 415 million (approximately \$US 110 million) for 2010.

Member Profiles:

National Observatory for New and Emerging Technologies – COTE at the National Agency for Regional Healthcare (Agenas)

Maria Rosaria Perrini, Alessandra Lo Scalzo, Antonio Migliore, Tom Jefferson, Marina Cerbo



The National Agency for Regional Healthcare (Agenas) is a technical body of the Ministry of Health (MoH) in Italy totally financed by public funds. It supports Regions and the MoH in healthcare service research, development and organization.

In 2008, Agenas started a pilot project financed by the MoH (September 2008 - November 2009) for the implementation of a national Horizon Scanning System (HSS) called COTE (Observatory for New and Emerging Technologies). The COTE project led by the Agenas Health Technology Assessment unit, attempted to involve all stakeholders (MoH, Regions, industry, universities, technical government bodies and scientific societies), in the definition of the key characteristics of the system.

During three workshops representatives of different groups of stakeholders agreed on a HSS for Italy. The workshops' themes were: "Identification, filtration and prioritization" (September 2008), "Assessment and dissemination" (January 2008), and "First HS reports and proposals for a permanent observatory" (November 2009).

Identification, filtration and prioritisation

During the first workshop for the *identification* step, participants decided to adopt a "reactive" method based on information provided by the network of stakeholders and the general public. A structured form has to be sent to Agenas with specific information on the technology (target population, evidence available, reasons for introduction). With regards to *filtration* it was decided that this has to be carried out by Agenas on the basis of a structured procedure which considers the completeness of information available and the life-cycle of the technology. For *prioritization* the group decided that the Committee of Medical Devices of the MoH has to choose the technologies to undergo an early assessment on the basis of set of criteria identified by workshop's participants:

- clinical-epidemiological
- economical-organizational
- ethical-social
- level of evidence
- potential for inappropriate diffusion.

From September to January Agenas collected submitted

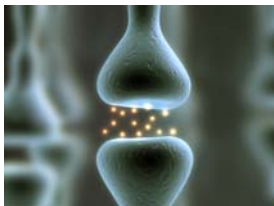
forms and three technologies were chosen for assessment.

Assessment & Dissemination

In the second workshop Agenas proposed an *assessment* template (see next article) and discussed *dissemination*. The main direct channels for diffusion of outputs were newsletters, public bodies websites and scientific journals, while indirect channels were regions, universities and scientific societies. After this process Agenas produced the first three HS reports using the agreed method.

A permanent system?

In the third workshop Agenas is going to propose the establishment of a permanent horizon scanning system for Italy. This system will be based on a more powerful system for identification, with both a reactive and proactive step and a broadening of the number of identified technologies. With regard to prioritisation a Committee of stakeholders will be appointed to select technologies every six months, on the basis of five criteria.



We're on the Web!

See us at:
<http://www.agenas.it/cote>

COTE - HS Assessment template and method

Alessandra Lo Scalzo, Antonio Migliore, Maria Rosaria Perrini, Tom Jefferson, Marina Cerbo

The report's production process at Agenas takes approximately 4 weeks and is carried out by a part-time multidisciplinary team. Clinical experts are also involved to feed into the understanding of the uses of the technology. Reports are almost 10-15 pages in length including a bibliography and glossary.

The assessment template contains sections on:

- target population,
- description of technology,
- clinical importance/ burden of disease,
- comparators,
- safety and effectiveness,
- manufacturers/ distributors,
- approval status,
- costs,
- potential benefits to patients,
- structural and organisational impact,
- conclusions, and
- future prospects.

Available evidence is searched using the EuroScan database; Medline, PubMed and the Cochrane Library; databases on on-going clinical trials; and registration and licensing sites. Moreover, Agenas involves manufacturers to collect any further information and evidence on the

technology. When the report is ready it is sent to a number of external reviewers (clinical experts and manufactures) for comments.

An example of a report: Transapical Transcatheter Aortic Valve Implantation (TA-TAVI)

Patients suffering from severe aortic stenosis often require surgical valve replacement. These patients are generally elderly with a high risk of death during a conventional surgical procedure.

Transcatheter aortic valve implantation (TAVI) consists of the insertion of a prosthetic valve, which functionally replaces the native damaged aortic valve, by means of minimally invasive surgical approaches. Recently a new approach has been developed and consists of delivering the valve through the cardiac apex by a small incision in the intercostal space.

At the time of writing, the Edwards SAPIEN™ heart valve with Ascendra delivery system (Edwards Lifesciences) is the only device on the market that can be used for transapical TAVI (TA-TAVI). This technology gained the CE

mark in December 2007 and has been on the Italian market since January 2008 where more than 100 procedures have been performed.

The potential impact of the technology seems to be promising especially if its diffusion and use are linked to appropriate training programs for the multidisciplinary staff performing the procedure. Benefits to the patients must be confirmed by further studies with a broader population range and longer follow-up, since available evidence is mainly referred to case-series in small groups of patients with follow-up around 12 months.

Further evidence will come from the ongoing multi-centre randomised controlled trial called the Placement of AoRtic TraNscathetER Valve Trial or the PARTNER trial, from the registers managed by the manufacturer (the SOURCE register operative in Europe) and from the Italian regional registers that are under construction.

The HS report on TA-TAVI is available on www.agenas.it



"Moreover, Agenas involves manufacturers to collect any further information and evidence on the technology"



"Early awareness and alert systems (EAASs) were born to support policy-makers in their decisions since HTA could not provide them with timely information."



The Italian Horizon Scanning Project

Roberta Joppi

The Italian Horizon Scanning Project (IHSP) predicts which new drugs are likely to have a significant impact on the Italian National Health System (NHS), issuing periodical evaluations of emerging medicines for which a European Marketing Authorization (M.A.) is expected within 12-36 months.

How does IHSP work?

IHSP collects information on emerging medicines from websites (pharmaceutical companies, financial analysis companies, international scientific societies, international regulatory authorities, health information websites, etc.), medical-scientific literature, pharmaceutical companies' press releases, and other early warning systems.

A scientific committee, a database team, and an evaluation team for emerging pharmaceuticals all support IHSP's activities. The database is available on the web, with restricted access. The scientific committee (IHSP-SC) includes regional and national stakeholders with nationally and internationally recognized experts in drug evaluation. The IHSP-SC assigns priority to emerging drugs according to their possible M.A. date and their

potential grade of innovation, therapeutic and economic impact, possible price and NHS sustainability. Other tasks include the revision of all assessments produced, decisions on their dissemination, identification of possible therapeutic needs and priority research areas for the Italian NHS and development of links with other relevant organisations.

The IHSP database team (IHSP-DT) includes Internet Technology (IT) support and a scientific secretariat (pharmacists, and an administrative employee). Its tasks are to collect information, to maintain and update the database, to guarantee the confidentiality of the data stored, to support the production of the assessment reports on emerging medicines and to provide IHSP-SC and/or the IHSP evaluation team (IHSP-ET) with any additional documents required.

The IHSP-ET for emerging medicines is made up of a panel of about 50 clinicians, with expertise in different medical and surgical fields, and a scientific secretariat. The IHSP-ET produces the New Product Information Report (NPIR). Currently IHSP is publicly funded and private sponsors are accepted only if they have

no conflict of interest. In any case private funds should represent only a minority share in the global IHSP financial resources.

What drugs have been identified so far?

From January 2007 to October 2009, the IHSP database has included 1,000 drugs in development corresponding to 2,059 items (i.e. new chemical entities, new indications, new formulations, new associations and new dosages). Pharmaceuticals from phase I of development onwards have been added to the database. At present 32% of the drugs are in phase II of development and 29% in phase III. Eighty medicines are in pre-registration in the European Union and 116 in the USA.

Which reports does IHSP issue?

IHSP produces three different reports: 36, 18, and 12 months before the European M.A. date. The report issued 36 months before the potential M.A. date gives information on the mechanism of action of an emerging drug, on phase II trials (which are often available) and provides

indications of ongoing phase III trials, which are recorded in national and international clinical trial registries. This report provides the Italian Medicines Agency (AIFA) with information concerning the development plans of emerging drugs. Since AIFA directly funds an independent research program, this information is useful to identify research needs of interest to the Italian NHS which are not met by pharmaceutical companies. The report produced 18 months before an M.A. , assesses available results of the first phase III trials completed and allows the identification and prioritization of emerging medicines likely to have a clinical and economical impact on the Italian NHS. Thus this report is not specifically aimed at policy makers, but is essentially used for internal purposes. The assessment report issued 12 months ahead of the planned licensing date, the NPIR, critically reports on available data on efficacy and safety of the new medicine, possible advantages over existing treatments (level of innovation) and its possible place in therapy as well as estimated direct costs and information on other potentially relevant indication(s) in development

or on competitors in development for the same indication. At this stage any changes in the prescription details can also be assessed using historical prescription data on available treatments and defining the target population according to the inclusion/exclusion criteria and the results of the trial(s). The NPIR and the transferability analysis are particularly useful to decision-makers to improve planning and optimize the most appropriate use of resources, deciding the level of reimbursement of a new drug and possible limitations in its prescribing.

How does IHSP prioritize emerging medicines?

The prioritization criteria adopted by the IHSP-SC are related to the burden of the specific disease, to efficacy, to safety and compliance of the emerging drug compared to available treatments, to the potential social, economic and organizational impact of the new medicine on the Italian NHS and to its possible M.A. date. For a drug to be prioritized, efficacy/safety results of phase III trials (phase II trials for certain anticancer drugs) and a possible M.A. date are essential. As a second step,

epidemiology of the disease and potential organizational /social consequences of the emerging medicine are evaluated. Finally, the economical aspects (direct costs, when available) of new therapeutic agents are examined. The IHSP-SC has resolved not to rate the reported items or to establish a threshold for drugs to be prioritized. Instead it has decided to utilize these criteria very pragmatically for two to three years. After this period, the adequacy of the criteria adopted to identify products of major interest and their impact on the NHS early will be retrospectively verified. This analysis will suggest any points in the prioritization process that could usefully be revised.

Recent outputs

In years 2008 and 2009 IHSP assessed 92 drugs for which a M.A was expected within 36 months, 73 for which an M.A. was expected within 18 months and 17 for which an M.A. was expected within 12 months.

Horizon Scanning: not only a forecasting tool

Early awareness and alert systems (EAASs) were born to support policy-makers in their decisions since HTA could not provide them with timely

technologies on the NHS, EAA activities can also foster a constructive debate on development plans of new drugs, considere interests of NHSs and highlighting research needs for further investigation.

Once a product has reached the market, EAASs can retrospectively track its development, identifying the studies reported in clinical trial registries and verifying which ones were completed, published or included in the registration dossier. This could be of particular interest in view of the recent debate on discrepancies between the trial information reviewed by the regulatory agencies and information found in published trial reports, on the limited and incomplete public access to clinical trial results to be found on the "Product Label" (FDA) or in the European Public Assessment Report (EMA), and on requirements for study results to be posted in the Clinical Trials Registry.

For further information see:

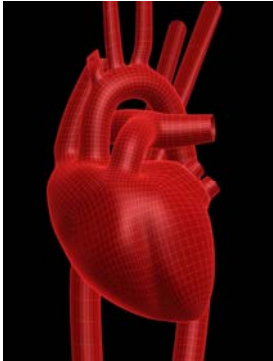
<http://horizon.cineca.it>

Joppi R et al. The Italian Horizon Scanning Project. *Eur J Clin Pharmacol* 2009; 65(8):775-81.

Early Awareness & Alert Activities – a case study

Percutaneous aortic valve replacement

Irving Lee & Alun Cameron, ASERNIP-S, Research & Academic Surgery Division



Percutaneous valve replacement is a rapidly diffusing technology and has garnered substantial interest from the medical community in recent years. The Australian and New Zealand Horizon Scanning Network (ANZHSN) identified percutaneous aortic valve replacement as an emerging technology in Australia and conducted an assessment in February 2007 in view of its potential. This assessment noted that the technology is promising and may reduce patient morbidity and decrease the length of hospital stay. However, the limited evidence on this technology and the paucity of long-term data led the committee to conclude that it should be monitored for future developments.

Within several months of this assessment, ANZHSN was informed that the technology had appeared in Australia and started diffusing within the healthcare system despite the fact that the Therapeutics Good Administration had not approved its use. It was understood that the technology was obtainable via

a special access scheme or via clinical trial notification as part of a clinical trial or registry. Following this, ANZHSN recommended that the state jurisdictions should monitor and collect the clinical data from hospitals on the use of percutaneous aortic valve replacement. The committee was aware that the potential rapid and uncontrolled diffusion of this technology may have substantial implications if it was proven to be ineffective when long-term data becomes available.

Since February 2007, the original horizon scanning assessment has been updated three times (the latest version being produced in August 2009) to capture the latest clinical data on the safety and effectiveness of percutaneous aortic valve replacement. The updates highlight that a large majority of the evidence available on this technology remains limited to case series studies, most of which confirm the feasibility of the technology in high risk patients who are not suited for open surgery. However, the safety of this technology remains unclear and

long-term data (>1 year) is scarce. Fortunately, the efforts of the ANZHSN have encouraged the collection of clinical data from hospitals within Australia that are using this technology. In the near future, the ANZHSN will be reviewing this data as it becomes available with the hope of elucidating the long-term effectiveness.

This case highlights the need for strong communication between horizon scanning agencies and the clinical community. Without these links, valuable clinical data may be lost and this technology may have diffused rapidly without evidence of its long-term effectiveness. The ANZHSN will continue to monitor this technology within Australia and looks forward to the availability of local clinical outcomes.

We're on the Web!

See us at:

www.horizonscanning.gov.au

Related Activities

Out with the old, in with the new?

The first strategy to integrate the identification of new and emerging health technologies with those that could be removed from the health care system

Ibargoyen-Roteta N, Gutierrez-Ibarluzea I, Benguria-Arrate G

Osteba the Basque Office for HTA has designed a process to integrate the identification of new and emerging health technologies with the identification of those technologies that potentially should not be funded. The process incorporates information including details on a technologies potential for harm, its effectiveness and its cost-effectiveness.

Based on previous experience in EuroScan and GENTECS, a new web-database, named SorTEK-ZaharTEK, has been designed. This software incorporates a domain designed for the identification of those technologies that have become outmoded or obsolete or that can be substituted by new ones. To complete this global identification system, a recently designed initiative to structure the process for disinvestment in health care (GuNFT) has also been linked to the SorTEK-ZaharTEK database. Any person can identify new and emerging or

obsolete health technologies via the SorTEK-ZaharTEK database.

SorTEK (new technologies database) includes 38 variables, grouped in 11 areas, and ZaharTEK (obsolete technologies database) includes 31 variables divided into 6 different areas. Both domains can be connected: in SorTEK, the variable that records the existence of a complementary/alternative technology to the identified new one allows the creation of a new ZaharTEK file, and in ZaharTEK, the variable that specifies the name of a new technology that can substitute one in use can generate a SorTEK new file.

The connection with the GuNFT initiative (the guidance for disinvestment processes) is the provision of information about those technologies whose financing is being questioned. In this way, the information about all those technologies that can

influence investment and disinvestment decision-making can be all in the same place. This connection has been established through 21 variables that are present both in ZaharTEK and in the application-form of the GuNFT initiative. Through this process Osteba wants to integrate the identification process of new and emerging health technologies with those that are obsolete or that should not be funded in terms of promoting a more efficient system. An implementation plan including meetings with professionals, managers and biotechnological companies has been drawn up to enable this process to work.

www.osanet.euskadi.net/oste/ba/es





Exploring ways to improve disinvestment in health care: the establishment of an international group of interest at Health Technology Assessment International (HTAi)

Gutierrez-Ibarluzea I, Ibarгойen-Roteta N, Benguria-Arrate G, Galnares-Cordero L
Osteba, Basque Office for HTA

A group of members and organizations of the Health Technology Assessment international (HTAi) society, many also members of EuroScan, have established an interest group on: disinvestment of health technologies, to include the methodological approach to this field. The final proposal has been positively considered by the International Society and it has been considered as part of the Interest Sub-groups of HTAi (ISGs).

The topic of disinvestment has been presented, discussed and debated at the last two HTAi meetings held in Montreal and Singapore with the interest articulated through two panel sessions, one in each meeting. The last Panel Session had a broad audience and many questions were raised on the topic after the panellist's talks. In recent times, papers have also been published in the society's journal, the International Journal of Technology Assessment in Health Care

and other related journals.

Disinvestment as defined by A. Elshaug in 2007¹ *"...relates to the processes of withdrawing (partially or completely) health resources from any existing health care practices, procedures, technologies and pharmaceuticals that are deemed to deliver no or low health gain for their cost and are thus not efficient health resource allocation"*

At the moment, 47 people who are members of 27 organizations (4 continents), around the world have expressed their interest in participating in the group and collaborating. Moreover, some HTA networks, including EuroScan, are currently discussing the topic and trying to define their role in this field.

ISG's have been established to allow members of HTAi across different nations, fields of interest, and expertise to share information and collaborate on projects of mutual interest in HTA. The ISG's

are recognized as being the most important ways for the members of HTAi to interact and share information throughout the year, not just at the Annual Meetings of the Society.

The purposes of the group on disinvestment in the following years are to: formalize a forum of discussion on this topic in HTAi, to make a repository of current experiences and methodological approaches all around the world, to establish criteria on common approaches to the topic, to propose methodological approaches and finally to give advice to those members of HTAi and related networks that wish to work on this topic.

1. Elshaug AG, Hiller JE, Tunis SR, Moss JR. Challenges in Australian policy processes for disinvestment from existing, ineffective, health care practices, Australia and New Zealand Health Policy 2007, 4:23



Scanning the Horizon

In August 2009, the Canadian Agency for Drugs and Technologies in Health published its eleventh issue of Health Technology Update. This second newsletter of 2009 included articles on:

- Future alternatives to molybdenum-99 (mo-99) production for medical imaging.
- Liquid based techniques for cervical cancer screening
- Fetal fibronectin testing for pre-term labour
- Emerging issues in genetics technology including
 - a new gene test for the treatment of breast cancer,
 - a test for future risk of blindness,
 - predictive gene testing for colon cancer treatment options,
 - a Type 2 diabetes gene test,
 - a new genetic test for Down Syndrome and'
 - genetic predictors of IVF success

http://www.cadth.ca/media/pdf/hta_htupdate_issue11_e.pdf



Telehealth Literature Review

A literature review prepared for members of the Canadian Society of Telehealth (CST) presents a snapshot of news and recent developments in telehealth over a two year period. The review used articles from *Telemedicine, e-Health* (the official journal of

the American Association), *Canadian Healthcare Technology* magazine, and several trade publications.

The report can be accessed at http://www.cst-sct.org/en/index.php?module=library&VV_DocumentManag

[er_op=downloadFile&VV_File_id=538](http://www.cadth.ca/media/pdf/hta_htupdate_issue11_e.pdf)



Adoption and Assimilation

Organisational factors influencing technology adoption and assimilation in the NHS: a systematic literature review (2009) is a report carried out for the National Institute for Health Research Service Delivery and Organisation programme in the UK. The review focuses solely on studies of non-pharmaceutical technologies and was commissioned in the spring of 2008 to make recommendations to facilitate

the increased adoption and use of beneficial technological innovations in NHS organisations. This builds on a much broader review carried out by the authors (Robert G., Greenhalgh T., MacFarlane F. and Peacock R.) published in 2004.

One conclusion from the study was that the adoption, implementation and assimilation of technological innovations comprise

both social and organisational processes, and outcomes are largely determined by the dynamics between these. Whilst a detailed set of 'instructions' that guarantee success for any particular technological innovation cannot be formulated, forwarding a set of evidence-based 'design principles' may help practitioners make sense of the complexity they face.

The report can be accessed at:
<http://www.sdo.nihr.ac.uk/files/project/223-final-report.pdf>

Technological Medicine

About EuroScan

EuroScan - the International Information Network on New and Emerging Health Technologies - is a collaborative network of member agencies for the exchange of information on important new and emerging health technologies.

The aim of EuroScan is to promote a permanent network among organisations involved in early awareness and alert activities (also known as horizon scanning or early warning) to:

- exchange information on new and emerging health technologies;
- evaluate the sources of information used for identification;
- share applied methods for identification, filtration, prioritisation and early assessment;
- disseminate information on early identification and assessment activities.

EuroScan is a membership agency with an Executive Committee and a Secretariat. Membership is open to any agency which:

- has a substantial program for the early identification and assessment of emerging, new or changing health technologies.
- has an ongoing, officially recognized role in relation to regional or national government.
- is a non-profit organization and at least 50 percent funded from public sources.
- has no link other than scientific with commercial companies or R&D centers.

The Changing World of Doctors and Patients

Stanley J. Reiser
The George Washington University School of Medicine and Health Sciences

This book explores how the technologies of medicine are created and

how we respond to the problems and successes of their use. The author explores the ways medical innovations exert their influence by discussing a number of selected technologies, including the X-ray, ultrasound, and respirator. Reiser suggests new methods to

effectively meet the challenges of living with technological medicine. As healthcare reform continues to be an intensely debated topic in America, Technological Medicine demonstrates the pros and cons of applying technological solutions to health and illness.

Dates for your diary

EuroScan Members meeting

23rd -24th November 2009, Madrid, Spain.



HTAi 2010 Maximising the Value of HTA, 6th – 9th June 2010 – Dublin, Ireland

The 7th HTAi Annual Conference will take place in Dublin, Ireland. The conference theme "Maximising the Value of HTA" will be explored in three plenary sessions:

1. Policy Issues
2. Methods
3. International collaboration

Visit the HTAi website

<http://www.htai2010.org/site>

for more information

EuroScan Executive Committee

Position	Current Post Holder	End of term
Chair	Dr Iñaki Gutiérrez-Ibarluzea, Osteba	31/12/09
Vice Chair	Professor Brendon Kearney, ANZHSN	31/12/09
Registrar	Dr Kees Groeneveld, GR	31/12/10
Treasurer	Christoph Künzli, SFOPH	31/12/10
Head of Secretariat	Dr Claire Packer, NHSC	n/a

Visit <http://www.euroscan.org.uk> to find out more about EuroScan, its work and how to become a member.

If you have any feedback, questions, would like to know more or have any articles that would be of interest for the next edition of the newsletter please contact **Dr Sue Simpson**, EuroScan Newsletter Editor, NHSC, Department of Public Health, Epidemiology and Biostatistics, University of Birmingham
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Views of individual authors are not necessarily the views of the editor or EuroScan members