Developing HTA frameworks in emerging markets: the road ahead

The case of Poland

Maciej Nowicki

Poland has a mixed system of public and private financing of health care. The 1997 Law on Universal Health Insurance established the framework for mandatory health insurance, including the universal health insurance contribution and budgetary contributions to expenditure by the state voivodship*, county and commune authorities. Mandatory health insurance contributions are the major public source of health care financing; it is not possible to opt out of the system. The National Health Fund (NHF) has the responsibility for overall planning and the allocation of resources in the Polish health care system.

The state budget plays a limited role in the publicly funded health care system. It covers the costs of some public health activities, the health insurance contribution for specific population groups, investments in public health care institutions, and reimbursement of health services provided for a number of listed life-threatening situations (called highly-qualified provisions). Private financing includes both formal and informal sources of payments, as well as prepaid plans. There are public discussions underway on the development of a system of alternative (private) or complementary health insurance which could be offered to the public.

This insurance-budgetary model of health care funding is regulated by the Law on the Basic Benefit Package (BBP). BBP regulations were set out by an Act of Parliament in 2004 and respective Government Orders. Important changes to these regulations were introduced in the second half of 2009; because these changes are so recent, the law contains a lot of imperfections, divergence and ambiguity that requires constant improvement.

The BBP covers a number of areas including: basic health care, ambulatory specialist care, hospital treatment, psychiatric care, long-term nursing care, dental care, medical devices (orthopaedic and medical equipment) and prescription drugs. Each of the BBP provisions is well described in the relevant Government Orders, and these descriptions include the names of procedures, as well as International Classification of Disease codes Version 9 (ICD-9) for procedures and ICD-10 for disease indications. In some cases, there are detailed requirements for health care providers (for example, hospital/department conditions/equipment to be used, number of doctors and their experience, diagnostic tool availability etc). Government Orders are announced by the Ministry of Health on an annual basis, with the first of these issued in September 2009.

These Government Orders are also the basis for the NHF to set tariffs and enter into contracts with health care providers. Only procedures listed in Government Orders may be performed by health care providers and reimbursed by the public budget. Indications (according to ICD-10) are also guidelines for NHF reimbursement. The most recent Government Orders were issued in October 2010/January 2011.

Pathway for reimbursement

The BBP Act also describes the reimbursement pathway for procedures and technologies to be included in the BBP catalogue and also how the conditions or level of reimbursement can be changed. In this article, the focus is on procedures related to medical devices. In order to be included in the BBP catalogue, a technology is assessed in terms of impact on: health improvement of the population; consequences of illness; clinical efficacy and safety; risk of use; cost-effectiveness; and impact on the health care system.

New medical technologies

The process for the introduction of a new medical technology into the BBP catalogue is initiated by the Ministry of Health, which orders the President of the Polish Health Technology Assessment Agency (AHTAPol), a body comparable to NICE in England, to make recommendations. AHTAPol has published guidelines on conducting a health technology assessment (HTA), which are strictly respected by the authorities.

Following a request from the Ministry of Health, the President of AHTAPol invites opinions about the new technology from (i) National Consultant bodies in the appropriate medical specialisation and (ii) the NHF for financial concerns. These two groups have thirty days to issue their opinions, which are then passed on to a Consulting Committee (CC) working under AHTAPol umbrella. This CC analyses the opinions and presents a position to the President of AHTAPol as soon as possible. Finally the President of AHTAPol will make recommendations to the Ministry of Health based on the CC’s position and the results of the assessment.

There are, however, several limitations in this process including the lack of clear indications on how the Ministry of Health decides when to initiate this process. There

---

* There are currently sixteen voivodship or provinces in Poland.
is also a lack of a clearly defined timeframe for the entire process and no clear definition on how and by whom the assessment is performed. Moreover delays are also due to the need for an announcement of new technologies through Government Orders. These announcements are needed before the NHF starts negotiations with health care providers.

Changes in the conditions for reimbursement

Changes in the conditions for procedures or technologies in the BBP catalogue (such as changes in ICD-9 or ICD-10 related codes or hospital/department requirements) must be initiated and approved by the Ministry of Health. Applicants may be one of the following: the National Consultant body for the relevant medical specialisation; professional medical societies via the National Consultants; the President of the NHF; societies and/or foundations protecting patient rights (according to their statutory objectives) via the National Consultants. The assessment criteria are the same as those for inclusion in the BBP catalogue. The limitations described previously in reimbursing new medical technologies, also present barriers to any change in the catalogue. There are also additional requirements to present basic information about epidemiology, determination of any societal health improvement and the financial implications for the publicly funded health care sector.

Changes in the level of reimbursement

The Ministry of Health is also responsible for any change in the level of reimbursement for a medical technology. An application for change may be made by any of the bodies already identified. The President of AHTAPol then produces a HTA report in respect of changes in the catalogue. There are some limitations for any change in the catalogue. There are also additional requirements to present basic information about epidemiology, determination of any societal health improvement and the financial implications for the publicly funded health care sector.

Reimbursement of Implantable Medical Devices

The idea of a BBP is still very fresh in Poland. In fact the Diagnosis Related Group (DRG) system that was put in place in hospitals in 2009 drew on historical data. This means that today many of the procedures with implantable medical devices (IMDs) are reimbursed.

The DRG tariff includes the costs of hospital stay, medical service (surgery, nurse and medical care etc.), medical devices and drugs, as well as other direct and indirect costs. DRG tariffs are updated by the NHF on an annual basis with some corrections on a quarterly basis. However, the initial use of historical data has meant that the level of the tariff used for reimbursement is, in the majority of the cases, too low for health care providers. This had led to long patient waiting lists for innovative procedures, as well as growing debts within hospitals.

Some examples of major procedures in the Polish DRG system with usage of IMDs include:
- Deep brain stimulation
- Spinal cord stimulation
- Implantation of ophthalmic lenses
- IMDs for hearing-impaired patients
- Angioplasty with bar stents/drug eluting stents
- ICD, pacemakers, CRT
- Orthopaedic surgery with implants (total knee replacement, total hip replacement, spinal surgeries with dynamic stabilisation of vertebrae)
- Meshes in abdominal/uro-gynaecology surgeries

For new innovative procedures that are not already listed in the BBP catalogue, there is an application pathway (see above), where HTA guidelines must be respected by the applicant.

Future for Implantable Medical Devices

In the future, one can expect growing demand for IMDs in Poland. Firstly, this is due to the constant increase in medical knowledge and skills of the professionals. Secondly, there is a tendency for total and public health care expenditures to grow as new innovative technologies replace old and less effective surgeries. Thirdly, there is growing awareness among patients about new technologies. Finally, the expected development of private/alternative health insurance will additionally have a positive impact on the development of implantable procedures in Poland.

References


Acknowledgment

The papers on health technology assessment follow on from an expert meeting on “The development of HTA for implantable medical devices in emerging markets”, held in Prague in March 2010 and funded by Medtronic Trading NL BV. The views expressed in these articles are those of the authors alone and not necessarily those of Medtronic Trading NL BV.

Observatory Venice Summer School

San Servolo, Venice, Italy
24–30 July 2011

The Ageing Crisis: A Health Systems Response

More information is available at: www.healthobservatory.eu

The Summer School provides a chance to spend a week working intensely with other senior to mid-level health policy makers, planners and professionals with expert support to marshal the evidence on ageing, to review what it means for health systems and to share experiences of responding through policy and in practice.

The Summer School addresses a fundamental change that affects the entire health system in its widest sense and sectors beyond. It creates a chance for you to focus on state-of-the-art knowledge with your peers and to build lasting networks across Europe. Early applications are encouraged as places are limited.