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Director, Cochrane Canada
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@schunemann_mac

GRADEpro: eine web-basierte Lösung für die Zusammenfassung, Darstellung und Vermittlung von Wissen für klinische Entscheidungen

HEI
Department of Health Research Methods, Evidence and Impact
McMaster University

1967 - http://hei.mcmaster.ca

“Birthplace of evidence-based medicine and problem based learning”

Department of Health Research Methods, Evidence, and Impact (HEI)

Welcome to the Department of Health Research Methods, Evidence, and Impact (HEI), formerly the Department of Clinical Epidemiology and Biostatistics (CE&BI. Recognizing that the CE&B name captured only some of the depth and breadth of disciplines and expertise in the department, we formally changed its name effective January 1, 2017.

The name is outcomes focused: we produce, synthesize, package, share, and support the best available research evidence in the health and health-related fields, and we undertake a variety of initiatives designed to achieve impacts at all levels within as well as across health systems. The name effectively connects us to the department's history in evidence-based medicine and the global impact that this and other departmental initiatives have had. Moreover, the new name captures the department's strategic goal of extending its leadership in developing new health research methods, generating and synthesizing actionable research evidence, and achieving impact.

MORE ABOUT HEI

HEI welcomes your enquiries, requests, comments, suggestions and proposals. Please contact chairhei@mcmaster.ca

HEI

Disclosures

Cochrane Canada - Director

GRADE working group - Co-chair

Guidelines International Network - GIN Board, Member

Views expressed are my own

Content

GRADE in the context of guideline development

GRADEpro Guideline Development Tool

- Examples of application
  - World Health Organization Guidelines
  - European Commission Initiative on Breast Cancer and ARIA allergic rhinitis guidelines
  - American Society of Hematology
- GRADEpro Panelvoice
- GRADE-based interactive Decision Aids

Guideline development Process

American Thoracic Society Documents

A Guide to Guidelines for Professional Societies and Other Developers of Recommendations

Introduction to Integrating and Coordinating Efforts in COPD Guideline Development. An Official ATS/ERS Workshop Report

Holger J. Schünemann, Mark Woodhead, Antonio Anzueto, A. Sonia Buist, William MacNee, Klaus F. Rabe, and John Heffner; on behalf of the ATS/ERS Ad Hoc Committee on Integrating and Coordinating Efforts in COPD Guideline Development

Proc Am Thorac Soc Vol 9, Iss. 5, pp 215–218, Dec 15, 2012

Health Research Policy and Systems

WHO

BioMed Central

Review

Open Access

Improving the use of research evidence in guideline development: introduction

Andrew D Oxman*[1], Atle Fretheim[1], Holger J Schünemann[2] and SURE[3]

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Received: 07 April 2006
Accepted: 21 November 2006

This article is available from: http://www.health-policy-systems.com/content/4/1/13

CMAJ RESEARCH

Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise

Holger J. Schünemann MD PhD, Wojtek Wiercioch BHSc, Itziar Etxeandia Pharm D, Maicon Falavigna MD PhD, Nancy Santesso MLIS, Reem Mustafa MD MPH, Matthew Ventresca BHSc, Romina Brignardello-Petersen DDM, Kaja-Triin Laisaar MD MPH, Sérgio Kowalski MD PhD, Tejan Baldeh, Yuan Zhang BHSc, Ulla Raid PhD, Ignacio Neumann MD, Susan L. Norris MD MPH, Judith Thornton PhD, Robin Harbour BSc, Shaun Treweek PhD, Gordon Guyatt MD MS, Pablo Alonso-Coello MD PhD, Marge Reinap MA, Jan Brožek MD, Andrew Oxman MD MS, Elie A. Akl MD PhD

Abstract

Background: Although several tools to evaluate the credibility of health care guidelines exist, guidance on practical steps for developing guidelines is lacking. We systematically compiled a comprehensive checklist of items linked to relevant resources and tools that guideline developers could consider, without the expectation that every guideline would address each item.

Methods: We searched data sources, including manuals of international guideline developers, literature on guidelines for guidelines (with a focus on methodology reports from international and national agencies, and professional societies) and recent articles providing systematic guidance. We reviewed these sources in duplicate, extracted items for the checklist using a sensitive approach and developed overarching topics relevant to guidelines. In an iterative omissions and involved experts in guideline development for revisions and suggestions for items to be added.

Results: We developed a checklist with 18 topics and 146 items and a webpage to facilitate its use by guideline developers. The topics and included items cover all stages of the guideline enterprise, from the planning and formulation of guidelines, to their implementation and evaluation. The final checklist includes links to training materials as well as resources with suggested methodology for applying the items.

Interpretation: The checklist will serve as a resource for guideline developers. Consideration of items on the checklist will support the development, implementation and evaluation of guidelines. We will use crowdsourcing to

Competing interests: None declared. Authors of this manuscript have been involved in the development of various guideline manuals which are referenced in this article.

This article has been peer reviewed.

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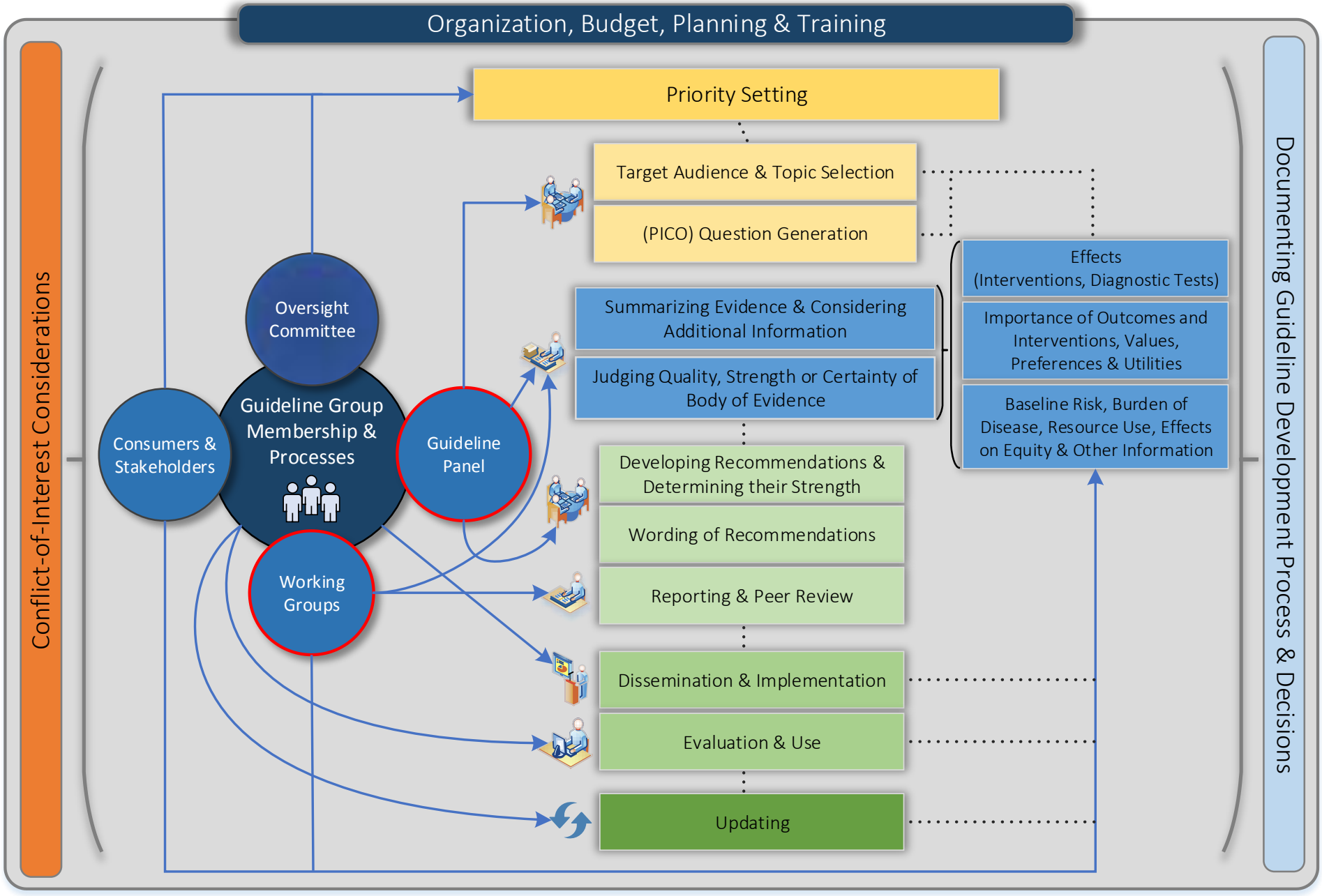
CMAJ 2014. DOI:10.1503/cmaj.131237



Schünemann et al. Guidelines 2.0. CMAJ. 2014 Feb 18;186(3):E123-42.
http://cebgrade.mcmaster.ca/guidecheck.html

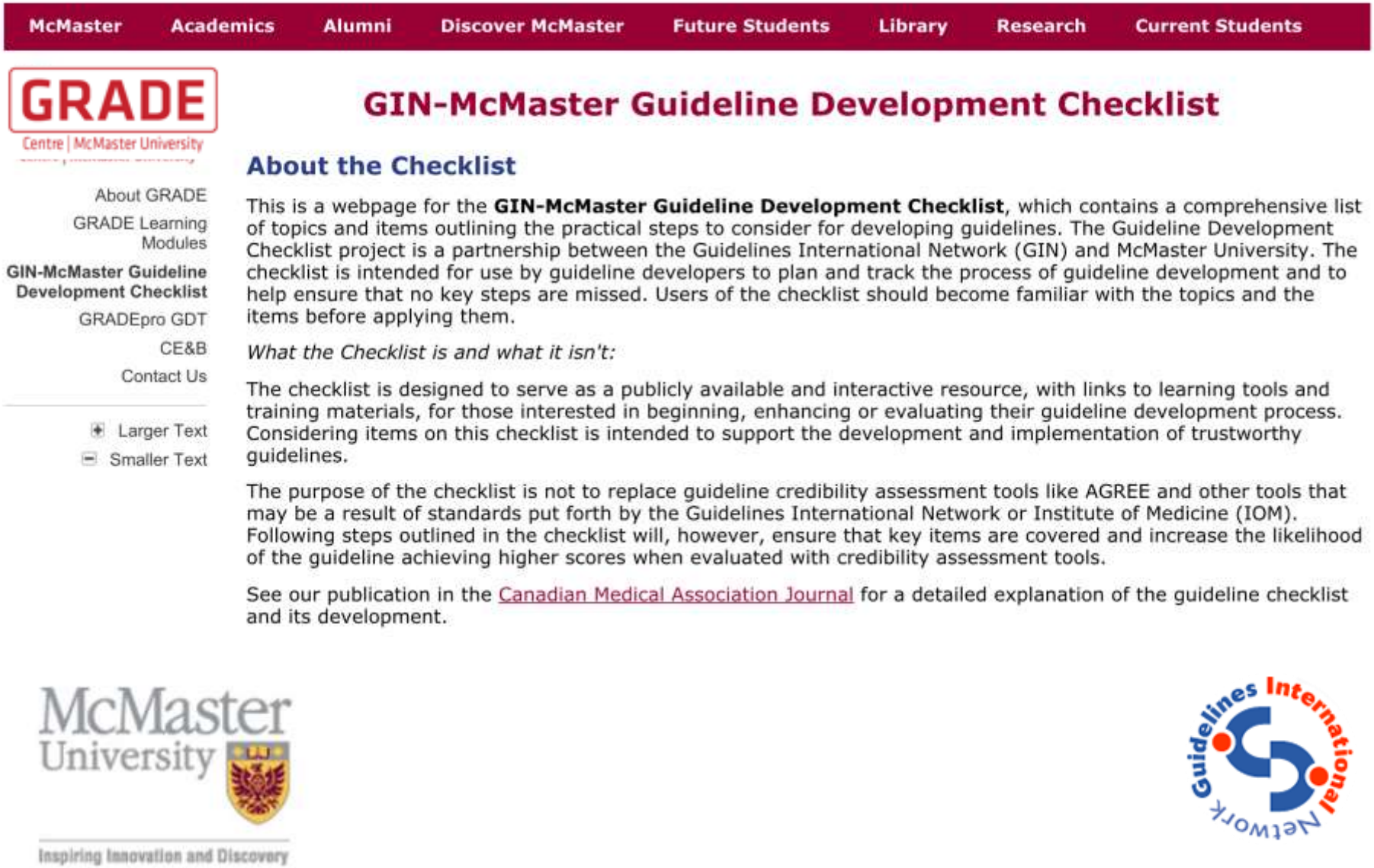
Tool of 18 topics with resources 144 items

Box 2: Topics included in checklist for guideline development

Topic	Description
1. Organization, budget, planning and training	Involves laying out a general but detailed plan describing what is feasible, how it will be achieved and what resources are required to produce and use the guideline. The plan should refer to a specific period and be expressed in formal, measurable terms.
2. Priority setting	Refers to the identification, balancing and ranking of priorities by stakeholders. Priority setting ensures that resources and attention are devoted to those general areas (e.g., chronic obstructive pulmonary disease, diabetes, cardiovascular disease, cancer, prevention) where health care recommendations will provide the greatest benefit to the population, a jurisdiction or a country. A priority-setting approach needs to contribute to future plans while responding to existing, potentially difficult circumstances.[100,101]
3. Guideline group membership	Defines who is involved, in what capacity, and how the members are selected for the guideline development and at other steps of the guideline enterprise.
4. Establishing guideline group processes	Defines the steps to be followed, how those involved will interact and how decisions will be made.
5. Identifying target audience and topic selection	Involves describing the potential users or consumers of the guideline and defining the topics to be covered in the guideline (e.g., diagnosis of chronic obstructive pulmonary disease).
6. Consumer and stakeholder involvement	Describes how relevant people or groups who are not necessarily members of the panel but are affected by the guideline (e.g., as target audience or users) will be engaged.
7. Conflict of interest considerations	Focuses on defining and managing the potential divergence between an individual's interests and his or her professional obligations that could lead to questioning whether the actions or decisions are motivated by gain, such as financial, academic advancement, clinical revenue streams or community standing. Financial or intellectual or other relationships that may affect an individual's or organization's ability to approach a scientific question with an open mind are included.
8. Question generation	Focuses on defining key questions the recommendations should address using the PICO (patient/problem, intervention, comparison, outcome) framework, including the detailed population, intervention (including diagnostic tests and strategies) and outcomes that will be relevant for decision-making (e.g., should test A be used, or should treatments B, C, D or E be used in chronic obstructive pulmonary disease?).

9. Considering importance of outcomes and interventions, values, preferences and utilities	Includes integrating, in the process of developing the guidelines, how those affected by its recommendations assess the possible consequences. These include patient, caregiver and health care provider knowledge, attitudes, expectations, moral and ethical values, and beliefs; patient goals for life and health; prior experience with the intervention and the condition; symptom experience (e.g., breathlessness, pain, dyspnea, weight loss); preferences for and importance of desirable and undesirable outcomes; perceived impact of the condition or interventions on quality of life, well-being or satisfaction, and interactions between the work of implementing the intervention, the intervention itself, and other contexts the patient may be experiencing; preferences for alternative courses of action; and preferences relating to communication content and styles, information and involvement in decision-making and care. This can be related to what in the economic literature is considered *utilities*. An intervention itself can be considered a consequence of a recommendation (e.g., the burden of taking a medication or undergoing surgery) and a level of importance or value is associated with that.
10. Deciding what evidence to include and searching for evidence	Focuses on laying out inclusion and exclusion criteria based on types of evidence (e.g., rigorous research, informally collected), study designs, characteristics of the population, interventions and comparators, and deciding how the evidence will be identified and obtained. It also includes but is not limited to evidence about values and preferences, local data and resources.
11. Summarizing evidence and considering additional information	Focuses on presenting evidence in a synthetic format (e.g., tables or brief narratives) to facilitate the development and understanding of recommendations. It also involves identifying and considering additional information relevant to the question under consideration.
12. Judging quality, strength or certainty of a body of evidence	Includes assessing the confidence one can place in the obtained evidence by transparently evaluating the obtained research (individual studies and across studies) and other evidence applying structured approaches. This may include, but is not limited to, evidence about baseline risk or burden of disease, importance of outcomes and interventions, values, preferences and utilities, resource use (cost), estimates of effects and accuracy of diagnostic tests.
13. Developing recommendations and determining their strength	Developing recommendations involves use of a structured analytic framework and a transparent and systematic process to integrate the factors that influence a recommendation. Determining the strength of the recommendations refers to judgments about how confident a guideline panel is that the implementation of a recommendation exerts more desirable than undesirable consequences.
14. Wording of recommendations and of considerations about implementation, feasibility and equity	Refers to choosing syntax and formulations that facilitate understanding and implementation of the recommendations. Such wording is connected to considerations about implementation, feasibility and equity, which refer to the guideline panel's considerations about how the recommendation will be used and what impact it may have on the factors described.
15. Reporting and peer review	Reporting refers to how a guideline will be made public (e.g., print, online). Peer review refers to how the guideline document will be reviewed before its publication and how it can be assessed (e.g., for errors), both internally and externally, by stakeholders who were not members of the guideline development group.
16. Dissemination and implementation	Focuses on strategies to make relevant groups aware of the guidelines and to enhance their uptake (e.g., publications and tools such as mobile applications).
17. Evaluation and use	Refers to formal and informal strategies that allow judgments about: evaluation of the guidelines as a process and product; evaluation of the use or uptake, or both; and evaluation of impact and whether or not the guideline leads to improvement in patient or population health or other consequences.
18. Updating	Refers to how and when a guideline requires revision because of changes in the evidence or other factors that influence the recommendations.

Interactive website
cebgrade.mcmaster.ca/guidecheck.html



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Inspiring Innovation and Discovery

Guidelines International Network

Please also view the two **videos** below to learn about the features of each version of the checklist.

Go to Online Checklist | Download Checklist PDF | Download Glossary PDF

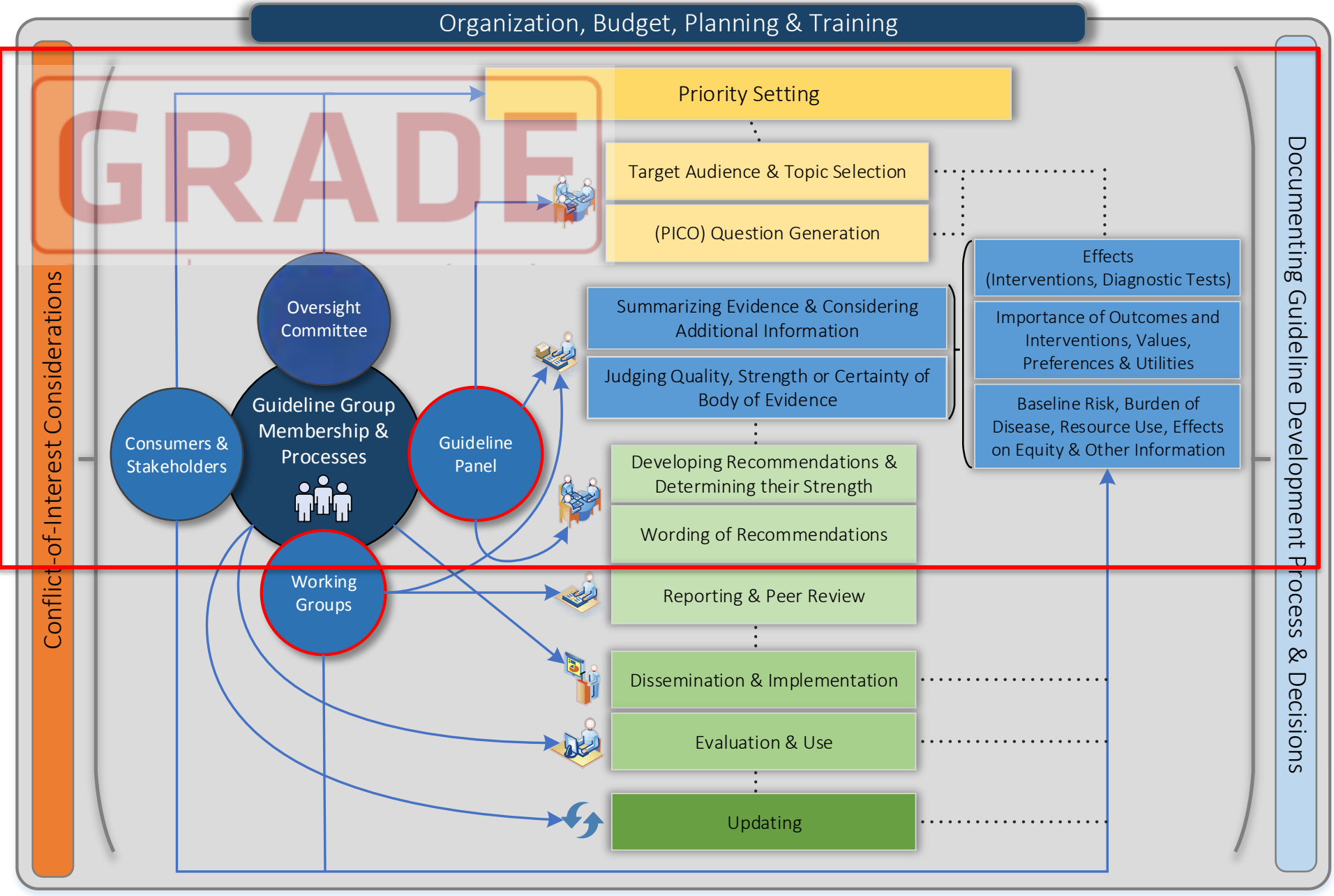
The Guideline Development Checklist is officially endorsed by:

GRADE working group

Developed in collaboration with:

AUB American University of Beirut
AWMF
Estonian Health Insurance Fund
IATS
INPECS Instituto para la Excelencia Clínica y Sanitaria
Osteba
RAVIJUHEND
SIGN 1993-2013
UFRGS Universidade Federal do Rio Grande do Sul
University of Aberdeen
UMKC University of Missouri-Kansas City
University of Tartu

Guidelines International Network



Schünemann et al. Guidelines 2.0. CMAJ. 2014 Feb 18;186(3):E123-42.
http://cebgrade.mcmaster.ca/guidecheck.html

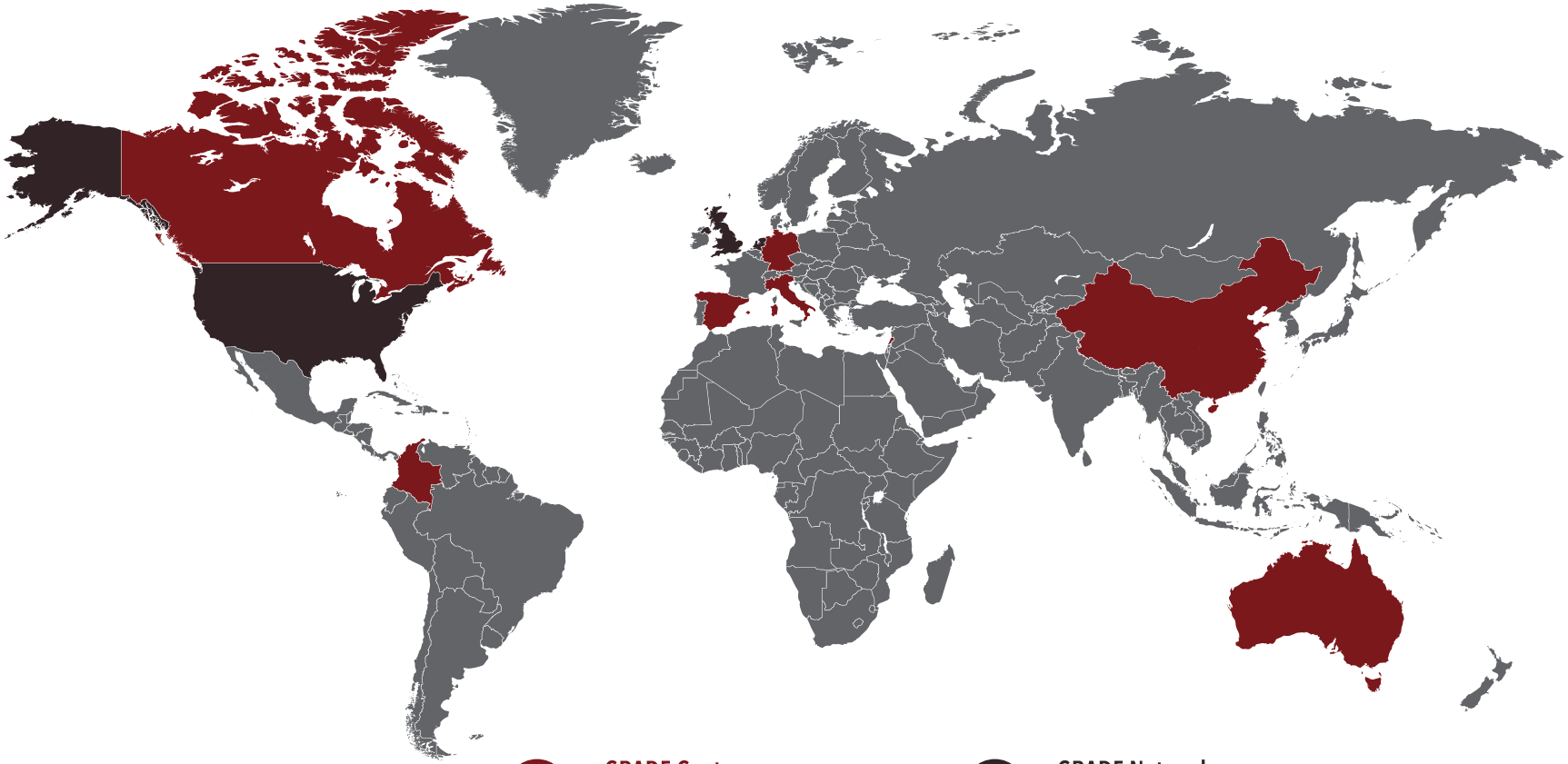
GRADE working group

After 30 years of increasing confusion, GRADE developed a unifying, transparent and sensible system for grading the certainty of evidence and making decisions

- Over 100 organizations: WHO, European Commission, NICE, CADTH, CDC, professional societies, academics
- For systematic reviews, HTA and guidelines
- International & diverse contributors (>600)
- 2008 BMJ series; 2011 JCE series – over 30,000 cites
- Various other publications (incl. GRADE Handbook)
- Official IT applications GRADEpro GDT

CMAJ 2003, BMJ 2004, BMC 2004, BMC 2005, AJRCCM 2006, Chest 2006, BMJ 2008 & 2016, JCE 2011-2017

GRADE



GRADE Centers

McMaster University GRADE Center, **Canada**
Lanzhou University GRADE Center, **China**
Barcelona GRADE Center, **Spain**
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American University of Beirut GRADE Center, **Lebanon**
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Javeriana Bogota GRADE Center, **Colombia**
JBI Adelaide GRADE Center, **Australia**

GRADE Networks

U.S. GRADE Network, **United States**
Dutch GRADE Network, **Netherlands**
UK GRADE Network, **United Kingdom**

GRADEpro GDT

Formulate question

P
I/E
C
O

Outcome Critical
Outcome Critical
Outcome Important
Outcome Not important

Create
evidence profile or Summary of Findings
Table with GRADEpro

Certainty of evidence for each outcome

High
Moderate
Low
Very low

Randomization raises initial quality

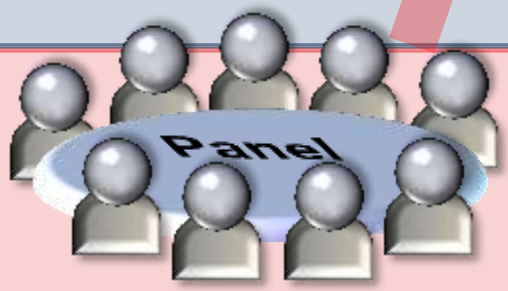
Grade down
1. Risk of bias
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias

Grade up
1. Large effect
2. Dose response
3. Opposing bias & Confounders

Evidence synthesis (systematic review/HTA)

Input?

Recommendation/Decision



Grade overall Certainty of evidence across outcomes

Grade recommendations (Evidence to Recommendation)
- For or against (direction) ↓↑
- Strong or conditional/weak (strength)

By balancing **consequences** (evidence to recommendations):
- ❑ **Certainty of evidence**
- ❑ **Values and preferences (utilities)**
- ❑ **Balance benefits/harms**
- ❑ **Resource use (cost)**
- ❑ **Equity, Feasibility, Acceptability**

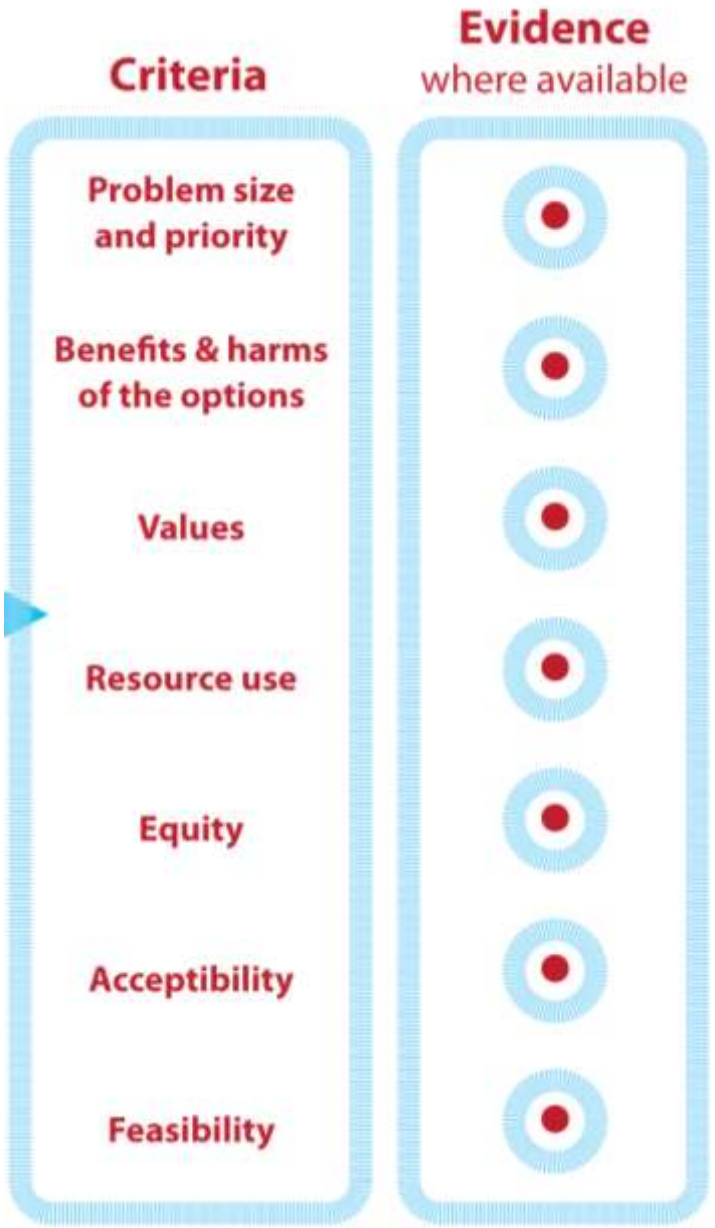
EtD framework

Recommendation /Decision

Formulate Recommendations (↓↑ | ⊕…)
"The panel recommends that ….should..."
"The panel suggests that ….should..."
"The panel suggests to **not** ..."
"The panel recommends to **not**..."

GRADE decision criteria

Systematic reviews or HTA



Recommendation

thebmj | BMJ 2016;353:i2016 | doi: 10.1136/bmj.i2016

GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction

Pablo Alonso-Coello,[1,2] Holger J Schünemann,[2,3] Jenny Moberg,[4] Romina Brignardello-Petersen,[2,5] Elie A Akl,[2,6] Marina Davoli,[7] Shaun Treweek,[8] Reem A Mustafa,[2,9] Gabriel Rada,[10,11,12] Sarah Rosenbaum,[4] Angela Morelli,[4] Gordon H Guyatt,[2,3] Andrew D Oxman[4] the GRADE Working Group

GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines

Pablo Alonso-Coello,[1,2] Andrew D Oxman,[3] Jenny Moberg,[3] Romina Brignardello-Petersen,[2,4] Elie A Akl,[2,5] Marina Davoli,[6] Shaun Treweek,[7] Reem A Mustafa,[2,8] Per O Vandvik,[3] Joerg Meerpohl,[9] Gordon H Guyatt,[2,10] Holger J Schünemann,[2,10] the GRADE Working Group

ELSEVIER

Journal of Clinical Epidemiology ■ (2016) ■

ORIGINAL ARTICLE

GRADE Guidelines: 16. GRADE evidence to decision frameworks for tests in clinical practice and public health

Holger J. Schünemann[a,b,c,*], Reem Mustafa[a,c,d], Jan Brozek[a,b,c], Nancy Santesso[a,c], Pablo Alonso-Coello[a,c,e], Gordon Guyatt[a,b,c], Rob Scholten[f], Miranda Langendam[c,g], Mariska M. Leeflang[g], Elie A. Akl[a,c,h], Jasvinder A. Singh[c,i], Joerg Meerpohl[c,j],

Neumann et al. Implementation Science (2016) 11:93
DOI 10.1186/s13012-016-0462-y

Implementation Science

RESEARCH Open Access

The GRADE evidence-to-decision framework: a report of its testing and application in 15 international guideline panels

Ignacio Neumann[1,2], Romina Brignardello-Petersen[1,3], Wojtek Wiercioch[1], Alonso Carrasco-Labra[1,3], Carlos Cuello[1], Elie Akl[4], Reem A. Mustafa[1,5], Waleed Al-Hazzani[1], Itziar Etxeandia-Ikobaltzeta[1,7], Maria Ximena Rojas[8], Maicon Falavigna[9], Nancy Santesso[1], Jan Brozek[1,6], Alfonso Iorio[1], Pablo Alonso-Coello[1,10] and Holger J. Schünemann[1,6*]

OPEN ACCESS Freely available online

PLoS MEDICINE

Health in Action

Transparent Development of the WHO Rapid Advice Guidelines

Holger J. Schünemann*, Suzanne R. Hill, Meetali Kakad, Gunn E. Vist, Richard Bellamy, Lauren Stockman, Torbjørn Fosen Wisløff, Chris Del Mar, Frederick Hayden, Timothy M. Uyeki, Jeremy Farrar, Yazdan Yazdanpanah, Howard Zucker, John Beigel, Tawee Chotpitayasunondh, Tran Tinh Hien, Bülent Özbay, Norio Sugaya, Andrew D. Oxman

Key Problems

1. Time is short
2. Money is tight
3. Guidelines are complicated (and shouldn’t be simplistic)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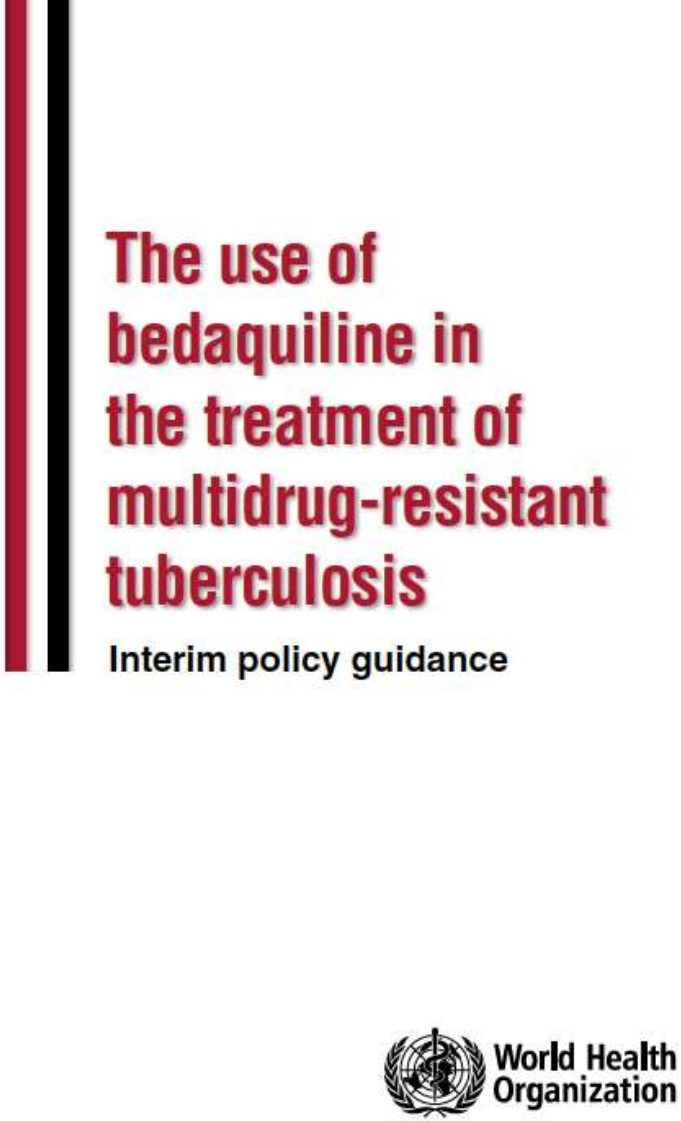
DECIDE
GRADE
HOME
GRADEpro GDT OVERVIEW
GUIDELINE RESOURCES
CALENDAR OF EVENTS
GRADE HANDBOOK
CONTACT SUPPORT
LOG IN
GRADE's software for Summary of Findings tables, Health Technology Assessment and Guidelines
LOG IN / SIGN UP

WHO Guideline on the use of Bedaquiline for Drug Resistant Tuberculosis

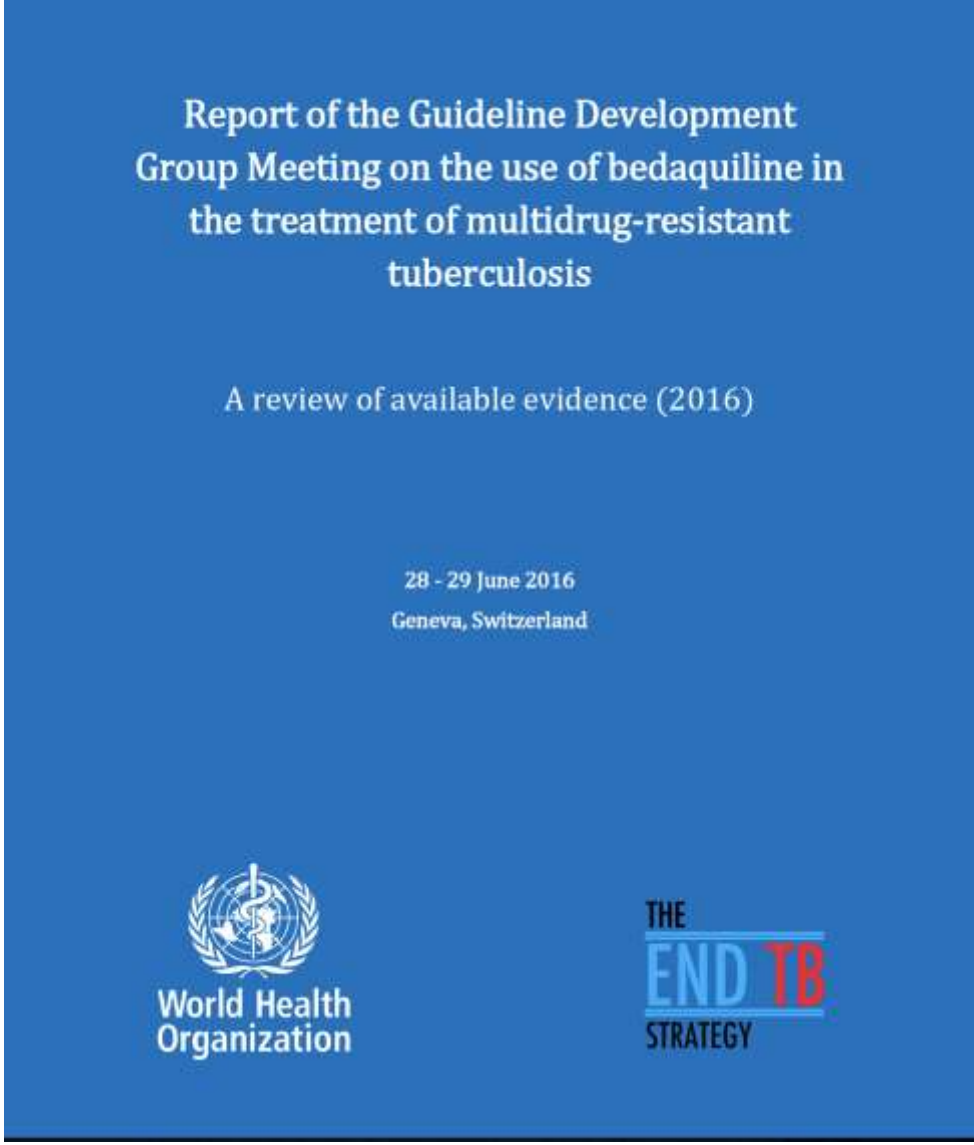
GRADEpro Evidence to Decision Frameworks piloting

Grading of evidence

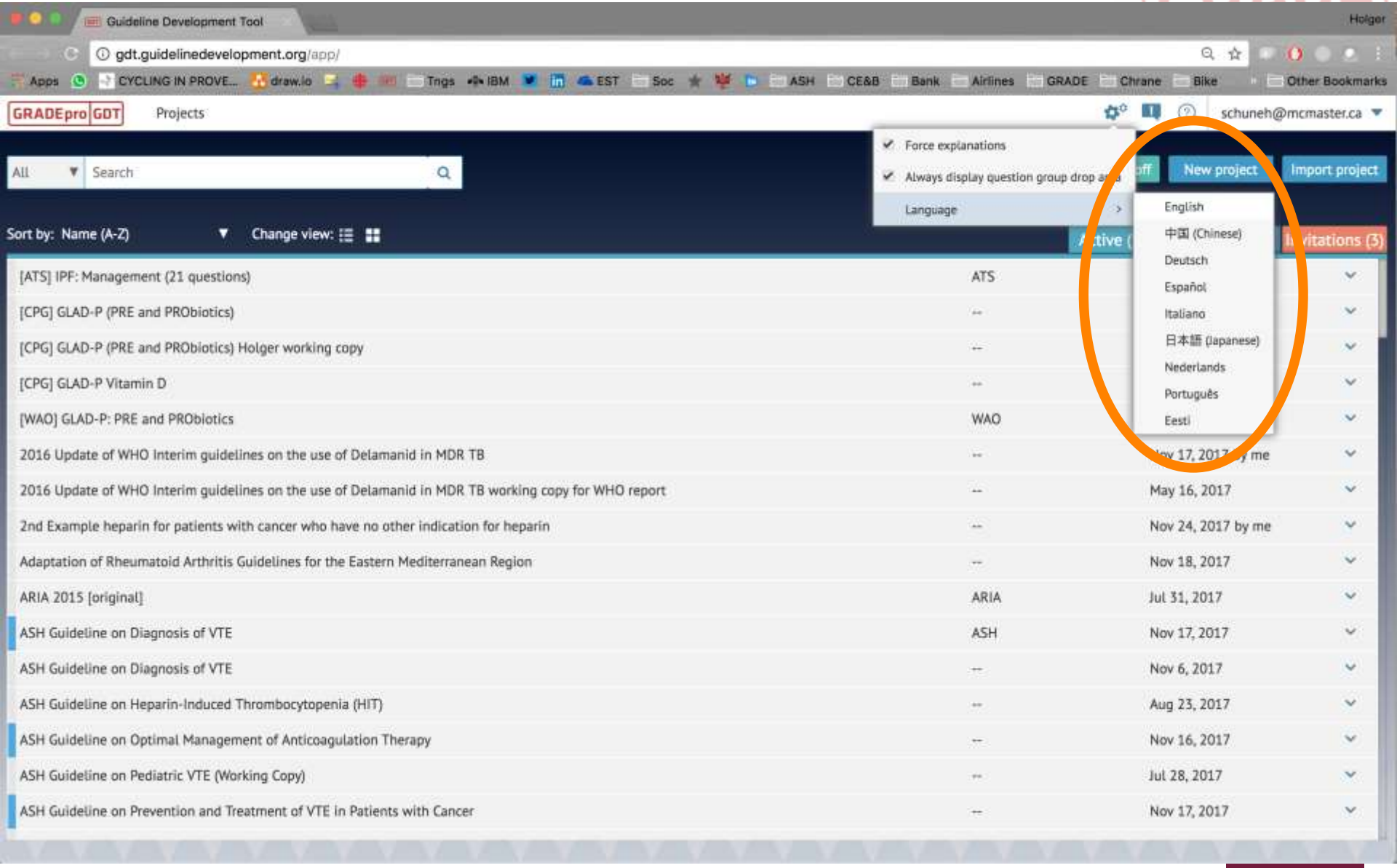
Updating of guidelines



WHO 2013



WHO 2017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Projects
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Force explanations
Always display question group drop
Language
New project
Import project
English
中国 (Chinese)
Deutsch
Español
Italiano
日本語 (Japanese)
Nederlands
Português
Eesti
All
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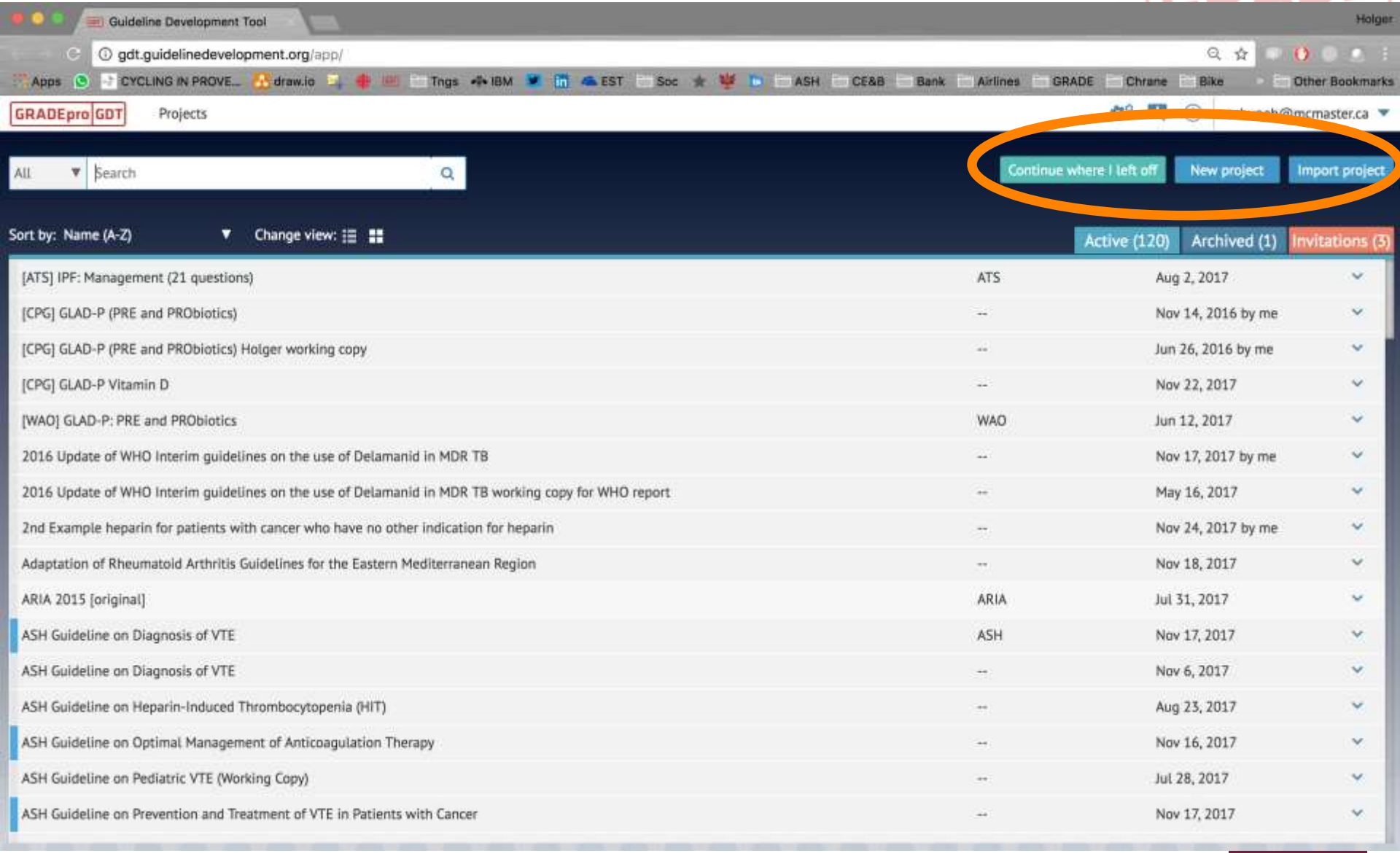
Change view:
[ATS] IPF: Management (21 questions) ATS
[CPG] GLAD-P (PRE and PRObiotics)
[CPG] GLAD-P (PRE and PRObiotics) Holger working copy
[CPG] GLAD-P Vitamin D
[WAO] GLAD-P: PRE and PRObiotics WAO
2016 Update of WHO Interim guidelines on the use of Delamanid in MDR TB
2016 Update of WHO Interim guidelines on the use of Delamanid in MDR TB working copy for WHO report May 16, 2017
2nd Example heparin for patients with cancer who have no other indication for heparin Nov 24, 2017 by me
Adaptation of Rheumatoid Arthritis Guidelines for the Eastern Mediterranean Region Nov 18, 2017
ARIA 2015 [original] ARIA Jul 31, 2017
ASH Guideline on Diagnosis of VTE ASH Nov 17, 2017
ASH Guideline on Diagnosis of VTE Nov 6, 2017
ASH Guideline on Heparin-Induced Thrombocytopenia (HIT) Aug 23, 2017
ASH Guideline on Optimal Management of Anticoagulation Therapy Nov 16, 2017
ASH Guideline on Pediatric VTE (Working Copy) Jul 28, 2017
ASH Guideline on Prevention and Treatment of VTE in Patients with Cancer Nov 17, 2017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GRADEpro GDT
Projects
All
Search
Continue where I left off
New project
Import project
Sort by: Name (A-Z)
Change view:
Active (120)
Archived (1)
Invitations (3)
[ATS] IPF: Management (21 questions) ATS Aug 2, 2017
[CPG] GLAD-P (PRE and PRObiotics) -- Nov 14, 2016 by me
[CPG] GLAD-P (PRE and PRObiotics) Holger working copy -- Jun 26, 2016 by me
[CPG] GLAD-P Vitamin D -- Nov 22, 2017
[WAO] GLAD-P: PRE and PRObiotics WAO Jun 12, 2017
2016 Update of WHO Interim guidelines on the use of Delamanid in MDR TB -- Nov 17, 2017 by me
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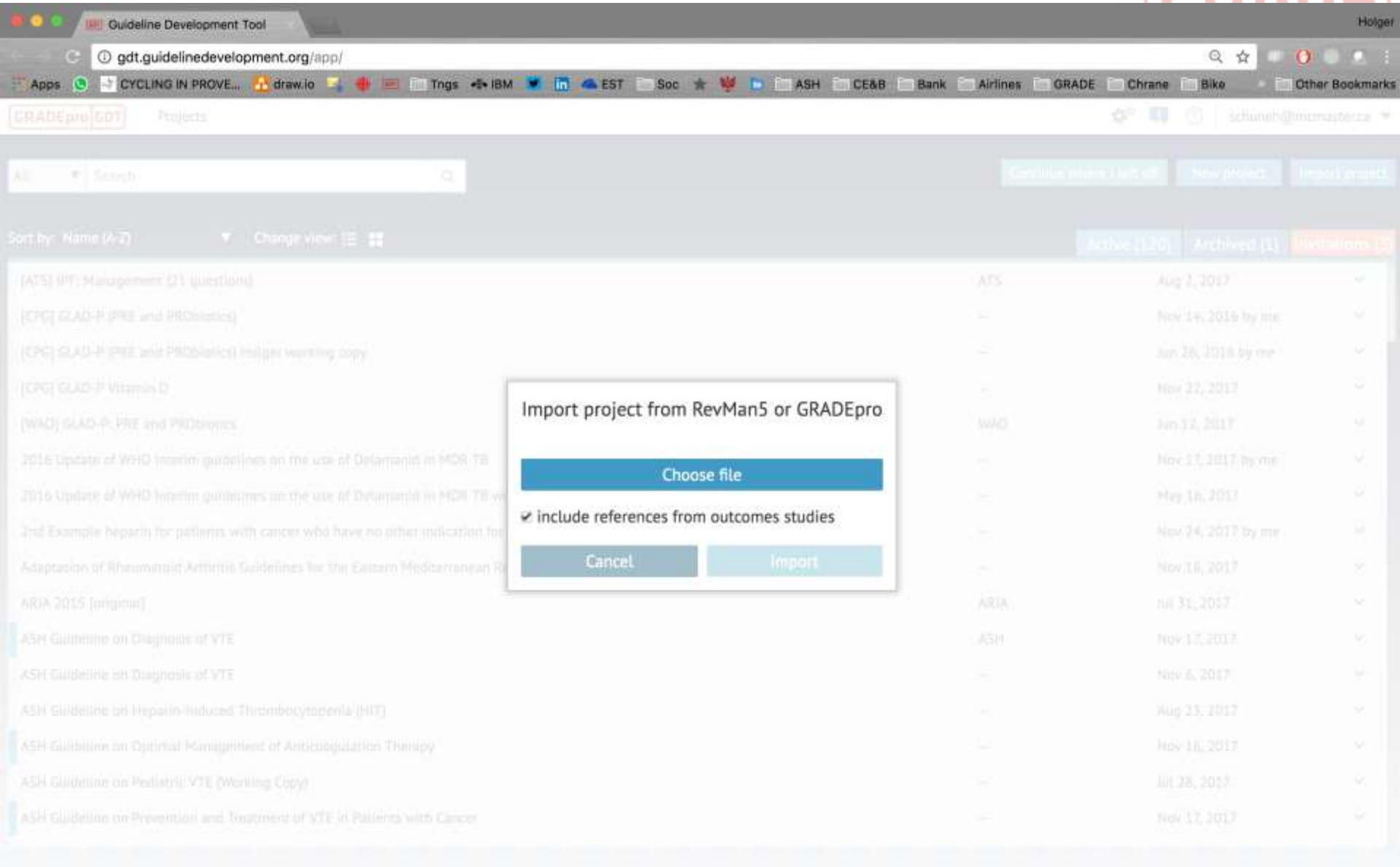
ASH Guideline on Prevention and Treatment of VTE in Patients with Cancer -- Nov 17, 2017

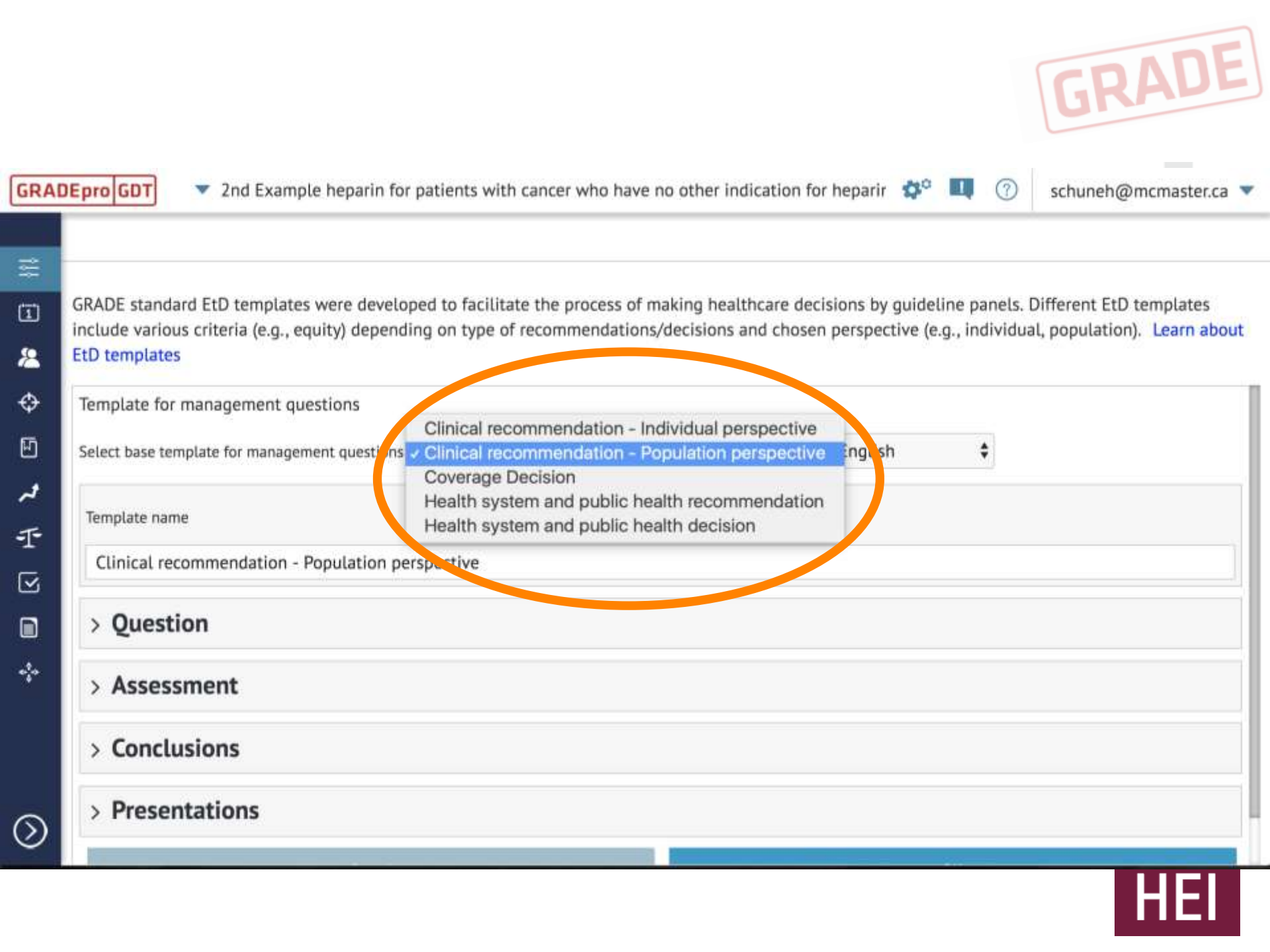

Guideline Development Tool
Holger
gdt.guidelinedevelopment.org/app/
Import project from RevMan5 or GRADEpro
Choose file
include references from outcomes studies
Cancel
Import

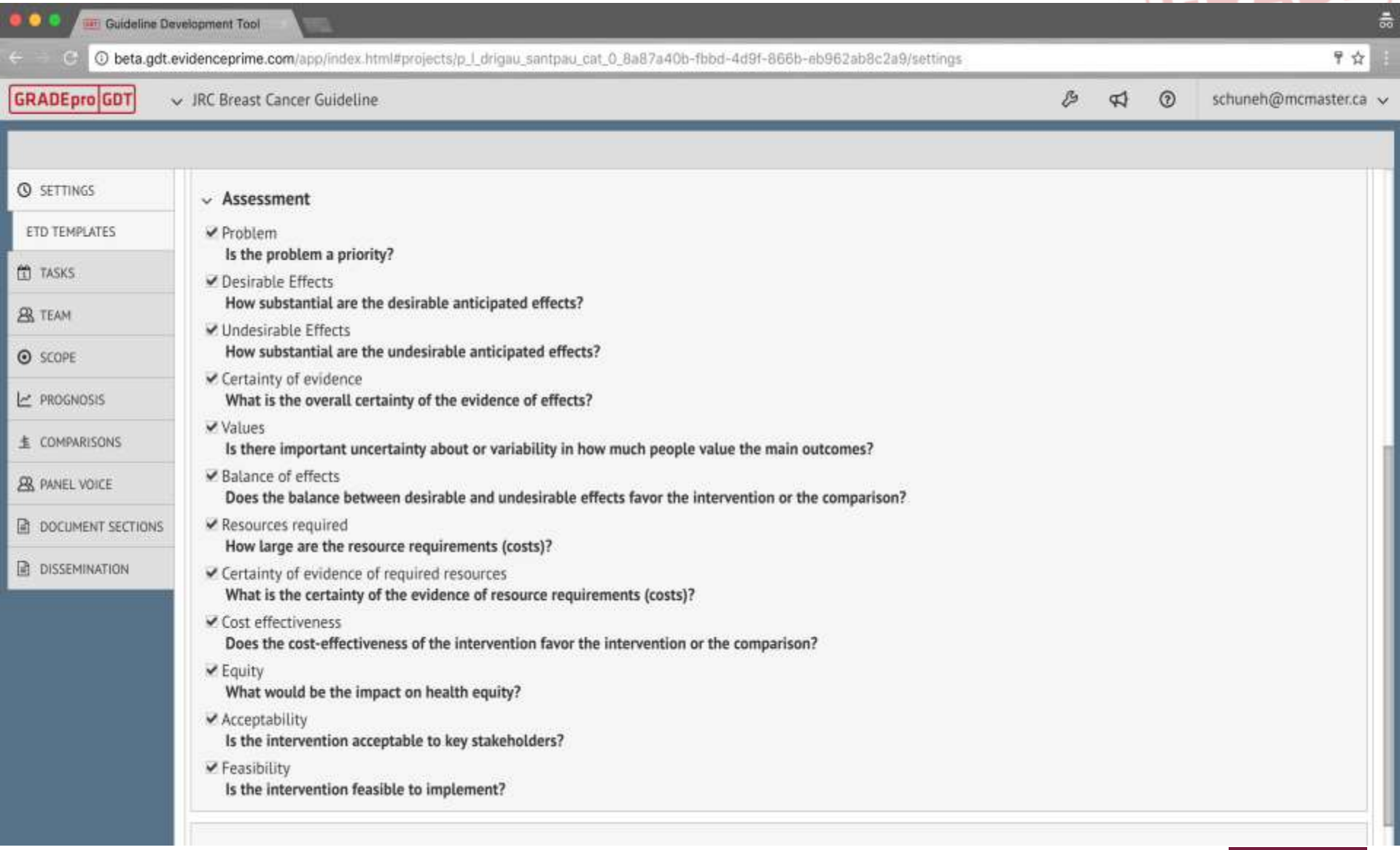
6. WHO Interim policy recommendations

In view of the aforementioned evidence assessment and advice provided by the EG, WHO recommends that ***bedaquiline may be added to a WHO-recommended regimen in adult patients with pulmonary MDR-TB (conditional recommendation, very low confidence in estimates of effects).***

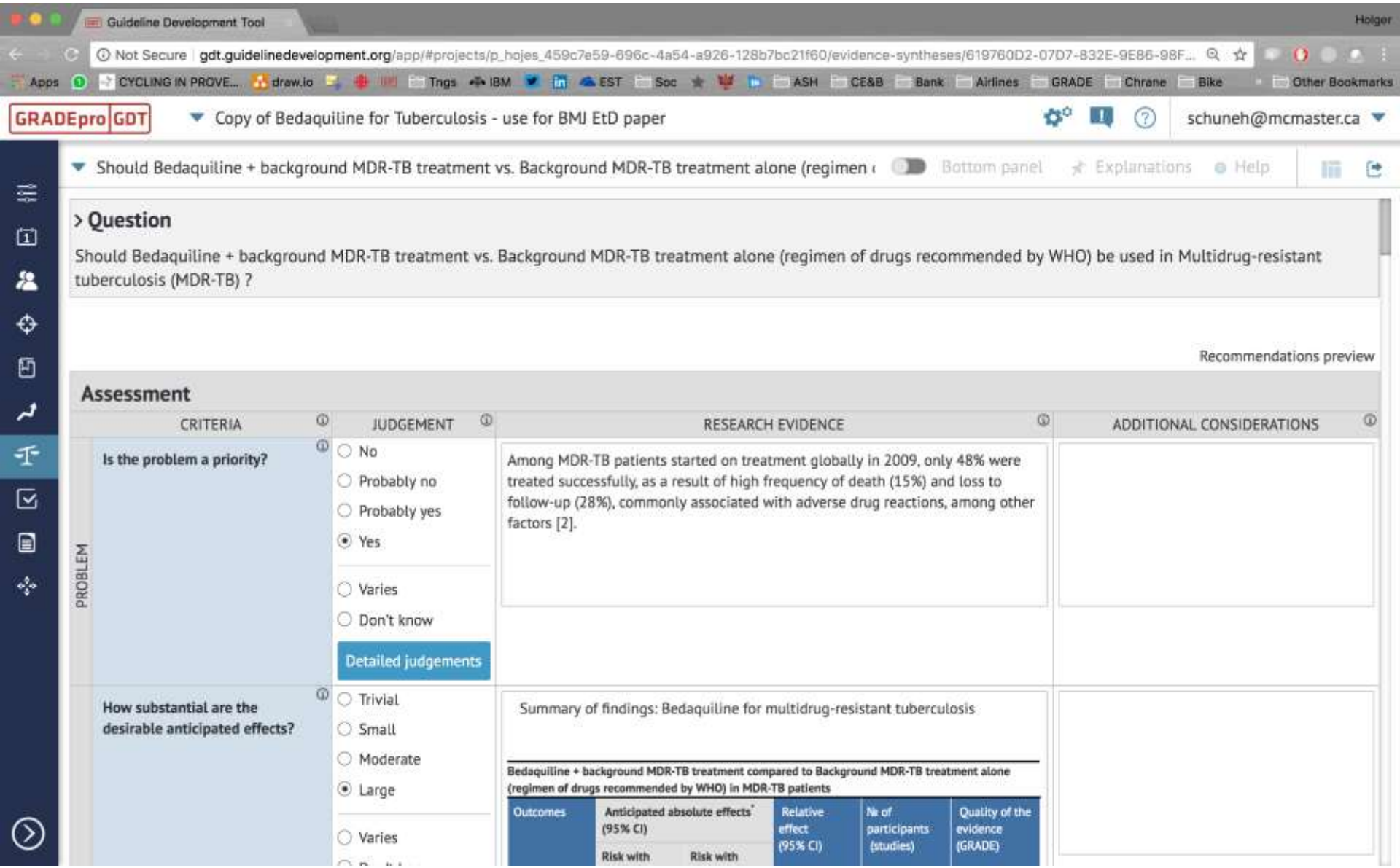
Given the limited data available on bedaquiline and its use under the various situations that may be encountered in different clinical settings, adequate provisions for safe and effective use of the drug must be in place. Consequently, countries are advised to follow

5. **Pharmacovigilance and proper management of adverse drug reactions and prevention of drug–drug interactions.**
    a. Special measures need to be put in place to ensure the early detection and timely reporting of adverse events using active pharmacovigilance methods, such as 'cohort event monitoring'. Any adverse drug reaction attributed to bedaquiline should also be reported to the national pharmacovigilance centre as part of the spontaneous reporting mechanism in the country. As for any other drug in the MDR-TB regimen the patient should be encouraged to report to the attending health worker any adverse event that occurs during the time the drug is being


GRADE
GRADEpro GDT
2nd Example heparin for patients with cancer who have no other indication for heparir
schuneh@mcmaster.ca
GRADE standard EtD templates were developed to facilitate the process of making healthcare decisions by guideline panels. Different EtD templates include various criteria (e.g., equity) depending on type of recommendations/decisions and chosen perspective (e.g., individual, population). Learn about EtD templates
Template for management questions
Select base template for management questions
Clinical recommendation - Individual perspective
Clinical recommendation - Population perspective
Coverage Decision
Health system and public health recommendation
Health system and public health decision
English
Template name
Clinical recommendation - Population perspective
Question
Assessment
Conclusions
Presentations
HEI


Guideline Development Tool
beta.gdt.evidenceprime.com/app/index.html#projects/p_l_drigau_santpau_cat_0_8a87a40b-fbbd-4d9f-866b-eb962ab8c2a9/settings
GRADEpro GDT
JRC Breast Cancer Guideline
schuneh@mcmaster.ca
SETTINGS
ETD TEMPLATES
TASKS
TEAM
SCOPE
PROGNOSIS
COMPARISONS
PANEL VOICE
DOCUMENT SECTIONS
DISSEMINATION
Assessment
Problem
Is the problem a priority?
Desirable Effects
How substantial are the desirable anticipated effects?
Undesirable Effects
How substantial are the undesirable anticipated effects?
Certainty of evidence
What is the overall certainty of the evidence of effects?
Values
Is there important uncertainty about or variability in how much people value the main outcomes?
Balance of effects
Does the balance between desirable and undesirable effects favor the intervention or the comparison?
Resources required
How large are the resource requirements (costs)?
Certainty of evidence of required resources
What is the certainty of the evidence of resource requirements (costs)?
Cost effectiveness
Does the cost-effectiveness of the intervention favor the intervention or the comparison?
Equity
What would be the impact on health equity?
Acceptability
Is the intervention acceptable to key stakeholders?
Feasibility
Is the intervention feasible to implement?

Interactive Evidence to Decision



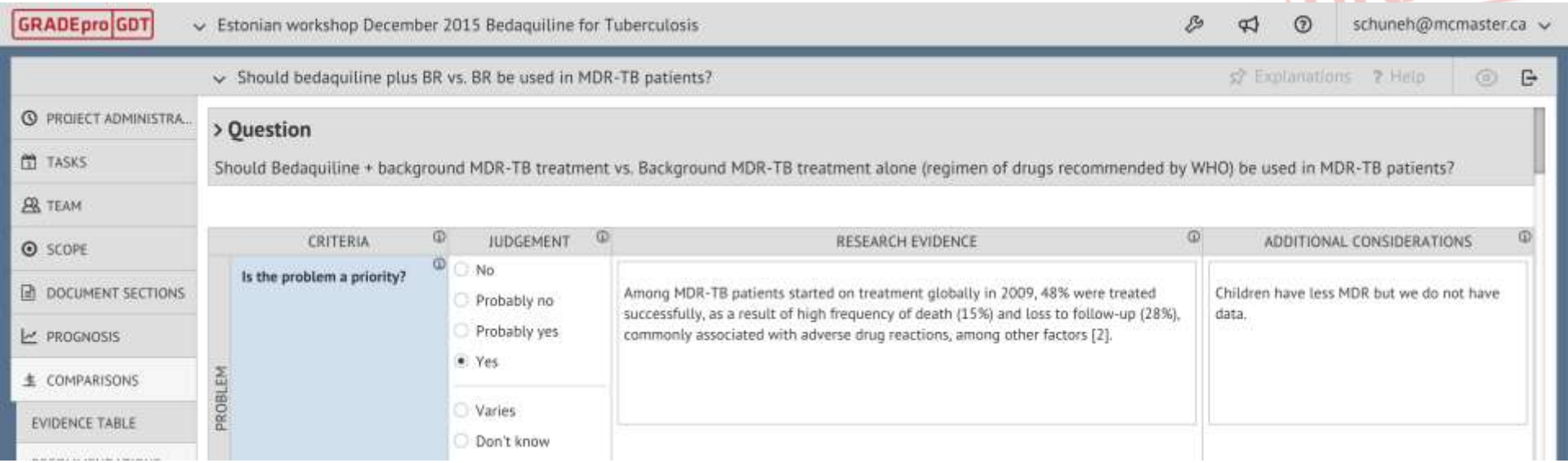
Presentation and use of criteria can be tailored

Interactive EtDs (iEtD)

Lets us choose the criteria

If obvious or not considered omit

EtD frameworks



Criteria on which a recommendation is based

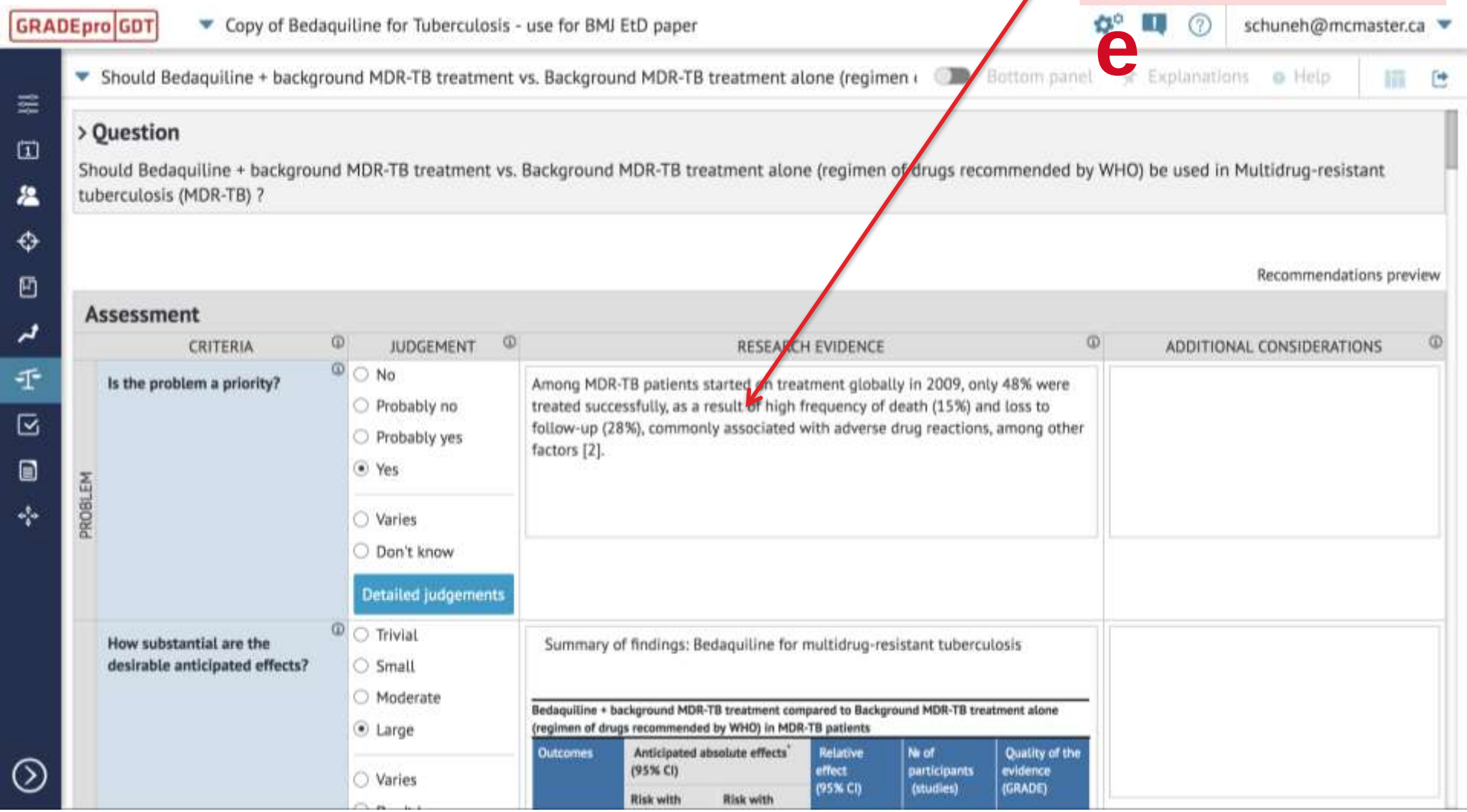
Judgements that must be made in relation to each criterion

Research evidence to inform each judgement

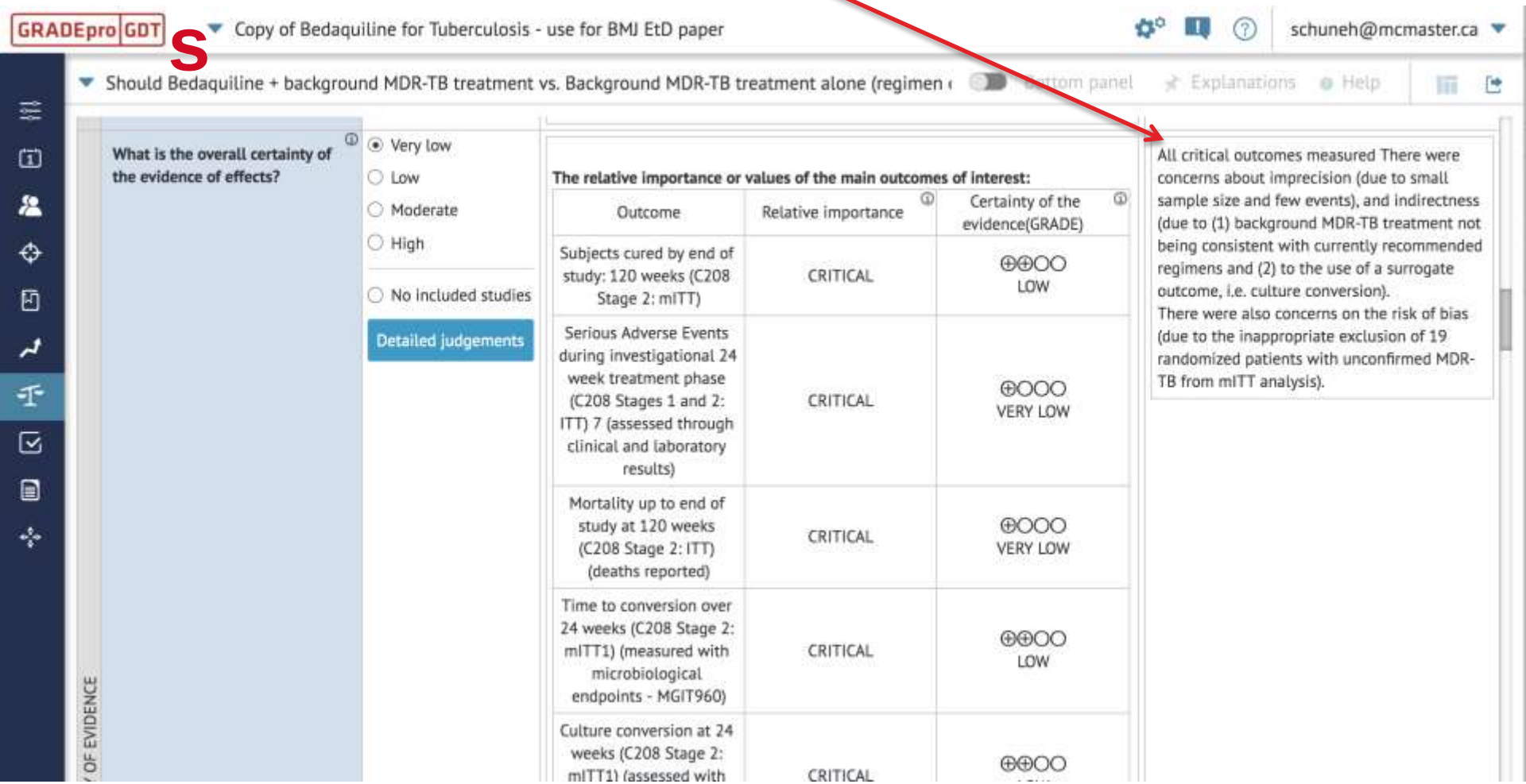
Additional considerations that inform or explain each judgement

What are guideline panel members doing?

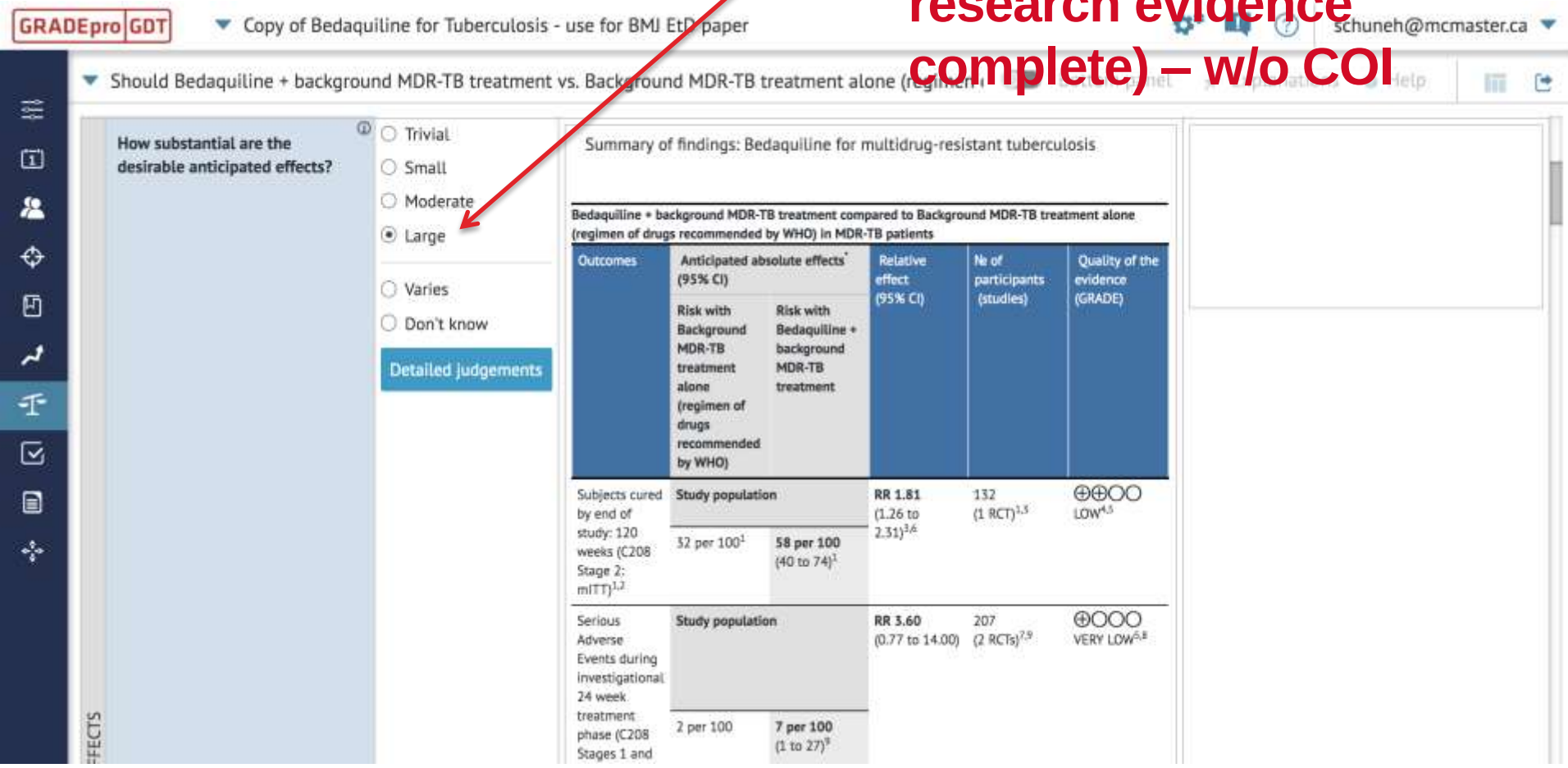
Discuss evidenc e



Add relevant considerations



Make judgments (when research evidence complete) – w/o COI



Interactive Summary of Findings

Tables

Participants: *MDR TB patients*
Intervention: *bedaquiline + background MDR TB treatment*
Comparison: *background MDR TB treatment alone*

▸ About this summary

Add or remove columns: | Visual overview

Outcome	Plain language summary	Absolute Effect: Without bedaquiline	Absolute Effect: With bedaquiline	Relative effect (95% CI) N° of participants & studies	Certainty of the evidence (GRADE)
Cured by end of study Follow-up: 120 weeks	*Bedaquiline may increase the number of patients cured.*	32 per 100	58 per 100	RR 1.81 (1.26 to 2.31) Based on data from 132 patients in 1 study	⊕⊕◯◯ Low
		Difference 26 more per 100 patients (95% CI: 8 to 42 more per 100 patients)			
Serious adverse events Follow-up: 24 week treatment phase	*It is uncertain whether bedaquiline increases the number of patients who have adverse effects.*	2 per 100	7 per 100	RR 3.6 (0.77 to 14.00) Based on data from 207 patients in 2 studies	⊕◯◯◯ Very low
		Difference 5 more per 100 patients (95% CI: 0 to 25 more per 100 patients)			
Mortality Follow-up: 120 weeks	*It is uncertain whether bedaquiline increases the number of patients who die.*	3 per 100	13 per 100	RR 9.23 (1.20 to 72.95) Based on data from 160 patients in 1 study	⊕◯◯◯ Very low
		Difference 10 more per 100 patients (95% CI: 0 to 53 more per 100 patients)			

Detailed judgements

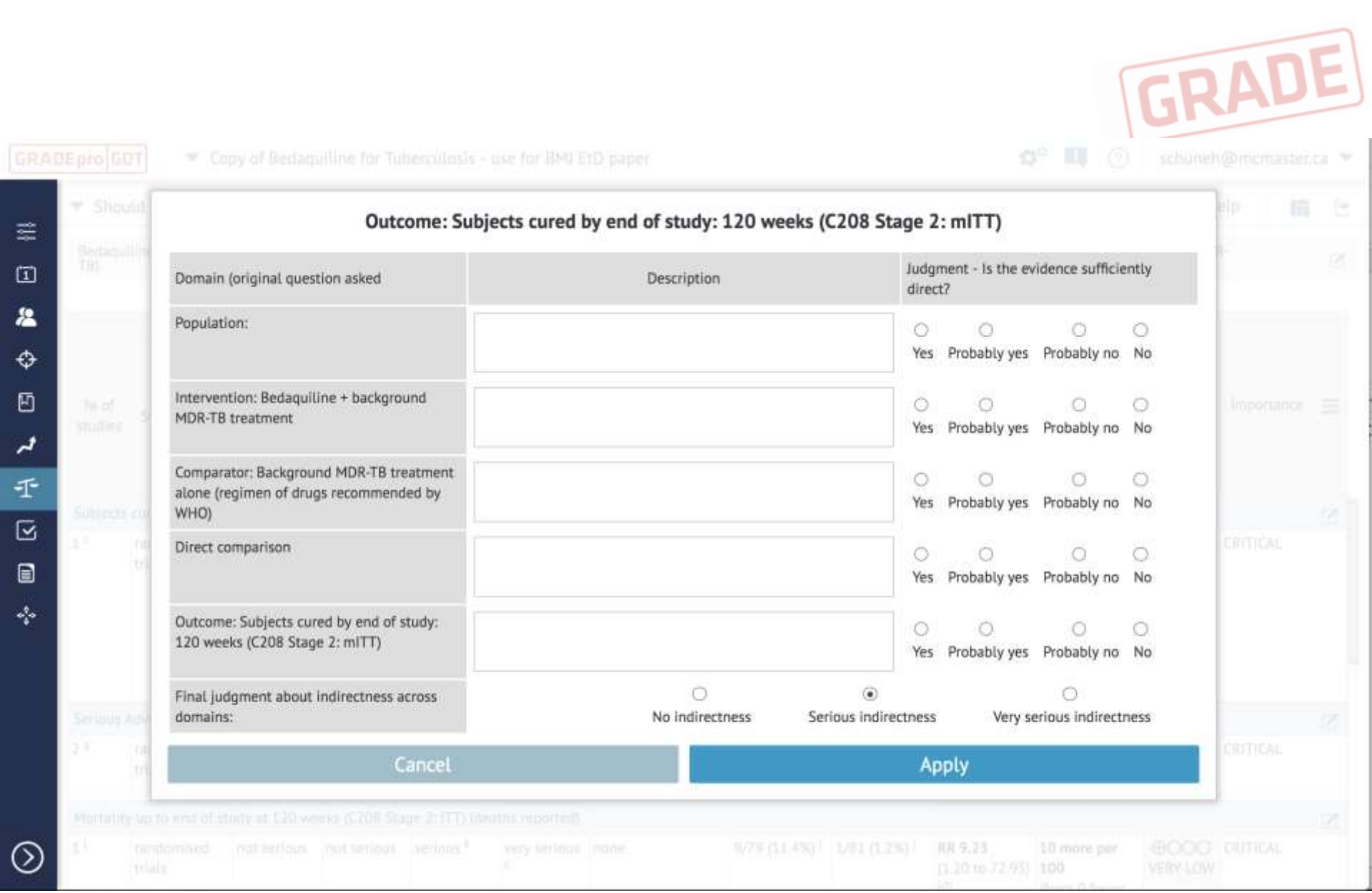
DESIRABLE EFFECTS: **How substantial are the desirable anticipated effects?**

Panel discussion

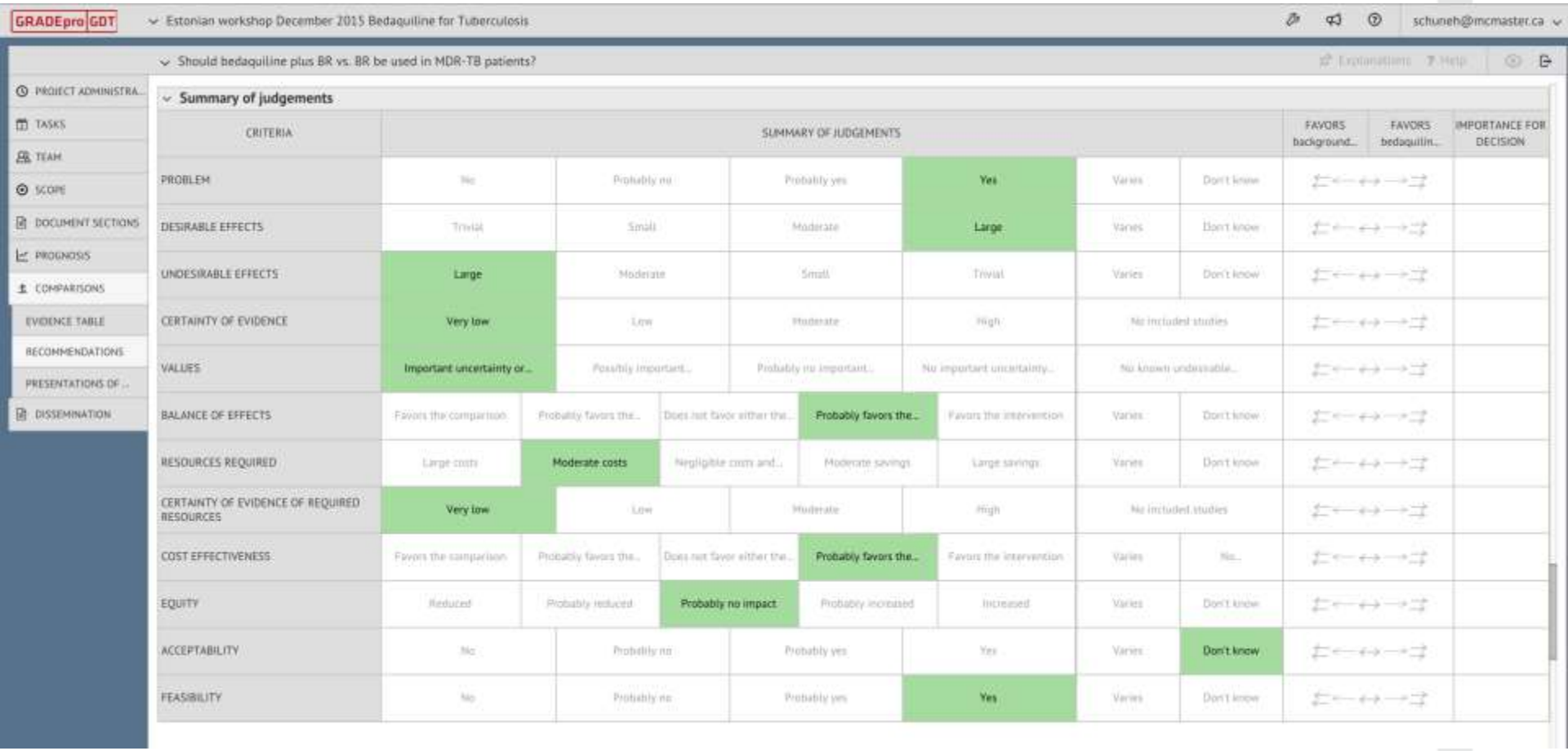
Detailed questions

How substantial is the anticipated effect (difference) for each main outcome for which there is a desirable effect?

Main outcomes	Judgements
Subjects cured by end of study: 120 weeks (C208 Stage 2: mITT)	○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know
Serious Adverse Events during investigational 24 week treatment phase (C208 Stages 1 and 2: ITT) 7 (assessed through clinical and laboratory results)	○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know
Mortality up to end of study at 120 weeks (C208 Stage 2: ITT) (deaths reported)	○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know
Time to conversion over 24 weeks (C208 Stage 2: mITT1) (measured with microbiological endpoints - MGIT960)	○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know
Culture conversion at 24 weeks (C208 Stage 2: mITT1) (assessed with microbiological endpoint - MGIT960)	○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know


GRADE
GRADEpro GDT
Copy of Bedaquiline for Tuberculosis - use for BMJ EtD paper
schuneh@mcmaster.ca
Outcome: Subjects cured by end of study: 120 weeks (C208 Stage 2: mITT)
Domain (original question asked
Description
Judgment - Is the evidence sufficiently direct?
Population:
Intervention: Bedaquiline + background MDR-TB treatment
Comparator: Background MDR-TB treatment alone (regimen of drugs recommended by WHO)
Direct comparison
Outcome: Subjects cured by end of study: 120 weeks (C208 Stage 2: mITT)
Yes
Probably yes
Probably no
No
Final judgment about indirectness across domains:
No indirectness
Serious indirectness
Very serious indirectness
Cancel
Apply

RESOURCES REQUIRED	**How large are the resource requirements (costs)?**	○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ◉ Varies ○ Don't know Detailed judgements	Cost data for the base case in each country were sourced from published studies [1], with additional supplementary data provided by study authors. For the primary estimates for the unit cost per patient treatment with Bedaquiline, a regimen cost of US $900 (for Global Fund Eligible countries) and US $3000 (for all other countries) was used for a full course of bedaquiline based on estimates from Janssen. In addition the costs of four electro-cardiograms were added. To estimate the possible cost savings from a shortened course with bedaquiline, the costs of an intensive phase of six months were estimated. Eight month intensive phase drug costs were adjusted to take into account reductions in hospitalization and required length of second-line parenteral agents (injectable anti-tuberculosis drugs). Where hospitalization was not used extensively in the intensive phase of treatment (Peru and Nepal), a reduction was made in the cost of clinic visits. All other costs (programme management, testing costs etc.) were conservatively assumed to remain the same as the non-shortened bedaquiline regimen.	
REQUIRED RESOURCES	**What is the certainty of the evidence of resource requirements (costs)?**	◉ Very low ○ Low ○ Moderate ○ High ○ No included studies Detailed judgements	Results were ambiguous in low-income settings, and highly dependent on the assumptions made about the generalizability of trial results to routine settings. The expert group noted that further analysis would be needed to test the robustness of the assumptions in various settings and to separately assess affordability [1].	


GRADEpro GDT
Estonian workshop December 2015 Bedaquiline for Tuberculosis
schuneh@mcmaster.ca
Should bedaquiline plus BR vs. BR be used in MDR-TB patients?
PROJECT ADMINISTRA...
TASKS
TEAM
SCOPE
DOCUMENT SECTIONS
PROGNOSIS
COMPARISONS
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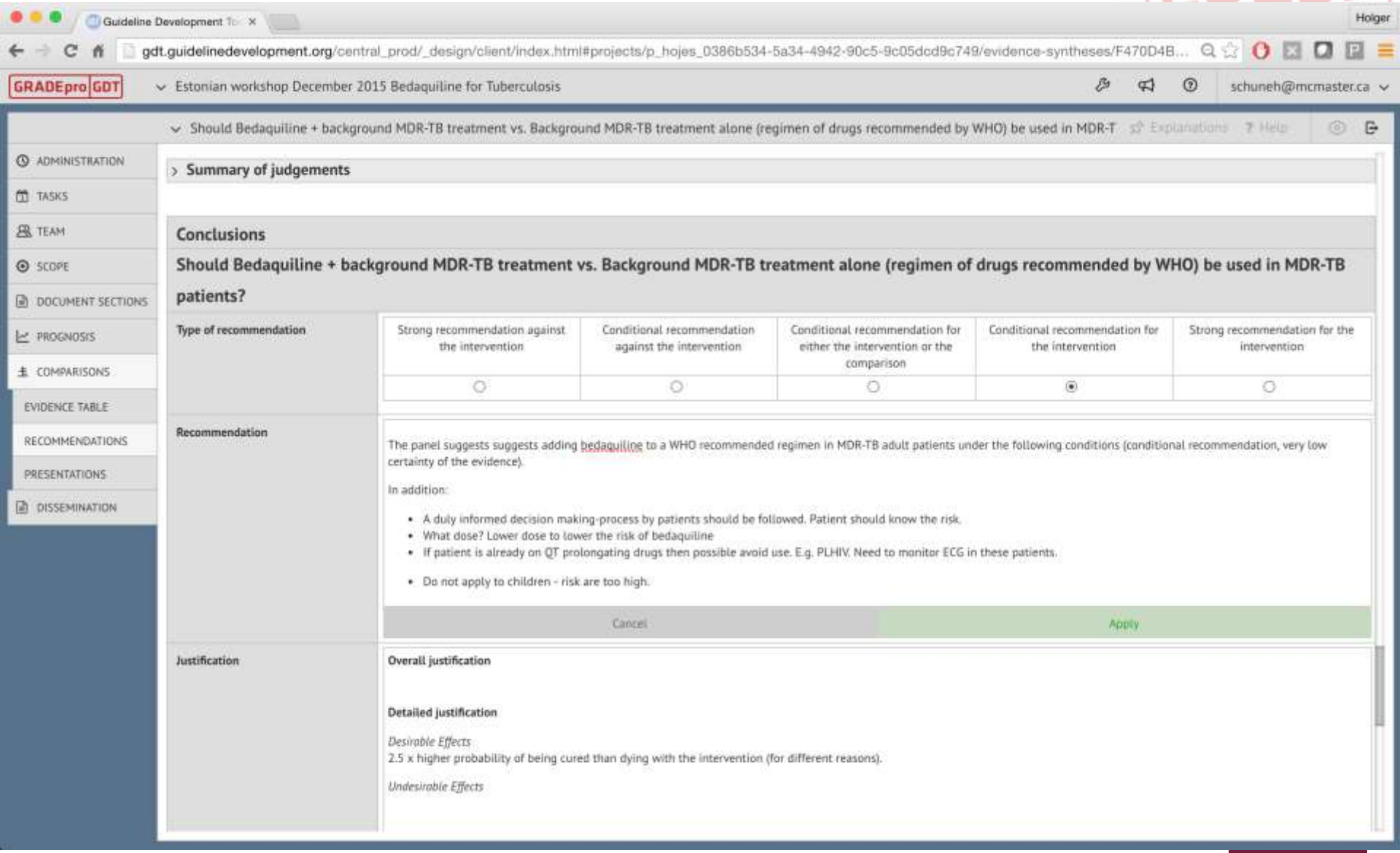
RECOMMENDATIONS
PRESENTATIONS OF ...
DISSEMINATION
Summary of judgements
CRITERIA
SUMMARY OF JUDGEMENTS
FAVORS background...
FAVORS bedaquilin...
IMPORTANCE FOR DECISION
PROBLEM
No
Probably no
Probably yes
Yes
Varies
Don't know
DESIRABLE EFFECTS
Trivial
Small
Moderate
Large
Varies
Don't know
UNDESIRABLE EFFECTS
Large
Moderate
Small
Trivial
Varies
Don't know
CERTAINTY OF EVIDENCE
Very low
Low
Moderate
High
No included studies
VALUES
Important uncertainty or...
Possibly important...
Probably no important...
No important uncertainty...
No known undesirable...
BALANCE OF EFFECTS
Favors the comparison
Probably favors the...
Does not favor either the...
Probably favors the...
Favors the intervention
Varies
Don't know
RESOURCES REQUIRED
Large costs
Moderate costs
Negligible costs and...
Moderate savings
Large savings
Varies
Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES
Very low
Low
Moderate
High
No included studies
COST EFFECTIVENESS
Favors the comparison
Probably favors the...
Does not favor either the...
Probably favors the...
Favors the intervention
Varies
No...
EQUITY
Reduced
Probably reduced
Probably no impact
Probably increased
Increased
Varies
Don't know
ACCEPTABILITY
No
Probably no
Probably yes
Yes
Varies
Don't know
FEASIBILITY
No
Probably no
Probably yes
Yes
Varies
Don't know


Guideline Development
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GRADEpro GDT
Estonian workshop December 2015 Bedaquiline for Tuberculosis
schuneh@mcmaster.ca
Should Bedaquiline + background MDR-TB treatment vs. Background MDR-TB treatment alone (regimen of drugs recommended by WHO) be used in MDR-T
Explanations
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TEAM
SCOPE
DOCUMENT SECTIONS
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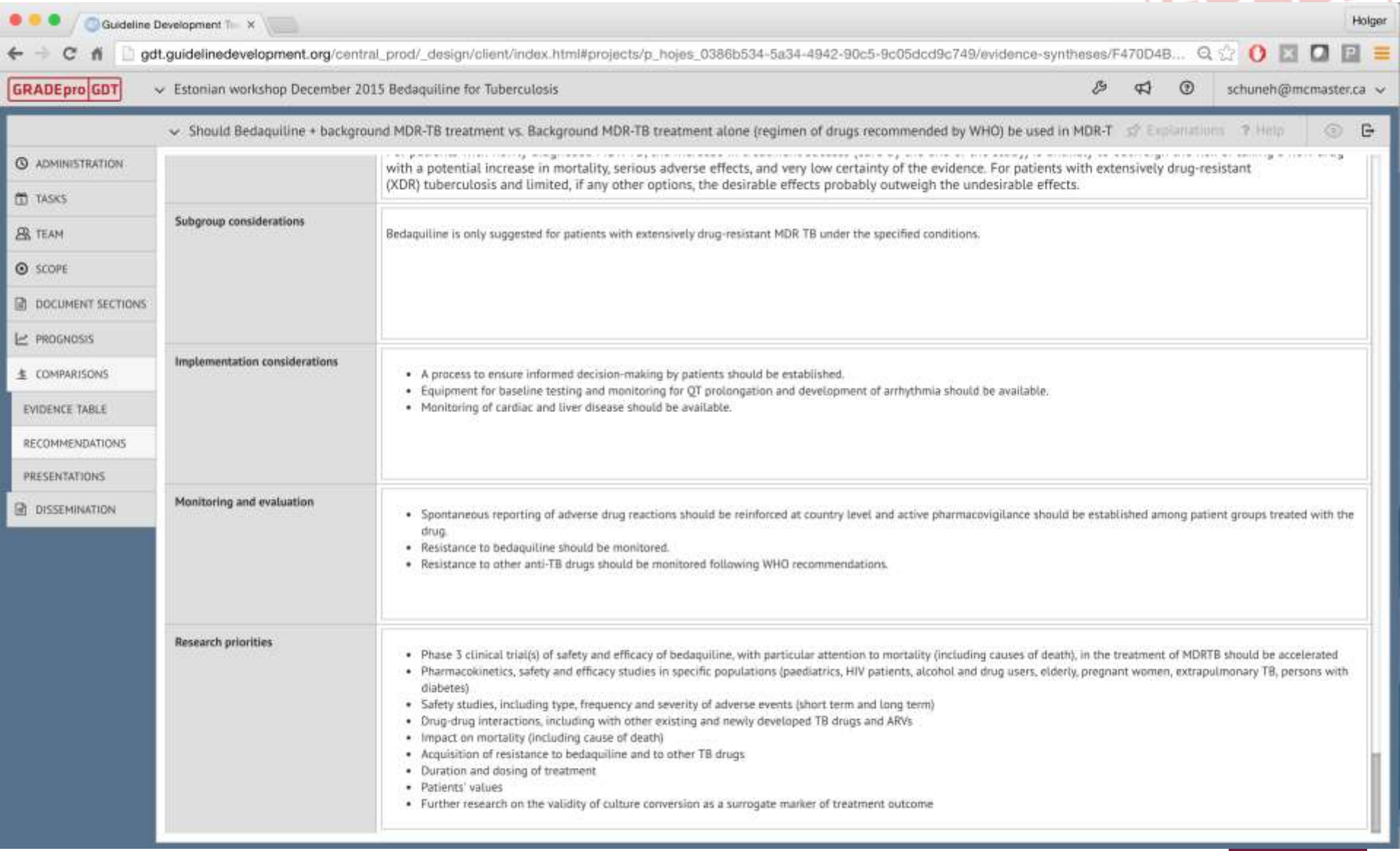
COMPARISONS
EVIDENCE TABLE
RECOMMENDATIONS
PRESENTATIONS
DISSEMINATION
Summary of judgements
Conclusions
Should Bedaquiline + background MDR-TB treatment vs. Background MDR-TB treatment alone (regimen of drugs recommended by WHO) be used in MDR-TB patients?
Type of recommendation
Strong recommendation against the intervention
Conditional recommendation against the intervention
Conditional recommendation for either the intervention or the comparison
Conditional recommendation for the intervention
Strong recommendation for the intervention
Recommendation
The panel suggests suggests adding bedaquiline to a WHO recommended regimen in MDR-TB adult patients under the following conditions (conditional recommendation, very low certainty of the evidence).
In addition:
A duly informed decision making-process by patients should be followed. Patient should know the risk.
What dose? Lower dose to lower the risk of bedaquiline
If patient is already on QT prolongating drugs then possible avoid use. E.g. PLHIV. Need to monitor ECG in these patients.
Do not apply to children - risk are too high.
Cancel
Apply
Justification
Overall justification
Detailed justification
Desirable Effects
2.5 x higher probability of being cured than dying with the intervention (for different reasons).
Undesirable Effects


Guideline Development
Holger
gdt.guidelinedevelopment.org/central_prod/_design/client/index.html#projects/p_hojes_0386b534-5a34-4942-90c5-9c05dcd9c749/evidence-syntheses/F470D4B...
GRADEpro GDT
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EVIDENCE TABLE
RECOMMENDATIONS
PRESENTATIONS
DISSEMINATION
with a potential increase in mortality, serious adverse effects, and very low certainty of the evidence. For patients with extensively drug-resistant (XDR) tuberculosis and limited, if any other options, the desirable effects probably outweigh the undesirable effects.
Subgroup considerations
Bedaquiline is only suggested for patients with extensively drug-resistant MDR TB under the specified conditions.
Implementation considerations
A process to ensure informed decision-making by patients should be established.
Equipment for baseline testing and monitoring for QT prolongation and development of arrhythmia should be available.
Monitoring of cardiac and liver disease should be available.
Monitoring and evaluation
Spontaneous reporting of adverse drug reactions should be reinforced at country level and active pharmacovigilance should be established among patient groups treated with the drug.
Resistance to bedaquiline should be monitored.
Resistance to other anti-TB drugs should be monitored following WHO recommendations.
Research priorities
Phase 3 clinical trial(s) of safety and efficacy of bedaquiline, with particular attention to mortality (including causes of death), in the treatment of MDRTB should be accelerated
Pharmacokinetics, safety and efficacy studies in specific populations (paediatrics, HIV patients, alcohol and drug users, elderly, pregnant women, extrapulmonary TB, persons with diabetes)
Safety studies, including type, frequency and severity of adverse events (short term and long term)
Drug-drug interactions, including with other existing and newly developed TB drugs and ARVs
Impact on mortality (including cause of death)
Acquisition of resistance to bedaquiline and to other TB drugs
Duration and dosing of treatment
Patients' values
Further research on the validity of culture conversion as a surrogate marker of treatment outcome

Live use of iEtDs

EtDs are shared with panel members before the meeting and online:

Clarify the process

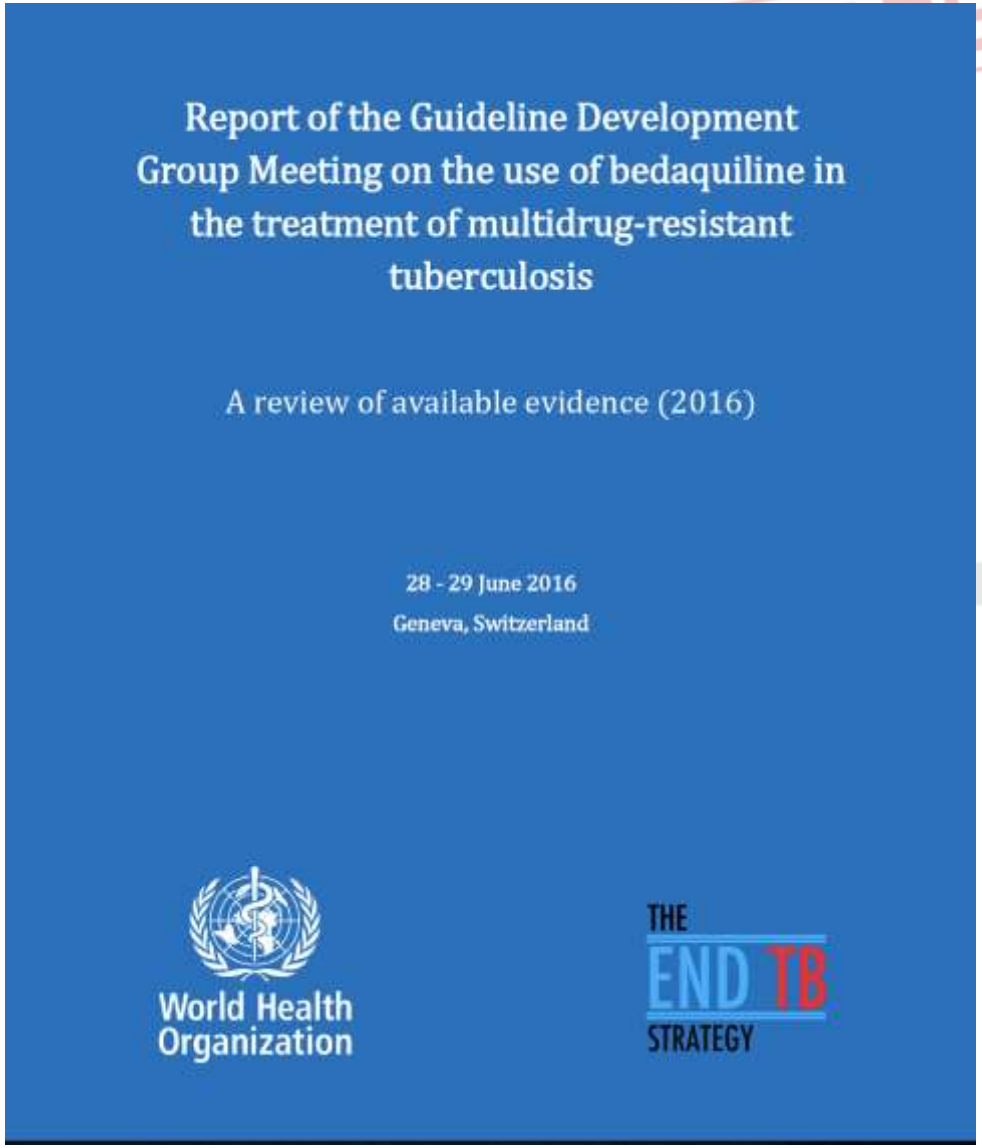
During the preparation for input on the evidence (all members including conflicted members could be involved)

For initial agreement on the included evidence and additional considerations

If possible, feasible and appropriate for agreement on judgments for specific decision criteria (but may all happen at an in-person meeting)

Final draft EtDs before a final meeting

Review of previous judgments and update through online tool



RESOURCES REQUIRED	**How large are the resource requirements (costs)?**	○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ◉ Varies ○ Don't know Detailed judgements	Cost data for the base case in each country were sourced from published studies [1], with additional supplementary data provided by study authors. For the primary estimates for the unit cost per patient treatment with Bedaquiline, a regimen cost of US $900 (for Global Fund Eligible countries) and US $3000 (for all other countries) was used for a full course of bedaquiline based on estimates from Janssen. In addition the costs of four electro-cardiograms were added. To estimate the possible cost savings from a shortened course with bedaquiline, the costs of an intensive phase of six months were estimated. Eight month intensive phase drug costs were adjusted to take into account reductions in hospitalization and required length of second-line parenteral agents (injectable anti-tuberculosis drugs). Where hospitalization was not used extensively in the intensive phase of treatment (Peru and Nepal), a reduction was made in the cost of clinic visits. All other costs (programme management, testing costs etc.) were conservatively assumed to remain the same as the non-shortened bedaquiline regimen.	
REQUIRED RESOURCES	**What is the certainty of the evidence of resource requirements (costs)?**	◉ Very low ○ Low ○ Moderate ○ High ○ No included studies Detailed judgements	Results were ambiguous in low-income settings, and highly dependent on the assumptions made about the generalizability of trial results to routine settings. The expert group noted that further analysis would be needed to test the robustness of the assumptions in various settings and to separately assess affordability [1].	

European Commission Initiative on Breast Cancer and ARIA (allergy)

Live decision-making for guidelines

Presentation formats of recommendations

Breast cancer services quality

Holger

ecibc.jrc.ec.europa.eu/home

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EC Initiative on Breast Cancer (ECIBC)

Guidelines and Quality Assurance scheme for Breast Cancer

The European Commission, in response to the Council of the European Union's conclusions on reducing the burden of cancer, initiated a ground-breaking

Report of a European Survey on the Implementation of Breast Units

Breast units implementation? À la carte, survey says. Breast units patchy panorama confirms ECIBC evidence-based approach is needed.

European Breast Guidelines

ECIBC recommendations for breast cancer screening and diagnosis.

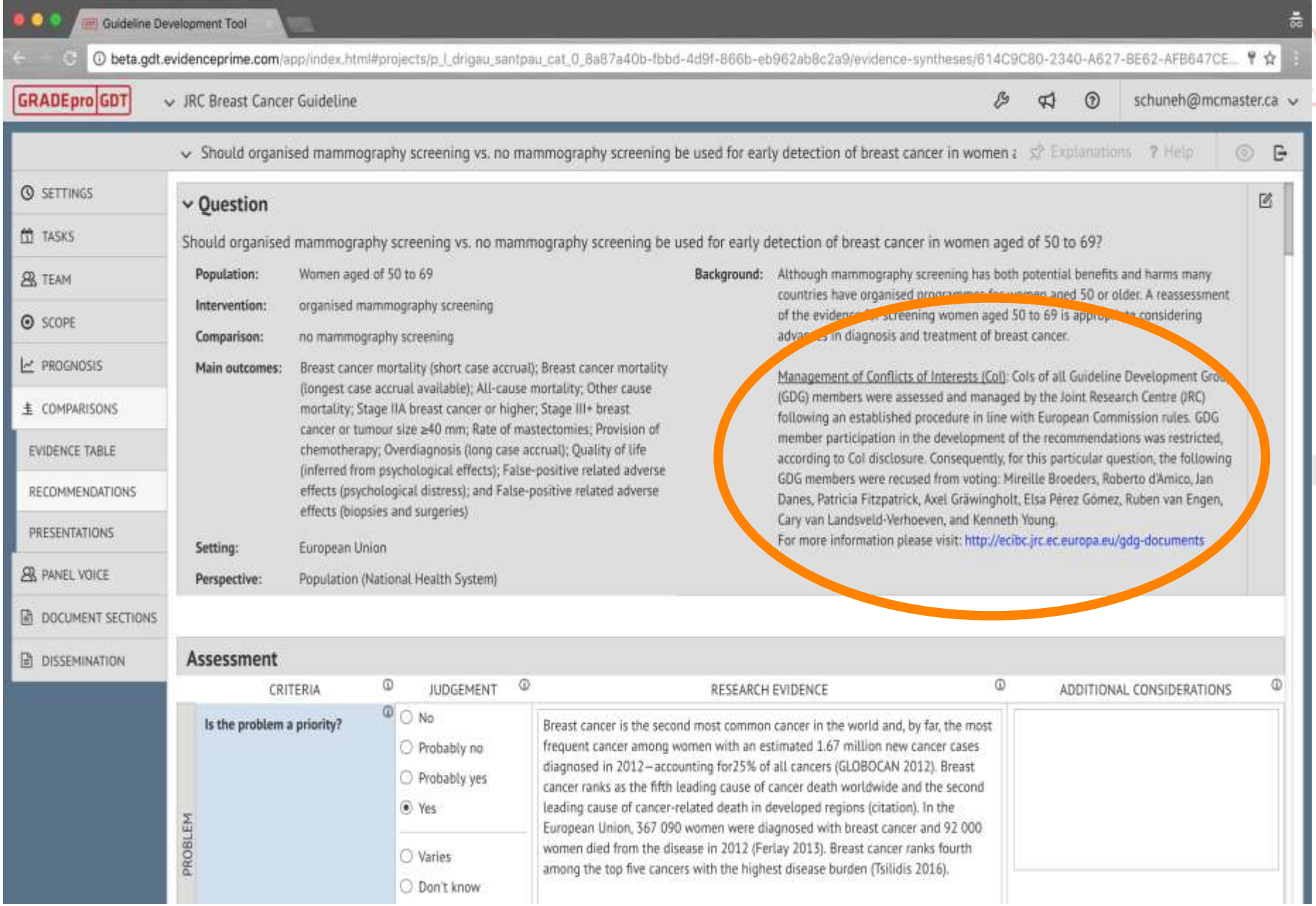
Breast Cancer screening recommendations for different age groups by the European Commission

For asymptomatic women aged **40 to 44** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **suggests not implementing mammography screening** (conditional recommendation, moderate certainty in the evidence).

For asymptomatic women aged **45 to 49** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **suggests mammography screening** over no mammography screening, in the context of an organised screening programme (conditional recommendation, moderate certainty in the evidence).

For asymptomatic women aged **50 to 69** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **recommends mammography screening** over no mammography screening, in the context of an organised screening programme (strong recommendation, moderate certainty in the evidence).

For asymptomatic women aged **70 to 74** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **suggests mammography screening** over no mammography screening, in the context of an organised screening programme (conditional recommendation, moderate certainty in the evidence).


Guideline Development Tool
beta.gdt.evidenceprime.com/app/index.html#projects/p_l_drigau_santpau_cat_0_8a87a40b-fbbd-4d9f-866b-eb962ab8c2a9/evidence-syntheses/614C9C80-2340-A627-BE62-AFB647CE...
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JRC Breast Cancer Guideline
schuneh@mcmaster.ca
Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women a
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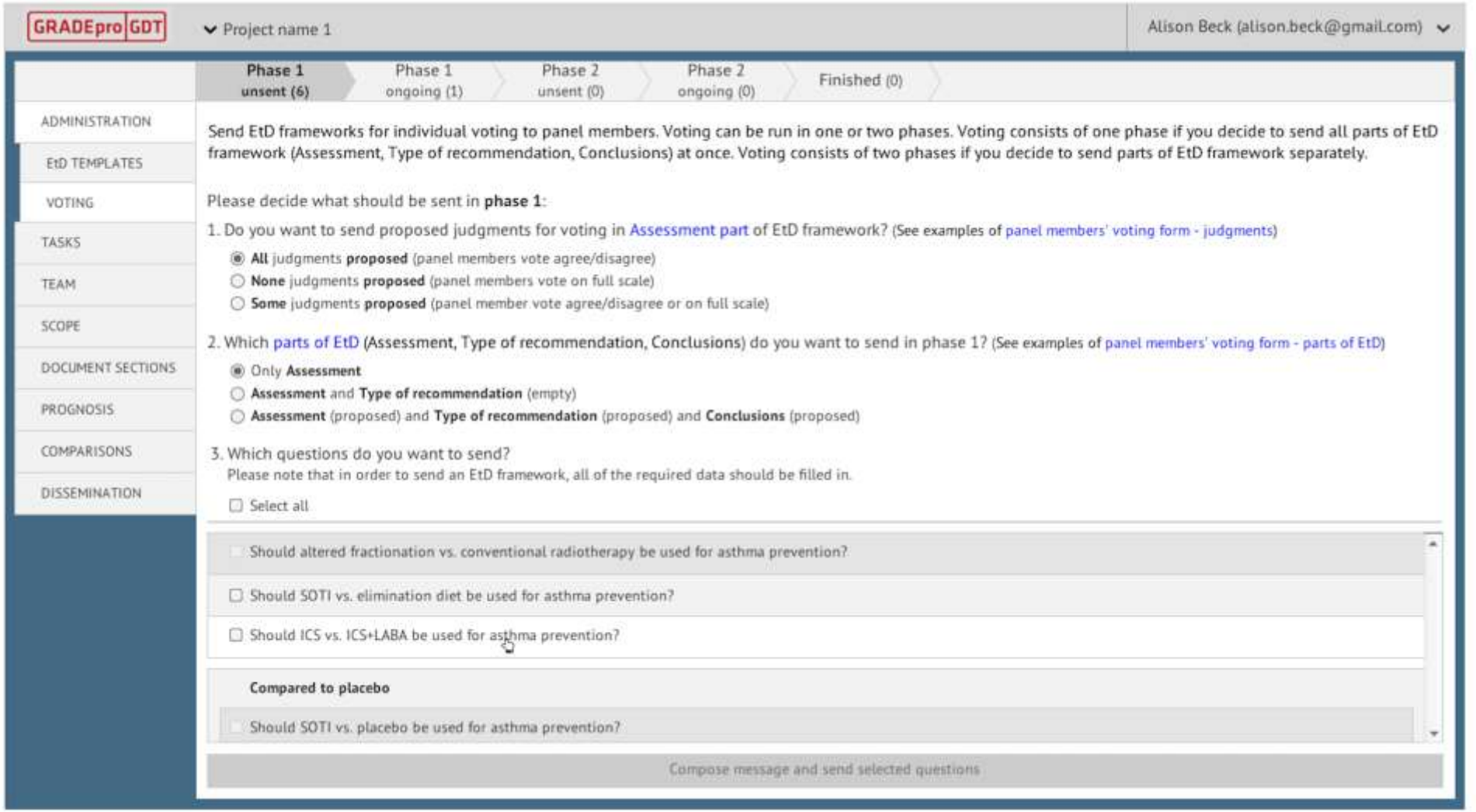
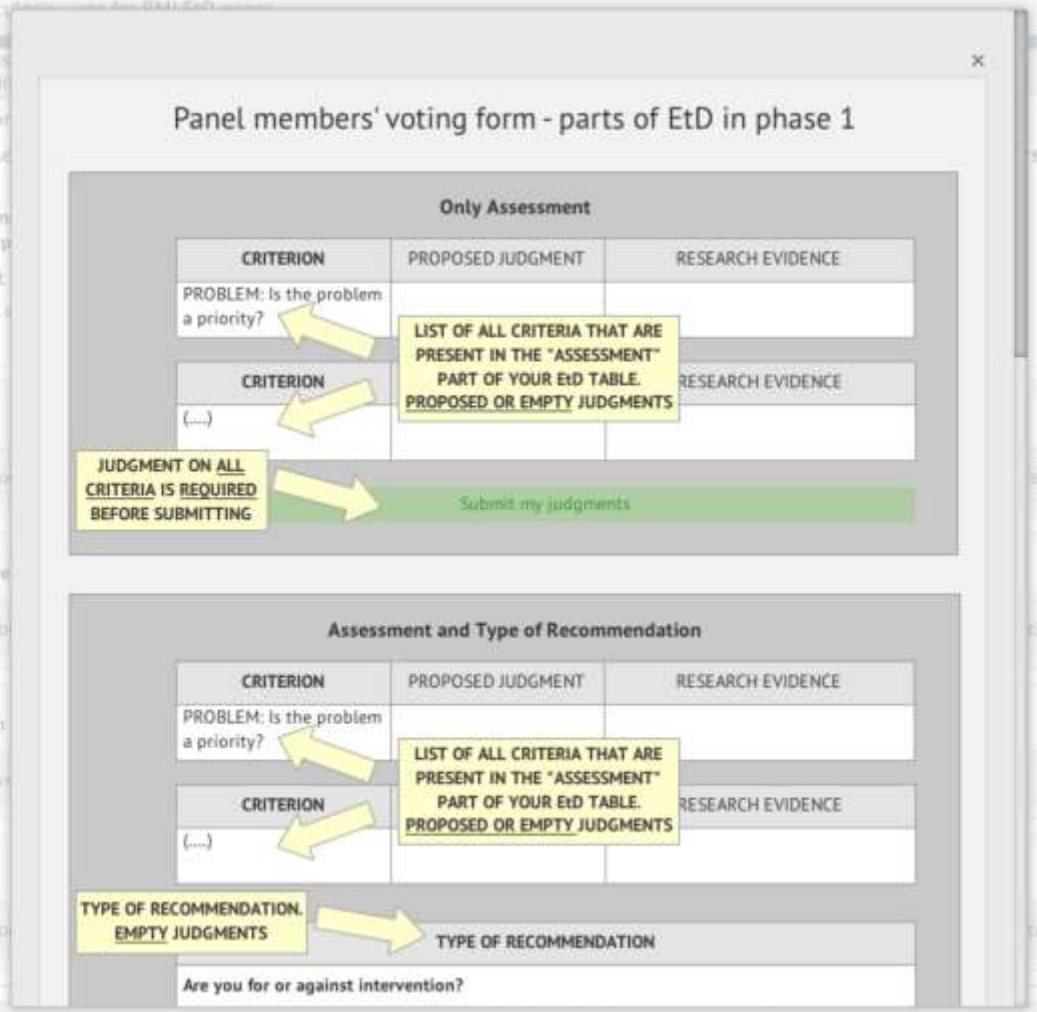
Question
Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged of 50 to 69?
Population: Women aged of 50 to 69
Intervention: organised mammography screening
Comparison: no mammography screening
Main outcomes: Breast cancer mortality (short case accrual); Breast cancer mortality (longest case accrual available); All-cause mortality; Other cause mortality; Stage IIA breast cancer or higher; Stage III+ breast cancer or tumour size ≥40 mm; Rate of mastectomies; Provision of chemotherapy; Overdiagnosis (long case accrual); Quality of life (inferred from psychological effects); False-positive related adverse effects (psychological distress); and False-positive related adverse effects (biopsies and surgeries)
Setting: European Union
Perspective: Population (National Health System)
Background: Although mammography screening has both potential benefits and harms many countries have organised
in diagnosis and treatment of breast cancer.
Management of Conflicts of Interests (CoI): CoIs of all Guideline Development Group (GDG) members were assessed and managed by the Joint Research Centre (JRC) following an established procedure in line with European Commission rules. GDG member participation in the development of the recommendations was restricted, according to CoI disclosure. Consequently, for this particular question, the following GDG members were recused from voting: Mireille Broeders, Roberto d'Amico, Jan Danes, Patricia Fitzpatrick, Axel Gräwingholt, Elsa Pérez Gómez, Ruben van Engen, Cary van Landsveld-Verhoeven, and Kenneth Young.
For more information please visit: http://ecibc.jrc.ec.europa.eu/gdg-documents
Assessment
CRITERIA
JUDGEMENT
RESEARCH EVIDENCE
ADDITIONAL CONSIDERATIONS
PROBLEM
Is the problem a priority?
No
Probably no
Probably yes
Yes
Varies
Don't know
Breast cancer is the second most common cancer in the world and, by far, the most frequent cancer among women with an estimated 1.67 million new cancer cases diagnosed in 2012—accounting for25% of all cancers (GLOBOCAN 2012). Breast cancer ranks as the fifth leading cause of cancer death worldwide and the second leading cause of cancer-related death in developed regions (citation). In the European Union, 367 090 women were diagnosed with breast cancer and 92 000 women died from the disease in 2012 (Ferlay 2013). Breast cancer ranks fourth among the top five cancers with the highest disease burden (Tsilidis 2016).

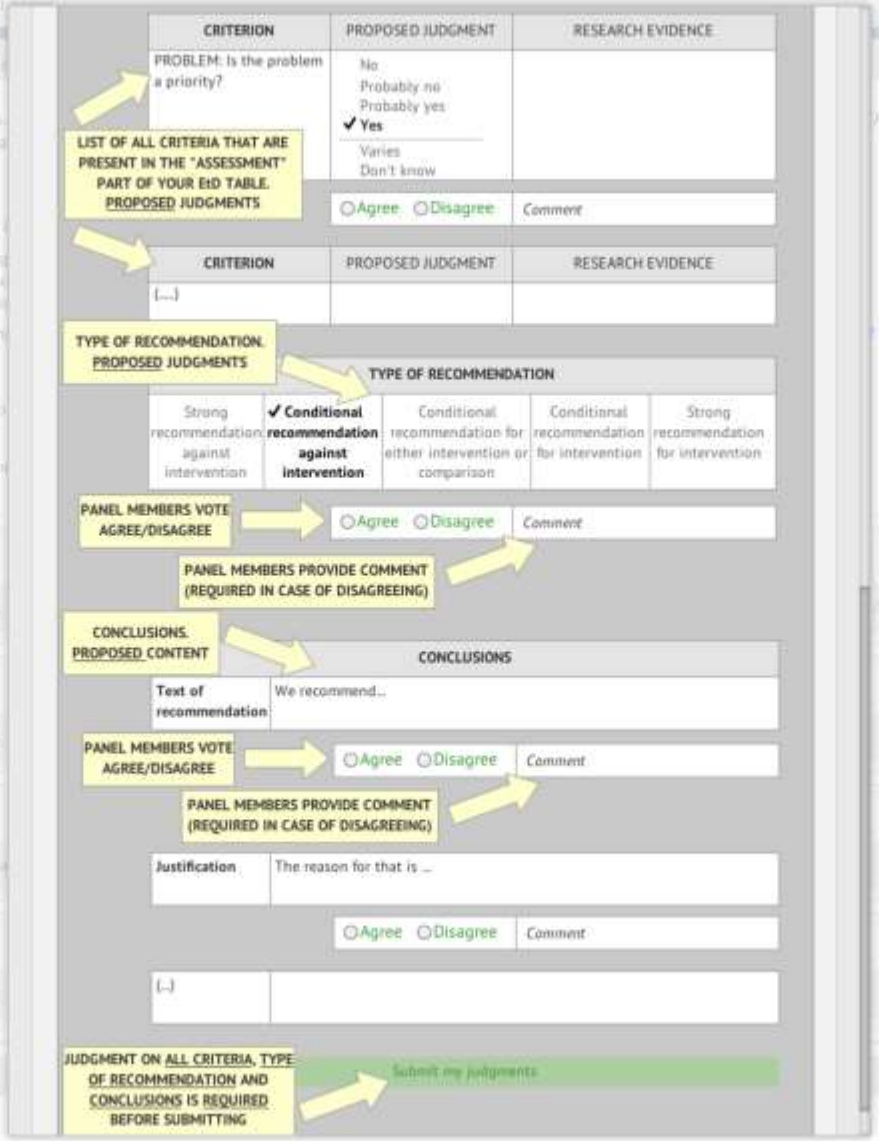
Online interaction of panel



Online agreement



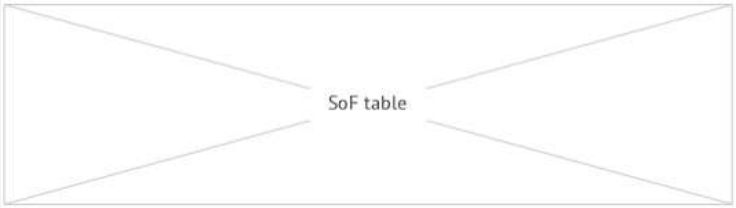
Online agreement



cases are SAR, 40% of cases are perennial rhinitis, and 40% of cases are mixed (Skoner 2001).

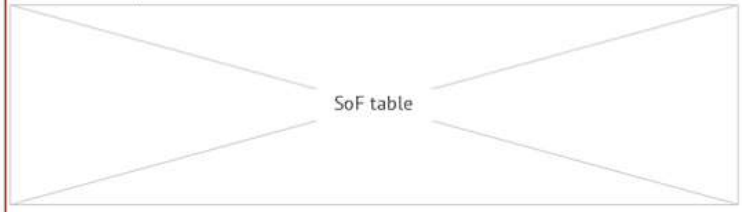
Comment

Provide a reason for your decision or other comments

CRITERION	YOUR JUDGMENT	RESEARCH EVIDENCE
DESIRABLE EFFECTS: **How substantial are the desirable anticipated effects?**	○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	**The relative importance or values of the main outcomes of interest:** 

Comment

Provide a reason for your decision or other comments

CRITERION	YOUR JUDGMENT	RESEARCH EVIDENCE
UNDESIRABLE EFFECTS: **How substantial are the undesirable anticipated effects?**	○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	**The relative importance or values of the main outcomes of interest:** 

Judgment is required.

Comment

Provide a reason for your decision or other comments

Save

Save and submit

Voting on "Assessment" part when judgments are empty.

Question: Should ICS vs. ICS+LABA be used for asthma prevention?

Population: Adults with asthma

Intervention: ICS

Comparison: ICS+LABA

Main outcomes: Any AE (95% CI); Any AE (99% CI); Any AE (90% CI);

Setting: Global

Perspective: Patient

Evidence to Decision framework

Instructions

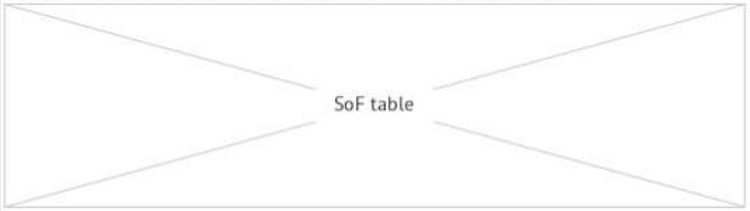
CRITERION	PROPOSED JUDGMENT	RESEARCH EVIDENCE
PROBLEM: **Is the problem a priority?**	No Probably no Probably yes ✓ **Yes** Varies Don't know	AR is a worldwide common disease in children and adolescents. Although the great majority of the cases begin during childhood, its prevalence changes throughout the life. The overall prevalence of AR is 14.6% (range 1.0 to 45%) in 13-14 years old children, and for the 6 to 7 years old children is 8.5% (range 4.2-12.7%) (Ait-Khaled 2009). Some studies have shown that the overall prevalence in adult patients with AR clinically confirmed is between 17% to 30%, with an overall value of 23% in Europe (Bauchau 2004, Cingi 2010), a range between 8 to 21% in China (Zhang 2009), and approximately 7% in Latin America (Izquierdo 2013). The distribution of SAR vs Perennial is more difficult to estimate because it varies among studies and among countries, being similar in some countries, while in others they are not. In the United States it has been estimated that 20% of cases are SAR, 40% of cases are perennial rhinitis, and 40% of cases are mixed (Skoner 2001).

○Agree ○Disagree

Comment*

Provide a reason for your decision or other comments

Comment is required. Please give the reason for disagreeing.

CRITERION	PROPOSED JUDGMENT	RESEARCH EVIDENCE
DESIRABLE EFFECTS: **How substantial are the desirable anticipated effects?**	Trivial Small ✓ **Moderate** Large Varies Don't know	**The relative importance or values of the main outcomes of interest:** 

○Agree ○Disagree

Comment

Provide a reason for your decision or other comments

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European Commission > EU Science Hub > ECIBC > Recommendations

Home | Recommendations

Recommendations on Breast Cance

Read me

General Information

I'm a patient/individual

I'm a policy maker

If you are aged 40 to 44, should you attend an organised mammography screening programme?

Recommendation | Justification | Considerations | Assessment | Bibliography

Recommendation

The ECIBC guidelines suggests not providing mammography screening to women between 40 and 44 years old who are at average risk of breast cancer and do not have symptoms.

Recommendation strength

Conditional recommendation against the intervention*

Recommendations on Breast Cancer Screening

Read me | I'm a patient/individual | I'm a professional | I'm a policy maker

General Information

Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged 40 to 44?

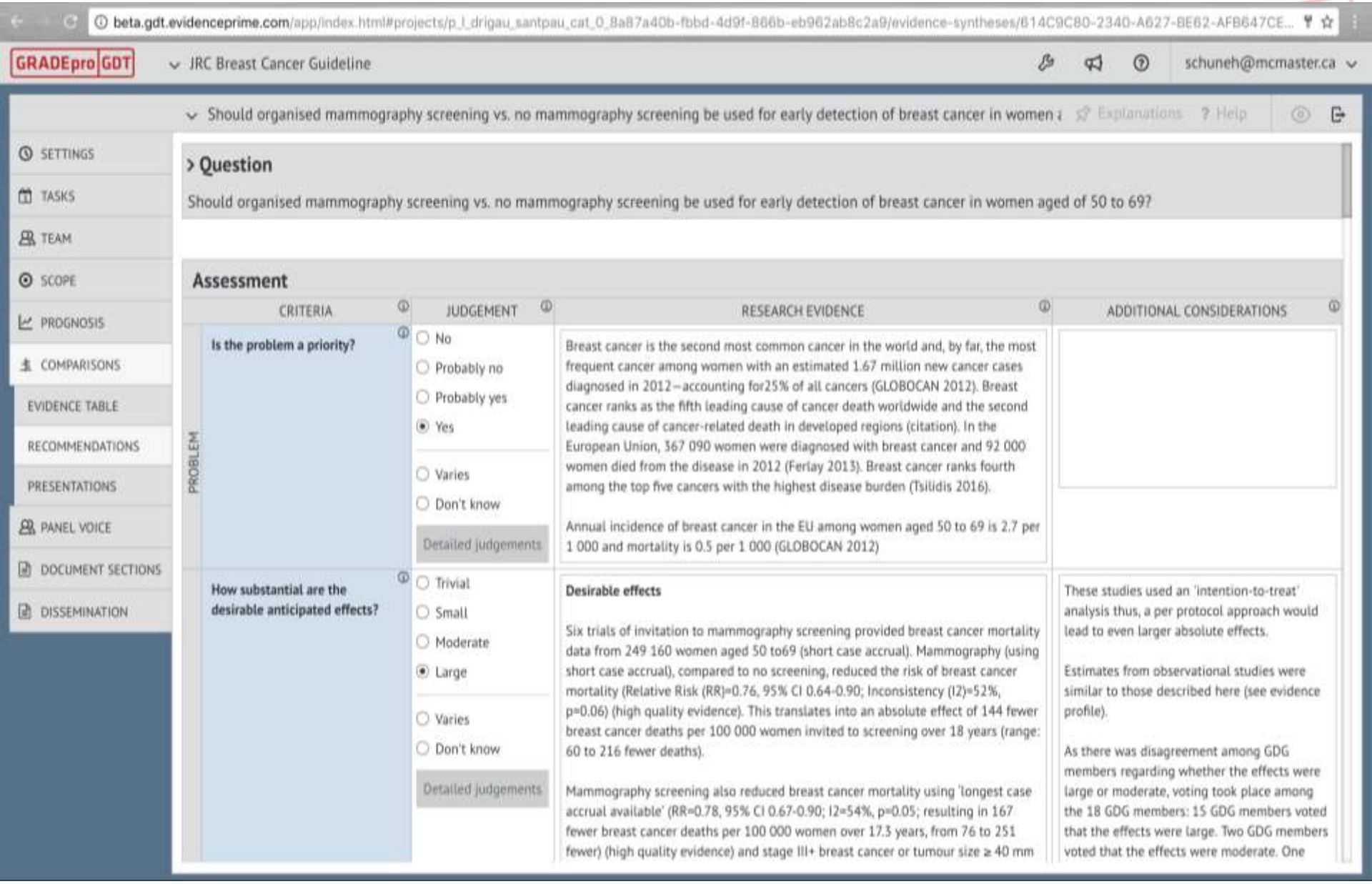
Recommendation | Justification | Considerations | Assessment | Bibliography

Recommendation

For asymptomatic women aged 40 to 44 with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests not implementing mammography screening (conditional recommendation, moderate certainty in the evidence).

Recommendation strength

Conditional recommendation against the intervention*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GRADEpro GDT
JRC Breast Cancer Guideline
schuneh@mcmaster.ca
Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women a
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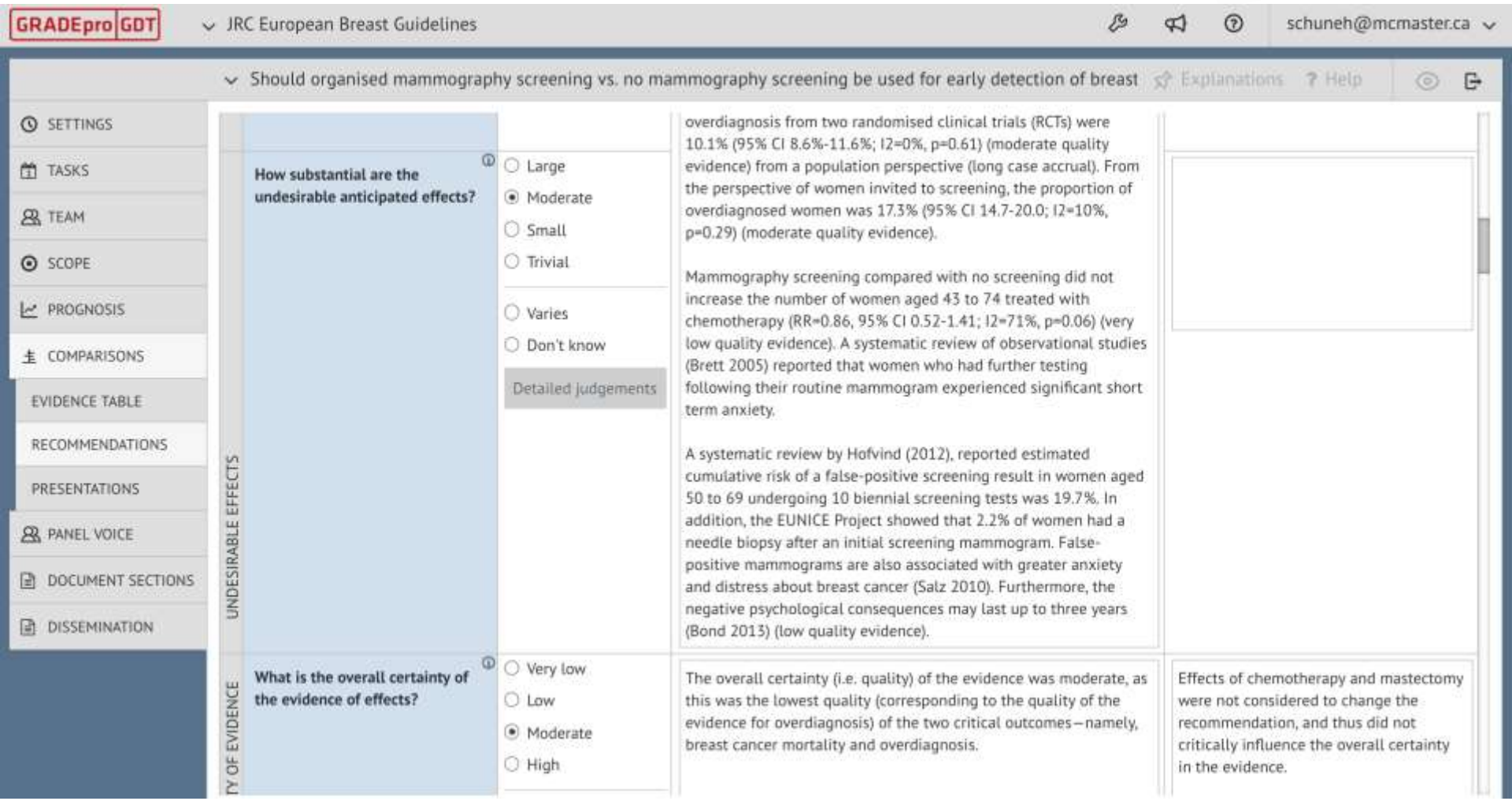
DOCUMENT SECTIONS
DISSEMINATION
Question
Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged of 50 to 69?
Assessment
CRITERIA
JUDGEMENT
RESEARCH EVIDENCE
ADDITIONAL CONSIDERATIONS
PROBLEM
Is the problem a priority?
No
Probably no
Probably yes
Yes
Varies
Don't know
Detailed judgements
Breast cancer is the second most common cancer in the world and, by far, the most frequent cancer among women with an estimated 1.67 million new cancer cases diagnosed in 2012—accounting for25% of all cancers (GLOBOCAN 2012). Breast cancer ranks as the fifth leading cause of cancer death worldwide and the second leading cause of cancer-related death in developed regions (citation). In the European Union, 367 090 women were diagnosed with breast cancer and 92 000 women died from the disease in 2012 (Ferlay 2013). Breast cancer ranks fourth among the top five cancers with the highest disease burden (Tsilidis 2016).
Annual incidence of breast cancer in the EU among women aged 50 to 69 is 2.7 per 1 000 and mortality is 0.5 per 1 000 (GLOBOCAN 2012)
How substantial are the desirable anticipated effects?
Trivial
Small
Moderate
Large
Varies
Don't know
Detailed judgements
Desirable effects
Six trials of invitation to mammography screening provided breast cancer mortality data from 249 160 women aged 50 to69 (short case accrual). Mammography (using short case accrual), compared to no screening, reduced the risk of breast cancer mortality (Relative Risk (RR)=0.76, 95% CI 0.64-0.90; Inconsistency (I2)=52%, p=0.06) (high quality evidence). This translates into an absolute effect of 144 fewer breast cancer deaths per 100 000 women invited to screening over 18 years (range: 60 to 216 fewer deaths).
Mammography screening also reduced breast cancer mortality using 'longest case accrual available' (RR=0.78, 95% CI 0.67-0.90; I2=54%, p=0.05; resulting in 167 fewer breast cancer deaths per 100 000 women over 17.3 years, from 76 to 251 fewer) (high quality evidence) and stage III+ breast cancer or tumour size ≥ 40 mm
These studies used an 'intention-to-treat' analysis thus, a per protocol approach would lead to even larger absolute effects.
Estimates from observational studies were similar to those described here (see evidence profile).
As there was disagreement among GDG members regarding whether the effects were large or moderate, voting took place among the 18 GDG members: 15 GDG members voted that the effects were large. Two GDG members voted that the effects were moderate. One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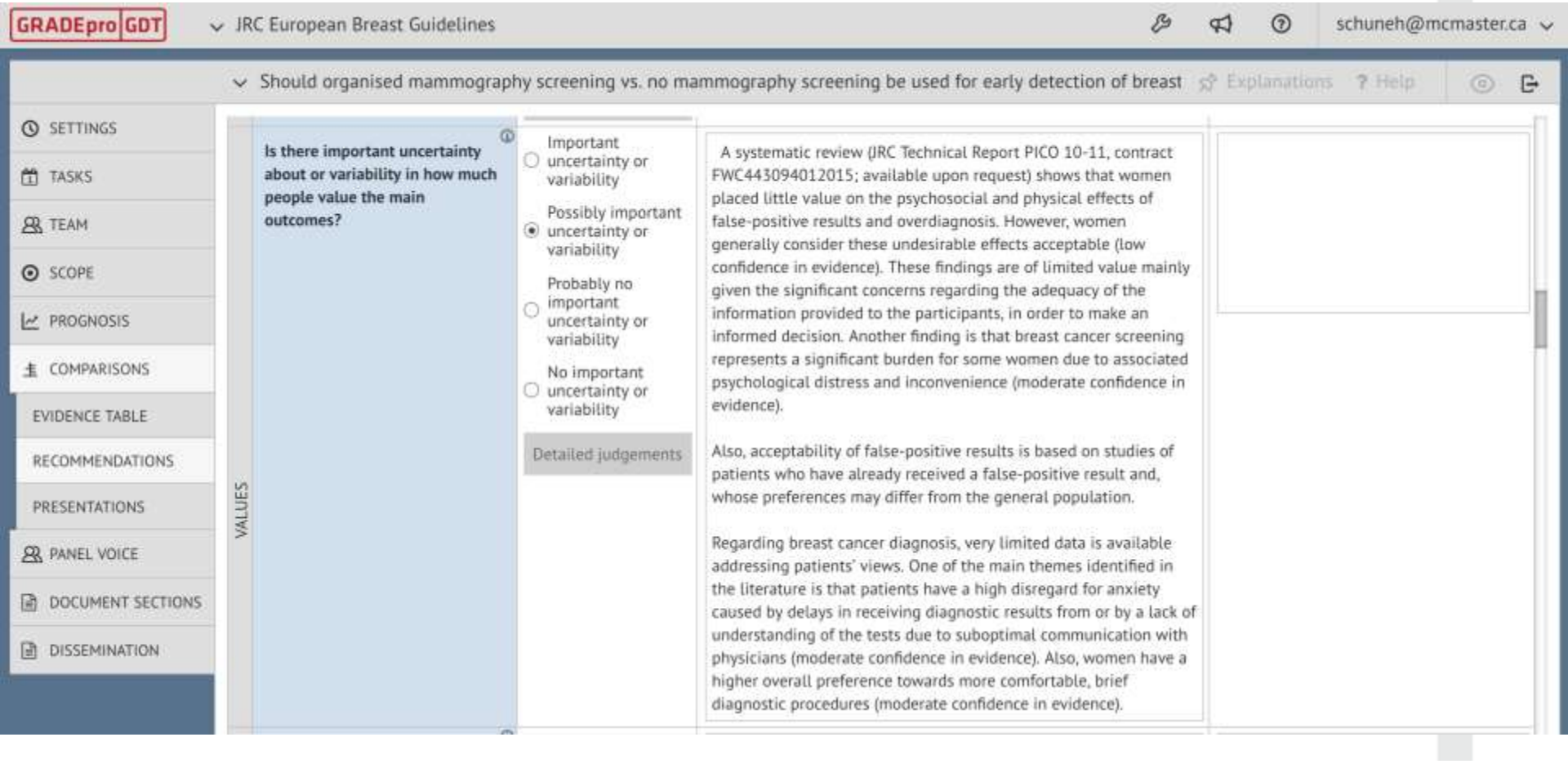
DISSEMINATION
UNDESIRABLE EFFECTS
How substantial are the undesirable anticipated effects?
Large
Moderate
Small
Trivial
Varies
Don't know
Detailed judgements
overdiagnosis from two randomised clinical trials (RCTs) were 10.1% (95% CI 8.6%-11.6%; I2=0%, p=0.61) (moderate quality evidence) from a population perspective (long case accrual). From the perspective of women invited to screening, the proportion of overdiagnosed women was 17.3% (95% CI 14.7-20.0; I2=10%, p=0.29) (moderate quality evidence).
Mammography screening compared with no screening did not increase the number of women aged 43 to 74 treated with chemotherapy (RR=0.86, 95% CI 0.52-1.41; I2=71%, p=0.06) (very low quality evidence). A systematic review of observational studies (Brett 2005) reported that women who had further testing following their routine mammogram experienced significant short term anxiety.
A systematic review by Hofvind (2012), reported estimated cumulative risk of a false-positive screening result in women aged 50 to 69 undergoing 10 biennial screening tests was 19.7%. In addition, the EUNICE Project showed that 2.2% of women had a needle biopsy after an initial screening mammogram. False-positive mammograms are also associated with greater anxiety and distress about breast cancer (Salz 2010). Furthermore, the negative psychological consequences may last up to three years (Bond 2013) (low quality evidence).
TY OF EVIDENCE
What is the overall certainty of the evidence of effects?
Very low
Low
Moderate
High
The overall certainty (i.e. quality) of the evidence was moderate, as this was the lowest quality (corresponding to the quality of the evidence for overdiagnosis) of the two critical outcomes—namely, breast cancer mortality and overdiagnosis.
Effects of chemotherapy and mastectomy were not considered to change the recommendation, and thus did not critically influence the overall certainty in the evidence.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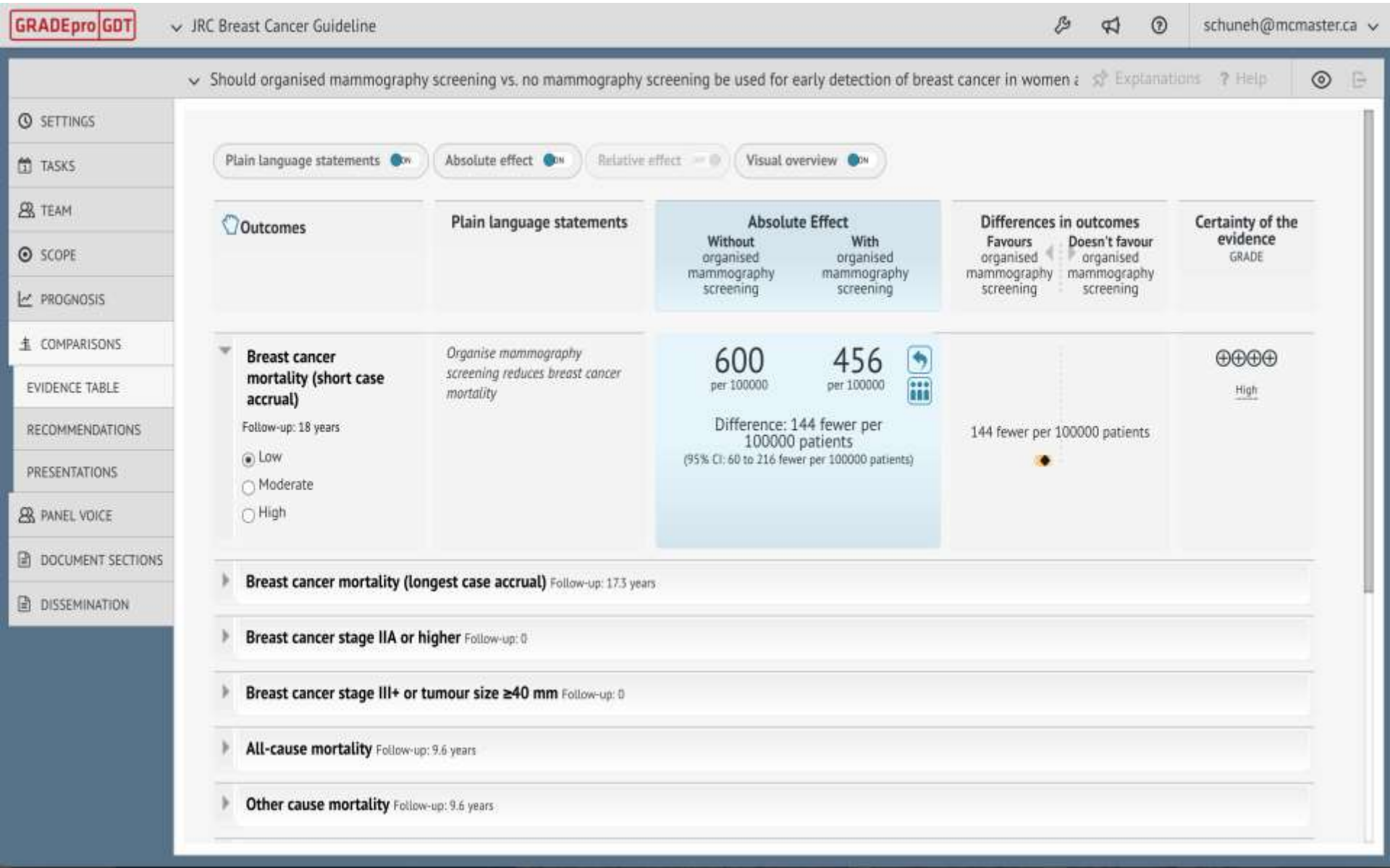
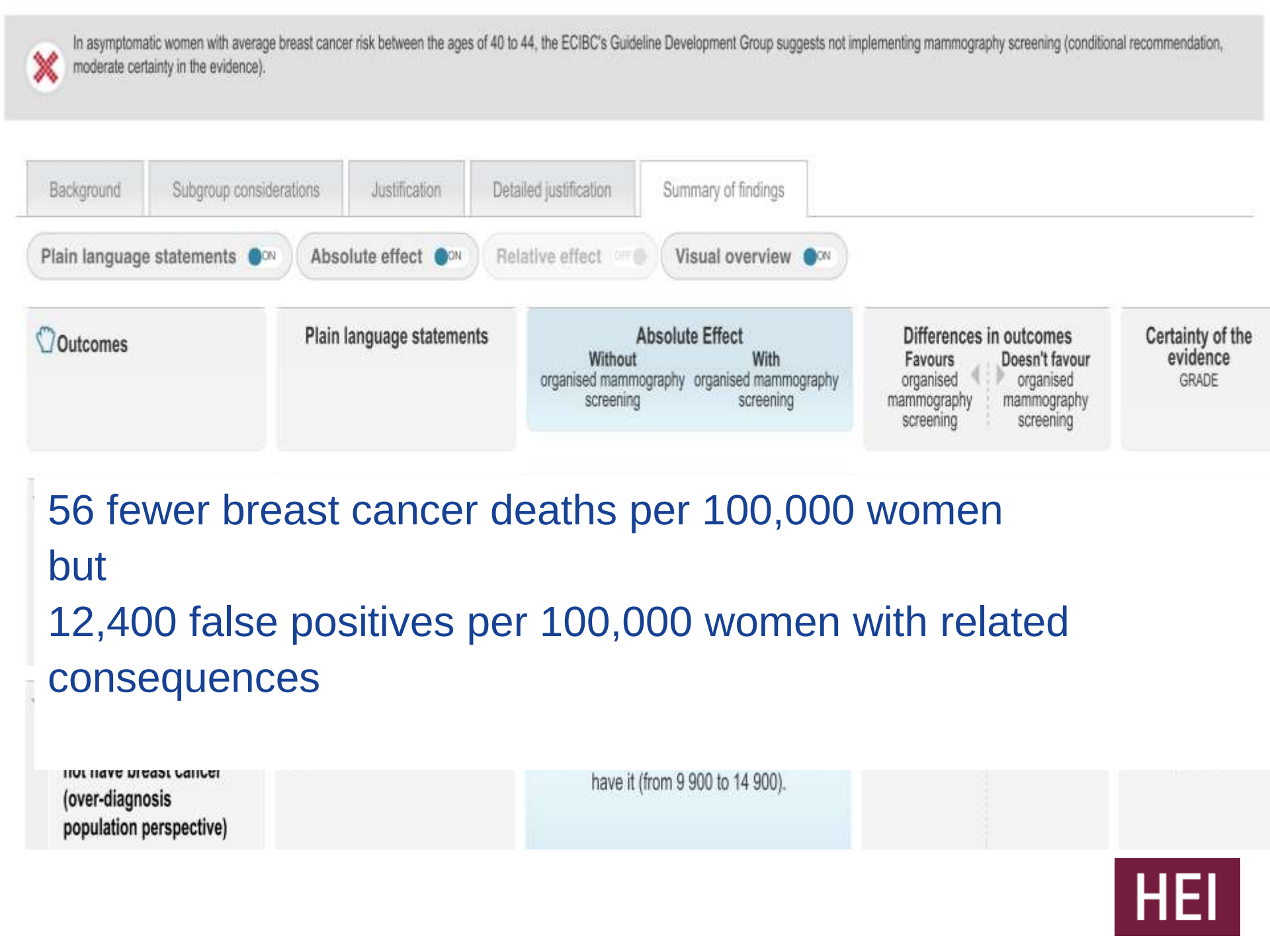
DISSEMINATION
VALUES
Is there important uncertainty about or variability in how much people value the main outcomes?
Important uncertainty or variability
Possibly important uncertainty or variability
Probably no important uncertainty or variability
No important uncertainty or variability
Detailed judgements
A systematic review (JRC Technical Report PICO 10-11, contract FWC443094012015; available upon request) shows that women placed little value on the psychosocial and physical effects of false-positive results and overdiagnosis. However, women generally consider these undesirable effects acceptable (low confidence in evidence). These findings are of limited value mainly given the significant concerns regarding the adequacy of the information provided to the participants, in order to make an informed decision. Another finding is that breast cancer screening represents a significant burden for some women due to associated psychological distress and inconvenience (moderate confidence in evidence).
Also, acceptability of false-positive results is based on studies of patients who have already received a false-positive result and, whose preferences may differ from the general population.
Regarding breast cancer diagnosis, very limited data is available addressing patients' views. One of the main themes identified in the literature is that patients have a high disregard for anxiety caused by delays in receiving diagnostic results from or by a lack of understanding of the tests due to suboptimal communication with physicians (moderate confidence in evidence). Also, women have a higher overall preference towards more comfortable, brief diagnostic procedures (moderate confidence in evidence).

Is there important uncertainty about or variability in how much people value the main outcomes?	○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ◉ No important uncertainty or variability Detailed judgements	**The relative importance of the outcomes is as follows:** **Pulmonary embolism: 0.63-0.93** **Deep vein thrombosis: 0.64-0.99** **Deep vein thrombosis patients' own current health: 0.95 (Time trade off)** Patients highly value the benefits of VTE risk reduction of VTE prophylaxis; patients would like to avoid adverse events but most of them are "not afraid of" the adverse events. For patients using mechanical methods to prevent VTE, in general patients would like to continue with the same methods. However, discomfort with the mechanical methods is a major complaint with this intervention. Most patients prefer knee-length stockings rather than thigh-length stockings.	The tolerability of the stockings was described as very good with no complaints of side effects. None of the other trials reported adverse effects of wearing the stockings (**Clarke et al., 2016**). For patients using any mechanical methods to prevent VTE, in general, they would like to continue with the same methods. Most patients prefer knee-length stockings rather than thigh-length stockings.

The panel evaluated the effects of screening




In asymptomatic women with average breast cancer risk between the ages of 40 to 44, the ECIBC's Guideline Development Group suggests not implementing mammography screening (conditional recommendation, moderate certainty in the evidence).
Background
Subgroup considerations
Justification
Detailed justification
Summary of findings
Plain language statements ON
Absolute effect ON
Relative effect OFF
Visual overview ON
Outcomes
Plain language statements
Absolute Effect
Without organised mammography screening
With organised mammography screening
Differences in outcomes
Favours organised mammography screening
Doesn't favour organised mammography screening
Certainty of the evidence
GRADE
56 fewer breast cancer deaths per 100,000 women
but
12,400 false positives per 100,000 women with related consequences
(over-diagnosis
population perspective)
have it (from 9 900 to 14 900).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Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged of 50 to 69?
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DISSEMINATION
CRITERIA
SUMMARY OF JUDGEMENTS
FAVORS no mammogr...
FAVORS
IMPORTANCE FOR DECISION
PROBLEM
No
Probably no
Probably yes
Yes
Varies
Don't know
DESIRABLE EFFECTS
Trivial
Small
Moderate
Large
UNDESIRABLE EFFECTS
Large
Moderate
Small
Trivial
CERTAINTY OF EVIDENCE
Very low
Low
Moderate
High
No included studies
VALUES
Important uncertainty or...
Possibly important...
Probably no important...
No important uncertainty...
BALANCE OF EFFECTS
Favors the comparison
Probably favors the...
Probably favors the...
Favors the intervention
RESOURCES REQUIRED
Large costs
Moderate costs
Moderate savings
Large savings
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES
Very low
Low
Moderate
High
No included studies
COST EFFECTIVENESS
Favors the comparison
Probably favors the...
Probably favors the...
Favors the intervention
Varies
EQUITY
Reduced
Probably reduced
Probably increased
Increased
Varies
Don't know
ACCEPTABILITY
No
Probably no
Probably yes
Yes
Varies
Don't know
FEASIBILITY
No
Probably no
Probably yes
Yes
Varies
Don't know
Conclusions
Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged of 50 to 69?
Type of recommendation
Strong recommendation against the intervention
Conditional recommendation against the intervention
Conditional recommendation for either the intervention or the comparison
Conditional recommendation for the intervention
Strong recommendation for the intervention
Recommendation
For asymptomatic women aged 50 to 69 with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) recommends mammography screening over no mammography screening, in the context of an organised screening programme (strong recommendation, moderate certainty in the evidence).

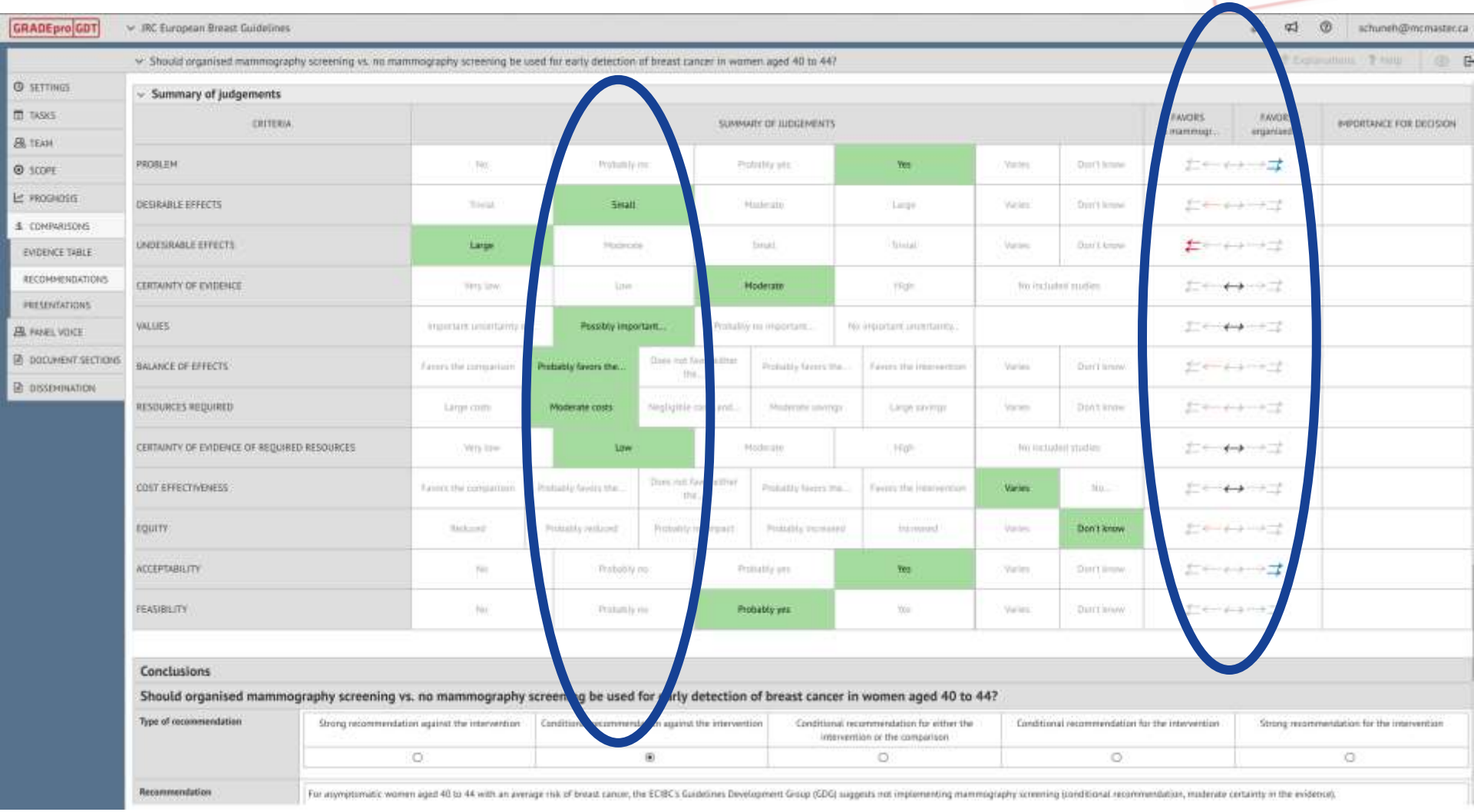
What about younger women

For asymptomatic women aged **40 to 44** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **suggests not implementing mammography screening** (conditional recommendation, moderate certainty in the evidence).

For asymptomatic women aged **45 to 49** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **suggests mammography screening** over no mammography screening, in the context of an organised screening programme (conditional recommendation, moderate certainty in the evidence).

For asymptomatic women aged **50 to 69** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **recommends mammography screening** over no mammography screening, in the context of an organised screening programme (strong recommendation, moderate certainty in the evidence).

For asymptomatic women aged **70 to 74** with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) **suggests mammography screening** over no mammography screening, in the context of an organised screening programme (conditional recommendation, moderate certainty in the evidence).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Summary of judgements
CRITERIA
SUMMARY OF JUDGEMENTS
IMPORTANCE FOR DECISION
PROBLEM
Yes
DESIRABLE EFFECTS
Small
UNDESIRABLE EFFECTS
Large
CERTAINTY OF EVIDENCE
Moderate
VALUES
Possibly important...
BALANCE OF EFFECTS
Probably favors the...
RESOURCES REQUIRED
Moderate costs
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES
Low
COST EFFECTIVENESS
Varies
EQUITY
Don't know
ACCEPTABILITY
Yes
FEASIBILITY
Probably yes
Conclusions
Should organised mammography screening vs. no mammography screening be used for early detection of breast cancer in women aged 40 to 44?
Type of recommendation
Strong recommendation against the intervention
Conditional recommendation against the intervention
Conditional recommendation for either the intervention or the comparison
Conditional recommendation for the intervention
Strong recommendation for the intervention
Recommendation
For asymptomatic women aged 40 to 44 with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests not implementing mammography screening (conditional recommendation, moderate certainty in the evidence).

American Society of Hematology

Panelvoice

- Online interaction, voting, consensus, public comment

Health Marker States

Semi-automated development of interactive decision aids

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The American Society of Hematology and McMaster University Announce Partnership to Develop Clinical Practice Guidelines on Venous Thromboembolism

Guidelines on the Treatment and Diagnosis of VTE Anticipated in 2017

(WASHINGTON, November 30, 2015) – The American Society of Hematology, the world's largest association of clinicians and scientists dedicated to conquering blood diseases, is collaborating with McMaster University, a world leader in guideline development and an international authority on thrombosis, to develop clinical practice guidelines on the diagnosis and treatment of venous thromboembolism (VTE).

VTE is a blood clotting disorder that includes both deep-vein thrombosis (DVT) and pulmonary embolism (PE). DVT is a blood clot

Protect Medical Research

Urge your members of Congress to support continued medical research funding.

Take action

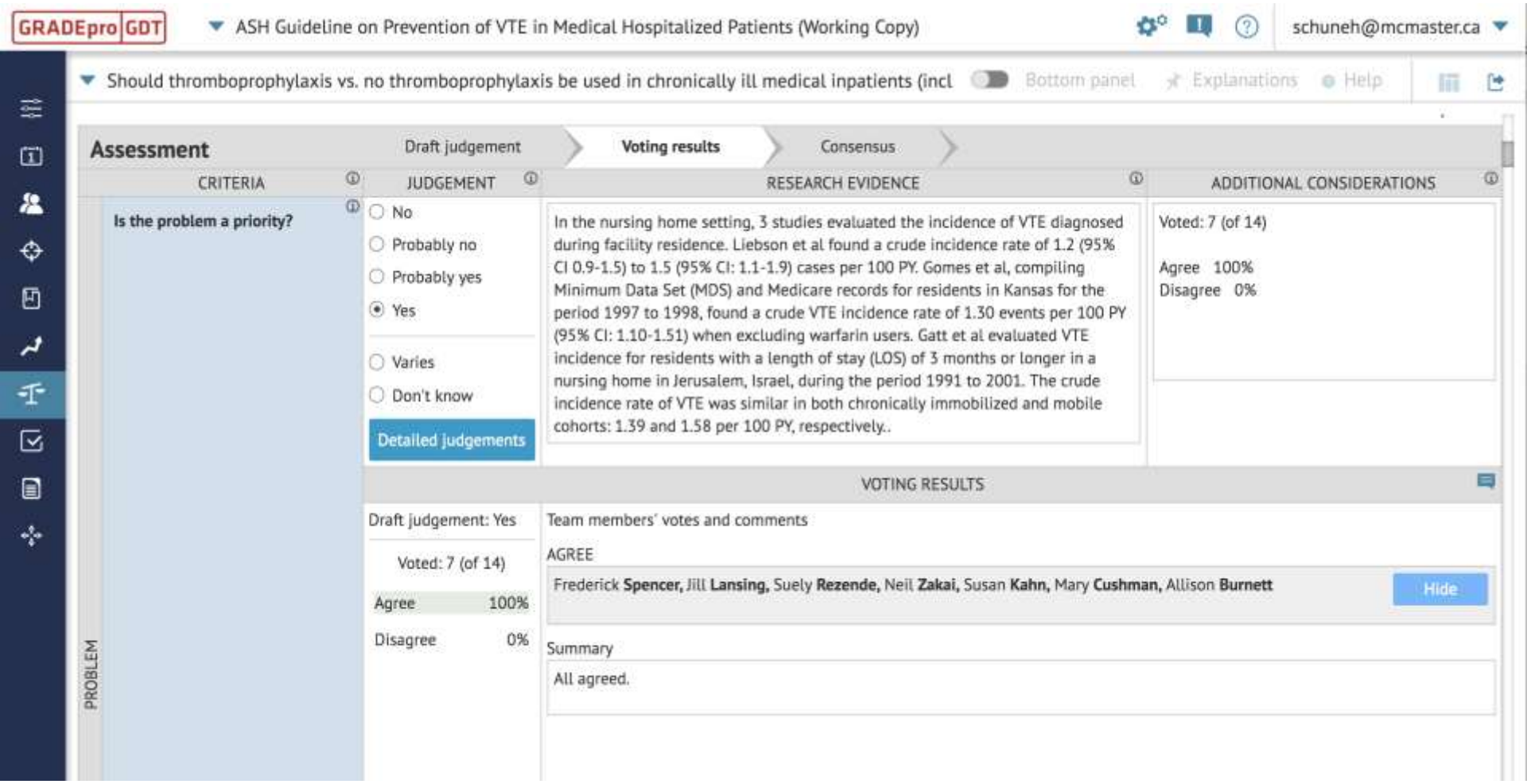
10 topics | >200 recommendations | 150 panelists

In-person and teleconference meetings

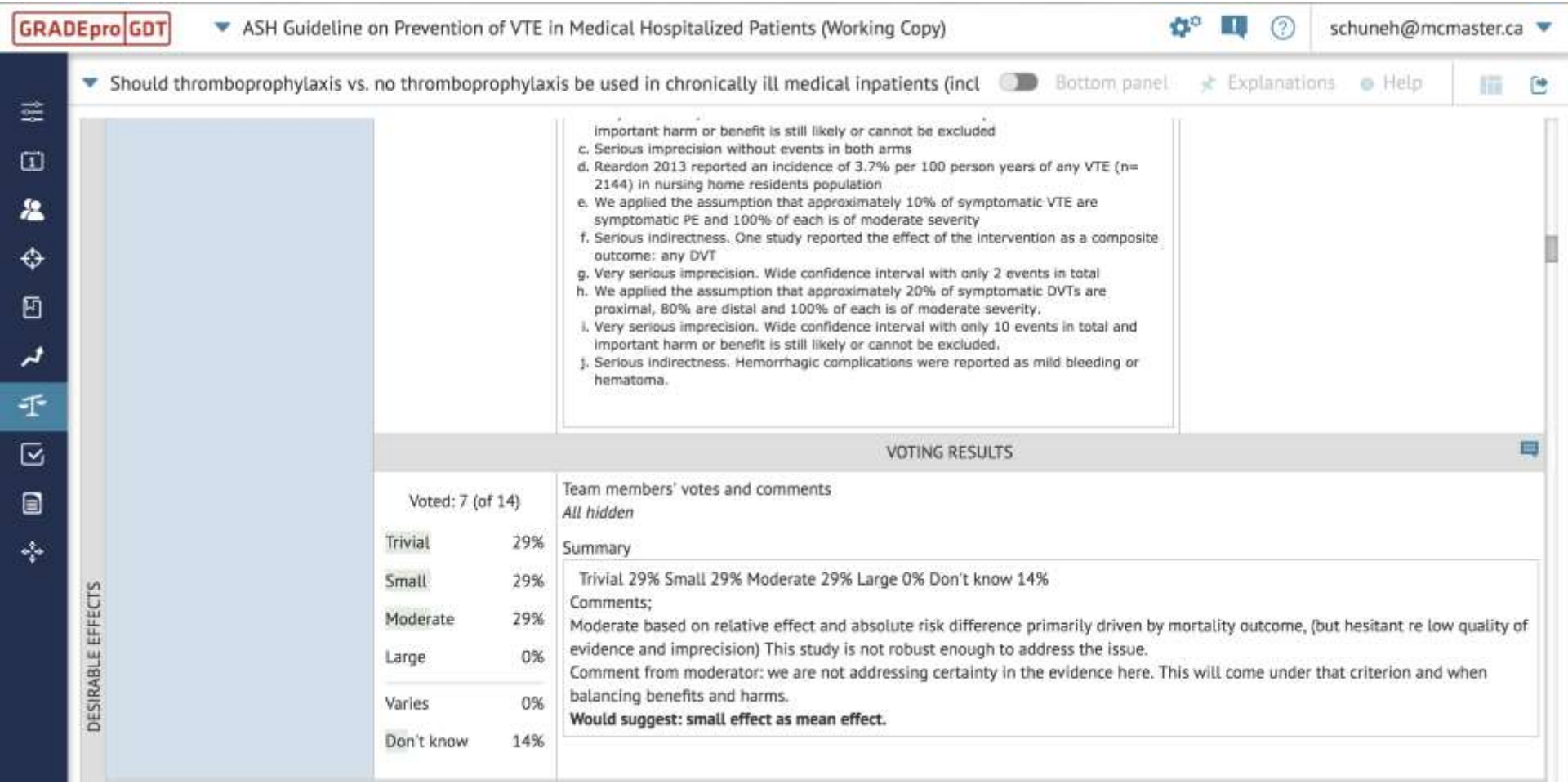
Learning how to make recommendations: in-person meeting

Follow-up work: online interaction and teleconferences

Helps with deciding about degree of discussion needed



Helps with deciding about degree of discussion needed



Comments

DESIRABLE EFFECTS: **How substantial are the desirable anticipated effects?**
DRAFT JUDGEMENT: **Small**

Team members' votes and comments

TRIVIAL

Frederick **Spencer,** Suely **Rezende** Show

SMALL

Mary **Cushman,** Allison **Burnett** Show

MODERATE

Susan **Kahn** Show
Moderate based on relative effect and absolute risk difference primarily driven by mortality outcome, (but hesitant re low quality of evidence and imprecision)

Jill **Lansing** Show

DON'T KNOW

Neil **Zakai** Show
This study is not ribust enough to address the issue.

Summary

Trivial 29% Small 29% Moderate 29% Large 0% Don't know 14%
Comments;
Moderate based on relative effect and absolute risk difference primarily driven by mortality outcome, (but hesitant re low quality of evidence and imprecision) This study is not robust enough to address the issue.
Comment from moderator: we are not addressing certainty in the evidence here. This will come under that criterion and when balancing benefits and harms.

Most recommendations

Will be conditional

Require support with implementatio

GRADE Conditional/weak recommendations

Patients/people: The majority of people in this situation would want the recommended course of action, but many would not

Clinicians: Be more prepared to help patients to make a decision that is consistent with their own values/**decision aids and shared decision making are useful**

Policy makers/QA: There is a need for substantial debate and involvement of stakeholders. Performance measures **should assess if decision-making appropriate**

ELSEVIER

Journal of Clinical Epidemiology 65 (2012) 584–589

Journal of Clinical Epidemiology

COMMENTARY

Clinical practice guidelines and patient decision aids. An inevitable relationship

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[d]*Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada*
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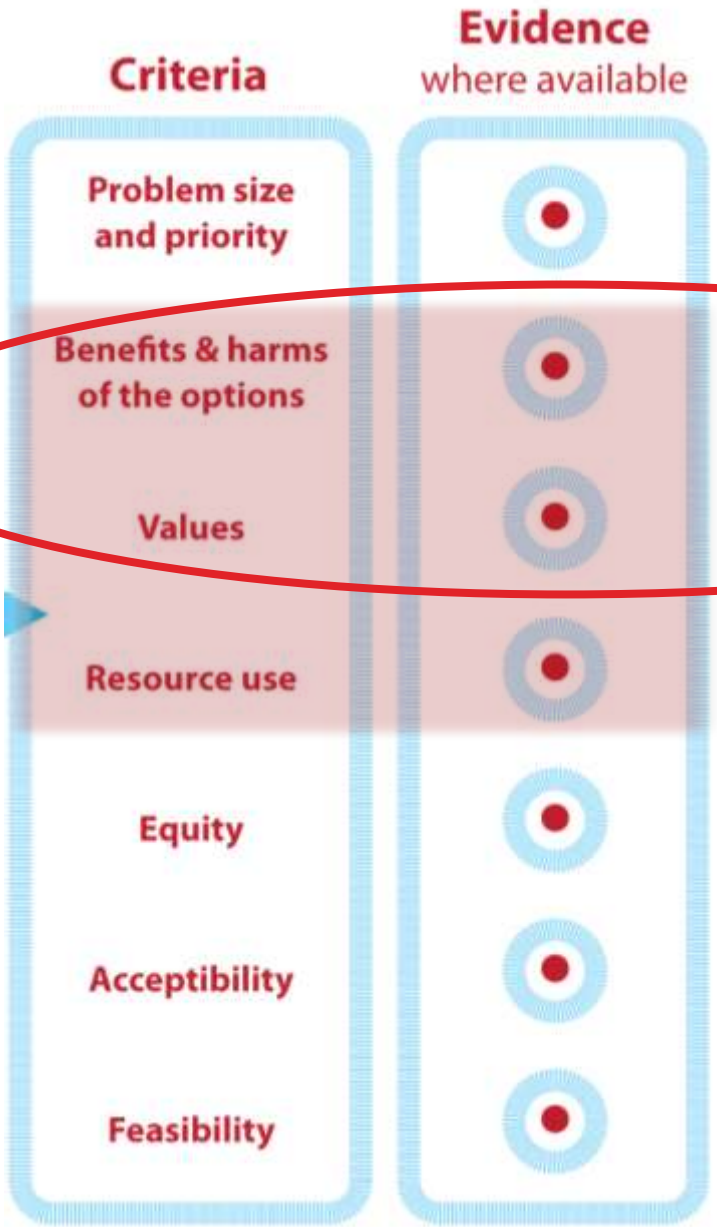
Accepted 2 October 2011; Published online 31 January 2012

Should patients with unprovoked (no reason found) deep venous thrombosis receive up to 12 months or lifelong anticoagulation?

The ASH guideline panel suggests using indefinite duration of antithrombotic therapy over defined duration antithrombotic therapy (12months or less) in patients patients with unprovoked DVT/PE (conditional recommendation based on moderate certainty in the evidence about effects).

GRADE decision criteria

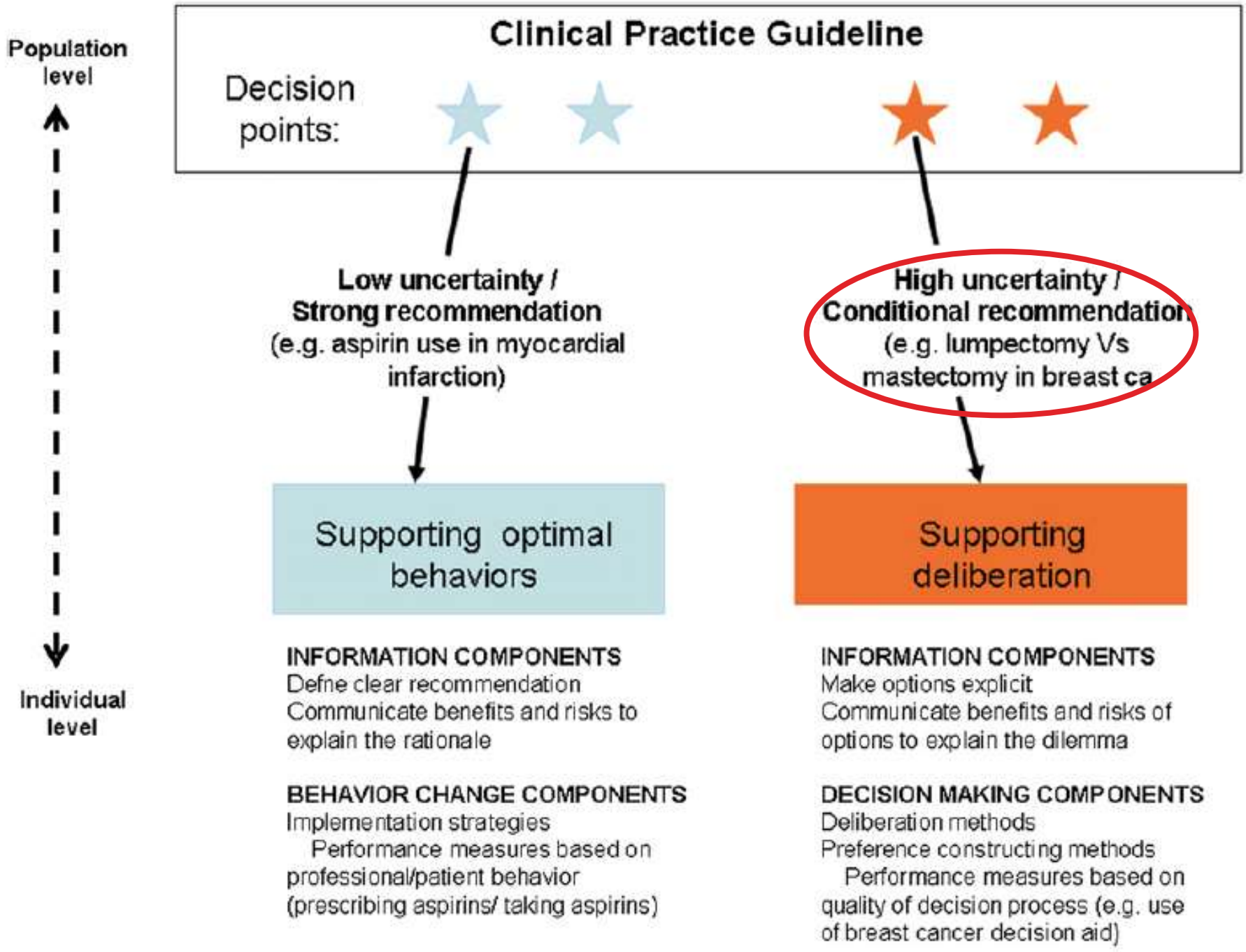


You

$$$$$?

Values

Treatment	Comparison
5% fewer **death** from PE	5% more **small bleeds**
1% fewer **death** from PE	99% more **small bleeds**


Population level
Individual level
Clinical Practice Guideline
Decision points:
Low uncertainty / Strong recommendation (e.g. aspirin use in myocardial infarction)
High uncertainty / Conditional recommendation (e.g. lumpectomy Vs mastectomy in breast ca
Supporting optimal behaviors
Supporting deliberation
INFORMATION COMPONENTS
Defne clear recommendation
Communicate benefits and risks to explain the rationale
BEHAVIOR CHANGE COMPONENTS
Implementation strategies
Performance measures based on professional/patient behavior (prescribing aspirins/ taking aspirins)
INFORMATION COMPONENTS
Make options explicit
Communicate benefits and risks of options to explain the dilemma
DECISION MAKING COMPONENTS
Deliberation methods
Preference constructing methods
Performance measures based on quality of decision process (e.g. use of breast cancer decision aid)

supporting patients' decisions

1. Inform and let patient walk off makes decision by themselves
2. Inform patient but asks for decision to be made by others
3. Inform and share decision

GRADE-based interactive Decision Aids

University at Buffalo, State University of New York
SCHOOL OF MEDICINE AND BIOMEDICAL SCIENCES

INTRODUCTION

Inhaled steroids present a treatment option for Chronic Obstructive Pulmonary Disease (COPD). Inhaled steroids have some of benefits, but they come with certain downsides. That's why deciding whether to use inhaled steroids or not will depend on each individual's values.

If a clinician has told you that inhaled steroids are a possible treatment option for you this Decision Aid can help you decide whether to use inhaled steroids or not.

We believe that your participation in making this treatment decision about your health is very important. However, the degree to which you

DEMO - ASH - Copy - UXPin

Holger

Secure | https://preview.uxpin.com/5bbe92a12e2ca776f0b3f33f42620b1c08a1b147#/pages/72115747/simulate/no-panels

Apps | CYCLING IN PROVE... | Tngs | IBM | EST | Soc | ASH | CE&B | Bank | Airlines | GRADE | Chrane | Bike | Mac | Other Bookmarks

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GRADE DECISION

Support

GRADEpro GDT

Key facts — Comparison — Your values — Summary

Should **Indefinite duration of Antithrombotic Therapy** vs. **defined duration(12months or less) Antithrombotic Therapy** be used in **patients with unprovoked DVT/PE**?

What you should remember?

Problem

Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE) are major contributors to global disease burden. Their estimate incidence range from 0.7 to 2.7 per 1000 patients-year in Western Europe, 1.1 to 2.4 per 1000 patients-year in

Myths and Facts

Deep Vein Thrombosis (DVT) is a blood clot that forms in a major vein of the leg or, less commonly, in the arms,

Key facts — Comparison — Your values — Summary

Should **indefinite duration of Antithrombotic Therapy** vs. **defined duration(12months or less) Antithrombotic Therapy** be used in **patients with unprovoked DVT/PE**?

COMPARISON

Events per 1000 people

Outcomes	Favours: Defined duration (12months or less) Antithrombotic Therapy	vs.	Favours: Indefinite duration of Antithrombotic Therapy	Quality of Evidence
Mortality follow up: mean 36 months	18		**4 fewer** (6 fewer to 2 more)	⊕⊕⊕◯ MODERATE
Moderate PE follow up: mean 24 months	28		**20 fewer** (24 fewer to 14 fewer)	⊕⊕⊕⊕ HIGH
	33		24 fewer (28 fewer to 16 fewer)	LOW
All DVT follow up: mean 24 months	58		**46 fewer** (51 fewer to 39 fewer)	⊕⊕⊕⊕ HIGH
	41		24 fewer (28 fewer to 16 fewer)	LOW
Major bleeding follow up: mean 28 months	7		**9 more** (3 more to 16 more)	⊕⊕⊕⊕ HIGH
	21		26 more (10 more to 49 more)	LOW

EXPERTS RECOMENTATION

Summary of findings table

DEFINED DURATION (12MONTHS OR LESS) ANTITHROMBOTIC THERAPY

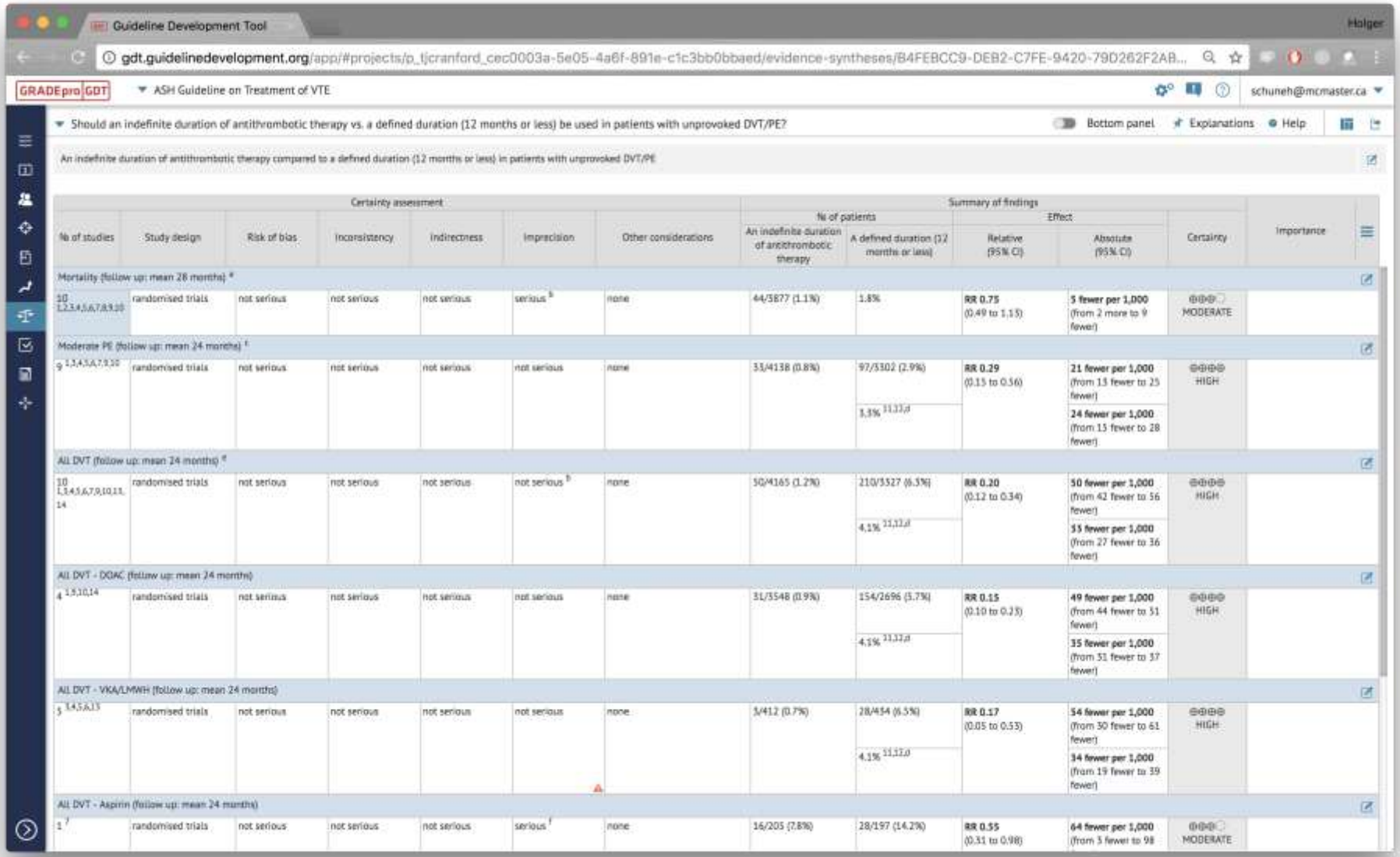
INDEFINITE DURATION OF ANTITHROMBOTIC THERAPY

WEAK RECOMENDATION

The ASH guideline panel suggests using indefinite duration of antithrombotic therapy over defined duration antithrombotic therapy (12months or less) in patients patients with unprovoked DVT/PE (conditional recommendation based on moderate certainty in the evidence about effects).

Remarks:

The majority of the panel felt that most patients with an unprovoked VTE would benefit from indefinite anticoagulant therapy. However, this needs to include a careful assessment of risks and benefits for the individula patient and the patient's preferences, as well as a regular re-evaluation of these parameters.


Guideline Development Tool
Holger
gdt.guidelinedevelopment.org/app/#projects/p_tjcranford_cec0003a-5e05-4a6f-891e-c1c3bb0bbaed/evidence-syntheses/B4FEBCC9-DEB2-C7FE-9420-79D262F2AB...
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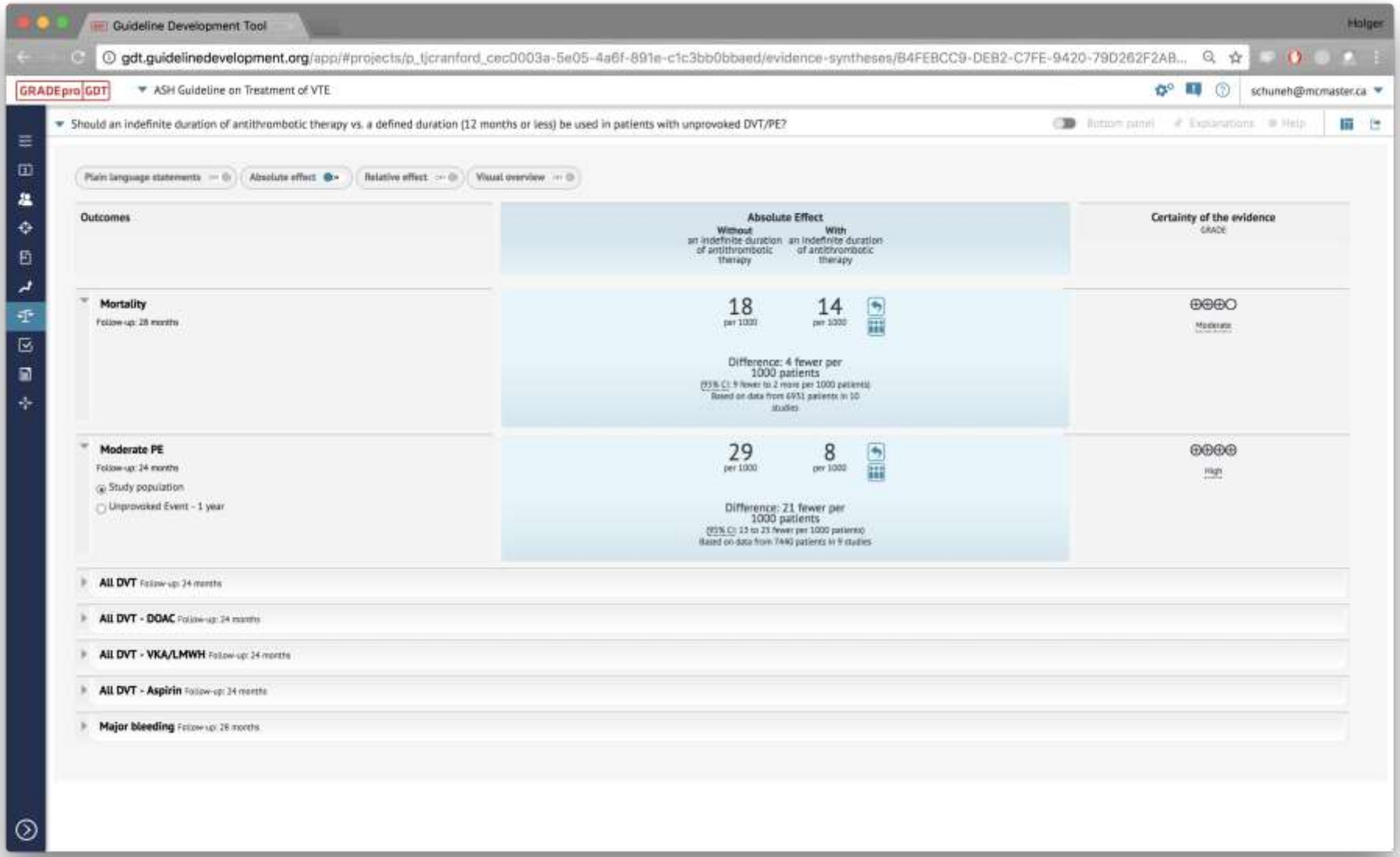
Should an indefinite duration of antithrombotic therapy vs. a defined duration (12 months or less) be used in patients with unprovoked DVT/PE?
Bottom panel
Explanations
Help
An indefinite duration of antithrombotic therapy compared to a defined duration (12 months or less) in patients with unprovoked DVT/PE
Certainty assessment
Summary of findings
№ of patients
Effect
№ of studies
Study design
Risk of bias
Inconsistency
Indirectness
Imprecision
Other considerations
An indefinite duration of antithrombotic therapy
A defined duration (12 months or less)
Relative (95% CI)
Absolute (95% CI)
Certainty
Importance
Mortality (follow up: mean 28 months)
10 1,2,3,4,5,6,7,8,9,10
randomised trials
not serious
not serious
not serious
serious
none
44/5877 (1.1%)
1.8%
RR 0.75 (0.49 to 1.15)
5 fewer per 1,000 (from 2 more to 9 fewer)
MODERATE
Moderate PE (follow up: mean 24 months)
9 1,3,4,5,6,7,9,10
randomised trials
not serious
not serious
not serious
not serious
none
33/4138 (0.8%)
97/3302 (2.9%)
3.3%
RR 0.29 (0.15 to 0.56)
21 fewer per 1,000 (from 13 fewer to 25 fewer)
24 fewer per 1,000 (from 15 fewer to 28 fewer)
HIGH
All DVT (follow up: mean 24 months)
10 1,3,4,5,6,7,9,10,13,14
randomised trials
not serious
not serious
not serious
not serious
none
50/4165 (1.2%)
210/3327 (6.5%)
4.1%
RR 0.20 (0.12 to 0.34)
50 fewer per 1,000 (from 42 fewer to 56 fewer)
35 fewer per 1,000 (from 27 fewer to 36 fewer)
HIGH
All DVT - DOAC (follow up: mean 24 months)
4 1,9,10,14
randomised trials
not serious
not serious
not serious
not serious
none
31/3548 (0.9%)
154/2696 (5.7%)
4.1%
RR 0.15 (0.10 to 0.23)
49 fewer per 1,000 (from 44 fewer to 51 fewer)
35 fewer per 1,000 (from 31 fewer to 37 fewer)
HIGH
All DVT - VKA/LMWH (follow up: mean 24 months)
5 3,4,5,6,13
randomised trials
not serious
not serious
not serious
not serious
none
3/412 (0.7%)
28/454 (6.5%)
4.1%
RR 0.17 (0.05 to 0.53)
54 fewer per 1,000 (from 30 fewer to 61 fewer)
34 fewer per 1,000 (from 19 fewer to 39 fewer)
HIGH
All DVT - Aspirin (follow up: mean 24 months)
1 7
randomised trials
not serious
not serious
not serious
serious
none
16/205 (7.8%)
28/197 (14.2%)
RR 0.55 (0.31 to 0.98)
64 fewer per 1,000 (from 3 fewer to 98
MODERATE


Guideline Development Tool
Holger
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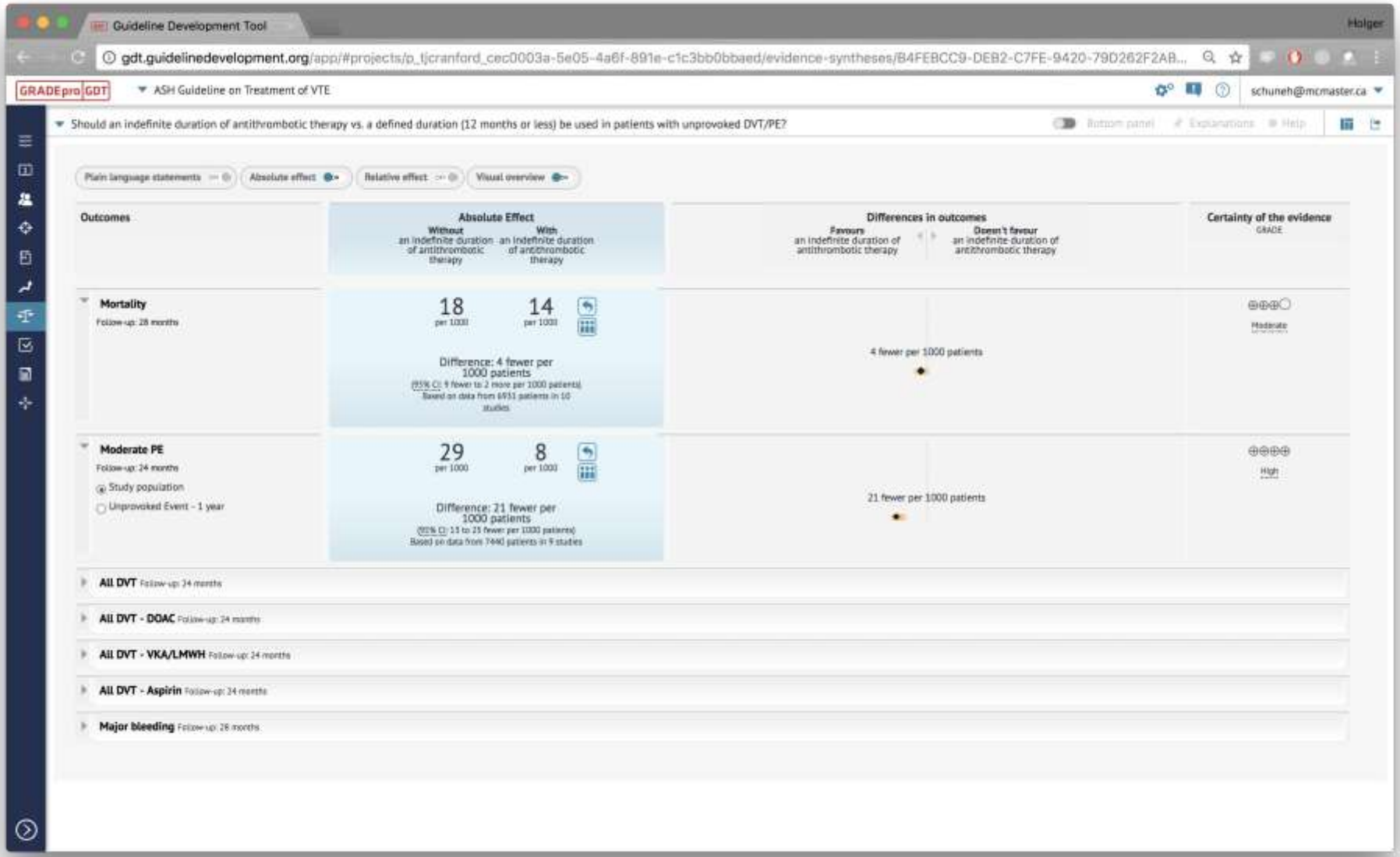
GRADEpro GDT
ASH Guideline on Treatment of VTE
schuneh@mcmaster.ca
Should an indefinite duration of antithrombotic therapy vs. a defined duration (12 months or less) be used in patients with unprovoked DVT/PE?
Bottom panel
Explanations
Help
Plain language statements
Absolute effect
Relative effect
Visual overview
Outcomes
Absolute Effect
Without an indefinite duration of antithrombotic therapy
With an indefinite duration of antithrombotic therapy
Certainty of the evidence
GRADE
Mortality
Follow-up: 28 months
18
per 1000
14
per 1000
Difference: 4 fewer per 1000 patients
(95% CI: 9 fewer to 2 more per 1000 patients)
Based on data from 6951 patients in 10 studies
Moderate
Moderate PE
Follow-up: 24 months
Study population
Unprovoked Event - 1 year
29
per 1000
8
per 1000
Difference: 21 fewer per 1000 patients
(95% CI: 13 to 23 fewer per 1000 patients)
Based on data from 7440 patients in 9 studies
High
All DVT Follow-up: 24 months
All DVT - DOAC Follow-up: 24 months
All DVT - VKA/LMWH Follow-up: 24 months
All DVT - Aspirin Follow-up: 24 months
Major bleeding Follow-up: 28 months


Guideline Development Tool
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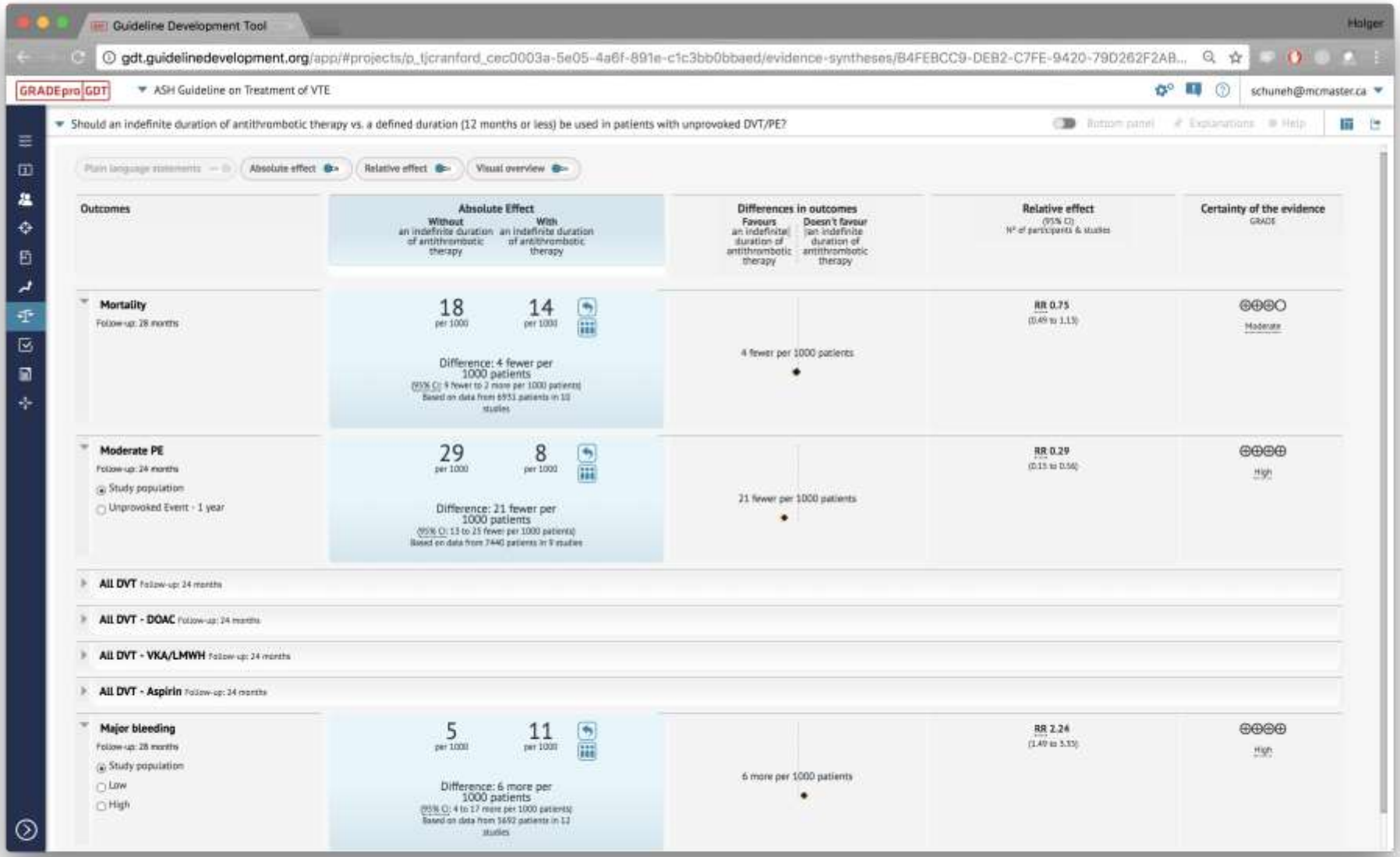
Outcomes
Absolute Effect
Without an indefinite duration of antithrombotic therapy
With an indefinite duration of antithrombotic therapy
Differences in outcomes
Favours an indefinite duration of antithrombotic therapy
Doesn't favour an indefinite duration of antithrombotic therapy
Certainty of the evidence
GRADE
Mortality
Follow-up: 28 months
18
per 1000
14
per 1000
Difference: 4 fewer per 1000 patients
(95% CI: 9 fewer to 2 more per 1000 patients)
Based on data from 6931 patients in 10 studies
4 fewer per 1000 patients
Moderate
Moderate PE
Follow-up: 24 months
Study population
Unprovoked Event - 1 year
29
per 1000
8
per 1000
Difference: 21 fewer per 1000 patients
(95% CI: 13 to 25 fewer per 1000 patients)
Based on data from 7440 patients in 9 studies
21 fewer per 1000 patients
High
All DVT Follow-up: 24 months
All DVT - DOAC Follow-up: 24 months
All DVT - VKA/LMWH Follow-up: 24 months
All DVT - Aspirin Follow-up: 24 months
Major bleeding Follow-up: 28 months


Guideline Development Tool
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Absolute effect
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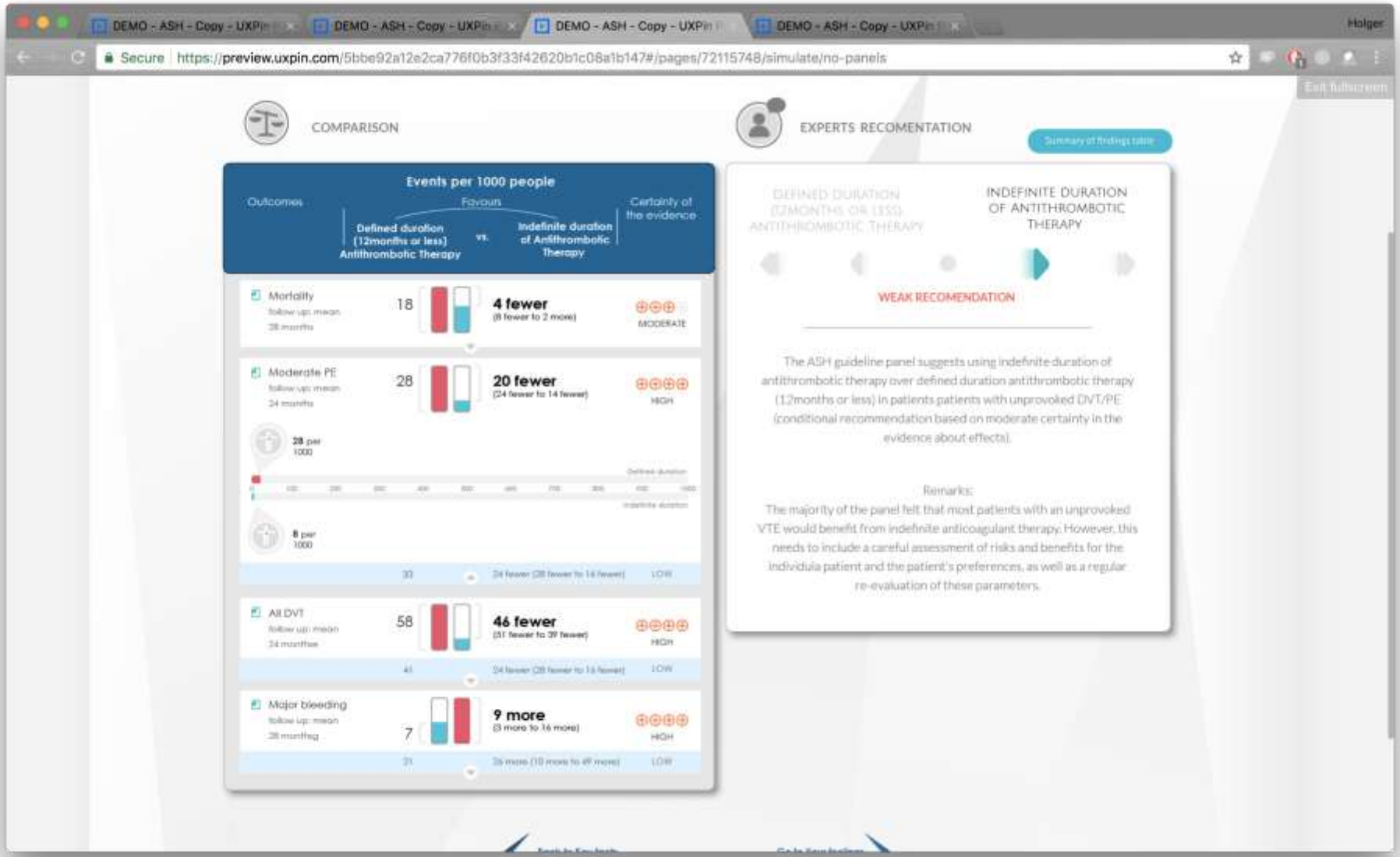
Outcomes
Absolute Effect
Without an indefinite duration of antithrombotic therapy
With an indefinite duration of antithrombotic therapy
Differences in outcomes
Favours an indefinite duration of antithrombotic therapy
Doesn't favour an indefinite duration of antithrombotic therapy
Relative effect
(95% CI)
N° of participants & studies
Certainty of the evidence
GRADE
Mortality
Follow-up: 28 months
18
per 1000
14
per 1000
Difference: 4 fewer per 1000 patients
(95% CI: 9 fewer to 2 more per 1000 patients)
Based on data from 6931 patients in 10 studies
4 fewer per 1000 patients
RR 0.75
(0.49 to 1.13)
Moderate
Moderate PE
Follow-up: 24 months
Study population
Unprovoked Event - 1 year
29
per 1000
8
per 1000
Difference: 21 fewer per 1000 patients
(95% CI: 13 to 25 fewer per 1000 patients)
Based on data from 7446 patients in 9 studies
21 fewer per 1000 patients
RR 0.29
(0.15 to 0.56)
High
All DVT Follow-up: 24 months
All DVT - DOAC Follow-up: 24 months
All DVT - VKA/LMWH Follow-up: 24 months
All DVT - Aspirin Follow-up: 24 months
Major bleeding
Follow-up: 28 months
Study population
Low
High
5
per 1000
11
per 1000
Difference: 6 more per 1000 patients
(95% CI: 4 to 17 more per 1000 patients)
Based on data from 5692 patients in 12 studies
6 more per 1000 patients
RR 2.24
(1.49 to 3.33)
High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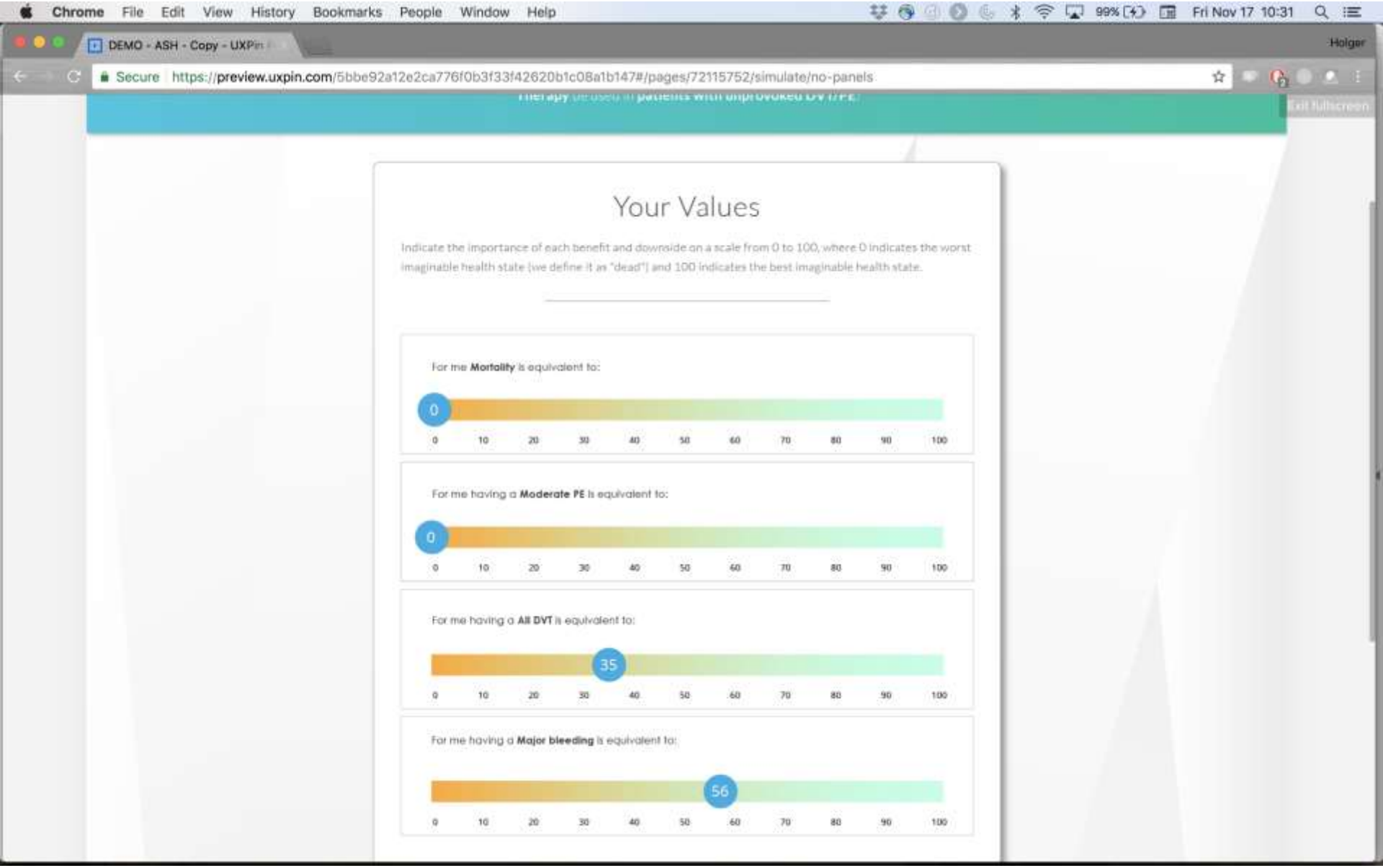
COMPARISON
EXPERTS RECOMENTATION
Summary of findings table
Events per 1000 people
Outcomes
Favours
Certainty of the evidence
Defined duration (12months or less) Antithrombotic Therapy
vs.
Indefinite duration of Antithrombotic Therapy
Mortality
18
4 fewer
(8 fewer to 2 more)
MODERATE
Moderate PE
28
20 fewer
(24 fewer to 14 fewer)
HIGH
28 per 1000
8 per 1000
All DVT
58
46 fewer
(51 fewer to 39 fewer)
HIGH
Major bleeding
7
9 more
(3 more to 16 more)
HIGH
DEFINED DURATION (12MONTHS OR LESS) ANTITHROMBOTIC THERAPY
INDEFINITE DURATION OF ANTITHROMBOTIC THERAPY
WEAK RECOMENDATION
The ASH guideline panel suggests using indefinite duration of antithrombotic therapy over defined duration antithrombotic therapy (12months or less) in patients patients with unprovoked DVT/PE (conditional recommendation based on moderate certainty in the evidence about effects).
Remarks:
The majority of the panel felt that most patients with an unprovoked VTE would benefit from indefinite anticoagulant therapy. However, this needs to include a careful assessment of risks and benefits for the individula patient and the patient's preferences, as well as a regular re-evaluation of these parameters.

How important are the outcomes?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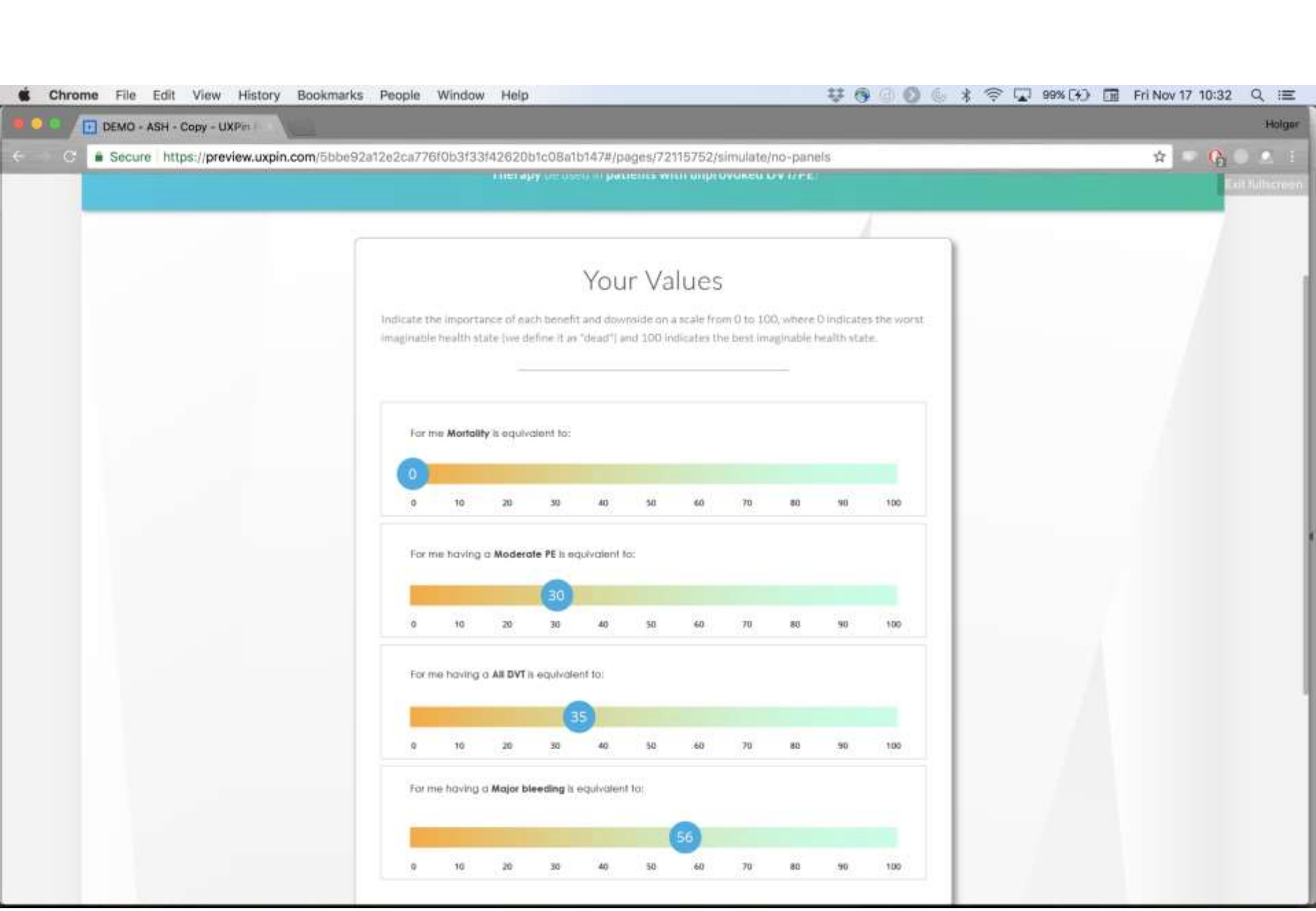
Your Values
Indicate the importance of each benefit and downside on a scale from 0 to 100, where 0 indicates the worst imaginable health state (we define it as "dead") and 100 indicates the best imaginable health state.
For me Mortality is equivalent to:
0
For me having a Moderate PE is equivalent to:
0
For me having a All DVT is equivalent to:
35
For me having a Major bleeding is equivalent to:
56
0 10 20 30 40 50 60 70 80 90 100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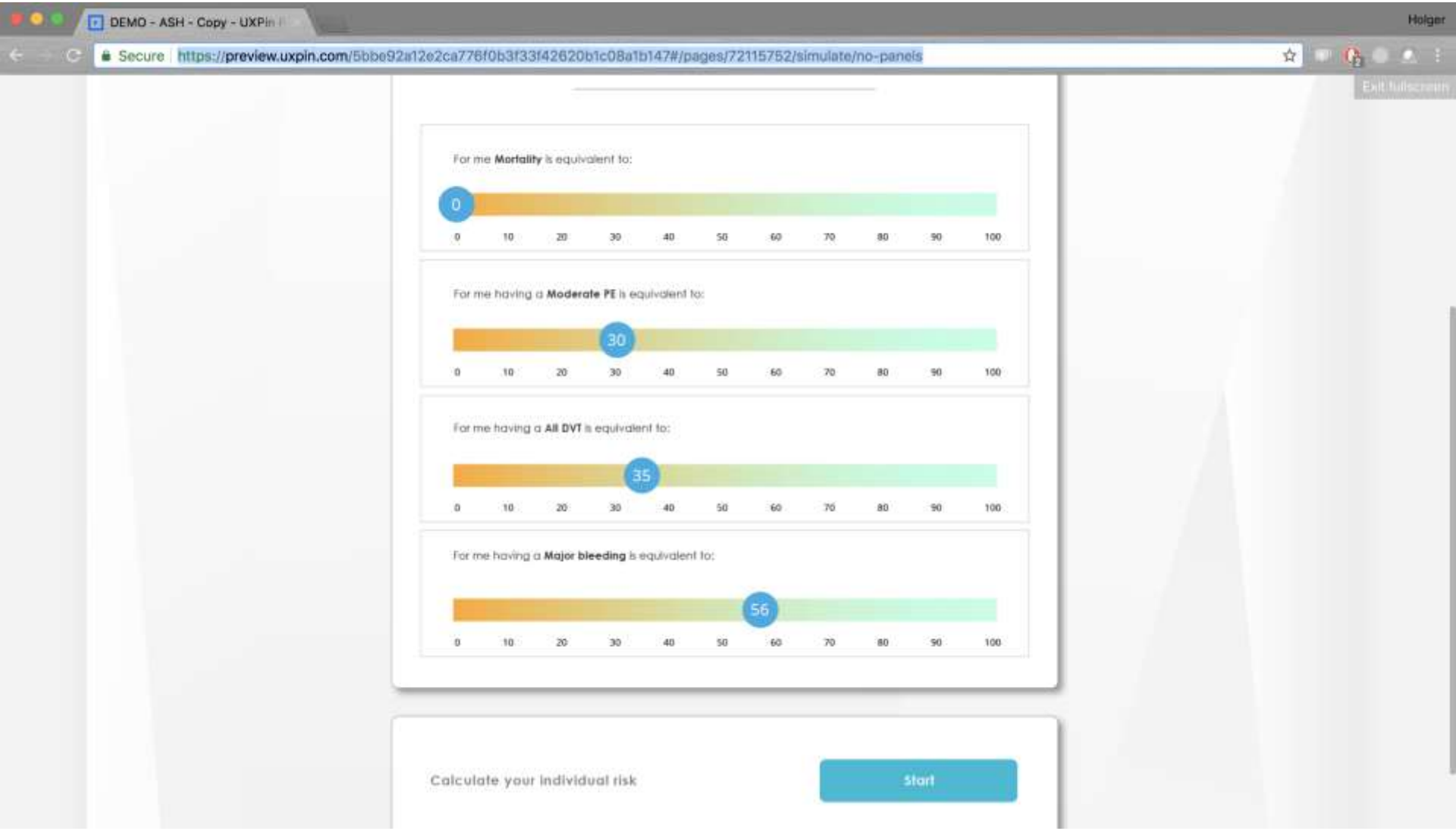
Your Values
Indicate the importance of each benefit and downside on a scale from 0 to 100, where 0 indicates the worst imaginable health state (we define it as "dead") and 100 indicates the best imaginable health state.
For me Mortality is equivalent to:
0
For me having a Moderate PE is equivalent to:
30
For me having a All DVT is equivalent to:
35
For me having a Major bleeding is equivalent to:
56
0 10 20 30 40 50 60 70 80 90 100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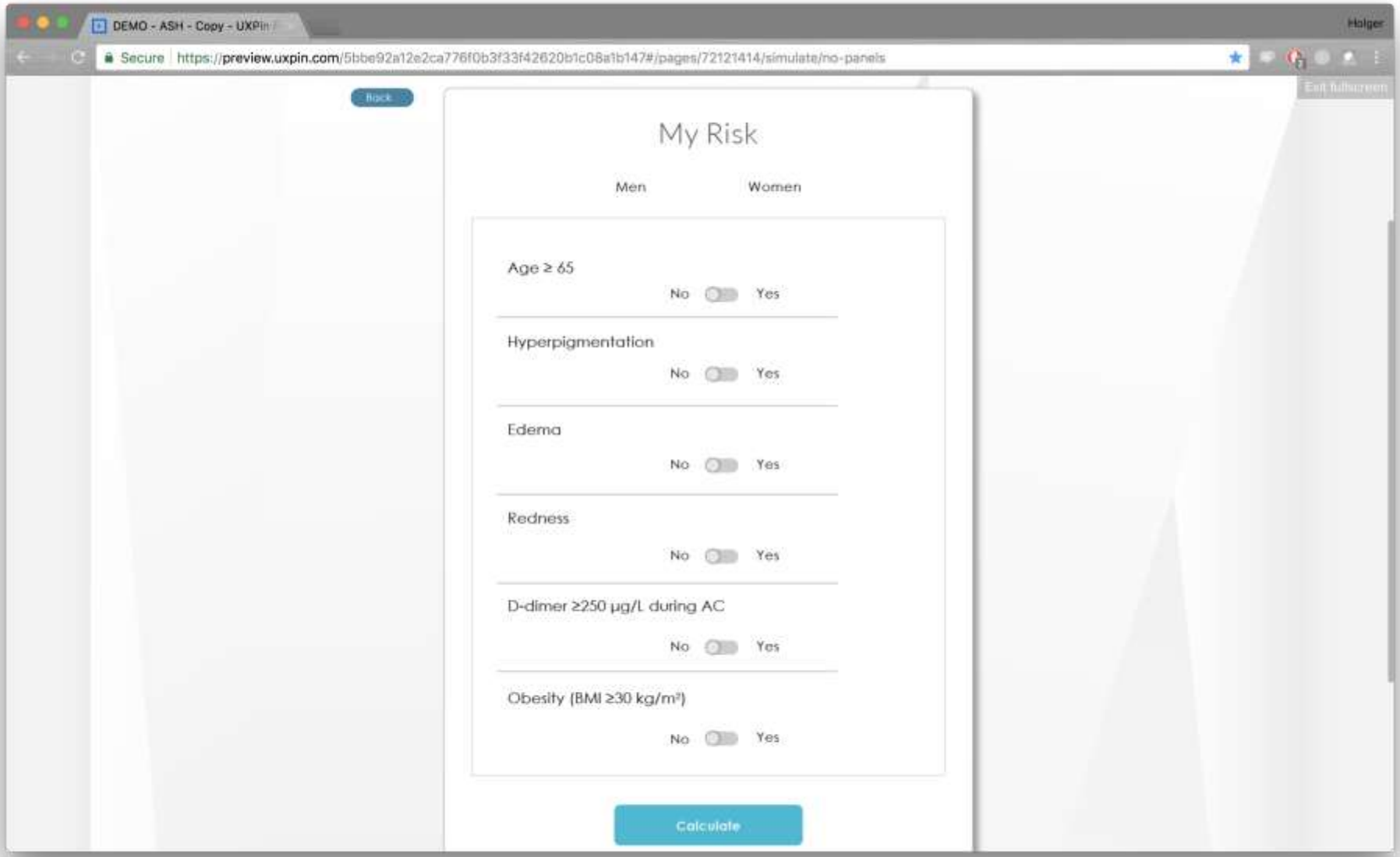
For me Mortality is equivalent to:
0
0 10 20 30 40 50 60 70 80 90 100
For me having a Moderate PE is equivalent to:
30
0 10 20 30 40 50 60 70 80 90 100
For me having a All DVT is equivalent to:
35
0 10 20 30 40 50 60 70 80 90 100
For me having a Major bleeding is equivalent to:
56
0 10 20 30 40 50 60 70 80 90 100
Calculate your individual risk
Start

What is your baseline risk?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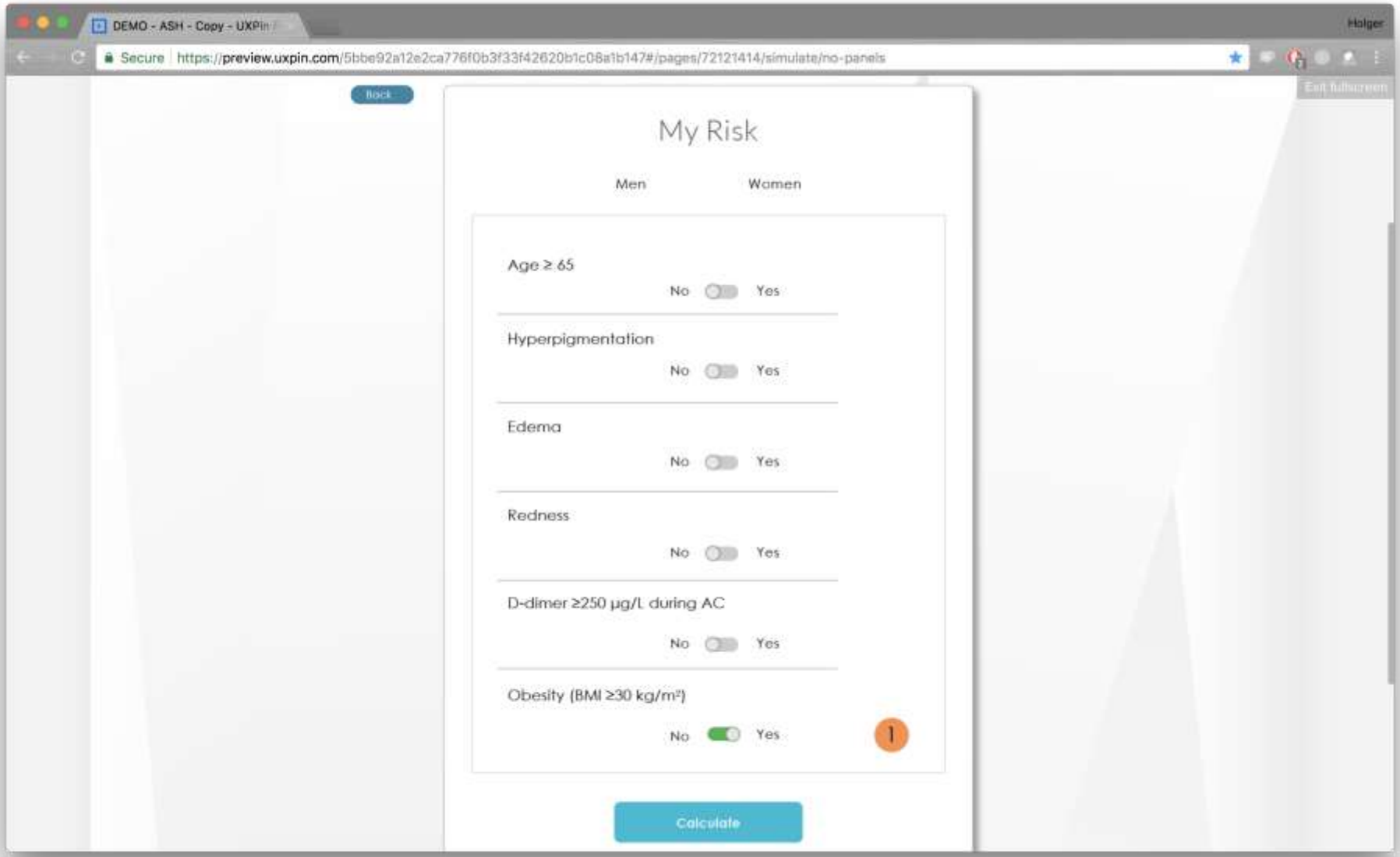
Back
My Risk
Men
Women
Age ≥ 65
No
Yes
Hyperpigmentation
No
Yes
Edema
No
Yes
Redness
No
Yes
D-dimer ≥250 µg/L during AC
No
Yes
Obesity (BMI ≥30 kg/m²)
No
Yes
Calculate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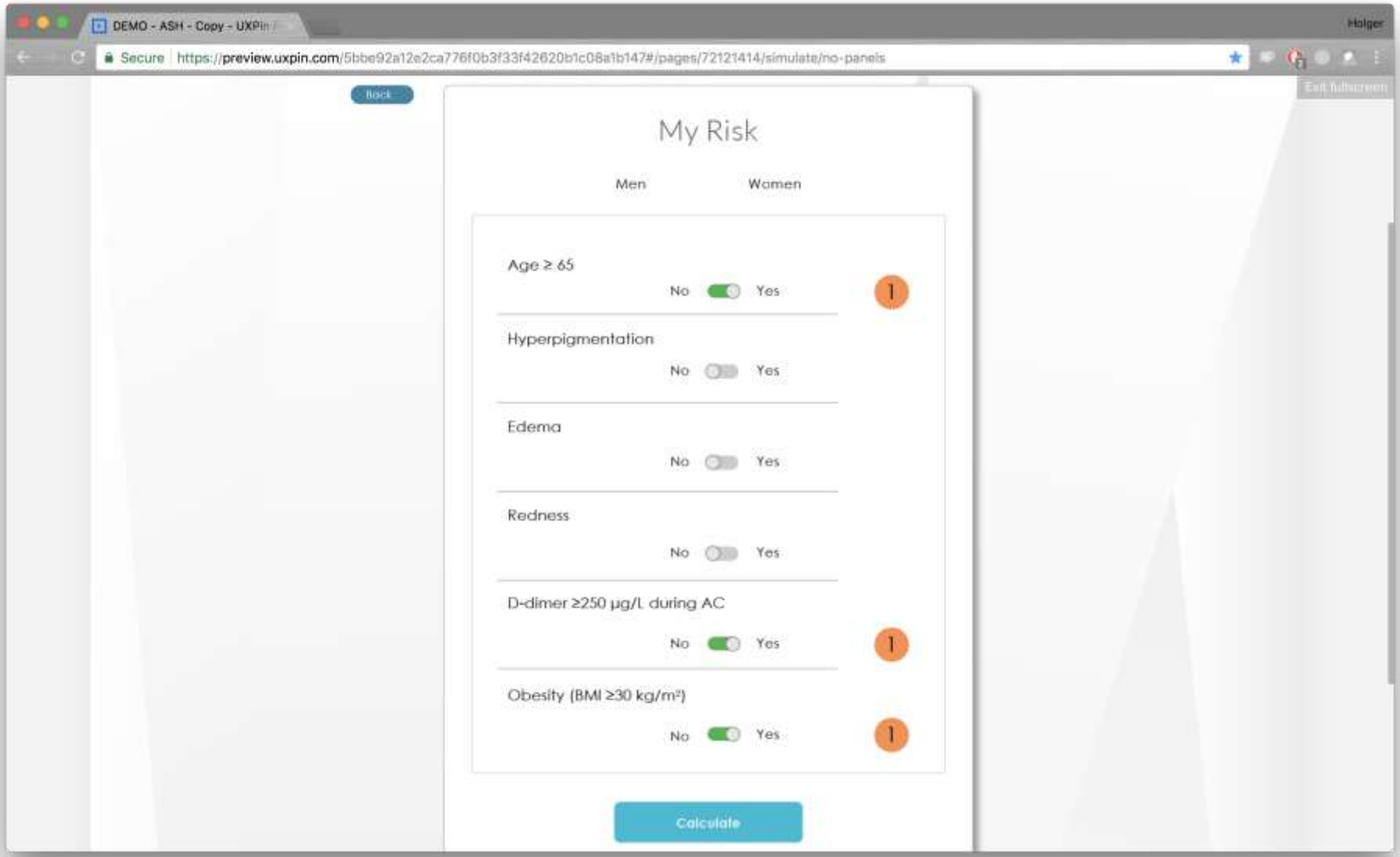
Back
Exit fullscreen
My Risk
Men
Women
Age ≥ 65
No
Yes
Hyperpigmentation
No
Yes
Edema
No
Yes
Redness
No
Yes
D-dimer ≥250 µg/L during AC
No
Yes
Obesity (BMI ≥30 kg/m²)
No
Yes
1
Calculate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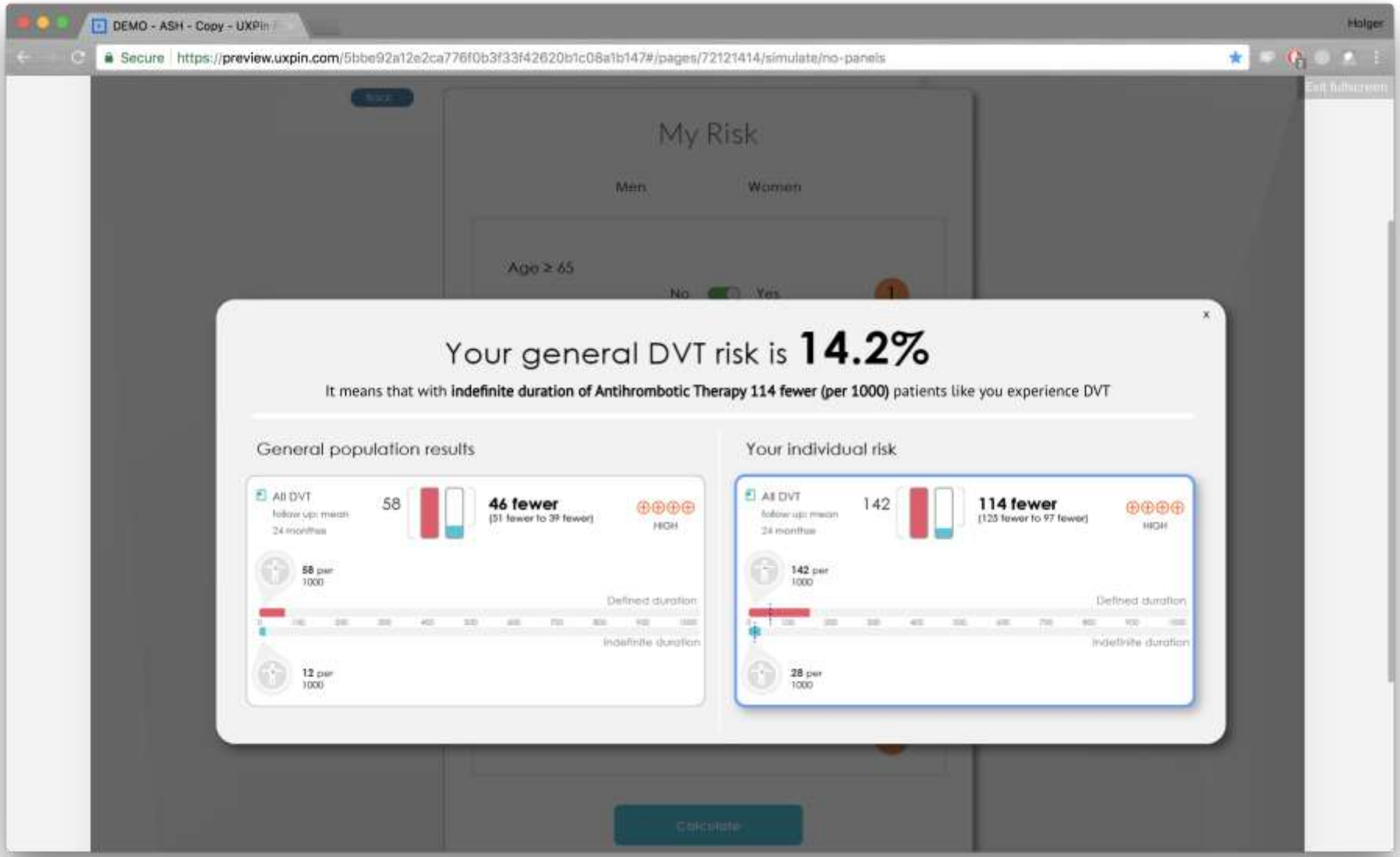
Back
Exit fullscreen
My Risk
Men
Women
Age ≥ 65
No
Yes
1
Hyperpigmentation
No
Yes
Edema
No
Yes
Redness
No
Yes
D-dimer ≥250 µg/L during AC
No
Yes
1
Obesity (BMI ≥30 kg/m²)
No
Yes
1
Calculate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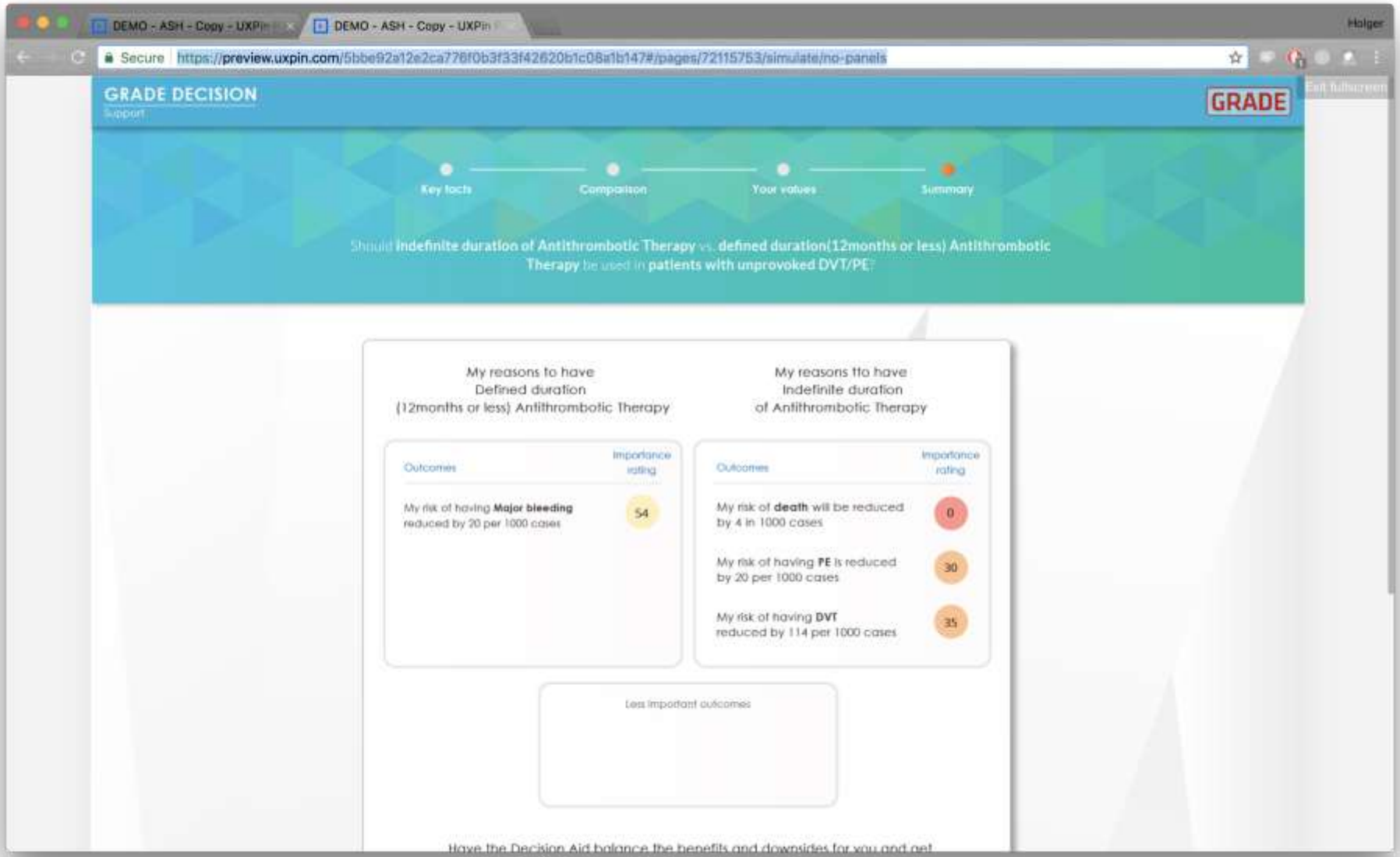
My Risk
Men
Women
Age ≥ 65
No
Yes
Your general DVT risk is 14.2%
It means that with indefinite duration of Antihrombotic Therapy 114 fewer (per 1000) patients like you experience DVT
General population results
All DVT
follow up: mean 24 months
58
46 fewer
(51 fewer to 39 fewer)
HIGH
58 per 1000
Defined duration
Indefinite duration
12 per 1000
Your individual risk
All DVT
follow up: mean 24 months
142
114 fewer
(125 fewer to 97 fewer)
HIGH
142 per 1000
Defined duration
Indefinite duration
28 per 1000
Calculate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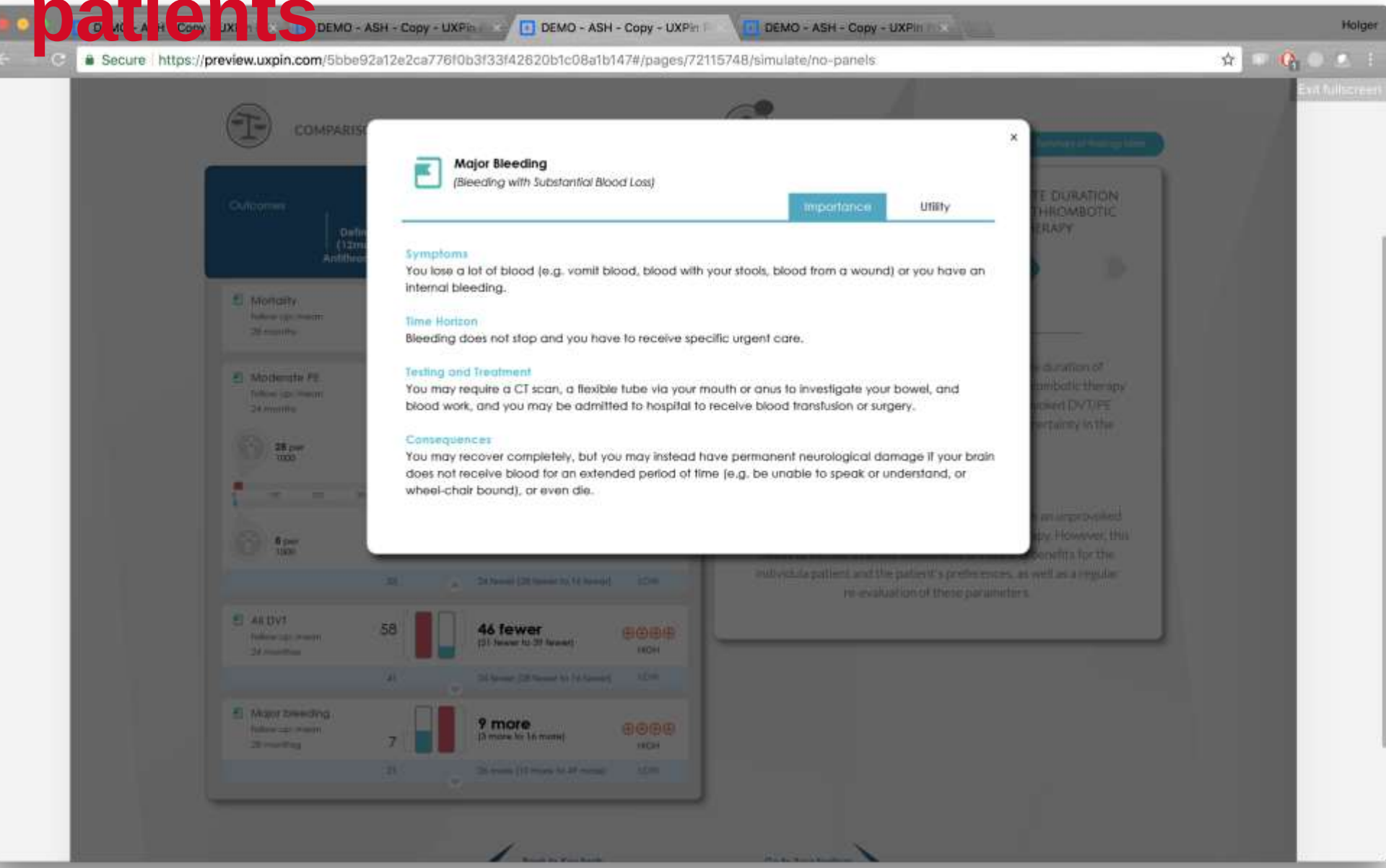
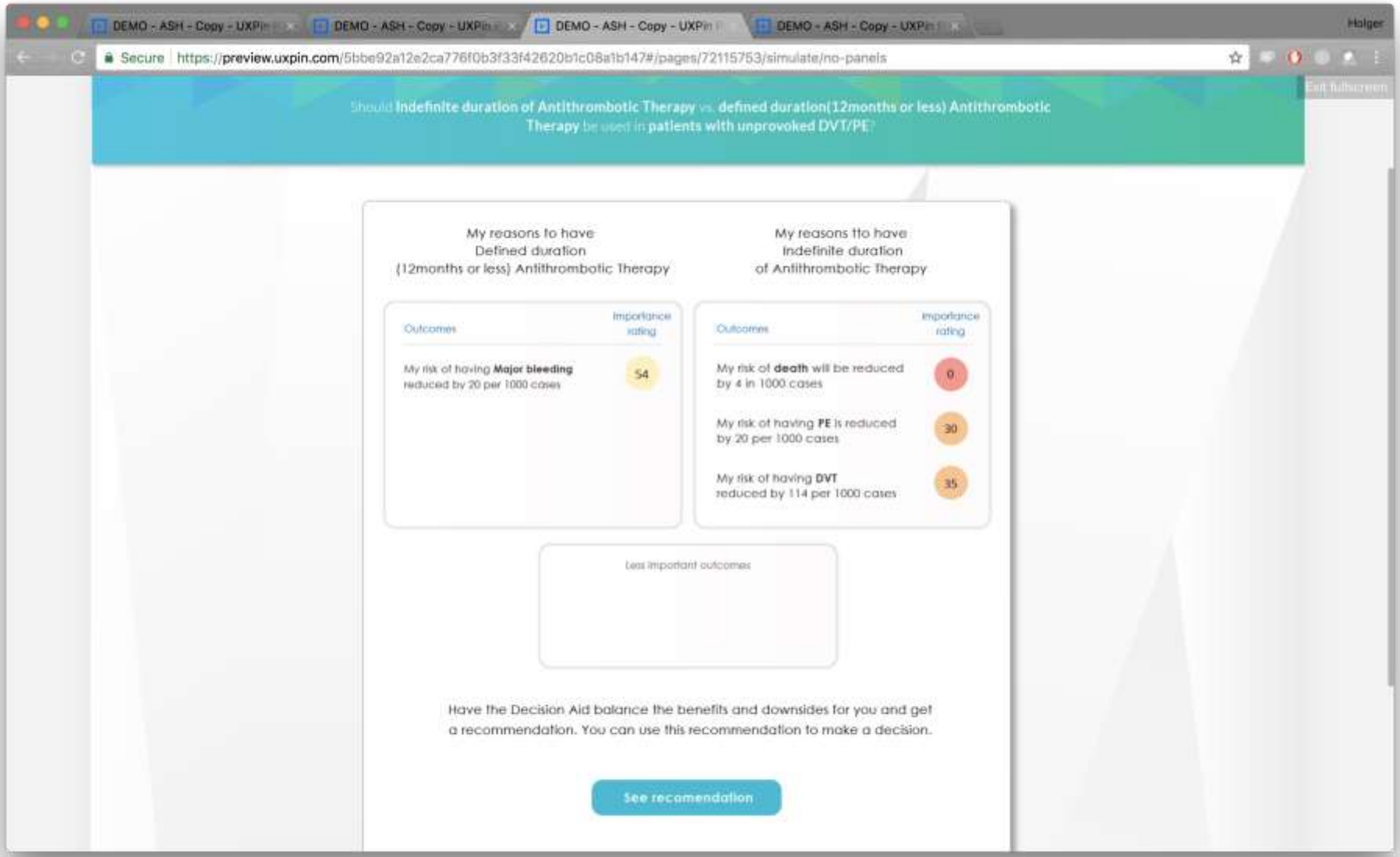
GRADE DECISION
Support
GRADE
Key facts
Comparison
Your values
Summary
Should indefinite duration of Antithrombotic Therapy vs. defined duration(12months or less) Antithrombotic Therapy be used in patients with unprovoked DVT/PE?
My reasons to have Defined duration (12months or less) Antithrombotic Therapy
My reasons tto have Indefinite duration of Anfithrombotic Therapy
Outcomes
Importance rating
My risk of having Major bleeding reduced by 20 per 1000 cases
54
Outcomes
Importance rating
My risk of death will be reduced by 4 in 1000 cases
0
My risk of having PE is reduced by 20 per 1000 cases
30
My risk of having DVT reduced by 114 per 1000 cases
35
Less important outcomes
Have the Decision Aid balance the benefits and downsides for you and get

Link to outcomes for panel and patients

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Should Indefinite duration of Antithrombotic Therapy vs. defined duration(12months or less) Antithrombotic Therapy be used in patients with unprovoked DVT/PE?
My reasons to have Defined duration (12months or less) Antithrombotic Therapy
My reasons tto have Indefinite duration of Antithrombotic Therapy
Outcomes
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My risk of having Major bleeding reduced by 20 per 1000 cases
54
Outcomes
Importance rating
My risk of death will be reduced by 4 in 1000 cases
0
My risk of having PE is reduced by 20 per 1000 cases
30
My risk of having DVT reduced by 114 per 1000 cases
35
Less important outcomes
Have the Decision Aid balance the benefits and downsides for you and get a recommendation. You can use this recommendation to make a decision.
See recomendation

Summary

GRADEpro | GDT

1. GRADEpro – official tool of GRADE working group – linkage to GIN-Guideline checklist
2. Grading evidence and recommendations
3. Remote, web/browser-based interaction
4. Panel input, voting and consensus
5. Highly flexible and not prescriptive
6. Interactive Summary of Findings Tables (iSoF)
7. Interactive Decision Aids (iDA)
8. Adaptation, etc.

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