What Review is Right for You? v2.0

Explanation and Elaboration

Quantitative Methods

This tool is designed to provide guidance and supporting material to reviewers on methods for the conduct and reporting of a knowledge synthesis.

Please contact Dr. Andrea Tricco at KnowledgeSynthesis@smh.ca for more information on this tool.

Question 1: What is your goal or objective?

Answer Response A: Assess the effectiveness and/or safety of interventions

- The effectiveness of interventions refers to the effects of an intervention under real life conditions (e.g., the effects of a vaccine in older adults), as compared to efficacy, which refers to the effect of an intervention in research studies, such as randomized controlled trials (e.g., the effects of a vaccine among participants in a randomized controlled trial).
    - Example 1: *Systematic review: Comparative effectiveness and safety of oral medications for type 2 diabetes mellitus*

      "Background: As newer oral diabetes agents continue to emerge on the market, comparative evidence is urgently required to guide appropriate therapy.

      Objectives: To summarize the English-language literature on the benefits and harms of oral agents (second-generation sulfonylureas, biguanides, thiazolidinediones, meglitinides, and alpha-glucosidase inhibitors) in the treatment of adults with type 2 diabetes mellitus."[1]

    - Example 2: *Efficacy and Safety of Prophylactic Vaccines against Cervical HPV Infection and Diseases among Women: A Systematic Review*

      "Background: We conducted a systematic review and meta-analysis to assess efficacy and safety of prophylactic HPV vaccines against cervical cancer precursor events in women.

      Objectives: The present study aims to provide a comprehensive assessment of vaccine safety and efficacy against multiple virological and clinical endpoints using the techniques of systematic review and meta-analysis."[2]

- The safety of interventions refers to the assessment of harms associated with an intervention. For example, determining the risk of adverse events when taking a blood pressure medication.

    - Example 1: *Systematic review: Comparative effectiveness and harms of treatments for clinically localized prostate cancer*

      "Background: The comparative effectiveness of localized prostate cancer treatments is largely unknown.

      Objectives: To compare the effectiveness and harms of treatments for localized prostate cancer."[3]

    - Example 2: *Fatal and non-fatal repetition of self-harm. Systematic review*

      "Background: Non-fatal self-harm frequently leads to non-fatal repetition and sometimes to suicide. We need to quantify these two outcomes of self-harm to help us to develop and test effective interventions.

      Objectives: To estimate rates of fatal and non-fatal repetition of self-harm."[4]

Answer Response B: Assess the burden of illness, monetary costs or the cost-effectiveness of interventions

- Cost-effectiveness studies assess the trade-offs of effectiveness and costs of interventions (i.e. examining the amount of money spent to gain a certain amount of effectiveness or benefits). Systematic reviews of cost-effectiveness studies are often used to support decision-making. For example, a Public Health agency may want to compare the effectiveness and costs of different vaccine strategies, such as a universal program to reduce the burden of the common flu. As an alternative strategy, the program may target the elderly and high-risk groups who are immunologically compromised to decide which program offers the best value for money.

    - Example 1: *A systematic review and meta-analysis of the direct epidemiological and economic effects of seasonal influenza vaccination on healthcare workers*

      "Background: Given the uncertainty in attributions of patient benefits to healthcare workers (HCW) vaccination, having strong evidence of the direct effectiveness of vaccination on healthcare workers and the cost-effectiveness of these campaigns in reducing the incidence of illness and absenteeism among HCW is important. Previously, a systematic review evaluated the direct effectiveness of influenza vaccination of HCWs but failed to provide any conclusions due to the limited number of included studies [16]. Moreover, only epidemiological effects were examined, and no systematic review has summarized economic evidence despite the substantial costs involved in implementing HCW vaccination.

      Objectives: The specific objective in this review was to synthesize evidence to whether influenza vaccines reduced influenza related morbidity among HCWs, which

includes incidence rate and absenteeism, and the associated costs of these programs."[5]

- Example 2: *Assessing the impact and cost-effectiveness of needle and syringe provision and opioid substitution therapy on hepatitis C transmission among people who inject drugs in the UK: an analysis of pooled data sets and economic modelling.*

  "Background: There is limited evidence of the impact of needle and syringe programmes (NSPs) and opioid substitution therapy (OST) on hepatitis C virus (HCV) incidence among people who inject drugs (PWID), nor have there been any economic evaluations.

  Objectives: The aim of this project was to assess the impact and different coverage levels of needle and syringe provision with and without OST on the incidence of HCV infection among PWID as well as the costs and cost-effectiveness of NSPs."[6]

- Cost studies examine monetary cost or other burdens of diseases or health conditions, such as the costs of care for HIV individuals or the burden of the disease on life expectancy, health-related quality of life, and the social and psychological implications of the disease.

  - Example 1: *Public prescription drug plan coverage for antiretrovirals and the potential cost to people living with Human Immunodeficiency Virus (HIV) in Canada: a descriptive study*

    "Background: Antiretrovirals are expensive and people living with HIV may experience a range of financial burdens when accessing these medications.

    Objectives: Our aim was to describe the policy of all Canadian public drug insurance programs for antiretroviral drugs and illustrated how these policies might affect patients' annual out-of-pocket expenditures."[7]

  - Example 2: *Associations between multimorbidity and additional burden for working-age adults with specific forms of musculoskeletal conditions: a cross-sectional study*

    "Background: Multiple health conditions are increasingly a problem for adults with musculoskeletal conditions. However, multimorbidity research has focused primarily on the elderly and those with a limited subset of musculoskeletal disorders.

    Objectives: We sought to determine whether working-age adults with specific forms of musculoskeletal conditions are worse off in the presence of multimorbidity compared to the rest of the musculoskeletal sample."[8]

Answer Response C: Assess the epidemiology of a disease or health condition

- Epidemiological studies often measure the prevalence and incidence of a disease or health condition on the population level, as well as variation in epidemiological findings.

  - Example 1: *Epidemiology of heart failure and trends in diagnostic work-up: a retrospective, population-based cohort study in Sweden*

"Background: Diagnosis of heart failure (HF) is challenging, particularly so in the elderly because many of the characteristic signs and symptoms are non-specific and serve only to raise suspicion of HF rather than to give a definitive diagnosis, thus limiting their diagnostic value. With evolving changes in patient demographics and overall HF management, including diagnostic procedures and treatment regimens, there is need for an improved understanding of the temporal trends in the epidemiology of HF. In particular, an insight into changes in HF annual incidence rate and prevalence is necessary to inform healthcare stakeholders on the burden of HF to determine its impact on allocation of hospital resources.

Objectives: The purpose of this study was to examine the trends in heart failure (HF) epidemiology and diagnostic work-up in Sweden.

Key questions that this analysis aims to answer include:
1) Are the annual incidence rate and prevalence of HF increasing or declining in Sweden, both nationally and regionally?
2) How does the diagnostic work-up of patients in real clinical practice compare with recommendations made in management guidelines and does this change over time?
3) Have advances in the treatment of HF translated into patients living longer?"[9]

- Example 2: *Epidemiology of gastrostomy insertion for children and adolescents with intellectual disability*

  "Background: The use of gastrostomy insertion in pediatrics is increasing and the most common recipients during childhood have neurological impairment, most of whom also have intellectual disability (ID).

  Objectives: This study investigated trends in first gastrostomy insertion according to markers of disadvantage and ID etiology. Linked administrative and health data collected over a 32-year study period (1983-2014) for children with ID born between 1983 and 2009 in Western Australia were examined."[10]

- Other types of epidemiological studies, for example cohort studies, evaluate the association of body weight with total mortality and with cardiovascular events in coronary artery disease."

  - Example 1: *Association of bodyweight with total mortality and with cardiovascular events in coronary artery disease: a systematic review of cohort studies*

    "Background: Studies of the association between obesity, and total mortality and cardiovascular events in patients with coronary artery disease (CAD) have shown contradictory results.

    Objectives: Our aim was to undertake a systematic review of cohort studies and perform a meta-analysis to better estimate the effect of bodyweight and other measures of obesity on total mortality, cardiovascular mortality, reinfarction, and revascularization in patients with established CAD."[11]

- Example 2*: Risks of stillbirth and neonatal death with advancing gestation at term: A systematic review and meta-analysis of cohort studies of 15 million pregnancies*

  "Background: Prolonged pregnancy is a known risk factor for stillbirth. To avoid this adverse outcome, women are routinely offered induction of labour after 41 weeks gestation. This recommendation is based on evidence of increased stillbirth risk beyond 41 weeks. However, 1 in 3 stillbirths occur prior to 41 weeks gestation. The stillbirth risks before 41 weeks are not routinely discussed with women who have no clinical indication for delivery. This is in part because of how 'term pregnancy' is defined as normal in standard texts, and in part because of concerns about adverse neonatal outcomes that may occur from delivery before 41 weeks. Individual studies on the risk of stillbirth in what is considered as normal term gestation vary in the magnitude and consistency of findings by gestational week. Corresponding neonatal mortality estimates are imprecise.

  Objectives: We undertook a systematic review to evaluate the additional weekly risks of stillbirth in term pregnancies that continue versus deliver at various gestational ages. We also assessed the week-specific risks of neonatal death by gestational age at birth."[12]

Answer Response D: Assess the prognosis of a disease or health condition

- Prognostic studies examine the likely course or development of a disease or health condition.

  - Example 1: *Prognosis of pregnancy-associated breast cancer: A meta-analysis of 30 studies*

    "Background: Prognosis of pregnancy-associated breast cancer (PABC) has been addressed in several studies with inconsistent results. The relative rarity of the disease precludes the conduction of large powered controlled studies to address this question. Some studies have found that PABC is more commonly diagnosed at an advanced stage suggesting that the poor prognosis is secondary to diagnostic delay rather than an inherent effect of pregnancy or lactation on breast cancer prognosis. However, other studies have shown an independent effect of pregnancy on outcome. Nevertheless, the small number of patients examined in each of the individual studies has hindered the proper interpretation of these data.

    Objectives: We aimed to perform a comprehensive analysis of all published studies that addressed the prognosis of PABC. We specifically wanted to clarify whether diagnosis during pregnancy or 1-year afterwards has an impact on long-term patient outcome."[13]

  - Example 2: *Risk factors for necrotizing enterocolitis in neonates: a systematic review of prognostic studies*

    "Background: Many observational studies have reported clinical and non-clinical risk factors associated with necrotizing enterocolitis (NEC), but the prognostic value usually is unclear. Most of these studies were not designed to answer prognostic questions properly. To identify independent risk factors for a complex disease as

NEC, a (preferably prospective) prognostic cohort design with multivariable analysis including multiple co-variates is considered most appropriate.

Objectives: The aim of this study was to provide a systematic review of the literature on prognostic studies reporting on independent risk factors for NEC in neonates."[14]

Answer Response E: Assess a diagnostic test for precision and accuracy

- A diagnostic test or procedure is an examination to identify an individual's specific areas of weakness and strength in order to determine a condition, disease or illness. It is used to gather clinical information on an individual in order to make a diagnosis (e.g., x-rays, CT scan etc.).
    - Example 1: *Diagnostic Accuracy of (Computed Tomography) CT for Local Staging of Colon Cancer: A Systematic Review and Meta-Analysis*

      "Background: CT is being used as a staging tool in the FOxTROT trial, but it remains unclear what the accuracy of CT is for selection of these high-risk colon cancer tumors. This is partially because, in the literature, colon and rectal cancer are combined, despite the fact that colon and rectal cancers differ in terms of anatomy, diagnostic workup, and treatment, as described already…

      Objectives: The purpose of this article is to determine the accuracy of CT in the detection of tumor invasion beyond the bowel wall and nodal involvement of colon carcinomas."[15]
    - Example 2: *Accuracy of interferon-γ-induced protein 10 for diagnosing latent tuberculosis infection: a systematic review and meta-analysis*

      "Background: Effective diagnostic methods for detecting latent tuberculosis infection (LTBI) are important for its eradication. A number of studies have evaluated the use of interferon-γ-induced protein 10 (IP-10), which is elevated after tuberculosis infection, as a biomarker for LTBI, but conclusive results regarding its effectiveness have not been reported.

      Objectives: Our objective was to assess the diagnostic value of IP-10 for LTBI."[16]
- Screening tools (e.g., self-assessment questionnaires) and clinical assessments (e.g., psychometric testing) can be used to assist with determining a specific diagnosis
    - Example 1: *Screening for alcohol problems in primary care: A systematic review*

      "Background: Primary care physicians can play a unique role in recognizing and treating patients with alcohol problems.

      Objectives: To evaluate the accuracy of screening methods for alcohol problems in primary care."[17]
    - Example 2: *Clinical neurophysiological assessment of sepsis-associated brain dysfunction: A systematic review*

"Background: Several studies have reported the presence of electroencephalography (EEG) abnormalities or altered evoked potentials (EPs) during sepsis. However, the role of these tests in the diagnosis and prognostic assessment of sepsis-associated encephalopathy remains unclear.

Objectives: The aim of our study was to answer the following questions:

1. What is the incidence of EEG/EP alterations in patients with severe infections or sepsis?
2. What is the accuracy of EEG/EP abnormalities in the diagnosis of SAE/SABD?
3. What is the prognostic value of such abnormalities in this setting?"[18]

Answer Response F: Identify/clarify concepts, definitions, available research, and gaps in research

- The responses A-E above describe relatively precise goals and objectives. This response pertains to the need to clarify working definitions and/or the conceptual boundaries of a research topic, and to identify available research as well as research gaps (e.g., research questions or problems which have not been answered appropriately or at all in a given topic).
    - Example 1: *Prevention and management of unprofessional behavior among adults in the workplace: a scoping review*

      "Background: Previous attempts to mitigate unprofessional behaviour include feedback to perpetrators and educational interventions. However, the effectiveness of these strategies, in particular targeting faculty in academic medical centres and universities, is not clear.

      Objectives: The aim of this scoping review was to identify interventions to prevent and manage unprofessional behavior among adults in any workplace or professional setting."[19]

    - Example 2: *Utility of social media and crowd-intelligence data for pharmacovigilance: a scoping review*

      "Background: In order to advance pharmacovigilance (defined as the science and activities related to detection, comprehension and prevention of adverse drug events), monitoring and analysis of data collected from social media sources (i.e., social media listening) is being researched as a potential to supplement traditional drug safety surveillance systems. Three reviews have been recently published to explore the breadth of evidence on the methods and use of social media data for pharmacovigilance; however, none of the reviews found rigorous evaluations of the reliability and validity of the data.

      Objectives: To assess the utility of social media data for detecting adverse events related to health products, including pharmaceuticals, medical devices, and natural health products.

The specific research questions were:
(1) Which social media listening platforms exist to detect adverse events related to health products, and what are their capabilities and characteristics?
(2) What is the validity and reliability of data from social media for detecting these adverse events?"[20]

Question 2: If your review is about interventions or diagnostic tests, how many?

- This question is referring to the number of interventions or diagnostic tests that will be involved in your review questions, and is only relevant if your answer to question 1 is A or E. It is not about the number of comparisons, subgroups or outcomes you will be including.
    - [2 interventions] Example 1: *Comparison of early intervention services vs treatment as usual for early-phase psychosis: A systematic review, meta-analysis, and meta-regression*
        - This systematic review compares early intervention versus treatment as usual for early-phase psychosis services.
    - [2 diagnostic tests] Example 2: *Diagnostic accuracy of point-of-care natriuretic peptide testing for chronic heart failure in ambulatory care: Systematic review and meta-analysis*
        - This systematic review evaluated the diagnostic accuracy of two point-of-care tests, natriuretic peptide testing (B-type natriuretic peptide (BNP) or N terminal fragment pro B-type natriuretic peptide (NTproBNP)), against any relevant reference standard, including echocardiography, clinical examination, or combinations of these, in humans.
    - [>2 interventions] Example 3: *Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with major depressive disorder: a systematic review and network meta-analysis*
        - In this systematic review, 21 antidepressant drugs were assessed.
    - [>2 diagnostic tests] Example 4: *Diagnostic performance of imaging modalities in chronic pancreatitis: a systematic review and meta-analysis*
        - In this systematic review, three diagnostic tests were assessed: endoscopic ultrasonography, magnetic resonance imaging, and computed tomography molecular rapid diagnostic testing.

Question 3: What type of evidence will you be using?

Answer Response A: Systematic reviews only

- A systematic review attempts to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. Specifically, the unit of synthesis in a systematic review is a primary study (as defined below).
    - Example 1: *Interventions for adolescent mental health: an overview of systematic reviews*
        - This review provides a summary of findings from systematic reviews.

Answer Response B: Primary studies only

- Primary studies refer to research studies in which data were often collected from individuals, such as patients or healthy subjects. Specifically, the unit of analysis in a primary study is a subject.
    - Example 1: *Alterations in fecal microbiota composition by probiotic supplementation in healthy adults: A systematic review of randomized controlled trials*
        - This systematic review includes randomized controlled trials only.

Question 4: What type of analysis will you conduct?

- This question is in reference to the *planned* analysis for the review. The intended analysis may not be possible based on the available evidence.

Answer Response A: Descriptive analysis only

- Descriptive analysis refers to tabulating and summarizing characteristics of included studies, and narratively summarizing the results and findings of the included studies. No statistical analysis is planned or feasible due to heterogeneity of study findings.
    - Example 1: *What is polypharmacy? A systematic review of definitions*
        - " . . . The definitions of polypharmacy and associated terms were categorised as: i. numerical only (using the number of medications to define polypharmacy), ii. numerical for a given duration of therapy or healthcare setting for e.g., during hospital stay or iii. Descriptive (using a brief description to define polypharmacy). Once the primary data extraction was complete all authors reviewed the content analysis for each of the extracted studies, with data further categorised and summarised in tables."[21]

Answer Response B: Quantitative synthesis only

- Quantitative synthesis:

- A meta-analysis synthesizes quantitative results comparing pairs of interventions of the included studies.
    - Example 1: *Aspirin for the prevention of preterm and term preeclampsia: systematic review and meta-analysis*
        - "We performed a systematic review and meta-analysis that evaluated the prophylactic effect of aspirin during pregnancy . . . Relative risks of the prophylactic effects were calculated with their 95% confidence intervals."[22]
- A network meta-analysis synthesizes quantitative results comparing three or more interventions of the included studies, allowing for indirect comparisons of interventions that have not been directly compared in these studies (see below).

Known comparisons: A vs. B and B vs. C
Unknown comparison: A vs. C
Method: A vs. C = (A vs. B) – (B vs. C)

- Example 1: *Comparative efficacy and acceptability of 21 antidepressant drugs for the acute treatment of adults with major depressive disorder: a systematic review and network meta-analysis*
    - "We included placebo-controlled and head-to-head trials of 21 antidepressants used for the acute treatment of adults (≥18 years old and of both sexes) with major depressive disorder . . . We estimated summary odds ratios (ORs) using pairwise and network meta-analysis with random effects."[23]

Question 5: Do you have time and/or cost constraints to complete your review?

- These constraints may be considered from the perspective of the knowledge users (i.e., the people requesting the review or information). Engaging with knowledge users throughout the review process is highly encouraged to ensure that the resulting evidence meets their needs.[27]
- It is important to note that approaches related to the shortened timelines of reviews should not be used as a preferential choice, and if they are used, they should be transparently reported. The emergence of these mechanisms was a result of knowledge users requiring evidence within a condensed timeframe in order to make informed decisions. These approaches include using review shortcuts, narrowing the scope of the review, intensifying the work on review processes, and automating review steps.[27]
    - Example 1: Patient safety initiatives in obstetrics: a rapid review
        - " . . . In order to provide decision-makers with timely results, a rapid review approach was collectively agreed on with a 6-week timeline for completion.

Rapid reviews tailor the systematic review process to produce information that is relevant to decision-maker needs in an abbreviated period of time. The streamlined steps followed in this review included limiting: the study design to randomised clinical trials (RCTs), search dates to a period of 10 years and language of publication to English."[28]

Answer Response A: Yes

- Time constraints[24, 25]: On average, systematic reviews take six months to a year to complete. If you have a shorter time frame (<6 months), select "yes".
- Cost restraints[25, 26]: On average, conducting a systematic review requires $50,000-$100,000. If you have limited or no funding, and time constraints, select "yes". The number of appropriate KS methods is reduced when both time and cost constraints are involved.

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