Using "Semaphores" to Summarize Findings

Introduction

- Evidence-based reviews should be transparent and include text summaries, evidence syntheses and individual study reviews along with methods.
- Key points from systematic and other reviews are often difficult for readers or audiences to quickly grasp.
- Adding a semaphore may help users understand key points.
- Semaphores can be used to convey answers to key questions or information about evidence quality, confidence in findings, size of results, etc.
- Variables include considerations/questions, ratings or other information.
- Several examples are provided below.
- LOE = Level of Evidence

> **Semaphore**
> A semaphore is a way of signaling or conveying information using visual systems such as charts or flags.

1. Example of Rating Studies for Bias

Study	Selection Bias	Performance Bias	Attrition Bias	Assessment Bias	Other
Study A	Low risk	Low risk	Low risk	Unclear risk	Single author
Study B	Low risk	Unclear risk	High risk	High risk	

2. Example of Drug Comparison

Drug A Compared to Acyclovir For Genital Herpes Infection	Rating	Comments
Evidence for efficacy (outcome)	Moderate	2 equivalence trials comparing to acyclovir
Size of outcomes	Similar	Difference in healing (days): <1 day
Evidence for safety (outcomes)	Low	Longer track record for Acyclovir
Alternatives are [available / not available]	Yes	2 other agents available
LOE for alternatives (outcome)	Moderate	
Weighting of other considerations (e.g., tolerability, ease of use, dependency or abuse potential, unmet needs, special populations, clinician perspective)	Moderate	Dosing is BID versus 5 times daily with acyclovir
Comparative Cost	Similar	
Cost for QALYS:	N/A	
Other evidentiary considerations	N/A	

3. Example Of Drug Comparison: Summary Of Comparative Safety Drugs V, W, X, Y, Z

THE EVIDENCE IS SUGGESTIVE THAT...

SAFETY ISSUE	LOWER RISK	DIRECTION	HIGHER RISK	
Serious Infections In RA	Drugs V, Y, Z 3 to 4 serious infections/100 patients treated for 6 to 12 months	<	Drug W 8.6 serious infections/100 patients treated for 6 months	
Tuberculosis	Drug Y 0.4 TB cases/1000 pt-years.	<	Drugs V and Z	
Infections (OIs) in Studied Populations	Drug Y 0.07 OIs/1000 pt-years	<	Drug V 0.61 OIs /1000 pt-years	Drug Z 2.9 OIs /1000 pt-years
Lymphoma in Studied Populations	Drug Y 0.07 lymphomas/1000 pt-years	<	Drug V or Z 0.62 to 2.91lymphomas/1000 pt-years	
Withdrawals and Withdrawals due to Adverse Events in RA Absolute risk estimates for withdrawals not provided because of inconsistent results from RCTs and observational data.	Drug V Odds Ratio (95% CI 0.32 to 0.78) Drug Y Odds Ratio 0.63 (95% CI 0.41 to 0.950) Drug X Odds Ratio 0.55 (95% CI 0.30 to 0.99	<	Drug Z	

4. Magnetic Resonance Imaging (MRI) for Diagnosis and Treatment of Women at High Risk For or With a Personal History of Breast Cancer

Delfini Conclusions Summary by Considerations (Based on Delfini Systematic Review: available http://www.hta.hca.wa.gov/breast.html**)**

Values Key:		
+ **Positive or Use**		
? **Medium Strength to Borderline Uncertainty**		
— **Negative or Avoid**		

Criteria Key & Notes

Evidence Quality: Therapies [Diagnostics]

+ Low-risk of bias RCT data [low-risk of bias observational studies meeting critical appraisal criteria for diagnostic testing]

? Med/borderline-risk of bias RCT data; all-or-none observations with low-risk of confounding [med/borderline-risk of bias observational studies meeting critical appraisal criteria for diagnostic testing]

— RCT data at high-risk of bias, observational studies, opinion [high risk of bias observational studies OR observational studies not meeting critical appraisal criteria for diagnostic testing]

Clinical Significance (with consideration of size of outcomes)

+ Morbidity, mortality, symptom relief, emotional/physical functioning, health-related quality of life

? Intermediate outcomes with proof of direct causal chain to clinically meaningful outcomes

— Intermediate outcomes without proof of direct causal chain or other outcomes

Size of the Outcomes

Sufficient size is a judgment depending on context and outcome. Review confidence intervals. **No difference may reflect a power issue.**

Safety

NNH is a judgment depending on the harm.

+ Sufficient to determine safe

— Borderline or insufficient to determine safe or determined not safe

Cost Analysis

+ Low-risk of bias plus reasonable assumptions

? Medium/borderline risk of bias and/or questionable assumptions

— High risk of bias or questionable or poor assumptions

Considerations

Alternatives

Including evidence quality, effectiveness, safety, cost, QALY assessment

Patient Perspective

· benefits
· harms and risks
· costs
· uncertainties
· applicability
· satisfaction
· clinical considerations (eg tolerability, ease of use, dependency, abuse potential)
· unmet needs, special populations

Other Considerations: Examples

· accreditation issues
· clinician perspective
· community standards
· ethical considerations
· liability and risk management issues
· marketing
· media or press issues
· medical community impacts
· medical-legal
· public relations
· purchasing issues
· regulatory
· research realities (eg likelihood that no evidence will be able to answer clinical questions etc.)
· utilization (eg impacts of provider change including demand do you have the capacity to support this change impact of substitution etc.)
· overall impact on the health care organization or entity

Project Key Questions

For women at risk of breast cancer based on presentation of with an abnormal mammogram; palpable breast abnormality; or relevant demographic and clinical risk factors:

1. What is the evidence that breast MRI has the ability to diagnose or exclude breast cancer in women at high risk compared to current tests including mammography?
    a. Describe sensitivity, specificity, and other key test characteristics
2. What is the evidence that breast MRI improves health outcomes for patients with suspected or diagnosed breast cancer? Including consideration of:
    a. reduced need for other tests
    b. more accurate diagnosis
    c. change in treatment plan
    d. reduced mortality and morbidity
3. What is the evidence of the safety of breast MRI in this population?
4. What is the evidence that breast MRI has differential efficacy or safety issues in subpopulations? Including consideration of:
    a. Age, breast tissue characteristics; breast implants
    b. Other patient characteristics or evidence of appropriate patient selection criteria
    c. Type of scanning machine and software, reader training, and other operational factors
    d. Provider type, setting or other provider characteristics
    e. Health care system type, including worker's compensation, Medicaid, state employees
5. What is the evidence about the cost implications and cost effectiveness of breast MRI?

Delfini Decision Support Examples
"Semaphores"

Criteria, Considerations, Comparisons & Examples to Inform Decisions & Judgments	Questions: What is the level of confidence that…	Outcome	Level of Confidence	Other Considerations (eg, clinical significance)	Your Judgment "Worksheet"
Likelihood of Outcomes (See above for considerations for Clinical Significance)	1. these outcomes will be achieved, realized or experienced?	Increased detection of breast cancer	HIGH		
		Decreased need for other tests	LOW		
		Changes in treatment plans (e.g., wider excisions, more mastectomies, unnecessary mastectomies)	HIGH		
		Decreased re-excision rates	LOW		
		Decreased recurrence rates	LOW		
		Decreased mortality	LOW		
Size of the Outcomes	2. the estimate is likely to be correct?	2-5 additional cancers detected/100 MRIs, but with uncertain benefit in mortality, potential for risk and increase in cost	HIGH		
Size of the Outcomes	3. the estimate is likely to be correct?	Up to 11 additional benign biopsies/100 MRIs	MEDIUM		
Safety	4. the estimate is correct?	No increase in meaningful adverse psychological outcomes	MEDIUM		
		No increase in adverse outcomes from radiation	HIGH		
Cost	5. the estimate is correct?	Increased cost of technology: MRI 10 times the cost of mammography	HIGH		
QALY: Evidence Quality for Mortality and Methods Overall [Possibly reasonable QALY judgment: +<$50K, ? $50-150k, — >$150K]	6. the estimate is correct?	Cost per QALYs saved: ~$30,000 to ~$310,000 depending upon risk and assumptions	LOW		
Alternatives Available	7. the information about alternatives is correct?	Mammography: lower sensitivity, but fewer false positive biopsies	HIGH		

Patient Perspective	If goal is increased detection, MRI is preferred. If goal is assurance that benefits outweigh harms, MRI is not preferred.
Conclusions Regarding Net Benefit	There is no proof of net benefit, and there is potential harm.

Other Evidentiary Considerations

1. Intervention or technology is considered to be safe or has low likelihood of harm or the adverse effects are acceptable. The intervention or technology is unlikely to result in other unacceptable untoward effects or unacceptable unintended consequences and is of acceptable cost (e.g., dietary change).
    [ ] Meets criteria

2. No other effective treatments or technologies exist, and adverse clinical outcomes are likely if the condition is not treated.
    [ ] Meets criteria

3. Other related interventions or technologies already in use also have insufficient evidence, and there may be advantages for intervention or technology over alternatives. Caution is urged if assuming "class effect." The criteria for concluding the existence of "class effect" are controversial.
    [ ] Meets criteria

4. Well-designed studies are unlikely (e.g., condition or disease is rare, topic does not lend itself to valid study design or execution and adverse clinical outcomes are likely if the
    condition is not treated.)
    [x] Meets criteria

5. There is sufficient evidence of effectiveness and safety in other populations to suggest net clinical benefit in this population.
    [x] Meets criteria

5. Examples of Ratings
HIGH
LARGE
MODERATE
BORDERLINE
INCONCLUSIVE
SMALL
LOW or LOWER
YES
NO
UNCERTAIN
UNCLEAR
HIGHER
SIMILAR
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