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## Rotavirus vaccines contribute towards universal health coverage in a mixed public-private healthcare system

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### Abstract

**Objectives:** To evaluate rotavirus vaccination in Malaysia from the household's perspective. The ECEA framework quantifies the broader value of universal vaccination starting with non-health benefits such as financial risk protection and equity. These dimensions better enable decision-makers to evaluate policy on the public finance of health programs.

**Methods:** We use an extended cost-effectiveness analysis (ECEA). The incidence, health service utilization and household expenditure related to rotavirus gastroenteritis according to national income quintiles were obtained from local data sources. Multiple birth cohorts were distributed into income quintiles and followed from birth over the first five years of life in a multi-cohort, static model.

**Results:** We found that the rich pay more out-of-pocket (OOP) than the poor, as the rich use more expensive private care. OOP payments among the poorest although small, are high as a proportion of household income. Rotavirus vaccination results in substantial reduction in rotavirus episodes and ex-

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penditure, and provides financial risk protection to all income groups. Poverty reduction benefits are concentrated amongst the poorest two income quintiles.

**Conclusion:** We propose that universal vaccination complements health financing reforms in strengthening UHC. ECEA provides an important tool to understand the implications of vaccination for UHC, beyond traditional considerations of economic efficiency.

**Keywords:** universal health coverage, poverty, catastrophic expenditure, equity, vaccines, mixed public-private healthcare systems.

## Introduction

The United Nations General Assembly has unanimously endorsed the goal of achieving Universal Health Coverage (UHC) (1). Towards achieving this goal, health systems are responsible for expanding the range of services that can be accessed, while ensuring equitable distribution of benefits and financial risk protection against the 'catastrophic' or impoverishing impact of healthcare payments (2, 3).

The path to UHC is complex in middle-income countries with mixed public-private healthcare systems. Malaysia is widely credited as having achieved UHC through a public healthcare system that ensures access to subsidized healthcare for the whole population (4). However, perceptions of shortcomings in public healthcare, including long waits to access care and inadequate staff numbers, lead patients to seek care in the private sector (5). This exposes many to the financial risks of out-of-pocket (OOP) payments for private healthcare (6). Recent evidence suggests that OOP expenses for rotavirus gastroenteritis requiring hospitalization in Malaysia results in financially 'catastrophic' expenditure and even impoverishment, especially amongst the poor (7). Such OOP expenses are inconsistent with the stated aims of UHC, which is to deliver effective interventions while ensuring financial risk protection for all.

Reliance on OOP healthcare payments, or direct payments for healthcare at the point of receipt of care, results in financial hardship among millions of people worldwide (8, 9). Unanticipated healthcare expenditure may not necessarily be large, but if above a critical fraction of household resources may disrupt household living standards, and can be considered 'catastrophic' - exceeding a certain fraction of household income (10-13). Even small healthcare payments may push household income below the poverty line, resulting in or worsening poverty (12, 14, 15).

The financial implications of OOP healthcare payments are different for the rich and the poor. The poor are likely to spend more of household income on basic necessities, like food, shelter and other es-

entials, thus are more vulnerable to unanticipated expenses. The rich have more resources and a better ability to smooth consumption (9, 16). Large OOP payments may deter the poor from seeking care, underestimating the financial consequences of ill health (17). Other than the costs of actual treatment, the cost of seeking care including transportation and food, may adversely impact household welfare (18).

Financial risk protection, an essential component in achieving UHC, can be defined as access to quality healthcare as needed without incurring financial hardship (19). Preventive measures such as vaccination may be complementary to reducing the cost of treatment as a means to achieve UHC, since they remove the risk of having to pay for illness-related care. Their universal nature is particularly attractive in mixed public-private healthcare systems where financial risk protection cannot be achieved simply by offering free-at-the-point-of-use access to public healthcare services.

Rotavirus is an important determinant of childhood diarrhea (20). By age of five years, almost every child worldwide would have experienced an episode of rotavirus diarrhea (21). In high- and middle-income countries, mortality due to rotavirus is small, but associated morbidity may impose a heavy financial burden on families (22). The homogeneity of rotavirus incidence across high- and low-income countries, irrespective of standards of sanitation and hygiene, is testament to the high transmissibility of the virus (20, 23, 24).

As improvement in water and sanitation does not directly prevent viral infection, rotavirus vaccines are the only effective preventive measure. Two rotavirus vaccines have been licensed and widely available globally. These vaccines are safe, efficacious and effective (25-28) and are recommended by the World Health Organization (WHO) for inclusion into National Immunization Programs worldwide (24). Although widely regarded as cost-effective interventions (29-31), rotavirus vaccines are expensive and vaccine introduction has been slow for middle-income countries, like Malaysia, with low rotavirus mortality (22, 32, 33).

In this study, we use an extended cost-effectiveness analysis (ECEA) to evaluate the impact of rotavirus vaccination in Malaysia. The ECEA explicitly estimates financial risk protection, considered essential by the WHO towards UHC (2). Also, the ECEA methods exhibit a vector of poverty reduction critical for Ministers of Finance, development agencies and funders, in considering investments in health. The global importance of poverty alleviation is exemplified with the Sustainable Development Goals, in which the first goal is a commitment to eradicate poverty in all its forms everywhere (34). These dimensions provide additional information to better enable decision-makers to evaluate policy on the public finance of health programs (35).

## **Methods**

### ***Overview***

The ECEA framework was used to evaluate public financing of universal rotavirus vaccination in Malaysia from the household's perspective, across four dimensions (a) health benefits gained - hospitalizations and clinic visits averted, (b) household healthcare expenditure crowded out - direct medical and non-medical costs averted, (c) financial risk protection afforded - prevention of financially catastrophic and impoverishing payments, and (d) equity - the distributional consequences of vaccination across national income quintiles.

Rotavirus incidence, health service use, illness-related expenditure and other input parameters were obtained from local data sources. Age-stratified cohorts were distributed into national income quintiles and followed from birth over the first five years of life in the POLYMOD model. The POLYMOD model is a static, multi-cohort model designed by researchers at several European countries (36-38). The impact of monovalent Rotarix® (GlaxoSmithKline, Rixensart, Belgium) was considered in the base-case.

We assume that a universal rotavirus vaccine in Malaysia, will follow the routine schedule for diphtheria-tetanus-pertussis (DTP) vaccines and be administered at two and three months for Rotarix®. Rotavirus vaccine coverage is based on the 2013 third dose DTP coverage of 97 percent in Malaysia (39).

Malaysia had an under-five mortality rate of nine per 1,000 live births in 2013, and is categorized in the low mortality strata according to WHO Strategic Advisory Group of Experts on Immunisations (SAGE) definitions (40, 41). Vaccine efficacy was estimated for rotavirus vaccines in Malaysia, based on studies conducted in countries within the low mortality strata. This estimation is detailed in the appendix (Supplementary text 1).

The base year for analysis is 2013. An annual discount rate of three percent was used (42). Analysis was conducted using Microsoft Excel® Professional Plus 2013 and R version 3.2.0 (2015-04-16). Parameters in the base-case are listed in Table 1. Presented next are the main data sources, a description of terms and methods used in the analysis.

### ***Data sources***

The National Health and Morbidity Survey 2011 (NHMS 2011), a nationwide health survey conducted by the Ministry of Health (MOH), Malaysia provided us with average OOP healthcare expenditure and utilization patterns for inpatient and outpatient care, at public and private health facilities by national income quintiles in Malaysia (43).

A two-year, prospective rotavirus study conducted at two public hospitals in Malaysia collected in-

formation on illness-related expenditure for all children under-five years admitted for acute diarrhea (7). As income groups from this 2010 hospital-based rotavirus study corresponds with the national income quintiles from the NHMS 2011, we obtained healthcare expenditure for rotavirus episodes treated at public hospitals by income quintiles from this study (7, 43).

An estimation of the health and economic burden of rotavirus diarrhea in Malaysia has recently been published (44). This paper uses multiple data sources including national administrative data, national health surveys, annual reports, published and unpublished studies to estimate rotavirus deaths, hospitalizations, outpatient visits, and home-treated episodes, and the economic burden of rotavirus diarrhea to the healthcare provider and society. Please see the appendix for a summary of this estimation. (Supplementary text 1 to 3).

### **Description of terms**

*Rotavirus incidence* refers to episodes of rotavirus diarrhea presenting to the healthcare system, requiring either inpatient or outpatient care, at public or private facilities. As rotavirus diarrhea occurs in all children irrespective of socio-economic status (20, 24), episodes of rotavirus diarrhea were distributed evenly across income quintiles. Malaysia has a tax-based, public healthcare system which permits access to healthcare for all people regardless of income. However, use of public and private healthcare varies according to household income. Health service use by income quintile obtained from the NHMS 2011, allowed for the distribution of rotavirus episodes to public or private care in each income quintile (43). (Table 2)

*Illness-related expenditure* incurred by households includes OOP direct medical costs on the receipt of care, like consultation and medication charges, and non-medical costs above normal consumption for transportation, diapers and food, during an illness episode. We obtained direct medical costs for public inpatient care from the 2010 hospital-based rotavirus study (7). The ratio of healthcare costs at private to public healthcare by income quintile from NHMS 2011 was multiplied to the public inpatient costs, to allow for the estimation of private inpatient costs. OOP direct medical costs for public and private outpatient visits were obtained directly from the NHMS 2011 (43). Direct non-medical costs for public inpatient care by income quintile were obtained from the 2010 hospital-based study (7). Direct non-medical costs for episodes requiring private inpatient care, and outpatient care at public and private settings, were recently estimated for Malaysia (44). These costs were distributed into income quintiles, using weighted averages of direct non-medical costs from the 2010 hospital-based study (Table 3).

*Catastrophic expenditure* is defined here as illness-related expenditure exceeding 10% of monthly

household income. Illness-related expenditure exceeding the threshold of 10% of total household income is considered to be at the expense of consumption of essential goods and services, adversely impacting household living standards and thus financially catastrophic (13, 45). Although there is some debate on the appropriate threshold for use as a marker of catastrophic expenditure, we use here a threshold of ten percent of monthly household income as previously employed by the World Bank (13). Analysis with catastrophic expenditure thresholds of 5, 10, 15 and 20% of household income have been included in the appendix (Supplementary text 4). While illness-related expenditure is usually defined as catastrophic when it exceeds a fraction of household income over a given period of a year, here expenditure incurred is compared with monthly income (13). As rotavirus gastroenteritis is an acute illness, lasting no longer than a week and unlikely to be repeated, costs and income were not annualized in this analysis. (46).

*Impoverishment:* Illness-related payments were considered impoverishing when households with monthly income above the poverty line fall below the 2009 Poverty Line Income for Malaysia (US\$ 271 in 2013 US\$), after payment of expenses for rotavirus episodes (47).

### **Analytical methods**

The distributions of OOP direct medical costs and household income were approximately log-normal. The mean and standard deviation of each income quintile were used to generate log-normal distributions of income. Mean of direct costs and standard deviation of OOP direct medical costs were used to generate log-normal distributions of direct costs by income quintile. Subsequently, the proportions of those incurring catastrophic expenditure or impoverishment in each income quintile were estimated. The estimation of standard deviation of OOP direct medical costs by income quintile is shown in the appendix (Supplementary text 2).

To evaluate the impact of vaccination in reducing catastrophic and impoverishing payments, vaccine efficacy specific to inpatient and outpatient treated episodes was multiplied with the proportions of catastrophic payments and impoverishment for each of these categories.

### **Sensitivity analysis**

To test the robustness of our findings, we first pursued univariate sensitivity analysis, in which individual parameters were varied while others were fixed at base case values. These parameters were OOP direct costs, health utilization of public and private healthcare, and vaccine efficacy. Secondly, we conducted scenario analysis.

Alternate scenarios were considered to explore the uncertainty around vaccine impact estimates.

These scenarios were vaccination with RotaTeq® (Merck & Co. Inc., West Point, PA, USA), and the additional benefits of herd protection. By means of scenario analysis the impact of vaccination on all illness-related costs relevant to households was evaluated, including all direct and indirect costs. Detailed methods and results for the univariate sensitivity analysis and scenario analysis are provided in the appendix. (Supplementary text 7 and 8).

## **Results**

### ***General***

Although rotavirus episodes are distributed evenly across income quintiles, utilization of public and private services vary by income. The rich use more private care than the poor, and the poor use more public care. However, despite the availability of subsidized public care, the poorest still use private care, especially for outpatient treatment (Tables 1 and 2).

We found that the richest spend more on rotavirus-related direct costs compared to all other income groups especially the poorest (US\$ 277 vs. US\$ 24). (Figure 1). The richest are likely to incur higher healthcare expenditure due to utilization of more expensive private care (Tables 2 and 3).

Prior to deducting healthcare expenditure, thirty-nine percent of the poorest quintile had monthly income below the national poverty line. Although the poor pay less than the rich in direct costs, the poorest pay almost as much as the richest as a proportion of monthly income (8% vs. 11%) (Figure 1).

Direct costs paid OOP for rotavirus results in catastrophic expenditure among all income groups, and impoverishment among the poorest two quintiles. Surprisingly, 43% of the richest quintile spent more than 10% of household income on illness-related expenditure, although none were impoverished. Despite the high-frequency of catastrophic payments among the richest, the poorest were more vulnerable to health shocks with sixteen percent experiencing catastrophic payments and 7% impoverished due to rotavirus-related expenditure (Table 4).

### ***Base-case***

We found that rotavirus vaccination resulted in substantial reduction in rotavirus episodes and expenditure across all income groups. Annually, rotavirus vaccination resulted in savings of almost US\$ 6 million to households seeking care for rotavirus episodes. These benefits were evenly distributed across income quintiles (Table 4). In terms of financial risk protection, vaccination averts catastrophic expenditure among all income groups. However, poverty reduction benefits were concentrated among the poorest

two quintiles.

### ***Sensitivity analysis***

We found that changes in direct costs have proportionate impact on households, in terms of catastrophic and impoverishing events. When healthcare usage patterns were assumed to be equal for all income groups, the household impact of healthcare payments in terms of catastrophic and impoverishing events was blunted amongst the richest income quintile. Even at a lower estimation of vaccine efficacy, Rotarix® is effective in reducing about 67-70% of rotavirus episodes, direct costs, catastrophic and impoverishing events in all income quintiles.

Our findings suggest that both commercially available vaccines have similar impact and distributional implications. Herd protection provides additional benefits particularly to those with the least access to healthcare services. Results of the univariate sensitivity analysis and scenario analysis are detailed in the appendix (Supplementary text 7 and 8).

### **Discussion**

We found that all households regardless of income, experienced some degree of catastrophic payments due to illness-related expenditure for rotavirus care. However, only households in the two poorest quintiles were impoverished as a result of healthcare payments. Universal rotavirus vaccination helps alleviate catastrophic expenses among all income quintiles, and prevents impoverishment among the poorest two quintiles.

Hence universal rotavirus vaccination, free at the point of use, can be considered a pro-poor policy that reduces health and social inequalities. However, these benefits are not exclusive to the poor. Our results show that people in all income quintiles benefit in terms of financial risk protection. Preventive measures such as rotavirus vaccination are able to avert both the cost to households of actual treatment, which are highly subsidized in the public sector in the Malaysian context, but also the cost of seeking care.

These findings suggest that universal, publicly-financed rotavirus vaccination, and potentially other childhood vaccines administered to all, may be best regarded as common goods to be made freely available to everyone, rather than a means-tested benefits program targeted at the poor only. A publicly-financed, universal vaccine policy can be seen to protect all income groups. Hence it is most likely to achieve political support for cross-subsidization from the rich to the poor. This has implications beyond Malaysia to other middle-income countries considering between alternative strategies towards UHC.

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Demonstrated here are the social values of fairness and distributional justice promoted by universal vaccination, by allowing access to health benefits and financial risk protection for all. Public financing of programs designed for promoting equity benefits, for example a basic package of essential care including childhood vaccines, may enhance social solidarity.

Healthcare in many middle-income countries is often delivered by mixed health systems. In this environment, publicly-financed government healthcare delivery coexists with privately-financed market delivery, in which OOP payments dominate as a means of financing (48). Reliance on OOP payments may have detrimental consequences on household welfare, exacerbating poverty and inequities in both health outcomes and healthcare payments.

In Malaysia, the availability of a parallel private health system exposes many to the financial risk of direct payments for healthcare (49). Household OOP expenditure in Malaysia is the largest source of financing in the private sector amounting to 79 percent of spending in this sector, or 37 percent of total health expenditure in 2012 (50). Our findings, that the rich opt-out of public care in Malaysia, has similarities with Thailand, where the better-off are at risk of catastrophic expenditure despite universal coverage (51). However, our findings show that the poor also rely on private healthcare, despite the heavy financial burden this often causes.

Health financing strategies towards achieving UHC, either general taxation or national insurance-based, provide protection against OOP healthcare payments for accessing public healthcare, but not against non-medical spending associated with illness nor against user fees for private healthcare. We propose universal vaccination as a social protection policy against medical and non-medical spending, associated with ill health.

There are several limitations to this study. Firstly, there is no universally accepted definition of what is considered an 'excessive' financial loss following illness, against which governments should protect their populations. Because of this, we used two alternative but widely accepted measures. The first defines healthcare expenditure as catastrophic if it exceeds a defined threshold of household income over a specified duration of time. This acknowledges that households of any income can be badly hit by healthcare expenditure even if they are not forced into poverty. The second defines healthcare expenditure as impoverishing when the post-expenditure household income falls below a fixed threshold, either international or national. In both cases, the use of threshold-based metrics for measuring financial risk protection, has inherent methodological issues.

These metrics may underestimate financial hardship, as the poor may be deterred from using healthcare as a result of high user fees. Also threshold-based metrics fail to consider coping mechanisms

like savings, borrowing or selling of assets (12, 19, 52). Despite these acknowledged limitations, threshold-based metrics are well established and widely used by policymakers, thus chosen for this study.

Measures of financial risk protection are usually conducted for research on health systems financing. In health systems research, definitions of catastrophic expenditure usually compare all healthcare expenses against all household resources, over a period of a year. This current study examines the effect of illness-related expenditure for rotavirus on monthly income, and the benefits of universal vaccination in alleviating this burden. This differs from health systems research in two ways.

Firstly, the numerator used in this study are expenses specific for rotavirus gastroenteritis and not all healthcare expenses, generally used in health systems research. Secondly, we consider illness-related expenditure to be catastrophic when it exceeds the defined threshold of household income over a duration of a month. As rotavirus gastroenteritis is an acute illness (46), we compare illness-related expenses with monthly income. Expenses over a short term have a different impact on household welfare compared to expenses over a longer period, as some households are better able to use current income, savings and established family or social networks to cope. Nevertheless, an unexpected, large expense may adversely impact poor households with less resources to cope with (18).

We chose not to consider the impact of wage loss on household income in the base case. While indirect costs are important when considering the impact of illness on the national economy, when a household perspective is taken, these costs are more important in low-income countries with a large informal sector, where household income is dependent on daily wage (18). In most high- and middle-income countries, much of the labor force is part of the formal market, and as such absenteeism for a short illness may not impact household income. In the Malaysian context, lost wages may only impact the poorest, as they are more likely to be employed in the informal or casual workforce. Hence as seen in the scenario analysis, the distributional impact of vaccination may be even more pro-poor.

The economic costs of diarrheal deaths were not considered here as Malaysia has low rotavirus mortality, with 15 rotavirus deaths among children younger than five years estimated for 2008 (22). While, rotavirus vaccination would substantially reduce rotavirus mortality in Malaysia, estimation of the productivity gain of mortality averted is likely to be more important in low-income countries, with higher rotavirus mortality. Also, we do not consider expenditure for informal care as this is not relevant to the setting. In Malaysia, less than three percent of children under-five years with acute diarrhea seek care at non-medical facilities, like traditional healers or Chinese medicine shops (53).

Vaccines have long been regarded as cost-effective interventions towards improving population health (54). However, newer vaccines such as rotavirus are more expensive than traditional vaccines,

particularly in middle-income countries ineligible for lower prices offered by Gavi, the Vaccine Alliance (32). Some economists have suggested that the economic case for vaccination has been understated because traditional evaluations of vaccines focus on health gains and savings to the health system, underestimating the broader benefits of vaccination to households and the wider economy (55-57).

From a household perspective, poverty reduction and financial risk protection could be viewed as important aims of healthcare systems that would strengthen the case for vaccine introduction. Middle-income countries like Indonesia, Sri Lanka, Viet Nam and others (58) that have yet to introduce rotavirus vaccines could potentially benefit from the broader social and economic impact of rotavirus vaccination. The tools employed here are easily adaptable to other settings with different immunization programs and health systems, to measure the essential role of vaccines towards UHC.

### **Conclusions**

A key objective of UHC is to reduce social disparities in healthcare spending. We propose that well-designed universal vaccination programs complement health systems financing reforms in attaining and strengthening UHC. ECEA provides an important tool to understand the implications of vaccination for UHC beyond traditional considerations of economic efficiency. Our findings may hold lessons for other settings, particularly emerging economies with mixed public-private healthcare systems.

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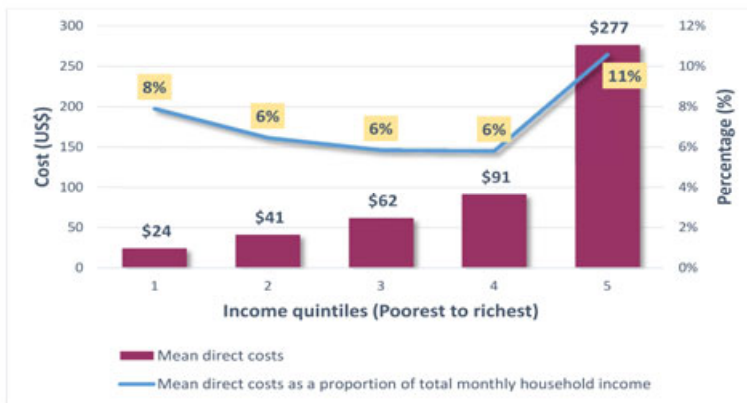
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**Figure 1. Household expenditure for rotavirus diarrhea by income quintile in Malaysia**

Note: All costs are presented in 2013 US\$. Direct costs are direct medical and non-medical costs per-episode of rotavirus diarrhea by income quintile. The purple bars denote average out-of-pocket direct costs to households resulting from rotavirus diarrhea episodes seeking care. The blue line denotes average direct costs as a proportion of household income for each quintile. Purple bars relate to the left-hand y-axis. The blue line relates to the right-hand y-axis.