

HRM 775

Health Care **Guideline** Development Methods

Health Research Methods,
Evidence & Impact



Course Syllabus

(Spring/Summer 2023)

1. Brief Description

This online course focuses on making evidence-based health care recommendations in the development of clinical practice guidelines. It uses facilitated interactive learning modules, required readings, discussion boards, tutorials, and assignments to highlight the steps of the guideline development process. This includes: planning the guideline project, choosing the group, managing conflicts of interest, formulating guideline questions, finding and appraising evidence, summarizing evidence, deciding on the final recommendations as well as dissemination, and implementation. This course is structured around the steps of executing one full recommendation in a guideline and students are required to complete their own recommendation in a guideline, end-to-end with all framework documents by the end of the course.

2. Prerequisites

1. Students must meet McMaster School of Graduate Studies admission criteria (<http://academiccalendars.romcmaster.ca/content.php?catoid=4&navoid=191>)
2. Students must meet **at least one** of the following criteria:
 - a. have taken Health Research Methodology graduate course in systematic review methods **HRM 743** or Graduate Diploma in Clinical Epidemiology course **HTRSM 773**, or equivalent
 - b. have **prior experience performing a systematic review** (in this case students must also obtain the permission from the course coordinator).

Although not strictly a prerequisite, prior to commencing the course, students are requested to submit their **proposed topic for a guideline** (which will make the final assignment) and have it approved by an instructor during the 1st introductory week during the course.

Students are also encouraged to have thought over potential clinical questions to be covered in their guideline, and make sure that at least one recent systematic review addressing one of their questions exists (this may be student's own systematic review, e.g. completed during the prior Systematic Review Methods course, or another published systematic review). The course coordinator and instructors will review the submitted proposals, provide feedback, and approve the topic. Students will also be able to contact course instructors for suggestions of the topic and a systematic review.

3. Course Objectives

Students who successfully complete this course will understand the guideline development process and will have knowledge and basic skills on how to develop health care recommendations.

Students will also gain familiarity with:

- the GRADE approach to rating the certainty of evidence and the strength of recommendations.
- current concepts and controversies in methods for developing guidelines and other recommendations in health care.

4. Course Format

This online course consists of 10 units. New unit is posted every week. Each unit includes an audio-visual presentation, self-assessment questions, required readings, an assignment, online discussion, and an online tutorial session.

Unit	Topic
1	Introduction, overview of guidelines and their critical appraisal
2	Planning the guideline project, priority setting, budget, and organization
3	Guideline group composition, group processes, and management of conflicts of interest
4	Identifying questions and outcomes of interest
5	Evidence synthesis
6	Grading quality of evidence, summarizing, and presenting evidence
7	Assessing the evidence about testing
8	Going from evidence to recommendation
9	Reporting and dissemination of guidelines
10	Implementation, evaluation, adaptation and updating guidelines

All activities, except for online tutorial sessions, will be performed in the McMaster University online learning environment – Avenue to Learn (<http://avenue.mcmaster.ca>).

Students are expected to:

- review and complete the weekly lectures and readings
- participate in discussion boards related to each unit
- participate in a live tutorial session led by the instructor each week
- complete and submit on time all assignments
- consolidate issues and topics in the preparation of a final assignment to be submitted at the end of the term.

Discussion boards

There are two parallel discussions being held each week:

1. [Readings Discussion](#) (evaluated; contributes 10% to the final mark)

2. Discussion about assignments and all other topics (not evaluated).

Students are required to actively participate in the discussions. Each week selected students will facilitate reading discussions. Student facilitators will be evaluated separately on their facilitation and their written summary of the discussion. Facilitation of the discussion is worth another 10% of the final course score.

Discussion participation

Participation in discussions with fellow students and instructors is critical to developing a sound understanding of course material. Messages should generally introduce accurate and relevant information, which teaches others something new. Purely gratuitous or assentive posts (e.g. "Thank you!" or "I agree") will not be considered and will not contribute to a student's evaluation. To allow significant time for discussion each week the timing of a student's post will also be considered in evaluations. Quality, quantity and timing of participation in course activities will be considered in the final participation grade.

Additional guidelines for successful participation in discussion boards:

- Contribute regularly to the discussion each week
- Posts should not be longer than 75 words
- Ensure any message you post is accurate and meaningful
- Post information that is relevant to the discussion thread and that teaches others something new
- Properly reference content when appropriate; if you refer to the information from any source (e.g. papers, websites), provide the citation – this will enable others to refer to it later. The most valuable messages, however, are written in your own words.
- Thank someone for their assistance or let them know that you agree with what they have said.
- Include a subject line that conveys the main point you make in the message. It may not be enough to use a keyword or phrase as your subject. The most beneficial is a short sentence that states the main point of your message and provides enough information to determine its essence.
- Consider addressing issues that may not be of interest to the other students with instructors privately (e.g. more complex or advanced issues that you are personally vested in).

Discussion participation rubric

	Yes, and more!	Yes, and...	Yes	Yes, but...	No
	10/10 points	8/10 points	6/10 points	3/10 points	0/10 points
Responsiveness to group discussion Weight: 25%	Multiple points from multiple participants clearly built upon/refuted in postings	At least one point from multiple participants clearly built upon/refuted in postings	At least one point from one other participant clearly built upon/refuted in postings	One or more points from one or more participants only vaguely built upon/refuted in postings	No evidence that any other postings have been read/Unwitting repetition of questions or points made by others
Timeliness of discussion contributions Weight: 25%	Postings well distributed throughout the week	Postings somewhat distributed throughout the week	Postings neither distributed nor concentrated throughout the week	Postings somewhat concentrated during the week (i.e., all posted within a relatively brief period of time)	No posting or all postings very concentrated during the week (i.e., all posted within the same day and short period of time)
Quality of contributions Weight: 30%	Original posts (starting new topic) and replies are concise (fewer than 75 words), to the point, introduce a new thought, support it with quotations and references, share extra materials, drawings of concepts, etc., and/or summarize previous discussion if needed	Original posts and replies are concise (fewer than 75 words), to the point, introduce a new thought, and support it with quotations and references	Original posts and replies are concise (fewer than 75 words), to the point, and introduce a new thought	Original posts and replies are long, unclear, or any new thought (if present) is buried	Responses with a minimum effort (e.g. "Thank you" or "I agree")
Quantity of contributions Weight: 20%	Starts several new topics and actively follows most topics posting more than 1 reply per topic	Exceeded the minimum number of postings (original post and replies)	Met the minimum number of postings (1 original post and replies to 50% of other topics)	Less than the minimum number of postings or replies only (regardless of number)	No poststing

Discussion facilitation

Each week one or two students will be assigned to facilitate discussion about the readings. If the class is divided into 2 or more tutorial groups, then there will be one for each tutorial group. Responsibilities of the facilitator include:

- Posting a summary of the readings (as early in the week as possible, preferably the first day) on their readings discussion board. The summary should not be prepared article by article but an overall synthesis of the readings and no longer than 200 words (including a question for discussion).
- Facilitating discussion related to the readings (e.g. posting additional resources, posting thought provoking questions early in the week to start discussion and later to stimulate discussion, responding constructively to fellow students' posts, and working to direct discussion to the important issues of the session)
- Updating reading summaries as appropriate
- Preparing and posting a summary of the discussion (at the end of the week) that includes any outstanding issues or questions that will direct the online live tutorial.

Discussion facilitation rubric

	Yes	Comme ci comme ça...	No
	max 2 points each	max 1 point each	0 points each
Initiation of discussion Weight 30%	Posted summary of the readings and initiated discussions not later than Monday morning	Posted summary of the readings and initiated discussions between Monday morning and Wednesday	Posted summary of the readings and initiated discussions on Wednesday or later or did not post them at all
Quality of postings Weight 20%	Summary of all readings was accurate and highlighted important points, it was thought provoking, well organized, and appropriately concise (within reason but generally not longer than 200 words)	Summary of readings had limitations in its accuracy and organization, and was unnecessarily longer than the essential information	No summary of readings or the summary was inaccurate, incomplete, lengthy, or not organized
Facilitation Weight 30%	Regularly posed critical questions and responded to others to facilitate and maintain the discussion	Posed a few questions and infrequently responded to others to facilitate and maintain the discussion	Did not facilitate and maintain the discussion
Issues to clarify during Friday tutorial Weight 10%	Collected all outstanding and interesting issues to be discussed during Friday live tutorial and shared the list with tutors on Thursday evening	Collected some issues to be discussed during Friday live tutorial and shared them during the tutorial	Did not collect the outstanding issues to be discussed during Friday live tutorial
Summary of the discussion Weight 10%	Posted brief summary of the main points from the discussion at the end of the week (no longer than 200 words)	Posted an incomplete, not organized or too long summary of the main points from the discussion at the end of the week	Did not summarize the discussion.

Weekly live online tutorials

Tutorials will be held on Fridays on Zoom:

<https://mcmaster.zoom.us/j/94667749806?pwd=dWVOa2NWNzB3MjBQSm51YzRNTWhEQT09>

Meeting ID: 946 6774 9806. Passcode: guidelines

Participation in the live tutorial sessions is mandatory as per HRM Program Attendance Policy (*dura lex sed lex*). Tutorial is an important opportunity to discuss and clarify conceptual issues related to each unit. Missing one session is possible, missing two sessions requires permission from the instructor, missing three sessions means you may be asked to drop the course. The agenda for the individual tutorials will be tailored based on the unresolved issues and questions raised by students on the discussion boards. Students will have the opportunity to post additional questions directly to the instructor in advance of each tutorial session. Please refer to section 13: Attendance Policy.

Assignments

Assignments will be posted together with other materials for each unit. Assignments are designed to guide you in the process of developing a section of a guideline with a final recommendation. Assignments will be due at the end of the week on Saturday, 11:59 pm EDT (midnight).

Assignments are submitted online by uploading them on Avenue to Learn. Students should appropriately name submitted documents to avoid confusion (e.g. HRM775s23_A#_FirstName_LastName.docx; where “s22” stands for Spring 2023 session, A# is the number of an assignment followed by the first and last name of a student).

Final project

The final project is completing one guideline recommendation end-to-end on a topic of the student's choice (this includes all supporting documents: summary of the evidence, discussion of the balance of benefits and harms, patient or society values and preferences, evidence profile, Evidence-to-Decision table and final recommendation with appropriate remarks). This project consists of 2 parts: draft materials for the guideline panel members and the final document section with recommendation. Each part is worth 15% of the final course mark. All students should ensure at the beginning of the course that they choose a health care question that can

be feasibly addressed given the time and resource-limited nature of this course. Course instructors will help to assess feasibility of the project, if needed. Sample guidelines and the criteria for evaluation of the final project will be made available to students. (For details see Unit 9)

5. Evaluation

Students are given many opportunities to demonstrate their mastery of the course material. Final course marks will be calculated as follows:

40% = Assignments

30% = Final project (written guideline section with a recommendation):

15% draft materials for guideline panel members

15% final section of the guideline document with recommendation

10% = Discussion participation

10% = Discussion facilitation

10% = Online tutorial participation

Grades in graduate courses at McMaster University are reported as letter grades using the following breakdown:

A+ = 90 to 100 (consistently outstanding)

A = 85 to 89 (overall superior quality)

A- = 80 to 84 (high achievement)

B+ = 77 to 79 (competent, but not consistently high quality)

B = 73 to 76 (satisfactory quality)

B- = 70 to 72 (only marginally acceptable)

F = 0 to 69 (inadequate)

6. Course Instructors

Elie Akl MD, MPH, PhD

Professor of Medicine, Department of Internal Medicine and Department of Epidemiology and Population Health, American University of Beirut, Lebanon
Associate Professor, Department of Health Research Methods, Evidence, and Impact (McMaster University)

Email: akle@mcmaster.ca

Romina Brignardello-Petersen, DDS, MSc, PhD

Associate Professor, Department of Health Research Methods, Evidence, and Impact (McMaster University)

Email: brignarr@mcmaster.ca

Carlos Cuello-Garcia, MD, PhD

Canadian Agency for Drugs and Technologies in Health, Toronto, Canada
Assistant Professor, Department of Health Research Methods, Evidence, and Impact (McMaster University)

Email: cuelloca@mcmaster.ca

Andrea Darzi, MD, MPH, PhD

Assistant Professor, Department of Health Research Methods, Evidence, and Impact (McMaster University)

Email: darzia@mcmaster.ca

Maicon Falavigna, MD, MSc, PhD

Clinical Epidemiology and Internal Medicine, Hospital Moinhos de Vento, Porto Alegre, Rio Grande do Sul, Brazil

Assistant Professor, Department of Health Research Methods, Evidence, and Impact (McMaster University)

Email: falavim@mcmaster.ca

Reem Mustafa, MD, MPH, PhD

Assistant Professor of Medicine and Biomedical and Health Informatics, Department of Internal Medicine, University of Missouri-Kansas City, Kansas, USA

Assistant Professor, Department of Health Research Methods, Evidence, and Impact (McMaster University)

Email: ramustafa@gmail.com

Nancy Santesso, RD, PhD

Assistant Professor, Department of Health Research Methods, Evidence, and Impact
(McMaster University)

Email: santesna@mcmaster.ca

Zhikang Ye, PhD

Postdoctoral Fellow at Michael G. DeGroote National Pain Centre
(McMaster University)

Email: yez39@mcmaster.ca

Yuan Zhang, PhD

Health Economist, Health Quality Ontario, Toronto, Canada

Assistant Professor, Department of Health Research Methods, Evidence, and Impact
(McMaster University)

Email: epizhangyuan@gmail.com

Course Coordinators

Jan Brozek, MD, PhD

Associate Professor, Department of Health Research Methods, Evidence, and Impact
(McMaster University)

Email: jan.brozek@mcmaster.ca

Holger Schünemann, MD, MSc, PhD

Professor, Department of Health Research Methods, Evidence, and Impact (McMaster
University)

Email: holger.schunemann@mcmaster.ca

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7. Course and Instructor Evaluations

Similar to other HRM courses, at the end of the course students will be asked to complete a formal evaluation of the course and of their primary instructor.

8. Where to get help

1. Anything concerning HRM 775 course organization:
 - a. ask fellow students
 - b. contact course coordinator sending an email to jan.brozek@mcmaster.ca.
2. Anything concerning this HRM 775 course content:
 - a. look in the course syllabus
 - b. review course materials
 - c. ask fellow students
 - d. search the Web
 - e. if all fails: contact your instructor.
3. Avenue to Learn technical help:
 - a. ask fellow students
 - b. go to <http://avenue.mcmaster.ca/support.html>
4. Anything concerning the HRM Program: contact Abir Abdulla <abdula27@mcmaster.ca>.

A 775 Cafe discussion area will also be available throughout the duration of the course where students can post and discuss suggestions for improving and augmenting the content, organization and running of the course. This forum gives students an opportunity to discuss with others the pros and cons of specific tasks as well as allowing, where necessary and possible, the instructor to make immediate modifications to the course (e.g. the addition of a discussion forum or a student-created resource library).

9. Communication Expectations & Netiquette

What you can expect from us

- We will respect you and take your questions and concerns seriously
- We will do our best to make the course relevant to you
- We will respond to your requests for assistance in a timely fashion
- We will monitor the discussion forums and occasionally post a comment when issues arise; we will not respond to every post in a discussion board.

- we will provide feedback on your assignments within 1 week of submission; if this is not possible, we will let you know within that time when you can expect your mark and feedback.

For important personal matters please email your instructor or course coordinator directly (using the contact information above) and we will respond as soon as we are able to.

What we expect from you

- We assume that you are a self-motivated adult who learns for herself/himself
- We expect you to communicate in a pleasant, respectful, and efficient manner

You may want to review the rules of netiquette:

<http://www.albion.com/netiquette/corerules.html>

10. Academic Integrity

You are expected to exhibit honesty and use ethical behavior in all aspects of the learning process. Academic credentials you earn are rooted in principles of honesty and academic integrity.

Academic dishonesty is to knowingly act or fail to act in a way that results or could result in unearned academic credit or advantage. This behavior can result in serious consequences, e.g. the grade of zero on an assignment, loss of credit with a notation on the transcript (notation reads: "Grade of F assigned for academic dishonesty"), and/or suspension or expulsion from the University.

It is your responsibility to understand what constitutes academic dishonesty. For information on the various types of academic dishonesty please refer to the Academic Integrity Policy, located at <http://www.mcmaster.ca/academicintegrity>

The following illustrates only three forms of academic dishonesty:

1. Plagiarism, e.g. the submission of work that is not one's own or for which other credit has been obtained.
2. Improper collaboration in group work.
3. Copying or using unauthorized aids in tests and examinations.

11. Students with Disabilities

If you have a disability that may affect your ability to participate or complete the requirements of this course you may wish to contact the instructor to discuss appropriate accommodations. Or, you can contact McMaster University's Centre for Student Development (<http://csd.mcmaster.ca/sswd/>). Among other things CSD provides counseling and support services.

12. Policy on Late Assignments

In extreme situations final papers will be accepted up to 7 days after the due date. However, 10% will be deducted from all late papers.

Discussion summary documents will not be accepted late. The timely submission is crucial to the smooth running of the weekly tutorial sessions; therefore, flexibility on this issue would be to the detriment of the whole class. If something unforeseen comes up in the week you are assigned to facilitate the discussion it will be your responsibility to find another student who would be willing to switch weeks with you.

Exceptions to this policy are at the discretion of the online instructor. It is, however, important that you contact the instructor as soon as possible in the case of an emergency and well before a deadline in the case of previous commitments or restrictions.

13. HRM Attendance Policy

- Any absence must be due to a reasonable excuse that is exceptional and out of the control to some extent of the student.
- One absence from a tutorial with a legitimate excuse is reasonable, 2 may be acceptable at the discretion of the instructor, but if you miss 3 or more tutorials you will not obtain credit for the course. You will be required to withdraw from the course before the last drop deadline or you will receive an 'F' in the course.

- Attendance is considered in the assignment of participation grades. In cases where participation is credited for each session, you will normally receive 0 for participation for any day you are absent.

14. Required Materials

Students are required to access readings online as outlined in weekly reading lists. Students are responsible for any costs incurred for other materials necessary for final projects. This may include library fees to obtain original full text publications of systematic reviews and studies to be reviewed.

Note: mailing of the materials to students

McMaster University Libraries do not have the ability to mail books obtained through inter-library loans directly to students (these materials are available to McMaster students only through library pick-up). Articles that are available in print only through McMaster Libraries may be mailed to students; however, the student is responsible for covering the cost of the reproduction, shipping and handling of these resources.

Course Calendar

Spring/Summer 2023

If any changes need to be made, you will be notified by tutors as soon as possible.

Weekly Units will become available in Avenue on **Sundays at 12:01 am** EDT.

Assignments will be due the following **Saturday at 11:59 pm** EDT.

Online tutorials will run for 1 hour on Friday mornings (time to be confirmed with students).

Unit	Topic	Unit start	Online tutorial
0	Introduction to the Course	May 1	May 5
1	Introduction, overview of guidelines, and their critical appraisal	May 7	May 12
2	Planning a guideline project, priority setting, budget, and organization	May 14	May 19
3	Group composition, processes, and management of competing interests	May 21	May 26
4	Identifying questions and outcomes of interest	May 28	June 2
5	Evidence synthesis	June 4	June 9
6	Grading certainty, summarizing, and presenting evidence	June 11	June 16
7	Assessing the evidence about testing	June 18	June 23
8	Going from evidence to recommendation	June 25	June 30
9	Reporting and dissemination of guidelines	July 2	July 7
10	Implementation, evaluation, adaptation, and updating guidelines	July 9	July 14
–	–	–	July 21 (OPTIONAL)
–	–	–	July 28 (OPTIONAL)

Schedule for Assignments

Unit	Assignment	Description	Due (23h59)	% final grade
0	Assignment 0	1. Choose a topic for your guideline 2. Sign up for discussion list facilitation 3. Share your bio blurb	–	–
1	Assignment U1	Search for an existing guideline and appraise it with AGREE II instrument	May 20	5
2	–	No assignment	–	–
3	–	No assignment	–	–
4	Assignment U4	1. Specify the overall objectives of your guideline 2. Specify questions for your guideline 3. Select one question and determine the outcomes of interest and their importance	June 3	10
5	Assignment U5	Assess the risk of bias in an existing systematic review using the ROBIS tool	June 10	5
6	Assignment U6	Create the GRADE evidence profile for your question	July 1	10
7	–	No assignment	–	–
8	Assignment U8	Complete the Evidence-to-Decision table	July 8	10
9	–	No assignment	–	–
10	–	No assignment	–	–
–	Final assignment	Guideline “package” and final recommendation	July 29	30

WEEKLY UNITS

UNIT 0: Orientation

Introduction

Some of you may be new to the online learning environment or to McMaster University's learning management system – Avenue to Learn, thus, there is no learning module for this week. Instead, we want you to use this time to meet each other and ensure that everyone is comfortable navigating around the course.

You will also choose and present to the instructor the topic of a guideline project that you intend to work on during the course. It is essential that your instructor approves the guideline topic for your final project by the end of this week, so make sure to send your proposal early and attend the online tutorial on Friday.

Objectives

At the conclusion of this session you should:

- Understand the course format, assignments, and evaluation methods.
- Know the expected format of final assignment (guideline recommendation and accompanying materials)
- Get to know your peers and your instructor
- Know where to find help
- Have an approved topic for a final project

Readings

Glasziou P, Haynes B. The paths from research to improved health outcomes. ACP J Club. 2005 Mar-Apr;142(2):A8-10.

NOTE: We recommend it wholeheartedly as an illustration of the "big picture"

Assignments for this week

1. **Sign-up for facilitation** of the Readings Discussion board (see section 4 – Course format – above)
2. **Choose a guideline topic** that you would like to work on during the course and send them to the Course Coordinator by **Sunday, May 7th**.
3. **Decide whether you prefer to work in pairs** during the course, which may be beneficial as guideline development is always a group effort. Please let the course coordinator know whether you will work on your topic alone or together with another student. If you choose to work together, both of you would select the same guideline topic (e.g. nonpharmacological management of knee osteoarthritis) but

each of you would work on different questions within this topic (e.g. Should acupuncture be added to usual medical therapy for patients with knee OA? and Should joint lavage rather than medical therapy alone be used for patients with knee OA?)

4. Carefully review the course syllabus and post any questions in the *775 Café* (see the discussion forums on Avenue).
5. **Prepare your bio-blurb** and post it on the *775 Café* discussion board (1-3 short paragraphs, not more than 200 words), including:
 - a. A brief description of your background and explanation of your area of study/work (explain it to us as if you tried to explain it to your family members who have no relation to health care – e.g. your aunt or your friend's grandmother)
 - b. Reason(s) for taking this course – what you hope to gain by completing it
 - c. Some interesting information about you – e.g. how would you like others to address you (by your name, nickname etc.), how far from McMaster you currently live (pictures and short video clips are welcome), etc., etc. Use your imagination.
6. Make sure that you can access online readings through McMaster University library. For more information please refer to: <https://hsl.mcmaster.ca/>
(Note: your login and password are your MAC ID and your MAC ID password).

UNIT 1: Introduction, overview of guidelines, and their critical appraisal

Introduction

The first step is to understand the purpose of guidelines and recommendations in different health care settings (e.g. clinical, public health, health systems, coverage decisions, etc.). This unit provides an overview of the guideline process and describes what a guideline panel needs in order to make recommendations.

Before commencing our own guideline, we need to be aware of already existing relevant guidelines. In this unit you will be introduced to sources of existing guidelines and the criteria to assess the rigor of development and quality of reporting of guidelines.

Learning Objectives

1. To understand what is a guideline and the overall process of its development
2. To understand the overall objectives of guidelines
3. To become familiar with the sources of existing guidelines
4. To practice critical appraisal of existing guidelines

Required Readings

1. Burgers J. et al. Clinical guidelines as a tool for implementing change in patient care. In *Improving Patient Care: The Implementation of Change in Health Care*, 2nd Edition. Grol et al. Chichester, West Sussex : Wiley-Blackwell/BMJ Books, 2013.
2. Schünemann HJ et al. Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise. *CMAJ*. 2014 Feb 18;186(3):E123-42. (<http://www.cmaj.ca/content/186/3/E123>).

NOTE: The guideline development checklist can be downloaded from the HEI website: <http://cebgrade.mcmaster.ca/guidelinechecklistprintable.pdf>. You may want to keep it handy during the entire course and check each item that you actually completed. As part of the final assignment you will be asked to submit the final guideline development checklist with all items that you did during this course marked as addressed.

3. AGREE II (<http://www.agreetrust.org/>)
AGREE II instrument (<https://www.agreetrust.org/resource-centre/agree-ii/>)
4. Shiffman RN et al. Standardized reporting of clinical practice guidelines: a proposal from the Conference on Guideline Standardization. *Ann Intern Med.* 2003;139(6):493-498.

Additional Materials (good-to-know-about)

1. Guidelines International Network (GIN): International Standards for Clinical Practice Guidelines
(<https://www.acpjournals.org/doi/10.7326/0003-4819-156-7-201204030-00009?articleid=1103747&>)
2. ASH Users' guide for guidelines:
(<https://ashpublications.org/bloodadvances/article/4/9/2095/455055/A-user-guide-to-the-American-Society-of-Hematology>)
3. Institute of Medicine (IOM) standards for developing trustworthy clinical practice guidelines (<https://www.ncbi.nlm.nih.gov/books/NBK209539/>)

Not necessarily readings, but you may find them useful

1. Example of the use of AGREE II instrument:
Padjas A et al. Methodological rigor and reporting of clinical practice guidelines in patients with allergic rhinitis: QuGAR study. *J Allergy Clin Immunol.* 2014 Mar;133(3):777-783

Assignment 1

This assignment is worth 5% of your final grade.

1. Critically appraise a guideline relevant to your topic
 - a. Search for guidelines on the same or similar topic to the one you chose.
 - b. Critically appraise one relevant guideline using the AGREE II instrument. You may use the template AGREE II Score Sheet (https://www.agreetrust.org/wp-content/uploads/2017/08/agreell_score_sheet.docx).
 - c. If you chose to work on the same topic with a fellow student, both of you may assess the same guideline and compare your assessments; it might be beneficial to discuss any disagreements, so that you see how people differ in their judgments.
2. Write and submit as Assignment 1:

- a. your search strategy (how did you search for relevant guidelines)
- b. your completed assessment of a sample guideline on AGREE II Score Sheet
- c. a short paragraph summarizing how and where you searched for existing guidelines, what you found, and what were the limitations of the guideline that you appraised (in reality we would assess and describe all guideline documents that we found). Try to keep it short but informative (maximum 250 words). This paragraph will become a part of the introduction in your final project.
- d. submit 2a–c as the Assignment 1 (please also attach the guideline document that you appraised).

NOTE: If you find no existing guideline on your topic, please choose any guideline that is of interest to you and evaluate it using the AGREE II instrument as above.

Please save and submit your assignment in Microsoft Word or RTF format using the following naming rule: HRM775s23_A1_YourName.docx

Where to look for existing guidelines

These are the places where we may

- MacPLUS: <http://plus.mcmaster.ca/McMasterPLUSDB/>
- Canadian Medical Association Infobase: <https://joulecma.ca/cpg/homepage>
- TRIP Database: <http://www.tripdatabase.com>
- Epistemonikos: <https://www.epistemonikos.org/en/>
- PubMed Medline: <http://www.ncbi.nlm.nih.gov/pubmed/> (using a filter for guidelines, e.g. systematic[sb])
- Topic-specific professional societies
- Interdisciplinary websites:
 - Alberta Medical Association – Toward Optimized Practice
 - British Columbia Council on Clinical Practice Guidelines
 - National Institute for Health and Care Excellence (NICE)
 - National Institutes of Health (NIH)
 - Scottish Intercollegiate Guidelines Network (SIGN)
 - World Health Organization (WHO)
 - CADTH Grey Matters

UNIT 2: Planning the guideline project priority setting, budget, and organization

Introduction

This unit focuses primarily on the initial phases of guideline development: choosing a guideline topic, preparation of the project, and defining the overall objectives of the guideline. By the end of this unit, you should have specified the general scope of your guideline project. You will also be introduced to the GRADE approach to making recommendations.

Make sure you review the relevant section in the Guideline Development Checklist that was among the required readings for Unit 1.

Learning Objectives

1. To understand the first steps of developing a guideline, including priority setting, preparing a budget, and project organization
2. To recognize which of the above are the responsibility of the guideline methodologist and which depend mainly on the organization sponsoring the guideline (that still may need guidance from a methodologist)
3. To become more familiar with the concept of guideline adoption, adaptation, *de novo* development, and “adoption” (for: adoption, adaptation, and development)
4. To understand the principles of the GRADE approach to developing guidelines and how the decision to follow this approach (or not to follow it) may influence the initial steps in the process.

Required Readings

1. WHO Handbook for Guideline Development, 2nd Ed, 2014.
(https://apps.who.int/iris/bitstream/handle/10665/145714/9789241548960_eng.pdf?sequence=1&isAllowed=y)
Chapter 1: Introduction
Chapter 2: Planning guidelines
2. Browman GP et al. When is good, good enough? Methodological pragmatism for sustainable guideline development. *Implement Sci.* 2015 Mar 6;10:28. doi: 10.1186/s13012-015-0222-4.

3. Fervers B et al. ADAPTE Collaboration. Guideline adaptation: an approach to enhance efficiency in guideline development and improve utilisation. *BMJ Qual Saf.* 2011 Mar;20(3):228-36.
4. Guyatt GH et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol.* 2011;64(4):383-94.

Additional Readings

1. Atkins D et al. 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. Article 2: Priority Setting in Guideline Development. *Proceedings of the American Thoracic Society.* 2012;9(5):225-228.
2. Yawn BP et al. 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. Article 1: Identifying Target Audiences: Who Are the Guidelines For? *Proceedings of the American Thoracic Society.* 2012;9(5):219-224.

Assignment

There is no written assignment this week. You may, however, start thinking – with your fellow student (if you chose to work in a pair) or individually – about the overall objectives for your guideline please assume that you are planning the whole guideline project which would have multiple recommendations and cover a broader topic, despite the final deliverable of this course (i.e. final assignment) will be only one selected recommendation. Consider the following items and specify them for your guideline (be as specific as you think would be needed for the guideline group members and for the users of your guideline to understand your intentions):

- Purpose and expected benefits or outcomes (e.g. reduced variability in practice, improved care for patients with some condition, prevention, diagnosis, treatment, etc.).
- Target population (individuals to whom those recommendations will apply – patients).
- Key comorbidities or coexisting conditions to consider.
- Healthcare setting (healthcare system, level of healthcare – primary, secondary, etc. – where recommendations are supposed to be implemented).
- Types of interventions (which preventive, therapeutic, and diagnostic interventions will be covered and which will not be).

- Key stakeholders and users (all relevant professional groups, institutions, patients, public, who are target users or beneficiaries of these guidelines and/or whose views should be sought).
- Key resources to consider (resources needed for the implementation of recommendations, e.g. additional human resources, cost of medications, equipment, infrastructure, system changes, etc., and potential barriers to implementation).
- Title (title of your guidelines that would concisely describe the above).

You may also consider what specific questions your guideline will address (what would one like to do, instead of what else, and in whom), which one of those questions you will choose to work on and develop recommendation, and what outcomes (what would we want to achieve for those people in question) would be of interest in the context of that question.

The above will be your assignment the following week (Unit 4) but you may want to have more time to discuss with other experts in the field, patients, and other stakeholders. Despite being seemingly easy, it is not straightforward to figure out what issues are important to address in a guideline (i.e. what problems people need advice on) and what is the *actual* question, and from whose perspective...

“How startlingly different a place the world is when viewed from a point only three feet to the left” (Douglas Adams, *The Salmon of Doubt*).

UNIT 3: Guideline group composition, group processes, and management of competing interests

Introduction

This unit focuses on the membership and function of a guideline development group (aka: guideline panel, decision makers). Specifically, we will discuss group processes, consensus building methods, the importance of declaring competing interests and how to deal with conflict of interest issues should they arise.

Learning Objectives

1. To recognize the importance of guideline group composition
2. To become familiar with group processes and consensus building methods used during guideline development
3. To become familiar with strategies for reporting and managing actual or potential conflicts of interest

Required Readings

1. WHO Handbook for Guideline Development, 2nd Ed, 2014.
(https://apps.who.int/iris/bitstream/handle/10665/145714/9789241548960_eng.pdf?sequence=1&isAllowed=y)
Chapter 3: Contributors and their role in guideline development
Chapter 6: Declaration and management of interests
2. Guidelines International Network (GIN): Principles for Disclosure of Interests and Management of Conflicts in Guidelines
(<https://www.acpjournals.org/doi/10.7326/m14-1885>)
3. Kunz R et al. 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. Article 3: Guideline Group Composition and Group Processes. Proceedings of the American Thoracic Society. 2012;9(5):229-233.
(<http://www.atsjournals.org.libaccess.lib.mcmaster.ca/doi/abs/10.1513/pats.2012.08-056ST>)

4. Boyd EA et al. 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. Article 4: Guideline Funding and Conflicts of Interest. Proceedings of the American Thoracic Society. 2012;9(5):234-242.
(<http://www.atsjournals.org.libaccess.lib.mcmaster.ca/doi/abs/10.1513/pats.201208-057ST?src=recsys>)
5. Hutchings A, Raine R. A systematic review of factors affecting the judgments produced by formal consensus development methods in health care. Journal of Health Services Research and Policy. 2006; 11(3): 172–179.
(<http://hsr.sagepub.com.libaccess.lib.mcmaster.ca/content/11/3/172.full.pdf+html>)

Additional readings

1. Cluzeau F et al. 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. Article 9: Stakeholder Involvement: How to Do It Right. Proceedings of the American Thoracic Society. 2012;9(5):269-273.
(<http://www.atsjournals.org.libaccess.lib.mcmaster.ca/doi/abs/10.1513/pats.201208-062ST?src=recsys>)
2. Pagliari C et al. The potential influence of small group processes on guideline development. J Eval Clin Pract. 2001 May;7(2):165-73.
(http://journals2.scholarsportal.info.libaccess.lib.mcmaster.ca/pdf/13561294/v07i0002/165_tpiosgpogd.xml)
3. Pagliari C1, Grimshaw J. Impact of group structure and process on multidisciplinary evidence-based guideline development: an observational study. J Eval Clin Pract. 2002 May;8(2):145-53.
(http://journals1.scholarsportal.info.libaccess.lib.mcmaster.ca/pdf/13561294/v08i0002/145_iogsapegdaos.xml)
4. Murphy MK et al. Consensus development methods and their use in clinical guideline development. Health Technology Assessment, 1998, 2(3)
(http://www.journalslibrary.nihr.ac.uk/__data/assets/pdf_file/0003/64839/FullReport-hta2030.pdf).

Assignment

There is no written assignment this week.

UNIT 4: Identifying questions and outcomes of interest

Introduction

In order for the guidelines to be useful, they need to address appropriate health care questions that are relevant for the target users. This is a critical part of the guideline development process – not getting the questions right may produce a perfect answer to a wrong question. Despite being seemingly easy, this part of the process is usually challenging for guideline groups.

This unit focuses primarily on the process of identifying all important questions being in the scope of a guideline and prioritizing them, as it is usually not feasible to answer all questions. It is equally important to *a priori* identify all outcomes of interest for each question (i.e. how will one measure that one action is better than the other) and rating their importance, or weight for the decision, usually from the perspective of affected individuals (most often the patients).

By the end of this unit, you will have identified and formulated questions to be addressed in your guideline. You will also have chosen one question that you will work on during the course. For that question you will have identified and prioritized patient-important outcomes. In addition, you will be able to distinguish between questions to be answered with recommendations (referring to actions) and other questions not to be answered with recommendations (those not about actions).

Learning Objectives

1. To determine and formulate the appropriate guideline questions
2. To determine outcomes of interest and rate their importance
3. To understand the importance of values and preferences in choosing outcomes of interest and deciding about their importance
4. To decide what types of evidence to include in order to answer the question with recommendation

Required Readings

1. WHO Handbook for Guideline Development, 2nd Ed. 2014. Chapter 7. Formulating questions and selecting outcomes (<https://apps.who.int/iris/handle/10665/145714>)

2. GRADE guidelines 2: Framing the question and deciding on important outcomes ([https://www.jclinepi.com/article/S0895-4356\(10\)00331-8/fulltext](https://www.jclinepi.com/article/S0895-4356(10)00331-8/fulltext))
3. Wilt TJ et al. 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. Article 5: Deciding What Type of Evidence and Outcomes to Include in Guidelines. *Proceedings of the American Thoracic Society*. 2012;9(5):243-250. (<http://www.atsjournals.org.libaccess.lib.mcmaster.ca/doi/abs/10.1513/pats.201208-058ST?src=recsys>)
4. Uhlig K et al. A framework for crafting clinical practice guidelines that are relevant to the care and management of people with multimorbidity. *J Gen Intern Med*. 2014; 29(4): 670–679. (http://journals2.scholarsportal.info.libaccess.lib.mcmaster.ca/pdf/08848734/v29i0004/670_affccpamopwm.xml)
5. Tong A et al. Consumer involvement in topic and outcome selection in the development of clinical practice guidelines. *Health Expect*. 2012; 15(4): 410-423. (http://journals1.scholarsportal.info.libaccess.lib.mcmaster.ca/pdf/13696513/v15i0004/410_ciitaotdocpg.xml)

Useful resources

Core Outcome Measures in Effectiveness Trials (COMET):
<http://www.comet-initiative.org/>

Assignment 4

This assignment is worth 10% of your final grade.

Specify the overall objectives of your guideline.

You may use the template provided among the resources for this unit or the template in GRADEpro (www.grade.pro).

When working on the Assignment 2 please assume that you are planning the whole guideline project which would have multiple recommendations and cover a broader topic, despite the final deliverable of this course (i.e. final assignment) will be only one selected recommendation. Consider the following items and specify them for your guideline (be as specific as you think would be needed for the guideline group members and for the users of your guideline to understand your intentions):

- Purpose and expected benefits or outcomes (e.g. reduced variability in practice, improved care for patients with some condition, prevention, diagnosis, treatment, etc.).

- Target population (individuals to whom those recommendations will apply – patients).
- Key comorbidities or coexisting conditions to consider.
- Healthcare setting (healthcare system, level of healthcare – primary, secondary, etc. – where recommendations are supposed to be implemented).
- Types of interventions (which preventive, therapeutic, and diagnostic interventions will be covered and which will not be).
- Key stakeholders and users (all relevant professional groups, institutions, patients, public, who are target users or beneficiaries of these guidelines and/or whose views should be sought).
- Key resources to consider (resources needed for the implementation of recommendations, e.g. additional human resources, cost of medications, equipment, infrastructure, system changes, etc., and potential barriers to implementation).
- Title (title of your guidelines that would concisely describe the above).

Note: you may find it helpful at this stage to get familiar with GRADEpro – software to write guidelines (www.gradepro.org) – of particular interest will be the section on defining the scope of the guideline.

Specify questions for your guideline.

1. Generate at least 5 questions for your guideline in the appropriate format (should A vs B be used for/to ...).
2. Choose one specific question that you will address in your final project and justify why this question is important, i.e. why people need advice about what to do in such a case – a recommendation. **Please make sure that the systematic review addressing this question is available (either your own or another published one).**
3. Determine which outcomes are important to know in the context of the population and interventions in your chosen question and rate their relative importance (assign weight to each outcome).

Please save and submit your assignment using the following naming example:
HRM775s23_A4_YourName.docx

UNIT 5: Evidence synthesis

Introduction

Every guideline question should ideally be answered based on a systematic review and a summary of the available evidence. In an ideal world this would be a full-fledged systematic review, but in real life one sometimes resorts to a pragmatic evidence synthesis.

Learning Objectives

1. To be able to assess the quality of an existing systematic review.
2. To use existing reviews to answer guideline questions – determining their usefulness and requirement for updating.
3. To decide what to do when there is more than one systematic review answering the same guideline question.
4. To understand the methods of evidence synthesis.
5. To decide what to do when experimental studies are lacking – when to include observational or indirect evidence.

Required Readings

1. Whiting P et al. ROBIS: a new tool to assess the risk of bias in systematic reviews. *J Clin Epidemiol.* (in press) DOI: <http://dx.doi.org/10.1016/j.jclinepi.2015.06.005>
[http://www.jclinepi.com/article/S0895-4356\(15\)00308-X/pdf](http://www.jclinepi.com/article/S0895-4356(15)00308-X/pdf)
2. WHO Handbook for Guidelines Development, 2nd Ed. 2014. Chapter 8. Evidence retrieval and synthesis
3. Tsertsvatze A et al. How to conduct systematic reviews more expeditiously? *Syst Rev* 2015; 12: 160
(<http://systematicreviewjournal.biomedcentral.com/articles/10.1186/s13643-015-0147-7>)

Assignment 5

This assignment is worth 5% of your final grade.

Use the ROBIS tool to assess the quality of the systematic review that you selected to answer your guideline question. Determine if an update of the review is required. In addition to completing the ROBIS assessment, provide a short paragraph describing: 1) the limitations of the systematic review, 2) whether an update is required, and 3) how you will go about that update (maximum 200 words).

Please save and submit your assignment as a single file using the following naming example: HRM775s23_A5_YourName.docx.

Please also submit the review that you assessed.

UNIT 6: Grading certainty of evidence, summarizing and presenting evidence

Introduction

There are many ways in which guideline authors may summarize the evidence. Today, the GRADE approach has become a de facto standard for assessing and presenting the available evidence about health effects. It provides specific criteria for rating the certainty of evidence (aka quality of evidence or confidence in the estimates of effects). This unit focuses primarily on using the GRADE approach to rate the certainty of evidence. By the end of this unit, you will have some experience in application of the GRADE approach and in presentation of the essential information in GRADE Evidence Profiles or Summary of Findings tables.

REMEMBER: certainty of evidence is always being assessed for each outcome separately across all studies that measured that outcome – the body of evidence about that outcome.

Learning Objectives

1. To practice rating the certainty of the body of evidence for each important outcome in the context of your guideline question.
2. To present the summary of evidence.
3. To understand the differences among various presentations of the evidence (GRADE Evidence Profiles, Cochrane Summary of Findings tables).

Required Readings

1. Atkins D et al. for the GRADE Working Group. Systems for grading the quality of evidence and the strength of recommendations I: critical appraisal of existing approaches. *BMC Health Serv Res.* 2004;4(1):38 [PMID: 15615589].
<http://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-4-38>
2. Guyatt G et al. GRADE guidelines 1: Introduction – GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol.* 2011;64(4):383–394. (you have already read this article but it may be beneficial to review once more the part

about the presentation of information)

<http://www.sciencedirect.com.libaccess.lib.mcmaster.ca/science/article/pii/S0895435610003306>

3. Balshem H et al. GRADE guidelines 3: Rating the quality of evidence – introduction. *J Clin Epidemiol*. 2011;64(4):401–406.
<http://www.sciencedirect.com.libaccess.lib.mcmaster.ca/science/article/pii/S089543561000332X>
4. Guyatt G et al. 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. Article 7 Synthesis, Grading, and Presentation of Evidence in Guidelines. *Proceedings of the American Thoracic Society*. 2012;9(5):219-224.
<http://www.atsjournals.org.libaccess.lib.mcmaster.ca/doi/abs/10.1513/pats.201208-060ST?journalCode=pats#readcube-epdf>

Additional readings

1. Guyatt GH et al. GRADE guidelines: 4. Rating the quality of evidence--study limitations (risk of bias). *J Clin Epidemiol*. 2011;64(4):407–415.
2. Guyatt GH et al. GRADE guidelines: 5. Rating the quality of evidence-publication bias. *J Clin Epidemiol*. 2011;64(12):1277–1282.
3. Guyatt GH et al. GRADE guidelines 6. Rating the quality of evidence-imprecision. *J Clin Epidemiol*. 2011;64(12):1283–1293.
4. Guyatt GH et al. GRADE guidelines: 7. Rating the quality of evidence-inconsistency. *J Clin Epidemiol*. 2011;64(12):1294–1302.
5. Guyatt GH et al. GRADE guidelines: 8. Rating the quality of evidence-indirectness. *J Clin Epidemiol*. 2011;64(12):1303–1310.
6. Guyatt GH et al. The GRADE Working Group. GRADE guidelines: 9. Rating up the quality of evidence. *J Clin Epidemiol*. 2011;64(12):1311–1316.
7. WHO Handbook for Guidelines Development, 2nd Ed. 2014. Chapter 9: Evidence assessment
8. Hultcrantz M et al. The GRADE Working Group clarifies the construct of certainty of evidence. *J Clin Epidemiol*. 2017 Jul;87:4-13.
[https://www.jclinepi.com/article/S0895-4356\(16\)30703-X/fulltext](https://www.jclinepi.com/article/S0895-4356(16)30703-X/fulltext)

Assignment 6

This assignment is worth 10% of your final grade.

Rate the certainty of the evidence for each patient-important outcome that you selected following the GRADE approach. Justify your decisions in footnotes. You may use GRADEpro (www.grade.pro) to produce the GRADE evidence profile.

Please save and submit your assignment as a single file using the following naming example: HRM775s23_A6_YourName.docx

UNIT 7: Assessing the evidence about testing

Introduction

The approach to making recommendations about the use of diagnostic tests is based on the assumption that it should bring benefit to patients. In this unit, we will discuss the differences in approaches to formulating questions, summarizing and assessing the evidence, and making recommendations about tests, specifically when only the information about given test accuracy is available.

Learning Objectives

1. To understand the different approaches to making recommendations about the use of medical tests
2. To be familiar with QUADAS II instrument used to assess the risk of bias in diagnostic accuracy studies

Required Readings

1. Schünemann HJ et al. GRADE guidelines: 22. The GRADE approach for tests and strategies-from test accuracy to patient-important outcomes and recommendations. *J Clin Epidemiol*. 2019. PMID: 30738926
2. Whiting P et al. QUADAS-2: A Revised Tool for the Quality Assessment of Diagnostic Accuracy Studies. *Ann Intern Med*. 2011; 155: 529-536
<http://annals.org/aim/article/474994/quadas-2-revised-tool-quality-assessment-diagnostic-accuracy-studies>
3. Mustafa RA et al. Decision-making about healthcare related tests and diagnostic strategies: A review of methodological and practical challenges. *J Clin Epidemiol*. 2017. PMID: 28916488.

Additional readings

1. Schünemann HJ et al. GRADE Guidelines: 16. GRADE evidence to decision frameworks for tests in clinical practice and public health. *J Clin Epidemiol*. 2016 Aug;76:89-98. doi: 10.1016/j.jclinepi.2016.01.032. Epub 2016 Feb 27. PubMed PMID: 26931285.

2. Mustafa RA et al. Decision-making about healthcare related tests and diagnostic strategies: a qualitative study with experts suggests that test accuracy data alone is rarely sufficient for decision-making. *J Clin Epidemiol.* 2017. PMID: 28917629.
3. Hsu J et al. Application of GRADE: Making Evidence-Based Recommendations about Diagnostic Tests in Clinical Practice Guidelines. *Implementation Science.* 2011; 6(1):62
<https://www.ncbi.nlm.nih.gov/libaccess.lib.mcmaster.ca/pmc/articles/PMC3126717/pdf/1748-5908-6-62.pdf>
4. *Cochrane Handbook for Diagnostic Test Accuracy Systematic Reviews* (<http://methods.cochrane.org/sdt/handbook-dta-reviews>)
5. *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice Second Edition.* Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J Cook. Copyright © 2008 American Medical Association. Chapter 14: The Process of Diagnosis
6. *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice Second Edition.* Gordon Guyatt, Drummond Rennie, Maureen O. Meade, Deborah J Cook. Copyright © 2008 American Medical Association. Chapter 16: Diagnostic Tests

Assignment

There is no written assignment this week.

UNIT 8: Evidence to decision framework and final recommendation

Introduction

When deciding about the final recommendation, there are other factors important to consider, in addition to the magnitude of health effects and the certainty of that evidence. They include values and preferences of patients, their family members and the society, required resources (cost), equity issues, acceptability of the interventions to other stakeholders, and feasibility of implementation of interventions. This unit focuses on using the evidence to decision (EtD) framework to integrate all that information when formulating a recommendation. By the end of this unit you will have some experience using the EtD framework to integrate all important information and finalize a recommendation.

Learning Objectives

1. To identify all factors that influence the final decision when making a recommendation.
2. To formulate a final recommendation and determine its strength.

Required Readings

1. Andrews J et al. GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. *J Clin Epidemiol.* 2013;66(7):719–725.
([http://www.jclinepi.com/article/S0895-4356\(12\)00138-2/pdf](http://www.jclinepi.com/article/S0895-4356(12)00138-2/pdf))
2. Andrews J et al. GRADE guidelines 15: Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol.* 2013;66(7):726-735
([http://www.jclinepi.com/article/S0895-4356\(13\)00054-1/pdf](http://www.jclinepi.com/article/S0895-4356(13)00054-1/pdf))
3. Alonso-Coello P et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. *BMJ* 2016;353:i2016
(<http://www.bmj.com/content/353/bmj.i2016.long>)
4. Alonso-Coello P et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare

choices. 2: Clinical practice guidelines. *BMJ* 2016;353:i2089
 (<http://www.bmj.com/content/353/bmj.i2089.long>)

5. Matchar DB et al. Strategies for Incorporating Resource Allocation and Economic Considerations. *American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition)*. *Chest* 2008; 133:132S–140S
 (<http://journal.publications.chestnet.org.libaccess.lib.mcmaster.ca/data/Journals/CHEST/22073/132S.pdf>)

Additional readings

1. Schünemann HJ et al. GRADE Guidelines: 16. GRADE evidence to decision frameworks for tests in clinical practice and public health. *J Clin Epidemiol*. 2016;76:89-98
2. Zhang Y et al. Using patient values and preferences to inform the importance of health outcomes in practice guideline development following the GRADE approach. *Health and Quality of Life Outcomes* 2017;15:52
 (<https://hqlo.biomedcentral.com/articles/10.1186/s12955-017-0621-0>)
3. Kelson M et al. 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. Article 8 Integrating Values and Consumer Involvement in Guidelines with the Patient at the Center. *Proceedings of the American Thoracic Society*. 2012;9(5):262-268.
 (<http://www.atsjournals.org.libaccess.lib.mcmaster.ca/doi/abs/10.1513/pats.201208-061ST?src=recsys>)
4. Brunetti M et al. GRADE guidelines: 10. Considering resource use and rating the quality of economic evidence. *J Clin Epidemiol*. 2013;66(2):140-50.
5. Schünemann HJ et al. 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. Article 11: Moving from Evidence to Developing Recommendations in Guidelines. *Proceedings of the American Thoracic Society*. 2012;9(5):282-292.
 (<http://www.atsjournals.org.libaccess.lib.mcmaster.ca/doi/abs/10.1513/pats.201208-064ST?src=recsys>)
6. Schwartz JA, Pearson SD. Cost consideration in the clinical guidance documents of physician specialty societies in the United States. *JAMA Intern Med*. 2013;173(12):1091-7

Examples of systematic reviews of values and preferences

1. Giacomini M et al. Experiences of Living and Dying With COPD: A Systematic Review and Synthesis of the Qualitative Empirical Literature. Ontario Health Technology Assessment Series; Vol. 12: No. 13, pp. 1–47, March 2012 (http://www.hqontario.ca/en/mas/tech/pdfs/2012/rev_COPD_Qualitative_March.pdf)
2. MacLean S et al. Patient values and preferences in decision making for antithrombotic therapy: a systematic review: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012;141(2 Suppl):e1S-23S. (<https://www.ncbi.nlm.nih.gov/libaccess.lib.mcmaster.ca/pmc/articles/PMC3278050/pdf/112290.pdf>)

Assignment 8

This assignment is worth 10% of your final grade.

Complete the Evidence to Decision framework and formulate the suggested final recommendation. Search for and summarize the critical issues about the patient values and preferences, resources, and feasibility. You may do it either using a document template or using GRADEpro (www.GRADEpro.org).

Note, that in the real guideline development process the best option is not to provide any suggestions for recommendations to a guideline panel and let them decide themselves once they review all evidence and make judgments about all decision criteria in the EtD. The alternative is to provide a “template” for a recommendation, so the guideline development group has some framework to start with. This may be in the form of so called “neutral recommendation”:

We suggest/recommend that clinicians use/do not use the intervention A, rather than intervention B, in some population of people (strong/conditional recommendation based on high/moderate/low/very low certainty evidence).

UNIT 9: Reporting and dissemination of guidelines

Introduction

This unit focuses on reporting and drafting a guideline document and on wording of recommendations. We will also discuss guideline dissemination methods and tools. By the end of this unit you will be able to follow a structured format when preparing the guideline report and you will be familiar with the effective (and ineffective) methods for dissemination of guidelines.

Learning Objectives

1. To become familiar with the external review process (tools, rationale, and stakeholder engagement)
2. To structure the final guideline report
3. To review guideline dissemination methods: tools, derivative products, and accompanying materials

Required Readings

1. Wilson KC et al. 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. Article 12: Reporting and Publishing Guidelines. Proceedings of the American Thoracic Society. 2012;9(5):293-297.
(<http://www.atsjournals.org.libaccess.lib.mcmaster.ca/doi/abs/10.1513/pats.201208-065ST?src=recsys>)
2. Grimshaw JM et al. 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. Article 13: Disseminating and Implementing Guidelines. Proceedings of the American Thoracic Society. 2012;9(5):298-303.
(<http://www.atsjournals.org.libaccess.lib.mcmaster.ca/doi/abs/10.1513/pats.201208-066ST?src=recsys>)
3. A Reporting Tool for Practice Guidelines in Health Care: The RIGHT Statement (<https://pubmed.ncbi.nlm.nih.gov/27893062/>)
RIGHT Checklist (<http://www.right-statement.org/right-statement/checklist>)

4. WHO Handbook for Guideline Development, 2nd Ed. 2014.
Chapter 12: Producing and publishing the guideline

Additional Readings

1. Shiffman RN et al. Standardized reporting of clinical practice guidelines: a proposal from the Conference on Guideline Standardization. *Ann Intern Med.* 2003;139(6):493-498.
(<http://sfx.scholarsportal.info.libaccess.lib.mcmaster.ca/mcmaster?sid=Entrez%3aPubMed&id=pmid%3a13679327>)
2. Shekelle P et al. Developing clinical practice guidelines: reviewing, reporting, and publishing guidelines; updating guidelines; and the emerging issues of enhancing guideline implementability and accounting for comorbid conditions in guideline development. *Implement Sci.* 2012 Jul 4;7:62. doi: 10.1186/1748-5908-7-62.
(<https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-7-62>)
3. Hussain T et al. The Yale Guideline Recommendation Corpus: a representative sample of the knowledge content of guidelines. *Int J Med Inform.* 2009 May;78(5):354-63.
4. Lomotan EA et al. How "should" we write guideline recommendations? Interpretation of deontic terminology in clinical practice guidelines: survey of the health services community. *Qual Saf Health Care.* 2010 Dec;19(6):509-13.

Assignment

There is no written assignment due this week. You may still work on Assignment 8 and you may want to start preparing the draft of the final assignment.

Notes about the final assignment:

In a real guideline development process your guideline document would most likely include more than just one question, evidence profile, EtD, and recommendation. For the purpose of the course, however, you may prepare a draft guideline document that will just list other questions as you determined them in Assignment 4. You may want to refer back to the AGREE II instrument to see what is considered a well-reported guideline. Try to include that information in your draft. If you chose to work in pairs, then some parts of this assignment will be common to your final assignments, so best is to prepare them together.

Collate materials that you already prepared in previous assignments, edit if necessary, and prepare a comprehensive package including:

1. Overall objectives of your guideline. Write between a sentence to a short paragraph about each: purpose of the guideline and why it is important to make recommendations, scope of the guideline, target patient population and the intended healthcare setting, management options being considered, target users/stakeholders, etc. as you determined them in Assignment 4. Write only the essential information. This section should not exceed 400 words.
2. A GRADE evidence profile for your one selected question (Assignment 6)
3. Complete Evidence-to-Decision table for your question (Assignment 8)
4. Text of the document for the selected question including:
 - a. One paragraph summarizing the evidence: what reviews you found, ended up using, whether they needed an update, if you included observational studies etc.) (maximum 200 words)
 - b. A summary of desirable and undesirable health consequences (i.e. outcomes) (maximum 300 words)
 - c. Any specific considerations related to implementation of the recommendation, cost implications, etc. based on the information that you collected in the EtD (maximum 300 words)
 - d. A very short summary of what other guidelines on the same topic are recommending and whether your recommendation is similar or different (if different, try to explain the reasons for the difference) (maximum 200 words).

At this stage you may also review the guideline development checklist again (see Unit 1) and mark the items that you actually did during this course. Please submit it together with the final assignment.

Please save and submit your final assignment as a single file using the following naming example: HRM775s23_A11_YourName.docx.

UNIT 10: Implementation, evaluation, adaptation, and updating guidelines

Introduction

Development and dissemination of guidelines is the first step in a continuous process, in which implementation, evaluation, and adaptation to local circumstances are important components. Guideline adaptation and implementation strategies are available but may vary according to the guideline context and scope.

A recommendation is an advice, a guideline is a set of advices. Advice may change if new information becomes available or when the situation changes. As a result guidelines may need to be periodically updated.

Learning Objectives

1. To review the available guideline implementation and evaluation methods and tools.
2. To familiarize oneself with the strategies for guideline adaptation.
3. To learn how to keep guidelines updated, and be familiar with the concept of “living guidelines”.

Required Readings

1. Burgers JS et al. 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. Article 14: Adaptation, Evaluation, and Updating of Guidelines. Proceedings of the American Thoracic Society. 2012;9(5): 304-310.
(<http://www.atsjournals.org.libaccess.lib.mcmaster.ca/doi/abs/10.1513/pats.201208-067ST?src=recsys>)
2. Schünemann HJ et al. GRADE Evidence to Decision Frameworks for adoption, adaptation and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT. J Clin Epidemiol. 2016 Oct 3.
(<http://www.sciencedirect.com.libaccess.lib.mcmaster.ca/science/article/pii/S0895435616304826>)
3. Cancer Care Ontario Program in Evidence-Based Care: Document Assessment and Review

(<https://www.cancercareontario.ca/sites/ccocancercare/files/assets/CCOPEBCDARP.pdf>)

4. Alonso-Coello P et al. The updating of clinical practice guidelines: insights from an international survey. *Implementation Science* 2011;6:107
(<https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-6-107>)

Additional readings

1. WHO Handbook for Guideline Development, 2nd Ed. 2014.
Chapter 13: Adaptation, implementation and evaluation
2. Living systematic reviews: 4. Living guideline recommendations
(<https://pubmed.ncbi.nlm.nih.gov/28911999/>)
3. Gagliardi AR et al. How can we improve guideline use? A conceptual framework of implementability. *Implement Sci.* 2011; 6: 26.
(<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3072935/>)
4. Gagliardi AR et al. Do guidelines offer implementation advice to target users? A systematic review of guideline applicability. *BMJ Open* 2015;5:e007047
(<http://bmjopen.bmj.com/content/5/2/e007047.full>)
5. Gagliardi AR et al. Integrating guideline development and implementation: analysis of guideline development manual instructions for generating implementation advice. *Implementation Science* 2012;7:67
(<https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-7-67>)
6. Wang Z et al. Implementation plans included in World Health Organisation guidelines. *Implementation Science* 2016;11:76
(<https://implementationscience.biomedcentral.com/articles/10.1186/s13012-016-0440-4>)
7. Martínez García L et al. Strategies for monitoring and updating clinical practice guidelines: a systematic review. *Implementation Science* 2012;7:109
(<https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-7-109>)
8. Vernooij R et al. Guidance for updating clinical practice guidelines: a systematic review of methodological handbooks. *Implementation Science* 2014;9:3
(<https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-9-3>)
9. Martínez García L et al. Updated recommendations: an assessment of NICE clinical guidelines. *Implementation Science* 2014;9:72
(<https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-9-72>)

Assignment

There is no written assignment this week.

Final assignment

Assignment 12

This assignment is worth 30% of your final grade.

See Unit 9 for instructions

