Preoperative Fasting for Liquids — Systematic Review Protocol

# Background

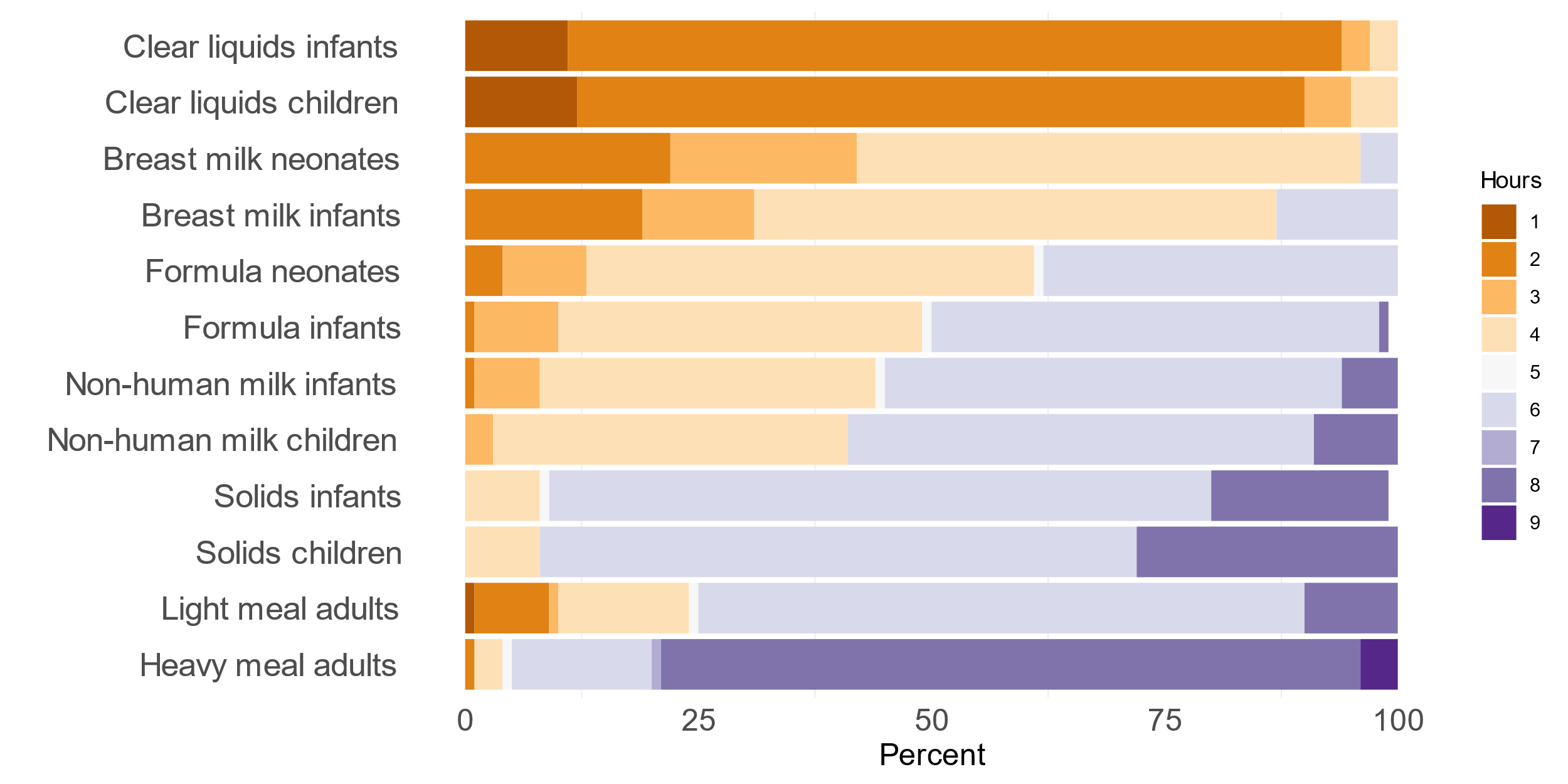
With the loss of protective laryngeal reflexes during anesthesia, aspiration of gastric contents can occur. Pulmonary aspiration can cause pneumonitis, pneumonia, and airway obstruction resulting in significant morbidity and mortality.1,2 During elective surgery, the incidence of aspiration is 3 to 5 per 10,000 in adults and 4 to 8 per 10,000 in children.3 In the general surgical population, morbidity and mortality range from 1 to 2.5 per 100,000 and 0.4 to 2.0 per 100,000, respectively.4 Among healthy (ASA physical status I-II) patients undergoing elective surgery (population addressed in the 2017 guidelines), the aspiration incidence appears lower. For example, results from two studies5,6 (n = 164,518) suggest an aspiration rate of 1.1 per 10,000 (95% CI, 0.7 to 1.8); a study of ASA physical status I-II children7 (n = 55,616) reported a rate of 1.3 per 10,000 (95% CI, 0.6 to 2.6).

Minimizing gastric volume can decrease the risk of pulmonary aspiration, but clinical evidence defining the relationship between volume and risk is limited. Based on animal models, avoiding a low gastric pH lowers the risk of pneumonitis following aspiration.

There is general agreement concerning the duration of fasting following a meal that minimizes the risk of pulmonary aspiration. However, due to the variety of liquid compositions, synthesizing evidence and developing recommendations on the duration of fasting following liquids is challenging.

The 1999 guideline surveyed 84 consultants concerning the length of fasting times judged appropriate for various age and liquid or food combinations.8 displays the correspondence of expert opinion with fasting times. The recommended fasting times (e.g., 2-4-6-6-6 rules) remained unchanged in the 2011 and 2017 updates.

Figure 1. Consultant survey (n = 84) of appropriate fasting times included in the 1999 guidelines—percentages agreeing with different fasting times.



8 hours

2 hours

1 hour

6 hours

4 hours

The 2017 guideline update reviewed evidence examining the association between fasting duration (liquids or solids) and gastric volume, pH, and adverse consequences of fasting (hunger, thirst, serum glucose, and insulin).9 Evidence was rated for 21 PICOs across adults, children, and infants—16 were judged equivocal or insufficient. Recommendations accordingly appear supported by limited strength of evidence and rely on intermediate outcomes (). summarizes the ratings and meta-analytic results for liquids from the 2017 guideline.

Table 1. Summary of 2017 ASA strength of evidence ratings for fasting in adults.



# Key Questions

1. For adults undergoing elective procedures with general anesthesia, regional anesthesia, or procedural sedation, what are the benefits and harms of carbohydrate-containing clear liquids ingested until 2 hours prior to the procedure compared with fasting and non-caloric clear liquids?
2. For adults undergoing elective procedures with general anesthesia, regional anesthesia, or procedural sedation, what are the benefits and harms of protein-containing clear liquids ingested until 2 hours prior to the procedure compared with fasting and non-caloric clear liquids?
3. For adults undergoing elective procedures with general anesthesia, regional anesthesia, or procedural sedation, what are the effects of chewing gum on residual gastric volume, gastric pH, and pulmonary aspiration prior to anesthesia induction?
4. For pediatric patients undergoing elective procedures with general anesthesia, regional anesthesia, or procedural sedation, what are the benefits and harms of 1- versus 2-hour clear liquid fasting?

# PICOTS

## Population(s):

* Patients undergoing general anesthesia, sedation, or regional anesthesia for elective procedures (intended population same as 2017 guideline, “healthy” patients)
* Subgroups of interest
* Age
* Adult
* Adolescent 12 to < 16 years
* Children 2 to 12 years
* Infant 1 month to 2 years
* Neonate (birth – 1 month)
* Health status
* ASA I-II
* ASA III or higher
* Groups with potentially higher risk of aspiration
* Obesity
* Pregnancy
* Diabetes

## Interventions:

* Type of liquid
  + Water
  + Carbohydrate-containing clear liquids
* Complex carbohydrates
* Simple carbohydrates
* Protein-containing clear liquids
  + Chewing gum or hard candy
* Duration of fasting
* Amount of ingested liquid

## Comparators:

* NPO
* Placebo
* Other clear liquids (for example, black tea, black coffee, broth, fruit juice without pulp)
* Quantity of liquid
* Duration of fasting

## Outcomes:

* Pulmonary aspiration
* Aspiration-related morbidity including pneumonia, pneumonitis
* Mortality
* Adverse effects of fasting: hunger, thirst, pain, postoperative nausea and vomiting, fatigue, irritability (children)
* Patient comfort and satisfaction
* Length of stay
* Complications
* Intermediate
* Regurgitation
* Gastric emptying
* Gastric volume
* Gastric pH
* Insulin resistance

## Timing:

* + - Perioperative period

## Settings:

* + - In-patient or ambulatory

## Analytic Framework (Evidence Model)

Figure 2. Analytic framework for preoperative fasting. Dotted arrows indicate the strength of the link between intermediate and final outcomes is uncertain.



## Methods

### Task Force

The director of ASA’s Committee on Practice Parameters assembled a guideline task force of anesthesiologists, methodologists, and a patient representative. Members were asked to disclose relevant relationships (industry and other entities) that might pose a conflict of interest. The task force was responsible for developing the key questions; the PICOTS; and the study inclusion/exclusion criteria for the systematic review.

The task force will be asked to prioritize outcomes by key question on a scale of 1 to 9 (1-3, limited importance; 4-6, important; 7-9, critical).10 These prioritizations will be used to guide the evidence synthesis.

### Criteria for Inclusion/Exclusion of Studies

#### Publication Types

* + Published journal articles, reports
  + Language restrictions: English language only
  + Limited to humans
  + Grey literature

#### Study Designs

* + Include
    - Randomized and clinical trials
    - Non-randomized clinical trials
    - Quasi-experimental studies
    - Observational studies
  + Exclude
    - Case reports and case series
    - Letters
    - Editorials
    - Comments
  + Systematic reviews and meta-analyses [for bibliographies]

#### Settings

* + Any practice setting

### Search Strategies

Comprehensive bibliographic database searches will be conducted by a medical librarian of the following: PubMed, EMBASE, and SCOPUS. For key questions 1 and 2, studies examining carbohydrate- and protein-containing clear liquids published in January 2000 or later will be eligible for inclusion. For key questions 3 and 4, studies examining gum chewing and 1-hour fasting in pediatric patients published from January 1990 and later will be eligible for inclusion. In addition, the Cochrane Central Register of Controlled Trials (cochranelibrary.com/central) will be searched; task force members will be queried for potential studies; references from systematic reviews and meta-analyses will be hand-searched; and trial registries (clinicaltrials.gov and apps.who.int/trialsearch) will be searched.

### Data Abstraction and Management

DistillerSR will be used to conduct title and abstract screening, full-text screening, data abstraction, and data management.11 Screening will be performed independently by two methodologists. Conflicts will be discussed, and when necessary, a third methodologist will be included to resolve all conflicts. Finally, potential inclusion-exclusion discrepancies will also be examined using the DistillerAI tool. Eligible studies will include randomized and nonrandomized trials, quasi-experimental, cohort (prospective and retrospective), and case-control designs. Case reports and case series, conference abstracts, letters not considered research reports, non-English publications, and animal studies will be excluded.

A single methodologist will abstract the data into DistillerSR which will be reviewed by a second methodologist for quality control. Data elements of interest include: study design (randomized controlled trial, nonrandomized comparative study, observational study); number in study; type of procedure; type of anesthesia; patient characteristics (age, BMI, co-morbidities, ASA physical status); intervention (fasting duration, type of liquid or solid ingested, quantity of liquid or solid); outcomes (aspiration, regurgitation, gastric volume, gastric pH, physiologic measures such as insulin and glucose, adverse events of fasting, patient comfort and satisfaction), and outcome measurement method (scintigraphy, ultrasound, gastric suctioning, magnetic resonance imaging). Conflicts will be resolved by consensus. When relevant data is not reported in the published work, attempts will be made to contact authors. Figures will be digitized as necessary to obtain quantitative results for synthesis.

### Risk of Bias of Individual Studies

Quality assessment of randomized clinical trials will be conducted using the Cochrane Risk of Bias (RoB) tool, version 1.12 For non-randomized studies, the Risk Of Bias In Non-randomised Studies of Interventions (ROBINS-I) tool will be used.13 RoB and ROBINS-I include bias assessments on confounding, selection of participants, classification of interventions, deviations from interventions, missing data, outcome measurements, and selection of reported results. In addition, RoB assesses the randomization process.

### Evidence Synthesis

Study characteristics and treatment arm details will be tabulated by key question. Results will be summarized in tabular form by outcome. Pairwise and network random-effects meta-analyses of results from randomized designs will be performed.14,15 Small study effects and the potential for publication bias will be evaluated using funnel plots and regression-based tests.16 Analyses will be conducted in R (R Foundation for Statistical Computing, Vienna, Austria, 2022).17-19

### Grading the Strength of Evidence

The strength of evidence for select important and critical outcomes will be appraised using both the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE)20 and ACCF/AHA frameworks.21 In GRADE, RCTs start as high strength of evidence and nonrandomized studies start as low. The strength is downgraded based on risk of bias, inconsistency, indirectness, imprecision, and publication bias. Strength may be upgraded if the effect is large, a dose-response is present, or if unaccounted residual confounding would likely have increased the effect.20 For network meta-analyses, the strength of evidence will be assessed with the Confidence in Network Meta-Analysis tool.22

### Strength of Recommendations

The GRADE system will be used to determine the strength of the recommendations: strong in favor, conditional in favor, conditional against, and strong against an intervention. Strong recommendations reflect the task force believing all or almost all clinicians would choose the specific action or approach. Conditional recommendations are those where most, but not all, would choose the action or approach.23 When the task force judges the body of evidence inconclusive, a best practice statement may be considered.24

Table 2. Protocol development timeline

|  |  |  |
| --- | --- | --- |
| **Date** | **Section** | **Modification** |
| January 2020 |  | First outline |
| April 2020 | Analytic Framework | Add complications from pulmonary aspiration (pneumonia and pneumonitis) to analytic framework |
| November 2020 | Key questions | Key questions refined to carbohydrate-containing clear liquids, protein-containing clear liquids, and gum chewing |
| December 2021 | Key questions | Key question on pediatric 1-hour fasting added |

# References

1. Marik PE: Aspiration pneumonitis and aspiration pneumonia. N Engl J Med 2001; 344:665-71

2. Mandell LA, Niederman MS: Aspiration pneumonia. N Engl J Med 2019; 380:651-63

3. Janda M, Scheeren TW, Noldge-Schomburg GF: Management of pulmonary aspiration. Best Pract Res Clin Anaesthesiol 2006; 20:409-27

4. Engelhardt T, Webster NR: Pulmonary aspiration of gastric contents in anaesthesia. Br J Anaesth 1999; 83:453-60

5. Sakai T, Planinsic RM, Quinlan JJ, Handley LJ, Kim TY, Hilmi IA: The incidence and outcome of perioperative pulmonary aspiration in a university hospital: A 4-year retrospective analysis. Anesth Analg 2006; 103:941-7

6. Warner MA, Warner ME, Weber JG: Clinical significance of pulmonary aspiration during the perioperative period. Anesthesiology 1993; 78:56-62

7. Warner MA, Warner ME, Warner DO, Warner LO, Warner EJ: Perioperative pulmonary aspiration in infants and children. Anesthesiology 1999; 90:66-71

8. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: Application to healthy patients undergoing elective procedures: A report by the american society of anesthesiologist task force on preoperative fasting. Anesthesiology 1999; 90:896-905

9. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: Application to healthy patients undergoing elective procedures: An updated report by the american society of anesthesiologists task force on preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration. Anesthesiology 2017; 126:376-93

10. Guyatt GH, Oxman AD, Kunz R, Atkins D, Brozek J, Vist G, Alderson P, Glasziou P, Falck-Ytter Y, Schunemann HJ: Grade guidelines: 2. Framing the question and deciding on important outcomes. J Clin Epidemiol 2011; 64:395-400

11. Evidence Partners: Distillersr. Ottawa, Canada, 2020

12. Higgins JP, Altman DG, Gotzsche PC, Juni P, Moher D, Oxman AD, Savovic J, Schulz KF, Weeks L, Sterne JA, Cochrane Bias Methods G, Cochrane Statistical Methods G: The cochrane collaboration's tool for assessing risk of bias in randomised trials. BMJ 2011; 343:d5928

13. Sterne JA, Hernan MA, Reeves BC, Savovic J, Berkman ND, Viswanathan M, Henry D, Altman DG, Ansari MT, Boutron I, Carpenter JR, Chan AW, Churchill R, Deeks JJ, Hrobjartsson A, Kirkham J, Juni P, Loke YK, Pigott TD, Ramsay CR, Regidor D, Rothstein HR, Sandhu L, Santaguida PL, Schunemann HJ, Shea B, Shrier I, Tugwell P, Turner L, Valentine JC, Waddington H, Waters E, Wells GA, Whiting PF, Higgins JP: Robins-i: A tool for assessing risk of bias in non-randomised studies of interventions. BMJ 2016; 355:i4919

14. Rucker G, Krahn U, Konig J, Efthimiou O, Davies A, Papakonstantinou T, Schwarzer G: Netmeta: Network meta-analysis using frequentist methods., 2022

15. Beliveau A, Boyne DJ, Slater J, Brenner D, Arora P: Bugsnet: An r package to facilitate the conduct and reporting of bayesian network meta-analyses. BMC Med Res Methodol 2019; 19:196

16. Schwarzer G, Carpenter JR, Rücker G: Meta-analysis with r, Springer, 2015

17. Team RC: R: A language and environment for statistical computing. 2020

18. Balduzzi S, Rucker G, Schwarzer G: How to perform a meta-analysis with r: A practical tutorial. Evid Based Ment Health 2019; 22:153-60

19. Schwarzer G, Carpenter JR, Rucker G: Metasens: Statistical methods for sensitivity analysis in meta-analysis., 2022

20. Schunemann H, Brozek J, Guyatt G, Oxman A: Grade handbook, 2019

21. Methodology manual and policies from the accf/aha task force on practice guidelines, 2010

22. Nikolakopoulou A, Higgins JPT, Papakonstantinou T, Chaimani A, Del Giovane C, Egger M, Salanti G: Cinema: An approach for assessing confidence in the results of a network meta-analysis. PLoS Med 2020; 17:e1003082

23. Andrews JC, Schünemann HJ, Oxman AD, Pottie K, Meerpohl JJ, Coello PA, Rind D, Montori VM, Brito JP, Norris S, Elbarbary M, Post P, Nasser M, Shukla V, Jaeschke R, Brozek J, Djulbegovic B, Guyatt G: Grade guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. J Clin Epidemiol 2013; 66:726-35

24. Guyatt GH, Alonso-Coello P, Schünemann HJ, Djulbegovic B, Nothacker M, Lange S, Murad MH, Akl EA: Guideline panels should seldom make good practice statements: Guidance from the grade working group. J Clin Epidemiol 2016; 80:3-7