KEY QUESTION 1

Should mesh vs. NO mesh be used for adult patients with Type II, III, or IV hiatal hernia who are candidates for mesh placement during their surgical repair?	
POPULATION:	adult patients with Type II, III, or IV hiatal hernia who are candidates for mesh placement during their surgical repair
INTERVENTION:	mesh
COMPARISON:	NO mesh
MAIN OUTCOMES:	CD3 - Randomized trials; HBurn - Randomized trials; HH - Randomized trials; Leak - Randomized trials; Mesh - Randomized trials; NewDysE - Randomized trials; NewDysL - Randomized trials; ObjReflRec - Randomized trials; PPI - Randomized trials; RadRec>2 - Randomized trials; Regurg - Randomized trials; ResDys - Randomized trials; RtOR - Randomized trials; TdysE - Randomized trials; TDysL - Randomized trials; UnResDysE - Randomized trials; UnResDysL - Randomized trials; DeME - Randomized trials; QoLpost - Randomized trials;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know		

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ● **Moderate** ○ Large ○ Varies ○ Don't know		

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with NO mesh	Risk difference with mesh
CD3 - Randomized trials	357 (3 RCTs)	⨁⨁◯◯ Low[a,b]	**RR 0.94** (0.14 to 6.50)	Study population	
				11 per 1,000	**1 fewer per 1,000** (10 fewer to 63 more)
HBurn - Randomized trials	168 (2 RCTs)	⨁◯◯◯ Very low[a,b,c]	**RR 0.83** (0.27 to 2.54)	Study population	
				71 per 1,000	**12 fewer per 1,000** (52 fewer to 110 more)

HH - Randomized trials	350 (4 RCTs)	⨁◯◯◯ Very low[a,b,c]	**RR 0.97** (0.26 to 3.66)	Study population	
				98 per 1,000	**3 fewer per 1,000** (73 fewer to 261 more)
PPI - Randomized trials	203 (2 RCTs)	⨁⨁◯◯ Low[a,b]	**RR 0.77** (0.47 to 1.28)	Study population	
				248 per 1,000	**57 fewer per 1,000** (131 fewer to 69 more)
RadRec<2 - Randomized trials	476 (5 RCTs)	⨁◯◯◯ Very low[a,b,c]	**RR 0.57** (0.15 to 2.12)	Study population	
				169 per 1,000	**73 fewer per 1,000** (144 fewer to 189 more)
Regurg - Randomized trials	100 (1 RCT)	⨁◯◯◯ Very low[a,b,c]	**RR 0.50** (0.05 to 5.34)	Study population	
				40 per 1,000	**20 fewer per 1,000** (38 fewer to 174 more)
ResDys - Randomized trials	40 (1 RCT)	⨁⨁◯◯ Low[a,b]	**RR 3.00** (0.34 to 26.45)	Study population	
				50 per 1,000	**100 more per 1,000** (33 fewer to 1,273 more)
RtOR - Randomized trials	529 (5 RCTs)	⨁◯◯◯ Very low[a,b,c]	**RR 0.83** (0.29 to 2.41)	Study population	
				54 per 1,000	**9 fewer per 1,000** (38 fewer to 76 more)
TDysL - Randomized trials	276 (3 RCTs)	⨁⨁⨁⨁ High[c]	**RR 0.49** (0.28 to 0.86)	Study population	
				212 per 1,000	**108 fewer per 1,000** (153 fewer to 30 fewer)
UnResDysE - Randomized trials	38 (2 RCTs)	⨁⨁◯◯ Low[a,b]	**RR 0.86** (0.45 to 1.64)	Study population	
				526 per 1,000	**74 fewer per 1,000** (289 fewer to 337 more)
DeME - Randomized trials	169 (2 RCTs)	⨁⨁⨁◯ Moderate[c]	-	The mean deME - Randomized trials was **0**	MD **1.94 lower** (3.09 lower to 0.79 lower)
QoLpost - Randomized trials	244 (3 RCTs)	⨁⨁⨁⨁ High	-	The mean qoLpost -	

					Randomized trials was **0**	

a. The confidence interval for this outcome crosses the threshold of significance.
b. This outcome was underpowered.
c. This outcome included a study rated at high risk of bias on the Cochrane Risk of Bias Tool due to concerns over the randomization process.

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT

- ○ Large
- ● **Moderate**
- ○ Small
- ○ Trivial
- ○ Varies
- ○ Don't know

RESEARCH EVIDENCE

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with NO mesh	Risk difference with mesh
Leak - Randomized trials	385 (3 RCTs)	⨁⨁◯◯ Low[a,b]	**RR 2.62** (0.13 to 53.37)	Study population	
				0 per 1,000	**0 fewer per 1,000** (0 fewer to 0 fewer)
NewDysE - Randomized trials	37 (1 RCT)	⨁⨁◯◯ Low[a,b]	**RR 4.75** (0.24 to 92.65)	Study population	
				0 per 1,000	**0 more per 1,000** (0 fewer to 0 fewer)
TdysE - Randomized trials	100 (1 RCT)	⨁◯◯◯ Very low[a,b,c]	**RR 3.00** (0.64 to 14.16)	Study population	
				40 per 1,000	**80 more per 1,000** (14 fewer to 526 more)
UnResDysL - Randomized trials	38 (2 RCTs)	⨁⨁◯◯ Low[a,b]	**RR 1.51** (0.71 to 3.21)	Study population	
				316 per 1,000	**161 more per 1,000** (92 fewer to 698 more)

a. The confidence interval for this outcome crosses the threshold of significance.
b. This outcome was underpowered.
c. This outcome included a study rated at high risk of bias on the Cochrane Risk of Bias Tool due to concerns over the randomization process.

ADDITIONAL CONSIDERATIONS

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● **Low** ○ Moderate ○ High ○ No included studies		

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty or variability		

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ● **Does not favor either the intervention or the comparison** ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know		

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know		some places/patients may not have access due to cost of mesh. accessibility of nonabsorbable vs absorbable meshes

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● **Probably yes** ○ Yes ○ Varies ○ Don't know		Insurance companies may not find it acceptable. Some patients just do not want mesh.

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ● **Probably yes** ○ Yes ○ Varies ○ Don't know		

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	**Moderate**	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	**Low**	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	**Does not favor either the intervention or the comparison**	Probably favors the intervention	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	Conditional recommendation for the intervention	Strong recommendation for the intervention
○	○	○	○	○

CONCLUSIONS

Recommendation

The expert panel decided not to make an evidence-based recommendation for or against the use of mesh in hiatal hernia repair.

Justification

The GRADE process emphasizes the quality of evidence. For this question, the quality of evidence was low. While the effect estimates for critical outcomes showed essentially no difference, the confidence intervals for these estimates crossed from meaningful harms to meaningful benefits associated with the use of mesh. After discussion within the panel and consultation with an expert methodologist, the panel declined to make a recommendation; there was

sufficient uncertainty in the existing data the panel felt making a recommendation would be speculative at best. However, it does anticipate being able to make a recommendation once more evidence accumulates.

Subgroup considerations

When the crura can be approximated vs when mesh is utilized for bridging.
tension of crural closure
need for relaxing incisions –use mesh
Type IV PEH or x diameter of hernia, area of defect
Poor quality of crura

Implementation considerations

Monitoring and evaluation

Research priorities

More granular data about type of mesh – absorbable/non
Location of mesh placement

KEY QUESTION 3

Should fundoplication vs. NO fundoplication be used for Adult patients with Type II, III, or IV hiatal hernia undergoing surgical repair?

POPULATION:	Adult patients with Type II, III, or IV hiatal hernia undergoing surgical repair
INTERVENTION:	fundoplication
COMPARISON:	NO fundoplication
MAIN OUTCOMES:	NewDysE - Observational studies; NewDysL - Observational studies; UnResDysE - Observational studies; UnResDysL - Observational studies; TdysE - Randomized trials; TdysL - Randomized trials; HBurn - Observational studies; PPI - Randomized trials; ObjRef - Randomized trials; RadRec - Randomized trials; HH - Randomized trials; RtOR - Randomized trials; Leak - Randomized trials; DeMEpost - Randomized trials; QoLpost - Observational studies;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know		

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT

○ Trivial
○ Small
○ Moderate
● **Large**
○ Varies
○ Don't know

RESEARCH EVIDENCE

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with NO fundoplication	Risk difference with fundoplication
HBurn - Observational studies	313 (4 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.56** (0.21 to 1.50)	Study population	
				190 per 1,000	**74 fewer per 1,000** (143 fewer to 70 more)
PPI - Randomized trials	37 (1 RCT)	⨁⨁◯◯ Low[b,c]	**RR 0.64** (0.28 to 1.47)	Study population	
				471 per 1,000	**169 fewer per 1,000** (339 fewer to 221 more)
ObjRef - Randomized trials	147 (2 RCTs)	⨁⨁⨁⨁ High[d]	**RR 0.31** (0.17 to 0.56)	Study population	
				465 per 1,000	**321 fewer per 1,000** (386 fewer to 205 fewer)
RadRec - Randomized trials	33 (1 RCT)	⨁⨁◯◯ Low[b,c]	**RR 0.50** (0.14 to 1.76)	Study population	
				333 per 1,000	**167 fewer per 1,000** (287 fewer to 253 more)
HH - Randomized trials	148 (2 RCTs)	⨁◯◯◯ Very low[b,c,d]	**RR 0.55** (0.20 to 1.51)	Study population	
				113 per 1,000	**51 fewer per 1,000** (90 fewer to 57 more)
RtOR - Randomized trials	154 (2 RCTs)	⨁◯◯◯ Very low[b,c,d,e]	**RR 0.54** (0.01 to 23.15)	Study population	
				288 per 1,000	**132 fewer per 1,000** (285 fewer to 6,372 more)
				Study population	

ADDITIONAL CONSIDERATIONS

Evidence consistent across all outcomes so panel focused on outcome of objective reflux

Leak - Randomized trials	40 (1 RCT)	⨁⨁◯◯ Low[b,c]	**RR 0.33** (0.01 to 7.72)	50 per 1,000	**33 fewer per 1,000** (50 fewer to 336 more)
DeMEpost - Randomized trials	89 (2 RCTs)	⨁⨁⨁◯ Moderate[d]	-	The mean deMEpost - Randomized trials was **0**	MD **5.63 lower** (9.69 lower to 1.56 lower)
QoLpost - Observational studies	58 (1 observational study)	⨁◯◯◯ Very low[a]	-	The mean qoLpost - Observational studies was **0**	MD **1.5 lower** (5.66 lower to 2.66 higher)

a. Included studies rated high risk of bias on the Newcastle Ottawa scale due to concerns over the comparability of the two groups.
b. Suboptimal power.
c. This outcome's confidence interval crosses the boundary of significance.
d. Included a study rated high risk of bias on the Cochrane risk of bias tool due to concerns over the randomization process.
e. The papers contributing to this outcome had non-overlapping confidence intervals.

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT

○ Large
○ Moderate
● **Small**
○ Trivial
○ Varies
○ Don't know

RESEARCH EVIDENCE

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with NO fundoplication	Risk difference with fundoplication
NewDysE - Observational studies	74 (2 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 75.00** (3.16 to 1782.78)	Study population	
				0 per 1,000	**171 more per 1,000** (0 fewer to 0 fewer)
NewDysL - Observational studies	218 (2 observational studies)	⨁◯◯◯ Very low[b,c,d]	**OR 1.33** (0.25 to 6.99)	Study population	
				38 per 1,000	**12 more per 1,000** (28 fewer to 177 more)
TdysE - Randomized trials	122 (1 RCT)	⨁⨁⨁◯ Moderate[e]	**RR 2.08** (1.16 to 3.76)	Study population	
				197 per 1,000	**212 more per 1,000** (31 more to 543 more)
	157 (2 RCTs)			Study population	

ADDITIONAL CONSIDERATIONS

TdysL - Randomized trials		⨁⨁◯◯ Low[b,d,e]	**RR 2.94** (0.46 to 18.79)	13 per 1,000	**25 more per 1,000** (7 fewer to 225 more)

a. The papers contributing to this outcome had non-overlapping confidence intervals.
b. Suboptimal power.
c. Included studies rated high risk of bias on the Newcastle Ottawa scale due to concerns over the comparability of the two groups.
d. This outcome's confidence interval crosses the boundary of significance.
e. Included a study rated high risk of bias on the Cochrane risk of bias tool due to concerns over the randomization process.

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● **Low** ○ Moderate ○ High ○ No included studies		

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ● **Possibly important uncertainty or variability** ○ Probably no important uncertainty or variability ○ No important uncertainty or variability		depends on severity of the symptoms, duration, and presenting complaint, which we are not able to evaluate

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● **Probably favors the intervention** ○ Favors the intervention ○ Varies ○ Don't know		

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● **Yes** ○ Varies ○ Don't know		

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● **Yes** ○ Varies ○ Don't know		

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	**Large**		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	**Small**	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	**Low**	Moderate	High			No included studies
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	•	○

CONCLUSIONS

Recommendation

We suggest fundoplication over no fundoplication; evidence from prior guideline in GERD populations suggests partial fundoplication may be a better option with regards to post op dysphagia. The panel had no evidence regarding partial fundoplication in hiatal hernia population but felt it was reasonable to use this indirect evidence.

Justification

Our data is based exclusively on pts receiving Nissen fundoplication – no partials were included
We know based on indirect evidence from prior studies in pts w GERD w/o hiatal hernia that dysphagia rates are lower with partial rather than Nissen fundoplication.

Subgroup considerations

Presenting complaint
Relative severity of reflux vs dysphagia
type of fundoplication

Implementation considerations

Monitoring and evaluation

Research priorities

separating out Nissen and partial fundoplication in RCT for hiatal hernia population
distinguishing pts by primary complaint of GERD vs dysphagia
and grading severity of symptoms as well