

# Health Technology Assessment – what for and for whom? Immunisation as an example of use

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## INTRODUCTION

In brief, Health Technology Assessment (HTA) may be characterised as *»the provision for health care decision-makers of high-quality research information on the cost, effectiveness and broader impact of health technologies«*<sup>1</sup>. By this definition HTA is what one expects: a scientific policy support – made for decision makers.

But on closer examination, the following roles of patients in HTA can be seen: Firstly, HTA's aim *»to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value«*<sup>2</sup>. Secondly the development of HTA in the last two to three decades has been driven by the rise in consumer expectations (as well as concerns about the adoption of unproven technologies and rising costs)<sup>1</sup>.

And last but not least, in the age of shared decision making, evidence-based patient information, nowadays provided by many EBM and HTA organisations, is a necessary tool for patients to make informed choices.

In this article I would like to give an example of how HTA can be used, for decision makers as well as for patients.

## HTA AND HPV

It has been demonstrated that infection with certain types of Human Papilloma Virus (HPV) is a prerequisite for developing cervical cancer. In addition to successful prevention programs, such as cervical cancer screening via *»Pap«* smear, the possibility of immunisation against high-risk virus genotypes has recently been introduced. Both of the two available HPV vaccines prevent infection from two high-risk HPV genotypes (16 and 18), one additionally protects against two low-risk types (6 and 11) which are related to further diseases. Clinical studies of type-specific vaccination have proven their efficacy in preventing precancerous cervical lesions, which are surrogate parameters for cervical carcinoma. There is hope that the number of new cervical cancers will decrease substantially.

## HTA FOR DECISION MAKERS

The questions if and to what extent an HPV vaccination program was to be introduced and financed by public means in Austria should have been answered on the basis of an economic evaluation<sup>3</sup>, that was carried out from our institution (Ludwig Boltzmann Institute for Health Technology Assessment<sup>4</sup>) at the end of 2007. In addition to a systematic literature review, long term health effects and

costs of HPV vaccination have been analysed with a dynamic transmission model. As a result total costs (per year) and cost efficiency ratios (Euros per life year gained) were given for 3 different prevention strategies with varying assumptions on vaccination coverage, effectiveness and duration of protection.

Preoccupation with this core business of HTA – to give advice on intervention specific issues – stimulated further questions: looking across borders revealed differing decisions on HPV vaccine introduction and funding as well as a wide heterogeneity in national immunisation programs in general. There seemed to be a lack of standardised approaches for *»rational«* vaccine introduction on national levels. Assuming that decisions on vaccine introduction should be unbiased, comprehensive and systematic and therefore be based on deliberate, rational, comprehensible and evidence-based criteria, we asked ourselves if decision aids concerning rational vaccine introduction existed and which criteria were crucial for a rational decision making process.

## LITERATURE REVIEW ON BROADER HTA PERSPECTIVE

These questions were the basis of the follow-up project on *»rational vaccination policies«*<sup>5</sup>. By systematic literature research and manual search five *»key documents«* providing an analytical framework or key questions aiming at rational decision making were found. A comparison of these documents revealed an overall similarity with some differences in the approach as well as the criteria. Burden of disease and vaccine characteristics play a key role in the decision making process. The cost-effectiveness analysis is influenced by various factors and has several limitations. Therefore, the authors vary in their views on its significance. Other relevant factors also should be considered before vaccine introduction. These include the immunisation program itself as well as its conformity with other programs, its feasibility and how easily it can be evaluated. Acceptability, equity as well as ethical, legal and political considerations are discussed to highly differing extents. Assuming that the most comprehensive framework possible would not provide a feasible tool for decision makers, a stepwise procedure was then suggested.

## INTERNATIONAL DISCUSSION OF RESULTS

Based on this *»rational vaccination policies«* document, a Delphi process – as a second follow-up project – was carried out during summer 2008 to discuss our model of a stepwise approach in decision making, to assess the completeness of criteria and to reveal unpublished knowledge and specific cut-off limits for vaccine introduction.

Forty international immunisation experts in 16 industrialised countries were invited to participate in this discussion. Most of them had been identified by contacting international HTA organisations. Sixteen experts (in 10 countries) agreed to participate and data of 13 completed questionnaires were extracted, summarised and redistributed for comments on other expert's opinions and specification of their previously given answers wherever necessary and reasonable.

Most of the experts stated that they were not aware of any publications other than the five documents listed in the *»Rational Vaccination Policies«* report focusing on rational vaccine implementation decision-making in industrialised countries. The majority of ex-

experts agreed that »burden of disease«, »vaccine safety« and »cost effectiveness« criteria have been considered, but »no defined cut-off limits« have been used (except a cost-utility ratio below a defined threshold in one country). On a scale between 1 (very important) and 5 (not important) participants ranked the 14 main criteria that had been discussed in our »rational vaccination policies« decision support paper, depending on the influence these criteria should have on vaccine introduction decisions. The median of grades given for all criteria ranged between 1 and 3, therefore experts agreed that the influence of each single criterion should be at least »important«.

A potential delay in the decision making process was the main argument mentioned as a negative consequence that could arise from a rigid stepwise procedure by a few experts. But all experts acknowledged strengths of the proposed model. These strengths include the transparency, the comprehensiveness and the systematic and evidence-based standardised way for Public Health policy decisions. Furthermore, the model would enable the repetition of the process and the comparison of the result with others and could promote the consistency of decision making by ensuring that all relevant factors are appropriately considered.

#### APPLICATION OF KNOWLEDGE TO PATIENT INFORMATION

While immunisation experts discussed general inclusion criteria and processes for vaccine implementation via Delphi, the public discussions on HPV vaccination continued. Other than the scientific general immunisation discussions, those were – and still are – often emotional and one-sided, and occasionally persuasive. Therefore the target group rarely has access to objective and reliable information about the disease, the vaccine and its alternatives. To provide evidence-based information on HPV for young girls and their parents, we started – as a third follow-up project – to develop an online decision aid at the request of a German insurance company.

First of all we conducted a systematic literature research to assess the demand for information and knowledge within the target group and update our HPV-report. Additionally an unsystematic internet search identified existing decision aids on HPV vaccination. The content analysis of online patient information on HPV vaccination confirmed the lack of adequate information. For example, only 4 to 16% gave a morbidity or mortality ranking of cervical cancer in relation to other cancers and only 8% stated that even after vaccination, continued cervical cancer screening is necessary. Finally, the content of our decision aid was compiled by a multidisciplinary team, and readability and comprehensibility were tested in a focus group. To ensure the completeness while avoiding an excess of information, we chose a »multi-level design« for the online decision aid. The two main parts, »disease« and »vaccine«, consist of eight main pages each and up to 26 supplementary pages. Based on this information, individuals can make an informed decision as to whether or not they want to be HPV-vaccinated or wish their daughters to be HPV-vaccinated.

The main challenges in this development process were identifying the evidence and the accurate presentation of the results based on the needs of the target group. Our decision aid<sup>6</sup> cannot and should not replace expert advice, but will hopefully encourage shared decision making.

#### CONCLUSION

HTA stands for the systematic synthesis of the best available evidence in a multi-perspective context and the transparent presentation of the existing knowledge. HPV vaccination provides an excellent example for the multi-faced potential of HTA as input in informed decision-making on different levels under different perspectives. An economic analysis on HPV immunisation resulted in the input into a decision on coverage and investment. A systematic

comparison of international approaches for the in-/exclusion of new vaccines in national programs showed support for consistency of policy decisions over time and across different stakeholders and politicians. Last but not least, HTA offers the comprehensible basis independent of interests for informed decisions of health care consumers and potential patients. The (HPV) immunisation example shows well that HTA may contribute to informed decision making processes on different levels. ■

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## Abstract

### HEALTH TECHNOLOGY ASSESSMENT

**WOZU UND FÜR WEN? – IMPFUNGEN ALS ANWENDUNGSBEISPIEL**  
Hauptaufgabe des Health Technology Assessment (HTA) ist die wissenschaftliche Unterstützung gesundheitspolitischer Entscheidungen zum Nutzen und zu den Kosten medizinischer Interventionen. Anhand von Folgeprojekten, die sich aus dem HTA-»Kerngeschäft«, einer ökonomischen Analyse zur Impfung gegen Humane Papilloma Viren (HPV) in Österreich ergeben haben, lässt sich jedoch das weite Anwendungsspektrum und das heterogene Zielpublikum für HTA verdeutlichen.

In einem ersten Folgeprojekt wurde die Ebene der HPV-spezifischen Fragestellung verlassen und mittels systematischer Literatursuche nach allgemeinen Kriterien für rationale Entscheidungen zur Implementierung neuer Impfungen in nationale Impfprogramme gesucht. Der Vergleich von fünf internationalen Publikationen zu Analyserastern oder zu Schlüsselfragen für rationale Impfentscheidungen führte zu einer umfassenden Auflistung und Darstellung von zu berücksichtigenden Entscheidungskriterien, die für die praktische Anwendung zu komplex erschienen. Um deren Anwendung für EntscheidungsträgerInnen zu erleichtern, wurde ein Stufenmodell für Entscheidungsprozesse entwickelt. Die 14 identifizierten, allgemein zu berücksichtigenden Kriterien und das Stufenmodell wurden in einem weiteren Folgeprojekt internationalen ImpfpertInnen via Delphi-Prozess zur Diskussion vorgelegt.

Im bisher letzten Folgeprojekt wurden erneut die HPV-spezifischen Informationen, aber diesmal für eine individuelle Entscheidungsfindung aufbereitet. Das Stufenmodell wurde verwendet, um die Inhalte für eine evidenz-basierte online-Entscheidungshilfe zur HPV-Impfung für junge Mädchen und deren Eltern möglichst vollständig zusammen zu stellen.

Das Beispiel der (HPV-)Impfung zeigt, dass HTA auf verschiedenen Ebenen einen Beitrag zu informierten Entscheidungsprozessen leisten kann.