DEPARTMENT OF GLOBAL HEALTH
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Budget Impact Analysis

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Introduction

- Sovaldi (Sofosbuvir) approved for treatment of **chronic hepatitis C** by the US FDA on December 6th 2013
  - This drug is a cure for an otherwise incurable condition
- Initial cost
  - $1,000 per pill or $84,000 per 12-week course
- Cost-effectiveness at list price (compared to pre-launch standard of care)
  - $12,825 per QALY gained (Najafzadeh M. et al. Ann Intern Med 2015)
  - $55,400 per QALY gained (Chhatwal J. et al. Ann Intern Med 2015)
  - "Highly" cost-effective
- Budget impact for treating all eligible hepatitis C patients in the US in 5 years
  - $65 billion (2014 $US) (Chhatwal J. et al. Ann Intern Med 2015)
  - $16 billion in cost offsets

Budget Impact Analysis (BIA)

- A BIA addresses the expected changes in the expenditure of a healthcare system after the adoption of a new intervention
- Estimates the financial consequences of adoption and diffusion of a **NEW** healthcare intervention within a specific healthcare setting given budget constraints
- Is part of the comprehensive economic assessment of healthcare technologies along with CEA before the technology is approved for addition to a formulary or reimbursement by healthcare payers
- BIA provides a framework for stakeholders to examine how different assumptions about the potential impact of the new interventions with regard to
  - Changes in technology mix
  - Changes in treatment cost

Budget Impact Analysis (BIA)

- Predicts how a change in the mix of interventions used for a condition affects the trajectory of spending on that condition
- BIA evaluates a scenario and not a single intervention
- The comparator in BIA is the status quo
- Uses of BIAs
  - Budget planning
  - Forecasting
  - Estimating impact of health technology changes on health insurance premiums
  - Estimating (potential) fiscal impact of pursuing an intervention at the national level

Comparison of CEA and BIA

	CEA	BIA
Objective	Quantify net health ROI	Quantify impact on resource consumption
Outcomes	Net health benefits, net resource consumption	Net resource consumption
Perspective	Societal, healthcare sector, payer	Payer
Time horizon	Long-term (until all costs and benefits realized)	Budget cycle (1 – 5 years)
Unit	ICER	Absolute costs and savings
Interpretation	↓ICER = ↑Cost-effectiveness	↓Cost = ↑Affordability
Threshold	ICER—WTP threshold	No metric or threshold for individual intervention assessment

Citation: Bilinski A, Neumann P, Cohen J, Thorat T, McDaniel K, Salomon JA (2017) When cost-effective interventions are unaffordable: Integrating cost-effectiveness and budget impact in priority setting for global health programs. PLoS Med 14 (10): e1002397. https://doi.org/10.1371/journal.pmed.002397

Impact of New Interventions on Budgets

- New interventions (usually) increase costs
- New interventions may reduce condition/disease costs because of clinical benefits to patients
  - E.g., reduce hospital days
  - Reduce out-patient visits
- The reduced disease costs may offset the costs of the new intervention
- Timing of changes in costs of intervention or disease costs have an impact on budget changes

Six Steps of Budget Impact Analysis

1. Characterize the population with the potential to be impacted by the intervention
2. Select the time horizon
3. Determine the current and future mix of interventions
4. Estimate intervention costs
5. Estimate changes in disease-related costs
6. Present results

Step 1: Characterize the Population

- Use epidemiology data from multiple sources
- Start with country (or health plan) population to determine population with potential to be impacted by the new intervention
  - Include all people with the condition who have been diagnosed and are currently undergoing treatment
  - Include people who might enter the treatment pool because of the new intervention
  - Include both new entrants to the treatment pool who will start on the new intervention and patients who will switch from other interventions
- Sub-divide population by disease severity and disease stage and allow population in stages to vary over time if necessary

Step 2: Select the Time Horizon

- Decision makers prefer short time horizon
- When designing an analysis, ensure that the framework (model) is flexible with regard to the time horizon

Step 3: Determine Current and Future Mix of Technologies

- Characterize all the current interventions that are currently in use and are likely to be changed when the new intervention sets in
  - Data may come from observational studies or market research
- Determine future intervention mix:
  - Is the new intervention an add-on or a substitute?
  - If it is a substitute, which of the current interventions will loose "market" share?
  - Estimate market share for new intervention each year after introduction
  - Data come from expert/stakeholder projections

Step 4: Estimate Intervention Costs

- Costs of interventions come from cost studies
- If the time horizon is long, there is a need for discounting
- Consider impact of adherence to interventions on costs and outcomes

Step 5: Estimate Changes in Disease-Related Costs

- Estimates of changes in disease-related costs come from the same disease-related models as are used for other economic evaluations
- Data may come from trials (e.g., for drugs) for acute illnesses

Step 6: Present Budget Impact

- BIA results are presented for each year as costs per person per month or costs per treated person per month
  - May be presented for a country or a health plan or a district
  - For a country, the members may be tax payers i.e., impact on the taxes of tax payers
- Health outcomes are usually presented alongside budget impact results
  - Same format and same time horizon

Example: BIA of Rotavirus Vaccination in Uganda

- Joint effort
  - **Gloria Ikilezi**, DGH/IHME
  - **Solomon J. Lubinga**, DGH Global Medicines Program/CHOICE (Pharmacy)

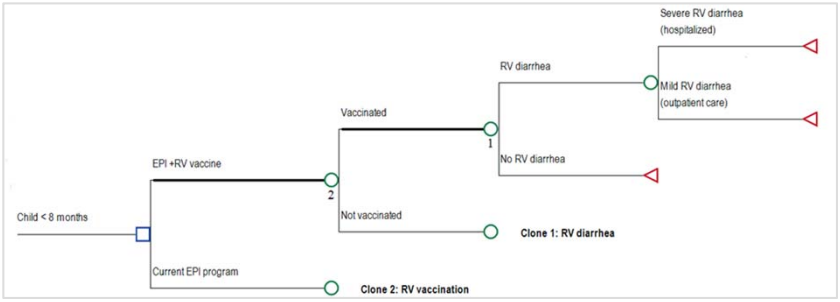
Background

- Rotavirus vaccination is highly cost-effective in Uganda
  - Cost-saving (Tate et al. Vaccine (2011))
  - $29 - $34 per DALY averted (Sigei et al. Vaccine (2015))
- Given:
  - Planned 2017 introduction of rotavirus vaccination in Uganda (now delayed)
  - GAVI commitment of $21.1 million for rotavirus vaccine support to Uganda (2018 – 2020)
- How would introduction and scale up of rotavirus vaccine affect:
  - Healthcare budget in Uganda
  - Healthcare budget in Uganda given GAVI commitments

Methods

- Analytic framework – Decision tree
- Perspective – Uganda MOH
- Time horizon – 2018 to 2020
- Coverage – 25% increase per year to 75% coverage in 2020
- Vaccine efficacy – published data
- Population – UN and census numbers adjusted for neonatal mortality

Model



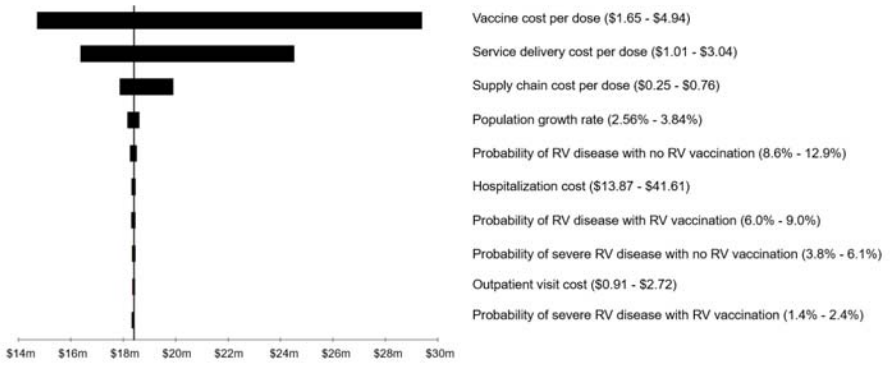
Data

Parameter	Baseline	Low	High
Population			
Total Ugandan population	39,570,125	—	—
Annual growth rate	3.2%	—	—
Annual number of births (2018)	1,924,093		
Neonatal mortality (per 1,000 live births)	19	—	—
RV vaccine diffusion			
2018	25%	—	—
2019	50%	—	—
2020	75%	—	—
Efficacy estimates			
RV diarrhea			
Vaccinated	0.075	0.060	0.090
Unvaccinated	0.107	0.086	0.129
Severe RV diarrhea			
Vaccinated	0.029	0.014	0.024
Unvaccinated	0.049	0.038	0.061
Costs			
Vaccination			
RV vaccine price per (2-dose)	$3.30	$1.65	$4.94
International handling (% of vaccine cost)	3%	3%	3%
International shipping (% of vaccine cost)	2%	2%	2%
Wastage (% of doses discarded)	5%	5%	5%
Supply chain costs	$0.51	$0.25	$0.76
Service delivery costs	$2.02	$1.01	$3.04
Rotavirus-related care			
Out-patient visit	$1.82	$0.91	$2.72
Hospitalization	$27.74	$13.87	$41.61

Baseline Results

	Vaccine costs	Vaccine BI	OP costs	OP BI	Hospital costs	Hospital BI	Treatment costs	Treatment BI	Total costs	Total BI
2018										
EPI	$0	—	$349,567	—	$274,525	—	$624,092	—	$624,092	—
EPI + RVV	$5,844,753	$5,844,753	$250,177	-$99,390	$113,838	-$160,687	$364,060	-$260,032	$6,208,813	$5,584,721
2019										
EPI	$0	—	$360,753	—	$283,309	—	$644,063	—	$644,063	—
EPI + RVV	$12,063,570	$12,063,570	$258,182	-$102,571	$117,528	-$165,781	$375,710	-$268,353	$12,439,280	$11,795,217
2020										
EPI	$0	—	$372,298	—	$292,375	—	$664,673	—	$664,673	—
EPI + RVV	$18,674,406	$18,674,406	$266,444	-$105,854	$121,289	-$171,086	$387,833	-$276,840	$19,062,139	$18,397,466
3-year total										
EPI	$0	—	$1,082,618	—	$850,209	—	$1,932,828	—	$1,932,828	—
EPI + RVV	$36,582,729	$36,582,729	$774,803	-$307,815	$352,655	-$497,554	$1,127,603	-$805,225	$37,710,232	$35,777,404

Sensitivity Analysis



Discussion

- Phased-in introduction of the rotavirus vaccine to the EPI program in Uganda between 2018 and 2020 will increase the Uganda MOH budget by:
  - $5.6 million in 2018
  - $11.8 million in 2019
  - $18.4 million in 2020
  - $35.8 million over the 3-year time period
- 0.82% of domestic healthcare expenditure
- $21.1 million GAVI commitment ~ 40% less (0.34% of domestic healthcare expenditure)

Key Reference

VALUE IN HEALTH 17 (2014) 5–14

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ISPOR TASK FORCE REPORT

Budget Impact Analysis—Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force

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ABSTRACT

Background: Budget impact analyses (BIAs) are an essential part of a comprehensive economic assessment of a health care intervention and are increasingly required by reimbursement authorities as part of a listing or reimbursement submission. **Objectives:** The objective of this condition-specific model may be used to estimate the budget impact of the new intervention, accounting appropriately for those entering and leaving the eligible population over time. In either case, the BIA should use data that reflect values specific to a particular decision

End

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