Reflections on the feasibility of undertaking economic evaluations of medical devices for resource constrained settings

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Background

- The World Health Organisation: Health Technology Assessment (HTA) systems with regulatory and management frameworks should play a role in Medical Devices and Equipment (MDE) administration and policy-making.

- In Low and Middle Income Countries (LMICS), if present, HTA focus is on safety and clinical effectiveness (2015 Global Survey on HTA)

- We wished to explore the feasibility of HTA in this context using Generalised Cost Effectiveness Analysis (GCEA)

- GCEA is endorsed by the WHO CHOosing Interventions that are Cost Effective (WHO-CHOICE) group
Generalized Cost-Effectiveness Analysis (GCEA)

- Comparison of all potential treatments against a hypothetical null no treatment available
- Scenario is sectoral CEA assuming all funds and resources can be reallocated

Guideline document: Societal perspective Disability-adjusted life-year (DALY)
Annual 3% discount rate of costs & health effects

Tool-set:
PopMod dynamic life-table population model
CostIt template: health facility, regional & program costs
MCLeague stochastic league table simulations
Methods

**Purpose:** to ‘road-test’ the feasibility of generalized cost-effectiveness analysis in a case study

**Success:** defined as the ability to construct appropriate economic model and obtain a cost-effectiveness estimate

**Judgment** draws on *NICE Methods guide (2015)*:
- Strength of underpinning clinical evidence
- Appropriateness of the model, including decision-problem, inputs and assumptions plausibility
- Health service delivery/budget impact implications
Case study: the SIGN intramedullary nail

Orthopaedic surgery:
13-31% surgical need met in Sub-Saharan Africa and South Asia
2.5% of GDP lost output in LMIC economies
Fractures alone 22million years lived with disability 2013
Scarce CE information on orthopaedic surgery suggests comparable to ophthalmic surgery or Caesarean Section

SIGN nail:
Low cost implant for long bone fracture
No power reaming or image intensification
Case study – GCEA of the SIGN intramedullary nail for femur fracture

**Perspective:** health service (Bill & Melinda Gates Reference Case (BMG-RC))

**Time horizon and discounting:** Lifetime for DALY, 10 year implementation for costs (WHO-CHOICE/BMG-RC)
3% annual rate to discount health effects and costs

**DALY:** - age weighted, discounted, Japanese life expectancy
- discounted, Japanese life expectancy
- Japanese life expectancy
- age weighted, discounted, Africa D life expectancy

**Societal recommended by WHO-CHOICE, data collection not feasible**
Case study – GCEA of the SIGN intramedullary nail for femur fracture

**Population:** Patients with fracture of the femur shaft, aged 16-65, no contra-indication to surgery

**Interventions/Comparators:** Surgical and non-surgical interventions *where effectiveness data are available compared to a no-treatment baseline.*

**Outcomes:** Mortality and fracture union versus mal- and non-union.

**Setting:** Africa D and Africa E regions (Global Burden of Disease study)
**Open Reduction**

ORIF-IM: Definitive internal fixation with intramedullary nails

ORIF-P: Definitive external fixation with plates

ORIF-IM following EF: Temporary external fixation and definitive internal fixation with intramedullary nails

Open reduction requires specialised surgical equipment (fluoroscopy)

**Closed Reduction**

CRIF-IM: Definitive internal fixation with intramedullary nails

CRIF-P: Definitive internal fixation with plates

**Traction with cast or brace support**

**No treatment**

- Death
- Union
- Mal- or non-union
Data and sources
AO Foundation Surgical Reference database
Systematic literature search on long bone fixation
Mortality estimates: intramedullary nailing and null from cohort studies, otherwise all-cause mortality following musculoskeletal trauma and surgery (Foote et al 2015)
Costs: systematic literature review, Lancet Commission on Global Surgery Meara 2015, Alibaba (website)

Assumptions (data paucity)
First line treatment only
Outcomes: death, union, mal-union/non-union
Simplified decision tree (eg reaming not included)
Subgroup heterogeneity not considered (type of fracture, injury severity score, violence, traffic regulation)

CHEERS checklist
Cost-effectiveness of alternative interventions in comparison to null scenario and standard care (I$/DALY averted)

<table>
<thead>
<tr>
<th>Regions and Interventions</th>
<th>Cost (I$) per DALY averted</th>
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<td><strong>1092</strong></td>
<td><strong>610</strong></td>
<td><strong>38</strong></td>
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<td>526</td>
<td>1175</td>
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Aw=Age weighting, D=discounting, J=Japanese A=Africa life expectancy
Findings: Cost-effectiveness of treatments modelled compared to the $1*GDP$ per capita ($I\$)$ threshold

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<td>Lower quartile</td>
<td>Average</td>
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<td>Estimates Africa D</td>
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<td>Africa D</td>
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<td>Traction</td>
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<tr>
<td>ORIF-IM</td>
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<tr>
<td>ORIF-P</td>
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<tr>
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<tr>
<td>ORIF-IM after EF</td>
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<tr>
<td>Estimates Africa E</td>
<td>554.56</td>
<td>1953.01</td>
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Probabilistic sensitivity analysis:

- surgical interventions clustered together
- Predictable given parameter uncertainty

Deterministic sensitivity analysis:

- sensitive to capacity utilization and cost discount rate
Discussion: Case study findings

- CRIF-IM and ORIF-IM after EF are the most cost-effective but not for all countries within the regions considered, highly uncertain
  - CRIF IM – most appropriate for immediate repair/stable patient, didn’t account for patient heterogeneity in full
  - ORIF IM after EF consistent with damage control orthopaedics in the context of violence/RTAs
- Model assumes operation rooms would be solely for orthopaedic use – unrealistic
- Likely not to be affordable (the budget impact should be evaluated according to CHOICE)
- Possible to construct a model but lack of high quality comparative data
Discussion: reflections on feasibility

- Assumptions may not hold:
  - Base case capacity utilisation of 80% unrealistic
  - Cost discounting at 3% at variance with practice (15% bank lending rate for Kenya)
- Comparisons with 1, 2, 3 x GDP per capita not utilised (alternative national adjustments in practice, e.g. 1 x GDP, current nurse salary)
- Improved guidance required on:
  - assessment of data adequacy to prevent futile model development (opportunity cost)
  - Null treatment comparator (potentially useful if no service in place, otherwise assumes mobility of scarce resources)
Barriers to GCEA feasibility:
- IT access and capacity
- Access to:
  - health technology expertise
  - health systems data (ingredients costing)
  - data required to implement societal perspective

BMG-RC better reflected reality of decision-making: GCEA might be preferred but not be deliverable.
Conclusions

- GCEA was feasible in this case study with major modifications but data quality was poor, compromising the findings: little added value?
- The modifications result in an analysis that does not fit with the original decision-making paradigm.
- Both NICE and BMG-RC focus on integration of findings into decision-making paradigms:
  - unclear how findings of this case study could be contextualised with consideration of budget impact and resource release
  - Countries with potential to benefit most may not have appropriate decision-making paradigm
Conclusions continued

- More pragmatic options include:
  - heuristics for prioritization of devices for in-depth consideration
  - Multiple Criteria Decision Analysis
  - marginal programme budgeting
- Accountability for Reasonableness may provide a framework for evaluation of implementation of such methods
- In the case of the SIGN intramedullary nail, GCEA may not be the optimal tool for decision-making
Conclusions continued

- GCEA implementation would be more pragmatic:
  - With better guidance on handling missing data (extrapolation models)
  - Where multi-arm/multi-country trials are available (e.g. multi-country comparison of cholera vaccine doses and hygiene interventions)

- A database of GCEA findings could be particularly useful to direct investment away from dominated interventions.
Acknowledgements

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