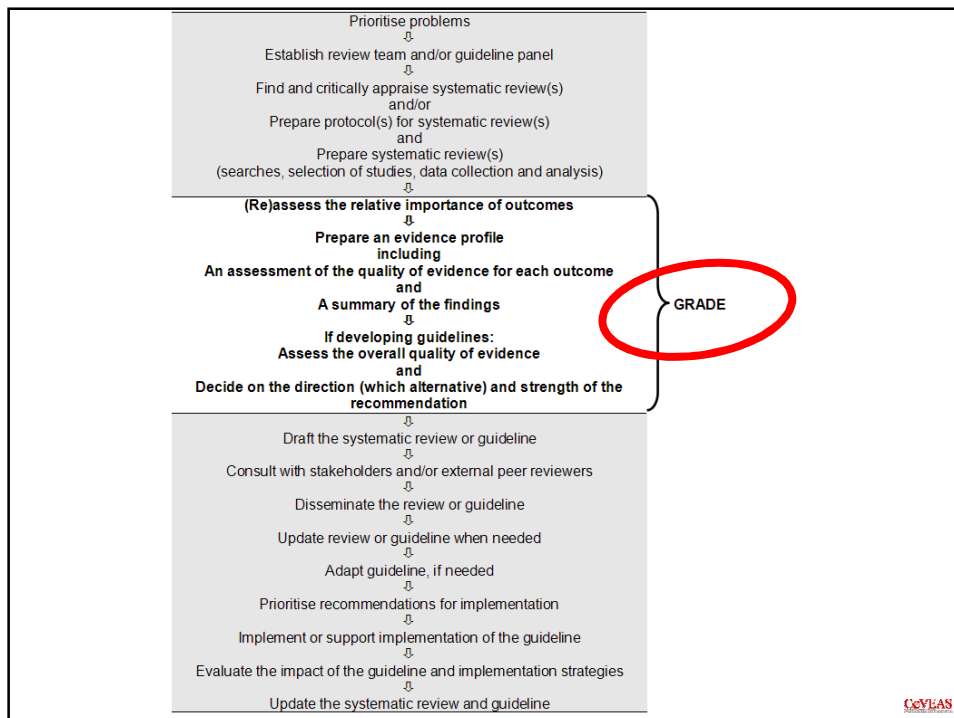


GRADE: La scelta degli outcomes

Nicola Magrini



Formulare il quesito clinico

- ◆ **popolazione** (o gruppo) ben individuato
- ◆ **intervento** (che può essere positivo, come una terapia, una dieta, un test diagnostico, oppure negativo, come l'esposizione a un fattore di rischio o a un effetto avverso di un farmaco), studiando l'effetto sottoforma di un
- ◆ **esito** (traduzione di **outcome**, unica iniziale differente in italiano). Non dimenticando mai che l'efficacia di un intervento si misura sempre facendo un
- ◆ **confronto** (con un altro farmaco, con il nulla, con la storia naturale della malattia, con l'assenza di rischio, o con altri test diagnostici, ecc)

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Formulating the questions

Annex 3. Methods used for developing guidelines

Preparation of the background documentation

Summaries of the best available evidence were prepared to answer nine primary questions regarding the treatment and prophylaxis of postpartum haemorrhage:

Should active management of the third stage of labour be used by skilled providers for all women to prevent postpartum haemorrhage? Should active management of the third stage be used by non-skilled providers to prevent PPH?

Should oxytocin (10 IU IM) or ergometrine/methylergometrine (0.2 mg IM) be used for all women by skilled providers to prevent PPH? Should non-skilled providers use either drug?

Should oxytocin (10 IU IM) be used for all women by skilled providers to prevent PPH instead of oral misoprostol (600 mcg)? Should either drug be used by non-skilled providers?

Should oxytocin (10 IU IM) be used for all women by skilled providers to prevent PPH instead of sublingual misoprostol (600 mcg)? Should either drug be used by non-skilled providers?

Should oxytocin (10 IU IM) be used for all women by skilled providers to prevent PPH instead of rectal misoprostol (600 mcg)? Should either drug be used by non-skilled providers?

Should oxytocin (10 IU IM) be used for all women by skilled providers to prevent PPH instead of carboprost 0.25 mg/sulprostone 0.5 mg)? Should either drug be used by non-skilled providers?

In the absence of active management, should uterotonics be used alone for prevention of PPH?

When should the cord be clamped to maximize benefits for mother and baby?

Should the placenta be delivered in all women by controlled traction?

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Scelta degli outcomes, 1

explicit judgements should be made about which outcomes are critical, which ones are important but not critical, and which ones are unimportant and can be ignored.

all important outcomes should be considered in making a recommendation, but only critical ones should be considered when making judgements about the overall quality of the evidence underlying a recommendation

Schünemann HG et al. Health Res Policy Syst 2006:4:18

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Scelta degli outcomes, 2

studies using surrogate outcomes generally provide weaker evidence than those using outcomes that are important, and these only should be included when evidence for important outcomes is lacking.

Thus, important outcomes (e.g. mortality, morbidity, quality of life) should be preferred over surrogate, indirect outcomes (e.g. cholesterol levels, lung function) that may or may not correlate with patient important outcomes.

Schünemann HG et al. Health Res Policy Syst 2006:4:18

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Classificazione degli *outcomes*

Invito ai membri del panel a classificare ogni beneficio e ogni rischio (*each beneficial and harmful outcome*) in una scala 1-9

- punteggio medio 7-9 = *critical outcome*
- punteggio medio 4-6 = *important but not critical*
- punteggio medio <4 = *not important*

WHO Recommendations for the Prevention of PPH; 2007. pag. 4

CoVEAS

Rating the outcomes

Recommendations for the Prevention of Postpartum Haemorrhage
Provisional list of outcomes for inclusion

Please enter your initials in the box

Do not attempt to rank the outcomes
– score each one individually from 1– 9.

Score	Relative importance
1–3	Not important
4–6	Important but not critical
7–9	Critical

What are the most important beneficial outcomes of interventions to prevent postpartum haemorrhage?

Outcome	Relative Importance
Fewer maternal deaths	
Fewer admissions to intensive care unit	
Less blood loss \geq 500 ml	
Less blood loss \geq 1000 ml	
Less use of blood transfusion	
Less use of additional uterotonics	
Decreased mean blood loss	
Less postpartum anaemia	
Earlier establishment of breastfeeding	
Less anaemia in infancy	
Other (please specify)	

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Recommendations for the Prevention of Postpartum Haemorrhage

Provisional list of outcomes for inclusion

Please enter your initials in the green box ■

Do not attempt to rank the outcomes – score each one individually from 1–9.

What are the most important beneficial outcomes of interventions to prevent postpartum haemorrhage?	Relative Importance
Outcome	Relative Importance
Fewer maternal deaths	
Fewer admissions to intensive care unit	
Less blood loss \geq 500 ml	
Less blood loss \geq 1000 ml	
Less use of blood transfusion	
Less use of additional uterotonics	
Decreased mean blood loss	
Less postpartum anaemia	
Earlier establishment of breastfeeding	
Less anaemia in infancy	
Other (please specify)	

WHO Recommendations for the Prevention of PPH. Annexe 2; 2007

COVIMS

What are the most significant risks in interventions to prevent postpartum haemorrhage?

Outcome	Relative Importance
Any side effect of intervention	
Any side effect requiring treatment	
Nausea	
Vomiting	
Diarrhoea	
Headache	
Abdominal pain	
High blood pressure	
Shivering	
Temp > 38° C	
Temp > 40° C	
Maternal death	
Anaemia in infancy	
Other (please specify)	

WHO Recommendations for the Prevention of Postpartum Haemorrhage

WHO Recommendations for the Prevention of PPH. Annexe 2; 2007

COVIMS

Benefici: punteggio medio

Table 1
Average scores

What are the most important beneficial outcomes of interventions to prevent PPH?

Fewer maternal deaths	8.5
Fewer admissions to intensive care unit	6.4
Less blood loss > 500 ml	6.3
Less blood loss > 1000 ml	7.7
Less use of blood transfusion	7.8
Less use of additional uterotonics	5.9
Decreased mean blood loss	5.6
Less postpartum anaemia	6.1
Earlier establishment of breastfeeding	5.1
Less anaemia in infancy	4.8
<i>Other (please specify)</i>	

WHO Recommendations for the Prevention of PPH; 2007. pag. 6

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Rischi: punteggio medio

What are the most significant risks in interventions to prevent PPH?

Any side effect of intervention	4.9
Any side effect requiring treatment (e.g. manual removal of placenta)	6.2
Nausea	4.0
Vomiting	4.7
Diarrhoea	4.6
Headache	4.8
Abdominal pain	4.8
High blood pressure	6.5
Shivering	4.7
Temp > 38° C	5.4
Temp > 40° C	6.8
Maternal death	6.7
Anaemia in infancy	4.6

WHO Recommendations for the Prevention of PPH; 2007. pag. 6-7

COVIAS