

# McGill Journal of Global Health

Volume IX, Issue I

Spring 2020



COVID-19



Respectons les  
consignes sanitaires



Soyons responsables  
et solidaires





McGill University is situated on the traditional territory of the Kanien'kehà:ka, a place which has long served as a site of meeting and exchange amongst nations. We recognize and respect the Kanien'kehà:ka as the traditional custodians of the lands and waters on which this Journal was produced.

McGill Journal of Global Health | Spring 2020 | Volume IX | Issue I

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Spring 2020

Dear Readers,

Thank you for taking the time to read the McGill Journal of Global Health. We have dedicated this past year to reshaping the future of the Journal, in efforts to better reflect the changing ways students and researchers engage with public health discourse. The past few months have been an ongoing moment of uncertainty, during which the volume and speed of information consumption has accelerated. Our current reality continues to highlight the fissures in our system, the ways in which our current resource distribution system has undermined health, and most of all — that public health is global health. The pandemic has forced us to push the boundaries of what is imaginable for our collective futures, converging on the intersections of the social, biomedical, global and local aspects of health.

This year, we changed our name to reflect our mandate better — moving away from The Prognosis (which carries a heavy biomedical ethos), to describe what we do in simplest terms: Global Health. Bringing together case studies offers an opportunity for readers to take a closer look at health in other contexts, the unique impacts of policy and programming in each context, and to see the calibre of work and analysis McGill students do. The case studies we selected are broad in range: from interrogating the racialized experience of healthcare across the globe to taking a closer look at how Universal Health Care can feasibly be implemented. In putting together this current issue, we sought to bring together case studies which highlight policy, history, the intersectionality of health, and technical and policy solutions to health disparities. We hope that in this moment, these case studies can offer alternate perspectives on health outside of the pandemic context, and motivate discussions on how we can best collaborate moving forward.

The 2019-2020 Editorial Team is proud to present to you this issue. Working on this issue, we've been impressed with the thoughtful work students are doing to shape the future of global health academic practice. We thank you for supporting our future global health leaders, and we hope you enjoy reading.

Sincerely,

The MJGH Editorial Board



# Editorial Board

Lamiah Adamjee

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Lamiah is a first year Master of Science in Public Health candidate with a Bachelor in Kinesiology from the University of British Columbia. She is passionate about bridging the social science and quantitative sectors of public health to create a lasting impact. Her research interests include neglected global diseases, child and maternal health, early childhood development, infectious disease control, and the effects of climate change on health. She is inspired by the interdisciplinary nature of global health work and is excited to be involved in showcasing students work through the journal. When she's not searching for flight deals, she enjoys cooking, reading, and being outdoors.

Nabeela Jivraj

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Nabeela is a second year Master of Science in Public Health candidate and is a graduate of Queen's University, where she studied Life Sciences and Global Development. She is interested in increasing access to information, to services, and to diverse perspectives. She appreciates the interdisciplinary nature of Public Health, and how the journal highlights this work being done by McGill students. She has previously worked on community development projects and research to increase access to sexual health services in both Canada and Kenya, and currently works with philanthropy at McGill. In her writing, she seeks to amplify interesting and under-represented community stories. In her free time, she loves to read, write, and explore Montreal.

Leslie Brown

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Leslie is in her second year of her BSc. in Physiology with a minor in health Geography at McGill University. Her primary research interests are in cardiovascular disease and population health, and she is also passionate about writing and science journalism. In her spare time, she loves collecting fridge magnets!

## Allison MacNeil

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Allison MacNeil is in the second year of her PhD in Clinical Psychology at McGill University and is a graduate of the University of Ottawa where she received her Honour's Bachelor of Health Sciences and Bachelor of Social Sciences (gold medalist). She has worked at the Children's Hospital of Eastern Ontario, the Canadian Institutes of Health Research, and the Douglas Mental Health University Institute on a number of community-based mental health projects with a focus on marginalized youth. Her current research, funded by the Social Sciences and Humanities Research Council as well as the Fonds de Recherche du Québec, focusses on the association between food security and mental health among youth at the local, national and international levels. As a mental health clinician, Allison strives to integrate the lessons from global health into her everyday work with patients. She looks forward to a career as a socially engaged clinician-scientist, deeply committed to local and global health equity.

## Amanda Marcinowska

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Amanda is in the second year of her Master of Science in Family Medicine at McGill University. Her current study aims to identify primary health care research priorities for an underserved area of Sao Paulo, Brazil. She will be investigating research priorities within several primary health care domains including health services management, child and maternal health, infectious diseases, non-communicable diseases, mental health, patient safety, and care coordination. Amanda's research interests are in improving the quality of primary health care. She presented her research at multiple international global health conferences. She continuously enriches her knowledge through global health courses and literature.

Prior to graduate studies, she received an Honours Bachelor of Science in Biology for Health Sciences and Psychology at the University of Toronto, where she conducted a research project at the Social-Emotional Development and Intervention laboratory that aimed to understand the biological underpinnings of different forms of aggression in children and their connections to future psychopathologies. In her spare time, Amanda enjoys writing and designing.



## Ayoub Rebaine

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Ayoub is a third-year student at McGill University in Cognitive Science, with a minor in Interdisciplinary Life Sciences. He is currently pursuing research on Parkinson's Disease with the Faculty of Medicine's School of Communication Sciences and Disorders, focusing on speech markers predictive of the disease as well as their neural correlates using fMRI. Ayoub is passionate about community involvement, and is currently the coordinator of a mentorship program for elementary school students in Kahnawake Mohawk Territory. He is excited to be a part of the McGill Journal of Global Health team and hopes to inform the student community of the global health initiatives on campus that they can be involved in. As Ayoub finishes up his undergraduate degree, he hopes to explore questions surrounding neurodegenerative diseases and the ways that public health initiatives, namely in terms of proper education, can help curb the increasing burden that these conditions have on society and on the health care system.

## Gajanan Velupillai

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Gajanan did not experience your traditional university trajectory: after spending two years in Dentistry at McGill through the accelerated Dent-P pathway from CEGEP, he found himself increasingly interested in upstream factors and issues shaping the lives of people more than the actual care episode itself. So, he dropped out and is currently completing an undergraduate degree so that he can pursue his interests in Public Health and Policy, Global Health and Law. His research interests are centered on quality of care, healthcare access and economics, cultural safety and the interaction between medicine and marginalized groups.

## Sarah Zhao

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Sarah is a third year B.Sc. Neuroscience student at McGill University. She is interested in studying and understanding the underlying mechanisms of and potential treatments for autism and depression. Apart from the neuroscience aspect of these neurodevelopmental and neuropsychiatric conditions, she is also curious and passionate about global mental health solutions. Sarah also serves as the Director of Development and External Affairs for School of Music Montreal, an organization that brings free music education to children in underserved communities in the Montreal area. In her spare time, Sarah loves to bake, read in local cafés, and play the violin and piano.

McGill Journal of Global Health

Spring 2020

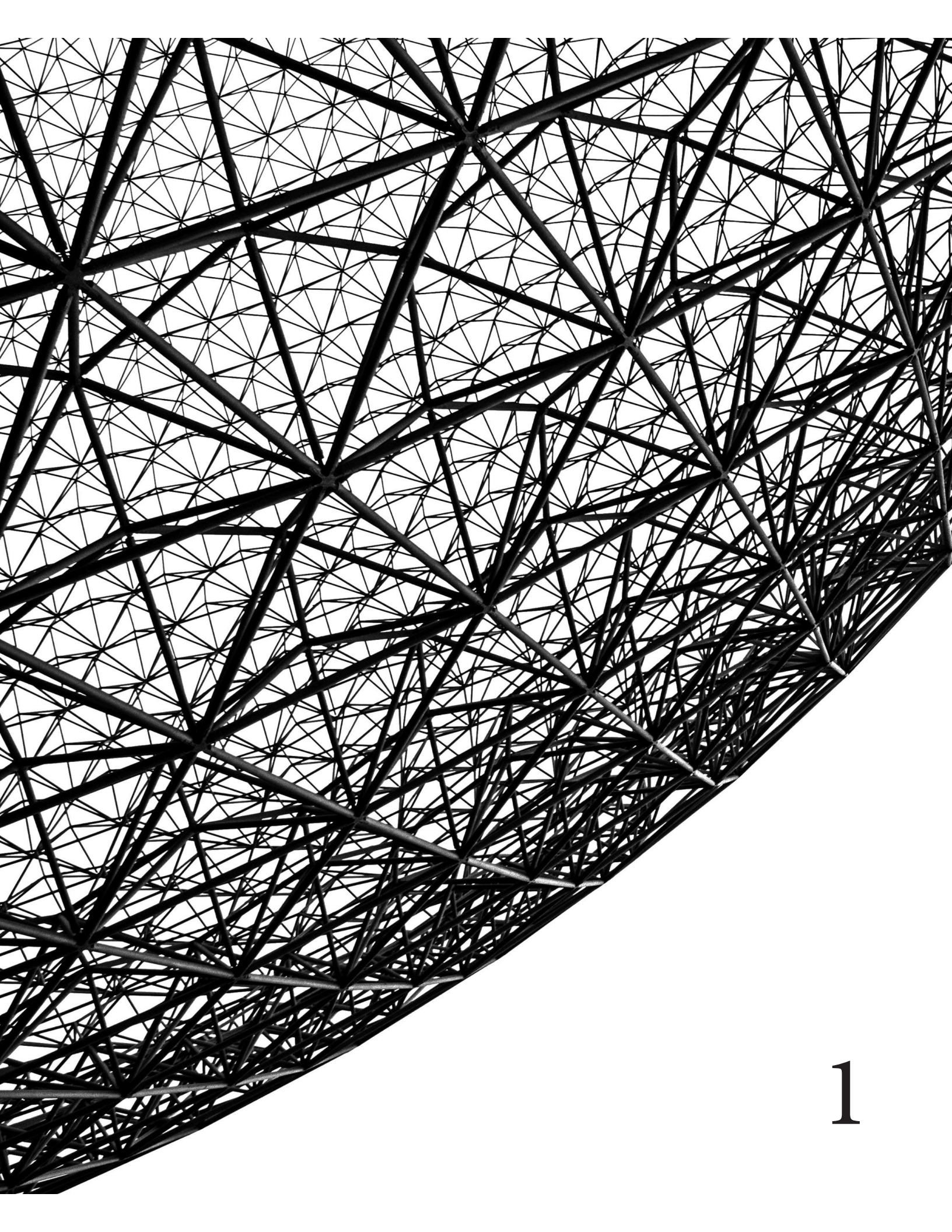


# TABLE OF CONTENTS

	Research Article	page
1	The Failure of User Fees: The Outcome of the Bamako Initiative in Mali	12
2	A Health Care System Divided: How Apartheid's Lingering Effects Harm South African Maternal Health	28
3	Walmart's Singular Solution Falls Short in the Insulin Crisis	46
4	Black Mothers in America: Why Racial Discrimination in the American Healthcare System is Disproportionately Killing Black Women	60
5	The Global Gag Rule: The Impact of U.S. Funding Restrictions on Foreign NGOs' Delivery of Comprehensive Reproductive Services	78
6	Reducing Open Defecation Through Community-Led Total Sanitation in Fort Dauphin, Madagascar: A Case Study	96
7	Did Dengvaxia-associated deaths result in an increase in vaccine hesitancy in the Philippines?	114







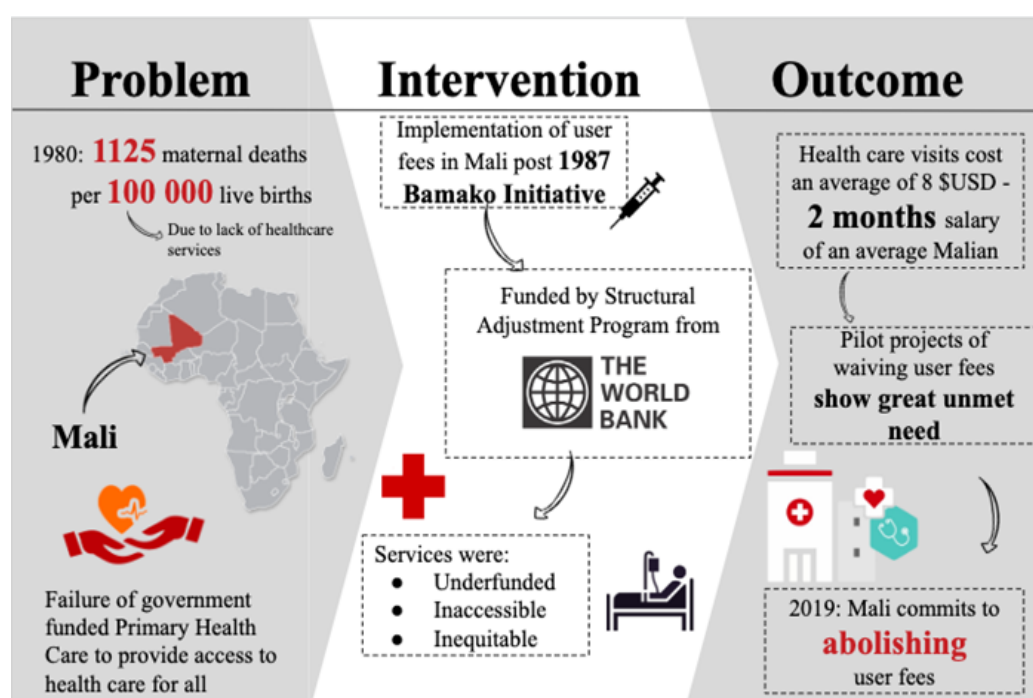


# The Failure of User Fees: The Outcome of the Bamako Initiative in Mali

Bea Lehmann, Sophia Sheng-Ya Huang, Christina Chavenet, Homa Danaie, Laura Douglas, Kevin Jutras, Sydney Phillips

## ABSTRACT

The end of health care user fees is within sight for an increasing number of African countries whom this policy was imposed upon in the late 1980 and early 1990s. User fees were part of structural adjustment programs (SAPs) dictated to developing countries by the World Bank, influenced by the Bamako Initiative. The West African country of Mali is presently working towards eliminating user fees and implementing Universal Health Care (UHC). This paper investigates health indicators of pregnant women in Mali during user fee implementation to show the negative impact of the policy, and extrapolates to future outcomes when UHC is available. For example, when user fees were removed in pilot projects, Caesarean costs decreased from 95-136 \$USD to 0.80-10 \$USD, and Caesarean rates increased by a factor of 2.5. As well, with user fees, Malian citizens had to pay an average of 2 months of salary per health care visit, severely limiting those who could access services. These numbers show that vulnerable individuals in Mali, such as expecting mothers, likely experience unmet need for healthcare services in Mali, and the current user fees system is insufficient and inequitable.





## Introduction

This paper seeks to evaluate whether the period of user fees in Mali was able to provide adequate health care—in terms of the goals of costs, accessibility, and quality for maternal health. Since Mali's journey to phasing out user fees is fairly recent, we reviewed pilot projects of user fee exemption to predict outcomes of user fees abolition, and compared these numbers to the timeframe when user fees were in place. Table 1 provides a summary of the comparisons.

It is important to note that the private health care sector accounts for 40-50% of health care services in Mali (1). The most inequities appear to be within the private health sector, with most private institutions located in cities; mainly in Bamako (1). Our evaluation focused on the public sector, since a comprehensive understanding of

Mali's public health system is required before moving towards the international goal of universal health care (UHC). However, this limits this paper's ability to conclusively evaluate the entire health care system of Mali.

## Background History

In 1978, the International Conference on Primary Health Care, hosted in Alma Ata, aimed to make Primary Health Care (PHC) the foundation of low- and middle-income countries' (LMIC) public health care systems in order to improve health services in impoverished communities. However, severe underfunding lead to low quality services and a lack of supplies, including drug shortages (2). Meanwhile, budget allocations to health care resources had decreased due to debt repayment issues,

Table 1: Summary of impact evaluation (with and without user fees) in Mali. The cost, availability, and quality of various indicators were compared during the period of user fees and as Mali has begun moving towards UHC.

	Indicator Assessed	During Period of User Fees		Towards UHC
Costs	Cost compared to per capita income	8 \$USD (2 months of wage) per illness episode in 2005		Unknown
	Caesarean Cost (not including additional treatment costs)	FCFA 47,400 - FCFA 68,000 (Approximately US \$95-136) Prior to January 2005		FCFA 400 and FCFA 4,800 (Approximately US \$0.8-10) After January 2005
Accessibility	Consultation Rates for malaria treatment (MSF Malaria project)	0.1% consultation for pregnant women 2005-2006		1.0% curative consultation for pregnant women 2007
	Caesarean Rates	0.5% Caesarean rates (USAID report for Mali MOH) 2005		2.3% Caesarean rates (USAID report for Mali MOH) 2009
Quality	Skilled Birth Attendant	40.6% Total	70% Total	67.3% Total
		1.5% deliveries by physicians 39.1% midwives/nurses 2001 (EDSM-III)	1.4% physicians 36% midwives/nurses 33% matrons 2006 (EDSM-IV)	6% physicians 40% midwives/nurses 22% matrons 2018 (EDSM-VI)

(Table legend: FCFA=Franc CFA. MOH=Ministry of health. EDSM=Enquête Démographique et de Santé or in English, DHS=Demographic and Health Surveys)

declines in commodity prices, natural and man-made disasters, political unrest, and military spending (2).

By the mid-1980s, many governments in African LMIC had determined that the implementation of government funded PHC was unrealistic. Meanwhile, countries faced overwhelming pressure to achieve financial sustainability in their health sectors. World Bank health economists began to embrace neoliberal economic principles, transforming the predominant understanding of health policy internationally (3). In 1987, African health ministers met in Bamako, Mali, during the 37th WHO regional meeting to examine issues facing the financing of PHC (4). From this meeting, the Bamako Initiative was developed. It was comprised of four main components:

1. The reconstruction of the health care delivery system;
2. Increase in the availability and affordability of essential drugs;
3. Creation of long-term sustainability through financing of basic health care services;
4. Increase in community mobilization for financial support and management of community-based health services (4).

In theory, the Bamako Initiative had several good principles, including decentralization of health systems as opposed to taking a vertical and project dependent approach (5). It also attempted to address the lack of

drugs available at health centres by proposing the creation of a revolving drug fund, which would sell essential drugs at a slight markup from wholesale prices in order to prevent shortages (6, 7). However, the third component, which implicated user fees, was to lead to policy failure.

Since the 1980s, multilaterals such as the International Monetary Fund (IMF) and the World Bank had been supplying loans for LMICs with “stringent conditions,” such as withdrawals of food subsidies, trade liberalization, and reduction in government expenditure in social sectors (8, 9). These conditional loans were called Structural Adjustment Programs (SAPs), and were meant to kickstart indebted LMICs’ economies through the implementation of austerity measures and reliance on the market to provide previously government-funded services. However, many of the countries receiving these types of loans already had low levels of human capital investment in sectors such as education and health (9). The Bamako Initiative, with its promise of relieving governments of financing the health sector, was supported by the IMF and World Bank. These policies forced the implementation of cost recovery strategies, such as creating and increasing user fees (9).

User fees were predicted to improve the health care system on various levels by increasing: cost-effectiveness, availability

in terms of allocative efficiency and equity, and quality of services (10). The argument for cost-effectiveness was made on the basis of several earlier cost-recovery experiments which showed there was relative price inelasticity for health care, suggesting increases in the cost of services would not significantly decrease the use of these services, and people were “ready to pay” for services (5, 10). However, these failed to take into account the ability to pay of the entire population, including those most vulnerable. In terms of allocative efficiency, preventing the overutilization of free services would ensure that those with highest need would have access to basic health services (10). In terms of equity, by having communities in charge of the funds, services would be more aligned with the needs of the community served. Measures such as fee exemptions were to be put into place to ensure the poorest people would also be able to access health services. However, it was to be the responsibility of individual communities, not the government, to ensure mechanisms to protect the most vulnerable were actually put in place (4). Lastly, with the increased revenue from fees, and monetary incentives for caregivers, quality in the health care provided was predicted to improve.

#### Review of user fees in other countries

Charging user fees for health services in African countries was not limited to Mali in the 1980s and 1990s. Several countries,

such as Kenya and Tanzania, provided government-funded free health care, although later decided to move to a user-fee system. By the late 1990s, one study found that 28 out of 37 surveyed African nations had begun to move away from ideas of UHC instead opting to implement some form of user fees at government health facilities (11).

In general, user fees negatively impacted the health systems they were implemented in. The World Bank report on cost recovery in Sub-Saharan Africa showed countries with user fees experienced drops in utilization when fees were introduced or increased, as well as changes in the quality of care, with variable and infrequent protective measures to ensure the poorest could access health care (9). Finally, very low amounts of revenue were shown to be generated from user fees (9).

#### Problem Statement

Even prior to the implementation of user fees in the mid-1980s, health care in Mali was lacking on many fronts, with services being overcrowded, underfunded and scarce in resources. These issues particularly affected already vulnerable groups of the population, such as expecting mothers(12). For example, in 1980 the maternal mortality ratio in Mali was one of the highest worldwide: Mali recorded 1,125 maternal deaths per 100,000 live births, compared to 7 in Canada (13). The Bamako



Initiative proposed the implementation of user fees with the hope of increasing revenue and improving the quality and quantity of offered health services (14). In 1989, Mali implemented a new policy including user fees based on the Bamako Initiative while under pressure from the World Bank (5), which led to negative impacts on the most vulnerable in the population and decreased both the sustainability and equity of the healthcare system (32, 33, 34).

### Implementation

The widespread implementation of user fees in Africa occurred following the 1987 Bamako Initiative (4). Mali finalized and submitted the project to the national government at the end of 1989. The new policy was formulated under the name “Health, Population, and Rural Water Project” (HPRWP), which was to be sustained through the implementation of user fees (5). A loan between the government of Mali and the World Bank was agreed upon on May 3, 1991 (5).

Mali adapted guidelines from UNICEF and WHO to fit the demands of the World Bank’s loan, and streamlined and decentralized their health system (4). Before, the system had been made up of non-uniform entities such as maternity units, village health teams, and subdistrict level dispensaries. The heterogeneity and project-dependent nature of the antecedent system meant less reporting transparency

policy included the creation and expansion of Community Health Centres and District Health Centres which provided basic health services and referrals to secondary and tertiary care. Regional and national levels were responsible for defining policy, planning, and coordinating funding (5).

### Financing

Mali received its largest funding for the implementation of the HPRWP from the World Bank, with a loan of \$29,760,000 USD, with several other multilaterals committing funding as well (5). However, the actual release of the funds did not occur until months or even years later, as each organization followed its own internal disbursement guidelines. (5) (Table 2). This made implementation of the program challenging, and stalled progress.

Before the implementation of the HPRWP, cost recovery already existed in the health system and accounted for about 50% of recurrent expenditures. However, only 2% came from user fees, with the remaining 48% from overpriced drugs from the People’s Pharmacy of Mali (5). The new system increased or created user fees for all health services. Patients were additionally responsible for covering the cost of prescribed drugs, which were purchased at slightly elevated prices as compared to wholesale (7). The revenues from drugs sold went towards ensuring a constant drug supply, called a revolving drug fund (7).

Table 2: Chronology of financing by the partners of the HPRWP. Adapted from Maiga et al., 2003: “Health Sector Reform in Mali, 1989-1996”. The schedule of commitments (C), financial agreements (A) and release of funds (shaded) for Mali’s HPRWP by World Bank, UNICEF (United Nations Children’s Fund), USAID (United States Agency for International Development), KFW (German Development Bank), EDF (European Development Fund) and Fonds d’Aide et de Coopération (5).

	1990			1991			1992			1993			1994		
Mali Government	C			A											
World Bank - US\$ 29,760,000		C					A								
UNICEF - US\$ 15,398,000		C								A					
USAID - US\$ 15,000,000		C			A										
KFW - US\$ 8,970,000		C							A						
EDF - US\$ 13,081,600			C									A			
Fonds d’Aide et de Coopération - US\$ 1,700,300															

## Impact Evaluation

### 1. Costs

1.1 Cost compared to Income. When user fees were rolled out in 1991, Mali’s gross domestic product per capita (GDP per capita) was 315.46\$ in current USD (16). By 2003, the GDP per capita had only increased to 488.83 \$USD (to compare, in the same time frame the USA experienced per capita growth from 24,342.26 \$USD to 39,496.49 \$USD) (16). The increase in GDP per capita was low, and insufficient to cover basic health care costs. Additionally, Mali had and continues to have extreme wealth inequality, scoring a Gini coefficient of 39 in 2006 (17). In order to assess the average cost of user fees compared with income, Médecins sans Frontières (MSF) carried out a survey of 930 households in 2005 in rural Mali.

In the area assessed, average income per person per day was 0.12 \$USD, and an average illness episode would cost 8.00 \$USD – the equivalent of 2 months of labour (18).

1.2 Caesarean Cost. To assess the changes in cost as Mali moves to UHC, the Free Caesarean Policy was used as an indicator. In 2005, Mali implemented user fee exemption policies for caesareans, as a strategy to combat high maternal mortality ratio (19). The policy exempted “direct costs of the caesarean procedure, including preoperative examinations, provision of a caesarean kit (drugs and surgical supplies), surgery, post-operative treatment, hospitalization and laboratory tests.” (20). Prior to the Free Caesarean Policy, the direct cost for a caesarean was between FCFA 47,400 and

FCFA 68,000 (Approximately 95-136 \$USD) (21). The patient or community also had to contribute to excess fees as well as transportation costs for referrals (22), creating an additional burden for rural women (19).

After the policy change, the price for a caesarean was reduced to between FCFA 400 and FCFA 4,800 (Approximately 0.80-10 \$USD) (21). However, since government contribution only consisted of materials required for the caesarean procedure itself and “any immediate post-intervention complications” (19, 22), this meant that the mothers had to pay around 59,241 FCFA (126 \$USD) of excess fees for treatments including transfusion, antibiotics, and antihypertensive medications post-caesarean (19). The additional costs due to transportation were also still incurred, since they were not reimbursed by the policy. While the overall price for a Caesarean was significantly decreased after the direct cost of the operation was removed, the remaining excess fees may have contributed to the drop shown in Figure 1.

## 2. Accessibility

**2. 1. Health-seeking behavior.** To assess how user fees would impact service utilization, the MSF malaria project is used as our indicator. In 2005, MSF offered rapid diagnostic tests (RDT) and artemisinin-based combination therapy (ACT) for 0.17 \$USD for everyone in Kangaba Circle, Mali (18).

This intervention, referred to as the MSF malaria project, was a subsidization for treatment—but crucially was not a complete removal of user fees. The subsidized treatments resulted in only around 0.1-0.2% of the population accessing consultations (18).

In December of 2006, the MSF malaria project expanded to “[provide] free care for children under five with any disease and for pregnant women with any case of fever” (18). This meant a complete removal of user fees and free treatment for the people fitting this criterion. This resulted in five times more malarial treatment for pregnant women and more curative consultations (18). By 2007, the consultation rates had increased to almost 1.0% (18).

## 2. 2 Frequency of service utilization

To assess the frequency of service utilization and availability of services, the Free Caesarean Policy is used again as an indicator. During the years 1995 to 2001, around 1.1% of deliveries were by caesarean section (23). In 2005, the start of the Free Caesarean Policy, 1.6% deliveries required caesareans (24).

By 2009, four years after the policy change, caesarean rates had rose to 2.3%—around 2.5 times higher than the rates in 2005 (22). Maternal deaths post-caesarean also decreased from 2.1% in 2006 to 1.3% in 2009 (Figure 1) (22) (25).

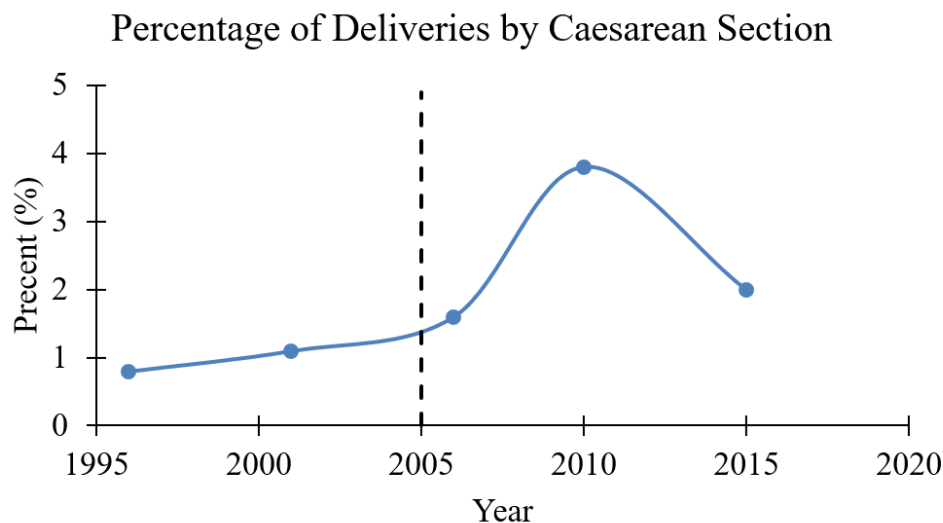


Figure 1. Percentage of deliveries by Caesarean Section Mali from 1996 to 2015. This value is calculated from the number of women age 15-49 years whose most recent live birth in the last 2 or 5 years was delivered by Caesarean section divided by the total number of women age 15-49 years with a live birth in the last 2 or 5 years. Dash line indicates the implementation year of the Free Caesarean policy. Estimates generated using the UNICEF Maternal and Newborn Health Coverage Database (25).

### 3. Quality of care

Quality of care in the Malian health care system has been low, historically as well as contemporarily. No user fees have been explicitly waived that would directly affect quality, however it was a goal of the Free Caesarean Policy to increase levels of skilled birth attendants, one measure of quality of care, along with maternal mortality rates (MMR). Tracing the history of MMR as well as skilled birth attendants shows that improvements in these indicators have occurred, but at a slow rate and seemingly without relation to user fees or the Free Caesarean Policy.

In 1982, there was one midwife available for every 3,000 inhabitants in Bamako (26). However, the ratio in rural regions was closer to one midwife

for every 80,000 people (26). From 1988 to 1992, around 18% of women in Mali had deliveries attended by trained professionals (26). The institutional maternal mortality ratio (iMMR) for 24 out of 25 maternal health facilities in Mali was 201 maternal deaths per 100,000 live births (26), while MMR was around 1000 per 100,000 live births (5). Hemorrhage was the highest cause of mortality; yet only two national hospitals had functioning blood banks (26). Out of the 25 hospitals, only seven institutions had surgical facilities (26). Oxytocic drugs, used to induce labour and stop bleeding due to birth, were unaffordable for many patients (26). Many vaginal examinations were done without gloves, because of “habit” (26).

During the period of user fees, the 1996 l'Enquête Démographique et de Santé (EDSM-II) reported an improvement in



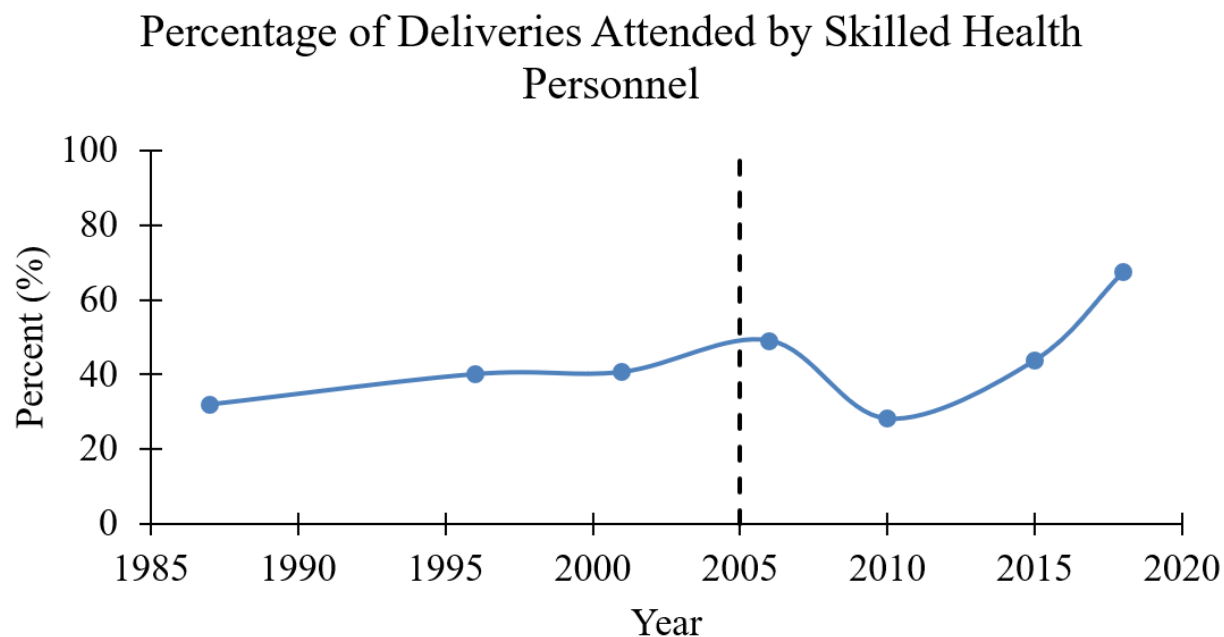


Figure 2. Percentage of deliveries attended by skilled health personnel in Mali from 1987 to 2018. This value is calculated from the number of women age 15-49 years with a live birth in the last 2 or 5 years who were attended by skilled health personnel during their most recent live birth (typically a doctor, nurse, or midwife) divided by the total number of women age 15-49 years with a live birth in the last 2 or 5 years. Dash line indicates the implementation year of the Free Caesarean policy. Estimates generated using the UNICEF Maternal and Newborn Health Coverage Database (25).

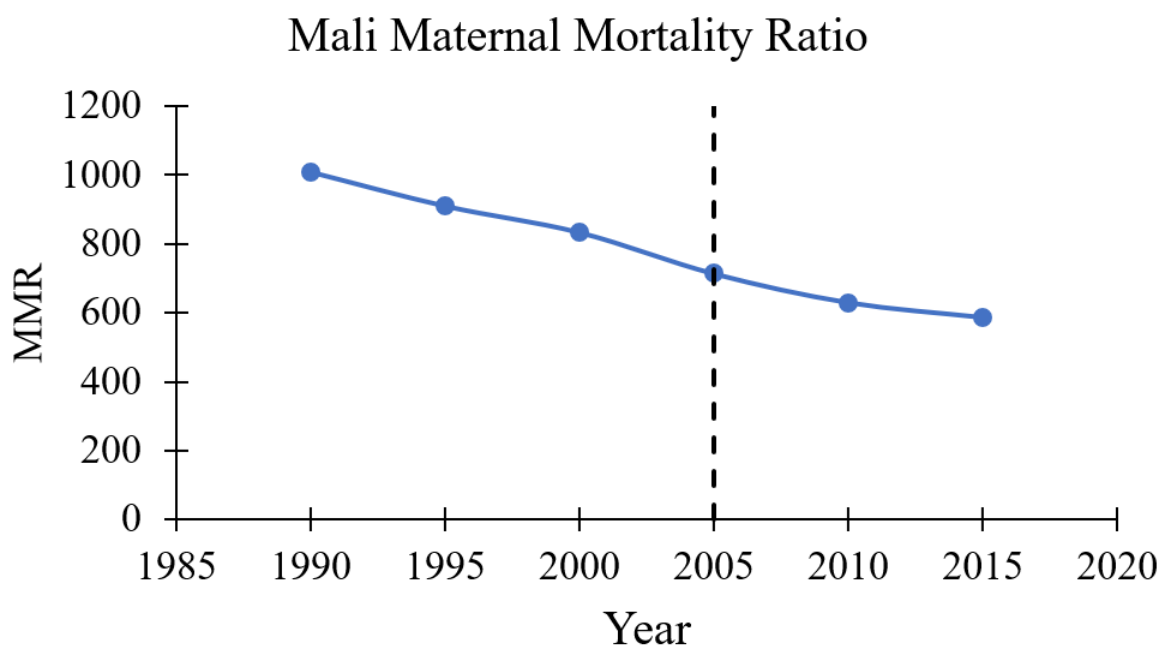


Figure 3. Mali's Maternal Mortality Ratio from 1990 to 2015. Dash line indicates the implementation year of the Free Caesarean policy. Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division (29).

Mali's MMR, at approximately 577 per 100,000 live births during 1989-1996 (27). Skilled birth attendant (SBA)-assisted deliveries were as follows: 0.7% by doctors, 23% by nurses or midwives, 16.3% by matrons—making a total of 40% (27). The 2001 DHS report showed that 1.5% deliveries were by physicians and 39.1% were by midwives, making a total of 40.6% (23). In 2006, 1.4% deliveries were by physicians, 36% were by nurses or midwives, 33% by matrons, totaling 70.4% (24). Due to low levels of skilled health personnel, there were high levels of birth related complications and MMR. High MMR and delivery associated complications indirectly suggests poor quality of care despite the implementation of user fees.

Thus far, user fees in regard to skilled birth attendants have not been waived in any projects in Mali. However, the Free Caesarean policy also aimed to improve access to skilled birth attendance, in order to better deal with obstetric complications (22). In 2018, the DHS report showed the SBA-assisted deliveries had lowered slightly to 67.3% (28). Yet according to UNICEF, there is a 35.4% increase in the percentage of deliveries attended by skilled health personnel over 31 years (Figure 2). While this is certainly an improvement, Mali lags behind the global average of 81.1% of births with skilled attendants. Despite Mali's reduction in MMR (Figure 3), UNICEF also categorized Mali to have “insufficient progress” towards UN's Millennium De-

velopment Goal 5A (MDG5A), which is to reduce MMR by three quarters from 1990 to 2015 (29). As no explicit policies have been passed on fee exemption, and due to the increase in SBA as well as decrease in MMR seen during the period of user fees, no conclusion can be drawn on the impact of user fees or their removal on quality.

## Discussion

### Did User Fees Work?

In our evaluation of Mali's health care system for expecting mothers, we found mixed evidence as to the actual impact of user fees. Firstly, while the removal of direct costs of caesareans led to an initial rise of caesareans being performed, these numbers later dropped again. This may be due to the fact that direct costs do not take into account excess fees such as transportation and medications for complications due to the surgery. Secondly, MMR and rates of SBA both improved during the period of user fees, as well as during the period in which Mali began to phase them out. These improvements may have little to do with user fee policy, but may be related to other aspects of Mali's development progress. However, in other cases, user fees must be considered to be a significant barrier to health care access. In the case of MSF malaria project, as soon as user fees were abolished, there was a marked increase in those seeking care. It should be noted that this increase did not occur until fees were completely removed. Additionally, the cost of illness with respect to actual wages

underscores the unsustainability of the user fee policy.

### Future Implications

While Mali has started to move towards UHC, there is still far to go. In 2010, the WHO's World Health Report formally decried user fees and urged countries to move towards UHC (30). In late February of 2019, Mali announced it would be increasing the national healthcare budget and reforming its health care system, beginning with providing free health care to pregnant women and children under 5 (31), which “effectively end(s) a 30-year practice known as the Bamako Initiative” (32). The new program is scheduled to be rolled out by 2022 but requires 120 million

\$USD of additional funding (31). However, this is only one step in providing health care that is truly universal and further policy change will be required to extend cover to the entire population.

Currently, Mali ranks low for UHC, although there are tentative signs of improvement. The WHO tracks countries' progress towards the Sustainable Development Goal 3.8—“Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all” (33). The indicators used are health service coverage and relative health expenditures. These

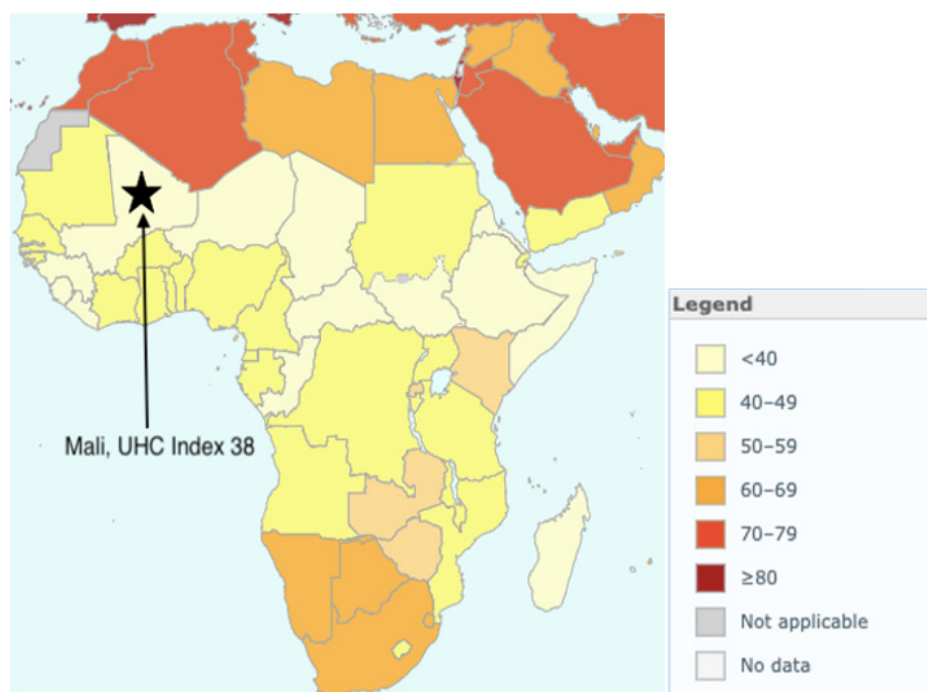


Figure 4. Mali's progress towards UHC. Mali has one of the lowest scores on the WHO index of UHC, even in comparison with its geographic neighbours. Data retrieved from WHO Universal Health Coverage Service Index (35).

two indicators create a composite, unitless index from 0 to 100, with 80 being the threshold of achieving UHC (34). Between 2015 and 2017, Mali increased 3 points on the UHC index, from an overall score of 35 to 38 (Figure 4) (34, 35). Much of this can be attributed to immense gains in reproductive, maternal, newborn and child health, with an increase from 37 to 50 on that index (35). Indices for infectious diseases, noncommunicable diseases, and service capacity and access remained stable and relatively low (35). The Government of Mali's strategy for UHC is building a community-based insurance scheme, yet this scheme only covered around 5% of the population in 2015 (36).

### Recommendations for Implementing UHC in Mali

As Mali moves away from user fees, it will likely experience a surge in demand for services previously inaccessible to users. There are several steps Mali can implement in the transition away from user fees. Firstly, an analysis on how user fees currently affect health care utilization—in terms of revenue generated—and the actual impact of fees on service utilization must be conducted. For example, the relative cost of user fees to household income and the effectiveness of a waiver system to fees can predict how dramatic the increase in demand will be when fees are removed (37). Secondly, this data

can be used to decide how much more resources and human capital will be required to meet demand, and define ways in which to mobilize the needed financial resources (37). Lastly, both political commitment to the new health policy as well as civil engagement and communication is crucial to create long lasting and sustainable changes (37).

Additionally, without income from user fees, Mali must find alternative methods to finance its health care system. Expanding prepayment systems is one option, by implementing health insurance in a social, private, community or tax-based context, while providing exemptions for the poorest (10). The government may also consider providing direct subsidies for vulnerable groups such as vouchers or conditional cash transfers (10). Mali's roll-out of user fees will require many changes to its current public health system, but the benefits from UHC may just be what the country needs for strengthening their poor health indicators.

### Acknowledgements

We would like to thank Dr. Carmen Christian for the valuable insight and expertise to our study. We also thank Dr. Madhu Pai and Ms. Lena Faust for the helpful feedback and guidance on this manuscript. Finally, thanks to our faculty reviewer for their thorough and thoughtful edits.



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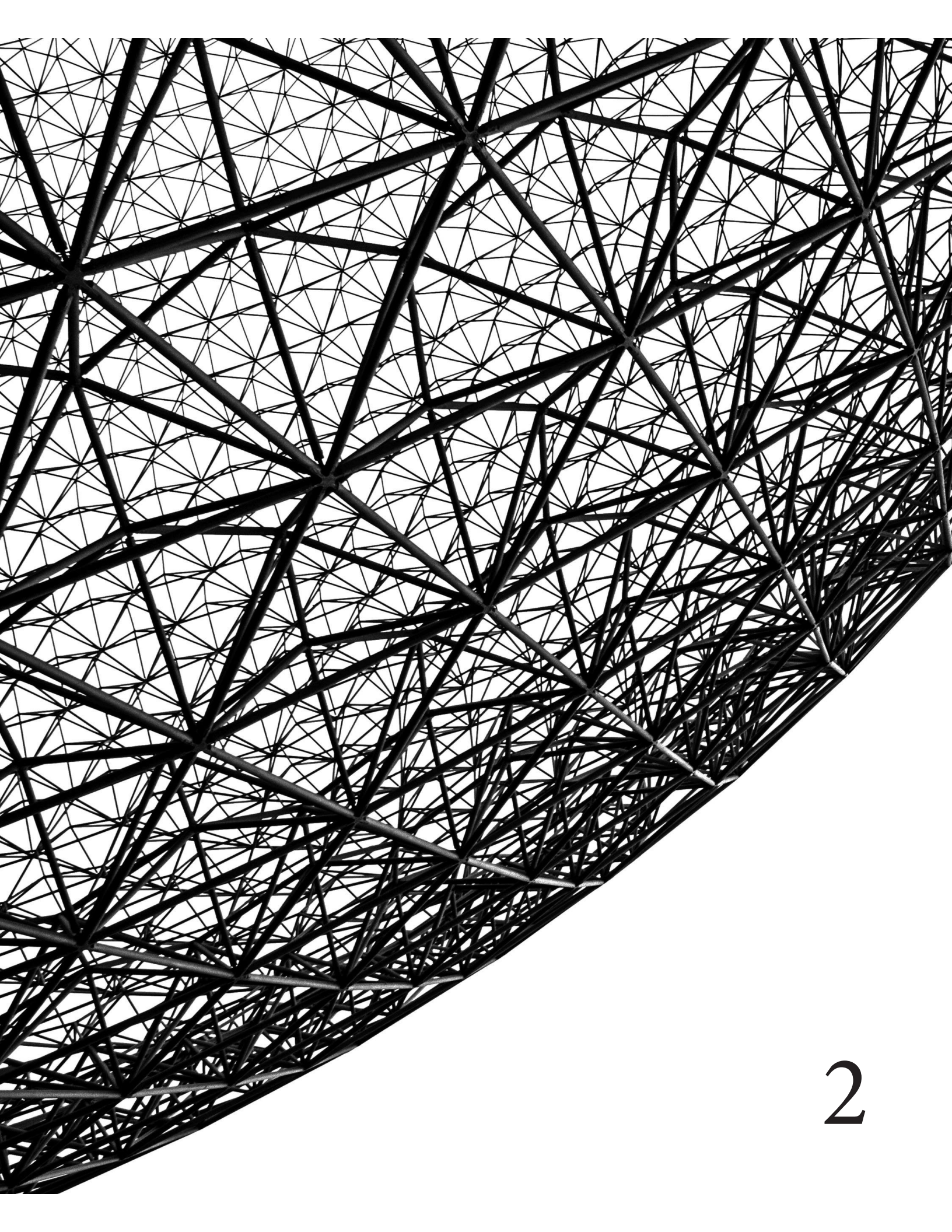
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# A Health Care System Divided: How Apartheid's Lingering Effects Harm South African Maternal Health

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Gabe Polidori, Lois Chen, Diane Sautter

## ABSTRACT

From 1948 to 1994 South Africa was under the repressive Apartheid regime. Among many other actions taken to ensure white South Africans maintained power, the regime put in place discriminatory health policies that deprived black South Africans of equitable health care. As the apartheid era came to an end in 1994, the newly elected African National Congress sought to prioritize equity by creating the National Health Act. Despite this, major disparities in health care persist. The purpose of this case study is to shed light on such disparities in the South African health system by using maternal health as a proxy. Mothers living in rural areas continually contend with barriers to access, affordability and availability. Rural areas account for about 46% of South Africa's population but service provision is only 12% and 19% of the nation's doctors and nurses respectively. The lack of medical professionals in these areas make it difficult for mothers to receive vital procedures, such as emergency obstetric care, without traveling unmanageable distances. Moreover, high transport costs offset progress made by the elimination of out-of-pocket expenses and continues to make the cost of accessing care prohibitively expensive, accounting at times for 51.4% of household income.

## Introduction

Apartheid (Afrikaans: "apartness"), the racial segregation and discrimination of non-whites, was first officially introduced in South Africa in 1948(1, 2) During the apartheid years, race was classified into three categories: white, black (African), and coloured, based on appearance, social acceptance and descent (4). Riots and protests by black South Africans eventually

Population of South Africa (2010)

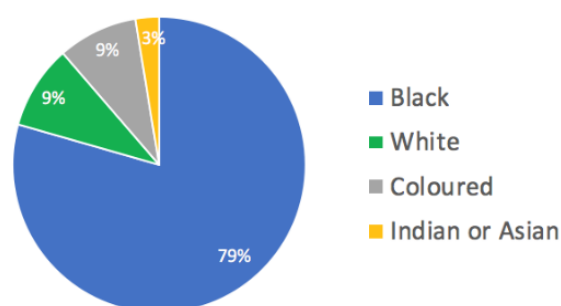


Figure 1. Demographics of South Africa in 2010 by ethnic group. (7)

garnered substantial resistance to white rule (2).

The African National Congress (ANC), with Nelson Mandela at its helm, fought to end the apartheid regime and successfully did so in 1994, at which point the nation transitioned to a constitutional democracy. (2, 3) Central to this transition was the need to eliminate the racial discrimination and segregation in health care to ensure proper care for the whole South African population (3). The South African government's aim was to place health care reform high on the agenda to promote accessible and affordable primary health care (5). This reform was meant to improve access to health care for the poorest South Africans by eliminating out-of-pocket health care fees and expanding health care facilities (5). At the time, the burden of disease rested heavily on the shoulders of poor black South Africans (5), as they received the least amount of resources, despite constituting the major demographic in South Africa as per Figure 1 (7).

The inverse care law, coined by Julian Tudor Hart, posits that, "The availability of good medical care tends to vary inversely with the need for it in the population served". (6, 8) Despite the changes made since the end of apartheid, the inverse care law can still be used to describe the South African health care system; health services are distributed unequally and the utilization

and benefits of health services are enjoyed primarily by wealthy South Africans, who happen to be mostly white, in the public and especially the private sector (6). The purpose of this case study is to show that health care reform in South Africa has failed to address the systemic disparities produced by apartheid, thereby making South African health care yet another example of the inverse care law taking shape in global health. This study will use maternal health as a proxy for the South African health system and therefore draw on maternal health for evidence of this failure.

### The Apartheid Era

During the apartheid era in South Africa, extreme inequalities in health status between the white and non-white populations reflected the top-down discrimination that permeated throughout the country. In addition to discriminatory health policies, the policy of forced relocation of Black South Africans away from the major cities and into what were referred to as Bantustans were instrumental in maintaining economic and political power for the white population (9). This resulted in health resources being disproportionately allocated in favour of the white population outside the Bantustans, to the detriment of non-white people's health (9).

Under apartheid, many laws and policies that encouraged racial discrimination against black Africans were put in place,



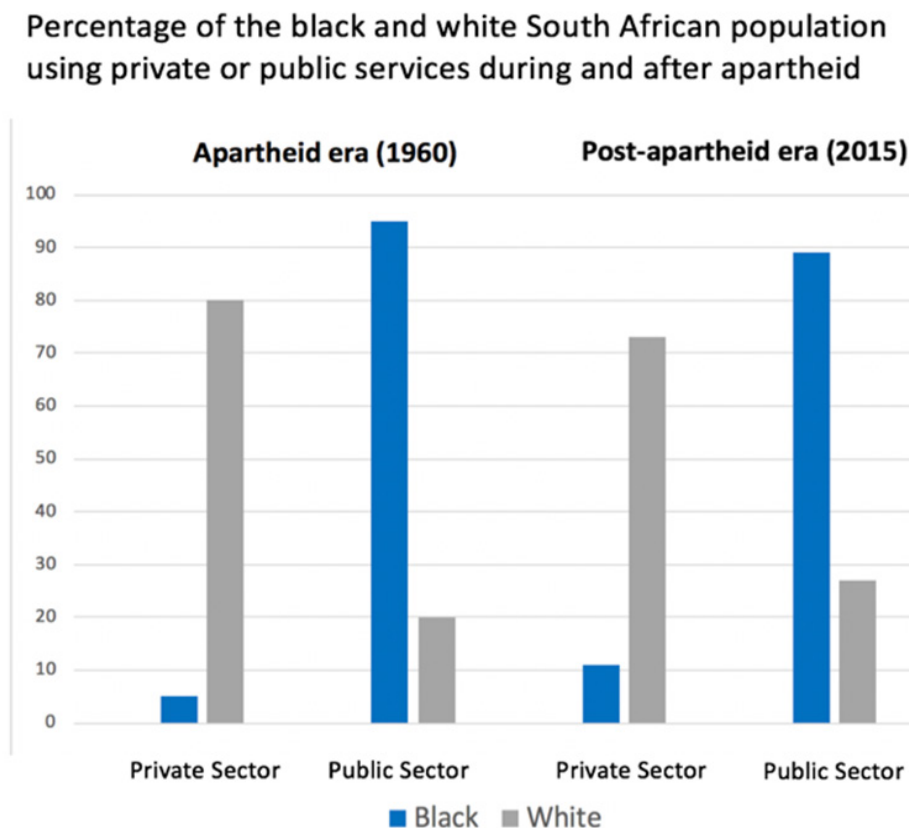


Figure 2. Private and public sector users by ethnic group.

thereby hindering their access to health care services. Deregulation of public health care led to the expansion of the private sector in South Africa as well (10). The privatization of health care further enhanced the gap between the white and the black South African populations. This resulted in health care being very expensive and therefore inaccessible to the non-white lower classes (10). While white South Africans dominated the use of the private sector, very few black South Africans could afford the cost associated with those services (Figure 2)(11, 12).

Consequently, health system privatization increased the disparities in health between South Africa's racial groups (13). In the

1960s, 80% of whites were covered by medical schemes, whereas 95% of blacks relied heavily on the public sector (13). Another metric that heavily points to the systemic inequality of the Apartheid health care system, is the number of health care workers and resources available for black South Africans. According to the health minister Rina Venter, there was a surplus of 11700 beds for white patients, while there was a deficit of 7000 beds for the black population (14). In 1992-1993, expenditure in the private sector was estimated to be 61% of total health expenditure, which cared for a mere 23% of the population (Figure 3)(11). Between 1992 and 1993, 59% of doctors, 93% of dentists, and 89% of pharmacists

worked in the private sector (15), demonstrating the lack of health resource allocation towards the public sector.

Apartheid's private health system lacked a primary health care strategy and was instead biased towards curative services (13). This lack of primary care for non-white South Africans led to serious health problems, manifested by higher infant mortality and lower life expectancies in the black population. In 1980, the infant mortality rate was a staggering 20% in the black population compared with only 2.7% in the white population (16). In the same year, life expectancy was only 55 years of age for black South Africans - 15 years short of the 70-year life expectancy of the white upper class (17).

Furthermore, the racial segregation of health facilities meant that 'black' hospitals were often overcrowded and understaffed due to the large proportion of health resources being allocated towards 'white' hospitals (10). In 1981, there was one physician for every 330 whites but only one for every 91,000 non-white persons (17). This disparity was maintained by an inefficient health care system fragmented across 14 different departments: 10 'homelands' departments, three "own affairs" departments, and one 'general affairs' department (13). Separate departments were established for the different racial groups (16). The apartheid system produced white doctors who did not practice in rural areas or black townships, the very same areas that needed doctors the most (18). This fragmentation resulted in major cost-inefficiencies and provided differential access and quality of care for

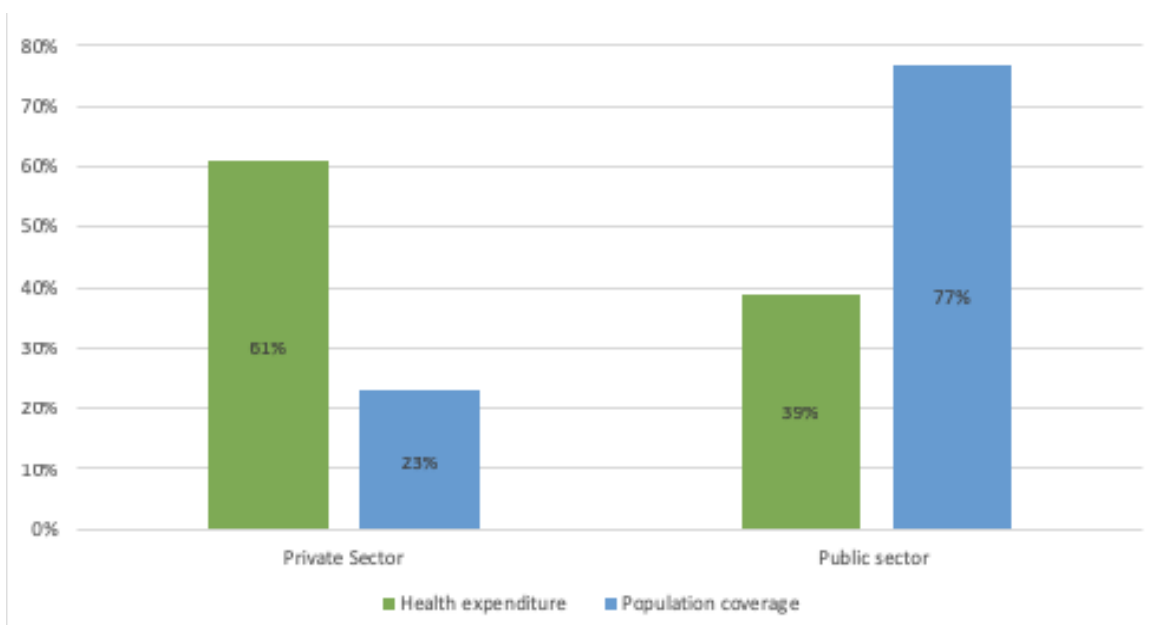


Figure 3. Health expenditure and population coverage (1992-1993)

white versus non-white groups. After the end of apartheid in 1994, this fragmented system was absorbed into nine provincial health services (19).

## The Post-Apartheid Era

In 1994, South Africa held its first democratic election, in which the ANC won with an overwhelming victory, thus marking the end of the apartheid era. The ANC National Health Plan was established as the first comprehensive sectoral plan with deeply rooted principles of social justice and equity (13). This plan acknowledges that health goes beyond simply providing health services as it strives to improve the health of South Africans through equitable social and economic development, through such provisions as standards of education, the provision of housing, clean water, sanitation and electricity (20). The National Health Plan was given a high priority within the Reconstruction and Development Programme (RDP), as it was understood that addressing health inequities was required in order to resolve the racialized socio-economic inequities in South Africa in a timely manner (20).

In order to implement these plans, the ANC drafted the white paper in 1999, which was used as the basis for the National Health Act in 2003, whose goal was “to regulate national health and to provide uniformity in respect of health services across the nation” (21). The act strived to achieve

this goal by establishing a national health system with both private and public health providers that provides the public with the best possible health services in an equitable manner. The National Health Act is viewed, at least in theory, as being one of the most progressive pieces of health legislation, with firm values of equity and social justice (13). However, accessing private health care is dependent on one’s ability to pay. In South Africa, the National Department of Health created and implemented a national health policy, which the nine provinces’ Departments of Health deliver to their populations (22). Additionally, there are local departments of health that are charged with health promotion and preventative services (22). The public hospital system is organized into three tiers: tertiary, district and regional, with the majority of patients accessing their primary health needs at the level of the District Health System (9, 23).

Given that the private sector serves the richest 16% of the population but employs 70% of the country’s doctors while the public serves 84% of the population but employs 30% of the country’s doctors is where this global health failure lies (22). Despite 4,373 new doctors being added to the public sector between the years 2002 to 2010, most health care professionals, especially specialists, are still found in the private sector (Figure 4)(24).

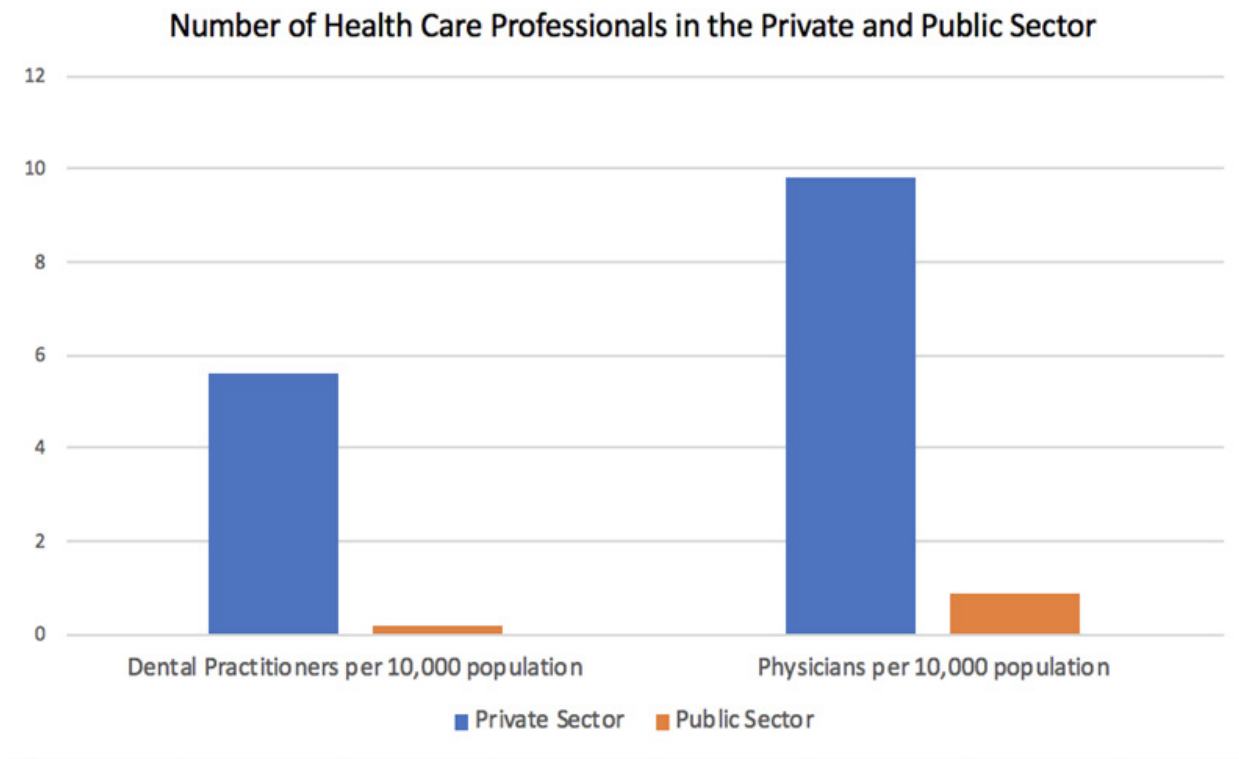


Figure 4. Number of health care professionals in the private and public sector.

In order to benefit from the private health sector, one must be part of medical schemes (i.e. private health insurance), to which individuals and their employers will contribute 1571 USD per year on average (9). This systematically excludes those in lower socioeconomic standings, namely black people, as white South Africans have a significantly higher likelihood of being part of a medical scheme than their black counterparts. In 2017, 72.4% and 10.1% of white South Africans and black Africans respectively were covered by private health insurance (Figure 5)(25). Since the government does not fund private health care, only those with private insurance or who have enough to pay out-of-pocket, are able

to access private sector services. However, those who can afford to be privately insured make up most of the top two income quintiles. According to statistics South Africa published in 2015 (26), almost half (46.58%) of black households fall within the two lowest income quintiles, whereas only 11.09% are found in the upper quintile. As a comparison, 84.60% of white households were situated in the upper quintile, with as few as 0.13% in the lowest quintile (26). The lack of access to healthcare for the black population is undeniable as this demographic represents 80% of yearly deaths in South Africa, while only representing 70% of the population (27).



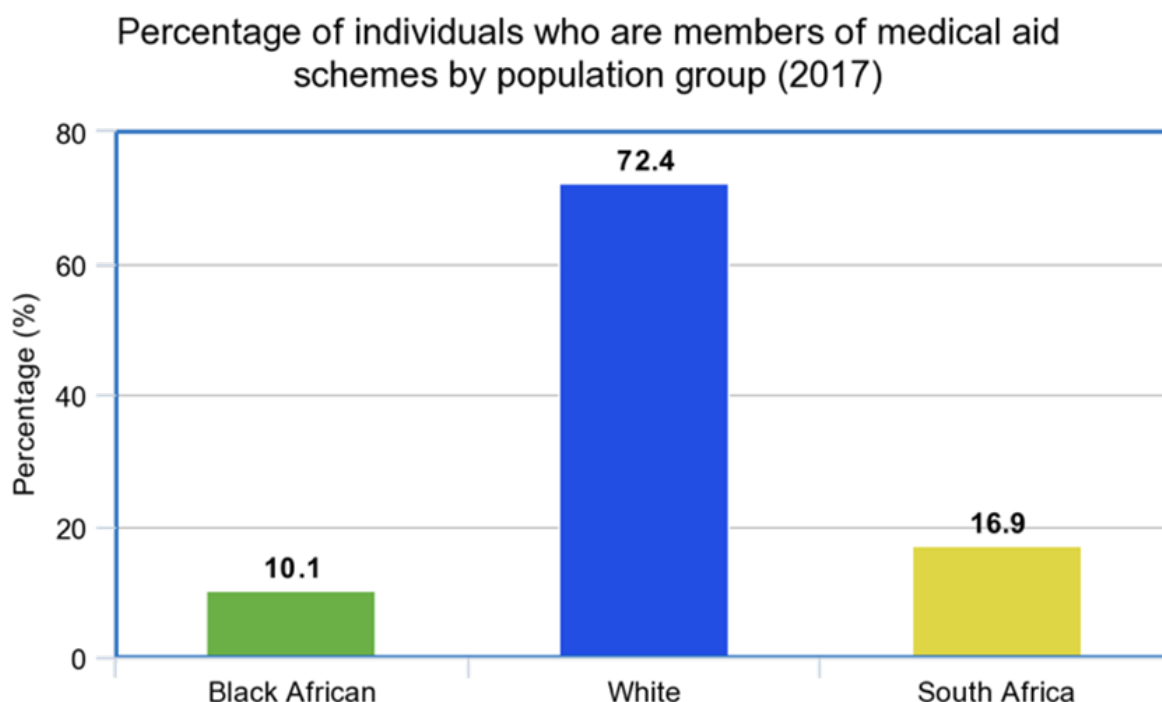


Figure 5. Members of medical aid schemes by ethnic group. (25)

The public health sector as of now still has no real formal coverage, resulting in low quality public health care available to those who rely on it (9). This demonstrates that although apartheid ended 25 years ago, there remains deep-rooted systemic racism in South Africa, as black people to this day do not have access to adequate health care, a fundamental human right as set by the constitution of the WHO in 1946 (28). The South African Department of Health initiated the National Health Insurance plan (NHI) in 2009 to reduce disease burden, improve overall health and make healthcare more accessible and affordable for all (29). This plan, however, relies on enforced contribution from employers and employees to fund part of the system. This is where the

plan falls apart as the subset of the population that earns the most and would therefore contribute a large portion of this fund, is already covered by medical schemes (22). They are therefore uninterested in moving to the public system and having their money distributed across the nation. A lack of stewardship, economic support and action has left the NHI in its implementation phase and as such South Africa has been, is and will remain a shining example of the inverse care law.

### Health Care Financing and Expenditure

The manner in which the South African health system is financed heavily influences the access and financial burden individuals will face when obtaining healthcare, as

described by Carrin et al. (30). The private and public sectors are financed through a combination of sources including general taxes, private insurance and out-of-pocket payments (31). Overall, private sources dominate in relative contribution, as seen in Figure 6 (31).

The majority of the South African population is dependent on the public sector, which is primarily funded by public financing, almost entirely through allocations from general tax revenue (27). In 2005, general tax revenue allocations accounted for an estimated 43% of the total health care finance, which corresponds to coverage for about 68% of the population, which primarily consists of individuals that are

completely dependent on the private sector (31). Private insurance contributions accounted for an estimated 44% of total health care finance, which corresponds to coverage of about 16% of the population (31). Private insurance contributions accounted for an estimated 44% of total health care finance, which corresponds to coverage of about 16% of the population (31). Less than 1% of total health care funding is contributed by donor or non-governmental organisation (NGO) funding, (32) however, these funds are mainly earmarked for specific diseases, such as malaria, tuberculosis and HIV/AIDS (32).

In 1996, the user fee for the public sector primary health care services was abolished

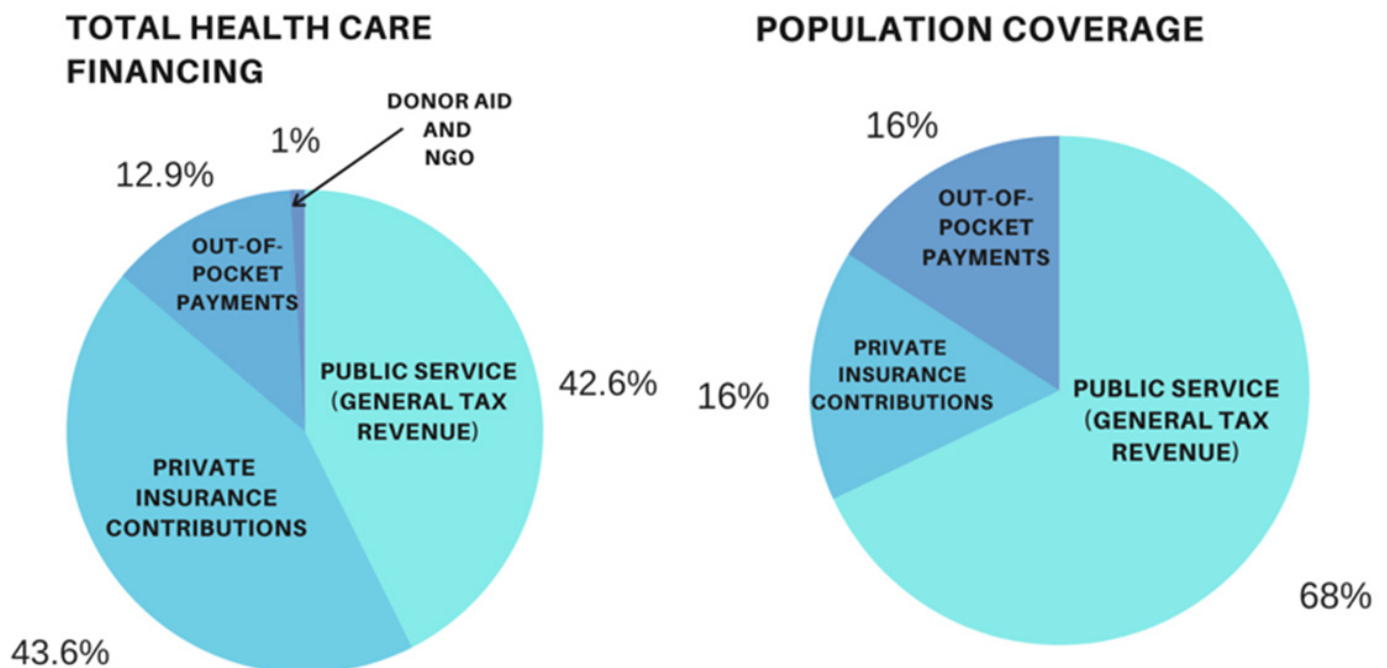


Figure 6. Health care financing and population coverage, 2005. (31)

as a step towards reducing the financial barriers to accessing health care, particularly for those of low socio-economic status (33). Thus, the utilisation of health services increased specifically among the poor. However, the government failed to increase total health care financing accordingly (33).

Between 1996 and 2007, greater health care allocations were given to provinces with predominantly white populations and with pre-existing infrastructure, depriving provinces with greater need for health care allocations (34). By 2007, the South African provinces with the greatest health burdens, least economic resources and largest black populations received the smallest allocation of the national public health care funds (33). This distribution of health care funding allocation in South Africa highlights the essence of “The Inverse Care Law”, as the regions with greater health needs receive fewer financial resources (34).

According to the World Health Organization (WHO) National Health Account Database, the total health expenditure as a percentage of gross domestic product slightly increased from 8.3% in 1995, to 8.8% in 2014, with the total private sector expenditure outweighing that of the public sector (31, 35). Over the past two decades, less than 15% of general government expenditure was consistently spent on the health sector. This proportion of health expenditure ranks less than the global

average and less than that of upper-middle-income countries (31).

### Accessibility, Affordability and Availability

Drawing from Frost and Reich’s access framework, maternal and child care in South Africa can be assessed via a three-pronged approach: accessibility, affordability and availability (36). The World Health Organization (WHO) defines accessibility as the availability of good health services, such as emergency obstetric services, within reasonable reach to those who need them (37). Affordability is “a measure of people’s ability to pay for services without financial hardships” and takes into account the price of the health services and indirect costs to receive maternal and child care (37). Finally, the availability of health care is defined by the WHO as “the sufficient supply and appropriate stock of health workers with the competencies and skills to match the health needs of the population.” (38).

### Accessibility and Affordability

One of the lasting impacts of apartheid is the spatial and racial dimensions of poverty. The apartheid regime put policies in place that restricted the geographic mobility of black South Africans, in order to create a segregated South Africa. Spending on sanitation and housing was also highly unequal, racialized, and tied to regional segregation. From the 1960’s to 1980’s, the Apartheid regime moved, sometimes force-

fully, black South Africans to Bantustans. The Bantustans were artificially created provinces that only covered 13% of the land of South Africa, but were meant to host 72% of the population, namely all the black South Africans (39).

Now even after apartheid has ended, the poorest households are most often black, and often lay in the outskirts of cities or in rural areas (40). A study has found that 14% of black South Africans live further than 5 kms away from a clinic, while that number is only 4% for white South Africans (41). McCray demonstrated that most mothers that began prenatal visits only after their third trimester, or never received prenatal care at all, lived more than five kilometers away from a healthcare facility (42). This is again related to the spatial consequences of apartheid, and more precisely the Bantustans, as South Africa's rural areas account for about 46% of the population but only 12% of doctors and 19% of nurses (43).

An issue resulting from geographic segregation is the high cost of transport for poor women. While there are no user fees for receiving maternal healthcare, there can often be high costs related to transport to the nearest clinic or hospital. This was found to be a significant barrier especially for women giving birth. A study found that transport costs present a significant barrier for women, especially in rural areas where

there is little public transit and ambulances are difficult to arrange (44). Overall, health facilities, goods and services cannot be accessed within a safe physical reach as easily for black South Africans compared to white South Africans.

Compounded with transport fees, the costs associated with childbirth at a clinic or even hospital presents a significant barrier to the affordability of maternal healthcare services in South Africa. A study found that women often have to buy supplies for delivery at smaller clinics, such as nappies, sanitary towels, and food (44). Silal et al. found that poor women might even have to borrow money to be able to access healthcare services, despite these services being free at the point of use (45). The same study found that in two rural and poor districts, women had to spend upwards of 51.4% of their household expenditure on said delivery costs, and upwards of 14% of households had to resort to borrowing money or selling assets to pay for delivery costs (45).

There are stark socioeconomic inequities that remain from the days of Apartheid, as poor and black women still face costs associated with healthcare. There is also a divergence in health outcomes for poor women versus wealthy women. A study found several key characteristics about the Maternal Mortality Rate (MMR) in South Africa. There was also a huge inequity



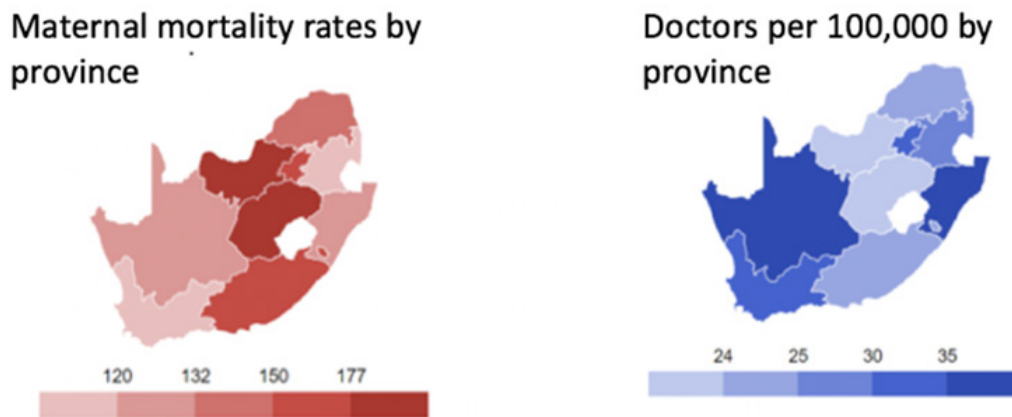


Figure 7. Maternal mortality rates and doctors per 100,000 population by province. (50)

in the MMR in different racial populations, where the MMR for black women was 614, and the MMR for white women was 67, meaning that the mortality rate for black women was ten times higher than for white women (46). While the relationship between socioeconomic status and MMR was not entirely linear, the MMR was much lower for wealthier women, as the MMR for women who declared no income was 650, and for women who made more than 28,800 Rand (SA currency) the MMR was 208 (46).

### Availability

In terms of availability, there are several services that can be assessed to determine the quality and accessibility of maternal and child care. One service that is vital to the survival of mothers and children is the availability of emergency obstetric care. One study found that only hospitals, and not all district clinics, had proper emer-

gency obstetric care protocol services and drugs (47). A large issue with the availability of maternal health services is the lack of qualified medical professionals. As discussed earlier, there is a significant disparity between the resources available in the public health system and in the private medical scheme system. This has serious consequences for the accessibility of medical services, maternal or otherwise. One consequence is the lack of medical practitioners in the public system, as there is one government-employed doctor for every 2,457 people (48). This can be contrasted with the private system, in which there is one doctor for every 429 people (49).

The disparate public system is then further distributed unequally amongst the provinces, with some provinces having double the number of doctors per 100,000. Figure 7 clearly illustrates this disparity in coverage between provinces. When compared

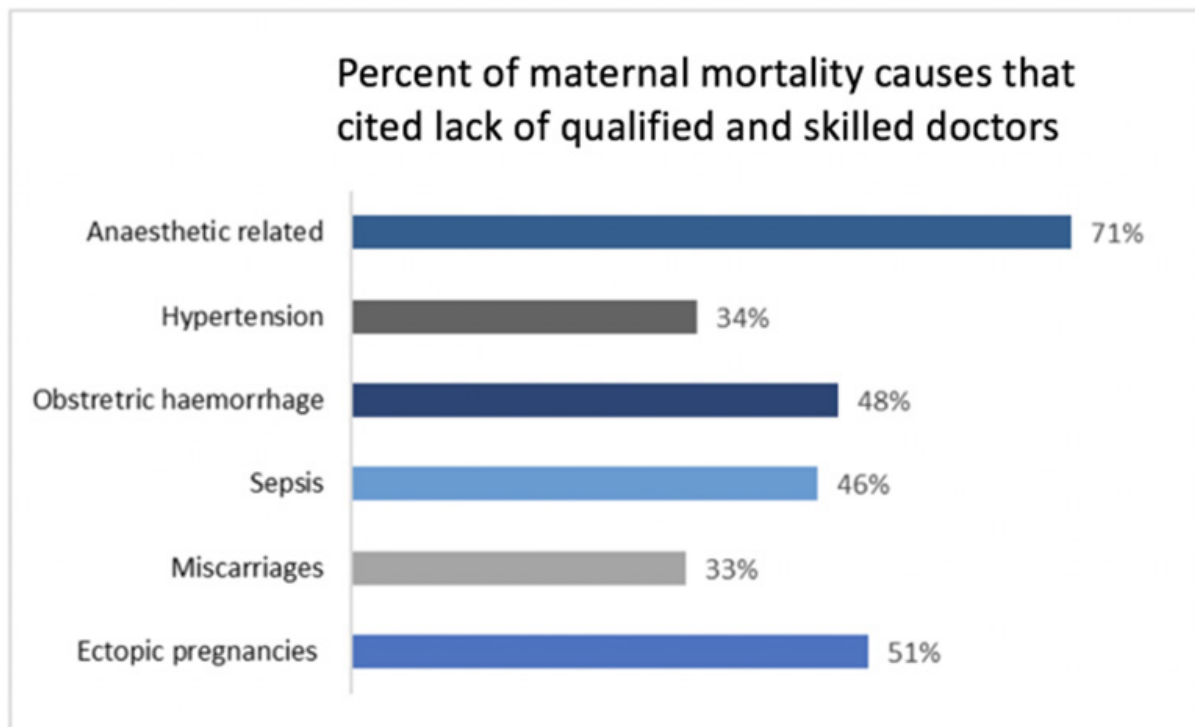


Figure 8. Maternal mortality causes that cited lack of qualified and skilled doctors. (50)

with a map of the relative maternal mortality rates between the provinces, it is evident that the provinces with the highest mortality rates are also the ones with the lowest rate of doctors, showing a clear correlation between the two indicators (50).

However, there is also evidence that the lack of medical practitioners has a direct effect on maternal health. The 2014-2016 'Saving Mothers Report' published yearly by the South African government stated that a lack of qualified and skilled doctors was recorded in 51% of women who died due to ectopic pregnancies, 33% due to miscarriages, 46% due to pregnancy related sepsis, 48% due to obstetric haemorrhage,

34% due to hypertension and 71% due to anaesthetic related cases (50). Figure 8 illustrates the percentage of deaths during delivery that cited lack of qualified and skilled doctors. It is clear that there are issues pertaining to the availability of maternal and child health services, as there is a lack of proper facilities as well as health care professionals.

### Limitations

While the health care pillars addressed above provide a good overview of the health outcomes in the South African health care system as it pertains to maternal health, this review comes with its share of limitations. One such limitation stems

from the South African government's rising corruption. According to Transparency International, which ranks the corruption of every country on a scale of 0 (most corrupt) to 100 (least corrupt), South Africa's corruption score for 2018 is 43 (51). This score is down 18 points from 61 in 2015, meaning that corruption in South Africa is rapidly getting worse (51). South Africa currently sits at the global corruption average and is ranked as the 73rd most corrupt country in the world (51). A corrupt South Africa, whose government is already hypersensitive to its image pertaining to apartheid, is likely to distort statistics and silence research that it feels unhinges its progress in moving away from the Apartheid Era. This puts the research that this study draws on in the direct line of fire, especially considering that much of it is recent research, and therefore would have been published at around the same time as South Africa's spike in corruption.

Not all gaps in knowledge on maternal health in South Africa's health care system can be attributed to malice, however. There is also a strong possibility that research simply does not exist, or certain aspects of maternal health are understudied. Discrepancies are especially likely when considering the quality of data coming out of both the private and public sector respectively. While data in the public sector may be poorer in quality, data in the private sector is proprietary and may not be

accessible to public researchers. Gaps might also exist when comparing data on white South Africans, who have experienced quality care for several decades, to coloured and black South Africans whose data only goes as far back as 1994 in many cases, but comprise a larger subset of the population in South Africa. Finally, by applying a national scope to the research question, this study may also be blind to local realities and the cultures and norms that shape them.

## Conclusion

While 26 years have passed since South Africa was freed from the Apartheid regime, the racial inequalities in health persist. The lasting legacy of the forced relocation and systematic exclusion of black South Africans from the healthcare system has had lasting consequences for the current geographic and material distribution of access to healthcare. Resources and medical manpower are unequally distributed within the underfunded and overextended public healthcare system. This public and private divide in the healthcare system will keep reproducing the racial inequalities as long as there is a lack of affordable, accessible, and available access to maternal healthcare, and even healthcare in general, within the public system. In addition, the racial inequities that persist in economic activities, land allocation, education, also contribute to differential health outcomes,

as they are social determinants of health, thus contributing to the persistence of racial gaps in maternal health care. The National Health Insurance policy that is currently being debated and drafted will therefore have to take these inequities seriously in order to ensure better healthcare for all women in South Africa.

### ACKNOWLEDGMENTS

We would like to thank Dr. Madhukar Pai, Tryphine Zulu, and Sophie Huddart for their guidance, feedback, and assistance while developing our case study.

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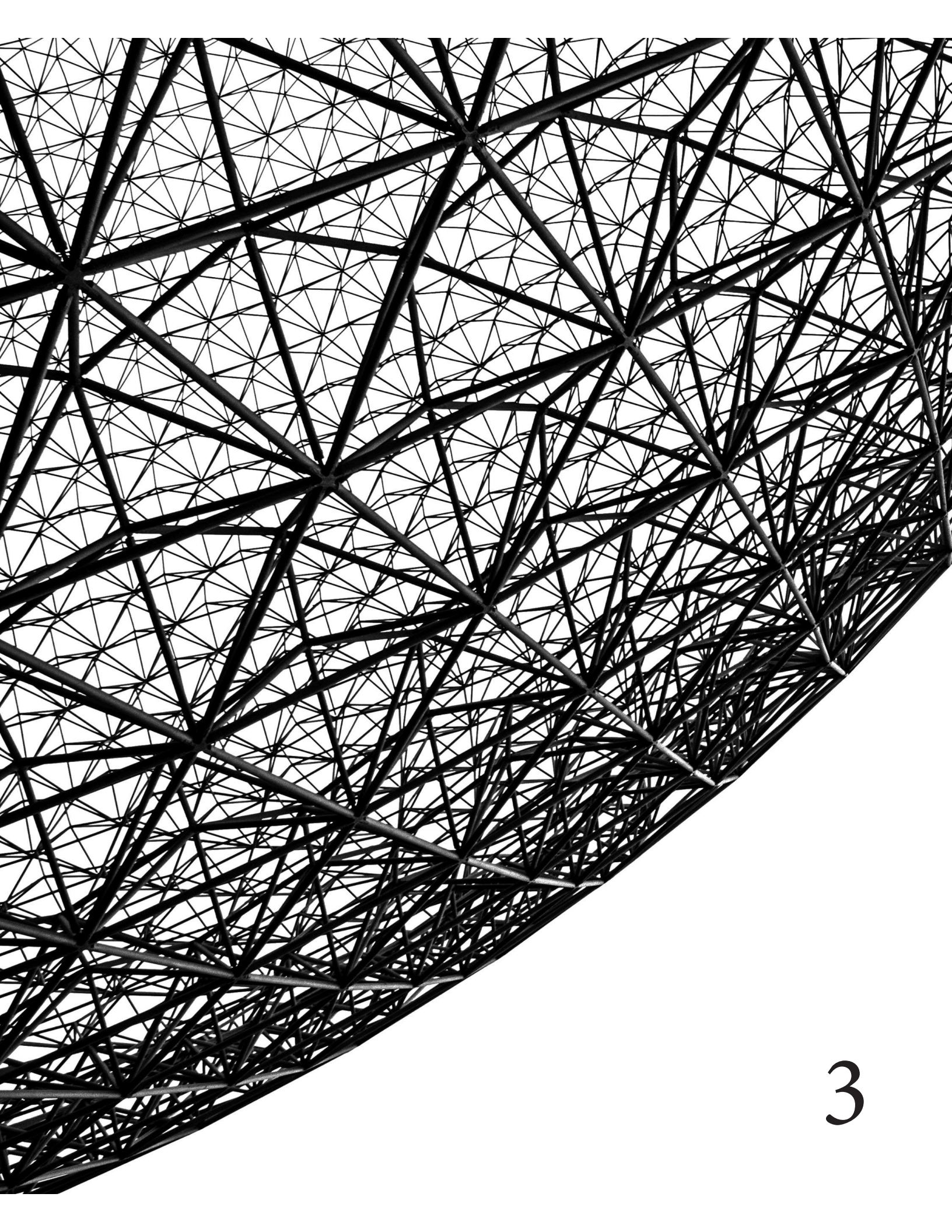


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# Walmart's Singular Solution Falls Short in the Insulin Crisis

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## ABSTRACT

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Globally, 1 in every 11 adults (463 million people) live with diabetes and the numbers are increasing at an alarming rate. While the majority of diabetes cases are type II, where patients become insulin resistant, approximately 5-10% of adults and the vast majority of youth with diabetes are affected by type I diabetes, an autoimmune disease where patients do not produce insulin at all. While type II diabetes can initially be treated with oral antihyperglycemic agents, insulin as an injection is the only medication that can be used to treat type I diabetes. Many patients with type II diabetes also eventually become dependent on insulin. In the U.S., three major pharmaceutical companies own patents for the manufacturing of biologic analogs of insulin. Without legislative regulation, these companies have been increasing the price of insulin substantially such that many people living with diabetes can no longer afford the required doses. In an attempt to provide a cheaper alternative, Walmart recently rolled out sales of human insulin under the brand ReliOn, which is manufactured by the same three pharma companies but marketed by Walmart at a lower cost of 25 USD per vial. This paper evaluates whether ReliOn can be considered a solution to the current insulin crisis.

Although ReliOn successfully provides patients with diabetes an alternative, lower-cost insulin, the number of deaths and medical complications related to improper use continue to increase since its rollout. This effort was a failure for two reasons: firstly, ReliOn is human insulin (Regular, NPH, pre-mixed NPH/R) which is less adaptable compared to more modern analog insulins (specifically for patients with type I diabetes); secondly, there was a lack of education provided to patients switching medications causing an increase in acute complications. The results show that while there could be effective measures set in place to target the insulin crisis, Walmart's rollout of ReliOn is merely a band-aid solution and does not solve the underlying issue of price-surfing.

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## Background

### Diabetes in the United States

30.3 million adults in the United States and 463 million adults globally are currently living with diabetes, numbers that have more than doubled over the last 20 years (1). Approximately 90% of diagnosed cases are classified as type II diabetes, a form of the disease where the body becomes resistant to insulin, making it difficult to maintain consistent blood sugar levels. Initially, anti-hyperglycemic oral agents are frequently used to treat this form of diabetes, but many patients eventually become insulin-dependent (2). While type II diabetes can typically be influenced by healthy lifestyle choices, it is also affected by genetic, social, economic and environmental determinants. In contrast, type I diabetes is a condition that requires a strict, life-long insulin regimen to control blood glucose levels (2). Caused by an autoimmune reaction where the body stops making insulin, blood sugar levels in patients suffering from type I diabetes can become dangerously elevated which, if left untreated, leads to diabetic coma (diabetic ketoacidosis) and death. Currently, there is no solution to prevent type I diabetes, which affects about 5-10% of adults with diabetes, and 90-95% of children with diabetes (2). Gestational diabetes, a form of diabetes that occurs only during pregnancy, is similarly on the rise globally (2). If dietary control is insufficient, insulin treatment is required to prevent serious

health complications from occurring, both during pregnancy and postpartum for the mother and child. In 2017, the crude death rate of diabetes was set at approximately 21.5 per 100,000 people in the U.S. and is listed as the seventh leading cause of death according to the latest U.S. mortality data (3).

### Various Types of Insulin

Insulin is a hormone produced by the beta-cells of the pancreatic islets that helps maintain constant blood sugar levels, especially following meals. Insulin dysfunction or the dysregulation of beta-cells in the body can lead to insufficient insulin secretion resulting in elevated blood glucose levels, known as hyperglycemia (4). There is currently no cure for diabetes, but there are different techniques to manage and treat the disease, including the administration of insulin (5). Insulin is available in ultra-rapid-, rapid-, short-acting- (also known as regular-), intermediate-, and long-acting types that can be used alone or in combination to effectively manage blood glucose levels relative to food intake and exercise (6). Insulin comes in different strengths, with the standard in the U.S. being U-100, or 100 units of insulin per milliliter of fluid (7). Although all insulins work to control blood glucose levels, there are various formulations of insulin that act with different strengths over different periods and there is therefore a clear need for precise and specific dosing.

Two main types of insulin are available to patients with diabetes: human insulin, which is the same molecule produced by the human body and was the only option until the 1990s, and analog insulin, an altered, synthetic form of the hormone (8). According to a study published in the American Diabetes Association journal, analog insulins are a better alternative compared to human insulins and are now largely the standard of care in diabetes care delivery, especially in type I diabetes (9). According to the study, analog insulins have “been shown to improve treatment adherence and treatment satisfaction due to fewer injections, flexibility of timing of basal analogs, less fear of dose adjustments, mealtime administration of prandial analogs, as well as user-friendly injection devices” (9). Human insulin takes longer to enter the bloodstream and has pharmacokinetics that does not effectively match the physiologic insulin production, whereas analog insulin, which has improved pharmacokinetics, acts faster and maintains steady levels in the bloodstream throughout its course (10). Due to this difference, human insulin requires much more planning on the patients’ part by matching their dietary intake to ‘feed’ their pre-injected insulin. If meals, snacks, and exercise deviate from a rigid routine, they could risk reaching both hypoglycemic and hyperglycemic levels (11). Patients need to undergo a significant amount of education to learn how to self-manage their insulin regimen. Switching

from one approach to another (e.g. from a ‘basal-bolus’ approach using analog insulins, to a human insulin that is premixed) requires a different dietary approach and must be carefully managed.

### The Rise of Insulin Prices in the U.S.

Insulin as a treatment has been available since 1922, where successful human clinical trials at the Toronto General Hospital made headlines around the world (12). To distribute the insulin to patients who needed it, the Canadian research team famously sold the patent to the University of Toronto for 1 USD (13). Due to strong demand, production was eventually transferred to pharmaceutical giants Eli Lilly and Novo Nordisk following initial rationing in 1923 (13). As production efficiency increased, 100 units of short-acting insulin prices dropped from 1 USD to less than 20 cents in the 1940s (13).

Currently, three companies represent 99% of the insulin market in the United States: Eli Lilly and Company, Novo Nordisk, and Sanofi. They have quickly gained an oligopoly over the industry, driving prices up exponentially in the process (14). The average price of insulin increased by 300% between 2002 and 2013 (15). The main factors causing the rise of insulin prices in the U.S. are the negotiating power and market exclusivity of these pharmaceutical companies (16). In particular, the lack of specific legislation regarding insulin pricing allows

pharmaceutical manufacturers to price their products however they see fit for the market, entitling them to raise the prices over time with no limit. Additionally, direct competition from cheaper or generic options is lacking, because the current analog insulin products are protected by patents that cover the insulin delivery method or formulation (13). Furthermore, because insulin is a biologic drug derived from various organisms using biotechnology rather than a small-molecule chemical drug, its synthesis is difficult and costly. This further limits other companies from attempting to create biosimilars. This combination of hurdles has contributed heavily to the constant rise of insulin prices in the United States.

In recent years, several attempts have been made to mitigate the insulin crisis. For example, the 2019 cost-sharing cap-appropriation act of Colorado, the “Emergency Access to Insulin Act of 2019,” and the “Affordable Drug Manufacturing Act” from 2018 were both introduced to decrease the burden of the insulin crisis (17-19). While these pieces of legislation present hope for the future of insulin access in the U.S., they have not produced any observable effects mostly because the legislation has simply been introduced and not yet passed.

### Walmart’s Rollout of ReliOn

In 2012, Walmart partnered with Novo Nordisk and began selling an over-the-counter (OTC) human insulin known as

ReliOn. Novo Nordisk was already selling their version of human insulin, Novolin, and they rebranded this identical drug for sale in Walmart pharmacies throughout the U.S. at a cheaper price as a part of their Patient Assistance Program to introduce affordable medication (20). Throughout this case study, the successes and failures of ReliOn insulin will be dissected and unpacked to understand why ReliOn is not a singular solution in addressing the insulin crisis that exists in the United States. This will be examined by discussing how this crisis came to be, the impacts ReliOn had or failed to have in the insulin crisis, and the future implications of the crisis.

Available in all states except Indiana, where OTC insulin is banned (21), ReliOn is considerably less expensive (approximately 25 USD per 10mL vial) than the OTC human insulins, Humulin (Lilly) and Novolin, bought at other pharmacies (approximately 155 USD per 10mL vial), and significantly cheaper than human insulin and analog products requiring a prescription (21). The apparent goal of the ReliOn rollout is to provide an alternative insulin product that is competitive with other pharmacies offering OTC insulin (11). This alternative may fill a gap in the healthcare system that gives patients with diabetes of a lower socioeconomic status an accessible insulin option (22).

As the world’s largest retail firm with an annual growth rate of 17.8%, Walmart is



a for-profit entity (23). By choosing to sell low-cost human insulin, this intervention leads to the attraction of a vulnerable consumer base to profit off of.

The roll-out of Walmart's insulin joined the retailer's line of already implemented ReliOn brand insulin products, which includes cheaper access to other testing tools required daily by patients with diabetes including blood glucose meters, syringes, and blood sugar test strips. The ReliOn brand insulin administration and testing products were designed by Walmart to appeal to patients with diabetes who cannot fiscally access these products elsewhere (11). Often, these patients are uninsured or cannot afford the copayments required to acquire sufficient insulin and without access to affordable insulin, many of these patients can face life-threatening consequences (14, 22). To these financially strained populations, ReliOn is an appealing option. ReliOn insulin is accessible as it is cheap and does not need to be prescribed. While this is a key attraction of the program, a lack of necessary prescription allows for the purchase of Walmart's insulin without any support or supervision from a medical professional (11). Due to the significant pharmacokinetic differences between human and analog insulin, a lack of medical supervision can seriously affect the efficacy and safety of the drug. Such a significant flaw in Walmart's insulin roll-out puts in jeopardy the effectiveness of the entire program (24).

## Finances

Based on our research, Walmart has not issued any information with regards to the financial cost of manufacturing ReliOn. All documents related to financial investments, contributing stakeholders, and the amount invested by each stakeholder are kept private. As a result, the public does not know who is funding ReliOn, how much it costs to manufacture, or who the interested stakeholders are. Therefore, there is currently no data to carry out a cost-benefit analysis of the intervention. From the available data, a comparison between the cost of insulin for consumers versus production is available below in Tables 1 and 2.

A national telephone-based survey conducted in 2018 investigated the frequency of OTC insulin sales in Walmart and chain pharmacies in 49 states in the U.S. (21). The results provided evidence that OTC insulin was sold significantly more often in Walmarts compared to other chain pharmacies. OTC insulin was being sold weekly in 10.9% of Walmart pharmacies and only 1.4% in chain pharmacies (21). The reason for this difference among pharmacies is likely the price. As seen in Table 1, Walmart-brand insulin (ReliOn) is sold at 24.88 USD per 10mL whereas Novolin and Humulin sold OTC at chain pharmacies cost anywhere between 90-185 USD per 10mL. Overall, based on the 4,700 Walmart pharmacies interviewed in the 2018 survey, the authors

Table 1: Cost of insulin for consumers of short-acting human and analog insulin in the United States as of 2019. Prices are in USD and reflect the prices per one U-100 10mL vial of insulin.

Retail price (USD for 10mL)			
Human Insulin		Analog Insulin	
Novolin R	93	Humalog	296
Humulin R	185	NovoRapid	312
Relion® sold by Walmart	24.88		

Table 2: Production cost of short-acting insulin in the United States as of 2019. Prices are in USD and reflect the price per mL of insulin.

Production cost (USD/mL)		
	Human Insulin	Analog Insulin
Short-Acting (Regular) Insulin	2.85	4.93

concluded that Walmart pharmacies sell on average 18,000 vials per day across the U.S., with a single pharmacy selling between 1 and 50 vials daily (21).

Regarding the cost of insulin in diabetes care, as seen in Table 2, the estimated production cost for one vial of analog insulin is between 3.69 and 6.16 USD, while a vial of the human insulin costs between 2.28 and 3.42 USD (25). Based on these numbers, it should not cost more than 133 USD each year per person to get the best treatments such as ultra-rapid analog insulin (25). This cost of 133 USD includes expenses for raw ingredients, production, and delivery. Therefore, despite ReliOn being the cheapest insulin option by far for American

patients with diabetes, the price of 25 USD per vial still represents a significant mark-up. Considering the average adult with type I diabetes requires two to three vials per month, in addition to syringes, test strips and needles, this can add up to over 75 USD per month, or 900 USD per year for insulin alone. It is clear that although ReliOn is advertised as a cheap alternative to prescription insulins, a price tag this high still limits Americans of the lowest socioeconomic demographics from accessing consistent and affordable care.

A carton of insulin that costs 300 USD in the U.S. sells for 20 USD in Canada as Canadian laws prevent medication markups (26, 27). In the U.S., the lack of

similar government legislation allows for substantial markups of insulin throughout the supply chain. Typically, the customers' healthcare coverage, if any, does not cover these added costs, which increases overall out of pocket spending (14).

## Impact

Walmart's rollout of ReliOn did not have the impact on the insulin crisis that patients with diabetes in the U.S. had hoped for. As a human insulin, ReliOn has an inconvenient peak and duration of action times compared to the analog products and does not offer the same coverage. According to Luo et al., ReliOn provides an effective switch for patients with type II diabetes who cannot afford analog insulins, yet it states this is not true for patients with type I diabetes (28). As human insulin works differently than analogs, many patients who make the switch to this cheaper alternative face serious medical complications, or in some cases death, due to improper use (22). Furthermore, according to a systematic review and meta-analysis of results from twenty-two randomized clinical trials comparing short-acting insulin analogs versus regular human insulin for type I diabetes mellitus, short-acting insulin analogs are associated with a lower number of total hypoglycemic episodes per month (29). More specifically, the study found that the short-acting insulin analogs have a 45% lower risk rate of nocturnal hypoglycemia and a 32%

lower risk rate of a severe hypoglycemic episode (29). Cheaper options, such as ReliOn and other OTC human insulins, do not offer the same clinical benefits that the more developed analog versions of insulin provide.

Evaluating the ease of use and reliability of insulin drugs is difficult due to the lack of data on their long-term benefits and clinical outcomes. The U.S. Food and Drug Administration (FDA) approves new diabetes drugs based solely on short-term glucose-lowering efficacy and safety (30). Furthermore, it is impossible to measure the direct effects of OTC insulin due to the unavailability of a tracking system for non-prescription medication. While ReliOn sales are successful, the issue with this insulin lies in the lack of medical follow up and education in patients who make abrupt switches from analog insulin, which can have severe impact on glycemic control leading to adverse health consequences.

Given the lack of data to measure the direct effects of Walmart's ReliOn, a possible proxy measure to evaluate the effects of a new drug is to study changes at the population level. According to Peter and Lipska, findings from a nationally representative study revealed that between 2007 and 2010, about 8% more patients had excellent glycemic control than between 1999 and 2002. However, close to one-third of patients with diabetes between

2007 and 2010 had failed to achieve their individualized targets for glycemic control (30). Furthermore, the study also revealed that younger adults aged 18 to 44 years with diabetic complications, experienced no improvements in their glycemic control during this period (30). Therefore, although many new drugs are available for lowering blood glucose concentrations, only modest improvements in glycemic control are being observed at the population level. There was also a significant increase in the rate of hospital admissions due to hypoglycemia during this period (30). Peter and Lipska also cite the U.S. Institute for Clinical and Economic Review and Drug Abacus, indicating that drugs with few benefits to patients are priced lower, and those with significant benefits are priced higher (30). As such, the convenience of a cheaper option of insulin, such as ReliOn, is counteracted by its poorer quality and lower level of effectiveness in benefiting the patient. This also brings up the discussion of how offering a cheaper, less effective form of insulin disproportionately affects the poor and further exacerbates their unmet needs for quality insulin accessibility and affordability.

Evaluating the outcomes of patients who switched from analog to human insulin is difficult due to the lack of data; however, many news articles have surfaced shedding light on the numerous hospitalizations and deaths in people with diabetes after

making the switch (31). These deaths and increased hospitalization rates are linked to the lack of education the patients had been given when switching to an OTC human insulin, which is essential to avoid adverse effects. Yet, if a patient is desperate for a cheaper alternative due to their current socioeconomic status, they may not seek professional opinion prior to switching, especially if they need to pay extra for a doctor's advice.

### Why ReliOn Falls Short

There is still a debate as to whether the rollout of ReliOn is an effective option for patients with diabetes (11). While OTC human insulin provides an affordable alternative to analog prescriptions, the pharmacokinetics of human insulin requires a significant understanding by the patient for proper and safe dosage. We argue that Walmart is failing to address the insulin crisis in the U.S. because the program is lacking the necessary educational tools to ensure proper insulin administration by patients. Additionally, Walmart's intervention is profit-oriented, and ReliOn is simply a band-aid to the insulin crisis. ReliOn distracts consumers from the main issue that three major pharmaceutical companies have an oligopoly on insulin production, allowing them to quasi-fix insulin prices, with resulting soaring prices of an essential medicine that is now unaffordable for patients who need it to survive.



As ReliOn is available without a prescription, it is very hard to measure the effectiveness of the intervention and acquire accurate numbers on how many people have used this product. Additionally, if any information is available, Walmart and Novo Nordisk have not made this data public. There are not many studies available that have tracked the use of OTC insulin since the rollout, with the closest data available being the telephone survey mentioned above. Although the survey indicated a high demand for cheaper insulin, no reports indicate if these consumers are regularly following up with physicians, or if they have been properly educated on the use of ReliOn. Due to this lack of data, there is a clear knowledge gap in the actual impact of ReliOn and further studies following the purchases of OTC insulin are highly recommended.

The lack of education and follow up in patients with diabetes opting for OTC insulin remains the central concern regarding the sale of ReliOn. Since they can all access ReliOn without a prescription, patients with diabetes do not need to visit their doctors, meaning there are no regular check-ups to assess adherence to the drug regime, drug effectiveness, and overall health of the patient. Walmart pharmacists may provide basic education to patients with diabetes purchasing this product for the first time, but there is a clear lack of instruction for the proper use of human insulin. The

pharmacokinetics of human versus analog insulins are different, and patients need to be re-educated when they switch from one to another. It is very difficult to receive the proper tools and information to manage diabetes when buying an OTC medication. When taking human insulin, one needs to match their diet accordingly. Yet, when taking prescribed analog insulin, it is prescribed by a doctor with considerations to the patient's diet. The standard of care in type I diabetes management includes three to four injections per day (or more), which is known as a 'basal-bolus' approach (10). For patients switching from ultra-rapid-analog insulin to regular human insulin, an adjustment to their management method is necessary. An approach to selling human insulin would require significant education of both healthcare providers and patients with diabetes, which is not currently provided by Walmart (14). Although the rollout of ReliOn successfully provided patients with a cheaper alternative, the deaths and medical complications caused by improper or lack of insulin use are not decreasing (32). This intervention only succeeded in segregating poorer patient populations from the rich and provides them with a cheaper, less effective alternative, and therefore has not improved the state of the U.S. Insulin Crisis.

## Discussion

With the price trajectory insulin has taken over the last few years, there is an evident need for cheaper and more effective insulin. The fate of such a program strongly depends on the change in accessibility and cost of high-grade analog insulin moving forward, with the possible legislature that may be involved for such a move to take place. To properly evaluate the effectiveness of an OTC insulin, Walmart, as well as other private pharmaceutical distributors, must release their data to the public. Although OTC human insulin may have once been deemed as a safe alternative; additive psychological and physical stressors become evident upon switching to a lower-grade medication, further emphasizing that this is not a long-term sustainable solution as it also further drives the inequities and inequalities within the U.S. healthcare system. The co-existence of both high-cost analog insulin and low-grade OTC insulin in the same market further raises questions over what the profitability manufacturers of analog insulin can get away with and the cost of individual lives that these companies are willing to put at stake. The different treatment options between analog and OTC human insulin strongly demonstrates many of the wide-ranging weaknesses and inequities in the domestic health care infrastructure that has allowed such a situation to occur. This would therefore require more attention to adequately solve this crisis.

Currently, the sales and usage data remain private among respective retailers and manufacturers which further hinders the process of new policymaking. Therefore, increased sales data transparency from these private companies is a crucial step moving forward. Due to the complexities of the U.S. healthcare system, finding an appropriate solution and direction to this crisis will require policy-making on a state and federal level. Moving forward, any effort to mitigate the insulin crisis must facilitate a transition to a model that incorporates patients with diabetes from both high and low socioeconomic statuses and will facilitate equitable treatment for all. To adequately provide such a system and reach a solution to the insulin crisis, pharmaceutical companies must end their dehumanizing and profit-centered actions by providing insulin at an affordable price.

## Acknowledgments

We would like to thank Dr. Julia von Oettingen (MD, PhD, MMSc, FRCP) for taking the time to provide us with valuable information and advice during the writing process. All of her hard work was pivotal in the success of this project. We would also like to thank Sophie Huddart, Lena Faust, and Dr. Madhukar Pai (MD, PhD) for their feedback throughout the semester.

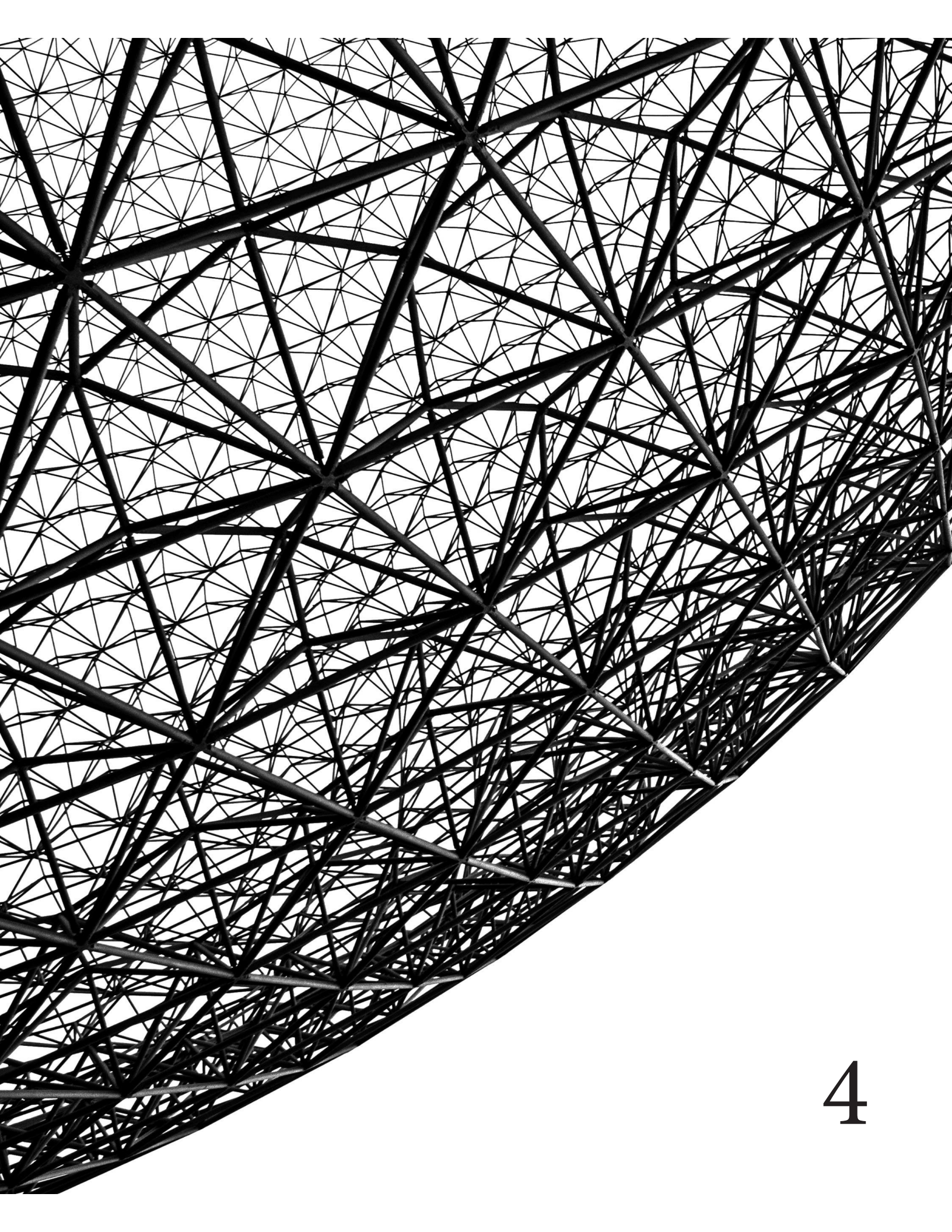
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# Black Mothers in America: Why Racial Discrimination in the American Healthcare System is Disproportionately Killing Black Women

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## ABSTRACT

The United States has the highest rate of maternal mortality among high-income countries, despite spending the single-largest percentage of GDP on healthcare. This burden disproportionately affects Black mothers who experience a maternal mortality ratio that is four times that of White mothers. This case study demonstrates that the disparities in maternal outcomes between Black and White mothers are rooted in racial discrimination. This racial inequality manifests in part through increased allostatic load as a result of intergenerational experiences of racism; unequal access to high quality insurance coverage; and racial discrimination by healthcare practitioners. Potential interventions to explore include federal and state employment regulations that lessen the socioeconomic barriers preventing Black Americans from accessing quality insurance coverage; cross-cultural training programs in healthcare facilities and teaching institutions; and a systematic shift toward holistic models of childbirth. Though these interventions can serve to diminish the consequences felt on the individual level, collaborative multi-systemic change is necessary to address the social determinants of health that result in poor maternal outcomes on a national level.

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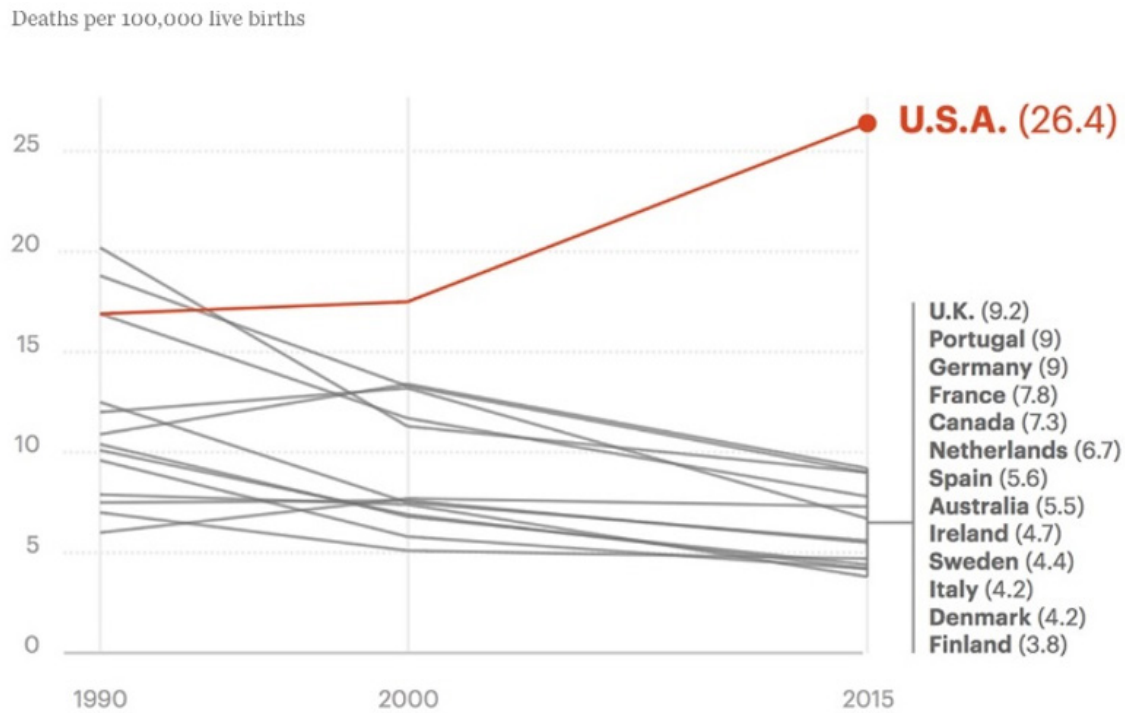


Figure 1: Maternal Mortality (deaths per 100,000 live births) in a Selection of OECD Countries in 1990, 2000, and 2015.<sup>1</sup>

## Background

The United States has the highest maternal mortality rate among high-income countries (1). From 1990 to 2015, the maternal mortality ratio in the United States has climbed consistently from approximately 15 deaths per 100,000 live births in 1990, to over 26 deaths in 2015, as seen in Figure 1 (1).

According to the World Health Organization's 2015 data, the United States is one of very few countries to experience a worsening of maternal outcomes between 1990 and 2015, alongside low-income countries such as the Democratic People's Republic of Congo, Guyana, and the Tonga (1).

These outcomes are shamefully inadequate given the economic investment into healthcare. Specifically in relation to their spending on childbirth-related care, in the United States in 2006, two of the top five most expensive conditions requiring hospitalization were pregnancy-related: pregnancy itself and delivery of newborn infants (2). These two conditions resulted in a combined total of \$86 billion spent on child-birth related care in hospitals, or 9.1% of the national hospital bill (2). Considering this alongside the fact that the country has such a high maternal mortality rate and scores poorly on many other child-birth-related outcomes, indicates a very poor return on investment.



Table 1. Maternal and Child Health Disparities between Black and White Americans.(4,5,6)

	Black Americans	White Americans
Life expectancy at birth (years). <sup>4</sup>	74.8	78.5
% Low birth weight (< 2,500 g). <sup>4</sup>	13.05	7.07
Infant Deaths/1,000 live births. <sup>5</sup>	11.4	4.9
Maternal Deaths/100,000 live births. <sup>6</sup>	42.4	13.0

Table 2: Healthcare expenditure and subsequent consequences in the US, by race. (7,8,9)

	Black Americans	White Americans
Total Health Care Spending (Ages 27-30). <sup>7</sup>	\$2,191.98	\$3,540.00
% Non-elderly adults who did not see a doctor due to cost in the past 12 months. <sup>8</sup>	17%	13%
% Adults that had problems paying or were unable to pay for medical bills in the last 12 <u>month</u> . <sup>9</sup>	31%	18%
% Adults that had to declare bankruptcy because of medical bills in the past 2 year. <sup>9</sup>	8%	3%

Though this represents a massive public health failure on behalf of the United States healthcare system, the risk of maternal mortality is a burden that is distributed unevenly amongst women. For over fifty years, Black women have consistently experienced rates of maternal mortality four times higher than that of White women (3). Even when studies controlled for prevalence, risk in the pregnancy, socioeconomic status, level of education, insurance type, and age of the mother, Black women had an increased likelihood of dying in pregnancy and post-

partum (3). Though Black women are not more likely to experience the conditions causing maternal deaths (including but not limited to preeclampsia, eclampsia, abruptio placentae, placenta previa, and postpartum hemorrhage) they are significantly more likely to die as a result of these conditions when compared to the case-fatality rate of a White woman with the same complications (3). Further, the inequalities in pregnancy and childbirth do not uniquely manifest in poor maternal mortality outcomes: when compared to White

mothers and children, Black Americans experience decreased average birth weight, decreased life expectancy, and increased infant and maternal mortality rates (Table 1). All of these indices are evidence of poor pre-and-postnatal care. In addition, financial barriers to healthcare disproportionately affect Black Americans (Table 2). On average, Black people in the US spend less on healthcare, have more trouble paying medical bills, and are more likely to avoid seeing a doctor due to cost than White Americans.

This racial inequality is indicative of a larger socio-political reality in the American healthcare system: despite controlling for health-related factors, “evidence of racial and ethnic disparities in healthcare is, with few exceptions, remarkably consistent across a range of illnesses and healthcare services” (10). Institutional racism is embedded in American institutions as present-day manifestations of a long history of colonization and slavery (11). Healthcare is a system through which “historic patterns of legalized segregation and discrimination” at the individual, community, and institutional levels interact, reinforcing health outcome disparities (10). Among these institutional barriers are multigenerational inequality in employment opportunities, access to safe housing and quality education, and disproportionate representation in low socioeconomic ranks (10).

This case study seeks to illustrate that

disparities in maternal outcomes between Black and White mothers in the US are rooted in racial discrimination which acts in part through weathering, inequity in insurance access, and racial bias in the American healthcare system.

### The Intergenerational Effects of the Weathering Hypothesis

Allostatic load is defined as the biological cost of exposure to elevated endocrine responses as a result of chronic or repeated stressful experiences (12). Black women, on average, have the highest allostatic load scores in the United States, when adjusting for socioeconomic status (13). The “stress age” hypothesis posits that the health of Black women prematurely begins to deteriorate as a result of their cumulative exposure to stress (14, 15). Through this mechanism, heightened exposure to stressors associated with racism throughout the life course increases Black mothers’ risk of pregnancy complications (14).

An emerging mantra for understanding these poorer maternal outcomes includes a feedback loop through which these racial inequities are perpetuated and repeated throughout American society. It has been shown, for example, that Black mothers experience elevated stress levels simply because they fear their children will be subject to racism and discrimination (16). The “stress age” hypothesis posits that traumatic

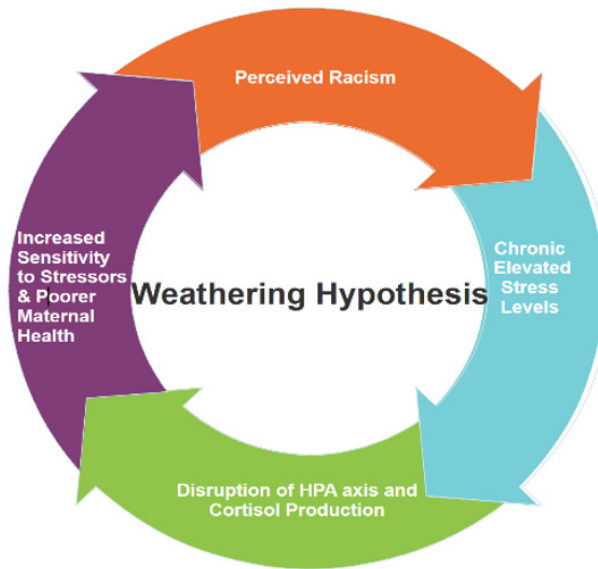


Figure 2: The Weathering hypothesis and accumulation of allostatic load in response to experiences of racism.

events early on in life may continue to stress an individual and even sensitize them to how current stresses are perceived (14). Historically marginalized groups, including Black women in the United States, perceive prejudice to be more stressful than non-stigmatized groups, and may often experience prejudice where others do not (17). Chronic stress experienced by Black women may sensitize these individuals to future stressors, resulting in prolonged and recurring physiological trauma, which may increase the risk of complications during both pregnancy and delivery, as outlined in Figure 2 (18).

Comparing allostatic load scores for Black women, Black men, and White women demonstrates the significance of experiences of racism and discrimination on maternal outcomes. Black women have been found to bear the largest burden of

allostatic load compared to Black men and White women (13,19). Further, significant differences in allostatic scores were found for “non-poor Black women” and “non-poor White women”, suggesting that differential birth outcomes for Black and White mothers emerge from systemic racism, not socioeconomic status (20).

Moreover, another study found Black mothers ages 23-34 to have higher infant mortality rates than their teenage counterparts (see Table 3) (21). The opposite trend was found for White women: infant mortality rates are higher for babies born to White teenagers than to older White mothers. Notably, neonatal mortality rates for Black women were excessive compared to White women at every age studied, but finding lower neonatal mortality rates for Black teenagers contradicts the assumed socioeconomic

Table 3: Comparing neonatal mortality rates (number of deaths per 1000 live births) as a function of age for Black and White mothers.(21)

Mother’s Age	Neonatal mortality (Black Babies)	Neonatal mortality (White Babies)	Rate ratio (Black/White)
15	18.5	12.0	1.54
16	16.8	13.8	1.22
17	14.3	9.9	1.44
18	14.3	8.7	1.64
19	13.3	7.4	1.79
20-23	12.7	7.3	1.74
24-26	16.5	6.1	2.68
27-29	15.0	6.8	2.19
30-34	15.3	8.1	1.88
Over 34	14.3	7.2	1.97

advantage of older mothers of all races. Weathering of Black women’s bodies may cause poorer birth outcomes due to the accumulation of toxic psychological stress from enduring racism; whereas teenagers, being younger, have accumulated less allostatic load throughout their life course (20, 21).

In the United States, societal and environmental determinants, especially experiences of racism and discrimination, are more significant determinants of maternal outcomes for Black women than biological factors (26). Further, the disproportionate burden of allostatic load for Black women frames the risk period for adverse maternal outcomes as stemming from before pregnancy and culminated over their life course. This illustrates the conditions experienced as a Black woman living in the United States

actively jeopardizes maternal outcomes (20). The state of maternal healthcare of Black women is an urgent and nuanced public health crisis, which mandates social determinants of health analysis. Conceptually, weathering identifies a physiological response to social inequities experienced by Black mothers, on top of the challenges from insurance and racial bias in the healthcare system.

Insurance access

Health insurance coverage for Black women is a major issue when it comes to maternal care. Black women are less likely to be insured than other women in the United States (22). Indeed, in 2018, 13.7% of Black women were uninsured, compared to 8% of White women (22). Not being insured increases the risk of not receiving preventive and basic medical treatments (23). The



absence of suitable medical services during pregnancy is associated with higher child mortality (24).

On average, Black women in the United States earn approximately \$22,000 less per year than White men (24). Therefore, paying for expensive health care charges is a complex challenge, and reduces the household funding available for other basic needs such as food, housing and education (24). Furthermore, paying high fees for a chronic disease or reimbursing a heavy medical debt can cause mental distress, poverty, and impair quality of life (23). According to Attanasio and Kozhimannil, uninsured patients also felt more discrimination and received poorer treatment compared to insured patients (25).

Black women are more likely to be covered by public insurance than other Americans. The proportion of Black women covered by Medicaid (61.5%) is approximately two times higher than White women (37.2%) (25). This difference could be explained by the fact that racialized people often work for companies not providing private insurance (23). These low paying jobs pay too much to qualify for Medicare but pay too little for employees to be able to afford private insurance policies (26, 27).

A recent 2013 survey titled *Listening to Mothers III* has provided an up-to-date

snapshot of the difficulty of access to private insurance that Black mothers face (25). Of the 368 Black women surveyed, only 33.7% of Black mothers rely on private insurance as the main source of payment for maternity care, compared to 59.7% of White mothers as outlined in Figure 3 (25). According to the CDC in 2015, although some mothers had access to private insurance before pregnancy, most eventually transitioned to Medicaid at delivery (28). Although not specific to Black mothers, the authors of this report suggested that the reason for this observed pattern could be due to the lack of coverage for maternity services, for prenatal care or for hospital delivery for dependents (28). Furthermore, the authors noted that the other reason for the aforementioned transition was due to the cost or difficulty of purchasing coverage for additional services for existing private insurance plans. For women with maternity services through private plans, high deductibles and out-of-pocket costs presented financial barriers and contributed to the transition to Medicaid. Interestingly, among a small population of mothers (1.1%) who retained private insurance before and during delivery, Black mothers are more likely to report having private insurance coverage than White mothers (28). However, data on private insurance coverage and services offered for post-partum complications are still lacking.

Since the establishment of the Affordable Care Act (ACA), access to Medicaid has

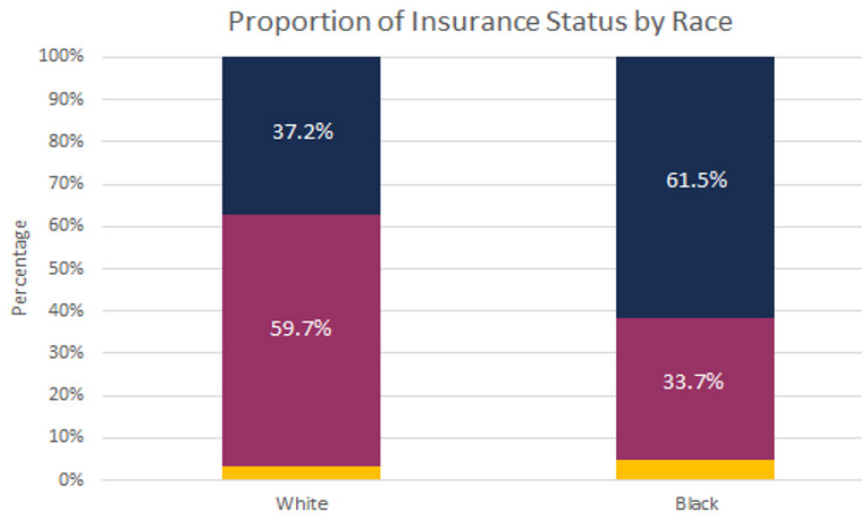


Figure 3: Primary source of payment for maternity care by race.(25)

been extended to pregnant women (29). This program is now covering the fees of prenatal care and delivery for low income women (29). Relative to the rest of the population, Black women rely heavily on the public insurance. 21.1 % of Medicaid patients are Black women, while this group represents 13.0 % of the United States population (29). A study conducted by the Medicaid and CHIP Payment and Access Commission (MACPAC) concluded that women covered by Medicaid were receiving inadequate prenatal care in a higher proportion (29). Indeed, women covered by Medicaid were more likely to have less than nine prenatal care visits and to start prenatal care after the first trimester (29). Therefore, women covered by public insurance had a higher incidence of preterm births and low birthweight infants compared to privately insured women (29). Critically, the Institute of Medicine claims

that insurance status, more than any other factor, determines the timeliness and quality of healthcare (30, 31).

### Discrimination of Minorities by Health Care Providers

The burden of ethnic and racial discrimination within the US healthcare system has prominent effects on Black women, who must face the compounded consequences of gender and racial discrimination. Although multiple factors contribute to these maternal health disparities, a recent nationwide study of hospital deliveries found that hospitals serving higher proportions of Black patients also had the highest rates of severe maternal mortality (32). Even after adjusting for sociodemographic characteristics, clinical factors, and hospital characteristics, Black women delivering at hospitals that serve many Black patients

Table 4: Comparing indicators for implicit bias among US physicians against Black and White mothers.(34,35)

	Black Mothers	White Mothers
Discrimination when going to a doctor or clinic. <sup>34</sup>	22%	17%
Avoiding health care for fear of discrimination. <sup>34</sup>	24%	7%
Treated poorly due to race, ethnicity, cultural background, or language. <sup>35</sup>	21%	8%

had the highest risk, while White women delivering at hospitals that serve few Black patients had the lowest risk (32). Hospitals serving primarily Black patients also had higher rates of maternal complications as they performed worse on 12 of 15 birth outcomes compared to White-serving hospitals (33). This evidence adds to a growing body of literature suggesting the hospitals serving Black and minority communities provide lower quality of care. There is pervasive evidence in recent studies suggesting implicit racial bias towards coloured patients among physicians, and can be a potential explanation for the lower quality of care received by Black mothers (see Table 4, 34). For example, a study by Hall et al. (2015) found that 22% of Black women reported discrimination when going to a doctor or clinic (34). This can lead to Black women avoiding health care entirely, as 24% of Black women avoided seeking health care out of concern they would be discriminated against, contrasting sharply with the 7% of White women (34). The Listening to Mothers III Survey found that when answering the question, “During your recent hospital stay when you had

your baby, how often were you treated poorly because of your race, ethnicity, cultural background, or language?”, Black mothers responded “sometimes”, “usually” or “always,” 21% of the time, compared to 8% for White mothers (35).

While there is evidence that explicit bias does still exist in health care it is important to note that these attitudes or beliefs are often subconscious and can occur despite good intentions (36). This can be a particular struggle for health care providers when they are under time pressure, as they can activate and respond to biased beliefs without awareness (36). Implicit biases are a persistent problem that represent “overlearned cultural associations” that are difficult to re-program (36). White physicians have been shown to display strong implicit preferences for White patients over Black patients, despite seeing themselves as unbiased (36). In one study 72 physicians reported having no explicit biased attitudes against Black patients relative to White ones. Yet, the implicit attitudes of physicians tended to be more negative toward Black patients, and they exhibited stronger stereotypes of Black

patients as being uncooperative (36). Biases are systematic complex beliefs and they go beyond love-hate polarities between groups (36). Biases have the power to adversely affect medical decision-making and clinical interactions which can lead to systematic discrimination in health care and subsequent disparities in health outcomes (36). Racial biases can significantly alter treatment decisions made by physicians and therefore, patient needs are potentially less well matched (37). A 1995 study conducted in California found that Black women were 24% more likely to have a caesarean delivery than White women, even after accounting for insurance, personal, community, and medical characteristics, suggesting inappropriate impacts on medical decision making (38).

Furthermore, patients may respond to bias by feeling mistrust for their healthcare provider; this can discourage individuals from seeking care, decrease their responsiveness, and ultimately reduce adherence to medical regimes (36). Distrust of the healthcare system remains understudied in the obstetric context, but evidence in other healthcare settings shows that distrust of the healthcare system is associated with increased racial discrimination (39). This opens the door to a vicious cycle between racial discrimination and bias by the provider.

## Interventions and Future Steps

Systemic inequality requires diverse collaboration at individual, community, and national levels of intervention. Effective solutions will result from the interaction of healthcare, economics, politics, and education systems to tackle both the upstream and downstream consequences of racial inequality in the American healthcare system. While there are limited opportunities to directly minimize the intergenerational health consequences highlighted by the weathering hypothesis, policy changes and interventions addressing the social determinants of health that lead to these health inequalities can hopefully decrease their detrimental effect over time. Targeted interventions that increase insurance access and decrease healthcare provider bias are possible mechanisms through which long-term systemic change can begin.

## Interventions to Address Insurance Access Inequity

Public policies could be implemented to reduce inequalities across America. To reduce the gap between Black women and the rest of the population, the public insurance program should focus on accessibility for marginalized population segments. Indeed, too many Black women do not have access to adequate prenatal care, contraception or abortion (24). Many studies found that access to Medicaid reduces disabilities, hospitalizations, and infant mortality, and



increases salary in the long-term (40). In 2013, the Affordable Care Act (ACA) was implemented by the Obama administration. The objective of this legislation was to reduce the number of Americans without health insurance. Some preliminary studies have looked at the short-term consequences of this law and found a reduction in minorities without insurance (8). More studies need to be done to determine the long-term consequences of the ACA. To address the lack of private insurance coverage among Black mothers, it is important for policy-makers to be aware of the chronic conditions that many Black women and mothers face. Thus, it is imperative to provide Black mothers with more access to non-hospital facilities with continuity of care instead of acute care centres (Emergency rooms, personal physicians, Health Maintenance Organizations, etc.) through public insurance schemes (41). Furthermore, regulations would be necessary to reduce premium costs and encourage businesses to provide flexible and personalized private insurance options. It is imperative to perform nationwide, specific surveys and studies to visualize coverage trends in recent years and assess how recent policies affect coverage of private insurance for Black women.

### Interventions to Address Healthcare Provider Bias

One important potential solution for decreasing experiences of racial bias in health care would be to enhance the

diversity of the healthcare workforce. While Black people make-up 13% of the population, only 4% of American physicians are Black (43). Older studies (from the 1990s) found that patients are more satisfied with their care when they are treated by a physician of their same race/ethnicity (44). Further, when compared to White physicians, Black physicians are also more likely to serve medically neglected populations, increase access to health care for Black patients, and achieve higher levels of patient trust and satisfaction (43). There is work to be done on this front as well, as minority health care providers also frequently face discrimination at work (36).

The development and implementation of training programs for healthcare providers offers an intervention strategy that can reduce healthcare disparities caused by racial biases. Cross-cultural education programs should be enforced to enhance health professional's awareness of how culture and social factors influence healthcare, while learning how to implement the knowledge in a healthcare mediated context(45). In particular, public policies and medical practices should incentivize providing patient-centred care that highlights the unique needs of Black mothers (34). Programs such as cultural competency training are important to help health care providers acknowledge and compensate for their implicit biases. Hospitals, clinics, and other institutions could adopt policies

on requirements for this training as well as provider requirements for health plans (25). Policies must emphasize efforts to eliminate cultural biases and discrimination in medical practice and medical education, increase provider diversity in maternity care, and hold providers and hospitals accountable if unbiased, equitable, and high-quality care is not provided.

### Alternative Models of Care to Improve Maternal Outcomes

Community-based doulas and midwives present a model of care for Black mothers that can be effectively integrated into the medical setting. Continuous care throughout childbirth by doulas or midwives has been shown to improve maternal and infant outcomes (46). A 2013 study by Gruber et al. found that pregnant mothers matched with a doula experienced improved birth outcomes. In particular, mothers who received communication and encouragement from a certified doula were four times less likely to give birth to a low birth weight baby, and two times less likely to experience a birth complication affecting themselves or their baby, compared to mothers without doula assistance (47). According to the Listening to Mothers in California survey, among mothers of different races, Black mothers showed the highest interest in receiving future care from doulas and midwives (48). For example, the San Francisco Department of Public Health implemented a doula program for pregnant Black and

Pacific Islander women from low income backgrounds, in an effort to build a community where these women have access to support and a more satisfying birth experience (49). This program is integrated into the maternity care continuum and diversifies the birth provider workforce by fostering relationships with more traditional providers such as physicians and hospitals (49). Expansion of similar initiatives across the state level throughout the US presents a potential course of action to improve maternal outcomes for Black mothers, but further research in this field is necessary.

### Limitations

It is important to recognize that there are limitations to the data and methods used in this case study. Firstly, the data analyzed is not comprehensive; due to differences between hospitals, regions, and states, there may be gaps in this data. Secondly, the conclusions made may not reflect the lived experiences of all Black American mothers, as the majority of the data was gathered at a local level and extrapolated to hypothesize national realities. Thirdly, the use of White mothers as the standard of comparison may serve to perpetuate the structural racism that is harmful to Black mothers in American society. Further, White mothers in America do not have the best maternal outcomes compared to those of other OECD countries and therefore may not be the ideal comparison. Finally, one must acknowledge

the lack of representation in research on this topic as the majority of authors cited in this paper are Caucasian. Future research should aim to empower Black voices and research conducted by Black Americans.

## Conclusion

Disparities in maternal outcomes for Black mothers are only one example of the many poor health outcomes for Black people in the United States. Thus, this case study provides one possible starting place from which to investigate the racial asymmetries which plague the US healthcare system. The United States has failed to provide equitable, reasonable care for its Black mothers. This public health failure mandates improved research of racialized access to quality insurance, discrimination in US healthcare, and the disproportionate burden of poor outcomes for Black women. Our analysis of Black maternal health in the US has been grounded in the historical roots of institutional racism in America. Black women's disproportionate accumulation of allostatic load, access to quality insurance, and racial discrimination in the US healthcare system have been drawn upon to begin to explain why maternal mortality rates for Black mothers are four times higher than that of White mothers.

Institutional racism is embedded in the US healthcare system and it is cutting the lives of US Black mothers unjustifiably short. Unfortunately, suboptimal maternal outcomes

for Black women serve as a poignant example of the systematic harm enacted on US Black women for generations. Healthcare first must "do no harm" under the Hippocratic Oath. The United States' failure to Black mothers negates this obligation: racial inequities in maternal care are fundamentally harming Black American mothers. Only systematic shifts – such as awareness, access, and involvement of Black voices into healthcare policy decisions – can combat the systematic roots of poor maternal health for Black women.

## Acknowledgments

We would like to thank Dr. Madhukar Pai, Sophie Huddart, and Lena Faust of the McGill Global Health Program for their guidance and leadership. We would also like to thank Dr. Monica McLemore from the University of California San Francisco for providing consultation and expertise on our case study.

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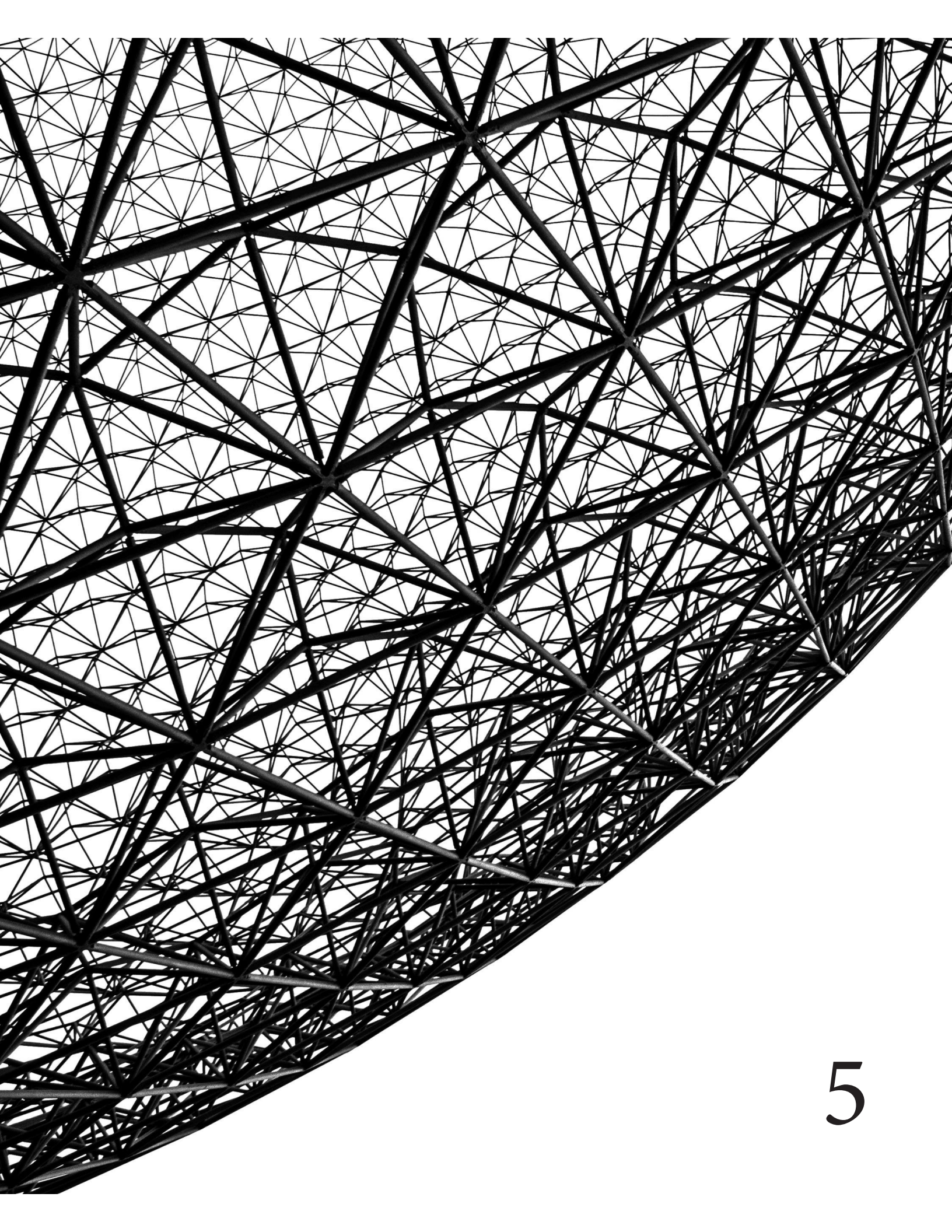
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# The Global Gag Rule: The Impact of U.S. Funding Restrictions on Foreign NGOs' Delivery of Comprehensive Reproductive Services

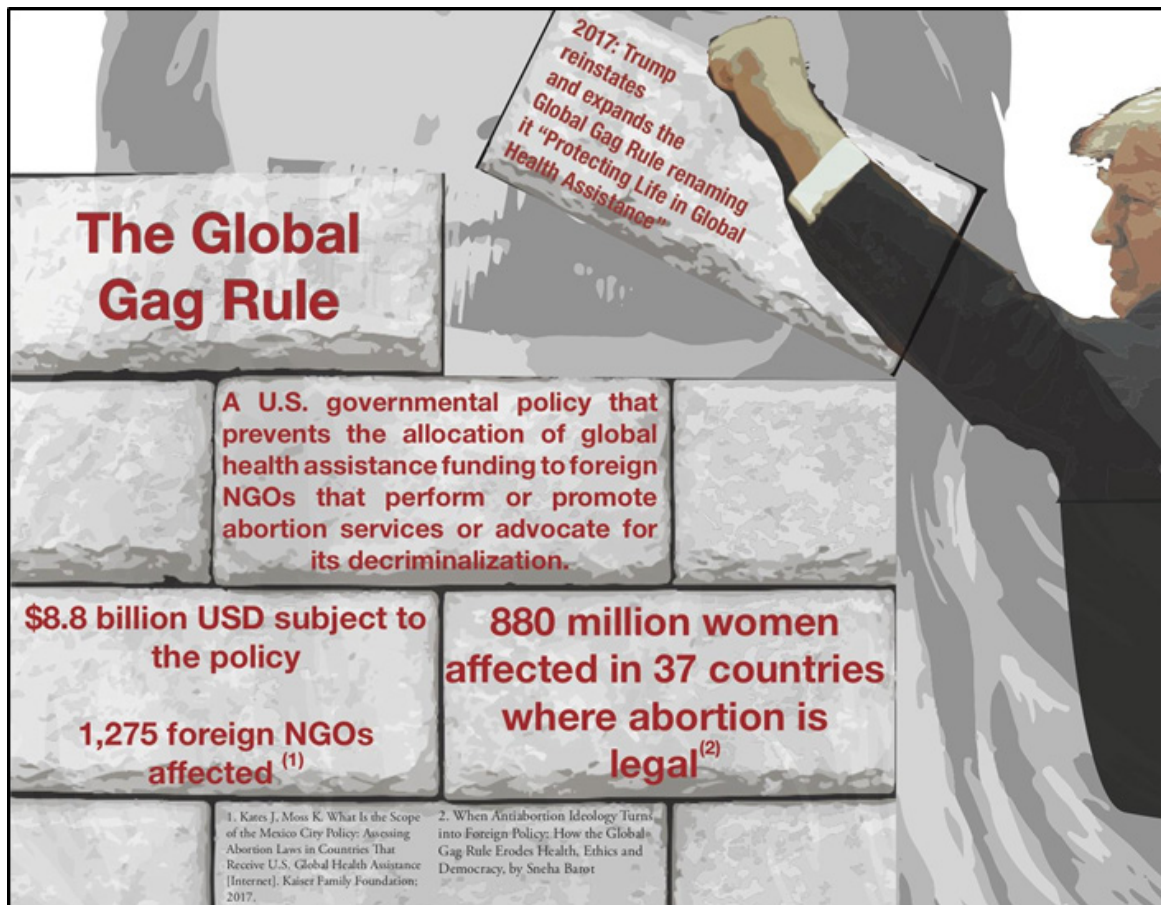
Sandy Shergill, Bowen Lan, Camille Zeitouni, Julia Biris, Salome Henry, Lily Yang, Rebecca Wan

## ABSTRACT

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The Mexico City Policy, also known as the Global Gag Rule, is a U.S. policy that requires foreign non-governmental organizations (NGOs) receiving U.S. global health funding to certify that they will not perform or actively promote abortion as a method of family planning. In 2017, President Donald Trump expanded the policy's reach to include all global health assistance funding from U.S. agencies and departments. It is estimated that 1,275 foreign NGOs and US\$8.8 billion in global health funding are subject to Trump's expanded policy. Globally, an additional 2.2 million abortions, including 2.1 million unsafe abortions, are estimated to occur from 2017 to 2020 under President Trump's administration. The Global Gag Rule undermines local sovereignty and jurisdiction over reproductive health law in countries that require these funds to operate and provide comprehensive reproductive services. This case study will highlight the effects of this policy by evaluating its quantitative and qualitative impacts and discussing the future implications for countries impacted by the policy. Results of this report demonstrate the policy's failures in both achieving its own goals as well as international aims to improve global health and women's rights among others.

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## Background & Motivation for the Policy

The Mexico City Policy is a U.S. governmental policy that prevents the allocation of U.S federal funds to foreign NGOs that perform or promote abortion services or advocate for its decriminalization. President Ronald Reagan first introduced the Mexico City Policy in 1984 during the 2nd International Conference on Population in Mexico City. Prior to this policy, the Helms Amendment forbade foreign NGOs from offering and promoting abortion using US funds (1). However, after implementation of the

Mexico City Policy, NGOs receiving US global family planning assistance were no longer permitted to offer or promote abortion services, even if they were using funds from other sources. Since the initial implementation, the policy has been rescinded during every Democratic term and reinstated in every Republican term (1). Yet, even when the Mexico City Policy is rescinded, the Helms Amendment still stands (2).

On January 23rd 2017, President Donald Trump reinstated and expanded the Mexico City Policy, renaming it "Protecting Life in

Global Health Assistance.” Previously, the policy applied to aid from the department of family planning assistance totaling around \$575 million (3). Trump’s extended policy now includes almost all bilateral global health assistance provided by all US agencies and departments, notably the US Agency for International Development (USAID), the Department of State, and the Department of Defense (DoD). Funding for maternal and child health, nutrition, HIV & malaria (under the President’s Malaria Initiative and President’s Emergency Plan for AIDS Relief), tuberculosis, neglected tropical diseases and global health security are newly affected. The implications of this policy expansion are far-reaching; it is estimated to affect approximately \$8.8 billion in global health aid (4). In March of 2019, Secretary of State Mike Pompeo extended “Protecting Life in Global Health Assistance” yet further, prohibiting NGOs receiving US funding from providing funds to any of their partner NGOs that perform or actively promote abortion as a method of family planning (3).

The Mexico City Policy and “Protecting Life in Global Health Assistance” are commonly referred to as the Global Gag Rule (GGR) in the literature. We will be using this term henceforth. This name for the policy reflects how the policy “gags” healthcare providers’ ability to provide comprehensive reproductive services and comply with the United Nations resolution of Sexual and Reproductive Rights of women.

## Rights to Sexual and Reproductive Health

The history of American domestic reproductive health reform reflects the strong partisan divide on the issue of reproductive health care and abortion. The *Roe v. Wade* Supreme Court ruling in 1973 upheld a woman’s right to abortion as a constitutional right, thereby overturning state-specific laws criminalizing and restricting access to abortion services. A series of subsequent appeals and policy changes have further limited access to reproductive services for American women. The GGR is a clear example of domestic political values seeping into foreign aid policy, as well as the politicization of global health matters. This report will analyze the global health impacts of the GGR and offer a critical perspective discussing the policy’s failure to actually “protect life”. Throughout this case study, we will seek to understand how the GGR’s suspension of funding under President Donald Trump (January 23, 2017 to present) impacts the number of global organizations able to offer comprehensive reproductive services, including abortions, compared to the funding granted under Democratic Party presidents.

## Goals of the Policy

The goal of the GGR is to prevent US taxpayer dollars from being used to perform or promote abortion, upholding pro-life conservative political values with the intent of reducing abortions. Using fiscal pressure, this effectively impedes an NGOs’ ability to provide and promote abortion services (1).

As such, the GGR requires that foreign NGOs accepting US funding certify that they will not “perform, actively promote or lobby for abortion as a method of family planning”; this clause includes using funds from any source towards this action. Organizations will thus only receive US global family planning and health assistance funding if these conditions are met (3).

## GGR Key Details

### Specific Policy Regulations

Foreign NGOs and agencies must comply with the updated USAID regulations in order to receive most forms of global health assistance and/or family planning funding assistance from the US. Foreign NGOs and agencies must not: 1. perform abortions, 2. actively promote abortions as a method of family planning and 3. fund partner organizations in violation of 1 and 2. Here, actively promoting abortions includes operating family planning counseling services about the availability of abortions, encouraging women to consider abortions, campaigning the benefits of abortions, or lobbying a foreign government to legalize abortions (5).

### Scale of Intervention

The GGR has widespread international effects seen mostly in low income countries, most notably in Sub-Saharan Africa. With the US as one of the largest foreign aid donors (6), foreign NGOs and agencies who rely on receiving funds

to carry out global health assistance are directly and dramatically affected. Many of these affected NGOs are large scale organizations that play a significant role domestically in promoting global health. Limitations in funding due to this policy result in severe adverse effects that impact hundreds of millions of people globally (7). Two of the largest international family planning agencies that have been affected by the GGR are the International Planned Parenthood Federation (IPPF) and Marie Stopes International (MSI). USAID is one of the largest bilateral agencies affected; it provides global health assistance to 64 countries, 37 of which have legalized abortion. Due to the restrictive measures of the GGR, legal abortion services in these 37 countries can no longer be provided by the NGOs that receive US funding under the GGR(8).

## Impact

### Rates of Abortions:

One of the first studies assessing the impact of the GGR was conducted in Sub-Saharan Africa in 2011. As indicated, “the induced abortion rate in Sub-Saharan Africa rose in high-exposure countries relative to low-exposure countries when the Mexico City Policy was reintroduced”(9). High-exposure countries are defined as countries who received a higher amount of financial aid from the United States for family planning and reproductive health services. More recently, research by Brooks et al. in



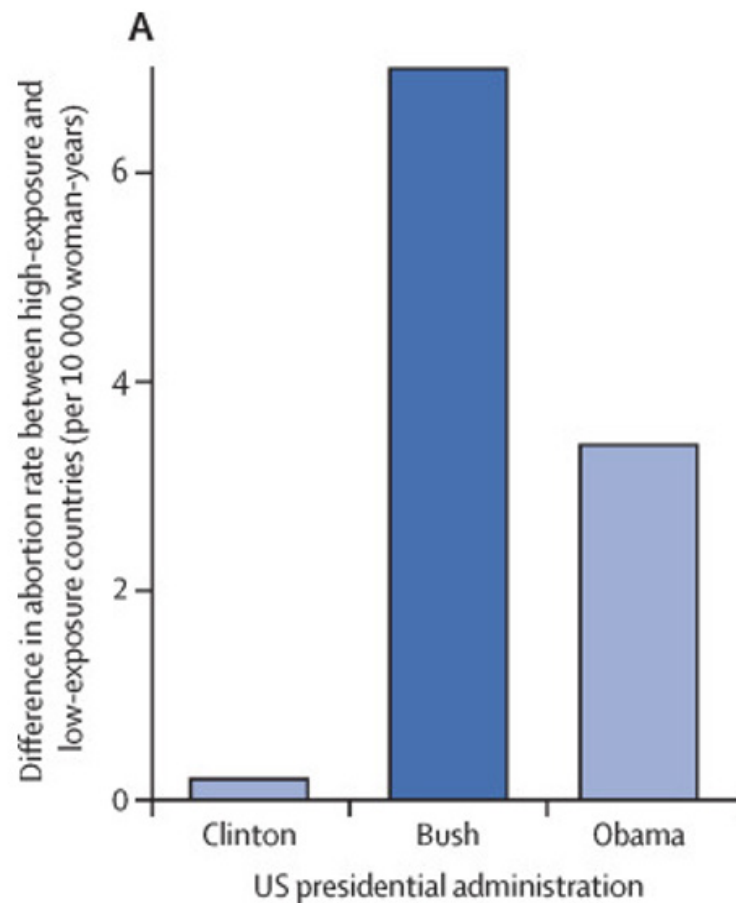


Figure 1: Difference in abortion rates between high-exposure and low-exposure countries between different US presidential administrations Note: Reprinted from USA aid policy and induced abortion in sub-Saharan Africa: an analysis of the Mexico City Policy, by Nina Brooks et al (11).

2019, found that there was a 40% increase in abortions and a 14% reduction in use of contraceptives among women living in countries most affected by the GGR (high-exposure countries) during periods when the policy was enacted (during the Bush administration (2001-2008)), compared to when the GGR was not in effect with the Clinton (1995-2000) and Obama (2009-2014) administrations) (3). Furthermore, data from the same study, outlined in Figure 1, shows a clear difference between administrations for the abortion rates

between countries most affected by the GGR (high-exposure countries) and countries least affected by the policy (low-exposure countries). It is apparent that under the Bush administration, the difference in abortion rates between high and low-exposure countries is much greater than the difference during the Clinton and Obama administrations (10). Thus, the data suggests a direct impact of the GGR on increasing abortion rates and that the GGR has failed to achieve its goal to reduce abortions. Due to the recency of the

implementation of Trump's expanded GGR, data has on the policy's impacts on abortion rates is yet to be available. However, it can be predicted that if the historical trend follows, Trump's extended policy will result in a significant increase in rates of abortion. In fact, it is estimated that from 2017 to 2020, under the Trump administration, there will be an additional 2.2 million abortions, including 2.1 million unsafe abortions, internationally (10).

#### Impact on NGOs:

In order to project future impacts of the expanded GGR under the Trump administration, a study by Moss and Kates (2017) has estimated the number of NGOs and amount of related funding that would have been impacted if Trump's expanded policy had been in effect between 2013 and 2015. 1,275 foreign NGOs (639 as prime recipients of U.S. global health assistance and 658 as sub-recipients) and approximately \$2.2 billion in funding directed to these NGOs would have been subject to the policy. In addition, 469 U.S.-based NGOs receiving U.S. global health assistance would have been required to ensure that their foreign NGO sub-recipients were in compliance. Among prime recipients alone, 92% of the affected foreign NGOs and 88% of their funding would not have been impacted prior to President Trump's expansion of the policy. Overall, the study claims that, although it may be too soon to estimate the actual

impacts of the expanded GGR, a significant number of NGOs across the globe will be newly affected by the expanded policy due to its extended reach on all major global health programs. However, it is also important to note that many NGOs chose not to accept US aid under these provisions and offset the loss of funding by acquiring aid elsewhere (8).

More recently, a report conducted by amfAR, the Foundation for AIDS Research, demonstrated in early 2019 that a third of the implementing partners previously receiving funding from the President's Emergency Plan for AIDS Relief had to change their operational structure to comply with Trump's expanded policy. These changes included decreased provisions to recipient populations of non-abortion related information related to HIV and contraception (12).

#### Impacts on Maternal Mortality:

The World Health Organization has stated that a key step in reducing maternal deaths is for states to ensure access to comprehensive reproductive health services, including abortions (13). Research has stated that unsafe abortions are a preventable cause of maternal mortality. An observed reduction in organizations offering women's health services internationally along with a global increase in abortion rates under the GGR indicates that women are forced

to choose unsafe abortions to terminate pregnancies as an emergency family planning option (14).

Prior evidence indicates that more restrictive laws on abortions have been associated with higher proportions of women seeking unsafe abortions. While maternal mortality has been decreasing overall, Doctors Without Borders reported that unsafe abortions still account for 1 in every 12 maternal deaths globally. These deaths attributed to unsafe abortions are associated with infections, severe bleeding, and obstructed labour. Unsafe abortions account for injuries and disabilities in approximately 7 million women and for 22,000 reported deaths annually (15).

#### Long Term Health Impacts of GGR:

Key stakeholders, including leaders of organizations receiving US global health funding, are unclear about the scope of applicability of the GGR. Many were aware that the funding impacted by the policy had expanded, but they were unaware that the policy does not restrict provision of post-abortion care and other reproductive health services. The policy is often misinterpreted as applying to all reproductive and maternal health care services. Some sub-recipients reported that the implementation of the policy was never explained to them (16).

Consequently, a “chilling effect” has been associated with the GGR, meaning that NGOs and health care providers restrict their activities beyond what is required by the policy in order to protect themselves from the reprimands of non-compliance. In order to be cautious, health providers refused to deliver health services that are permissible under the policy. The consequences of this include reductions in the supply of contraceptives, removal of sexual and reproductive health care information, and even closure of clinics. The confusion and stigma surrounding the GGR leads to organizations intentionally avoiding being associated with any abortion services, even those permitted by the policy (17).

Furthermore, there is a significant burden on non-U.S. donors: without replacement funding from other sources, NGOs are forced to shut down many maternal healthcare clinics. Oftentimes, this is also associated with the closure of comprehensive health clinics that serve as the only source of healthcare in remote communities (16,17). Interviews with local providers and NGOs in South Africa, Kenya, Nepal and Nigeria reveal the extensive repercussions of the new policy (18). Access to abortion and reproductive services are becoming increasingly inaccessible.

Additionally, contraceptive services, antenatal care, HIV testing and treatment,

and screening for cervical, breast, and prostate cancers are affected (7). The Lancet report highlights the importance of “coupling” or integrating certain interventions (e.g. reproductive planning and HIV) in under-resourced locations (7). Ultimately, the closing of clinics due to the reinstated GGR reveals the key role that these coupled services play in regions where risk factors are highly shared, and how the continued funding of NGOs is essential for general healthcare provision in these communities. For example, a case of the GGR’s widespread impact on funding for NGOs can be seen in Ethiopia. The US Centers for Disease Control and Prevention (CDC) withdrew a five-year grant that was awarded in 2017 (an average US\$2 million per year) as a direct result of the Family Guidance Association of Ethiopia’s (FGAE) noncompliance with the GGR. Without short-term replacement funding, 10 CDC-supported, confidential, sex worker-friendly clinics and 21 additional clinics that provide integrated HIV/AIDS services would be forced to close (17).

### Discussion on the Failures of the GGR: Failure to Decrease Abortion Rates and Maternal Mortality

The GGR was introduced as a means to limit global abortion rates; however, analyses on the policy have demonstrated the opposite effect. Brooks et al. (2019), found a 40% increase in the rates of abortion in countries with reduced services

due to the GGR between 2000-2008, when the policy was in effect, compared to countries with minimal service disruption due to the GGR during the same time period or when the policy was not in effect (11). Their findings attributed this failure primarily to a reduced access to modern contraceptives (10).

The chilling effect also created uncertainty concerning which services NGOs were permitted to perform. Thus, many NGO-operated clinics reduced their maternal healthcare services to avoid losing US funding. Additionally, the reduced access to contraceptive supplies in a community is associated with an increase in unintended pregnancies. When legal abortion is not available, pregnant women often resort to unsafe illegal abortion, which has been shown to result in an increase in maternal mortality (7).

### The Policy Lacked Participant Voice

A significant failure of the GGR was the lack of respect and inclusion of participant voices from the organizations affected by the policy. Research shows that independent country representatives oppose the implementation of the GGR. One interviewee stated, “Why a [low income] country like us decided that we need a provision that decriminalizes abortion in certain circumstances [is] because we know that it’s important...safe abortion important. ...Safe abortion will save



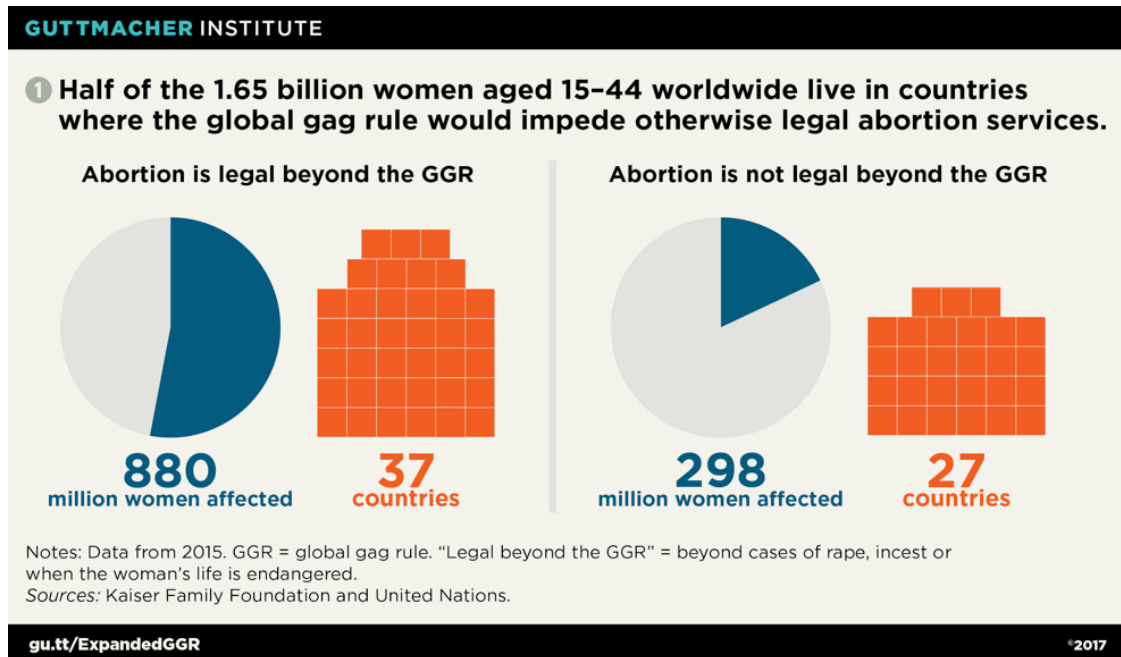


Figure 2: Effect of GGR on countries and amount of women affected in countries where abortion is legal beyond the GGR vs where abortion is not legal beyond GGR  
Note: Reprinted from When Antiabortion Ideology Turns into Foreign Policy: How the Global Gag Rule Erodes Health, Ethics and Democracy, by Sneha Barot (20).

abortion will save lives.” (19). The GGR disrespected the political stances of many countries by forcibly restricting the accessibility of and discussion surrounding abortion. Consequently, it violates human rights by infringing on national sovereignty and priorities (9). Additionally, the policy neither made use of local knowledge nor was it culturally appropriate or adapted to the specific cultural contexts of each region it affects.

Furthermore, for many nations, US funding is essential to the operation of foreign NGOs that provide essential reproductive health services beyond just abortion. Due to the US’s global political power and influence as the largest foreign aid donor,

it has the capacity to implement the GGR without consultations with international partners(6). In an American Governmental review conducted on the GGR’s implications within 6 months of instatement under the Trump administration, only 31 of approximately 1,275 organizations that lost direct funding were included in the data collection. Therefore, there is clearly a disproportionate representation of the magnitude of stakeholders affected by the policy and a lack of stakeholder engagement in shaping the policy or deciding whether it should be implemented in the first place (9).

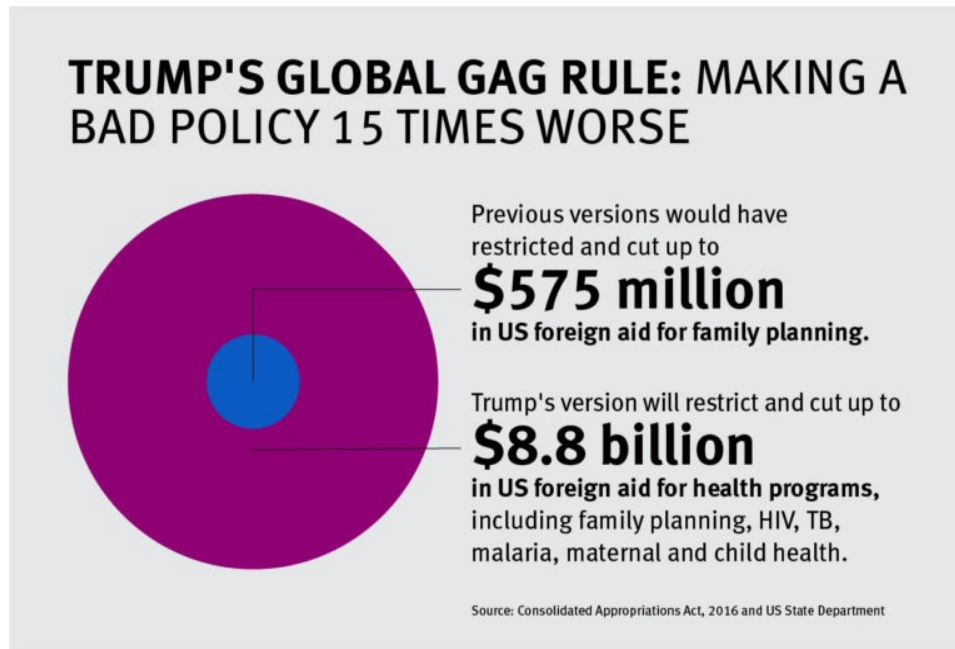


Figure 3: Funding cuts due to Trump's extended version of the Global Gag Rule. Note: Reprinted from Fight the Global Gag Rule, by International Women's Health Coalition (22).

### The Implications of Foreign Policy: From Local Governance to Human Rights

The implementation of the GGR seriously undermines local sovereignty and jurisdiction over reproductive health law. It represents a more profound, yet subtle continuation of colonialism in foreign policy. The introduction of the GGR and its restrictions of organizational funding pose tremendous legal and administrative issues in countries with pre-existing abortion laws. As shown in Figure 2, in 37 of the countries subjected to the restrictions on organizational funding, abortion is legal for women in specific cases, such as in the case of rape or when there are detrimental health risks for the mother (7). The vast variety of laws surrounding abortion and reproductive health only serve to complicate the applicability and

feasibility of GGR implementation. This policy demonstrates the delicate relationship between foreign policy administration and legal pluralism.

The GGR may also be viewed as a serious threat to human rights. It detracts significantly from Sustainable Development Goal 3: "to achieve gender equality and empowerment of all women and girls that includes a target to achieve universal access to sexual and reproductive health and rights" (21). In failing to meet this goal, other outcomes of women's health have also been affected, including maternal mortality due to unsafe abortions.

### Effects on United States Funding

The GGR is a policy that has an enormous impact on financing for global health assistance, as it applies to \$8.8

billion in global health funding from the US government (8).

Currently, the US government is the largest contributor of global health assistance; these funds sustain critical programs which aim to improve the health and lives of people, and healthcare systems around the world (8). The expansion of the GGR under the Trump administration applies to all global health assistance funding from U.S agencies and departments. Before, only the department of family planning was affected by the GGR. This amounts to 15 times the amount of funding when compared to previous versions of the GGR (8). The consequences of this could derail years of progress in improving health care services and systems, particularly in low income countries (8).

MSI, an organization that provides contraception and safe abortion in various countries worldwide, estimates a funding loss of \$30 million per year due to the GGR(23). Furthermore, MSI estimates that from 2017 to 2020, the loss of funding and related discontinuation of their organization's services will result in \$400 million in direct health care costs. Besides the economic impact of the GGR, MSI also estimates that the cuts to its programs will result in 1.6 million fewer women having access to contraceptives from their trained providers, 6.5 million unintended pregnancies, and 21,700 maternal deaths (8).

These statistics reflect the impact on MSI clients alone. The IPPF estimated that it too would lose \$100 million in funding during the Trump administration's expansion of the GGR (24). The estimated consequences of these cuts in funding include 20,000 preventable maternal deaths, 4.8 million unintended pregnancies, and 1.7 million unsafe abortions according to the IPPF. Furthermore, IPPF anticipated using these funds to pay for 70 million condoms to prevent unintended pregnancies, HIV, and other STIs; 725,000 HIV tests to enable people to know their HIV status; treatment for 275,000 pregnant women living with HIV; and treatment for 525,000 STIs (9,23). IPPF states that there has been a decrease in the scale of projects, less availability of technical assistance, difficulties for small healthcare enterprises to remain in operation, and communities have experienced a significant decrease in the provision of safe, comprehensive, rights-based healthcare by IPPF (24).

MSI and IPPF are only two of the NGOs impacted by the GGR and their combined loss in funding could lead to a total of 7.5 million unwanted pregnancies and 2.5 million unsafe abortions (25). However, the overall cuts in funding and decrease in comprehensive healthcare provision globally reach an even larger scale. Reports in 2017 estimated that the total amount of global health funding subject to cuts due

to the GGR is between \$8 and \$9 billion (26). Crucial US funds to some of the most effective foreign NGOs in 60 low- and middle-income countries are impacted (27). The impact of the GGR is especially devastating considering that many NGOs provide comprehensive healthcare in areas where no other clinics or services are available (27).

Another important financial consideration is that family planning globally is currently a struggling sector in terms of funding. In 2017, funding did increase to \$1.27 billion, although it was the first increase following 2 years of declines and did not reach the peak funding level of \$1.43 billion in 2014 (23). Critically, the US provided 38% of total bilateral funding in 2017, making it the largest bilateral donor to family planning. As a result, the US GGR's regressive and extreme policy poses a major threat at a time when contraceptive healthcare funding is already at crisis levels (23).

### Future Implications

Even if overturned, the lasting impacts of the GGR will still remain. The local impact in communities forced to cancel health services and close clinics will not be immediately remedied if the policy is reversed. As well, many NGOs have been unable to continue operations due to a lack of funding and as such, the abortion services and other services they provided are no longer available.

The funding for the NGOs that remain will take time to resolve as these organizations are concerned that the next administration coming into office may have an even more extreme version of the GGR (8). Finally, this policy violates women's rights in making decisions regarding their own body.

Ending this oppressive policy will require decisive legislative action. The Global Health, Empowerment and Rights (HER) Act, was reintroduced on February 7, 2019 by family planning champions in the US House and Senate. The HER act would allow foreign NGOs receiving US funding to use non-US funds to provide medical services that are legal domestically, including safe abortion (28). The HER Act would also support freedom of speech and democratic engagement by removing the prohibition on funding for health NGOs that use their own funds to advocate for the right to legal abortion. Additionally, this act aims to nullify any existing US policy that interferes with these provisions. Therefore, this legislation would permanently repeal the expanded GGR by prohibiting future administrations from inflicting assistance restriction on foreign health care providers and preventing any future US presidents from reinstating the GGR unilaterally (29). Although this is a critical first step to halt the detrimental effects of the GGR, the bill will not be enacted until the US Congress presents the Global HER Act to a future president who is willing to sign the bill into law (29).



Therefore, it is of critical importance that both the US Congress and a future president reach consensus to support reproductive health and rights of women and girls around the world.

## Conclusion

The GGR is a global health failure that uses fiscal pressure to prevent foreign NGOs from providing and promoting abortion services, even when this is against evidence-based best clinical practices. The policy forces NGOs to apply restrictive policies that are not even applied to US citizens. Research done by many groups shows increasing abortion rates as a result of the policy, demonstrating its failure in its desired goal. Other consequences of the policy include decreased access to reproductive services and less comprehensive maternal care.

Trump's expansion of the GGR has also left a substantial funding gap for global health. Despite this significant setback, other countries, including Canada, Norway, Sweden, and Denmark, among others, have stepped up. The Liberal Canadian government, under Prime Minister Justin Trudeau, has pledged to donate \$1.4 billion CAD annually by 2023 for women's and girls' health (27). Furthermore, studies have shown that the effects of the GGR are reversible as data shows increased contraceptive use and a decrease in abortion rates when the policy is rescinded

compared to when it is in effect.

Nevertheless, cutting access to care and advocacy via the GGR results in cutting access to human rights. Case studies showing the impact of the GGR reveal that it not only cuts services, but breaks trust and relationships, thus impacting communities negatively in the long term (23). Finally, the vice-president of MSI, Marjorie Newman-Williams, stated that, "Evidence shows that by blocking funding to the world's largest NGO providers of modern contraception, unintended pregnancies and abortions go up. As a result, women and girls are less able to complete their education, have a career, or pursue their dreams for the future" (25).

## Limitations

We acknowledge our case study's limitations as some of sources contain bias and have not undergone a rigorous peer-review process. We ultimately decided to include these numbers, as we found difficulty in accessing peer-reviewed sources concerning the impacts of the GGR. We understand abortion is difficult to study. The stigma around abortions discourages women from speaking out or seeking medical care. In many countries, numerous abortions are performed in unsafe conditions without proper medical assistance because women fear for their safety if their families and communities were to find out. Even in western countries such as our own, abortions are

still debated and met with stigma. We urge our readers to continue to fight against the stigma surrounding abortion and promote women's autonomy over their own body.

### Acknowledgements

We would like to thank Dr. Angel Foster, Professor at the University of Ottawa for providing her feedback and expertise while developing and refining our case study. We also thank Dr. Madhukar Pai and Lena Faust for their guidance, feedback and support throughout the semester and in preparation of this case study.

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# Reducing Open Defecation Through Community-Led Total Sanitation in Fort Dauphin, Madagascar: A Case Study

Joannie Richer, Anne Mouillier, Sevrenne Sheppard

## ABSTRACT

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Globally, an estimated 4.5 billion people lack safe water and sanitation services. In Madagascar, open defecation is particularly commonplace, with nearly half of the population practicing it. Construction of latrines alone is often insufficient in reducing this number, as availability does not mean the latrines will be used by the community. Community-Led Total Sanitation (CLTS) is an approach which aims to reduce the prevalence of open defecation by catalyzing community action towards increasing use of latrines and other personal hygiene behaviors. This case study evaluates the hybrid-CLTS approach implemented by SEED Madagascar in Fort Dauphin, Madagascar, between 2014 and 2017. Specifically, the intervention's impact on sanitation and hygiene behavior outcomes, and health outcomes are investigated. The report concludes that this intervention is a successful example of adapting a CLTS approach to an urban context where open defecation practices are driven by a complex set of traditional and cultural beliefs. However, significant challenges must be overcome to support such an approach, including ensuring adequate stakeholder engagement, sustainable financing, and broader Water Sanitation and Hygiene (WASH) strategies. Recommendations include fostering partnerships with other organizations, integrating participatory planning approaches, and promoting sustainable sanitation entrepreneurship.

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## Introduction

Lack of access to safe water, sanitation, and hygiene (WASH), is a significant issue in many low- and middle-income countries. While improving WASH for all is one of the 17 Sustainable Development Goals (SDGs), there is still an estimated 4.5 billion people lacking safe services (1). In 2015, open

defecation was practiced by more than 892 million people worldwide. According to the WHO/UNICEF Joint Monitoring Program (JMP), open defecation (defined as defecating in fields, surface water, or other open area), is the least safe sanitation alternative (2). The practice has been linked to increased incidence of diarrheal

diseases and poor health indicators such as stunting and is thought to be a limiting factor for the achievement of other SDGs, such as ending hunger and poverty, improving gender equality, and ensuring an inclusive and quality education (3, 4).

Increasing access to latrines alone is not sufficient to reduce the incidence of diarrheal diseases and fecal exposure if usage is inadequate (5). The Community-Led Total Sanitation (CLTS) approach recognizes this limiting issue and has become increasingly popular for WASH management and improvement. Since its creation by Dr. Kamal Kar in Bangladesh, CLTS has been implemented in up to 60 countries across the south and east Asia, Latin America and Sub-Saharan Africa (6). The approach aims to facilitate community actions against open defecation by using triggering language and activities, forcing retrospection regarding hygienic behaviors, and identifying natural leaders within the community. This approach differs from other interventions by focusing on inputs of all community members rather than depending on subsidies (7). This bottom-up approach showed potential to improve sanitation, especially in contexts where multiple social and behavioral factors intervene to influence participation, compliance, and maintenance of the infrastructure (8). WaterAid, UNICEF, the World Bank, and other non-governmental organizations (NGOs) endorsed the potential of CLTS as an effective, sustainable, and empowering initiative (7).

Madagascar ranks among the worst countries in the world in terms of access to safe water and sanitation (9). Half of Madagascar's population lacks access to safe water, and only 12% have access to improved sanitation facilities (9). Unfortunately, improvement in these areas has been slow. In 2015, an estimate of 44% of the population practiced open defecation, equivalent to more than 10 million people, with an increase of 0.4% per year between 2000 and 2015 (4). In 2017, an estimated 92.5% of Malagasy (citizens of Madagascar) were using unsafe or unimproved latrines (10).

Over 33% of Malagasy live in urban settings, and an estimated 75% live in slums. In 2008, 89.6% of the population living in urban centers in Madagascar, excluding Antananarivo, used unimproved sanitation, and 15.5% practiced open defecation (11). Considering that a majority of the increasing urban population in Madagascar lives in slums, it is crucial to address the issue of sanitation with an innovative and integrated approach (12, 13). Despite being mainly implemented and assessed in rural communities, inclusive and participatory interventions such as CLTS offer important advantages for heterogeneous and complex urban areas where poor, middle- and rich-income groups may be present (14). Therefore, this case study aims to review a completed intervention, inspired by the CLTS approach, in the urban area of



Fort-Dauphin between November 2014 and April 2017. The goal is to determine whether Sustainable Environment, Education and Development (SEED) Madagascar, through the Project Malio, was effective to successfully improve health and reduce open defecation practice among permanent residents in Fort Dauphin, Madagascar.

## BACKGROUND

### The Population of Fort Dauphin, Madagascar

Madagascar is divided into regions, districts, municipalities, and fokontany. The latter can cover hamlets, neighborhoods, villages or commercial and uninhabited area, and are managed by the fokontany leader who is appointed by the district leader (15, 16).

This intervention took place in the southeastern city of Fort Dauphin in Madagascar. Fort Dauphin, also known as Tolanaro, is the capital of the region, despite being mostly inaccessible from the rest of the country (17). It is an urban municipality in the district of Tolagnaro, composed of 11 fokontany, ten of which were part of the Project Malio (18).

Antanosy people have a tumultuous history including monarchism, colonialism, and slavery. Family history is a strong determinant of the fate of individuals, and people from the Anosy region have robust beliefs regarding the importance of

respecting deceased relatives and ancestors (19). These beliefs and social norms can act as barrier to stopping open defecation. For instance, the underground is seen as sacred, and burying feces can be viewed as a profaning act. Moreover, social norms, disinformation, and the presence of various taboos and other superstitious beliefs are frequent and active contributors to the current sanitation practices (20).

### Description of the Intervention

From 2014 to 2017, hybrid-CLTS techniques were used through the Project Malio, an expansion of a small-scale project in the deprived fokontany of Ambinanikely (18). Both projects were initiated by UK-based SEED Madagascar, also known as Azafady. While the intervention included providing hardware subsidies and structured training, which formal CLTS interventions prohibit, multiple campaigns addressed to the population of Fort Dauphin aimed to influence behavioral changes through use of techniques and principles from CLTS (21, 7). The primary goals were to motivate the development of action plans specific for each community to increase access to latrines for disadvantaged families, to improve sanitation for the 14 schools, and to reduce the frequency of open-defecation practices. The entire Fort Dauphin population was directly or indirectly reached by at least one arm of the intervention. (Figure 1) (22, 23).

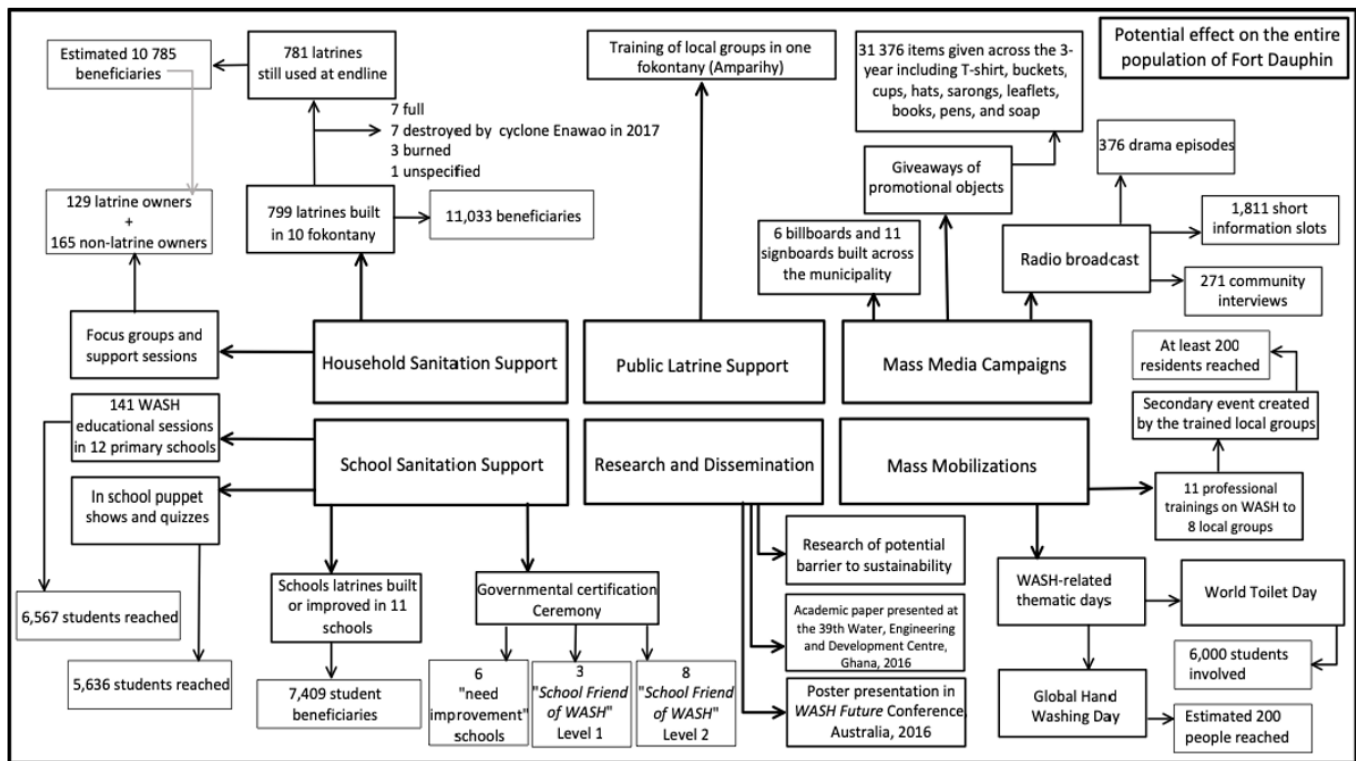


Figure 1. Flowchart of the different interventions implemented during the 3-year Hybrid-CLTS Malio project and their outcomes regarding amount of people affected, involved or targeted in Fort Dauphin (23)

Many on-site strategies were implemented simultaneously during the 3-year intervention. First, training and educational opportunities, also defined as triggering events because of the graphic content and choice of words used in these meetings (e.g., “shit calculations”) strengthen knowledge on adequate sanitation practices and latrine maintenance. Workshops mainly targeted latrine owners and stakeholders, including opinion leaders and the chief of each fokontany. Secondly, mass media campaigns and mass mobilizations helped diffuse messages about the importance of hand washing, the possibility of fecal-oral contamination, and the use of latrines. Distribution of promotional items and radio broadcasts

were the primary means of communication, in addition to various community events (e.g., Global Handwashing Day). Thirdly, the construction and improvement of household, public, and school latrines were facilitated to increase hygiene privacy, improve sanitation, and ensure safety for students and community members. Finally, school activities and certification ceremonies, as incentives for proper maintenance of latrines and related infrastructure, contributed to student and school staff engagement into the project (24). Other activities and research were conducted to improve the sustainability of the project, to ensure adequate management in the future, and to disseminate the results of the intervention.

Local groups and associations were trained through the Partnership Association Mentor (PAM) on activity design and development, on monitoring and evaluation, on planning and implementation, and on financial management (23).

### Modification to the CLTS approach

The intervention implemented by SEED Madagascar avoided many extreme aspects of the CLTS approach as proposed by the Practical Guide to Triggering Community-Led Total Sanitation (25) and went beyond fundamentals principles by helping households and schools to construct and improve latrine and hygienic facilities (26). Time constrain and urban characteristics forced the omission of some triggering activities. For instance, transect walks were not be possible for large fokontany and the lack of defined borders between each community created tensions between neighbors fokontany du to the tendency to blame others for the presence of feces in a specific spot (24). The combination of triggering activities and provision of subsidies was justified by the desire to build more robust and long-lasting latrines (24). Stakeholders involved in the planning and implementation of the Malio project estimated that providing technical and financial supports would ensure the construction of more sustainable latrines based on the possibility to reach a higher standard (24).

### Method of Monitoring Changes in Behaviours and Latrine Coverage

In order to monitor changes, several indicators were attributed to four outcomes of interest: development of community action plans, usage of household latrines, effectiveness of school sanitation programs, and adequacy of maintenance of communal latrines. For each Fokontany, monitoring was done continuously and ultimately by one of the ten monitoring committees comprised of Community Sanitation Agents. Every 3 months, new groups of beneficiaries were asked to assess and rate the adequacy of maintenance, utilization and hygiene of each other's latrines and washing station (23). Indicators for all outcomes were based on quantitative evaluations and measured whether there was changes in absolute numbers or in levels of adequacy. For instance, indicators to estimate coverage and latrine usage included: the calculation of the number of households maintaining latrine built as plan, the number of households considered open-defecation free, and the level of diarrheal disease amongst children aged under 5 years old in recipient families. Because reports of the project were not written by formal researchers, there are missing information regarding specific methods used to collect information and to determine the level of improvement. In general, data was collected from quantitative surveys at the household levels and observations reported by community mem-

bers and Sanitation Agents. Local medical centers were also involved in data collection regarding the implementation and impact of community action plans. However, accuracy was low, and data were retrieved from the final analysis. For school latrine, the Ministry of Education, Water, Sanitation and Hygiene and the regional WASH network were involved to evaluate schools and determine whether or not they qualified as School Friend of WASH. Finally, while this intervention was not specifically designed as a randomized control trial, comparison between beneficiary and non-beneficiary of latrine was available regarding diarrheal incidence and changes in hygiene behaviors.

## Impact on Health and Behavioural Outcomes

### Outcomes

As mentioned, project Malio's impact was evaluated according to four main community outcomes: the development of community action plans, access and usage of household latrines, effectiveness of school sanitation programs, and adequate maintenance of communal latrines. Presented information are retrieved from SEED Madagascar final report published in 2017. The latter contains more detailed information regarding health and behavioral indicators briefly reviewed in this Case Study (23).

## Community Action Plans

According to the final Project Malio report, the development of community action plan, as a result of this intervention, was very successful. Improvements in hygienic practices such as washing hands and using latrines were also documented, likely leading to improved overall health across the community (23). However, there are several weaknesses in the way these results are presented. For the most part, outcomes are not comparable to baseline since public health data is limited across Madagascar, there are no nationwide health surveys, and there was no baseline assessment in the communities. We also do not know how the targeted fokontany compare to others across the country. The disclosed 98% of participants who self-reported washing their hands after using the latrine and before eating, at the end line, seems artificially high and this suggest potential presence of biases (e.g., interviewer bias, social-desirability bias) (23, p.19).

## Household Latrines

An increased number of latrines combined with efforts to change perceptions of open defecation and the importance of maintaining the latrines might be related to the decreased incidence of diarrheal disease at the end of the intervention. Indeed, 49% of the households achieved Project Malio's "gold standard" on the rating scale for participatory monitoring. However, this is lower than the 75% project objective (23).



Specifically, to this indicator, the three components of the rating scale were latrine cleanliness, latrine maintenance and condition, and presence of a hand-washing station. In order to reach the highest rating, the latrine needed to have no dirt, trash or waste in and around it, have very surrounding flies and be free of bad smell. The latrine needed to have well-built roof, nothing broken and an adjusted and hermetic lid at the time of the investigation (23, p.7). The hand-washing station needed to be utilized and functional, close to the latrine, and equipped with soap. Despite being listed as an important outcome, the “number of households no longer practicing open defecation and now using improved sanitation facilities” was unknown by the end of the project (23, p. 7). This could indicate a lack of methodic monitoring and a lack of forethought on the part of the implementing and monitoring team.

### School Sanitation

The third outcome was the effectiveness of school-based interventions in sensitizing students to adequate sanitation practices. The strategies implemented to reach this outcome are depicted in Figure 1. Again based on project Malio’s final reports, the school interventions were overall successful and there have been plans to expand the outreach program to other schools in the region. The WASH program, however, cannot ensure that good hygiene practices

were maintained outside the school environment. Older students might be less sensitized than the younger school children, and maintenance of latrines and soap availability may not be consistent since these infrastructure and products are used by many people. Due to the lack of demographic data we have on Madagascar and Fort Dauphin, we do not know the proportion of children attending school, which is a major limitation in terms of the outreach of the school intervention.

### Communal Latrines

The fourth outcome is the adequate maintenance of communal latrines. In order to be considered adequate, latrines had to be operational, regularly cleaned, and in good condition. This was important to increase improved sanitation access for overcrowded households, to limit the risk of fecal contamination of water sources, and to protect the poorer and most vulnerable members of the community. Once again, the objectives set by Project Malio were largely met since maintenance and cleanliness were generally up to the standards set, which included daily wash for the entire duration of the project. However, throughout the 3-year project, public latrine technical and financial support by SEED Madagascar or peer association was done in only one fokontany (e.g., Amparihy) and belatedly introduced in another during the last months of the intervention. Agreement regarding funding

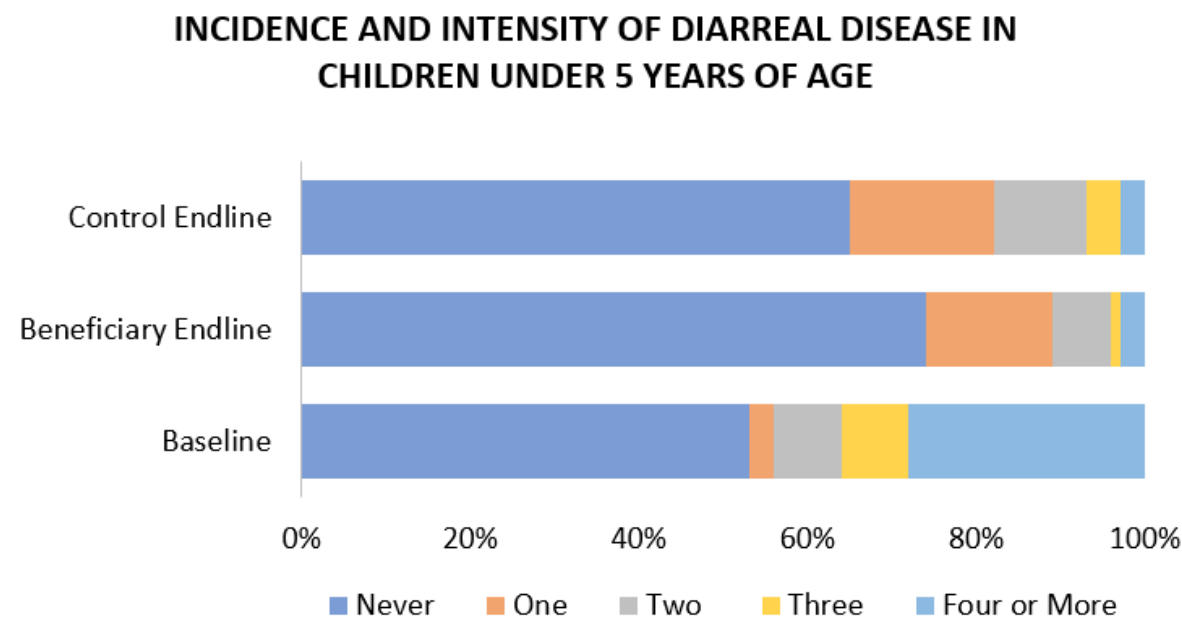


Figure 2. Yearly incidence of different frequencies of diarrheal disease in children under the age of five who were direct beneficiaries of the Malio latrine (23)

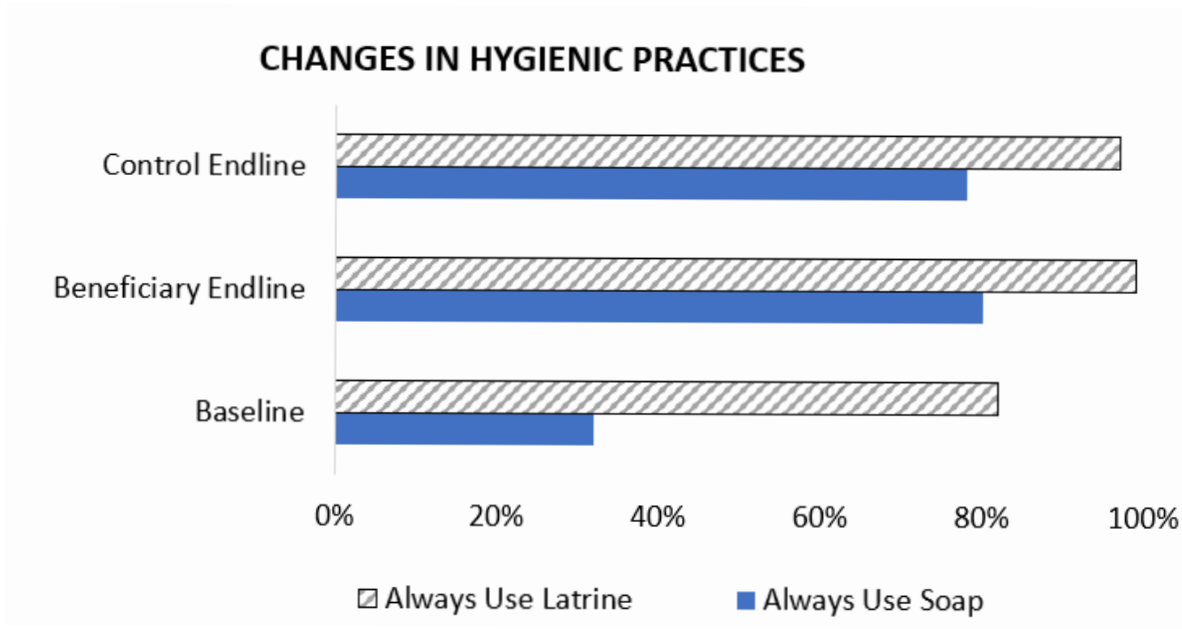


Figure 3. Percentage of the population using latrines and washing hands at baseline and endline for both latrine and non-latrine(control) beneficiaries (3)

seemed precarious and sustainability of communal latrines remains unclear.

### Self-Reported Incidence of Diarrheal Disease in Fort Dauphin

Self-reported measures of health, which comprised incidence of diarrheal disease in children under five years old and hygiene behaviors (e.g., use of latrines and soap in hand-washing), were the main indicators of the intervention's success. Evaluated with questionnaires, the self-reported changes in diarrheal incidence and hygiene behaviors were favorable to the project objectives. Based on the final report, latrine beneficiaries as well as household without latrine had reduced incidence of diarrheal diseases in children under 5 years old, and improved hygiene behaviors at the end of the 3-year intervention (Figure 2; Figure 3).

### Financial Implication

Project Malio was funded by the National Community Lottery Fund and Guernsey Overseas Aid & Development Commission (27). In February 2013, and December 2014, the National Lottery Fund gave £2,502 and £374,065 through the International Community grant programme for Project Malio (28). The £58,443 given by the Guernsey Overseas Aid & Development Commission was distributed over all 3 years of the project (29). These funds were ultimately used to build 799 household latrines and improve

17 school sanitation infrastructures, to educate students from 12 primary schools, to train eight local groups regarding good hygienic behaviors and knowledge transmission, to support mass mobilisation and mass media campaigns, to conduct monitoring and follow up, to disseminate the project evolution, and to evaluate the project sustainability beyond the end of the intervention (23). A negligible amount of community contributions, equating to less than 1000 out of 435k, were also received as part of the community commitment (24).

In terms of financial management, it is not possible to determine exactly how much was spent on each activity due to a lack of availability of the financial records. While the NGO uses social media regularly (e.g. Twitter), it was difficult to communicate with their personnel, and they were unable to provide any further details regarding the financial aspects of this project. Moreover, it is challenging to have an accurate estimate regarding the number of people affected by the intervention, since many activities targeted the permanent residents of Fort Dauphin indirectly.

Based on SEED Madagascar's final report, the project affected many people both directly and indirectly (Figure 1): an estimated 11,000 people benefit from the additional 799 latrines constructed over the duration of the project, and an estimated 7,000 students have now greater access to

improved sanitation at school. About 200 permanent residents who were not beneficiaries of the latrine subsidies participated to focus groups and support sessions. Ultimately, mass mobilization reached up to 6,500 residents, students and local groups through the Global Handwashing Day and World Toilet Day events and professional trainings, and mass communication campaigns that included more than 31,000 giveaway items, 17 billboards and signboards, and 2,000 radio broadcasting, targeting all people living in Fort Dauphin (23). Therefore, it is difficult to believe that less than half a million pounds were needed in the course of the 3-year intervention, and the possibility of more funding involved in the project is plausible.

## Discussion

Overall, the outcomes of Project Malio highlight a number of lessons that can be applied to future CLTS projects in urban areas, in Madagascar and beyond. Key factors driving the success of this project included: adaptations to respectfully navigate cultural traditions and values surrounding open defecation, sanitation and hygiene; adaptations to better fit the CLTS approach to the urban (as opposed to rural) context; and the donors' flexibility in allowing for ongoing change and adaptation throughout the life of the project. There remain, however, several ongoing challenges within this approach and its reports, including: the scope

of stakeholder engagement; and a lack of rigor in the impact evaluation report. More transparency and sustainability in financing, and recognition of the limited scale of the intervention within the context of a broader WASH strategy are needed to adequately compare outcomes to other interventions, and to estimate effectiveness for other contexts. These strengths and challenges are discussed in more detail in the following section.

## Successful Adaptations

A major factor in the prevalence of open defecation in Madagascar is the set of traditional cultural beliefs and values that normalize and even encourage the practice (20). Taboo surrounding mere discussion of these topics, for example, can make it particularly challenging to implement a CLTS approach. Adapting to the local cultural context, in response to this challenge, was a motivating factor in the development of Project Malio's 'hybrid' CLTS approach. These adaptations included employing local Malagasy staff as 'Community Liaison Officers,' to facilitate meetings and activities on behalf of the project understood how to respectfully navigate cultural taboos and social norms (26). Project staff also commenced all community meetings and activities with a formal apology to elders for the content of the ensuing discussions, as a way of respecting existing social structures, and ongoing discussions between project staff,



elders, and local community members helped ensure that the ‘shock-value’ driving the CLTS methodology was preserved, while avoiding causing such offense to community members that the intervention would become ineffective (26).

Some specific difficulties in implementing CLTS in an urban (as opposed to rural) context are the lack of defined borders between neighborhoods, as well as difficulties in getting a critical mass of people to attend in-person meetings and events (27). Overall, Project Malio organizers were successful in adapting the CLTS approach to these conditions. For example, by eliminating transect walks, which are normally part of CLTS, community members were less likely to shift the ‘blame’ for sanitation issues onto their neighbors and avoid taking responsibility themselves. By including mass media campaigns (through radio programs, or visual messaging such as billboards), Project Malio was able to transmit their message to a much wider audience. Finally, donors were supportive of the ongoing evolution of the project itself, facilitating the necessary adaptations and ongoing discussions (27).

### Ongoing Challenges

Although the engagement activities themselves were well-adapted to the local urban and cultural contexts, the scope of stakeholders involved in the project remained an ongoing challenge within Project Malio’s

hybrid-CLTS approach. Specifically, the project’s failure to include stakeholders beyond residents (such as enterprises, health-care providers, and financial institutions) neglects the reality that in urban contexts, residents often need to work in collaboration with governments and other actors to achieve meaningful changes (30). A barrier to widening the scope of stakeholders involved, however, is the potential to introduce more complexity in terms of management, illustrated by the difficulties Project Malio organizers already faced in coordinating between the behavioral change and construction teams (27).

In terms of financing, the high costs of constructing latrines in urban areas, due to a lack of availability of land and local building materials relative to rural areas, presented challenges in terms of providing material subsidies for the poorest and most vulnerable schools and households (27). While providing these subsidies – a departure from more traditional CLTS approaches – contributed to the overall success of the project, the amount that households were required to contribute towards latrine construction (approximately 1.75 CAD) was reported as being prohibitively high for many of the poorest households (31). The high costs associated with latrine maintenance, including emptying once latrines reach capacity, and a lack of service provider options for latrine pit emptying and fecal sludge management is another

ongoing challenge to this intervention, and could present a major barrier to the long-term sustainability of the intervention (32).

Overall, a lack of transparency in terms of financing, including a lack of information regarding the cost of the intervention and where funds were allocated throughout the project's duration makes it difficult to evaluate the cost-effectiveness of the intervention, and makes it challenging to determine whether it might be effective at other scales or in other regions.

Finally, it is vital to recognize that CLTS is only one tool within a larger category of behavioral change and communication-based interventions, which themselves are only one set of tools within a broader sanitation strategy. Therefore, while this hybrid-CLTS intervention does address key cultural and behavioral factors that contribute to open defecation in Madagascar, it does not address broader structural factors such as a lack of clean water, intermittent water supply, or overall low socioeconomic status, which affect most households and institutions in the country.

### Strengths and Limitations

Overall, SEED Madagascar's reports gave an optimistic interpretation of their intervention's results. While the intervention met most of its objectives, some of the indicators used were difficult to quantify

due to limited access to the dataset. Only superficial and potentially incomplete data was available from the Project Malio reports and lack of national statistics limits the validity of the historical comparison.

Some of the figures presented in the final report contained contradictions to other sources of data and could be indicative of flaws in the data collection process. For instance, 84% of people interviewed reported using a latrine at home, while interviewers only observed latrines in 69% of households. Inconsistency in the results might indicate the need for better training of the personnel regarding data collection and bias management.

It is worth noting that the project success could be exaggerated due to the potential influences of biases from both the interviewees and the interviewers involved in follow-up monitoring. There is a lack of information required to determine whether the method used in Fort Dauphin could be replicable elsewhere and results should be interpreted with caution.

### Future Directions

Despite construction of latrine being insufficient on its own to solve sanitation issues, it is estimated that an additional 1,500,000 latrines are needed in order to eliminate open defecation in Madagascar, a number over 1800 times more than

the amount constructed through Project Malio (5, 33, 24). Moreover, community-based approaches to promote behavioral changes and foster usage of latrines are deeply needed to ensure efficacy of WASH interventions in low income settings (5). The hybrid-CLTS approach can be seen as successful in addressing key behavioral and cultural drivers of open defecations, with a limited capacity to respond to structural-level drivers of open defecation, such as limited sanitation infrastructure, poor water management, and insufficient allocation of funding to sanitation nationally. Therefore, the Malio project by SEED Madagascar must be framed as only one tool within what must be a broader strategy for improving sanitation in Madagascar. Overall, the evidence presented in this report suggests that SEED Madagascar's hybrid-CLTS approach may be better suited to act on the cultural and behavioral drivers of open defecation than to improve infrastructure through latrine construction, particularly in urban areas where costs are high. Partnerships between organizations or institutions that focus on implementing cost-effective behavioral-level and structural-level interventions, respectively, in addition to participatory planning approaches, may prove to be important future directions in terms of scaling up efforts to eliminate open defecation in Madagascar completely. Increasing access to documents related to costs and outcomes of future projects can

also help in choosing where to focus future efforts and identifying which interventions or organizations should be involved.

To ensure that Malagasy continue to use the tools provided in the intervention once the project organizers leave, measures promoting long-term, sustainable latrine use and maintenance need to be developed.

This could include promoting sanitation entrepreneurship via microfinance in order to increase local, affordable service provision options for latrine pit emptying and fecal sludge management, as well as general maintenance (27). However, research on fecal sludge management services in developing urban areas is limited (34), and this is a barrier that will need to be overcome in the long-term.

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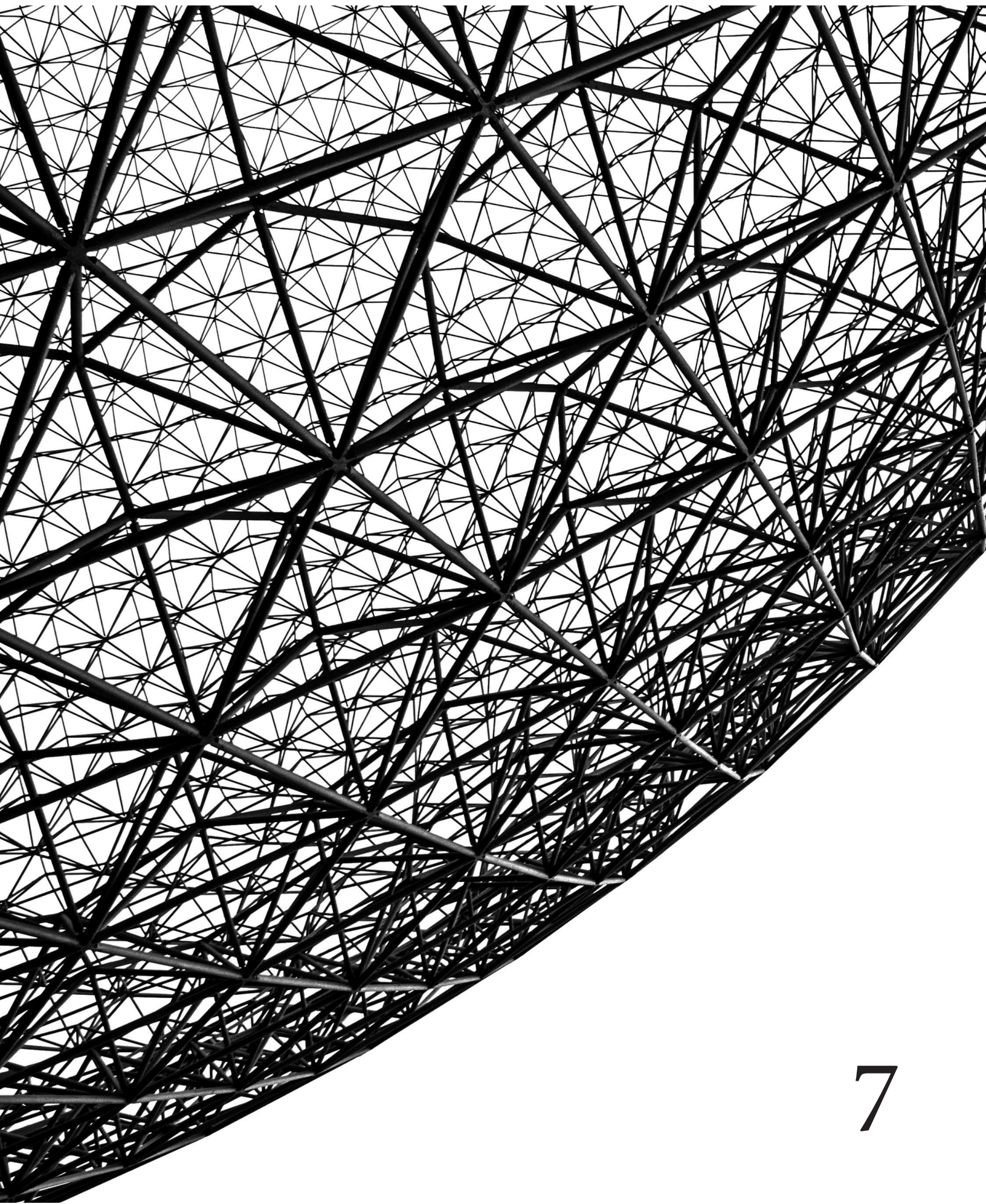
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# Did Dengvaxia-associated deaths result in an increase in vaccine hesitancy in the Philippines?

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## ABSTRACT

The development of the Dengvaxia vaccine and the subsequent vaccination campaign of 2016 in the Philippines proved to be an outstanding failure. This case study focuses on the impact of the vaccination campaign, which had a goal of vaccinating one million schoolchildren, ultimately reaching 830 000 students. Sanofi Pasteur's failure to adequately warn the Filipino public about Dengvaxia's effect on antibody-dependent enhancement (ADE), coupled with rushing the implementation of the program by the Department of Health, ultimately led to the shutdown of the campaign in 2017. Therefore, we predict that the media sensationalization of the campaign, which created a public outrage, led to distrust of the healthcare system and vaccine hesitancy as well as an increase in vaccine-preventable diseases such as measles in the Philippines.

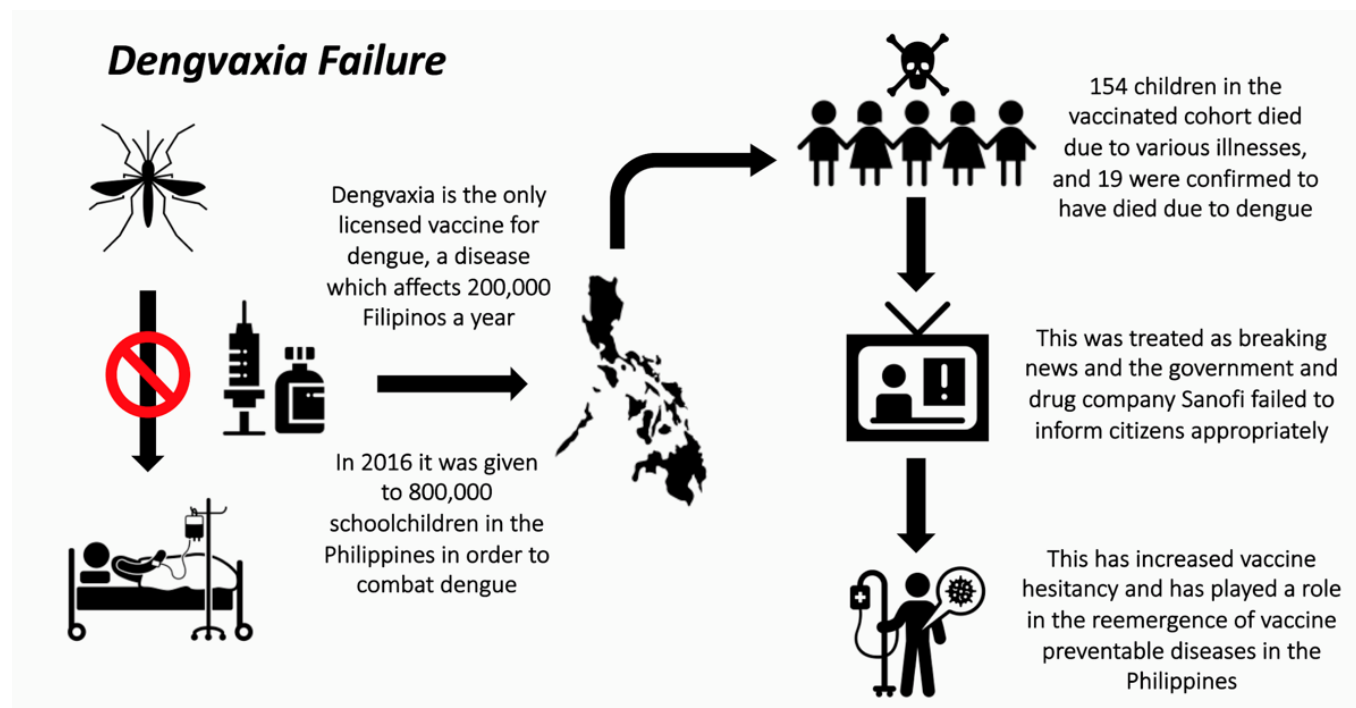


Figure 1: Visual Abstract of the Case Study

## Background and Motivation for the Intervention

Dengue (DENV) affects over 100 countries and caused 390 million infections globally in 2013. It is a viral disease transmitted by the *Aedes aegypti* mosquito which has four different serotypes. While dengue is self-limiting in most cases, a small proportion progress to more severe manifestations, such as dengue hemorrhagic fever (1). In the past 50 years, incidences of dengue have risen 30-fold, but there is still no dengue-specific vaccine (2). The development of vaccines is quite complicated, as an initial infection with DENV can trigger an immune response that can either protect or enhance the disease during the subsequent infection. Although controversial, this theory, proposed by Halstead, is called antibody-dependent enhancement (ADE) and explains why a second encounter with a different dengue serotype might be deadlier than the first. A first infection with DENV-1 prompts B-cells to make antibodies to coat and kill the virus; the B cells become dormant after the infection. A second infection with a different serotype activates these cells to make the exact same antibodies as before. However, antibodies to DENV-1 do not bind well to the other DENV serotypes, making the immune response ineffective and causing a more severe form of dengue. The ADE theory is thought to prove especially true in children who have never had dengue before in regards to vaccination. It is theorized that when uninfected but

vaccinated children are first infected with dengue, the vaccination serves to prime the immune system, which then responds dangerously to the first infection following vaccination (3).

Severe dengue was first recognized in the 1950s during epidemics in the Philippines and Thailand (4). About 170,503 symptomatic Dengue infections and 750 deaths were recorded annually from 2010 to 2014, with a reported case fatality rate of approximately 0.44% (5). Dengue remains a serious public health issue in the Philippines, with recurring epidemics every 2-3 years (6). Tackling dengue is one of the country's top priorities for infectious diseases. Dengue outbreaks are viewed as a political issue; the public often blame their government for not doing enough to prevent the disease as it's seen as a governmental responsibility to prevent the disease. A leading Filipino pediatrician summarizes the situation quite well, stating that: "Any politician who brought a dengue vaccine to the Philippines through the national immunization program could become President" (7).

According to the WHO, if an intervention in a country costs less than its GDP per capita to avert one DALY then it is considered highly cost-effective. If the regimen costs up to three times the GDP per capita then it is considered merely cost effective. Anything higher than three times

the GDP per capita will be deemed cost ineffective (8).

In 2015, the Filipino GDP per capita was \$2867 USD (9). The Dengvaxia program was expected to average a value of US\$5,101/DALY averted in the Philippines, making it merely cost-effective from a healthcare perspective, which incorporates costs of the vaccine compared to the number of cases treated. From a societal perspective, which incorporates the indirect social costs of illness (ex. unemployment) and the opportunity cost of time required to obtain each vaccine dose, the Dengvaxia program was expected to average a value of US\$ 3063/DALY averted, making it even almost highly cost-effective (10).

This shows that the Dengvaxia program was thought to be more cost-effective when the time to carry out the vaccination campaign is taken into consideration, evidence of the indirect social costs Dengue has on productivity(10). This reinforces a social and economic argument for the need of a more effective Dengue vaccine, especially in countries where the incidence is high, as in the example of the Philippines.

In 2015, the Filipino government acquired the only licensed dengue vaccine at the time from Sanofi Pasteur, Dengvaxia. The vaccine was studied in 26 clinical trials including more than 41,000 volunteers, notably CYD23 in Thailand, CYD14 in Asia and CYD15 in Latin America. (11). It is registered in 20 dengue-endemic countries, but immunization implementation has been

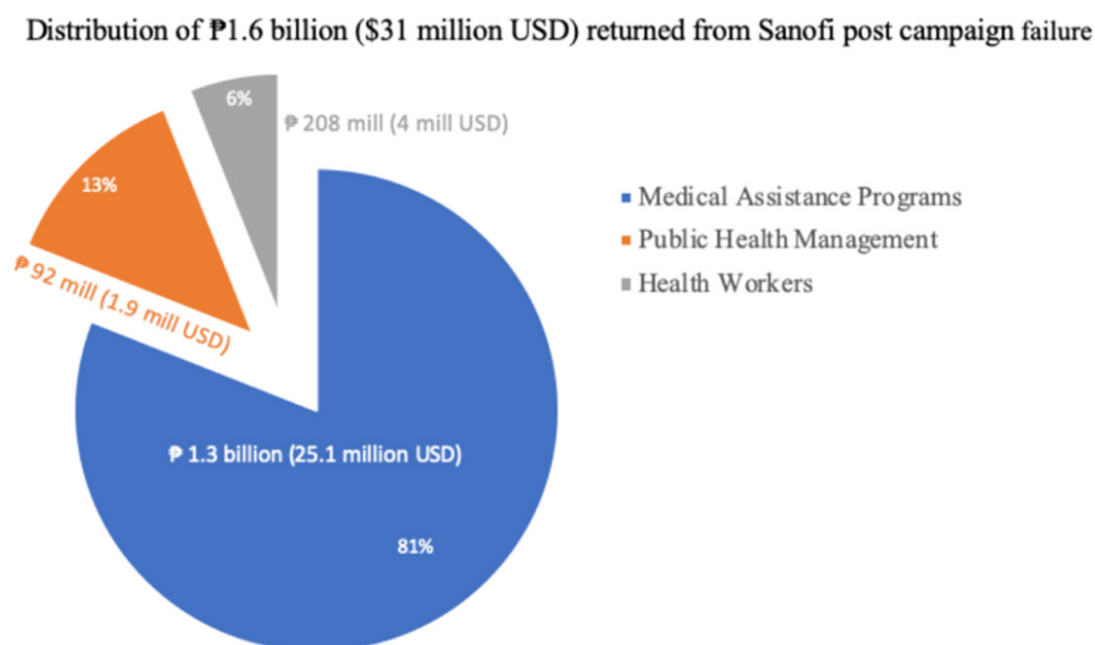


Figure 2: Allocation of \$31 million USD returned from Sanofi by the Filipino Department of Health

limited to Brazil and the Philippines (11). Upon negotiating a deal with Sanofi, the Department of Health in the Philippines wanted to purchase three million doses of Dengvaxia to achieve the immunization of one million schoolchildren, nine years of age. Each child was anticipated to receive three doses of the vaccine, each dose 6 months apart, by June 2016. The goal was to reduce up to 80% of the 200,000 annual domestic dengue cases in the Philippines, focusing predominantly on 9-year olds in highly infected areas of Central Luzon, Metro Manila and the Southern Tagalog region (12). As predicted by the ADE theory, it was later discovered that the vaccine actually put people at risk of being more severely affected by the virus, especially if they never had dengue before (2). This raised concerns regarding the true safety and efficacy of the vaccine, and public confidence in vaccines plunged.

This case study focuses on the impact of the 2015 Dengvaxia campaign in the Philippines, which had a goal of vaccinating one million schoolchildren. Sanofi Pasteur's failure to adequately warn the Filipino public about Dengvaxia's effect on ADE, coupled with rushing the implementation of the program by the Department of Health, ultimately led to the shutdown of the campaign in 2017. Therefore, we predict that the media sensationalization of the campaign, which created a public outrage, led to public

distrust of the healthcare system and vaccine hesitancy in the Philippines.

## Financing

The Dengvaxia campaign, which included the purchase of 3 million doses of Dengvaxia, cost the Filipino Department of Health paid ₱3.5 billion (\$67.7 million USD). This amount surpassed the cost of the entire national Filipino vaccination program of 2015, which covered pneumonia, tuberculosis, polio, diphtheria, tetanus, pertussis, measles, mumps and rubella (3).

Protests surrounding the failure of the campaign pushed the Filipino government to ask for a refund of the entire ₱3.5 billion (\$67.7 million USD) from Sanofi Pasteur. Settling a compromise, the Filipino government received ₱1.6 billion (\$31 million USD) after returning the unused Dengvaxia vaccine vials. The returned funds were mainly allocated towards medical assistance programs for Dengvaxia recipients seeking treatment, as well as public health management and employment of health workers to follow up with complaints of the vaccine recipients (13).

## Methodology

For the purposes of this case study, we define program failure as the lack of appropriate pharmacovigilance information prior to vaccine rollout, which in this case



led to 19 deaths among vaccinated children, inadequate communication channels between health authorities, researchers and the general population, and ultimately, the creation of mistrust towards vaccination programs. There are many key points that led to the program failure. Firstly, Filipino authorities did not oblige Sanofi Pasteur to submit results from pharmacovigilance trials. It was later found that the pharmaceutical company had not carried out testing in the complete sample included in the trial, leading to the false assumption that in children above 9 years of age the vaccine was safe, however, age served in part as a proxy for prior dengue infection. In November 2017, Sanofi Pasteur issued an advisory, limiting the use of the vaccine to children who had a previous dengue infection. Again independent researchers argued that there was “no biological basis for a threshold age of 9 years” beyond which Dengvaxia could be assumed to be safe (14). Secondly, after the death of a child who had been vaccinated, the authorities gave a press briefing declaring that the boy’s death was unrelated to the vaccine. However, local researchers insisted it was, posting a video on Facebook that warned that if a child had never had dengue before, the vaccine could cause a more severe reaction to dengue.

This lack of appropriate communication channels and the magnified media attention to the vaccination campaign led to public

panic (15). Lastly, the program was stopped in December 2017, after more than 830,000 schoolchildren had been vaccinated and 19 deaths due to dengue had occurred amongst vaccinated children, leading to virtually every death in the vaccinated group being blamed on Dengvaxia, even if it was clearly unrelated.

We hypothesize that the failure of the Dengvaxia campaign contributed to increased vaccine hesitancy in the Philippines. Vaccine hesitancy is defined by the WHO as “the delay in acceptance or refusal of safe vaccines despite the availability of vaccination services”. It can be caused by factors such as: negative beliefs based on myths, e.g. that vaccination of women leads to infertility; misinformation; mistrust in the health care professional or health care system; the role of influential leaders; costs; geographic barriers and concerns about vaccine safety (16). We analyzed qualitative studies evaluating vaccine acceptance to gain an understanding of the public’s reaction to the Dengvaxia program, which provided insights into vaccine hesitancy. We obtained surveillance data on vaccination rates from the WHO and the Department of Health of the Philippines to show correlation with increased vaccine hesitancy after the Dengvaxia campaign. We also obtained data on the incidence rates of measles cases in the Philippines. Given that measles is a highly infectious disease

that can spread very fast when vaccination rates in children decline, we considered it to be an efficient marker for a decrease in vaccine uptake. Using this data, we examined the temporal trends before and after the Dengvaxia program for both vaccination rates and measles cases. Data from the DoH on a national deworming program was used as a proxy for mistrust in health programs and to further illustrate how the Dengvaxia program set the stage for vaccine hesitancy.

## Impact

### A Sensation, a Scandal, and Significant Misinformation

In an announcement on November 29, 2017, Sanofi stated that vaccinated but not previously infected children were more likely to contract “severe dengue” than those who had not received a vaccination. No context was given, only this fact buried within the announcement. They did not explain what “severe” specifically meant, and this allowed people who just read the announcement to make their own conclusions. In this case, “severe” was directly from the clinical trial’s lexicon, but it painted pictures of death in the minds of those who read the announcement. Sanofi also did not provide any statistics or rates of risk, making citizens believe that their children would almost certainly contract a deadly version of the disease.

The government was quick to distance itself from the vaccination campaign,

which had been started under a previous regime. Officials during the scare were all different from officials during rollout of campaign, and the control of the government had shifted parties in the interim. The Department of Health (DoH) was struggling to effectively describe how low the risk actually was to the general public. In the age of mass and social media, measured discussion rarely makes headlines. Thus, news agencies in the Philippines ran with reports of Dengvaxia associated deaths, images of childrens autopsies, and stories from grieving parents before anyone within Sanofi or the DoH could confirm or deny the factual basis of these claims. The Centre for Media Freedom and Responsibility found that the three main news agencies in the Philippines focused primarily on the politics of the failure, as reports at these agencies surrounding the Dengvaxia controversy outnumbered reports regarding dengue statistics or other aspects of the disease (17). Posts about the vaccine went viral, including one by prominent public health experts and Dengvaxia critics Dr. Antonio and Dr. Leonila Dans (18). Enormous outrage in the general public soon followed.

Media is not solely to blame for the sensationalization of the campaign(18). The Senate organized a series of public hearings on the campaign, interrogating current and former officials as well as Sanofi executives. The trials were meant to

provide the general public with someone to blame for the disaster, and the finger pointing often fell along partisan lines (18). The politics of dengue are entrenched within the Philippines, and the failure of the campaign offered ammunition to rival politicians. This trial ultimately published a report which called for the prosecution of several key former officials (19,20). The Public Attorney's Office also initiated an investigation that claimed that deaths from the vaccine were not from severe dengue associated with the vaccine, but rather from the vaccine itself. This criminal investigation cited cause of death as viscerotropic and neurotropic-like diseases, which are listed as side effects of the vaccine. However, Sanofi found zero instances of these side effects through clinical trials, and medical experts say that the actual causes of death in

the cases being utilized as evidence by the Public Attorney's Office were unrelated to the vaccine. The claims that the deaths were related to Dengvaxia are likely due to widely shared misinformation; scared parents did not understand why their children died (listed reasons included rabies, enlarged heart, leukemia) and pointed to a public vaccination failure which they had heard so much commotion about (18).

### Vaccine Hesitancy

This brings us to our primary impact of the Dengvaxia failure: increase in vaccine hesitancy. The situations described above created an environment which was rife for further misunderstandings regarding vaccines and other health interventions. Qualitative and quantitative data shows that people in the Philippines were scared,

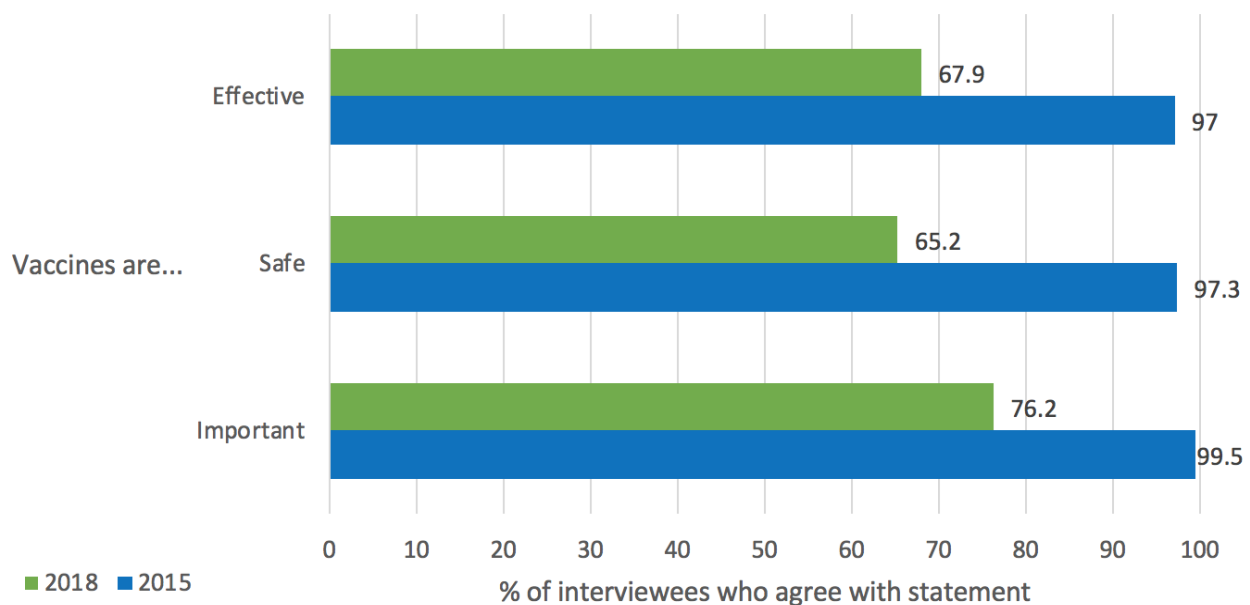


Figure 3: Percentage of interviewees who agree with statements listed in 2015 (1000 surveyed) vs. 2018 (2500 surveyed). Data taken from the Vaccine Confidence Project™.

and that this fear was easily spreading. Interviews and focus groups in Quezon City, Philippines revealed that acceptability of the dengue vaccine was associated with parental experience with vaccination and dengue, trust in public health institutions, and communication received by parents. Following the dengue vaccination campaign, parents regretted the experience, trust in public institutions was eroded and the communication strategy was deemed inadequate. This led to low vaccine acceptability post-vaccine suspension (21). As displayed in Figure 3, there has been a dramatic shift in the perceptions of Filipinos regarding the safety, efficacy, and importance of vaccinations following the Dengvaxia program failure. Those “strongly agreeing” with the statements listed in the table decreased by an even more significant degree (15)

A study which sought to qualify the impact of Dengvaxia on mothers’ perceptions of the program and of vaccines in general found that participants felt fear, empathy, and anger over the Dengvaxia associated deaths. Most participants knew why vaccines were important. Additionally, most participants stated that they had or were planning on giving their children vaccines, but specified that they were only confident in vaccines which had been on the market for a long time period. Two women stated that they were scared of injecting their children with vaccines following the Dengvaxia

failure (22). This might impact the rollout of new vaccines, which could harm future public health initiatives within the country. Even routine health interventions, like the administration of deworming medications, have been greeted with scepticism. In an interview with the Philippine Daily Inquirer, a mother said she would not allow health workers to give her two children deworming tablets and has shunned all drugs from the DoH: “Be it a vaccine, a chewable, a syrup, I said no. I have my options to bring my sons to a hospital or our family doctor for deworming or whatever it is in the DOH program. I don’t trust their services now after the Dengvaxia controversy” (23).

### Rise in vaccine-preventable diseases, and fall in vaccine coverage

The Dengvaxia controversy extended further beyond vaccine hesitancy in the Filipino population. Figure 4 demonstrates data from the DoH’s Annual Report (24), which shows the proportion of fully immunized children in the Philippines from 2015 to 2018. There is a clear downward trend of vaccinated children which starts after 2016 (25), which correlates with the height of the Dengvaxia controversy.

Figure 5 shows WHO-estimated vaccine coverage in the Philippines from 2010 to 2018 (26). As with Figure 4, there is a clear downward trend. Beginning from 2016, there was a decrease in coverage of



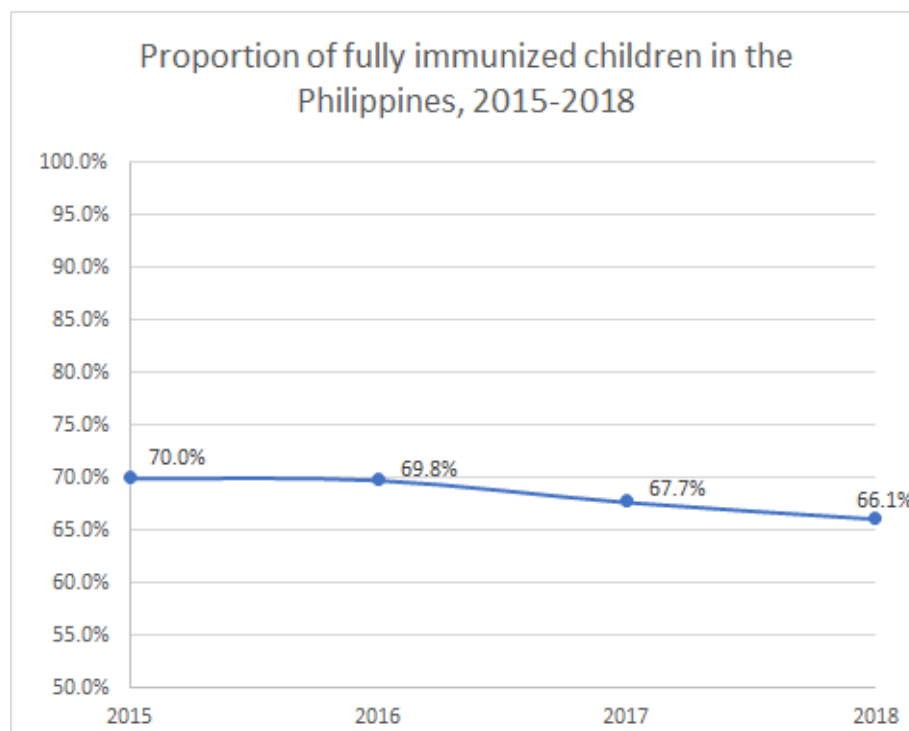


Figure 4: Proportion of fully immunized children in the Philippines, 2015-2018

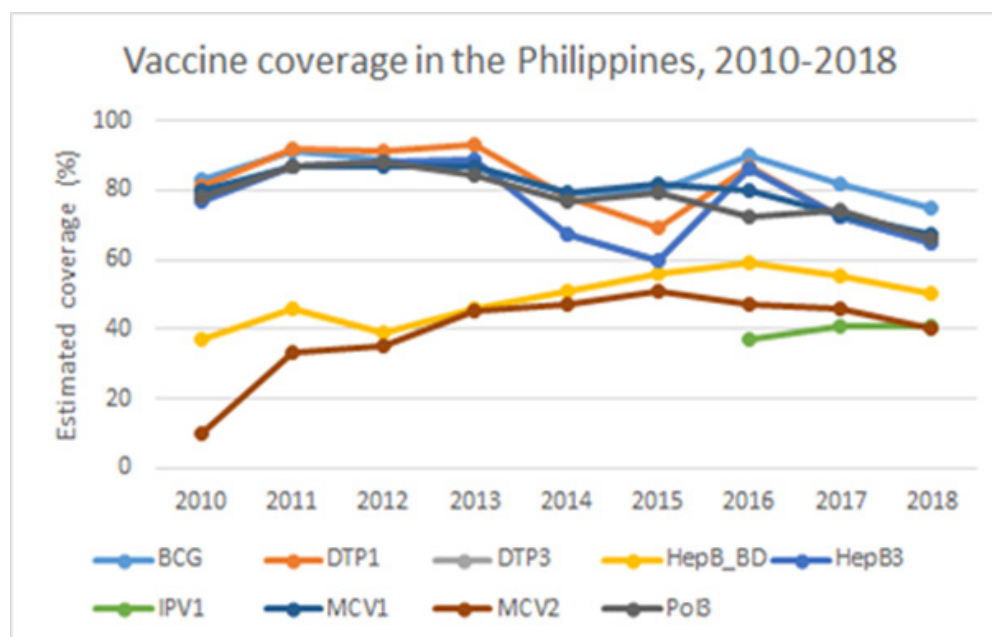


Figure 5: Vaccine coverage in the Philippines, 2010-2018. Vaccination data for BCG (Bacille-Calmette Guerin), DTP (diphtheria, tetanus and pertussis), hepatitis B, IPV (inactivated polio vaccine), MCV (measles containing vaccine) and Pol3 (oral polio vaccine).

the following vaccines: BCG, DTP, HepB, IPV, MCV, and Pol. This decrease in vaccine coverage correlates with an increased mistrust in the government public health agency, and increased vaccine hesitancy as a direct result of the media campaign surrounding the Dengvaxia campaign. Furthermore, Figure 5 demonstrates MCV coverage coupled with incidence of measles in the Philippines. As vaccine coverage decreases from 2016 onwards, measles cases rise, with an outbreak in 2018. According to WHO-estimated data, there were 20,827 measles cases in 2018 with 199 deaths. In 2017, there were 2,428 measles cases. In 2016 and 2015, there were 716 and 619 cases, respectively (26).

According to the DoH's measles surveillance program as seen in Table 1, data from January 1st to July 27th 2019 shows 39,856 cases of measles, with 538 deaths (27). Compared to the same time period in 2018, which had 12,469 cases and 107 deaths, this represented a 220% increase in measles cases since the fallout from the Dengvaxia campaign. Of the measles cases in 2019, 75% were unvaccinated or had unknown vaccination status. These cases were calculated from laboratory confirmed (3,301) cases, epidemiologically-linked (1,442) or measles compatible/clinical measles (35,383) cases. Lab confirmed cases show positive results for measles-specific antibodies, and epi-linked cases are defined as those who have had close contact

with a lab-confirmed or another epi-linked case. In 2018 (28), confirmed measles cases were calculated only from either laboratory-confirmed or epidemiologically-linked cases, with 5,120 total cases (and 59 deaths). Of these confirmed cases, 89% were unvaccinated or had unknown vaccination status. However, there were still 13,287 measles compatible/clinical measles cases which were not analyzed. Clinical measles cases are defined as a suspect case for which no blood sample was taken, not an epidemiological link, or lab results are still pending. Comparing confirmed cases with 2017, which had 791 cases with 17 deaths, 2018 had a 547% increase in numbers of measles cases. These results differ slightly from WHO estimated cases, which may be the result of variations in the disease surveillance or access to data.

Furthermore, Figure 6 demonstrates WHO estimated data of pertussis and diphtheria cases (26) in the Philippines, both of which show a rising incidence which correlates with decreased vaccine coverage. The number of cases was increasing before the Dengvaxia controversy, perhaps pointing to an increase in overall vaccine hesitancy or other reasons for decreased vaccine uptake. However, from 2017 to 2018, there is a larger increase in cases, with a jump of 339 pertussis cases in 2018 (from 88 in 2017) and 183 diphtheria cases (from 68 in 2017) which may be correlated with

increased vaccine hesitancy from the Dengvaxia campaign.

### Why are there measles outbreaks?

Measles is a highly communicable disease. On average, 90% of those exposed to measles will get the disease unless they have been vaccinated, or have already been infected (29). When a community has low immunization coverage, the likelihood of measles outbreak increases. The WHO recommends that a vaccine coverage of about 95% of all children is required in order for a community to be fully protected against measles (30). This includes protection for the vulnerable members of the population such as infants that are too young to receive vaccination, individuals who may be immunocompromised, or older adults. The results of the Dengvaxia campaign, which was heavily sensationalized in the media, pointed towards distrust in the government public health system and vaccine programs according to the qualitative studies surveyed. Decreased vaccine coverage was observed after the Dengvaxia campaign, subsequently decreasing herd immunity to measles, allowing for this highly infectious disease to spread as seen in Figure 7, and pointing towards increased vaccine hesitancy.

### Deworming in the Philippines

Increased distrust in government public health programs manifested not only in vaccination campaigns, but impacted

other programs as well. In 2015, the DoH introduced a deworming program called OPLAN: Goodbye Bulate, which targeted public school children aged 5-18 years and preschool children aged 1-4 years (31). This program aimed to combat the high prevalence of soil-transmitted helminth diseases in the Philippines, and administered anti-helminth drugs albendazole and mebendazole in January and July of every year with a target of 85% coverage. In 2015, the program enrolled 11,740,245 children out of a target of 14 million, reaching a coverage of 84%. In 2016, the program's success continued, with 15,853,687 public school children (82.4%) enrolled in the program (32). In January 2017, the deworming coverage among enrolled public school-age children was 84.5% (17,060,163 children were dewormed out of 20,194,252) (25). However, since the Dengvaxia campaign, the program coverage fell to 45% in 2018, representing approximately a 40% decrease in coverage (24) as seen in Figure 8. According to an article in the Philippine Daily Inquirer, the low deworming rates in 2018 were due to parents who refused to sign consent waivers, citing the Dengvaxia controversy as the reason behind their fear of DoH health programs (23).

### Funding for the Department of Health

The Dengvaxia controversy was also correlated with budget cuts to the DoH. Under the 2020 National Expenditure Plan

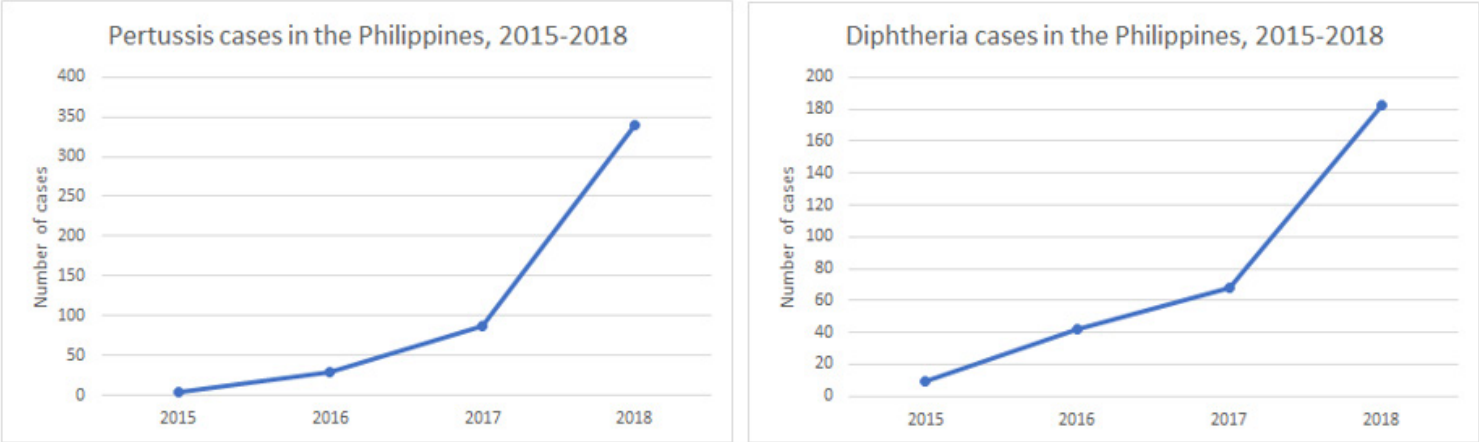


Figure 6: Pertussis and diphtheria cases in the Philippines, 2015-2018.

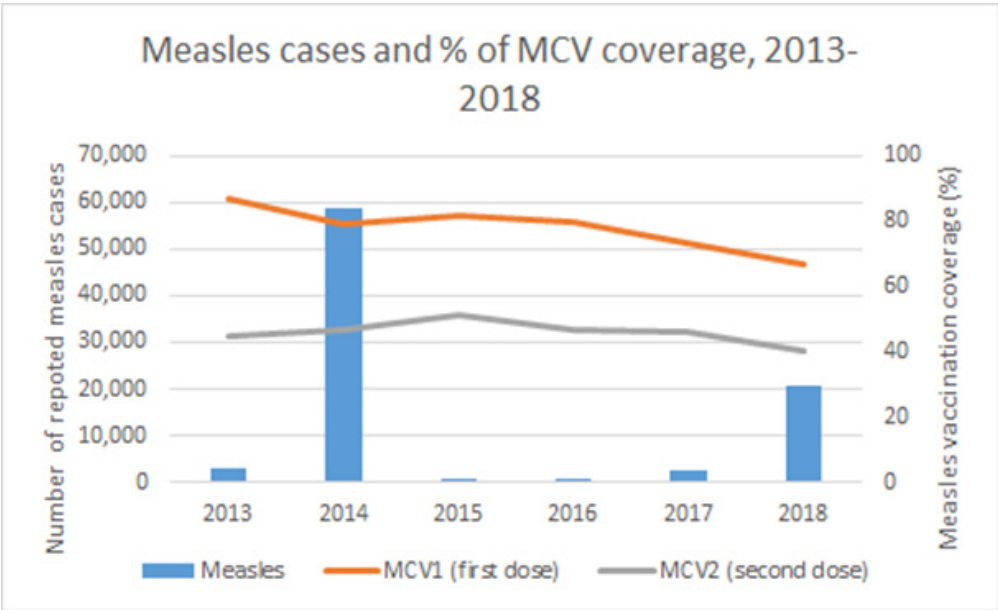


Figure 7: Measles cases and % of MCV coverage in the Philippines, from 2013-2018.



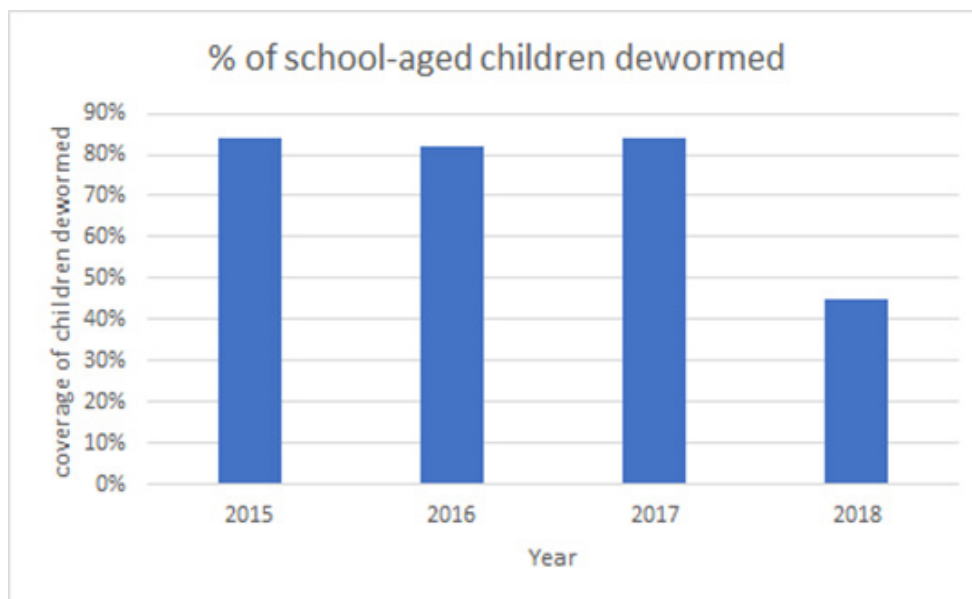


Figure 8: Decrease in coverage of the DOH deworming program, 2015-2018.

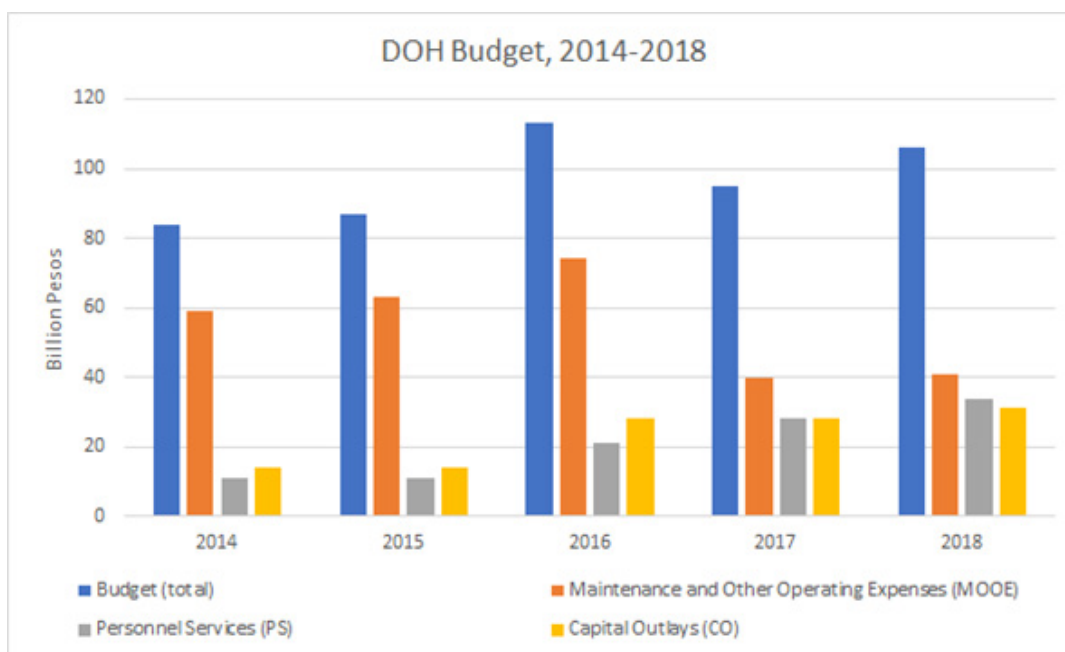


Figure 9: DoH budget from 2014-2018, broken down by PS, MOOE, and CO.

created by the Department of Budget and Management, the health department has a combined allocation of ₱160.15 billion (US\$3.1 billion), of which ₱92.2 billion (US\$1.8 billion) is allocated to the DoH. This amount is 5% lower than the 2019 appropriation of ₱169.45 billion (US\$3.3 billion). This comes in just as President Rodrigo Duterte is set to implement Universal Health Care. The DoH's Human Resource for Health Deployment Program (HRHDP) will be heavily affected (from ₱8.5 billion (US\$166 million) in 2019 to ₱2.45 billion (US\$48 million) in 2020), which could lead to the loss of over 10,000 health personnel, such as nurses, dentists and medical technologists (33). The 2019 budget was already decreased from the 2018 budget for the DoH by about 17% (25), which received around ₱106 billion (US\$2 billion). Figure 9 shows the DoH budget from 2014 to 2018, which is publicly available on the DoH's website (34). In 2016, a special provision of the budget was included for purchasing the Dengvaxia vaccine. In 2017, the budget dropped from ₱113 billion (US\$2.2 billion) to ₱95 billion (US\$1.9 billion). Large cuts were made to Maintenance and Other Operating Expenses (MOOE) in 2016 as well as in 2019, which is used for medicines, medical supplies and other operational expenses in public hospitals. Budget for MOOE for government hospitals and facilities, was reduced by ₱1.5 billion from the 2016 budget. According to

the Manila Times, the cuts in the budget were supposed to be allocated for vaccines and facility enhancement programs (35).

Zooming in on the 2019 DoH budget in comparison to the 2018 budget (Table 2), cuts were made in three different programs: Health Policy and Standards Development, Health Systems Strengthening, and the Public Health program (36). The Health Policy program aims to ensure the alignment of policies, programs and standards towards sectoral goals on equity, access and quality of care. The Health Systems Strengthening Program provides technical support (service delivery) to local government units to ensure high quality health care services, and contains the Health Facilities Enhancement Program (HFEP) and the HRHDP. This program was decreased by 94% going from 2018 to 2019, and cuts to the HRHDP affect medical centres in the Philippines. The Public Health Program, the biggest program in the DoH, was cut by 12%, and includes programs for immunization, prevention and control of infectious diseases, and family health. On the other hand, the Epidemiology and Surveillance budget was increased by 403%, due to surveillance for children who received Dengvaxia (37). While the Dengvaxia controversy may not necessarily be behind the cuts to the health budget, public outcry and distrust of DoH public health programs during this period may be linked to the

funding of the Philippines' Department of Health. Furthermore, cuts to hospitals may exacerbate negative opinions of the healthcare system, in turn creating a feedback loop of fear and distrust.

In summary, the Dengvaxia controversy was heavily sensationalized by both the media and the Senate, leading to public outrage. The campaign was quickly stopped, but the fallout from the campaign affected many Filipino families, who began to feel as though they could not trust what government programs provided. This led to an increase in vaccine hesitancy immediately after the controversy, correlated with a decrease in vaccine coverage and an increase in incidence of vaccine-preventable diseases such as measles, pertussis, and diphtheria. Moreover, the outrage from the campaign affected other health programs such as the DoH's deworming program, leading to a decrease in coverage. Since the campaign, funding for the DoH has dropped, with budget cuts for healthcare facilities and supplies such as vaccinations. However, the evidence cannot prove that the Dengvaxia campaign was responsible for causing these massive changes, nor can it fully explain the decrease in vaccine uptake and measles outbreak. These data can only show that the Dengvaxia controversy is correlated with vaccine hesitancy, and future studies will need to be done in order to fully assess the direct impact the Dengvaxia campaign had on the Filipino population.

## Limitations

This case study is not without its limitations. Firstly, the data used for vaccination rates, measles incidence and deworming is ecological. This constrains the inferences that can be made to comparisons between prevalences, without being able to assess cause and effect, as well as limiting the inferences that can be made about changes in vaccination behavior over time. It is therefore impossible, due to the confines of our study, to directly ascribe casual relationships between Dengvaxia and vaccine hesitancy, vaccination coverage, or vaccine preventable diseases. However, the observations that were made in this study could serve as the basis for the hypothesis of longitudinal studies.

Secondly, the data used in the analysis was not collected for the purpose of measuring vaccine hesitancy. Thus, the causes for a shortfall in rates may be due to reasons completely out of the scope of hesitancy such as stock outs or lack of vaccination programs in certain areas. It is also important to note that since the data was not specifically collected for our outcome, it may not depict the entire population exposed to the Dengvaxia program. Additionally, the impacts of a decline in vaccination coverage might not be seen for several years. Such was the case in the 2014 measles outbreak in the Philippines, it is thought to be caused by a decrease in vaccination coverage in 2011. At this time, vaccine confidence was

Table 1: Measles disease surveillance data from the DoH

	2019 - Jan. to July	2018 - Jan. to July	% change	2018 - Jan. to Dec.	2017 - Jan. to Dec.	% change
Measles incidence	39,856 cases	12,469 cases	↑ 220%	5,120 cases (lab confirmed & epi-linked)	791 cases (lab confirmed & epi-linked)	↑ 547%
Deaths	538 deaths	107 deaths	↑ 403%	59 deaths	17 deaths	↑ 247%

Table 2: % change in budget by program between 2019 and 2018

Operations by Program	% change from 2018 budget
Health Policy & Standards Development Program	↓ 28%
Health Systems Strengthening Program	↓ 94%
Public Health Program	↓ 12%
Epidemiology & Surveillance	-↑ 403%



high, as shown in the figures above, but vaccine coverage was lower than surrounding years. Notwithstanding, given that the controversy surrounding the vaccination program was presented in media outlets throughout the whole country, we believe that this could have contributed to vaccine hesitancy and would be captured in subsequent surveillance data.

Thirdly and most importantly, vaccine hesitancy is the result of multiple factors which we were not able to measure for this case study. There are many factors beyond the Dengvaxia program that may influence hesitancy in the Philippines. These may include, but are not limited to; geographical barriers, personal beliefs or complacency. These factors are hard to measure and more so through indirect data sources. All these factors combined may influence vaccination rates overall and may subsequently confound our results. It would be necessary to carry out longitudinal studies with a representative sample of the population, in order to obtain data that would allow us to control for confounding factors and thus provide better insight into the association between the Dengvaxia program and vaccine hesitancy.

## Future Implications

The Philippines have recurring DHF epidemics every 2-3 years (6) A national epidemic of dengue was recently declared in the Philippines as infections doubled since 2018, killing 662 people, many of

them being children. However, following the Dengvaxia controversy, there are little resources available in order to protect the population not only against Dengue, but also against the social drivers of Dengue propagation. Dengvaxia will not be used in the current epidemic, a decision supported by the WHO. With the loss of the public trust in vaccination campaigns in the Philippines, an increase in vaccination rates and awareness campaigns is necessary to prevent future outbreaks and stop the increasing incidence of diseases like measles.

With the current Dengue outbreak in the Philippines, a clear identification of the source of vaccine hesitancy is needed to assist advocacy efforts for resource allocation that can positively impact vaccination rates by the re-introduction of Dengvaxia or other preventive measures for outbreak control. Given that there is qualitative information available on the populations knowledge, attitudes and practices regarding vaccination, it would be important to use these findings towards creating social outreach programs to regain the public's trust in vaccination. Strategies could include media campaigns on social networking platforms which feature trusted community leaders or social influencers to bring to attention the benefits of vaccination. One of the main shortfalls that should be targeted is the lack of a robust vaccine safety monitoring program. Currently the pharmacovigilance monitoring system that is in place uses web based

technology to keep track of adverse events, however, it may be useful to implement other safety procedures. Many resources are available through the WHO such as a manual on surveillance of adverse events following immunization and activities supporting countries to ensure quality of vaccines (26, 29).

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