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## **The Prognosis | Spring 2019 | Volume 8, Issue 1**

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McGill GHP supports initiatives working to address health inequities and improve global health. GHP efforts focus on education, partnerships, and active research and training around the world.



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# From the Editor-in-Chief

Dear Reader,

The Prognosis, McGill's peer-reviewed student journal of global health, was founded in 2011 to highlight outstanding content at the intersection of social, biomedical, environmental, global, and local perspectives of health. Our 2018-2019 editorial board has worked hard to compile a diverse collection of articles that address the health challenges of an increasingly globalized world.

This project would not be possible without the commitment of our editorial board; it's been a great pleasure to work with Sarah, Haroon, Tori, Armaan, Alexa, Sol, and Joy, and I wish them all the best in their future endeavours. On behalf of myself and the editorial board, I wish to extend our sincere thanks to McGill Global Health Programs for their support and to Kristin Hendricks for her dedication to this publication.

Volume VIII of the Prognosis features exceptional research and articles from undergraduate and graduate students at McGill University. The topics we address range from the multi-level factors contributing to tuberculosis in Nunavut to a home-based neonatal care intervention in Gadchiroli, India. The journal opens with Laal Daag, a narrative piece that speaks to the stigmatisation of female menstruation in a rural context in India and the importance of education for reproductive health. We feature two case studies on health policy, which respectively address Costa Rica's integrated health reforms to its primary care system under the EBAIS model, and the successes and challenges of implementing Thailand's Universal Coverage Scheme. We conclude with a paper on the implementation of Seasonal Malaria Chemoprevention in Mali and an article on the introduction of ROTAVAC, an indigenously-developed rotavirus vaccine in India.

The Prognosis is a unique platform that gives a voice to the next generation of global health leaders, empowering them to address emerging health inequities in a global context. By highlighting interdisciplinary approaches to our common challenges, we intend to catalyze dialogue surrounding global health and inspire ideas that may spark productive change.

We hope you learn as much as we did from the following articles, and that this publication will encourage you to engage with your communities to foster health equity at the grassroots level and beyond.

Anna de Waal  
Editor-in-Chief, The Prognosis

# Editor-in-Chief

## **Anna de Waal - B.A., Psychology**

Anna is in the final year of her B.A. at McGill University in Psychology, with a double minor in Microbiology & Immunology and the Social Studies of Medicine. Her research interests are in HIV, Indigenous health, and primary care access. She currently works as a research assistant with Dr. Nitika Pant Pai's lab in Clinical Epidemiology, and has worked on qualitative analysis to improve primary care access for marginalized populations as a Queen Elizabeth II Scholar. She is passionate about community involvement and works to plan initiatives on the McGill campus with Santropol Roulant, Montreal's intergenerational meals-on-wheels organization. As she continues her studies at McGill in the MSc Public Health program in Fall 2019, she hopes to pursue research that addresses the intersection of policy, the environment, and society in shaping health outcomes.

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# Editorial Board

## **Sarah Williams - M.Sc., Public Health**

Sarah is a second year Master of Science in Public Health (MScPH) student at McGill. Originally from St. John's, NL, she holds a Bachelor of Science Honours in psychology and biology from Memorial University of Newfoundland and completed her honours thesis in developmental psychology. Her interest in global health stems from working at the Center for Rural Health Studies in the Faculty of Medicine at Memorial University during her undergrad, which culminated in a publication in the Canadian Journal of Rural Medicine. This past summer she completed her MScPH Practicum at the Janeway Pediatric Research Unit conducting research on the pediatric to adult care transition experience of young adults with type 1 diabetes. She is interested in child health and development, chronic disease, and social determinants of health.

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## **Armaan Fallahi - B.Sc., Neuroscience**

Armaan is a second year B.Sc. Neuroscience student at McGill University. He is passionate about the study and treatment of severe mental illness, as well as the phenomenon of suicide at multiple levels. He conducts post-mortem suicide studies with the McGill Group for Suicide Studies at the Douglas Mental Health University institute where he examines the biological underpinnings of depression. His interest in public and global health stems from his experience conducting a retrospective chart review of suicide presentation to the emergency department within the homeless population at St. Michael's Hospital in Toronto; ever since, he has been fascinated by the necessity of public health initiatives in preventing and intervening at a systematic level. In his free time, he indulges in litera-

ture, philosophy, and discussion over tea. The Prognosis serves to represent the multi-disciplinary nature of addressing complex global health issues, which he hopes will remain a key tenet of the field moving forwards.

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### **Victoria Ford - B.A., Gender, Sexuality, Feminist, and Social Justice Studies**

Victoria Ford is a third-year student at McGill University pursuing a major in Gender, Sexuality, Feminist and Social Justice Studies. She is also completing minors in History and in the Social Studies of Medicine. Her research interests involve the intersections of gender, medicine, and psychiatry. Throughout her studies, Victoria has dedicated herself to the pursuit of gender equality and is actively involved at McGill's Office for Sexual Violence Response, Support, and Education. She is a passionate intern at the Institute for Health and Social Policy and serves as Vice President of the Women's Health Advocacy Club. Victoria is proud to be on McGill's Dean's Honour List and hopes to pursue a master's degree in the history of medicine while continuing to break down stigma in both her scholarship and activism.

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Haroon is in the final year of his Bachelor's Degree in Anatomy and Cell Biology with a minor in Psychology McGill University. His early childhood experiences in witnessing inadequate medical care in low resource conditions has garnered his research interest in global surgery, specifically trauma care in acute settings through local capacity building. He previously has conducted research at the Centre for Neuronal Survival at the Montreal Neurological Institute under the mentorship of Dr. Leonard Levin. As Haroon finishes up his undergraduate degree, he hopes to engage in research with the McGill Centre for Global Surgery in implementing their trauma registry in low-resource settings.

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### **Alexa Cirillo - B.Sc., Rehabilitation Sciences, Occupational Therapy**

Alexa is in her last semester of her BSc. in Rehabilitation Sciences, with a Major in Occupational Therapy at McGill University. She is passionate about social justice, Indigenous health, and transgender youth health. She currently works as a part-time research student with Dr. Noemi Dahan-Oliel at the Clinical Research Department at the Shriners Hospitals for Children Canada. In her spare time, she volunteers with Colours for All, a non-profit organization which provides free art workshops to children with developmental disabilities. As Alexa continues her Masters in Occupational Therapy at McGill University, she hopes to pursue clinical work with underserved and marginalized populations within the Montreal community. She is excited to be a part of the Prognosis team and has specific interests in global health, rehabilitation, and disability.

**Sol Park – M.Sc., Psychiatry**

Sol Park is a second year Master's Student in the Division of Social and Transcultural Psychiatry at McGill University under the supervision of Dr. Mónica Ruiz-Casares. She is currently researching the influences of immigration on the norms and practices of child supervision amongst South Korean immigrants in Canada, as well as the experiences of children home alone in a cross-cultural context. Sol is passionate about research addressing child protection, child participation in research, human rights, and immigrant/refugee mental health.

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**Joy Hannam – B.A., International Development**

Joy is in her second year of her B.A. at McGill University in International Development, with a double minor in Psychology and Health Geography. Her interest in global health stems from her experience working with others in a community setting, where she has had a growing passion for understanding various factors in social determinants of health and the importance in access to medical resources. She is currently honing her skills on the student run web journal Catalyst and continues to engage with articles that explore living standards, society, culture and politics.

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# Laal Daag



Paulami Sen

## Abstract

Indian women, in the roles they adopt, are vital to the family. Yet rural India continues to shame women, and this reality is shown most prominently during menstruation. The narrative piece *Laal Daag* showcases how female menstruation has been interpreted in the light of the following myth: women bleed to mitigate God Indra's guilt for slaying a sacred creature. Furthermore, the patriarchal society and lack of knowledge prevent a true understanding of this biological process.

Girls and women consequently experience a downward trajectory in many aspects of their life: 1) absenteeism in schools partly from unsatisfactory toilet facilities, which contributes to stunting of their academic performance; 2) contraction of Reproductive Tract Infections from using unsanitary cloths as pads; and 3) psychological morbidity due to social stigma. Addressing this issue is imperative to attaining the 2030 Sustainable Development Goals.

Government stakeholders must fund and facilitate collaboration between community health workers and leaders. Women and girls' opinions must be solicited to create adequate toilet facilities, while safe incinerators and affordable locally-crafted pads must be made available. Education on reproductive health is needed and should be discussed in formal (school) and informal settings (home) by all—including boys and men. With this, rural India may progress while celebrating womanhood.

## Laal Daag

She espouses the colour *laal*, or red, in a magnitude of different ways. It is the symbol of her future marriage which she will learn to honour daily by applying *sindoor*, or vermilion over her head. She adorns herself carefully by wrapping eight meters of red fabric which she calls a *saree* before setting foot into temple to offer her prayers. This same colour which she honours strips her of her rights ever so easily, leaving her to hide the red stain marking her womanhood every month. Indian woman primarily living in remote locations are not permitted to stay in their home during their menstruation cycle. They must not sleep next to their husband and are prohibited from practicing their faith. They are deemed 'impure' by society and are treated like livestock until the 'curse' has left their body (1-3). An ancient Vedic tale narrates that women bleed every month because of God Indra's wrongdoing in slaying Vritras. As a result, the blood shed during a woman's menstrual cycle is the representation of the guilt that accompanies this act (1). From there, the patriarchal framework of rural Indian society has only heightened the perception which dictates that women should be seen as secondary. Yet again, the "Man" has the power and she is given the utmost difficult task to desensitize the stigma and oppression that undermine her humanity (4). She has not asked for this.

Parvati's name has been given to her in honour of the Hindu Goddess of fertility and strength, in the hope that one day she would blossom into a mother. During her walk home from school

she thinks about the day she'll be happily wed and ponders what motherhood will bring. She then giggled in disbelief that she forgot to factor in that she must at least complete her college degree before taking marital vows. As Parvati is a few kilometers from her village, she overhears footsteps approaching.

“Eh filthy *Churel!* Didn't your mother teach you to stay home when you are 'cursed'?” Parvati quickens her pace. She recognizes the voice and that horrid word for “witch.” It was Dilip's voice. Soon the rest of his goons would be summoned and she'd be left to fend them off by herself. She observes Dilip staring at the bottom half of her body. She takes a swift glance at the back of her uniform and finds the culprit that gave her away. Parvati vulnerably bolts off to the side road that would lead to the back entrance of her modest home. She could hear him laughing from afar...”

As she unlocks the back door, Parvati's father greets his daughter and from her panting, he pours water in a grey metallic cup. Knowing that he would hand it to her, Parvati quickly distances herself, slips out of the room and into her own (1). She locks the doors. She then peels off her white uniform that was stuck to her with sweat. There was that familiar *laal*—mocking her this time. Although a new “victim” to this burden, Parvati knew her place for the next several days. “Maa told me I cannot enter our kitchen. I cannot touch my father and brothers. I must sleep in the shed until I no longer bleed, this will keep my family safe,” she told herself in consolation (5). She knew that she wouldn't

be able to write her mathematics test at school. She would be absent and once returned, Jilal Sir would not question where she was nor would he offer her remedial sessions (6). How could she attend her classes? The school latrine was a dirt hole with two bricks placed on either side. Without running water and the assurance that no one would peek around the three-walled arrangement, she wouldn't dare risk it (5). She remembers how Lali had tried to do so in the woods, only to find members of the younger class watching her. It wasn't worth being embarrassed like Lali, she decided. Parvati also considered that she couldn't wash her used cloth, which served as her pad, nor could she get rid of it. Not to mention that the waste disposal system was inexistent (5). Finding no solution, she leaves aside her bleak thoughts. She knew she could not bathe but nevertheless, Parvati grabs a ragged cloth and change of clothes and heads to the furthest pond to bathe and rinse off her *laal daag*, or stain, far from anyone's sight (1). She wondered how other girls living elsewhere coped with this spell and why it happened to only girls. No one knowledgeable spoke about it and her school friends did not have much insight (7, 8). She wished the closest hospital would not be so far; she could have visited the doctor on her own (1)...

At nightfall, she returns home and gathers her things for the cold night in the mud shed (9). Parvati enters the stale room. Her father follows her shortly with the spare cutlery they owned, a box of matches, spare candles and the covered platter that contained her dinner. He followed the protocol by leaving it all at the doorstep. He

stood there silent for a moment. “Shamoli Kaki came by for a cup of *chai*. We didn’t expect her, but she had asked where you were. I thought you should know.” Before Parvati could say anything, she watched his hesitant shadow disappear. She knew Dilip’s grandmother patrolled the village and made sure the rules were followed (5). Although her own family had good intentions, no one would oppose against fixed norms. She ignored this and closed the door to eat her meal in silence.

Sitting on her bed, she lifted the cover to her dinner. There was the usual *aloo baja*, *daal*, and rice. Knowing Parvati liked spice, her mother had added a *laal* chili. The red streak across the plate filled her vision. That red which she had trusted so much – the red of marriage, a bright future, and joy – now was treacherous. Now was the red of shame. A shame which would never leave her, every month falling from her body ... Slowly, she covered the plate and set her dinner aside. She leaned over and blew out the candle: the red couldn’t haunt her in the dark. She lay down on her bed, and black covered red.

\* \* \*

The monsoon season welcomed the village and nourished its crops. With the endless rain showering over, the rivers were now filled and prospered with fish. Every monsoon marked the coming of a local tradition: to fish as a community and compete against the neighbouring villagers. Parvati’s family went to the river Sunday afternoon, just like all other families. Parvati was particularly excited; she preplanned to purchase handmade *kulfi* with

her allowance. As she walked to the river, she thought about the treat’s cold texture on her tongue and how some of it will inevitable melt and drip away. Once arrived, she immediately called out to her family that she was going to the *kulfi* stand. The line was already fairly long, but Parvati was prepared to be patient.

Suddenly, a hand from behind gently tapped her shoulder. Parvati did not respond, she was fourth in line now and could not lose sight of what she wanted. When her turn came—before Parvati could speak to the vendor—the same young woman behind her interjected and purchased several *kulfis*—one for each of the children in line. A boy Parvati failed to recognize immediately exclaimed to the woman, “Didi! Sister! You are so kind! Please stay a little while longer in our village.”

The young woman was dressed in a multicoloured cotton saree. The border of her maroon petticoat was visible and her flowery blouse complemented her warm smile. “Ranu, I will visit soon, but another didi will tend to your village. I have some work at Babu Ghat.” The woman then called the children to take harbor under the shade from the trees. Parvati was compelled to follow; her village’s name echoed in her ears.

They sat around in a circle. Parvati looked perplexed, so a younger girl sitting next to her described the woman as a “*Kaa-meee-o-ni-tee Warh-ker*”. Parvaati noticed the girl was still growing most of her teeth. The woman wearing the coloured saree overheard and said “It is

Community Worker, I am an Accredited Social Health Activist or ASHA worker. My name is Meghla (5). *Baccho*—Kids, let us talk about our health. Tell me what things matter to you.” My parents! My muscles said the boys! My teeth! When a teenage girl said, “my womanhood,” most of the boys made silly faces. – “Which includes menstruation,” finished off the ASHA woman (10). Ranu, the boy who spoke earlier nodded. “I want to be like the Padman – Arunachalam Muruganatham—and create local sanitary pads for all!” he interjected (10). “Yes, Ranu. Local pads made carefully are economic and will create jobs for mothers,” said Meghla (3, 10).

Parvati did not notice her *kulfi* melting away, she was mesmerized by the moment. Some boys left the circle, but that didn’t bother her.

Meghla explained that she has been working with other community health workers and community leaders to ensure that better resources were made available for women and girls, as well as ensure that mothers are knowledgeable about reproductive health (3, 10-12). The children who already knew Meghla took turns telling how reproductive health was openly discussed at school now, and that their teachers—male and female—spoke about it; although most girls preferred when Rupa Madam fostered discussion (10). The topic was even gradually being spoken at home, when the ASHA worker visited (3, 12). They also described how vending machines dispensing sanitary napkins will soon be installed in the schools and that incinerators would get rid of

the used ones (10). Meghla added that toilet facilities will also undergo a positive change (11). As the group chatted off comfortably about such community taboos, the day slowly came to an end (3, 10-12).

On her walk back home, Parvati noticed the bright red sunset glaring throughout the sky. Her gaze was fixed, but she did not hesitate. She enjoyed how the warm colours blended into the darkness. “Tomorrow’s monsoon rain will surely bring another rainbow!” she said aloud. Parvati hummed and skipped the rest of the way home, for life was colourful.

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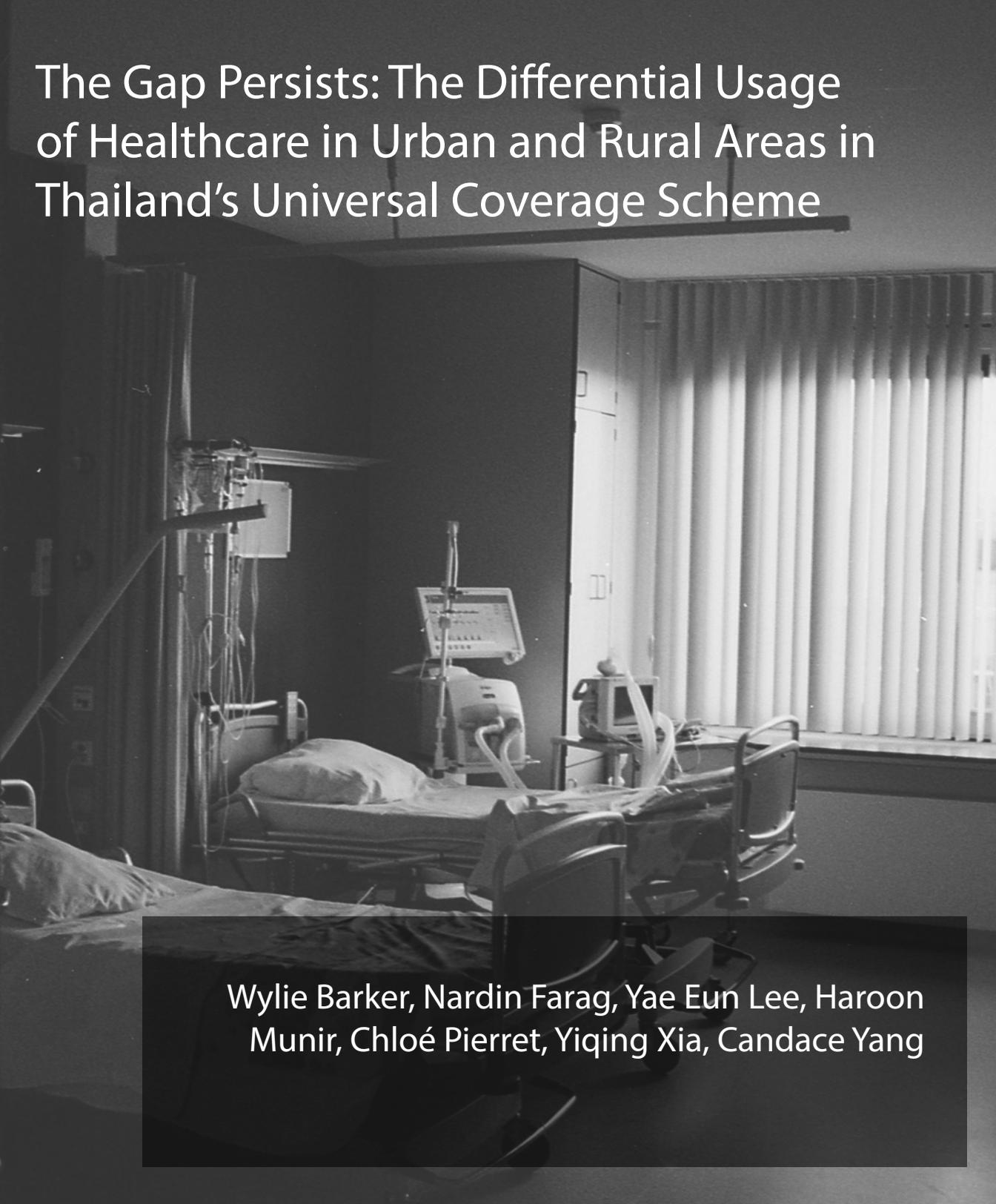
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# The Gap Persists: The Differential Usage of Healthcare in Urban and Rural Areas in Thailand's Universal Coverage Scheme



Wylie Barker, Nardin Farag, Yae Eun Lee, Haroon Munir, Chloé Pierret, Yiqing Xia, Candace Yang

## Abstract

Universal health care is often seen as a distant dream for many low- and middle-income countries, but for Thailand, it was achieved through the implementation of its Universal Coverage Scheme (UCS). By 2001, nearly 18 million people were falling through the cracks of Thailand's healthcare system, serving as the main driving force behind the establishment of the UCS. After implementation of this scheme in 2002, 47 million people received coverage, equating to approximately 75% of the country's population. The goal of the UCS was to entitle all citizens to quality health care regardless of socioeconomic status, and the scheme provided beneficiaries with a comprehensive benefits package focused on primary health care. Although the impact of the UCS was significant, disparities between rural and urban areas prevail. This case study assesses the impact that implementation of UCS had on the utilization of healthcare in rural areas compared to urban ones by examining health service utilization, rate of catastrophic health expenditure, health indicators, and quality of care. The UCS ultimately increased healthcare coverage for all Thais, but the perpetuated inequity between rural and urban areas remains a persistent issue, demanding the prioritization of equal distribution of resources.

## Background and Motivation

Prior to the introduction of the Universal Coverage Scheme (UCS), Thailand had four public health insurance programs that covered the entire population: The Civil Servant Medical Benefit Scheme (CSMBS), the Social

Security Scheme (SSS), the Medical Welfare Scheme (MWS), and the Voluntary Health Card Scheme (VHCS) (1). The CSMBS covered people in the government employment sector, including their dependents and retirees, while the SSS covered private sector employees (1). The MWS was a free health insurance program for socially vulnerable people and covered the poor, the elderly, the disabled, and children under 12 years of age (1). Finally, the VHCS was a voluntary program for those ineligible for the other three programs; it allowed each household to purchase one year of coverage for 500 Baht (approximately \$15 USD) (1).

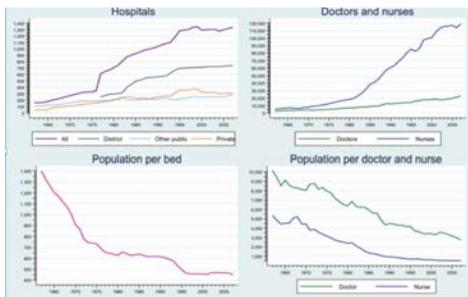
The MWS and VHCS faced administrative issues that left approximately 18 million people (nearly 30% of the population) uninsured, and these were mostly informal sector workers from lower socioeconomic groups (1). The MWS encountered mistarget difficulties in assessing the incomes of people in the informal employment sector. This resulted in MWS cards tending to be distributed to the non-poor rather than the poor (1). In addition, the VHCS faced an adverse selection issue, where illness was positively correlated with purchase and utilization of the VHCS insurance card (1).

Hence, the driving force behind the decision of the Thai government to establish the UCS was the 18 million uninsured people (1). Through the integration of the MWS and VHCS, the UCS eliminated the mistarget and adverse selection issues that these two programs previously faced (1).

Public health service infrastructure has seen

large-scale investments from the government in the two decades leading up to UHC.

Since the 1970s, the government of Thailand had invested in local health infrastructure (2). More hospitals were built, and more nurses and doctors were educated; this resulted in the significant improvement of the ratios of population per bed and population per nurse and doctor, as seen in Figure 1 (2). The purpose of this investment was to develop the district health system throughout Thailand; staffing was improved at the district level through the introduction of mandatory rural service for all graduated health professionals, starting with doctors and nurses in 1972 and later covered pharmacists and dentists (2). This investment in local health infrastructure aided in the gradual extension of health coverage in Thailand and set the groundwork for the implementation of UCS by improving physical access to services (2).



**Figure 1:** (2) The number of hospitals in Thailand, number of doctors and nurses, population per bed, and population per doctor and nurse.

Furthermore, to insure proper implementation of Universal Health Care, two rounds of survey (called the Delphi technique), as well as an in-depth interview were conducted among

stakeholders before 2001, when UHC was established, for policy formulation. Although the results obtained were limited, it was a good starting point and although the Delphi questionnaire did not provide the expected amount of answers, the in-depth interviews provided more viewpoints from non-health sectors. Five groups were aimed for data collection: the academician, the insurer, the government welfare scheme and policy body, the health care providers and the public at large. While politicians didn't agree on UHC for the rich, it was concluded that risk protection was a right for all. Also, this research helped establish that a comprehensive package including basic as well as catastrophic illness coverage were necessary. The results of this study were then made available to the Office of Healthcare reform in 2000 and allowed policymakers to establish a policy and finally be used in the political campaign.

### Goal of Intervention

The Universal Coverage Scheme is a scheme for all, not just the disadvantaged or the vulnerable. The goal of the Universal Coverage Scheme is “to equally entitle all Thai citizens to quality health care according to their needs, regardless of their socioeconomic status” (2). In order to strengthen the healthcare system, the scheme was intended to shift the focus to primary health care. Primary health care is more cost-effective than outpatient services at hospitals, and lowers the costs of transportation for patients (2).

The UCS has four strategic goals to efficiently provide healthcare for the population. It

focuses on curative care, and health promotion and prevention; emphasizes primary health care, and the use of effective and integrated services in a rational manner; promotes proper referral to hospitals; and ensures that the entire population is protected against the catastrophic health expenditures associated with out-of-pocket payments for healthcare services (2).

### **Description of Intervention**

The Universal Coverage Scheme (UCS) aimed to provide equitable entitlement to health care for all Thais (1). Established in 2001 and implemented in 2002, the UCS provided almost-free healthcare coverage for approximately 47 million people (75% of the entire population): the 18 million people that were left previously uninsured and members of the two existing public programs, the MWS and the VHCS. In 2004, UCS beneficiaries were mostly comprised of the poor, with the poorest quintile representing 25% (3). The remaining 25% of the population remained covered under the CSMBS and the SSS (1); 52% of CSMBS beneficiaries and 49% of SSS beneficiaries belonged to the richest quintile (3).

There are three defining features of UCS: a tax-financed scheme with a co-payment of 30 baht (\$0.75 USD) per visit or admission; a comprehensive, primary-care focused benefits package; and a fixed annual budget that has a cap on provider payments (1).

The UCS provides a comprehensive benefits package with a focus on primary care, including

curative and rehabilitation services, annual check-ups, and health promotion and disease prevention services (1). This includes coverage of inpatient and outpatient services, accident and emergency services, dental care, special investigations, medicines, and medical supplies (1). Clinic-based preventive and health-promoting services were also provided at health centers, thereby filling the gap left by CSMBS and SSS, which did not cover these services (1).

The UCS uses diagnosis-related groups (DRGs), a system that classifies patients based on diagnosis, treatment, and length of hospital stay in order to standardize prospective payment for inpatient services (4). These payments are predetermined, fixed amount, and made to hospitals based on the economic and medical similarity of cases from the previous year (5). Outpatient, disease prevention, and health promotion services covered through the UCS are paid through capitation payments. These are set amounts physicians receive per patient assigned to them, regardless of whether or not the patient seeks care. These capitation payments also serve as deterrents to keep physicians from over-treating patients (4). The UCS requires beneficiaries to receive services from a designated facility. When beneficiaries of the UCS bypass these designated facilities, they must pay 100% of the costs out-of-pocket (OOP) (1). These designated facilities also act as the gatekeeper to refer patients to secondary and tertiary care, thereby preventing utilization of unnecessary specialized health services.

In terms of delivery, the National Health Security Office (NHSO) contracts UCS

beneficiaries to providers, such as district hospitals and health centers and pays these providers through contract agreements (6). Providers deliver services to UCS members and submit data back to the NHSO (6). Only 70% of Thailand's health care facilities are state owned; there are 11,000 publicly-owned clinics and 4,900 privately owned clinics (8). When it comes to hospitals, 75% are run by the Minister of Public Health and the remaining 25% are privately owned (8). As a result, UCS contracts out complex procedures such as heart surgeries or craniotomies to certain private hospitals in urban regions (7). However, many private hospitals are disincentivized from working with UCS due to low reimbursement rates (7). Due to overcrowding and long waiting periods at public facilities, those who can afford private services will choose to access them, thus benefiting the private healthcare industry (8).

### **Financing**

Inadequate funding is the most common obstacle presented as a reason why many countries cannot provide universal health coverage to its citizens. Nevertheless, Thailand, a middle-income country, has established UCS, without the wealth of a high-income country. Initial strides to establish universal healthcare coverage in the country was made in 2001 through the 30 Baht health scheme program, whereby no patient was required to pay more than 30 baht per visit (9). However, this program was abolished in 2006 for political motivations, then reimplemented in 2012 with exceptions that include emergency, prevention, promotion, visits without prescriptions and visits to health

centers below the community level (10).

Thailand's total health expenditure is 3.7% of its GDP, for an annual budget of 153,152 million baht (4,646 million USD) (11). Completely funded by general taxes, 40.2% of the annual budget funds the UCS and the remaining 59.8% funds the SSS and CSMBS (10). Through this funding, UCS provides coverage for 73.71% of Thailand's population (11).

The national health expenditure is split between government, including UCS, and private health expenditure. While private health expenditure comprised the majority of the nation's health expenditure in 1994, by 2013 the ratio of government to private expenditure was 77% to 23% (11). From 2005 to 2010, UCS's budget continued to increase from 5.41% to 6.94% of total Thai governmental budget (11). This budget included all health expenditures and the salaries of governmental health staff (11).

### **Metrics of Evaluation**

Four metrics of evaluation were chosen to evaluate the UCS. The first metric was patient utility of the UCS, and reasons for not utilizing. The inpatient and outpatient utilization rates indicate the number of beneficiaries accessing the services available to them. Understanding the reasons that beneficiaries do not utilize these services may provide insight to the weaknesses of the UCS and identify areas for improvement.

The second metric was the rate of catastrophic health expenditure. This is defined as the out-

of-pocket spending for healthcare exceeding a certain proportion of a household's income (15). Evaluating the UCS through rate of catastrophic health expenditure incurred by its beneficiaries enables the measurement of the incidence of financial hardship caused by health payments. It also offers insight into the disparities in accessing healthcare that still exist after implementation of the UCS.

Health status indicators such as life expectancy, vaccine coverage, and infant mortality rate were used as the third metric of evaluation. These indicators provide a more detailed assessment of the health status of the population, and can also be used to evaluate the overall health performance of the country.

The distribution of healthcare professionals was the fourth metric of evaluation. The distribution affects a healthcare system's ability to deliver essential health services to all beneficiaries in different regions. This metric not only demonstrates a healthcare system's capability of providing coverage, but showcases the disparity that exists between regions as well.

The final metric used to evaluate the UCS was the quality of care provided by the scheme. In order to do so, patient satisfaction was used as an indicator of quality of care to measure how successful the UCS was in providing care. It provides the patient's perspective of their experience with the system, and can provide guidance for necessary improvements to the healthcare system.

## Impact

### Healthcare service utilization

Overall, there has been an increase in both inpatient and outpatient healthcare service utilization across the country from 2003-2015 (2). However, when surveyed by the International Health Policy Program and National Statistical Office, reasons for unmet needs were those disproportionately affecting the rural poor, such as too far to travel and service not covered by benefit package (2,15).

Figure E: (15)

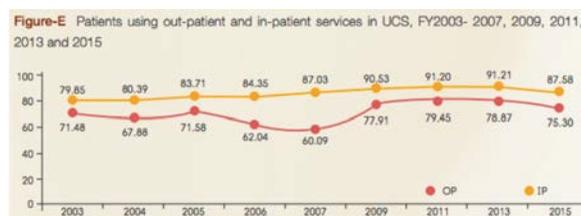
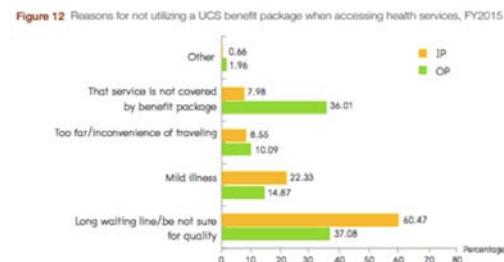


Figure 12: (15)



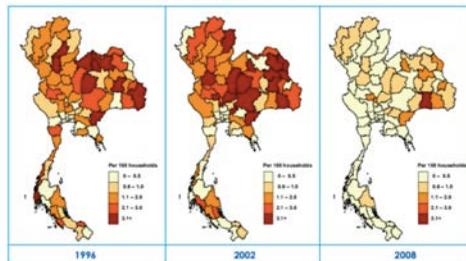
### Rate of catastrophic health expenditure

As seen in figure G, the percentage of household budget spent on healthcare has dramatically decreased for all quintiles from 1988-2015 (15). Indeed, according to data from The World Bank, the number of households pushed below the poverty line due to out-of-pocket healthcare expenditures dramatically decreased from 183,000 in 1996 to 83,000 in 2010 (16). However, this impact was disproportionately

distributed between urban and rural regions. Figure 15 shows a map of Thailand and the rate of catastrophic health expenditure per 100 households in 1996, prior to UCS implementation, 2002, at the beginning of UCS implementation and in 2008, 7 years after the implementation of UCS (2). From this map, we see that the catastrophic health expenditure has decreased in almost all provinces. However, the province of Surin, a vastly rural poor area, shows an increase in household health impoverishment.

**Figure G: (15)**

Figure 15: Household health impoverishment map, prior to UCS (1996), at the time of UCS implementation (2002) and post-UCS (2008)

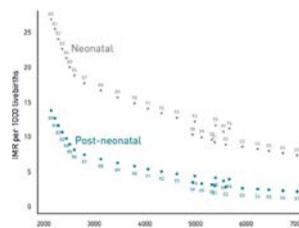


**Figure 15: (2)**

Initiative (PHCPI), Thailand had the highest DTP3 coverage of all low- and middle-income countries (LMICs) in 2017, with 99% of one-year-olds receiving three doses of the combined diphtheria, tetanus toxoid, and pertussis vaccine (18).

In addition, the infant mortality rate in Thailand has been on the decline (19), most likely due to the synergistic effects of the UCS and development. However, the rural-urban mortality rate ratio has increased from 1.3 in 1964 to 1.8 in 2005 (20). This increase indicates that the infant mortality rate has fallen much slower in rural regions compared to urban regions.

**Figure 3: (14)**



**Distribution of healthcare professionals**

In 2009, more rural residents were covered under UCS than urban residents (21). However, when the distribution of healthcare professionals is observed, there is an obvious skew of more healthcare professionals in urban areas; only 18% of doctors served in rural areas in 2017 (22). This staggering difference between the rural and urban distribution can be attributed to the brain-drain of healthcare professionals both from rural to urban areas, and from public to private hospitals due to higher quality of life and pay respectively.

**Figure-G** Percentage of health care expenditure from the overall household budget classified by income groups, FY1988 – 2015



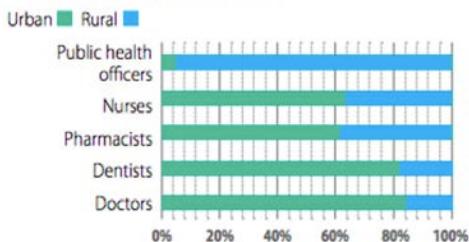
Source: Supon Limwattananonta analyzed from Household socio-economic survey of the National Statistics Office (NSO), FY1988 – 2015  
 Note: 1) The survey has been done by the NSO annually since 2006.  
 2) Calculated from health expenditure as a ratio of the overall household expenditure

**Health indicators**

Thailand’s life expectancy has increased steadily since the implementation of the UCS: from 70.8 years in 2001, one year prior to implementation, it has risen to 75.3 years in 2016 (17). According to the Primary Health Care Performance

Figure 5: (22)

Figure 5. Proportional distribution of number of health workforces per 1000 population



Quality of Care

Rates of satisfaction amongst UCS beneficiaries has been steadily increasing since 2002, reaching 90% in 2015 (Figure 52-(15)). According to a 2012 study from KhonKaen University in Thailand, the sense of wellbeing amongst villagers in the rural Northern Region increased significantly after the implementation of UCS, further contributing to the overall sense of security (23). Despite these positive results, around 30% of card holding villagers never utilized UCS services, and 20% of card-using villagers reported dissatisfaction; these percentages are significantly higher than the overall country averages (23). In addition, the number of complaints concerning quality of care for lack of service, inconvenience, being charged and substandard care remained relatively constant from 2011-2015 (Figure 51-(15)). These are all factors that disproportionately affect the rural poor, once again confirming the lack of improvement in quality of care in rural areas.

Figure 7: (2)

Figure 7: Satisfaction of UCS members and health-care providers, 2003-2010

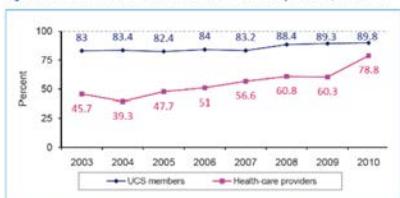


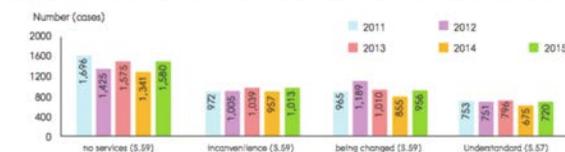
Figure 52: (15)

Figure 52 Consumers' and providers' satisfaction scores, FY2003-2015



Figure 51: (15)

Figure 51 The number of complaints concerning quality of care classified by issues, FY2011-2015



Why It Worked and Why It Did Not

Why it worked

The first reason for the success of the UCS in Thailand was the strong leadership behind its implementation. The Thai Rak Thai party used the promise of a universal healthcare scheme in their 2001 electoral campaign and continued to push for its implementation during their mandate (24). Hence, there was strong advocacy and political effort to adopt a universal health system coverage. There was also continuity, as the subsequent leaders of Thailand worked to keep the momentum going (24).

Secondly, the implementation of UCS was a result of Thailand's ongoing effort to strengthen its health system—notably through investment in rural medical facility infrastructures (25). Therefore, not only did UCS increase access to healthcare services, it provided patients with

an increased quality of care as a result of this investment (25). Finally, a tax-financed scheme ensured the percentage of country's GDP spent on healthcare would not increase (26). In other words, the Thai government was able to extend healthcare coverage to more citizens without a significant increase on its current spending on healthcare.

All in all, the reason of success of Thailand's UCS can be best described by a quote of Prateep Tanakijjaroen, Acting Secretary-General of the NHSO: "Finally, the participation of every stakeholder is still the most important mechanism moving the universal health coverage scheme towards its ultimate goal. With strength and cooperation we can we can all have a brighter, happier future" (15).

### **Challenges still faced**

With strong evidence of an overall improvement of health conditions in Thailand, the UCS has been rightfully praised. However, the program is still facing challenges, notably in sustainability and equity. The fact that Thailand had not increased overall spending on healthcare after implementation of UCS has been cited as a reason for the success of the program, but this also calls into question its financial sustainability (11). Indeed, clinicians expressed concerns regarding the inadequately small allocated budget of \$31.63 per registered person per year in inpatient care (26). Moreover, the overall reallocation of resources, based on population density, that came with the implementation of UCS was originally intended to reduce rural-urban inequities; instead, this led to financial

troubles for more than 30% of UCS hospitals, small rural community hospitals in the north and northeast being overly affected by this issue (26). This new allocation of resources led to small rural villages having insufficient budgets due to small population size, which further deepened urban/rural inequities (26).

Overall, Thailand's Universal Coverage Scheme did manage to attain its goals with the help of strong political and population support, however there is a need of a stronger financing scheme as well as focus on rural inequities to ensure the long-term success of the project (26).

### **Future Implications**

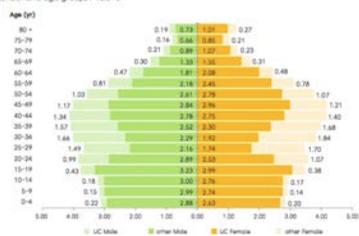
The UCS was well-received by the people of Thailand, as seen by its high satisfaction rates. However, for it to be sustainable, UCS must establish and adhere to strict financial targets. Currently, the funding of UCS is renegotiated with the Ministry of Health every year (6). This jeopardizes the sustainability and improvement of the system.

Related to the lack of consistent funding, the adequacy of the funding is also an issue. Currently, the Thailand government does not spend the 5% of their GDP recommended by the World Health Organization (WHO) that is necessary to sustain a universal healthcare plan (27). This could potentially be one the biggest reasons for inequality between rural and urban regions. Additional funding is also necessary to support policy research into understanding the changing needs of the population. There

are worries that the current funding will not be able to sustain the aging population and rising expectation of UCS beneficiaries (15). Indeed, Thailand is projected to enter a health crisis in 2025 unless significant changes are made and funding is increased (2,28). A possible solution to this could be to implement increased taxes on tobacco and alcohol, which could lead to healthier practices while also providing the government with a constant source of revenue. Such a strategy would increase UCS's funding by 0.64% of the GDP, allowing Thailand to continue towards the 5% minimum (4).

**Figure 10: (15)**

Figure 10 Proportions of the population using UCS or other government health schemes classified by gender and age group, FY2015



Finally, as discussed in this study, distribution of healthcare resources between rural and urban regions needs to be improved, particularly with regards to healthcare professionals. The fact that only 18% of doctors work in rural areas is an obvious sign of need for improvement (22). Policies can be implemented to incentivize healthcare professionals to work in rural regions such as recruiting students from rural areas, higher pay, or subsidizing student loans.

**Conclusions**

The achievements and handicaps of Thailand's universal coverage scheme serve as an example for other countries in the global health community that wish to achieve universal health

coverage. With the successful implementation of UCS, Thailand has proved that universal health coverage is possible in an LMIC setting, which has the potential to provide guidance for other countries with similar economic statuses. An important lesson learned from Thailand's success is that universal health coverage cannot be achieved without the cooperation of multiple agencies; this includes strong political commitments, reliable policy research and public interest. Without the Thai Rak Thai party's advocacy for universal healthcare coverage throughout their electoral campaign and mandate, the UCS likely would not have been implemented as early as 2001.

The establishment of healthcare infrastructure at the rural level is essential to the successful implementation of a scheme like UCS. Through years of investment in building district hospitals and centers and implementing a policy of mandatory rural service for health professional graduates prior to the establishment of UCS, the scheme was able to be implemented at the rural level (2). Despite these efforts, this case study has shown that disparities between the urban and rural populations continue to exist within UCS. Indeed, there needs to be work done to close these gaps and create an equitably-distributed healthcare coverage scheme.



**Visual Abstract: Approach, Impact and Cost of**

## Thailand's Universal Coverage Scheme

### Acknowledgements

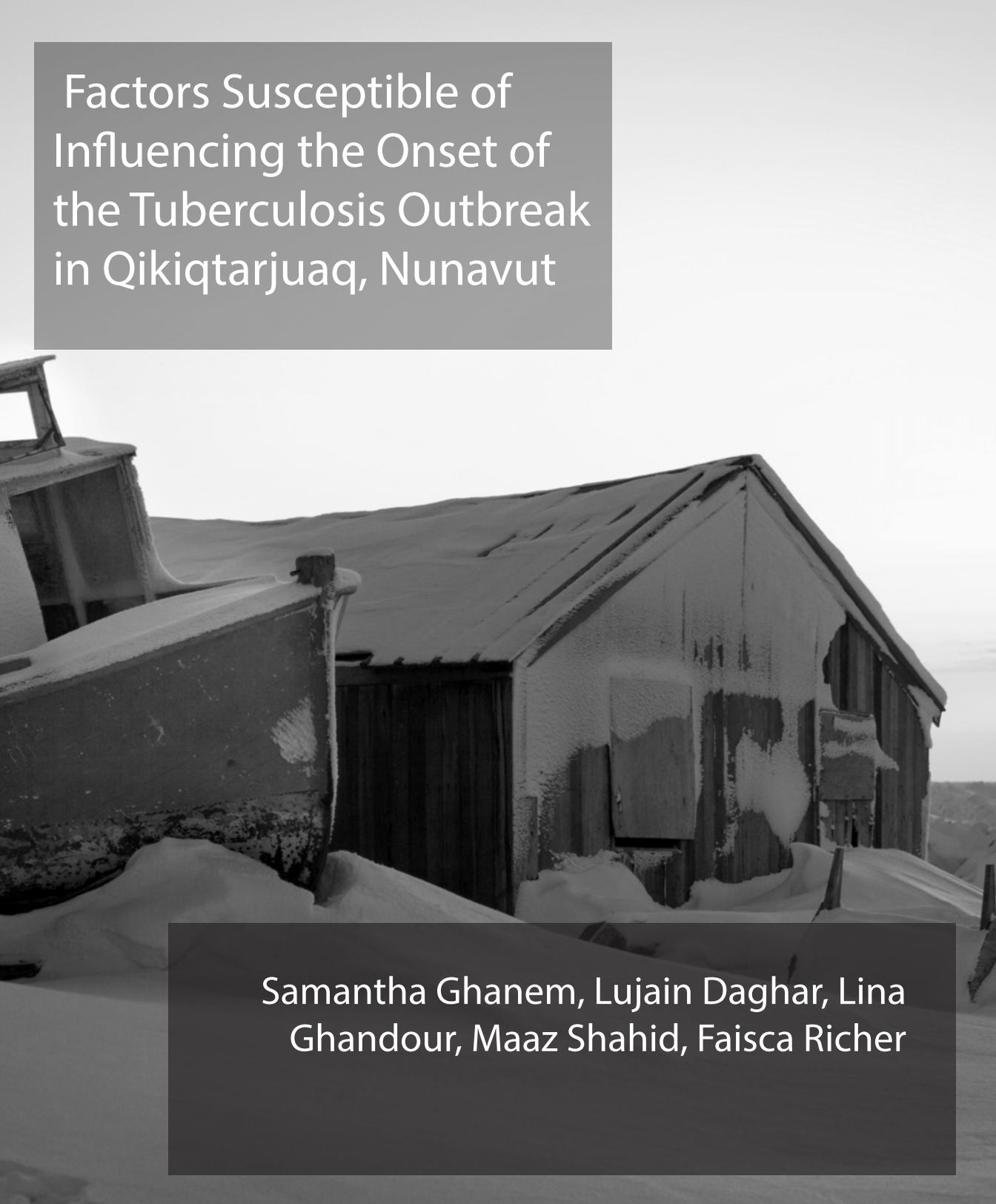
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Factors Susceptible of  
Influencing the Onset of  
the Tuberculosis Outbreak  
in Qikiqtarjuaq, Nunavut

Samantha Ghanem, Lujain Daghar, Lina  
Ghandour, Maaz Shahid, Faisca Richer

## Abstract

Recurrent tuberculosis (TB) outbreaks in the North point to the need for a change in the management of this disease. We propose to use a PRECEDE-PROCEED inspired framework to identify three different levels of factors that have contributed to the ongoing TB outbreak in Qikiqtarjuaq, Nunavut. The main predisposing factor discussed is the sustained impact of colonialism, due to the Inuit community's historical experiences with TB eradication efforts led by the Canadian government. Enabling factors that prevent a sustained reduction in the prevalence of TB include inadequate housing and sanitation infrastructure; food insecurity and malnutrition; and a lack of access to healthcare services. Lastly, reinforcing factors including stigma and fear surrounding TB act to sustain the impact of the underlying factors. Addressing these multi-level causes via governmental interventions will contribute to gains in the fight against TB in Inuit communities.

## Introduction

1,600 new cases of Tuberculosis (TB) are reported every year in Canada, 90% of which affect two main populations: Canadian-born Indigenous Peoples and foreign-born individuals (1). Qikiqtarjuaq has the highest prevalence rate of Tuberculosis (TB) in the territory of Nunavut; in 2017, 10% of its Inuit population was affected by TB (2,3). In this community, TB predominantly affects individuals over 15 years of age and children under 1 year of age, whereby more cases are reported among men (62%) than women (38%)

(4,5).

The TB outbreak in Qikiqtarjuaq has resulted in significant psychosocial repercussions for affected individuals, including feelings of isolation from the community (6). During the latest TB outbreak in the Qikiqtarjuaq region, residents have reported mental health disorders related to the lack of effective patient-physician communication and the period of quarantine following a diagnosis of active TB (3,6). Community members have also reported feelings of isolation due to their lack of knowledge of TB and the lack of access to mental health workers (3,6).

The PRECEDE-PROCEED (Predisposing, Reinforcing, Enabling Constructs in Ecological Diagnosis and Evaluation – Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development) is an eight-phase planning model often used in public health programming (7). The PRECEDE component of the model “consists of a series of planned assessments that generate information that will be used to guide subsequent decisions” (7), based on the understanding of the factors influencing health behaviours, namely: [1] predisposing factors, which include knowledge or attitudinal characteristics which motivate behaviour; [2] enabling factors, such as access to services or support, which can facilitate the adoption of a particular behaviour); and [3] reinforcing factors, such as immediate feedback and consequences of the behaviours which contribute to its repetition and maintenance (7).

The TB outbreak in Qikiqtarjuaq, Nunavut, spurred our inquiry into the factors – predisposing, enabling, and reinforcing from the PRECEDE-PROCEED framework – that could inform how similar outbreaks could be prevented and abated in Indigenous populations. Therefore, the purpose of this determinant analysis is to better understand the factors which could be targeted in programs aiming at reducing TB transmission among this population.

The determinant analysis presented in this article is based on a rapid review of peer-reviewed and grey literature on TB in Indigenous populations in Canada. We identified peer-reviewed articles in Medline and EMBASE. In the two databases, we searched using terms related to three concepts: [1] Tuberculosis, [2] Indigenous, and [3] risk factors. In addition to the scientific database searches, additional articles were identified through a grey literature search in google, which identified articles and reports from the Government of Nunavut, Public Health Agency of Canada (PHAC), World Health Organization (WHO), and Canadian Broadcasting Corporation (CBC). From the scientific database searches and grey literature search, five peer-reviewed articles and eight grey literature articles were included in this determinant analysis.

### **Predisposing Factors**

Predisposing factors are usually defined as personal or population-wide characteristics that motivate individuals in adopting a specific

health behaviour; these include knowledge, values, and attitudes which may explain individuals' behaviours (7). One important predisposing factor is the sustained impact of colonial public health practices.(8). For instance, community mistrust towards governmental institutions is rooted in a historical legacy of TB in the Canadian North which originates from a time when individuals of all age groups, from children to elders, were forcibly removed from their communities to be treated at southern (often segregated) hospitals, known as TB sanatoriums (6,9,10). Although this approach resulted in a decrease in TB cases in the North, it led to distress among family and community members who were often not informed of their families' living situation. Many of these patients passed away and hence never returned home, often without their families being notified (4,5). Overtime, this practice led to severe community mistrust of the Inuit population around TB control and treatment policies, thus impeding efforts to eradicate TB in the North.

### **Enabling Factors**

The sustained impacts of colonialism have also influenced the following enabling factors, which increase the risk of TB transmission in Nunavut communities: [1] inadequate housing and sanitation infrastructure, [2] food insecurity, hunger, malnutrition, and [3] lack of access to health care services and poor observance of TB treatment recommendations. Inadequate government funding for social housing has led to housing overcrowding and homes that are in need of major repairs (4,11). Overcrowded

diagnosis and evacuation from the community for treatment (3).

### Discussion and Conclusion

The identified predisposing, enabling, and reinforcing factors can illuminate some of the potential reasons underlying the onset of the TB outbreak in Qikiqtarjuaq. In addition to the implementation of acute public health measures, the eradication of the TB outbreak will require long-term investment to address underlying root causes of the disease. Qikiqtarjuaq would benefit from increased family income and improved funding for housing and food security. All efforts undertaken to eradicate TB in Qikiqtarjuaq should address issues rooted in the sustained impact of colonialism and socio-cultural factors, including mistrust, language barriers, and access to health care. Furthermore, the development and implementation of TB prevention programs should be community-led to respect the imperative of cultural safety principles. The success of such interventions will require the financial support of key federal and territorial government bodies, as well as active governance by local Inuit leadership and non-governmental organizations.

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# Costa Rica's Health Care Reform: Impact and Success of the EBAIS Model

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## Abstract

In 1995, Costa Rica reformed its Primary Health Care System and implemented the EBAIS model to provide health care for all its citizens. This model created multidisciplinary teams to provide holistic and integrated preventative, curative and public health services to established health areas. With a focus on primary health care, accountability, monitoring and community involvement, the Equipos Básicos de Atención Integral de Salud (EBAIS) model received strong political support and was backed by both private and public funding. In 2017, over 93% of the population had access to primary health care and Costa Rica ranked 62 out of 195 for the Healthcare Access and Quality (HAQ) index. Due to an increasing prevalence and burden of non-communicable diseases worldwide, re-commitment of this plan is imperative. The United Nations Sustainable Development Goal (SDG) 3.8 aims to achieve universal healthcare (UHC) coverage through the provision of essential health care services for all (1). As countries look towards reforming their health care systems, Costa Rica serves as an example of an innovative and successful model for delivery of primary health care. In this case study, we will examine the impact of Costa Rica's reformed Primary Health Care System on access to health care from 1995 onwards.

**Visual abstract: EBAIS model objectives, outcomes and health care coverage impacts**



## Costa Rica's Health Care Reform: Impact and Success of the EBAIS Model

### Background

Prior to 1941, Costa Rica's citizens obtained health care through town or workplace doctors or by paying out-of-pocket (2). In 1941, Costa Rica established the Caja Costarricense de Seguro Social (CCSS) to provide health care insurance to workers (3, 4). In the 1960s and 70s, the Ministry of Health expanded insurance to include primary health care for workers' dependents and vulnerable groups (2, 5). In 1973, primary health care became a core component of Costa Rica's health care system, focusing on "health promotion, sanitation, child health, and infectious disease eradication" (6). In the same year, Costa Rica began the Programa de Salud Rural, or Rural Health Program to extend primary care to rural populations (7). These early systems were already improving health status and later served as building blocks for the 1995 reform. In the 1980s, Costa Rica experienced an economic crisis, which led to decreased funding to the Ministry of Health (MOH). Financial hardships, along with a government that supported neoliberal policies, led to a transition to the Selective Primary Health Care (SPHC) model—a cost-effective and resource-maximizing primary health care model (6, 7).

In 1991, dissatisfaction in Costa Rica's health care system was at an all-time high. A measles outbreak overwhelmed the public sector, resulting in a failure to meet the needs of the population, including long wait times and pressure upon employers to finance their employees' private clinic visits (2). Growing demand from

users and communities to occupy active roles in their health care facilities, along with political support, reinforced the need for change (7). President Rafael Calderón Fournier of the Social Christian Unity Party called for health care reform, with the goal to increase coverage and comprehensiveness of health care for Costa Ricans (6). A team of officials from the CCSS and MOH, along with health care providers, developed the new primary care model, the Equipos Básicos de Atención Integral de Salud (EBAIS) model, with the goal of equal health care for all of Costa Rica's citizens. Following the reform, delivery of primary health care was transferred from the MOH to CCSS, which granted them control over the incorporation of preventive, curative and public health services. Meanwhile, the MOH would supervise the overall health system (6). The first EBAIS team was established in February 1995 and was the product of long negotiations between Costa Rica and the World Bank (2).

### **Implementing the EBAIS Model**

#### *The EBAIS Model Explained*

Prior to reform, the Costa Rican health care system was inefficient and costly, creating long waiting lists for its recipients (4, 8). Moreover, several clinics were unable to provide holistic care to their patients, choosing to instead focus on curative approaches. The EBAIS model was created as a reformative intervention for Costa Rican health care and established the following four goals: (1) the improvement of primary care, (2) the ability to hold hospitals & clinics accountable, (3) the active participation and involvement of the community in their health

care, and (4) the gain of administrative independence by the hospitals & clinics (8). This was done by focusing on four key strategies to develop their EBAIS model: bureaucratic integration, multidisciplinary teams, empanelment/measurement and feedback loops (6). In the new model of primary care, EBAIS, or Integrated Primary Health Care Teams, emerged with the goals of providing unified and holistic care throughout the course of a patient's life.

With firmly established goals, political commitment and financing, the CCSS formed EBAIS teams by building or converting existing health clinics all over the country (9). By February 1995, the first EBAIS team had been set up. Existing staff were trained in the new holistic approach and many were transferred from the MOH to the CCSS. Services provided by the EBAIS are integrated and intended to cover one's lifespan, including treatment of diseases, rehabilitation, vaccination, detection and monitoring of risk groups occurring at every age (6, 10).

To best provide comprehensive coverage throughout the country, the CCSS delineated seven health regions into a total of 104 health areas. In early implementation, the EBAIS clinics were established in geographic areas with the highest prevalence of health inequities, followed by broadening to more urban and metropolitan regions (11). Each health area has between 5-15 EBAIS teams which is equivalent to one EBAIS team, or five workers per every 1000 households, or around 4000 patients (12). Each EBAIS clinic is run by an EBAIS team and

falls under the service network of primary care. For complex medical needs, people are referred to secondary or tertiary care in public hospitals and specialized clinics mainly found in San José. Costa Rica's decision to geographically empanel the population to specific EBAIS teams was hoped to support robust, proactive population health management (3).

Each insured Costa Rican is entitled to one yearly wellness visit, or four if the patient has a chronic condition. The goal of each team is to be composed of a physician, a nurse, a technical assistant (ATAPs), a medical data clerk and a pharmacist (6). Nurses and doctors work in clinics and provide preventive care, counseling and treatment. Physicians offer directed care by following health forms with prompts based on health concerns associated with the client's age. Pharmacists facilitate the delivery of medication and work out of a pharmacy attached to the clinic. ATAPs or technical assistants work as community health workers. Their roles are diverse and include home visits, acting as a social worker, providing education on disease prevention and facilitating community-wide health promotion. Finally, medical data clerks are responsible for the recording of all epidemiological data and reporting on quality of care (6).

### **Funding**

Following the finalization of reforms, Costa Rica turned to the World Bank Group (WBG) for financing. Negotiations were complex as both the WBG and CCSS had different ideologies related to health care provision. The WBG sought to reduce costs, privatize, and imple-

ment a purchase-provider split in which the CCSS would not be the only organization providing health insurance (7). The CCSS pushed to implement the EBAIS model, where the implementation and financing of Costa Rican health could be integrated under one public institution. Ultimately, the WBG supported the EBAIS model, defined by federal autonomy and preventive care, through the provision of a USD \$22 million to be repaid over a 17-year period (6). The WBG loan had three main intentions, (1) to consolidate health under the CCSS, (2) to fund the foundation of the EBAIS model, and (3) to increase Costa Rican enrollment into the CCSS insurance program, thus modernizing payment, while also increasing the efficiency of health, pharmaceutical services and distribution (13). This has culminated in a 70% return on WBG investment (14). In total, Costa Rica raised USD \$123 million, including USD \$47 million from the Inter-American Development Bank, and funding from other international providers such as the governments of Sweden and Spain. These loans were complemented by Costa Rican contributions coordinated by the Pan American Health Organization (15). Through these contributions, the CCSS was able to provide a comprehensive multifaceted system of health care for all.

CCSS purchases services that cover all health needs of the population, including EBAIS teams, medications and lab tests (16). When a patient requires a medication or service not usually offered, they must submit a claim to the CCSS. Patients who are unemployed are only asked to pay for services once they find employment and

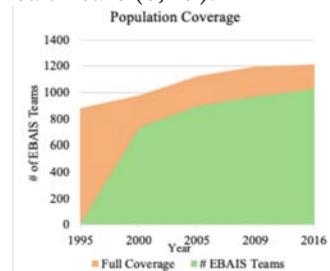
those uninsured are charged the cost of services at lower than market prices (16). Most importantly, no one is denied first time for emergency care. The CCSS does not seek to make profits and upholds equity in financing and financial protection.

CCSS health insurance is financed by three key parties: employees, employers, and the government. Contributions are financed by 15% payroll tax towards which employers, employees, and the government contribute 9.25%, 5.5%, and 0.25% respectively. CCSS funds are then pooled and managed by the central financial administration unit of the CCSS, distributing funds to administrative and health care units (5). A current concern is that CCSS dependence on payroll taxation for revenue could eventually lead to financial scarcity as the informal labor market increases in size, thus limiting the amount of people providing direct financial contributions (17). Furthermore, an analysis of public expenditure illustrates how economic status is inversely related to health care utilization, and how the saturation of public services is pushing those of a higher financial status to utilize private care. The poorest 20% of the population who receive only 4.7% of the national income are the recipients of nearly 30% of all health expenditures, while the wealthiest 20% of the population who receive 48% of the national income receive 11.1% of CCSS resources (5). In addition, household surveys show that 30% of the population utilize private health services at least once a year. This depicts an increasing willingness, by those financially predisposed, to opt in to private services for basic procedures

and utilize the CCSS for major operations, thus bypassing the extended wait times found in the public system while avoiding catastrophic out-of-pocket expenditure (18).

### Impact Evaluation

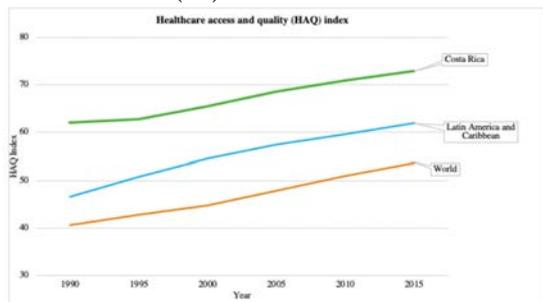
One of the primary goals of the 1990s health care reform was to extend coverage of health care for Costa Ricans (6). The EBAIS model aimed to provide one EBAIS clinic for every 4,000 citizens, especially targeting rural and low-income groups. Before 1990, only 25% of Costa Ricans had access to primary health care (19). From 1995 to 2001, the number of EBAIS teams increased from 0 to 736 clinics, covering 80% of the population (2) (Figure 1). While still 295 less clinics than needed for full coverage in 2017, over 93% of the population has access to primary health care (6, 19).



**Figure 1.** Estimated and actual coverage of Costa Rica's population through the EBAIS system from 1995 to 2016. Data provided by Pesec 2017 (6). Full coverage calculated based on population of Costa Rica divided by 4,000.

From 1990 to 2016, the Healthcare Access and Quality (HAQ) Index increased from 62.1 to 73.7 in Costa Rica, an absolute change of 13% (20) (Figure 2). Compared to 195 countries, Costa Rica ranked sixty-second according to

this index, with Iceland as number one with an HAQ Index of 97, and the Central Africa Republic as last with a score of 19 (20). Out of Latin American countries, Costa Rica ranked fourth out of 21, preceded only by Puerto Rico, Chile and Cuba (20). Based on The World Bank's data on Universal Healthcare coverage index, Costa Rica had a score of 75 in 2015. This means Costa Rica has ranked 34th out of 130 with available data. Although many of PHCPI's 38 indicators are missing data for Costa Rica, there are some that show the success of the intervention. For example, antenatal care coverage, which means four or more visits, was at 97.6% compared to the "worst" world value of 6.3%, and the "best" value of 99.7% (18).



**Figure 2.** Healthcare access and quality (HAQ) index of Costa Rica compared to Latin America and the world from 1990 to 2015. Data provided by GBD collaborators 2018 (19).

One of the main aspects of primary health care, as seen in the Comprehensive Primary Health Care (CPHC) model, is prevention and control of infectious disease (6). Before the 1970s, many health care programs were vertically oriented towards fighting specific diseases. For example, in the 1960s, Costa Rica ran four disease-specific campaigns: tuberculosis (TB), venereal dis-

ease, parasites and malaria (6). The implementation of the EBAIS model, which promotes prevention and care at the primary level, should be evaluated on its ability to address infectious disease prevention and eradication. Since 1990, Costa Rica has decreased the rates of communicable diseases from 65 cases per 100,000 people to 4.2 in 2010, likely due to the use of vaccination, better sanitation and the EBAIS system (6). PHCPI performance indicators validate Costa Rica's Primary Health Care through an 85.0% TB treatment success rate among new TB cases, with a total of 80% of TB cases being detected and treated and with 54% of people living with HIV receiving ART (18).

The increase in health care access and the decrease of infectious diseases seem to be signs of a successful primary health care program. However, non-communicable diseases, such as cardiovascular disease, have been increasing worldwide. Countries are now experiencing an epidemiological transition, with non-communicable diseases becoming the leading cause of death worldwide. It is important to evaluate the performance of the EBAIS model on NCDs, as it must now meet the country's growing health care needs stemming from chronic conditions. It should be noted that Costa Rica's primary health care system achieved the best result for lower-middle income countries regarding adult mortality from NCDs: 12% (18). As of 2012, cardiovascular disease accounts for 30% of deaths in Costa Rica (21). Cardiovascular disease may be a formidable challenge for Costa Rica's health care system, where some report 12 to 18 month long wait times for specialty care

services, such as cardiology (6, 18).

### **Strengths of the Intervention**

The implementation of the EBAIS system in Costa Rica has led to remarkable changes. A large majority of the population now has access to primary health care. Above all, the achievements of Costa Rica's health system from 1995 onwards stem from the strong determination of the Costa Rican government in prioritizing population health and development. In the 1990s, during the creation of the EBAIS system, 7% of the GDP was allotted to the health care system, of which only 30% came from private funds, while the remaining 70% was sourced from public funds (7). This proportion of resources coming from public funds prior to the reform was unusually high when considering that Costa Rica was classified as developing country. Remarkably, health expenses coming from public funding are comparable to the rates of high-income countries like Canada, with 71% public funding in 2000, New Zealand (78%) and Sweden (85%). Costa Rica's funding programs and financial commitment to health care are in part why the country has health outcomes that resemble those of high-income countries.

The CCSS first targeted the poorest health areas, making a sensible choice in providing comprehensive care and reducing the inequities present predominantly in these areas. The rapid increase was substantial due to the previous lack of presence (6). This allowed for the reduction of inequities within the health system and a rapid increase in coverage. An important goal established post-reform was to create a system

where hospitals and clinics could be held accountable (8). In order to measure and evaluate the EBAIS model, management contracts (MC) were implemented in 1997. The first MCs were structured as performance-based payments for Health Areas able to reach the indicators and targets negotiated between CCSS administration and service providers (4). The MCs had several important limitations, such as being time consuming, drawing away from consultations, monitoring certain health problems while neglecting others and being poorly aligned with EBAIS objectives. Given the difficulty of monitoring unique MC targets for each Health Area, and in efforts to optimize performance for all 104 Health Areas, MCs were replaced in 2014 by the EPSS (Provision of Health Services Evaluation) and a national set of targets and indicators for the period of 2014 to 2018 were introduced (6). Despite the limitations of the MCs, it is Costa Rica's dedication to monitoring the quality of care that allowed the EBAIS model to adapt and respond to factors like access of care, continuity, effectiveness, efficiency and user satisfaction. For instance, one of the MC requirements included having a physician present from Monday to Friday, which assured that the patients could be seen, and care was provided (4). Since replacing the MCs with the EPSS, the health areas have sustained their efforts to meet targets, enforced by disciplinary action for health areas ranked in the bottom 20% who do not improve their performance within a year (6).

### **Limitations and Challenges Faced**

There are several factors which underlie chal-

lenges faced during EBAIS implementation. Despite the impressive realization speed, Costa Rica still has not met its original goal of 4,000 patients per EBAIS team. Moreover, in 2017 an addition of 295 clinics were missing to complete the reform's targets (6). Since the EBAIS originally started in rural areas, EBAIS teams in larger metropolitan clinics, like in the San Jose capital, are often missing key team members and must share clinics. Furthermore, there remain issues with integrating primary, secondary and tertiary care. Some patients still face issues of access and experience long wait times for specialized doctors, resulting in many going to emergency rooms (6). The recourse of patients towards emergency rooms places a strain on emergency care staff and services, increases wait times and emergency room crowding, leads to less comprehensive evaluations by physicians and only temporarily relieves individuals when specialized care remains needed. As frustrations towards long wait times for specialized procedures grow (sometimes upwards of a year or more) Costa Ricans are increasingly paying out-of-pocket for privatised health care. Thus, the country's health care faces the risk of becoming a divided, two-tiered system.

The rise of the private sector is now challenging the EBAIS model by further exacerbating existing flaws within the public system. Firstly, strong mandatory preventive programs in EBAIS have led doctors to dismiss activities that have not been included in established performance agreements, such as addressing obesity (7). With an aging population and the doubling of the population over 65 since 1990,

Costa Rica has undergone and an epidemiologic shift towards a higher NCD burden (6, 21). Furthermore, the long wait times for specialty care mentioned earlier may additionally worsen the problem, especially since many cancer screenings fall under secondary care where wait-times could interfere with access to preventative, screening and treatment services (6). The private health care costs represent a small but growing portion of total health expenditures. In fact, private health costs represented approximately 25% of total health care costs in 2013 (6).

As previously mentioned, health care expenses have been on an upward trajectory and although this reform has attempted to tackle such challenges, political arrangements could be at the source of these limitations. The MOH's role in planning, funding and delivering health care can still be strengthened. Furthermore, audits are lacking and data on needs and activities are still not fully linked to outcomes pertaining to costs and care (21). Even though Costa Rica's institutions are stable, they are quite inflexible, as portrayed through the failure of programs to improve quality and efficiency, such as diagnosis-related group accounting or accreditation programmes, which have been abandoned. This demonstrates how initiatives to improve transparency and accountability have not been well accepted (21).

## Reflections

The Costa Rican experience serves as an important lesson for the global health community. Unlike Brazil and other rural health programs,

the EBAIS model was implemented on a national scale and thus dramatically improved health coverage as well as the quality of care received (6). Costa Rica's reform did not use novel interventions but rather combined multiple disciplines and strategies to create a comprehensive system.

Geographic empanelment has been tried by numerous countries, but few have gone beyond simply assigning patients to primary care providers. For example, Turkey has successfully used geographic empanelment for the past two decades, but not in conjunction with integrated restorative and preventative care or multidisciplinary teams, which make up the core of the EBAIS model (6). In contrast, Costa Rica complimented the use of geographic empanelment by simultaneously building teams and programs to ensure accountability and monitoring of population health. Around the world, community health workers play valued roles. In Costa Rica, technical assistants are unique in their professionalism, in-depth training and responsibility for community data collection. Geographic empanelment and multidisciplinary teams have been implemented by countries before, but when used together, they form a strong foundation for measurement and feedback loops (3). This benefits the identification of at-risk populations, cascade of care flaws and allows stronger systems to work on a large scale. Comparing Brazil and Turkey to Costa Rica highlights the latter's unique success in the integration and combination of reforms at a national scale (6).

Finally, UHC policies and values must remain high and prioritized on the political agenda both throughout and after implementation (12). Governments that are currently developing or reforming their health care systems must be willing to motivate stakeholders, make resources available and push for the coordination of UHC across institutions. Like Costa Rica, countries will have to respond flexibly to evolving population health and demands.

### **Future of the Model**

Although the reformed system of health embodied by the EBAIS model was largely effective and efficient, the future of the CCSS may be at stake financially if it does not control expenditures, improve the collection of financial resources and mobilize new sources of funding (21). As the population changes, financial strain will grow from both the expenditure and income side. Researchers predict a rising demand for costly health services as well as a shrinking pool of citizens' contribution through taxes. Some future steps may be required to improve financial sustainability. For one, Costa Rica could work to further optimize the collection of existing revenue sources in response to evolving labour market structures. The CCSS financial model could also be reformed to better monitor health-care costs associated to personnel and information system implementation (21).

Lastly, Costa Rica will have to adapt their model to the growing NCD burden by targeting issues such as nutrition, obesity and exercise. The model will need to survey the factors contrib-

uting to NCDs, such as alcohol use and high fat diets, and educate the public regarding prevention, identification and treatment. Costa Rica has already started educational programs teaching about risk factors and symptoms as well as the ability to self-manage chronic diseases (6).

Overall, Costa Rican health indicators mimic those of middle-high incomes countries despite low income per capita. Costa Rica provides important takeaway lessons for countries around the world looking to reform their primary health care systems. Although the model still has flaws and is undergoing transitions, Costa Rica's successful reformation, implementation and sustainment of their prosperous primary health care system serves as a valuable example for the global health community.

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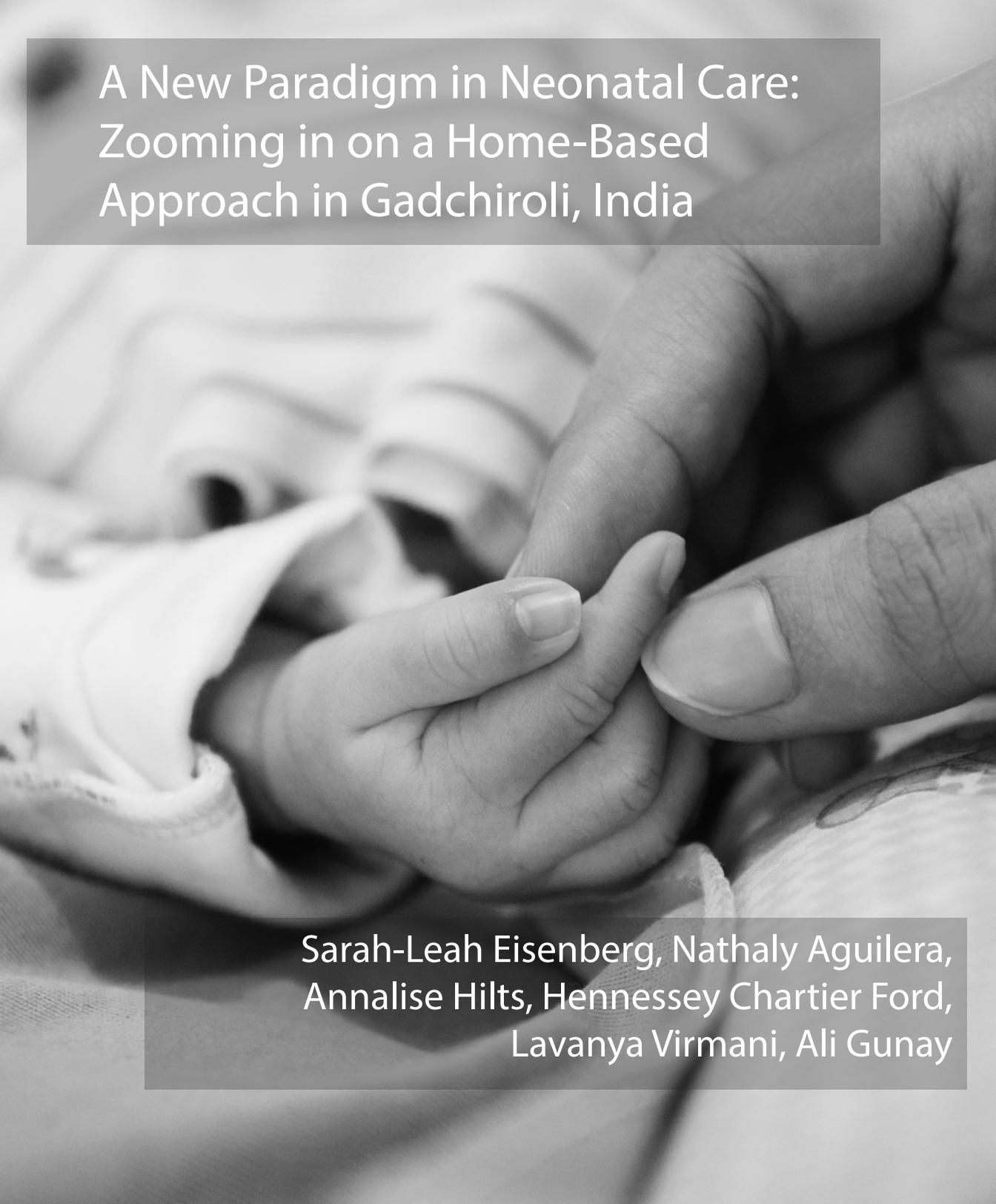
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A New Paradigm in Neonatal Care:  
Zooming in on a Home-Based  
Approach in Gadchiroli, India

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**Abstract**

Neonatal mortality accounts for the highest amount of under-five deaths worldwide, particularly in developing countries. The Society for Education, Action, and Research in Community Health (SEARCH) sought to address neonatal mortality in Gadchiroli, India. In 1993, SEARCH created the Home-Based Neonatal Care (HBNC) model in order to improve neonatal outcomes. The goal of the HBNC intervention was to deliver primary neonatal care to reduce the neonatal mortality rate (NMR) by at least 25%, and the sepsis-related NMR by at least 40% in 3 years. This case study provides a description of the HBNC, and analyzes the cost-effectiveness, outcomes, and future implications of the intervention. Compared to the 47 control villages, the HBNC improved NMR in the 39 trial villages during the study period, between 1993 and 2003. In response to the positive outcomes of the trial, a nationwide scale up was implemented in 2011, administered by the Indian government. The HBNC intervention was cost-effective and addressed the needs of the community in a culturally sensitive way. The HBNC has the potential to be reproduced in other regions with a high NMR. However, since each region is different, context-specific modifications should be taken into consideration.

**Introduction**

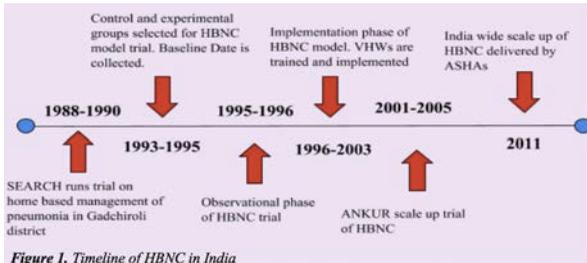
In 2017, neonatal mortality accounted for 47% of the 5.4 million under-five deaths worldwide. Currently, neonatal mortality is 14 times higher in developing countries, totalling at 69 deaths per 1000 live births, in comparison to 5 deaths

per 1000 live births in developed countries (1). Although neonatal mortality rate (NMR) has considerably decreased in India to an estimated 24 deaths per 1000 live births, the NMR was dramatically higher in the 1990s, at 59 deaths per 1000 live births (2). The Society for Education, Action, and Research in Community Health (SEARCH), a non-governmental organization working in the Gadchiroli district of India, sought to address child health and NMR in one of India's poorest areas, creating what came to be known as the Gadchiroli Field Trial in the late 1980s.

SEARCH, established in 1986, prioritizes community-identified needs and operationalizes interventions that empower the existing local workforce to achieve sustainable health outcomes (3, 4). The Gadchiroli district is the least economically and educationally developed area in the Maharashtra state of Western India, and SEARCH launched a field trial from 1988-1990 in this region to improve management of pneumonia and sepsis in neonates. At the time, the few hospitals that were established were far away from the villages where SEARCH implemented their intervention and were unable to address the needs of the community (5). SEARCH recognized this gap in the provision of local care, introducing a community-based intervention for pneumonia management in children. This new intervention included mass education about childhood pneumonia and case-management using the oral antibiotic co-trimoxazole, which was administered by the trained village health workers (VHWs) and traditional birth attendants (TBAs). The intervention signifi-

cantly reduced pneumonia-specific childhood mortality in the intervention villages compared to control. However, mortality from other causes remained similar and the SEARCH team recognized the need to broaden their strategy to include other factors associated with neonatal mortality (6). As a result, the Home-Based Neonatal Care (HBNC) model was developed. The HBNC trial had great success in Gadchiroli and was later scaled up by the Indian government to cover more rural areas. In this article, we will provide an in-depth description of the Gadchiroli HBNC model and compare its clear success to potential future outcomes of the HBNC scale-up in India.

**Figure 1. Timeline of HBNC in India**



*Figure 1. Timeline of HBNC in India*

**The Gadchiroli HBNC Model**

**Goal of the HBNC trial**

In the 1990s, hospitals were not readily accessible to families living in the Gadchiroli district, so most women opted to give birth at home. Rather than pushing women towards institutional delivery and transporting sick neonates to hospitals, the SEARCH team decided it would be more beneficial to establish a low-cost, HBNC system that utilized the human potential in the villages. The main goal of this intervention was to reach 75% of the neonates

in the community and 60% of the neonates with sepsis because neonatal sepsis accounts for much of the neonatal mortality in developing countries. Additionally, the researchers aimed to deliver primary neonatal care in order to better manage illness and reduce the NMR by at least 25% and the sepsis-related NMR by at least 40% in 3 years (7).

**Description of the HBNC trial**

	Period	Description
Baseline phase	1993-1995	<ul style="list-style-type: none"> <li>- Collection of information on neonatal health and traditional practices: demographic characteristics, availability of healthcare, and vital rates (NMR, perinatal mortality rate (PMR) and infant mortality rate (IMR))</li> <li>- Control and intervention villages had similar characteristics</li> </ul>
Observation phase	1995-1996	<ul style="list-style-type: none"> <li>- Assessment of neonatal morbidities and causes of death</li> <li>- Employed simplified diagnostic criteria (ICD-9 codes) to identify neonatal disorders</li> <li>- Helped guide design of the HBNC intervention</li> </ul>
Intervention phase	1995-2003	<ul style="list-style-type: none"> <li>- Selection and training of VHWs and simple home visits/observations</li> </ul>

**Table 1. Description of Gadchiroli trial phases.**

The Gadchiroli HBNC model was implemented in 39 villages in the Gadchiroli district and was compared to 47 adjacent control villages. The Gadchiroli district was selected as SEARCH was based and working in this district. Intervention and control villages were chosen based on where SEARCH was already well-established and respected for their previous work on improving reproductive health and neonatal pneumonia between 1986-1993 (7). All infants born in the intervention villages were eligible to participate in the trial (7). By the end of the trial, the HBNC intervention had covered 93% of newborns in the intervention area, with VHWs present for 84% of home deliveries (8). The development and implementation of the

HBNC consisted of three main phases: the baseline phase, the observational phase, and the intervention phase (7) (Table 1). All VHWs were trained to manage birth asphyxia, sepsis, breastfeeding problems, premature or low-birth-weight, and hypothermia. VHWs were paid an honorarium depending on their work and performance level (8). Other components of the intervention package included: attending deliveries along with the TBA, administration of vitamin K, early diagnosis and treatment of sepsis, health education of mothers and grandmothers, keeping track of pregnant women in the villages, monitoring of vital rates, repeated home visits after birth to monitor the newborn for infections, teaching mothers to properly breastfeed, thermal care, and weekly weighing. Throughout the intervention, the morbidity and mortality rates were carefully monitored.

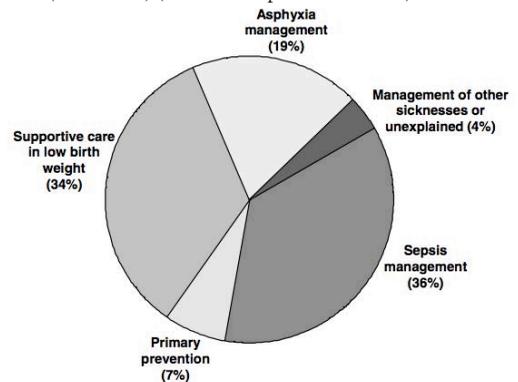
#### Main Outcomes of the HBNC trial

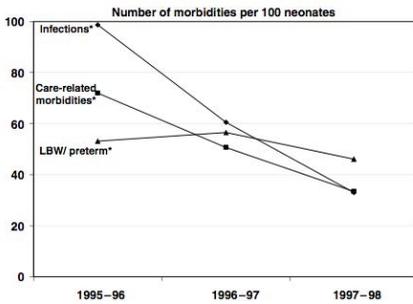
In order to evaluate the effectiveness of both the Gadchiroli HBNC program, the HBNC team focused on two main metrics: NMR and incidence of neonatal morbidities. According to the World Health Organization (WHO), neonatal mortality can be defined as the number of deaths that occur within the first 28 days of life per 1000 live births for a given population or geographical area during a given year (1). Incidence of neonatal morbidities was defined as the mean number of morbidities per 100 neonates accordingly to the definition provided by Bang and his co-authors (7).

The researchers of the Gadchiroli trial compared NMR in the control and intervention

areas from 1993-2003. By 2003, NMR in the intervention area had decreased from 62 to 25 neonatal deaths per 1000 live-births. This 70% decrease in relation to the control area was associated with sepsis and low birth weight management, as well as improved care for other neonatal morbidities such as those presented in Fig. 2 (7). Furthermore, the mean number of neonatal morbidities (per 100 neonates) decreased by 50% in the intervention area from 1995-1998. This was due to decreases in infections, in incidence of low birth weight and other neonatal morbidities as described in Fig. 3 (7). An important factor responsible for this reduced mortality was that the mothers began acquiring the knowledge and behaviours to help them manage newborn illnesses through the intervention. The researchers also discussed a dose-response relationship between increasing quality of the intervention and decreases in neonatal morbidity. The Gadchiroli field trial also had other positive effects, such as decreasing IMR and PMR by 57% and 56%, respectively.

**Figure 2.** Image from Bang et al., 2005: "Proportion of neonatal deaths prevented by different components of home-based neonatal care (1996-2003) (total deaths prevented = 161)".





**Figure 3.** Image from Bang et al., 2005: “Home-based neonatal care in action”.

## What determined the success of the HBNC trial?

### Background research and contextual sensitivity

The success of the HBNC trial can partially be attributed to its in-depth consideration of local context. The researchers understood the traditional beliefs and practices surrounding newborn care in the area through focus group discussions with mothers and grandmothers. This tactic ensured contextual feasibility and a long-term, sustainable approach, identifying appropriate education programs and consideration of taboos and harmful practices that needed to be averted (8). The initial field trial for community-based pneumonia management had also identified an intervention strategy that was successful in reducing NMR and IMR in the villages, which served to inform the design of the HBNC package. In the initial trial, awareness of pneumonia management was achieved through mass health education in rural villages, and local terminology was adopted to ensure precise communication (8). Special training utilizing visual diagnostics was implemented to ensure that illiterate TBAs were successful in the identification of conditions and delivery of

medication (6). These strategies for catering to the community demographic were carried onto the HBNC intervention. As such, ongoing consultation and education to sensitize community members to the intervention ensured its continual success (8).

### Mobilizing and empowering women in the villages

The Gadchiroli model placed the women, mothers, and grandmothers of the villages as active leaders in the implementation of the HBNC program. The program ensured the harmonious integration of the VHWs within the existing TBA network. The VHW’s remuneration was kept marginally higher per hour than the wages she could earn as an agricultural worker; incentivizing women in the villages to apply for VHW positions (8). Performance-linked remuneration was also provided, with one third of the VHW wage fixed and the other two-thirds depended on workload and performance (8). In addition to monetary incentives, the acquisition of skills and a prestigious role in the community was further motivation for the VHWs (8).

### Selection and training of the VHWs

The thorough selection and training process of the VHWs resulted in the provision of high-quality care. Only women were chosen for the position, allowing for open communication between the VHWs and mothers. The selection process of VHWs involved the setting of an eligibility criteria and wide advertisement of the position within Gadchiroli to obtain high numbers of applicants (8). Women meeting the eligibility criteria attended a three-day workshop

that included personality and in-field testing to ensure a good fit for the VHW role, increasing the likelihood of success of the HBNC program (8). The training program followed a curriculum of 26 days of in-class training over a period of 10 months (8). Only small amounts of information were taught at a time and trainees were given time to practice acquired skills on the field. A field supervisor visited each VHW twice each month to provide additional training and to improve their motivation and performance. Only a 15% drop-out rate was observed (8).

### **Ensuring high coverage and cost-effectiveness**

The VHW method allowed for the HBNC intervention to save one DALY (Disability Adjusted Life Year) for only \$7, whereas other interventions (i.e. growth monitoring, provision supplementary food) are reported to cost up to \$8235 per DALY saved (7). Moreover, the HBNC provided health services at the community level, where a void of care existed. The integration of two services (pneumonia case management and HBNC) into one resulted in a successful intervention that was sufficiently comprehensive and cost-effective.

### **Scaling-up of the HBNC trial**

Since the 1990s, the NMR in all of India has declined from 52 per 1000 live births to 28 per 1000 live births (2013), with an acceleration in this decline in the past decade (17% decrease 1990-2000, 33% decrease 2000-2013) (9). It is projected that neonatal death rates will decrease to 22 per 1000 by 2020, extrapolating from the trends of average annual rates of reduction between 2000-2012 (9). The success of the Gad-

chiroli HBNC model motivated the intervention to be scaled up to a HBNC model delivered by Accredited Social Health Activists (ASHAs) in 2011. The program was provided through the Indian government country-wide, with the goal to “improve community newborn care practices, early detection of neonatal illnesses and appropriate referral through home visits” (10).

### **Potential outcomes of scaling-up**

As no official metrics exist to evaluate the efficacy of the scale up, the following results are based off a cost-effectiveness study conducted by Ashok et al., which compared the two following scenarios regarding coverage of the intervention (11):

1. Developing an HBNC package using the existing ASHA network that covers 54% of the rural neonate population.
2. Developing an HBNC package that would be delivered via an extended ASHA network, which would offer coverage to 83.4% of the rural newborn population.

The authors used both scenarios as well as other estimations in order to derive possible cost-effectiveness of each intervention (Table 2). The authors assumed a cohort of 10.48 million rural newborns born in 2013 who would not have had access to any other form of care otherwise. They used a baseline incidence of morbidity of 28.3% and baseline NMR of 29.2 deaths per 1000 live births to model outcomes for each scenario. The results of their modelling are presented in Figure 4.

	Intervention 1		Intervention 2	
	54% coverage	95% uncertainty range	83% coverage	95% uncertainty range
Incidence averted	804 718	476 612 – 1 217 799	1 246 812	751 155 – 1 950 785
Deaths averted	89 022	44 199 – 149 050	138 162	76 358 – 244 072

**Table 2.** Adapted from Ashok et al., 2016: “Estimates of the Impact of Home-Based Neonatal Care through Community Health Workers”.

**Comparison of outcomes for Gadchiroli field trial and Scale-up of HBNC**

	Baseline Gadchiroli	Gadchiroli HBNC (% reduction)	Baseline rural India	Basic ASHA network (% reduction)	Extended ASHA network (% reduction)
Neonatal morbidity	370	50%	2 965 840	27%	42%
Neonatal mortality	48	70%	3 060 160	2.9%	4.5%

**Table 3.** Comparison of outcomes of the Gadchiroli field trial and potential outcomes for a scaling-up of the HBNC intervention in all of rural India.

Since both studies used different measures to present their results and these were not comparable, the estimates for NMD and neonatal morbidity described in the cost-effectiveness study were used in order to derive percent reduction in NMR and neonatal morbidity (11) (Table 3). Even when considering an extended ASHA network which would provide higher coverage of an HBNC intervention in rural India, the initial Gadchiroli field trial appears to be considerably more effective.

**Why is the scaling-up of the intervention not as successful as the Gadchiroli model of HBNC?**

One of the main reasons why the scaling-up of

the HBNC was not as successful is that the program had slow uptake. In the financial year of 2013-2014, only 4 million out of 17 million rural neonates had been visited by ASHA workers, and only 120 thousand neonates out of that 4 million had been identified as sick and referred to healthcare facilities (10). The slow uptake of the program motivated the Norwegian-India Partnership Initiative to adapt the model in regions with high levels of NMR, including Madhya Pradesh, Rajasthan, Bihar and Odisha (10). Another cadre of worker, the Yashoda, was introduced to provide care and counselling services to mothers and newborns. A supportive supervision mechanism was also introduced to support ASHAs (10). The combined effect of both ASHA and Yashoda exposure, when trained by the Norwegian-India Partnership, increased the newborn care indicators related to counselling and practice by almost threefold (10). Furthermore, there have been several issues concerning the use of ASHAs in the HBNC scale up. ASHAs receive different training than that given to VHWs in the initial 1993-2003 HBNC trial. While VHWs were selected by community members, ASHAs were involved in the healthcare system prior to the introduction of the HBNC scale up (10). As such, neonatal care duties were simply an addition to their responsibilities. While ASHAs receive four rounds of a seven-module training over the course of a year, only 17% of ASHAs have completed all four rounds, and only 2 modules involve training in neonatal care (10). This lack of training is potentially responsible for ASHAs’ low level of effectiveness at delivering newborn care services. Moreover, there are reports of

ASHAs expressing lack of clarity concerning their job responsibilities, and of large discrepancies across states in the quality of the drug kits dispersed to ASHAs (10). The reports have stated that ASHAs have not received refills in a timely manner, and at times, not at all (10). Overall, it is difficult to replicate the same attention to community detail and uniform standard of care across such a wide scale up.

### **Cost and Financing**

Financing for the initial 1993-2013 trial was provided by the Ford Foundation and the John D and Catherine T, MacArthur Foundation USA (12). As this study began over 2 decades ago, exact amounts of grants and funding were not publicly available. However, based on the figures provided by Bang et al (12), we estimate the initial cost of implementation for the 39-village trial to be \$6045, plus an addition annual recurring cost of \$5070 (\$130 per village). Over the 10-year period of the Gadchiroli trial, this would amount to \$56745 (in 2003 USD). In comparison to other interventions, the Gadchiroli trial is considered “very cost-effective” by the WHO Cost Effectiveness Matrix (12). In comparison, the cost of a hospital stay in India can range from \$17.3 to \$44.2 per day, resulting in significant out-of-pocket expenditures (11). Since its implementation in 2011, HBNC within the ASHA network is funded through the Government of India’s Integrated Management of Child Illness program. Although precise data are not available for the exact costs and metrics associated with this scale-up, Ashok et al. provide an extended cost-effectiveness analysis of the ASHA HBNC system (11, 13). Within its

current scope, the ASHA network serves 60% of the population not currently receiving care (72% of India’s rural neonate population), at an estimated annual cost of \$33 million and a marginal cost of \$5.89 per neonate (11, 13). A further scale up to 83.4% of the population not receiving care (90% of the rural population) would raise this annual cost to \$53 million annually or \$6.54 per neonate (11, 13). In comparison, the Indian government puts \$386.1 million annually into all of its child health programs. The cost of death in the first scenario is \$382, decreasing to \$379 in the potential scale-up (13). Another significant economic benefit to this intervention is the decrease in out-of-pocket (OOP) costs, which present a significant challenge to rural families in India.

### **Future Implications**

As development increases, there is a rising trend towards institutional deliveries. In India, the proportion of institutionalized deliveries increased from 46.9% in 2007 to 78.9% in 2015 (14). Specifically, in rural areas, institutionalized deliveries have increased by 2.5-fold in the past ten years (14). This presents important implications for scaling-up of the HBNC program. Since institutionalized deliveries have increased, there is arguably less interest in creating a program that focuses on home births, hinting that the need for a national HBNC program will naturally decrease over time. However, some communities in India, particularly those in tribal areas, may still have a cultural preference for home deliveries. Thus, ensuring that a program such as the HBNC is set up is important in order to address the needs of these

populations.

The HBNC model operationalizes a community-based approach that can be effectively applied to other low-income rural settings with poor neonatal outcomes. However, much of the model's success can be attributed to its strong community support and culturally relevant care. Therefore, in future applications, context specific modifications should be taken. A HBNC model based off SEARCH's initial Gadchiroli trial has already been undertaken in Ghana, in the form of the Newhints intervention (15). Overall, the Newhints intervention showed similar results to the Gadchiroli trial, resulting in a 12% decrease in NMR (16). These results are promising for the success and feasibility of future interventions in other African countries.

In terms of future directions and challenges of the HBNC trial, it should be noted that every country, village, and region is different in terms of their cultural practices and historical background. Appropriate levels of care and respect should be taken when beginning to conduct the HBNC intervention in a new area. The method by which researchers conduct the study should be carefully analyzed prior to the start of the intervention and the financial requirements of an HBNC program should be evaluated. In the Gadchiroli HBNC trial, the intervention and control villages were specifically chosen. Perhaps when conducting the same intervention in another area, it would be best to conduct a cluster randomized sampling of the intervention and control villages. Even so, the HBNC in-

tervention has immense potential and has been proven to be cost-effective.

The Gadchiroli trial demonstrates that addressing community needs in a context-sensitive way and involving the target stakeholders results in effective intervention outcomes. This is a lesson for all areas in global health. While increased urbanization may lead to a decreased need for home-based care, community-based interventions go a long way towards achieving "health for all".

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# Seasonal Malaria Chemoprevention in Mali: An Effective Intervention or an Unsustainable Burden?



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**Abstract**

Malaria presents an enormous health challenge for children and pregnant women around the world. In Mali, malarial infections were the leading cause of premature death from 2005 - 2016. The high incidence of malaria in Mali is partially attributable to its location within the Sahel region of Africa, where the annual rainy season correlates with peaks in malaria transmission. In 2012, Seasonal Malaria Chemoprevention (SMC) was recommended by the World Health Organization (WHO) to combat this seasonal spike in infections. As SMC interventions are now undergoing a major transition in funding, we believe that this a crucial time to evaluate the cost-effectiveness and sustainability of this project. Through our evaluation, we find that SMC interventions in Mali achieved their 80% coverage goal and reduced the incidence of malaria by 49%, all while maintaining a cost-effective price per round of SMC for each child (under US\$5). Major obstacles that persist for this intervention are the lack of integration with local health systems and potential effects on adaptive immunity. Overall, SMC is a successful short-term strategy for combating malaria, however, the verticality of funding, logistical burden of annual treatments, and risk to adaptive immunity pose serious challenges to the sustainability of the project.

**Introduction**

Malaria is a devastating disease that contributes immensely to morbidity and mortality worldwide. In 2017, there were an estimated 219 million cases of malaria around the world, representing a slight increase from 2016, when

217 million cases were observed. Children and pregnant women were most vulnerable to the disease, as 61% of global malaria deaths in 2017 occurred in children under 5, and both children and pregnant women were found to be at an increased risk for malaria-related anemia (1). In particular, malaria has posed a significant public health challenge in Mali, consistently emerging as the leading cause of premature death and disability in this country from 2005 to 2016 (2). In the 2016 Global Burden of Disease Study, Mali had the highest probability of death from malaria for children under 5 in the world (Figure 1). In addition, Mali has the highest mortality rate from malaria (232.8 deaths / 100,000 people), and the highest number of years of healthy life lost due to malaria (19, 328.2 years / 100, 000 people) in Africa (3).

The high incidence of malaria in Mali is partly due to the country's geographical location. 90% of Mali's population resides in central and southern Mali, which falls within the Sahel region of Africa (4). In this area, malaria transmission is exacerbated by the short annual rainy season (5). Given that peaks of malaria transmission correlate predictably with the rainy season, the implementation of Seasonal Malaria Chemoprevention (SMC) was proposed to combat the high burden of malaria in Mali.

SMC is the "intermittent preventive treatment of malaria in children" using a monthly administration of two drugs (sulfadoxine-pyrimethamine (SP) plus amodiaquine (AQ)) during the rainy season. Several studies have shown that SMC is highly effective and safe (6,7), and

a pilot study conducted by Médecins Sans Frontières (MSF) showed that this is also true in the context of Mali (8). Furthermore, in a Cochrane meta-analysis, populations receiving SMC interventions saw a reduction of 75% in clinical and severe malaria episodes. This reduction was also observed in regions which, like Mali, have high long-lasting insecticide-treated bed net (LLIN) usage (9,10). Given the positive evidence for SMC treatments, in March 2012, the World Health Organization (WHO) recommended that SMC targeting children under 5 should be integrated into malaria prevention programs in the Sahel (11). With this recommendation, the National Malaria Control Program (NMCP), under Mali's Ministry of Health, adopted SMC as a policy in 2012 and scaled up the program nationally in 2016 (12).

As the SMC intervention in Mali is currently undergoing a transition in major funding partners (13), we believe this is a crucial time to evaluate the cost-effectiveness and sustainability of the project. Although studies have evaluated the sustainability of other malarial programs (14), no such studies have extensively explored the sustainability of SMC after transitioning to scale. Our case study will address this gap in information by critically appraising the efficacy and sustainability of the SMC program in Mali. Our discussion considers: (1) the effectiveness of the intervention in reaching its initial coverage, efficacy, and finance goals; (2) the strategic successes of the project, including the ability to coordinate international funding and utilize existing community healthcare worker (CHW) infrastructures; and (3) the strategic problems

that challenge the sustainability of the project, including the verticality of funding, the logistical burden of annual treatments, and unforeseen consequences on adaptive immunity.

### Goals and Strategy

Following the incorporation of SMC interventions into the NMCP policy in Mali in 2012, SMC distribution was scaled up to 42 districts in 2015, and to all 65 districts nationally in 2016. We established three core objectives to evaluate the efficacy of SMC interventions based on goals announced by funding partners (12, 13).

#### Goals

- 80% coverage of eligible children under five with the full course of treatment
- 70% reduction in the number of malarial cases during the rainy season
- Achieve cost-effectiveness: maximum US\$5.00 for each round of SMC annually per child

#### Strategy

What: SMC involves preventatively administering intermittent doses of antimalarial drugs to children aged 3 to 59 months during the rainy season when malaria transmission is highest. The objective is to maintain high levels of antimalarial drugs in the body throughout the duration of the rainy season to reduce morbidity and mortality from *P. falciparum* malaria in these children. The treatment regimen consisted of an AQ tablet daily for three days, with a SP tablet on the first day only. Since SP and AQ confer a high degree of protection for only four weeks, the 3-day cycle was repeated 4 times at

monthly intervals (11).

Where: Targeted areas had extremely high burden of malaria, with more than 10 cases in every 100 children during the transmission season. Additionally, these regions exhibited strong seasonality effects: more than 60% of annual cases of malaria occurred within 4 months (11). In Mali, the target season for SMC administration was composed of August, September, October, and November (4).

How: CHWs were used for the delivery of SMC due to the strict timing required for the regimen and the vast number of individuals that needed to be reached. As well, mobile delivery through CHWs was shown to be more effective at achieving high coverage than stationary delivery through health facilities (15). In this case, CHWs either visited families door-to-door or gathered children at an agreed fixed-site in the neighborhood (12). CHWs administered the first dose and instructed the caregiver to administer the second and third doses of AQ over the following two days (16).

Impact evaluation

### Coverage

In Mali, coverage goals were generally met despite geographical challenges. According to the WHO annual report in 2016, the intervention reached 93% of its targeted 3,702,724 recipients in Mali (10). The cooperation of districts was also high, with 89% of targeted districts implementing the full 4-course SMC treatment (10). According to ACCESS-SMC's final report, however, the implementation of SMC in their pro-

grams only reached the 80% coverage goal in 2015, but not 2016 (This discrepancy in data reporting, between the WHO and ACCESS-SMC's reports, is further discussed in subsection "Strategic Challenges: Caveats of Data"). Notably, this failure in 2016 for ACCESS-SMC's interventions in Mali contrasted with the success of similar interventions in other Sahel countries in both years. Upon more critical examination of the data, however, it is reasonable to associate this failure partially to the enormous increase in eligible individuals in 2016 (from 2.8 million to 4.6 million) due to the national upscaling of the program. Thus, we conclude that although coverage in ACCESS-SMC programs did not reach their 2016 goal, there was still a sizeable increase from 2015 in the number of interventions offered (13). Overall, SMC interventions made significant progress in attaining their coverage goals.

### Reduced incidence of malaria

Anecdotal evidence reported a 49% decrease in cases of malaria throughout the rainy seasons in Mali after implementation of SMC from 2015 - 2017 (13). The Malaria Consortium also found a 50% reduction of mortality in areas with SMC implementation throughout the Sahel region (17). Importantly, however, these studies represent only a correlational finding between SMC deployment and reduced malaria incidence, as other interventions may have been introduced during the same period that may confound the benefit attributable to SMC alone. The only study that provides comparative causal analysis is presented by Diawara et al. In this study, researchers compared the efficacy of SMC de-

ployment in the Kita district to a socio-demographically matched Bafoulabe district that received no SMC intervention. They found that SMC reduced malaria infection from 24.1% to 18.0% in the Kita region, whereas the Bafoulabe region saw an increase in malaria incidence from 30.5% to 46.0%. Thus, SMC helped reduce malaria incidence by 61% when accounting for the increase in baseline mortality in the control group (Figure 2) (16). Overall, evidence suggests that implementation of SMC did significantly reduce malaria incidence in Mali.

### **Effects on adaptive immunity**

A case-specific consideration for evaluating the efficacy of SMC treatments, and other interventions that do not permanently interrupt transmission, is the potential that they may reduce the adaptive immune response of children to malaria and prompt an age-shifted delay in morbidity (18, 19). This can occur if access to the treatment regimen is ever disrupted, leaving a population with a lower immunity towards malaria and prompting a possible resurgence in morbidity and mortality. This is also known as the “rebound effect” (18, 19). Before transitioning to scale, studies reported conflicting evidence on the impact of SMC on adaptive immunity a year following treatment (18-21). However, none of those trials followed children through all 5 years of SMC treatment. More recently, after deploying the intervention across the Sahel region, a few controlled studies support a correlative relationship between SMC interventions and reduced adaptive immunity. A study in Ouelessebouyou, Mali, found that children who received SMC, regardless of the num-

ber of years they received it, had lower levels of antibodies towards both blood and liver-stage malarial antigens (22). Although it is currently unclear whether these findings correlate with more severe clinical infections, similar results were found in a study in Southern Senegal (3). These findings must be considered when discussing the long-term sustainability of SMC programs.

### **Financing**

The NMCP has been able to finance SMC projects primarily through partnerships with various international organizations. The pilot project in 2012 was funded by MSF, and subsequent projects were funded by WHO, UNICEF, Save the Children, the President’s Malaria Initiative (PMI), the World Bank, and the Global Fund (4, 12, 13, 16). The scaling up of SMC in 2015 and 2016, conducted by ACCESS-SMC, was funded primarily by UNITAID, which has donated US\$67 million for ACCESS-SMC’s work in seven Sahel countries (4, 12). ACCESS-SMC is a consortium composed of 6 charities, including the Malaria Consortium (MC) and Christian Relief Services (CRS) (4, 13). In 2017, Global Fund replaced UNITAID as the primary funder of ACCESS-SMC (13), although other aid organizations, such as UNICEF and the World Bank, continued to play a role in funding SMC interventions (12).

Altogether, the pilot project in 2012 cost MSF a total of US\$815,548 to reach 159,317 children in a single district (8). In 2014-2016, PMI spent US\$314,000 for its work in covering 77,497 children in another district (12). The cost dis-

tribution is shown in Figure 3, with the majority of funding going towards staff, supplies, and transport. (8, 13).

A maximum US\$5.00 target was established for the cost of a four-round cycle of SMC for a single child (13). The initial pilot project performed by MSF cost US\$1.44 for each round, implying a cost of US\$5.76 for a full four-round course (8). By 2015, however, the cost for a child's complete annual four-round treatment of SMC was brought down to only US\$4.05. This was accomplished, in part, by securing drug prices at 27 cents per dose with the manufacturer Guilin (13).

Overall, the cost for each disability-adjusted life year (DALY) saved has been calculated to be US\$39. According to the WHO, a highly cost-effective intervention costs no more than US\$724 per DALY, making SMC a cost-effective intervention. In terms of cost per DALY, SMC is comparable to other preventative malaria interventions, such as LLIN (US\$29/DALY) and Indoor Residual Spraying (US\$31/DALY). Compared to malaria case treatment (US\$9/DALY), however, SMC is less cost-effective (13).

## **Strategic Successes**

### **Effective partnerships**

Partnerships between the NMCP, district and local health authorities, and various international organizations were key to the success of the SMC program (16). The NMCP's partnerships with multiple international organizations allowed it to acquire the technical and financial support required for the project. Additionally,

local actors, such as the Malaria Research and Training Center, were also involved in contributing skills and knowledge to the project (8). This transfer of knowledge allowed for local capacity building that created hundreds of jobs in healthcare and improved supply chain management tactics, among other benefits (12, 13). Despite the large number of players involved, the NMCP was largely successful in coordinating these actors to efficiently implement SMC (13). These connections have been critical in allowing Mali to become the only country to adopt SMC nationwide. For example, MC was instrumental in securing a low cost for SMC drugs through effective partnership with Guilin. As well, CRC used its prior relationship with Global Fund to attract funding for the 2017 and 2018 seasons (13).

### **Use of pre-existing local CHWs and distributors**

Another reason for SMC's success is the use of existing health care networks. For example, SMC was delivered in combination with previously implemented malaria prevention strategies, such as LLIN (8). Furthermore, the local distributor, Pharmacie Populaire du Mali, was used for the transportation of the SMC drugs (4). The Ministry of Health (MoH) had also trained 2,377 CHWs between 2010 and 2016 to address the shortage of healthcare workers in Mali (12), and these workers were effectively adopted for the delivery of SMC treatments (4, 16). Overall, the use of these established local resources allowed for smoother implementation of the SMC intervention.

## Monitoring and adaptability

The monitoring and responsiveness of key players was a highlight for the SMC intervention that allowed the project to adapt and improve its implementation strategies over time. For example, in 2015, fixed-point distribution was used as the primary method of drug delivery. However, when this strategy was found to provide poor coverage results, ACCESS-SMC tested and switched to a door-to-door delivery method. After the success of the change, the 2016 strategy was altered to include a combined fixed-point and door-to-door approach (13). The ability to quickly identify and adapt to problems was key to the success of SMC interventions in Mali.

## Strategic Challenges

### Sustainability

**Verticality of funding:** Despite meeting the goal for cost-effectiveness based on costs per DALY, SMC is not a financially sustainable intervention in the long-term. This is evident when considering that (a) unlike a vaccine, this intervention must be repeated indefinitely to reduce incidence of malaria, and (b) the funding to support SMC is presently sourced almost exclusively from international institutions. This sustainability problem is further exacerbated when considering that national funding for SMC programs is currently out-of-reach for the Malian Ministry of Health. Although the government of Mali allocates a budget of US\$2.5 million annually towards malaria control (12), this is only a small fraction of the > US\$18 million that would be necessary to provide SMC for all of Mali's 4.6 million eligible children (13). This

unreasonable demand for resources means that, for the conceivable future, funding for SMC interventions in Mali must continue to rely largely on international donors. Thus, despite successfully utilizing local health care infrastructure to deliver SMC drugs, the lack of local funding prevents the full integration of SMC interventions. Additionally, as with all top-down funding, the unreliability of donor support presents severe risks to the future sustainability of SMC interventions in Mali.

A shift towards more horizontal funding requires the successful integration of various strategies at the national and local levels. Integrated community case management (iCCM), for example, has been shown to improve access to preventive care and treatment for children in underserved communities by allowing interventions to integrate with existing local and horizontal infrastructures (1). While full integration with iCCM has not been achieved by the SMC intervention, a highlight of the 2015-2017 fiscal years is that the funding per person at risk for Malaria in Mali has increased by approximately 20% from the periods 2012-2014 (1).

**Logistical burden:** Logistically, employing SMC anywhere is complicated. To sustain suppression, CHWs must deliver multiple rounds of SMC therapeutics each year. This continuous requirement for SMC drugs greatly increases the burden of funding and human resources, and potentially leads to incomplete coverage (24). Furthermore, the eligibility of children presents an ongoing logistical problem for SMC

interventions. Currently, there are no monitoring mechanisms set in place to ensure the health of children aging out of the program each year or to ensure adherence of children to the drug regimen. As well, the number of new children added to the program annually presents an administrative challenge.

The implementation of SMC in Mali, specifically, also faces unique logistical challenges. Geographically, many of the target areas that would benefit most from the intervention are rural and difficult to access due to poor infrastructure (24). As well, in the rainy season, flooding can impair SMC drug delivery (25). These geographic and infrastructure barriers can have a large impact on coverage, as shown in a study in Kita, Mali, in which travel-associated difficulties accounted for 43% of drop-outs between SMC treatment rounds (16). Violent conflict, particularly in Northern areas of Mali, also occasionally contributed to preventing SMC delivery (12, 13). Additionally, local health authorities were often inexperienced in supply chain management, which led to sporadic stock-outs of SMC drugs in certain districts (13). Lastly, orchestrating the large number of international stakeholders in Mali posed certain bureaucratic and communication difficulties. For instance, on some occasions, when approval was required from multiple actors, decision-making was delayed due to disagreements (13).

These logistical concerns pose a serious challenge to the sustainability of SMC interventions in Mali. Currently, 35% of the cost for SMC interventions is solely devoted to the transport of

drugs and supplies (Figure 3) (8, 13). Innovations to decrease costs in delivery of care and increase integration with local funding are required to build the capacity for local governments to handle these logistical problems on their own.

**Considerations for long-term sustainability:** The finding that SMC interventions rely heavily on vertical funding, face logistical burdens, and pose risks to adaptive immunity calls for a reassessment of the sustainability of this intervention. Although the delivery of SMC drugs successfully reduced disease burden and suffering in the short-term, the inability for local governments to independently fund this initiative poses a risk: a sudden lapse in international funding could result in a collapse of the program and the “rebound effect,” whereby malaria resurges due to reduced immunity. In light of this risk, and given little evidence that SMC interventions can or will be integrated sustainably in the future, we argue for a move towards a more integrative approach, where multiple interventions, like SMC, vaccination, LLIN, indoor spray, rapid diagnosis and treatment ect... are deployed as an integrated initiative that utilizes resources to improve the sustainability of any one intervention.

#### **Caveats of the data**

Through our evaluation of SMC interventions in Mali, we also observed that the reporting and monitoring of these project faces some limitations. For example, the shortage of peer-reviewed literature on the efficacy of the intervention in Mali is worrisome. Even

more concerning is the inconsistencies in data reporting that indicate a lack of communication among key stakeholders. For example, the WHO report found that the coverage goal for SMC was reached in Mali in 2016, whereas the ACCESS-SMC report asserted otherwise (10, 13). Furthermore, data reports do not attempt to discuss or control for the effects of simultaneous interventions. For example, initiatives promoting LLINs in Mali (10) present confounding factors when considering efficacy of SMC interventions. Overall, these limitations in data reporting show how the overabundance of international aid organizations promotes the decentralization of data collection. These problems in data reporting should be addressed by increasing partnerships between international aid and research organizations in addition to increasing partnerships between local governments.

### **Future Implications**

The most pressing issue for the continuation of SMC interventions in Mali is the need to secure future funding that will go towards supporting the long-term benefits of the project. For the 2018 season, the Global Fund will continue to fund ACCESS-SMC as part of a US\$70 million grant for the prevention of malaria (12, 13). PMI will also spend over US\$3.3 million to support SMC for 650,000 children in 12 districts (12). Despite these grants, certain aspects of monitoring will have to be discontinued due to insufficient resources (13). Furthermore, funding for 2019 and beyond is still uncertain (13). To address these potential future gaps in funding, the delivery of SMC drugs could be integrated

with other CHW delivered interventions. For example, CHWs could administer SMC alongside nutritional interventions or deworming medications to split delivery costs between different projects (13).

The other pressing issue for the future of SMC interventions is the need to verify the effects on adaptive immunity. To date, the evidence for this effect is still controversial at best. Thus, to address this gap in knowledge, children aging out of the SMC program should be monitored for their susceptibility to malaria. As well, the adaptive immunity of new children entering into the SMC program should be monitored for the entire 5-year treatment regimen. These findings should then be incorporated into an ethics board evaluation of SMC programs to justify the continuation of this intervention.

### **Conclusion**

Overall, the NMCP was able to cost-effectively implement a short-term SMC program in Mali. Other interventions can learn from this project with regards to the successful mobilization of local and international partners, use of CHWs, and adaptability in response to challenges. Due to precarious vertical funding and potential risks to adaptive immunity, the sustainability of SMC treatments must be seriously evaluated before committing to future funding.

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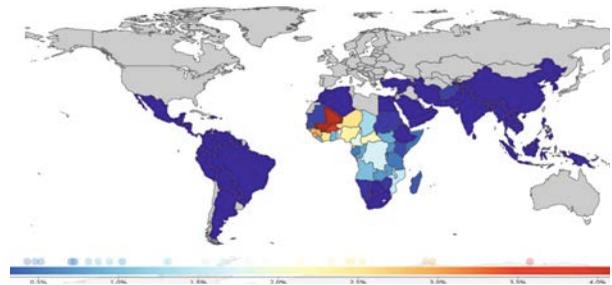
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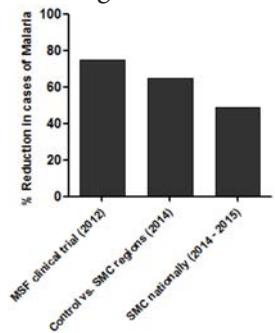
**Appendix**



**Visual Abstract**

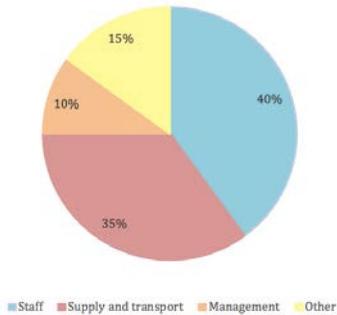


**Figure 1:** The probability of death from malaria in 2015 from birth to age 5 around the world. Mali is the country in red, showing that it has the highest probability of death from malaria for children under 5 in the world (4.3%) (2).

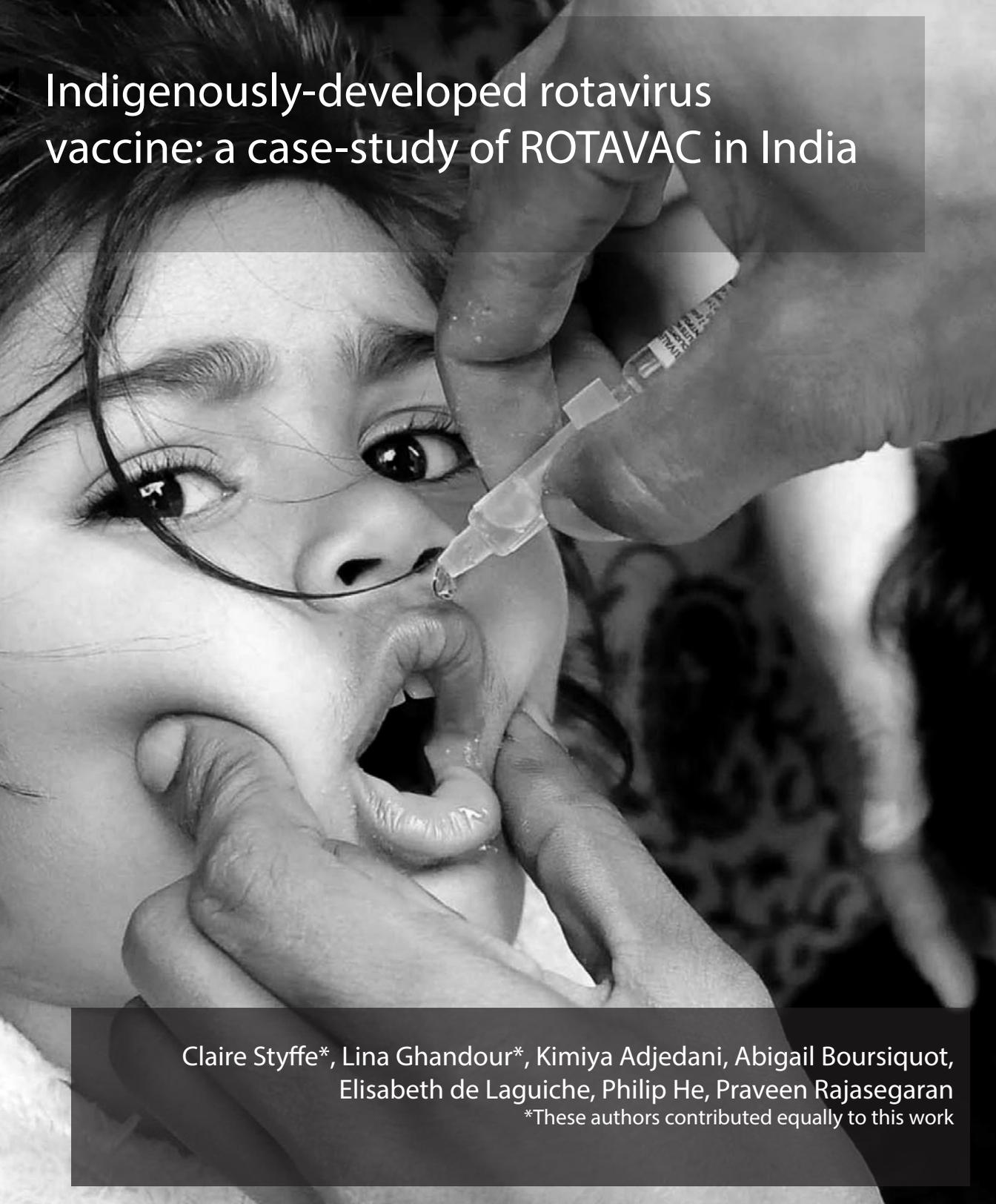


**Figure 2:** Comparing the efficacy (reduction in ma-

alaria incidence) of three SMC interventions in Mali: the initial 2012 clinical trial by MSF, the 2014 regional case-control study in Kita, and the 2014-2015 transition to scale (8, 13, 16).



**Figure 3.** Distribution of SMC project costs (8, 13).



# Indigenously-developed rotavirus vaccine: a case-study of ROTAVAC in India

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\*These authors contributed equally to this work

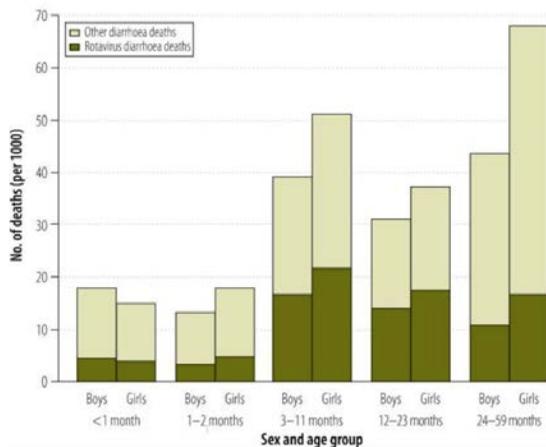
## Abstract

India has a high burden of rotavirus, a disease that causes gastroenteritis. ROTAVAC is an indigenously-developed rotavirus vaccine that was researched and manufactured in India by Bharat Biotech. It was introduced in India's Universal Immunization Program in four states in 2016 and expanded to five more in 2017. While its efficacy rate is similar to that of other rotavirus vaccines, it is far cheaper, making its introduction in the Indian health care system cost-efficient. Bharat Biotech were able to market ROTAVAC at only USD 1 per dose due to savings incurred by manufacturing locally, and the innovative team science approach used in the vaccine development. Challenges in implementing ROTAVAC remain, including lack of funding, vaccine coverage disparities and a lack of medical consensus on the vaccine's importance. The absence of data on project funding, vaccine uptake and rotavirus incidence rates renders a conclusive analysis difficult, and stresses the importance of strong surveillance systems and data transparency. Despite such challenges, ROTAVAC remains an encouraging example of a low-income country researching and developing a successful vaccine, a process usually reserved for high-income countries. Its development and WHO pre-qualification have immense potential to reduce the rotavirus burden in India and other developing nations.

## Introduction

Diarrheal disease is the most common cause of hospitalization and death in children globally and accounts for roughly one in six deaths among children under five years of age.<sup>1</sup> Ap-

proximately 15% of India's child mortality is attributable to diarrheal diseases.<sup>2</sup> Rotavirus is a viral infection that predominantly affects children; it can cause gastroenteritis, an inflammation of the stomach and intestines, which results in severe diarrhea and dehydration.<sup>3</sup> Rotavirus is the leading cause of severe diarrheal disease-associated morbidity and mortality among children in developed and developing countries, accounting for 37% of diarrheal-related deaths worldwide.<sup>4,5</sup> Notably, over 22% of all rotavirus deaths are estimated to have occurred in India, approximately 50% of which occurred in the first year of life and affected girls disproportionately (Figure 1).<sup>6</sup>



**Figure 1.** Estimated overall number of diarrheal deaths and rotavirus-attributable diarrheal deaths among Indian children younger than 5 years, by age and sex, during 2005.

Currently, there is no treatment for rotavirus infection; however, immunizing infants against rotavirus has shown to protect them from acquiring the infection and decreases the risk of infant death due to diarrhea.<sup>7</sup> Several licensed vaccines have been shown to be safe and effec-

tive against rotavirus, including Rotarix and RotaTeq.<sup>7</sup> India has recently manufactured ROTAVAC, an indigenously researched and developed vaccine. This paper explores the progress, ongoing challenges and potential future implications of the ROTAVAC vaccine for children under 5 in India.

## Rotavirus Vaccines

### Development of the ROTAVAC Vaccine

The road to developing of ROTAVAC was a long one, beginning in 1985 when a pediatrician at the All India Institute of Medical Sciences remarked that several infants were becoming infected with rotavirus in the hospital, but were not showing symptoms.<sup>8</sup> Infection with the neonatal 116(E) strain protected these babies from reinfection, thus highlighting its potential to be used in a vaccine.<sup>9</sup> From there, Indian and American scientists collaborated through the Indo-American Vaccine Action Program to characterize the strain and develop it into a vaccine candidate.<sup>9</sup> In 1998, the Indo-American Vaccine Action Program held a meeting in India to identify potential manufacturers; Bharat Biotech International, a young Hyderabad-based company without any licenced products at the time was selected to manufacture the vaccine.<sup>9</sup>

A number of different partners collaborated to ensure that the vaccine moved through development and manufacturing efficiently; Bharat Biotech International, the Center for Disease Control and Prevention, the National Institutes of Health, the All India Institute of Medical Sciences, Stanford University and the Indian Institute of Science were supported by the Bill

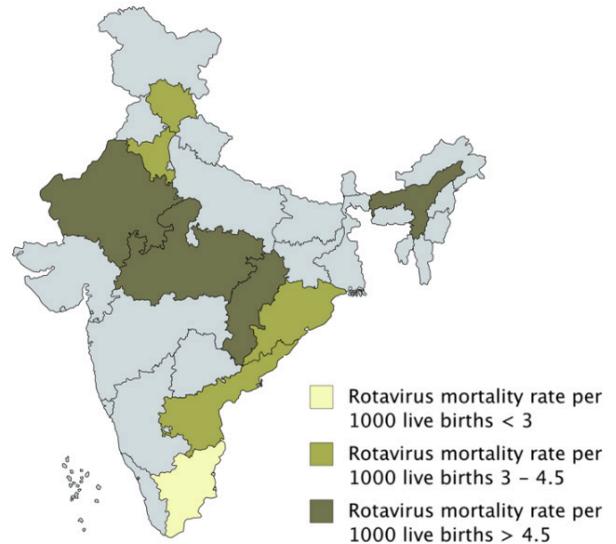
and Melinda Gates Foundation-funded Children's Vaccine program to move the candidates through production, testing and surveillance.<sup>8</sup> Thus, public-private partnerships were created and the Indian government played a key role in supporting the intervention.<sup>8</sup> While Bharat Biotech reportedly invested USD 20 million into the manufacturing process, little information exists regarding how much funding other partners contributed to the development effort.<sup>10</sup> Greater transparency with regards to funding is necessary to fully evaluate the expenses incurred by the Indian government and the cost-effectiveness of the intervention.

Clinical trials began in India in 2005 under the supervision of researchers at the Society for Applied Studies, the KEM Hospital and Research Center and the Christian Medical College. This represents a remarkable divergence from the traditional development pathway in India; usually well-known vaccines from the West are manufactured in Indian government labs and then distributed through the public and private health sector.<sup>11</sup> ROTAVAC is not only based on a strain of rotavirus found in India, but was also researched with Indian partners, manufactured by an Indian pharmaceutical company and underwent clinical trials in India, making it a rare example of a health technology that was developed and tested primarily in India; it can therefore be considered an indigenous vaccine.<sup>9</sup>

A randomised double-blind, placebo-controlled, multicentre trial was conducted, whereby infants were randomly assigned to receive either placebo or three doses of the 116E vac-

cine at ages six to seven weeks, ten weeks and fourteen weeks.<sup>12</sup> Results indicate a 56% efficacy rate for the first year, with a slight decrease to 49% in the second year.<sup>12</sup> In addition, results also revealed that the vaccine entails lower risks of intussusception compared to first generation rotavirus vaccine.<sup>13</sup> In fact, clinical trial on ROTAVAC showed no association with intussusception, and post-marketing surveillance of ROTAVAC is in place to monitor alterations of intussusception risk of the vaccine.<sup>13</sup> Following Phase I and II clinical trials in infants, toddlers and adults, ROTAVAC has also been found to be safe and immunogenic.<sup>13</sup> The demonstrated efficacy and safety of the ROTAVAC vaccine led to its licensing in India in 2014, and the obtainment of the World Health Organization (WHO) prequalification in 2018.<sup>14,15</sup>

ROTAVAC is now being implemented in the Universal Immunization Program in India.<sup>16</sup> The vaccine has been integrated to the routine immunization programs of 9 states, following a phased introduction model.<sup>17</sup> The initial stage in 2014 targeted 4 states: Andhra Pradesh, Himachal Pradesh, Haryana and Orissa.<sup>18</sup> Diarrheal disease burden, routine immunization coverage, system preparedness and state willingness to introduce the vaccine were taken into consideration to identify suitable states for the initiation of the vaccine introduction (Figure 2).<sup>17</sup> Five additional states were added in 2017: Assam, Chhattisgarh, Madhya Pradesh, Rajasthan and Tamil Nadu.<sup>17</sup> The Rota Council reports that up to this day, close to 35 million doses of ROTAVAC have been administered in India.<sup>18</sup>



**Figure 2.** Estimated rotavirus-attributable diarrheal mortality rates among children under 5 years of age in 9 states in India prior to introduction of ROTAVAC, in 2005.

### Comparative analysis of Rotarix, RotaTeq and ROTAVAC

Along with ROTAVAC, there are currently two other licensed rotavirus vaccines: RotaTeq and Rotarix. While ROTAVAC's 56% efficacy rate is comparable to that of RotaTeq and Rotarix, it differs in terms of origin and price. Rotarix and RotaTeq are both designed and manufactured by large Western pharmaceutical companies in high-income countries and cost USD 20 and USD 15 per dose, respectively.<sup>19-21</sup> In contrast, ROTAVAC is designed and manufactured in India and is marketed at only USD 1 per dose.<sup>20,21</sup> Rotarix and RotaTeq were deemed too expensive for the Indian market, and much of the impetus for ROTAVAC's fabrication lied

in creating an effective vaccine that could address the high rates of Rotavirus in India at an affordable price.<sup>11</sup> For a more detailed comparison of Rotarix, RotaTeq and ROTAVAC, see Table 1. As data regarding uptake and incidence rates following ROTAVAC immunization in India is lacking, it remains difficult to fully evaluate the effectiveness of ROTAVAC introduction in India and compare its effect with other vaccines.

### Cost-effectiveness Analysis

The prevalence of rotavirus episodes in India translates into significant financial strains on the national healthcare system.<sup>24</sup> The introduction of ROTAVAC on a national level therefore represents the potential to greatly reduce the prevalence of rotavirus and thus its associated costs. The initial approach to evaluate the impact of the ROTAVAC vaccine relied on a comparison of rotavirus incidence rates prior to and post ROTAVAC introduction. However, this data was unavailable, which called for a shift towards an economic impact analysis, looking at the cost effectiveness of the introduction of ROTAVAC.

Various studies examine the potential savings that the ROTAVAC vaccine could generate, comparing the forecasted cost of the vaccination programme with the current costs incurred by the medical treatment of rotavirus.<sup>24-27</sup> ROTAVAC vaccine is not yet available in all states in India; thus, all analyses presented rely on projected figures and numbers. This highlights the need for national surveillance to obtain accurate data to monitor and project the impact

of introducing ROTAVAC vaccine on a national scale.

The existing literature measuring the financial impact of ROTAVAC provides an overview of the number of deaths, hospitalizations and outpatient visits that are caused by rotavirus. While authors tend to provide similar estimates for the numbers of deaths and hospitalizations, the numbers of outpatient visits vary. For clarity purposes, this review is therefore based on the numbers given by John et al. who provide a recent and targeted cost benefit analysis for the introduction of ROTAVAC in India.<sup>25</sup>

Attribute	Rotarix	RotaTeq	ROTAVAC
Manufacturer	GlaxoSmithKline <sup>20</sup>	Merck <sup>19</sup>	Bharat Biotech <sup>20</sup>
Country of Origin	United Kingdom <sup>20</sup>	United States <sup>19</sup>	India <sup>20</sup>
Year of Issue	2008 <sup>28</sup>	2006 <sup>29</sup>	2014 <sup>14</sup>
Development Stage	Phase IV WHO pre-qualified <sup>20</sup>	Phase IV WHO pre-qualified <sup>20</sup>	Phase IV WHO pre-qualified <sup>20</sup>
Strain	G1, P[8] <sup>23</sup>	G1, G2, G3, G4, P1A[8] <sup>19</sup>	116E <sup>22</sup>
Type of Vaccine	Attenuated human <sup>22</sup>	Bovine reassortants <sup>19</sup>	Natural bovine neonatal <sup>22</sup>
Efficacy in LMICs	71.7% in Latin America <sup>29</sup> 61.7% in Africa <sup>20</sup>	51% in South East Asia <sup>29</sup> 64.2% in Africa <sup>29</sup> 48.1% in India <sup>21</sup>	56% in India <sup>20</sup>
Efficacy in HICs	92.4% in Finland <sup>20</sup> >96% in Southeast Asia <sup>20</sup>	98% in Europe/US <sup>20</sup>	n.a.
Vaccination schedule	2 doses (2 and 4 months of age) <sup>21</sup>	3 doses (2, 4 and 6 months of age) <sup>21</sup>	3 doses (6, 10, and 14 weeks of age) <sup>21</sup>
Scale	Latin America, Europe, Southeast Asia, Africa <sup>20</sup>	United States, Europe, Southeast Asia, Africa <sup>20</sup>	Nine States in India <sup>17</sup>
Cost in India	USD 20 per dose <sup>21</sup>	USD 15 per dose <sup>21</sup>	USD 1 per dose <sup>21</sup>
Cost-effectiveness analysis	In India, incremental cost-effectiveness ratio is USD 21.4 to USD 24 per DALYs <sup>21</sup>	n.a.	Cost-effectiveness is superior to Rotarix <sup>21</sup>

DALYs: Disability-adjusted life years; LMICs: Low and middle income countries; HICs: High income countries

**Table 1.** Comparative analysis of Rotarix, RotaTeq, and ROTAVAC vaccines

Based on the 2011 Indian birth cohort comprising of 27,098,000 children, John et al. found that 42.0% (n= 11,373,098) had an episode of rotavirus, 28.8% (n= 3,271,187) received outpatient

care, 7.67% (n= 872,315) were hospitalized, and 0.69% (n= 78,583) of children died from the infection (Figure 3).<sup>25</sup> The cost of hospitalization added up to INR 4.7 billion (~USD 65 million) annually, while outpatient visits cost 5.5 billion (~USD 75 million)\* annually.<sup>25</sup>

The total cost of a ROTAVAC vaccination campaign in India for the 2011 cohort is estimated to amount to INR 4.47 billion (~USD 62 million)\*.<sup>25</sup> This estimation is contingent on ROTAVAC's price, which was kept at USD 1 per dose.<sup>21</sup> In comparison, Rotarix and RotaTeq cost USD 20 and USD 15 per dose respectively.<sup>21</sup> The total cost of a vaccination campaign using one or the other of these two vaccines would be incrementally higher. More data would, however, be needed to make a more precise analysis comparing the total cost of a vaccination campaign using either one of these three vaccines, given the detail of the elements accounted for in the total estimated cost provided by John et al.

Complementing John et al.'s cost benefit analysis, Rose et al. forecast the introduction of the vaccine to result in a 13% nation-wide reduction in symptomatic rotavirus infection, and a 34.6% drop in rotavirus mortality.<sup>27</sup>

According to John et al.'s analysis, the hospitalization and outpatient care costs tied to rotavirus in India exceed INR 10.4 billion (~USD 143 million)\*.<sup>25</sup> The introduction of the vaccine would however cost INR 4.5 billion (~USD 62 million)\*, and is projected to result in a 13% reduction in the nation-wide rotavirus infection

as well as a 34% drop in mortality.<sup>27</sup> While these impacts substantiate the necessity to scale up the vaccination program, further data regarding the prevalence and the savings would be required to have a reliable estimation of the benefits of the ROTAVAC vaccine scale up in India.



**Figure 3.** Estimates of the burden of rotavirus in India based on the 2011 birth cohort of 27,098,000 children.

## Discussion

### Downstream outcomes of ROTAVAC scale-up in India

Much of the success of ROTAVAC lies in its efficacy; with a 56% efficacy rate, it is comparable to the other leading vaccines Rotarix and RotaTeq, making it a valid alternative.<sup>24,12</sup> Its reduced cost is also a key factor in its success; with a price of USD 1 per dose, it is far cheaper than Rotarix and RotaTeq which cost around USD 15 per dose.<sup>30</sup> This reduction in price makes the distribution of ROTAVAC highly cost effective, and would be cheaper than the current expenditure on rotavirus hospitalizations.<sup>31</sup>

The indigenous nature of the vaccine develop-

ment and production is not only a victory for the Indian pharmaceutical company Bharat Biotech International, but is also an important contributor to the vaccine's potential success. Production of the vaccine in India allowed stakeholders to mitigate costs and taxes associated with importing the vaccine, rendering it even more cost-beneficial. India maintains very high basic customs duties, in some cases exceeding 20 percent, on drug formulations, including life-saving drugs and finished medicines.<sup>32</sup> These high tariffs contribute to the higher costs associated with each dose of the two licensed and imported vaccines, RotaTeq and Rotarix.<sup>32</sup> By manufacturing and distributing the ROTAVAC vaccines in India, these costs could be averted and the vaccine was made available at a lower cost.

Particularly important to consider is the manner in which the vaccine was developed; an innovative, 'team science' strategy was employed, along with funding from both public and private stakeholders, facilitating the production of the vaccination.<sup>8</sup> The efforts of clinical and translational investigators from thirteen different institutions, including the US Center for Disease Control and Prevention, the Indian Institute of Science, Stanford University and the National Institute of Allergy and Infectious Diseases aided in technical challenges, while funding from the Indian government, Bharat Biotech International and PATH helped enable local manufacturing.<sup>8</sup> Sharing costs between such a variety of partners was paramount to keeping the price to only USD 1 per dose, and Bharat Biotech International used highly efficient manufacturing procedures and inventive

production techniques to further limit costs.<sup>25</sup>

### **Implementation Challenges**

Despite the success in developing a cheap and effective vaccination, there still remain challenges in ensuring that the vaccine is distributed equitably and reduces the incidence of rotavirus. There lacks a strong political will in India to invest heavily in health; currently, only 2.2% of the 2018-2019 annual GDP is spent on health, less than half of the WHO recommended 5%.<sup>33,34</sup> Of that 2.2%, 9.9% is allocated to routine immunizations.<sup>33</sup> It is important to note, however, that this is a substantial increase from the 3% of the health budget that was previously allocated to vaccination.<sup>35</sup> This lack of financial commitment echoes the lack of political will, which further trickles down to a lack of supply as there are only two domestic manufacturers of the vaccine in India, despite the considerable demand.<sup>36</sup>

As India is a large, diverse country with a population of over 1.34 billion people, significant implementation challenges exist. Vaccinations are provided free of charge under the Universal Immunization Program, yet disparities in coverage pose a challenge to widespread implementation. Factors such as gender, birth order, area of residence, parental education, religion, caste and community literacy levels influence vaccine uptake rates.<sup>31</sup> Boys generally have higher vaccination coverage as compared to girls and urban areas tend to have increased vaccination coverage as compared to rural areas. Furthermore, those living in slum housing have lower rates of coverage compared to other urban dwellers, as

do migrants compared to the resident population.<sup>31</sup> Both urban and rural poor populations have lower vaccination coverage as compared to wealthier ones.<sup>31</sup>

While an efficacy rate of 56% is comparable to that of other rotavirus vaccinations and is often cited as an indication of the vaccine's success, there are arguments that such an efficacy rate is not high enough to justify implementing ROTAVAC as a standard vaccination. As Dr. Jacob Puliyl, head of the Department of Pediatrics at the St. Stephen's Hospital in Delhi, notes: "Do you know another vaccine with 50% efficacy that is used for public health programs? It is a toss up [Sic] if the vaccine will work for you. If 100% [of the] population is vaccinated it will reduce 50 [of the] rotavirus deaths. What are the numbers needed to treat [to prevent one death]?"<sup>30</sup> Others argue that the ROTAVAC vaccine trial enrolled only 6800 participants, a small sample necessary to establish safety for rare events.<sup>12</sup> In comparison, over 70,000 and 17,500 subjects were enrolled in the clinical trials for RotaTeq and Rotarix respectively.<sup>19, 37</sup>

Further challenges include a varying degree of medical confidence in the vaccine. Studies found that the vaccine was more favourably accepted among paediatricians, 70-88% of whom would recommend it, while only 46-55% of family physicians were willing to recommend it with a smaller proportion seeing a need for rotavirus vaccination relative to paediatricians.<sup>16</sup> Family physicians serve as patients' first point of entry into the medical system, while paediatricians work at a more specialized level and often

work in hospitals. Furthermore, family physicians provide quality and cost-effective health-care relative to the ever increasing costs of tertiary care facilities and hospital-based settings where most pediatricians work.<sup>38</sup> As such, the average Indian citizen is more likely to interact with a family physician than a paediatrician and is thus less likely to receive a recommendation to become immunized against rotavirus.

### Lessons Learned

ROTAVAC challenges the notion that only high income countries (HICs) are capable of researching and manufacturing technological innovations such as vaccines. Vaccine development is usually undertaken by large pharmaceutical companies in high-income countries which can lead to high vaccine prices, making such lifesaving innovations expensive and inaccessible to low and middle-income countries (LMICs).<sup>39</sup> The successful production of ROTAVAC demonstrates that LMICs are in fact capable of developing technologies usually reserved for HICs and that such an endeavour can lead to decreases in costs, making these innovations more affordable to those who need them most.

The reduced price of ROTAVAC allows for greater access in India, and has profound implications for reducing rates of rotavirus and associated mortality in Indian children.<sup>25</sup> The affordability of ROTAVAC compared to RotaTeq and Rotarix however, is not only a positive development for India, but also for those in other LMICs. ROTAVAC achieved WHO prequalification in January 2018, meaning that United

Nations Agencies and the Global Alliance for Vaccines and Immunisation (GAVI) can now include it as part of their programmes to equitably distribute vaccinations, though GAVI does not currently include ROTAVAC on its distribution list.<sup>15,40</sup> By being available for procurement by GAVI and other agencies, the low cost benefits of ROTAVAC may be distributed to other heavily burdened countries and may play an essential role in reducing rotavirus in a number of low-income settings. India has previously faced concern over cheap and low-quality vaccines, but the recent WHO pre-qualification of ROTAVAC is an indication of a high quality and may improve global perceptions on Indian vaccine production.<sup>41</sup>

The successful development of ROTAVAC owes much to its innovative, 'team science' structure, which incorporated a multidisciplinary research and development team with a variety of public and private funders.<sup>9</sup> Further, using public-private partnerships and team science has created structures and relationships in India and abroad that may now be used again in the future development of other health technologies.<sup>42</sup> Such approach is an inventive model that has profound implications for the future development of other health technologies and stresses the potential of public-private partnerships. By adopting such a strategy, other LMICs may be able to develop their own affordable health tools that have so far been reserved for HICs and multinational corporations. This is consequently not only an encouraging example for other LMICs but also a pioneering endeavour that has laid the framework for successive

locally produced innovations.

Limited surveillance data on the uptake of ROTAVAC vaccine has made it difficult to evaluate its impact in India. The WHO Global Vaccine Action Plan outlines the importance of improving the quality of immunization data, strengthening disease surveillance systems and promoting the use of technologies for comprehensive collection and analysis of immunization data.<sup>43</sup> While there is abundant information on the burden of rotavirus in India and projected cost-benefit analysis, there is little to indicate how the introduction of ROTAVAC to nine states has proceeded, what the coverage has been or what impact it has had on rotavirus incidence. Thus, while there exists plenty of data suggesting how promising this novel vaccine is, there is little to confirm its predicted impact. This stresses the importance of strong immunization surveillance systems and the dissemination of transparent data. ROTAVAC remains a new vaccine and it is possible that data is currently being collected; however, while other countries may look toward ROTAVAC as a successful example of how to develop an indigenous health technology, they should consider the importance of accompanying the distribution of such an intervention with a robust surveillance system, to ensure that the innovation is meeting predicted targets and functioning adequately.

### **Conclusion**

The introduction of the indigenous rotavirus vaccine, ROTAVAC, presents a useful case-study to understand the value in promoting

sustainable research and development pathways in developing countries like India. ROTAVAC's main strengths lie in its reduced price and potential to prevent rotavirus associated morbidity and mortality. It remains an encouraging example that LMICs can in fact locally develop high quality, efficacious vaccines to improve access to preventive health tools. There continues to be a number of challenges in the distribution of ROTAVAC, including a lack of political will and funding, implementation difficulties associated with a large and diverse country and a lack of medical consensus on the benefit of administering the vaccine. This is not uncommon and demonstrates that despite the immense potential that an indigenously researched and manufactured vaccine can have, there are also obstacles associated with the rollout and scale up of such an intervention. In spite of all the challenges and logistical difficulties, inclusion of the indigenously developed rotavirus vaccine in national immunization schedules should remain one of India's major commitments against vaccine preventable diseases.

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