NIPH
Norwegian Institute of Public Health

HTA adaptation and evidence transferability

The findings from a recent scoping review and an example from Palestine

1 November 2022

Lieke Heupink – LFHE@fhi.no

Background

- Lieke Heupink, Health Economist at NIPH
- Support to HTA institutionalization in Ghana
  - Institutional collaboration in Ghana since 2015
- Program ‘Building Stronger Public Health Institutions and Systems’

Norad

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Objectives

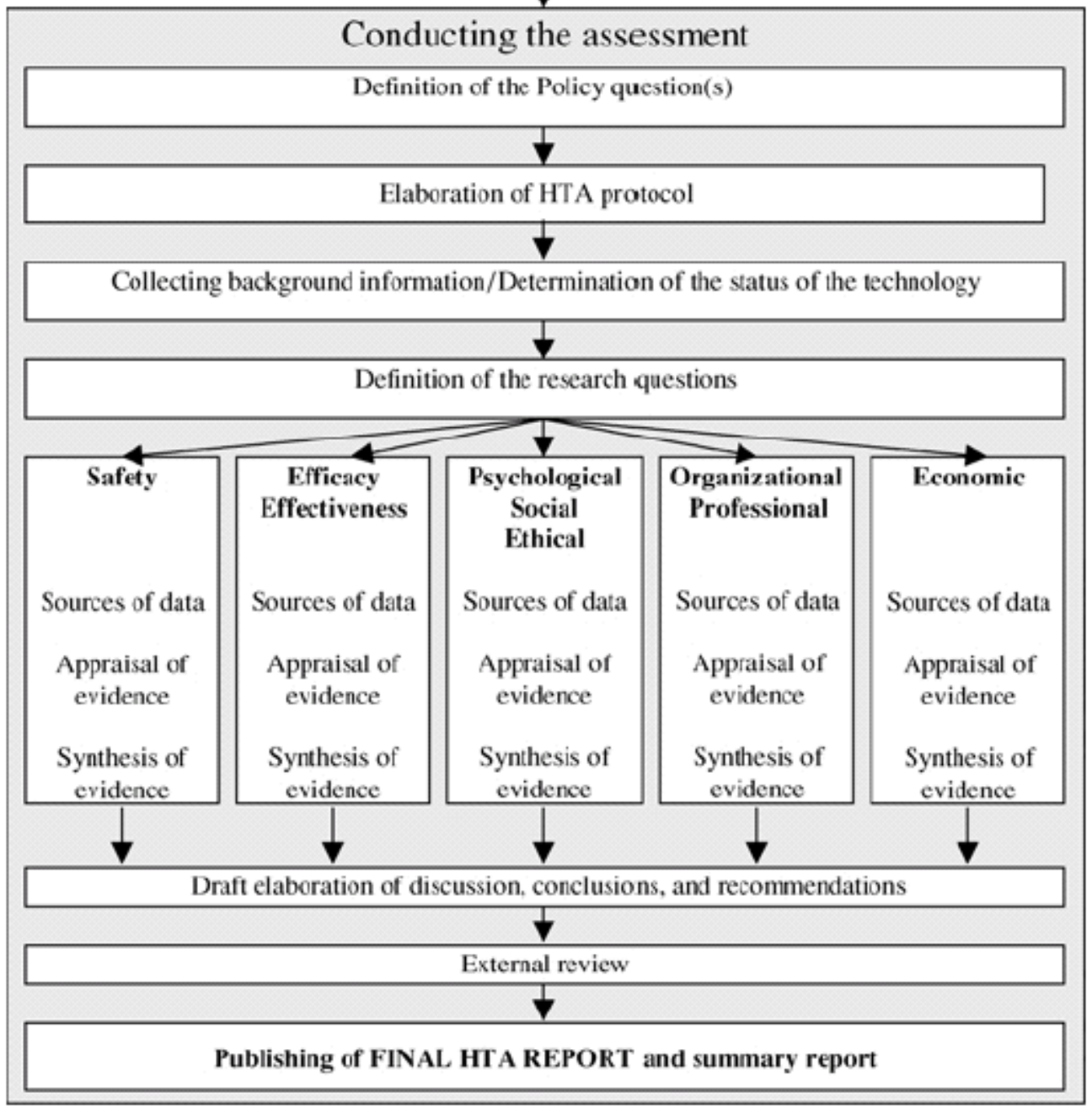
- Recap – Defining HTA

- What are the tools available to transfer HTAs?
- Experience of adapting evidence to produce a Health Technology Assessment of mammography screening for the Palestinian West Bank

HTA defined

Recap – What is health technology assessment

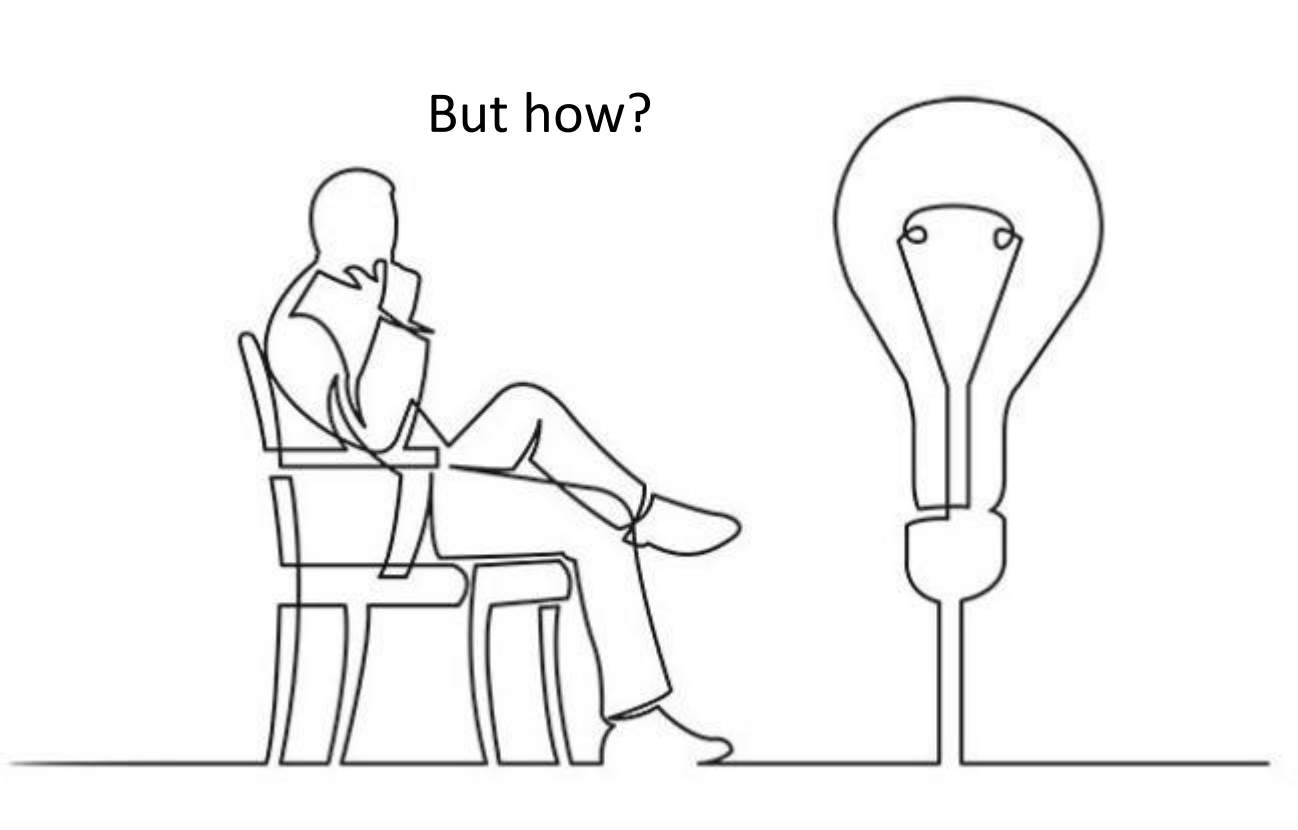
- "A multidisciplinary process that uses explicit methods to **determine the value of a health technology*** at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system." (INAHTA, 2020)



International Journal of Technology Assessment in Health Care, 18:2 (2002), 361–422.

Why transfering HTAs?

- Producing HTAs requires time and resources
- Decision makers often need information **fast**!
- Solution: re-using relevant and high-quality HTAs, because:
  - Increase speed of HTA production
  - Reduce duplication



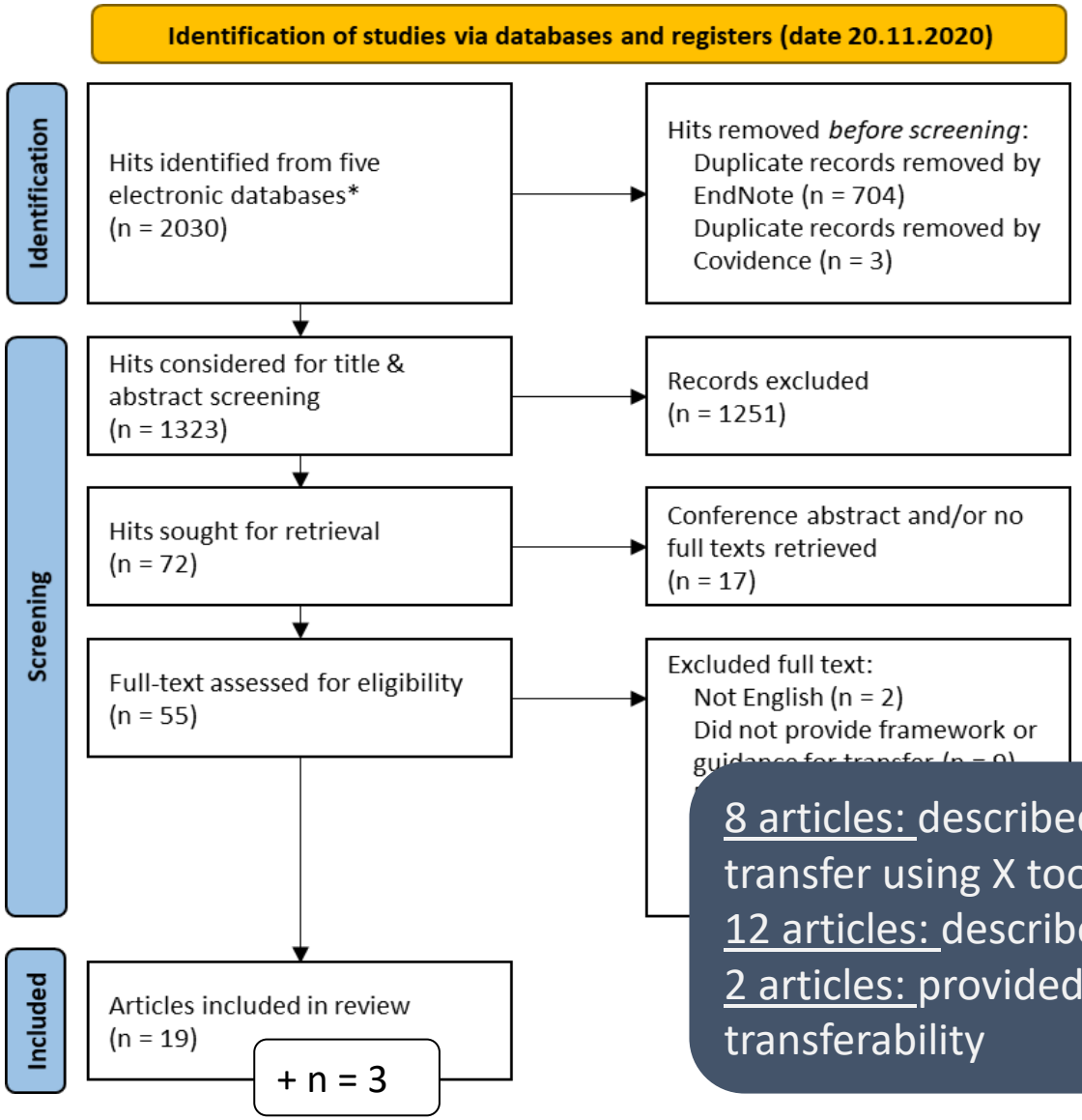
Scoping review

Tools That Can Aid Adaptive HTA To Ensure Rapid, Efficient, And Pragmatic Priority Setting: A Scoping Review *By Heupink, Peacocke, Sæaterdal, Chola*

- Research questions:
  - What methods, including approaches, checklists, or tools, are available for the adaptation and adoption of HTAs?;
  - What factors of these methods aid or hinder the process of integrating an existing HTA in a new context?;
  - Are there any methodological gaps associated with these methods, specifically for LMICs?

- Methods
  - Systematically search the literature
  - Eligible articles: introducing and describing a transferability tool *and/or* describing experience of using a transferability tool
  - Map the extracted data and synthesize

Inclusion



8 articles: described experience conducting HTA transfer using X tool
12 articles: described transferability tools
2 articles: provided an overview of tools aiding transferability

Findings I: A common structure for an HTA transfer process

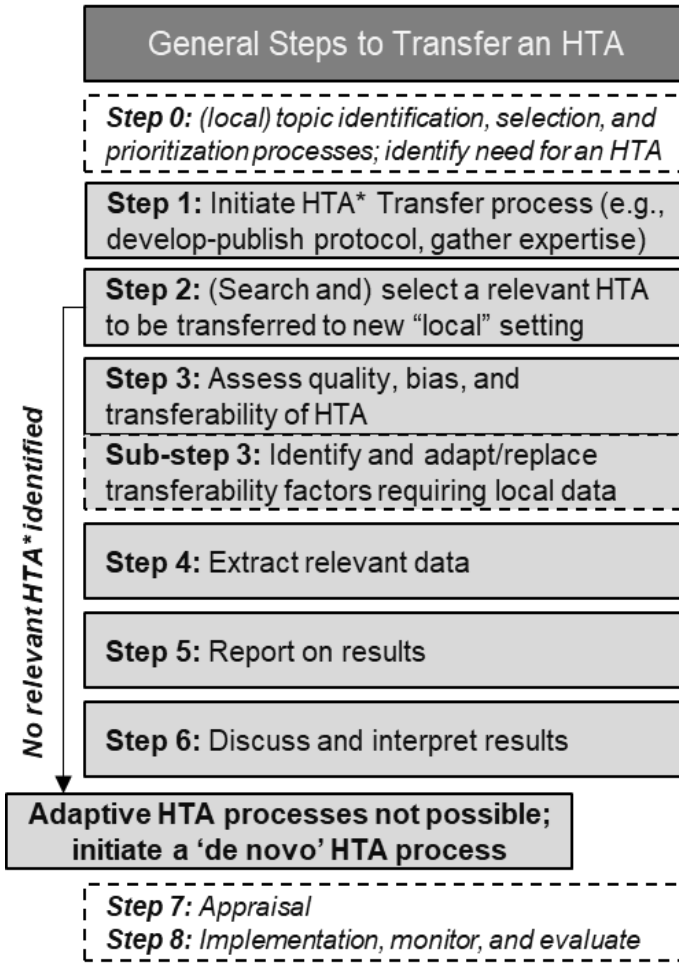


Table 2 – Checklist to frame HTAs to the decision problem.

Factor	Question
1. Objective	How will the HTA be used? (e.g., contribute to evidence, inform adoption decision)
2. Audience	What is the audience (principal users) for the HTA? (e.g., government, pharmaceutical companies, insurance companies, patient groups, jurisdiction)
3. Perspective	Which viewpoint or perspective is relevant for the HTA? (e.g., societal, health care, insurer, payer)
4. Population	What is the patient population relevant for the decision problem? (e.g., age, health status, sex, other characteristics)
5. Comparators	What are relevant comparators for the decision problem? (e.g., care as usual, alternative technologies)
6. Clinical practice	How are the technologies embedded in clinical practice? (e.g., diagnostics, clinical instead of research protocol)
7. Time horizon	Which time horizon is relevant for the decision problem? (e.g., lifetime, one year)
8. Consequences	Which consequences are relevant for the decision problem? (e.g., final versus intermediate outcomes, indirect and/or rare consequences)
9. Patient use	What is the patient use that is relevant for the decision problem? (e.g., uptake, compliance, adherence)
10. Professional use	What is the use of the technology by health care professionals that is relevant for the decision problem? (e.g., skills, experience, beliefs)
11. Price and resource use	What price level and resource use are relevant for the decision problem? (e.g., personnel providing the intervention)

Grutters checklist

Grutters, J. P., Seferina, S. C., Tjan-Heijnen, V. C., van Kampen, R. J., Goettsch, W. G., & Joore, M. A. (2011). Bridging trial and decision: a checklist to frame health technology assessments for resource allocation decisions. Value in Health, 14(5), 777-784.

Findings II: Transferability tools that can guide transfer of HTA

- Covering guidance

Multiple HTA domains
EUnetHTA Adaptation toolkit
MAST (adapted EUnetHTA for telemedicine)

Country specific checklist(s) from HTA agencies
(e.g., SBÜ)

Clinical effectiveness (systematic reviews)
TRANSFER approach

Economic evaluations
Systematic review of Economic Evaluations

- Catalyst for transfers 'of economic evaluations'

Economic evaluations
Mullin checklist
Boulenger checklist
Welte checklist
Drummond ISPOR checklist
Drummond checklist
Augustovski checklist
Urdahl checklist
Antonanzas transferability index
Heylands generalizability criteria
Späth's transferability indicators

Grade 'conceptual' approach (for underlying models)

Zooming in to transfering economic evaluations

- Two options:
  - Systematic review (evidence synthesis) of published economic evaluations
    - Advantages: Relatively easy to do
    - Disadvantages: Availability of relevant information, transferability

EXPERT REVIEW OF PHARMACOECONOMICS & OUTCOMES RESEARCH, 2016
VOL. 16, NO. 6, 689–704
http://dx.doi.org/10.1080/14737167.2016.1246960

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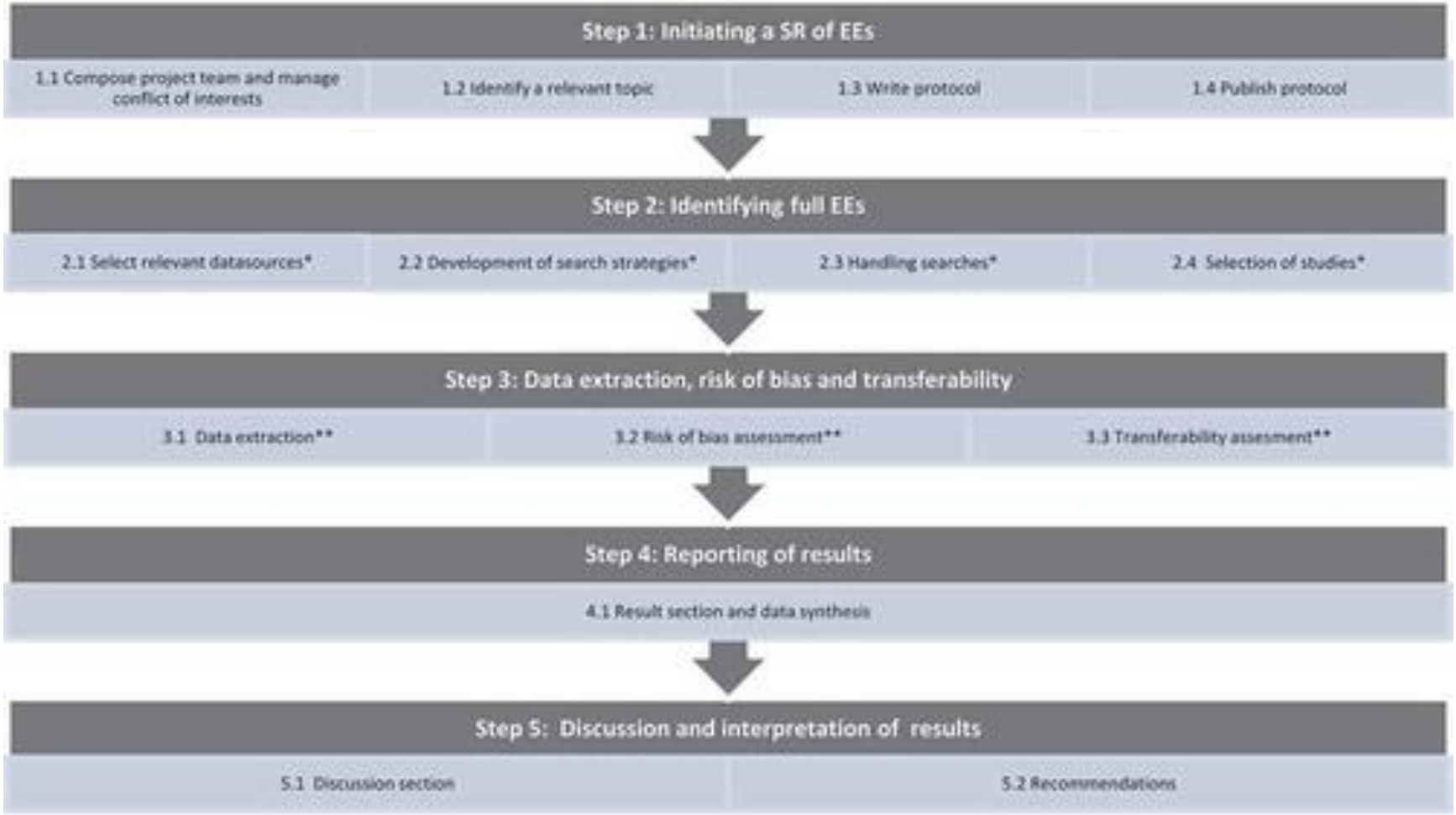
REVIEW

OPEN ACCESS

How to prepare a systematic review of economic evaluations for informing evidence-based healthcare decisions: a five-step approach (part 1/3)

Ghislaine A.P.G. van Mastrigt [a], Mickaël Hiligsmann [a], Jacobus J.C. Arts [b], Pieter H. Broos [c], Jos Kleijnen [d], Silvia M. A.A. Evers [a,e] and Marian H.J.M. Majoie [f,g,h,i]

Zooming in to transfering economic evaluations



Zooming in to transfering economic evaluations

- Two options:
  - Systematic review (evidence synthesis) of published economic evaluations
  - Adapting an existing economic evaluation
    - Advantages: Possible to adjust existing evidence to national context, incorporate best available evidence on individual aspects
    - Disadvantages: Can be complex, data for certain aspects are likely unavailable

Zooming in to transfering economic evaluations

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Cost-Effectiveness of Docetaxel and Paclitaxel for Adjuvant Treatment of Early Breast Cancer: Adaptation of a Model-Based Economic Evaluation From the United Kingdom to South Africa

Abualbishr Alshreef BPharm, MPH, MSc [1], Kim MacQuilkan MPH [2], Bryony Dawkins MSc [3], Jane Riddin BPharm, PharmD [4], Sue Ward BA [1], David Meads PhD [3], Matthew Taylor PhD [5], Simon Dixon PhD [1], Anthony J. Culyer DEcon [6], Francis Ruiz MSc [7], Kalipso Chalkidou PhD [7,8], Ijeoma Edoka PhD [2]

Methods

A cost-utility analysis was undertaken based on a UK 6-health-state Markov model adapted for South Africa using the Mullins checklist. The analysis assumed a 35-year time horizon. The model was populated with clinical effectiveness data (hazard ratios, recurrence rates, and adverse events) using direct comparisons from clinical trials. Resource use patterns and unit costs for estimating cost parameters (drugs, diagnostics, consumables, personnel) were obtained from South Africa. Uncertainty was assessed using probabilistic and deterministic sensitivity analyses.

Parameter	Value	Distribution	Updated/replaced with data from South Africa (N/Y)
General parameters			
Time horizon	35 years	NA	N
Cycle length	1 year	NA	N
Start age	50 years	NA	N
Discount rate (QALYs)	5%	NA	Y
Discount rate (costs)	5%	NA	Y
HRs			
DAC vs FAC (based on BCIRG 001)	0.71 (95% CI: 0.58-0.87)	Log-normal	N
ACP vs AC (based on NSABP B28)	0.82 (95% CI: 0.72-0.94)	Log-normal	N
ACP vs AC (based on CALGB 9344)	0.83 (95% CI: 0.73-	Log-normal	N

Mullins Checklist

No.	Recommendation	Implementation	Yes	No
1	Conduct good research practice for Pharmacoeconomic studies	The original model should be vetted for structure and scientific integrity.		
2	Use recommended economic appraisal guidelines and required reporting and appraisal standards	Refer to recommended economic appraisal guidelines. If no such guidance exists, consider recruiting a local expert and/or key opinion leader from the region to assure credibility and applicability.		
3	Determine perspective of economic appraisal	In the absence of specific guidance from local decision maker, use both the societal perspective and a narrow focus on direct medical costs only. If desirable, include intermediate perspective.		
4	Select available treatment options (comparators)	Use current practice or the most widely used therapy/therapies in the jurisdiction of interest.		
5	Consider the source of cost data	If cost data from the specific country is not available, apply a standard cost per procedure.		
6	Identify and quantify resource use and costs	Include relevant direct and indirect costs associated with the treatment. An activity-based costing method can generate a more accurate product costs.		
7	Consider clinical practice patterns and guidelines	When using decision analytic modeling, incorporate clinical practice patterns/guidelines of the intended country/jurisdiction of interest.		
8	Use country/region specific epidemiologic data	If country/region specific epidemiologic data are not available, use random-effect meta-analysis models and transition probabilities where necessary.		
9	Explain and justify use of estimated treatment effect	Use the average treatment effect from a multinational trial. Conduct a sensitivity analysis using treatment effect based upon patients from the specific country or region.		
10	Use health state preferences/utilities that are applicable to the region	Use local health state preferences and utilities whenever they are available; Use the average of published ones if local utilities are not available. If a revalidation is required/desired, include forward translation, back translation, and pretesting of the instrument.		
11	Utilize expert opinion sparingly and appropriately	Expert opinion represents lower levels of evidence. Whenever expert opinion is used, multiple experts should be involved. Use the Delphi method for consensus.		
12	Use modeling to address nontransferable elements	For data elements that are nontransferable, the model structure, data used as inputs to models, and model validation are important when assessing the quality of models. See http://www.ispor.org/taskforces/GRPModelingTf.asp for more information.		
13	Utilize quality-adjusted life years(QALYs)	Determine threshold to enable transfer and applicability of QALYs across jurisdictions unless local guidelines recommend a different metric or approach.		
14	Determine and justify discount rate	Use local guidance for discount rate. If none exist, use a "real riskless" discount rate of 3% and conduct sensitivity analysis.		
15	Source and justification of each data element in PE model	To reflect an evidence-based approach to PE modeling, systematic reviews of the literature should be conducted.		
16	Translate findings for the desired perspective	The perspective, the recommendations concerning evaluation of resource use/costs, the choice of the comparator, and the valuation of costs should be considered before considering the transferability and reproducibility.		

Mullins Checklist

- Of note:
  1. Before applying checklist, EE has to satisfy minimum requirements (local data, fit quality standards, etc.)
  2. Use senstivity analysis
  3. Transferability is a ‘spectrum’
  4. If affordability is the main concern, a budget impact analysis is preferred

Finding III: Overview of transferability issues to consider

Lack of access to original studies or models

- Language restrictions
- No (PRISMA) guidance for searches for economic evaluations
- Models not published

Poor quality of HTAs, underlying studies, and models

- Poor primary or secondary data
- Non-comprehensive reporting
- No validation of models

Lack of local data limits possibility to adapt existing HTAs

- Input (effectiveness and/or cost) for economic evaluation is not available in local context → sensitivity analysis / stakeholders
- "Cost-data should always be local", but can be hard to estimate depending on the complexity of intervention

HTA requirements in the local setting

- Non-standardized local requirements from HTA agencies → need for reference cases specific to disease or country
- Standard practice or context of the problem is not the same between settings
- No consensus on 'essential' transferability factors

Important notes

- Aim of this scoping review was to find tools for ‘transferability’
  - Transferability is NOT the same as quality, but quality is an important prerequisite

- There is no consensus on how to transfer an HTA

- ***‘Check your checklist’***
  - Why are you using a checklist…
    - Comprehensive reporting = CHEERS (economic evaluation)
    - Applicability = Grutters checklist
    - Quality = AMSTAR II (systematic reviews)
    - Transferability = EUnetHTA adaptation toolkit

- Transferability of existing HTAs is only one approach in a larger toolbox of adaptive HTA

In summary…

from the scoping review, we learned:

- There are lots of tools and checklist to assess *'generalizability'* (more scientific effort) or *'transferability'* (more practical effort with purpose to adopt or adapt findings)

- Pre-requisite for transfers
  - 1) ability to identify a relevant HTA
  - 2) ability to access the (underlying) reports

- No tool covered all HTA domains
  - Transferability tools for 'non-transferable domains' - Ethics, Organizational, Legal, and Social (ESLO) - were not available
  - EUnetHTA most complete transferability tool

- Existing tools provide limited practical guidance for <u>when to use what</u> tool in HTA transfers (specifically for LMICs)

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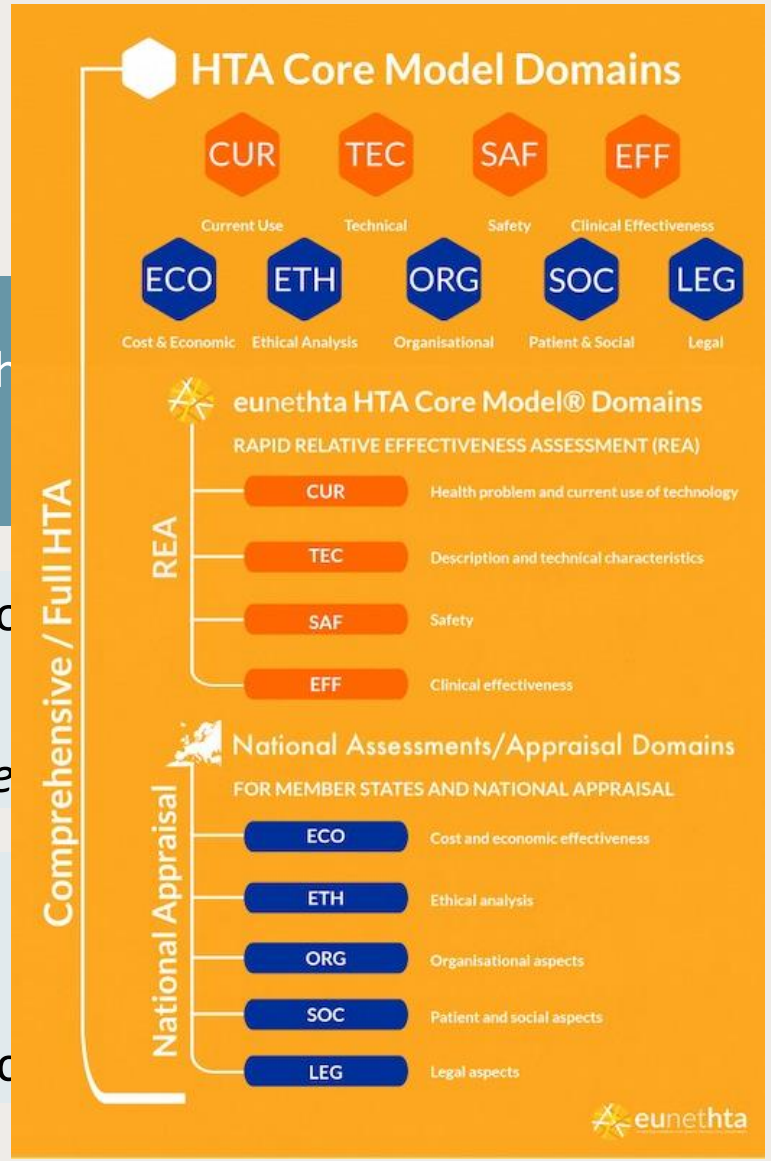
Part 2 – experience of transfering an HTA in the west bank

a collaboration between PNIPH and NIPH

Purpose of the project

Objective	• To test the **feasibility** of conducting health analysis in the West Bank
HTA Transfer	• Given time and available resources, team c relevant up-to-date evidence synthesis • *Using the Rapid Relative Effectiveness Asse*
Topic Selection	• Selected by PNIPH, informed by evidence in Palestine • Mammography screening (age & frequenc



Background

Mammography screening in the West Bank

- Breast cancer is the most common cancer among women in the West Bank (WB) and Gaza Strip (GS)
  - Accounts for 22% of cancer deaths among women in WB
  - Survival rates are still worse than in countries with stronger health systems
  - Both incidence and mortality are projected to double by the year 2040
- Palestinian Ministry of Health offers women free mammography screening for women over 40

- Challenges:
  - Low awareness & low performance of breast self-examinations
  - Social and physical barriers hinder access to timely and right care
  - Screening program is opportunistic, more similar to early diagnosis (*providing service to people with symptoms)*
  - Costs related to cancer take up a significant amount of the health budget

Need for evidence on effectiveness and associated cost of mammography screening to understand and inform screening practices

Abu-Rmeileh (2016), Ferlay et al. (2019), Ferlay et al. (2020), Alwaheidi (2019), Alwaheide et al. (2020), Azaiza (2010), PNIPH (2014)

Methods underlying the transfer

Initiate aHTA approach — Setting up core team and designate responsibilities.

Topic selection & prioritization — Propose a list of relevant topics and prioritize one for the project; with relevant stakeholders or commissioner. Agree on research question(s).

Synthesizing (local) evidence — Identify relevant domains for the HTA report

Use EUnetHTA REA format

Situational Analysis

- Literature review (semi-systematic in PubMed)
- Gray literature *(incl., stakeholders)*
- Interviews

Transferability process

I. Perform systematic search
II. Select a relevant HTA*(or evidence synthesis)
III. Assess transferability of evidence (HTA)
IV. Extract relevant data

Use EUnetHTA Adaptation Toolkit

Budget Impact Analysis

Use ISPOR BIA Guidance

- Make model in Excel
- Collect (local) input data *(incl., stakeholders)*

Producing the HTA report — Core team members write the HTA report (incl. executive summary, methods, recommendations, etc.) and report on the results.

Stakeholder engagement — Share with stakeholders, presentation and guided discussion and circulate the final draft for feedback and comments with stakeholders.

Disseminate final report — Core team to finalize report and disseminate findings

Appraise and implement

HTA Core Model Domains
1. Description and technical characteristics of technology (TEC)
2. Health problem and current use of the technology (CUR)
3. Clinical Effectiveness (EFF)
4. Safety (SAF)
5. Cost and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Patient and social aspects
9. Legal aspects

1-4: Rapid REA Model 6-9: Replaced by checklist

Formulating the research question

Topic selection and prioritization

- Literature reviews; discussions with Palestinian colleagues to identify topics relevant to MOH and policy makers; feedback from stakeholders.

- **Should organized mammography screening in women be used?**
  a) Should mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged 40 to 44?
  b) Should mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged 45 to 49?
  c) Should mammography screening vs. no mammography screening be used for early detection of breast cancer in women between the ages of 50 and 69?
  d) Should mammography screening vs. no mammography screening be used for early detection of breast cancer in women 70 years of age and older?
- **What is the budget impact of screening?**

Transferability - effectiveness

Synthesizing (local) evidence

Transferability process

I. Perform systematic search
II. Select a relevant HTA*(or evidence synthesis)
III. Assess transferability of evidence (HTA)
IV. Extract relevant data

Use EUnetHTA Adaptation Toolkit

- Systematic search to identify systematic review (evidence synthesis) for effectiveness of screening
- **Found:**

CLINICAL GUIDELINE

Annals of Internal Medicine

Breast Cancer Screening and Diagnosis: A Synopsis of the European Breast Guidelines

Questions 1-3: Should mammography screening vs. no mammography screening be used for detecting breast cancer in women?

Transferability - effectiveness

Transferability process

I. Perform systematic search
II. Select a relevant HTA*(or evidence synthesis)
III. Assess transferability of evidence (HTA)
IV. Extract relevant data

Use EUnetHTA Adaptation Toolkit

- Assess transferability
  - EUnetHTA toolkit
  - WHO Guidelines for screening

Transferability - effectiveness

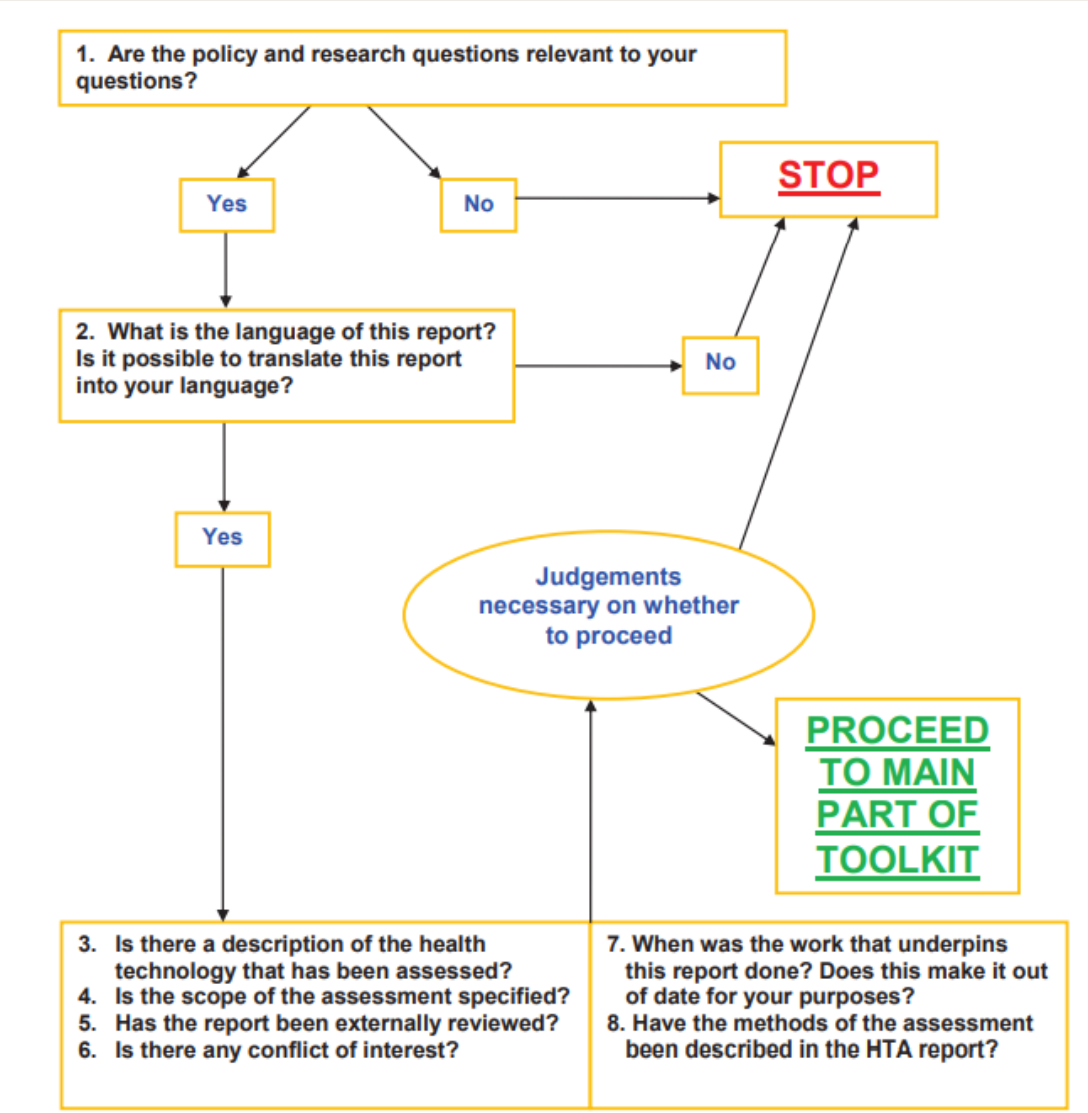
Transferability process

I. Perform systematic search
II. Select a relevant HTA*(or evidence synthesis)
III. Assess transferability of evidence (HTA)
IV. Extract relevant data

Use EUnetHTA Adaptation Toolkit

- Transferability

EUnetHTA →



Transferability - effectiveness

Transferability process

I. Perform systematic search
II. Select a relevant HTA*(or evidence synthesis)
III. Assess transferability of evidence (HTA)
IV. Extract relevant data

Use EUnetHTA Adaptation Toolkit

- Transferability

EUnetHTA →

Question Box 6: Safety domain questions

a) To assess relevance

1. Were harms or safety assessed?

c) To assess transferability

15. Does the population described for eligibility match the population to which it is targeted in the target setting?

16. Are there any reasons to expect differences in complication rates (e.g. epidemiology, genetic issues, healthcare system (quality of care, surveillance))?

17. Are the requirements for its use (special measures needed for use/implementation, maintenance etc.) available in the target setting?

18. Is the necessary expertise (knowledge and skills) available in the target setting?

19. a) Is safety particularly dependent on training?
    b) Are there types of teams to which the procedure should be limited for safety reasons?
    c) Is there a need for special training or certification to deliver the intervention properly.
    d) Would it be possible (affordable) to organise such training, if any?

9. Were the criteria used for assessing the validity of the included studies reported?

Transferability - effectiveness

Transferability process

I. Perform systematic search
II. Select a relevant HTA*(or evidence synthesis)
III. Assess transferability of evidence (HTA)
IV. Extract relevant data

Use EUnetHTA Adaptation Toolkit

- Extract information from systematic review
-

Transferability - effectiveness

Transferability process

I. Perform systematic search
II. Select a relevant HTA*(or evidence synthesis)
III. Assess transferability of evidence (HTA)
IV. Extract relevant data

Use EUnetHTA Adaptation Toolkit

- Synthesize

Outcomes	Age Intervals		
	40-49	50-69	70-74
Mortality (breast cancer related)* RR (95% CI)	RR: 0.92 (0.83-1.02)	RR: 0.77 (0.67-0.88)	RR: 0.77 (0.54-1.09)
Stage IIA or Higher RR (95% CI)	RR: 0.88 (0.78-0.99)	RR: 0.80 (0.64-1.00)	RR: 0.64 (0.55-0.73)
Mastectomies RR (95% CI)	RR: 1.20 (1.11-1.30)		
False positive related adverse events	-	CR false positive: 19.7% (range: 8%-21%) CR invasive procedure: 2.9% (range: 1.8-6.3%)	-
Overdiagnosis women perspective* (% of examined cases)	22.7% (range: 18.4%-27.0%)	17.3% (range: 14.7%-20.0%)	-
Overdiagnosis population perspective* (% of examined cases)	12.4% (range: 9.9%-14.9%)	10.1% (range: 8.6%-11.6%)	-
Psychological effects Screening	No increased in anxiety among women (who received a clear result and placed on the routine recall). Mixed results in anxiety among women who were recalled.		
Psychological effects False positive	Increased distress, anxiety, fear and worry among women who needed any type of follow-up test, highest at 5 months and still elevated at 35 months.		

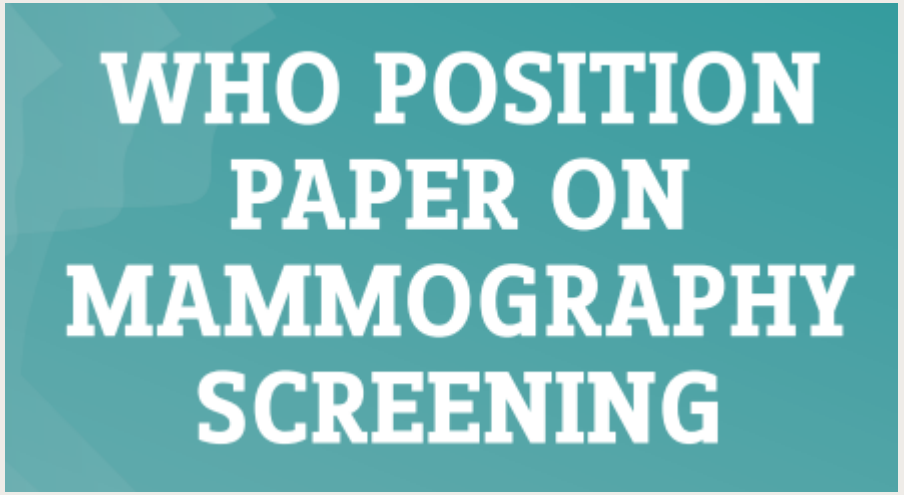
Transferability - effectiveness

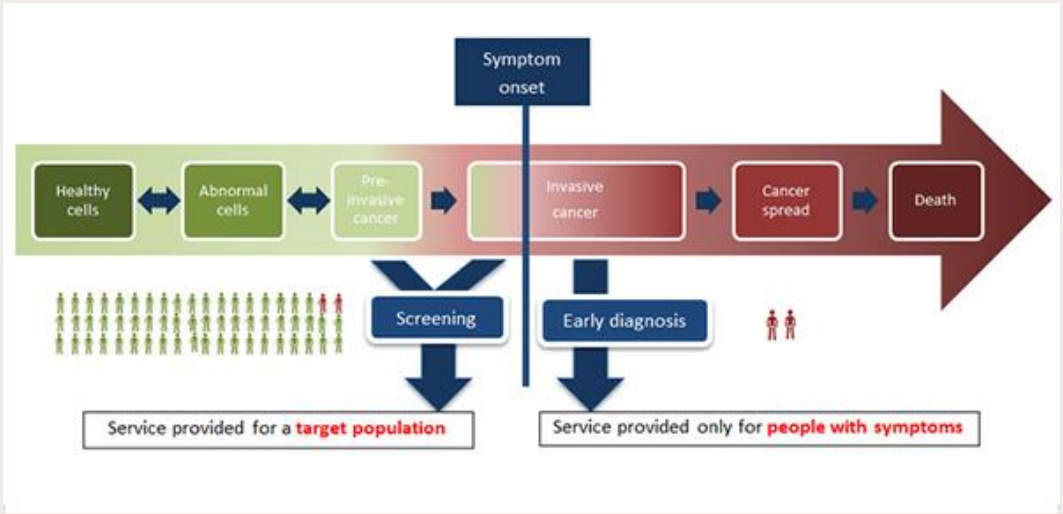
Transferability process

I. Perform systematic search
II. Select a relevant HTA*(or evidence synthesis)
III. Assess transferability of evidence (HTA)
IV. Extract relevant data

Use EUnetHTA Adaptation Toolkit

- Assess transferability
  - EUnetHTA toolkit
  - **WHO Guidelines for screening**
  - **Use almost same evidence as European systematic review**
  - **Made recommendations, depeding on resources:**
    - Well-resourced settings
    - Limited resource settings with relatively strong health systems
    - Limited resource settings with weak health systems





Recommendations on age and frequency of screening

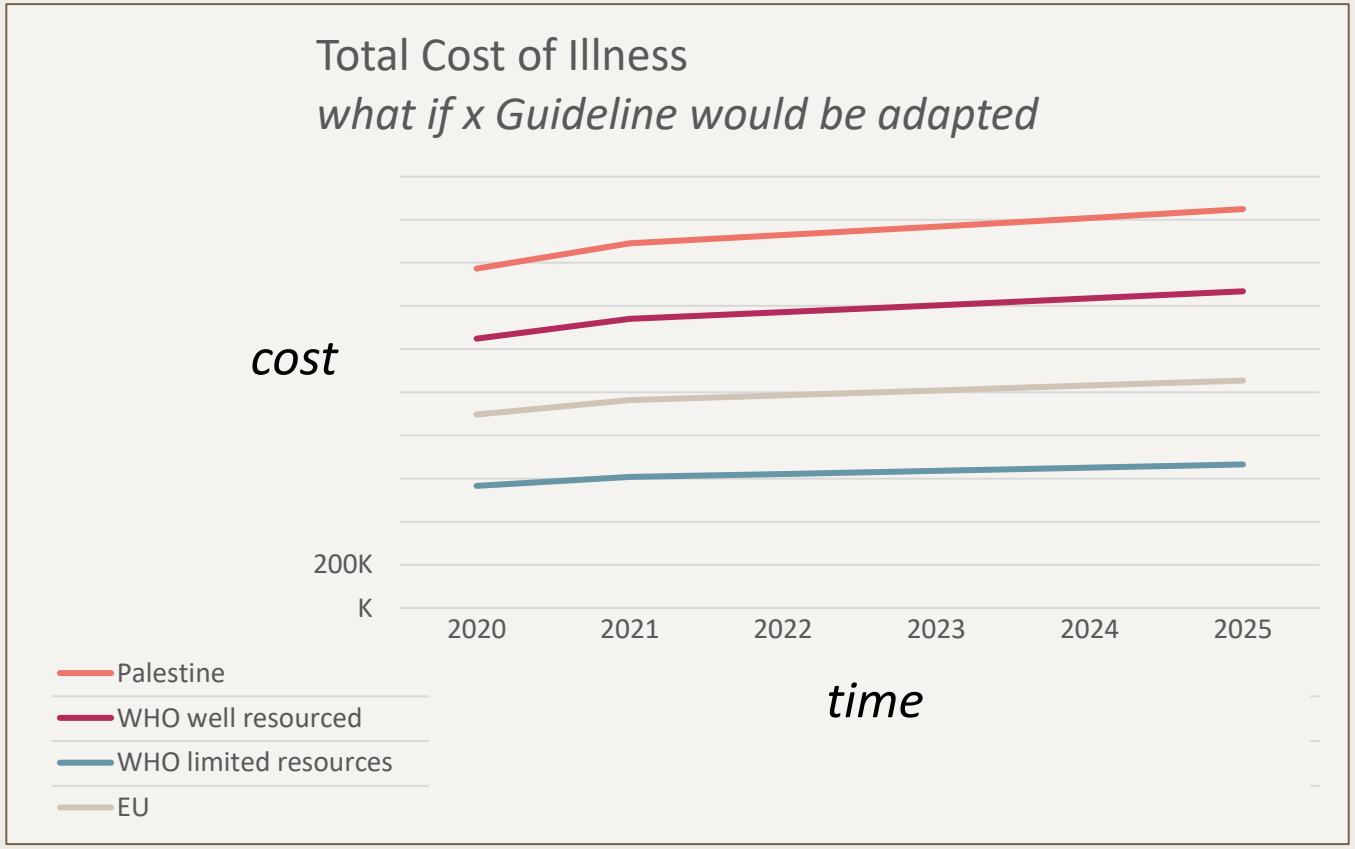
Age interval	WHO			EU Guideline	Palestine Protocol
	Well-resourced	Limited resource, strong health systems	Limited resource, weak health systems		
40-49					
Recommended screening, frequency	O Yes, more research	X No screening focus on early diagnosis	X No screening focus on early diagnosis	O Yes, every 2 ~~or 3 years~~ (for 45-49)	O Yes, 1x per year
50-69					
Recommended screening, frequency	O Yes, every 2 years	O Yes, every 2 years	X No screening focus on early diagnosis	O Yes, every 2 years	O Yes, every 2 year
70-75					
Recommended screening, frequency	O Yes, more research	X No screening focus on early diagnosis	X No screening focus on early diagnosis	O Yes, every 3 years	

Preliminary results: Budget Impact

Budget Impact Analysis

- Make model in Excel
- Collect (local) input data *(incl., stakeholders)*

Scenario: coverage of 20%, assumes 20% of the women 'invited' to mammographic screening under the guideline are screened



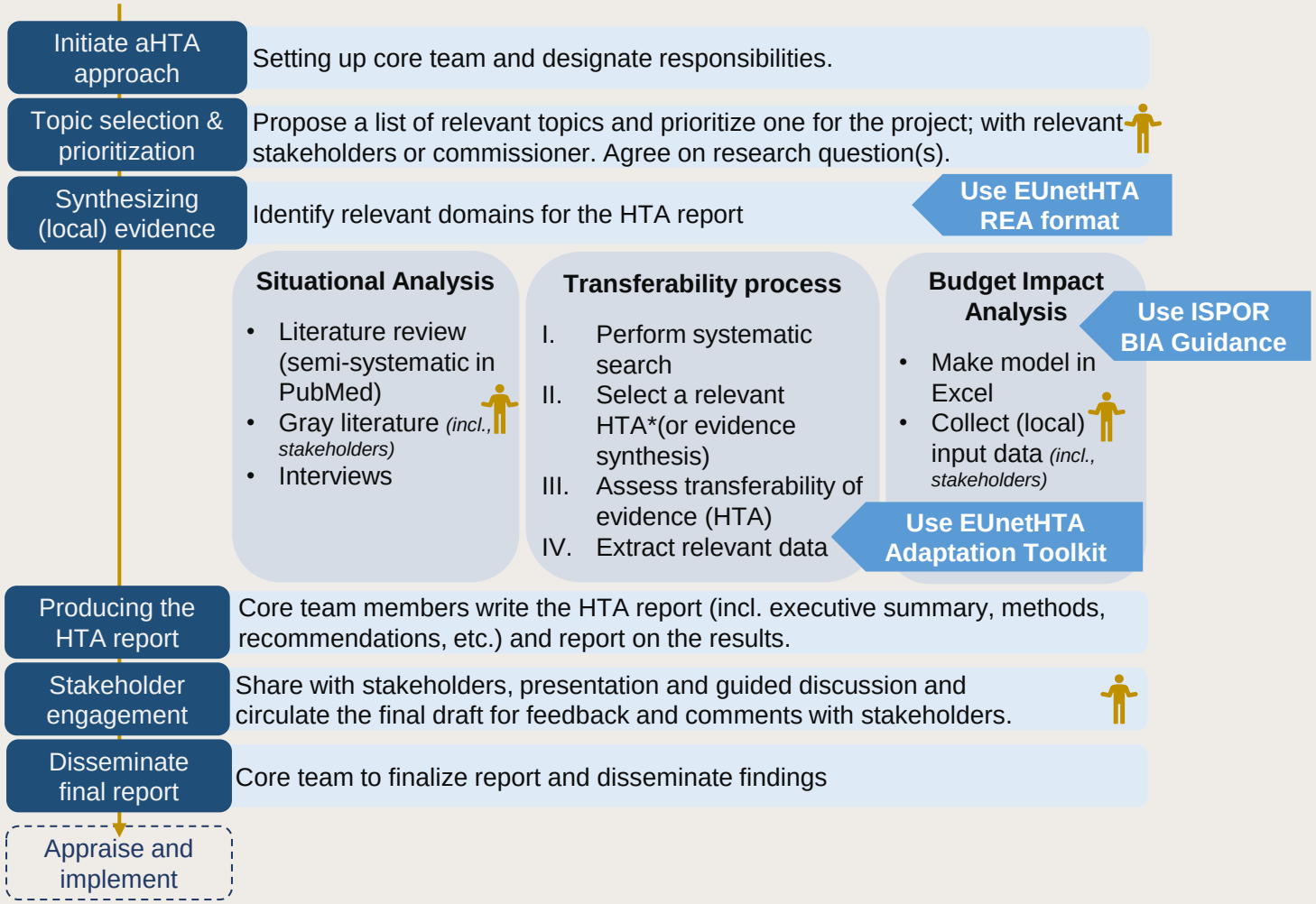
The (preliminary) cost in the table present **total cost of illness** (= cost mammograms & cost tests at recall) if a certain guideline would be implemented in the West Bank.

Palestine guideline invites women 40-49 (screening once per 1 year) & 50-59 (screening once per 2 years)
Scenario: 20% coverage

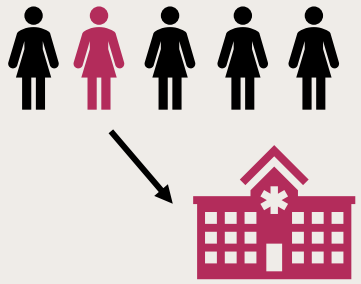
WHO limited resource recommendation invites women 50-69 (screening once per 2 years)
Scenario: 20% coverage

If Palestine would change their existing guideline to adopt WHO recommendation, budget impact = **1 million US Dollars (savings)**

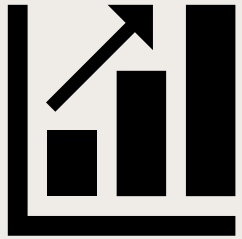
Writing down the main results



Main findings



- Focus on early diagnosis: test women who show symptoms, either when doing breast self-examinations or breast exams by professionals
  - If screening: focus on the implementation of an organized population-based screening program in the West Bank the age group 50 to 69.
  - Without invitational program evidence suggest that cost-effectiveness of screening is doubtfull due to false positives and overdiagnosis



- The more people you need to screen the higher the cost.
  - Current Palestinian protocol addresses the largest population group
  - Most likely unsustainable for organizational capacity and financial means, if participation increases when screening becomes more accepted

Issues in HTA transfers *'it is possible but not easy'*

Our experiences in the West Bank

- It was possible to adapt a REA and make it locally relevant in Palestine
  - Appraisal skills are required and should not be discounted
  - Pragmatic guidance for (low resource settings) is missing
  - Transfer is challenged as Palestine/LMICs have limited health resources and different healthcare pathways
- Local data is available
  - But access is difficult (e.g., not in public domain, missing infrastructures)
- Stakeholder engagement important for buy-in
  - But takes time
  - Make use of political momentum
- Most evidence in HTAs/underlying Systematic reviews is from RCTs conducted in HICs
  - Lack of access to original studies or models

In conclusion

- Transferring existing evidence, as HTA reports, can help to speed up HTA production, reduce duplication, and optimize resource use
- Transferring evidence is only one approach in larger ‘Adaptive HTA’ toolbox
- The EUnetHTA tool is most comprehensive, but specific tools are available for systematic reviews and economic evaluations – the choice of tool, should be argued properly
- Transferring evidence should NOT be discounted

NIPH
Norwegian Institute of Public Health

Thank you for your attention

Lieke Fleur Heupink – liekefleur.heupink@fhi.no

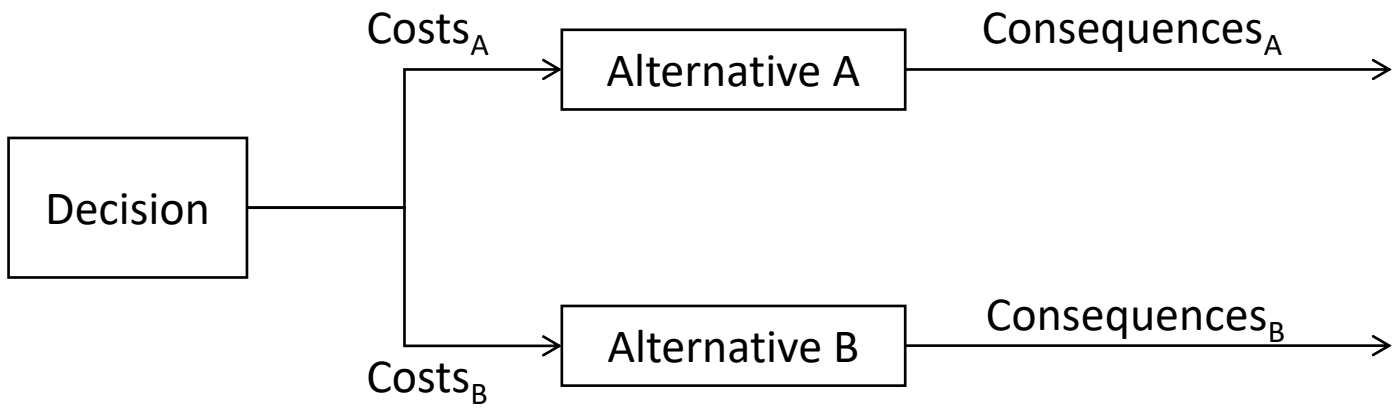
Read more on our work at NIPH

HTA in LMIC (here)

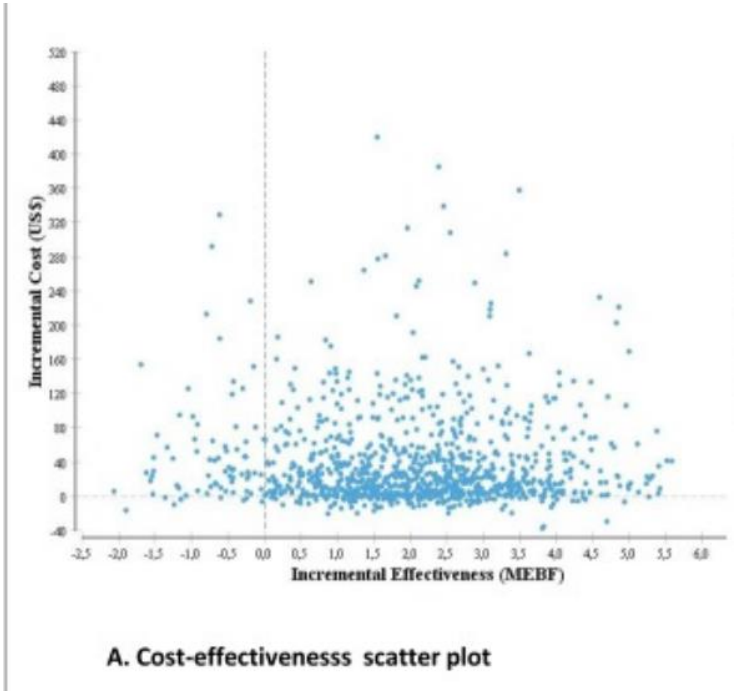
Building stronger institutions (here)

Economic Evaluation & Sensitivity Analysis

- Full economic evaluation is the **comparative analysis** of alternative courses of action in terms of both **costs** (resource use) and **consequences** (outcomes, effects)



Uncertainty in economic evaluations



Probabilistic sensitivity analysis

Figure from: Chola L, Fadnes LT, Engebretsen IM, Nkonki L, Nankabirwa V, Sommerfelt H, Tumwine JK, Tylleskar T, Robberstad B; PROMISE-EBF Study Group. Cost-Effectiveness of Peer Counselling for the Promotion of Exclusive Breastfeeding in Uganda. PLoS One. 2015 Nov 30;10(11):e0142718. doi: 10.1371/journal.pone.0142718.