Key methodological considerations for developing cost-offset budget impact models for a range of medical technologies and cost perspectives in ophthalmology

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Background and Objectives

- Budget impact models (BIM) for pharmaceuticals often follow a consistent structure whereas this is not the case for medical devices given varying stakeholders, types of devices, settings of use, and data availability.
- Several costing perspectives may be relevant which necessitates additional considerations for model parameters to inform a cost-offset structure.
- **The objective of this research is to illustrate key methodological considerations within ophthalmology given the range of device types and costing perspectives.**

Methods

- The focus of this study is the design of cost-offset BIMs for a range of diagnostic, consumable, implantable, equipment, and surgical devices used in ophthalmology.
- Many costing perspectives were considered including practice owners, clinicians such as optometrists, ophthalmologists and technicians, patients, public and private payers.
- It is important to clearly define the cost categories of interest for the target audience of BIMs and source the data appropriately.
- ISPOR guidelines on developing the framework for BIMs recommends the use of published literature or studies, market research, and then clinical expert opinion for parameterization.[1]
- However, a key limitation with medical devices is that comparative published literature is often scarce upon product launch, as many medical devices in the United States (US) are approved through the 510(k) pathway, relying on benchtop and descriptive data rather than pre-market approval requiring a clinical trial.[2]
- **Various aspects were considered in the BIMs in ophthalmology including:**

1 Population

- Patients undergoing ophthalmic surgery (cataract, vitreoretinal, etc), receiving intraocular lens implants or contact lenses, or receiving a service

2 Inputs

- Efficiency (e.g., consultation time, procedure time, additional services)
- Safety (e.g., complications)
- Costs of systems, services, consumables, and/or procedures (e.g., staff/overhead)

3 Outputs

- Incremental time savings/impact leading to additional procedures
- Incremental cost savings/impact
- Return-on-investment

Results

- Typically, these models are designed with a time horizon of 1 year or less, and parameters can change substantially depending on stakeholder(s) of focus (**Table 1**).
- More traditional model input types include product costs, rate of complications and/or repeat procedures, operating room and staff time, follow-up visits, device failures, or repairs (**Table 2**).
- Less common inputs which are essential for certain stakeholders (eg, practice owners) include consignment or lending fees, contracting efficiencies, re-order rates of consumables, value-added services, avoidance of cancelled surgeries, potential revenue capture, and risk of legal consequences (**Table 2**).

Table 1: Key aspects to consider for classic budget impact assessments, and considerations for applicability to various medical devices and services in ophthalmology

Aspects*; [1]	Premium Equipment (Refractive/Diagnostic)	Consumable Devices	Manufacturer Services	Practice Support Platforms
Examples	Biometer or intraoperative laser	Retina surgery consumables	Repair contracts	Contact lens ordering platform
Features of the Healthcare System	Payer reimbursement and patient out-of-pocket payments apply	Consumables covered as part of procedural reimbursement	No outside coverage for downtime	Patient orders covered by insurance or patient-funded
Perspectives	Provider and patient	Provider	Provider	Provider
Use and cost of current and new interventions	Acquisition cost (upfront, payment term, interest) "Click fee"	Acquisition cost	Repair cost (parts and labor), contract cost, maintenance and training specialist visits	Reorder rates, order sizes, and contact lens costs
Impact on other costs	Indirect (QoL, productivity) ROI offsets (additional revenue stream beyond insurance coverage)	Procedure time efficiency reduces facility and labor costs per procedure	Reduced system downtime can avoid cancelled procedures and lost revenue	Potential revenue from patients not placing reorders
Time horizon	Should be sufficient to cover ROI period	Procedure time or 1 year	Flexible depending on the length of contracts available	1 year
Uncertainty and scenario analysis	Should adequately reflect potential for variations between practices and min/max expected for critical inputs	Flexibility to reflect facility-specific device utilization, costs for overhead staff, inventory management	Use regional or global repair cost data from manufacturer and enable user flexibility for different region, reimbursement amounts, and procedure costs	Flexibility to reflect practice-specific order rates and sizes at the time of exam and in subsequent reorders

* Time dependencies and discounting are often not included given that the time horizons are usually around 1 year or less. Models are validated with stakeholders.

- These models typically consider multiple perspectives within one structure but can often follow a traditional cost-offset BIM design with a mix of current and future product utilization and overall budget impact.
- Return on investment (ROI) is an important result that should be considered with upfront investment of capital equipment.
  - The investment of capital equipment is converted into an annualized cost based on the estimated lifespan of the system in order to calculate the ROI over the time horizon.
- Furthermore, substantial gaps in the literature often necessitate estimation of resource use from clinician opinion, surveys, or Delphi panels.

Table 2: Potential sources for model inputs to consider

Model Inputs	Perspectives to Consider			Typical Sources
	Payer	Facility / Provider	Patient	
Traditional Model Inputs				
Procedure reimbursement	X	X		• CMS costing files[3] and Physician Fee Schedules[4]
Product costs	X*	X	X	• Manufacturer data • ASPs
System repairs		X		• Manufacturer data
Device failures		X	X	• Published literature • Manufacturer data • Delphi panel/clinical expert opinion
Complications rates and/or repeat procedures*	X	X		• Published literature • Delphi panel/clinical expert opinion
Complications and/or repeat procedures* costs; Follow-up visits costs	X†	X		• CMS costing files[3] and Physician Fee Schedules[4] • Delphi panel/clinical expert opinion
Operating room costs		X		• Published literature
Staff costs		X		• U.S. Bureau of Labor Statistics[5]
Medication costs	X	X		• Medicare Part B Drug ASP[6] • Navlin database[7]
Less Common Inputs				
Consignment or lending fees		X		• Manufacturer data
Reorder rates		X		• Market reports, manufacturer data
Value added services		X	X	• Manufacturer data
Legal consequences		X		• Model assumptions

* Dependent on whether the payer reimburses the cost of the new technology

† Dependent on whether the complication occurs outside of the global period.

Discussion

An important caveat of budget impact models for medical devices and services is ensuring that they consider the relevant inputs for stakeholders. This research illustrates the need for flexible model design considerations that incorporate less traditional parameters and results for various device types that require costing perspectives outside of traditional payers.

Abbreviations ASP = average selling price; CMS=Centers for Medicare & Medicaid Services;; QoL = quality-of-life; ROI = return-on-investment; U.S. = United States.

References **1.** ISPOR (2014) Budget Impact Analysis – Principles of Good Practice. **2.** Dubin JR, Simon SD, Norrell K, et al. (2021) JAMA Netw Open. 3;4(5):e217274. **3.** Centers for Medicare and Medicaid Services (2023) Hospital Outpatient Regulations and Notices. **4.** Centers for Medicare and Medicaid Services (2023) Physician Fee Schedule Look-Up Tool. **5.** Bureau of Labor Statistics, U.S. Department of Labor. Occupational Employment Statistics, May 2020. Available online at: https://www.bls.gov. **6.** Centers for Medicare and Medicaid Services (2023) Medicare Part B Drug Average Sales Price. **7.** Navlin (2023) Price & Access Data. Online [subscription]. Available online at: https://data.navlin.com/alspc/#!/.

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