So O'Neil, Divya Vohra, Matt Spitzer, Shveta Kalyanwala, and Dana Rotz

Maternal Health Care Quality Improvement in Rajasthan, India: A Series of Insights from a Development Impact Bond Verification Agent

December 2021

Mathematica strives to improve public well-being by bringing the highest standards of quality, objectivity, and excellence to bear on the provision of information collection and analysis to our clients.

Mathematica®
Progress Together

Photo by: Project Ujjwal, a UK Department for International Development project implemented by Palladium

About this report

This endline report on quality of maternal health care from the Utkrisht Development Impact Bond (DIB) includes a series of standalone briefs to enable readers to choose the specific aspect of the DIB to learn about (endnotes for each brief appear directly after the brief). Mathematica, the independent verification agent for the Utkrisht DIB in India, developed this report sponsored by MSD for Mothers.* The views, thoughts, and opinions expressed in this report belong solely to the authors and reflect their current learning and understanding at the time of dissemination. The report contents do not necessarily reflect the official policy or position of Mathematica, or any other agency or organization.

Acknowledgments

A development impact bond (DIB) requires coordination among several partners to ultimately impact lives. By the end of the DIB, we had the opportunity to work with diverse individuals from various organizations aligned in our mission to advance social good. First, we would like to acknowledge Scott Higgins at MSD for Mothers, whose diplomatic candor aligned partners to successfully complete the DIB. We also thank Pompy Sridhar at MSD for Mothers, who kept us grounded in the availability and limitations of external data, as well as Mary-Ann Etiebet at MSD for Mothers and Michael Quinlan for their external counsel and collaboration at critical junctures. We are grateful to Gautam Chakraborty, Omer Imtiazuddin, Amy Lin, and Priya Sharma at the United States Agency for International Development, and Sietse Wouters, Dhun Davar, and Maya Ziswiler at UBS Optimus Foundation for their firm belief in the value of a DIB model as a vehicle to leverage private capital for social good. We are also grateful to implementation partners, Ellen Smith and Adesh Chaturvedi (Palladium), and countless Population Services International and Hindustan Latex Family Planning Promotion Trust staff for a willingness to overcome the wrench COVID-19 threw into all aspects of the DIB.

We also thank Pathfinder International for their thought partnership on the design and implementation of the mannequin-based simulations we conducted in Round 3 of the verification, and especially Dr. Anupama Rao and Dr. Anuj Dandotia, who trained our field investigator team on these assessments. To the many private facilities across Rajasthan that allowed us to visit and conduct verification, we are grateful for the time and consideration provided to upload documents and facilitate site visits, even when done virtually and with unreliable internet connections, to make data collection possible.

To all partners, collaboration and trust make a DIB successful. As we close our time with you, we wish you success in your next endeavors.

Finally, at Mathematica, we thank Anitha Sivasankaran for her thoughtful review; Sheena Flowers, whose creativity fueled the graphics and layout of this document; and Cindy George, whose copyediting makes our writing more coherent and accessible to potential audiences interested in DIBs.

* MSD for Mothers is MSD's $500 million initiative to help create a world where no woman has to die while giving life. MSD for Mothers is an initiative of Merck & Co., Inc., Kenilworth, NJ, U.S.A.

Catalyzing progress in maternal health: Overview of the Utkrisht Development Impact Bond

So O'Neil, Divya Vohra, Matt Spitzer, Shveta Kalyanwala, and Dana Rotz

Social sector issue. Requiring that private sector facilities have high quality standards could improve health for many of the 1.4 billion people in India and make progress toward health-related Sustainable Development Goal 3. Private facilities—which provide 80 percent of all outpatient and 60 percent of all inpatient care in the country and house the vast majority of Indian physicians—are subject to limited regulations (Tripathi et al. 2019; Chakravarthi 2018). As a result, private facilities vary greatly in size, services, and quality. Private sector clients are subject to arbitrary costs, inconsistent clinical care, and variable treatment by facility staff—and they rarely have any formal means of seeking recourse or accountability should an issue occur in their care (Chakravarthi 2018; Shukla et al. 2018).

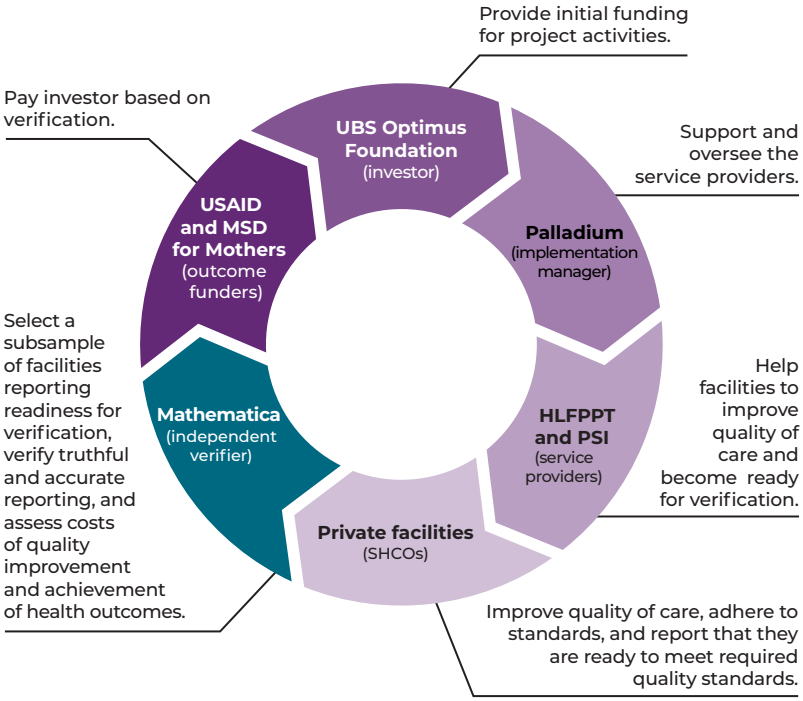
Indian activists and civil society organizations have sought to expand standardization and accountability in the private sector through a combination of advocacy for governmental regulatory reform and private health system capacity building, such as supporting quality improvement (Shukla et al. 2018). Some organizations have expanded on the latter approach by developing quality standards for private facilities and encouraging these facilities to formally adopt them (Jhpiego 2017).

Development impact bond (DIB) mechanism for change. DIBs are a pay-for-results financing mechanism that uses private sector financing and emphasis on efficiency to achieve a public good. DIB contracts link payment to outcomes rather than to inputs, activities, or outputs. The Utkrisht DIB leverages this pay-for-results mechanism as a means to improve maternal health quality of care in private facilities and, ultimately, maternal and child health outcomes.

Under the Utkrisht DIB, experienced NGO partners (service providers) provide technical assistance to help private facilities implement National Accreditation Board for Hospitals & Healthcare Providers (NABH) and Manyata quality standards for safe motherhood developed by the Federation of Obstetric & Gynaecological Societies of India (FOGSI) (NABH 2015; FOGSI n.d.) (Exhibit 1.1). Investors who provide capital for the technical assistance subsequently receive payments from participating outcome funders for every facility that went on to demonstrate an ability to meet a pre-determined set of quality standards. Proof of facilities meeting standards is determined by a verification agent to prompt payments from outcome funders to investors.

This brief was prepared by Mathematica, an independent verification agent, for the Utkrisht Development Impact Bond in India, and was sponsored by MSD for Mothers. MSD for Mothers is MSD's $500 million initiative to help create a world where no woman has to die while giving life. MSD for Mothers is an initiative of Merck & Co., Inc., Kenilworth, NJ, U.S.A.

Exhibit 1.1. Utkrisht DIB partners and roles



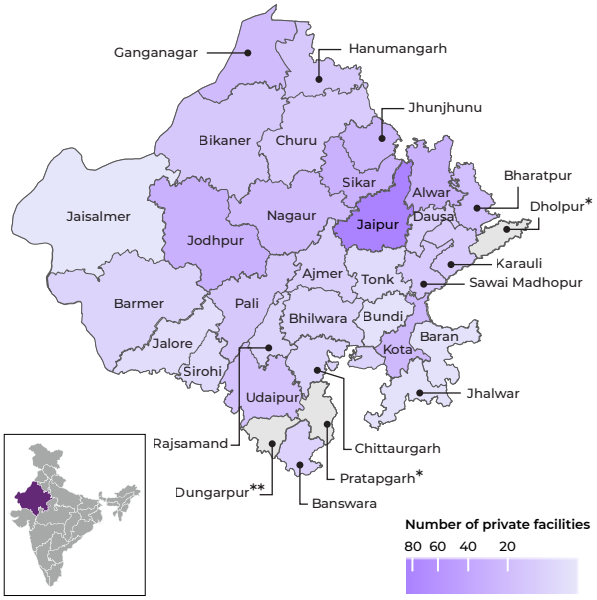
Key partners in the DIB included the investor, outcome funders, the implementation manager, service providers, and the verification agent. Each has a distinct role to play. The investor (UBS Optimus Foundation) provides the capital for the implementation team, which included the implementation manager, Palladium, and two service providers, Population Services International (PSI) and Hindustan Latex Family Planning Promotion Trust (HLFPPT). The implementation team used the capital to provide technical assistance to private small health care organizations (SHCOs). The SHCOs then worked toward improving quality of care and meeting standards set by the DIB. Contracted by MSD for Mothers, Mathematica acted as an objective third party to verify performance of SHCOs. Finally, outcome funders (MSD for Mothers and the United States Agency for International Development [USAID]) made payments to the investor based on how many SHCOs improve quality of care to a sufficient degree, as measured by meeting the quality standards, included in the National Accreditation Board for Hospitals & Healthcare Providers Pre-Entry level quality standards for SHCOs and Manyata certification standards for safe motherhood developed by the Federation of Obstetric & Gynaecological Societies of India.

Source: USAID 2017.

Setting of the Utkrisht DIB. Between April 2018 and April 2021, service providers helped 516 facilities in Rajasthan, India, to implement NABH and Manyata standards, with 405 verified as meeting standards according to DIB guidelines and the rest still in process of meeting standards.[1] They provided training to facility staff, and technical assistance to support infrastructure improvements to enable facilities to meet standards.

The implementation team began working in Rajasthan's capital, Jaipur, and gradually expanded to all 33 districts in the state of Rajasthan, except Dungarpur (Exhibit 1.2).[2] DIB participating facilities ranged from multispecialty hospitals to one-physician practices with an average of 33 beds and 24 births per month. Approximately 60 percent had headquarters designation, a proxy for urban status, and 40 percent did not have the headquarters designation and were considered rural. During this period, implementation partners did not note major policy and systems shifts related to quality of health care delivery in the private sector. However, the COVID-19 pandemic led to virtual, rather than in-person, provision of technical assistance by service providers once the government ordered a nationwide lockdown in March 2020. In August 2020, service providers adopted a hybrid virtual and in-person technical assistance approach until the end of the DIB in April 2021. In the year of the pandemic, the average number of births in participating DIB facilities was similar to that for previous and subsequent years.

Exhibit 1.2. DIB facilities in Rajasthan, 2019–2021



*No private facilities submitted for verification in this district.

**No private facilities participating in Utkrisht in this district.

Source: Mathematica analysis of facility-level administrative data provided by Palladium.

Outcomes. The key outcomes from the Utkrisht DIB include whether participating facilities improved care to meet DIB requirements for quality standards and whether this care correlated with better maternal and child outcomes. At the midline of the DIB in October 2019, achieving the Manyata level of certification was correlated with small, though not statistically significant, reductions in Caesarean sections, delivery complications, high-risk deliveries, preterm births, and low birth weight births, as well as increased referrals to the facility's NICU (O'Neil et al. 2020). At the end of the DIB, modeling using the Lives Saved Tool (LiST) predicts that facilities meeting DIB quality standards will avert an estimated 13,449 maternal and neonatal deaths across 405 private healthcare facilities in Rajasthan by 2023.[3]

Using the Lives Saved Tool, quality of care achieved by participating Utkrisht DIB facilities will avert an estimated 13,449 maternal and neonatal deaths by 2023

Sustainability. Costs for the technical assistance provided and quality improvements implemented by the facilities provide insights into the potential sustainability of interventions like the Utkrisht DIB. Estimations of costs for service providers' technical assistance and facility inputs to meet quality standards were developed using the activity-based costing method, which accounts for direct costs and helps allocate indirect costs to the specific effort.[4] Overall estimated costs for getting 405 facilities to quality standards was $8.8 million. Facilities bore approximately half these costs ($4.2 million), which came to approximately $10,400 per facility. The technical assistance provided by service providers and Palladium's management made up the other half of the costs and was approximately $11,400 per facility. Thus, to be cost-effective and sustainable, the monetary or social return on investment to funders, whether facilities themselves, the government, or another entity, would likely need to exceed $21,800 per private facility.

Concluding insights. Overall, participation in the Utkrisht DIB led to quality improvements in private facilities in Rajasthan, India. Although no evaluation was conducted to assess the DIB's direct impact, the LiST, which leverages the latest evidence linking health care practices to mortality rates and maternal health outcomes, predicts that the gains in quality for participating facilities achieved as a result of meeting the quality standards will lead to fewer maternal and neonatal deaths. With an estimated cost of $21,800 per private facility needed to improve quality, further studies on potential returns could provide more insights into whether a case could be made to implement and sustain related quality improvement efforts.

About our methods

LiST modeling. To derive an estimate of lives saved, Mathematica calculated the gain in coverage of life-saving interventions as a result of achieving the quality standards as defined by the Utkrisht DIB. The change in coverage is a function of the number of births in facilities achieving Manyata certification (as indicated by Mathematica's verification process or certification from FOGSI) and the average quality improvement in each facility on Manyata standards over the period it was engaged with Utkrisht. Baseline scores for facility quality were collected by implementation partners when they began to work with each facility. Mathematica assumed certified facilities at endline had 100 percent coverage for interventions in the LiST that overlap with Manyata standards.

Cost analysis. Using an activity-based costing method, Mathematica collected data on the cost associated with quality improvements for randomly sampled facilities and the costs for implementing partners to provide training and technical assistance. Together with the number of facilities meeting the quality standards supported by the DIB, Mathematica used these costs to estimate the total costs for quality improvement across all facilities that met standards as well as the average quality improvement cost per facility.

References

Chakravarthi, Indira. "Regulation of Private Health Care Providers in India: Current Status, Future Directions." *Indian Journal of Public Administration,* vol. 64, no. 4, 2018, pp. 587–598.

FOGSI. "FOGSI Accreditation Standards." Available at https://www.fogsi.org/wp-content/uploads/2016/12/FOGSI-CLINICAL-STANDARDS-for-accreditation-to-ensure-SAFE-DELIVERY.pdf. Accessed November 8, 2021.

Jhpiego. "Improving Quality of Maternal and Newborn Health in India." Baltimore, MD: Jhpiego, 2017. Available at https://www.jhpiego.org/wp-content/uploads/2017/07/mnh-factsheet-april-2017.pdf. Accessed November 8, 2021.

National Accreditation Board for Hospitals and Healthcare Providers (NABH). "About Us." n.d. Available at https://nabh.co/introduction.aspx#a1. Accessed November 8, 2021.

O'Neil, So, Divya Vohra, Matthew Spitzer, Shveta Kalyanwala, and Dana Rotz. "Maternal Health Care Quality and Outcomes Under the Utkrisht Impact Bond: Midline Findings and Insights." Washington, D.C.: Mathematica, 2020. Available at: https://www.mathematica.org/publications/maternal-health-care-quality-and-outcomes-under-the-utkrisht-impact-bond-midline-findings

Shukla, Abhay, Abhijit More, and Shweta Marathe. "Making Private Health Care Accountable: Mobilising Civil Society and Ethical Doctors in India." *IDS Bulletin,* vol. 49, no. 2, 2018.

Tripathi, S., A. Srivastava, P. Memon, et al. "Quality of Maternity Care Provided by Private Sector Healthcare Facilities in Three States of India: A Situational Analysis." *BMC Health Services Research,* vol. 19, no. 971, 2019.

USAID. "The Utkrisht Impact Bond: Improving Maternal and Newborn Health Care in Rajasthan, India." Washington, DC: USAID, 2017. Available at: https://www.usaid.gov/sites/default/files/documents/1864/Utkrish-Impact-Bond-Brochure-November-2017.pdf

Endnotes

[1] These facilities met the DIB-supported quality standard either as indicated by Mathematica's verification approach, or by accreditation from NABH or certification from Manyata.

[2] Implementation partners began working with facilities in Pratapgarh and Dholpur but these facilities were not submitted as part of any Ready Pool.

[3] More information about LiST is available at https://www.livessavedtool.org/.

[4] Reported costs include all costs associated with improving facility quality to meet quality standards, not only costs related to the DIB-funding mechanism itself.

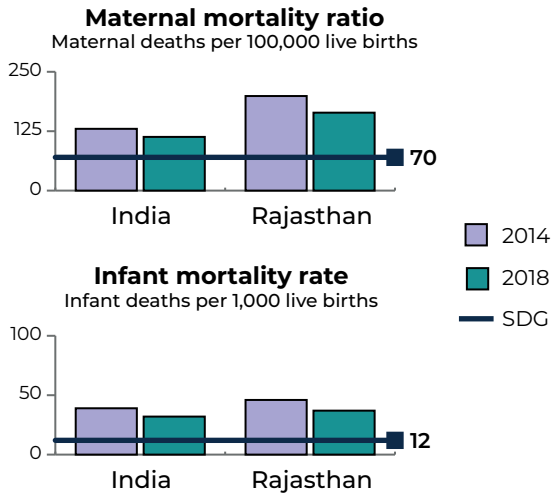
Insights on lives saved through quality improvements during birthing in India

Divya Vohra, Matt Spitzer, and So O'Neil

India has significantly improved maternal health over the past several decades, reducing its maternal mortality ratio from 556 to 113 deaths per 100,000 live births between 1990 and 2018. (Singh 2018; Government of India 2021) (Exhibit 2.1). However, progress toward the Sustainable Development Goal maternal mortality target of 70 deaths per 100,000 live births has slowed in recent years, especially in the poorer states of northern India. Researchers and policymakers have hypothesized that inadequate and inequitable access to quality health care has impeded further progress on maternal health (Balarajan et al. 2011). As private facilities are the main source of health care for many households, improving services provided in the private sector is a key strategy for improving maternal health (Tripathi et al. 2019; Chakravarthi 2018) (Exhibit 2.2).

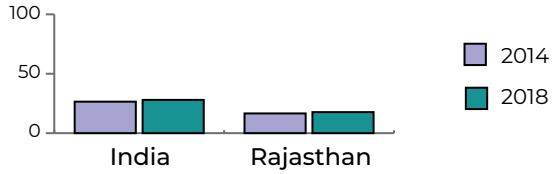
Recognizing the potential of private facilities as a pathway to further reducing maternal mortality in India, the Utkrisht Development Impact Bond (DIB) sought to use meeting quality standards as a means for improving and standardizing care in the private sector.

Exhibit 2.1. Reduction in Births and Deaths in India and Rajasthan, 2014–2018



Source: Sample Registration Statistical Reports, 2018 and 2014; Special Bulletin on Maternal Mortality in India; Sustainable Development Goals.

Exhibit 2.2. Percentage of deliveries in private facilities



Source: Sample Registration Statistical Reports, 2018 and 2014; Special Bulletin on Maternal Mortality in India; Sustainable Development Goals.

This brief was prepared by Mathematica, an independent verification agent, for the Utkrisht Development Impact Bond in India, and was sponsored by MSD for Mothers. MSD for Mothers is MSD's $500 million initiative to help create a world where no woman has to die while giving life. MSD for Mothers is an initiative of Merck & Co., Inc., Kenilworth, NJ, U.S.A.

Specifically, the DIB funded expert organizations that provided no-cost technical assistance to private facilities in Rajasthan, India, and helped them meet National Accreditation Board for Hospitals & Healthcare Providers (NABH) pre-entry level accreditation and Manyata certification standards for safe motherhood developed by the Federation of Obstetric & Gynaecological Societies of India (FOGSI) (NABH 2015; FOGSI n.d.) (Exhibit 2.3).[1] Meeting these standards enabled facilities to elevate their brand and be eligible for certain government reimbursement schemes. In this brief, we discuss the quality improvements observed in facilities participating in the Utkrisht DIB and estimate the potential impact of the program on lives saved.

Achieved health care quality improvement. Over the course of the DIB from April 2018 to April 2021, 405 of 516 facilities were verified as having met quality standards related to NABH and Manyata as required by the DIB.[4] A higher proportion of facilities in urban areas met quality standards than those in more rural areas. For example, in Jaipur—the most urban district—85 percent of facilities participating in the DIB ultimately met required standards, whereas in Jalor—the least urban district—only 20 percent did so (Rajras 2020; Exhibit 2.4). Implementation partners observed that facilities in more remote locations have a lower baseline level of quality than those in more accessible areas and might therefore find it more difficult to meet quality standards.

Exhibit 2.3. About quality standards for the Utkrisht DIB

NABH. These standards for small health care organizations (SHCOs) cover a variety of aspects to ensure standard operating procedures and facility infrastructure will facilitate high quality care. The standards include five chapters with patient-centered standards to assess patients' experience with care, and five chapters with organization-centered standards to assess SHCO infrastructure, management practices, and service delivery. These 10 chapters include a total of 47 standards, which are further divided into 149 measurable elements. Facilities pass a chapter if they score at least 50 percent of total points on a chapter and meet DIB requirements if they pass all the chapters.[2]

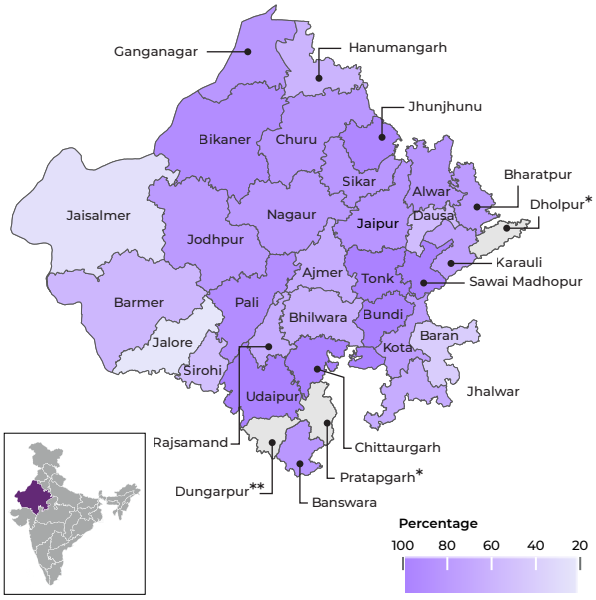
Manyata. These standards focus specifically on health care provider practices and facility equipment to deliver quality maternity and newborn care services. The standards address antenatal care, intra-natal care, delivery, post-natal care, and Caesarean sections. There are 16 Manyata standards, including 57 objective elements and 111 verification criteria. Facilities pass a standard if they earn all points in the standard. Facilities pass the Manyata portion of DIB requirements if they pass 11 standards.[3]

Source: NABH 2015; FOGSI n.d.

Note: The practices and thresholds FOGSI and NABH use for their own certification and accreditation, respectively, are subject to change and therefore might not align with these definitions. In 2018, FOGSI began requiring facilities to meet 14 of the 16 Manyata standards to receive certification. DIB requirements had already been established when this change was made. Given that FOGSI and NABH standards could change further over time, DIB partners agreed to adhere to the initially contracted criteria for "passing."

See Appendix A, Exhibits A.1 and A.2 for lists of standards.

Exhibit 2.4. Percentage of participating DIB facilities that met quality improvement standards, by district



*No private facilities submitted for verification in this district.

**No private facilities participating in Utkrisht in this district.
Source: Mathematica analysis of facility-level administrative and landscaping data provided by Palladium.

Even with the diversity in baseline level of quality, the vast majority of facilities met all NABH standards. Facilities performed best on chapters focused on the presence of documentation, signage, and other relatively straightforward and inexpensive improvements;

facilities earned an average score of 97 percent across patient rights and education chapters and 88 percent across chapters related to hospital quality management, both of which rely heavily on the presence of written protocols, but do not assess adherence to these protocols. Facilities scored lowest on the chapter related to facility management and safety, though they still earned 79 percent on this chapter. Performance on NABH standards was strong across the board.

Most facilities also met Manyata standards related to preparing for safe maternal care, assessing pregnant women at admission, and providing a safe and clean birth (passed by 68 percent, 67 percent, and 72 percent of facilities, respectively). The individual verification criteria within these standards focus heavily on the availability of key equipment and supplies. In contrast, facilities showed relatively low performance on standards related to caesarean section practices and monitoring the progress of labor (passed by 31 percent and 38 percent of facilities, respectively). These standards focused more on documentation and review of case records than other Manyata standards, suggesting that facilities may have found it more challenging to pass standards where they were required to demonstrate adherence to best practices.

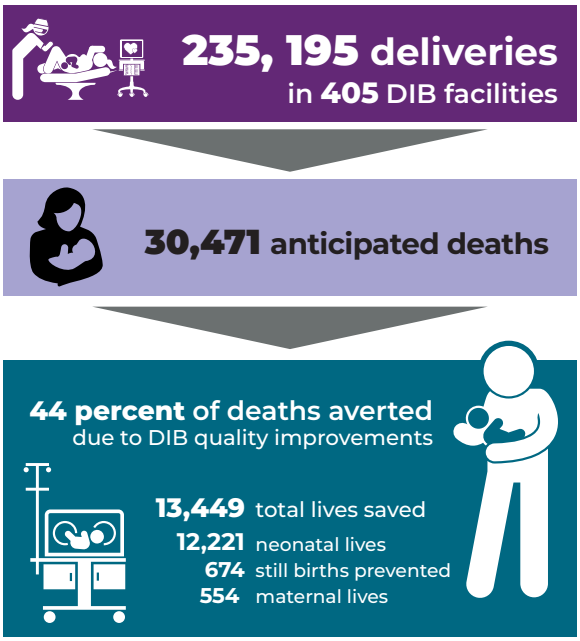
Impact on lives saved. Both NABH and Manyata standards aim to improve the quality of critical life-saving interventions while promoting a patient-centered approach to care. These are practices that are known to improve patient experience and health outcomes (Montagu et al. 2020; Semrau et al. 2017). The quality improvements achieved by DIB facilities could therefore have a meaningful impact on the experiences of people who deliver in these facilities.

About the Lives Saved Tool (LiST)

The LiST allows users to estimate the impact of changes in coverage of maternal and child health interventions on averting deaths. Interventions included in the tool have evidence of saving maternal and neonatal lives, such as managing hypertensive disorders during pregnancy, ensuring a clean birth environment, and managing postpartum hemorrhage. Many of these interventions align with quality improvements supported by Manyata standards.

To assess the potential impact of DIB facilities' quality improvement, we used the Lives Saved Tool (LiST), a predictive model that assesses the potential impact of implementing various maternal and child interventions on averting maternal and neonatal deaths. Based on estimated changes in coverage of interventions aligned with Manyata standards, the LiST estimates that DIB quality improvements will lead to 13, 449 lives saved between 2018 and 2023 (Exhibit 2.5 and Appendix A, Exhibit A.3).[5] This represents 44 percent of 30,471 anticipated neonatal and maternal deaths from 235,195 deliveries occurring in DIB facilities (Exhibit 2.5).[6]

Exhibit 2.5. Estimated lives saved through DIB



Source: Mathematica analysis using LiST.

Because the time period in which LiST estimates lives saved includes future years, unanticipated events in 2021 and beyond could make the real number of lives saved different than the estimate. Although the COVID-19 pandemic did not reduce the number of deliveries in DIB facilities reported through January 2021, the ongoing pandemic could change people's comfort level in having an institutional delivery in the future.[7]

Fewer people delivering in DIB health facilities would mean fewer births and fewer lives saved from the quality improvements through the DIB. Similarly, recent changes to insurance coverage under the Bhamashah Swasthya Bima Yojana in 2021 could potentially spur people that would have delivered in private facilities to seek care in public ones—also leading to fewer lives saved than estimated here. Our results from LiST should be considered with these contexts in mind.

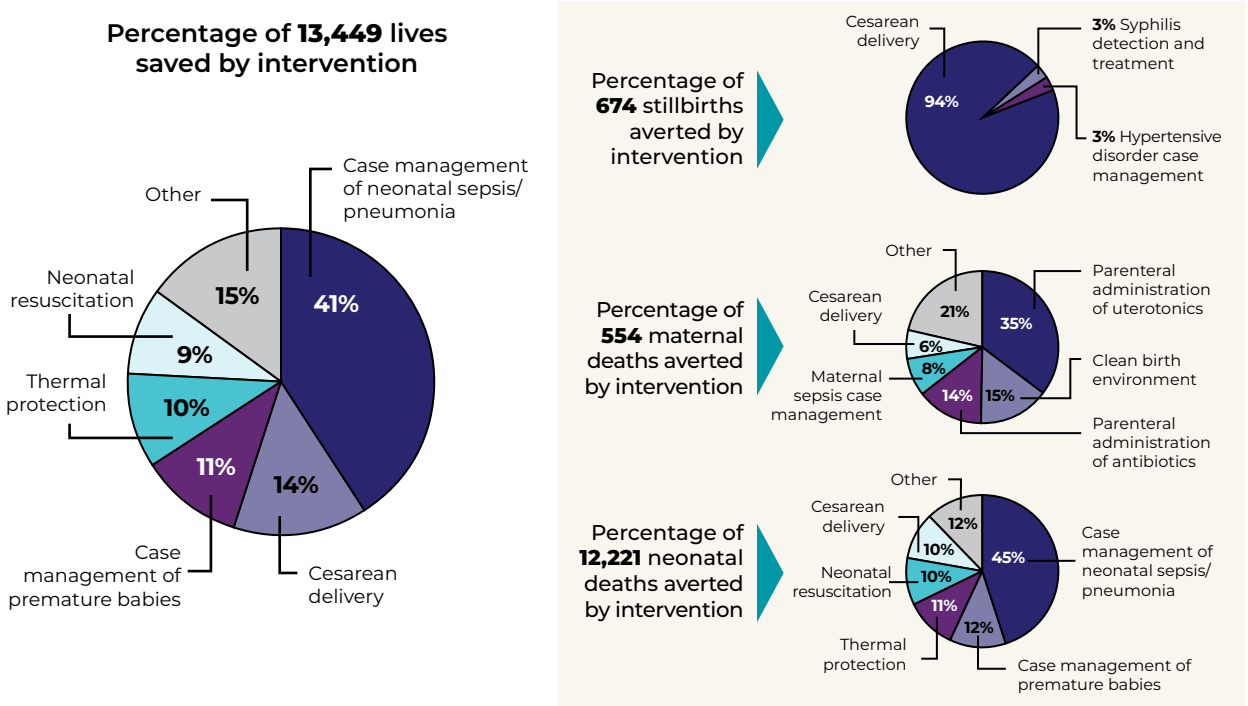
The LiST predicts the vast majority of deaths averted to be among newborns within the first month of life (91 percent). Maternal deaths (5 percent) and stillbirths (4 percent) account for smaller proportions. The LiST predicts that 90 percent of neonatal deaths, 89 percent of maternal deaths, and 24 percent of still births in Utkrisht facilities will be averted because of DIB quality improvements.

Almost half (45 percent) of the lives saved were due to facilities improvement in adhering to the Manyata standard related to improved case management of neonatal sepsis/pneumonia (Exhibit 2.6).

The large share of lives saved as a result of this intervention is influenced by the associated 75 percent reduction in neonatal mortality from implementing this[7] and Utkrisht facilities' substantial gains in their adherence to this practice.[8] More detailed findings from the LiST modeling are in Appendix A, Exhibit A.4.

Notably, the interventions in the LiST model that resulted in the most lives saved generally correspond to quality standards where individual facilities achieved significant quality improvements over baseline (Exhibit 2.5). Furthermore, two of the standards the highest proportion of facilities passed—preparing for safe care during delivery and assessing all pregnant women at admission—did not correspond to any LiST interventions in the model and, therefore, did not result in any predicted lives saved. These results underscore that, although meeting Manyata quality standards plays a role in increasing the coverage of life-saving quality improvements generally, the particular type of quality improvement achieved and degree of improvement can greatly affect the number of estimated lives saved by LiST.

Exhibit 2.6. Performance on Manyata standards related to critical life-saving interventions



Source: Mathematica analysis of LiST results.

The lack of a link between a Manyata standard and an intervention included in the LiST does not necessarily minimize the value of that particular standard. Manyata standards were chosen because they address interventions that have been shown to be crucial to quality maternal and neonatal outcomes, such as respectful and patient-centered care. The LiST model may not include such interventions because quantitative evidence meeting model inclusion criteria is not available on the impacts on outcomes. Therefore, facilities should not dismiss achievement of other standards not included in the LiST model and their potential to improve health outcomes.

All in all, these findings suggest that scaling up Quality improvement efforts centered on Manyata standards could have a large potential impact on maternal and neonatal mortality in private facilities, especially if facilities with lower initial levels of quality achieve Manyata standards. At the same time, one time achievement of the standards will likely not lead to ongoing impacts without a strong quality culture. Facilities might need additional, ongoing support to maintain the quality gains they achieve and bring about lasting improvements in maternal and neonatal health in Rajasthan.

Concluding insights. Evidence from previous studies suggests that adherence to the best practices covered by Manyata and NABH standards should produce improvements in patient experience and outcomes (Semrau 2017). Importantly, it is the incremental improvement in quality, not necessarily the finite achievement of standards, that will translate into lives saved. These findings will hopefully encourage health systems to promote facilities beginning, continuing, and sustaining their quality improvement journey.

About our methods

To derive an estimate of lives saved, Mathematica calculated the gain in coverage of life-saving interventions as a result of achieving the quality standards as defined by the Utkrisht DIB. We used the Lives Saved Tool (LiST), a mathematical modeling tool that allows for estimation of the impact of changes in the coverage of evidence-based life-saving interventions on maternal and neonatal mortality. Our approach involved the following key steps:

Identifying interventions impacted by the DIB quality improvement. Mathematica mapped Manyata standards to LiST interventions. The mapping identifies Manyata standards that, if achieved, would increase coverage of interventions included in the LiST model. Every Manyata standard was categorized as having complete, partial (50 percent), or no overlap with LiST interventions. Because NABH standards focus on more general hospital practices, there is not a strong overlap between NABH standards and LiST interventions, so NABH standards were not used as an input for the LiST.

Quantifying the extent of quality improvement. Implementation partners conducted a baseline assessment to understand each DIB facility's initial level of quality before it participated in the DIB. We calculated quality improvement for each passing facility by taking the difference between this baseline score and the endline score. (Because facilities needed to earn a perfect score in each standard in order to pass, we assumed that every passing facility scored perfectly on all standards at endline.) The change in coverage of each LiST intervention in Rajasthan in a given year was calculated as the average difference between baseline and endline scores on the corresponding Manyata standard multiplied by the share of Rajasthan births estimated to be taking place in Utkrisht facilities in that year. The five interventions that were responsible for the greatest number of lives saved corresponded to the Manyata standards related to providing adequate postpartum care to mother and baby, ensuring care of newborn with small size at birth, performing newborn resuscitation if baby does not cry immediately after birth, and reviewing clinical practices related to C-section at regular intervals. Over 80 percent of certified facilities met each of these standards.

Estimating the number of births in DIB facilities. The estimated number of lives saved is a function of the gain in coverage of LiST interventions (as described above) and the number of births in facilities achieving the Manyata standards. To determine the extent to which Utkrisht interventions are responsible for Rajasthan-wide coverage of LiST interventions, Mathematica calculated the share of Rajasthan births taking place at DIB facilities. Palladium provided data on facility births through January 2021. Mathematica used a Poisson regression with the observed data to predict births in future months (and past months with missing data) that assumes births within a facility continue on a similar trend. The model incorporates the timing of certification and its effect on the number of births, seasonality, and facility-fixed effects. Poisson was chosen as the regression model because of its strength in modelling count data, such as births, where the likelihood of one birth is not correlated with the likelihood of another.

Quantifying lives saved due to quality improvements. The LiST is a part of the Spectrum software developed by Avenir Health. The software creates a mathematical model of population (considering births and deaths) over time by drawing on estimates of life expectancy, fertility rates, and mortality rates for certain populations. Specific health interventions, such as vaccination, are modelled as reducing mortality rates according to estimates from the latest scientific literature. Mathematica entered into the LiST data on the estimated coverage of specific interventions as a result of the DIB, as described above. The LiST then incorporated the extent to which these interventions would reduce mortality rates over a specific time period (2018–2023) relative to a scenario in which the DIB was not implemented to estimate the number of lives saved.

References

Balarajan, Y., S. Selvaraj, and S.V. Subramanian. "Health Care and Equity in India." *The Lancet,* vol. 377, no. 9764, 2011, pp. 505–515.

Chakravarthi, Indira. "Regulation of Private Health Care Providers in India: Current Status, Future Directions." *Indian Journal of Public Administration,* vol. 64, no. 4, 2018, pp. 587–598.

FOGSI. "FOGSI Accreditation Standards." Available at https://www.fogsi.org/wp-content/uploads/2016/12/FOGSI-CLINICAL-STANDARDS-for-accreditation-to-ensure-SAFE-DELIVERY.pdf. Accessed November 8, 2021.

Government of India. "Maternal Mortality Rate (MMR)." Ministry of Health and Family Welfare, February 2021. Available at https://www.pib.gov.in/PressReleasePage.aspx?PRID=1697441. Accessed September 16, 2021.

Lives Saved Tool (LiST). "The Lived Saved Tool." Available at: https://www.livessavedtool.org/. Accessed November 20, 2021.

Montagu, Dominic, Katie Giessler, Michelle Kao Nakphong, et al. "A Comparison of Intensive vs. Light-Touch Quality Improvement Interventions for Maternal Health in Uttar Pradesh, India." *BMC Health Services Research,* vol. 20, 2020.

National Accreditation Board for Hospitals and Healthcare Providers (NABH). "About Us." n.d. Available at https://nabh.co/introduction.aspx#a1. Accessed November 8, 2021.

Rajras. "Urbanisation in Rajasthan." March 2020. Available at: https://www.rajras.in/urbanisation-in-rajasthan/. Accessed November 8, 2021.

Semrau, Katherine E.A., Lisa R. Hirschhorn, Megan Marx Delaney, et al. "Outcomes of a Coaching-Based WHO Safe Childbirth Checklist Program in India." New England *Journal of Medicine,* vol. 377, 2017, pp. 2313-2324.

Singh, Poonam Khetrapal. "India Has Achieved Groundbreaking Success in Reducing Maternal Mortality." Geneva, Switzerland: World Health Organization, June 2018. Available at https://www.who.int/southeastasia/news/detail/10-06-2018-india-has-achieved-groundbreaking-success-in-reducing-maternal-mortality. Accessed September 16, 2021.

Tripathi, S., A. Srivastava, P. Memon, et al. "Quality of Maternity Care Provided by Private Sector Healthcare Facilities in Three States of India: A Situational Analysis." *BMC Health Services Research,* vol. 19, no. 971, 2019.

Zaidi A. K., H.A. Ganatra, S. Syed, S. Cousens, A.C. Lee, R. Black, Z. A. Bhutta, and J.E. Lawn. "Effect of Case Management on Neonatal Mortality Due to Sepsis and Pneumonia." *BMC Public Health,* vol. 11, no. S13, 2011.

Endnotes

[1] Organizations providing technical assistance to private facilities included Population Services International and Hindustan Latex Family Planning Promotion Trust.

[2] NABH chapters are titled (1) Access, Assessment and Continuity of Care; (2) Care of Patients; (3) Management of Medication; (4) Patient Rights and Education; (5) Hospital Infection Control; (6) Continuous Quality Improvement; (7) Responsibilities of Management; (8) Facility Management and Safety; (9) Human Resource Management; (10) Information Management System.

[3] Manyata standards include: (1) Provider screens for key clinical conditions that may lead to complications during pregnancy; (2) Provider prepares for safe care during delivery (to be checked every day); (3) Provider assesses all pregnant women at admission; (4) Provider conducts PV examination appropriately; (5) Provider monitors the progress of labor appropriately; (6) Provider ensures respectful and supportive care; (7) Provider assists the woman to have a safe and clean birth; (8) Provider conducts a rapid initial assessment and performs immediate newborn care (if baby cried immediately); (9) Provider performs Active Management of Third Stage of Labor (AMTSL); (10) Provider identifies and manages Post-Partum Hemorrhage (PPH); (11) Provider identifies and manages severe Pre-eclampsia/Eclampsia (PE/E); (12) Provider performs newborn resuscitation if baby does not cry immediately after birth; (13) Provider ensures care of newborn with small size at birth; (14) The facility adheres to universal infection prevention protocols; (15) Provider ensures adequate postpartum care package is offered to the mother and baby– at discharge; (16) Provider reviews clinical practices related to C-section at regular intervals.

[4] Mathematica verified 338 facilities as reaching the Utkrisht quality standards (as indicated by membership in a verified Ready Pool), and the remaining 67 received official Manyata certification from FOGSI and small health care organization accreditation from NABH.

[5] The number of stillbirths and neonatal and maternal deaths in Rajasthan during the period 2018–2023 predicted by the LiST is 306,048. Scaling this number by the proportion of deliveries anticipated to take place in Utkrisht facilities yields 30,471.

[6] The LiST bases its estimate for lives saved as a result of this practice on Zaidi et al. (2011), who use a meta-analysis of four studies to calculate that proper case management of sepsis reduces all-cause neonatal mortality by approximately 75 percent (95 percent confidence interval of 41 to 82 percent).

[7] In the year of the pandemic, DIB facilities averaged 275 deliveries per year; the average number of births was similar to estimates for previous and subsequent years.

[8] In the LiST, the coverage for this intervention is a function of two related interventions: (1) oral antibiotics for neonatal sepsis and (2) injectable antibiotics for neonatal sepsis, both of which overlap with Manyata standard 15, objective element 15.2.5, which requires the provider to give the correct regime of antibiotics or refer the newborn to specialist care in cases of neonatal sepsis. At baseline, facilities scored an average of 4.46 points out of 10 on this standard, and we estimate that certified facilities would achieve 10 out of 10 points.

Insights on costs of meeting maternal health quality standards among private facilities in India

Divya Vohra, Matt Spitzer, and So O'Neil

The majority of health care is delivered through private sector facilities in India. Building capacity and improving practices in these facilities could have great societal benefits. In particular, averting adverse outcomes associated with maternal morbidity in private facilities in India could prevent more than 150,000 maternal deaths and save $1.5 billion in costs over five years (Goldie et al. 2010).

For decision makers, a key consideration when deciding whether to invest in quality improvements is the expense of implementing the intervention relative to the net outcomes/impacts of the improvement. To aid decision makers on whether to invest in quality improvement in private facilities in India, we estimated costs for meeting quality standards established by the National Accreditation Board for Hospitals & Healthcare Providers (NABH) and Federation of Obstetric and Gynaecological Societies of India (FOGSI) through the Utkrisht Development Impact Bond (DIB). The costs estimated included those related to:

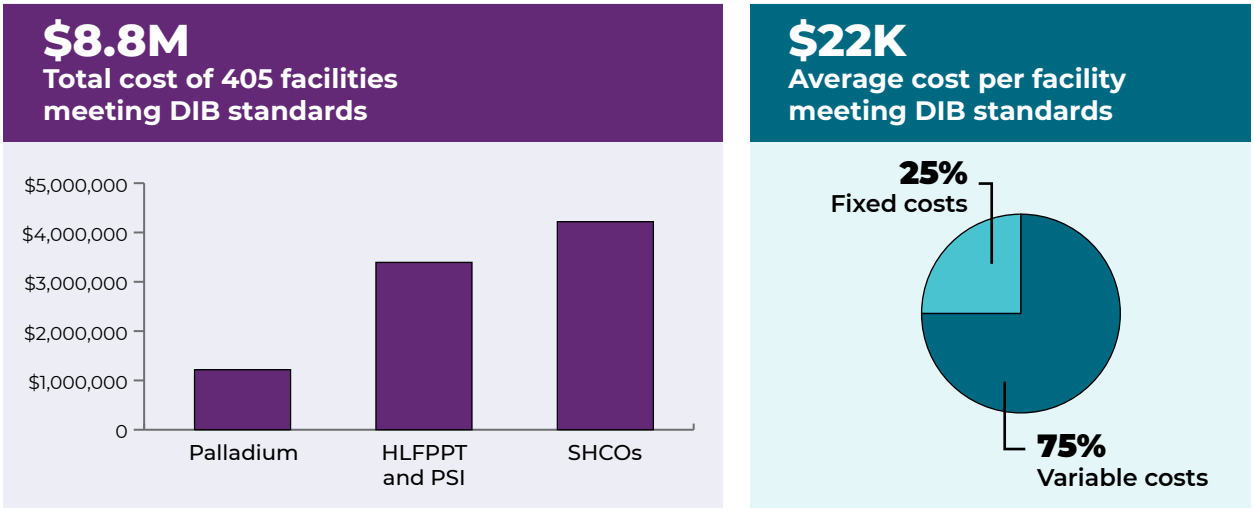
- **Quality improvement technical assistance to private facilities in India.** The Utkrisht DIB implementation partners (Palladium, Population Services International [PSI], and Hindustan Latex Family Planning Promotion Trust (HLFPPT]) provided technical assistance to support private facilities in meeting NABH standards (pre-entry level accreditation) for small health care organizations (SHCOs) and Manyata standards for safe motherhood set by FOGSI. These costs include all labor time and materials devoted to administering and implementing the DIB by implementation partners and facilities (including time spent working on a pro bono basis), as well as capital expenses.
- **Implementation of quality improvements by private facilities.** SHCOs invested in structural improvements, process enhancements, and staff time to achieve NABH and Manyata standards. These costs include those associated with purchasing capital equipment, repairs and improvements, disposable equipment, outsourced services (for example, housekeeping or cafeteria services), and staff time.

From February 2018 through May 2021, the total cost of quality improvement under the DIB for 516 facilities, 405 of which met defined quality standards, was approximately $8.8 million.[1] Altogether, the average cost per participating SHCO that met quality standards was $21,801.

Costs of quality improvement technical assistance. Provision of training and technical assistance accounted for approximately half of the total quality improvement costs. Palladium incurred $1.2 million to serve as the coordinating hub and the implementation partners expended another $3.4 million to directly assist facilities in meeting standards (Exhibit 3.1).

This brief was prepared by Mathematica, an independent verification agent, for the Utkrisht Development Impact Bond in India, and was sponsored by MSD for Mothers. MSD for Mothers is MSD's $500 million initiative to help create a world where no woman has to die while giving life. MSD for Mothers is an initiative of Merck & Co., Inc., Kenilworth, NJ, U.S.A.

Exhibit 3.1. Total and average costs for meeting quality improvement standards in the Utkrisht DIB, February 2018–May 2021



Source: Mathematica analysis of cost data provided by implementation partners and SHCOs.

DIB = Development Impact Bond; SHCO = small health care organization.

Note: Total cost was calculated by multiplying the average costs reported by facilities in the verification samples by the total number of SHCOs considered to have met the quality standards supported by the DIB as of May 2021.

The average cost for technical assistance per SHCO meeting DIB required quality standards was $11,000. Most technical assistance costs were variable, such as the costs related to the time and travel associated with delivering technical assistance. About one-quarter of the costs were considered fixed costs, such as those associated with developing the technical assistance materials and approach.

As the DIB progressed, the average cost per facility for Palladium's coordination, management, and monitoring fell (Exhibit 3.2). Notably, the share of Palladium's costs dedicated to assessments ensuring facilities' readiness for verification increased considerably, from 3 percent at midline (October 2019) to 13 percent at endline (April 2021), while the share of costs dedicated to overall program management fell slightly, from 25 percent at midline in October 2019 to 20 percent at endline in April 2021.

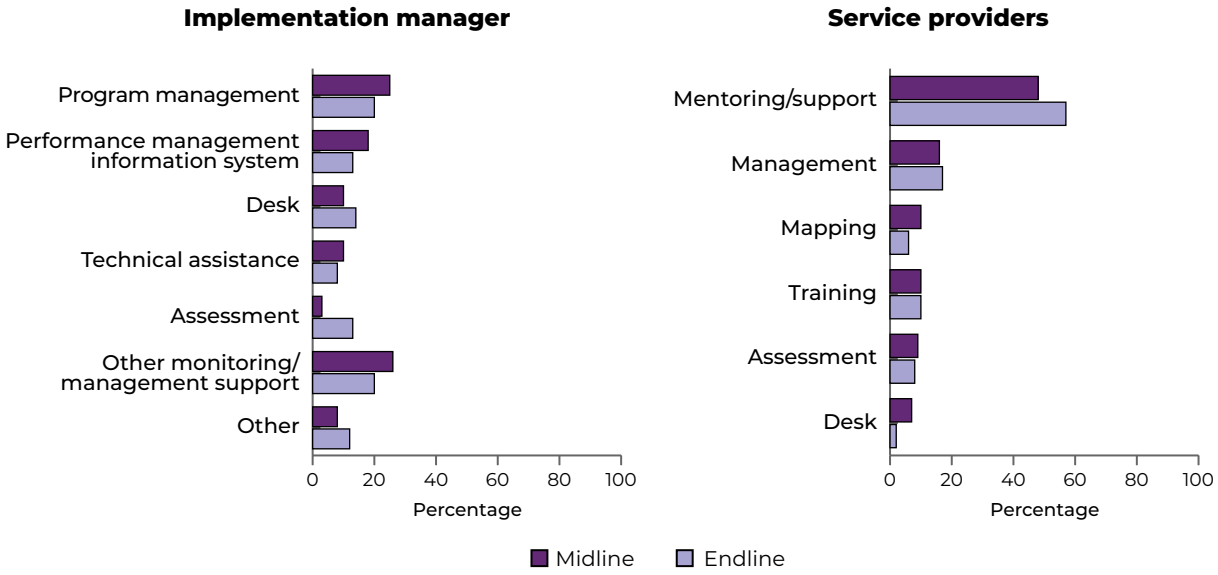
At the same time, average costs for on-the-ground technical assistance increased by 24 percent. The majority of service providers' costs were dedicated to providing mentoring support and technical assistance to participating SHCOs, which is consistent with their expenditures at midline.

These decreasing coordination costs are aligned with Palladium and implementation partners codifying coordination processes, while the increasing technical assistance costs are consistent with implementation partners working with more remote and less resourced private facilities as the DIB went on.

Costs of quality improvement implementation. SHCOs bore the other half of quality improvement costs, devoting approximately $4.2 million to staff time and other resources to meet NABH and Manyata standards (Exhibit 3.1). SHCOs that met quality standards spent about $10,000 each.

Nearly two-thirds of the SHCO costs were for staff labor; consumable materials accounted for almost all of the remaining one-third, with equipment, outsourced services, and repairs accounting for less than 8 percent all together. The distribution of costs for SHCOs was similar at midline and endline; this may be because only one additional round of cost data was collected after the midline analysis was conducted.

Exhibit 3.2. Distribution of technical assistance and training costs at midline (October 2019) and endline (April 2021)



Source: Mathematica analysis of cost data provided by implementation partners and SHCOs.

Private facility costs of participation

We examined cost data shared by all participating facilities, regardless of whether the individual facilities met the standards required by the DIB. Overall, SHCOs spent an average of about $6,600 to participate in the DIB. Average costs for private facilities that went on to meet DIB quality standards were not substantially different than the average costs for those that did not end up meeting standards. For all facilities, the largest component of SHCOs' costs was labor, which averaged $4,407 per facility but was over $45,000 in some facilities.

Exhibit 3.3. Average SHCO costs by type (in dollars)

	Overall			Met quality standards			Did not meet quality standards		
Cost type	Mean	Median	Max	Mean	Median	Max	Mean	Median	Max
Overall	$6,641	$2,629	$45,733	$6,990	$3,114	$39,169	$5,943	$2,082	$45,733
Capital	$319	$40	$4,755	$305	$49	$3,089	$348	$40	$4,755
Labor	$4,407	$418	$45,725	$4,102	$518	$35,276	$5,015	$342	$45,725
Materials	$1,915	$141	$38,645	$2,583	$181	$38,645	$580	$58	$4,115

Source: Mathematica analysis of cost data provided by SHCOs.

Contextualizing quality improvement costs under the DIB. In Africa and South Asia, maternal health care quality improvement costs per facility have ranged from $22,000 to over $2 million (Fox-Rushby and Foord 1996; Goodman et al. 2017). This variation reflects differences in intensity and type of quality improvement efforts (including differences in initial quality of facilities and the extent of change targeted), size of facilities undergoing quality improvement, and methods for accounting for expenditures (Fox-Rushby and Foord 1996; Goodman et al. 2017).

In comparison to these other programs, costs of quality improvement per DIB facility fell at the lower end of the spectrum, likely because of the relatively smaller size of participating DIB facilities on average. Thus, in terms of cost, expansion of quality improvement interventions similar to the DIB might be considered reasonable and scalable across similarly small private facilities in India.

Concluding insights. Under the DIB, SHCOs paid out of pocket almost half of the $8.8 million spent on the DIB, with each facility spending an average of about $10,000, three-fourths of which are variable costs that could continue if facilities maintain achieved quality. Facilities may be willing to pay more in an ongoing way should quality improvements lead to greater psychological satisfaction with providing quality care and returns on investment from increases in client volume or eligibility for higher reimbursement through government schemes. However, if SHCOs are not willing to take on additional costs, other entities would have to step in. For these external funders, including government and non-government entities, benefits could take the form of savings to health and other social systems, as higher quality care results in less acute adverse health episodes requiring expensive care and can improve productivity.

Methods and limitations

Estimating quality improvement technical assistance costs

Principles of the activity-based costing (ABC) method provide the basis of the approach to assess implementation partners' costs for quality improvement (World Health Organization 2003). ABC identifies all the activities in which an organization engages and assigns costs to each activity. This method allowed us to obtain accurate cost information regardless of the information available through partners' accounting systems. The approach to collecting implementation partners' quality improvement costs involved three key steps: (1) identify mutually exclusive and collectively exhaustive list of activities, (2) identify the quantities and prices of inputs used for each activity, and (3) allocate costs to activities. Cost workbooks guided the implementation partners in assigning direct and indirect costs to specific activities.

The costs were collected first in April 2019 (documenting costs incurred between February 2018 and March 2019) and again in April 2021 (documenting costs incurred between April 2019 and March 2021). We obtained data on actual costs accrued by implementation partners from February 2018 to March 2021 to provide technical assistance to facilities by April 2021. Costs for April and May 2021 were assumed to be equal to average monthly costs for the period in the second round of data collection, April 2019 to March 2021. Costs were converted to 2018 dollars using a 3 percent discount rate. We included the costs borne by the implementation partners to assist all SHCOs (treating costs for SHCOs that did not yet meet the quality standards as collateral expenditures). Other costs have been inflation-adjusted and capital costs were adjusted to account for the use versus actual cost of capital. Costs incurred by the implementation partners were classified as fixed costs, which do not change with the number of facilities assisted, and variable costs, which increase with the number of facilities served.

Estimating SHCO quality improvement implementation costs

For SHCOs, we administered a cost survey to collect information on various cost drivers and determine the extent to which each could be attributed to quality improvement. To understand the costs borne specifically by SHCOs that achieved the quality standards, we first estimated average SHCO costs using all SHCOs that were in the Round 3 and Round 4/5 verification samples, all of which were judged to have met standards. (We did not collect cost data from sampled facilities in Round 6 as a result of the COVID-19 pandemic; we assumed costs for these facilities were equal to average costs for facilities in Round 4/5.) We then estimated the total cost incurred by SHCOs to meet the standards by multiplying this average cost by the total number of facilities that have been judged to have achieved the quality standards throughout the DIB. All costs incurred by SHCOs were considered variable.

References

Fox-Rushby, Julia A., and Frances Foord. "Costs, Effects and Cost-effectiveness Analysis of a Mobile Maternal Health Care Service in West Kiang, The Gambia." *Health Policy,* vol. 35, no. 2, 1996, pp. 123–143.

Goldie, Sue J., Steve Sweet, Natalie Carvalho, Uma Chandra Mouli Natchu, and Delphine Hu. "Alternative Strategies to Reduce Maternal Mortality in India: A Cost-Effectiveness Analysis." *PLOS Medicine,* vol. 7, no. 4, 2010, e1000264.

Goodman, David M., Rohit Ramaswamy, Marc Jeuland, Emmanuel K. Srofenyoh, Cyril M. Engmann, Adeyemi J. Olufolabi, and Medge D. Owen. "The Cost Effectiveness of a Quality Improvement Program to Reduce Maternal and Fetal Mortality in a Regional Referral Hospital in Accra, Ghana." *PloS One,* vol. 12, no. 7, 2017, e0180929.

World Health Organization. Making Choices in Health: WHO Guide to Cost-Effectiveness Analysis, volume 1. Geneva, Switzerland: World Health Organization, 2003. Available at https://www.who.int/choice/publications/p_2003_generalised_cea.pdf. Accessed November 8, 2021.

Endnotes

[1] Note that this figure includes costs borne by facilities but does not include transaction costs related to setting up the DIB (e.g., identifying funders and investors, developing contracts) or pro bono work on the part of implementers.

Insights on the evolution of maternal health quality-of-care verification for a development impact bond

So O'Neil, Divya Vohra, Matt Spitzer, Shveta Kalyanwala, and Dana Rotz

Development impact bonds (DIBs) offer an innovative financing mechanism that leverages private capital to achieve social impact. Private investors provide the capital and earn a financial return when the social program meets pre-specified outcomes. Service providers implement a specified intervention using this capital. The "outcome funder" pays an agreed price per outcome (or output) to the investor on achievement of outcomes.

This focus on outcomes allows flexibility for service providers to adapt implementation to improve the efficiency and effectiveness of the intervention. At the same time, the emphasis on outcomes alone can produce incentives to take shortcuts to achieve specified results or employ a pro forma mindset in considering complex social issues.

As a result, DIBs usually build in an external verification process to confirm authentic achievement of outcomes. This verification can occur through many mechanisms, including using existing administrative data, collecting new data, or both. Depending on the outcomes for measurement, the verification methods can vary from auditing to an experimental design.

As an example, for the Utkrisht DIB in India, verification of private facilities that meet specified quality outcomes ideally would come from the facilities receiving pre-entry-level accreditation from the National Accreditation Board for Hospitals & Healthcare Providers (NABH) and certification from the Federation of Obstetric & Gynaecological Societies of India (FOGSI). However, accreditation from NABH small health care organizations (SHCOs) and FOGSI Manyata certification for safe motherhood can take up to one year. As result, to ensure timely payments to the investor, the Utkrisht DIB initially established verification through an external agency, Mathematica, following an approach similar to the one used by NABH and FOGSI.

Verification for the Utkrisht DIB balanced needs for efficiency, timeliness, and accuracy, as follows:

- **Efficiency,** such that the cost of verification did not exceed the costs of the intervention itself. This has been a criticism of early impact bonds (Gustafsson-Wright and Osborne 2020). As a result, Mathematica's verification relied on assessing a sample of SHCOs in a "ready pool" to confirm whether the entire "ready pool" of participating facilities met the quality standards and to determine whether outcome funders issued payments.

This brief was prepared by Mathematica, an independent verification agent, for the Utkrisht Development Impact Bond in India, and was sponsored by MSD for Mothers. MSD for Mothers is MSD's $500 million initiative to help create a world where no woman has to die while giving life. MSD for Mothers is an initiative of Merck & Co., Inc., Kenilworth, NJ, U.S.A.

Where possible, Mathematica's verification also focused on assessing elements of quality that related directly to maternal and neonatal health care—a departure from NABH accreditation, which assesses the quality of the full range of an SHCO's services.

- **Timeliness,** such that the investor received payments at regular intervals and outcome funders saw results being achieved progressively. Regular payments minimized the investor's risk in providing large sums of initial investment and allowed them to realize timely returns. For outcome funders, the routine achievement of results guarded against slow and inconsistent implementation and results. The Utkrisht DIB included a six-month verification and payment cadence.
- **Accuracy,** such that outcome funders were reasonably sure that SHCOs reached specified quality standards. Because of the high resource requirements to conduct verification assessments for the census of SHCOs in the "ready pool," the verification relied on a lot quality assurance sampling (LQAS) approach. The verification agency used this approach to assess whether the process the implementation team used to identify SHCOs that reached quality standards and to place them in the ready pool for verification was sufficiently accurate. The sample size for each round was large enough so that the sum of the probabilities of making a false positive error (judging the process to have been accurate when in fact it was not) or false negative error (judging the process to have been inaccurate when it was) was 5 percent or less.

Innovation for verification as well as implementation in a DIB. The DIB mechanism was developed mainly with innovation in the context of implementation in mind, such that service providers could pivot to incorporate emerging learning and respond to shifts in the environment. The Utkrisht DIB revealed that innovation can happen to the verification as well as implementation processes of a DIB, especially as new contexts arise. But these changes also likely caused variation in the efficiency, timeliness, and accuracy of the DIB.

The initial design of verification for the Utkrisht DIB included six rounds of verification semiannually, but the fourth and fifth rounds were combined in the end. Changes to the verification process began in the third round (Exhibit 4.2). After the second round, partners asked for the verification process to be reexamined and modified. Of note, the ready pool did not pass and outcome funders did not distribute payments for the second round, which led to concerns that the verification process did not sufficiently mirror the NABH and Manyata processes.

COVID-19 also prompted changes to the verification process, leading to the combining of the fourth and fifth rounds. Overall, the changes to the Utkrisht DIB verification methods included how to assess quality, which modes to use for verification, and who could conduct verification.

Key changes to approach for Utkrisht DIB verification

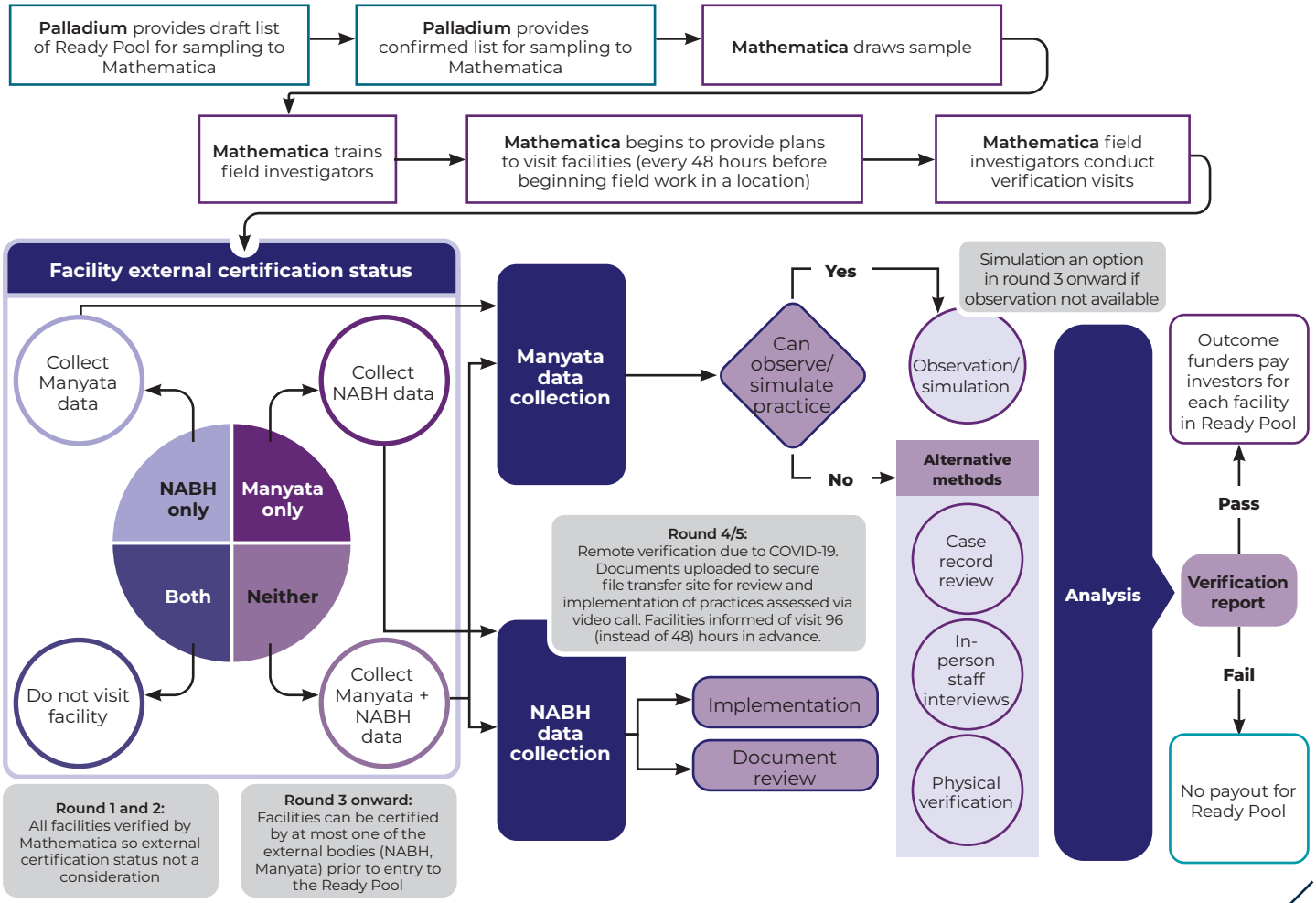
Addition of assessment method. Manyata standards allow multiple combinations of various modes for verification, including documentation, interview, observation, and maternal care practice simulations. Of these, simulations require the most time, and to limit the length of verification site visits to a day, the verification agency used other modes for verification. However, after the results of the second round, partners asked that simulations be included as a preferred mode for verification.

Verification by accreditation bodies. In contrast to the long lead time for NABH accreditation, partners discovered that FOGSI certification could be obtained relatively quickly. Implementation partners asked that Manyata certification also count as verification in lieu of verification by Mathematica during the third round.

In-person to virtual verification mode. COVID-19 overwhelmed health facilities in India and made in-person visits not only inconvenient but dangerous to public health. As a result, verification for the fourth round did not occur as scheduled and ready pool facilities in the fourth round were combined with those in the fifth round. In-person site visits transitioned to virtual site visits for this combined and final subsequent round. Facilities uploaded necessary documentation and used video to conduct virtual facility tours.

Verification by licensed NABH assessors. Once the verification model transitioned to virtual and FOGSI took over assessments for Manyata standards, it became feasible to satisfy implementation partner requests to have the NABH portion of Mathematica's verification conducted by NABH-certified assessors, who were not available for the multi-week period needed for DIB in-person verification rounds. NABH assessors became more available for virtual visits and could spend a relatively limited amount of time on each site because they did not have to assess Manyata standards.

Exhibit 4.1. Evolution of Mathematica's verification process in the Utkrisht DIB



Source: Mathematica analysis of its administrative records.

Each change had various potential impacts on the efficiency, timeliness, and accuracy of verification. In general, Exhibit 4.2 presents these impacts from the perspective of the overall DIB, though it might have differential effects on individual DIB partners. For example, efficiency of the DIB increased when the mode of verification shifted from field visits involving travel to virtual assessment. However, facilities experienced greater burden as they had to prepare and upload more documents in advance rather than allowing field investigators to pull them on site. Similarly, although accuracy of verification for a standard likely increased when NABH licensed assessors conducted verification, payments to these assessors were more than twice as high as payments to previous rounds of assessors even though they spent less time conducting the assessment as they did not have to review Manyata standards.[1]

Exhibit 4.2. Mathematica assessment of changes impact on DIB results

	Efficiency	Timeliness	Accuracy
Addition of assessment method, simulations	–	–	↑
Verification by accreditation bodies	↑	–	?
In-person to virtual verification mode	↑	–	↓
Verification by licensed NABH assessors	↓	–	↑

↑ = increased; ↓=decreased; – = no change; ? = unable to assess impact of change.

Source: Mathematica's examination of consequences from changes to the verification process.

Key considerations for innovating verification in the DIB. Several factors drove the need to adapt and modify the verification process for the DIB, including the need to increase partners' trust in the verification process and shifting environmental contexts. However, in adapting verification approaches during the life cycle of a DIB, DIB partners should consider the impacts described below.

Period for achieving outcomes. For DIBs, verification is a process to confirm achievement of targeted, narrowly defined outcomes. The Utkrisht DIB required verification that private facilities in Rajasthan, India, met quality standards.

As the verification agent, Mathematica approached verification as an audit exercise to confirm whether visited facilities met the quality standards at a specific moment in time. Furthermore, to maximize efficiency, Mathematica designed the verification to assess a sample of facilities to confirm the accuracy of *implementation partners' placement of facilities having met standards in the ready pool.* Mathematica's verification approach required facilities to achieve outcomes before the assessment visit.

As time went on, partners realized that Manyata certification could be received more quickly than originally anticipated and they wanted to add receipt of certification from FOGSI and accreditation from NABH as a verification method. Manyata and NABH assessors viewed the verification as a mode for helping facilities reach standards and routinely offered "coaching to facilities" during the assessment visit. Their goal was for facilities to reach standards by *the end* of the assessment.

In the end, partners were not concerned about when facilities achieved outcomes. As long as the integrity of the verification process remained, partners found innovation in the verification process acceptable.

Uses of verification data. Partners can use data from verification for various purposes, including monitoring performance, identifying specific areas for program improvement, and evaluating program impact. The Utkrisht DIB partners designed and structured verification to provide data on performance on quality standards for each data element, but they had not initially planned to use verification data to assess the impact of the DIB on maternal and neonatal outcomes. Instead, partners planned to use the Lives Saved Tool (LiST) to model the potential impact of the program.

Because participating facilities were asked to track some key outcomes, DIB partners saw an opportunity to examine the association between performance on specific quality standards and maternal and infant health outcomes. At midline, Mathematica conducted such an assessment.

Starting in the third round of verification, introduction of other verification agents (from NABH and FOGSI) meant that Mathematica no longer had access to detailed data for facilities we did not verify directly. Without data on specific standard elements in later rounds from Manyata and NABH, we did not have enough granularity and variation in data to analyze the association between achieving specific standards and changes in health outcomes after midline.

Partners discussed the tradeoffs and felt the original intention for an outcomes analysis using the LiST mitigated the need for further data to conduct an analysis similar to the midline analysis.

Need for sustainability of the verification process. Many DIBs aim to demonstrate proof of concept, catalyze innovation, and promote uptake of successful interventions by other funders, including government. Thus, the verification process should not be overly costly and ideally should rely on existing data collection and analysis. Using NABH accreditation and FOGSI certification as a verification method increased efficiency because a third-party agent was not required to assess facilities. NABH and FOGSI exist as accreditation bodies already operating in India and could sustain the verification beyond the lifetime of the Utkrisht DIB.

Concluding insights. If DIBs aim to allow for innovation to solve pressing social issues, then all aspects of a DIB can gain from this philosophy of adaptive management for efficiency in achieving societal improvements. The Utkrisht DIB has demonstrated that broader context changes and learning related to partner needs can spur innovation in the approach to verification and clarify thinking around whether and how verification processes can answer broader questions about the DIB's contribution to social change. However, before making drastic changes to verification processes, DIB partners should consider the implications carefully, in terms of accuracy in prompting payments, comparability of and need for verification data over time, and demonstrating success of the DIB model to solve the specific social issue and induce other funders to sustain the DIB intervention going forward.

References

Gustafsson-Wright, E., and S. Osborne. "Do the Benefits Outweigh the Costs of Impact Bonds?" Brookings Institution, September 2020. Available at: https://www.brookings.edu/research/do-the-benefits-outweigh-the-costs-of-impact-bonds/. Accessed November 8, 2021.

Endnotes

[1] Previous rounds of assessors had experience as quality managers of hospitals or were members of quality or audit teams for hospitals. All were trained in NABH standards either by consultants or as part of their master's degrees. Before each round of verification, they also went through a 3-day intensive training on NABH and Manyata standard assessment that NABH-certified assessors did not.

Appendix A: Supplemental Exhibits

Exhibit A.1. NABH and Manyata standards

NABH standards

Acronym	Chapter
AAC	Access, Assessment and Continuity of Care
COP	Care of Patients (COP)
MOM	Management of Medication (MOM)
PRE	Patient Rights and Education (PRE)
HIC	Hospital Infection Control (HIC)
CQI	Continuous Quality Improvement (CQI)
ROM	Responsibilities of Management (ROM)
FMS	Facility Management and Safety (FMS)
HRM	Human Resource Management (HRM)
IMS	Information Management System (IMS)

Chapter	No.	Standard	Objective elements
AAC	1	The SCHO defines and displays the services that it can provide.	The services being provided are clearly defined. The defined services are prominently displayed. The relevant staff are oriented to these services.
AAC	2	The SCHO has a documented registration, admission and transfer process.	Process addresses registering and admitting outpatients, inpatients, and emergency patients. Process addresses mechanism for transfer or referral of patients who do not match the SHCO's resources.
AAC	3	Patients cared for by the SHCO undergo an established initial assessment.	The SHCO defines the content of the assessments for inpatients and emergency patients. The SHCO determines who can perform the assessments. The initial assessment for inpatients is documented within 24 hours or earlier. During all phases of care, there is a qualified individual identified as responsible for the patient's care, who coordinate the care in all the setting within the organization.
AAC	4	Patient's care is continuous and all patients cared for by the SHCO undergo a regular assessment.	All patients are reassessed at appropriate intervals. Staff involved in direct clinical care document reassessments Patients are reassessed to determine their response to treatment and to plan further treatment or discharge.

Chapter	No.	Standard	Objective elements
AAC	5	Laboratory services are provided as per the scope of the SCHO's services and laboratory safety requirements.	Scope of the laboratory services are commensurate with the services provided by the SHCO. Procedures guide collection, identification, handling, safe transportation, processing and disposal of specimens. Laboratory results are available within a defined time frame and critical results are intimated immediately to the concerned personnel. Laboratory personnel are trained in safe practices and are provided with appropriate safety equipment or devices.
AAC	6	Imaging services are provided as per the scope of the hospital's services and established radiation safety program.	Imaging services comply with legal and other requirements. Scope of the imaging services are commensurate to the services provided by the SHCO. Imaging results are available within a defined time frame and critical results are intimated immediately to the concerned personnel. Imaging personnel are trained in safe practices and are provided with appropriate safety equipment / devices.
AAC	7	The SHCO has a defined discharge process.	Process addresses discharge of all patients including medico-legal cases (MLCs) and patients leaving against medical advice. A discharge summary is given to all the patients leaving the SHCO (including patients leaving against medical advice). Discharge summary contains the reasons for admission, significant findings, investigations results, diagnosis, procedure performed (if any), treatment given, and the patient's condition at the time of discharge. Discharge summary contains follow-up advice, medication and other instructions in an understandable manner. Discharge summary incorporates information about when and how to obtain urgent care. In case of death the summary of the case also includes the cause of death.
COP	8	Care of patients is guided by accepted norms and practice.	The care and treatment order are signed and dated by the concerned doctor. Clinical Practice Guidelines are adopted to guide patient care wherever possible.
COP	9	Emergency services including ambulance and guided by documented procedures and applicable laws and regulations.	Documented procedures address care of patients arriving in the emergency including handling of medico-legal cases. Staff should be well versed in the care of Emergency patients in consonance with the scope of the services of hospital. Admission or discharge to home or transfer to another organization is also documented.

Chapter	No.	Standard	Objective elements
COP	10	Documented procedures define rational use of blood and blood products.	The transfusion services are governed by the applicable laws and regulations. Informed consent is obtained for donation and transfusion of blood and blood products. Procedure addresses documenting and reporting of transfusion reactions.
COP	11	Documented procedures guide the care of patients as per the scope of services provided by the SCHO in intensive care and high dependency units.	Care of patients is in consonance with the documented procedures. Adequate staff and equipment are available.
COP	12	Documented procedures guide the care of obstetrical patients as per the scope of services provided by the SCHO.	The SHCO defines the scope of obstetric services. Obstetric patient's care includes regular antenatal check-ups, maternal nutrition, and postnatal care. The SHCO has the facilities to take care of neonates.
COP	13	Documented procedures guide the care of pediatric patients as per the scope of services provided by the SCHO.	The SHCO defines the scope of its paediatric services. Provisions are made for special care of children by competent staff. Patient assessment includes detailed nutritional growth and immunization assessment.
COP	13	Documented procedures guide the care of pediatric patients as per the scope of services provided by the SCHO (continued)	Procedure addresses identification and security measures to prevent child or neonate abduction and abuse. The children's family members are educated about nutrition, immunization and safe parenting.
COP	14	Documented procedures guide the administration of anesthesia.	There is a documented policy and procedure for the administration of anaesthesia. All patients for anaesthesia have a pre-anaesthesia assessment by a qualified or trained individual. The pre-anaesthesia assessment results in formulation of an anaesthesia plan which is documented. An immediate preoperative revaluation is documented. Informed consent for administration of anaesthesia is obtained by the anesthetist. Anaesthesia monitoring includes regular and periodic recording of heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, airway security, and potency and level of anesthesia. Each patient's post anaesthesia status is monitored and documented.

Chapter	No.	Standard	Objective elements
COP	15	Documented procedures guide the care of patients undergoing surgical procedures.	Surgical patients have a preoperative assessment and a provisional diagnosis documented prior to surgery.
			Informed consent is obtained by a surgeon prior to the procedure.
			Documented procedures address the prevention of adverse events like wrong site, wrong patient, and wrong surgery.
			Qualified persons are permitted to perform the procedures that they are entitled to perform.
			The operating surgeon documents the operative notes and postoperative plan of care.
			The operation theatre is adequately equipped and monitored for infection control practices.
MOM	16	Documented procedures that guide the organization of pharmacy services and usage of medication.	Documented procedures incorporate purchase, storage, prescription, and dispensation of medications.
			These comply with the applicable laws and regulations.
			Sound alike and look alike medications are stored separately.
			Medications beyond the expiry date are not stored or used.
			Documented procedures address procurement and usage of implantable prosthesis.
MOM	17	Documented procedures guide the prescription of medications.	The SHCO determines who can write orders.
			Orders are written in a uniform location in the medical records.
			Medication orders are clear, legible, dated and signed.
			The SHCO defines a list of high-risk medication and process to prescribe them.
MOM	18	Policies and procedures guide the safe dispensing of medications.	Medications are checked prior to dispensing including expiry date to ensure that they are fit for use.
			High risk medication orders are verified prior to dispensing.
MOM	19	There are defined procedures for medication administration.	Medications are administered by trained personnel.
			High risk medication orders are verified prior to administration, medication order including patient, dosage, route and timing are verified.
			Prepared medication is labelled prior to preparation of second drug.
			Medication administration is documented.
			A proper record is kept of the usage administration and disposal of narcotics and psychotropic medication.
MOM	20	Adverse drug events are monitored.	Adverse drug event are defined and monitored.
			Adverse drug events are documented and reported within a specified time frame.

Chapter	No.	Standard	Objective elements
PRE	21	Patient rights are documented displayed and support individual beliefs, values and involve the patient and family in decision making process.	Patient rights include respect for personal dignity and privacy during examination procedures and treatment.
			Patient rights include protection from physical abuse or neglect.
			Patient rights include treating patient information as confidential.
			Patient rights include obtaining informed consent before carrying out procedures.
			Patient rights include information on how to voice a complaint.
			Patient rights include on the expected cost of the treatment.
			Patient has a right to have access to his / her clinical records.
PRE	22	Patient families have a right to information and education about their healthcare needs.	Patients and families are educated on plan of care, preventive aspects, possible complications, medications, the expected results and cost as applicable.
			Patients are taught in a language and format that they can understand.
HIC	23	The SCHO has an infection control manual which it periodically updates; the SHCO conducts surveillance activities.	It focuses on adherence to standard precautions at all times.
			Cleanliness and general hygiene of facilities will be maintained and monitored.
			Cleaning and disinfection practices are defined and monitored as appropriate.
			Equipment cleaning, disinfection and sterilization practices are included.
			Laundry and linen management processes are also included.
HIC	24	The SCHO rakes actions to prevent or reduce the risks of hospital associated infections (HAI) in patient and employees.	Hand hygiene facilities in all patient care areas are accessible to health care provide.
			Adequate gloves, masks, soaps, and disinfectants are available and used correctly.
			Appropriate pre and post exposure prophylaxis is provided to all concerned staff members.
HIC	25	Bio-medical management practices are followed.	The hospital is authorized by prescribed authority for management and handling of bio-medical waste.
			Proper segregation and collection of bio-medical waste from all patient care areas of the hospital is implemented and monitored.
			Bio-medical waste treatment facility is managed as per statutory provisions (if in-house) or outsourced to authorized contractors.
			Requisite fees, documents and reports are submitted to competent authorities on stipulated dates.
HIC	25	Bio-medical management practices are followed (continued).	Appropriate personal protective measures are used by all categories of staff handling bio-medical waste.

Chapter	No.	Standard	Objective elements
CQI	26	There is a structures quality improvement and continuous monitoring programme in the organisation.	There is a designated individual for coordinating and implementing the quality improvement program. The quality improvement programme is a continuous process and updated at least once in a year. Hospital Management makes available adequate resources required for quality improvement program.
CQI	27	The SCHO identifies key indicators to monitor the structures, processes, and outcomes which are used as tools for continuous improvement.	The SHCO identifies the appropriate key performance indicators in both clinical and managerial areas. These indicators shall be monitored.
ROM	28	The responsibilities of management are defined.	The SHCO has a documented organogram. The SHCO is registered with appropriate authorities as applicable. The SHCO has a designated individual(s) to oversee the hospital-wide safety program.
ROM	29	The organization is managed by the leaders in an ethical manner.	The management makes public the mission statement of the organization. The leaders/management guide the organization to function in an ethical manner. The organization discloses its ownership. The organization's billing process is accurate and ethical.
FMS	30	The SHCO's environment and facilities operate to ensure safety of patients, their families, staff and visitors.	Internal and external signage shall be displayed in a language understood by the patients or families and communities. Maintenance staff is contactable round the clock for emergency repairs. The SHCO has a system to identify the potential safety and security risks including hazardous materials. Facility inspection rounds to ensure safety are conducted periodically. There is a safety education programme for relevant staff.
FMS	31	The SCHO has a program for clinical and support service equipment management.	The SHCO plans for equipment in accordance with its services. There is a documented operational and maintenance (preventive and breakdown) plan.
FMS	32	The SCHO has provisions for safe water, electricity, medical gas, and vacuum systems.	Potable water and electricity are available round the clock. Alternate sources are provided for in case of failure and tested regularly. There is a maintenance plan for medical gas and vacuum systems.
FMS	33	The SCHO has plans for fire and non-fire emergencies within the facilities.	The SHCO has plans and provisions for early detection, abatement, and containment of fire and non-fire emergencies. The SHCO has a documented safe exit plan in case of fire and non-fire emergencies. Staff is trained for their role in case of such emergencies. Mock drills are held at least twice in a year.

Chapter	No.	Standard	Objective elements
HRM	34	The SCHO has an ongoing programme for professional training and development of the staff.	All staff is trained on the relevant risks within the hospital environment. Staff members can demonstrate and take actions to report, eliminate/ minimize risks. Training also occurs when job responsibilities change/ new equipment is introduced.
HRM	35	The SCHO has a well-documented disciplinary and grievance handling procedure.	A documented procedure regarding disciplinary and grievance handling is in place. The documented procedure is known to all categories of employees in the SHCO. Actions are taken to redress the grievance.
HRM	36	The SCHO addresses the health needs of employees.	Health problems of the employees are taken care of in accordance with the SHCO's policy. Occupational health hazards are adequately addressed.
HRM	37	There is documented personal record for each staff member.	Personal files are maintained in respect of all employees. The personal files contain personal information regarding the employee's qualification, disciplinary actions and health status.
IMS	38	The SCHO has a complete and accurate medical record for every patient.	Every medical record has a unique identifier. The SHCO identifies those authorized to make entries in medical record. Every medical record entry is dated and timed. The author of the entry can be identified. The contents of medical records are identified and documented.
IMS	39	The medical record reflects continuity of care.	The record provides an up-to-date and chronological account of patient care. The medical record contains information regarding reasons of admission, diagnosis and plan of care. Operative and other procedures performed are incorporated in the medical record. The medical record contains a copy of the discharge note duly signed by the appropriate and qualified personnel. In case of death, the medical records contain a copy of the death certificate indicating the cause, date and time of death. Care providers have access to current and past medical record.
IMS	40	Documented policies and procedures are in place for maintaining confidentiality, security, and integrity of records, data and information.	Documented procedures exist for maintaining confidentiality, security and integrity of information. Privileged health information is used for the purposes identified or as required by law and not disclosed without the patient's authorization.
IMS	41	Documented procedures exist for retention of the patient's records, data and information.	Documented procedures exist for retention time of the patient's clinical records, data and information. The retention process provides expected confidentiality and security. The destruction of medical records, data, and information is in accordance with the laid down procedure.

Exhibit A.2. Manyata standards

No	Standard	No	Objective elements
1	Provider screens for key clinical conditions that may lead to complications during pregnancy	1	Screens for anemia
		2	Screens for hypertensive disorders of pregnancy
		3	Screens for DM
		4	Screens for HIV
		5	Screens for syphilis
		6	Screens for malaria
		7	Establishes blood group and Rh type during first ANC visit
2	Provider prepares for safe care during delivery (to be checked every day)	1	Ensures sterile/ HLD delivery tray is available
		2	Ensures functional items for newborn care and resuscitation
3	Provider assesses all pregnant women at admission	1	Takes obstetric, medical and surgical history
		2	Assesses gestational age correctly
		3	Records fetal heart rate
		4	Records mother's BP and temperature
4	Provider conducts PV examination appropriately	1	Conducts PV examination as per indication
		2	Conducts PV examination following infection prevention practices and records findings
5	Undertakes timely assessment of cervical dilatation and descent to monitor the progress of labour	1	Undertakes timely assessment of cervical dilatation and descent to monitor the progress of labour
		2	Interprets partograph (condition of mother and fetus and progress of labour) correctly and adjusts care according to findings
6	Provider ensures respectful and supportive care	1	Encourages and welcomes the presence of a birth companion during labour
		2	Treats pregnant woman and her companion cordially and respectfully (RMC), ensures privacy and confidentiality for pregnant woman during her stay
		3	Explains danger signs and important care activities to mother and her companion
7	Provider assists the woman to have a safe and clean birth	1	Provider ensures six 'cleans' while conducting delivery
		2	Performs episiotomy only
		3	Provider allows spontaneous delivery of head by flexing it and giving perineal support; manages cord round the neck; assists delivery of shoulders and body

No	Standard	No	Objective elements
8	Provider conducts a rapid initial assessment and performs immediate newborn care (if baby cried immediately)	1	Delivers the baby on mother's abdomen
		2	Ensures immediate drying, and asses breathing
		3	Performs delayed cord clamping and cutting
		4	Ensures early initiation of breastfeeding
		5	Assesses the newborn for any congenital anomalies
		6	Weighs the baby and administers
9	Provider performs Active Management of Third Stage of Labour (AMTSL)	1	Performs AMTSL and examines placenta thoroughly
10	Provider identifies and manages Post-Partum Hemorrage (PPH)	1	Assesses uterine tone and bleeding per vaginum regularly after delivery
		2	Identifies shock
		3	Manages shock
		4	Manages atonic PPH
		5	Manages PPH due to retained placenta/ placental bits
11	Provider identifies and manages severe Pre-eclampsia/Eclampsia (PE/E)	1	Identifies mothers with severe PE/E
		2	Gives correct regimen of Inj. $MgSO_4$ for prevention and management of convulsions
		3	Facilitates prescription of anti- hypertensives
		4	Ensures specialist attention for care of mother and newborn
		5	Performs nursing care
12	Provider performs newborn resuscitation if baby does not cry immediately after birth	1	Performs steps for resuscitation within first 30 seconds
		2	Initiates bag and mask ventilation for 30 seconds if baby still not breathing
		3	Takes appropriate action if baby doesn't respond to ambu bag ventilation after golden minute
		4	Performs advanced resuscitation in babies not responding to basic resuscitation when chest is rising and heart rate is < 60 per minute
13	Provider ensures care of newborn with small size at birth	1	Facilitate specialist care in newborn weighing <1800 gm
		2	Facilitates assisted feeding whenever required
		3	Facilitates thermal management including kangaroo mother care (KMC)
14	The facility adheres to universal infection prevention protocols	1	Instruments and re-usable items are adequately and appropriately processed after each use
		2	Biomedical waste is segregated and disposed of as per the guidelines
		3	Performs hand hygiene before and after each procedure, and sterile gloves are worn during delivery and internal examination

No	Standard	No	Objective elements
15	Provider ensures adequate postpartum care package is offered to the mother and the baby - at discharge	1	Conducts proper physical examination of mother and newborn during postpartum visits
		2	Identifies and appropriately manages maternal and neonatal sepsis
		3	Correctly diagnoses postpartum depression based on history and symptoms
		4	Counsels on importance of exclusive breast feeding
		5	Counsels on danger signs, post- partum family planning
16	Provider reviews clinical practices related to C-section at regular intervals	1	Ensures classification as per Robson's criteria and reviews indications and complications of C-section at regular intervals

Exhibit A.3. Deaths prevented by year

Year	Stillbirths	Neonatal	Maternal	Total
2018	0	0	0	0
2019	32	554	27	613
2020	126	2,288	103	2,517
2021	168	3,045	136	3,349
2022	175	3,183	144	3,502
2023	173	3,151	144	3,468
Total	674	12,221	554	13,449

Exhibit A.4. Cumulative lives saved by intervention

Intervention	Lives saved
Pregnancy	
Syphilis detection and treatment	33
Maternal age and birth order	49
Childbirth	
Clean birth environment	512
Immediate drying and additional stimulation	682
Thermal protection	1,369
Parenteral administration of antibiotics	209
Neonatal resuscitation	1,251
Curative after birth	
Case management of premature babies	1,487
Case management of neonatal sepsis/pneumonia	5,470

The contents of this brief reflect the authors' lived experience of conducting verification for the Utkrisht DIB. The viewpoints expressed do not reflect those of Mathematica or any other individuals and organizations. Although representatives from Utkrisht partner organizations provided review and helpful insight, the authors determined the final content. Additional results from and reflections about verification at midline of the DIB can be found at https://www.mathematica.org/publications/maternal-health-care-quality-and-outcomes-under-the-utkrisht-impact-bond-midline-findings. **For any questions related to this brief, please contact So O'Neil, Senior Researcher and Director of Health Philanthropy, soneil@mathematica-mpr.com**.