InterQuality

Work Package 3
Pharmaceutical care

Work Plan and Collaborative Work

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Work Plan

Task 3.1. **Comparative analysis of pharmaceutical benefit financing models**

**Objectives:** Identification and description of the pharmaceutical benefit financing models in selected countries: UK, US, Poland, Italy, France, Denmark.

**Methods:**
- Literature review on pharmaceutical benefit financing models in selected countries – published and grey literature.
- Comparative analysis of the systems based on the collected literature.
Work Plan

Task 3.2 – **Financing access to medicines**

**Objectives:** Evaluation of a different aspects of financing access to medicines and their consequences.

**Methods:**
- Case study on the role of different agents.
- Conjoint analysis- different stakeholders’ preferences
- Analysis and simulation of the utilization of medications as an effect of e-prescribing technology and adjudication of pharmacy claims
Task 3.1. – literature review

- Non-systematic review - limitations
- Databases
- Search strategy
- Type and Quality of publications
- Preliminary results
Databases

• **Main databases:**
  - Medline (PubMed);
  - Embase;
  - The Cochrane Library;

**Other bases/webpages:**
- Scopus
- EconLit
- Social Sciences Citation Index
- Research Papers in Economics
- OECD (*Organisation for Economic Co-operation and Development*);
- AHRQ (*Agency for Healthcare Research and Quality*);
- ISPOR (*International Society For Pharmacoeconomics and Outcomes Research*);
- CRD (*Centre for Reviews and Dissemination*);
- WHO (*World Health Organisation*);
- NHS (*National Health Service*);
- NICE (*National Institute for Health and Clinical Excellence*);
- INAHTA (*International Network of Agencies for Health Technology Assessment*);
- HTAi (*Health Technology Assessment international*);
- ISQUA (*The International Society for Quality in Health Care*);
### Search strategy - concept

#### OR
- Key words for **statins** and generics
- Key words for **innovative drugs**
- Key words for E-Health
- Transparency
- Access
- Accessibility
- Affordability
- Key words for personalised medicine
- Germany
- Italy
- "United Kingdom"
- UK
- "United States"
- US
- Poland
- Denmark

#### OR
- Time limit: last 10 years
- Randomised
- Randomized
- "double-blind"
- "cross-over"
- Crossover

#### NOT

#### AND
Search strategy Pubmed

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Pubmed - results

Medline
11 494

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xxx

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xxx

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References/other sources
xxx

Finally included
xxx
Types of publications (quality of evidence)

• Analysis (e.g. economic)
• Case-studies
• Registries, data bases
• Reviews
• Descriptive publications
Critical appraisal

Critical appraisal of such articles should base on three main aspects:

• **Consistency** – the extent to which diverse approaches, such as different study designs or populations, for studying a relationship or link between a factor and an outcome will yield similar conclusions

• **Coherence** – whether the cause-and-effect conclusions conflict with what is known of the reality

• **Strength** – the size of estimated effect

Each of these category may be assessed as high, moderate or low
Propositions of Collaborative Work (CW) for WP3

• Pharmaceutical Care & E-Health
• Innovative drugs
• Conflict of interests
• Off-label and issues with registration
• Statins
• Pharmacovigilance
• Personalised medicine
CW – Pharmaceutical Care

• Comparative analysis of pharmaceutical care with elements of E-Health in Poland and Denmark (Denmark Partner?)
• Policies to control pharmaceutical expenditures
• Issues concerning the Danish health system related to pharmaceuticals
Danish Health System

As far as we know…the reimbursement rate depends on the patient’s accumulated pharmaceutical expenses during 12 months. Expenses thresholds are adjusted every year.

Questions:
• Ex post control of pharmacies
• Instituting a national budget cap for the health sector
• Collecting data for thresholds for every year
• Central register
E-health in Poland

*Centre of IT systems for healthcare:*

- started in 2000
- coordinate the information technology introduction to public healthcare system in Poland
- financed by national budget and EU structural founds
E-health in Poland

The information system in healthcare will include (according to Information System in Healthcare Act):

- electronic databases that contains information about provided and planned health services
- electronic patient records
- health insurance cards
- e-prescribing
- electronic patient registration in healthcare facilities
- system of healthcare statistics
- system of access to health service monitoring
E-health in Poland

Currently:

• electronic system under development
• inspections because of tenders irregularities
Do you think there is data to do such analysis in your country?

- Independent / chain pharmacies’ profitability
- Controlling pharmacies profitability
- Components of pharmacy profit
- Regulated profit margins
- Rebates paid to pharmacies
In order to increase the cost-effectiveness of targeted cancer therapies, patients should be carefully selected based on the application of diagnostic tests to exclude non-responsive patients.

• Has the selection become a standard practice?
• Who is responsible for the financing of diagnostic tests? (public payers or pharmaceutical companies?)
• Do you think that reimbursement scheme for IVD is appropriate in your country? (in vitro diagnostic (IVD) market)
• What type of pricing is more popular in your country (in the field of IVD)
  – Value-based pricing?
  – Cost-based pricing?
"My physician prescribed a customized formulation for me. Here's my DNA sequence."
In general, HTA procedures are not adjusted to the IVD market needs. Moreover, nearly all work is done by test manufacturers, who have to submit all appropriate diagnostic evidences to budget holders.

- What does the situation look like in your country?
- Are risk-sharing/cost-sharing agreements applied in the field of personalized medicine?
Off-label indication in taking reimbursement decisions

The scope of collaborative work on presentation of the issue of „off-label indication in taking reimbursement decisions”. Proposed design of the questionnaire – continuation:

• Please explain, whether in your country are taken into account off-label indication in taking reimbursement decisions?

• If yes, please explain, which kind of off-label Indications are reimbursed in your country:
  – the use of innovative drugs beyond the indications listed in SPC,
  – the use of drugs (for which the originators have lost the right to exclusive) in indications and doses recommended by medical associations (eg ARA, EULAR), but beyond the indications listed in SPC,
  – the use of drugs in indications listed in SPC, but beyond the doses listed in SPC,
  – whether is allowed in your country reimbursement of experimental use of drugs?
CW – Innovative drugs

- Value based pricing approach (UK)

- PPRS – framework for determining reasonable limits to the profits

- ROC can be 21% annually

- New price of drug can increase no more than that required for the company to achieve 65% of the ROC target

- A margin of tolerance up to 140% of the ROC target.
The sources of the information about the profits of pharmaceutical companies, obtained in making reimbursement decisions.

The scope of collaborative work on presentation of the issue „the sources of the information about the profits of pharmaceutical companies, obtained in making reimbursement decisions”. Proposed design of the questionnaire:

• Which sources about the information concerning profits of pharmaceutical companies, are taking into consideration in making reimbursement decisions in your country?
• whether do you use the annual reports published by pharmaceutical companies?
• Which financial data contained in the information obtained about the profits of pharmaceutical companies are taken into consideration when making reimbursement decisions in your country?
Transparency and the issue of conflict of interest in the process of reimbursement of drugs

The aim of this presentation is to focus on the issue of transparency and conflict of interest potentially occurring in national processes of reimbursement of drugs.

• In Poland the issue of transparency and conflict of interest potentially occurring in the national system of reimbursement of drugs is nowadays specially important because of currently being implemented the reform of the drug reimbursement system and also because of press releases about this issue.

• In 2011 was published by Cambridge University Press a report* on this issue, which has analyzed the issue in detail.

Transparency and the issue of conflict of interest in the process of reimbursement of drugs

The scope of collaborative work on presentation of the issue of conflict of interest in the process of reimbursement of drugs. Proposed design of the questionnaire - continuation:

• Please explain, if in your country there are cases of informal methods of lobbying for obtaining of reimbursement of drugs:
  – through opinion leaders
  – through patients' organizations
  – through media
  – through parliamentarians
  – through diplomatic services of foreign countries, e.g. USA
Transparency and the issue of conflict of interest in the process of reimbursement of drugs

Diplomatic services of foreign countries, e.g. USA

The scope of collaborative work on presentation of the issue of conflict of interest in the process of reimbursement of drugs. Proposed design of the questionnaire:

• Please explain, if in your country are allowed informal contacts between pharmaceutical companies and employees of the Ministry of Health, employees of the NHS or employees of governmental HTA agencies.

• Does your country have noticed a link between low pay for employees of the Ministry of Health, employees of the NHS or employees of governmental HTA agencies, and prone to corruption?

• Does in your country the amount of remuneration for employees of the Ministry of Health, employees of the NHS or employees of governmental agencies HTA is comparable to the salaries of employees of pharmaceutical companies?
Who considers expanding of this example analysis on your countries interesting and contributive?


- Authors investigate how health care systems of Germany and UK responded to availability of simvastatin generics (a cholesterol lowering drug)

- In Germany, generic simvastatin reduced sales volume for both branded simvastatin and atorvastatin, while in UK, only the sales of branded simvastatin fell

- They concluded, that prescribing behaviour was the reason for this difference:
  
  - In Germany, physicians are effective agents for their patients because of the impact of drug choice on copays
  
  - In UK, flat copayment causes that prices are not transmitted to patients and physicians.
Is a use of such example for comparative analysis appropriate? Can we expand it to your countries? Who is interested?


- Authors investigate how health care systems of Germany and UK responded to availability of simvastatin generics (a cholesterol lowering drug)

- In Germany, generic simvastatin reduced sales volume for both branded simvastatin and atorvastatin, while in UK, only the sales of branded simvastatin fell.
Thank You for Your attention!