

Impact of a multi-component intervention to build capacity of public health workers to make algorithmic diagnosis and management of high-risk pregnancies: Protocol for a matched-control, before-after quasi-experimental study with a mixed-method design in Uttar Pradesh, India.

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Submitted to: JMIR Research Protocols
on: March 26, 2025

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Abstract

Background: In India, 20-30% pregnancies fall under high-risk category, contributing to 75% of perinatal mortality and morbidity. An effective approach to reduce maternal and neonatal mortality/morbidity is early identification, effective management, and timely referral of high-risk pregnancies (HRPs). The Integrated High-Risk Pregnancy Tracking and Management (IHRPTM) program aims to enhance capacity of auxiliary nurse midwives (ANMs), medical officers (MOs), and specialist gynaecologists by: i. providing algorithmic, color-coded, detailed (yet simple) protocols for six HRP conditions, customized for each role, ii. offering live training, iii. delivering digital training and hand-holding, and iv. facilitating tracking pregnancies and management of HRPs. Equipping health workers (HWs) on these interventions facilitates early identification, effective management, and timely referrals, ultimately improving primary care and satisfaction of mothers with HRPs. Stated interventions are implemented in the intervention arm for 18 months, while during this period, HWs of intervention and control arms will receive routine training through state and national programs, ensuring pregnant women have equal access to routine maternity services.

Objective: At the system level, the program evaluates the impact on improvement in the knowledge and skills of HWs in diagnosing and managing HRPs. At the community level, it assesses the translation of this knowledge and into practice, in terms of early diagnosis and effective management, among women with HRPs.

Methods: The program will be implemented in two intervention districts (Sambhal and Shravasti) and two matched control districts (Baduan and Gonda) of Uttar Pradesh, on six HRPs. Study uses a 'quasi-experimental, before-and after trial design', with intervention and control arms. However, impact of program will be assessed only on three HRPs: moderate/severe anaemia, pregnancy-induced hypertension, and antepartum haemorrhage (APH), including placenta previa/abruptio placenta. System level impacts will be assessed through qualitative data collected from district officials, specialist gynaecologists, MOs and ANMs, at baseline and endline. Community level outcomes will be measured quantitatively using baseline and endline data from recently delivered women (RDW), with or without HRPs.

Results: The impact evaluation protocol was approved by ARMMAN's Scientific Review Board and Sigma's Institutional Review Board. The protocols for six HRP-conditions were vetted by the government of Uttar Pradesh. By November 2024, all the ANMs, MOs, specialist gynaecologists, staff nurses, and community health officers in two intervention districts were trained on six HRP-protocols. Digital learning tool and WhatsApp support system was also introduced to facilitate continued learning and handholding of ANMs in managing HRPs and/or to clear doubts. Pre-intervention/baseline data was collected from two

arms, during June-October 2024.

Conclusions: This trial will provide valuable insights into the feasibility and effectiveness of the program, at system and community levels, in a low resource setting like Uttar Pradesh. If successful, these insights can feed into capacitating HWs, at scale, in all the districts on diagnosis and management of HRPs, with significant potential for improving maternal and neonatal outcomes of the state.

(JMIR Preprints 26/03/2025:74993)

DOI: <https://doi.org/10.2196/preprints.74993>

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ABSTRACT

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of the state.

Key words: high-risk pregnancies; diagnosis and management; antenatal care; impact of program; capacity building of health workers; quasi experimental; before-after; intervention control arm.



Introduction

Background

Most maternal health complications that lead to maternal and/or newborn death develop during pregnancy, and with quality antenatal care (ANC) most of these complications can be prevented or treated [1]. Although the goal is to ensure a non-problematic pregnancy, all pregnancies carry some risk. Pregnancy risks are categorized as low, moderate, and high risk [2]. A high-risk pregnancy (HRP) is defined as one that is complicated by factors that adversely affect the pregnancy outcome (maternal, perinatal or both). An HRP may result from conditions that exist either before pregnancy (e.g., diabetes, hypertension) or complications from a previous pregnancy, or conditions that develop during pregnancy or delivery [3]. Through effective management of HRPs and by preventing pregnancy complications in non-HRP woman, quality antenatal care services can be ensured, leading to significant impact on reducing maternal deaths, stillbirths, and early neonatal deaths—a triple return on investment [4].

Globally, around 20 million pregnancies are classified as high-risk, leading to approximately 800 maternal deaths [5], and over 70% of maternal deaths are because of complications of pregnancy and childbirth such as haemorrhage, hypertensive disorders, sepsis, and abortion [6]. Excluding moderate anaemia, 30-37% pregnancies globally can be classified as high-risk, accounting for 70-80% of perinatal mortality and morbidity [7]. In India 20-30% pregnancies are high-risk and are responsible for 75% of perinatal morbidity and mortality [8]. According to a recent (2019-20) analysis in India, prevalence of HRPs was 49.4%, with 33% having single high-risk condition and 16.4% having multiple high-risk conditions [9]. However, prevalence of HRPs across different states are ranging from 18% to 59% [10-13], perhaps due to differences in estimation methods. According to the National Family Health Survey-5 (2019-21) estimate, 59% of Indian women were anaemic. Despite high levels of anaemia, only 44% of pregnant women consumed the recommended dose of iron-folic acid (IFA) for 100 days [14].

In India, particularly in rural areas, routine ANC is provided at three primary care facilities [health sub-centres (HSCs) managed by auxiliary nurse midwives (ANMs¹); primary health centres (PHCs) by medical officers (MOs²); and community health centres (CHCs) by specialist gynaecologists³], while women at risk/HRPs are referred to advanced centres in cities. The HSCs primarily provide ANC and birthing services; PHCs provide either basic emergency obstetric and newborn care (BEmONC) or only birthing services; and community health centres (CHC), although, are supposed to provide comprehensive emergency obstetric and newborn care (CEmONC), mostly provide

¹ Placed at health sub-center (1 per 5,000 population, 3,000 in tribal areas). Provides antenatal care, vaccinations, iron supplements, safe deliveries, postnatal care, newborn immunization, and family planning. Identifies high-risk pregnancies, facilitates referrals, and maintains health records.

² Placed at Primary Health Centre (PHC) (1 per 30,000 population). Supervises ANMs and nurses, conducts ANC, manages pregnancy complications, performs normal deliveries, and handles obstetric emergencies. Initiates referrals, administers life-saving treatments, and supports family planning services.

³ Placed at CHC (CHC: 1 per 1,20,000 population) and DH. Manages high-risk pregnancies, performs cesarean sections, and handles obstetric emergencies. Provides specialized ANC, supervises labor, trains staff, and ensures quality maternal care.

BEmOC or even less. These facilities primarily focus on child birthing services and fail to address management of complications in early pregnancy [15]. Also, there are gaps in knowledge of emergency treatment for obstetric complications during pregnancy and pre-referral first-aid. Staff generally lack confidence and do not have adequate resources to manage obstetric complications [16]. Staff nurses have a limited role in decision-making when it comes to managing these complications. However, all the staff desire skill building, mentoring, moral support, and motivation [16]. In addition to these gaps, there is often a confusion regarding the individual roles of the ANM, MO and specialist gynaecologist in managing HRP conditions, resulting in many pregnant women falling through the gaps in the system after being diagnosed with an HRP-condition. With limited or no resources to manage HRPs, staff in these three settings should be highly competent in prevention, risk assessment, stabilisation of complicated HRPs, and arranging transfer and care at functional higher referral levels [17].

During pregnancy, regular health assessments, specialized pregnancy care, and screening for early detection of HRPs have the potential to significantly reduce maternal complications and lower maternal mortality and morbidity rates. Therefore, all pregnant mothers need to undergo screening for HRPs and those identified should be managed and followed up regularly [18]. The World Health Organization's (WHO) 2015 guidelines on HRPs recommends early assessment, as they serve as a guide for clinical decisions and are primarily intended for primary care at the facility/community level [19]. Although the revised guidelines describe the management of obstetric complications at the district level according to the period of gestation [20], their application at different facilities and levels of referral system in low-resource settings is not well understood [16]. In India, the skilled birth attendant (SBA) guidelines on HRPs provide guidance only on clinical management of low-risk and common HRPs and complications during pregnancy, childbirth, and postpartum care, and suggest referral, if the facility is incapable of managing a case [21]. In India, programs like Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA), Labour Room Quality Improvement Initiative (LaQshya), Surakshit Matritva Aashwasan (SUMAN), Live Saving Anaesthesia skills (LSAS), etc., were initiated to address HRPs [22], their focus is primarily on strengthening BEmONC and CEmONC services, with limited or no focus on building capacity of ANMs at HSCs or MOs at PHCs. Hence, there is a need for a program that can build the capacity of ANMs, MOs and specialist gynaecologists in the identification, tracking and end-to-end management of HRPs, tailored according to three primary care facilities.

Program interventions

The Integrated High-Risk Pregnancy Tracking and Management (IHRPTM) program by ARMMAN (*Advancing Reduction in Mortality and Morbidity of Mothers, Children and Neonates*), a non-profit organization, has been working directly with pregnant women to improve their health-seeking behaviour by building capacities of health workers to ensure efficient antenatal and child care, and

timely diagnosis, management, and referral of high-risk pregnancies. The program is designed to address gaps in HRP management through an integrated, comprehensive, multi-step, systemic approach for improved identification, tracking and end-to-end management of HRPs. Its aim is to reduce delayed, complicated, and irrational referrals to tertiary facilities, allowing these facilities to focus on truly critical cases, leading to satisfaction of women/families with HRP conditions. By capacitating and motivating HWs through handholding interventions leads to prevention of pregnancy complications among non-HRP women. Integration of different interventions of the program leads to improvement in quality of ANC services, thereby lowering overall maternal and neonatal mortality and morbidity in the intervention area.

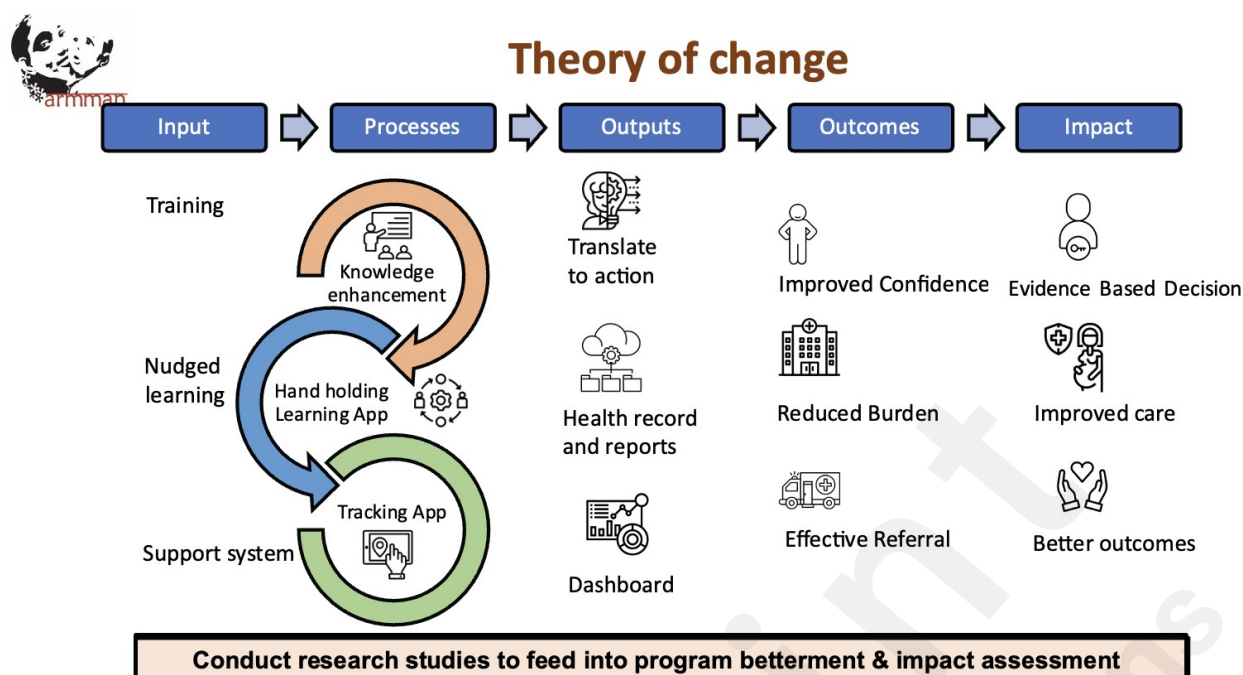
Key interventions of the program include:

- **Colour-coded protocols:** Developed algorithmic, colour coded protocols that are easy-to-understand (yet simple) for end-to-end management, referral, and follow-up of 35 HRPs, tailored according to ANMs, MOs and specialist gynaecologists.
- **Training:** Live training sessions for HWs (ANMs, MOs and specialists) to enhance skills in identifying and managing HRPs, according to facilities they are associated with.
- **Digital Learning app:** Is designed to encourage continuous, self-faced learning and consists of a 'learning app' for ANMs. The app has learning materials (videos, power point presentations, practice questions) and quizzes organized according to a HRP-protocol, with a new HRP-protocol released once in every 2-3 weeks.
- **The WhatsApp support helpline:** Combines mobile technology with personalized support is built for doubt-solving and hand-holding for ANMs, as they go through the learning content and apply it to real-life situations in the field. The queries raised by ANMs are responded by state-appointed MOs or trainer-of-trainers or dedicated ARMMAN staff, within 24 hours.
- **Tracking/data integration:** Linking HRP-specific data with the state's monitoring system for better tracking and decision-making on HRPs, at various levels of public health care system.

Interventions and Anticipated Theory of Change

For ensuring quality antenatal care, an integrated, comprehensive, multi-step, systemic approach is needed, including early identification, improved tracking, and end-to-end management of HRPs. As shown in Figure 1, the program provides such an approach by ensuring that three types of public health functionaries (*ANM, Medical officer and specialist gynaecologist*) at three levels of public health care system (*HSC, PHC and CHC/AH*) are capacitated to diagnose & manage HRPs in their respective facilities.

Figure 1: Logical framework conceptualising the theory of change of program to improve knowledge and skills of health workers to diagnose and manage HRPs.



The training will build the capacity of HWs for early diagnosis of HRP, providing them with tailor-made decision-supported management tool (in the form of a protocol) for managing the case according to the resources available with the facility, and/or tailor-made algorithms for referring those cases that cannot be managed at the facility of the HW, to a higher level. The program also offers a 'learning app' for ANM on each HRP-condition for complementing the knowledge they have gained through training, with a ready to use digital tool (videos, power point presentations, practice questions and quizzes). The learning app being a self-paced learning tool provides scope for the ANM to upgrade her skills on HRPs management according to availability of time with her. The learning app is complimented with a 'WhatsApp supported helpline' for a (almost) real-time doubt resolution on the management/referral of the case. Thus, the learning app and WhatsApp supported helpline serve as handholding tools to ANM in management/referral of the mother with a HRP-condition. Lastly, there is a 'tracking app', a real-time data collection and decision support app integrated with the state's HRP-conditions monitoring system/RCH portal, provides management/referral journey of woman with a HRP-condition, from anywhere in the state.

By capacitating and handholding health functionaries at three levels of public health care system on early diagnosis, tailored algorithmic management, and follow-up, there will be an increase in early diagnosis of the HRPs, timely referrals and reduction in unnecessary referrals to tertiary facilities, like CHC, AH and district hospital. In the long-run, this will lead to a reduction in maternal morbidities and mortality rates. The program also ensures continuous support for the trained health functionaries through digital learning app and WhatsApp support system. Capacitated and motivated HWs will be able to provide quality ANC and/or HRP management services to the satisfaction of all pregnant women, with/without an HRP-condition. Thus, such a comprehensive approach will strengthen the maternal healthcare system and contribute to better health outcomes for the mothers

and their newborns.

Rationale for the study

By early 2024, the program was live in two states of India, Telangana (all 33 districts) for 20 HRP-conditions and the program duration is 2021-26 and in Andhra Pradesh (all 26 districts) for 19 HRP-conditions and the program duration is 2023-28 - in partnership with respective state governments. The type of HRP-conditions and the duration of the program/interventions are fixed by respective state governments, although, most of the HRP-conditions are common across these two states. In Telangana and Andhra Pradesh, the five year program is being implemented in three broad phases, and in each phase interventions are provided for six/seven HRP-conditions. After reviewing uptake of the program for six phase-1 HRP-conditions in these two states, government of Uttar Pradesh, intended to introduce the IHRPTM-program on a pilot basis with fewer HRP-conditions and with a shorter duration of intervention, as part of its Enhanced Pregnancy Management and Monitoring (EPMM) initiative, in mid-2024. As part of pilot testing, government of Uttar Pradesh prioritized six HRP-conditions, two intervention districts and duration of implementation/intervention as 18 months. The six HRPs prioritized by government of Uttar Pradesh are: quality ANC (QANC); Anaemia (moderate & severe); Pregnancy Induced Hypertension (PIH); Ante Partum Haemorrhage (APH), including placenta previa and abruptio placenta; heart disease or shortness of breath; and fever. However, the program's impact evaluation will focus only on the following three HRPs: anaemia (moderate & severe); PIH; and APH.

Reasons for not conducting impact evaluation on below HRPs:

• **Quality Antenatal Care** is excluded from impact evaluation as QANC is not an HRP-condition, but a set of multiple tried & tested processes to be followed by health functionaries at three levels of health care system. ARMMAN has included QANC as one of the protocol because, this protocol sensitizes ANMs and MOs about comprehensive history taking and conducting necessary ANC examinations/tests according to trimester, leading to quality of the antenatal care services. The program's effect on QANC will be assessed using the following proxy indicators:

1. Proportion of women who received three essential tests/examinations (*weight, haemoglobin, blood pressure*) in all the ANC visits.
2. Proportion of women who received complete ANC package (*at least four ANC visits; plus at least one Tetanus Toxoid injection; plus consumed at least 100 IFA tablets/consumed IFA for a minimum of 100 days*).

Heart disease or shortness of breath is excluded from impact evaluation due to its low prevalence (0.3-3.5%) [23]. Evaluating changes for a condition with such a low prevalence over an intervention period of 18 months, would require an unfeasibly large sample size of RDWs, with this condition. Also, severe cases with this condition require care at medical college hospitals or specialised facilities with 24x7 availability of

- **Fever in pregnancy** is excluded from impact evaluation, as it is generally a co-morbidity associated with a non-HRP conditions (e.g., dengue, hepatitis-E, urinary tract infection, vector- or water-borne diseases, etc.) [25].

Hypotheses

The program's impact evaluation will test the following research hypotheses:

- Does the program, implemented over 18 months, enhance knowledge, skills, and confidence of the ANMs and the MOs to make early diagnosis and manage the three HRPs in the intervention arm, compared to usual care arm?
- Can the capacitated ANMs and MOs translate their knowledge and skills into practice, particularly for early diagnosis and end-to-end management of the three HRP-conditions in the intervention arm, compared to control arm?
- Does the program improve the quality of ANC services in the intervention arm, compared to usual care arm?

System-Level Indicators

The following system level indicators will be assessed as part of impact evaluation, by interviewing district health officials, specialist gynecologists at CHC, MOs at PHC and ANMs at HSCs in the sampled facilities, at baseline and endline surveys:

1. Assess the capacity of ANMs and MOs to identify the three selected HRPs as per the protocol.
2. Evaluate the capacity of ANMs and MOs to manage (treat, counsel, refer and follow-up) women with the three HRPs according to the protocol.
3. Measure the confidence levels of ANMs and MOs in identifying, managing, and referring women with the three HRPs.
4. Get views from district officials on the facilitators and barriers to implementing the IHRPTM program in their respective districts.

Community-Level Indicators

The following community level indicators will be assessed through interviews with recently delivered women (RDW) with or without the three HRP-conditions, in the sampled areas, at baseline and endline surveys:

1. Proportion of RDW sensitized by ANMs and/or MOs about HRP conditions.
2. Determine the stage of pregnancy when the three HRPs were first diagnosed and by whom.

3. Proportion of RDW diagnosed with any of the three conditions who received timely diagnosis, management, counselling, referral, and follow-up as per the protocol.
4. Proportion of irrational and delayed/complicated referrals among RDW diagnosed with any of the three HRP-conditions.
5. Proportion of RDW with the three HRPs who were satisfied⁴ with the care they received through the public or private health care system.

Methods

Study design

The study adopts a *'matched, before-after quasi-experimental design with a control (usual-care) arm'*. Both qualitative and quantitative data will be collected at system and community levels respectively, during baseline (*prior to implementation of interventions*) and end-line (*after 18 months of interventions*), in the intervention and control arms. Program's effectiveness at system level will be evaluated by assessing the *'capacity of ANMs and MOs to diagnose and manage the three HRPs'* and at the community level by measuring the *proportion of 'RDW who reported receiving appropriate care for any of the three HRPs'*. Effectiveness of program through quantitative indicators will be analysed using the *'difference-in-difference (DiD) technique'*.

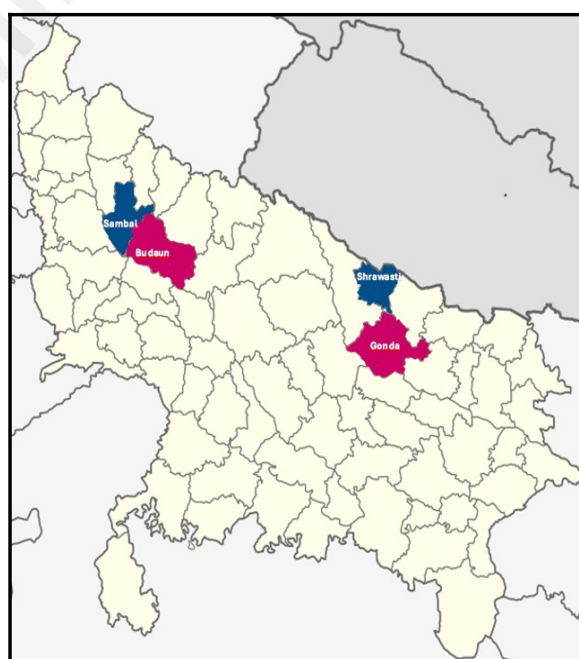
Duration of intervention

In the intervention districts, the IHRPTM program will be implemented district-wide for 18 months, starting June-July 2024 and ending February-March 2026. In the usual-care-arm, health workers will receive routine capacity-building sessions conducted by the state and the national governments. Pregnant women in both the arms will have access to antepartum, intrapartum, and postpartum care programs provided by the state and the national governments.

Study geography

For this study, the government of Uttar Pradesh identified Shravasti and Sambhal as the intervention districts, to implement the program. Keeping in view the two-arm nature the study design, the study team has identified usual-care arm districts that closely match with intervention districts - using latest socio-demographic, antenatal and immediate postpartum care indicators for the district (NFHS-5, 2019-21) [30]. Identified Gonda as the matching usual-care arm district for Shravasti. Distance between these two districts is less

Figure 2: Intervention and control districts of Uttar Pradesh



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⁴ Satisfaction level of RDW is measured using a five-point Likert scale on the topics of: 'attitude and behaviour of staff', 'cleanliness and hygiene', 'comfort and care' and 'overall satisfaction with management of high-risk pregnancy condition at the facility'.

50 KM. Identified Budaun as matching usual-arm care district to Sambhal. Distance between these two districts is less than 100 KM. Table 1 provides, socio-demographic and ANC and delivery practices in four study districts and Figure 2 depicts the four study districts. The matched control districts were approved by the government of UP.

Table 1: Socio-demographic and health care seeking profile of four study districts

	Intervention arm districts		Usual care arm districts	
	Shravasti	Sambhal	Gonda	Budaun
Socio-demographic profile*				
Population (2011)	11,17,361	21,99,774	34,33,919	36,81,896
Sex ratio of population	881	891	921	871
% Urban population	4	3	7	22
Number of Tahsils	3	3	4	6
Number of villages	541	993	1817	2061
% Literacy	47	55	59	53
% Scheduled caste population	16.9	16.6	15.5	17.7
ANC, delivery & immediate post-partum care indicators (2019-21)**				
% Received at least 4 ANC visits	42.3	32.9	41.7	40.6
% Mothers protected against TT	94.4	90.3	90.4	90.1
% Mothers who consumed 100 IFA	16.6	21.3	17.2	15.9
% Institutional births	80.4	74.2	81.8	72.3
% Mothers who received PNC in 2 days	68.3	67.5	68.6	62.4
% Mothers received MCP card	95.9	93.5	97.1	94.4

*: Master data: Census 2011 – State and district wise primary census abstract.

**: International Institute for Population Sciences (IIPS) and ICF. 2021. National Family Health Survey (NFHS-5), India, 2019-21: Uttar Pradesh. Mumbai: IIPS.

Study tools

Baseline and endline surveys will utilize qualitative methods for collecting data from the system stakeholders and quantitative methods for collecting data from the community, specifically the RDW. The data collection tools were pre-tested in Telangana in 2022 and 2023 as part of the program in that state, and subsequently, adapted to align with the programs and policies of Uttar Pradesh. Table 2 provides details of respondents interviewed using qualitative data collection technique.

Table 2: Respondents, data collection method, sample size and information areas of qualitative data collection tools

S No	Type of respondent & tool	Data collection method	Sample size	Who collects data?	Recruitment strategy	Key information areas of tool
1	Chief Medical Officer – CMO (Annexure 1)	In-depth interview (IDI)	1 per district	Qualitative researchers	Purposive	<ul style="list-style-type: none"> District policies and programs on maternal & newborn health Facilitators and barriers to implement IHRPTM program in district
2	Associate chief medical officer - ACO (Annexure 2)	Semi structured interview (SSI)	1 per district	Qualitative researchers	Purposive	<ul style="list-style-type: none"> Most prevalent HRPs in district Vulnerable areas/populations Issues with collection of

						RCH/HMIS/HRP data • Human Resources availability
3	Specialist gynaecologist-gynaecologists - District hospital (Annexure 3)	IDI	1 per district	Qualitative researchers	Purposive	• ANC case load at facility • HRP case load at facility • Volume of high-risk cases referred to facility • Volume of late/unnecessary referrals • Strategies for coping with referrals
4	Medical Officers (MOs) working in PHC/CHC (Annexure 4)	SSI	4-5 per district	Qualitative researchers	From four randomly selected PHCs of two blocks in a district	• Support systems available for ensuring quality ANC • Case load of ANC/HRPs • Knowledge about three specific HRPs • Management skills to care woman with three HRPs • Knowledge about referral practices to woman with three HRPs
5	Auxiliary Nurse Midwives (ANMs) working in HSCs (Annexure 5)	SSI	8-10 per district	Qualitative researchers	Two ANMs per PHC, from above four randomly selected PHCs of two blocks in a district	• Support systems available for ensuring quality ANC • Case load of ANC/HRPs • Knowledge about three specific HRPs • Management skills to care woman with three HRPs • Knowledge about referral practices to woman with three HRPs

Community-Level Data Collection

Recently delivered women (RDW) who gave birth within the past year, regardless of HRP status, will be surveyed in all the four study districts, at baseline and at endline. Some unique features of the RDW tool are: documentation of the previous pregnancy including details of HRP-condition (if applicable), as a story in mother's own words; a picture of the MCP card to supplement with the question specific data collected from the RDW through interview; ANC details; and HRP-specific detailed questions data collected, where applicable (Annexure 6).

Key data collected in the RDW tool:

Data point collected	Details
<i>Pregnancy and delivery details</i>	Age, delivery date, type and place of delivery, outcome of delivery, child's age, birth weight, term/preterm status, MCP card availability, HRP status
<i>Reproductive history</i>	Children ever born and surviving, and pregnancy terminations
<i>MCP card photo</i>	With details of each ANC visit, in picture format

<i>Story of recent pregnancy in mother's own words</i>	Investigators ask the mother to describe about her most recent pregnancy in her own words, from conception to delivery, including details of any HRP, if applicable. The story told by mother is documented in here in a text format
<i>ANC characteristics</i>	Number of ANC visits, details of first ANC visit, experience of risk factors, TT and IFA usage, supplementary nutrition, high-risk condition(s) experienced including duration of problem and referrals made for the HRP.
<i>Delivery & newborn characteristics</i>	Breech presentation, prolonged labour, excessive bleeding, facility stay after delivery, congenital anomalies, reasons for caesarean-section
<i>Details about severe/moderate anaemia, PIH, APH and other HRP-conditions experienced by mother in most recent pregnancy (if applicable)</i>	Timing of first diagnosis of HRP and who diagnosed, risk factors associated with the HRP, management /referral /counselling /follow-up details related to the HRP-condition.
<i>Satisfaction</i>	Level of satisfaction with care received if HRP(s) were present
<i>Background characteristics</i>	Literacy, schooling, religion, caste/tribe, occupation, owning of own mobile phone by the mother.

Sample size of the qualitative surveys

The sample size of RDW to be included in the baseline and endline surveys was determined to generate indicators for each of the three HRP conditions (moderate/severe anaemia, PIH and APH/placenta previa/abruptio placenta) separately for the intervention and usual-care arms. To achieve this, the sample size was estimated based on the HRP condition, with the lowest prevalence among the three conditions. This approach ensures that sample size estimated for a HRP-condition with the lowest prevalence will suffice for the HRP-conditions with higher prevalence as well, using the most recent prevalence data for the HRP-conditions among the pregnant women in India and/or north India.

From recent available literature in India, the prevalence of: moderate/severe anaemia among pregnant women in north zone was 25% [26], PIH in India ranged from 5-17% [27] and prevalence of APH is 2-5%, with placenta previa at 4-5% [28], implying, among the three HRP-conditions, PIH has the lowest prevalence. Assuming the prevalence of PIH among RDW in the intervention arm and in the control arm, at baseline and end-line surveys is 5%, the estimated sample size for PIH is not expected to differ by more/less than 1% (i.e., 4-6%), with a 95% confidence level – the sample size of RDW with PIH-condition required in both the intervention and in usual-care arms, at baseline and at end-line surveys is 1,825 (rounded to 2,000) [29]. It means that we need to interview 2,000 RDW in each arm, both at baseline and end-line surveys to generate required sample size for each HRP-condition. Assuming above prevalence of HRPs holds true in the two study arms, by interviewing 2,000 RDW cross-sectionally in each arm, we anticipate there will be at least 400-500 RDW with moderate/severe anaemia, 120-200 RDW with APH/placenta previa/abruptio placenta, 100-340 women with PIH. Some of these RDW may have more than one of the three HRP-conditions. Approximately, 900-1000 RDW in each arm will be without any of the three HRP-conditions.

Survey Design

A multi-stage sampling approach will be employed to select RDW from each arm:

As census data at the village/ward level is old (2011), ASHA⁵ jurisdiction was used to serve as a Primary Sampling Unit (PSU). Fifty PSUs per district (100 per arm) were selected using a two-stage sampling approach. The 2023 list of RDW in a ASHA's jurisdiction served as the basis for the selection of a PSU. Assuming an average PSU will have 20 RDW, we expect to cover 1000 RDW per district (2000 per arm) at baseline and endline surveys.

As part of first-stage of sampling, 50 PSUs in each district were allocated according to proportion of block population of the district. As part of second stage of sampling approach, the allocated number of PSUs in a block were selected using the probability proportionate to size (PPS) sampling technique.

In a selected PSU, the list of women who got delivered in the past one year, regardless of delivery outcome, and the delivery data maintained by ASHA/AWW⁶ served as the basis for identifying the eligible respondents for survey. This list by ASHA/AWW was cross-verified with the list available with the ANM of the respective PSU, and a comprehensive list of RDW to be approached for

⁵ Placed at Village level (1 per 1,000 population). Mobilizes pregnant women for ANC, institutional deliveries, and immunization. Educates on nutrition, danger signs, and family planning. Assists in postnatal care, escorts women to facilities, and facilitates Janani Suraksha Yojana (JSY) benefits.

⁶ Placed at Anganwadi Centre (1 per 1,000 population, 700 in tribal areas). Supports maternal and child health under the Integrated Child Development Services (ICDS). Provides supplementary nutrition, monitors growth, promotes ANC, immunization, breastfeeding, and family planning. Identifies malnutrition, educates mothers, and coordinates with ASHAs and ANMs for healthcare referrals.

interview is prepared. By adopting this strategy, we will eliminate the need for doing households listing exercise to identify eligible RDW in the selected PSUs.

In a sampled PSU, all the households with eligible respondent(s)/RDW were approached by female investigator/supervisor for consent/assent, for a face-to-face interview. All consented RDW were interviewed by female investigators, mostly in RDW's home. To ensure, 100% enumeration of eligible respondents in a PSU, a 'snowballing' technique was also used with interviewed RDW to check if any peer RDW in her neighbourhood was missed by ASHA/AWW/ANM list. If any new RDW is found through snowballing technique, she will be interviewed, provided she belongs to the selected PSU. **Table 2** provides inclusion and exclusion criteria used for selecting the respondents for the baseline and endline surveys in four study districts of Uttar Pradesh

Table 2: Inclusion exclusion criteria for respondents of baseline/endline surveys

Respondent	Data collection method	Inclusion criteria	Exclusion criteria
RDW	Personal interview	<ul style="list-style-type: none"> Woman aged 15-49 years, have had delivery during the past one year from the date of survey AND (details of such woman are available with ASHA/AWW/ANM in the sampled PSU OR woman was identified through snowballing technique from an interviewed RDW) RDW who is resident of non-sampled PSU but had delivery in sampled PSU in past one year and is willing to participate in survey 	<ul style="list-style-type: none"> All those who do not give consent to participate in survey RDW listed by ASHA/AWW/ANM, but not available for interview on day(s) of survey Had delivery just within three days of survey Maternal deaths and RDWs with severe illness and unable to participate in interview
District officials and Specialist gynaecologists	IDI	<ul style="list-style-type: none"> Currently serving in the stated position in survey district 	<ul style="list-style-type: none"> With less than one year experience in current position, in survey district Who do not give consent to participate in survey
Medical officer and ANM	SSI	<ul style="list-style-type: none"> Currently serving in the stated position in the sampled PHC/HSC 	<ul style="list-style-type: none"> With less than one year experience in current position in sampled PHC/HSC Who do not give consent to participate

Using above stated survey design, tools, and inclusion and exclusion criteria; data for the baseline survey component of the impact evaluation of the IHRPTM program was collected during July-October, 2024. Baseline qualitative data from system stakeholders was collected by ARMMAN researchers, from four districts, during July-August 2024. Baseline quantitative data was collected from 4,000+ RDW by around 75 female investigators and supervisors, during September-October 2024, from 200 PSUs, spread across four districts and two arms.

Ethical considerations

Qualitative data at baseline and endline surveys will be collected by ARMMAN researchers using computer assisted personal interview (CAPI) tools, while quantitative data will be outsourced to a professional data collection agency, with prior experience in collecting maternal and child health related data in Uttar Pradesh. A two-day meeting of the qualitative researchers was held to discuss specific nuances of each question of the qualitative tool, how to ensure uniformity while asking questions, distribution of qualitative data collection workload, etc., issues. For the baseline RDW tool, the investigators/ supervisors of the shortlisted agency were trained for five days by ARMMAN program/research team on the following topics: IHRPTM program and its objectives; ethical practices to be adhered to while collecting data from RDW; how to and when to approach potential gatekeepers; which RDW are eligible for consent/assent; how to obtain consent/assent; how to collect data using CAPI technique; importance of privacy during data collection; confidentiality of data; data quality; potential risks & mitigation measures, etc. Baseline RDW data was collected by female investigators/supervisors using CAPI tool. All the tools were translated into Hindi and back translated into English, to ensure accuracy and retain the meaning of questions and most of the questions in the background, ANC and delivery care sections were tried and tested in other large-scale surveys like NFHS.

All listed RDWs in a PSU were approached by a female investigator/supervisor for participation in the survey using the RDW tool (Annexure 6). Only those RDW who express interest in participating in the survey were interviewed after obtaining informed consent. Respondents who are literate and comfortable in reading the informed consent form (ICF) were given the option to read the form themselves or the investigator read it aloud to them. Once informed consent is received, the survey will begin. If respondent feels the time is not appropriate to participate in survey, a convenient time was sought, and the investigator returned at the time specified by the respondent to conduct the interview. Prior to approaching RDW, the gatekeepers of RDW (*village leaders, teachers, religious heads, household heads, etc.*) were sensitised about the study and the safety of the RDW participating in the study by supervisors. For minors, informed consent was attained from the adult guardian, with assent from the minor. While interviewing RDW with severe morbidities, the procedure involved presence of guardian during interview. The informed consent was obtained from the participant in the presence of the guardian. If she is unable to answer or give a consent, the MCP card was copied with the consent of guardian. Including severe HRP-cases in the survey would provide us with specific signs and symptoms associated with severity of the HRP-condition, including gaps in diagnosis & management of these cases. Excluding severe HRPs from survey preview may result in collecting data only from the mild or moderately severe cases, and such a data is not representative of the actual situation on the ground, hence we have instructed investigators to collect data severe HRPs.

Privacy: While collecting qualitative or quantitative data from the field, there will be situations when interviews cannot be conducted in complete privacy, as participants may be surrounded by other adult members or co-workers. During the training of data collection teams, the issue of 'privacy' will be discussed in detail, specifically focusing on two sub-topics: 1) Ways to minimize situations where the investigator is surrounded by other adults (*starting interview with generic issues like crops, yield, etc., till other adults move; supervisor try to move other adults to a separate location, etc.*) 2) Strategies such as (*pre-interview briefings about privacy, choosing alternate locations and scheduling flexible times when fewer people are around*) that can be adopted during data collection to move other people away from the interview site.

Confidentiality: During data collection, the respondent's name will not be recorded whenever possible. In cases where names are collected during qualitative interviews, these will be converted into numeric codes (e.g., ANM-1, ANM-2, etc.), while presenting the results. At the time of IDIs with district officials, although we record name of the respondent on the hard copy of the tool, this is done solely to ensure we are interviewing the correct person. Identification details of these respondents will be anonymized once the transcription and translation of the IDIs are complete. IDIs were not audio recorded and were conducted in the presence of a note taker. Identification details of IDIs were anonymized once the notes are converted into digital data.

After completing the RDW interview, the interviewer saved and closed the file before leaving the interview site. Each interviewer was provided a password for sharing and uploading the completed files via email. A unique ID was assigned to each RDW to protect their identity. The uploaded datasets were downloaded centrally at ARMMAN-Hyderabad office on a password-protected computer. All electronic data was stored securely on password-protected computers at ARMMAN until the completion of the end-line survey. Access to identifiable information was restricted only to the research team. The data files containing identifiers will be stored separately from other data files and will be password-protected, with access restricted to the research team. To ensure confidentiality and secure data transfer/sharing, files containing identification details will be password-protected and encrypted. All hard copy records will be destroyed at the end of the project.

Data Analysis

Qualitative data will be back translated into English, coded and will be analyzed by ARMMAN's qualitative analysis experts, using ATLAS.ti and NVivo softwares. Using data validation checks, quality of the quantitative data will be assessed for coverage, consistency and completeness by ARMMAN researchers. The analysis of this data will be done using SPSS 21.0 or STATA 12.0 softwares. Preliminary analysis will include frequency tables and cross tabulations, while as part of advanced analysis multivariate analysis techniques will be used. The cleaned data will be analyzed according to: background characteristics; coverage and quality of the ANC/delivery/PNC care; the

outcome/output indicators; satisfaction with the care; etc., themes Advanced analysis will be carried out to quantify influence/associations of the background characteristics of RDW with output and outcome indicators.

Output and outcome indicators

Qualitative indicators	Quantitative Indicators
<ul style="list-style-type: none"> Identify facilitators and barriers to implementing the IHRPTM program in the two arms, through discussion with district officials. Explore facility- and community-level support systems for identifying and managing HRPs, with a focus on the three selected HRPs, through discussions with ANMs and MOs. Assess the readiness and confidence of the ANMs and MOs in diagnosing and managing HRPs, with a focus on three selected HRPs, through discussions with ANMs and MOs. 	<ul style="list-style-type: none"> Proportion of RDW who received complete package of ANC services. Proportion of RDW sensitized about HRPs by ANM or MO. Distribution of HRPs according to who/where the HRPs were diagnosed for the first time. Proportion of RDW who received HRP management according to protocols. Proportion of RDW with HRPs satisfied with the care and management they have received.

Use of Study Findings

Baseline study and impact evaluation findings will initially be shared with the Government of Uttar Pradesh, through power point presentations and respective reports. The reports will also be shared with district officials of the four program districts, for their review and consideration. Using data from baseline and endline surveys, ARMMAN will also develop research briefs on specific themes, and look for opportunities to share these findings at various forums. If possible, the findings will also be disseminated through publication in scientific/peer-reviewed journals as well as through presentations at professional meetings and conferences. Once, impact evaluation findings are available, ARMMAN plans to host meetings with state government officials and academicians to share relevant research findings, which could have implications for program modification when planning scale-up in other states.

Results

The study got approvals from ARMMAN's scientific review board (No: 017/2024) and Sigma, New

Delhi's institutional review board (IRB) (No: 10009/IRB/24-25). The impact evaluation protocol and the protocols for six HRP conditions were vetted by the Government of Uttar Pradesh in May-June 2024. In the two intervention districts of Sambhal and Shravasti, in June-July 2024, implementation of listed interventions started in a phased manner and these interventions will continue for 18 months (until March 2026), in collaboration with district health officials. By November 2024, all the ANMs, MOs, specialist gynaecologists, staff nurses, and community health officers of two intervention districts were trained on six HRP protocols, the learning app for ANMs on the six HRPs and the WhatsApp support system for real time clarification of doubts by the ANMs (*Tech-plus-touch approach*) was also introduced. The tracking/data integration system for improved tracking of the HRPs by health facilities at different levels of public health system, is yet to be introduced.

The proposed interventions, designed, developed, implemented, and evaluated using tech-plus-touch approach, will capacitate health workers at different levels to make early diagnosis of the HRPs and provide protocol-based management of the diagnosed condition. The findings of the study will identify issues that require need-based planning to ensure quality ANC, delivery and high-risk pregnancy care services by public health care system, and particularly the ANMs and MOs, who work at the grassroots. At policy level, findings of the study will provide cues on facilitators and barriers to pregnancy care services at block/district level, for necessary corrections. The study intends to make an important contribution by evaluating the usefulness and effectiveness of the proposed program, and suggest further improvements or modifications when scaled-up across the entire state of Uttar Pradesh, a region that is larger than many European countries.

Discussion

One of the major strengths of this study is that this study is being implemented in partnership with state/district health departments. Through our multi-component interventions, capacity of public health system stakeholders (ANMs, MOs and specialists) is being built to diagnose and manage HRP conditions at their respective facilities. If ANMs and MOs manage HRPs at their level, there will be reduction in unnecessary or late referrals to tertiary or higher-level facilities, allowing these facilities to concentrate mainly on most critical cases. The study will establish robust system for not only managing HRPs but for ensuring quality ANC services and continuum of care in geographies with poor maternal outcomes (Table 1). If the program is successful in these areas, it will pave way for future implementation efforts in other states.

The proposed study anticipates few limitations, such as delays in getting permissions to collect data from ANM, MOs, specialists and RDW from the two control districts. In intervention districts many MOs have recently joined the service and their focus is on preparing for higher studies. Therefore, they may not be very keen to participate in this program. Also, if they get admission in higher studies, they will leave the service and refilling the position may take time. We are also concerned about the

support for the program from system stakeholders who are nearing retirement and working on a contractual basis. The endline qualitative results, particularly from the two intervention districts might be influenced by 'social desirability bias', as by then, majority of the system stakeholders will be aware of the purpose of the program and its objectives. To minimize the social desirability bias, we will do data collection methods triangulation and by conducting information triangulation (collecting same data from multiple question formats). To minimize the bias, we will also triangulate both qualitative and quantitative data, where ever feasible. Frequent transfers of district and state officials may also create hurdles in the timely implementation of interventions and getting approvals for implementing interventions on ground.

Conclusions

The study will test the hypothesis of whether an integrated, comprehensive, system-driven intervention for improved identification, tracking, and end-to-end management of HRPs is feasible in geographies with poor maternal outcomes or not. At community level, the study will provide insights on the role of socio-demographic, as well as ANC and delivery factors, that influence HRP management and referral practices. This trial will provide valuable insights into the feasibility and effectiveness of the program, at system and community levels, in low resource setting like Uttar Pradesh. If successful, these insights can feed into capacitating HWs, at scale, in all the districts on diagnosis and management of HRPs, with significant potential for improving maternal and neonatal outcomes of the state. We will also explore the options for scaling the program to include conditions beyond the six HRPs to other districts of UP.

Conflict of interest

The author(s) declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding

The program is supported by funders such as Empowerment Foundation, LGT Venture Philanthropy and an anonymous foundation for the next 3 years.

Annexures

Annexures 1 to 6 will be shared as additional files for the journal and not for sharing with readers.

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Abbreviations

- ANC - Antenatal Care
- ANM - Auxiliary Nurse Midwife
- APH - Antepartum Haemorrhage

- ASHA - Accredited Social Health Activist
- BEmONC - Basic Emergency Obstetric and Newborn Care
- CAPI - Computer-Assisted Personal Interview
- CEmONC - Comprehensive Emergency Obstetric and Newborn Care
- CHC - Community Health Centre
- EPMM - Enhanced Pregnancy Management and Monitoring
- HSC - Health Sub-Centre
- HRP - High-Risk Pregnancy
- IFA - Iron-Folic Acid
- IDI - In-depth Interview
- IHRPTM - Integrated High-Risk Pregnancy Tracking and Management
- IRB - Institutional Review Board
- MCP - Mother and Child Protection
- MO - Medical Officer
- NFHS - National Family Health Survey
- PMSMA - Pradhan Mantri Surakshit Matritva Abhiyan
- PNC - Postnatal Care
- PPS - Probability Proportionate to Size
- QANC - Quality Antenatal Care
- RDW - Recently Delivered Women
- RCH - Reproductive and Child Health
- SSI - Semi-Structured Interview
- SBA - Skilled Birth Attendant
- SUMAN - Surakshit Matritva Aashwasan
- TT - Tetanus Toxoid
- UP - Uttar Pradesh
- WHO - World Health Organization