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Cost effectiveness of medical devices to diagnose pre-eclampsia in low-resource settings

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ABSTRACT

Background: Maternal mortality remains a major health challenge facing developing countries, with pre-eclampsia accounting for up to 17% of maternal deaths. Diagnosis requires skilled health providers and devices that are appropriate for low-resource settings. This study presents the first cost-effectiveness analysis of multiple medical devices used to diagnose pre-eclampsia in low- and middle-income countries (LMICs).

Methods: Blood pressure and proteinuria measurement devices, identified from compendia for LMICs, were included. We developed a decision tree framework to assess the cost-effectiveness of each device using parameter values that reflect the general standard of care based on a survey of relevant literature and expert opinion. We examined the sensitivity of our results using one-way and second-order probabilistic multivariate analyses.

Results: Because the disability-adjusted life years (DALYs) averted for each device were very similar, the results were influenced by the per-use cost ranking. The most cost-effective device combination was a semi-automatic blood pressure measurement device and visually read urine strip test with the lowest combined per-use cost of $0.2004 and an incremental cost effectiveness ratio of $93.6 per DALY gained relative to a baseline with no access to diagnostic devices. When access to treatment is limited, it is more cost-effective to improve access to treatment than to increase testing rates or diagnostic device sensitivity.

Conclusions: Our findings were not sensitive to changes in device sensitivity, however they were sensitive to changes in the testing rate and treatment rate. Furthermore, our results suggest that simple devices are more cost-effective than complex devices. The results underscore the desirability of two design features for LMICs: ease of use and accuracy without calibration. Our findings have important implications for policy makers, health economists, health care providers and engineers.

1. Introduction

Maternal mortality remains a major health challenge facing developing countries. Each year more than 280,000 women die due to complications related to childbirth, with the vast majority of these deaths occurring in low-income countries (Lozano et al., 2011). Very few countries achieved the Millennium Development Goal 5 of reducing maternal mortality by three-quarters by 2015 (Victora et al., 2015). In low-income countries pre-eclampsia accounts for 11–17% of maternal mortality (Say et al., 2014). Pre-eclampsia is characterized by high blood pressure and elevated levels of protein in the urine. A diagnosis of pre-eclampsia is made if blood pressure is above 140/90 mmHg and there is more than 30 mg/dL of protein in the urine after 20 weeks of gestation (Sibai et al., 2005). When not properly managed, pre-eclampsia may progress to eclampsia, which is characterized by the onset of seizures and can lead to dangerous complications such as stroke, heart failure, thrombosis, systemic endothelial dysfunction, HELLP syndrome, placental abruption, or even death (Sibai et al., 2005). The majority of deaths due to pre-eclampsia are preventable if the symptoms can be identified and if treatment can be

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administered in a timely manner. Treatment for pre-eclampsia consists of medical and surgical options, including the administration of magnesium sulfate and delivery through induction of labor or cesarean section (Altman et al., 2002).

The diagnosis of pre-eclampsia requires not only skilled health providers, but accurate medical devices that are appropriate for target settings, enabling users to identify pre-eclamptic women when the condition can be managed. In low- and middle-income countries (LMICs) access to the types of medical devices used to diagnose pre-eclampsia in high-income countries is hindered by high cost, limited trained users and inadequate distribution channels. A recent Lancet Commission called for collective approaches by academia, private sectors, non-governmental and international organizations, and ministries of health to prioritize pressing needs, co-identify appropriate solutions, and devise sustainable implementation plans (Howitt et al., 2012). Cost-effectiveness analysis provides a unifying framework to guide the allocation of scarce resources to reduce maternal mortality and morbidity. It has important implications for health policy, health care provision, and clinical and biomedical engineering.

Few studies have examined the cost-effectiveness of devices or procedures to reduce maternal mortality in LMICs. Tsu et al. examined the cost-effectiveness of the active management of third-stage labor (Tsu et al., 2009). Shmueli et al. performed an economic assessment of screening for pre-eclampsia using uterine artery Doppler and serum biomarkers relative to no screening in an Israeli healthcare system (Shmueli et al., 2012). Simon et al. assessed the cost-effectiveness of using magnesium sulfate for pre-eclampsia in low- and high- income countries, and the incremental cost of preventing one case of eclampsia (Simon et al., 2006). Hadker et al. found a novel diagnostic test to be more cost effective in managing a typical pregnancy than blood tests, urine tests, and uterine artery Doppler ultrasounds from the perspective of the UK health system (Hadker et al., 2010). Meads et al. compared 27 screening tests in a UK setting and found a no-test, treat-all strategy to be the most cost effective (Meads et al., 2008). The current study is the first to generate and compare cost-effectiveness ratios for multiple medical screening devices specifically designed for use in LMICs.

The purpose of this study is three-fold: (1) to tabulate cost and effectiveness data for medical devices appropriate for diagnosing pre-eclampsia in LMICs, (2) to develop a decision-tree framework for evaluating interventions that improve diagnosis and treatment of pre-eclampsia based on the costs and benefits to society as a whole, and (3) to generate cost-effectiveness estimates to guide decision-making in clinical practice and health policy to ultimately reduce maternal mortality. This study presents findings from a decision analysis model of medical devices used to diagnose pre-eclampsia in the population of pregnant women residing in LMICs from a societal perspective.

2. Methods

To identify the set of medical devices to include in this study we conducted several literature searches using PubMed, SciVerse Scopus, WHO Compendia of New and Emerging Health Technologies, Appropedia's Medical Devices Compendium and Medline. We contacted both health care professionals in the field of maternal health and product developers involved in the design and testing of maternal health related medical devices designed for use in LMICs to inquire about prototypes in the pipeline. Of the initial list of 15 devices identified, only eight devices had sufficient cost and effectiveness data to be included in the study (Table 1).

Pre-eclampsia is diagnosed by blood pressure measurement with subsequent confirmation of proteinuria by urinalysis. The mercury sphygmomanometer is the widely accepted “gold standard” manual blood pressure measurement device. The other blood pressure measurement devices in the study are either automatic or semi-automatic and designed for use in LMICs. Both auscultatory and oscillometric

Table 1
Proteinuria and blood-pressure devices.

Device category	Device type	Device name	Description	Per-use cost ($)	Device sensitivity	Device specificity
Diagnostic: Proteinuria	Dipstick Test	CLINITEK Status Microalbumin Strip Test (Guy et al., 2009)	Clinitek Status automated analyzer with single use plastic strips that detect albumin and creatinine in urine.	5.70–5.85	0.955	0.533
		Multistix Pro 10LS (Wilde et al., 2008)	Single use plastic strips that detect proteinuria (visually read).	3.29	0.263	0.729
		Uristik (Viswanathan et al., 2005)	Single use plastic strips that detect glucose and protein in urine (visually read).	0.2	0.680	0.680
		DCA 2000 + (Guy et al., 2009)	Automated, battery-powered device that displays the proteinuria content of a urine sample on an LCD screen.	12.90	0.994	0.840
Diagnostic: Blood-pressure	Auscultatory	Mercury Sphygmo-manometer (Hunyor et al., 1978)	Manual device that uses a mercury column to display the pressure of a cuff inflated around the upper arm. Requires a trained operator to listen to Korotkoff sounds with a stethoscope.	0.009–0.039	0.966	0.877
	Hybrid	Nissei DM-3000 (Duhig et al., 2009)	Hybrid device with manual auscultatory and automatic oscillometric settings, with digital display. This study uses values from the auscultatory setting only.	0.076–0.11	0.918	0.914
	Oscillometric	Spot Vital Signs (Alpert, 2007)	Rechargeable battery-powered device that automatically inflates cuff, obtains blood pressure through a built-in algorithm, and displays result on a digital display.	0.15–0.29	0.931	0.858
		Microlife (de Greeff et al. 2008)	Manually inflated device that automatically determines blood pressure with a built-in algorithm, and displays result digitally.	0.004	0.910	0.905

Notes: Costs are in US 2015 dollars.