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# Is an RCT comparing wound dressings in general surgery a cost-effective investment? A value of information analysis for the Bluebelle study

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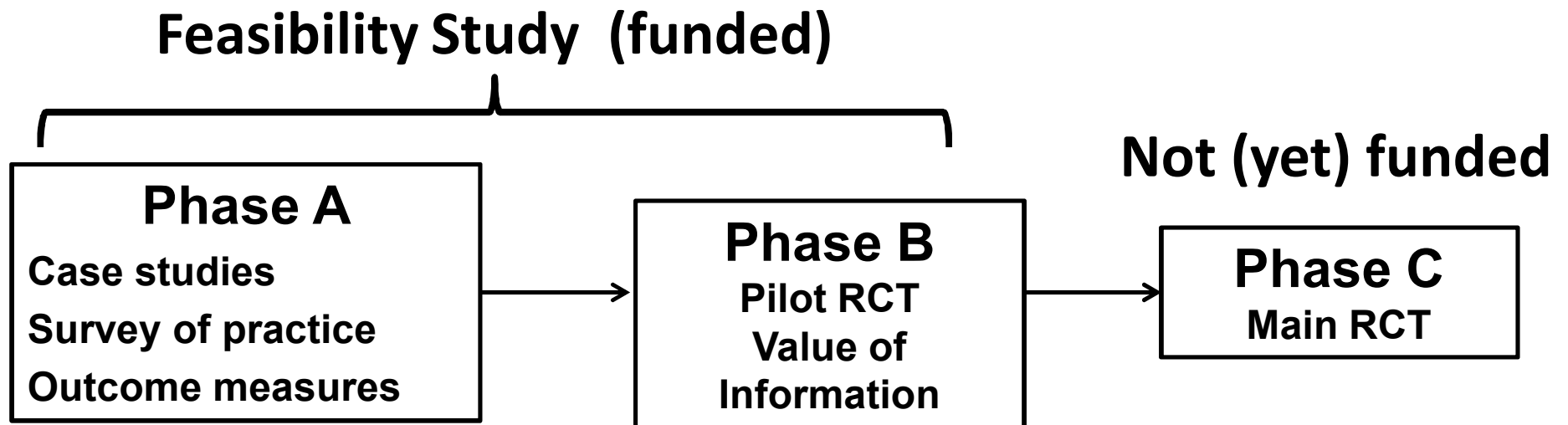


- A feasibility study of three wound dressing strategies in elective and unplanned surgery
- Primary outcome: surgical site infection

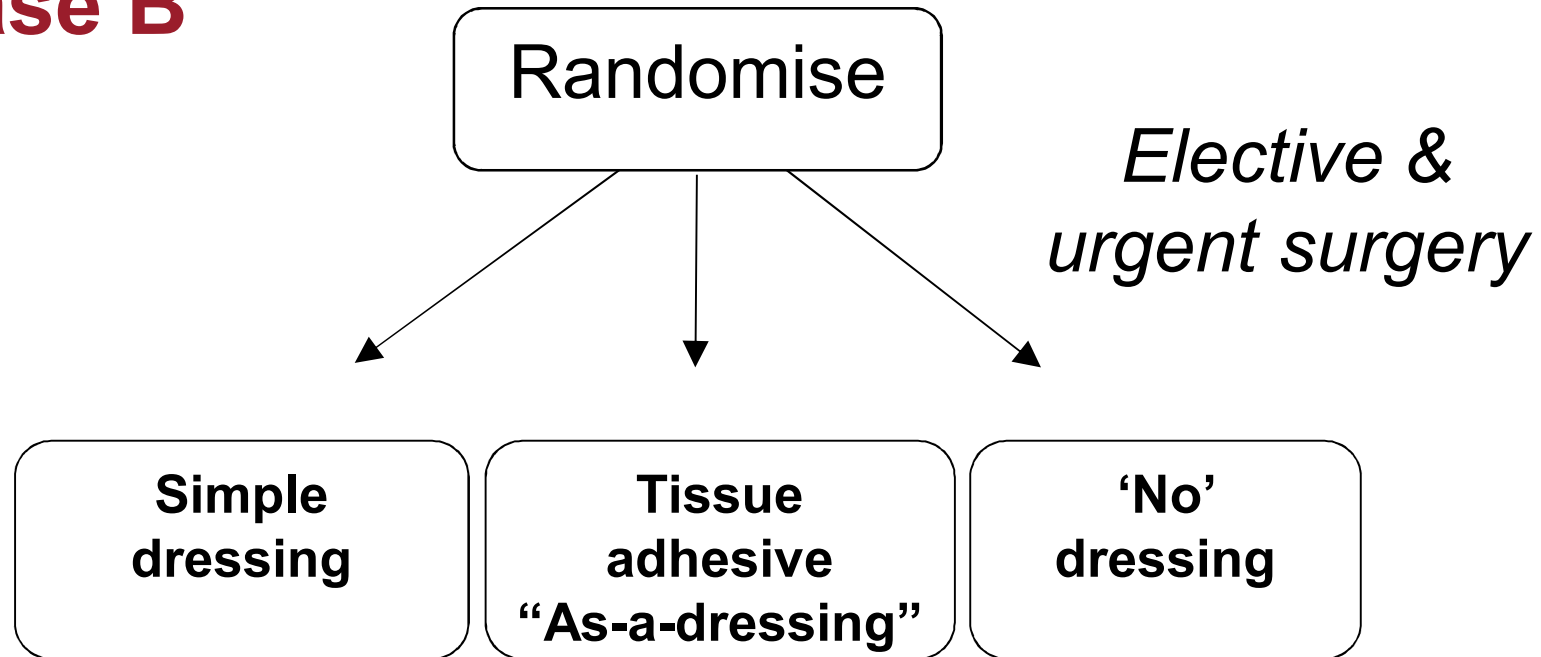
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## Feasibility study: Phase A & B

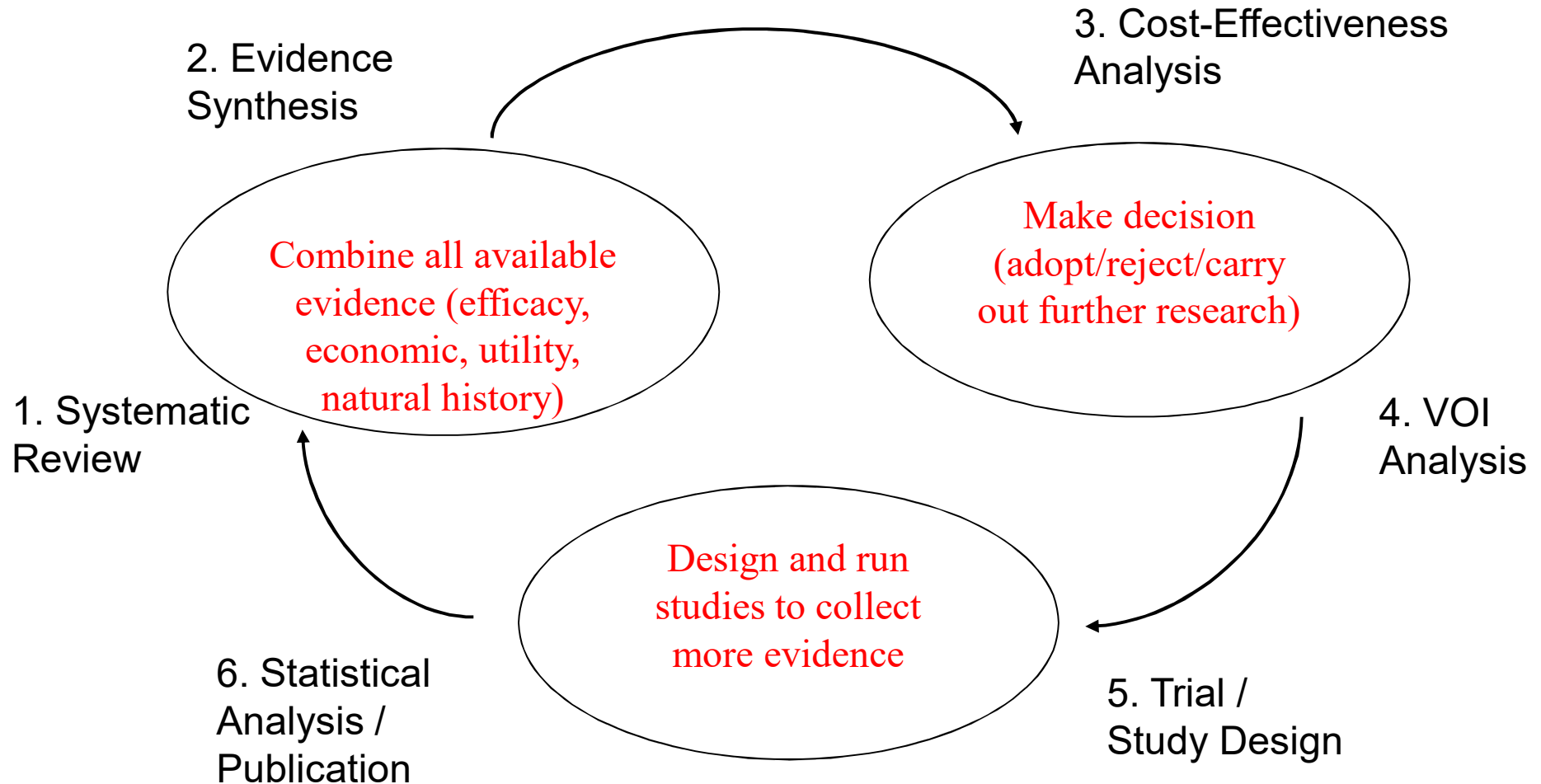


## Phase B

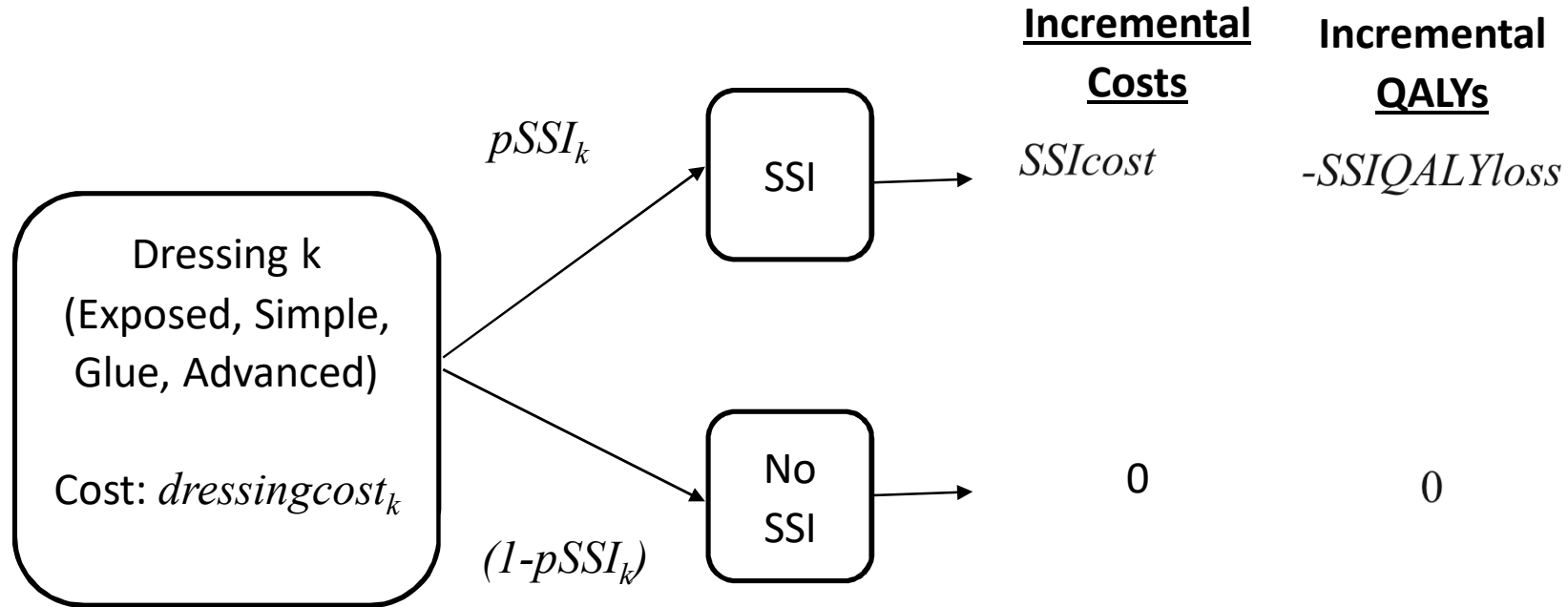


- Quantifies the potential benefits of conducting new research to help answer a decision question
  - do the benefits gained from collecting more evidence to help make better decisions outweigh the costs?
- Help decide which types of evidence to collect
  - intervention efficacy, natural history, quality of life, costs, etc.
- Help design trials/studies
  - choice of comparators, sample size, follow-up, etc.

# Evidence Based Decision-Making



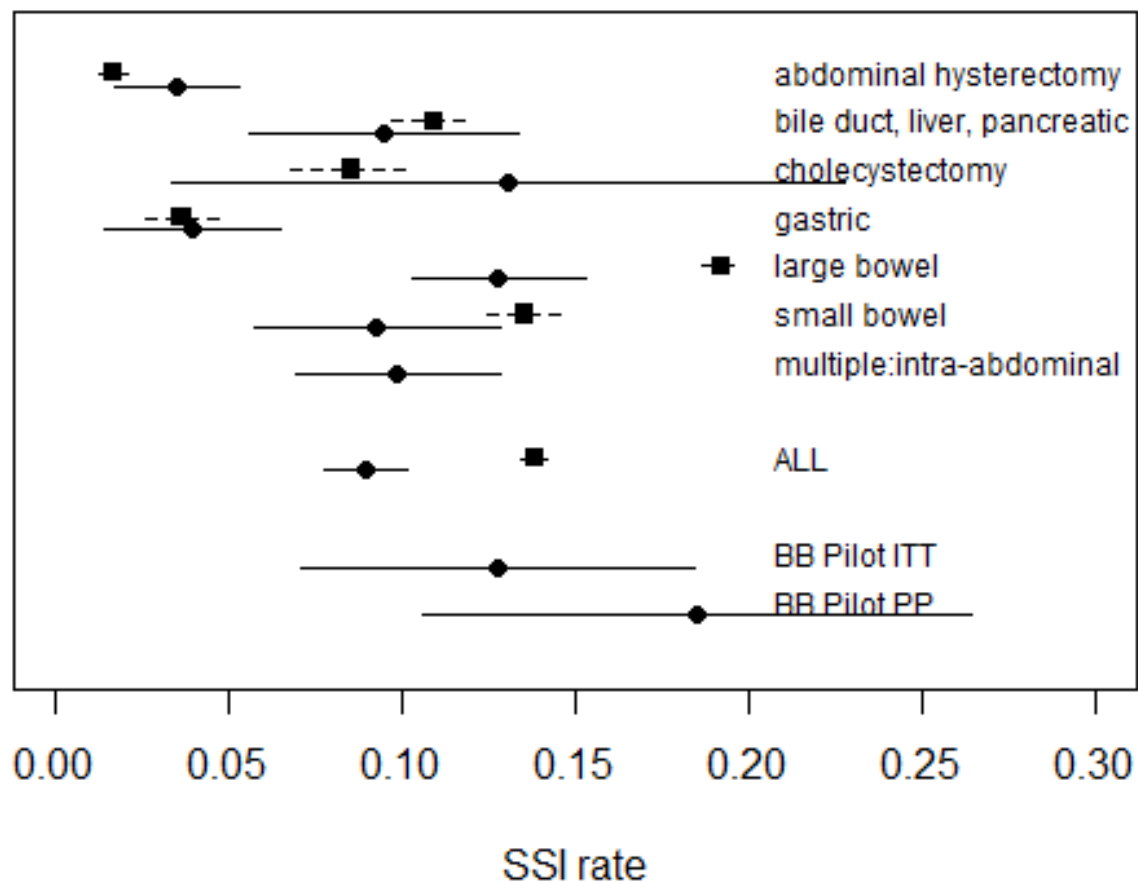
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- What is the most cost-effective dressing type for surgical wounds resulting from emergency and elective general surgery?
    - abdominal, oesophagus, stomach, small bowel, colon, liver, pancreas, gallbladder, bile ducts, thyroid, head and neck, breast, and thoracic
  - Interventions:
    - No dressing (E:Exposed)
    - Simple (S)
    - Tissue adhesive as a dressing (G:Glue)
    - Advanced (A) ... excluded in a scenario analysis





# SSI Risk for Simple Dressings

SSI Risk by Surgery Type



--- PHE survey  
(optional, 70  
hospitals, 2010-15)

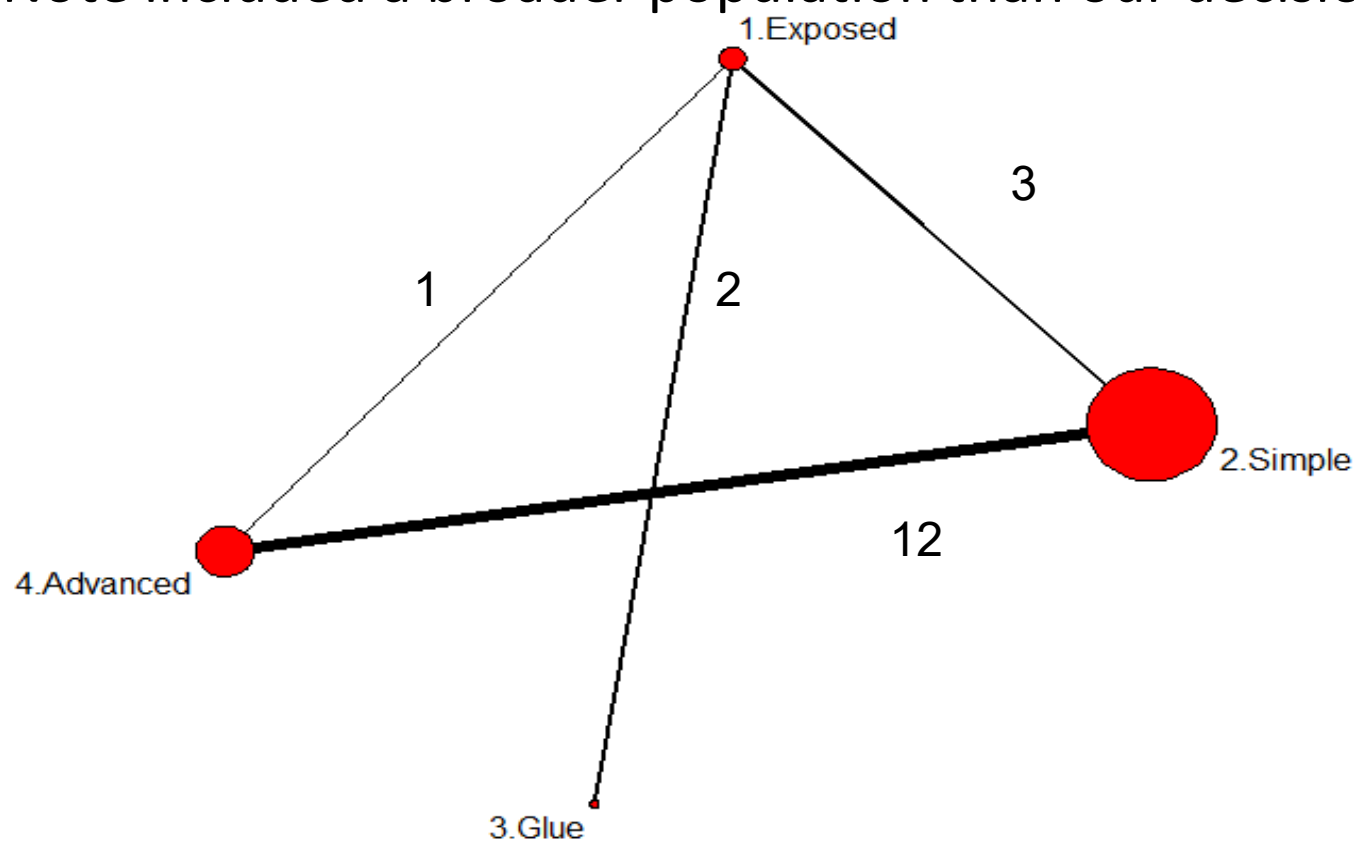
—Jenks (2014)  
(single region,  
elective, 2010-12)

PHE used in base-  
case

Jenks in scenario  
analysis

# Relative Effects of Dressing Types

- Network Meta-Analysis based on Cochrane Review Update (Dumville et al. 2016)
- Note included a broader population than our decision population



Odds Ratios (95%CrI)	Simple vs Exposed	Simple vs Glue	Simple vs Advanced
All wound types	0.979 (0.561, 1.546)	1.049 (0.371, 2.413)	0.858 (0.535, 1.263)
Clean wounds	0.787 (0.403, 1.388)	0.847 (0.278, 2.001)	0.740 (0.397, 1.277)
Mixed/Unclear/ Contaminated	1.153 (0.608, 1.92)	1.263 (0.392, 3.029)	1.068 (0.534, 1.865)

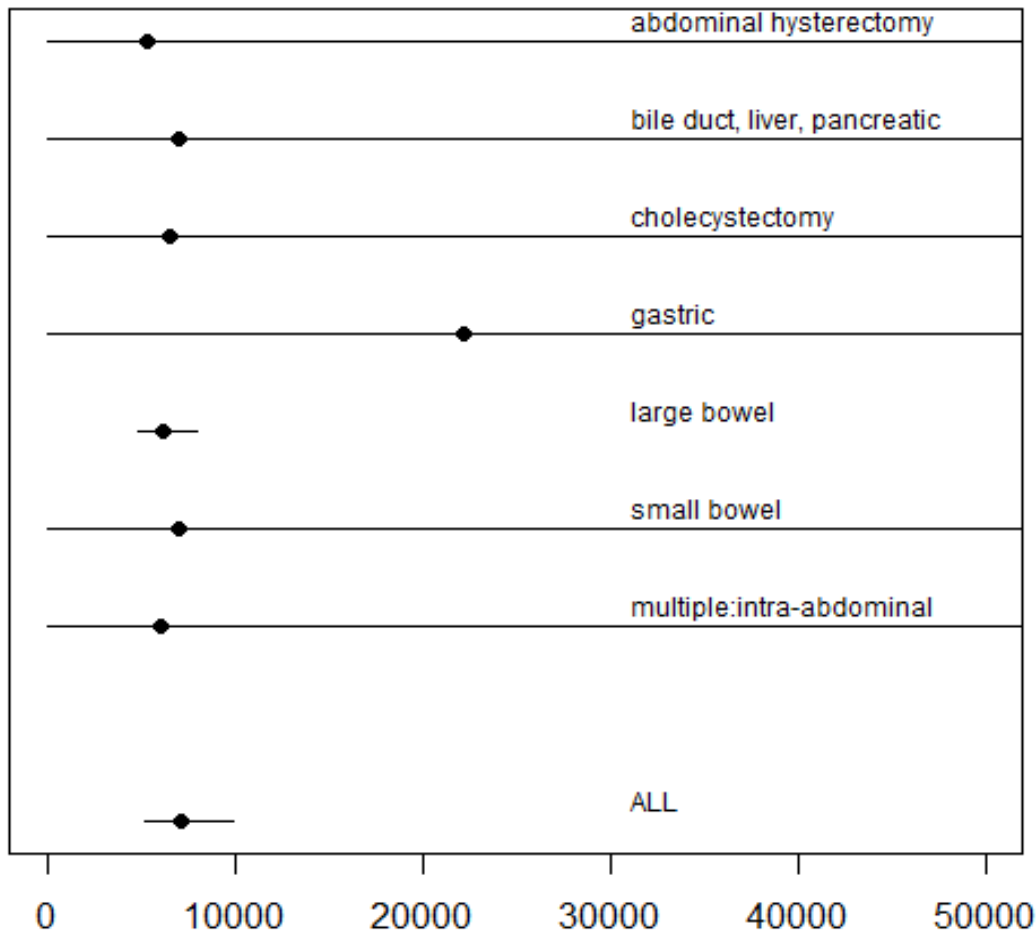
- All results uncertain
- No evidence for Glue
- Effects stronger for clean wounds
- Results similar when restricting to Bluebelle population

Odds Ratios (95%CrI)	Simple vs Exposed	Simple vs Glue	Simple vs Advanced
Including Bluebelle: ITT	1.019 (0.641, 1.494)	0.983 (0.480, 1.752)	0.868 (0.563, 1.228)
Including Bluebelle: PP	1.003 (0.627, 1.478)	0.999 (0.482, 1.828)	0.869 (0.566, 1.240)
Omitting Bluebelle	0.979 (0.561, 1.546)	1.049 (0.371, 2.413)	0.858 (0.535, 1.263)

- Results are similar
- Uncertainty is lower (especially for Glue), but still high



## Mean Cost Attributable to SSI by Surgery Type



Mean cost attributable to SSI 13

- Jenks (2014)
  - 2015/16 prices
- Mean cost for all (omitting gastric)
  - £7881 (5724, 10851)

	Exposed	Simple	Glue	Advanced
<b>Unit cost [BNF]</b>	£0	£0.29 [10x20cm absorbent perforated dressing with adhesive border (Cutiplast® Steril)]	£6.93 [1x500mg vial Histoacryl]	£8.36 [15x15cm hydrocolloid with silver antimicrobial (Aquacel® Ag (ConvaTec))]
<b>No. dressings per wound (including changes)</b>	N/A	2	2 vials	2
<b>Total Dressing Cost</b>	£0	£0.58	£13.86	£16.72
<b>Nurse Cost to change dressing (PSSRU)</b>	£0	£4.67	£0	£4.67
<b>TOTAL COST</b>	£0	£5.25	£13.86	£21.39

- QALYloss due to SSI
  - 0.12 (Pinkney et al 2013, Gheorghe et al 2015)
  - 0.06 and 0 in sensitivity analyses
- Prevalence 2.08m wounds
  - 1.2m general surgery procedures (Royal College of Surgeons, based on HSCIC)
  - 1.84 wounds per general surgery procedure (SPARCS and WMRC on behalf of Bluebelle Study Group 2016)

# Cost-Effectiveness Results

Willingness to pay per QALY= £20,000	Exposed	Simple	Glue	Advanced
Expected Net-Benefit (£)	-1463	-1443	<b>-1407</b>	<b>-1272</b>
Probability most cost-effective (including Advanced)	0.10	0.08	0.34	<b>0.48</b>
Probability most cost-effective (excluding Advanced)	0.23	0.28	<b>0.48</b>	

- Advanced is most cost-effective, followed by Glue
- High level of uncertainty in optimal dressing type

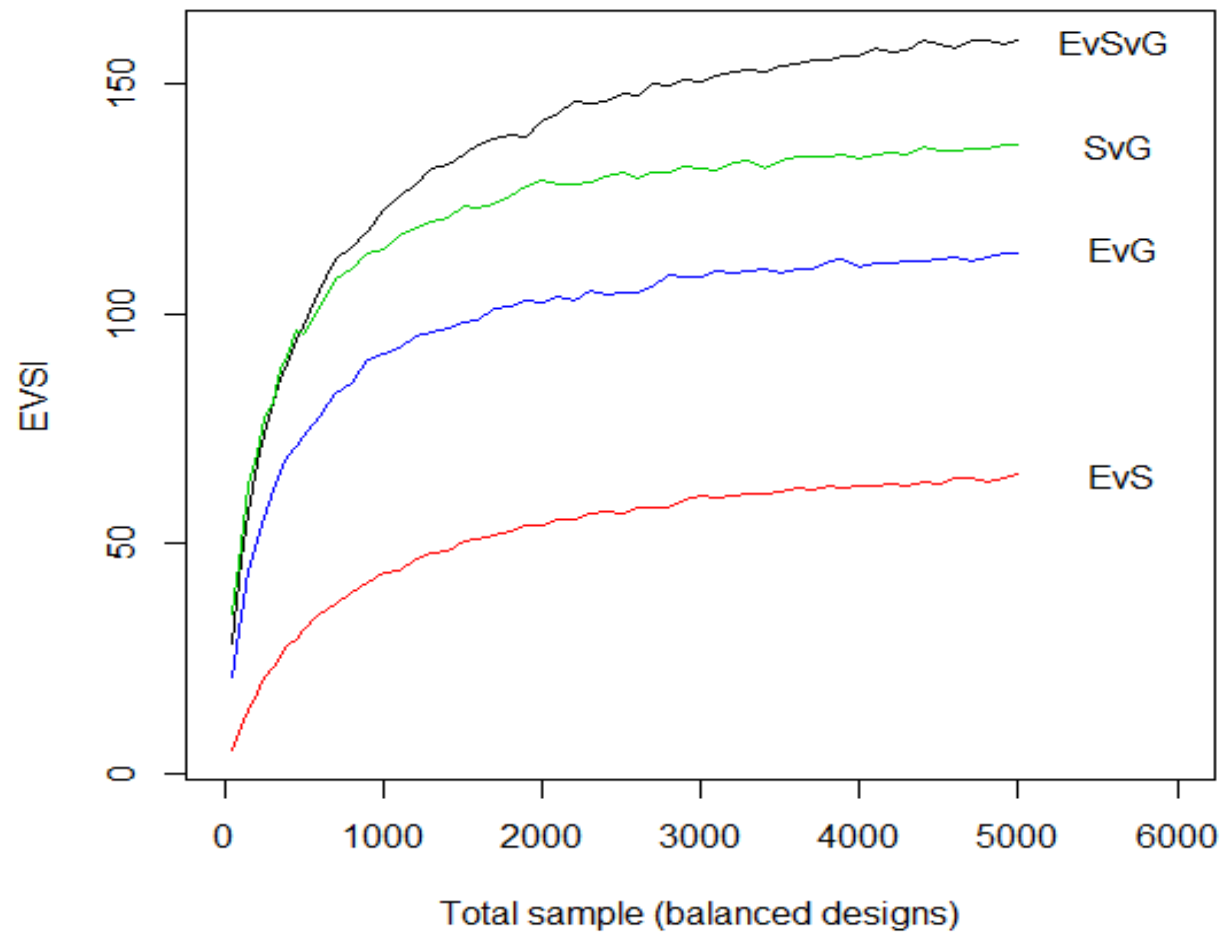


- Indicates model inputs of where most value in collecting further information

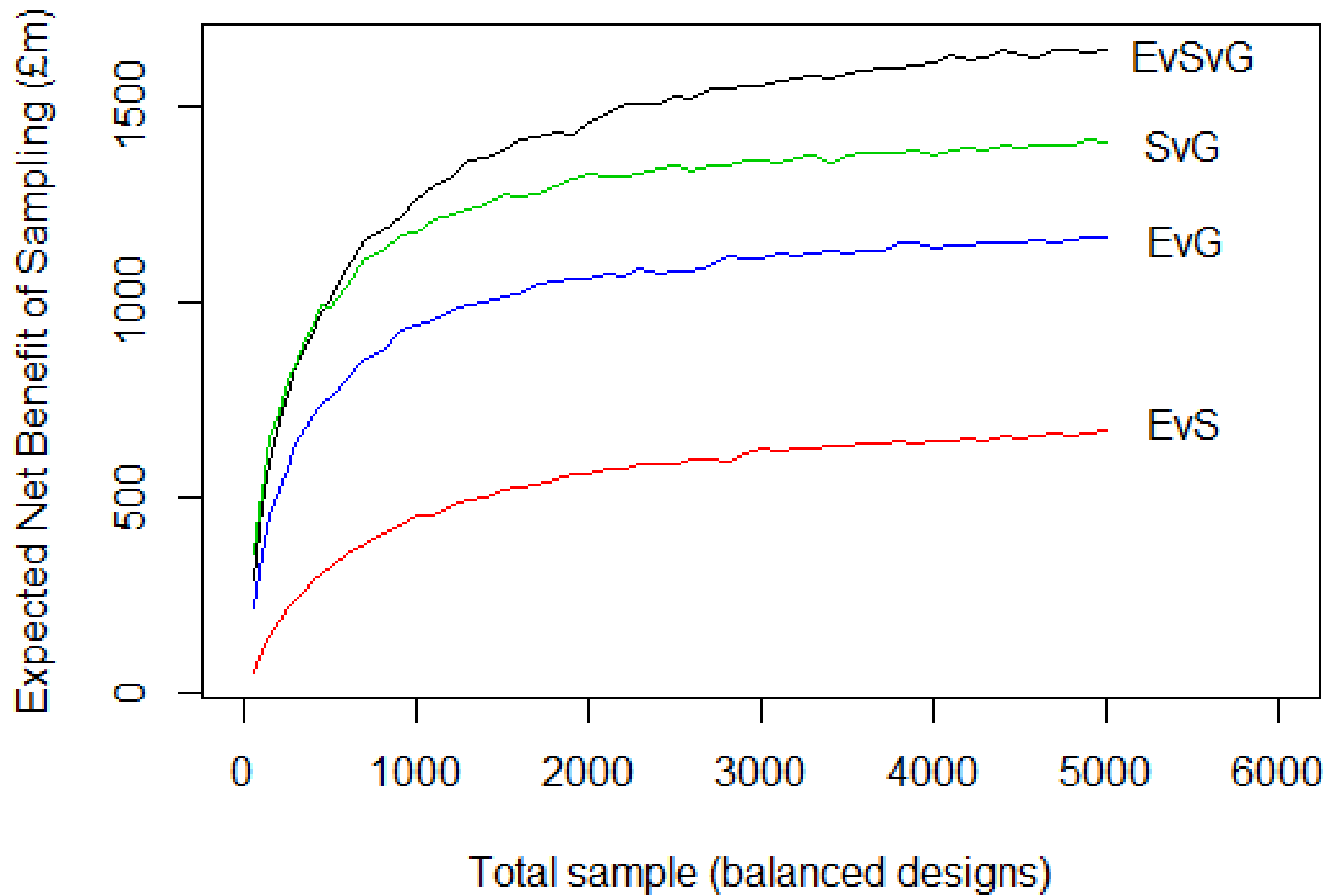
Willingness to pay per QALY= £20,000	EVPI for SSI costs (per wound)	EVPI for SSI risk on reference (per wound)	EVPI for relative effects (per wound)	Population EVPI for relative effects
Decision options: Exposed, Simple, Glue, Advanced	£0	£0	£138	£1419m
Decision options: Exposed, Simple, Glue	£0	£0	£177	£1823m

# EVSI for Different Designs

## Decision Options: E, S, G



- Population EVSI
  - EVSI multiplied by the population per year who will benefit and lifetime of technology
- Trial costs
  - Fixed costs, per site costs, per patient costs, intervention costs, opportunity costs
- ENBS = Population EVSI minus Trial costs



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- Decision is sensitive to the high level of uncertainty in relative efficacy of dressing types
    - Especially for “Glue”
  - There is value in a main trial
    - Greatest value is to include all of Glue, Simple, and Exposed dressing arms
    - Sample size needs to be sufficiently large for it to be worth including an Exposed arm
  - Consideration to relevance of Advanced dressings in this population is needed
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- Public Health England. Surveillance of Surgical Site Infections in NHS Hospitals in England 2014-15.
  - Jenks et al. Clinical and economic burden of surgical site infection (SSI) and predicted financial consequences of elimination of SSI from an English hospital. *J. Hosp. Infec.* 2014. 86:24-33
  - Dumville J, Gray T, Walter C, Sharp C, Page T, Macefield R, et al. Dressings for the prevention of surgical site infection (Review). *Cochrane Database of Systematic Reviews* 2016;12. <http://dx.doi.org/10.1002/14651858.CD003091.pub4>
  - SPARCS and WMRC on behalf of the Bluebelle Study Group (Blencowe et al). Feasibility work to inform the design of a randomised clinical trial of wound dressings in elective and unplanned abdominal surgery. *Br. J. Surgery.* 2016. doi: 10.1002/bjs.10274
  - Gheorghe et al. Health utility values associated with surgical site infection: a systematic review. *Value in Health* 2015. 18:1126-1137.
  - Pinkney et al. Impact of wound edge protectin devices on surgical site infection after laparotomy: multi-centre randomised controlled trial (ROSSINI trial). *BMJ* 2013:347