Organised session proposal

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**Session overview**

Session title: Incorporating demand- and supply-side constraints in economic evaluations of new technologies: lessons for scale-up

Primary field as outlined: Economic evaluation of health

Session description (750 word maximum)

Supply- and demand-side barriers to implementation may impede an effective scale-up of new interventions. The definition, measurement and inclusion of these constraints in economic evaluations is needed to improve both the understanding of resource requirements and cost-effectiveness analyses aiming to inform programmatic decisions for implementation at scale. In particular, demand-side constraints such as financial burden on patients or social stigma can ultimately reduce uptake, affecting projected effectiveness as well as costs of an intervention at scale; while supply-side constraints such as shortages of human resources might reduce service availability, affecting ultimately the maximum coverage that could potentially be achieved within country, subsequently impacting both population level impact and costs.

The aim of this session is to provide a framework to conceptualise intervention strategies that takes into consideration both the technology and the possible constraints to successful implementation, while providing examples of cost measurement to inform economic evaluations of these strategies at scale.

We organised this session into three presentations and a structured discussion. The first presentation introduces the role of supply- and demand-side constraints when introducing new technologies and proposes a framework for addressing these challenges in the design and evaluation of policy alternatives. This framework conceptualises interventions as actions affecting supply- and demand- factors within the health system and highlights the importance of including both the costs of instigating change and the consequential costs within the health system in cost-effectiveness analyses. The second presentation provides an example of how to incorporate local preferences and address local concerns and social stigma. In this example we illustrate the effect of relaxing demand-side constraints on costs at scale, using voluntary male circumcision for HIV prevention in Tanzania as a case study. The final presentation reflects on the role of demonstration projects in collecting data to inform the definition and measurement of data to inform economic evaluations including the relaxation of supply-side constraints. We illustrate this role using the example of a demonstration project of pre-exposure prophylaxis for HIV prevention among female sex workers in South Africa.

Each presentation will be 15 minutes followed by five minutes of clarifying questions. We will then focus on a structured, 30-minute discussion. A panel of four discussants will begin by reflecting on pre-determined topics (maximum of 5 minutes each). We chose a panel including experts able to provide perspectives from country level decision making (Dr Edwine Barasa, KEMRI-Wellcome Trust Research Programme, Nairobi, Kenya; Head, Health Economics Research Unit) to implementation issues (Dr Katharine Kripke, Avenir Health, Glastonbury, USA; Senior Health Policy Advisor), including data collection and methods (Dr Fern Terris-Presholt, London School of Hygiene and Tropical Medicine, London, UK; Associate Professor of Economics of HIV) and application into modelling (Dr Nick Menzies, Harvard T.H. Chan School of Public Health, Boston, USA; Assistant Professor of Global Health). Discussants will be asked to briefly comment on these issues to encourage a broader discussion with session participants. We will also invite comments from the audience on experiences and emerging methods.

Declaration on potential conflicts of interest: No conflicts of interests declared

Presentations

1. Title: **Conceptualizing interventions and their costs in analyses of effectiveness and cost-effectiveness**. Authors: Catherine Pitt, Anna Vassall, Kara Hanson
2. Title: **Spending to Alleviate Demand Constraints Lowers Unit Costs: A cost-effectiveness analysis of voluntary medical male circumcision to prevent HIV in Tanzania**. Authors: S. Torres-Rueda, H.A. Weiss, M. Wambura, H. Mahler, K. Kripke, J. Chilongani, E. Kuringe, R. Hayes, M. Plotkin, M. Makokha, A. Hellar, C. Schutte, G. Mshana, N. Larke, G. Lija, J. Changalucha, J.M. Grund, F. Terris-Prestholt
3. Title: **Defining supply-side constraints to the scale-up of pre-exposure prophylaxis of HIV: the role of costing within demonstration studies.** Authors: Gabriela B. Gomez, Sedona Sweeney, Robyn Eakle, WD Francois Venter, Anna Vassall, Helen Rees

Individual papers

Title: Conceptualizing interventions and their costs in analyses of effectiveness and cost-effectiveness

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In designing and evaluating alternative strategies to improve health, researchers rarely identify in full the actions needed or undertaken to induce change within a given context or the full (net) costs associated with these actions and their consequences. These omissions result in inaccurate estimates of the real-world effectiveness and cost-effectiveness of alternatives and inefficient policy choices.

Vassall et al (2016) published a conceptual framework showing how proximal and distal supply and demand factors within the health system influence the process by which interventions affect the care pathway and the importance of these issues for understanding transferability. We further develop this framework by presenting a more explicit conceptualization of interventions, how they may lead to changes in the health system and health outcomes, and their costs. We draw on insights from the complex intervention literature – notably the role of context, theories of change, and process evaluations - and from a recent review of cost-effectiveness analyses (Pitt et al, 2016, Griffiths et al, 2016). We illustrate our framework with a figure and a case study of a public health intervention to prevent malaria in Senegal.

Specifically, we argue that the description of each component of even a seemingly “simple” intervention strategy should identify the actor(s) and the action(s) and the specific supply and/or demand factor(s) it is expected to influence. Any resultant shifts in supply and/or demand may then cause changes in actions within the system, including, but not limited to the intended use of a new product, procedure, or technology. A clinical procedure or technology itself thus should not be conceived of as an intervention without actors and actions to instigate its use. For example, national disease control programme leaders could change clinical guidelines to recommend or require use of a new test, thereby addressing one proximal supply factor. In most contexts, however, this single intervention would be insufficient to instigate the intended changes in any, let alone all, clinicians’ behaviour. Nonetheless, this intervention will incur non-negligible costs, including the valuable time of senior managers. Other proximal supply factors to address may include clinicians’ knowledge of the guidelines, skills, and behaviour, and the availability of the technology in health facilities. Proximal demand factors to consider addressing may include patients’ perceptions of their symptoms, the tests, and treatments and their willingness and ability to pay.

Designing an intervention strategy therefore requires explicit consideration of local supply and demand context and choices regarding which factors to attempt to influence and how. Evaluating an intervention strategy requires identifying all the activities undertaken which could potentially have influenced supply or demand, as well as any (expected or unexpected) resultant changes in behaviour and health outcomes. Both the costs of instigating change and the consequential costs within the health system must then be included in cost-effectiveness analyses. Using this economic framework in the design of intervention strategies may improve their effectiveness and cost-effectiveness, while using it at the evaluation stage may facilitate more accurate assessments of the transferability of trial or pilot findings to real-world settings.

Declaration on potential conflicts of interest: Nothing to declare

Funding sources for research: Economic and Social Research Council

Title: Spending to Alleviate Demand Constraints Lowers Unit Costs: A cost-effectiveness analysis of voluntary medical male circumcision to prevent HIV in Tanzania

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**Background:** Although voluntary medical male circumcision (VMMC) reduces HIV acquisition by around 60% and is widely considered highly cost effective, demand side constraints result in sub-optimal efficiency in services provision. Not only do campaign-style VMMC programmes have site specific fixed costs, resulting in economies of scale, but there is also low uptake among men aged 20-34 years who have the highest HIV incidence. A cluster randomised controlled trial was conducted to assess the effectiveness of a locally-adapted demand creation intervention in increasing uptake of VMMC among men aged 20-34 years in Tabora and Njombe regions of Tanzania, with HIV prevalence rates of 6% and 15% respectively. The intervention included demand-creation messages targeting men aged 20-34 years, using circumcised men as peer promoters, separate waiting areas for older clients, and information sessions for female partners.

**Methods:**Cost data were collected from a provider’s perspective on surgical, demand-creation and supervisory activities across all clusters in both trial arms. The Decision Maker’s Program Planning Tool (DMPPT 2.1) was used to estimate the number of HIV infections averted and related cost savings given the number of circumcisions performed in each cluster. DALYs were calculated and used to estimate incremental cost-effectiveness rations (ICERs).

**Results:**The intervention resulted in large increases in VMMC uptake across all age groups, and led to a statistically significant increase in the proportion of older men in Tabora. Cluster-level client load varied widely across clusters and was higher in the intervention arms (480-1187 in Tabora and 218-500 in Njombe) than in the control arms (272-951 and 102-268, respectively). Despite the extra costs of tailored demand creation, demand increased more than proportionally. The mean costs per VMMC in the intervention arms were $61 in Tabora and $130 in Njombe, and in the control arm $70 and $193, respectively. However, likely due to the higher incidence of HIV in Njombe, more HIV infections were averted in Njombe in both control and intervention arms (102 and 164, respectively) than in Tabora (67 and 123, respectively). Consequently, although unit costs were lower in Tabora due to economies of scale, the cost-effectiveness of VMMC was lower in Njombe. Incorporating averted treatment costs, the intervention was more cost-saving in Njombe than in Tabora ($462,000 v. $228,000, respectively).

**Conclusions:**The number of clients in Tabora was 2.5 times higher than in Njombe, leading to lower unit costs in Tabora due to economies of scale. The achievement of cost savings attributable to spending more to address local preferences within the intervention, successfully reduced demand constraints. However, in the case of Njombe, it was still worth spending more on increasing demand among harder to reach men due to their higher risk of acquiring HIV.

**Declaration on potential conflicts of interest:** Nothing to declare

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Title: Defining supply-side constraints to the scale-up of pre-exposure prophylaxis of HIV: the role of costing within demonstration studies

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**Background:** Scaling up coverage of new intervention requires additional financial resources and a health system capable of delivering the intervention at large scale. Current commitment to scale-up HIV prevention programmes has put pre-exposure prophylaxis for HIV (PrEP) firmly on the agenda of national programmes. However, planning the scale-up of PrEP remains a challenge for the majority of countries. As a complex intervention, supply- and demand-side barriers will play an important role in an effective PrEP scale-up. To date, the inclusion of these barriers in current cost-effectiveness analyses has been hindered by a lack of empirical data, especially with regards to supply-side constraints. Demonstration studies are ongoing or planned to inform national PrEP roll-out in several countries and offer a unique opportunity to collect data to inform the parameterisation of these constraints for future economic evaluations at scale.

**Methods:** Using the “Treatment And Prevention for female Sex workers” (TAPS demonstration project) as a case study, we analysed the characteristics of PrEP as a complex intervention to identify supply-side constraints to scaling up. We use insights from this analysis to propose data collection and reporting principles for demonstration studies to ensure data availability for use in economic evaluations of PrEP scale-up incorporating supply-side constraints.

**Results:** The scale-up of PrEP should be considered as a complex intervention in economic evaluations, including, in its costing, both the technology and supporting activities to achieve the desired high coverage. We identified five areas where potential supply-side constraints may impede effective scale-up of PrEP within the South African health system: lack of adequate financing, shortage of qualified staff, insufficient laboratory capacity, weak drugs and medical supply chain management, and inadequate community engagement. We then proceeded to lay out a framework to quantify to which extent these constraints may limit the scale-up process and, if appropriate, the marginal cost of relaxing such constraints, specifically related to constraints related to shortage of inputs (e.g. staff, infrastructure and equipment) that are likely to be more amenable to change following additional expenditure.

**Conclusion:** Demonstration projects of new interventions can be leveraged to conceptualise and collect data for future economic evaluations of these interventions at scale. We recommend a list of areas (translating into supply-side constraints) and indicators for reporting of cost data collected within demonstration projects. These recommendations included disaggregation of costs for financial resource need projections and indicators for human and laboratory resource use for projections of non-financial resource needs. These data should be part of the reported results from demonstrations studies in addition to other indicators such as uptake, retention, adherence, safety, and service delivery costs. The consideration of supply-side constraints in economic evaluations at early stages in the planning and decision processes is needed to ensure local relevance of the evaluations, credibility with decision makers, and, in the context of resource optimisation, to lower the risk of sub-optimal investments.

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