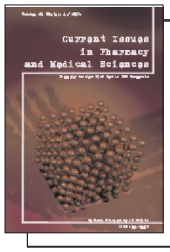

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Adverse events (AE) costs assessed in Poland based on existing Drug Programs – methodology of the project

MONIKA SZKULTECKA-DĘBEK[1*], MARIOLA DROZD[2],
NINA WIŚNIEWSKA[1], KAZIMIERZ DROZD[3]

[1] Dermatology, Military Institute of Medicine, Warsaw, Poland
[2] Department of Applied Pharmacy, Medical University of Lublin, Poland
[3] Department of Materials Engineering, Lublin University of Technology, Poland

ABSTRACT

The Drug Programs, Pharmaceutical Care and Pharmaceutical Law section (DPPCPL) within Polish Pharmacoeconomical Society decided to perform a research on the impact of the adverse events treatment costs incurred by National Health Fund (NHF) and by the public payer. The aim of the project is to develop a list of costs associated to different disease areas of adverse events treatment. The project consists of different phases. Firstly, a review of the drug programs financed by NHF will allow identifying the drugs used in the programs in Poland. It will be followed by a review of the SPCs of the identified drugs regarding the AEs occurrence. For the most common AEs treatment, Polish clinical guidelines will be searched. Additionally expert opinion on treatment patterns in Poland will be collected using an excel tool allowing for further costs calculations. Costs to identified resources used will be allocated using NHF and public payer perspective. The final report will describe the identified adverse events based on the list of drugs used in the Drug Programs in Poland, the results of clinical guidelines search, treatment patterns and related costs. The project will address an important issue related to the costs generated within the Drug Programs, being helpful for further calculations in pharmacoeconomic analysis.

Keywords: osts, adverse events, treatment

INTRODUCTION

Poland is one of the countries with strong Health Technology Assessment (HTA) demand being the reimbursement process described in the legal acts. To fulfill the minimal requirements verified by the Polish HTA Agency (AHTAPoL), a set of local data providing information about epidemiology, standard of care and costs is needed [3, 6]. A part of the costs analysis is always related to the treatment of adverse events observed during the disease treatment. Usually the method used to identify the adverse events in order to include in the HTA analysis is the review of literature and selection of the safety information from the published trials. The challenging part is to allocate costs to the identified events. That requires information about the treatment procedures and resources used in the therapeutic process. In practice, that information is very often based on provided experts' opinion, unless special publication is identified.

The Health Authorities in Poland have established a special way of reimbursement which are called Drug Programs and have been introduced since 2004 [7].There were changes in naming: from Drug Programs to Therapeutic Programs and again since 2012 we have again the Drug Programs. Despite the changes, the requirements for pharmacoeconomic analysis are still in place and have evolved over time. Within the Polish ISPOR Chapter there is Drug Programs, Pharmaceutical Care and Pharmaceutical Law section (DPPCPL) working on different projects [5]. Members of this Section in 2013 decided to perform a research on the impact of the adverse events treatment costs incurred by National Health Fund (NHF) and by the public payer. The project is ongoing and the aim of the project is to develop a list of costs associated to different disease areas of adverse events treatment to facilitate further analysis within HTA process making the results widely available in a publication.

Corresponding author
* Dermatology, Military Institute of Medicine, Warsaw, Poland
e-mail: monika.sz.debek@gmail.com

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METHODS

The project consists of different phases allowing for identification of AEs and data collection needed for final cost analysis.

The members of the Section agreed on the methodology and on the responsibilities for different project phases. Additional input from clinical experts is needed, so we invite clinical experts, specialists in the analysed disease area for cooperation, also those not being the members of the Polish ISPOR Chapter's DPPCPL Section.

The identified steps are as follows:

1. Review of drug programs financed by NHF, allowing for identification of the drugs used in the programs in Poland.
2. Identification of drugs used in the programs reimbursed by NHF in 2012.
3. Review of the published at EMA website SPCs of all identified drugs in the Drug Programs regarding the adverse events (AEs) occurrence.
4. Selection of the most common AEs based on the SPCs of the products. Only AEs described as very frequent (≥1/10) or frequent (≥1/100, <1/10) have been listed and selected for assessment of costs generated by the different resources used and therapy costs.
5. The separated AEs have been classified according to the anatomical systems.
6. Clinical guidelines search for treatment patterns recommended in Poland. The information from scientific guidelines will be compared to real life practice based on experts' opinion.
7. Excel tool preparation to collect and calculate the AEs costs in relation to treatment patterns provided by clinicians.
8. Data collection with 3–4 clinical experts' involvement (experts' opinion) in each of the fields of medicine. Clinical experts in alergology, pulmonology, dermatology, gastrology, internal diseases and hematology are employed in different medical institutions in Poland. They were asked to provide information about the treatment (products and resources used) based on a predefined questionnaire followed by phone or personal interview to clarify potential queries.
9. Cost data allocation (from public payer perspective). For reimbursed procedures and medical products by NHF during hospitalization the costing established by NHF was taken for calculation. For drugs used by the patients as treatment procedure or as continuation therapy in outpatient setting the cost generated for public payer was considered in addition to monitoring visits needed after hospitalization period.
10. Data analysis and preparation of final report and publication.

RESULTS

For the most common AEs selected based on the identified in the SPCs of Drug Programs therapeutic products, Polish clinical guidelines were searched for treatment recommendations. That information will be complemented by the experts' opinion in real practice. The experts' opinion will be collected using an MS Excel questionnaire. The collected data will be analysed and after the costs allocation and final calculation it will be described in a final report. Due to the number of Drug Programs and significant number of identified AEs, the final report will be presented with adverse events grouped by disease areas. That will allow for more comprehensive presentation. Some of the Programs include the same therapeutic products. That is why we analysed the Programs in groups guided by similar medicinal products used for the disease treatment. For instance because of that reson, we decided to analyse at the same time the Programs related to rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis and ankylosis (Fig. 1). During our work when analysing the first group of Programs we identified similarities regarding adverse events within the groups, i.e. due to the usage of the same therapeutic products the list of identified adverse events was similar (Fig. 2). As a result of the first analysis' phase we eliminated repetitions and then we grouped the adverse events related to the same area, e.g. adverse effects causing skin reactions are listed and the cost estimated for each single adverse event will be provided.

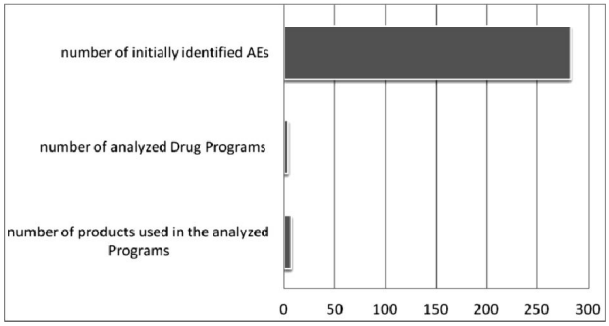

Fig. 1. Number of analyzed Drug Programs, Products and Adverse Events (phase 1 of the project)

As an example of how the results will be finally presented, we can use the mentioned above group of adverse events, which are manifested as skin reactions. The total cost of pharmacoterapy estimation for that AEs' group is from 1991.82 PLN to 6724.02 PLN. Among the skin reactions' treatment the highest cost corresponds to skin cancer with the exception of melanoma (including basal-squamous cell carcinoma) therapy and it equals 3283.18 PLN.

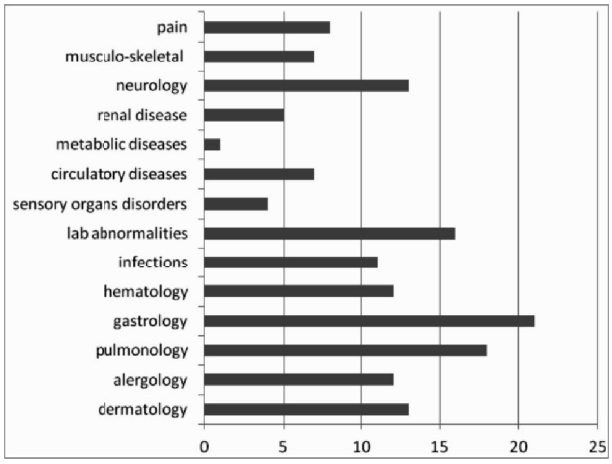

Fig. 2. Groups of Adverse Events identified during search of SPCs

DISCUSSION

HTA is a tool for evidence-based decision making. It combines both, scientific and economic data. The Task Force were convinced that there was a need for the AE costs' data and wanted to calculate it. However being aware of the challenge on how to implement it into practice, at the beginning of the project a discussion was initiated about the best methodology to be used. During the discussions, possible methods were explored but also the real chances to gather the data depending on the chosen methodology were assessed. In the literature there are different approaches presented, each one having positive and negative aspects. Our choice was the one we thought we could obtain data from real practice in a straightforward manner. We tried to minimize the risk of obtaining unrealistic estimations. The published treatment standards were checked and the collected experts' opinions were discussed and clarified during interviews with the experts. The number of interviewed experts was 3–4 in order to ensure a representative set of answers to the questionnaires. It is worth mentioning that e.g. EHTA working group recommends that the types of costs and the perspectives used in the analysis should be clearly stated in the report. It is due to different types of costs to be included into the analysis. Data on costs may be obtained from different sources; thus, the evidence used to calculate the costs must be stated and assessed for quality [2]. The Polish HTA guidelines from 2009 refer to two allowed options for resources and costs measuring.The measurement can be done either by collecting primary data within a properly designed research, or by collecting secondary data from existing databases.

Criteria such as research perspective, share of a given component in the total or incremental cost, data availability and a balance between internal and external reliability should be taken into account when making the decision regarding the final approach in methodology [1]. The Guidelines advice is to collect data on unit costs from a number of centres, which provide a given type of services taking into account reference centres in order to obtain a representative results.

The NIHR (National Institute for Health Research) and Pen CLAHRC (Collaboration for Leadership in Applied Health Research and Care for South West Peninsula) have undertaken a project dedicated to evaluation of methods of eliciting experts' opinion in HTA [4]. The author admits that despite available evidence from clinical trials, NHS databases there are still missing data to inform the HTA models. That is the reason why the clinical experts' opinion is widely accepted as a source for evidence, even if considered as potentially biased or uncertain in comparison to the scientific evidence [4].

CONCLUSIONS

We anticipate that the project will address an important issue related to the costs generated within the Drug Programs, being helpful for further calculations in pharmacoeconomic analysis.

REFERENCES

1. Agency for Health Technology Assessment: Guidelines for conducting Health Technology Assessment (HTA), Warsaw, April 2009. http://www.aotm.gov.pl/assets/files/wytyczne_hta/2009/Guidelines_HTA_eng_MS_29062009.pdf (access 18.10.2013).
2. Busse R., Orvain J. Velasco M. et al: Best practice in undertaking and reporting health technology assessments. *Intl. J. of Technology Assessment In Health Care*, 18:2, 2002, 361-422, http://www.inahta.org/upload/HTA_resources/AboutHTA_Best_Practice _in_Undertaking_and_ Reporting_HTAs.pdf (access 6.11.2013).
3. Guidelines for conducting Health Technology Assessment (HTA), version 2.1, April 2009; http://www.aotm.gov.pl/index.php?id=13 (access 26.09.2013).
4. National Institute for Health Research: An Evaluation of Methods of Eliciting Expert Opinion in Health Technology Assessment. http://clahrc-peninsula.nihr.ac.uk/an-evaluation-of-methods-of-eliciting-expert-opinion-in-health-technology-assessment.php (access 30.10.2013).
5. Note of the meetings the Polish ISPOR Chapter there is Drug Programs, Pharmaceutical Care and Pharmaceutical Law section http://www.farmakoekonomika.pl/cms/index.php/pl/ sekcja-programow-terapeutycznych-i-opieki-farmaceu tycz- nej (access 26.09.2013).
6. Rozporządzenie Ministra Zdrowia z dnia 2 kwietnia 2012 r. w sprawie minimalnych wymagań, jakie muszą spełniać analizy uwzględnione we wnioskach o objęcie refundacją i ustalenie urzędowej ceny zbytu oraz o podwyższenie urzędowej ceny zbytu leku, środka spożywczego specjalnego przeznaczenia żywieniowego, wyrobu medycznego, które nie mają odpowiednika refundowanego w danym wskazaniu. Dz.U.2012 nr 0, poz. 388.
7. Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych. Dz. U. 2004 nr 210, poz. 2135.