PICOSTEPS, Digitalization and Real-World Modelling: Communicating Complex Cases to the Decision Makers

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Evidence-based medicine (EBM) & evidence-based health economics and outcomes research (EBHEOR):
Approaches intended to optimize decision-making with evidence based on well-conducted research.

EBHEOR utilizes EBM.

Real-world evidence = modelled evidence.
PICO has important role in EBM

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<th>P</th>
<th>I</th>
<th>C</th>
<th>O</th>
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<td>Patients / population</td>
<td>Intervention</td>
<td>Comparator(s)</td>
<td>Outcomes</td>
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PICO: EBM framework for systematic reviews, meta-analyses and clinical care guidelines, e.g. Finnish national Current Care Criteria, CCC

CCC treatment guideline work for psoriasis was supplemented with review and assessment of published HE evaluations of biologic psoriatic arthritis treatments, and included PICOSTEPS (http://www.kaypahoito.fi/web/kh/suositukserset/suositus?id=nix02465&suositusid=hoi50062)
PICOSTEPS:
Convenient framework for communicating evidence-based health economics and outcomes research (EBHEOR) to different decision makers
**P I C O S T E P S**

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<th><strong>Examples: Health economics and outcomes research (HEOR)</strong></th>
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<td><strong>Sensitivity</strong></td>
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Summation: PICOSTEPS

- reports HEOR in a framework familiar and relevant to clinicians,
- suits in the assessment phases of EBHEOR (e.g. reviews, guidelines), and
- demonstrates if the minimum information of EBHEOR has been reported.

Is

- patient-oriented,
- simple,
- successfully applied to HEOR publications and
- crucial information.

PICO is used for e.g. the national CCC.
Guideline example: Assessment of health economic evaluations
How to? E.g. CCC guideline

1. **Systematic literature review** (SLR): Published full HE evaluation articles or reports available in Medline or Cochrane (http://www.terveysportti.fi/xmedia/nix/nix02465liitteet.pdf)

2. **Finnish applicability evaluation** (FAE): Sequential assessment / rating based on e.g.
   a) Pharmaceuticals Pricing Board guidelines,
   b) Consolidated Health Economic Evaluation Reporting Standards (CHEERS) and
   c) two earlier criteria (http://www.kaypahoito.fi/web/kh/suositukset/suositus?id=nix02465&suositusid=hoi50062)

3. **Level of evidence evaluation** (LoEE): Strong, moderate, minor/weak or no evidence (http://www.kaypahoito.fi/web/kh/suositukset/suositus?id=nix02465&suositusid=hoi50062)

PICOSTEPS framework can be applied in all phases of EBHEOR assessments
Digitalization example: Possibility for net benefit gains
The Virtual hospital 2.0 is a joint project between the university hospitals in Finland. The participants in the project include the Helsinki and Uusimaa Hospital District (HUS), which coordinates the project, and the Pirkanmaa Hospital District, the Northern Ostrobothnia Hospital District, the Hospital District of Northern Savo and the Hospital District of Southwest Finland. The project has received funding from the Ministry of Social Affairs and Health.

Further information: virtuaalisairaala2.fi
Digitalization: Cost-benefit analysis

Soini E, Vääätäinen S, Arvonen S. Predicted cost-benefit of Virtual Hospital 2.0 in terms of health care capacity freed: Towards potential economic efficiency with digitalization and customer-responsive secondary care services. WHO International Healthy Cities Conference, 1-4 October 2018, Belfast, Northern Ireland
PICOSTEPS for the cost-benefit analysis of digitalization

### ANALYSIS

#### Dynamic cost-benefit modelling of population structures, morbidity, resource use and costs for years 2017-2021

<table>
<thead>
<tr>
<th>Patients</th>
<th>All individuals who are expected to use specialized care services in 1) the hospital district of Helsinki and Uusimaa (HUS) and 2) Finland generally.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>The VH2.0 - a complete operational change with client-oriented digital specialist care practices.</td>
</tr>
<tr>
<td>Comparator</td>
<td>Modeled expected current practice based on population and morbidity information from HUS and national Finnish statistics real-world data.</td>
</tr>
<tr>
<td>Outcome</td>
<td>Predicted potential healthcare capacity freed (PPHCDF) represents the 2016 monetary value available for other uses within the health care system, allowed by digitalization and operational changes within the VH2.0.</td>
</tr>
<tr>
<td>Setting</td>
<td>Dynamic cost-benefit modelling (DCBM) covering the predicted changes in the patient cohorts based on the population structures and morbidity. DCBM measured the impacts in monetary terms.</td>
</tr>
<tr>
<td>Time</td>
<td>From year 2017 to 2021 in annual cycles; assuming VH2.0 had been implemented in the beginning of year 2017. No discounting of outcomes was done.</td>
</tr>
<tr>
<td>Effects</td>
<td>Expected over-time changes in population structure and morbidity, resource use (visits, letters, calls, e-appointments, e-messages, travelling) and unit costs based on the available sources and expert information (Figures 1 and 2).</td>
</tr>
<tr>
<td>Perspective</td>
<td>Primarily the third-party payer at producer (HUS) and at national Finnish level. Thus, only direct costs were considered. To supplement the primary analysis of direct cost, PPHCCF, the overall significance of the potential societal productivity cost savings was estimated in a secondary scenario.</td>
</tr>
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| Sensitivity | Two scenarios where the full VH2.0 application, implementation and cost benefits were achieved within 1) two or 2) five years instead of the four years used in the most probable case scenario.

Soini E, Väätäinen S, Arvonen S. Predicted cost-benefit of Virtual Hospital 2.0 in terms of health care capacity freed: Towards potential economic efficiency with digitalization and customer-responsive secondary care services. WHO International Healthy Cities Conference, 1-4 October 2018, Belfast, Northern Ireland
Net benefit of digitalization

At the Finnish level, average predicted annual PPHCCF with VH2.0 was around €261 million for first five years, reaching approximately €316 million in 2021, and summing up to approximately €1.3 Billion during the first five years.

Predicted potential health care capacity freed with VH2.0 was substantial and the importance of its value drivers differed

KEY MESSAGE

eHealth services such as VH2.0 can be a viable solution to sustain needed services and to target other interventions

Soini E, Vääätäinen S, Arvonen S. Predicted cost-benefit of Virtual Hospital 2.0 in terms of health care capacity freed: Towards potential economic efficiency with digitalization and customer-responsive secondary care services. WHO International Healthy Cities Conference, 1-4 October 2018, Belfast, Northern Ireland
Real-world modelling (RWM) examples:
Reporting complex data in comprehensible format
To evaluate the cost-effectiveness of first-line treatments of relapsing-remitting multiple sclerosis (RRMS) in Finland.

Table 1. PICOSTEPS: Summary of the research questions.

<table>
<thead>
<tr>
<th>PICOSTEPS</th>
<th>Description</th>
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<tbody>
<tr>
<td>P: Patients</td>
<td>Finnish adults with incident RRMS and EDSS scores 0.0-6.5 at baseline based on data from a Finnish MS registry.</td>
</tr>
<tr>
<td>I: Interventions</td>
<td>DMTs: DMF 240 mg PO BiD, teriflunomide 14 mg once daily, GA 20 mg SC once daily, IFN-β1a 44 µg SC TIW, IFN-β1b 250 µg SC EOD, IFN-β1a 30 µg IM QW.</td>
</tr>
<tr>
<td>C: Comparator</td>
<td>Common comparator: BSC (trial placebo).</td>
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<tr>
<td>O: Outcomes</td>
<td>Primary: ICER given as the cost/QALY gained based on the direct cost. Secondary: disaggregated and total QALYs (based on EQ-SD-3L) and costs, life-years, years without impaired mobility (EDSS &lt; 6; ie, years without cane use), cost-effectiveness and efficiency frontiers, cost-effectiveness acceptability frontiers, Bayesian treatment ranking, and cost-benefit assessment. Discounting: 3%/y.</td>
</tr>
<tr>
<td>S: Setting</td>
<td>Probabilistic decision analytical modeling (Markov cohort model), including 21 health states reflecting the disease progression (modified by treatment efficacy); and events reflecting relapses, AEs, and withdrawals.</td>
</tr>
<tr>
<td>T: Time horizon</td>
<td>15 years, based on the follow-up data from the Finnish registry, time since diagnosis in a Finnish cost and EQ-SD-3L MS study, years covered by the British Columbia, Canada, registry, and approximate time from RRMS to SPMS in the London Ontario MS registry database. For the London Ontario MS registry origins, see Weinshenker et al.</td>
</tr>
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</table>

P: Perspective | Finnish payer perspective. A scenario analysis with a societal perspective. |

AE = adverse event; BSC = best supportive care; DMT = disease-modifying therapy; EDSS = Expanded Disability Status Scale; EQ-SD-3L = EuroQol Five-Dimensional Questionnaire; Three-Level Version; GA = glatiramer acetate; ICER = incremental cost-effectiveness ratio; IFN = interferon; MS = multiple sclerosis; QALY = quality-adjusted life-year; RRMS = relapsing-remitting multiple sclerosis; SPMS = secondary progressive multiple sclerosis.

https://www.clinicaltherapeutics.com/article/S0149-2918(17)30074-7/pdf
Health Impact Modelling (HIM) to convert company turnover into health benefits

OBJECTIVES

Health impact modelling (HIM) tool: define concept, assess feasibility, describe real-world data (RWD) needs and estimate the effectiveness of Pfizer’s drug portfolio over time in Finland

Soini E, Hallinen T, Laine J. Health impact modelling (HIM): Concept, approach and real-world data needs for the estimation of potential effectiveness provided by a pharma company portfolio. Value Health 2018
PICOSTEPS for Health Impact Modelling (HIM)

DATA
Nationally representative quarterly RWD covering all Finns, over 2300 indication-intervention pairs. Modelled dynamically using 64 groups of health-related quality of life (HRQoL) beneficiaries.

Soini E, Hallinen T, Laine J. Health impact modelling (HIM): Concept, approach and real-world data needs for the estimation of potential effectiveness provided by a pharma company portfolio. Value Health 2018
Health impact modelling (HIM)

**KNOWLEDGE GAINED**

Novel HIM tool estimates patients treated, potential quality-adjusted life years gained and turns company’s turnover to health benefits. HIM’s feasibility relies on the indication-intervention portfolio, persistence and HRQoL data.

**CONCLUSIONS**

HIM tool can quantify the potential effectiveness gained from treatments or for indications. HIM highlights treatments most potential to lead to most influential health impacts and estimates the health needs or treatment impacts for political or business decisions.
What is good EBHEOR for communication?

- *Population* first! E.g. PICOSTEPS
- *Purpose* decided (leadership, management, statistics, research)
- *Objective* set
- *Level of evidence* sufficient for purpose
- *Applicability* sufficient for the decision context
- *Outcomes* suitable for purpose

⇒ *Fit for purpose & easy to understand* (a paradox?)
⇒ PICOSTEPS is fit and makes it easier to understand