A feasibility study to assess the usability, usefulness, and adherence to Standard Treatment Guidelines in Indian healthcare settings with the use of Elsevier's "Arezzo®" - a Declarative Artificial Intelligence based Clinical Decision Support System and pathway technology

Healthcare Artificial Intelligence Catalyst (HAIC) Pilot Study
Sponsored by NITI Aayog (GOI) & UK-DIT

Principal Investigator Team
Lady Hardinge Medical College and
All India Institute of Medical Sciences,
New Delhi

HAIC Pilot Project Report

JULY 2021

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Submitted by

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Lady Hardinge Medical College and
All India Institute of Medical Sciences,
New Delhi, India.

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List of Abbreviations

AIDS	*Acquired immunodeficiency syndrome*
AIIMS	*All India Institute of Medical Sciences*
AMRIT	*Accessible Medical Records via Integrated Technologies*
ANC	*Antenatal Care*
ANM	*Auxiliary Nursing Midwifery*
ANOVA	*Analysis of Variance*
API	*Application Programming Interface*
ASHA	*Accredited Social Health Activist*
BP	*Blood Pressure*
CDS	*Clinical Decision Support*
CDSS	*Clinical Decision Support System*
CHC	*Community Healthcare Centre*
CI	*Confidence Interval*
CIG	*Computer Interpretable Guideline*
COVID-19	*Novel Coronavirus disease (2019)*
CVD	*Cardiovascular Disease*
DBP	*Diastolic Blood Pressure*
DMPA	*Depot Medroxyprogesterone Acetate*
EDD	*Expected Date of Delivery*
EHR	*Electronic Health Record*
ERG	*Expert Reference Group*
ETAT	*Emergency Triage and Treatment*
FBNC	*Facility Based New-born Care*
FGD	*Focus Group Discussion*
FHW	*Frontline Health Workers*
GDM	*Gestational Diabetes Mellitus*
GOI	*Government of India*
HAIC	*Healthcare Artificial Intelligence Catalyst*
Hb	*Hemoglobin*
HBNC	*Home Based New-born Care*
HCW	*Healthcare Worker*

HIV	*Human Immunodeficiency Viruses*
HRP	*High Risk Pregnancy*
IFA	*Iron Folic Acid*
IMNCI	*Integrated Management of New-born& Childhood Illnesses*
IMR	*Infant Mortality Rate*
I-NIPI	*Intensified National Iron Plus initiative*
IYCF	*Infant and Young Child Feeding*
JSSK	*Janani Shishu Suraksha Karyakram*
JSY	*Janani Suraksha Yojana*
KMC	*Kangaroo Mother Care*
LBW	*Low Birth Weight*
LHMC	*Lady Hardinge Medical College*
LHV	*Lady Health Visitor*
LMP	*Last Menstrual Period*
LSU	*Lactation Support Unit*
MCP	*Mother and Child Protection*
MMR	*Maternal Mortality Ratio*
MO	*Medical Officers*
MOHFW	*Ministry of Health & Family Welfare*
NCD	*Non-Communicable Disease*
NFHS	*National Family Health Survey*
NHM	*National Health Mission*
NIS	*National Immunization Schedule*
NITI	*National Institute for Transforming India*
OGTT	*Oral Glucose Tolerance Test*
OPD	*Out-Patient Department*
ORS	*Oral Rehydration Solution*
PHC	*Primary Healthcare Centre*
PIH	*Pregnancy Induced Hypertension*
POC	*Proof of concept*
PPIUD	*Postpartum Intrauterine Contraceptive Device*
PSMRI	*Piramal Swasthya Medical Research Institute*

ReST	*Representational State Transfer*
Rh	*Rhesus Factor*
RO	*Research Officers*
SAANS	*Social Awareness and Actions to Neutralize Pneumonia Successfully*
SAM	*Severe Acute Malnutrition*
SBP	*Systolic Blood Pressure*
SC	*Sub-Center*
SDG	*Sustainable Development Goals*
SIM	*Subscriber Identification Module*
SN	*Staff Nurse*
STG	*Standard Treatment Guidelines*
TT	*Tetanus Toxoid*
U5MR	*Under Five Mortality Rate*
UK-DIT	*Department for International Trade, Govt of United Kingdom*
UN	*United Nations*
UP	*Uttar Pradesh*
VDRL	*Venereal Disease Research Laboratory test*
VHND	*Village Health, Sanitation, and Nutrition Day*
WHO	*World Health Organization*

Acknowledgements

The HAIC Study represents a massive collective effort of several teams who persevered through several obstacles and successfully completed the study despite several unforeseen challenges, COVID-19 being the foremost. The willingness of each member to go the extra mile was due to a keen inclination to contribute to improving health outcomes with the use of advanced technology grounded in knowledge-based systems.

Sincere thanks are due to the National Institution for Transforming India (NITI Aayog), particularly Prof V K Paul who envisioned the study and invited us to lead it. Our special thanks are due to Ms. Anna Roy, Mr. Sabyasachi Upadhyaya and the Panel of Experts from NITI who steered this study and provided expert guidance and facilitation, that was cardinal to the scientific conduct, smooth administration, Government-level approvals, and overall quality of this study.

The Principal Investigators would like to place on record their appreciation for the Government of the United Kingdom and the UK- Department of International Trade (DIT) for sponsoring this study and generating evidence for the feasibility of Artificial Intelligence (AI) based solutions in public healthcare settings in India.

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The expanse of this multi-phase study covering both maternal and pediatric illnesses in the context of community and first level care required a multi-disciplinary team. We are grateful to the entire Research Team including the Expert Reference Group, the Advisory Group, the Co- Principal Investigators (PIs) and Research Officers, who took time out from their busy schedules to guide every step of the process and give valuable clinical guidance for adaptation of guidelines, implementation, and evaluation. We also acknowledge the inputs received from the multidisciplinary steering group of NITI Ayaog on their valuable inputs on the possible improvements and technology use in the way forward studies.

We express our deep adulation for the Elsevier team based out of India and UK, whose tireless efforts in getting the technology up and running, modulating it based on our feedback, and supporting the implementation of the study, were critical to the success of this project.

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Finally, and most importantly, we express our sincere appreciation for all the Accredited Social Health Activists (ASHA), Auxiliary Nurse Midwives (ANM), Staff Nurses and Medical Officers from Bahraich district who participated in the study. They have put in extraordinary efforts during very difficult times and shown exemplary levels of commitment to adopt an advanced technology like Clinical Decision Support System (CDSS) to improve the health of their beneficiaries.

We are also thankful to Dr Rajiv Garg and Dr N N Mathur, incumbent Director(s) of Lady Hardinge Medical College during the course of this study for their approval and support for conducting this important study.

We sincerely hope that the outcomes of this study shall contribute to the development and use of knowledge-based technologies like CDSS & AI in India. We believe that this intervention can act as a steppingstone to the wide-scale adoption of Guidelines and evidence-based practices as the country marches to achieve the Sustainable Development Goals and an overall improvement in the health of every Indian.

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2. Introduction

2.1. Background

Maternal and child health are important indicators for evaluating the country's effort to provide equitable access to health and socioeconomic growth. Global trends indicate that maternal mortality rate dropped by 44% worldwide between 1990 to 2015, however, much remains to be done to achieve SDG target of reducing the maternal mortality ratio below 70 per 1,00,000 live births by 2030[1]. As per WHO, it is estimated that approximately 830 maternal deaths occur per day due to causes related to pregnancy and child-birth related complications. Out of the total deaths, 99% occur in developing countries, especially in low resource settings such as rural areas, poorer communities and hard to reach areas[2]. Though India has managed to bring down the MMR from 556 per 1,00,000 live birth in 1990 to 113 per 1,00,000 live births in 2016-2018, it remains one of major countries with high MMR burden[3]. In 2015, India accounted for 15% of all the maternal deaths[4].

Similarly, despite having made significant progress in reducing under-five mortality rate, it is still unacceptably high in India. As a signatory to meet Development Goals set out by the UN, India is not only committed to bring down the under-five mortality rate to 25 deaths per 1,000 live births by 2030; but intends to better it with a declared aim of reaching U5MR of 23 by 2025. Perinatal deaths, Pneumonia, Diarrhoea are most common causes of deaths to which undernutrition is an important contributor. While the country is making some headway but there is a wide variation in performance of the various constituent states. As per an estimate, only 73% of under-five children suspected to be suffering from pneumonia were taken to health care providers while only 20% of children suffering from diarrhoea received Oral Rehydration Solutions. Despite significant improvement in institutional deliveries (79%), early initiation of breastfeeding is seen in only 41%. Wasting, stunting, anaemia is unacceptably high in Indian children[5].

Antenatal Care (ANC) forms one of four pillars of Safe Motherhood Programme which aims to reduce maternal mortality. The commonly known causes of maternal mortality such as haemorrhage, sepsis, hypertension, prolonged labour, unsafe abortion, anaemia, etc. are easily preventable through quality of care during and after birth. Evidence suggest that Antenatal Care (ANC) reduces pregnancy and childbirth related morbidity and mortality by almost 80% and should begin from the early stages of pregnancy[6]. WHO recommends a minimum of eight ANC visits, ideally at 12, 20, 26, 30, 34, 36, 38 and 40 weeks,with health promotion including nutrition counselling as one of its important components[7]. Regular ANC enables early detection of high-risk cases, better management of low weight and micronutrient deficient cases, increased awareness among women regarding pregnancy care and birth preparedness. Indian guideline recommends at least four ANC visits with first visit preferably in the first trimester[8].

To increase the coverage and access of public health services, the government has started various programmes focusing on maternal and child health, family planning, and immunization. Few of the significant initiatives being, introduction of ASHAs in the health systems to act as a link between community and health facilities, launch of initiatives such as Janani Suraksha Yojana (JSY), a safe motherhood intervention promotes institutional deliveries to reduce maternal and infant mortalities by providing financial assistance to pregnant women (below poverty line) agreeing to deliver in government or accredited private health facilities. Janani Shishu Suraksha Karyakram (JSSK) is an initiative for providing free and zero expense delivery to all pregnant women delivering in public health institutions. It entitles free transport from home to health facilities, free drugs and consumables, free diagnostic, free blood, free diet for the duration of a woman's stay in the facility and covers new-born related illness till 30 days after birth. In case of referral, free transport and treatment is also provided for two ways[9,10].

However, the mere presence of ANC services and initiatives does not guarantee its utilization nor brings about a positive outcome. Various reasons exist for the gap in ANC coverage such as availability and accessibility of health services and care providers, socio economic status, education, community awareness[11]. As per NFHS 2015-16, only 58.6% of the mothers in India had ANC check-up in their first trimester whereas mothers who had at least four ANC visits accounted for 51.2%. The percentage of women receiving full ANC check (at least four antenatal visits, at least one tetanus toxoid (TT) injection and iron folic acid tablets or syrup taken for 100 or more days) in India is very low at 21%. Anaemia during pregnancy is associated with increased risk of maternal mortality. Fifty three percent of women in the age group of 15- 49 years are

anaemic in India[12]. It is pertinent to note that the quality of primary healthcare is severely affected by the strain on Primary Healthcare Centres (PHC) where the PHC, usually led by one Doctor, is expected to provide comprehensive primary care for up to 30,000 residents[13]. A major need for optimal care provision is to improve the availability of skilled human resources in health systems. There is a shortage of 10,907 ANMs as against the required number of 1,84,160 and there is a shortage of 3,773 doctors at PHC as against the required number of 25,743. A similar shortfall is experienced in the count of other specialists and health personals. Other challenges in providing quality of care is poor infrastructure, According to Rural Health Statistics 2018, as of 31st March 2018, India has a shortfall of SC, PHC and CHC by 18%, 22% and 30% respectively[14]. 66% of the Indian population lives in rural areas[15] and is largely dependent on the public sector for their medical needs. Process assessment for the health service components has shown gaps and needs to improve service delivery process, especially adherence to service guidelines by providers[16,17]. Lack of timely, quality, and convenient access to healthcare in the vicinity, compels them to travel long distances to seek care thus adding to out-of-pocket expenditure.

To address all the factors affecting poor coverage of maternal and child health, efforts ought to be directed towards leveraging existing capabilities to provide better quality of care and services to improve key priority indicators. One promising strategy involves 'task shifting,' where front-line, non-physician health workers are delegated some of the tasks traditionally performed by physicians[18]. In the setting of HIV/AIDS care, task-shifting has been shown to improve health outcomes and processes of care[19]. In India, there is some evidence that task shifting CVD risk assessment to non-physician health workers via a simple algorithm can increase the detection of CVD[20].

Empowering front-line health workers, and potentially the mid-level healthcare providers, with knowledge-based technology solutions, such as Clinical Decision Support System, based on Indian Guidelines can serve as a job aid and provide manifold benefits. It will allow the care provider administer care based on a standard treatment protocol while ensuring an appropriate triaging with seamless continuum of care; reduction of unnecessary intervention and inappropriate referrals; and, provision of pre-referral or definitive treatment at point of care.

There was an established need for localized clinical decision support, which has also been previously field-tested in Cardio-vascular diseases[18]. However, the need for transforming Standard Treatment Guidelines (STG) into active clinical decision support, including local dialects, to ensure adherence to STGs in maternal and child health, was yet to be fulfilled.

2.2. Arezzo®

Arezzo® is an active clinical decision support (CDS) and pathway technology that empowers personalised care delivery at patient and population level. The technology supports the authoring and execution of Level 3 "active" clinical guidelines that are made computer interpretable through Declarative Artificial Intelligence (AI). By integrating with clinical care systems, Arezzo® matches evidence-based guidelines with patient and disease information and dynamically evaluates best-practice treatment options specific to the patient at that stage in their care. Arezzo® is owned by Elsevier.

Arezzo® CDS proprietary software consists of the following components:

- **Arezzo® Composer** – for configuration of CIGs content
- **Arezzo® Bridge** – for configuration of display-logic, including patient summaries, referral letters, and to facilitate data-entry
- **Arezzo® Performer** – the high-performance AI engine that processes CIGs content against patient data to deliver ongoing recommendations, dynamic order sets, and alerts.
- **Arezzo® Conductor** – middleware component that manages external interfaces. In the pilot project, Arezzo® Conductor will provide the ReST API that is consumed by the mobile app.
- **MS SQL database** for storing the Arezzo® CDS state files and audit data.

In this study, the Arezzo® CIGs were delivered through an Android-based app that was installed on mobile tablet devices. The mobile app communicated online with the Arezzo® ReST API and dynamically

renderedthe outputs to healthcare workers. Outputs included requests for more data, decisions, and tasks. The app then sent user inputs back to Arezzo® for processing.

Arezzo® was validated through several studies in the UK, Europe, and New Zealand. The details of these validation studies can be found in Annexure 1.

2.3. Rationale

Arezzo® canenable transformation of primary healthcare by implementing multiple, merged STGs at the point-of-care, where the FHWs will only see content relevant to the patient. A longitudinal clinical pathway, based on the State Agent of Arezzo®, will be generated for every unique beneficiary, starting from her doorstep. Arezzo® will also record the decisions taken for monitoring compliance and variance from STGs, to automatically generate data about adherence to STGs.

The platform was envisaged to bridge some of the key gaps and challenges in effective healthcare delivery in the public healthcare delivery system of India. Some of these include:

a. Inadequate and inappropriate referrals from health outreach
b. Knowledge gap in FHWs
c. Non-availability of local language guidance for FHWs
d. Lack of evidence-based primary health screening
e. Inaccurate operational and clinical data for evaluation of compliance measures
f. Lack of health outreach information in the care pathway, which will be addressed by generating a unique pathway for a beneficiary which could be integrated with the Electronic Health Record (EHR) in the future

Arezzo® generates high-quality clinical data sets during usage. Whilst such data lends itself to post-hoc analytics and machine-learning, algorithms can be used to generate potential new clinical insights, but these must be validated before being incorporated back into CIGs.

It was expected that a secondary gain from a wide-scale Arezzo® implementation in India will be the significant increase in district-level data about care delivery, referrals, and outcomes, including the potential to partially automate NFHS-like national surveys.

3. Study Aim and Objectives

The purpose of the study is to test the feasibility of Elsevier's "Arezzo®", with adapted Indian Standard Treatment Guidelines, used in public health care settings through a Pilot intervention.

The study will focus on the following objectives:

a. To test the validity and accuracy of Arezzo® content after its customization based on Indian STGs demarcated for various levels of care in maternal and child health.
b. To study the feasibility of "Arezzo®" in primary and secondary healthcare settings.
c. To evaluate the following with the addition of Arezzo® in public healthcare settings:
    - Usability
    - Usefulness
    - Adherence to STGs

4. Hypotheses

a. Integration of "Arezzo®" - an active Declarative AI clinical decision support system is usable and useful to health workers in primary and secondary healthcare settings.
b. Provision of Arezzo® customized for Indian guidelines-based recommendations facilitates adherence to primary health screening guidelines.

5. Methodology

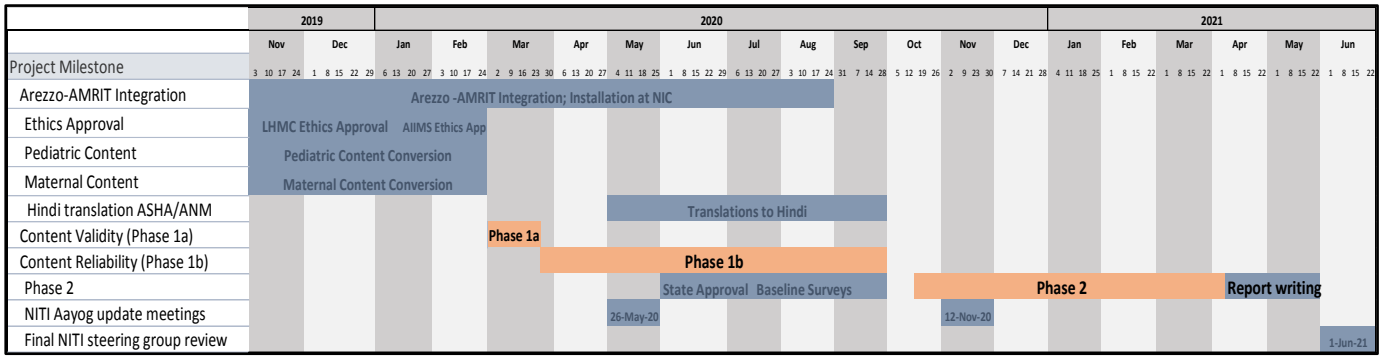
5.1. Study Phases

The study was carried out in two broad phases. Phase 1 was to digitise and transform the STGs to CIGs for incorporation into the CDS tool and then to assess the validity (Phase 1a) and the reliability (Phase 1b) of the of the converted guidelines (from STGs to CIGs) in the CDS tool. Phase 2 was to test feasibility of the tool in terms of the usability, usefulness, and adherence to STGs with its usein the field for Primary Healthcare and community healthcare workers (CHC, PHC and sub-centre level).

These phases were conducted as per the following timelines:

- **Preparatory phase:** Content conversion and incorporation into CDS (Nov 19-Feb 20)
- **Phase 1 a:** ContentValidity - March 2020
- **Phase 1b:** Content Reliability - April through September 2020
- **Training for Phase 2** - 28-30 September 2020
- **Phase 2:** Implementation at Study Site (Bahraich, UP) - October 2020 through March 2021
- **Study data collection** - 21-Oct-2020 to 8-April-2021.
- **Report Writing**
- **Final report submission to sponsors May 2021**
- **Presentation to NITI multidisciplinary steering group and discussions for inputs**
- **HAIC Pilot Project Report (updated post inputs from the steering group)**

Figure 1: HAIC Study GanttChart



The phase I was conducted at the department of Obstetrics & Gynaecology and Paediatrics at Lady Hardinge Medical College while the phase II was conducted in the community settings (Bahraich district in the state of Uttar Pradesh). The selected district is one of the aspirational districts of NITI and had the presence of a health support agency, who were taken on board for the study as implementation partner.

5.2. Target Health Workers

Computer interpretable guidelines (CIGs) using the Arezzo® platform were demarcated, and three levels of decision-making were programmed for the three roles*viz*:Accredited Social Health Activists (ASHA) workers, Auxiliary Nurse Midwives (ANMs) and Medical Officers (MOs) (Table 1).

Table 1: Target Health Workers

Health Worker	Role
Accredited Social Health Activist (ASHA)	Front-line health screening
Auxiliary Nurse Midwife (ANM)/Staff Nurse	Primary care screening and interventions as indicated
Medical Officer (MO)	Primary and secondary care

5.3. Constitution of Expert Reference Group

An ExpertReview Group (ERG) of Obstetricians and Pediatricians was constituted for this study (Section 2 – Key Stakeholders) to provide their expert opinion throughout the duration of the study. The Principal Investigators (PIs) and co-PIs led the ERG and provided directions on the design and execution of the study as well as the analysis of the study results. Two Research Officers were also onboarded to help conduct the study. Elsevier incorporated the STGs into the Arezzo application such that they were demarcated for various levels of health service providers i.e.MOs, ANMs and ASHAs with the support of the research team.

5.4. Preparatory Field Visit

In December 2019, team members visited Bahraich, UP to understand the workflow at the primary healthcare facilities and to gain insights for content conversion and development of the solution.The team met ASHA, ANMs and MOsat 2 pre-selected Primary Health Centers (PHCs), 1 sub-center, 2 Village Health, Sanitation and Nutrition Day (VHND) clinics and 1 Community Health Center (CHC). Our implementation partner, Piramal Swasthya Medical Research Institute (PSMRI) helped facilitate the visit including the meetings. The salient insights were that CHC had high volumes and was the preferred place to go by the villagers. The infrastructure of the PHCs was impressive but PHC and the sub-center experienced low volumes of patients. The PIs were impressed by the knowledge and capability of the ASHA workers and the ANMs. In the maternal population, incidence of anemia was high, but interestingly there were very few cases of gestational diabetes. This reflected their practice as they did not routinely do screening for GDM.

5.5. Infrastructure and Resources

Android-based tablets with 4G internet connectivity and a pre-installed instance of the **AMRIT** (Accessible Medical Records via Integrated Technologies) android-based mobile app, developed by the implementation partner **PSMRI** (Piramal Swasthya Management Research Institute), that was integrated with Arezzo®. This device was used by the Research Officers and the selected health workers enrolled in the study.

5.6. Selection and transformation of Guidelines

As a pilot project to test the hypotheses 10 conditions, 5 each from maternal and child health (Table 2) were initially finalized through a consensus of the Expert Reference Group (ERG). These guidelines were then digitized and transformed for use with Arezzo CIGs.

Table 2: Guidelines selected for the HAIC Pilot

Condition		Guideline
Maternal Health		
1.	**Antenatal care (ANC) for uncomplicated pregnancy**	• Guidelines for ANC Skilled Attendance at Birth by ANMs LHVs SNs 2010 MOH GOI • ASHA Skills That Save Lives – Module 6 and 7
2.	**Gestational diabetes mellitus (GDM)**	• Diagnosis and Management of Gestational Diabetes Mellitus - Technical and Operational Guidelines, NHM, MOH, GOI, 2018
3.	**Hypertension in pregnancy including eclampsia**	• Guidelines for ANC Skilled Attendance at Birth by ANMs LHVs SNs 2010 MOH GOI
4.	**Anemia in pregnancy**	• Anemia Mukt Bharat - Intensified National Iron Plus initiative (I-NIPI) Operational Guidelines, MOH, GOI, 2018
5.	**Postnatal Care**	• ASHA Skills That Save Lives – Module 6 and 7
Child Health		
6.	**Feeding**	• National Guidelines on Lactation Management Centres in Public Health Facilities • Guidelines for enhancing optimal and young child feeding practices, MOHFW, GOI, 2013 • ASHA Skills That Save Lives – Module 6 and 7 • IMNCI package for young infant and child
7.	**Immunization**	• National Immunization Schedule (NIS) for Infants, Children and Pregnant Women, MOHFW, GOI, 2017
8.	**Pneumonia**	• IMNCI package for young infant and child • Facility Based Care for Sick Children, NIPI, LHMC
9.	**Diarrhoea**	• IMNCI package for young infant and child • Facility Based Care for Sick Children, NIPI, LHMC
10.	**Care of the sick neonate**	• Facility Based New-born Care Operational Guideline, MOHFW, GOI, 2011 • Home-Based New-born Care Operational Guideline, MOHFW, GOI, 2014 • IMNCI package for young infant

5.7. Detailed Methodology

5.7.1.Phase I

The validity and reliability of the content was tested at the Obstetrics andGynaecology and Paediatric departments of Srimati Sucheta Kriplani Hospital and Kalawati Saran Childrens' Hospital associated with Lady Hardinge Medical College, andsupported by co-PIs atthe All India Institute of Medical Sciences, New Delhi.

The purpose of this phase was to assess the validity and the reliability of the of the converted guidelines (from STGs to CIGs) in the CDS tool. This was done in two parts:

Phase 1a: Content Validity

- The PIs tested the various steps and components of the individual standard treatment guidelines (STGs) converted into computer interpretable format (CIGs). both for content (through static interface) and logical flow (through web-based tester). After each testing session, feedback was sent for fixing of errors or improvisation to the Elsevier content transformation team and the content was re-tested again after amendment by Elsevier. Separate pathways were created for ASHA, ANM and MO keeping in mind their training and expected skill sets. These were further fine-tuned to offer actions keeping in mind the place of contact (CHC vs. PHC vs. SC vs VHND vs home visits). At all times, the fidelity to the guidelines was ensured at the concerned levels of care.
- The transformation of paper based STGs into computer CIGs went beyond simple digitization. It included harmonization of overlapping symptoms from the different guidelines and creating AI for stepwise optimization and unfolding of the action-oriented outcomes from the entered patient data. Flow of the guidelines had to be adapted according to the flow of real time conversation and interaction of the HCW with the patients to elicit relevant history related to various conditions.Dummy patient data was used to test all segments of the CIGs separately for each of the target health worker roles.
- Once all the subcomponents were tested, the whole program was retested using the entire content together, for example with complex patient journeys that involved multiple symptoms or conditions across several STGs. Feedback from the retesting was then used to rearrange the CIGs workflow as required.

Phase 1b: Content Reliability

Ethics committee approval was obtained prior to the commencement of phase 1b.

- Phase1b was also conducted in the controlled tertiary care setting at LHMC, using prospective data. For this phase, the Research Officers weretrained to use Arezzo® tool, now incorporating the CIG based on National STGs, through a training workshop. They were given mobile tablets equipped with Arezzo® tester and internet connection for the trial period.
- The system was tested prospectively by Research Officers (equivalent to the rank of MOs and Nurses) under the guidance of the Expert Review Group clinicians using an inter-rater agreement between the CDSS based decisions (as arrived by the Research Officers) and clinical assessment and management by ERG clinician.
- After each testing session, feedback was sent for fixing of any remaining errors or for improvisation to the Elsevier content transformation team and the content was re-tested again after amendment by Elsevier.
- Local language conversion in Hindi for standard treatment guideline content relevant to front-line health workers (ASHA/ANM) was done in parallel to testing in this phase. The testing was done in English and then in Hindi for the ASHA and ANM/SN content.

Milestones and course adjustments during Phase I:

The salient milestones of this exercise comprised of:

- Identification and correction of errors in the CIG content when the test flow did not match the source STG content.
- Adaptation of CIGs to the context of Indian patients; integrating the various vertical guidelines to cover co-morbidities and to cover different age groups (infant and young child)
- Clarifications of STG content: in certain places the flow on the paper guidelines was not clear andneeded to be articulated/clarified further.
- Requirements for new content that were not contained in the source STG but were required to ensure the appropriate clinical workflow were fulfilled.For example, the obstetric expert team provided list of questions for:
    - taking the obstetric history by a medical officer,
    - estimation of duration of pregnancy when the woman cannot recall her LMP

- Requirements or reorientation for new content that was considered important to cover service areas and skill set of the peripheral functionaries but was not covered in the selected STGs.
    - The guideline cover on Sick New-born was reoriented to cover the Integrated Management of New-born and Childhood Illness (IMNCI) based care of the sick young infant instead of facility-based guidelines keeping in mind the job profile, training and skill sets of the target health functionaries. In addition, home-based New-born care package – a critical community New-born care intervention- was also included (tested in the healthy New-born babies in the postnatal ward).
    - Emergency Triage and Treatment (ETAT) component of the Care of the Sick child to cover for cases other than Pneumonia and Diarrhoea for appropriate assessment and emergency management and/ or referral was created for MOs.
    - Developmental assessment for children was included to completely harmonize with the Mother and Child Protection (MCP) Card.

- Harmonization and updating with new guidelines that have been published since the STGs were created
    - For example, the recently published paediatric guideline on assessment and management of respiratory disease
    - Guidance on newer contraceptives: DMPA, Centchroman and PPIUD

- Expert opinion on managing the relationships between multiple CIGs in the same patient for prioritization of treatment
    - For example, hypertension in a pregnant woman is more important to manage urgently compared with anaemia that is not severe.

- Information about service provision within the target health district (Bahraich)
    - For example, gestational diabetes screening with oral glucose loading test is not performed routinely
    - Also, information about role-based activities enabled the STG content to be separated by role in the CIGs

In addition, the study plan was impacted severely by the reorganisation of the hospital services due to COVID. For a significant duration of time, the OPDs had been closed and even when they opened in a phased manner, the interactions were affected due to the users not willing to stay in the hospital for any longer than their primary needs for the visit. Travel related restrictions during lockdown, issues related to worker safety and similar challenges made us make amendments to study plan and the phase 1b was conducted using the case records of the patients under treatment instead of shadowing of real life OPD interaction as was originally planned. Many more interactions than the originally planned were done during this forced extension to extensively validate the digitised care pathways.

Overall, the Principal Investigators of both, the maternal and paediatric teams, met several times face to face and virtually to review the content. In addition, sub-component testing was also done individually by the PIs and research officers. The total number of hours spent collectively by the PIs for content conversion and phase 1 review was over 500 hours. The testing case mix for Phase 1 is detailed in Annexure 4.

Phase 1 study report was submitted and presented to the Expert Committee of NITI Aayog, whose express approval along with the Ethics Committee approval met the pre-requisites for kicking off Phase 2.

5.7.2.Phase II

This phase involved testing of the feasibility of implementing Arezzo® in primary and secondary healthcare settingsin the district of Bahraich in Uttar Pradesh, India. The study-site selection was based on discussions and consensus with NITI Aayog and PSMRI, the project implementation partner.Two CHCs of Kaiserganj and Nanpara and their associated PHCs were selected,based on feasibility, for the study.

Study Participants

50 health functionaries were approached to request voluntary participation in the study. One MO did not consent to participate in the study. Remaining 49,whoparticipated in the study belonged to the following cadres: Medical Officers: 8;Staff Nurses:7;ANMs: 14: and ASHAs: 20. Over the course of the study three ASHAs withdrew from the study for personal reasons and were replaced by 3 other ASHAs from the area. These changes occurred during the months of November and December' 20. From January' 21 onwards there was no further change in the participants. Of the eight MOs enrolled, three did not actively participatein doing the cases in the digital mode and evaluating the CDSS application. As a result, they also did not provide their feedback in the final scorecard. A baseline survey was conducted to document the work profile, language and smart mobile use proficiency and training of the participants.

Table 3: HAIC Study Participants

CHC	Nanpara		Kaiserganj	
Medical Officers	2		3	
Staff Nurse	2		2	
PHC	**Amwahussainpur**	**Gayghat**	**Kundasar**	**Bhakhla**
Medical Officers	1	1	0	1
Staff Nurse	1	2	0	0
ANMs	4	3	3	4
ASHAs	5	5	5	5

Training

Astravel to the field was severely impacted due to the COVID-19 lockdown, training was conducted virtually by the PIs, the research officers and Elsevier team. The field staff of PSMRI provided the handholding and training of the staff on the ground. Training was done over three days from 28-30 September 2020. Initially, the training was conducted only for ASHA and ANMs. Medical Officers were introduced to the tool later in November 2020.

Training Modules:

- Study overview
- Participant information sheet.
- Informed consent
- Mobile device tablets distribution.
- Hands-on training of AMRIT application and CDSS

After the training, the workers were asked to have familiarisation and run-in with the use of application using test data for 2-3 weeks. The workers were regularlycontacted and encouraged as well as facilitated to use the app. The study was officially rolled out on 21-October-2020.

Course of the Phase 2 Study

- During the initial phase of the phase 2 roll-out the uptake of the application was slow. Internet connectivity was a major hurdle in many places. Another challenge was related to adoption of the AMRIT mobile application. The initial plan was to roll out AMRIT one month before Arrezo clinical decision support system (CDSS) to facilitate familiarization of the HCWs with the app and the registration of the beneficiaries residing in the area. However, these timelines did not materialize due to the Covid-related lockdown and AMRIT and Arezzo CDSS were launched at the same time. As a result, the workers were unfamiliar with usage of the AMRIT, the enumeration application and were not able to record any interaction with the beneficiary on the digital platform or access CDSS for the guidance on such an interaction. The internet issues were solved by selecting alternative

functional network provider after a one-on-one discussion with the workers. In addition, where the internet issues persisted, the users were asked to note down the data while in the field and enter it into the app and complete the CDSS journey later in the day when they reached any area with better internet connectivity.All these interactions (care seeking journeys) wereanalysed by research officers and HCWs were regularly contacted by them for easing out any teething troubles and troubleshootingissues related to technical and/ or content aspect of the programme.

- Several issues cropped on integration of Arrezo CDSS with AMRIT, *e.g.* timing out of the CDSS server on not receiving timely inputs which were either due to learning curve or slowness of the connection or due to bugs arising in either of the two programmes. These issues were flagged, analysed for the cause and resolved in a systematic manner. Both the teams - Elsevier as well as PSMRI IT team supporting AMRIT - had to work in tandem to sort these.
- One month after the roll-out, the research officers and Elsevier team visited the field. This visit occurred from 22–25 November 2020. During this visit, many training gaps emerged. We found that the relatively fast-paced virtual trainings had prevented the workers from truly grasping the concept of the CDSS application and how it was to be used. This visit, therefore, was utilised for supervised interactions, identification of problem areas and individual feedbacks and reinforcements. Joint sessions were also held in smaller groups where all the identified problem areas were explained to the workers.
- One of the key outcomes of the app and CDSS tool was to allow identification of high-risk patients, appropriate referral and step-up care. This required mapping the continuum of care from ASHA to ANM to MO. However, the functionality to"Get Data"from one worker to the other inline superior had problems *e.g.*ANM was not able to see the beneficiary details of the beneficiary registered by the ASHA and likewise the MO was not able to view beneficiary details that the ANM or ASHA had entered. PSMRI technical team worked hard to resolve the integration issues and it required a lot of fixing, re-fixing and time to get sorted. Each build helped to make the AMRIT application more stable and the integration more reliable. In all, three successive app builds were released in an evolutionary Agile approach. Each time a new built was released all the tablets had to be physically collected from each worker from the field and brought to head office of Piramal at Lucknow, to be updated and then redistributed. This was a time-consuming exercise.
- A final buildincorporating all the desired enhancements was released beginning February2021. Starting from 7th February 2021, the journeys completed by the workers were analysed almoston adaily basisand feedback communication with the workers was continued.
- Anonymous online surveyswere launched to get feedback from all the users with regards to the usability and usefulness of the application twice in phase II (one during the 8-18 March '21 and another final one during the first week of April 21. These two surveys had identical questions but were repeated as the assessment of the usefulness and usability in first survey could have been affected as the app was not fully stabilized in the initial weeks and many workers who were slow to adopt the technology had not used the app often enough. We hypothesized that the second survey which was nearly 8 weeks after the release of the stabilized version of the app wouldallow to get a better more realistic assessment of its usefulness and usability. The trend of app usage and the access to STG supported this hypothesis as most of the incomplete journeys (recorded patient interactions) were mainly seen at the start of the study due to user hesitation, learning curve and technical reasons like poor or no internet connection, server timing out due to slow inputs/internet, software bugs, etc.
- As the questionnaire design of the score card did not allow any detailed understanding of the users' view, we invited all of them to participate in smalllocation-based focus group discussions (FGD). It helped to get detailed insights into their feedback on theusability and usefulness of the solution, its limitations, and possibilities for future benefits.
- 46 out of 49 participants responded to the survey. 3 medical officers were not able to respond and provide their feedback. The following section only details the responses from final survey while the findings of the midterm survey are detailed in annexure 5. The focus group discussions were executed from 6-10 April 2021 and the principal investigators were intimately involved in each of the six focused group discussion sessions that have been detailed in Section 5.1.3.3.

- The final report hasused parsed data,as compared to the interim report submitted in March 21, excluding duplicate and/ or unlinked entries forced due to anonymization required for the CDSS tool, in view of data privacy rules.

The overall process is described in the following flowchart (Fig 2):

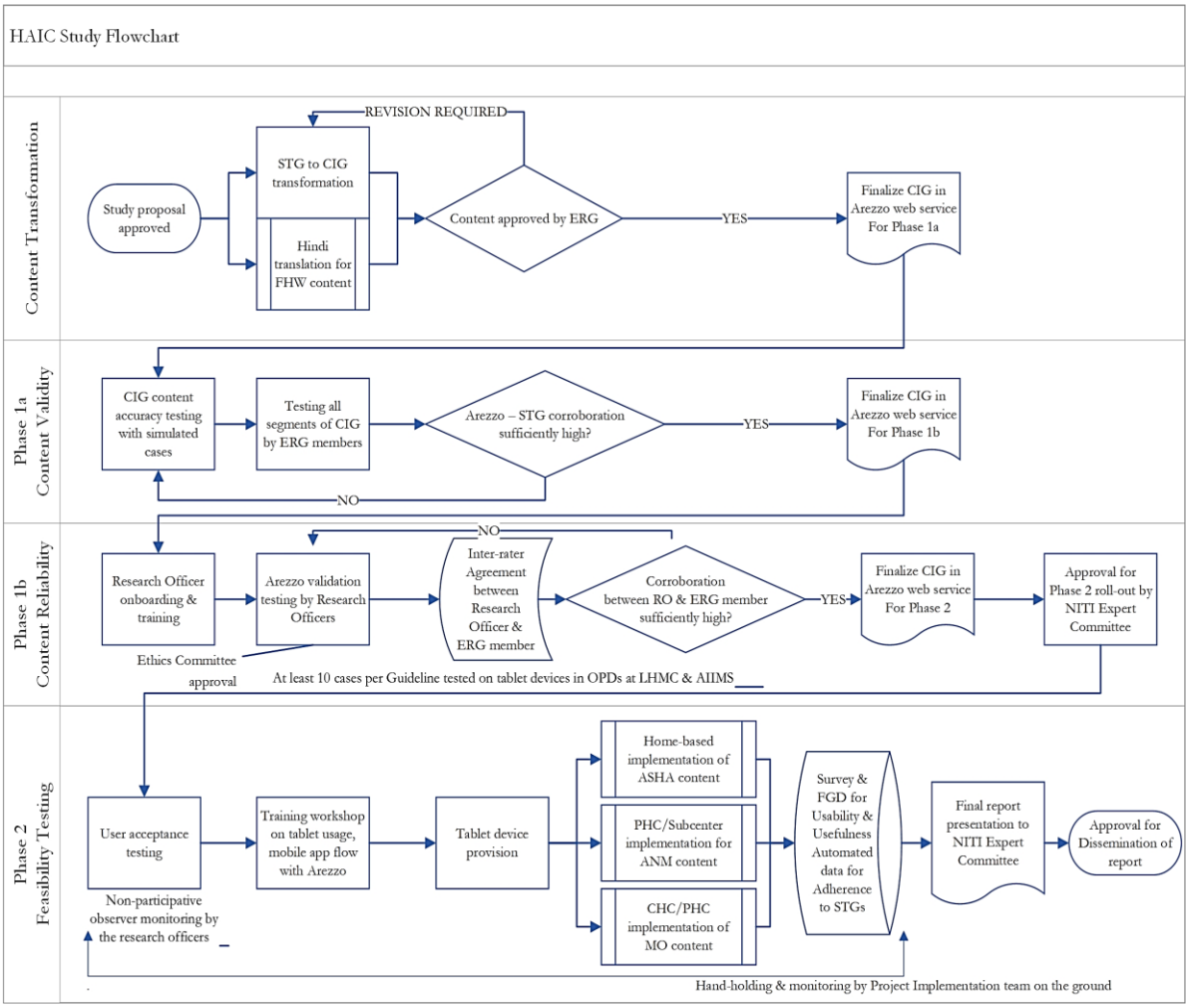


Figure 2: HAIC Study Flow-Chart

Sampling

Based on a study and field review by the Principal Biostatistical Investigator, a convenience sampling methodology with a sample size of 3000 journeys was finalized. Because this was a field study, there was no requirement for collecting a certain number of case journeys per guideline. Workers were asked to register and run Clinical Decision Support on a minimum of 5-8 cases a week.

Inclusion criteria

- Pregnant women seeking antenatal care or postnatal care and Children under 5 years, with any of the conditions included in the pilot (section 4.6) in contact with a health worker in community setting or those attending a PHC/CHC

5.8. Outcome Measures

The following outcome measures, based on operational criteria specific to the project, as well as clinical evaluation criteria for maternal and childhealth were evaluated.

Table 4: HAIC Study Outcome Measures

Phase	Outcome Measure	Type of Data	Evaluation Criteria	Data security
Phase 1a	Content validity	Qualitative	Concordance by PIs	Non-identifiable data
Phase 1b	Content reliability	Qualitative	Concordance by PIs	Anonymized patient data Secure transmission of data through encryption
Phase 2	Usability	Quantitative Qualitative	Anonymized Quantitative score card surveys@ FGD	Written informed consent
	Usefulness	Quantitative Qualitative	Anonymized Quantitative score card surveys@ FGD	Written informed consent
	STG Adherence	Quantitative	Cumulative STG Adherence Trend STG Adherence indicators	Pseudonymized patient data Secure transmission of data through encryption SSL certification DNS over HTTPS

@Score card-Annexure2

5.8.1.STG Adherence Indicators

The following STG adherence indicators were measured through automated data collection via Arezzo:

Table 5: STG Adherence Indicators

Condition	STG Adherence Indicators
Maternal Health	
Antenatal care (ANC) for uncomplicated pregnancy	1. Documented LMP 2. Documented EDD 3. History taken (specific symptoms, systemic illness, drug intake, family history of systemic illness etc.) 4. Weight measured 5. Blood Pressure taken 6. Blood sample taken (for Hb) 7. Blood sample taken (for blood group, Rh) 8. Blood sample taken (for VDRL) 9. Urine sample taken (for protein) 10. Urine sample taken (for glucose) 11. Abdomen examined 12. IFA supplements prescribed 13. Tetanus Toxoid prescribed 14. Calcium supplements prescribed 15. Anthelmintics prescribed 16. Counselling done (dietary advice) 17. Counselling done (contraception) 18. Counselling done (violence) 19. Counselling done (rest) 20. Documented referral when indicated
Gestational diabetes mellitus (GDM)	21. Screening for GDM done 22. History taken for signs & symptoms of hyperglycemia. 23. OGTT done for screen-positive women

Condition	STG Adherence Indicators
Hypertension in pregnancy including eclampsia	24. Documented history (hypertension or pre-eclampsia/eclampsia in the previous pregnancy or current pregnancy or family history) 25. Two consecutive BP readings taken four hours or more apart if SBP ≥ 140 mmHg or DBP ≥90 mmHg or more 26. Test for urine albumin in case of high BP
Anemia in pregnancy	27. Documented history suggestive of anemia (pallor, palpitation, fatigue) 28. Hemoglobin test at each visit 29. IFA supplements – one tablet twice a day
Postnatal care	30. Iron prescribed 31. Contraceptive advice given 32. Nutrition advice given 33. Breast feeding advice given
Child Health	
Feeding	34. Breast feeding within one hour of birth 35. Counselling done on lactation support, breast feeding, IYCF and KMC (as part of LSU requirements), on complementary feeding and done on feeding and recommendations during sickness and health
Immunization	36. Documented immunization history as per National Immunization Schedule (NIS) 37. Recommendations for vaccination as per NIS
Pneumonia	38. Documented assessment (signs of pneumonia and pneumonia severity) 39. Documented referral when indicated
Diarrhoea	40. Documented history (feeding, SAM, diarrhoea, blood in stool) 41. Documented assessment (persistent diarrhoea, dysentery, signs of dehydration) 42. ORS packet prescribed when indicated 43. Zinc prescribed when indicated 44. Documented referral when indicated 45. Antibiotics prescribed
Care of the sick neonate	46. Documented history (preterm, LBW, intrapartum/post-partum complications) 47. Documented assessment (ETAT) 48. Documented assessment (feeding, crying, breathing, icterus, pallor, cyanosis, abdominal distension, neck rigidity) 49. Documented referral when indicated
General	50. Documented birth weight 51. Weight measurement on every visit 52. Temperature measurement

6. Results

6.1.1. Base-line Survey

A baseline survey was conducted to understand the current practices of these field workers.

- While Hindi language proficiency was 100% across all three groups, it was evident that English proficiency was much higher in ANMs as compared to ASHAs, with 100% proficiency in MOs.
- All three cadres of health workers were familiar with STGs and were trained on newly published guidelines.
- The comfort level with mobile devices was highest in ANMs followed by MOs and then ASHAs. However, none of them used any mobile devices for any routine work.
- The perceived benefit of CDSS was highest for ASHAs, followed byMOs, and thenANMs.

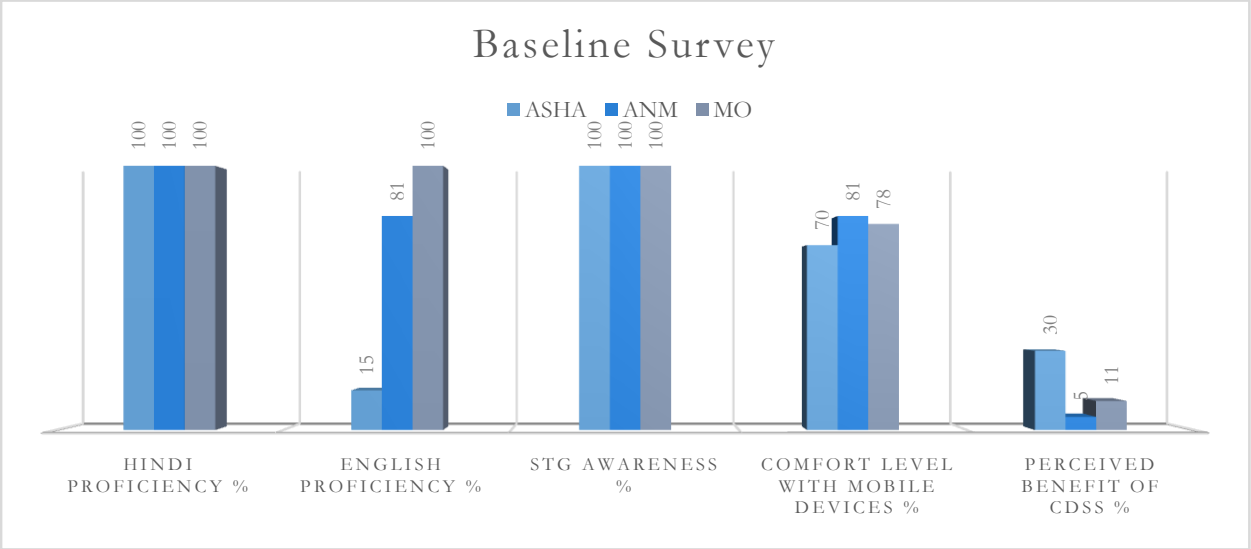


Figure 3: Baseline Survey Results

Further details of the baseline survey are contained in Annexure 3.

6.1.2. Phase 1 Results

Phase 1a: Content Validity

- All the content related to common illnesses and conditions selected for the pilot study could be accurately digitized with separate pathways for ASHA, ANM and MO keeping in mind their training, skills and job profile.
- The AI could allow accurate stepwise optimization and unfolding of valid and accurate action-oriented outcomes from the entered patient details, keeping in context the place of contact (PHC vs. CHC vs.VHND vs. home visits).
- The fidelity to the guidelines was maintained at all times and at all levels of care. It worked equally well with complex patient journeys that involved multiple symptoms or conditions across several STGs.

Phase 1b: **Content Reliability**

- Reliability Testing was done on 439 cases (208 maternal and 231 paediatric) as detailed in the Table below. It coveredmore than the proposed cases that were to be tested for both Maternal and

Paediatric guidelines covering the different health functionary roles. Multiple, relevant journeys were run on these cases, separately for each of the roles (ASHA, ANM and MO). In total, we evaluated 963 maternal and 2172 paediatric journeys. The details of the cases are given in Table 6 below and the breakdown of journeys is provided in Annexure 4.

Table 6: Phase 1 Reliability Testing Journeys

Each Case completed for all the three roles ASHA, ANM and Medical Officer.

Maternal Cases (N=208)	
ANC-without any complications	63
ANC with 1 or more complications • Anemia in Pregnancy • Preeclampsia/Hypertension/Eclampsia • Gestational diabetes mellitus	105 • 42 * • 38 ** • 33 ***
Post-natal	40
Pediatric Cases (N=231)	
Feeding and Immunization alone	33 #
Pneumonia • Pneumonia alone • With feeding and immunization	24 ## • 11 • 13
Diarrhoea • Diarrhea alone • Diarrohea w SYI • With sick child • With pneumonia • With feeding and immunization	76 ### • 31 • 10 • 6 • 5 • 24
Care of the sick child • Care of the sick child alone • With feeding and immunization	44 • 22 • 22
Sick Young Infant	32
New-born Care	22

* Includes women with anaemia alone and also women with anaemia and or preeclampsia/ GDM

** Includes women with preeclampsia alone and also women with preeclampsia and or anaemia/ GDM

*** Includes women with GDM alone and also women with GDM and /or anaemia/ preeclampsia.

In total, 92 cases each were done for Feeding and Immunization (rest depicted elsewhere in the table as and when they were overlapping with other guidelines; the feeding and immunisation does not get assessed in severe cases as referral takes precedence over these assessment)

Includes children with Pneumonia alone and also pneumonia with feeding and immunization.

Includes children with diarrhoea alone and diarrhoea for sick young infant, sick child, pneumonia and diarrhoea with feeding and immunization

- At the end of phase 1b, all the maternal and paediatric conditions for whom content conversion was done and AI was created have been tested. The CDSS content on the integrated software (Arezzo-Amrit app) was tested and retested on a sufficiently large dataset (Table 6) and all the bugs identified were removed. The software has achieved the capacity to effectively and seamlessly providing individualized intervention or management solutions with complete reliability, based on the beneficiaries' case details provided.
- Furthermore, this fine-tuning of content was coupled with further need based enhancements. Notably the application is also able to do the following:
    - create necessary clinical summaries when beneficiaries are referred from the ASHAs to ANMs and from front-line health workers to the medical officers.
    - covers the early development screening for children up to 3 years.
    - supplemented with the addition of images and harmonized with the content of the mother and child protection card introduced recently in the functioning of front line workers.
- The ERG led by PIs reviewed the journeys and agreed that the converted guidelines were sufficiently and satisfactorily tested for validity and reliability according to the pathways outlined. STG content was found to be fully transformed and supplemented with more recently published recommendations, where deemed essential by the experts. The content was further harmonized and fine-tuned across guidelines using advisory group opinion.
- The ERG led by PIs had concordance on the sufficiency of testing to cover majority of the likely case scenarios for the selected conditions having significant impact on maternal and child health in the primary setting.
- Further, there was concordance on the ability of the configured and optimized version of the Arezzo® Clinical Decision Support Systems integrated with AMRIT to reliably and accurately provide individualized treatment / care decision, appropriateto the role of the health functionary and in complete fidelity with the adopted National guidelines.

6.1.3. Phase 2 Results

In Phase 2 the computer interpretable guidelines and the CDSS were available to use by the health workers through the app, we used a mixed method approach and collected both quantitative data as well as qualitative data. The user's experience was assessed quantitatively using anonymised survey using scalar scale score cards. Adherence to the standard guidelines was assessed quantitatively through backend usage data.

Qualitative data was collected through focus group discussions done in smaller batches after the score card surveys were submitted to delve deep into the reasons for the scoring and get insights into challenges and desired modifications, if any.

6.1.3.1. *Quantitative Scorecard Surveys Analysis*

- Statistical analysis of the end of study scorecard results was performed using KNIME Analytics Platform (v4.3.2) and Microsoft Excel for Microsoft 365 MSO and detailed below (Fig 4).
    - The cumulative positivity rate (rated as agree and strongly agree) for questions related to **Usability**was**76.09%***(Mean Likert Score 3.99; 95% CI: 3.41 – 4.57).*
    - The cumulative positivity rate (rated as agree and strongly agree) for questions related to **Usefulness**was **80.43%***(Mean Likert Score 4.03; 95% CI:2.38– 4.77).*
    - The cumulative positivity rate (rated as agree and strongly agree) for questions related to **Overall Satisfaction** was **76.09%***(Mean Likert Score 4.10; 95% CI: 3.80 – 4.39).*

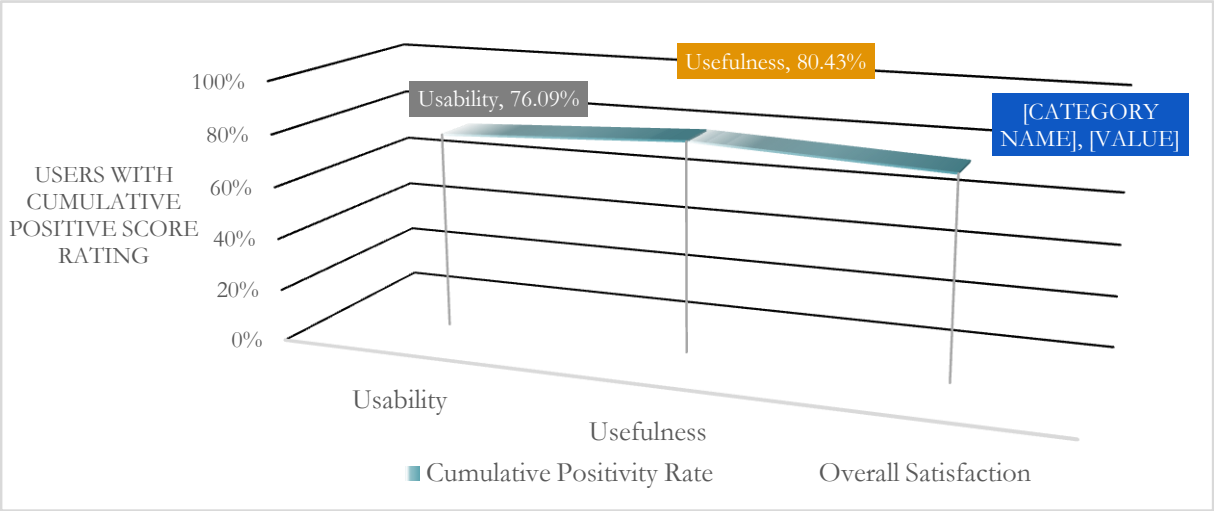


Figure 4: Quantitative Scorecard Survey Results Summary(Phase 2)

The slightly higher cumulative positivity rate for Usefulness indicates the participants inclination towards the features that they found valuable in their routine tasks, but this wasn't necessarily supported by an equal inclination towards the ease of use of the application, reflecting on its Usability, that wasinitially impacted by factors relating to technology, network availability and integration with the PSRMI AMRIT app. FGDs provided further insight into the reasons for these differences and are discussed later.

Usability

The cumulative positivity rate where respondents agreed or strongly agreed on the Usability of CDSS-integrated mobile was **76.09%***(Mean Likert Score 3.99; 95% CI: 3.41– 4.57)* with **statistically significant responses to all questions on usability** (*p <0.05*;one-sample *t*-Test).

The cumulative positivity rate and Mean Likert Scores for each question on Usability were as follows:

- The mobile application iseasy to use: 89.13%and 4.33*(95% CI: 4.08 - 4.57)*
- The necessary information and summariesare organized and displayed in a logical manner: 86.96% and 4.13 *(95% CI: 3.91 - 4.35)*
- I can accomplish my tasks more easily: 73.91% and 3.98 *(95% CI: 3.66 – 4.30)*
- Recording patient data and navigating through the workflow is seamless: 73.91% and 3.91 *(95% CI: 3.61– 4.21)*
- Feel comfortable using it in the social or community setting: 69.57% and 3.85*(95% CI: 3.55– 4.15)*
- It integrates and fits easily into my daily routine: 63.04%and 3.72*(95% CI: 3.41 – 4.03)*

There was also a statistically significant variance between different groups for the question "**It integrates and fits easily into my daily routine**" (*p <0.05*; One-way ANOVA) with mean Likert Scores for four groups, showing a higher positivity rate amongst ASHAs compared to the other groups, as follows:

- ASHA: 4.2 *(95% CI: 3.75 – 4.65)*
- ANM: 3.21 *(95% CI: 2.58 – 3.86)*
- Medical Officer: 3.20 *(95% CI: 2.64 – 3.76)*
- Staff Nurse: 3.71 *(95% CI: 2.83 – 4.59)*

There was no statistically significant variance between different groups of ASHAs, ANMs, Staff Nurses and Medical officers for the other questions on usability.

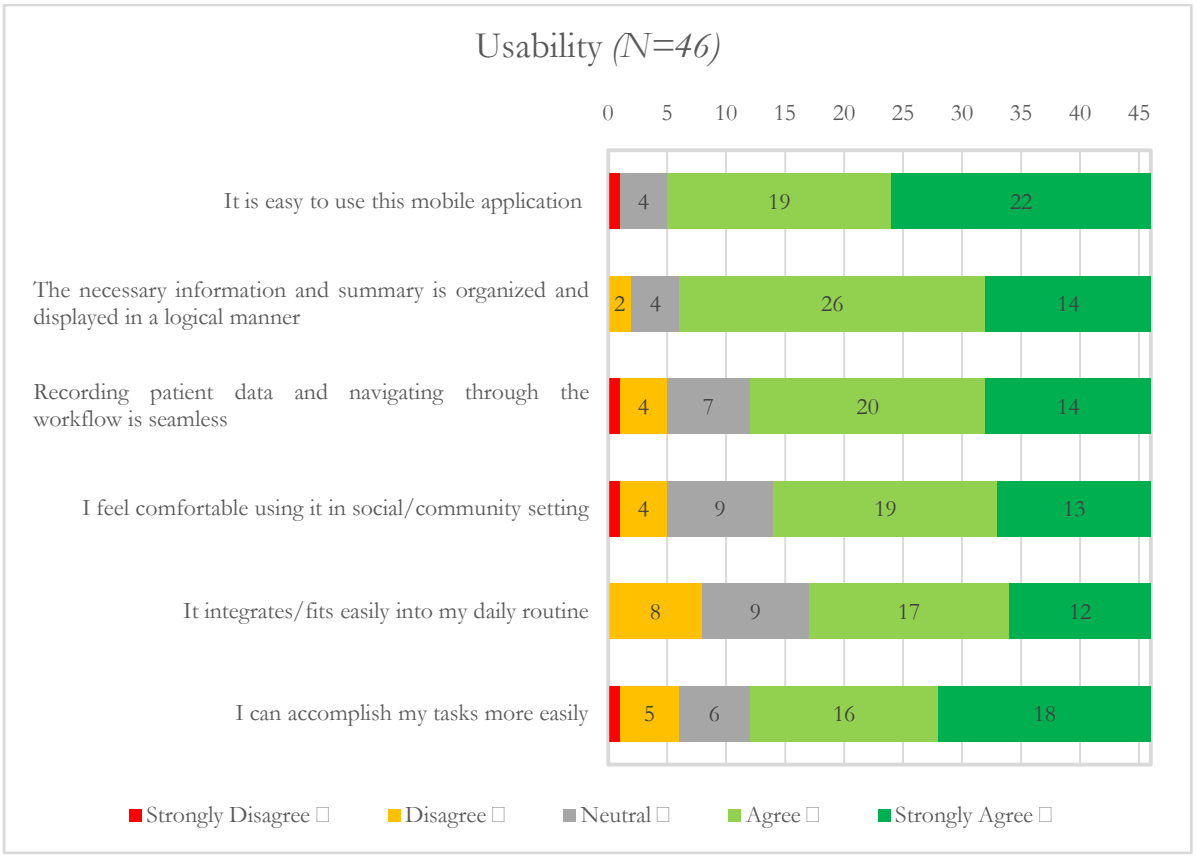


Figure 5: Usability Survey Results

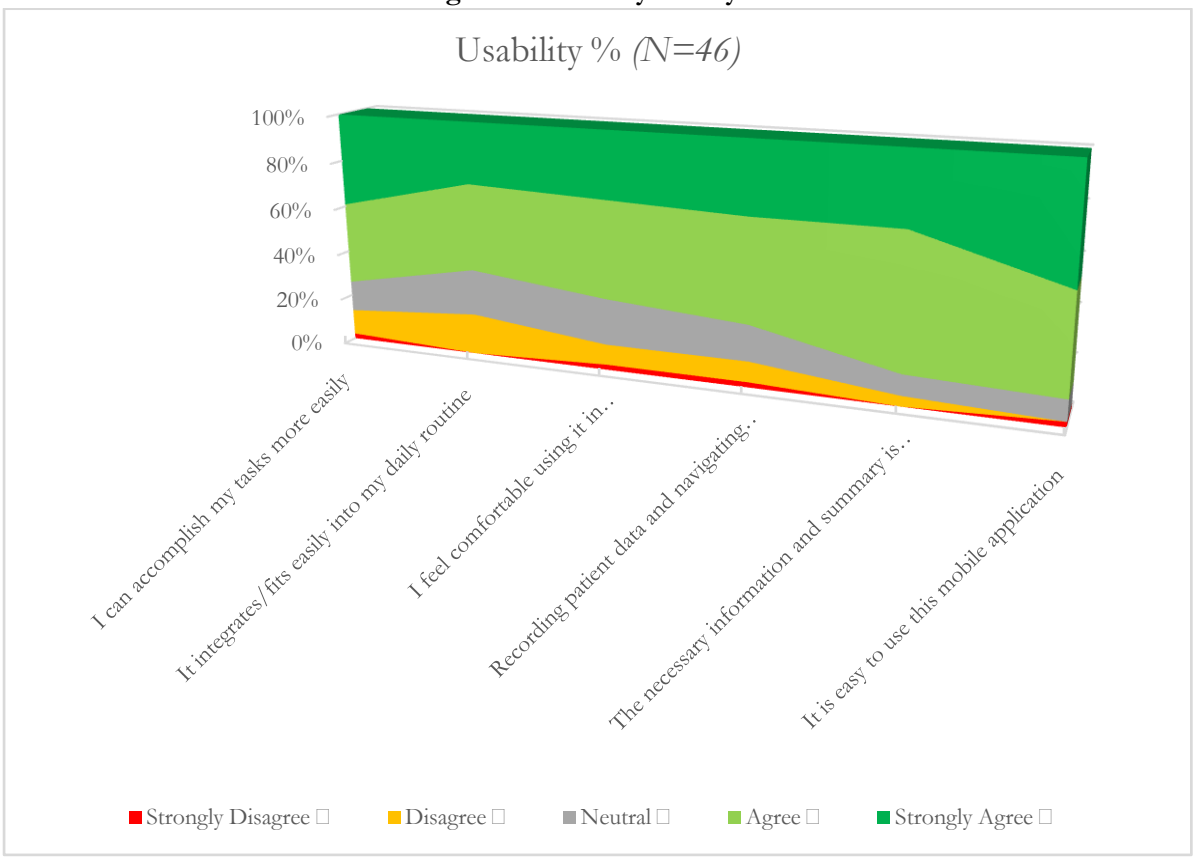


Figure 6: Usability Survey Stacked % Results

Usefulness

The cumulative positivity rate where respondents agreed or strongly agreed on the Usefulness of CDSS-integrated mobile was 80.43% *(Mean Likert Score 4.03; 95% CI: 2.38– 4.77)* with **statistically significant responses to the following questions on usefulness** (*p <0.05*;one-sample *t*-Test) with the positivity rate and mean Likert Scores as recorded below:

- It gives me more information on what to advise patients: 97.83 % and 4.59*(95% CI:4.40– 4.77)*
- It helps me remember all diagnostic procedures to be advised: 95.65%and 4.52*(95% CI:4.33–4.72)*
- This tool helps me administer the right treatment and the right drug at the right dose: 93.48% and 4.48*(95% CI:4.25– 4.70)*
- It enables me to determine which patients should be referred: 91.30% and 4.30*(95% CI:4.12– 4.49)*
- I am more confident when I talk to patients about their conditions and recommendations: 86.96% and 4.33*(95% CI:4.1–4.55)*
- It is useful in doing my daily tasks: 82.61%and4.20*(95% CI:3.98– 4.41)*
- By using this application, my work skills have increased, and I am able to accomplish my tasks quickly: 73.91% and 4.09*(95% CI: 3.81 – 4.37)*

Two questions on Usefulness had statistically insignificant responses (*p >0.05*;one-sample *t*-Test) with the positivity rate and mean Likert scores as follows:

- The quality of my interactions has reduced due to the time spent in entering data and reading instructions from the tool: 58.70% and 2.80 *(95% CI: 2.38 – 3.23)*
- I often need to override the suggestions made by the tool: 43.48% 2.96 *(95% CI: 2.53 – 3.38)*

In addition, there was a statistically significant variance between different groups of health functionaries for the question "**I often need to override the suggestions made by the tool**" (*p <0.05*; One-way ANOVA) with mean Likert Scores for four groups, showing a **higher negative rate amongst ASHAs** compared to the other groups:

- ASHA: 2.25 *(95% CI: 1.63 – 2.87)*
- ANM: 3.57 *(95% CI: 2.8 – 4.35)*
- Medical Officer: 3.20 *(95% CI: 2.16 – 4.24)*
- Staff Nurse: 3.57 *(95% CI: 2.17 – 4.97)*

These issues were further delved into during the FGD sessions to gain insights into when and why the users felt the need to override the suggestions made by the tool. During the facilitation of app use and shadowing of case interactions, we had noticed that many ASHAs and ANMs had some difficulty in correctly interpreting an indirect or negative question. The response to these questions may have similarly got affected.

There was no statistically significant variance between different groups of ASHAs, ANMs, Staff Nurses and Medical officers for the other questions on usability.

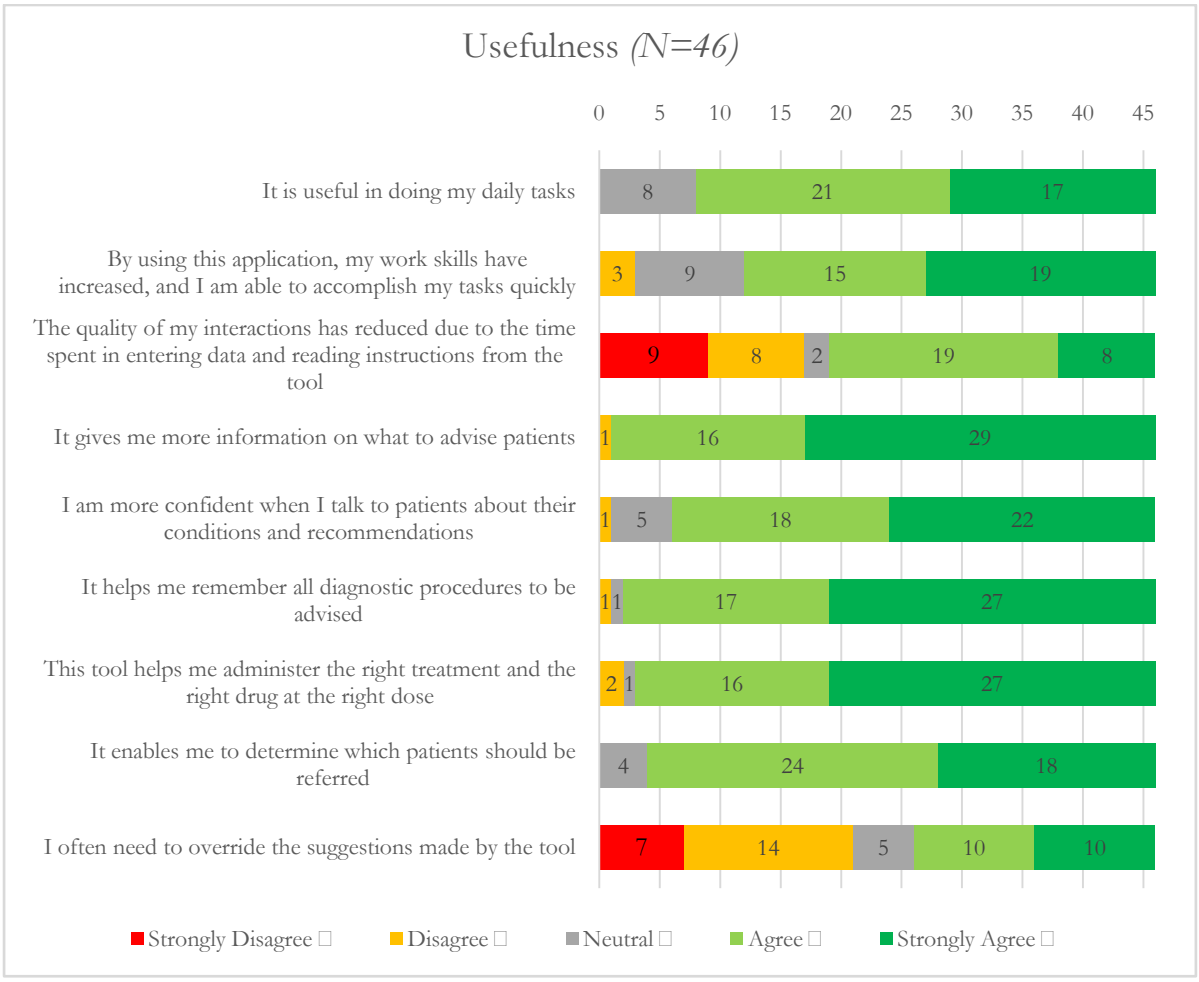


Figure 7: Usefulness Survey Results

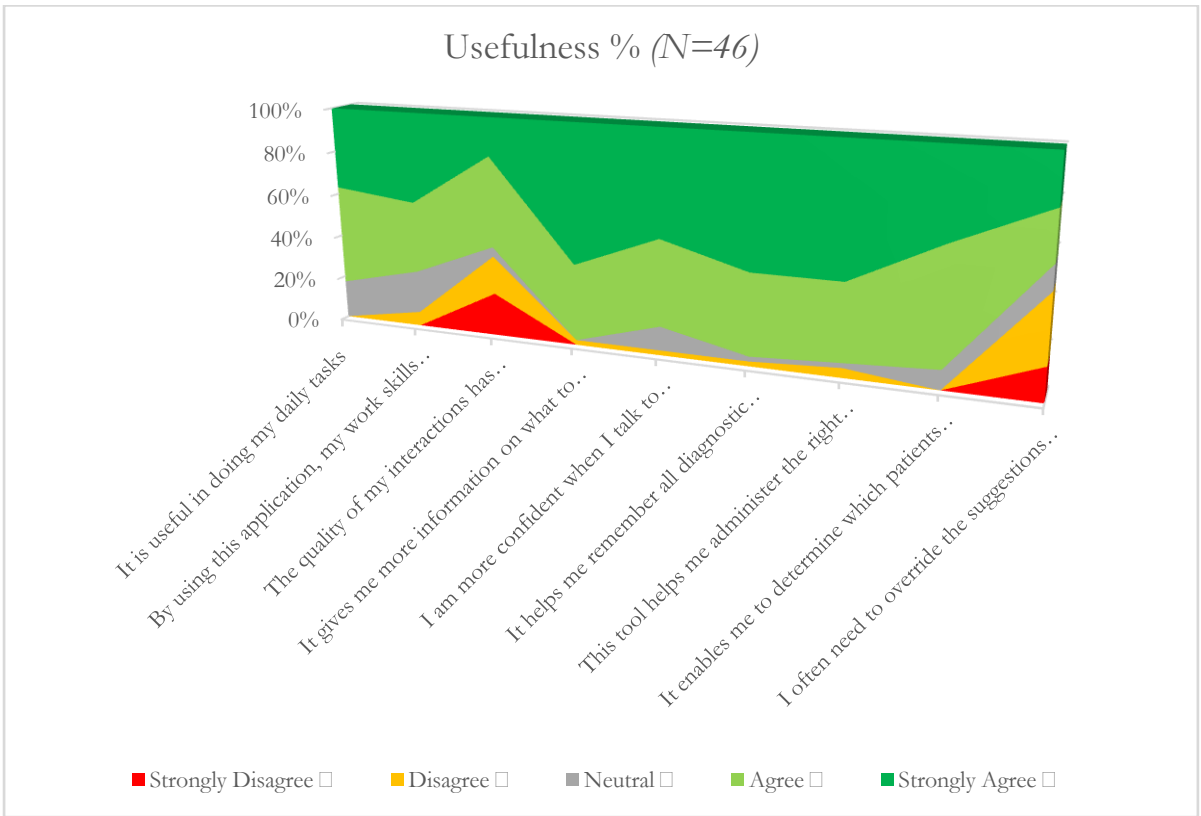


Figure 8: Usefulness Survey Stacked % Results

Overall Satisfaction

The cumulative positivity rate where respondents agreed or strongly agreed on the Overall Satisfaction with of CDSS-integrated mobile was **76.09%***(Mean Likert Score 4.10; 95% CI: 3.80 – 4.39)* with **statistically significant responses to the two constituent questions***(I would like to continue using this tool for my daily routine and work AND Overall, I am satisfied with the CDS tool)*($p < 0.05$;one-sample *t*-Test).

There was a statistically significant variance between different groups on the above two questions relating to the overall satisfaction ($p < 0.05$; One-way ANOVA) with mean Likert Scores for four groups, showing a **higher positive rate amongst ASHAs and Staff Nurses** compared to the other groups:

- **I would like to continue using this tool for my daily routine and work**: Overall Positivity rate and mean Likert Score:73.91% 4.04 *(95% CI 3.80 – 4.29)*
    - ASHA: Positivity rate: 100%4.50*(95% CI:4.26 – 4.74)*
    - Staff Nurse: Positivity rate: 57% 4.29 *(95% CI:3.41 – 5.17)*
    - ANM: Positivity rate: 50% 3.50*(95% CI:3.06 – 3.94)*
    - Medical Officer: Positivity Rate: 40% 3.40*(95% CI: 2.72 – 4.08)*
- **Overall, I am satisfied with the CDS tool**: Overall positivity rate: 78.26% 4.15 *(95% CI 3.91 – 4.39)*
    - ASHA: Positivity Rate: 100% 4.55*(95% CI:4.31 – 4.79)*
    - Staff Nurse: Positivity Rate: 85.71% 4.43 *(95% CI: 3.38 – 5.48)*
    - Medical Officer: Positivity rate: 60% 3.60 *(95% CI: 2.92 – 4.28)*
    - ANM: Positivity rate: 50% 3.64*(95% CI:3.21 – 4.07)*

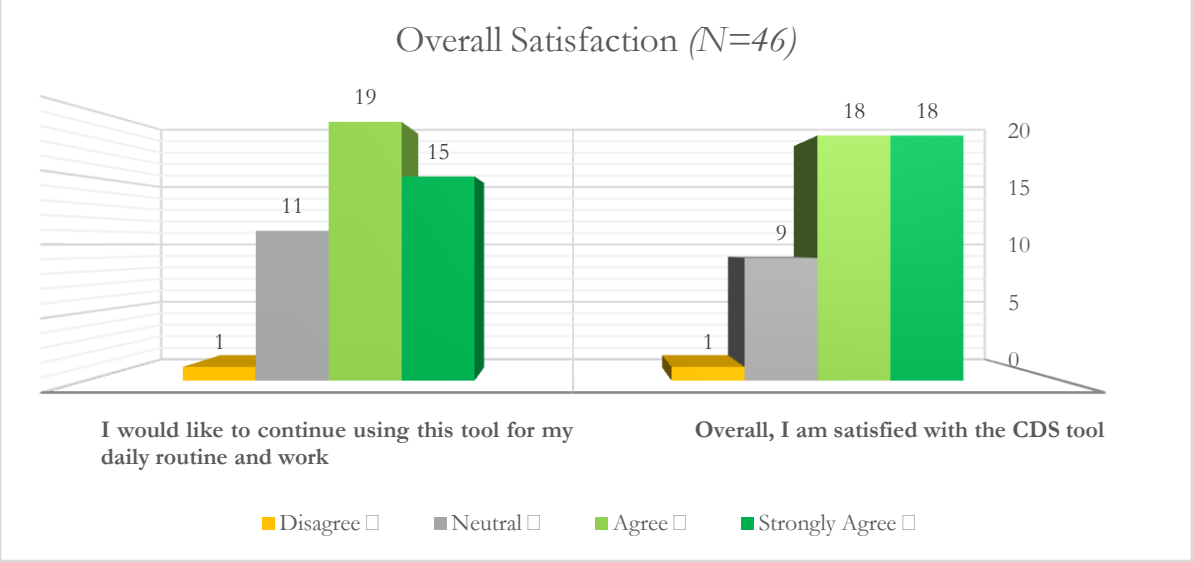


Figure 9: Overall Satisfaction Survey Results

It was intriguing that the proportion of users who were over all satisfied was higher than those who would like to continue using the tool. We delved into the reasons thereof in the FGDs.

Correlation

We were aware of the possibility of possibly receiving some random responses instead of a thought out answer from the users. We therefore tried to find correlation between the responses to various questions and see whether the correlations were logical.Certain responses to questions on Usability, Usefulness and Overall Satisfaction had **statistically significant correlations** ($p < 0.05$; Spearman's Rank Correlation test).

- *"It integrates/fits easily into my daily routine"* had a **strong positive correlation** with *"I would like to continue using this tool for my daily routine and work"*($\rho = 0.70$)
- *"It integrates/fits easily into my daily routine"* had a **strong positive correlation** with *"Overall, I am satisfied with the CDS tool"* ($\rho = 0.65$)

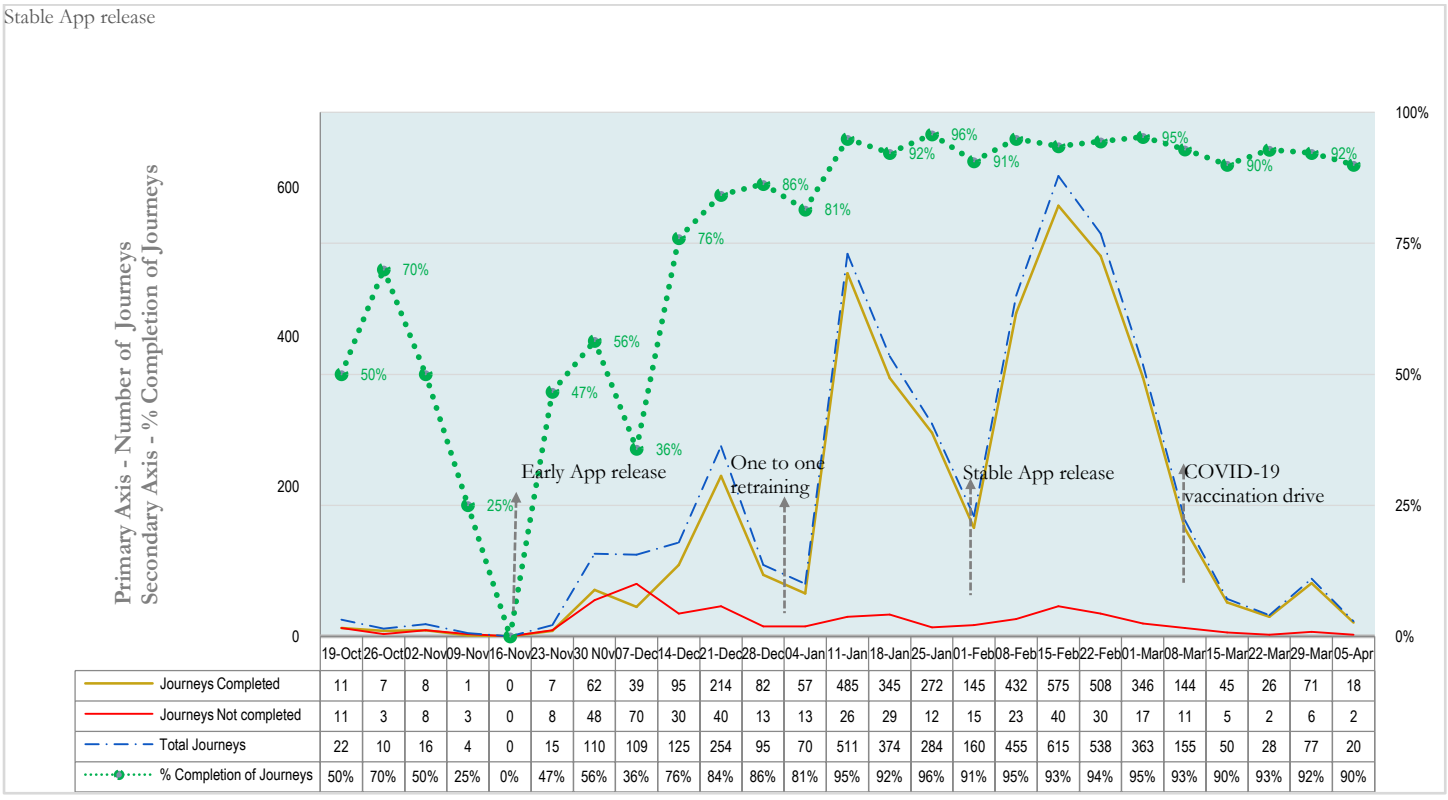
- *"By using this application, my work skills have increased, and I am able to accomplish my tasks quickly"*had a **strong positive correlation** with*"I would like to continue using this tool for my daily routine and work"(ρ = 0.62)*
- *"I can accomplish my tasks more easily quickly"*had a **strong positive correlation** with *"Overall, I am satisfied with the CDS tool"(ρ= 0.61)*
- *"I often need to override the suggestions made by the tool"*had a **moderate negative correlation** with*"By using this application, my work skills have increased, and I am able to accomplish my tasks quickly"(ρ =-0.50)*
- *"I often need to override the suggestions made by the tool"* had a **moderate negative correlation** with *"It integrates/fits easily into my daily routine(ρ =-0.42)*

6.1.3.2. STG Adherence

Two quantitative methods of STG adherence that were adopted included a cumulative STG adherence trend based on an analysis of completed journeys and specific STG adherence indicators for each of the 10 clinical conditions included in the study.

Cumulative STG adherence trend (based on proportion of completed CDSS journeys)

- Cumulative STG adherencerefers to a measure of the overall use of CDSS, regardless of the specific STGs content that was processed by the CDSS engine. When a user completes a CDSS journey then all necessary enquiries, decisions and recommendations that are part of the transformed content associated with the merged STGs is completed. Abandoning a journey midway may be considered as non-adherence to STGs.
  From 21 October 2020 through 8 April 2021, 4460 beneficiary interactions had a clinical decision support session started via the mobile app. Of these, 3995(90%) of the CDSS journeys started were completed by either an ASHA, ANM, nurse or MO. CDSS journeys were not completed in 10% of cases. At the start of the study, many journeys were incomplete possibly due to user hesitation, the learning curve and technical reasons like poor or no internet connection, or software bugs, etc but as the study progressed the numbers of completed journeys increased. The issues were monitored in real-time by the Project Team to facilitate prompt intervention, which resulted in more journeys being completed once the initial technical hitches (prior to December 2020) were sorted (Fig 10).



	19-Oct	26-Oct	02-Nov	09-Nov	16-Nov	23-Nov	30 N0v	07-Dec	14-Dec	21-Dec	28-Dec	04-Jan	11-Jan	18-Jan	25-Jan	01-Feb	08-Feb	15-Feb	22-Feb	01-Mar	08-Mar	15-Mar	22-Mar	29-Mar	05-Apr
Journeys Completed	11	7	8	1	0	7	62	39	95	214	82	57	485	345	272	145	432	575	508	346	144	45	26	71	18
Journeys Not completed	11	3	8	3	0	8	48	70	30	40	13	13	26	29	12	15	23	40	30	17	11	5	2	6	2
Total Journeys	22	10	16	4	0	15	110	109	125	254	95	70	511	374	284	160	455	615	538	363	155	50	28	77	20
% Completion of Journeys	50%	70%	50%	25%	0%	47%	56%	36%	76%	84%	86%	81%	95%	92%	96%	91%	95%	93%	94%	95%	93%	90%	93%	92%	90%

Figure 10: STG Adherence Trend for completed journeys(Oct-2020 to April 2021)

Adherence to Specific STG Adherence Indicators

A more detailed analysis of adherence to specific STG indicators was also carried out from analyzable journeys in the data-set where all the information could be accessed.

Tables 7and 8providesthe STG adherence indicator clinical measures that werecomputed through SQL queries on the Arezzo data base.

Summary of analysis:

- STG adherence for **maternal indicators** was **77.28%** (95% CI: 65.0 – 89.6) with statistically significant mean adherence ($p<0.05$; one sample *t*-Test).

- STG adherence for **paediatric indicators** was **74.96%** (95% CI: 58.1 – 91.8) with statistically significant mean adherence ($p<0.05$; one sample *t*-Test).

Interpretation of STG Adherence measures:

- Majority of the indicators had 100% adherence. However, there were indicators that had less than 5% adherence. Majority of these were a consequence of either practice gaps at the ground level or due to a lack of resources. E.g. Blood sample collection for blood grouping was 3%, but Urine Samples were regularly collected for urine proteins (87%) and sugar (83%), due to entrenched practices followed by the ANMs. Two consecutive BP readings are not taken four hours or more apart if SBP > 140 mmHg or DBP >90 mmHg, again indicating a practice gap.
- Another instance of practice gap in paediatrics is weight and temperature measurement on every visit which is as low as 16%.
- Screening for gestational diabetes mellitus was as low as 1% with zero OGTTs done for screen-positive women. This has a two-fold causation – firstly, as per the medical officers and nurses, there are virtually no cases of GDM in Bahraich, but interestingly there were not dipstick tests or OGTT packs available for screening, which could also signal some level of undetected GDM at the study site.
- Another prominent indicator with low adherence was "Documented referral when indicated", which corroborates with the on-ground findings that indicated low referrals. The research officers did try to do a root-cause analysis of this finding but the analysis was not able to be performed in real time, and thus some of these cases may have been missed. This is an issue that will need to be reviewed in more detail in future studies.
- In Pediatrics, earlier a single developmental delay was triggering a referral with a very low threshold, and it should have been set to only a high-risk level. This was subsequently fixed in the content and unindicated referrals reduced significantly. However, this did impact the overall STG adherence indicator related to referrals.

Details of secondary data analysis over the month of February of the STG adherence is contained in Annexure 6.

Table 7: STG Adherence Indicators for Maternal Health

No.	STG Adherence Indicator	Eligible visits*	No. of visits with evidence of compliance	Adherence (%)
	Antenatal care (ANC) for uncomplicated pregnancy			
1	Documented LMP **	1042	926	89%
2	Documented EDD	1042	1042	100%
3	History taken (specific symptoms, systemic illness, etc)	1042	1042	100%
4	Weight measured	930	930	100%
5	Blood pressure taken	930	930	100%
6	Blood sample taken (for Hb)	889	829	93%
7	Blood sample taken (for blood group, Rh)	683	18	3%
8	Blood sample taken (for VDRL)	889	710	80%
9	Urine sample taken (for protein)	951	827	87%
10	Urine sample taken (for glucose)	889	741	83%
11	Abdomen examined	930	930	100%
12	IFA supplements prescribed	1012	967	96%
13	Tetanus Toxoid prescribed	766	748	98%
14	Calcium supplements prescribed	889	872	98%
15	Anthelmintics prescribed	897	433	48%
16	Counselling done (dietary advice)	1159	1154	100%
17	Counselling done (contraception)	774	702	91%
18	Counselling done (violence)	775	773	100%
19	Counselling done (rest)	1159	1152	99%
20	Referral recommended ***	33	19***	58%
	Gestational diabetes mellitus (GDM)			
21	Screening for GDM (blood glucose)	889	15	2%
22	History taken for signs & symptoms of hyperglycaemia	1343	1343	100%
23	OGTT done for screen positive women	0	0	0%
	Hypertension in pregnancy including eclampsia			
24	History asked (hypertension or pre-eclampsia/eclampsia in any pregnancy or family history)	719	719	100%
25	Two consecutive BP readings taken four hours or more apart if SBP ≥ 140mmHg or DBP ≥ 90mmHg	20	0	0%
26	Test for urine albumin in case of high BP	20	14	70%
	Anaemia in pregnancy			
27	Documented history suggestive of anaemia (pallor, palpitations, fatigue)	1343	1343	100%
28	Haemoglobin test at each visit	889	829	93%
29	IFA supplements – one tablet twice a day	371	76	20%
	Postnatal care			
30	Iron prescribed	138	136	99%
31	Contraceptive advice given	124	121	98%
32	Nutrition advice given	124	124	100%
33	Breast feeding advice given	124	123	99%

* Eligible visits refer to the total number of visits that would have required STG adherence for each indicator. Not all visits required STG adherence for every indicator, depending on the STG recommendation and the role. For example, ASHAs were not expected to take blood pressure recordings on any visit. This is why the number of eligible visits varies throughout the Table.

** Marked as green because not all women were able to provide an LMP but the question was always asked.

*** 14 referral recommendations were not followed because: user overrode the recommendation (4); family reasons (4); transport issues (1); other reasons – not specified (9).

Table 8: STG Adherence Indicators for Child Health

No.	STG Adherence Indicator	Eligible visits*	No. of visits with evidence of compliance	Adherence (%)
	Feeding			
34	Breast feeding within one hour of birth	34	34	100%
35	Counselling done on lactation support, breast feeding, IYCF and KMC (as part of LSU requirements), on complementary feeding and on feeding and recommendations during sickness and health	2569	2569	100%
	Immunization			
36	Documented immunization history as per National Immunisation Schedule (NIS)	2893	2893	100%
37	Recommendations for vaccination as per NIS	1799	1799	100%
	Pneumonia			
38	Documented assessment (signs of pneumonia and pneumonia severity)	2798	2798	100%
39	Documented referral when indicated	16	5	31%
	Diarrhoea			
40	Documented history (feeding, SAM, diarrhoea, blood in stool)	3080	3080	100%
41	Documented assessment (persistent diarrhoea, dysentery, signs of dehydration)	3094	3094	100%
42	ORS packet prescribed when indicated	26	26	100%
43	Zinc prescribed when indicated	26	25	96%
44	Documented referral when indicated	7	2	29%
45	Antibiotics prescribed	47	12	26%
	Care of the sick neonate			
46	Documented history (preterm, LBW, intrapartum/post-partum complications)	356	356	100%
47	Documented assessment (ETAT)	62	62	100%
48	Documented assessment (feeding, crying, breathing, icterus, pallor, cyanosis, abdominal distension, neck rigidity)	356	356	100%
49	Documented referral when indicated	80	31	39%
	General			
50	Documented birth weight	179	128	72%
51	Weight measurement on every visit	3041	492	16%
52	Temperature measurement	3161	521	16%

* Eligible visits refers to the total number of visits that would have required STG adherence for each indicator. Not all visits required STG adherence for every indicator, depending on the STG recommendation and the role. This is why the number of eligible visits varies throughout the Table above.

6.1.3.3. Qualitative data: Focused Group Discussions

Following the quantitative surveys, it was deemed critical to uncover latent insights on the usability, usefulness, and propensity to facilitate adherence to STGs with CDSS through FGDs, that could further enhance the learnings from the results obtained thus far. All study participants were divided into five groups based on their role and district for five virtual FGD sessions. Each FGD usually had the members from a particular cadre so that there was an ease among the participants due to familiarity and no fear of a superior officer's presence. The health functionaries met at a convenient time and place of their choice near their work area. All sessions were attended virtually by the researchers while the project implementation partner representatives present on-site facilitated the meeting through virtual platforms. Although these FGDs externally transpired as informal discussions, the PIs leading the sessions followed a tacit structure that involved broad questions that further led into more specific areas of enquiry, with equal representation from all participants. There was a pre-decided checklist used by the investigators, which largely focused on the same questions as the quantitative survey but intended to unravel the reasoning behind the responses. The sessions were recorded with informed consent on the assurance of anonymity of individual responses.

The responses received in the meetings were broadly classified around the themes of usefulness and usability of the tool and have been organised thematically, on the same lines, below. We have recorded the verbatim comments in Hindi and also translated them into English for easy reckoning.

Usefulness of the tool

We asked the participants as to what was the best thing they liked about the tool to document what were the most useful features from their viewpoint. The responses are documented below clubbed under common thematic domains.

- **It was evident in all the FDGs across all sections of the users that the foremost perceived benefit was a sense of empowerment due to improved knowledge.**
  ASHAs and ANMs commonly supported a general perception of augmentation of knowledge as stated by two of the participants:
  - "ज़्यादाजानकारीमिलीहै"(*Got more information*) and "App सेकाफी knowledge मिलतीहै"(*The app provides a lot of knowledge*),
  - more specific elements of knowledge, as mentioned by another participant "बहुतसारीजानकारीजोहमेंनहींथीवहइस app केज़रिएमालूमहोतीहै, जैसेकीबच्चेजिसतरहबढ़तेहै, किसउम्रमेंउन्हेंबोलनाहै, चलनाहै, जोइसके Questions मेंआताहै, वहहमेंपहलेनहींपताथा(*A lot of information that we were earlier not aware of, we got to know through this app, such as the way children grow, at what age they should talk, walk, which comes in the form of questions, that we did not know before*).
  - There was also a sense of incremental knowledge compared to theearlier state, as suggested by one participant "जोपहलेपूछतेथे, उससेextra हैइस app में (*This app has extra information than what we used to ask earlier*).

- **There was a manifest inclination towards the capabilities of the app to serve as an effective job aide, particularly by ASHAs and ANMs.**
  - Automatic calculations of dates: One participant mentioned "गर्भवतीमहिलाकी LMP से EDD कापतालगजाताहै (*We get to know a pregnant woman's EDD based on her LMP*). "काफीसारीcalculations अपनेआपहोंजातीहैं" (*Quite a few calculations get done automatically*).
    "इसमेंहमटीकालगानेजातेहैतोअगलीतारिकआजातीहै" (*If we go for vaccination this gives you the next date*) said another.
  - Tips for situation specific and appropriate counselling: The app's capabilities to generate sound counseling and referral advice was also appreciated.
    "App जोसलाहबताताहैवोबहुतअच्छाहै (*The advice that the app give is very good*).
    "App मेंजो prompt आतेहैंउसकीवजहसेमुझेज्यादासोचनानहींपडता. App अपनादिमागलगाताहैं (*The prompts that come through the app ensure that I don't need to think too much. The app uses its brain*).
  - A significant insight on the clinical impact of CDSS was that latent High-Risk Pregnancies (HRP) were being uncovered.
    One participant mentioned "इससेहमेयेपताचलजाताहैकि HRP हैकिनही" (*With this we get to know whether it is an HRP or not*).
  - Identification of high-risk pregnancy or a sick child "Tab ज्यादाजानकारीपूछताहै, हमेंपताचलजाताहैकिसको refer करनाहै, किसकोनहींकरना" (*The tab asks for more information and we get to know whom to refer and whom not to*).

    "हमारेकाममेंबहुतआसानीहोगईहै. Referral cases पताचलजातेहै. बहुतसारे suggestions हमेमिलतेहै. (*Our job becomes much easier. We get to identify referral cases and get a lot of suggestions*).

    Another participant mentioned "हम HRP गर्भवतीकोबताभीदेतेहैकिवजनकम हैं, खूनकमहै, चलोहमआपकोदिखालातेहैं" (We tell HRP cases that your weight is less, or you have anemia, let me get you checked).

  - The Clinical Decision Support capabilities were lauded by the medical officers and nurses as well.

    One of the MOs mentioned "इसमेकाफीऐसीचीजेंहैजोहमclinical practice मेंmiss करजातेहै (*There are quite a few things in this app that we usually miss in our clinical practice*). A staff nurse said

"जोचीजहमनहींसोचपातेवोतुरंतहमे suggest होजातीहै (*There are things that we don't think of, but that get promptly suggested to us*).

Another medical officer mentioned "Paediatriciansकोसाराकुछयादरखनामुश्किलहोताहैं. Appमें age केहिसाबसेसाराकुछआजाताहै- treatment क्यादेनीहै, counseling क्याकरनीहै, diet advice येसाराकुछअच्छाहै (*It is difficult for Paediatricians to remember everything. The app provides everything based on the age - what treatment to give, what counseling to provide, diet advice – all of this is good*).

"Patient की history, symptoms, किसे refer करनाहै CDSS सेपताचलजाताहै" (*Patient's history, symptoms, whom to refer to – all of this we get to know from CDSS*) said another MO.

- **The ability to automatically generate clinical summaries also seemed to resonate with the participants.** They **a**ppreciated the fact that a readily organized complete summary is available to them at the end of interaction (for first responders) or when they receive a referral (staff nurses and MOs)
    - "Summary मेंजोपूराrecord आजाताहै, उसमेसारीजानकारीहमेएकसाथमिलजातीहै, वोदेखकेलगताहैकीवाकईमेंअच्छाहै. (*The complete record comes as part of the summary and we get all the information at once – looking at that makes one feel that this is really good*).
    - "लेखाजोखासेफायदाहोताहै, कमसमयमेअपनाकरकेलाभार्थीकोभीसमझादेतेहै" (*The clinical summary is beneficial, we do our jobs in less time and counsel the beneficiaries as well*).
    - "अपनेआप साराकुछ summarize होजाताहै. कुछही point हमे add on करनेपडतेहै, वर्नासाराकुछ summary मेंआजाताहै (*This automatically summarizes everything, and we need to add very few points, otherwise everything comes in the summary*).

- **Some of the participants, particularly at CHC, felt that it helped in an effective continuum of care and possibility of faster care for the high risk / referred cases**
    - One medical officer mentioned "पहलेहमेसारीhistory लेनीपड़तीथी, अभीहमज्यादातरtreatment part हीकरतेहै" (Earlier we had to take the entire history, but now we mostly focus on the treatment part).
    - One medical officer gave a clear description of the impact "HRP load बढ़जायेगा, परयहअच्छाहीहै. हमारेपासफिलहालANC case third trimester मेंआतेहैऔरउनकी screening अगरASHA ANM करेतो HRP काशुरुसेहीgrassroot identification होजाएगाऔरउनकाreferral and management अच्छेसेहोजाएगा, cases improve होजाएंगे. (*The HRP load has increased, however this is good, because we currently get ANCs in the third trimester and if their screening is done by ASHAs or ANMs, a possible HRP can be detected early with grassroot identification and their referral and management will be better and cases will improve*)
    - Patient जबहमारेपासअचानकआताहैतोपताचलजाताहैकिहमनेउसेपहलेदेखाहैकिनही, या ASHA, ANM देखचुकीहैकिनहीं. (*If a patient comes to us suddenly, we immediately get to know if we've seen the patient earlier, or if the ASHA or ANM have seen the patient earlier*) and we do not have to repeat the whole history. *"हमज़्यादाकामहोनेकेबावजूदरेफ्रेडमरीज़कोदेखसकतेहै"We are able to help the referred case appropriately despite our otherwise busy schedule*," said a staff nurse who immediately thereafter had to rush to conduct a delivery.

- **There was also an overall sense of satisfaction with CDSS**that could be extrapolated from comments such as "हमेंविश्वासहैइसपर" (*We have trust in this*), "अभीहमइससेसंतुष्टहै" (*We are now satisfied with this*) and "App आगेभीचलेगातोज्ञानमिलेगा" (*If the app continues in the future, we will get knowledge*).

Usability of the tool

As almost all the participants felt that the tool was useful to them in more than one ways, we wanted to know why did it not reflect as emphatically in their choice for continued usage of the tool. What were the hindrances and challenges which are not making it universally appealing?

- **The biggest concern raised by several participants was the amount of time it takes for data entry.**
    - One participant mentioned "जबहमफीडिंगकरतेहैतोबहुतसीदिक्कतेआतीहै, जल्दीहोताभीनहीहै. एकएकमरीज़केफीडिंगमेंकरीबआधाघंटालगजाताहैकभीकभी"(*When we enter data there are a lot of challenges, it does not happen quickly, it takes almost half-an-hour sometimes to enter data for one patient*).

  On further discussions, **it was clear that the longer time taken was due to several reasons, many not directlydue to the current interaction, *e.g.*** for the creation of the initial registration to create a family record; due to the initial **teething troubles and learning curve**. This was also reflected in the quantitative data as fall in incomplete journeys over time as discussed above (Fig 10).
    - as one participant mentioned "Register करके journey करनेमेंज्यादा time लगताहै, परअगली visit मेंआसानीहोजातीहै" (*It takes a lot more time for registration and then to complete a journey, but in the next visit it becomes much easier*).
    - "Starting हैइसलिएकुछissues लगरहेहै. करतेरहेंगेतोआसानहोजाएगा" (*It is just starting which is why we feel there are issues. If we keep doing it, it will get easier*).

  Another reason cited for more time required for the interaction using the tool was perhaps due to inability to skip any part of detailed history taking while using app. quite unlike prevalent direct interactions which are very pointed and limited like a firefighting approach.

    - "बहुतज्यादाचीज़ेंपूछनीपड़तीहैं।कभीकभीतोबेनेफिशरीकेहताहैक्यादीदीइतनासाराक्यूँजाननाहैहमकोदेरहोरहीहै।(*We need to asktoo much in detail. Sometimes the beneficiaries tell us 'Why do you need to ask so much. We are getting late'*).

  However, when we asked which areas were unnecessary and can be trimmed, there were no suggestions and often the group agreed that its lengthy but is useful.

    - अच्छाहै, सबकामकीबातहैंबसहमअभीतकपूछतेहीनहींथे।*(It is good the way it is because it ispertinent, it is just that we were not asking all this information till now).*

- It also become evident that the technology introduction was a disruptor in several ways. Currently the interaction with beneficiaries is somewhat limited and the expectation of the beneficiary is to get free vaccination or drugs and a quick turnaround. The time investment to create a detailed holistic health record by the provider and the beneficiary has not been made in the past. The present tool asks for more detailed and meaningful interaction to which both the stakeholders are not oriented.
    - It is also **challenging when multiple beneficiaries come together**, as one participant mentioned. "Beneficiariesहमारेहिसाबसेनहींआतेवोपूराझुंडबनाकेआतेहै. वहांएकएककी journey करनाimpossible होजाताहै. (*Beneficiaries don't come as per our schedule, they sometimes come as a group, when completing a journey for each one of them is impossible*).
    - The beneficiaries are not willing / able to give time for the complete detailed history. "लाभार्थीसमयनहींदेपातेहै, जल्दीमेंहोतेहै" (*Beneficiaries are not able to give time, they are in a hurry*).
    - Moreover, **it is currently not possible to see multiple patients together since the app allows only one journey at a time**. "जबतकएक journey पूरीनाहोदूसरीशुरूनहींकरसकते (*Unless you complete one journey, you cannot start the next*).

  Using of a smart device for collecting data may be misinterpreted due to lack of awareness, lamented a MO.

    - "Public ऐसीहैकिवहकहेंगे Doctor साहबmobile परखेलरहेहै, हमेनहींदेखरहेहै" *(The public here is such that they would say the Doctor is playing on his mobile and not seeing us*).

- Another underlying concern which affected the choice of continuing adoption of the tool, particularly among ASHAs, was the fear that it will increase their work load by increased identification of sicker cases. Interestingly, in one of the FGDs, a very motivated and champion user wished to retract her emphatic statement on the benefits of CDSS as it had made her co-workers unhappy for they felt she was asking for a change that is going to increase their workload.

- "औरज़्यादाबेनेफिशरीजकोसेंटरलेकरजानापड़ेगा" *(We will need to accompany many more to the health centers).*

- Thequantitativesurvey hadbrought about some concerns about the referrals being generated by the tool as **some of the recommendations for referrals were perceived to be unnecessary**. However, the participants were emphatic in stating across FGDs that they never had a situation where the app had not suggested a referral when the workers felt it was required.**The users agreed that it efficiently identified all probable referral cases.**
    - "कभीकभीapp refer करनेकोबोलताहैपरहमारीसमझमेrefer करनाजरूरीनहींहोता, परइसकाउल्टाकभींनहींहुआहै" (*Sometimes the app asks us to refer but we don't think referral is necessary, however the vice-versa has never happened*).

Discussion about possible facilitators, challenges and hindrances to adoption of CDSS tool brought some more interesting insights

- **The reluctance to use the tool in part was because the users thought that it will be an additional method and not a replacement of the physical mode** as was clearly brought up at one of the FGDs,involving 10 ASHA workers. When asked how many would like to continue using the app, 6 raised their hands. The four that did not, mentioned the following reasons for their reluctance: limited time available and demanding work, lack of adequate incentives/payments, and the additional work pressures during COVID-19. However, when asked that if the application were to replace the handwritten ASHA register and other reporting requirements, all 10 ASHAs unanimously said they would find it much easier to adopt. This was echoed by others too:
    - One participant mentioned"डायरीवालाकामइसमेहोजाएतोबहुतअच्छाहै" (*If the job of diary (daily registers) can be done by this app, it will be very good*).
    - "अभीदोदोकामहैं. अगर ASHA register कीजगहसिर्फयेapp आजाएतोअच्छाहोगा, क्योंकिबारबारभरनानहीपडेगा" (*Currently we have to do two things. If the ASHA register gets replace by this app, it will be good, and we won't have to duplicate our work*).
    - "OPD मेंdaily register भरनाकमहोजाएगा, हमारेपासएक handy app होजाएगाऔरबहुतआसानहोजाएगा" (*If the need for filling out the OPD daily register gets reduced and if we have a handy app to do this, it will become much easier*).

  However, there was a **concern with a fully digital mode** not being fully reliable

    - One participant, who was an early adopter and had done a lot of cases, mentioned "साराdigital होजाएये possible नहीहै, थोड़ातो manual रहनाचाहिए, अगरapp नाचलेतो" (*It is not possible that everything goes digital. Some of it should be manual – what if the app doesn't work*). (we will have no backup).

- **The issue of incentives was also raised by some participants**
    - "ज्यादासमयनिकालनापडताहै. इसकामकेलिएहमेकोईअलगसे payment भीनहींमिलताहै(*We need to take out extra time for this and do not even get paid for the additional work*).

  But when we reminded them that the app is not adding any new work rather easing their work through in a better and efficient method, it evoked mixed reactions from acceptance to need for better payment or incentives as they felt that they were poorly paid.

- **Suggestions for improvement to improve usefulness and usability**

Several participants had inputs on how to improve the app further. Although many of these suggestions were predominantly around the app workflow, and not directly related to the CDSS, it was felt that these suggestions, if incorporated, would increase the overall value, and consequently, the adoption of CDSS.

- **Internet connectivity emerged to be a critical bottleneck in adoption of CDSS and there was a clear preference for an "offline" mode**.

- One participant mentioned "सबसेबडी problem network कीहैं" (*The biggest problem is that of the network*). Another suggested "बिना internet केapp चलजाए to ज्यादाफायदाहोगा" (*If this works without the internet it will be more beneficial*).

- **The ability to correct data entry errors was perceived to be a critical missing feature of the product.**
  - "गलतentry कोcorrect करपाए" (*We should be able to correct wrong entries*).
  - "किसीलाभार्थीका data feed करदेतेहैऔरवोहमेकिसीगलतीकीवजहसेchange करनापडेतोहमनहींकरपातेहैंऔरफिरसेहमे feeding करनीपड़तीहै" (*If we make a mistake while feeding data and need to change we're not able to do this and have to start all over again*).
  - "CDSS मे next औरbackका system होनाचाहिए. कभीगलतीसेकुछ submit करेतोवो back नहींहोपाता"(*CDSS should have a system for going back and next. If we submit something by mistake, we aren't able to go back*). नएसिरेसेकरनापड़ताहै. We have to restart the journey.

  While the investigators agreed with the need but had concerns about the risk of data fudging by enabling re-entries.

- **A recurring and consistent suggestion was that of capability to generate due lists, missed appointment alerts, area or worker-wise list, an optimized workflow, and notifications to the nurse or doctor on when the beneficiary is scheduled to be seen by them**.
  - "Due List add होसकेतोउससेकाफीसुविधाहोजाएगी / बच्चोंकेटीकेकी due list आनीचाहिए" (*If a due list can be added, it will be very useful, a due list for pediatric vaccination should come*).
  - The need for a PNC due list was expressed clearly "डिलीवरीहुईऔरहमप्रसवोत्तरमाहमेंफीडिंगकरनेचलेगएतोहमेंदिखाईनहींदेता, तोहम CDS कैसेकरे(*If a delivery happens and the woman becomes postnatal, then we can't seethe patient details in app so how can we do the CDS?).*
  - *"*App ने indicate करनाचाहिएकीकोइ visit छूटगई" (*The app should indicate that a visit has been missed*).
  - "गर्भवतीमहिला delivery केबादअपनेआप lactating mothers कलिस्टमेंचलीजाएतोहमाराकामआसानहोजायेगा"(*After delivery if the mother gets added to the lactating mothers list, it will become much easier*).
  - "OPD में photo लेकरहमरातमे journey complete करतेहै. Time slot होऔर referral list होतोअच्छेसेकरपाएंगे"(*We take photographs of the case record and complete journeys at night (because of the rush in VHND). We will be able to do this better if there are time slots and referral lists*).
  - "Referral मेंoption होनाचाहिएकीहमकहा refer कररहेहै, मरीजकोकैसेभेजरहेहै, औरउनको alert करपाए. जैसे CHC पेrefer करोतो CHC पेहीजारहाहो, किस doctor कोrefer कररहेहै. जानकारीसबकोहोनीचाहिएऔर tab सबकेपासहोनाचाहिए" (*There should be options in referral – where are we referring, how are we sending the patient, and alerts. E.g. if we are referring to the CHC, the patient should go to a particular CHC and to a specific doctor. Everyone should have the information, and all should have the tab*).
  - "VHNDमे patient Register करकेjourney करनामुश्किलहै. हमेपतानहींचलताकिASHAनेVHND केलिएpatient Register कियाकीनहीं. कभीकबारdouble registration भीहोजाताहै" (*It is difficult to register patients during busy VHNDs. We don't get to know whether the ASHA has registered the patient for VHND. Sometimes there is duplicate registration*).
  - "Journey next day करनेकीसुविधाहोनीचाहिए, कुछदिक्कतहोतोलाभार्थीक specially बुलाकरadvice देपाए" (*There should be a facility to complete a journey on the next day. If there is a problem, we should be able to specially call the beneficiary and give them advice*).

- **Medical Officers suggested some improvements in clinical content.**
  - One MO mentioned "इसमें NCDs add होनीचाहिए" (*This should also cover Non communicable diseases)*
  - Another MO suggested "इसमेdifferential diagnosis का hint होनाचाहिए, जिससेहमारीpersonal knowledge में improvement होसके" (*This should have hints on differential diagnosis, so that there is improvement in our personal knowledge*).
  - "थोडी language clear होनीचाहिए. एक answer केदोअर्थनानिकले" (*The language should be clear. One answer should not have two meanings*).

- **There were concerns about the multiplicity of mobile apps, particularly the ANMs.**. One respondent mentioned that there were too many apps being introduced. The Government is also

releasing the ANMOL app which they are required to use. If all of them get integrated into one simple app, it will be much easier to use.

7. Discussion

This feasibility study to assess the usefulness, usabilityand adherence to STGs, with the use of CDSS in Indian public healthcare settings generated significant insights into the pre-study rationale, beyond conclusively proving the research hypotheses.

Transformation of clinical guidelines to a digital interactive smart tool

Feasibility of transformation of local guidelines and developing smart clinical decision support tools for use by health functionaries in the community and primary care settings was firmly established. Even though this pilot proof of concept study had worked only with few maternal and pediatric (under five yrs. age)conditions considered important from public health viewpoint, yet it demonstrated the ability to convert these into a reliable digital tool with complete fidelity to the written guidelines across various selected conditions and even with situation where more than one of these co-existed. The users had a choice to use the tool either in Hindi or English language.

Empowerment of Front-Line Healthcare Workers

There wasvast appreciation of the ability of the tool to usefully add value to interactions with the beneficiariesby the users.As was evident from the surveys and FGDs, the **CDSS intervention empowered FHWs at every stage**, with the **augmentation of knowledge that came sequentially at the right point in the flow in each screening journey**, so it **acted as a fantastic job aide for everyone**. This came out strongly from all the three cadres of the study participants. While ASHAs and ANMs remembered very less of their pre-study guidelines training sessions, the app reduced such kind of memory attrition, because the tool takes one through the whole process of evaluation and brings up all the relevant questions required for an individual patient, and the FHWs do not have to struggle to find what guidelines apply. There was also a strong sense of empowerment since the study **extended the FHWs' horizon into some areas that they had previously never worked on, like developmental milestones**, which they'd never used in the past because the recently introduced MCP card was not a part of their routine.

Broadly, the benefits accrued are described here.Firstly, the **knowledge of FHWs was augmented through CDSS**, based on reliable and extensive information gleaned from selected guidelines. Relevant advice within the CDSS app was generated at the right time and strategically placed to be invoked when it was required at the point-of-care. Normally they would have to refer to a guideline and look up static information, but the CDSS app is designed in such a way that relevant clinical information came as part of the flow, at the right place and at the right time, empowering FHWs with knowledge in context of the workflow. **Secondly the attitude of FHWs was also positively impacted** through better structured advice. They felt more confident in their interactions and appreciated the structured and detailed action-oriented advice relevant to the caseproduced by the tool.**Thirdly**, the workers also appreciated that the tool was more **comprehensiveand reliableas it never missed a case which required referral.** The structured summaries which were available at the end of an interaction made the functioning efficient and complete. This critical point of impact was made by several participants, particularly the MOs as they highlighted**the ability of the app to empower ASHA's and ANM's to systematically screen, identify and timely refer high-risk cases particularly HRPs** in early pregnancy rather than in third trimester when it is too late. The MOs expressed a clear desire to **augment the CDSS app with additional elements like differential diagnosis** and **suggested inclusion of conditions like non-communicable diseases (NCDs)**, indicating need for feature augmentation for improved acceptability.

Task Shifting and provision of seamless continuum of care

Although the actual process of effective task shifting is a gradual process, there was **a successful demonstration of the potential of task shifting with the CDSS intervention** as part of this study. Due to

the thoroughness of the app in capturing an entire visit in the form of a lucid summary, by the time the beneficiary reached the next level of care, a significant part of necessary clinical information was already available, and it reduced duplication of effort that occurs each time a frontline worker interacts with a patient. The app can also serve as **a two-way communication tool, between ASHA and ANM for seeking opinion and advice by sharing case summary and between ANM and MO, without the ANM needing to accompany the patient to higher center**. The ANM can send details that can be accessed by the MO and initiate management under the supervision of the MO. This provides a unique opportunity of **continuum of care** for an individual as long asthey are within the system. This also provides an opportunity to seamlessly provide escalation and de-escalation of healthcare-related activities to any beneficiary.

As there was clear documentation of the interaction and the MO has the opportunity to verify the inputs from ASHA/ ANM on a particular case, it provides an opportunity for on-the-job support and training to these functionaries through feedback. The opportunities to analyze which healthcare workers need to be trained on better health screening, based on information about practices available within the system, can **accommodate capacity-building efforts towards effective task shifting.** The timely and contextual cognitive guidance willmake theASHA or ANM more confident in taking on higher responsibilities with time. Through the CDSS App, **information capture has partially moved to the lower cadre and treatment has moved to the upper cadre in the field**, whereby medical officers just verify the history and assessments, reconfirm and add on to the treatment, if required, resulting in an optimized workflow and conducive grounds for task-shifting. In addition, this also provides credible information for supportive supervision across the cadre.

The clinical impact of such task-shifting could be significant. Clear communication between ANM and MOs can **optimize referrals, and early detection of HRPs**, when the ANM is able to send a list of HRP referrals and the staff nurses as well as MOs at the centers exactly know which patients are expected and whom to prioritize. This could also reduce waiting times for HRPs who would receive treatment and intervention earlier. Further, **follow-up care could also be shared with the MO in a two-way communication model**, allowing patients to be sent home on supervised domiciliary treatmentwith effective follow-up care by ANM and ASHA. This, in some ways, is step-down care in the reverse continuum, which is also one aspect of task shifting, economical and a patient and facility-friendly output. Some eligible high-risk patients can get care at home without disrupting their family life, income, or affecting caregivers, by seeking care closer to home and improving its acceptability. It will also allow fast turnover of inpatients in the higher centers like CHC. Task shifting is not merely about a complex task being performed at a lower hierarchy, but it is also **sharing of tasks**, which is extremely important from a public health point-of-view, especially in terms of breaking the silos, that most systems are currently working in,thus making the care continuum more efficient.

Acceptability of CDSS

Usability and usefulness of CDSS were two primary outcome measures that inherently impact its acceptability by FHWs. Some manifest benefits that accrued with CDSS included the **optimization of the continuum of care** through better two-way communication between the ASHA, ANM, Staff Nurses and Medical Officers based on the **automatically generated clinical summaries** obviating the need for personally accompanying patients. Also, a **longitudinal record grounded in health screening and clinical information ensures continuity of care** even if physical records like the Mother-Child Protection (MCP) card are misplaced.

Acritical insight was that **workflow improvements in the operational part of the App will have a bearing on the acceptability of CDSS** since the operational and clinical elements of health screening go hand in hand.The ability to integrate optimized workflows with CDSS recommendations is a powerful combination, allowing for due-lists, alerts, and reminders along with evidence-based screening and recommendations. This is do-able but was beyond the scope of the present proof of concept study which largely focussed on establishing feasibility of the idea of adoption and conversion of the guidelines to a computer interpretable format and creating a decision support system customised to the country guidelines.

Data Provenance

Arezzo® demonstrated the ability to generate high-quality clinical data sets during usage as part of the FHWs workflows during the study and this holds a lot of potential for further analysis and use in the

future. This operational and clinical data can lend itself to post-hoc analytics leading to a **secondary gain in terms of an increase in district-level data about care delivery, referrals, and outcomes.** It is also critical to realize that while electronic data does get captured as part of the workflow, the eventual **analytics processes need to be thought out at the outset**, specifically in terms of what reports, dashboards and views are required, how the data is indexed and standardized. The granularity of this data can be from the district-level to the PHC-level and further to the individual FHW-level, signifying a major potential for supervision and real-time monitoring. It must be supported with a simplified information retrieval process which is navigable evenby non-technical functionaries. The eventual goal would be to ensure that the desired analytic views are available at the click-of-a-button with the ability to drill down to the individual FHW-level, which is critical in terms of root cause analysis in terms of contributory factors such as deficiencies in infrastructure, **training and guide actions required.** This will enable early identification of weak spots in the system and weak links to direct focussed interventions to strengthen them instead of generalized interventions for all. This couldresult in effective and real time course correction and enable the system to reach predetermined goals efficiently without waiting for time and manpower consuming nationwide surveys every 5-10 years. Also, the possibility of district-level dashboards linking outcome measures to region-specific practices and training needs for FHWs is a significant public health opportunity. In fact, if used at scale, it **holds the potential to partially automate NFHS-like national surveys**.

8. Lessons learnt and lateral insights for future studies

Lack of Harmonized Standard Treatment Guidelines

The biggest issue that the research team faced in adaptation of STGs was the **lack of harmonized and updated guidelines** for most conditions. There were some variances observed between guidelines. Thus, e.g., what the ASHA Module recommends was at variance from what the SAANS (Social Awareness and Actions to Neutralize Pneumonia Successfully) program contained. The research team had to reach out to several functionaries to get a sense of the expected updates to guideline since they were cautious of introducing any element that was not part of existing guidelines and that could confuse health workers. A solution to digitize guidelines does partially address this issue, primarily by identifying the underlying fragmentation in order to institute corrective action. Another challenge faced was due to **vertical health programs that are focused on one problem**, but when it comes to an individual patient there usually are overlapping symptoms, and this can create a lot of confusion, especially with more than one terms describing it across different guidelines. Thus, the **need for harmonization of guidelines is also at the level of guideline-specific-language**. The PIs and ERG had to spend efforts to**merge multiple guidelines and** help the developingteam **to** create CDSS solution with the ability to **render them seamlesslyto the FHWs**, and thus the Arezzo® technology could facilitate the continuity of care required with comorbidities, complications, and disease clusters.

Another critical issue faced by the research team was the presence of rather out**dated guidelines**. Maternal guidelines from GOI have not been updated for quite some time now, and thus there were **mismatches between practices at the ground-level and published guidelines**, especially for ASHAs and ANMs. There were also some published guidelines that had not been implemented yet such as Anemia MuktBharat, GDM guidelines, and the research team had to join those pieces together. While health is primarily a state subject, there are vertical National Health Programs financed by the Central Government. But there are variations at the State-level implementation of these programmes as the State can always adapt these programmesby whatever they think is relevant to their own region.Also, some elements that are there in the guidelines may not exist in the periphery, especially due to lack of resources. However, the starting point of such a digital solution should be **a common minimum agenda that is acceptable across different state level health functionaries**. It is important that the final product is not devised in purely top-down approach and includes local adaptations for a confusion-less transition to digital mode. Importantly, the**process of digitization makes STGs more dynamic, improves the ability to harmonize various guidelines, leading to faster dissemination and therefore, may be more efficient way for implementing changes / modifications to guidelines.** Further the ability to capture practices in different areas enables uncovering of gaps that can be addressed in trainings or updates, thus improving the process of implementation of guidelines.

As for the adaptation of STGs to CIGs,**the process of content transformation to digitize guidelines was quite challenging**. Firstly, a change in the mode of delivery of guidelines into a format where the FHW would screen beneficiaries with initial questions and then leading questions based on previous responses required a thorough deconstruction followed by reconstruction of the STGs to align it in a conducive format. Further it took time for the research team to become familiar with the content transformation processand for the technology team to become more aware of locally relevant clinical practices. Furthermore, the need to incorporate increasing levels of sophistication in the upstream hierarchy of the healthcare workers required a cadre-wise distinction of various parts of STGs that did not always specify who had to execute what part of the guideline and how one could cater to variable patient cohorts based on their socio-economic status and level of education. This further complicated the scope of the content transformation process. Also, the level of manual effort involved in making small changes to the CIGs was something that took time. However, the delay in starting phase 2 due to COVID allowed a prolonged Phase 1 to the investigators to fine tune the conversionprocess. In the initial phases, a small change would shake the whole journey so incorporating changes in the app was a challenge and time-consuming task.

Local-language translations posed a significant challenge in this study. There was significant effort put in by the research team for Hindi translations and the process of using spreadsheets to communicate these translations to the technology team based in London (not familiar with Hindi) was not optimal leading to several iterations and rework.Although the local-language at the study site was Hindi and most of the research team was comfortable with Hindibut further changes had to be incorporated later in the implementation phase based on the user feedback. This largely resulted from differences from the acceptable or understandable vocabulary /locally used hindi words. Future scale-up efforts into other local languages will require fool-proof translation processes with involvement of few well-versed local health functionaries early on.

<u>Lack of protected time or incentive for study participants, COVID pandemic related disruptions</u>

Time and timing (occurrence of pandemic) were the biggest limiting factorsfor the study. The teams were working across continents and the time differences impacted coordinationand added to delays despite all efforts by the teams to find a time slot on a regular basis. Notwithstanding extended study period due to the COVID-19 pandemic, local restrictions and reorientation of the health care entailed that the opportunities were still limited for effectively evaluating workflow optimization. As ASHAs are notfull-time health functionaries, absences due to local festivals, social reasons and health or confinement also impacted the workflow.

Many homebased activities were suspended due to COVID hence related guidelines could not be evaluated in the context of continuum of care visit by visit. It affected evaluation of interventions during follow-up visits and the impact of the Home-Based New-born Care program. The study team could not stay in the field for long time for non-participant observations of the interactions. Shadowing of interaction with the beneficiary which were planned real time was not possible even virtually due to network issues in the field. The team had to resort to deferred virtual assessment and facilitation, usually in the afternoons or evenings after the workers were back to their stations.

With the raging pandemic that required the FHWs to put in additional effort for COVID-19 screening and vaccination, there was a significant increase in their workload and lack of a regular availability of the workforce for the study purpose.There was also an underlying **concern amongst the FHWs that the app is likely to increase their workload** without an increase in their remuneration. This feeling came in due to required partial duplication of effort since the existing manual workflows continued and the FHWs had to make data entries into the app for beneficiaries that met the inclusion criteria only for the purpose of the study. This led to a slow uptake by the workforce. The FHWs did not fully understand that this was in a study-mode and that the workload would decrease after the study, either by replacing the manual registers with the app, or by going back to status-quo, which is the reason why some of the FHWs were hesitant and not fully forthcoming on their feedback during the FGDs. The critical support by project execution partners Piramal (PSMRI) in the field under direct supervision by NITI Aayog was greatly helpful in execution of this project by convincing, motivating and monitoring the FHW participating in the study.

Nascent technology implementation in geographies with infrastructural challenges

The project was testing implementation of a customised technical solution in a nascent area in an aspirational remote district of the country. In addition to the customisation and adaptation it required a local vehicle for frontline access. In the absence of any individual electronic health records, it required a local digital vehicle to capture the patient or beneficiary related data. The local server then had to connect with the customised CDSS tool in an anonymised way. This system architecture created many challenges as it required a well synchronised functioning. As the Amrit app on which the CDSS tool (Arezzo) had to ride was also new and in its agile evolutionary phase, there were time lags in identifying problems and providing solutions.

This first prototype developed under the project **lacks many enhanced features in its user interface as CDSS had been riding on a new app environment.** The **prototype app also did not have an edit capability** or the ability to go back and forth between screens, which resulted in the need for restarting a journey if a data entry error was made. This requirement was unanimously voiced by most participants during the survey as well as the FGDs and is a critical requirement for future releases of the CDSS app.

In particular, the need for due lists and appointment-scheduling was a significant requirement stated by the FHWs. However, there was also some hesitation in expressing this feedback clearly, since the addition of such features would increase the transparency in the system leading to a higher level of accountability on the part of ASHAs and ANMs. Get data functionality essential for continuum of care from ASHA to ANM to MO could be made available towards the end of study with limited time for the HCWs to assess its usefulness.

There was also **a learning curve with the app**. The first visit involves registration of the beneficiary and takes time to enter demographic and social information before a CDSS journey can be initiated. Thus several participants reported usability issues, in terms of time, however, it was also evident that during subsequent periods the workflow was more efficient and progressively the data entry requirements reduced and the CDSS aspects of the app became more prominent, the journey itself took much less time. Moreover, the CDSS app ensures detailed history which wasn't elicited earlier and the FHWs weren't accustomed to this, but over the study period the benefits of this initial history became apparent, and several users gave positive feedback about its usefulness, despite some issues with usability in the short term.

Network connectivity was a significant bottleneck, and it was evident that the clear preference is for an app that can work in the offline mode. Technologically, it is possible to create an asynchronous app that has a device-level memory and that can further be synchronized once network is available, however this kind of app architecture was not available for the study and connectivity did impinge on the usability of the app significantly.

Hesitancy and unfamiliarity withlikely benefits with new technology among beneficiaries

There were quite a few **challenges with the CDSS workflow when beneficiaries presented as a group**, like in the case of VHNDs. While the expectation of beneficiaries is to be done within 2 or 3 minutes, the app would require significantly more time, sometimes up to 30 minutes, and the beneficiaries were not willing to wait for so long, due to their domestic and work-related priorities. Further, without a prior experience or clear **understanding of the benefit that such systems will provide to the beneficiary** there was also no clear trade-off that was apparent to the beneficiaries who were part of the study. The pertinent issue that emerges here is **what incentives do beneficiaries have to participate in a health system that is enhanced with knowledge-based technology** and addressing this would be a major implementation challenge in the future. This in many ways requires a cultural change in the community and their expectations from the healthcare delivery system. This comes with experience of the benefits and its word-of-mouth propagation within the community. The **value of preventive and promotive care in the minds of most people, including educated people, is far less than the curativeservices**. This is essentially the area that requires a cultural shift in the community as well as the workers.

Study design and plan limitations

A major limitation of the study was that it this initial POC prototype was **restricted to 10 conditions in maternal and child health**. This meant it was not possible to track all potential comorbidities and disease

clusters. Several beneficiaries did present with other common conditions or were of a different age group and the study design did not accommodate all of those due to its scope and inclusion criteria. An initial study had to avoid an uncontrolled scope that would have impinged on the primary outcome measures of usability, usefulness and adherence to STGs. However, it would be ideal to overcome this limitation in future study designs to assess the impact of a wide coverage of conditions like communicable and non-communicable diseases. It may be useful to do a pre study survey in the facilities to be included and list out all possible common conditions with which patients under consideration present and include most of those so that the HCWs use the app for all or most and not selectively.

There was also a **limitation in terms of the geographic coverage of the study sites**. Only a limited number of SCs, PHCs, CHCs and their constituent health workers were a part of this study. This impacted the follow-up of patients and referrals at the CHC, limiting the process of tracking referred patients.

Future implementation studies which will require some further degree and detail of customisation (e.g. being mindful of local language, cultureand practices) shall need to be planned in a more participative manner rather than a top down approach. The team may need to shadow-learn working of the end users and take specific inputs from them before and during the study to fine tune the final product as per their working and job needs. The planning period has to be fairly long and widespread to capture a detailed picture. The current study could have resulted in a better product if we could have done all the planned interactions which got impacted due to COVID. Learning from the improvement philosophy of Japanese industry - "Kaizen" may be pertinent here. It has three important components called 3G; which involves having the managers go to the actual floor (*gemba*); looking at the actual products involved (*gembutsu*) and gathering as many facts about the situation as possible (*genjitsu*) to plan improvements.

It is also important to **consider all the preparatory elements required for the study**. The need for a stable app, local language translations, technical integration to be completed prior to the commencement of the study was a key learning lesson from this study. Further the study site selection, transition period for training, absorption of technology, as precursors of the study would ensure **a higher level of preparedness before initiating the actual implementation process** and **ensuring that implementation challenges do not obscure the actual benefits of the study**. The preoccupation of the HCWs with their daily activities interspersed with focused activities left them with limited time to focus on learning this new technology. Familiarizing all HCWs with electronic data management of all beneficiaries would be a welcome first step for sensitizing them to this concept. Use of CDSS could then follow.

Our study was designed as a **qualitative feasibility study and did not directly address the impact of CDSS** on health outcomes. After having conclusively ascertained the feasibility of implementing CDSS in public healthcare settings, through primary outcome measures of usability, usefulness, and adherence to STGs, **future research efforts into CDSS need to be directed towards impact assessment, aimed at the direct effect of a CDSS intervention on health outcomes.**Such kind of an impact assessment would require a different study design and would need to be conducted over a longer duration since the effect of CDSS on health outcomes is a gradual process and it takes time for such interventions to start becoming visible in direct health outcome measures related to clinical effectiveness, morbidity and mortality. The indicators used for the study were, firstly, on the perception of participants and, secondly, on adherence to guidelines. An impact assessment study would entail verification of compliance on the ground, either through secondary surveillance systems or direct supervisory monitoring, aspects that were out of the scope of this study.

While a **Cluster RCT with and without the intervention of CDSS could be a valid study design, this methodology is fraught with the risk of uncontrollable confounding variables** between two study sites – in terms of locally relevant practices, language, dialect, infrastructure, healthcare administration and similar factors.

A before and after study design could partially offset these confounders but this need be calibrated with the right mix of study participants, clinical conditions, and an appropriate study duration. Ideally a study design that has an initial 'before' phase to evaluate current knowledge, attitude, practices and health indicators needs to be sequenced with an 'after' phase that has a considerable 'run-in" phase

toaccommodate the time it takes for any intervention to have an actionable impact on health outcome measures. This duration needs to be ascertained by statistical extrapolation of existing health indicators and ongoing health programs but is not likely to be lesser than 24-36 months.

Further **the choice of primary outcome measures is critical**. While the current study design included quantitative STG adherence measures, these were based on compliance of FHWs to recommendations contained within STGs. **For a through impact assessment study the indicators would be more proximal to the actual health status of beneficiaries and would be a combination of process and outcome indicators**. *E.g.* Anemia would include process indicators relating to the prescription of IFA, Anti-helminthics, medication adherence at the community level, and outcome measures relating to the Hb trends at the population level, and the impact of interventions on anemia over a period of time, since the supplements would take at least 12 weeks to have a measurable impact on anemia at the population level as well as in special groups like post-partum patients. Also, it would require that the outcome measures be cross-functional since simple interventions in combating anemia would result in remarkable improvements in other health indicators too.

The future studies certainly also need to take into account the technical issues related to functioning of the app and the intelligent controller ecosystem (software, server, internet access, rapidity of response, *etc.*).

Expanding from learnings from the study, with inputs from the multi-disciplinary steering group, the way ahead will need to use enhancements of the app as well as beyond it. The possible preparatory steps will need development of, action oriented implementable guidelines to cover the whole gamut of primary health care services and convert them to computer interpretable formso that the app replaces the paper registers in the implementation study area completely. The tool should have capacity to be the first care step for patients to get advice.

While that advancement happens, testing of the app with a large base of end-users may be useful to find, execute and fine-tune some important technical solutions required to remove the stumbling blocks, *e.g.:*

a. Solutions to decrease latency and ensuring almost no denial of service from the server when multiple users are using the app at the same time, due to which the requests may not be serviced by the app.
b. Solutions to decrease impact of lag due to slow internet connectivity in fringe areas by:
    - reworking out app with whole corpus of questions, prescriptions and other details being locally present in the handset itself or have some other local caching mechanism available over the site. It will also help to prevent fast drainage of battery owing to much network traffic going back and forth.
    - using local edge client servers for making sure that static components of the content are delivered from local edge servers, and dynamic components can be fetched from the cloud periodically to ensure there is low latency in content fetching.

Possibly, an easy to use interface can also be developed to assist self-guidance of the patients, based on their symptoms (like tele-medicine). Technology aided customized solutions have the potential for improving access to appropriate care through intelligent decentralized guidance. The use of telemedicine has just started during the current pandemic and definitely looks promising to continue as an additional tool for expanding the reach of health care.

Beyond the context of the present study, we do realize that there are immense possibilities for use of technological solutions to fill gaps and strengthen health care. Partners from technological, medical and field implementation ecosystems within India should work together to create solutions using artificial intelligence and machine learning. We need to test how far the conversational AI can be developed to improve the access for those who find it difficult to read and respond.

Intelligent solutions could be devised to harness the information collected through community users to identify early trends of a disease outbreak or to assess the health of the community from the nutritional data, illness records, etc. The use of digital technology could not only help task sharing and shifting across the various level of health functionaries but also between the man and machine, thus filling up some of the gaps due to low numbers of trained doctors in the periphery.

9. Conclusion

The present study conclusively demonstrated the feasibility to transform country guidelines and create advance data analytics to develop acustomized clinical decision tool. It required the local experts to harmonize and develop the guidelines to assist their metamorphosis to computer interpretable format. The expertise of the creative partners at Elsevier ensured **integration of "Arezzo®" - an active Declarative AI clinical decision support system to**an indigenous local app**.**The**adolopement**process had utilized all the elements *viz.* adoption, adaptation as well as development to create the final prototype**.**

We also established that the integrated CDSSis usable and useful to health workers in primary and secondary healthcare settings and is preferred by over three fourths of the users for continued adoption. Provision of Arezzo® customized for Indian guidelines-based recommendations empowered the frontline worker as it acted as an able job aide with resultant improved recognition of high-risk cases in the community. It showed added potential for efficient task share and task shift of care across the health care functionaries from community to FRUs and *vice versa*. The study results are convincing enough to support development of next version tools with further enhancements.

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11.Annexures

Annexure 1: Arezzo® Validation

The regulatory authority in the UK (MHRA) has advised that Arezzo does not need to be registered as a medical device currently. This is because: Arezzo provides explicit recommendations with clear rationales (i.e. is not a black box); the clinical user can review all data that has been used by Arezzo; and the user can access the primary source content at any time. External Legal Counsel has confirmed the same findings for the FDA and the European regulatory authority.

The original research work for Arezzo® was carried out by Imperial Cancer Research Fund (ICRF) in the UK. The work continued under Cancer Research UK, after the merger of ICRF. ICRF set up the Advanced Computational Laboratory with the primary research objective of ensuring existing cancer treatments of known efficacy are used to maximum benefit, whilst new treatments are being developed. The research and early prototype work are set out in the book 'Safe and Sound: Artificial Intelligence in Hazardous Applications', written by Professor Fox and Dr Das (ISBN: 978-0-262-06211-4).

Following delivery of the first Arezzo prototype, a series of research studies were carried out. These studies were the equivalent of phase 1/2 trials, seeking to understand what the potential benefits might be within the research laboratory:

CAPSULE Study

- Research objective: determine potential impact of Arezzo on prescribing by GPs
- Research design: Decision support vs unaided choice; 42 UK GPs, who made choices from a simple alphabetic list (control condition) or a computer-generated shortlist with a patient-specific rationale (arguments for and against each option on the shortlist).
- Outcome/s: CAPSULE demonstrated a 70% increase in GP decisions that matched those of an expert panel; a 50% increase in selection of a cheaper but equally effective drug, and decisions were made 15% more quickly.
- Publication: 'CAPSULE: Routine prescribing in general practice'. Walton et al. British Medical Journal 1997, 315:791

CADMIUM Study

- Research objective: determine potential impact of Arezzo on detection of breast cancers during mammography screening.
- Research design: Decision support vs unaided interpretation; 4 radiographers made decisions based on mammogram images with and without CDS interpretation.
- Outcome/s: Radiographers trained to interpret mammograms performed better when using the advice provided by CADMIUM: correct assessments of abnormalities were significantly increased and incorrect judgements were significantly reduced.
- Publication: 'CADMIUM: Detecting abnormalities in breast cancer screening'. Medical Image Analysis, Taylor et al 1999, 3 (4), 321-337.

RAGS Study

- Research objective: determine potential effect of Arezzo CDS on detection of familial cancer risk.
- Research design: Argumentation vs statistical vs paper and pencil; 36 GPs managed 18 simulated patients: 6 with a computerised decision support system (RAGS), 6 with an established pedigree drawing program designed for clinical geneticists (Cyrillic), and 6 with pen and paper.

- Outcome/s: RAGs resulted in significantly more appropriate management decisions than either Cyrillic or pen and paper. RAGs also resulted in significantly more accurate pedigrees than the other methods. 33 doctors (92%) preferred using RAGs overall.
- Publication: 'RAGS: Computer support for interpreting family histories. Emery et al British Medical Journal, 2000, 321; 28-32.

LISA Study

- Research objective: improved accuracy of prescribing.
- Research design: Decision support vs unaided care; A web-based decision-support system was designed to facilitate access to full blood count information across geographical locations and to assist with dosage for maintenance chemotherapy. 36 clinicians with varied experience decided on oral chemotherapy doses for 8 simulated cases: 4 with CDS; 4 without.
- Outcome/s: Significantly reduced the number of erroneous prescriptions (0/144 with CDS vs. 54/144 without; P <0.0001).
- Publication: 'LISA: Chemotherapy decisions in acute lymphoblastic leukaemia'. Bury et al British Journal of Haematology, 2005, 129, 746-754.
- These studies suggested that Arezzo could provide benefit, which led to more rigorous randomized controlled trials:

HAVANNA Study

- Research objective: reduction in HIV viral load.
- Research design: Cluster-randomised, multi-centre international controlled trial; HIV/AIDS patients underwent viral genotyping; HIV specialists randomized to use CDS or clinical judgement to prescribe anti-retroviral therapies.
- Outcome/s: 30% reduction in viral load in patients treated with Arezzo versus no CDS.
- Publication: C Tural et al. The Havana Trial. AIDS. 2002; 16:209-218.

FASTEST Study

- Research objective: reduction in all-cause mortality and vascular events; adherence to guidelines.
- Research design: Multi-centre, single-blind, cluster randomized, controlled trial (29 clinics) comparing electronic decision support guided management with usual care for TIA/stroke.
- Outcome/s: More intervention patients received guideline-adherent care (131/172; 76.2%) than control patients (49/119; 41.2%). 90-day stroke or TIA occurrence was lower in the intervention group (2.3%) than the control group (8.5%). User feedback was positive.
- Publication: 'Diagnosis and management of patients with acute stroke'. Ranta et al Neurology 2015 14; 84(15), 1545-51.

Several non-regulatory validation studies have been carried out with the national implementations of Arezzo®:

- Early Referrals Application (ERA) – implemented UK Department of Health guidelines for improving early detection of suspected cancers. An independent evaluation of the solution, which was used by GPs in Leicestershire, demonstrated a 30% reduction in inappropriate referrals and a significant improvement in the quality of referral documentation, as determined by cancer specialists.
- NHS Direct Health and Symptom Checker – delivered patient-facing online health and symptom checking CIGs via a website, syndication feeds, and mobile apps. In the first year the use of this service resulted in 1.3M fewer visits to other healthcare services, including 0.7M visits to GPs, saving the NHS

an annual total of £57M1. The solution also detected the second wave of the H1N1 pandemic in the UK in late 2010. More than 65 million users utilized the solution over 5½ years, with no reported clinical incidents.

- NHS24 telephone triage solution – is operating with Arezzo® live in Scotland since May 2016. The solution delivers CDS to clinical and non-clinical call handlers. It has been used to support more than 2 million calls. The solution integrates more than 300 separate CIGs into a unified call journey, utilizing Arezzo's innovative ability to merge CIGs. Call times have been reduced and a recent evaluation has shown that significantly fewer patients require GP appointments or visits after using the service.
- Great Ormond Street Hospital for Sick Children (London, UK) – where Arezzo® is being used to manage complex diagnostic endocrine and metabolic pathways, integrated with the electronic medical record. The solution has improved the safety and efficacy of the pathways execution, as well as saved one FTE junior doctor equivalent in resources.

In New Zealand where the solution is integrated with electronic medical records for more than 90% of family physicians. It has been used for more than 8 years. New Zealand has one of the highest rates of childhood asthma in the world, with 20% of children affected. In 2009 BPAC NZ established a Childhood Asthma programme for GPs which included Arezzo® CDS to help record patient histories and give advice on medication/hospitalisation. There was an average of 25.5 hospitalisations per 100 child-years prior to their first assessment with the BPAC module, and an average of 12.1 hospitalisations per 100 child-years following assessment, i.e. 2.1:1 hospitalisation before compared with after (95% CI = 1.2 to 3.7, p=0.01). At the same time in Australia, Arezzo® CDS was used by the largest health insurance provide to support a national workplace health solution. The solution resulted in a significant improvement in the quality of recommendations, as well as the efficiency of the service.

Annexure 2: Survey Questionnaires

For ASHAs:

General Details						
Role	**ASHA**			Facility Name:		
Age Group	< 20yrs	20-45 yrs	> 45yrs	**Location**		
Gender	Male		Female	**No. Years of Work Experience**		
Language Proficiency	Can Read-write and understand well	Can read-write little but understand well		Cannot read-write. Understand well.	Cannot read-write. Understand little.	Cannot read-write. Cannot understand.
Hindi						
English						
Other:						
Which language above:						

#	Questions	Response				
1.	How much time do you spend in advising women on reproductive health, pregnancy and taking care of young children including immunizations?	<5 min	5-10 min	10-15 min	15-30 min	>30 mins
2.	How many households to you visit weekly for above?	<10	10-25	25-50	50-75	>100
3.	Do you maintain records for above?	Yes		No		
4.	Is recording manual or electronic?	Manual		Electronic		
5.	When a new treatment guideline is released, are you given any training	Yes		No		
6.	If yes, what is the quality of training:	Very Poor 1	Poor 2	Neutral 3	Good 4	Excellent 5
7.	How many hours are allotted for training?					
8.	When new guideline training is given, rate your experiences with respect to:	Very Poor 1	Poor 2	Neutral 3	Good 4	Excellent 5
	Retention of knowledge					
	Ease of recollecting					
	Ease of reading/referring to the manual					
	Ease of reaching out to doctor					
9.	For making any recommendation, do you contact/refer to	Doctor/Nurse		Manual		Both
10.	How often do you refer to the guideline after its release/training?	Never	Only once	2-3 times	As and when required	Always till I am well verse with it
11.	Do you use any digital tool for daily routine?	Yes		No		
12.	If yes, what is the name and its purpose? (probe around: name, what is it for, integration with daily routine, user experience, how does it help, limitations)					
13.	If there is a tool which will help you in making clinical decisions/recommendations by personalized data analysis based on guidelines, will it be helpful?	Yes		No		May Be

General Details						
14.	What could incent you to use a tool like this? (money, time saving, help in becoming more knowledgeable….)					
15.	Which phone or tablet, if any do you use and since how long? (Type of handset: Feature/smartphones)					
16.	How will you rate yourself in terms of:	Very Bad 1	Bad 2	Average 3	Good 4	Very good 5
	Reading from a mobile device/tablet					
	Typing into a mobile device/tablet					
	Navigating through multiple screens					
17.	Any other suggestions and Feedback you would like to provide					
18.	What data do you need to provide on a regular basis to the center? If this app can help collect data electronically for automatic upload, will it be useful?					

For Doctors and Nurses

General Details						
Role (circle one)	**Medical Officer / GNM / ANM**			Facility Name:		
Age Group	< 20yrs	20-60 yrs	> 60yrs	**Location**		
Gender	Male		Female	**No. Years of Work Experience**		
Language Proficiency	Can Read-write and understand well		Can read-write little but understand well	Cannot read-write. Understand well.	Cannot read-write. Understand little.	Cannot read-write. Cannot understand.
Hindi						
English						
Other:						
Which language above:						

#	Questions	Response				
1.	How many patients on average do you see daily?	<10	10-25	25-50	50-75	>100
2.	What is the average time spent in one consultation (symptoms, diagnosis, taking medical history, checking past medical reports, prescribing medicine)	<5 min	5-10 min	10-15 min	15-30min	>30 mins
3.	Do you record patient's past medical history?	Yes		No		
4.	Is recording manual or electronic?	Manual		Electronic		
5.	How is the recording done? (Probe around: registers, process, storage, retrieval, etc). If electronic, tablet, mobile, computer).					
6.	How is the quality of records in terms of:	Very Poor 1	Poor 2	Neutral 3	Good 4	Very Good 5
	Completeness of the record (All data fields are captured)					
	Correctness of the records (All the information is correctly captured)					
	Legibility of the records (Can read and understand the records to act)					
7.	Continuing with Q7, what is the reason for poor record quality (If Q7 score is 2 or less than that)					
8.	Do you know what standard treatment guidelines (STGs) are?					
	For Medical Officers:					
9.	When a new treatment guideline (STG) is released, how much time does it takes to study and remember the guidelines?					
10.	How often do you refer to the guideline after its release?	Never	Only once	2-3 times	As and when required	Always till I am well versed with it
11.	How do you monitor the STG adherence of your staff (nurse/ANM/ASHA)? (probe around – Who does it, frequency, is this data documented, what action is taken compliance is low/poor)					
	For Nurses:					

General Details						
12.	When a new treatment guideline is released, are you given any training	Yes			No	
13.	If yes, what is the quality of training:	Very Poor 1	Poor 2	Neutral 3	Good 4	Excellent 5
14.	How many hours are allotted for training?					
15.	When new guideline training is given, rate your experiences with respect to:	Very Poor 1	Poor 2	Neutral 3	Good 4	Excellent 5
	Retention of knowledge					
	Ease of recollecting					
	Ease of reading/referring to the manual					
	Ease of reaching out to doctor					
16.	For making any clinical decisions/recommendations do you contact/refer to	Doctor		Manual		Both
17.	How often do you refer to the guideline after its release/training?	Never	Only once	2-3 times	As and when required	Always till I am well verse with it
	For everyone:					
18.	Do you use any digital tool for daily routine?	Yes			No	
19.	If yes, are you comfortable using this tool?	Yes			No	
20.	If yes, which tool and for what purpose? (probe around: name, what is it for, integration with daily routine, user experience, how does it help, limitations)					
21.	If there is a tool which will help you in making clinical decisions/recommendations by personalized data analysis based on guidelines, will it be helpful?	Yes		No		May Be
22.	What benefits do you foresee with the above tool in your daily routine?					
23.	What according to you will promote its uptake among the other doctors/nurses/ASHA workers?					
24.	Which phone/tablet do you use and since when?					
25.	How will you rate yourself in terms of?	Very Bad 1	Bad 2	Average 3	Good 4	Very good 5
	Browsing the internet					
	Typing/texting on phone or tablet					
26.	Any other suggestions and Feedback you would like to provide:					
27.	What data do you need to provide on a regular basis to the center? If this app can help collect data electronically for automatic upload, will it be useful?					

Final Scoreard:

Please rate the following about your experience with the clinical decision support tool:

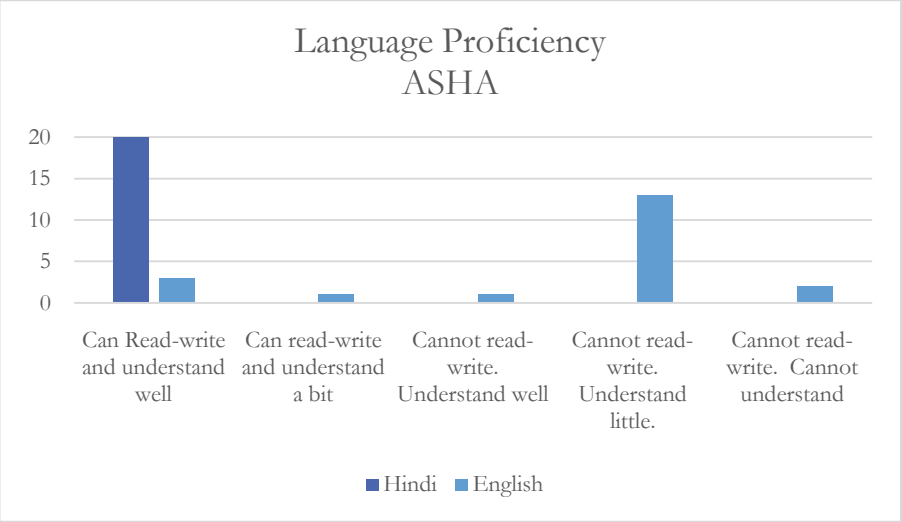
		Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5
	Overall, I was satisfied with the CDS tool					
	Usability					
1	It is easy to use					
2	The information is organized and displayed in a logical manner					
3	Recording patient data and navigating through the workflow is seamless					
4	I am able to access the particular guidelines as and when I need them.					
5	I feel comfortable using this tool in social/community setting					
6	The tool integrates/fits easily into my daily routine					
7	I am able to accomplish my tasks more easily by using this tool					
	Usefulness					
1	My productivity has increased					
2	The quality of my interactions has reduced due to the time spent in entering data and reading instructions from the tool					
3	The toolgives me more information on what toadvise patients than I possess					
4	I am more confident when I talk to patients about their conditions and recommendations					
5	I am able to accomplish my tasks more quickly					
6	This tool helps me remember all diagnostic procedures to be advised					
7	This tool helps me make better clinical decisions					
8	This tool helps me administer the right drug at the right dose					
9	This tool enables me to determine which patients should be referred					
10	I often need to override the suggestions made by the tool					
11	I would like to continue using this tool for my daily routine and work					
	Other Comments:					

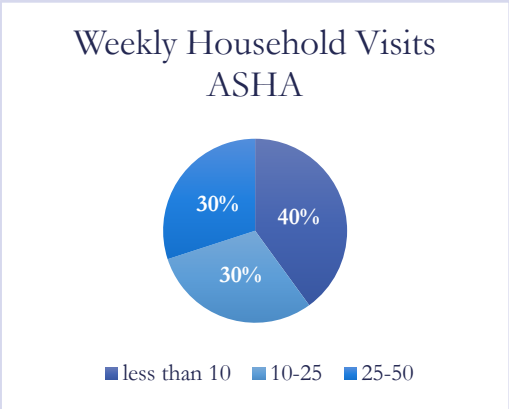
Annexure 3: Baseline Survey Results

ASHAs

The average age of the 20 female ASHAs was 29.4 years and their average experience was 5.4 years.

All 20 (100%) of them could read, write, and understand Hindi well, but only 3 (15%) could read, write, and understand English well. 13 (65%) could not read or write English, but understood a little, whereas 2 (10%) could not read, write nor understand English. It was thus evident that Hindi was the appropriate medium of instruction and not English.



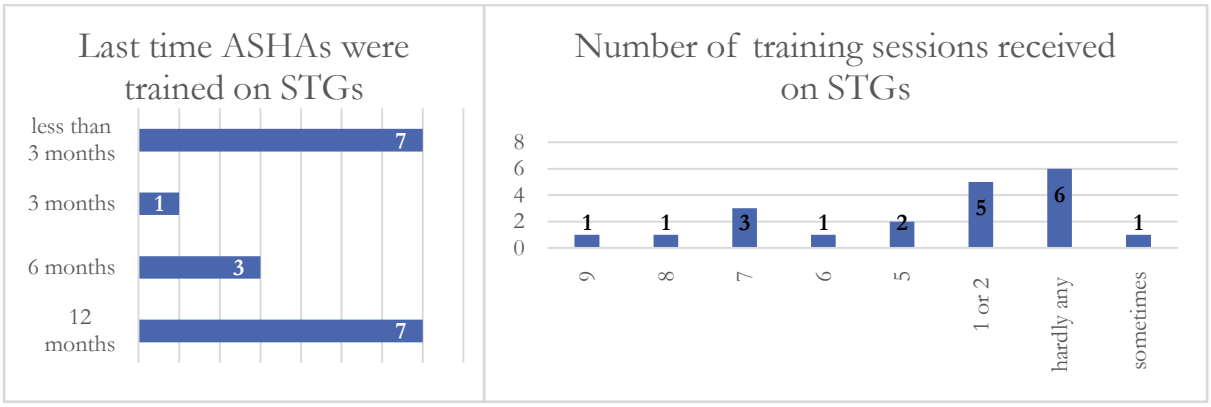


40% of the ASHAs visited less than 10 households a week, 30% visited between 10-25 households and 30% visited between 25-50 households.

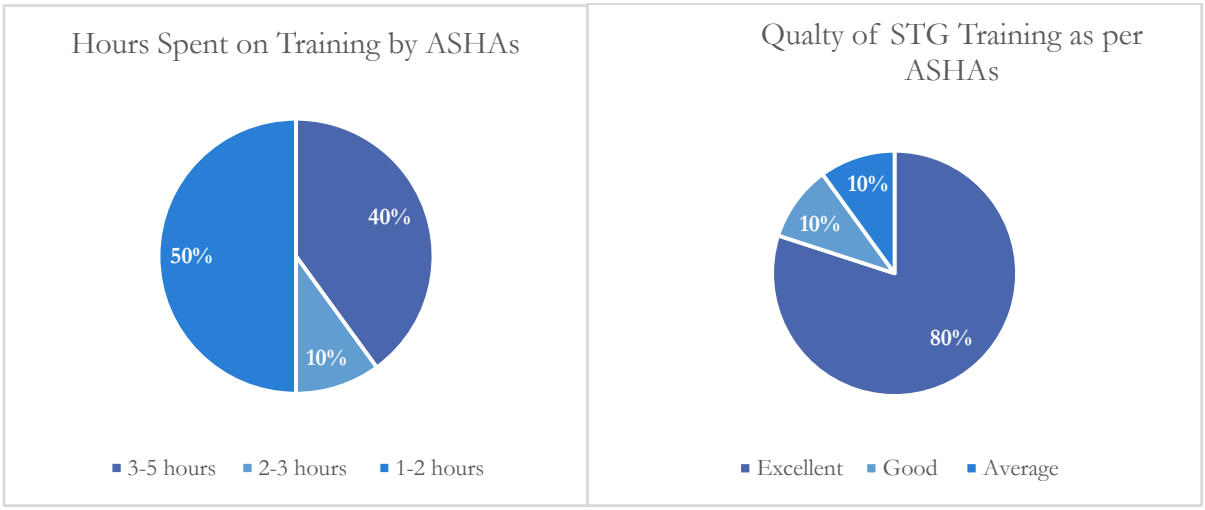
The average time spent on advising women on reproductive health, pregnancy and childcare including immunizations was 10-15 minutes.

All 20 (100%) of the ASHAs maintain manual records in the form of registers that they have access to for tracking individual or family health. The registers have separate sections for maternal and child health, where they record current symptoms as narrated by the beneficiaries.

All 20 (100%) of the ASHAs knew what Standard Treatment Guidelines (STGs) are. 7 (35%) of the ASHAs were trained on STGs one year ago, 3 (15%) were trained six months ago, 9 (45%) were trained less than three months ago and 1 (5%) was trained less than one month ago.

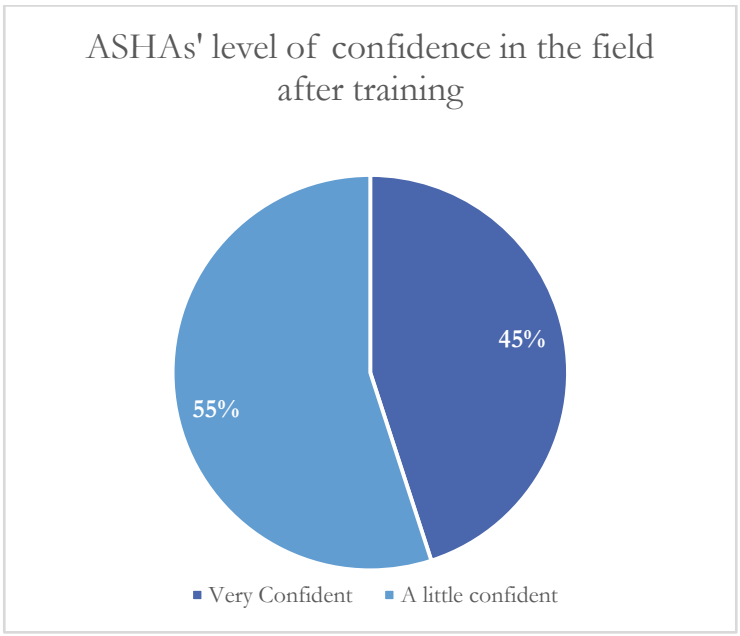


There is a wide variation on the hours spent on training - while 50% of the ASHAs responded saying they spent 3-5 hours, 40% spent 1-2 hours and 10% spent 2-3 hours.



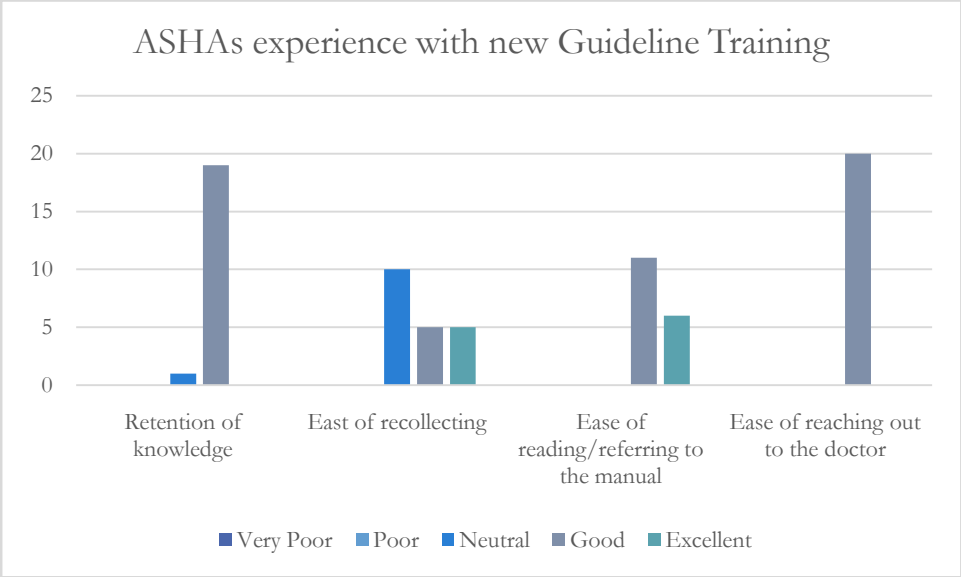
However, majority of the ASHAs (80%) perceived this training on STGs to be excellent.

As for the level of confidence in the field after training – 55% of the ASHAs felt a little confident and 45% felt very confident, and none of them reported having low or no confidence.

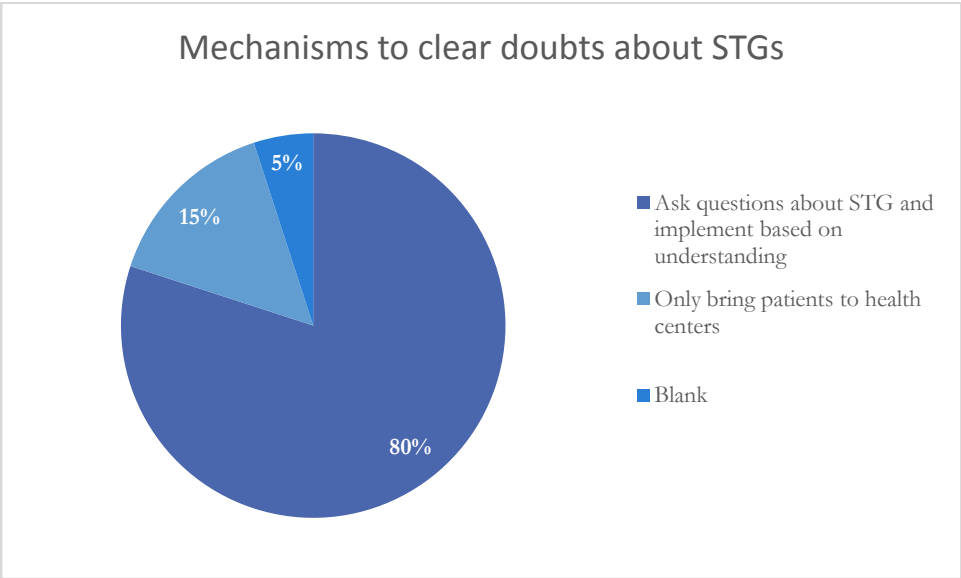


Post new guideline training all the 20 (100%) of the ASHAs responded that they refer to the STGs as and when required. The ease of referring to paper-based manuals was perceived to be good by 55%, excellent by 30%, and average by 5%, while 10% were not sure of this.

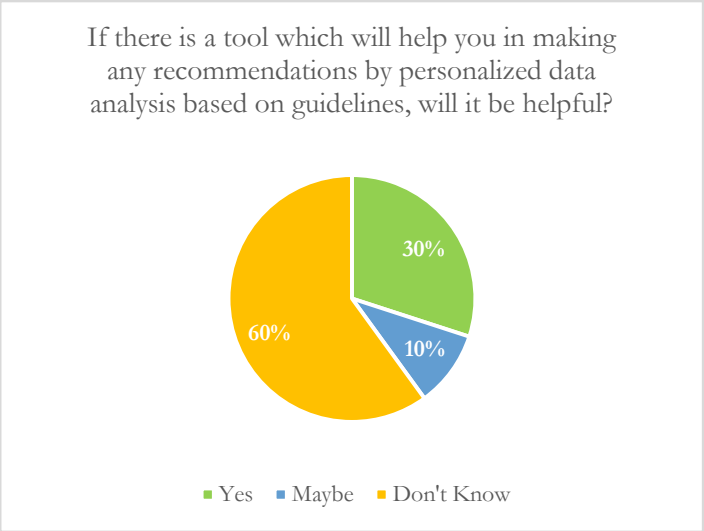
Their overall perceived retention of knowledge was good (95%), but the ease of recollecting was divided between neutral (50%) to good and excellent (25% each). The ease of reaching out to doctors was perceived as good (100%).



All 20 (100%) of the ASHAs responded positively to receiving handholding on the field. In case they are not clear about STGs, 80% of them ask questions about STG and implement guidelines based on their understanding, 15% of them are only mobilizing patients to health centres. All 20 (100%) of the ASHAs consult with either the Medical Officer, ANM or the Nurse for giving any care advice, treatment, or referral.

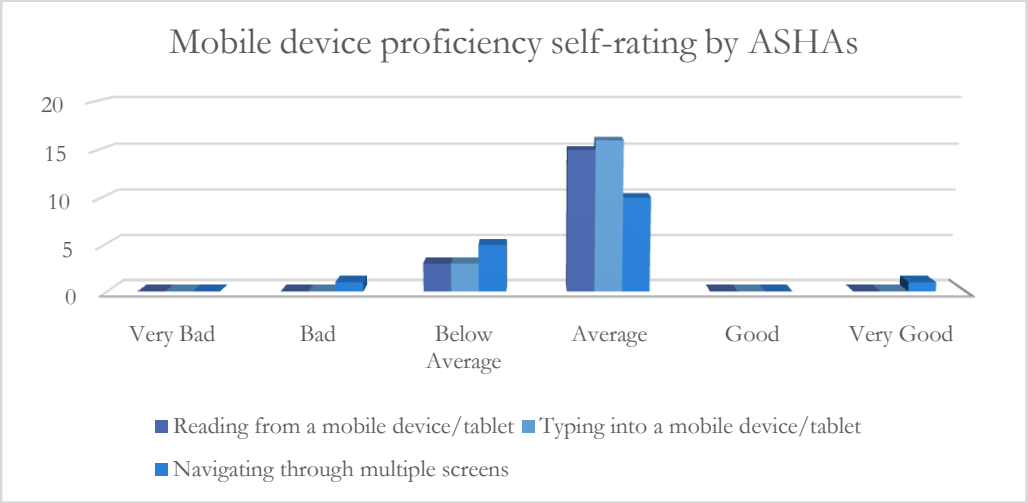


None of the ASHAs used any digital tools for their daily routine at the time the base-line survey was conducted. 60% of the ASHAs responded "don't know" when asked if it would be helpful to have a digital tool that helps them make recommendations through personalized data analysis based on STGs. 30% responded positively and 10% responded "may be". Thus it was evident that the level of awareness to the potential of digital health was low, however there were 6 ASHAs who responded positively prior to the Phase 2 kick-off and the hypothesis was that this number would increase post the phase 2 study completion.



The biggest perceived benefits to use such a digital tool were to save time and increase their knowledge, with 9 (45%) of the ASHAs responding positively to this. However, 11 (55%) of the ASHAs had perceived difficulties using such a tool, including 3 who thought it was not possible to use this tool at the site.

Only 5 (25%) of the ASHAs used smart phones and none of them had used a tablet device. Majority of the ASHAs rated themselves average or below average in terms of various functionalities of mobile devices or tablets.



All 20 (100%) ASHAs responded positively when asked If an app can help them collect data electronically for automatic upload.

Subjectively, the suggestions and feedback of ASHAs included:

"Consulting ANM or doctor is what I always do. I am ready to get trained and work on the tablet."

"Sometimes it is a bit cumbersome to transfer the patient to the doctor as we have to wait for them and sometimes the patient denies to go, it takes a lot of time to convince them.""

"I love the nature of my work and feel excited and happy doing it."

"I have never used tablets and never entered data electronically. So I am excited to look forward for the training on the tablet and then implement it in the field."

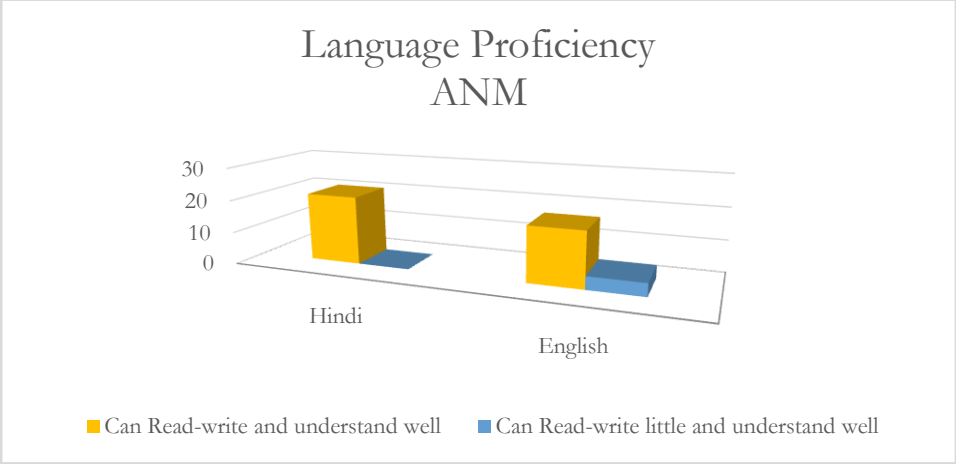
"Consulting ANM or doctor is always satisfactory for us and I am very positive toward the role I have been given and I find no difficulty in doing the same. I am ready to get trained and work on the tablet. I think this will take less time as against the manual method we use."

"My suggestion would be to provide features of camera, watsapp in the tablet so that if there is no network atleast we can click the photo of the information of the patient and later feed the information into the tablet. Alsowatsapp would help in sending the information to the higher authorities."

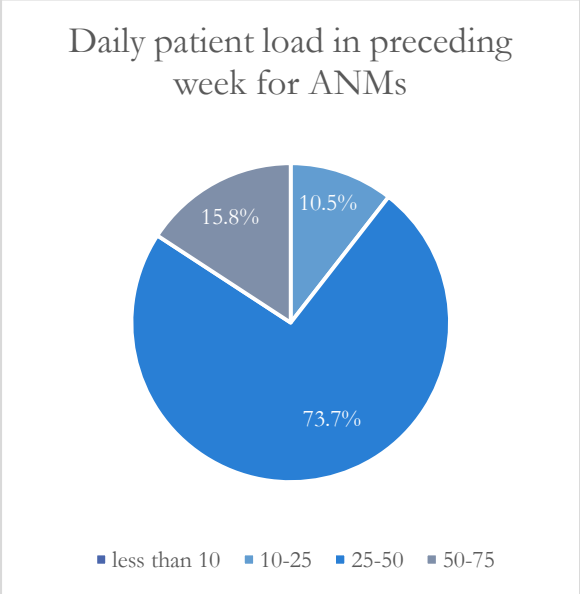
ANMs

The average age of the 21 female ANMs was 30.3 years and their average experience was 3.5 years.

All 21 (100%) of them could read, write, and understand Hindi well; 17 (81%) could read, write, and understand English well, and 4 (19%) could understand English well, but could read and write a little. It was thus evident that English proficiency was much higher in ANMs as compared to ASHAs.



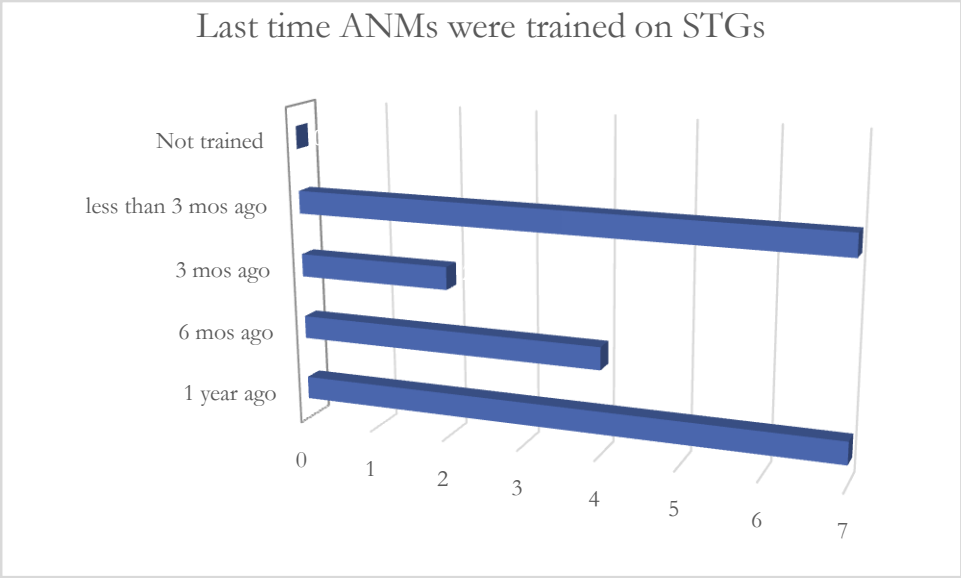
2 ANMSs (9.5%) saw between 10-25 patients daily in the preceding week, 14 ANMs (67%) saw between 25-50 patients per day, whereas 3 (14%) saw between 50-75 patients per day and 2 (9.5%) saw more than 100 patients per day in the preceding week.



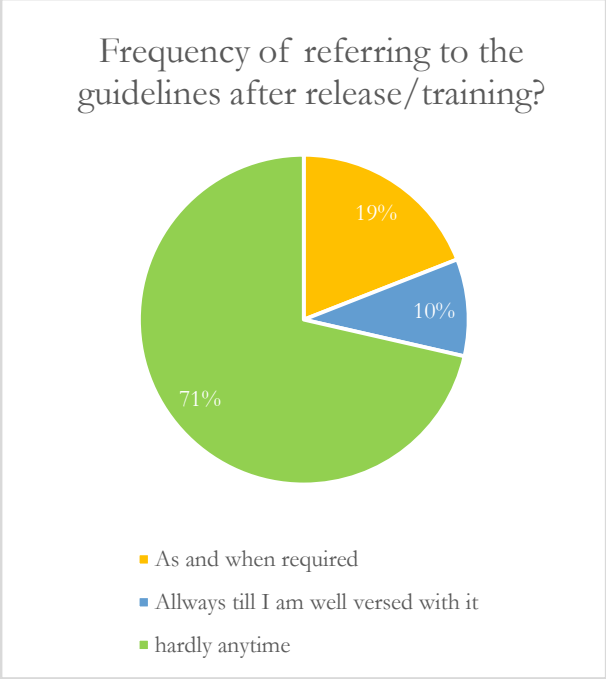
35% of these patient interactions took 10-15, minutes 40% took 15-30 minutes and 25% took more than 30 minutes. The average time spent on advising women on reproductive health, pregnancy and child-care including immunizations was 10-15 minutes.

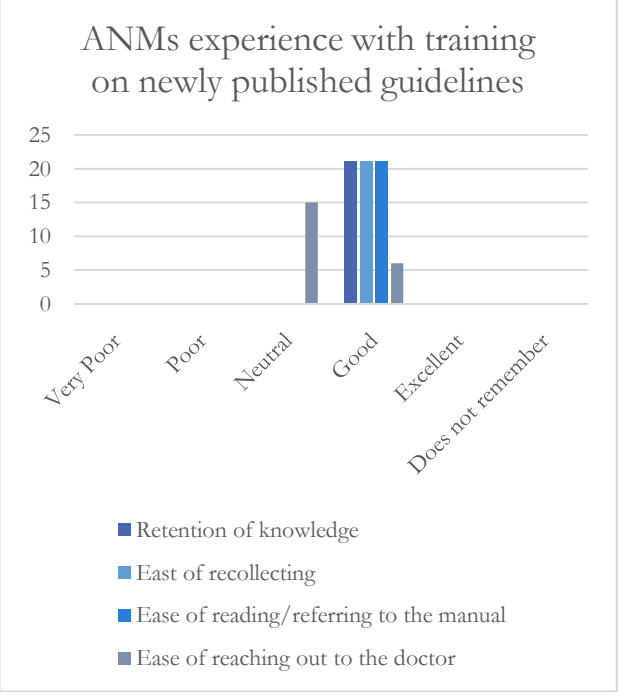
While 20 out 21 ANMs maintain manual medical records of beneficiaries in registers, one ANM maintains records both manually and electronically on the phone. ANMs maintain manual records in the form of two registers - ANC and master registers – that are stored in the almirah of the office and can be accessed any time for tracking individual or family health.

All 21 (100%) of the ANMs knew what Standard Treatment Guidelines (STGs) are. 7 (33%) of the ANMs were trained on STGs one year ago, 4 (19%) were trained six months ago, 7 (33%) were trained less than three months ago and 1 (4%) did not remember.



ANMs receive training manuals which they use as and when needed for self-study after the training sessions. 4-5 hours are allotted to re-training or post-training support. Majority of the ASHAs perceived this training on STGs to be good (62%) or excellent (32%).

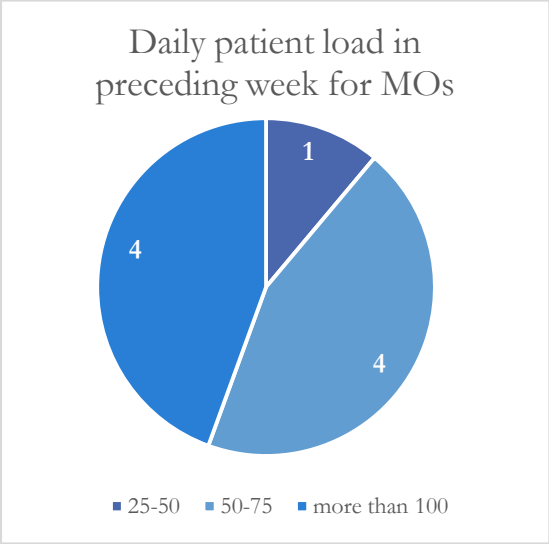




71% of the ANMs hardly refer to these guidelines once published and training concluded, 19% as and when required, and only 10% refer to the guidelines always until they are well versed with it.

ANMs overall perceived retention of knowledge, ease of recollecting, ease of referring to the manual were all good (100% each).

However, on the ease of reaching out to Doctors 15 (71%) were neutral and 5 (28%) rated this as good, showing definite opportunities for improvement in access to Doctors for ANMs, especially given the fact that 71% of them reach out to Doctors for making any clinical decisions/recommendations.



Only one ANM reported using a digital tool, but all 21 of them are comfortable using digital tools. 62% of the ANMs responded "may be" when asked if it would be helpful to have a digital tool that helps them make recommendations through personalized data analysis based on STGs. 5% responded positively and 10% responded "may be".

16 (76%) of the ANMs used smart phones and 5 (24%) used feature 'dumb' phones. None of them used a tablet device. 14 (67%) of the ANMs rated themselves good in terms of various functionalities of mobile devices or tablets, whereas 4 (19%) rated themselves are very bad.

Subjectively, the suggestions and feedback of ANMs included:

"Training sessions are very much helpful for us. When we find difficulty, we ask the trainers. Also, we look at the guidelines and material given to us during training.

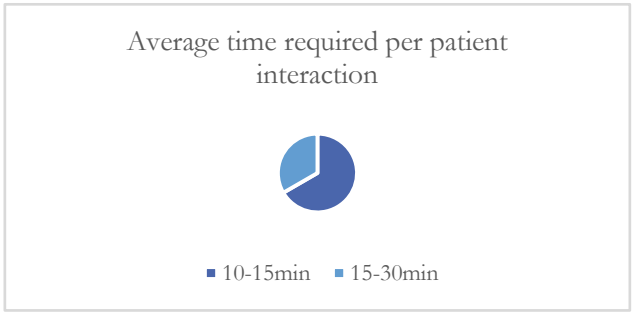
"There is a weekly AAA meeting i.e. ASHA, Anganwadi and ANM from 9 to 4 pm. It is scheduled for every Thursday and all the weekly records (pregnant women and 0-5 years children) of ANM are tallied with the ASHA's records. All the ASHA diaries are checked. The list of children which are due for vaccination are also discussed."

"I would love to work on the tablet if training is given. I find training very useful for execution of our work."

"In case of vaccination day, we are very busy. There is no private space to take the fundal height."

Medical Officers

There were six male MOs and 3 female MOs who participated. All 9 of them could read, write, and understand English and Hindi well.



Four MO's saw between 50-75 patients daily in the preceding week, 4 MOs saw more than 100 patients per day, whereas 1 MO saw between 25-50 patients per day in the preceding week.6 MO's took 10-15 minutes per patient interaction whereas 3 MO's took 15-30 minutes.

All 9 MO's maintain manual medical records of beneficiariesincluding current symptoms as narrated and additional screening questions on common and relevant illnesses. None of them used any digital tools for daily routine work, however all of them were comfortable using digital tools.

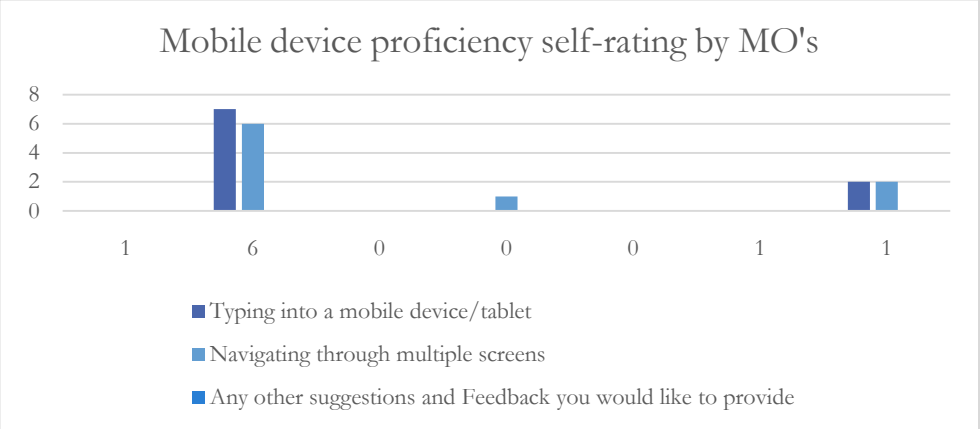
(What benefits do you foresee with the above tool in your daily routine?)

All 9 MO's (100%) thought it would be helpful if there is a tool which will help them in making any recommendations through personalized data analysis based on guidelines.

However, 8 of the MO's thought the use of the tablet-based digital health tool was questionable and 1 responded 'don't know' to the question about promoting the uptake of such a tool amongst doctors/nurses/ASHA workers.

All 9 MO's knew what Standard Treatment Guidelines (STGs) are and take 15-30 minutes to study and remember it and then refer to it as and when required.

6 of the MOs rated themselves good in terms of various functionalities of mobile devices or tablets, whereas 2 of them rated themselves as very bad.

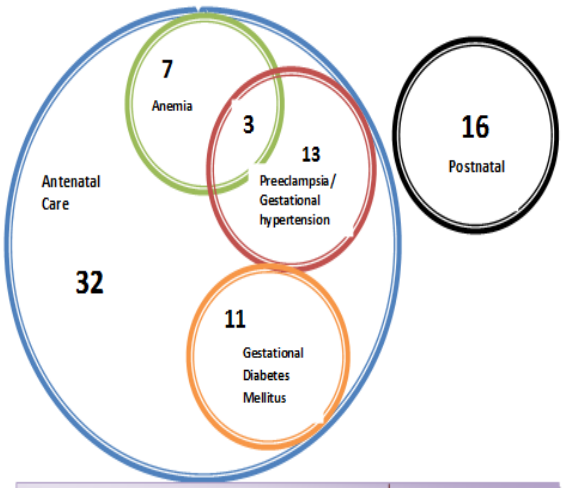


The MO's overall feedback was evident from their responses for suggestions - 4 were not interested, 3 were neutral, 1 could not say if it would work and 1 was interested. The feedback from MO's also was that their schedules were very busy especially with COVID-19 duties.

Annexure 4: Phase 1 testing case mix

Maternal Cases (Retrospective from record review during Lockdown Period) n=82
No. of Journeys 357 (continuum of Care Journeys completed for ASHA → ANM → Medical Officer)

	Cases = 82
ANC-without any complications	32
ANC with 1 or more complications 2. Anemia in Pregnancy 3. Preeclampsia/Hypertension Eclampsia 4. Gestational diabetes	34 5. 10 * 6. 16 ** 7. 11
Post-natal	16

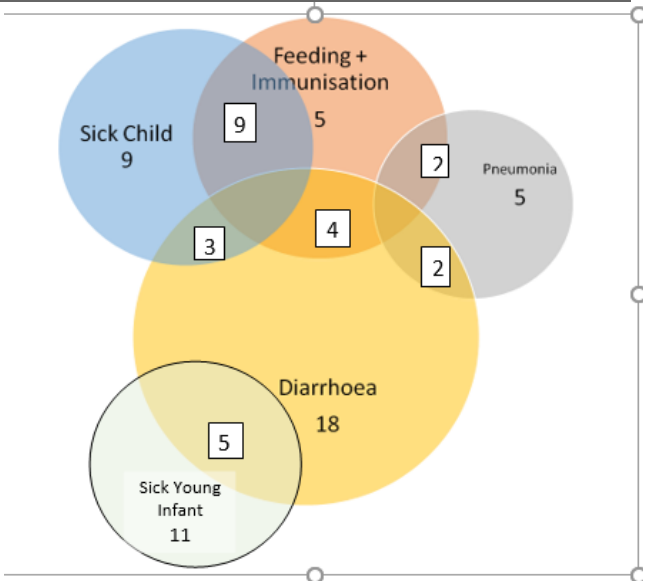


* These 10 women with anemia included 7 with only anemia and 3 women with anemia and preeclampsia

** These 16 women with preeclampsia included 13 women with only preeclampsia and 3 women with preeclampsia and anemia.

Paediatric Cases (Retrospective from record review during Lockdown Period) n=73
No. of Journeys 354 (continuum of Care Journeys completed for ASHA → ANM → Medical Officer)

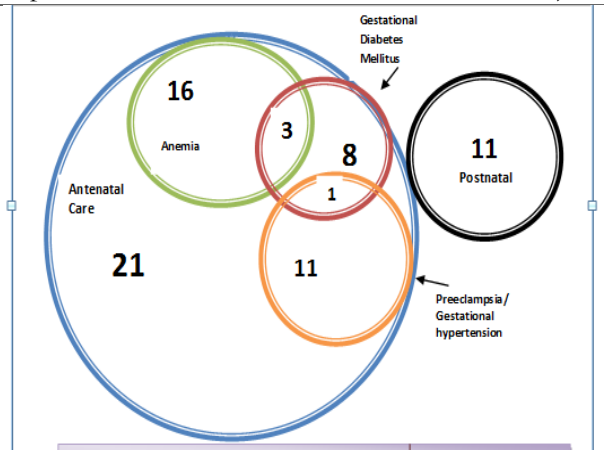
	Cases (n=73)
Feeding and Immunization alone	5 *
Pneumonia • Pneumonia alone • With feeding and immunization	7 • 5 • 2
Diarrhoea • Diarrhoea alone • Diarrhoea with Sick Young Infant • With sick Child • With pneumonia • With feeding and immunization	32 ** • 18 • 5 • 3 • 2 • 4
Care of the Sick child • Care of the sick child alone • With feeding and immunization	18 • 9 • 9
Sick Young Infant	11



* The actual cases assessed for this guideline were 20 (5 normal, 9 sick child, 2 with pneumonia, 4 with diarrhoea)

Maternal Cases done (Prospective): from OPD (English version) (n=71)
No. of Journeys 342 (continuum of Care Journeys completed for ASHA → ANM → Medical Officer)

	Cases (n=71)
ANC- without any complications	21
ANC with 1 or more complications • Anemia in pregnancy • Hypertension/Eclampsia • Gestational diabetes mellitus	39 • 19 * • 12** • 12***
Post-natal	11



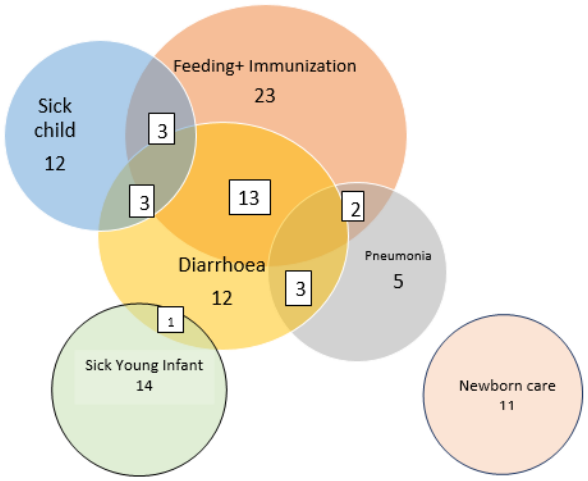
* These 19 include 16 with only anemia and 3 with anemia and GDM

** These 12 include 11 with only Preeclampsia and 1 with preeclampsia and GDM

*** These 12 include 8 with only GDM, 3 with GDM and anemia and 1 with GDM and preeclampsia.

Paediatric cases done (Prospective): from OPD (English version) n=102
No. of Journeys 504Continuum of Care Journeys completed for ASHA → ANM → Medical Officer

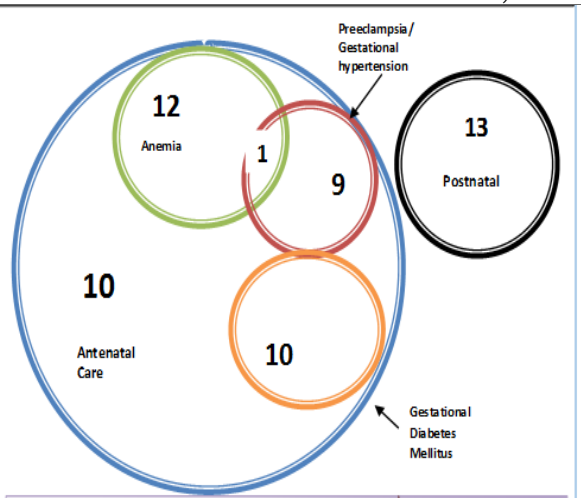
	Cases (n=102)
Feeding and Immunization	23*
Pneumonia • Pneumonia alone • With feeding and immunization	7 • 5 • 2
Diarrhoea • Diarrhoea alone • Diarrhoea w Sick Young Infant • With Sick child • With pneumonia • With feeding and immunization	32 ** • 12 • 1 • 3 • 3 • 13
Care of the sick child • Care of the sick child alone • With feeding and immunization	15 • 12 • 3
Sick Young Infant	14
New-born Care	11



*The actual cases assessed for this guideline were 41 (23 normal, 3 sick child 13 with diarrhoea and 2 with pneumonia)

Maternal cases done (Prospective): from OPD (English and Hindi version) n= 55
No. of Journeys = 264 (continuum of Care Journeys completed for ASHA → ANM → Medical Officer)

	Cases (n=55)
ANC-without complications	10
ANC with 1 or more complications • Anemia in Pregnancy • Preeclampsia/Hypertension/Eclampsia • Gestational diabetes mellitus	32 • 13* • 10** • 10
Post-natal	13

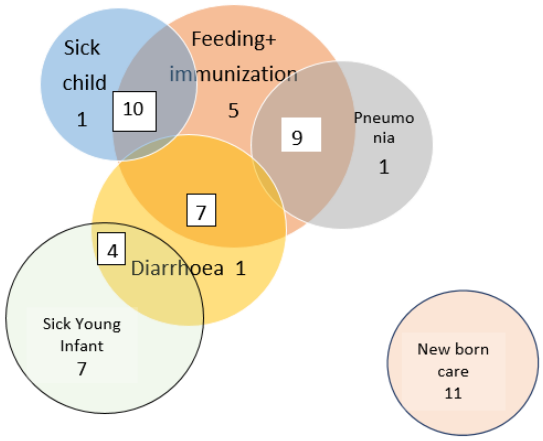


*These 13 include 12 cases of only anemia and 1 with anemia and preeclampsia

** These 10 include 9 cases of only preeclampsia and 1 with preeclampsia and anemia

PaediatricCases done (Prospective): from OPD (English and Hindi version) (n=56)
No. of Journeys 351(continuum of Care Journeys completed for ASHA → ANM → Medical Officer)

	Cases (n=56)
Feeding and Immunization	5*
Pneumonia • Pneumonia alone • With feeding and immunization	10** • 1 • 9
Diarrhoea • Diarrhoea alone • Diarrhoea with SYI • With Sick child • With Pneumonia • With feeding and immunization	12 • 1 • 4 • 0 • 0 • 7
Care of the sick child • Care of the sick child alone • With feeding and immunization	11 • 1 • 10
Sick Young Infant	7
New-born Care	11



* The actual cases assessed for feeding and immunization were 31(5 normal, 10 sick child, 9 with pneumonia,7 with diarrhoea)

The breakdown of the number of journeys is detailed below:

Maternal			
Total number of Cases:	208		
Total number of Journeys:	963		
Journeys Breakdown:	**ASHA**	**ANM**	**MO**
ANC-w/o complications	63	63	63
ANC w complications	105	105	105
ANC in Pregnancy	42	42	42
ANC-PE/HTN/EC	38	38	38
ANC-GDM	33	33	33
Post-natal	40	40	40

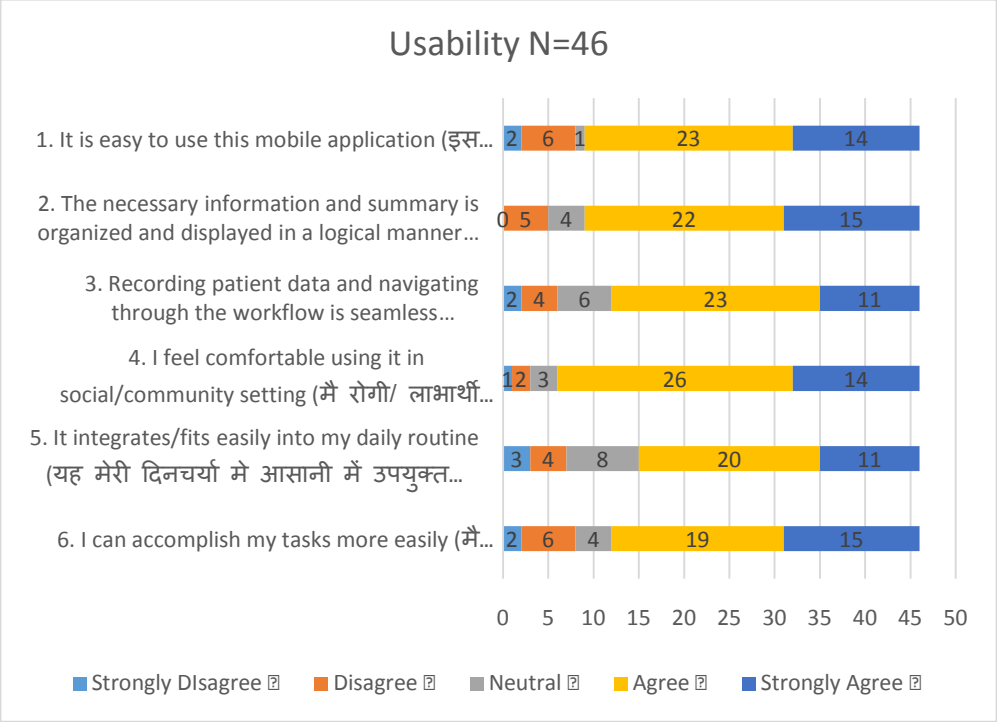
Pediatric			
Total number of Cases:	231		
Total number of Journeys:	2172		
Journeys Breakdown:	**ASHA**	**ANM**	**MO**
Feeding	92	92	92
Immunization	92	92	92
Pneumonia	29	29	29
Diarrhoea	76	76	76
Care of the sick child	50	50	50
Sick Young Infant	42	42	42
New born child	22	22	22

Annexure 5: Interim Survey Results

A qualitative survey was executed in early March.

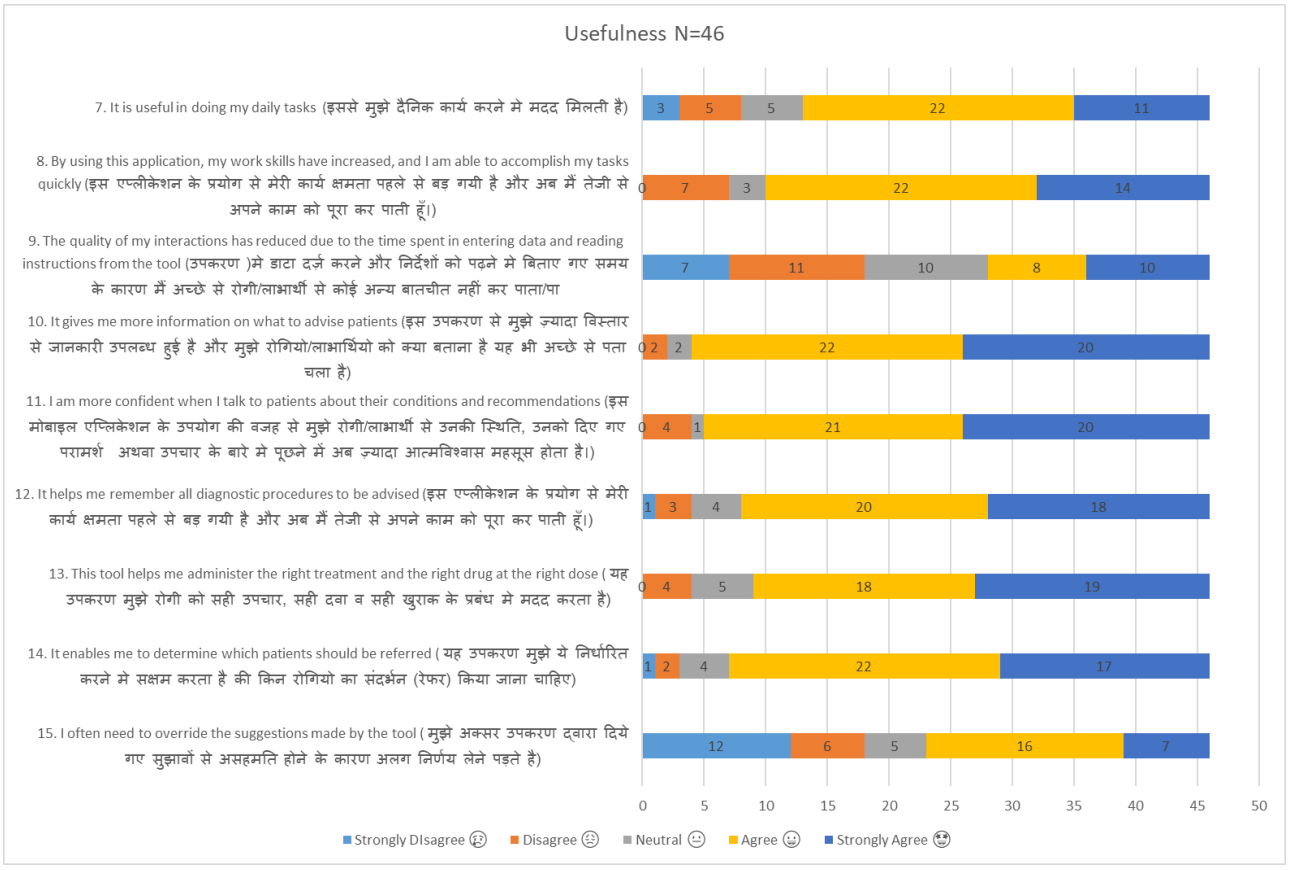
Usability

The overall positive response rate where respondents agreed or strongly agreed on the usability of CDSS-integrated mobile app was 77.17%.

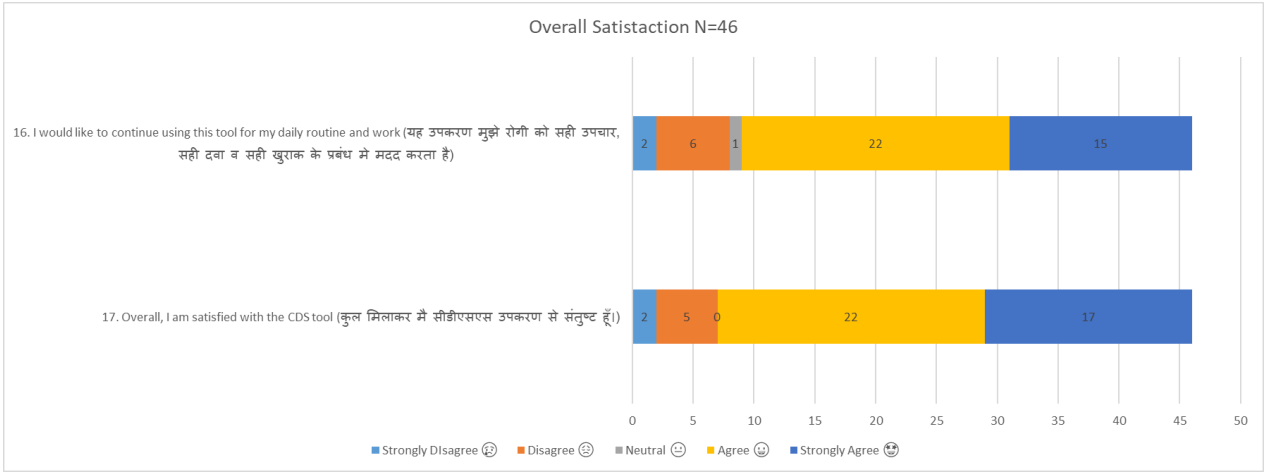


Usefulness

The overall positive response where respondence agreed or strongly agreed to useful features or disagreed or strongly disagreed on reverse questions on the usability of CDSS-integrated mobile app was 72.95%.



82.61% of the respondents would like to continue using the app in their daily routine and the overall satisfaction from the CDSS-integrated mobile app was 84.7%.



Annexure 6: STG Adherence Secondary Data Analysis on limited journeys

Paediatric cases

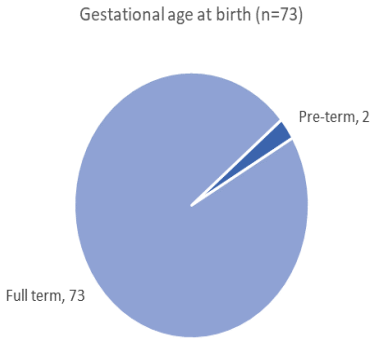
The risk status of infants 0-2 months is based on birth weight, period of gestation, and their ability to feed on day 1, and enables recommendation of an increased number of new-born home visits, and additional care advice.

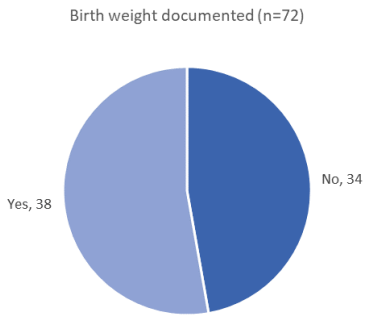
Assessment of the first feed was documented for 9 neonates. 100% reported successful breastfeeding within 1 hour of birth.

First feed:	**(n = 9 neonates)**
within 1 hour of birth	9
breastfed	9
suckled effectively	9

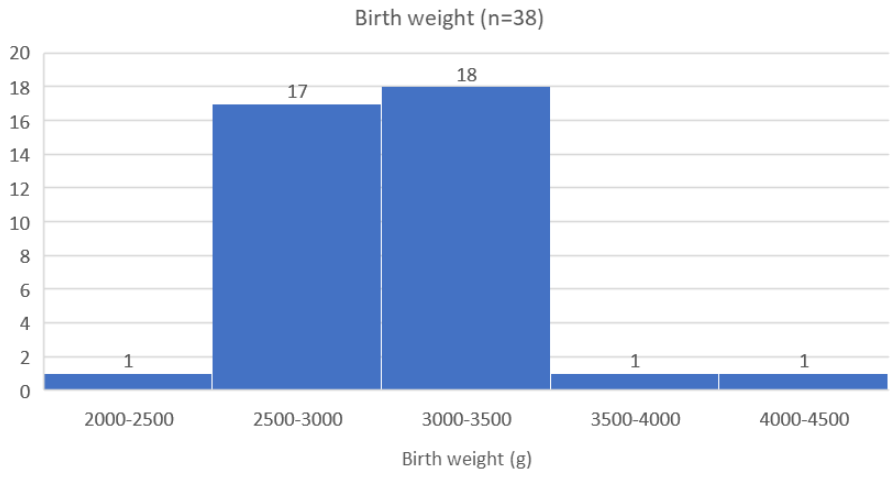
Gestational age at birth was documented for 75 infants, with 2 identified as high risk due to pre-term birth:

Birth weight was recorded for 53% of infants aged 0-2 months:

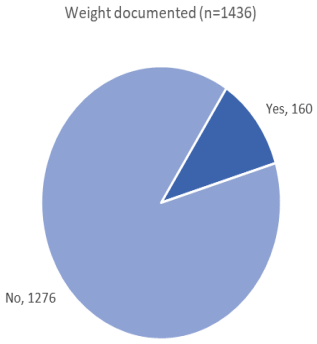


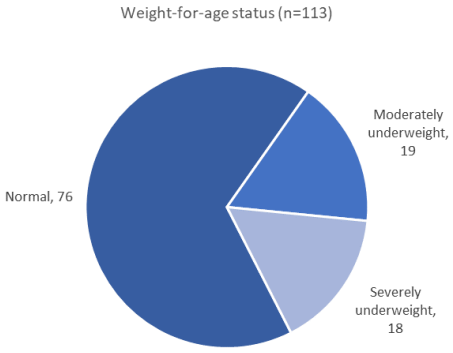


One infant was identified as high risk, due to a birth weight < 2500g:



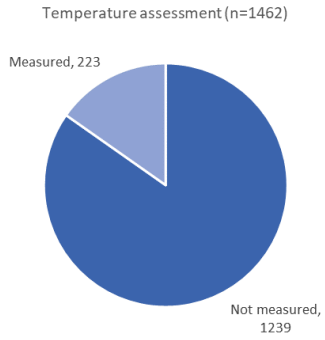
Across all age groups, a current weight measurement was documented at 11% of encounters:

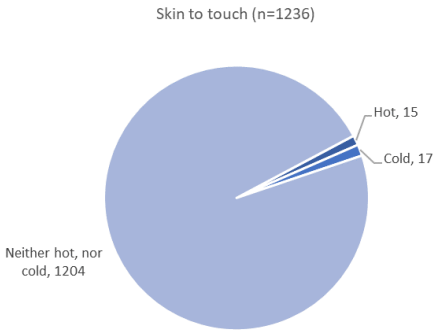




Weight-for-age status was automatically derived for children aged 2-60 months, according to WHO Child Growth Standards. 16% of the children were identified as severely underweight, and 17% as moderately underweight, for their age:

Symptom assessment for fever, pneumonia and diarrhoea-related diseases, and possible serious bacterial infection in neonates, formed part of each encounter.





Temperature was measured at 15% of encounters:

If a temperature measurement was not documented, the FHWs were prompted to assess skin temperature to touch. 19 cases of fever were documented: 4 based on a temperature measurement >= 37.5C; 15 based on assessment of the skin to touch.

5 cases of diarrhoea were documented across all encounters, with 1 recorded as persisting for 14 days or more:

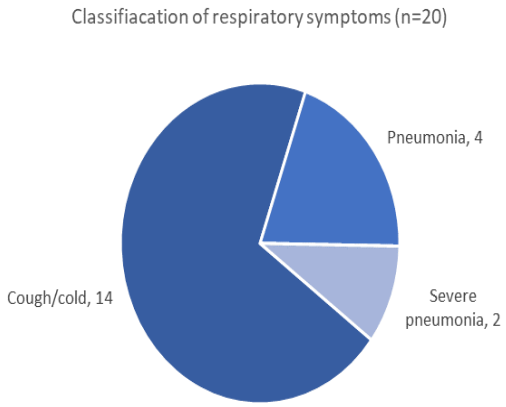
Diarrhoea	**(n = 1455)**
acute (< 14 days)	4
persistent (>= 14 days)	1
with blood in stool	0
none	1450

None of the cases recorded significant signs of dehydration. A prescription of zinc was documented in 3 of the cases.

Symptoms of acute respiratory infection were assessed at encounters with children 2-60 months. 20 cases of cough, breathing difficulty, or both were documented:

Symptom	**(n = 1320)**
cough	19
breathing difficulty	3
none of the above	1300

Further assessment identified symptoms consistent with fast-breathing pneumonia in 4 cases, and severe pneumonia in 2 cases:

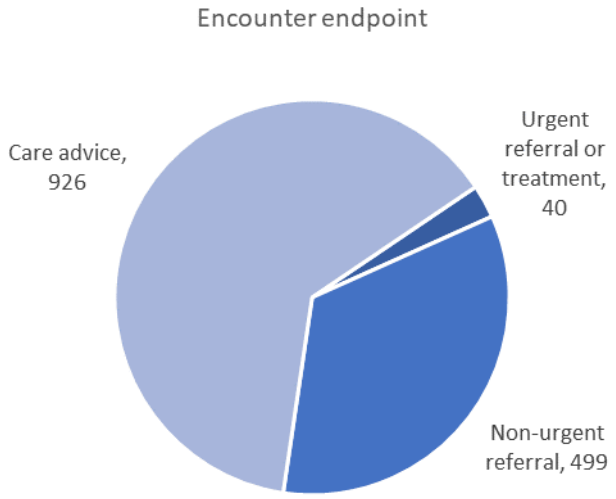


Encounters with infants 0-2 months included documentation of signs consistent with possible bacterial infection. The frequency of positive findings is shown in the below table:

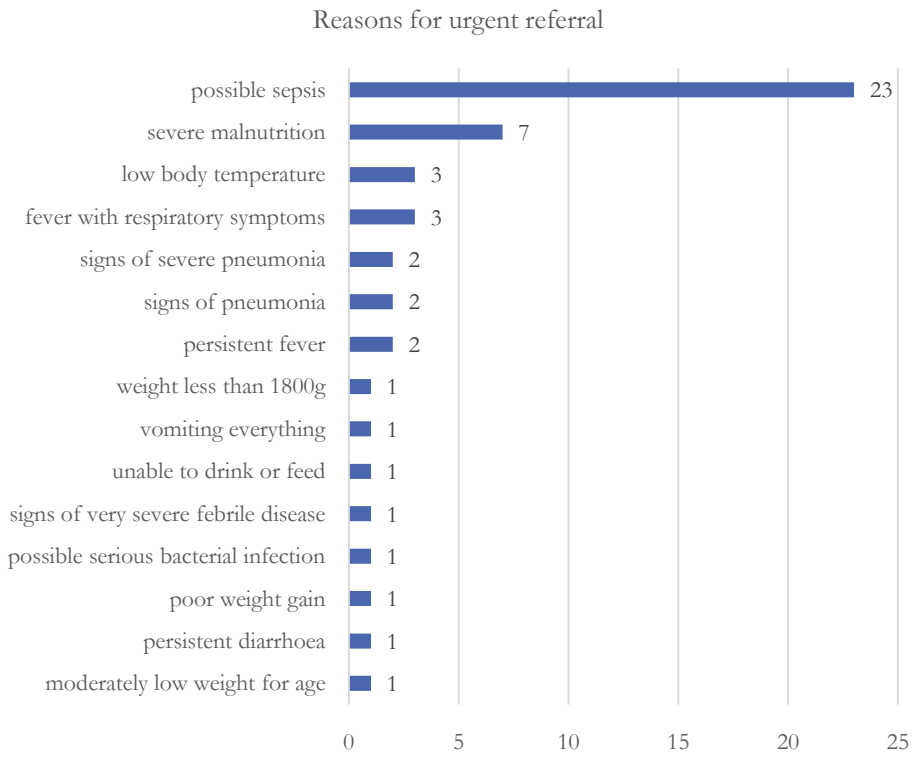
Sign	Positive	n
bulging fontanelle	12	162
cry weak or stopped	12	140
severe chest indrawing	1	155
frequent vomiting	1	140
large boil	1	148
crying incessant	1	140
redness of umbilicus	1	148
pus around umbilicus	0	148
jaundice	0	148
skin pustules	0	148
moving less or not at all	0	147
ear draining pus	0	147
abdomen distended	0	147

The outcome, or endpoint, of an encounter falls under three categories: urgent referral (or inpatient treatment if appropriate) for severe symptoms, non-urgent referral for further investigation, and general home care advice.

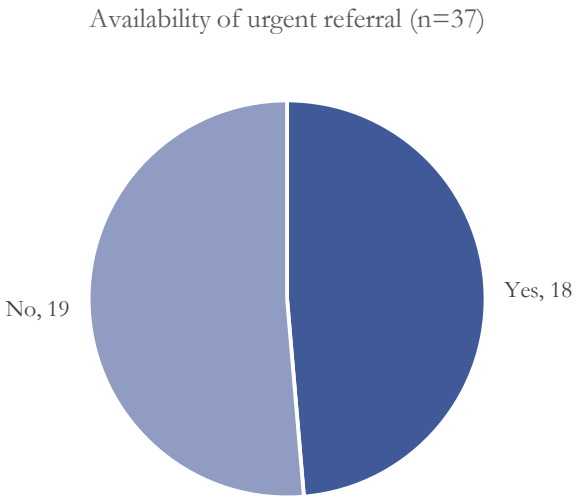
Urgent referral was recommended for 3% of cases, and non-urgent referral in 34% of cases:



A breakdown of the reasons for urgent referral is shown below. "Possible sepsis" refers to the presence of 1 or more severe signs, or 2 or more mild signs, of infection in an infant aged 0-2 months.

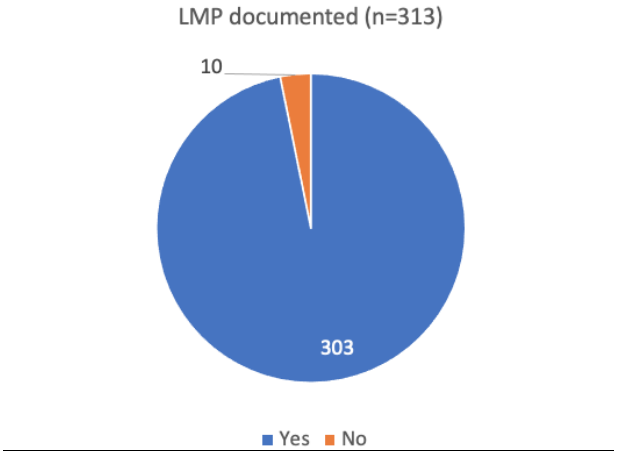


Of the cases where urgent referral was recommended, 51% documented that the child was unable to attend. Reasons reported included unavailability of transport (3 cases), family reason (6 cases), and other individual reasons (10 cases).

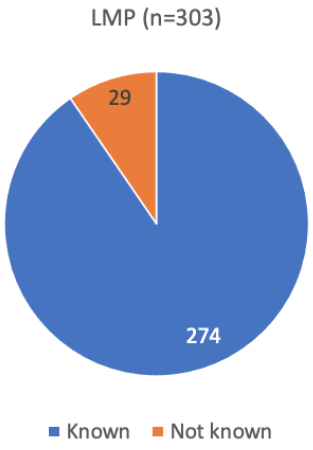


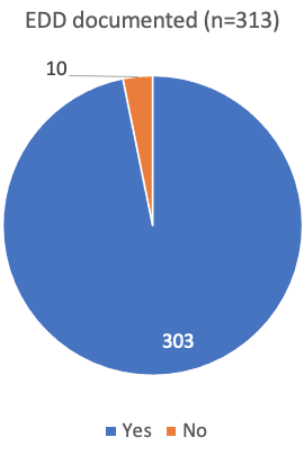
Maternal cases (antenatal)

LMP was recorded in all but 10 antenatal cases:



For the cases where LMP was documented, 90% had a date recorded. 10% of women did not know their LMP date:

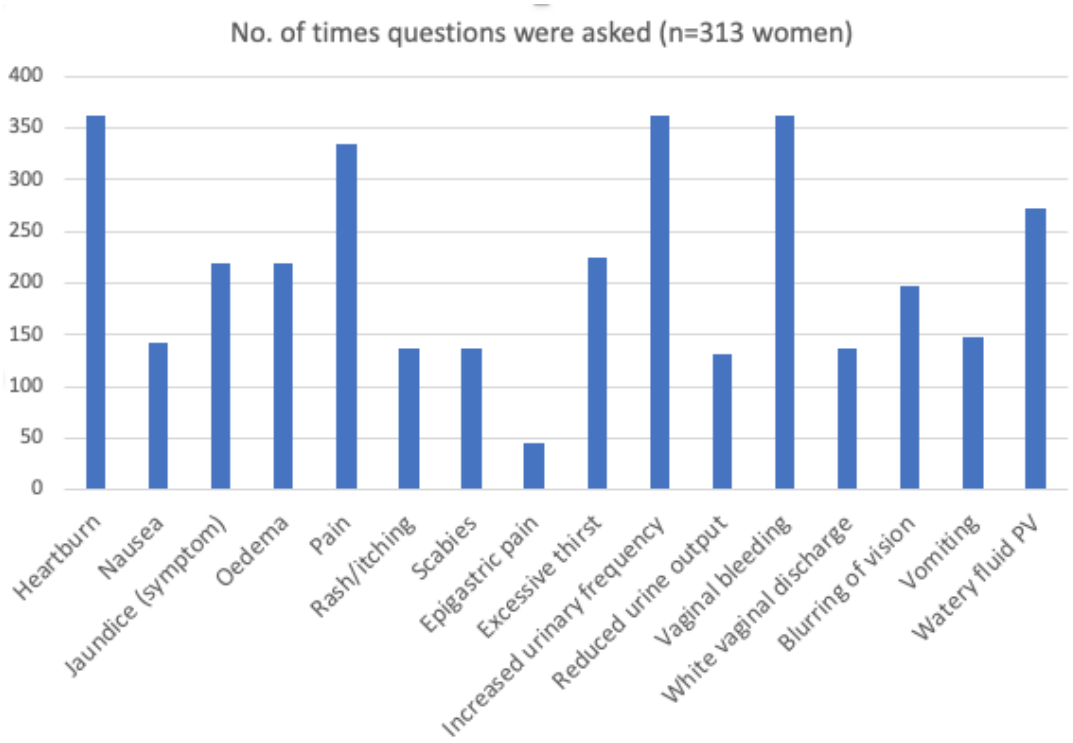




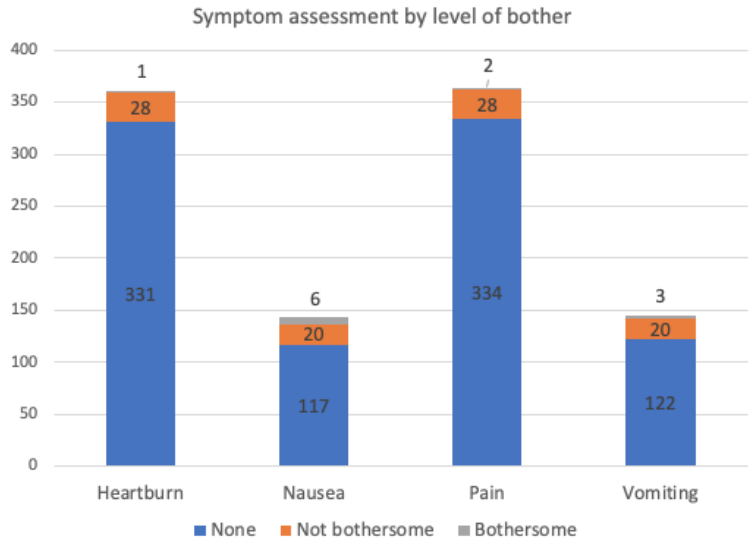
All cases where the LMP was documented also had the EDD documented, including for women who did not know the LMP date.

Women who did know the LMP date were asked for their best guess of the period of gestation in months. 11 women had an ultrasound to confirm the period of gestation, which was calculated as: 17 weeks (2 cases); 30 weeks (3 cases); 35 weeks (1 case); 38 weeks (1 case); and 40 weeks (1 case).

Symptoms were assessed by ASHAs and ANMs. The number of times that questions were asked varied depending on the period of gestation, etc. This reflected the ability of the AI solution to understand the context in which the questions were being asked, including the role of the User:



The range of answers was extended for some questions. Rather than just 'yes'/'no' responses, the concepts of 'bothersome' and 'not bothersome' were used to distinguish the impact of some symptoms:



Both women who reported bothersome pain had continuous symptoms: 1 had mild pain; the other woman had severe pain. The three women who had bothersome vomiting did not have persistent symptoms.

The frequency of positive findings for the other symptoms is shown in the following table:

Symptom	Present	
Jaundice (symptom)	0	
Oedema	1	(generalised)
Rash/itching	0	
Epigastric pain	0	
Excessive thirst*	12	
Increased urinary frequency	7	
Dysuria	2	
Polyuria	0	
Reduced urine output	0	
Vaginal bleeding	2	
White vaginal discharge	0	
Blurring of vision	0	
Watery fluid PV	2	

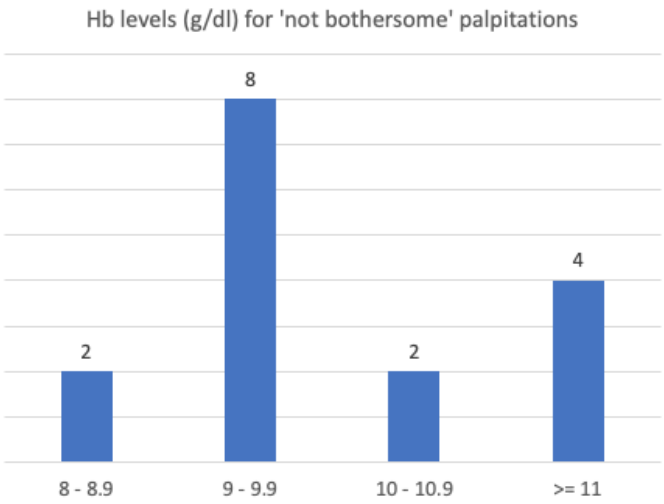
*None of the women who reported excessive thirst had glycosuria

Symptoms of anemia were assessed with questions about dizziness, palpitations, and fatigue:

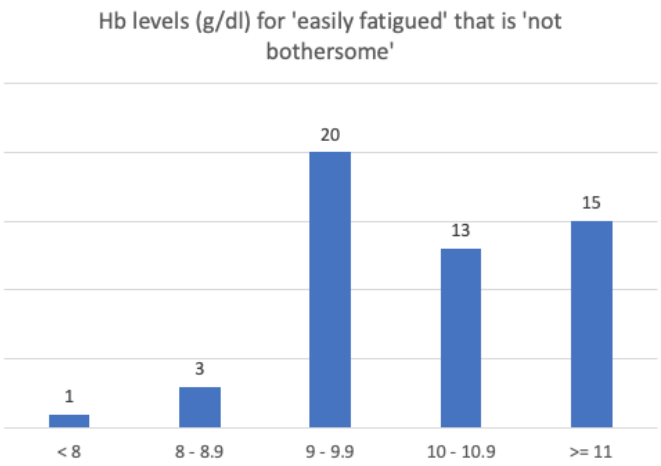
Bothersome symptoms	No.	Hb levels
Palpitations	1	Hb: 10.1
Fatigue	3	Hb: 7.8; Other 2 cases were >10
Dizziness	4	Hb: 9; 11; 11; 12
Breathless at rest*	2	Hb: 9; 11

**No longer asked as symptom of anemia but included for comparison*

The question on palpitations includes the option to rate the symptom as 'not bothersome'. The following chart shows the hemoglobin levels distribution for 16 women:



The question on easily fatigued includes the option to rate the symptom as 'not bothersome'. The following chart shows the hemoglobin levels distribution for 42 women:



Previous obstetric history was recorded for 123 women. The following table shows the number of previous pregnancies:

No. previous pregnancies	(n=123 women)
0	4
1	42
2	32
3	18
4	12
5	10
6	3
7	1
8	0
9	1

The number of previous children is recorded in this table:

No. previous children	(n=123 women)
0	8
1	40
2	32
3	19
4	13
5	8
6	3

Additional details of obstetric history are shown in the next table:

Obstetric history	'Yes'
Abortion	78
Previous Caesarean section	2
Previous complications	2
Previous neonatal death	1
Previous stillbirths	2

Past medical history was recorded for 180 women:

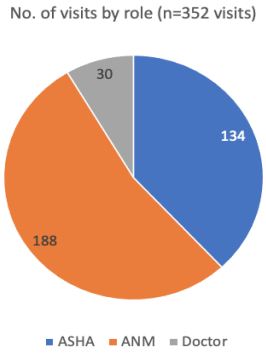
Past medical history	'Yes'	No. asked
TB	1	180
Diabetes	2	180
Heart disease	1	180

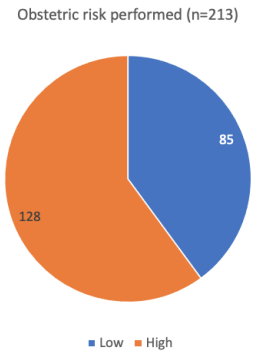
Tobacco use and alcohol consumption was recorded for 180 women:

Social history	'Yes'
Alcohol	1
Tobacco	16
Smoking tobacco	6
Smokeless tobacco	16

Family history was documented as completed for 180 women. There were no cases of hypertension, diabetes, multiple pregnancies, TB, thalassemia, or mental retardation recorded in any families.

Obstetric risk assessment was performed in 213 cases. This is lower than the total number of antenatal cases but reflects the fact that ASHAs do not perform risk assessments.





218 antenatal visits were performed by ANMs or MOs, which means that obstetric risk assessment was recorded for 98% of the women seen by someone who is able to perform a risk assessment.

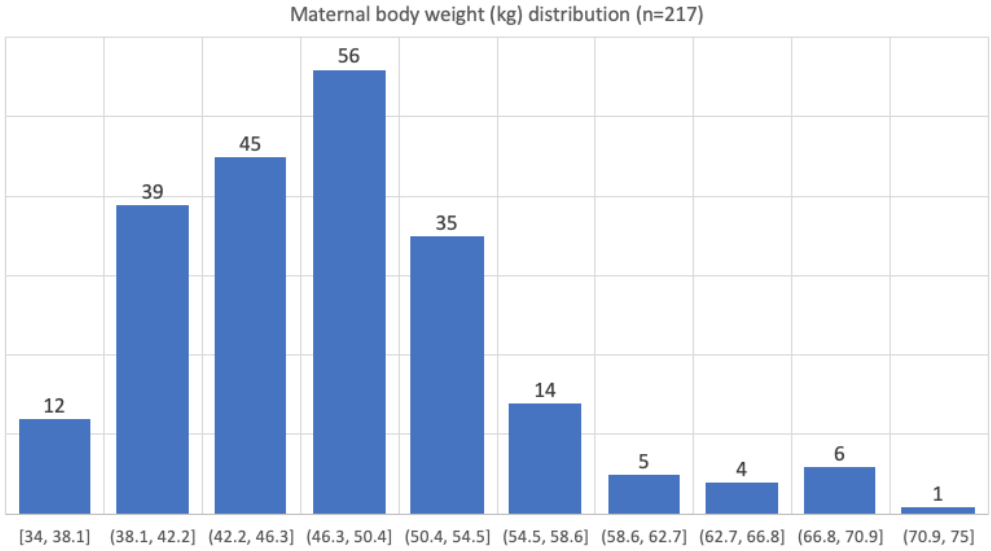
The proportion of high versus low obstetric risk cases is illustrated in the next chart, with the majority of women (60%) having a high obstetric risk.

The details of the positive risk factors are set out in the following table, with several women having more than one risk factor (209 risk factors distributed across 128 women):

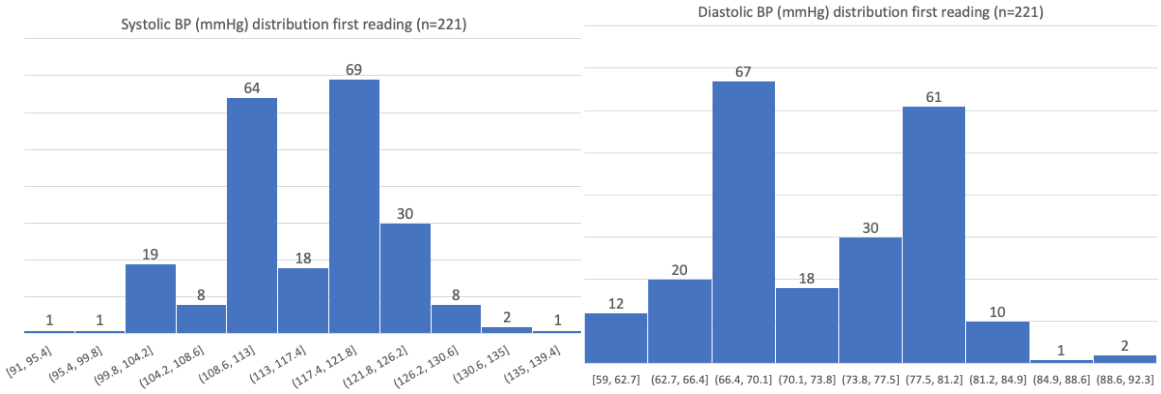
High risk factors	No. recorded
Anemia - mild	47
Anemia - moderate	40
Small-for-dates (good dating)	25
Smokeless tobacco usage	16
Previous neonatal loss	9
Foetal heart sounds absent	8
Large-for-dates (good dating)	8
Fundal height not increased	7
Smokers	6

Fever	4
Easy fatigability	3
Previous difficult labour	3
Tachycardia	3
Abdominal pain 12 EDD	2
Breathless at rest	2
Headache	2
Pallor	2
Past history - diabetes	2
Past history - hypertension	2
Premature birth	2
Previous eclampsia	2
Small-for-dates (uncertain dating)	2
Alcohol consumption	1
Foetal heart sounds reduced	1
Generalised oedema	1
Other illness	1
Palpitations	1
Past history - TB	1
Past history - Heart disease	1
Previous delivery with congenital anomaly	1
Previous pre-eclampsia	1
Rh negative	1
Vaginal bleeding <20 weeks	1
Vaginal bleeding >=20 weeks	1

219 women had body weight recorded in a visit, though 2 values were excluded as possible data-entry errors (11 kg and 121 kg respectively). The following chart displays the distribution of maternal body weight, with a median body weight of 48 kg:

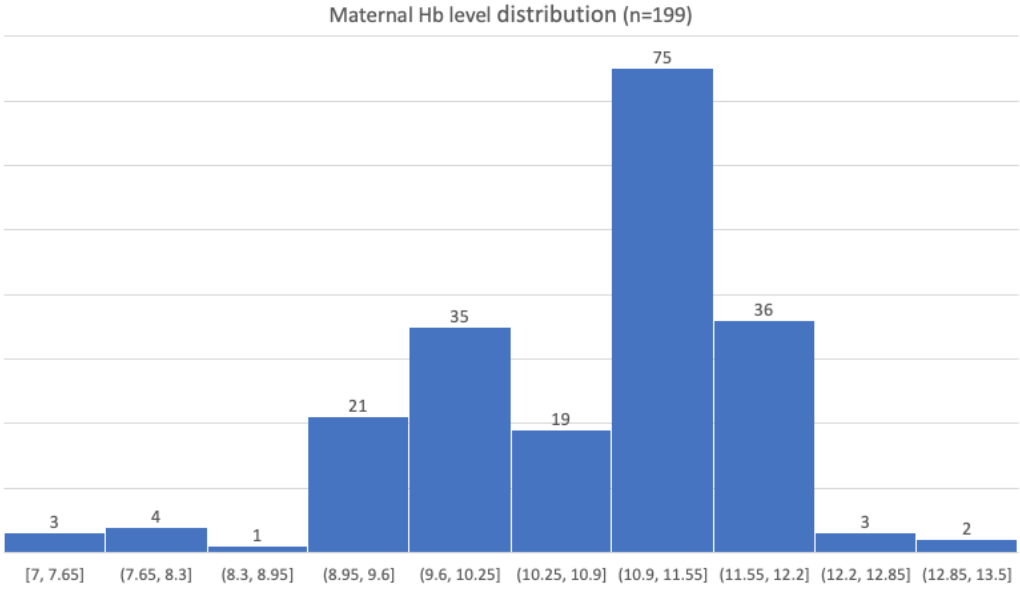


Maternal blood pressure was recorded in 221 visits. The distribution of systolic blood pressure readings is displayed in the next chart. There is a bimodal distribution, suggesting an effect related to the measuring device and/or the blood pressure measurement process:



All women who had elevated systolic blood pressure readings had repeat values taken during the visit. Two women had persistent mild elevated blood pressure and were recommended for referral (see detailed Referral Reasons section below).A similar bimodal distribution was seen for diastolic blood pressure readings.

Information was available on hemoglobin testing for 216 women. 197 women had hemoglobin measurements. The distribution of maternal hemoglobin levels is shown below:

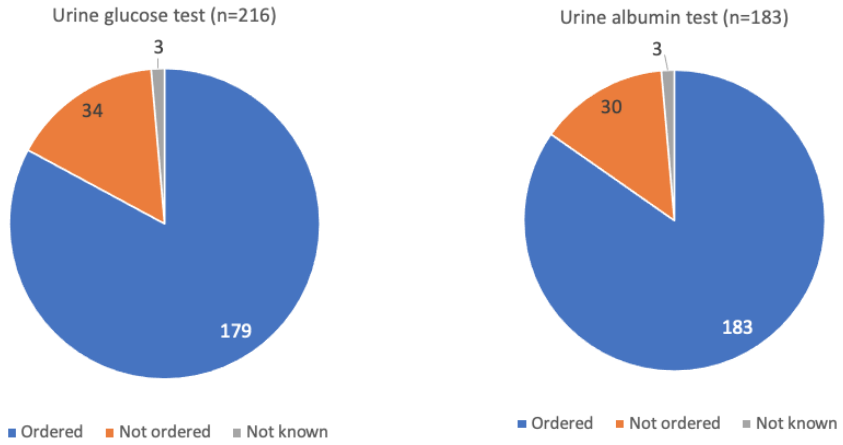


Blood group and Rhesus factor status was only measured in 3 women. In 174 visits, it was recorded that blood group was not available.

VDRL testing was carried out in 174 women and recorded as 'Not done' for 38 women. All tests that were performed had negative results.

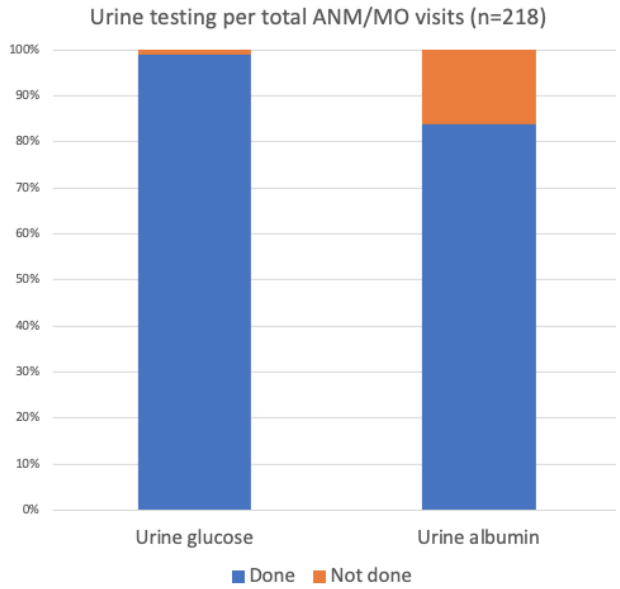
HIV testing was carried out in 196 women and recorded as 'Not done' for 16. All tests that were performed returned negative results.

Urine glucose was recorded as 'ordered' in 179 women, with all results returning as negative for glycosuria. 34 women were documented as having the test 'not ordered':



Urine protein was recorded as 'ordered' in 183 women, with all results returning as negative for proteinuria. 30 women were documented as having the test 'not ordered'.

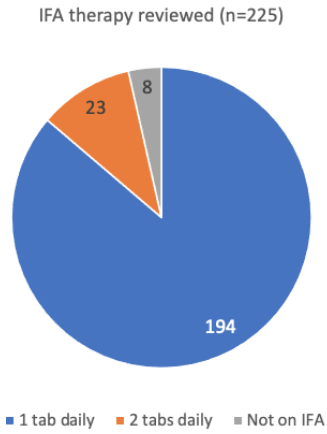
Urine testing for glucose and albumin is carried out by ANMs and MOs. The tests are carried out in the majority of visits:



Abdominal examination was carried out in 226 visits, with findings other than fundal height being recorded in 22 women. Nine women had an abdominal scar; 8 vertical and 2 'other'. Foetal lie and presentation, as well as foetal movements were also examined, depending on the period of gestation:

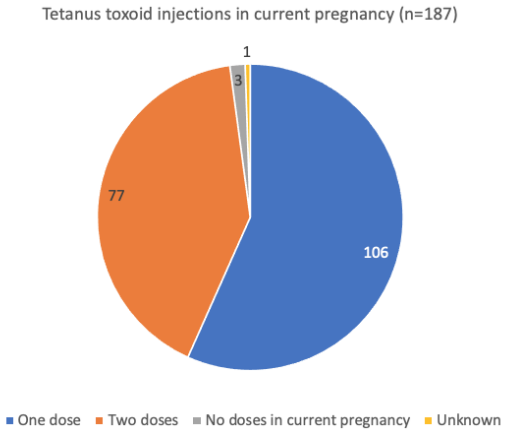
Foetal lie and presentation	
Cephalic	67
Breech	2
Cannot tell	4
Foetal movements	
Normal	110
Reduced	2

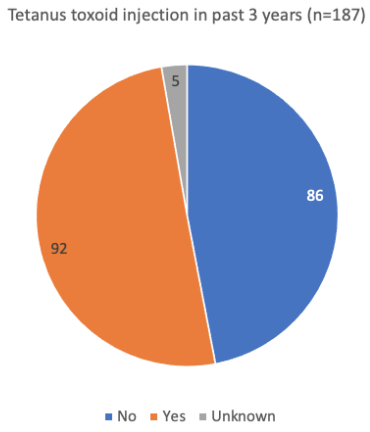
IFA therapy was reviewed in 225 women, with 8 women recorded as not taking IFA:



Only one woman was recorded as having received parenteral iron therapy.

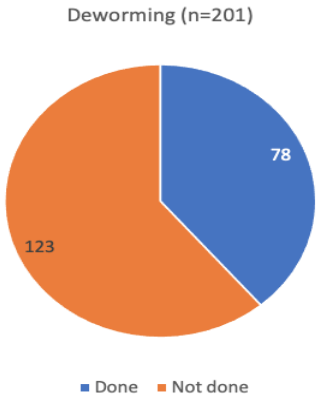
Tetanus toxoid vaccination status was reviewed in 187 women:





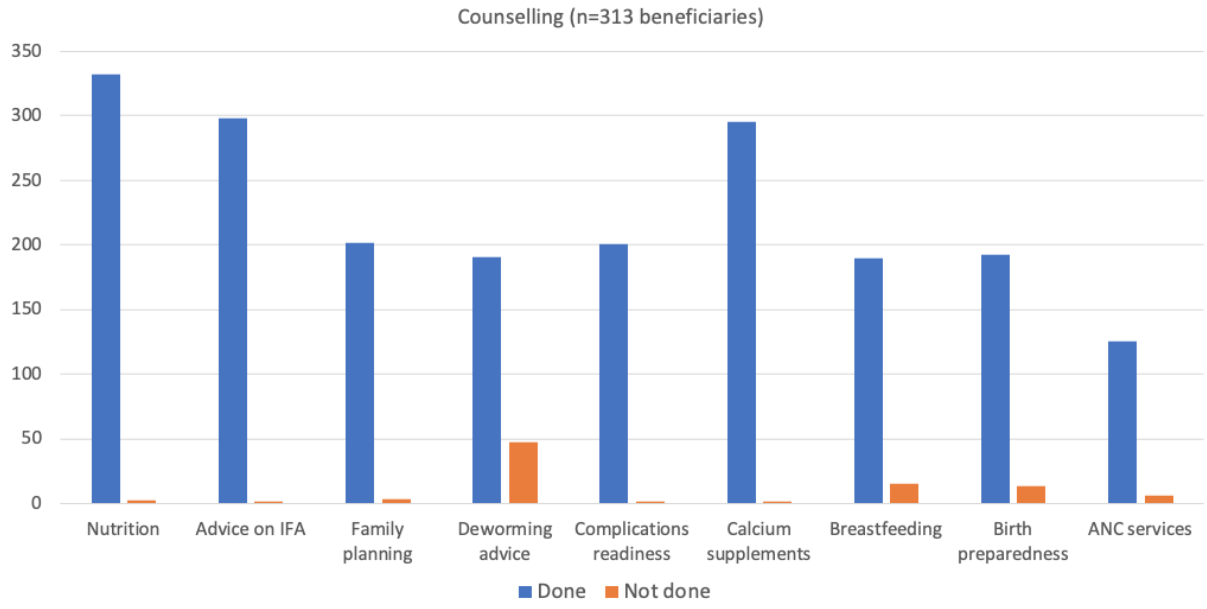
The AI solution calculated the scheduled date for a first tetanus toxoid dose in 43 women, for a second dose in 3 women, and a booster date for 1 woman.

Deworming in the past 6 months was recorded as 'done' for 123 of 201 women:not having treatment in the second and third trimesters:



Deworming treatment was analyzed separately, with about 2/3rds of women having treatment in the first trimester and 37% of women

Counselling was recorded as being provided to 313 beneficiaries across the following topics. Note that nutrition advice was provided on more than one occasion to some women:



Maternal cases (postnatal)

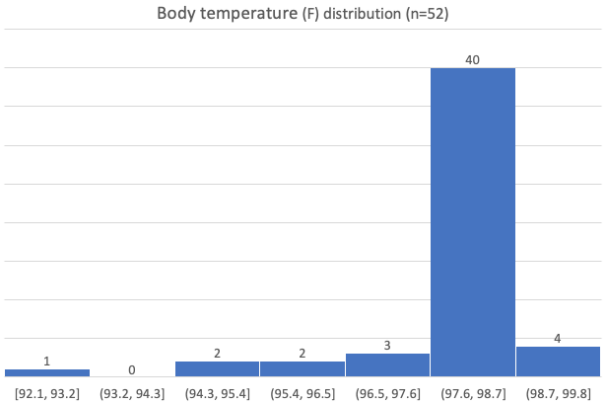
There were 44 women who were reviewed after delivery in February 2021. The demographic details have been presented in a previous section of this document.

The following table shows the range of symptoms and other issues that were reviewed during the visits:

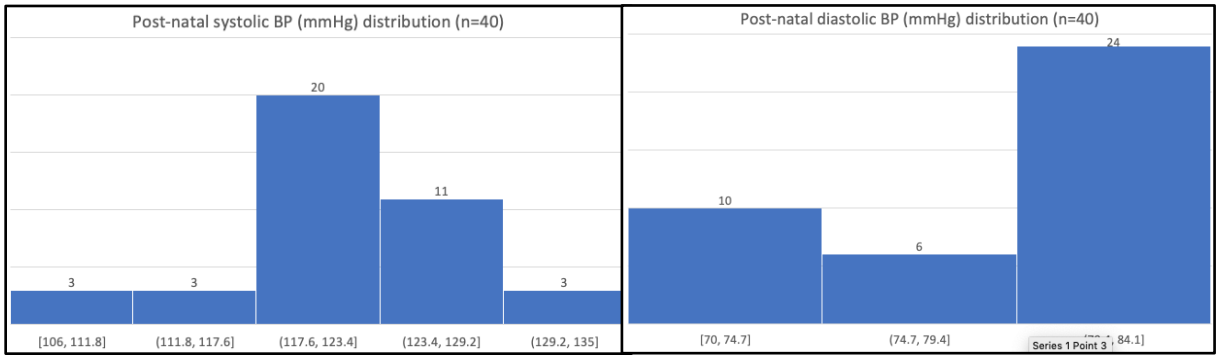
Postnatal review topics	**'Yes'**	**'No'**
Regular diet started	18	11
Breast feeding baby	40	1
Lower abdominal pain	3	54
Breast feeding - insufficient milk	3	53
Breasts sore	1	54
Perineal pain	1	56
Breast lump	0	42
Breast tenderness	0	42
Breasts engorged	0	56
Breathlessness	0	57
Chills	0	56
Constipation	0	56
Contraception	0	24
Convulsions	0	42
Excessive bleeding at time of delivery	0	42
Dizziness	0	57
Epigastric pain	0	43
Easy fatiguability	0	41
Fever	0	56
Severe headache	0	43
Leg pain	0	55
Lochia abnormal	0	55

Lochia foul-smelling	0	57
Mood changes	0	51
Nipples crusted or sore	0	57
Nipples inverted	0	55
Oedema	0	41
Pallor	0	41
Perineal swelling	0	57
Perineal tear	0	56
Urination burning	0	57
Urinary frequency increased	0	57
Urinary dribbling or retention	0	57
Uterus soft and tender	0	41
Vaginal bleeding	0	56
Blurring of vision	0	43

Body temperature of the mother was recorded during 52 visits. The following chart shows the distribution of temperature in degrees Fahrenheit:



Blood pressure was recorded on 40 visits. The distribution of systolic and diastolic blood pressure values are shown below:



Seven women had hemoglobin measured:

Hemoglobin measured	
Yes	7*
No	10
Not known	27

**All 7 had mild anemia.*

Anemia treatment was recorded for 11 women; 31 women were noted as not receiving anemia treatment.

Calcium and vitamin D3 tablet usage was recorded in 57 visits:

Calcium Vit D3 tablets	
One tab daily	35
Two tabs daily	21
No	1

The following advice was provided during 52 visits (91% of all visits):

- Breastfeeding advice
- Advice on calcium supplements
- Family planning
- IFA advice
- Post-partum hygiene
- Post-partum nutrition
- Post-partum rest
- Post-partum sexual activity

Family planning counselled was provided to 25 women. The number of women who agreed upon a family planning method is shown in the following table:

Family planning method agreed upon	
Yes	21
No	2*
Will decide later	2*

**No follow-up information is available for these women at the time of analysis*

The family planning methods that the women agreed upon are listed in the next table:

Family planning methods		
Centchroman*		9
	Satisfied	6
	Not satisfied	3
Condoms		12
	Satisfied	12
COCP		0
ECP		0
IUCD		0
MPA		0
POP		0

**Centchroman is a family planning option developed in India*

Referrals to a medical officer were recommended for the following reasons:

Recommended referrals to MO	
Anemia	1
Suspected infection	5
Post-partum pain	3

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