

# Digital Targeted Client Communication for Effective Coverage of Antenatal Care

Assessment, Development, and Evaluation

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Binyam Bogale Bungudo

Thesis for the degree of Philosophiae Doctor (PhD)  
University of Bergen, Norway  
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UNIVERSITY OF BERGEN



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## Scientific Environment

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The intervention was developed in close collaboration with the District Health Information Software 2 (DHIS2) team, the Health Information Systems Program (HISP), University of Oslo, Norway.

The dissertation was completed as part of a joint implementation and research project – eRegistries for maternal and child health – led by the Norwegian Institute of Public Health, and implemented in collaboration with the Palestinian National Institute of Public Health, and the World Health Organization, occupied Palestinian territories.

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## Summary

The effective provision of essential interventions in antenatal care (ANC) is crucial for a positive pregnancy experience. However, the effective coverage of essential interventions in ANC is often low, even in settings where there is high coverage of ANC visits.

Untimely use, and low quality, of services are both important factors that contribute to low effective coverage.

Digital health interventions are often moderately effective in improving the timeliness of attendance to ANC. The interventions with high effectiveness are often those that are individually tailored, theory based, and co-designed with the end users. Most research reports have focused on evaluating effectiveness, while the design, development, and implementation of such digital health interventions have been a “black box”. This limits the possibility to replicate interventions that proved to be effective, which ultimately results in a waste of research resources.

Digital health interventions that aim to change the behavior of end users, such as targeted client communication (TCC), need to be carefully designed to maximize effectiveness and minimize any unintended consequences. This can be achieved through underpinning the design on relevant behavior change theories; careful assessment of the context; co-creating the content, frequency, and mode of the intervention; and iteratively testing and improving the final intervention. To ensure that the finalized intervention results in the intended effects, both effectiveness and any potential unintended consequences should be estimated using robust study designs such as randomized controlled trials.

In this thesis we present the approaches we took to develop an acceptable and safe automated digital TCC intervention, and to test its potential unintended consequences in a cluster randomized controlled trial. The effectiveness of the digital TCC intervention is not included in this thesis. This thesis is part of a larger project that combines a national implementation of a digital maternal and child health registry in Palestine (called MCH eRegistry) with several effectiveness trials of digital health interventions.

We have used both quantitative and qualitative research methods. We started by identifying the gaps in effective coverage and worked with stakeholders to identify and target contextually relevant essential interventions. A national expert panel identified anemia, hypertensive disorders of pregnancy, diabetes mellitus, fetal growth restriction, and untimeliness of attendance to the routine visits as a priority – in this thesis simply referred to as “the target conditions”. Quantifying the coverage and effective coverage of the essential interventions informed the nature and goal of the digital health intervention – the digital TCC.

Understanding the perceptions of women and the healthcare providers was essential towards developing the digital intervention. This was conducted using in-depth interviews guided by a theory. The content of the TCC was developed in an iterative process based on the results of the in-depth interviews, recommended message framing approaches, and feedback from users and other stakeholders. We used concepts and models proven to be helpful in guiding the process of choosing the right words, which are simple to understand, culturally acceptable, and effectively convey the intended messages without increasing worries in pregnancy. We developed algorithms in the digital MCH eRegistry to tailor messages automatically to individual women based on selected variables. Finally, we evaluated any unintended effects of the TCC intervention, such as an increase in pregnancy-related worries (measured by the Cambridge Worry Scale) or reduced satisfaction with ANC services, in a cluster randomized controlled trial.

In public primary healthcare clinics in Palestine, we found that 60% of women attended four or more ANC visits and the majority of women started their first visit early. Coverage of at least one screening test of the target conditions was high, but the effective coverage was low. The main contributing factor for the low effective coverage was that the pregnant women did not attend care in a timely manner.

We identified three constructs of the Health Belief Model (HBM) that were important in understanding the patterns of ANC attendance. The contents of the intervention, therefore, focused on influencing women’s perceptions of the risks and seriousness (perceived

susceptibility and severity) of the target conditions and the benefits of timely ANC attendance. Through the iterative process of co-designing, testing, and refining using tools and methodologies for composing behavior change communication messages, we designed a digital TCC intervention considered acceptable by pregnant women, healthcare providers, and health education experts in Palestine. The TCC, which contained information about the risks of exposure and complications, did not increase pregnancy-related worries among the recipients of the intervention compared to the controls. The women were equally and highly satisfied with the ANC they received in both intervention and control arms.

This work contributes to the rapidly growing field of design and implementation of digital health interventions for maternal and child health and beyond. It adds to the limited literature on the scientific development process of TCC, and estimations of potential side-effects using robust study designs. Demonstrating the application of automated digital TCC to women using routine data from the MCH eRegistry, without adding burden to the healthcare providers, can further improve the investment returns of such digital health registries.

## Original papers

This PhD dissertation is based on the following papers, which will be referred to in the text by the respective Roman numerals:

### Paper I

Venkateswaran M, Bogale B, Abu Khader K, Awwad T, Friberg IK, Ghanem B, Hijaz T, Mørkrid K, Frøen JF. **Effective coverage of essential antenatal care interventions: A cross-sectional study of public primary healthcare clinics in the West Bank.** PLoS One. 2019 Feb 22;14(2):e0212635. doi: 10.1371/journal.pone.0212635. eCollection 2019.

### Paper II

Bogale B, Mørkrid K, O'Donnell B, Ghanem B, Abu Ward I, Abu Khader K, Isbeih M, Frost M, Baniode M, Hijaz T, Awwad T, Rabah Y, Frøen JF. **Development of a targeted client communication intervention to women using an electronic maternal and child health registry: a qualitative study.** BMC Med Inform Decis Mak. 2020 Jan 6;20(1):1.

### Paper III

Bogale B, Mørkrid K, Abbas E, Abu Ward I, Anaya F, Ghanem B, Hijaz T, Isbeih M, Issawi S, Nazzal Z, Qaddomi S, Frøen JF. **The effect of a digital targeted client communication intervention on pregnant women's worries and satisfaction with antenatal care in Palestine – a cluster randomized controlled trial.** (Accepted for publication after minor review PLoS One, Feb 2021)

## Supporting paper

Mørkrid K, Bogale B, Abbas E, Abu Khader K, Abu Ward I, Attalh A, Awwad T, Baniode M, Frost KS, Frost MJ *et al*: **eRegCom—Quality Improvement Dashboard for healthcare providers and Targeted Client Communication to pregnant women using data from an electronic health registry to improve attendance and quality of antenatal care: study protocol for a multi-arm cluster randomized trial.** *Trials* 2021, 22(1):47.

## Abbreviations and acronyms

<b>ANC</b>	Antenatal Care
<b>CI</b>	Confidence Intervals
<b>cRCT</b>	Cluster Randomized Controlled Trial
<b>CWS</b>	Cambridge Worry Scale
<b>DHI</b>	Digital Health Intervention
<b>DHIS2</b>	District Health Information Software 2
<b>HBM</b>	Health Belief Model
<b>ICC</b>	Intra-cluster Correlation Coefficient
<b>LMIC</b>	Low and middle-income countries
<b>MAF</b>	Model of Actionable Feedback
<b>MCH</b>	Maternal and child Health
<b>mHealth</b>	Mobile Health
<b>MOH</b>	Ministry of Health
<b>oPt</b>	Occupied Palestinian Territory
<b>PHC</b>	Primary Healthcare Clinics
<b>PNIPH</b>	Palestinian National Institute of Public Health
<b>RMNCH</b>	Reproductive, Maternal, Newborn, and Child Health
<b>SMS</b>	Short Message Service
<b>TCC</b>	Targeted Client Communication
<b>UHC</b>	Universal Health Coverage
<b>WHO</b>	World Health Organization

## Chapter I: Introduction

Antenatal care (ANC) is a core component of maternity care provided by skilled healthcare professionals to ensure positive pregnancy outcomes for both the mother and her baby [1, 2]. ANC provides an opportunity to identify, prevent, and manage health issues during pregnancy [3-5], and is a key link in the continuum of care across reproductive, maternal, newborn, and child health (RMNCH) services [6, 7]. The World Health Organization (WHO) recommends a package of evidence-based core essential interventions for routine ANC to ensure better perinatal and maternal outcomes [1, 6, 8]. The essential interventions package is adaptable to different settings, for countries to contextualize them according to their needs and resources. However, the interventions' effectiveness are better assured when provided with a specific frequency, timing, and with appropriate content [9]. Therefore, for pregnancies without any underlying conditions, a package of interventions at defined pregnancy time windows is suggested in a goal-oriented four-session ANC program [10].

The coverage of four or more contacts with trained healthcare providers (ANC 4+) is a commonly used indicator in monitoring ANC utilization [11, 12], and a benchmark indicator for the adequacy of ANC. Globally, the median coverage of ANC 4+ increased from 58% to 68% in the last five years [11, 13]. Sub-Saharan Africa and South Asia have the lowest coverage of ANC 4+ compared to other regions. There is marked variability in contact coverage (“the proportion of clients who have contact with relevant facilities, providers and services among the target population”) between and within countries [14].

The limitation of ‘crude’ or ‘contact’ coverage as a measure is that it only provides frequency of visits and fails to capture the quality of services provided in those visits.

Intervention coverage – the proportion of population in need of an intervention that receives it – is often used to measure progress of interventions in a broader context [11, 15, 16]. Measuring the contact coverage alone provides no indications of service quality and potentially overestimates the health benefits of the services [17, 18].

Content coverage, the proportion of women who received an appropriate intervention (e.g., screening for anemia), is used as a proxy indicator for quality. Globally, the content coverage of most essential interventions is low, including in countries with a high contact coverage of ANC 4+ [19]. In a pooled analysis of twenty countries in sub-Saharan Africa, the contact coverage (ANC 4+) was 51% (range: 32%–76%), but only 5% (range: 0.3%–19%) received all eight essential interventions [20]. The content of visits and the quality of actual services provided at each contact are less commonly evaluated [19, 20].

Quality of care is a crucial component in realizing the full benefits of ANC [12, 17, 19, 20]. The quality of healthcare services is a key component in universal health coverage (UHC), where all people have access to the quality health services that they need, without suffering financial hardship. UHC is critical to achieving the Sustainable Development Goals, where health is central in goal number 3 to “Ensure healthy lives and promote well-being for all at all ages” [21]. In monitoring achievements, universal coverage of quality essential healthcare services for all, at all ages, has become more relevant [22].

### **The effective coverage of essential interventions in antenatal care**

Effective coverage is “the proportion of people who have received satisfactory health services relative to the number needing such services” [23, 24], and can better capture both the use and quality of the health services [17, 25]. It is comprised of three components: need, use, and quality [25]. Effective coverage has been defined and measured differently in various studies and across disciplines [17-19]. Based on the Tanahashi framework [26] of measuring health service coverage, Amouzou et al. [17] and the Effective Coverage Think Tank Group [18] recommend measuring effective coverage as the losses to potential health benefits to the target population at each step. They recommend using ‘outcome-adjusted coverage’ (“the proportion of the population in need who receives the service according to quality-of-care standards, adheres to provider instructions, and has the expected health outcome”) to measure effective coverage.

In the context of ANC, effective coverage can be defined as the extent to which appropriate content of services are provided at each visit with the right frequency and

timing according to guidelines and recommendations [17, 18]. Referred to as ‘quality-adjusted coverage’, which simply means “the proportion of the target population receiving the service according to recommended standards” [18]. For ANC that includes multiple interventions linked to one or more health outcomes, ‘quality-adjusted coverage’ is a suitable measure of effective coverage than ‘outcome-adjusted coverage’ [17, 18].

The effective coverage indicator for ANC captures whether pregnant women are receiving timely and adequate care [27]. The timeliness refers to the early initiation of the first visit and attendance to relevant scheduled repeat visits. The content includes a set of evidence-based interventions that may cover a range of one-time screening tests to repeat screenings (e.g., blood pressure measurements). Effective coverage of a given essential intervention in ANC refers to the number of times the intervention was delivered (if it is a repeat intervention) and adherence to the timing of the intervention delivery according to the guideline. For example, effective coverage of the intervention to prevent and manage anemia during pregnancy could be measured as screening with a hemoglobin test at all visits where the ANC guideline recommends anemia screening. This helps capture not only the frequency of the intervention but also the timing. Timeliness of services with appropriate frequency and quality (assessed in terms of ANC content) are crucial in improving the effective coverage of essential ANC services [18, 27].

Systematic reviews have reported large gaps between crude and quality-adjusted coverage [17]. Among the countries comprised in a ‘Countdown to 2030’ report, the majority made strong progress in improving coverage of ANC 4+ [11]. However, even in areas where accessibility and affordability are not the major constraints, women do not receive all the essential components of ANC, such as health promotion and prevention, and screening and diagnosis according to appropriate evidence-based practices [11].

The challenge of measuring effective coverage mainly emanates from the complexity of measuring quality of care [28]. Quality of ANC is often measured from health systems’, patients’, or care providers’ perspectives. Traditionally, the measurement of quality has focused on structure, process, and outcomes of care [29]. Quality of ANC can also be



measured from the perspective of content indicators based on national or international guidelines and standards [30]. In effective coverage literature, clients' adherence to recommended practices or treatments were also accounted in measuring quality [17].

To measure effective coverage of evidence-based interventions in pregnancy, validated data sources and better ways of combining data from various sources are important [17-19, 25, 30]. The most common data sources used in reporting the progress towards UHC [11] are population-based, household surveys conducted at the national and sub-national levels. These data sources are cross-sectional in nature and often lack a quality-of-care aspect (e.g. timing and content of care) [11]. However, facility data can provide necessary information on quality-of-care for quality-adjusted coverage metrics. In this regard, improving the facility data, which are often characterized by poor quality data, especially in low- and middle-income countries (LMIC), is valuable [17, 18]. Using digital technologies for health facility data collection can support capturing key quality-of-care information such as the type, frequency, and timeliness of intervention uptake in a longitudinal and continuous manner [31, 32].

### **Satisfaction with antenatal care services**

Considering the needs and expectations of clients is among the foundations of a high-quality health system [33]. Women's satisfaction is an integral part of the quality of services in a client-centered maternity care model [22, 23]. The 2016 WHO ANC model aspires to provide a high-quality, women-centered services that promote positive pregnancy experiences [1, 34, 35]. ANC is not only aimed at survival of the mother and baby but also the provision of quality services that promote client satisfaction and have lasting overall health benefits. Available services might not always meet the expectations of women, often making them unacceptable [2]. Pregnant women need comprehensive psycho-social support through effective, respectful, and understandable communication [1]. The support and communication functions of ANC are key, not only to saving lives, but to improving lives, health-care utilization, and quality of care [1]. Well-informed pregnant women tend to be more often satisfied with the ANC services they receive [36].

## Digital technologies in healthcare interventions

Harnessing the power of Information and Communications Technologies for health and well-being is at the forefront of the global agenda [37]. The use of digital technologies for health is deemed to be an important tool towards health system strengthening [38-40] and a mean to realize UHC, as well as the health-related Sustainable Development Goals [41-43]. The application of digital technologies in the health sector spans all six of WHO's health systems' building blocks: service delivery, health workforce, health information systems, access to essential medicines, financing, and leadership and governance [44].

Digital health can be defined as the “use of information and communications technologies to improve human health, healthcare services, and wellness for individuals and across populations” [45]. The umbrella term encompasses electronic health (eHealth), defined similar to digital health, and mobile health (mHealth) [46] [39], defined as the use of wireless, portable information communication devices (e.g. wireless mobile and smart phones, personal digital assistants, ultra-portable computers) and technologies to support health and healthcare [40, 47-49]. The term digital health includes areas, such as the use of advanced computer sciences in ‘big data’, genomics and artificial intelligence.

Globally, the coverage of Information and Communications Technologies is rapidly growing, including in parts of the world where connectivity has been a challenge [50]. The worldwide availability of mobile devices and technologies presents a wide scope of opportunities for research and investment in digital health [51]. Mobile phone features such as text messaging via Short Message Service (SMS), voice calling, Voice over Internet Protocol, Multimedia Messaging Service, Interactive Voice Recording etc., have been used in many interventions [48]. Mobile app-based interventions have increased tremendously with the invention of smart phones and increased access to connectivity, particularly in LMICs [52]. The use of mobile technologies helps in leapfrogging to reap the benefits of digital technology in the health sector [37]. The WHO guideline on digital interventions has therefore focuses on digital health interventions (DHIs) that are

accessible via mobile devices, recognizing the growing influence of mobile devices and technologies in the sector [40].

In many LMICs, there has been a proliferation of pilot projects that aim to test DHIs of various kinds in small, stand-alone, vertical projects. ‘Pilotitis’ is a term used to describe these short-lived digital health implementations [53, 54], where the sustainability is severely hampered by the lack of integration into the health system, poor interoperability and data security standards. These problems call for systematic approaches to identify and apply DHIs relevant to the context [55]. Guidelines and toolkits can support the integration of DHIs to the broader digital health architecture [39, 40].

Globally, there are numerous and yet increasing applications of DHIs, but stakeholders involved have lacked common and standardized terms of description. Labrique and colleagues [38] identified 12 common applications of mHealth used towards health system strengthening to provide a shared language. Lee et al. [56] categorized all the identified interventions from 1990 to 2014 in a systematic review. Leveraging on these and other predecessors, the WHO developed the “Classification of Digital Health Interventions v1.0” [57] to provide a comprehensive classification of digital interventions in health. This simplified language for standardization is designed to adapt and evolve as new digital functionalities emerge.

Comprehensive evaluation of DHIs using robust study designs, with good documentation of the development process and safety evaluation across different settings, are scarce [39, 40, 49, 53, 58, 59]. Therefore, critical evaluations of emerging DHIs, intended to strengthen health systems, are needed. The assessment should include, not only the benefits of the DHIs, but also potential harms, acceptability, feasibility, cost and equity aspects [39]. This is reflected in WHO’s guideline for digital interventions for health system strengthening [40]. The authors highlight that DHIs are not magic bullets that can fix limitations of a health system, and can’t be used as substitutes for a functioning health system [40]. DHIs should be used to complement and enhance health system functions, but not replace fundamental components needed for the health system to function.

## **Targeted client communication**

Targeted client communication (TCC) can be defined as the transmission of targeted health information or content to a specific audience based on their health status or demographic categories [40, 57, 60, 61]. The aim is to improve the target individual's health-related knowledge and ultimately change behavior for better health outcomes. The communication can be tailored to the needs and preferences of individuals. It can be unidirectional or bidirectional depending on the intervention goal and medium used.

TCC can be undertaken using a range of digital channels, including text messages, voice messages, Interactive Voice Recording, multimedia applications and games (e.g., mobile Apps), as well as social media using phone numbers or other contact information. TCC via SMS has been one of the most common mobile phone-based digital interventions. Before the term TCC was introduced in WHO's classification of digital health interventions, similar interventions were referred to under the term "mHealth" [40, 57].

Digital TCC via SMS has been used in different domains of health care [62], mainly for appointment reminders [63], treatment adherence [52, 64, 65], and health promotion and education for behavior change [66-70]. Systematic reviews indicate that TCC is now increasingly being used in areas of RMNCH, including to improve ANC attendance, facility delivery, and postnatal care visits [59, 71-73]. However, a systematic review of systematic reviews concludes that the digital TCC intervention has a mixed effectiveness in improving knowledge and attitudes towards healthy behavior and utilization of maternal healthcare services [62].

Research on TCC via SMS interventions seldom report the process of content creation. This "black-box" hinders the possibility of replicating effective approaches and learning from the less effective or failed attempts [73]. Reporting the TCC via SMS intervention development also provides information to better understand the final intervention [74]. However, publications are rather few, and ways of reporting differ significantly [73, 75]. The multidisciplinary nature of a DHI warrants an organized approach of description that spans across disciplines, and as digital TCC focuses especially on changing behavior, it

needs to be guided by behavior change theories [76, 77]. The active components in a behavior change intervention are often difficult to characterize since there are different techniques and various constructs of a theory. Michie and colleagues [78] developed a behavior change technique taxonomy to systematize the reporting process of behavior change interventions. Specific to the design and pretesting of text message-based behavior change programs, Abrams et al. [79] recommended steps (conduct formative research for insights; design; pretest; and revise the text message program) based on their research experience in the field.

Frameworks can help structure conceptualization, development, implementation, and evaluation process of DHIs, but a holistic framework to report such process is lacking [76]. The mobile health evidence reporting and assessment (mERA) [80] and template for intervention description and replication (TIDieR) [81] checklists are useful tools in the reporting. TUDER (Targeting, Understanding, Designing, and Evaluating and Refining) is a more comprehensive framework that includes most of the essential components suggested by the preceding frameworks [76].

### **Factors affecting the effectiveness of a digital TCC**

Digital TCC interventions with certain traits are more effective according to systematic reviews [62, 63, 73, 82, 83]. The following factors are among the recommendations made in the WHO guideline [40], which are also the main interest to this thesis:

#### ***Underpinned in relevant theories***

Theory based interventions are often specific and replicable due to the theory driven description of the design, development, and implementation processes [56, 84, 85]. Theory in this context means “a set of concepts and/or statements with specification of how phenomena relate to each other”. Theory provides a way of organizing descriptions of a system that accounts for what is known, and explains and predicts phenomena [86]. Using explanatory theory, one can describe the reasons why a problem exists and explore factors that contribute to that problem [87]. Theory can also guide effective mechanisms of change, by identifying the active ingredient for change to the intended behavior [88]. It

is reported that only 22.5% (of 235 studies evaluated) applied a theory in the development of public health interventions [89]. Theories can also be applied in the assessment of existing problems or behavior to understand the context [84, 88].

To design a digital TCC intervention, theories can be used as a lens to guide the development of relevant content [84, 85, 90]. A TCC intervention, designed to improve attendance to visits through appointment reminders, is one type of behavior change intervention, which can be designed by means of a behavior change theory or a set of constructs from multiple behavior change theories [76]. TCC interventions that tend to be effective have applied behavior change theories and techniques of some form in the design process [56, 62, 66, 72, 83], although most are under-theorized [56]. There is an ongoing discussion to reach consensus about the most applicable behavior change theories, especially in the context of digital technology applications [77, 84]. Those studies that have applied a theory, often use classical behavior change theories [76, 77, 84, 85, 91, 92], such as the Health Belief Model (HBM) [93].

The HBM was originally developed to seek an explanation for why the uptake of public health programs to prevent and detect disease was low [93]. HBM has six constructs: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, ques-to-action, and self-efficacy. These constructs can be grouped into three: individuals' perception of the threat posed by a health problem, the benefit of an action to avoiding the risk, and factors influencing the decisions to act. As one of the exploratory theories in behavior change study, HBM has been widely applied to understand behavior at an intrapersonal level [87]. It has been used to understand peoples' perceptions, and in the design of interventions that promotes a desired behavior [85].

Frameworks can help create TCC content that is understandable, efficient, and acceptable. A recent qualitative evidence-synthesis stated that the choice and order of words in the text, as well as the length, timing, and frequency of the TCC messages are among important factors for effective digital TCC intervention [59]. A behavior change message

probes the receiver to act. To make it actionable, frameworks such as the Model of Actionable Feedback (MAF) can be used. According to MAF, messages communicated must be timely, individualized, non-punitive, and customizable [94, 95].

Behavioral scientists have increasingly been using nudging, a “gentle and gradual push” towards taking an action [96] in designing behavior change interventions. Nudging is a relevant concept in composing the content of digital TCC interventions and devising an efficient and acceptable delivery mechanism [96-98]. Nudging helps in addressing the gap between the intentions to change behavior and taking actual measures. Different nudging techniques are used across disciplines [96-98]. For example, framing the messages as a ‘social norm’, meaning the message is accepted and practiced by the majority, (e.g. “most clients attend ...”); personalizing the messages (e.g. calling the receiver by name, indicating personal level gains and losses, tailoring to own conditions, etc.); recalling previous joint decision for the action (e.g. phrases indicating agreement); and clearly signing off the message to encourage trust, are among the many nudging techniques that have resulted in the increased effectiveness of interventions [96, 97, 99].

By design, nudging makes it easier for recipients to choose the option regarded as better while not preventing the alternative. For example, the Enhanced Active Choice (EAC) [100] model nudges towards the intended behavior yet leaves the ultimate choice to the recipient of the behavioral intervention. Although dependent on the type of target health issue, a positively framed message presenting both the benefits of action and consequences of inaction is a recommended way to present behavior change communication as opposed to fear inducing, negatively framed messages [100].

### *Co-design with the users*

The DHIs that involve the end-users from the beginning, and throughout each phase of the project, are more effective [101], as described in the Principles for Digital Development [102]. Co-designing with users does not mean inviting users to only approve the final version, which is often done as an attempt to facilitate user acceptability. Co-design goes beyond stakeholder meetings held either only at the final phases or at the

beginning of the intervention design [56, 59, 101, 103]. Rather, it is an iterative process of designing the entire digital intervention with the users rather than for the users, at all steps [104]. A systematic review of qualitative research on the acceptability of digital TCC reported mixed results [59]. It is evident from the findings of the review that co-designing can improve the acceptability of the intervention by addressing frustrations that may arise from a one-size-fits-all approach.

### *Tailor to individuals*

Tailored health communication can improve the effectiveness of health education and promotion [61], as supported by a meta-analysis of tailored print health behavior interventions [105]. Tailoring based on theoretical, behavioral, or demographic variables are among the core interactive design features of effective DHIs [106]. A qualitative evidence synthesis also recommends personalization whenever possible [107].

TCC via SMS can be tailored or non-tailored communication [57]. A database containing tailoring variables, captured by a provider, is needed to tailor messages towards important individual characteristics [56, 57, 71, 72]. However, most health campaigns, especially in LMIC, recruit the recipients of the intervention on a demand-based subscription, where the client contacts the service providers first [57]. Often limited information on the recipients is stored in a database from which the intervention is sent. Limited amount of information, such as background data, also limits the extent of tailoring, as indicated in a review [82].

### **Unintended consequences of a digital TCC**

DHIs, especially those targeting behavior change, may result in unintended consequences for the recipients. Generally, documenting adverse outcomes of interventions in health education and promotion have not been given due attention [108]. The lack of evidence regarding potential unintended consequences of digital TCC, has made it among the priority questions for WHO's future research for [39]. One of the unintended consequences can be effects from the psychological response to the content. Pregnancy related information and appointment reminders tailored to women based on risk-factors,



obstetric and demographic characteristics may trigger unintended consequences psychologically. In a prior systematic review, the lack of studies about the adverse effect, in terms of clients' and providers' perception of safety, privacy, misrepresentation, was reported [63]. Although there were a few reports of research that utilized digital technology to reduce pregnancy related worries and concerns [52, 109], there has been limited information regarding the assessment of its potential adverse effects [110].

Pregnancy is a period when women are vulnerable to worries and anxiety, especially during early and late stages of pregnancy [111, 112]. The variabilities in the definition and the psychometric measurement tools used across studies, hamper the understanding of worries and anxiety in pregnancy [112-114]. One of the commonly used psychometric tools during pregnancy is the Cambridge Worry Scale (CWS) [115], which has been validated in several languages and cultures [116-121].

## **Study context**

### **Coverage of antenatal care services in Palestine**

The coverage of ANC and attendance by skilled health workers at delivery have been consistently very high in the occupied Palestinian territory (oPt). Despite this, access has been increasingly unpredictable [122, 123]. According to the 2018 annual service use report by the Ministry of Health (MOH), 98% of women had at least one ANC visit, and 94% had four or more, with the average rate being 4.5 visits [124]. According to the same report, 99.9% gave birth at health institutions.

Although primary healthcare facilities are available close to where people live, travel times can be prolonged in places where army checkpoints and separation walls exist due to the blockade [122]. Peer reviewed published articles that could have illuminated the status of effective coverage of maternal and child healthcare services are scarce [125]. However, studies that have assessed quality of ANC services in LMIC reported low effective coverage, which might also hold true for the oPt [12, 19, 30, 35, 126].

## **The organization of maternity care services**

The health system structure in the oPt is complex, following the overall governance structure of the territory. The West Bank and Gaza Strip are separated physically, and there are administrative, legislative, and political divisions between the two. East Jerusalem is further separated from the remainder of the West Bank by the separation barrier, and Palestinians living in East Jerusalem are accorded a different status and identity card than Palestinians in the rest of the West Bank. This means that the access to and quality of healthcare varies [127].

According to the 2018 MOH report [124], there were 732 public primary healthcare clinics (PHC) in Palestine (585 in the West Bank and 147 in the Gaza Strip). The Palestinian MOH owns about 64% of the PHCs, whereas the rest are operated by United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA), Military Health Services, Non- Governmental Organizations, and the private-for-profit sectors. Although all public PHCs can provide ANC services, high-risk pregnancies are referred to a high-risk clinic, which can be in the same facility or in another PHC. In 2018, from the total number of pregnant women's that have visited PHCs, 46.5% (34, 605) registered their first visit at a public PHC, of which 17.4% were referred to high-risk clinics according to the national ANC guideline [128].

## **eRegistries**

Electronic registries (eRegistries) are systems that use Information and Communications Technologies to collect and utilize uniform, systematic, and longitudinally and digitally entered individual-level clinical data to drive DHIs for health systems strengthening [31]. The MCH eRegistry in Palestine was developed in an effort to improve quality of care [31, 129, 130].

The MCH eRegistry is built on the District Health Information Software 2 (DHIS2), with the Tracker App as its backbone. DHIS2 is a free, open-source data collection and management software that provides users with a flexible interface for managing health data. As a software platform, DHIS2 also has built-in data validation, visualization, and

analysis tools, and offers select privileges for user access to data at different levels of the health system [131, 132]. DHIS2 is being used in over 70 countries at various capacities [131], and can be useful in managing large quantities of health data to monitor Sustainable Development Goal indicators [133]. The DHIS2 Tracker App is an extension of the DHIS2 platform for individual or disaggregated longitudinal data collection. It allows for tracking of patients over time, validating clinical measurements, scheduling clinical visits, tracking missed appointments, communicating with patients via SMS reminders, etc. It can be configured for online use and offline use in web browsers, and offline use with mobile devices that run on as Android operation systems [131].

The philosophy of an eRegistry is that all data should be useful and used [31, 134]. Palestinian residents have unique identifiers that make files of individual clients identifiable for subsequent visits, or in another facility after a referral by care providers. Individual-level data are documented by the healthcare providers at the point-of-care as part of routine clinical care. The healthcare providers are expected to document all services provided at each visit, and the data-points in the ANC clinical record are based on the MOH guideline [128], which is almost aligned with recommendations from the WHO [1]. The entered data drive interactive checklists and clinical decision support based on national ANC guidelines [129], and aggregated and disaggregated reports of routine indicators and other indicators of utilization of health services and provision of essential interventions, are available at the facility, sub-national, and national level.

### **Embedded research**

The rollout of the MCH eRegistry was done in phases with embedded cluster randomized controlled trials (cRCT). The first trial (eRegQual) aimed to test the effectiveness of the interactive ANC checklist with clinical decision support, compared with the existing paper-based ANC records, in improving the quality of care processes and corresponding birth outcomes [129]. A time-motion study [135] was also conducted in a sub-sample of PHCs involved in the eRegQual trial to compare the time spent in using an electronic tool.

The second effectiveness trial (eRegCom), to which the work in this thesis contributed, consisted of two additional digital health interventions added to the ‘basic’ MCH eRegistry. These digital interventions may be considered as one way of demonstrating the potential benefits of point-of-care data collection at the lower levels of the health system – where the clients and providers meet. These two main stakeholders often serve as data sources and data collectors in the health system, but have seldom been considered primary and direct users of the data they produce. The digital interventions assessed in the eRegCom trial do not require an additional data collection by the healthcare providers. These two digital interventions were tested in a four-arm cluster randomized trial (*supporting paper*)[136]. The two digital interventions are as follows:

- 1) Quality Improvement Dashboard (QID) to healthcare providers: this is a digital tool to help healthcare providers monitor their screening and management performances based on the national guideline and retention rate of their clients for subsequent ANC visits. The QID was co-designed with the end-users in an iterative process with multiple rounds of testing and improvements. In addition to the dashboard with different content, training on the concepts of quality improvement and how to use the QID were essential components of the intervention. Details on this intervention can be found under the ‘intervention’ subsection in *supporting paper* [136].
- 2) TCC via SMS to the pregnant women: the TCC intervention development and evaluation of the unintended consequences are emphasized in this dissertation. The eRegCom trial is presented in the *supporting paper* [136].

## Rationale of the thesis

The coverage of ANC 4+ in the public PHCs in Palestine is reported to be high, but evidence regarding the timeliness of visits and quality of care is lacking. Understanding the effective coverage, i.e., the appropriate number and timing of screening tests according to the national ANC guidelines, is recommended in the comprehensive measurement of service delivery. Identification of the main reason/s that have dragged down the effective coverage is the first step in the journey of developing a possible intervention. The MCH eRegistry provides opportunities for quality improvements through DHIs, including an opportunity to communicate with clients.

The concepts and application of TCC, within the wider health promotion and communication auspices, may have a natural position given the context. The TCC needs to be attached to a clear action to bring about the intended behavior.

The design and implementation of an effective, safe, acceptable, feasible, and sustainable DHIs, should follow the Principles of Digital Development and other relevant theories, models, and frameworks. The safety issue is often overlooked, but necessary steps need to be taken to prevent unintended consequences for stakeholders. These steps start from the planning phase: learning from the existing literature, following recommended ways of communication (e.g., composing a message), a good assessment of the existing organizational and behavioral context, and learning from the users throughout. A one-size-fits-all approach will not work where contextual differences matter.

This is to share the experiences and lessons learned in conducting studies in a rather unique context where the DHI for maternal and child health is embedded in a national health system.

## Chapter II: Objectives

### Aim

To develop a digital health intervention to improve effective coverage of antenatal care in public primary healthcare clinics in Palestine.

### Main objective

The overall objective of this PhD project was to identify gaps in the effective coverage of ANC that can be addressed by a digital intervention, develop the TCC intervention, and evaluate potential unintended consequences of the intervention.

Our specific objectives were:

1. to assess the effective coverage of ANC interventions in public primary healthcare clinics in the West Bank, Palestine (*Paper I*)
2. to describe the planning, development, and evaluation of a theory based targeted client communication intervention, tailored to pregnant women and automated from the Palestinian electronic maternal and child health registry (*Paper II*)
3. to evaluate any unintended consequences of the digital targeted client communication intervention –in terms of increasing pregnancy related worries or reducing satisfaction with the antenatal care services (*Paper III*)

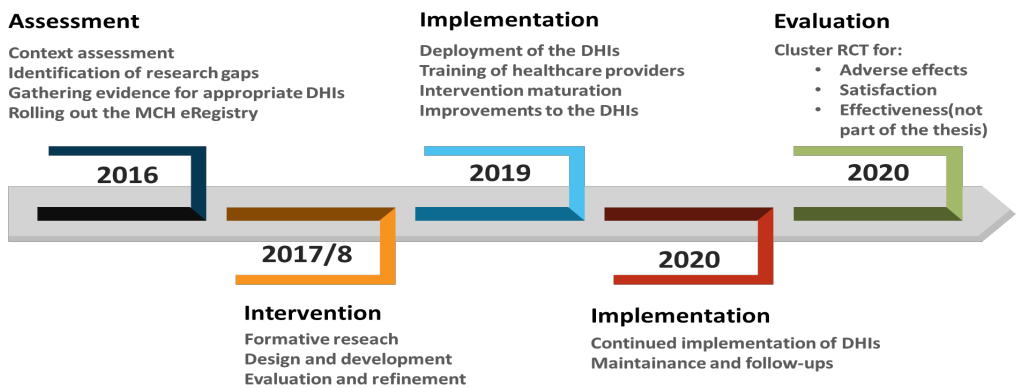
## Chapter III: Materials and Methods

### Study setting



This thesis is based on studies conducted in public PHCs that provide ANC services in the West Bank and the Gaza Strip. The data were collected from public PHCs before the MCH eRegistry implementation; and from clients and users of the MCH eRegistry. The work is part of the eRegCom trial (Fig 2).

**Fig 1.** Map of the West Bank and the Gaza Strip, oPt



**Fig 2.** eRegCom trial timeline and activities of the assessment, intervention development, implementation of the intervention, and evaluation.

The Palestinian national ANC guideline [128] recommends five routine ANC visits for all low-risk pregnancies booked before 16 weeks of gestation (Table 2). Each routine ANC visits includes specific screening tests, and some are repeated during the course of ANC (Table 2). E.g. for diabetes, a urine glucose test is performed at booking (< 24 weeks) and universal screening with a blood glucose test is performed at the 24-28 weeks visit [128].

**Table 2.** Palestinian national ANC guideline; recommended regular visits and corresponding screening focuses for selected conditions in pregnancy (source: Paper I; only target conditions for the targeted client communication intervention are included)

ANC essential interventions	Routine ANC visits schedule (gestational age in weeks)					
	Booking	16	18-22	24-28	32	36
Timeliness window*	Booking+	15-17	18-22	24-28	31-33	35-37
Screening for hypertension	X	X	X	X	X	X
SFH measurement	X	X	X	X	X	X
Screening for anemia	X			X		X
Antenatal ultrasound	X	X		X		X
Screening for diabetes mellitus	X (Urine)			X (Blood)		

\*one week at both ends were given to define the timeliness of screening tests by the research group  
 +Booking visit refers to the first ANC visit; some tests are adjusted to the gestational age at booking

The TCC intervention design, implementation, and assessment concentrated on a few selected pregnancy related target conditions and issues. We hereafter refer to these as the *target conditions* (Box 1). The prioritization process was conducted in consultation with local health experts at the beginning of this combined research-implementation initiative.

**Box 1.** Target conditions for digital health interventions identified by national experts

1. Hypertensive disorders of pregnancy
2. Anemia
3. Diabetes mellitus
4. Fetal growth restriction, and
5. Untimely attendance to ANC visits



## Design, materials, and methods

We summarized the methods and materials that we employed in this thesis in Table 3.

**Table 3.** Summary of methods and materials for each paper in the thesis

	<i>Paper I</i>	<i>Paper II</i>	<i>Paper III</i>
<i>Objective(s)</i>	To assess the effective coverage of essential antenatal care services	To describe the planning, development, and evaluation of a theory led digital TCC intervention, tailored to pregnant women and automated from the Palestinian electronic maternal and child health registry	To assess the unintended consequences (increased pregnancy related worries and decreased satisfaction with antenatal care) of the TCC intervention between clinics receiving the TCC intervention and controls
<i>Study design</i>	Quantitative: Cross-sectional	Qualitative: in-depth interviews (with iterative, theory-lead, co-designing of tailored digital TCC intervention)	Non-inferiority cluster randomized trial: sub-study
<i>Data sources, participants</i>	Paper-based antenatal care records of 1369 women (2015) from 17 PHCs in five districts, prior to implementation of the MCH eRegistry	In-depth interview from: -18 Pregnant women - 8 Healthcare providers -Health promotion experts (involved in testing phase)	From 137 clusters and 454 women in the West Bank and the Gaza Strip, randomized to the intervention and control clinics Phone interviews using validated and pre-tested questionnaire: -Cambridge Worry Scale -Satisfaction questions
<i>Outcome measures</i>	*Coverage of at least one, appropriate number, and appropriate number and timing (effective coverage) of anemia, hypertension, SFH, and ultrasound	Developed TCC via SMS intervention -Perception of women -Composing contents of the SMS messages -algorithm design and automation	-Level of worries measured by mean score and standard deviation on the CWS -Level of satisfaction with the ANC services measured by six-point Likert-scale type question
<i>Analyses methods</i>	Weighted proportion with 95% CI, logistic regression	Thematic analysis of the in-depth interview data	Intention-to-treat, mean score difference considering the clustering effect

*\*Only essential interventions for which we have data from antenatal care register were included. TCC = Targeted Client Communication, PHC = Primary Healthcare Clinics, SFH = Symphysis Fundal Height, CWS = Cambridge Worry Scale, CI = Confidence Interval, ANC = Antenatal Care, MCH = Maternal and Child Health*

## **Paper I: Effective Coverage of essential interventions in ANC**

### ***Design***

We used a cross-sectional study design to assess the effective coverage of selected essential ANC interventions using data from paper-based clinical records.

### ***Participants***

Public PHCs in five districts in the West Bank (Bethlehem, Jenin, Nablus, Ramallah/Al-Bireh, and Salfit) served as sources of the paper-based clinical records for ANC. The public PHCs were selected from these districts, which were part of the first phase of the MCH eRegistry implementation. There were 180 public PHCs in these districts at the beginning of the project, of which 165 offered routine ANC. These public PHCs served 11,416 new pregnancies out of about 32,000 pregnancies per year in 2014 [137]. There were no eligibility criteria for individual women within the selected PHCs.

### ***Sample size***

We calculated the sample size for the least prevalent outcomes in the study area (1% prevalence of severe anemia). We estimated the effective coverage of the selected essential interventions in the range of 40-60% since there were no published estimates in the similar approach we defined. The computed sample size was 1344 pregnancies assuming a margin of error of 0.5% (2-3% for the effective coverage assumption), with the finite population correction for about 11,400 pregnancies in the study site (obtained from the facility inventory). Calculations were made using ‘OpenEpi’ software [138].

### ***Sampling***

We selected PHCs based on probability proportional-to-size sampling to include representative samples from small and big clinics. Selection was continued until a certain number of PHCs were available to achieve the required number of pregnancies, as specified under the sample size section. The condition for including a PHC was that data from all clinical records of pregnancies registered for one year in 2015 in the selected PHC had to be extracted. The annual enrollment of the 17 selected PHCs corresponded to the calculated sample size. As part of the planning for implementation work and the

embedded research, Palestinian National Institute of Public Health (PNIPH) conducted a thorough inventory of each public PHC in all districts in the oPt (appendix 1). The inventory provided background information for all papers included in this thesis.

### *Variables*

The ANC record (appendix 2) consists of background and sociodemographic information; any pregnancy; obstetric, medical and family history; clinical examinations results; laboratory tests; ultrasound examination; managements; and complications warranting referrals. Apart from variables used to define the outcome, we included maternal age at pregnancy registration, age at marriage, parity and educational status for testing potential associations with the outcome. We obtained information on availability of ultrasound and laboratory services at the PHCs from the inventory (appendix 1).

The main outcome, effective coverage of essential interventions, was operationally defined as the combination of attending all ANC within the recommended gestational age windows for an intervention and receiving the right screening test to identify the target condition (Table 4). For example, a woman who came in contact with the PHC early in her pregnancy (at the latest before 24 weeks of gestation) and reached term had three opportunities to receive anemia screening according to the national guideline [128]. The one who attended all the recommended visits and was screened for anemia in each contact received a positive score for effective coverage of anemia screening (Table 2). This is based on the fact that the client has not been diagnosed with anemia in any prior visit during the current ANC follow-up.

To provide evidence of contributors for the effective coverage, we also computed the coverage of at least one screening and coverage of an appropriate number of screenings given the number of available opportunities (Table 4). The focus of this thesis is to see how attendance is related to the effective coverage of anemia, hypertension, diabetes, and fetal growth screenings based on the national ANC guideline recommendation [128]. We, therefore, excluded some of the essential interventions included in *Paper I* from discussion in this thesis.

**Table 4.** Definitions of coverage indicators for at least one screening, coverage of the appropriate number of screenings, and effective coverage of selected ANC interventions (source: Paper I; only target conditions for the targeted client communication are included)

<b>ANC intervention</b>	<b>Coverage of at least 1 screening</b>	<b>Coverage of the appropriate number of screening</b>	<b>Effective coverage (appropriate number and timing of screenings)</b>
<b>Screening for hypertension</b>	Proportion with at least one blood pressure measurement	Proportion with five blood pressure measurements	Proportion with blood pressure measurements at all recommended ANC visits
<b>SFH measurement</b>	Proportion with at least one SFH measurement	Proportion with five SFH measurements	Proportion with SFH measured at all recommended ANC visits <sup>†</sup>
<b>Screening for anemia</b>	Proportion with at least one hemoglobin test	Proportion with three hemoglobin tests	Proportion with hemoglobin tests at booking <sup>‡</sup> , 24-28 and 36 weeks*
<b>Antenatal ultrasound</b>	Proportion with at least one ultrasound examination	Proportion with three ultrasound examinations	Proportion with ultrasound examinations at booking <sup>‡</sup> , 24- 28 and 36 weeks*
<b>Screening for gestational diabetes mellitus</b>	Proportion with either urine sugar or blood sugar test	Proportion with both urine sugar and blood sugar test	Proportion with urine sugar test at booking <sup>‡</sup> and blood sugar test at 24-28 weeks*

*†*calculated for ANC visits that occur after 16 weeks; \*given that registration of pregnancy was before the recommended timing of screening; *‡*Booking: refers to first antenatal visit at the clinic.

ANC: Antenatal care; SFH: Symphysis-fundal height

### **Data collection**

For *Paper I*, the paper-based ANC records were gathered after the completion of the pregnancy. Two trained nurse-midwives extracted data from the paper-based ANC records (appendix 2). The extraction of data was completed in April 2017 and entered to the exact version of the record created in an electronic format in the DHIS-2 Tracker. All the different sections in the paper-based ANC records, including laboratory results on pieces of papers in the client’s file, were entered to the software. Double data entry for 10% of the data was performed to validate data entry. There were no significant quality issues in data entry. When there were differences, the field data entry coordinator checked for the correct value in the paper records, corrected the entry accordingly, and discussed the situation with data entry personnel to address those issues for the rest of the data entry.

## **Paper II: The digital TCC intervention development**

### ***Design***

The second paper (*Paper II*) in the thesis uses qualitative methodology through in-depth interviews for the assessment phase to explore perceptions of women and healthcare providers, which comprised the first part of the paper (the second part is about the development, evaluation and refinement of the TCC intervention). We identified HBM [93] as the guiding theoretical framework. The design, evaluation and refinement of the TCC intervention was an iterative process. The entire development of the DHI – a digital TCC via SMS – was generally guided by the Principles of Digital Development [102]. To compose the contents and timing of the TCC text messages, we used nudging concepts from behavioral sciences [96], including Enhanced Active Choice [100] for framing the messages. Borrowing from audit and feedback studies in healthcare, we used the constructs from the Model of Actionable Feedback [94, 95] to translate the behavioral communication to action. More explanation and examples are provided under the section on ‘underpinned in relevant theories’ in Chapter I: Introduction.

### ***Participants***

The participants of the in-depth interviews were pregnant women and healthcare providers using the MCH eRegistry in public PHCs from both the West Bank and the Gaza Strip. All healthcare providers involved in providing ANC services were eligible for participation. Pregnant women who came to the selected facility during the data collection period were eligible to participate. In a similar approach to the assessment phase, we collaborated with health education experts, the health care providers, and pregnant women in the iterative co-designing, evaluation, and refinement process.

### ***Sample size***

We decided the final number of participants for the in-depth interviews with pregnant women and healthcare providers based on theoretical saturation [139] after a first round of interviews. The goal of the sampling was to select public PHCs from distinct locations, including PHCs with or without laboratory and ultrasound services, to ensure

representation of the health system. We also aimed to include participants with characterizing profiles (risk-status, age, educational status, and parity) that can reflect the source population. Based on these criteria, we identified PHCs from three districts in the West Bank and two districts in the Gaza Strip. We used the size of annual new client enrollment, obtained from the facility inventory, as an indicator since it reflects the rest of variations (stated above) of PHCs and participants.

We interviewed 18 pregnant women in seven PHCs. Among the participants, seven of them had a target condition at some time during their current pregnancy. Seven of them were primigravidae. The age distribution ranged from 20 to 33 years. All of them had a formal education, of which seven had a college degree. We also interviewed three women to obtain the perspective of pregnant women who started ANC services in the public PHCs but never returned for follow-up visits. We included eight healthcare providers in the study, of which four were doctors providing RMNCH services for high-risk clients in addition to the routine care provision for low-risk women.

### *Sampling*

We purposively selected PHCs based on their size, location, and inclusion in the eRegCom trial. In the seven selected PHCs, all nurses, midwives, and doctors who had direct involvement in ANC services were eligible to take part in the in-depth interviews. We purposively selected the healthcare providers for the in-depth interviews from all the seven PHCs. We used a convenience sampling technique to invite pregnant women into the study from those attending the PHC on a data collection date. Interviewers selected women with different risk-status and parity in each clinic on a given date. To include women who did not come back after attending booking registration, we used a PHC in Ramallah city that was among the seven public PHCs, due to convenience, and requested a list of women who only came for booking registration but did not show up to the facility for subsequent visits. We only identified women who had a registered phone number and whose due dates had not passed.

For the evaluation and refinement phase, we presented the initial draft of the text message contents to health education experts in the MOH. We invited them to provide their inputs both verbally and in writing. These local health education experts provided feedback on overall text messages and specific areas that they perceived as important in their context. We then made improvements on the first version and subsequently presented the text messages to the healthcare providers for feedback. After incorporating the healthcare providers' feedback, the different categories of text messages were finally presented to pregnant women from across the trimesters. We selected PHCs from the Ramallah area for convenience to obtain feedback from the healthcare providers and pregnant women.

### *Variables and data collection tool*

While preserving the basic notion of in-depth interviews – where the informant leads the discussion – we designed two semi-structured in-depth interview guides using the HBM to understand the perceptions of women concerning the need and benefits of ANC attendance for each target condition. The HBM constructs in the in-depth interview guide for pregnant women (appendix 3a) can be grouped into the following main domains:

1. women's perceptions of personal risks for the target conditions (perceived susceptibility and perceived severity),
2. perception of the benefits of attending ANC for the target conditions (perceived benefit), and
3. factors influencing the decision to attend timely ANC after being aware of the risks and benefits (perceived barriers, cues-to-action, and self-efficacy).

The guide additionally included questions on women's knowledge and attitudes regarding the sources, quality, frequency, and adequacy of health information during pregnancy. The guide included questions regarding counseling and perceived gaps in health communication. Finally, we also included open ended questions about preferred digital interventions that the clients believed would facilitate timely attendance of ANC appointments. Conceptually similar topics were addressed in the in-depth interviews with

the healthcare providers – putting the needs of the pregnant women in the center – jointly discovering ways to bridge perceived gaps in providing quality care (appendix 3b).

We identified potential risk-factors to the target conditions and their magnitude from sources like *UpToDate* [140], the National Institute for Health and Care Excellence [141], The International Association of the Diabetes and Pregnancy Study Groups [142], and WHO recommendations [143]. We obtained the prevalence of target conditions from the MCH eRegistry data and calculated the Population Attributable Risk [144].

For the ‘evaluation and refinement’ of the content of the TCC, we conducted unstructured interviews with pregnant women to get feedback about the relevance, clarity, expression, richness, and logical sequence of the text messages. For example, we presented to the participants different ways of describing statistics concerning ones’ susceptibility to a target condition, such as in percentage (X %) format or as “X in Y” format. Additionally, in this final evaluation and refinement phase, we asked pregnant women about the convenient time of day to receive the text messages, and the proposed frequency.

### *Data collection*

In *Paper II*, four nurses were trained in conducting in-depth interviews. The training included the basics of in-depth interviews and explaining the aim of the assessment and using the interview guide to ensure clarity and common understanding among each other. All interviewers conducted mock in-depth interviews the day following the training. The differences in the interview techniques and understanding of the tools were discussed to minimize the differences before conducting the interviews of participants in the study.

The interviewers presented the information sheet and obtained oral informed consent before starting the in-depth interviews. The interviewers approached pregnant women who had completed their ANC visit in the PHCs. Participants that provided informed consent were interviewed in a private room in the PHC premises. The interviewers presented purpose of the research and assured the participants that the information they shared will have no impact on the health services received. Using the in-depth interview guide, each topic area was raised to capture the perceptions of the interviewee. The



interviewee led the flow of ideas while the interviewers probed and asked follow-up questions when deemed necessary. Three women, who were not attending ANC in the original public PHC where they were registered, were interviewed via a phone call following the same standard of in-depth interviews.

The healthcare providers in the selected PHCs were interviewed in their offices, after they completed their daily clinical work, using the in-depth interview guide. The process of obtaining informed consent and conducting interviews were similar to pregnant women's.

The interviews took 20-50 minutes. All in-depth interviews were tape recorded after obtaining permission from the participants. Every day, after the interviews, the interviewers shared the summary of each interview with the researchers. We discussed using these preliminary daily summaries to improve the quality of the in-depth interviews.

### *Intervention development*

The content of the text messages was developed based on the HBM with results from the in-depth interviews (*Paper II*). The research team agreed upon the different types of the text messages and the ways of structuring the content based on literature, user involvement, identified frameworks and models. We were guided by the message framing models [94-97, 100], described under 'underpinned in relevant theory' (Chapter I: Introduction), to compose messages that are acceptable to the recipients and can appropriately nudge them to effectively change behavior. The nudging concepts used, theoretical assumptions, and how the components of the TCC intervention were guided are presented in appendix 4. Based on the Population Attributable Risk, we identified the most relevant risk-factors for each of the target conditions, which were used to tailor the TCC intervention.

The text messages were first produced in English and then translated into Arabic by the project team members before the field testing was conducted. A separate member of the team not involved in the message development and original translation back-translated the text messages to check for consistency of language and structure.

There were two primary focuses of ‘evaluation and refinement’: 1) testing the understandability and usability of the content, structure, and timing of the TCC via SMS intervention; and 2) testing the algorithms and functionalities of the digital tool in triggering the correct message template to the right individual, which either sends the messages immediately or schedules the messages to be sent later, according to their type. Using appropriate local expressions were the results of the evaluation and refinement process. The draft messages were iteratively refined to produce the final set of messages.

### **Paper III: Unintended Consequences of the Digital Intervention**

#### *Design*

We applied a non-inferiority cluster randomized controlled design to assess the primary outcome of worries in pregnancy (measured by the CWS), as an unintended consequence of the digital TCC via SMS intervention. For the final study of this thesis, we followed the randomization done for the eRegCom trial [136] and reclassified the study arms into two. The eRegCom study is a four-arm cluster randomized controlled superiority trial design [136]. The interventions put to test are described under the ‘embedded research’ section in Chapter I. We collapsed the two arms where pregnant women were randomized to receive TCC via SMS (TCC and QID+TCC arms) into intervention and the other two arms (QID and control arms) into control, making a two-arm parallel cluster design.

Randomization of the clusters was conducted by an external statistician from the Center for Intervention Sciences in Maternal and Child Health (CISMAC). The randomization was stratified by the phase and location of the MCH eRegistry implementation and constrained on the availability of laboratory and ultrasound services, as well as the size (number of new pregnant women per year) of the clusters. All the clusters were users of the MCH eRegistry (an interactive checklist with decision support) [129].

#### *Participants*

The trial included 140 PHCs and 138 clusters (two pairs of clinics were considered as a cluster since a single nurse regularly worked in each of the two pairs). The public PHCs were from 14 districts in the West Bank (Bethlehem, Jenin, Nablus, Ramallah/Al-Bireh,

Salfit, Hebron, Jericho, Jerusalem, North Hebron, South Hebron, Qalqiliya, Tubas, Tulkarm, Yatta) and Gaza Strip. We excluded PHCs that had enrolled less than 45 new pregnancies per year in 2016 because of the unpracticality of evaluating the digital intervention we were implementing. We also excluded PHCs with more than 3000 pregnancies per year because these PHCs are atypical. The included public PHCs enrolled a mean of 344 and a median of 131 new pregnant women in the same year [136]. The list of public PHCs from each district with their average annual enrollment and the MCH eRegistry rollout phase is presented in appendix 6. The participants were women sub-sampled from 137 clusters (1 PHC was closed after the original randomization). From both the intervention and control arms, we included pregnant women whose gestational age was to be 38 weeks during the data collection week, who had no reported (or registered in the MCH eRegistry system) pregnancy outcome indicating that the pregnancy is still ongoing, and who had registered mobile phone number.

### *Sample size*

Out of 137 available clusters; 69 clusters received TCC intervention. The cluster size varied from 45 to 3000; unequal cluster sizes were accounted for in calculating the sample size for the four-arm trial (*Supporting Paper[136]*). For the sub-sample study, we decided on a one-month period for data collection, which corresponds to at least four eligible clients in smaller clusters. This led us to assume an equal cluster size of four in the power computation. The main outcome of the trial was women's worries, measured by the 13-items of the CWS [115]. Since there was variability in the reports of the standard deviation around the mean score of the CWS in previous studies, we conducted a meta-analysis of relevant literature and a pilot study (n = 45), which was conducted in the same study area (unpublished). The pooled mean score was 1.5 [95% CI, 1.09-1.92] with a standard deviation of 1.1. Assuming an intra-cluster correlation coefficient (ICC) of 0.01 and a one-sided significance level of 2.5%, the study was 90% powered to detect the difference with a non-inferiority margin of 0.3 (that means a one-point increase for every third question in the CWS). To our knowledge, there were no studies indicating how

much of an increase in the CWS is clinically important to determine the non-inferiority margin. The power of the study was estimated using PASS software for sample size calculation for a non-inferiority cluster randomized trial design [145].

### *Sampling*

We included women who fulfilled the inclusion criteria (see participant sub-section) from each PHC until the estimated cluster size was achieved. We extracted eligible women from the MCH eRegistry every week during the data collection period. When there were more eligible women than needed, we selected a random sample of participants needed.

### *Intervention*

The intervention was a theory-led, co-designed, and individually tailored digital TCC via SMS to pregnant women automated from the MCH eRegistry. In this section, we present the final output of the process (see intervention development sub-section for the design). The focus areas of the TCC via SMS interventions were in concert with the routine visits' recommendations according to the national ANC guideline. Table 5 presents the target conditions at each routine ANC visit, a description of the message contents, and the range of gestational age windows covered by the intervention.

### **Message library and algorithms**

A library of TCC messages in Arabic was created in the DHIS2 Tracker. Algorithms were created to individualize messages based on women's gestational age; presence or absence of target conditions and selected risk-factors for the target conditions; and assent to receive the messages. We developed separate algorithms for each template TCC message. When the criteria in the algorithm is fulfilled, the system automatically prepares a text message (pulls the right message from the library, inserts the date, and the name of a clinic and the recipient), and links it to the phone number of the recipient. The system is continuously running including the algorithms that trigger the correct text message type to be sent to the recipient. All the individualization and preparation work for the text message is completed in the DHIS2 Tracker, which is connected to the gateway of the service providers in order to deliver the text messages to the recipient's phone for free.

**Table 5.** The Palestinian national antenatal guidelines for routine visits and the target conditions of the digital Targeted Client Communication (TCC) intervention (source, *Paper I*)

Five routine Antenatal Care visits	The target conditions and recommended screening tests	Timing of the text message <sup>+</sup>	TCC content focuses of the target conditions
Booking visit (as early as possible)	Anemia: Hb HDP: BP, urine test for protein GDM/DM: urine test for glucose FGR: ultrasound, or fundal height for late booking visits	NA	Welcome and introduction to the aim of the TCC intervention, including opting out if change of mind
1 <sup>st</sup> visit (GW 16)	FGR: fetal growth monitoring (fundal height measurement, from GW 16) Routine vital sign follow-ups Other examinations up on indications	[15-17] GW	<b>Fetal growth and wellbeing:</b> stating the importance of pregnancy follow-ups, specifically focusing on the importance of early diagnosis for anemia (as a risk factor for FGR) and other risk-factors for FGR, when relevant
2 <sup>nd</sup> visit (18-22 GW)	HDP: routine BP measurement Urine test for protein FGR: regular ultrasound Other examinations up on indications	[18-22] GW	<b>Hypertension:</b> creating awareness about the importance of regular screening for elevated blood pressure and urine protein to diagnose for preeclampsia/ pregnancy induced hypertension and risk-factors for HDP
3 <sup>rd</sup> visit (24-28 GW)	GDM: Random/fasting blood glucose Anemia: Hb Routine vital sign follow-ups Other examinations up on indications	[24-28] GW	<b>Diabetes and Anemia:</b> focused persuasive messages and reminders for the lab investigations and risk-factors for GDM
4 <sup>th</sup> visit (GW 32)	FGR: fetal growth monitoring (fundal height measurement) Routine vital sign follow-ups Other examinations up on indications	[31-33] GW	<b>Fetal growth and wellbeing:</b> stating the importance of continued ANC visits to follow the babies' growth, and early detection of hypertension as a risk factor for FGR
5 <sup>th</sup> visit (GW 36)	Presentation Birth preparedness Anemia: Hb Other examinations up on indications	[35-37] GW	<b>Anemia and presentation:</b> informing the importance of screening for anemia and checking for presentation to rule-out or plan for the risk of complications during delivery

ANC = Antenatal Care; BP = Blood Pressure; GW = Gestational Week; Hb = Hemoglobin; HDP = Hypertensive Disorder of Pregnancy; GDM = Gestational Diabetes Mellitus; DM = Diabetes Mellitus; FGR = Fetal Growth Restriction; NA = Not Applicable

### **The frequency and timing of the digital TCC via SMS intervention:**

***At registration/first visit:*** a welcome message to the digital TCC via SMS intervention. It also contains information about options and ways to opt out of the messaging service. At this time, trained healthcare providers explain to women about the intervention and obtains assent from the women to enroll in the TCC via SMS program.

***A week before a routine scheduled visit:*** messages unique to each of the target conditions at each routine ANC visit. The text explains the personal susceptibility to, and severity of, each target condition and the benefits of attending ANC along with the expected actions. This TCC messages is for all, except for women who have been diagnosed with the specific target condition the TCC message focuses on at the specific routine visit.

***Three days before a routine scheduled visit:*** messages sent to women who have any of the common risk-factors identified for each of the target condition. The content states the increased susceptibility of women with the risk-factors without indicating that the receiver has the specific risk-factor. The benefit of attending ANC, and what can be done if one attends, are mentioned in a similar manner with a text message sent a week before the routine scheduled visit.

***24-hours before any visit:*** All women with a scheduled visit irrespective of the gestational age receive this simple reminder without additional health information.

***24-hours after a missed appointment for a routine scheduled visit:*** Only women with a missed appointment receive this reminder to help in re-scheduling to compensate for the missed routine visit.

***24-hours prior to the routine visits ('recapture' messages):*** only women with no scheduled appointment for the upcoming routine visit receive this message focused on reminding them of the importance to have timely visits. This can happen when women missed previously scheduled visits and hence were not scheduled for the successive routine visits.

### **Training of the healthcare providers**

We trained the healthcare providers to familiarize them with the content of the TCC message (since they are the primary contact persons when the women have any questions about the TCC messages they received). We included a brief explanation of the design of each message and how to interact when women ask questions about the messages. We emphasized the fact that TCC via SMS was not meant to replace the usual face-to-face health promotion and education services, but only to strengthen and support their continued effort. Additionally, the healthcare providers must explain the assent (and the texts added as information on the assent question on the registration page) and the ‘ticking off’ the field in the MCH eRegistry when the women agree to receive the messages. The healthcare providers were trained to explain to women that the participation is voluntary, and if they decline or withdraw anytime, there will not be negative consequences for the services they receive from the clinic. A half day training was provided by PNIPH staffs, with a hands-on demonstration for ‘ticking off’ the field in the MCH eRegistry.

### ***Variables and data collection tool***

For *Paper III*, we developed a structured questionnaire and pretested it with 42 pregnant women in a similar environment (unpublished). The Cambridge Worry Scale (CWS) was used to measure the main outcome [115]. We used the 13-item scale that has been translated into several languages and undergone validation studies [116-121]. The CWS [115] is a six-point Likert-type scale represented by the numeric values ranging from 0 = no worries at all to 5 = extremely worried. The higher the mean score, the higher the worries. We calculated the mean score by adding the values of the 13-items from all participants and dividing it by the total number of participants in each arm of the trial. We used the absolute mean difference between the intervention and control arms, with its corresponding 95% CI, to check whether the range was above the non-inferiority margin. We measured women’s satisfaction with the ANC services using a six-point Likert-type scale (0 = strongly disagree to 5 = strongly agree). Socio-demographic variables (age, education, occupation, parity, previous pregnancy outcome) that were found to be

associated with worries in pregnancy were also included (appendix 5). Two research team members who are fluent in both Arabic and English translated the original English version into Arabic. Another person back translated to English and the consistency of translations were checked by the research team. Data were entered into an online form.

The pretest was conducted to check for the clarity of the questions, the feasibility of phone interviews, the duration of each interview, and the logistics needed to facilitate the main data collection. We were unable to interview more than a third of the eligible women because we could not reach them due to wrong or inaccessible phone numbers or they were no longer pregnant (already given birth or had a miscarriage).

### *Data collection*

The data collection process for *Paper III* started with the weekly data extraction of eligible women from the MCH eRegistry. The interviewers were blinded to the trial allocation and the outcome measurement of the study. The data manager randomly allocated women from the same PHC to all the four interviewers. We gave the interviewers a password protected list of women to interview, with the woman's name and phone number. This was done every week throughout the data collection period.

The research team trained four female data collectors who have experience in collecting data for the project of which this study was a part. The training covered the interview techniques for phone interviews, securing informed oral consent, the use of the data collection forms (Google Form), and familiarity with the questions. There was a mock interview to improve the reliability of the data collection. Based on the information on the list of women with the contact information, interviewers made phone calls to obtain consent and the convenience to proceed. Otherwise, they agreed on the time that suited the interviewee. The data collectors tried to reach each woman on a maximum of three different occasions before counting them as not responding.



## Data analyses

### Quantitative data analyses

Data management and statistical analyses were performed in Stata version 15 (StataCorp. 2015. Statistical Software: Release 14. College Station, TX: StataCorp LP). Weighted proportions with 95% confidence intervals (CI) were produced to report the coverage and attendance measures. Descriptive analyses were done for the maternal socio-economic and healthcare facility infrastructure related variables. These were ultimately entered into the logistic regression model to produce adjusted odds ratios (*Paper I*).

For the non-inferiority cluster randomized trial (*Paper III*), the effect of clustering was taken into account to perform individual level analyses using the *lme4* package in R [146]. We computed the difference in mean score between the intervention and control arm with its standard deviation and corresponding 95% CI. All primary outcome analyses were based on the intention-to-treat approach. To check for the distribution of important predictors to pregnancy related worries in the randomization, we conducted a sensitivity analysis. Since the covariates were proportional in both arms, they were not entered into the final adjusted model.

### Qualitative data analysis

Two of the data collectors transcribed verbatim the audio-taped interviews. Fellow researchers from PNIPH translated the transcripts to English. All the transcribed interviews were uploaded to the NVivo software version 12 (QSR International Pty Ltd. Version 12, 2018), where all the data management and coding were done. The findings from the in-depth interviews were structured into HBM constructs. We performed thematic analysis after line-by-line coding, categorizing the texts into nodes under the HBM constructs based on Braun and Clark's reflexive thematic analysis approach [147]. The main themes from the codes were developed and named under each node by one of the researchers. Two researchers revised the codes and took part in defining the themes based on the data. Other data material outside of the HBM constructs were coded and grouped thematically.

## Ethical considerations

Ethical approvals were obtained to conduct the data collection for all papers included in the dissertation from the Helsinki Committee of the Palestinian Health Research Council. For the paper-based ANC record data, we obtained ethical approval from the Regional Committee for Health Research Ethics (REK) - Section South East B, in Norway. For the rest, we received an exemption from ethical review after submitting the whole protocols. It was exempted since the health systems research falls outside of the mandate for ethical review in Norway. The MOH provided access to anonymized data from the registry in preparation for the TCC intervention development. For all the data sets we received for analysis, all personal identifiers were removed to anonymize the data as per the operating procedures for routine registry data.

We secured informed oral consent before each interview for data collection from the women and healthcare providers (*Paper II* and *III*). According to the Helsinki declaration [148], we included all the different necessary components in the information sheet (Appendices 3a and 3b), and this was read out to the participants before the commencement of the interviews. For the qualitative interview, we asked the participants for signed informed consent. However, due to cultural reasons, participants were hesitant to sign on a consent form and preferred to provide informed oral consent instead (*Paper II*). The national ethics committee was informed of this and permission was obtained to proceed with only informed oral consent. The phone interview for *Paper III* was conducted after obtaining oral informed consent.

## Chapter IV: Synopses of results

### Paper I

#### *Effective coverage of essential antenatal care interventions: A cross-sectional study of public primary healthcare clinics in the West Bank*

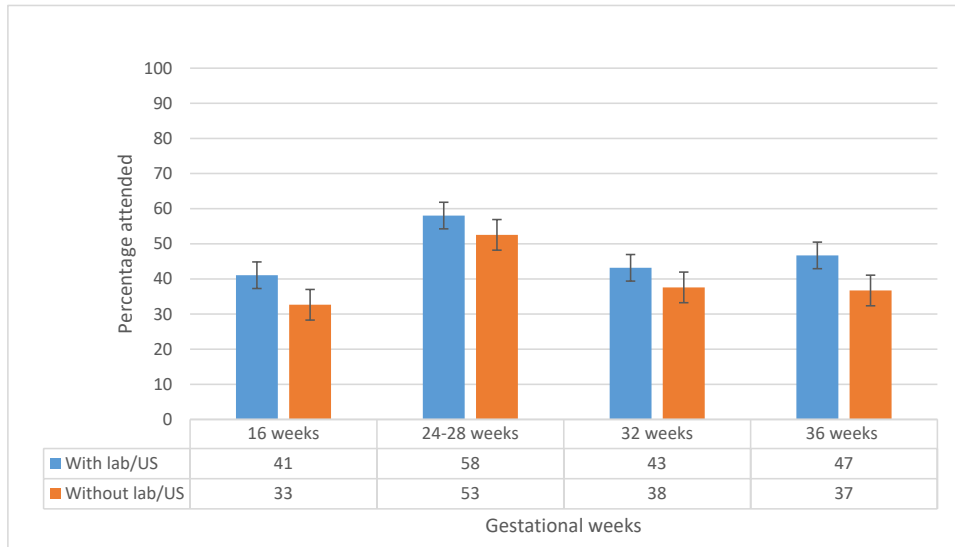
*Note: we present additional analyses of the dataset that was not presented in the paper*

#### **ANC attendance**

The coverage of any four or more ANC visits was 60%. Forty-eight percent of women attended at least five ANC visits. These were without considering the timing for the routine visits according to the national guideline. Only 6% of women had all five routine visits: a booking (first) visit before 16 weeks, followed by 15-17 weeks, 24-28 weeks, 32 and 36 weeks visits. This value increased to 13% when the gestational age at booking was taken into account.

Figure 3 shows additional results from the dataset to assess the impact of attendance on effective coverage and provide a more detailed analysis of the critical gaps in attendance to inform the planning of the TCC intervention (unpublished results). Out of those eligible for subsequent routine visits, the proportion of women who attended the 24-28 and 36 weeks visits were higher than the 16 and 32 weeks visits. A significantly higher proportion of women visited the 24-28 weeks visit at PHCs with laboratory/ultrasound services compared to those without. The availability of laboratory/ultrasound services was statistically significantly associated with attendance at the 36 weeks visit (Fig 3). In PHCs with both laboratory and ultrasound services, the percentage of timely ANC visits was 17%, but it was only 9% at those without such services. The difference was statistically significant (OR = 2.0, 95% CI: 1.4-2.8).

In another additional analysis, the following maternal sociodemographic variables: age, age at marriage, and parity, had statistically significant associations with the timeliness of ANC visits (Table 6). Women who booked at the PHC but did not return for ANC visits were not different in terms of sociodemographic characteristics from those who continued ANC in the PHC.



**Fig 3.** Comparison of attendance to the routine antenatal care visits between clinics with and without ultrasound and laboratory services (unpublished result)

**Table 6.** The association of sociodemographic factors with the timely attendance

Sociodemographic characteristics	N	Timely attendance (n= 171) n (%)	Adjusted OR (95% CI) <sup>y</sup>
<b>Age</b>			
≤ 20	222	22 (10)	1
21-35	1029	133 (13)	2.07 (1.12 – 3.82)
≥ 35	118	16 (14)	2.71 (1.06 – 6.91)
<b>Education</b>			
< 10	149	20 (14)	1
10-13	591	69 (12)	0.90 (0.51-1.61)
> 13	514	66 (13)	1.05 (0.58 – 1.92)
<b>Age at marriage</b>			
< 20	695	91 (13)	1
≥ 20	573	67 (12)	0.65 (0.44 – 0.99)
<b>Parity</b>			
Nulliparous	501	67 (13)	1
Multiparous (<4)	666	77 (12)	0.61 (0.42 – 0.95)
Multiparous (≥4)	186	27 (15)	0.66 (0.34 – 1.29)

<sup>y</sup>derived from multivariable logistic regression analyses including maternal sociodemographic variables: maternal age at pregnancy registration, age at marriage, education and parity; CI: confidence intervals; OR: Odds Ratio

## Coverage of ANC interventions

The coverage of at least one screening test for anemia, hypertension, and diabetes was more than 90%. The coverage of an appropriate number of tests (see Table 4), ranged from 31% for anemia to 69% for diabetes. Effective coverage of ANC interventions was lower than the coverage of at least one test and the appropriate number of tests for all interventions (Table 7). For anemia screening, the effective coverage was 14% (95% CI: 9, 21), attributed to untimely visits as only 33% had a booking visit prior to 24-28 weeks, and a visit at 24-28 and 35-37 weeks. PHCs with laboratory and ultrasound services had statistically significant higher odds of screening for anemia (OR: 1.5, 95% CI: 1.1, 2.1), hypertension (OR: 2.2, 95% CI: 1.5, 3.1), but not diabetes (OR: 1.2, 95% CI: 1.0, 1.5).

**Table 7.** Comparison of coverage at least one screening of ANC intervention, coverage of appropriate number of screenings prescribed for ANC interventions, and effective coverage of ANC interventions (source: Paper II).

ANC intervention	Coverage of ANC interventions <sup>§</sup> (%, 95% CI)			ANC visits (%, 95% CI)	
	At least one screening test	Appropriate number of screening tests	Effective coverage	Number of visits irrespective of timing <sup>‡</sup>	Appropriate number and timing of visits <sup>‡</sup>
Screening for hypertension	98 (96, 99)	38 (31, 47)	10 (8, 13)	48 (38, 58)	13 (9, 17)
SFH measurement	66 (50, 80)	35 (24, 48)	6 (4, 9)		
Screening for anemia	93 (89, 96)	31 (23, 40)	14 (9, 21)	73 (62, 81)	33 (26, 41)
Antenatal ultrasound	74 (59, 85)	43 (32, 54)	24 (18, 31)		
Screening for gestational diabetes mellitus	93 (88, 96)	69 (60, 77)	34 (26, 43)	85 (77, 90)	56 (50, 62)
Screening for asymptomatic bacteriuria*	55 (45, 64)		42 (36, 49) <sup>¶</sup>	NA	
Screening for Rh-type*	78 (67, 89)		64 (54, 73) <sup>¶</sup>	NA	
Screening for tetanus immunization status*	35 (23, 50)			NA	

<sup>§</sup>refer table 4 for definitions of coverage indicators of ANC interventions; <sup>‡</sup>refer table 2 for number of ANC visits and their timing for each ANC intervention recommended in the national guidelines; \*only one screening test during ANC is recommended in the national guidelines; <sup>¶</sup>refers to screening test provided during the first ANC visit.

ANC: Antenatal Care; SFH: Symphysis-fundal height; CI: Confidence Intervals

## Paper II

### *Development of a targeted client communication intervention to women using an electronic maternal and child health registry: a qualitative study*

#### Results of the assessment phase

Women knew about the susceptibility to, and severity of, anemia, hypertension, and diabetes in the general population, mainly as an effect of chronic conditions. However, they were unaware of these being common complications during pregnancy. Perceived susceptibility, perceived severity, and perceived benefits, related to the target conditions, were identified as the most prominent reasons for low timely ANC attendance.

Perception of risk (perceived susceptibility and perceived severity):

- Women with knowledge of the target conditions, a history of pregnancy complications, or who knew someone with a history of pregnancy complications perceived greater susceptibility to the target conditions compared to their peers
- Women who perceived that they are engaged in preventive behaviors (e.g. healthy diet, exercise) perceived that they were less susceptible to the target conditions
- Despite knowing the general consequences of anemia, hypertension, and diabetes as a chronic disease, women failed to mention the specific consequences they can have for either the mother or the fetus.

Perception of preventive actions (perceived benefits of attending ANC):

- The majority perceived that attending ANC is beneficial but had little awareness of the benefits associated with the timeliness of screening of the target conditions.
- Women identified with the target condition or with a history of pregnancy complications tended to attend ANC more often and were also better aware of what to expect and how useful a timely visit is.

Factors influencing (perceived barriers, cues-to-action, and self-efficacy):

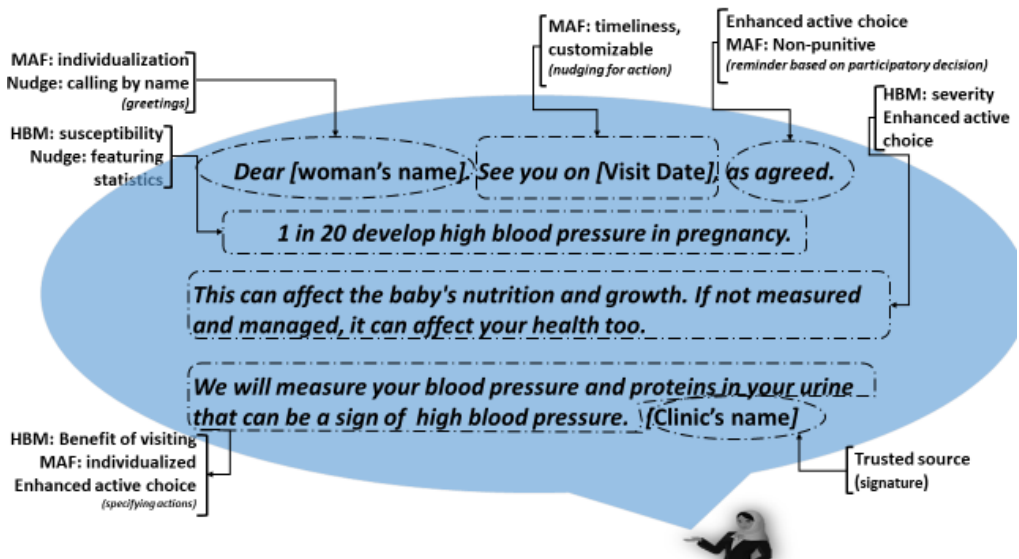
- Regarding self-efficacy, almost all women explained that they can independently decide to attend ANC. They were confident in doing so and perceived that they had

adequate social capital. Among the women interviewed, none mentioned barriers such as accessibility or lack of support from the partner/ family as important issues.

- The major factor that influenced women to not attend ANC visits in a timely manner was related to their perception of their susceptibility to, and the severity of, the target conditions and the correlation between the benefits of attending ANC and the mitigation of health risks and their consequences.

### Results of the development and refinement phase

The timing, frequency, corresponding gestational age, and types of TCC messages were determined in a co-design approach. The pregnant women, healthcare providers, and staff at the MOH accepted the final output of the TCC intervention structure as presented in the description of the ‘intervention’ in methods section.



[Woman's name] the first name of the recipient inserts here, [Visit Date] the date of scheduled visit appears in YYYY.MM.DD format automatically. [Clinic's name] the name of public primary healthcare is automatically inserted

**Fig 4.** The Health Belief Model (HBM), Enhanced Active Choice (EAC), Model of Actionable Feedback (MAF) and nudging were used to compose texts (source: Paper II)

**Table 8.** The process of content creation for the identified constructs of the Health Belief Model as guided by the concepts from other models and theories, an example (source: Paper II)

Targeted HBM constructs	Gaps and considerations	Source of information	Example phrases
<b>Perceived Susceptibility</b>	<ul style="list-style-type: none"> <li>Specifying risks to pregnancy</li> </ul>	<ul style="list-style-type: none"> <li><i>Finding from part I</i></li> </ul>	<i>1 in 20 develop high blood pressure in pregnancy.</i>
	<ul style="list-style-type: none"> <li>Statistics</li> </ul>	<ul style="list-style-type: none"> <li><i>Theory: nudging</i></li> </ul>	
	<ul style="list-style-type: none"> <li>Scaled intensity: more messages to those with risk-factors</li> </ul>	<ul style="list-style-type: none"> <li><i>Theory: MAF</i></li> </ul>	
<b>Perceived Severity</b>	<ul style="list-style-type: none"> <li>Consequences to the baby and the woman herself</li> </ul>	<ul style="list-style-type: none"> <li><i>Findings from part I</i></li> </ul>	<i>This can affect the baby's nutrition and growth. If not measured and managed, it can affect your health too.</i>
	<ul style="list-style-type: none"> <li>No mentioning of severe/grave consequences</li> </ul>	<ul style="list-style-type: none"> <li><i>Theory: EAC and MAF</i></li> </ul>	
<b>Perceived Benefits</b>	<ul style="list-style-type: none"> <li>Guideline based available screening services at the PHCs</li> </ul>	<ul style="list-style-type: none"> <li><i>Mapping: ANC guideline</i></li> </ul>	<i>We will measure your blood pressure and proteins in your urine that can be a sign of high blood pressure.</i>
	<ul style="list-style-type: none"> <li>Specifying the beneficial test beforehand</li> </ul>	<ul style="list-style-type: none"> <li><i>Findings from part I and EAC</i></li> </ul>	
	<ul style="list-style-type: none"> <li>Personalization</li> </ul>	<ul style="list-style-type: none"> <li><i>Theory: MAF</i></li> </ul>	
	<ul style="list-style-type: none"> <li>Timed to the benefit</li> </ul>	<ul style="list-style-type: none"> <li><i>Theory: MAF and EAC</i></li> </ul>	

*HBM = Health Belief Model, MAF = Model of Actionable Feedback, EAC = Enhanced Active Choice*

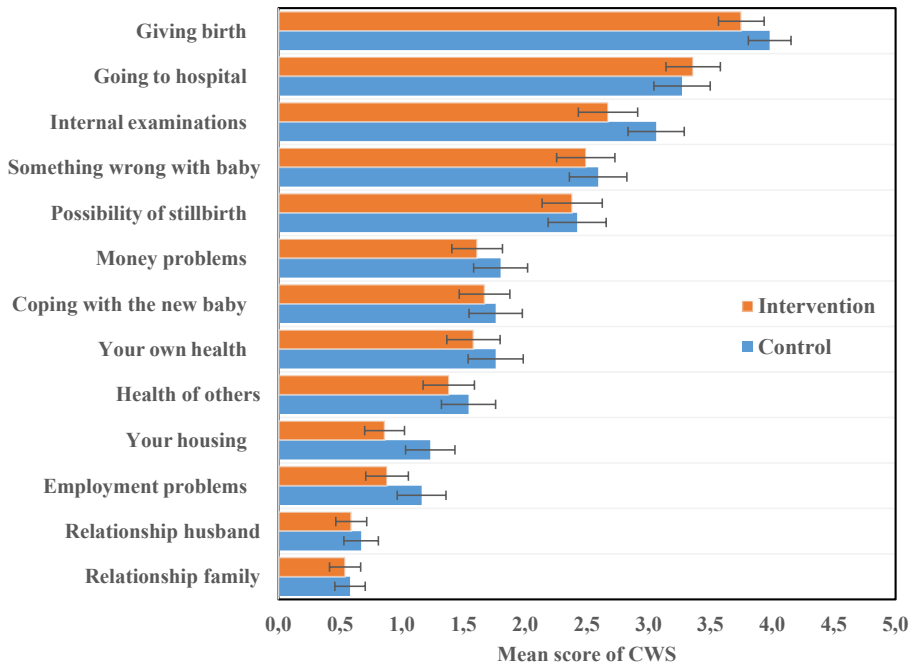


### Paper III

#### *The effect of a digital targeted client communication intervention on pregnant women's worries and satisfaction with antenatal care in Palestine – a cluster randomized controlled trial*

#### Worries in pregnancy

Generally, women who received TCC via SMS in the intervention clusters, scored lower on most of the items on CWS than women in the control clusters. In both arms, pregnant women scored higher on items directly related to the pregnancy and the baby. The unadjusted mean scores with error bars are presented in Figure 5.



**Fig 5.** Ranked mean score of the 13-items Cambridge Worry Scale for intervention and control arms (source: Paper III)

After adjusting for the effect of clustering, the mean difference in total CWS between the intervention and control arms was -0.16 (95%CI: -0.31 to -0.01). Considering the non-inferiority margin of 0.3, the upper limit of a 2.5% confidence level was lower. TCC via SMS did not increase worries among pregnant women in public PHCs in Palestine.

### **Satisfaction with the ANC services**

There was no statistically significant difference in women's satisfaction with the ANC services between the intervention and control PHCs. Most of the participants scored highly on the mean score in both groups. Almost all women responded to the satisfaction questions on general and health information related services as moderately or strongly satisfied.

## Chapter V: Discussion

In *Paper I*, we identified a gap between the crude coverage and effective coverage of essential antenatal care interventions. More than half of the participants had four or more ANC visits, but the timely attendance, as per the national guideline, was low, which led to low effective coverage. In *Paper II*, we identified HBM constructs that were important to the untimely attendance. Women generally perceived their susceptibility to, and the severity of, the target conditions in pregnancy as low. They did not perceive much benefit of attending routine ANC visits, but had high perceived self-efficacy towards attending them. With established concepts, theories, and models, we designed a TCC intervention containing simple appointment reminders and text messages to increase perceptions of risks for the target conditions in pregnancy, and benefits of timely ANC attendance. We used an iterative process with users to design an intervention acceptable to pregnant women, healthcare providers, and public health officials. In *Paper III* we identified that the TCC intervention did not increase pregnancy related worries and women were equally and highly satisfied with the ANC services they received, irrespective of our intervention.

### Discussion of main findings

#### Low effective coverage of essential interventions of ANC

Our finding of low effective coverage is similar to a systematic review of LMIC [17], and in line with studies using household survey data [17, 149-151]. To measure the ‘quality’ component of the effective coverage [25], these studies used checklists of the essential interventions provided at the ANC visits. We reported conceptually equivalent outcomes by reporting on the ‘coverage of at least one screening test’ of the target conditions. Measuring the content of care at a single time point may not provide adequate information about interventions, especially not for those that should be repeated at a certain gestational age [152]. We found that almost all women received a blood pressure measurement at least once during pregnancy, in line with large multi-country studies [19, 152]. We measured the number of opportunities for screening and the timeliness of visits throughout the pregnancy and found that the content of ANC has room for improvement.

The Lancet commentary on maternal and child health in the oPt similarly indicated that ANC services were frequent but of poor content [123].

We measured the quality-adjusted coverage, to report the effective coverage, by taking into account both the timing and content of care at each eligible visit [18]. This measure may better indicate the potential resulting health benefits of ANC essential interventions, compared to crude coverage that only counts the number of visits [18], or content coverage that only focuses on receiving the intervention once regardless of the needed frequency or timing [151, 152].

The main contributing factor for the low effective coverage of essential ANC interventions in our study was the untimeliness of ANC visits [128]. We found that about 60% of women had four or more ANC visits, which is similar to a study in Jordan that used facility-based data [153], but lower than facility reports from Palestine that stated 90% [124]. Only 13% of pregnant women had timely routine visits according to the ANC guideline, after accounting for the gestational age at the first visit. A reduced proportion is true for each of the selected interventions in our study after adjusting for gestational age.

Anemia screening, for example, is recommended at three time points: early booking at or before 16 weeks, at 24-28 weeks, and at 36 weeks. In total 73% of women were screened for anemia three times, irrespective of the timing of the test. This number drops to 33% when the timing was taken into account. Although published reports that have used similar approaches to ours are lacking, the likelihood of receiving specific elements of care is higher for women with more ANC visits [19]. The recommendation for specific timing of screening tests might change over time as the optimal number and content of ANC visits continue to be a matter of debate and subject to evaluation [9, 154-156]. Our findings indicate that interventions focusing only on increasing the number of visits, or improving the screening performance (content coverage), may have limited contribution in improving the effective coverage. Improving the timeliness of visits may contribute comparably more to improve effective coverage of essential interventions. Pregnant women tend to attend routine ANC visits that include planned interventions compared to

visits without interventions (Figure 3). As found by another study, although improved awareness of benefits can improve the attendance rate, merely informing women about planned interventions may not be the only solution [157].

Similar to findings in a systematic review [157], we found that women with up to four children were less likely to attend in a timely fashion compared to first time pregnant women. Also that older women were more likely to attend timely visits compared to their counterparts. Infrastructure is reported to have affected the use of ANC, and we also found a relatively low attendance across routine ANC visits in PHCs that lack laboratory and ultrasound services [157].

### **The development of the digital TCC**

We have structured the discussion of the digital TCC development process (*Paper II*) according to the TUDER framework [76].

#### ***Targeting the health problem and user group***

Targeting, according to the TUDER framework, refers to the identification of a health problem, and specifying the behavior that led to the health problem that could be addressed by a digital intervention, and the user group for which the intervention is made [76]. Most TCC interventions target a single health condition, such as diabetes [158], asthma [159], or HIV/AIDS [65], often identified at the beginning without going through a comprehensive targeting process as we have done. For services like ANC, where interventions span over several health conditions, TCC interventions often are often generic [71, 72]. The content of messages usually cover common themes across health problems, such as improving health seeking behavior, nutrition, quality of care, or satisfaction with the services [68, 160-163]. Some TCC projects, such as, the multicounty Mobile Alliance for Maternal Action (MAMA) identified priority health conditions for each of the participating country in addition to the generic messaging. [164]. The MAMA project primarily targeted anemia in India [165], HIV/AIDS in South Africa [166, 167], and continuity of care in Bangladesh [164], in addition to generic information to all pregnant women according to their gestational age. Despite the difference in generic

messages content, the process of selecting contextually relevant target condition was comparable to our approach. They also used consultation with the local experts and accounted for the magnitude of the health problems among pregnant population. Others have identified target conditions based on recipients' views. For example, Text4baby, a text message covering a wide range of topics during prenatal and postnatal periods, targeted the intervention to the most relevant conditions that the women preferred [168]. In another study of sexual health interventions for adolescents, informants from the target group were asked to identify and reach to consensus on target conditions they believed to be of interest [169]. Since ANC service packages include several essential interventions [1], identifying and targeting a few health conditions is important. Also, it goes in line with the importance of tailoring to enhance effectiveness in digital interventions [39, 62]. To highlight the process of targeting in our study, borrowing the TUDER statement [76], we defined that a digital TCC intervention has the potential to improve timely ANC attendance (the behavior), and increase the effective coverage of interventions for the target conditions (health problem) in pregnant women in the oPt (the user group).

The technology we used is more suitable for text messages compared to other applications of digital TCC intervention [38], such as voice messages. Moreover, the choice of text messaging relates to the literacy status of the user group, a very important element for a text message-based intervention [59]. Almost all women in Palestine are able to read and write [170]. Both healthcare providers and women who participated in our qualitative assessment agreed that reading a text message was not a difficult task for almost all women in the oPt. Therefore, it was not necessary to add voice messaging as it is done in a low literacy context to expand the reach [171]. Failing to recognize the literacy status and the preferences of the target user group and adjust the mode of intervention delivery can perpetuate inequity and minimizes the potential effect of the DHIs [59]. We designed the messages to be understandable for a "grade five reading level" and we evaluated the text's understandability before deploying. Access and ownership of a functional mobile

phone is an important component in a digital TCC intervention [59]; and more than 85% of women registered in the MCH eRegistry have access to a phone.

### *Understanding the behavioral context*

Several studies have indicated the importance of behavioral theories to make the process of understanding behavioral context more systematic [84, 85, 103, 172-174]. A theory led systematic approach is relevant for projects like ours, where the relationship between the behavior (untimeliness of attendance to ANC) and women's perceptions towards each of the target health condition is complex. Following the recommendations from systematic reviews about using theoretical frameworks to assess the behavior to which the digital intervention is designed to address [85], we used the HBM [93]. Despite that the HBM being one of the most commonly used theories for digital TCC intervention development, details on how it has been used to understand behavior is often not reported [85].

Our choice of using the HBM to explore the perception of women in a systematic way facilitated the design, conduct and interpretation of the qualitative research to better understand the behavioral context (*Paper II*). We used the findings to relate intervention strategies with specific constructs as suggested by Wang et al. [76]. Three out of the six constructs: perceived susceptibility, perceived severity, and perceived benefit were important constructs that the digital intervention specifically focuses on directly. This simply means that perceptions about risk and seriousness of the target health conditions and perceptions about the benefit of an intervention, (i.e., ANC visits) explains the target behavior (untimeliness of ANC attendance) the most. These are well established barriers to service use in LMIC [175]. Our findings are in line with a recent qualitative evidence synthesis that report that unless the women are aware of any risk conditions, they do not see the benefit of attending ANC [2]. A similar conclusion was made by a meta-synthesis of studies from LMIC on ANC utilization [176].

There are several ways of applying a theory to assess the behavioral context and use the findings to design an intervention. Similar studies that have used the risk and benefit constructs from the HBM model, as we did, to design an intervention, are scarce. A study

from the rural area of Uttar Pradesh, India, demonstrated that a text message intervention focusing on improving the recipient's knowledge on needs for services (emphasis on benefit), resulted in increased use of services through demand creation [177]. On the other hand, Evans and colleagues included all HBM constructs after conducting an HBM-led assessment [178]. Kamal et al., did not explain how they used the HBM constructs to assess the behavioral context, but stated that the content of the text-message intervention covered all constructs [179]. This ultimately directs what the TCC intervention content should include [180].

The main barriers to ANC utilization in various settings typically include physical access, lack of autonomy, and lack of money for transportation or service charge [2, 157, 176], but this was not identified in our study. A few women mentioned caring for small children with little support from their partner or family members as a barrier to ANC attendance. Access to the public PHCs is affected differently depending on where the women live in the oPt [122, 123]. The clients who must cross army checkpoints and separation walls to get to healthcare services, usually have longer travel times [122, 123]. That may discourage ANC attendance. While physical access to ANC services is an important determinant of its use [181], it is beyond the scope of a DHI to tackle the problem.

Self-efficacy was later added to the original construct of the HBM after it was understood by behavioral change researchers as an active ingredient of change [182]. Women who are financially dependent on their partners and have restrictions on movement often lack self-efficacy to make decisions about using the healthcare service [153, 157, 183, 184]. In our findings, most women demonstrated high self-efficacy about making independent decisions to attend ANC if and when they personally believe it is important. This might have to do with the relatively high-educational level of women and availability of public PHCs within close physical distances.

A meta-analysis of HBM constructs' effectiveness in predicting behavior, indicated that cues-to-action is an underdeveloped and rarely measured construct [185]. Rosenstock originally classified cues-to-action into internal and external cues [93]. In our study,



having been diagnosed with a high-risk condition served as a cue to timely attendance and uptake of screening and management services by pregnant women. Having a condition or physical symptoms such as pain may serve as internal cues [186].

External cues may include documenting the appointment date on the phone and receiving calls as a reminder from the healthcare providers [185], as indicated in our study. We found that phone calls by healthcare providers were not regularly made and it mostly depended on the workload of the healthcare providers. The healthcare providers also explained that the process was time consuming. Identifying women who missed their appointment and finding their contact addresses are not an easy tasks for most healthcare providers. Even though finding a contact address may have become easier with the introduction of the MCH eRegistry [135], phone calls are not sustainable. In this case, a text message reminder is a well-suited example of a cue-to-action [187]. The intensity of cues needed to prompt an action varies by the level of perception of susceptibility, seriousness, benefits, and barriers among individuals [93].

### *Designing the digital TCC intervention*

#### **The structure of TCC intervention**

The content, timing, and frequency of TCC messages can differ based on the target health issue, the understanding of the target behavior and its change process, and characteristics of the intervention recipients, among several factors [62, 75, 77, 79, 101, 103, 188-190]. Similar to our approach, others also have used formative qualitative research to determine the structure of their digital TCC interventions [73, 75, 77, 79, 103, 178, 191].

The prominent reasons for why women miss their scheduled visits, according to our qualitative assessment findings, can be summarized as women: 1) were not remembering the date of appointment, 2) know the date but do not see the need or benefit of attending ANC regularly, or 3) missed a given visit and did not manage to get re-scheduled (*Paper II*). Correspondingly, our message types are meant to remind them of an upcoming visit, or a missed visit, inform them of individual-level risks and persuade them about the benefits of timely attendance, as well as help them reconnect with the routine scheduling.

The results were in concert with the two applications of TCC: transmitting targeted health information to clients based on health status or demography, and transmitting targeted alerts and reminders to clients [40]. Decision about the type and framing of messages were done despite the difference in the processes in interventions that focused on different health conditions. For example, in an intervention for diabetes self-care, the designers categorized and framed the content of the messages into informational, motivational, or focused on a particular goal that the receivers have to perform since these were the focus areas they wanted to address [192].

We co-created the contents in an iterative process, which is also indicated as becoming common approach in a systematic review [101] and conforming to the Principles for Digital Development [102]. Unlike the steps we took, others used predesigned message contents and adjusted it to their condition through formative research [164]. Free et al, [193] used a slightly different approach in creating the content of the *Safetxt* intervention. They identified factors influencing safer sex behaviors from systematic reviews, including all behavior change techniques used in the reviewed interventions, and generated the content of the messages that might be used to influence the constructs of the theory that they have used. Eventually, they collected the users' views of the derived text messages to tailor to their needs. Contrary to this, we first identified the contextually relevant factors by engaging the end-users from the beginning using HBM [93]. Then, we drafted the content of the TCC towards those constructs identified during assessment of the behavior and perceived to have influenced the timeliness of ANC attendance (*Paper II*).

Clients have variable preferences on the appropriate timing and frequency of messages, as described in the evidence synthesis of several qualitative research projects [59]. For example, the frequency and timing for appointment reminders [63], medication reminders [64], lifestyle modification such as smoking cessation [69, 194] and weight loss [67] interventions differed widely. Many mobile phone-based text message intervention developers use systematic reviews as a starting point to determine the frequency, timing, and duration of the intervention [62, 72, 73, 82, 163]. Some have conducted formal pilot

assessments to decide the frequency and timing of text message delivery [193]. Presenting an explanation of how the decisions were made would be useful as a lesson for similar projects, but remains largely unknown for most of TCC via SMS interventions [73].

Our messages ranged from a simple reminder to complex algorithm-based decisions with personalized health content aligned with interventions during ANC [128] (Table 5). Simple appointment reminders work best when the reminder is sent close to the time when an intended action is planned to be undertaken [195]. Our simple reminder is set to be sent the day before the appointment, commonly applied in other appointment reminder studies [63, 195]. For the TCC messages that contained information to change women's behavior (health content), adequate time to think and make informed decisions is needed [195]. On the other hand, it should not be too far from the time they need to take action. Therefore, sending an SMS one week ahead of the appointment was an attempt to find a balance. According to the ANC guideline, there are two weeks of possible minimum gaps between consecutive routine ANC visits, where one week before message lies in the middle [128].

Most generic/less tailored text message interventions in the maternal and child health field send multiple messages per week [82]. Studies in Zanzibar [191, 196] and Malawi [197] reported sending text messages more frequently than in our study. The decisions about the dosage are often part of the development process of the intervention. In our project, the dosage was set in consultation with local experts as part of the co-design process. However, we did not directly involve the pregnant women to decide as Gatwood et al., [192], where they presented to the end users an alternative frequency to choose from during baseline survey, with a possibility to adjust in subsequent phases. The ideal 'dose' of a digital TCC via SMS intervention is complex to establish [79], and it differs based on the goal of the intervention, as well as the recipient's characteristics, personal preferences, and context [59]. With the continued discussions regarding sending too many versus too little messages [59, 198], there is no one-size-fits-all approach to decide on the ideal

number of messages, and few studies have measured the actual effect of dosage and content on the effectiveness of the intervention [198, 199].

Women in our study preferred to receive the SMS after work and before it became too late during the day. In most reported studies, researchers in consultation with the recipients, decided the convenient time of day that people wanted to receive messages, similar to our approach. The time one receives the text message is important to improve the chance of it being read, especially if the phone used belongs to someone else than the actual client. In other studies, sending an SMS at the time of a day when people are actively on the move, such as driving to and from work, could even lead to dangerous situations and should be avoided [59, 60].

Our study did not intend to evaluate the optimal ‘dosage’, frequency, and timing of TCC messaging by presenting different schemes to different participants applying a study design. However, the co-design effort was to obtain an intervention that was as acceptable as possible to the end-users. We recommend further studies using robust and adaptive designs to assess the acceptability and effectiveness of the TCC intervention’s dosage.

### **Composing the TCC content**

The quality of a text message, in terms of the content and composition, impacts the effectiveness and acceptability of a digital TCC intervention [59, 200]. Following the suggestion to use established theory [62, 76], the assessment that we conducted using the HBM [186] informed the content of our TCC intervention (*Paper II*). Our approach compares with similar digital interventions, such as a mHealth intervention designed to promote the uptake of HIV testing among African communities [178]. They also used the HBM to assess the respondents’ beliefs, and coined messages towards each construct in the model based on the assessment results.

After deciding what the content should be, composing the information in such a way that it conveys the intended message effectively, without causing any significant unintended effect, is recommended by the WHO to ensure safety of a digital intervention [39]. As others have described [73, 75-77, 84, 85, 90, 91, 189], we also used relevant theories and

frameworks to maximize the quality and acceptability (Fig 4). To accommodate all these aspects, most of our text messages surpassed 160 characters of a single text message in English (70 characters in Arabic) [190]. The messages are presented as one message as they appear on the recipients' phones despite counted as more than one. One of the limitations of this study was that the satisfaction with the contents of the messages and the acceptability of the intervention by the target group was not assessed using larger number of recipients as done by others [193]. We only evaluated and refined the content in a small population before the intervention was fully implemented. Working with a larger population of recipients could have allowed for more feedback and improvement to the intervention, in addition to having a stronger evidence to report its acceptability.

Digital TCC has a short history, and the process of composing its content is often underreported [200]. Single or combinations of the different ways of framing a health communication message have been used in health promotion and educational fields depending on the behavior, target population, and the medium used [201]. The choice of gain-framed over loss-framed messages may depend on the nature of the targeted behavior, but the former is generally more acceptable than the latter in most behavior change interventions [100, 202]. In our study, we used the Enhanced Active Choice model where we presented both the benefits of practicing the behavior (perceived benefit construct) and the consequences (reflected in the severity and susceptibility constructs). The final decision to act is left to the recipients of the messages with evidence-based information [100]. Similar concepts have been used in other studies from several countries included in a qualitative evidence-synthesis where the recipients of the message did not like being pressured, lectured, and frightened with the digital TCC message [59].

Communication strategies that utilize nudging concepts are more effective in changing behavior compared to only providing information [96]. The choice of different techniques used for nudging, e.g., slightly modifying ordinary messages during communication to give a little push, are context dependent. Nudging concepts informed the inclusion of the following components that have demonstrated effectiveness in the areas of behavioral

science [96]. We included the recipient's name, featured statistics to indicate how common the issue is, stating that the healthcare system is ready and waiting to see them at the specific date, stating their agreement (...as agreed), and mentioning the source that the receiver can trust (the clinic) among the lessons learned from several fields that have used nudging in composing various types of behavior change interventions [96, 97]. The inclusion of a greeting that the community uses was one of the suggestions, where the actual word was selected due to the co-designing concept we incorporated. These traits were identified as useful components of a text message by most recipients of text message interventions in several studies [59]. Understanding and contextually applying nudging concepts is even more useful in an increasingly complex digital environment [99].

The ultimate goal of this digital TCC intervention was centered on users taking a specific action. A goal setting technique for behaviors that require recipients' engagement has been commonly used, which provides an actionable component for a TCC intervention [75, 77, 79, 189]. The TCC message content we provide aimed at preparing the pregnant women internally ready to take an action [203]. Therefore, every message contained the actionable component, which is, attending an ANC visit on scheduled date. In studies of safer sexual behavior focused text message [193] and diabetes self-care intervention [192], participants have expressed that they need 'practical information' on what they need to do after receiving the messages. To effectively translate the knowledge and attitude change into practice, we used the elements of the Model of Actionable Feedback (timeliness, individualization, non-punitive, and customizable) [94], see appendix 4. We attached the action to be taken to the time where it was relevant. For example, for scheduled visits, the messages specify the date of visit and are scheduled to be sent at its most valuable period prior to the needed action (see intervention description).

We individualized the content based on the risk-factors for the target conditions and their gestational age at the scheduled visit. Tailoring may range from using one variable/criteria to applying complex algorithms [61, 105, 174], with several text message-based interventions tailor to a certain degree [174]. This is often done from the

beginning or as some have done, improved tailoring after getting feedbacks from the target users [204]. Since our TCC intervention is based on a registry where several variables are stored and continuously updated at each subsequent visit [129], we used multiple variables to tailor messages. This required using complex algorithms in the software. We personalized the TCC messages calling the receivers by name, specifying the exact date of schedule, and signing off as the trusted source – the clinic.

### **Evaluating and refining the digital TCC intervention**

The evaluation and refinement of TCC interventions are intertwined, and often carried out continuously throughout the project [76], which we also did. We used unstructured interviews and feedback from all stakeholders in an iterative process of co-design. A comparable approach was used by Gatwood et al, [192]. For example, we replaced “diabetes” with the more culturally appropriate “sugar” after getting feedback from the end-users in the translated version. Others evaluated the final intervention to acquire a complete information by applying a strong study design before implementing it at scale [73, 75, 103, 188]. Projects that adopt an intervention that was developed in a different context, are recommended to conduct a stronger pre-implementation evaluation compared to those that develop the intervention with the users [200].

### **Unintended consequences of digital TCC**

Some of the reported unintended consequences of text message-based interventions include privacy and confidentiality issues, road traffic accidents while reading messages, and disclosure and discrimination (e.g. HIV/AIDS), and domestic abuse [203]. We believe some of these issues were addressed in some degree through the co-designing and theory-based intervention development process. Our focus for this thesis is the effect of digital TCC on worries in pregnancy and satisfaction with the ANC services.

### **The effect of digital TCC on worries in pregnancy**

Our finding of no increased worries among the women who received TCC via SMS is comparable to a small RCT that found decreased worries among the participants of the intervention group that received gestational age based generic messages [205]. Generally,

studies that have measured worries as potential unintended consequences of TCC via SMS are scarce [62, 71, 161], and our results aimed at responding to the WHO's call for research in digital interventions [39]. We have not found any publications on the effect of tailored TCC messages that includes communication of risks, on worries in pregnancy.

The majority of health messaging interventions using mobile technologies, have up until now often delivered generic health promotion content [71]. It seems to be an understanding that health promotion interventions “might not always help (everyone), but surely they will not do any harm” according to Lisa G. [108]. This might explain the low attention to unintended consequences of public health interventions in general [206], and health promotion in particular [108]. There is a growing recognition of the need to plan prevention of unintended effect of health promotion interventions, and comprehensive evaluation approaches [108].

We used CWS, which is among the most used tools to measure worries in pregnancy [113]. Like in most other places, we did not identify any item in the CWS that the pregnant women were not worried about [113, 115-121]. Since the data collection was done during the early days of the Covid-19 pandemic, pregnant women might have shown increased worries compared to what they felt in a normal situation [207]. However, we expect this to be the case in both intervention and controls. The CWS items about giving birth, hospital visits, internal examinations, something might be wrong with the baby, and the possibility of stillbirth, were recorded with relatively higher mean scores, also reported elsewhere [117].

One explanation for the absence of an effect on worries could be that women felt cared for and were pleased to receive the TCC message [205]. When composing the text messages, particularly the tailored messages for those with risk-factors for the target conditions, we referred risk factors as collective risks using neutral language, compared to stating that they have got it. This technique is commonly suggested as a strategy to deal with privacy and confidentiality issues when sending text messages to clients dealing with stigmatized or personal health conditions such as HIV, family planning, or abortion [59].



More attention to the foreseeable unintended consequences in tailoring health education and promotion messages, may minimize potential adverse effects [61, 105].

### **The effect of digital TCC on satisfaction with the ANC service**

Most TCC satisfaction studies have explored the recipients' satisfaction with the text messages [59, 203], and not the overall improvement in satisfaction of care. We did not ask how satisfied recipients were with the TCC via SMS, as this would have required a separate study. Informal feedback from healthcare providers in the field, however, indicated that women are very interested in receiving TCC messages, and that the majority of women were willing to sign up for the service. Unlike our findings of statistically non-significant differences, Jareethum et al. [205] found that women who received SMS messages were more satisfied with ANC services than those who did not. A systematic review of reviews showed that receiving text message interventions often increase satisfaction with health services [208].

### **Methodological discussion**

#### **Study design, data, and analyses**

We used a cross-sectional study design to assess timeliness of ANC attendances and the coverage of screening for selected essential interventions (*Paper I*). Such a study design allows for description of a phenomenon where multiple variables in a study population can be assessed at once. However, it is not suitable to draw conclusions on causations, but can provide an indication of associations between predictor and outcome variables [209]. In our assessment of the association between selected documented socio-demographic and infrastructure-related variables with the outcome variables, we presented the direction and strength of the association without the intention of establishing causation. RCT design, as we used in *Paper III*, is the preferred method to establish causality [210].

We included paper-based clinical records for one year from 17 out of 165 PHCs. Instead, the estimated sample size could have been achieved by a simple random selection of paper-based clinical records from a higher number of PHCs selected from a wider geographic area. This could have improved the representativeness of the source

population [211], and is commonly used in household surveys for more diverse population [212]. However, the selected PHCs are similar in terms of the ANC record system they use, the infrastructure, and composition of human resources to the rest of the PHCs across the West Bank, as reflected in the facility inventory we created in this project. Our selection approach rather made the process more manageable, and we do not expect that the results would have differed significantly if the selection was made differently for such a homogenous population. We used a sample weighting procedure in the analysis to produce a robust standard error and improve representativeness, as recommended for survey data [213].

Most effective coverage studies use surveys as their main data sources, ranging from larger national representative surveys [214, 215], to facility-based assessments [216, 217], whereas we used facility-based individual-level data (*Paper I*). A systematic review summarizing 15 primary studies measured the effective coverage based on data obtained from women's recall of services received [17]. Using surveys as the data collection approach is prone to recall bias [17-19, 25]. We used data documented at point-of-care by the healthcare providers. Since poor quality of documentation of clinical services is a commonly reported problem, we do not know if services were provided but not documented. It is, nonetheless, a quality issue in itself as it hampers the appropriate follow-up and continuity of care that most of the interventions need [218]. All variables needed for extended analysis may not be found in such a data set predefined by clinical needs. For example, the paper records we used did not hold information about the women's next scheduled visit. We do not know if the low timely attendance is a result of inadequate scheduling by healthcare providers, or lack of adherence to appointments by women. Studies from LMICs report inequities in the quality of ANC provided to women based on their socioeconomic status [157, 183, 184]. The paper-based files in our study captured limited information about household socioeconomic status.

Qualitative in-depth interviews, the main scientific method in *Paper II*, are one of the most common techniques used to understand individuals' experiences and perspectives on

given issues [219]. The methods used in the design and development of TCC in *Paper II* have been discussed in depth under TUDER framework. In-depth interviews, using either unstructured or semi-structured interview guides, often focus on a single topic area [219-221]. We used a semi-structured interview guide, where key guiding questions were predefined under each construct of the HBM for the target conditions. This helped us make sure that all the topics were discussed, since we covered more than one health condition (Box 1) in a single in-depth interview. Semi-structured interview is a commonly used interview technique in qualitative health research where open-ended, predefined guiding questions are asked to make sure the main points are addressed without restricting participants' perspectives on the topic [219]. Inclusion of multiple topic areas in a single in-depth interview using a semi-structured interview guide might have affected the natural flow of in-depth interviews and limited the depth of the overall discussion. We could potentially have learned more about the in-depth perceptions of women for each target condition by focusing on only one target condition at a time. However, this did not hinder the information we intended to gather at the level of detail needed for the development of the digital intervention.

Individual in-depth interviews typically provide better insights about perceptions than using group interviews or structured interviews [221]. We did not use focus group discussion because of our low expectations for group dynamics to add to the understanding of individual perceptions. Moreover, conducting focus group discussion could have reinforced socially acceptable responses for some of the questions in the interview guide that could be perceived as assessments of the participants' knowledge level about the target conditions [219, 222].

The sample adequacy in qualitative research relates to the appropriateness of the sample in terms of composition [223]. Therefore, we employed purposive sampling and selected PHCs from different locations with different sizes in terms of annual recruitment (*Paper II*). In close collaboration with the healthcare providers, we selected women using convenience sampling (a woman with certain profile was approached before exiting the

facility), which is one of the widely used sampling strategies in qualitative research [224]. We did not use probability-based sampling to select participants from purposively selected PHCs since the aim was to include participants with various profiles. We could have attained this by probability sampling, but we did not have the intention to ensure equal chances of participation and extrapolating the result to the source population [224].

As qualitative research analysis starts from the field, having the researchers themselves conduct the interviews could have provided an opportunity to expand the discussion. Such approach could have helped identify the need for additional interviews early on, rather than our approach to add a segment of the target population (women who were not coming for follow-up visits after their registration at public PHCs) that were not included in the first rounds of interviews.

Thematic analysis is a qualitative data analysis method for identifying, analyzing and reporting patterns within data [147]. We aimed to understand the participants' perceptions descriptively, and hence used a semantic analysis approach. One of the advantages of thematic analysis is its flexibility, which allowed us to be more 'data-driven' in coding themes – an inductive approach – while maintaining the HBM theoretical constructs [147, 225]. Such flexibility helped us not to force the data to the HBM constructs [186]. The software we used is suitable to create multiple nodes of extracts of data that gave rise to codes, and later gather them into sub-themes, and then finally as themes under each HBM constructs [147, 186, 225]. Having two researchers code the same data independently, and validating their coding with inter-rater reliability measures, would have improved the verifiability of our analyses [226]. We took a softer validation technique whereby a second researcher reviewed the data, all codes and themes, as well as the final stages of the thematic analysis – reviewing, defining and renaming the themes [147].

Triangulation is one of the techniques used in improving credibility in qualitative research [227]. Triangulation of data sources by involving both the pregnant women and their healthcare providers added perspectives for the development of the digital TCC intervention. Our research team comprised individuals with different professional

background and practical experiences, some being native to the study area. This diversity added perspectives throughout the conceptualization, data acquisition, analysis, and interpretation of the results (*Paper II*).

Non-inferiority trials (*Paper III*) are used to examine whether an intervention is not worse than the control [228, 229]. To assess our interventions that were delivered at the facility level [230] we used a cluster randomized design [136]. Introducing the QID and TCC interventions at cluster level simplified the facilitation of the delivery of the intervention (i.e., recruiting the women to participate in the TCC intervention), and reduced the contamination and conflict of interests that may arise in an individual level randomization at each facility [230]. Maternal worries, as measured by CWS, could have been assessed based on individual randomization or other designs. However, in this sub-study of a larger trial, we had to follow the original clustered approach [136]. Randomization is one of the techniques used to control for known and unknown confounders [231]. The randomization in the eRegCom trial was stratified by the implementation phase of the eRegistry, and constrained on laboratory and ultrasound availability, and the size of the PHC [136]. None of these variables are known confounders for worries in pregnancy (e.g. women's educational status, previous adverse pregnancy outcomes, age, and parity) [111]. In that case, controlling for confounding during data analysis would have been an option [232]. We performed an exploratory analysis of these variables and did not find any imbalances between the study arms (*Paper III*). Therefore, the final model did not include any covariates besides measuring the effect of the intervention on the outcome.

We used a validated scale to measure worries in pregnancy [115] with an analysis package (*lme4* package in R) appropriate to the dataset, including adjusting for the clustering, which are among the strengths of our study. The CWS has not been validated in an Arabic speaking community, but we pilot-tested it on a similar population and the final reliability test also was good. We have not found evidence for what constitutes a clinically important increase of worries, as measured by the CWS. Using different cut-

offs for the non-inferiority margin affects the conclusion of the result. The method of defining non-inferiority margins have not been well reported for most clinical trials [233].

We did not reach the size of our estimated sample because the study was put on hold due to the Covid-19 pandemic, but the final sample was adequate to answer the research question despite the reduced power. The mean difference and corresponding 95% CI in our study was significantly below the inferiority margin with appropriate precision.

We interviewed women towards the end of their pregnancy to ensure that they had had the opportunity to receive the full intervention, i.e. all the TCC messages. We did not plan to verify that all women actually received the messages as intended, or that they had read them all after they received them. Verifying this in a large study requires additional functionalities in the digital tool we used, which was not feasible at the time. Therefore, per-protocol analysis could not be done for this analysis [234].

### **Generalizability**

Generalizability is the extent to which the findings from research in a specific context can be extrapolated to other contexts or the population that the sample is supposed to represent [235]. Our study focused on pregnant women who were attending public PHCs. In *Paper I*, we aimed to select a representative sample of the target population, which is reflective of the pregnant population using public ANC. The effective coverage definition includes the need, use, and quality of the specific care – in this case, the essential interventions in ANC [17-19, 25]. ‘Need’ is often referred to as the eligible population in the catchment area. Therefore, caution should be taken in generalizing the findings to the pregnant population in the catchment area, since 50% of the eligible women receive ANC outside of the public system. Women who attend public PHCs also received ANC services outside of public system. Our results only represent the contribution of the public PHCs to the effective coverage of essential interventions.

The effective coverage study was conducted only in the West Bank, although the intervention that followed included the Gaza Strip, which might differ slightly in terms of health system and socioeconomic characteristics [123]. Therefore, the study can be

generalized to the public PHCs in the West Bank, but caution should be taken in extrapolating to the Gaza Strip, as for other contexts.

Our application of a rigorous process of design, analysis, and interpretation of results, we believe, improves the generalizability of our findings [235]. We have aimed to improve the transferability of our research by detailing the process in each paper. *Paper II* aimed at providing evidence to the often ‘black box’ area in digital TCC development, which can be relevant to intervention developers elsewhere [73]. In *Paper III*, we presented a large-scale implementation of a digital intervention that required high initial investment (in terms of cost and time to develop the technology). This might affect the replicability of conducting similar research particularly in a resource limited area.

### **Reflexivity**

The choice of a research topic, the angle of investigation, the preferred methodological approach, the findings considered most relevant, and the ways of structuring and communicating the conclusion are affected by the background and position of the researchers [236]. The in-depth interviews, as part of the digital intervention development, were conducted through a collaboration of researchers from Norway and Palestine. We have diverse professional backgrounds and personal experiences regarding the topic under investigation, which we believe has improved the trustworthiness of the study. The PhD candidate has training in ANC service provision and experience in conducting qualitative interviews in other settings. However, conducting an in-depth interview as a male, non-native to the area, who does not speak the Arabic language was not an option. Hence we used local female data collectors who had experience in service provision and conducting qualitative interviews. That the eRegCom trial would include a digital TCC intervention, was planned before the results of the qualitative assessment were ready, as low attendance to ANC was an anticipated issue in Palestine and part of the national digital registry project’s research plan. Having the plan from the beginning might have influenced our approach to the qualitative assessment and the interpretation of the results.

## Chapter VI: Conclusion

We used effective coverage metrics to identify significant gaps in the provision of essential ANC interventions in public PHCs in the West Bank. Untimeliness of ANC visits was the main contributor to the low effective coverage of essential interventions for anemia, hypertensive disorders of pregnancy, gestational diabetes, and fetal growth restriction.

In our efforts to develop a TCC intervention to effectively address this problem, we followed the Principles for Digital Development and guidance from systematic reviews and international guidelines for the best available evidence on effectiveness and acceptability of digital TCC interventions. In this complex, multidisciplinary field of DHIs, we adhered to well-established theories and frameworks to create a systematic approach in exploring, understanding, iteratively developing, evaluating and refining our intervention. Throughout this process, we relied on co-designing with clients, care providers and other stakeholders, not merely as study subjects, but as partners engaged in the planning, finding, and selection of models and frameworks. In particular, the HBM was instrumental in identifying women's perceptions and information needs, which guided us in developing discrete message components to each construct that lent itself to the personalization of data from the MCH eRegistry. Evidence from social sciences on behavior change and nudging offered additional guidance on how to present such discrete pieces of information as a whole, while keeping strict limits to the length of the SMS.

Our TCC intervention presented women with information about the risks of complications in pregnancy, and their adverse health consequences for both the mother and her baby. However, based on guidance from established evidence and frameworks, the messages systematically balanced this with actionable information for women on the benefits and mitigation of risks associated with attending ANC. The result was an intervention that did not increase pregnancy related worries among recipients. We also informed women about what to expect from her ANC visits, creating expectations of quality of care. Empowering women this way did not affect their satisfaction with the ANC services.



In terms of future research, digital TCC, particularly in an eRegistry environment, has many aspects that need further exploration using robust study designs. As complex health systems research, integrating TCC with interventions towards healthcare providers can jointly improve its effectiveness. We recommend that future studies also focus on the level and appropriateness of the personalization of messages while retaining privacy, which is important for the recipients of the messages. Generally, there is a need for more evidence on the effectiveness of digital TCC interventions from different settings. Equity (like clients who have no access to phones), cost-effectiveness, and sustainability of TCC interventions integrated into health systems, can add to the body of knowledge.

### **Implications for policy**

Individual level data is increasingly being collected in LMIC to serve health data needs at different levels of the health system. Investments in digital technologies for health will be more rewarding when the efforts to collect data are minimized and the effective use of data is maximized. We have demonstrated that a tailored TCC via SMS can be implemented without additional data collection, solely using data from routine health records. Even though its effectiveness in improving the effective coverage is not reported in this thesis, the digital TCC intervention that we introduced to the MCH eRegistry can serve as a demonstration of maximizing the use of data for the benefit of clients.

The Palestinian MCH eRegistry is a digital point-of-care health record in the hands of care providers, and simultaneously a platform where multiple DHIs can be integrated to maximize the return on investment. Innovative ways of using data at all levels of the health system need to be further explored. Contextually assessing needs, generating demand, applying time-tested frameworks, and developing effective interventions carries great promise in improving the coverage and quality of care for women and children in Palestine.

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## Appendices

### *Appendix 1. List of information collected in facility inventory checklist*

<p style="text-align: center;"><b><u>Clinic infrastructure</u></b></p> <p>Types of MCH service provided (low and high-risk) Computer availability Internet connectivity Days of operation Number of rooms used to provide MCH services Availability of beds, measuring tapes, sphygmomanometers Laboratory and ultrasound availability</p>	<p style="text-align: center;"><b><u>Client-related</u></b></p> <p>Number of new pregnancies registered over one year (in 2014 and updated in 2016) Number of total pregnancies handled by the clinic over one year Number of primigravidae Number of pregnant women 40 years</p>
<p style="text-align: center;"><b><u>Health system mapping</u></b></p> <p>Place of referral of high-risk pregnancies Place of referral for laboratory and ultrasound examinations Place of referral for secondary and tertiary MCH care Place of referral for deliveries of pregnant women</p>	<p style="text-align: center;"><b><u>Human resources</u></b></p> <p>Number of doctors, nurses, midwives, specialists and non-nurse/midwife health workers Number of full-time and part-time staff positions</p>

State of Palestine

Ministry of Health



دولة فلسطين

وزارة الصحة

سجل رعاية ومتابعة الحمل  
Antenatal Record

MCH / Viliage Center		مركز رعاية / أمومة			
Governorate		المحافظة			
Date of First Visit		تاريخ الزيارة الأولى			
File No.		رقم الملف			
Personal ID No.		رقم الهوية الشخصية / جواز السفر			
Address	الهاتف Telephone	الحي Street	القرية Village	المدينة City	العنوان
Mother's of Education in Year		سنوات تعليم الام			
درجة القرابة بين الزوجين: <input type="checkbox"/> درجة أولى <input type="checkbox"/> درجة ثانية <input type="checkbox"/> درجة ثالثة <input type="checkbox"/> لا يوجد					
Personal Identification		التعريف الشخصي			
العائلة قبل الزواج Family befor Marriage	اسم العائلة Family Name	اسم الأب Father's Name	الاسم الأول First Name		
Date of Birth	اليوم Day	الشهر Month	السنة Year	تاريخ الميلاد	
Age at Marriage		العمر عند الزواج			
Age at first pregnancy		العمر عند الحمل الأول			
Husbands name		اسم الزوج الثلاثي			

Current Pregnancy				الحمل الحالي			
Obstetric History	عدد مرات الحمل	عدد الولادات	مرات الإجهاض	أطفال أحياء	تاريخ آخر ولادة		السيرة الولادية السابقة
	Gravida	Para	Abortion	Living		LD	
1) LMP C005			سنة Year	شهر Month	يوم Day	(١) تاريخ آخر ولادة	
2) First fetal movement			سنة Year	شهر Month	يوم Day	(٢) أول حركة للجنين	
3) EDD C006			سنة Year	شهر Month	يوم Day	(٣) التاريخ المتوقع للولادة	
4) Conception During Breast Feeding C002/14	No = 2 / لا = 2 <input type="checkbox"/>		Yes = 1 / نعم = 1 <input type="checkbox"/>		(٤) حمل أثناء الإرضاع		
5) Gestational age at first Visit (weeks) C008	-----					(٥) عدد أسابيع الحمل عند أول فحص	
6) Using medications C001, if yes, when, what?	No = 2 / لا = 2 <input type="checkbox"/>		Yes = 1 / نعم = 1 <input type="checkbox"/>		(٦) استخدام الدواء. متى وما هو؟ حدد		
Specify -----							
7) Medical & surgical Condition C010:				(٧) الحالة المرضية			
01	Abdominal surgery	06	Mental disturbance	11	Uterine anomaly or injury		
02	Cardiac disease	07	Renal disease	12	Anemia (Specify)		
03	Cervical suture	08	Type I Insulin dependent DM	13	Bronchial Asthma		
04	Epilepsy	09	Type II Insulin dependent DM	14	RTIs		
05	Hypertension	10	Gestational DM.	15	Others		
88	Others						
8) Cervical Cytology (Pap Smear) C004				(٨) المسحة الخلوية لعنق الرحم			
		1. Done	2. Not Done				
If Done –		1. Normal	2. Unnormal				
Specify -----							
9) Family History				(٩) أمراض عائلية			
1. Diabetes	2. Hypertension	3. Renal	4. Heart	5. Congenital Anomaly			
6. Inborn error of metabolism	7. Blood Disease	8. Bronchial Asthma					

## Risk Assessment

## تقييم عوامل الخطورة

A) Risks related to Medical & Obstetrical History (On booking)  
C012

العوامل المتعلقة بالسيرة المرضية والولادية

Age <16, > 40 year	العمر أقل من 16 سنة أو أكثر من 40 سنة	Y	N	Post APH	سوابق نزف قبل الولادة	Y	N
Consecutive Abortions (>=3)	3* إجهاضات متتالية أو أكثر	Y	N	Post PPH	سوابق نزف بعد الولادة	Y	N
Peri-natal Deaths (>=2)	وفيات حوالي الولادة (2 أو أكثر)	Y	N	* Diabetes M. (type)	* مرض السكري (النوع)	Y	N
Previous C-Section	* سوابق عمليات قيصرية	Y	N	* Chronic Hypertension	* ارتفاع توتر شرثاني مزمن	Y	N
Other uterine Surgery	* سوابق جراحة رحمية أخرى	Y	N	* Heart / Renal Disease	* مرض كلوي / قلبي	Y	N
Multiparity (>=6)	6 ولادات أو أكثر	Y	N	Others (Specify)	أمراض أخرى	Y	N

B) Risks Related to Current Pregnancy

ب) العوامل المتعلقة بالحمل الحالي

Date Of Visit	تاريخ الزيارة	Booked visit	28 weeks	32 weeks	36 weeks	Others
Gestational Age	عمر الحمل بالأسابيع					
Gestational Diabetes Mellitus (GMD)	مرض سكري الحمل					
SIGNS Of Pre-Eclampsia	عوارض تسمم الحمل					
Vaginal Bleeding	نزيف أثناء الحمل					
Moderate Anemia (HB<9.5 g/DL)	فقر دم متوسط (خضاب أقل من 9.5 جم)					
Discrepancy of Fundal Height	عدم توافق ارتفاع الرحم مع فترة الرحم					
Oligo/ Polydraminous	زيادة أو نقصان في السائل الامنيوسي					
Malpresentation At>=36 Weeks	سوء توضع الجنين اعتباراً من 36 أسبوعاً					
Loss Of Fetal Movement >24 Weeks	عدم الشعور بحركة الجنين بعد 24 أسبوعاً					
Multiple Pregnancy	حمل متعدد الأجنة					
PROM	تمزق الأغشية الجنينية المبكر					
RH Incompatibility	تنافر العامل الرايسي					
Pregnancy with pelvic mass	ورم في الرحم مع وجود حمل					
Others (Specify)	أخرى (أذكر)					
Name Who Perform The Assessment	اسم من قام بالتقييم	التوقيع	التوقيع	التوقيع	التوقيع	التوقيع

\* تعني الرجوع إلى نظام التحويل (الصحة الإنجابية)

\* تعني التحويل إلى عيادة الحمل الخطر



سيرة الحمول السابقة ( وتشمل الإجهاضات )

Previous pregnancies (including miscarriages)

الرقم No.	تاريخ الحمل Date of Pregnancy	عمر الحمل اسبوع Gestational Age C008	طريقة الولادة Mode of delivery C030		مكان الولادة Place of birth C039	مضاعفات الحمول السابقة والولادة والنفاس Previous pregnancies C012 (obstetric problems) & Postnatal Problems C045	المولود Newborn		
			Vaginal	Abdominal			النوع Sex B013	الوزن الولادي BWt. "gr" C055	Birth outcome C034
01									
02									
03									
04									
05									
06									
07									
08									
09									
10									
11									
12									
13									
14									

Additional Remarks on Previous Pregnancies

ملاحظات إضافية على سيرة الحمول السابقة

.....

.....

.....

Place of Delivery

مكان الولادة

Intended Place of Birth C038	مكان الولادة حسب رغبة الأم
Recommend place of birth	مكان الولادة (حسب توصية الطبيب)
Stamp & Signature	التوقيع والختم
Doctor's Name	اسم الطبيب

### *Appendix 3a. In-depth interview guide with informed consent form: pregnant women*

#### *Request for participation in a research project: In-depth interview*

*[This informed consent form has two parts (in two pages)]*

#### **Part I: Information Sheet**

My name is \_\_\_\_\_ and I and my colleague came from Palestinian National Institute of Public Health (PNIPH). We are here to invite you to participate in a research. The purpose of the research is to understand women's experiences and thoughts about antenatal care (ANC) and how they care for themselves during pregnancy. You are being invited only because you attended ANC today which is the day we randomly selected to do the interview.

**Risks and Benefits:** The information you are asked to share will have no apparent risk to you. There will be no incentives (payment) for participating, however, your participation will help us find ways of improving the quality of care for pregnant women in Palestine.

**Voluntary Participation:** Your participation is totally voluntary. You can choose not to be interviewed. Declining to participate will not affect your healthcare service provision. You can change your mind during the interview, and even after the interview is over, simply by contacting us without stating any particular reason.

**Procedures:** We will conduct an interview using interview guide here at the clinic or outside, where you feel comfortable. We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing. We would like to tape-record the entire interview not to miss the information you share with us while my colleague is taking notes. It would take about one hour or less.

**Confidentiality:** The information that you provide us during the interview will be used for the stated research objectives only. Any information about you will have a number on it instead of your name (or any personal identifiers). We will lock up the recorded tape with a lock and key and will destroy afterwards. It will not be shared with or given to your service providers or anyone outside of the research team. The results will be presented after putting information from all participants together.

**Contact:** If you need further information or have any question, kindly contact the principal investigators; \_\_\_\_\_ team leader at the PNIPH, [Email: \_\_\_\_\_; Mobile: \_\_\_\_\_], or \_\_\_\_\_ Norwegian Institute of Public Health [Mobile: \_\_\_\_\_; Email: \_\_\_\_\_].

This research has been reviewed and approved by Regional Committee for Health Research Ethics (REK) - Section South East B, Norway (REK) and the Palestinian Health Research Council which is a committee whose task is to make sure that research participants are protected from harm.

#### **Part II: Certificate of Consent**

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

**Statement by the researcher/person taking consent**

I have accurately read out or witnessed while the participant herself read the information sheet, and to the best of my ability made sure that the participant understand the information being provided. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

**A copy of this consent form has been provided to the participant.**

Name of Researcher/person taking the consent \_\_\_\_\_

Signature of Researcher /person taking the consent \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

**Semi-structured interview topic guide for low- and high-risk pregnant women attending high-risk clinics in Palestine**

**Preparatory activities:** Make sure you have secured (written) informed consent prior to starting the interview. Please, check with the interviewee if she is comfortable with the location. Check digital audio recorder’s functionality, battery, and make sure you start recording from the beginning. Remember checking the recorder while interviewing.

**How to use the interview guide:** This semi-structured interview guide shall be used only as a framework during the interview. All the topics for discussions are listed in sequence, however, you may take the topics as they are hinted or mentioned by the interviewee. Link the discussion topics in a way that helps the interviewee to build up on preceding discussion in a natural conversation style. Present the questions by using simple and common languages. Avoid medical terms when possible. Let the interviewee speak as freely as possible, however, have in mind that sometimes you need to guide to the purpose of the study if she goes off the topic.

**Purpose:** The overall purpose of this process is to send individualized actionable SMS messages to pregnant women in order to fill the information gap that they have. In this formative research, we are looking for client’s personal perception regarding what can be done at a clinic during ANC visits and what she can do at home to care for herself for each of the conditions. The interviewee might not have any of the conditions, but we want to assess her understanding of the perception of her community on those topics.

**Theoretical model:** The first two constructs of HBM (perceived susceptibility and severity) are referring to the condition (presented in **bold** as discussion topics) while the rest focuses on what can be done to

manage the condition and/or avoid its consequences. Since the effort is to overcome barriers amenable by our planned intervention, emphasize on identifying “perceived barriers” by the clients. Cues-to-action and self-efficacy components are mainly about ways and one’s ability to overcome barriers, respectively. The women might raise several practices that she might think is important, however, guide the conversation towards interventions and practices that are supported by guidelines and recommendations of the health service. Examples of these can be ANC visits or self-care practices such as adherence to supplements, healthy diet, rest, and exercise. Mention ANC visits or self-care practices and discuss their benefits, barriers, cues-to-action and self-efficacy when appropriate. Note that it is topic specific and hence some of the constructs may not apply to all.

### **Practical instructions:**

- ✓ Depending on each condition, all or some of the six constructs of HBM should be discussed
- ✓ Make sure you understand the HBM constructs so that you know which construct has been addressed when she speaks.
- ✓ You may use “generic opening questions” that we have suggested to bring the conversation forward. Then probe for more information when needed.
- ✓ Once you have exhausted the theme, check the box under each constructs (page 2) for you to remember and move on to the other constructs which haven’t been covered.

**Part I:** After consenting, continue the conversation by asking an opening question, e.g. So, is this your first pregnancy? Ask about the reason/s why she is attending a high-risk clinic, how old she is and her educational status in a usual simple conversation.

### **Part II: Interview topic guide**

1. **Attending antenatal care in a timely manner (ONLY HBM 2-6)** E.g. of opening question: Have you been to many ANC visits here? How helpful is it? Are you happy coming here? Have you scheduled next visits? Do you think you are going to attend as scheduled? If not, why wouldn’t you? How do you see attending ANC timely? What could be barriers or difficulties to attend? What would you like to do to overcome those barriers? How confident are you to overcome those barriers and attend the ANC regularly and timely?
2. **Information:** Do you think you get good information about pregnancy here? When you want more information, where do you get that? If you get confusing information, who do you go to? Whose information do you trust the most? Why?
3. **Concerns:** Do you get to speak about things you are concerned about in pregnancy here at the clinic? What are the things you are concerned about? Do you know of any pregnant women with other concerns? What are these?

*SKIP THEMES BELOW THAT HAVE BEEN MENTIONED AS A CONCERN AND DISCUSSED ALREADY*

You may use opening questions, e.g. you didn’t mention .....[Use local expression if the interviewee doesn’t understand] Isn’t that a concern? Then continue the discussion using the “generic opening questions” for HBM constructs for topic 4-9 (table below)

4. **Hypertensive disorders in pregnancy (High blood pressure)**
5. **Diabetes mellitus (high blood sugar)**
6. **Anemia**
7. **Overweight:** Some are concerned about gaining a lot of weight in pregnancy, what do you think about that? [Then turn the conversation gradually to the risk factors and consequences of



*overweight/obesity in pregnancy when discussing susceptibility and severity– if she is obese herself however that doesn't come into the conversation, make a note of it.]*

8. **Decreased fetal movements:** Have you ever experienced a time when your baby wasn't moving as much as it usually does? What are your expectations regarding fetal movement?
9. **Smoking:** Does anyone in your home smoke? Do you?

Thank you, we have gotten to the end, but is there anything we have forgotten to talk about? Do you have any questions or suggestions?

“Generic opening questions” for Constructs of HBM	Interview main questions								
	1	2	3	4	5	6	7	8	9
<b>Susceptibility</b> (“Is this a concern for you?” – “Why?”) “Do you think you are at risk of getting it?”									
<b>Severity</b> (“Do you think it can be serious for you?” – “Why?”) “Do you think there are any serious consequences for you?”									
<b>Benefit</b> (“What do you think can help?”)									
<b>Barriers</b> (“What would make it difficult for you to do what you know is the best?”) “Is there any reason you wouldn't do...?”									
<b>Cues-to-action</b> (“What could help you to do the right thing?”)									
<b>Self-efficacy</b> (“What do you think you can do?”) How confident are you to do the right thing?									

*Appendix 3b. In-depth interview guide with informed consent form: healthcare providers*

**Request for participation in a research project: In-depth interview**

*[This informed consent form has two parts (in two pages)]*

**Part I: Information Sheet**

My name is \_\_\_\_\_ and I and my colleague came from Palestinian National Institute of Public Health (PNIPH). We are here to invite you to participate in a research. The purpose of the research is to understand healthcare provider's perception of women's experiences and thoughts about antenatal care (ANC) and how they care for themselves during pregnancy.

**Risks and Benefits:** The information you are asked to share will have no apparent risk to you. There will be no incentives (payment) for participating, however, your participation will help us find ways of improving the quality of care for pregnant women in Palestine.

**Voluntary Participation:** Your participation is totally voluntary. You can choose not to be interviewed. Declining to participate will not have any consequences in your job security. You can change your mind during the interview, and even after the interview is over, simply by contacting us without stating any particular reason.

**Procedures:** We will conduct an interview using interview guide here in your office. We would like to tape-record the entire interview not to miss the information you share with us while my colleague is taking notes. It would take about one hour or less. You do not have to share any knowledge that you are not comfortable sharing.

**Confidentiality:** The information that you provide us during the interview will be used for the stated research objectives only. Any information about you will have a number on it instead of your name (or any personal identifiers). We will lock up the recorded tape with a lock and key and will destroy afterwards. It will not be shared with or given to anyone else outside of the research team. The results will be presented after putting information from all participants together.

**Contact:** If you need further information or have any question, kindly contact the principal investigators; \_\_\_\_\_ team leader at the PNIPH, [Email: \_\_\_\_\_; Mobile: \_\_\_\_\_], or \_\_\_\_\_ Norwegian Institute of Public Health [Mobile: \_\_\_\_\_; Email: \_\_\_\_\_].

This research has been reviewed and approved by Regional Committee for Health Research Ethics (REK) - Section South East B, Norway (REK) and the Palestinian Health Research Council which is a committee whose task is to make sure that research participants are protected from harm.

**An interview guide for healthcare providers to explore their perceptions about pregnant women's health-seeking and self-care behavior**

After introducing yourself and securing informed consent, extend the conversation by, e.g. stating her/his profession and ask how long the person has been working at ANC clinic here and elsewhere if any.

1. **ANC attendance:** We want to learn the healthcare providers' experiences about pregnant women's attitude and practices regarding ANC attendance (early booking visits and the scheduled

recurrent visits). The emphasis is to identify barriers and facilitators. *You may start the discussion by asking, for example:*

- How many ANC clients do you have in your clinic? Do the pregnant women feel that ANC attendance is important for them and their baby?
  - **Booking visits:** Do pregnant women come early (as soon as they suspect pregnancy)? If not, why not?
  - **Timeliness of recurrent visits:** Do pregnant women attend the scheduled ANC visit? What makes them attend or not attend?
  - **Action:** What do you do when pregnant women miss an appointment? Does that fit into your everyday workflow? Do you want to do it differently? How?
2. Concern: We want to assess healthcare providers' experiences regarding pregnant women's concerns and their response. Especially regarding the following conditions: **hypertensive disorders in pregnancy, diabetes mellitus, anemia, overweight/obesity, decreased or absent fetal movement, intra-uterine growth restrictions and smoking during pregnancy.**
- Explore what kind of **concerns most pregnant women** present. Opening question for this section can be: Tell me about your experiences. What kind of concerns do pregnant women present to you? If the interviewee do not mention the above conditions during the discussion, then ask them e.g. *"you didn't mention ....., what do you communicate to a pregnant woman who has....?"*
  - Explore how **care providers communicate** to women and their concerns (including how they communicate the importance of regular ANC attendance and home care practices for the woman's concerns). Express curiosity when discussing what and how they communicate, use examples from the ANC guidelines if the interviewee do not mention important interventions for the above conditions. E.g. for anemia *"Do you tell them about supplements? How motivated are they to take it regularly? ..."*
  - Ask whether the healthcare providers feel the clients are getting adequate health information or not. E.g. *"Where do pregnant women go for further information when they need it?"*
3. Thank you for your participation and invaluable information. We are planning to send SMS messages to women. What do you think SMS messages to women could be used for? What information gap can be covered by using SMS messages? What about reminders [if the interviewee does not mention]?

Any question you want to raise? Any suggestion you want to put forward? *Thank you for your time and participation. We value all your comments and opinions. Together we will develop effective ways of improving the quality of antenatal care.*

Appendix 4. Theories and concepts used in the design of the Targeted Client Communication (TCC) intervention

Theories/ concepts	Components	Theoretical assumptions	Theories/concepts guided the development of the TCC content to be sent via SMS
Model of Actionable Feedback (MAF)	Timeliness	The recipient has to receive the SMS at an appropriate time to be able to act upon it	<ul style="list-style-type: none"> <li>All the SMSes were sent within one week of the scheduled visits (intended behavioral action), to empower women to attend the Antenatal Care visit in a timely manner</li> <li>States the exact date of the scheduled/missed antenatal care visit in the SMS</li> <li>Use the most recent information, i.e. in the MCH eRegistry</li> <li>The eRegistry was scheduled to send the SMS at 17:00 hour, informants recommended this time</li> </ul>
	Individualization	The recipient will understand the content of the SMS and be able to act upon it, if it is specific for her	<ul style="list-style-type: none"> <li>Tailored to individuals based on gestational age, selected risk-conditions (anemia, hypertension, diabetes, and fetal growth restriction), and selected risk factors (age, BMI, previous hypertension, diabetes, and anemia) to the risk-conditions risk factor messages will only be sent the woman with specific risk factor/s</li> <li>States the recipient's name in a direct speech</li> <li>Directed to the recipient as an individual, not generic contents</li> </ul>
	Non-punitive	The recipient will change behavior if the instructions are communicated with positive reinforcement	<ul style="list-style-type: none"> <li>Positive tone; not dictating from top down; states mutual agreement</li> <li>States that the woman participated in the decision (e.g. phrase like "as agreed" was included in the messages), empowering</li> <li>Does not imply negative consequences in future ANC services if they fail to attend.</li> <li>Serious losses, e.g. death of the baby, were not mentioned</li> </ul>
	Customizable	The recipient will find the information in the SMS meaningful and acceptable if it is customized for her	<ul style="list-style-type: none"> <li>Each recipient receives the messages pertaining her conditions</li> <li>Any dynamic variable (gestational age, risk-status, risk-factors) are customized based on the routinely collected data at each visit</li> <li>Name of the recipients and name of the clinic as a sender</li> </ul>

<b>Other Nudging/Behavioral science concepts</b>	Enhanced Active Choice	The recipient will be empowered to make consciously informed decisions/ informed health choices and commit to them if they are provided with benefits of adopting the instructions, and consequences of not.	<ul style="list-style-type: none"> <li>Provides information about the benefits of timely attendance and consequences of not attending timely. Does not state fear-inducing or loss-framed content to avoid side-effects (pregnancy worries)</li> </ul>
	Calling by name	The recipient's name is preferable in communication	<ul style="list-style-type: none"> <li>First name of a recipient is included</li> <li>Culturally acceptable greeting</li> </ul>
	Using "trusted sources" as a sender	The recipient will welcome and accept the SMS if it is signed off by a trusted sources	<ul style="list-style-type: none"> <li>The name of the recipient's primary healthcare clinic is included as a sender</li> </ul>

## Appendix 5. Questionnaire for pregnancy related worries and satisfaction sub-study

### Front page

Interviewer: \_\_\_\_\_

Date: \_\_\_\_\_

Woman's phone (pick the phone herself)      Yes       No     

Time started: \_\_\_\_\_

Time ended: \_\_\_\_\_

Call no.: (try on 3 different occasions if no response)      1                      2                      3

Her suggested time to call back: \_\_\_\_\_

Error call reason:                      Person                      Week                      \_\_\_\_\_

Consent:                      Yes                      No

Withdrew                      No                      Yes, question no: \_\_\_\_\_

Questionnaire:                      Full                      Partial (excl. int. questions)

Comments:

### Introduction:

1. Staff presents initial greetings, presents herself and that she calls on behalf of the Palestinian National Institute of Public Health, and seeks confirmation that the correct respondent is on the line.
2. Staff presents the purpose of the call and confirmation of an appropriate time: *I am calling you because we are doing research to improve the quality of antenatal care in public Primary Health Clinics. To inform this research, we are asking pregnant women some questions about their experience with the care and information they have received in clinics, and if they have any concerns or worries in pregnancy. Do you have a minute to let me explain how we found you and what we are inviting you to?*
  - i. *If she indicates interest but lack of time/bad timing, it is allowable to suggest you call her back at a time suggested by her. You should not insist, and if she does not have time to respond at the subsequent planned call either, she should be considered as not consenting.*
3. Staff presents the mode of recruitment, the limits of information provided to her, and gets confirmation of pregnancy: *You have been selected randomly among women who are registered as pregnant by your care provider, and that has been reported to us, but I have no other information about you than your name and phone number. Is it correct that you are in the 9<sup>th</sup> month of your pregnancy? If she delivered, congratulate her, or if the pregnancy ended up in miscarriage, say sorry and thank for taking the call.*
4. Staff presents the content, and voluntary and confidential nature of the survey, ethics approval, as well as any potential benefit or harms, before seeking consent:
  - a. *I would very much like to ask you some questions about your experience with antenatal care, the information you have received, and any worries you have*

- b. *It is voluntary for you to participate, and you can end the interview at any time you like, and you can decline to answer any question you want.*
- c. *Whether you chose to answer my questions or not will have no impact on the care you receive, and we will not share your answers with your care provider.*
- d. *You do not need to say anything about your health to answer the questions. It will only be yes and no questions, and some statements. I will only note your answers on a blank form without your name, phone number or any other identifiers on it, so nobody else than me will know that these are your answers.*
- e. *Our research has been approved by ethics committees, and we are obliged to preserve confidentiality.*
- f. *I expect that the questions will take about 10 to 15 minutes in total.*
- g. *Are you willing to participate by answering my questions?*
  - i. *If now she indicates willingness but lack of time/bad timing, it is allowable to suggest you call her back at a time suggested by her. You should not insist, and if she does not have time to respond at the subsequent planned call either, she should be considered as not consenting.*

**Demographics:**

*First, for us to understand why different women have different experiences, I would like to note a few things about you:*

1. What is the name of your home district?
2. How many years of schooling have you completed?
3. Do you work/study outside your home?
4. Which year are you born?
5. Have you delivered a baby before?
6. In your previous pregnancy, have you ever encountered any adverse pregnancy outcomes (such as abortion, stillbirth, pre-term birth, or infant death)?
7. In this pregnancy, what was your gestational age at booking?
8. In this pregnancy, have you attended ultrasound in other clinics than your public primary healthcare clinic?
9. In this pregnancy, have you attended comprehensive ANC in other clinics than your public primary healthcare clinic?
10. In this pregnancy, have you been referred to a high risk clinic/specialist?

**Susceptibility, Severity, Benefit:**

*Thank you, now I have some statements about antenatal care in general. I will present the statements, and would like to hear how much you agree to this, from 0 if you strongly disagree to 5 if you strongly agree. In between you have 1 if you moderately disagree, 2 if you slightly disagree, 3 if you slightly agree and 4 if you moderately agree. I can repeat the scale for you at any point.*

11. It was important for me to attend all the scheduled antenatal care visits
12. The reason for why I chose to attend ANC was to be tested for diabetes
13. The reason for why I chose to attend ANC was to be tested for anemia
14. The reason for why I chose to attend ANC was to be tested for hypertension
15. The reason for why I chose to attend ANC was to have my baby's growth measured

**Satisfaction, Public antenatal care clinic:**

*Thank you, now I have some statements about your experience with your public antenatal care clinic. I will present the statements, and would like to hear how much you agree to this, from 0 if you strongly disagree to 5 if you strongly agree. In between you have 1 If you moderately disagree, 2 if you slightly disagree, 3 if you slightly agree and 4 if you moderately agree. I can repeat the scale for you at any point.*

16. I am always confident of when my next antenatal care visit is
17. The waiting time does cause me problems
18. The health staff take my questions and concerns seriously
19. I am well informed about the purpose of the tests the health staff run
20. I am well informed of when (gestational age) to do the tests
21. I would recommend the services to a friend
22. I would come back if I become pregnant again
23. I am satisfied with the antenatal care service I have received

**Worries and concerns (13-item Cambridge Worry Scale (Green 2003))**

Most of us worry about something. This list is not meant to give you more things to worry about, but we would just like to know if any of these things are worrying you at all. I will present the statements, and would like to hear how much of a worry it is to you at the moment, from 0 if not a worry to 5 if it is something that you are extremely worried about.

24. Your housing
25. Money problems
26. Your relationship with your husband/partner
27. Your relationship with your family and friends
28. Your own health
29. The health of someone close to you
30. Employment problems
31. The possibility of something being wrong with the baby
32. The possibility of stillbirth
33. Going to hospital
34. Internal examinations (gynecological examination)
35. Giving birth
36. Coping with the new baby

Thank you for your time and cooperation. Good luck with the rest of your pregnancy and the delivery. I wish you all the best!

(Respond to any other questions she may have. If questions arise about how she can find the results of this research, it will be made available on the PNIPH website.)



*Appendix 6. eRegCom trial: list of public primary healthcare clinics and variables used for randomization*

No.	Implementation Phase	Health District	PHCs (Clusters)	Cluster Size	Lab	UL	Intervention arm
1	Phase 2 the Gaza Strip	South	Absaan Al Jadejah	704	Yes	Yes	TCC_only
2	Phase 2 the Gaza Strip	Gaza	Al Daraj	2289	Yes	Yes	TCC_only
3	Phase 2 the West Bank	Qalqiliya	Al-gharbieh PHC	258	Yes	Yes	TCC_only
4	Phase 1 the West Bank	Bethlehem	Al-khader	56	Yes	Yes	TCC_only
5	Phase 2 the West Bank	Hebron	Al-Manshar	198	Yes	Yes	TCC_only
6	Phase 2 the West Bank	Qalqiliya	Al-markazyeh(central)	233	Yes	Yes	TCC_only
7	Phase 2 the West Bank	Jerusalem	Al-ram	56	Yes	Yes	TCC_only
8	Phase 2 the West Bank	North Hebron	Arabeyeh + Bani Na'im	396	No	No	TCC_only
9	Phase 2 the West Bank	Tulkarm	Attil	258	Yes	Yes	TCC_only
10	Phase 1 the West Bank	Nablus	Awarta	123	No	Yes	TCC_only
11	Phase 2 the Gaza Strip	South	Bani Sohelah	2674	Yes	Yes	TCC_only
12	Phase 1 the West Bank	Nablus	Bazria	94	No	Yes	TCC_only
13	Phase 2 the West Bank	Tulkarm	Beit Leed	105	Yes	Yes	TCC_only
14	Phase 2 the West Bank	South Hebron	Beit Awa	165	Yes	Yes	TCC_only
15	Phase 1 the West Bank	Ramallah&Al-bireh	Beit rema	140	Yes	Yes	TCC_only
16	Phase 1 the West Bank	Ramallah&Al-bireh	Beit Sera	47	Yes	Yes	TCC_only
17	Phase 2 the West Bank	Hebron	Ein Sarah	128	No	Yes	TCC_only
18	Phase 2 the West Bank	Qalqiliya	Hajah	101	Yes	Yes	TCC_only
19	Phase 1 the West Bank	Nablus	Hewarah	51	No	Yes	TCC_only
20	Phase 1 the West Bank	Jenin	Jaqamoos	69	Yes	No	TCC_only
21	Phase 2 the Gaza Strip	South	Joret Al loot	1205	Yes	Yes	TCC_only
22	Phase 2 the West Bank	Tulkarm	Kafr El-labad	102	No	Yes	TCC_only
23	Phase 2 the West Bank	Tulkarm	Kafr Jammal	85	Yes	Yes	TCC_only
24	Phase 1 the West Bank	Jenin	Meithalun	235	Yes	Yes	TCC_only
25	Phase 2 the West Bank	Tulkarm	Qafeen	241	Yes	Yes	TCC_only
26	Phase 1 the West Bank	Jenin	Raba	74	No	No	TCC_only
27	Phase 1 the West Bank	Ramallah&Al-bireh	Ramallah New MCH clinic	400	Yes	Yes	TCC_only
28	Phase 1 the West Bank	Nablus	Rojeeb	99	No	Yes	TCC_only
29	Phase 2 the West Bank	Yatta	Roqe't Al-Aroos	157	Yes	Yes	TCC_only
30	Phase 2 the West Bank	Tulkarm	Shwekeh	144	Yes	Yes	TCC_only
31	Phase 2 the West Bank	North Hebron	Surif Musqat + Beit Ummar	375	Yes	Yes	TCC_only
32	Phase 1 the West Bank	Nablus	Talfet	116	Yes	Yes	TCC_only
33	Phase 2 the West Bank	Tubas	Tamoon Al-wosta	190	Yes	Yes	TCC_only
34	Phase 2 the West Bank	Hebron	Tarqomia	174	Yes	Yes	TCC_only
35	Phase 1 the West Bank	Nablus	Tel	109	Yes	Yes	TCC_only
36	Phase 2 the Gaza Strip	Gaza	Al Falah	2842	Yes	Yes	Control

37	Phase 2 the West Bank	Hebron	Al-haram	137	No	Yes	Control
38	Phase 2 the West Bank	Yatta	Al-karmel	95	Yes	Yes	Control
39	Phase 2 the West Bank	Hebron	Al-Rama	406	Yes	Yes	Control
40	Phase 2 the West Bank	South Hebron	Al-reheieh	166	Yes	Yes	Control
41	Phase 2 the West Bank	South Hebron	AL-Samooa'	167	Yes	Yes	Control
42	Phase 2 the West Bank	South Hebron	Al-thahreyyeh	240	Yes	Yes	Control
43	Phase 1 the West Bank	Jenin	Al-zbabdeh	64	Yes	No	Control
44	Phase 2 the West Bank	Tulkarm	Anabta	124	Yes	Yes	Control
45	Phase 1 the West Bank	Jenin	Aneen	75	No	No	Control
46	Phase 2 the West Bank	Tubas	Aqaba	245	Yes	Yes	Control
47	Phase 1 the West Bank	Nablus	Beit Eba	69	No	Yes	Control
48	Phase 2 the West Bank	Hebron	Beit kahel	250	Yes	Yes	Control
49	Phase 2 the West Bank	North Hebron	Beit Ula	158	Yes	Yes	Control
50	Phase 1 the West Bank	Ramallah&Al-bireh	Bill'in	44	Yes	No	Control
51	Phase 1 the West Bank	Nablus	Central MCH clinic	1916	No	Yes	Control
52	Phase 1 the West Bank	Ramallah&Al-bireh	Ebween	52	Yes	Yes	Control
53	Phase 2 the West Bank	Hebron	Ethna	270	Yes	Yes	Control
54	Phase 2 the West Bank	Tulkarm	Far'oon	56	No	Yes	Control
55	Phase 1 the West Bank	Salfit	Health Directorate Salfit	486	Yes	Yes	Control
56	Phase 2 the West Bank	Jericho	Jericho MCH clinic	198	No	Yes	Control
57	Phase 1 the West Bank	Salfit	Kefel Hares	86	Yes	Yes	Control
58	Phase 2 the West Bank	North Hebron	Kfan Khamees	105	No	Yes	Control
59	Phase 2 the West Bank	North Hebron	Kharas	80	Yes	Yes	Control
60	Phase 1 the West Bank	Ramallah&Al-bireh	Kharbatha Bani Hareth	55	No	No	Control
61	Phase 1 the West Bank	Jenin	Misilyah	72	No	No	Control
62	Phase 1 the West Bank	Ramallah&Al-bireh	Nea'leen	109	Yes	Yes	Control
63	Phase 1 the West Bank	Nablus	Qabalan	184	Yes	Yes	Control
64	Phase 2 the Gaza Strip	South	Rafah	2290	Yes	Yes	Control
65	Phase 2 the West Bank	Yatta	Roqa'h	134	No	Yes	Control
66	Phase 2 the West Bank	Qalqiliya	Sanniriya	111	Yes	Yes	Control
67	Phase 2 the West Bank	Tubas	Tubas Central MCH clinic	204	Yes	Yes	Control
68	Phase 2 the Gaza Strip	Middle	Wadi Al Salqa	507	Yes	Yes	Control
69	Phase 1 the West Bank	Salfit	Yasooof and Izkaka clinic	92	Yes	Yes	Control
70	Phase 2 the Gaza Strip	Gaza	Al Salam	1756	Yes	Yes	QID_only
71	Phase 2 the Gaza Strip	Middle	Al Zawida	812	Yes	Yes	QID_only
72	Phase 1 the West Bank	Ramallah&Al-bireh	Al-Bireh MCH clinic	288	No	Yes	QID_only
73	Phase 2 the West Bank	Yatta	Al-derat	49	No	No	QID_only
74	Phase 2 the West Bank	Jerusalem	Al-Eizariya MCH clinic	347	Yes	Yes	QID_only
75	Phase 1 the West Bank	Jenin	Al-Fandaqumiya	89	No	No	QID_only
76	Phase 2 the West Bank	Yatta	Al-ghwetah	159	Yes	Yes	QID_only
77	Phase 2 the West Bank	Jericho	Al-ojah	81	Yes	Yes	QID_only

78	Phase 2 the West Bank	North Hebron	Al-Shuyukh	193	Yes	Yes	QID_only
79	Phase 2 the West Bank	South Hebron	Al-taqwa	112	Yes	Yes	QID_only
80	Phase 2 the Gaza Strip	Gaza	Atah Habeeb	2869	Yes	Yes	QID_only
81	Phase 2 the West Bank	Qalqiliya	Azoon	168	Yes	Yes	QID_only
82	Phase 2 the West Bank	Tulkarm	Bal'a	200	Yes	Yes	QID_only
83	Phase 1 the West Bank	Salfit	Bedia clinic	128	Yes	Yes	QID_only
84	Phase 1 the West Bank	Ramallah&Al-bireh	Beituniya	52	No	Yes	QID_only
85	Phase 1 the West Bank	Ramallah&Al-bireh	Deir Jarir	63	Yes	Yes	QID_only
86	Phase 2 the West Bank	South Hebron	Deir Samet Al-sharqyeh	90	Yes	Yes	QID_only
87	Phase 2 the West Bank	Qalqiliya	Hableh	202	Yes	Yes	QID_only
88	Phase 2 the West Bank	Jerusalem	Hezma	48	Yes	No	QID_only
89	Phase 1 the West Bank	Jenin	Jenin central clinic	1376	Yes	Yes	QID_only
90	Phase 2 the West Bank	Qalqiliya	kafr theleth	122	Yes	Yes	QID_only
91	Phase 1 the West Bank	Ramallah&Al-bireh	Kharbatha Al-mesbah	118	Yes	Yes	QID_only
92	Phase 2 the West Bank	Yatta	khelet al-Myeh	83	No	Yes	QID_only
93	Phase 1 the West Bank	Salfit	Kufr Al-deek	91	Yes	Yes	QID_only
94	Phase 2 the West Bank	Qalqiliya	kufr kadoom	59	Yes	No	QID_only
95	Phase 1 the West Bank	Jenin	Mirka	67	No	No	QID_only
96	Phase 1 the West Bank	Salfit	Qarawah	163	Yes	Yes	QID_only
97	Phase 2 the West Bank	North Hebron	Sa'eer	372	Yes	Yes	QID_only
98	Phase 1 the West Bank	Nablus	Salem	97	Yes	Yes	QID_only
99	Phase 2 the Gaza Strip	Gaza	Shek Radwan Clinic	1521	Yes	Yes	QID_only
100	Phase 1 the West Bank	Jenin	Silat adh Dhahr	337	Yes	Yes	QID_only
101	Phase 2 the West Bank	Hebron	Tafouh	259	Yes	Yes	QID_only
102	Phase 2 the West Bank	Hebron	Wad Azez	99	No	Yes	QID_only
103	Phase 2 the West Bank	Tulkarm	Zeita	62	Yes	Yes	QID_only
104	Phase 2 the Gaza Strip	South	Abasan Al Kabeerah	2555	Yes	Yes	TCC and QID
105	Phase 2 the Gaza Strip	Gaza	Abu Shebak	304	Yes	Yes	TCC and QID
106	Phase 2 the Gaza Strip	Gaza	Al Horyah	1408	Yes	Yes	TCC and QID
107	Phase 1 the West Bank	Bethlehem	Al-eabedieh	335	Yes	Yes	TCC and QID
108	Phase 2 the West Bank	Tubas	Alfara'h	85	Yes	Yes	TCC and QID
109	Phase 2 the West Bank	Hebron	Al-krantena	448	Yes	Yes	TCC and QID
110	Phase 2 the West Bank	Hebron	Al-masharqah	122	No	Yes	TCC and QID
111	Phase 2 the West Bank	Yatta	AL-mkabieh*	53	No	No	TCC and QID
112	Phase 2 the West Bank	Tulkarm	Al-reayeh Al-Janobeyeh	571	Yes	Yes	TCC and QID
113	Phase 1 the West Bank	Jenin	Al-Taibeh	57	No	Yes	TCC and QID
114	Phase 2 the West Bank	South Hebron	Al-thahreyeh Hosp. Emerg. & Delivery	411	Yes	Yes	TCC and QID
115	Phase 2 the West Bank	Tulkarm	Baqa ash Sharqiya	98	Yes	Yes	TCC and QID
116	Phase 1 the West Bank	Bethlehem	Bethlehem MCH clinic	229	Yes	Yes	TCC and QID
117	Phase 1 the West Bank	Nablus	Bieta	227	Yes	Yes	TCC and QID
118	Phase 1 the West Bank	Nablus	Borqah	65	No	Yes	TCC and QID

119	Phase 2 the West Bank	Tulkarm	Deir Al-ghsoon	213	Yes	Yes	TCC and QID
120	Phase 1 the West Bank	Ramallah&Al-bireh	Deir Amar	73	Yes	Yes	TCC and QID
121	Phase 1 the West Bank	Nablus	Doma	86	No	Yes	TCC and QID
122	Phase 2 the West Bank	South Hebron	Dora	303	Yes	Yes	TCC and QID
123	Phase 2 the West Bank	Qalqiliya	Emateen	51	Yes	Yes	TCC and QID
124	Phase 2 the West Bank	North Hebron	Halhol	214	Yes	Yes	TCC and QID
125	Phase 2 the West Bank	Tulkarm	Illar	164	Yes	Yes	TCC and QID
126	Phase 2 the West Bank	Qalqiliya	Jayous	90	Yes	Yes	TCC and QID
127	Phase 1 the West Bank	Jenin	Kferet	70	No	No	TCC and QID
128	Phase 1 the West Bank	Jenin	Kufr Raa'e	120	Yes	No	TCC and QID
129	Phase 2 the West Bank	Tubas	Old Tubas MCH clinic	229	Yes	Yes	TCC and QID
130	Phase 1 the West Bank	Ramallah&Al-bireh	Qarawah Bani Zeid	51	No	No	TCC and QID
131	Phase 1 the West Bank	Nablus	Ras Al-een	188	No	Yes	TCC and QID
132	Phase 1 the West Bank	Salfit	Sartah	111	No	Yes	TCC and QID
133	Phase 2 the West Bank	Tulkarm	Seda	109	No	Yes	TCC and QID
134	Phase 2 the West Bank	Yatta	Shoda Yata	53	No	No	TCC and QID
135	Phase 1 the West Bank	Ramallah&Al-bireh	Shuqba	60	Yes	Yes	TCC and QID
136	Phase 2 the Gaza Strip	South	Tal Sultan	1734	Yes	Yes	TCC and QID
137	Phase 2 the West Bank	Tulkarm	Thenabeh	70	Yes	Yes	TCC and QID
138	Phase 2 the West Bank	Tubas	Tyaseer	82	Yes	Yes	TCC and QID



\* closed after randomization, UL=Ultrasound, Lab=laboratory, TCC=Targeted Client Communication, QID=Quality Improvement Dashboard

Original articles

# PAPER I

RESEARCH ARTICLE

# Effective coverage of essential antenatal care interventions: A cross-sectional study of public primary healthcare clinics in the West Bank

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**Data Availability Statement:** All results and the data used for analyses are presented in the manuscript and its supporting information files. Data cannot be shared publicly because of the limitations in scope that is part of our agreement with the data owners, the Palestinian Ministry of Health. The richness of individual-level data makes it possible to address a number of unrelated research questions from this material, which have not been approved by Palestinian research ethics authorities or the data owner. Access to data

## Abstract

### Background

The proportion of women attending four or more antenatal care (ANC) visits is widely used for monitoring, but provides limited information on quality of care. Effective coverage metrics, assessing if ANC interventions are completely delivered, can identify critical gaps in healthcare service delivery. We aimed to measure coverage of at least one screening and effective coverage of ANC interventions in the public health system in the West Bank, Palestine, and to explore associations between infrastructure-related and maternal sociodemographic variables and effective coverage.

### Methods

We used data from paper-based clinical records of 1369 pregnant women attending ANC in 17 primary healthcare clinics. Infrastructure-related variables were derived from a 2014 national inventory assessment of clinics. Sample size calculations were made to detect effective coverage ranging 40–60% with a 2–3% margin of error, clinics were selected by probability sampling. We calculated inverse probability weighted percentages of: effective coverage of appropriate number and timing of screenings of ANC interventions; and coverage of at least one screening.

### Results

Coverage of one screening and effective coverage of ANC interventions were notably different for screening for: hypertension (98% vs. 10%); fetal growth abnormalities (66% vs. 6%); anemia (93% vs. 14%); gestational diabetes (93% vs. 34%), and antenatal ultrasound (74% vs. 24%). Clinics with a laboratory and ultrasound generally performed better in terms of effective coverage, and maternal sociodemographic factors had no associations with

requires ethical clearance by the Palestinian Health Research Council, or any institutional review board approved by the Ministry of Health, as well as approval from the Ministry of Health. Data are available from the Palestinian National Institute of Public Health. Detailed descriptions to re-create identical data, as well as contact addresses to the data source, are available as supporting information.

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**Competing interests:** The authors have declared that no competing interests exist.

effective coverage estimates. Only 13% of the women attended ANC visits according to the recommended national schedule, driving effective coverage down.

## Conclusion

Indicators for ANC monitoring and their definitions can have important consequences for quantifying health system performance and identifying issues with care provision. To achieve more effective coverage in public primary care clinics in the West Bank, efforts should be made to improve care provision according to prescribed guidelines.

## Introduction

Antenatal care (ANC) provides an opportunity to detect risk factors, prevent complications and improve birth preparedness of pregnant women in order to reduce maternal and neonatal morbidity [1, 2]. The proportion of women who attend four or more ANC visits (ANC 4+), is used extensively as an indicator for monitoring health of pregnant women as well as health system performance [3, 4]. However, measuring contact of pregnant women with the health system has limitations, since attending an ANC visit does not imply that pregnant women receive good quality care [5–7]. The quality of care received may also be inequitable. In low and middle-income countries (LMIC), even with high levels of ANC 4+, wealthier and better-educated women are significantly more likely to receive quality care [8].

Effective coverage, in contrast, combines utilization of healthcare services with the quality of care received. Conceptually, effective coverage is “the proportion of the population who need a service that receive it with sufficient quality for it to be effective” [9]. For ANC, effective coverage is conventionally comprised of ‘ANC attendance’, defined as having at least one or at least four ANC visits; and ‘quality’, assessed in terms of ANC content [10]. Standard ANC content includes a set of interventions, which entail single, two-step or repeat screening tests and managements at specified times during pregnancy [11, 12]. The World Health Organization has published widely accepted recommendations for ANC [13], including suggestions for appropriate contact (frequency and timing between clients and the health system) and content (screening and management) based on evidence of effectiveness [14, 15].

Whether pregnant women have received some or all components of a set of interventions as part of ANC at least once during pregnancy has been used to indicate quality of care [9, 16, 17]. This measure, without timing or frequency, is not adequate to measure effectiveness or quality of care provided. For example, one hemoglobin measurement in pregnancy does not correspond to the provision of effective interventions for prevention and management of anemia as recommended by the WHO guidelines—being tested only late in pregnancy excludes the opportunity for treatment, and being tested only early does not imply a safe hemoglobin level at delivery. Measuring effective coverage of essential ANC interventions is, therefore, more comprehensive than ANC+ for assessing ANC service provision [10].

Assessing effective coverage can help identify critical ‘bottlenecks’ around provision of healthcare such as care providers’ knowledge of clinical practice guidelines and infrastructure availability [18, 19]. Typical health systems ‘bottlenecks’, which limit its capacity to provide effective care, include access to care, availability of trained human resources and health infrastructure as well as utilization [20]. Studies assessing ANC content and quality in LMIC often use population-based surveys as the main data source. In general, household surveys provide limited information on processes of care and the accuracy of information collected is reliant

on recall of survey participants [21]. Facility-based documentation and direct observations [22] can be used to assess effective coverage of ANC interventions at a given visit. Facility-based data, if available routinely over a period of time, can provide information on the number and timing of screening tests of ANC interventions provided—aspects of healthcare provision not available from household surveys [23, 24].

Better health information systems and improving the quality of healthcare services are of high priority for the Palestinian health system [25, 26], with no published studies of health system performance or ANC provision in public primary healthcare clinics in the West Bank available. In the West Bank, maternal and child health services are organized in two tiers—primary healthcare where ANC, postpartum care and newborn care are provided; and secondary or tertiary healthcare where obstetric services are provided. The public sector is reportedly the single largest provider of ANC, catering to almost 50% of all women that give birth in a year [27]. Based on place of residence, pregnant women are assigned to a governmental primary healthcare clinic for care. ANC is also provided by private health facilities, non-governmental organizations and the United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA) [27]. A recent household survey suggests that more than 95% of women attend 4 or more ANC visits [28]. The Palestinian Ministry of Health and the Palestinian National Institute of Public Health are currently implementing an electronic health information system for maternal and child health consisting of individual-level data collected at the point-of-care (eRegistry) in public primary healthcare clinics [29]. As a result of this implementation, the existing data ecosystem for maternal and child health is shifting from aggregated data on the mean number of ANC visits per pregnant woman to individual-level data with accessible information on content and processes of ANC service delivery. Such a transition could be disruptive to the health system if the nature and magnitude of any changes to the available data and indicators, and associated factors are not anticipated or not understood by health system managers.

In this study, our objective was to assess the coverage of at least one screening and appropriate number of screenings of ANC interventions, and effective coverage of ANC interventions in public primary healthcare clinics in the West Bank, Palestine. Secondly, we explored selected infrastructure-related and maternal sociodemographic factors potentially associated with effective coverage.

## Materials and methods

We extracted data from paper-based clinical records of antenatal care to demonstrate the potential changes in health and health systems performance indicators that would be observed when transitioning from the existing aggregate health information system to the eRegistry. Since the Palestinian national eRegistry implementation was rolled out in phases, we extracted records from a random cross-sectional sample of clinics in the five districts that comprised phase one, from the year 2015, before any clinics started using the eRegistry.

## Study setting

ANC records (paper-based until 2016 and the eRegistry thereafter) are primarily used for clinical documentation in all primary healthcare clinics. Paper-based ANC records were structured data entry forms consisting of data elements pertaining to clients' medical history, screening tests results, clinical examinations, and clinical managements [29]. While nurses or midwives typically provide routine ANC in primary healthcare clinics, doctors visit the clinic once or twice a week and perform clinical and ultrasound examinations and interpret lab test results,



and manage complications in pregnancies. Clinics may either have their own laboratory and ultrasound or share these facilities with other clinics.

### Sample size and sampling

A single data collection exercise was set up to measure maternal morbidity rates [30] as well as effective coverage of ANC interventions. The overall sample size was determined by the least prevalent outcome expected, corresponding to a 1% prevalence of severe anemia in pregnancy. It was assumed that effective coverage of ANC interventions would be in the 40–60% range (based on expert opinion in the absence of relevant data). In order to estimate indicators in these ranges that were representative of the five phase 1 districts, and with margins of error of 2–3% for the coverage of ANC interventions and 0.5% for maternal morbidity rates, 1344 pregnancies were required [31]. OpenEpi was used for sample size calculations [31].

Primary healthcare clinics were selected by probability sampling proportional to clinic size until a sufficient number of clinics was sampled to achieve the calculated sample size ( $n = 1344$ ), provided that clinical records of all women registered for ANC in these clinics during January–December 2015 were included in the data collection. Since the primary healthcare clinics were selected by unequal probability sampling, inverse probability sample weights were assigned to individual pregnancies in order to produce results that were more generalizable to the five districts included in the data collection, and to produce robust standard errors [32]. The same dataset was used for the calculation of prevalences of maternal health conditions and details are presented elsewhere [30].

### Data collection

Data were extracted from paper-based ANC records and entered into electronic forms on the District Health Information System 2 (DHIS2) software, which were identical to the data capture forms of the eRegistry, to ensure similar data structures [33]. Two trained data collectors, who were nurse-midwives, extracted data from clinical records. Ten per cent of the clinical records were extracted and entered twice by each of the data collectors and the study team carried out consistency checks of the double-entered data [34].

An inventory assessment of all public primary healthcare clinics in the West Bank was completed by the study team at the Palestinian National Institute of Public Health in December 2014. Information needed to support the implementation of the eRegistry was collected, including details of infrastructure in the clinics, laboratory and ultrasound availability, and the number and type of care providers for maternal and child health [29, 34]. Clinic staff were asked to return completed assessment forms to the study team; 100% of clinics completed this form.

### Outcome variables

ANC interventions included in our analyses comprised those that were: 1) recommended as part of routine ANC content in the public health system in the West Bank; 2) applicable to all pregnant women irrespective of risk status; and 3) amenable to measurement using data from ANC records. Applying these criteria, eight ANC interventions were selected (Table 1). Three of these interventions were similar to the WHO Essential interventions [35], and four of the interventions were recommended as part of the WHO ANC model for a positive pregnancy experience [13] (Table 1). Six additional ANC interventions recommended in the public health system were excluded from this analysis, either because the ANC records did not contain the variables required to generate the indicators or because the interventions were not appropriate for the primary healthcare level (S1 Text).

Table 1. Recommended schedule of ANC visits and ANC interventions in the West Bank.

ANC interventions	Recommended ANC visits schedule				
	Booking <sup>†‡</sup>	16 weeks	24–28 weeks	32 weeks	36 weeks
Screening for hypertension*	X	X	X	X	X
SFH measurement <sup>‡</sup>	X	X	X	X	X
Screening for anemia*	X		X		X
Antenatal ultrasound <sup>§</sup>	X		X		X
Screening for gestational diabetes mellitus <sup>‡</sup>	X (Urine)		X (Blood)		
Screening for asymptomatic bacteriuria <sup>‡</sup>	X				
Screening for Rh-type <sup>‡</sup>	X				
Screening for tetanus immunization status*	X				

\* Similar to the WHO's Essential Interventions for RMNCH

<sup>‡</sup> Recommended in the 2016 WHO ANC model for a positive pregnancy experience

<sup>§</sup> Context-specific recommendation

<sup>†‡</sup> Booking: refers to first antenatal visit at the clinic; ANC: Antenatal care; SFH: Symphysis-fundal height.

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For each ANC intervention selected, we defined indicators of coverage of at least one screening test, coverage of appropriate number of screenings (only applicable to ANC interventions requiring repeat or two-step screening), and effective coverage, based on ANC guideline in the West Bank (Table 2). Definitions for effective coverage of ANC interventions included both the recommended timing and number of screening tests of the intervention (Table 2).

In the definitions for effective coverage of ANC interventions, the appropriate number of timely screening tests were adjusted according to the gestational age of pregnant women at

Table 2. Definitions of indicators of coverage of at least one screening, coverage of appropriate number of screenings, and effective coverage of ANC interventions.

ANC intervention	Coverage of at least 1 screening	Coverage of the appropriate number of screening	Effective coverage (appropriate number and timing of screenings)
Screening for hypertension	Proportion with at least one blood pressure measurement	Proportion with five blood pressure measurements	Proportion with blood pressure measurements at all recommended ANC visits
SFH measurement	Proportion with at least one SFH measurement	Proportion with five SFH measurements	Proportion with SFH measured at all recommended ANC visits <sup>†</sup>
Screening for anemia	Proportion with at least one hemoglobin test	Proportion with three hemoglobin tests	Proportion with hemoglobin tests at booking <sup>†‡</sup> , 24–28 and 36 weeks*
Antenatal ultrasound	Proportion with at least one ultrasound examination	Proportion with three ultrasound examinations	Proportion with ultrasound examinations at booking <sup>†‡</sup> , 24–28 and 36 weeks*
Screening for gestational diabetes mellitus	Proportion with either urine sugar or blood sugar test	Proportion with both urine sugar and blood sugar test	Proportion with urine sugar test at booking <sup>†‡</sup> and blood sugar test at 24–28 weeks*
Screening for asymptomatic bacteriuria	Proportion with urine microscopy test		Proportion with urine microscopy test at booking <sup>†‡</sup>
Screening for Rh-type	Proportion with Rh-typing		Proportion with Rh-typing at booking visit
Screening for tetanus immunization status	Proportion whose tetanus immunization status is checked by asking for history of immunization or reviewing immunization record		Proportion whose tetanus immunization is checked by asking for history of immunization or reviewing immunization record at booking <sup>†‡</sup>

<sup>†</sup> calculated for ANC visits that occur after 16 weeks

\* given that registration of pregnancy was before the recommended timing of screening

<sup>†‡</sup> Booking: refers to first antenatal visit at the clinic.

ANC: Antenatal care; SFH: Symphysis-fundal height

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registration for ANC. For example, women who were registered for ANC before 24 gestational weeks were considered effectively screened for anemia if they had three hemoglobin tests—at first ANC visit, at 24–28 weeks and 36 weeks (Table 2), while women that were registered for ANC after 28 weeks were considered effectively screened if they received two hemoglobin tests, one at their first ANC visit and another at 36 weeks (Table 2).

We calculated the proportion of women with any four and any five ANC visits irrespective of timing of visits. Since coverage of appropriate number of screening tests and effective coverage are influenced by attendance rates following pregnancy registration, we calculated the proportion attending all timely visits appropriate to when the first ANC visit occurs. We measured the proportion of women attending ANC visits in the specific time windows where interventions were recommended (Table 1). We also assessed the proportion attending all 5 timely visits including an early first ANC visit before 14 weeks.

### Variables potentially associated with effective coverage

Laboratory and ultrasound availability were the infrastructure-related factors chosen for analyses, since these were expected to be associated with effective coverage. Clinics were grouped into those that had all relevant infrastructure and those that had one or more missing infrastructure. Since the sample of clinics had similar cadres of care providers, and were expected to be similar in terms of availability of other infrastructure needed for ANC (e.g. sphygmomanometers), we did not use these for exploratory analyses.

Maternal sociodemographic variables used in the analyses were those available in the ANC records, including women's age at pregnancy registration, age at marriage, education and parity.

### Data analyses

All analyses were done using STATA version 15 (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP), using the command 'svyset' for generating weighted proportions and 95% confidence intervals (CI) [36]. Descriptive statistics were produced for the following variables and categories: women's age at pregnancy registration (<21 years, 21–34 years, >34 years); age at marriage (<20 years and  $\geq$ 20 years); number of years of education of women (<10 years, 10–13 years, >13 years); and parity (nulliparous, multiparous<4, multiparous $\geq$ 4). These categories were pre-defined in the dataset obtained for this analysis in accordance with the data sharing policies outlined in the Standard Operating Procedures for routine registry operations [34].

Chi-square tests of differences were used for exploratory analyses of effective coverage of ANC interventions across sub-groups based on infrastructure-related and maternal sociodemographic variables. Adjusted odds ratios (OR) and 95% CI were generated for each of the interventions, through a logistic regression model consisting of infrastructure-related characteristics (laboratory and ultrasound availability) and all maternal sociodemographic variables (women's age at pregnancy registration, education, age at marriage and parity).

### Ethics approval

Anonymous secondary data for analyses were obtained with approvals from the Palestinian Ministry of Health, in accordance with the data sharing principles outlined in the Standard Operating Procedures for routine registry operations [34]. Ethics approvals for this study were obtained from the Palestinian Health Research Council (PHRC/HC/272/17) and the Regional Committee for Medical and Health Research Ethics in Norway (2017/1537). Descriptions to

re-create identical data, as well as contact addresses to the data source, are available as supporting information (S2 Text).

## Results

Data were collected from 1369 clinical records of pregnant women first registered for ANC in 2015 in 17 primary healthcare clinics. Totally, these women attended 6397 ANC visits during 2015 and 2016. One out of the 17 primary healthcare clinics had a non-nurse/midwife health worker that was the sole provider of ANC, while all other clinics had a nurse or midwife providing ANC. All 17 clinics had a doctor visiting once a week to provide ANC. Of the 17 primary healthcare clinics, six were equipped with both a laboratory and ultrasound. Two clinics each had either only a laboratory or only an ultrasound, while seven clinics had neither.

Fifty-four pregnancies in the sample (4%) ended in a documented spontaneous miscarriage. The mean gestational age at first ANC visit was 14 weeks (SD = 7), 47% of the women (95% CI: 38, 55, n = 638) attended their first ANC visit within 3 months and 67% of women (95% CI: 60, 73, n = 914) attended their first ANC visit within 4 months. The majority (75%) of women were between 21–35 years of age at the time of their first ANC visit, and 37% were nulliparous (Table 3).

### ANC attendance

About half of the women attended at least five ANC visits, while 60% (95% CI: 50, 70) attended at least four ANC visits, when not considering the schedule or timing of visits (Table 4). Only 6% (95% CI: 5, 8) of the women attended all ANC visits according to the recommended ANC 5-visit schedule, including an early first ANC visit before 16 weeks. Disregarding early attendance and only considering the schedule of visits after pregnancy registration, 13% (95% CI: 9, 17) attended ANC visits as per the recommended national schedule (Table 4), and thus could have received complete hypertension and SFH screening.

The proportion of women attending all recommended ANC visits according to the national guidelines was higher in clinics with both laboratory and ultrasound (17%), compared to clinics with one or no such infrastructure (9%), with an adjusted OR of 2.0 (95% CI: 1.4, 2.8).

**Table 3. Background sociodemographic characteristics of pregnant women in the sample.**

Sociodemographic characteristics	Population (n)	Percentage
Age		
<20	222	16
21–35	1029	75
>35	118	9
Education		
<10	149	11
10–13	591	43
>13	514	37
Age at marriage		
<20	695	50
>20	573	42
Parity		
Nulliparous	501	37
Multiparous (<4)	666	48
Multiparous (≥4)	186	14

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**Table 4. Comparison of coverage at least one screening of ANC intervention, coverage of appropriate number of screenings prescribed for ANC interventions, and effective coverage of ANC interventions (number and timing of screening of ANC interventions).**

ANC intervention	Coverage of ANC interventions <sup>§</sup> (% , 95% CI)			ANC visits (% , 95% CI)	
	At least one screening test	Appropriate number of screening tests	Effective coverage	Number of visits irrespective of timing <sup>‡</sup>	Appropriate number and timing of visits <sup>‡</sup>
Screening for hypertension	98 (96, 99)	38 (31, 47)	10 (8, 13)	48 (38, 58)	13 (9, 17)
SFH measurement	66 (50, 80)	35 (24, 48)	6 (4, 9)		
Screening for anemia	93 (89, 96)	31 (23, 40)	14 (9, 21)	73 (62, 81)	33 (26, 41)
Antenatal ultrasound	74 (59, 85)	43 (32, 54)	24 (18, 31)		
Screening for gestational diabetes mellitus	93 (88, 96)	69 (60, 77)	34 (26, 43)	85 (77, 90)	56 (50, 62)
Screening for asymptomatic bacteriuria*	55 (45, 64)		42 (36, 49) <sup>‡</sup>	NA	
Screening for Rh-type*	78 (67, 89)		64 (54, 73) <sup>‡</sup>	NA	
Screening for tetanus immunization status*	35 (23, 50)			NA	

<sup>§</sup>refer Table 2 for definitions of coverage indicators of ANC interventions

<sup>‡</sup>refer Table 1 for number of ANC visits and their timing for each ANC intervention recommended in the national guidelines

\*only one screening test during ANC is recommended in the national guidelines

<sup>‡</sup>refers to screening test provided during the first ANC visit.

ANC: Antenatal Care; SFH: Symphysis-fundal height; CI: Confidence Intervals

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### Coverage of ANC interventions

Coverage of at least one screening of ANC interventions ranged between 55% (95% CI: 45, 64) for screening for asymptomatic bacteriuria and 98% (95% CI: 96, 99) for hypertension screening (Table 4).

Compared to the coverage of at least one screening, coverage of the appropriate number of screenings was considerably lower for all interventions requiring repeat or two-step screening (Table 4). In clinics that had ultrasound equipment, coverage of any symphysis fundus height (SFH) measurement was 29%, while in clinics without ultrasound the coverage was 63%.

For diabetes screening, coverage of blood sugar test was 73% (95% CI: 65, 79) and urine sugar test was 89% (95% CI: 82, 94).

### Effective coverage

Effective coverage of ANC interventions was lower than the coverage of at least one screening and coverage of appropriate number of screenings for all interventions except screening for tetanus immunization status (Table 4). Regarding screening for gestational diabetes mellitus, 43% (95% CI: 35, 52) had a blood sugar test at 24–28 weeks and 71% (95% CI: 63, 78) had a urine sugar test at booking visit.

Among those attending the prescribed number and timing of ANC visits (Table 4), the percentage receiving the relevant screening tests were as follows: hypertension screening: 77%, antenatal ultrasound: 73%, gestational diabetes: 61%, SFH measurement: 46% and anemia screening: 42%.

Effective coverage of six of the eight ANC interventions was highest in primary healthcare clinics with laboratory and ultrasound availability (Table 5). Clinics with a laboratory and ultrasound were associated with statistically significant higher odds of effectively screening for four ANC interventions. Screening for tetanus immunization status was the only ANC

Table 5. ANC interventions and infrastructure-related characteristics: effective coverage (%) and adjusted odds ratios from logistic regression analyses.

ANC interventions	Effective coverage (%)		Adjusted odds ratio (95% CI) <sup>‡</sup>
	One or more missing infrastructure (n = 728)	Both lab and ultrasound (n = 631)	
Screening for hypertension	7	14	2.2 (1.5, 3.1)
SFH measurement	7	4	0.6 (0.4, 1.0)
Screening for anemia	12	17	1.5 (1.1, 2.1)
Antenatal ultrasound	20	36	2.2 (1.7, 2.8)
Screening for gestational diabetes mellitus	32	37	1.2 (1.0, 1.5)
Screening for asymptomatic bacteriuria	42	43	1.0 (0.8, 1.3)
Screening for Rh-type	59	70	1.7 (1.3, 2.1)
Screening for tetanus immunization status	37	29	0.7 (0.5, 0.9)

<sup>‡</sup>derived from multivariable logistic regression analyses including all infrastructure-related and maternal sociodemographic variables: laboratory and ultrasound availability, maternal age at pregnancy registration, age at marriage, education and parity  
 ANC: Antenatal care; SFH: Symphysis-fundal height; CI: Confidence Intervals

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intervention that had a statistically significant lower odds ratio (adjusted OR = 0.7, 95% CI: 0.5, 0.9) (Table 5).

A higher proportion of multiparous women (≥ four births) had their tetanus immunization checked, compared to nulliparous women (41% vs. 29%; adjusted OR = 2.1, 95% CI: 1.4, 3.2) (S1 Table). None of the other maternal sociodemographic variables had statistically significant associations with effective coverage (S1 Table).

## Discussion

This is the first study to our knowledge to use effective coverage metrics for assessment of the Palestinian health system. By assessing the effective coverage of ANC interventions in public primary healthcare clinics, along with infrastructure-related and maternal sociodemographic factors that may be associated with effective coverage, it was possible to gain insight into ANC service provision in these clinics.

Studies informed by household survey data or direct observations have demonstrated lower effective coverage of ANC than crude service coverage in diverse settings such as Kenya [10], Ethiopia [37] and other countries in sub-Saharan Africa [22]. These studies have assessed the ‘quality’ component of effective coverage using a checklist of services provided during ANC, which would be conceptually equivalent to the outcome ‘coverage of at least one screening of ANC intervention’ in our study. Almost all pregnant women in our sample had received a blood pressure measurement, and this result was similar to the findings from large multi-country studies of ANC content using survey data [7, 23].

In contrast to other studies of effective coverage that have reported a one-time provision of clinical interventions [10, 22], we also assessed the number and timing of screening tests for the full duration of the pregnancy to produce quality-corrected coverage of ANC interventions using facility-based data. According to outcome definitions used in this study, coverage of at least one screening is not dependant on follow-up care of pregnant women throughout the antenatal period. Coverage of appropriate number of screenings, on the other hand, reflects care provision throughout the antenatal period, but did not factor the timing of screening tests. Effective coverage of ANC interventions is essentially a combination of timely attendance rates and the provision of the prescribed screening test during attendance in the clinics.

Our ANC 4+ coverage rate (60%) was similar to that found in a study using facility-based data conducted in Jordan [38], which has a comparable population and health system as the

West Bank. Compared to ANC4+, attendance rates of ANC visits at guideline-specified timings was low in our sample of clinics. As a result, effective coverage of ANC interventions consisting of two-step (screening for gestational diabetes mellitus) or repeat screening tests (screening for anemia and hypertension, SFH measurement, and antenatal ultrasound) were significantly lower than both coverage of at least one screening and coverage of appropriate number of screenings. A multi-country study reported that 10% of women in Jordan and 27% in Egypt had received a set of routine care components as part of ANC [23]. Despite methodological distinctions in the data source used, this study hints at a trend of low coverage of essential ANC interventions and can corroborate our findings. The difference between coverage of any screening test provided and effective coverage of screening for gestational diabetes (69% vs. 34%) was primarily due to the timing at which the tests were provided.

For ANC interventions consisting of a one-time screening test, the magnitude of the differences between coverage of at least one screening and effective coverage were smaller because timing of provision of ANC interventions played a less decisive role in achieving effective coverage. Indicators of hemoglobin and blood pressure measurement, which are commonly reported worldwide [39], had high coverage of at least one screening but much lower effective coverage in our study.

In general, two underlying contributing factors will lead to low effective coverage of ANC interventions, attendance and service provision. Hijazi et al [38] demonstrated that scheduling of follow-up ANC visits and counseling by care providers were strongly associated with women's utilization of ANC services in Jordan. Similar explorations are recommended to identify possible issues with providing timely appointments for follow-up ANC visits and potential barriers to ANC utilization in public clinics in the West Bank. Service provision is determined by adherence of care providers to prescribed ANC guidelines, which, in turn, could be influenced by training and supervision, or dissemination of guidelines. Other health systems factors such as lack of supplies of sufficient lab test kits have been shown to be determinants of service delivery in other contexts [19], but is less likely in our setting, considering the relatively high coverage of at least one screening of interventions that need such supplies.

Structural inputs to care such as infrastructure in health facilities have been shown to be weak predictors of content of ANC provided and clinical quality [40], although these results were for countries in sub-Saharan Africa with health systems that may be different from the West Bank. In our study, availability of laboratory and ultrasound in the clinics had varying degrees of associations with effective coverage of the different ANC interventions. A much lower proportion of women had SFH measured in clinics with an ultrasound compared to clinics without, presumably because of the use of antenatal ultrasound for fetal growth monitoring instead. It was beyond the scope of this paper to assess the quality of ultrasound-based fetal growth monitoring. Effective coverage of screening for hypertension and tetanus immunization status, that can be provided to pregnant women without a laboratory or ultrasound in the clinics were still associated with these infrastructure-related variables. Clinics with both a laboratory and ultrasound had a higher effective coverage of hypertension screening due to higher attendance rates in these clinics and relatively routine and non-invasive nature of taking blood pressure. The data available for this study could not shed light on the possible reasons for lower effective coverage of a simple screening test for tetanus immunization status in these better-equipped clinics.

In contrast to infrastructure-related factors, maternal sociodemographic characteristics (maternal age at pregnancy registration, age at marriage, education and parity) were not significantly associated with effective coverage. Differences in effective coverage based on sociodemographic variables may be due to characteristics that were not available for our study. For example, household income or expenditure are commonly used variables for equity analyses,

but were not available from the clinical records. Other studies done in LMIC have reported differences in the quality of ANC provided to clients based on their socioeconomic characteristics [16, 41]. These studies used data from household surveys and may have been able to capture populations across social, economic and demographic gradients, compared to our study using only facility-based data of women that receive ANC in public clinics.

In this study, we have presented one approach to the generation of effective coverage using facility-based data. For comprehensive health systems monitoring, such assessments capturing the timing and frequency of care may be used to complement the deficiencies of population-based survey data [23, 42]. Given the availability of routine health facility data from the newly implemented eRegistry in Palestine, health systems monitoring through such metrics is more feasible than with paper-based systems. Inferences derived from our analysis can provide policy-makers with information on some health system factors for consideration to increase effective coverage in public clinics. The eRegistry has incorporated several features designed to increase the level of effective coverage in this population. Specifically, interactive checklists with clinical decision support and automated dashboards providing performance feedback for care providers, can support the provision of complete ANC interventions, while tailored SMS messages to pregnant women, can encourage better uptake of ANC [29].

A limitation of this study was that only documented care was analyzed. Interventions may have been provided without documentation, but for many of these interventions, undocumented screening will be ineffective screening for the purpose of appropriate follow-up during pregnancy. Women may also have received additional targeted tests based on symptoms, as per care providers' clinical judgements, and subsequently not been re-screened at the time recommended by the guidelines. Such targeted tests may represent reasonable substitutes for routine screening, but would have been missed in our analyses. Effective coverage indicators of screening at specified timings will change over time, as the optimal number and timing of ANC contacts, as well as ANC content, continues to be a matter of debate and subject to evaluation [14, 43–45]. Similar to health systems in other countries in the region [23], pregnant women in the West Bank reportedly seek ANC from private providers and non-governmental organizations, sometimes in addition to receiving ANC from public health facilities. Therefore, the results of this study may not be indicative of the totality of effective coverage of ANC at the population-level in the West Bank, and cannot necessarily be used to estimate how changes in effective coverage in the public health system alone will impact maternal and neonatal health outcomes.

## Conclusion

The choice and definitions of metrics can have substantial impact on health systems monitoring of ANC, both in terms of ascertaining the magnitude of the problem as well as identifying potential solutions. Effective coverage of ANC interventions in public primary healthcare clinics in the West Bank can be increased by improving the timely and complete provision of ANC interventions. Further exploration of specific aspects of care provision in primary healthcare clinics such as care providers' adherence to guidelines and women's perceptions and utilization of ANC services in public clinics, can help address these issues to increase effective coverage of ANC interventions.

## Supporting information

**S1 Text. ANC interventions in the public health system not included in the analyses.** (DOCX)



**S2 Text. Details of data used in the study.**

(DOCX)

**S1 Table. Effective coverage and maternal sociodemographic variables.**

(DOCX)

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## Additional file to Paper I

### Effective coverage and maternal sociodemographic variables

Table A: Effective coverage (%) of essential ANC interventions across sub-groups based on maternal socioeconomic variables

Maternal sociodemographic variables	Effective coverage (%; 95% CI)									
	Screening for hypertension	SFH measurement	Screening for anemia	Antenatal ultrasound	Screening for tetanus immunization status	Screening for asymptomatic bacteriuria	Screening for Rh-type	Screening for gestational diabetes mellitus		
<b>Age (years)</b>										
<=20	8	5	15	27	32	48	71	33		
21-34	11	5	14	27	33	41	63	35		
>=35	12	6	16	30	38	42	61	38		
<b>Education (years)</b>										
<10	10	5	12	30	34	41	67	37		
10-13	10	6	16	27	34	42	68	37		
>13	11	5	13	27	32	43	60	32		
<b>Age at marriage (years)</b>										
<20	11	5	14	27	33	44	67	35		
>20	10	6	15	28	33	41	60	34		
<b>Parity</b>										
0	10	6	15	27	29	44	67	33		
1-4	10	5	14	26	35	41	62	36		
≥4	13	6	12	33	41	44	62	35		

CI: Confidence intervals; SFH: Symphysis-fundal height; ANC: Antenatal Care

Table B: Associations of effective coverage and maternal sociodemographic variables: adjusted odds ratios and 95% CI

Maternal sociodemographic variables	Adjusted OR (95% CI) †									
	Screening for hypertension	SFH measurement	Screening for anemia	Antenatal ultrasound	Screening for tetanus immunization status	Screening for asymptomatic bacteriuria	Screening for Rh-type	Screening for gestational diabetes mellitus		
<b>Age (years)</b>										
<=20	1	1	1	1	1	1	1	1	1	1
21-34	1.7 (0.9,3.3)	1.1 (0.5,2.4)	1.0 (0.6,1.6)	0.9 (0.6,1.4)	0.8 (0.5,1.1)	0.8 (0.6,1.1)	0.9 (0.6,1.3)	1.1 (0.8,1.6)		
>=35	1.8 (0.7,4.5)	1.1 (0.4,3.7)	1.3 (0.6,2.8)	0.8 (0.4,1.5)	0.8 (0.4,1.4)	0.8 (0.5,1.4)	0.8 (0.4,1.4)	1.3 (0.7,2.3)		
<b>Education (years)</b>										
<10	1	1	1	1	1	1	1	1	1	1
10-13	0.9 (0.5,1.8)	1.2 (0.5,2.7)	1.3 (0.8,2.3)	0.9 (0.6,1.3)	1.2 (0.8,1.8)	1.0 (0.7,1.5)	0.9 (0.6,1.3)	1.0 (0.7,1.5)		
>13	1.1 (0.6,2.2)	0.9 (0.4,2.2)	0.9 (0.5,1.7)	0.8 (0.5,1.2)	1.1 (0.7,1.7)	1.3 (0.8,1.7)	0.7 (0.4,1.0)	0.8 (0.5,1.2)		
<b>Age at marriage (years)</b>										
<20	1	1	1	1	1	1	1	1	1	1
>20	0.7 (0.5,1.1)	1.2 (0.7,2.2)	1.2 (0.8,1.7)	1.2 (0.9,1.7)	1.2 (0.9,1.7)	0.9 (0.7,1.2)	0.8 (0.6,1.1)	1.0 (0.8,1.4)		
<b>Parity</b>										
0	1	1	1	1	1	1	1	1	1	1
1-4	0.8 (0.5,1.2)	0.7 (0.4,1.3)	1.0 (0.7,1.4)	1.1 (0.8,1.4)	1.4 (1.0,2.0)	0.9 (0.7,1.2)	0.8 (0.6,1.0)	1.1 (0.8,1.4)		
≥4	1.0 (0.5,2.0)	0.9 (0.4,2.2)	0.7 (0.4,1.4)	1.4 (0.9,2.2)	2.1 (1.4,3.2)	1.1 (0.7,1.6)	0.7 (0.5,1.1)	0.9 (0.6,1.4)		

† derived from multivariable logistic regression analyses including all infrastructure-related and maternal sociodemographic variables: laboratory and ultrasound availability, maternal age at pregnancy registration, age at marriage, education and parity; CI: confidence intervals; SFH: symphysis-fundus height


# PAPER I I

RESEARCH ARTICLE

Open Access

# Development of a targeted client communication intervention to women using an electronic maternal and child health registry: a qualitative study



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## Abstract

**Background:** Targeted client communication (TCC) using text messages can inform, motivate and remind pregnant and postpartum women of timely utilization of care. The mixed results of the effectiveness of TCC interventions points to the importance of theory based interventions that are co-design with users. The aim of this paper is to describe the planning, development, and evaluation of a theory led TCC intervention, tailored to pregnant and postpartum women and automated from the Palestinian electronic maternal and child health registry.

**Methods:** We used the Health Belief Model to develop interview guides to explore women's perceptions of antenatal care (ANC), with a focus on high-risk pregnancy conditions (anemia, hypertensive disorders in pregnancy, gestational diabetes mellitus, and fetal growth restriction), and untimely ANC attendance, issues predefined by a national expert panel as being of high interest. We performed 18 in-depth interviews with women, and eight with healthcare providers in public primary healthcare clinics in the West Bank and Gaza. Grounding on the results of the in-depth interviews, we used concepts from the Model of Actionable Feedback, social nudging and Enhanced Active Choice to compose the TCC content to be sent as text messages. We assessed the acceptability and understandability of the draft text messages through unstructured interviews with local health promotion experts, healthcare providers, and pregnant women.

**Results:** We found low awareness of the importance of timely attendance to ANC, and the benefits of ANC for pregnancy outcomes. We identified knowledge gaps and beliefs in the domains of low awareness of susceptibility to, and severity of, anemia, hypertension, and diabetes complications in pregnancy. To increase the utilization of ANC and bridge the identified gaps, we iteratively composed actionable text messages with users, using recommended message framing models. We developed algorithms to trigger tailored text messages with higher intensity for women with a higher risk profile documented in the electronic health registry.

(Continued on next page)

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**Conclusions:** We developed an optimized TCC intervention underpinned by behavior change theory and concepts, and co-designed with users following an iterative process. The electronic maternal and child health registry can serve as a unique platform for TCC interventions using text messages.

**Keywords:** Targeted client communication, Digital health, mHealth, SMS, Text messages, Antenatal care, Maternal and child health, Electronic registry, DHIS2

## Background

The introduction of information and communication technologies in the health sector is revolutionizing health information communication [1, 2]. Digital health applications, such as Short Message Services (SMS), are increasingly common, including in resource-limited settings [3–5]. Targeted Client Communication (TCC) via SMS is being used to improve people's knowledge and attitudes towards healthy behaviors and utilization of healthcare services [6–9]. TCC, in this context, is defined as transmission of unidirectional targeted health content (pregnancy related information and appointment reminders) tailored to individuals, based on static and dynamic information about recipients from a routine maternal and child health registry system (adapted from World Health Organization [3], and Agarwal et al. [10]).

Well-informed clients can participate in the decision making processes of their own clinical care, and are empowered to make informed health decisions in dialog with their healthcare providers [11]. Therefore, well-informed clients, have the potential to improve the quality content of care they receive. Simple appointment reminders, alone or with health promotion content via SMS, have the potential to boost antenatal care (ANC), postnatal care (PNC), and newborn care service utilization [8, 12–16], but the effectiveness is mixed [17, 18].

Development of an effective behavior change intervention, including TCC intervention, is complex and requires careful design, implementation and evaluation [19]. Despite the growing number of TCC interventions via SMS [20], recent systematic review found that most of them are “*under-theorized, poorly specified and vaguely described*” [14], and the process of end-user involvement is seldom reported [17]. TCC interventions are more effective if the assessment of the current behavior, the identification of gaps between the current and preferred behavior, and the approach to bridge these gaps are grounded on sound behavioral change theories [13, 14, 17, 18]. Theory based interventions are often specific and replicable due to the theory driven description of the design, development and implementation processes [21–23]. Behavior change theories, such as the Health Belief Model (HBM) [24] can be used to assess the context and guide development and evaluation of TCC interventions [22].

The text message content in TCC interventions via SMS, tends to be generic and is rarely tailored towards important individual characteristics [7, 8, 14]. Most health campaigns, especially in low-and middle-income countries, recruit recipient on-demand and gather a few background characteristics [3]. This approach may have limited the availability of information about the recipient, and thus make the development of individualized messages difficult. Furthermore, most digital maternal and child health interventions are without a focus on continuity of care [7]. Developing and sending TCC interventions from a longitudinal registry environment, that includes dynamic information over the course of pregnancy and delivery, to our knowledge, has not been reported previously. The national electronic maternal and child health registry (MCH eRegistry) in Palestine, built on the District Health Information System 2 (DHIS2) software [25], provides such an opportunity [26, 27]. Healthcare providers enter individual-level patient information into the eRegistry at the point of care. The systematic, uniform and longitudinally collected data generate algorithms that drive the eRegistry, including TCC via SMS, which can increase timely attendance and the quality of ANC and PNC [26].

Following Abrams' [28] recommendation of setting goals for TCC interventions, our goal was to encourage pregnant and postpartum women to attend scheduled visits in a timely manner, and empower them to come with expectations, demand services, and make informed health choices. Therefore, TCC intervention can improve the effective coverage of ANC and PNC services by influencing both the utilization of services (coverage) and quality (appropriate quality contents and timeliness of essential interventions) [29, 30].

This paper presents a theory-driven process from conceptualization and contextual assessment, to development and evaluation of a tailored TCC intervention using individual background characteristics from the MCH eRegistry in Palestine. We used recommended steps for developing and evaluating text messages [28] and relevant components of related reporting checklist, mERA [31] and TiDieR [32] throughout. The intervention described in this paper has subsequently been implemented in Palestine as a cluster-randomized controlled effectiveness trial (ISRCTN10520687).

## Methods

### Setting

We conducted this research to prepare a TCC intervention for a cluster-randomized trial (trial registration No: ISRCTN10520687), embedded in the national MCH eRegistry in the public primary healthcare clinics in Palestine [26, 27]. Approximately 50% of women in Palestine utilize public primary healthcare clinics for ANC and PNC services [33]. The organizational structure of the public primary healthcare clinics is reported elsewhere [27, 34]. The female literacy rate is above 94% [35], and approximately 85% of the women registered in the MCH eRegistry, have provided a mobile phone number.

A national expert panel identified anemia, hypertensive disorders of pregnancy (HDP), gestational diabetes mellitus (GDM), fetal growth restriction (FGR), and untimely ANC attendance as priority issues, on which we concentrated our efforts.

### Theoretical framework and data collection instruments

We used the HBM [24] to guide our interviews and assessments of women's beliefs and perceptions towards the prioritized high-risk conditions described above. We developed two in-depth interview guides, one for pregnant women and one for healthcare providers, to explore all six constructs (perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cue to action, self-efficacy) of the HBM [24]. The HBM constructs were consolidated into three domains: 1) women's perceptions of personal risks for the high-risk conditions (susceptibility and severity), 2) perception of benefits of attending ANC for those high-risk conditions, and 3) factors influencing the decision to attend timely ANC (perceived barriers, cues-to-action, and self-efficacy). The interview guides also included additional questions regarding health information sources, counseling, and views on the use of SMS to address knowledge gaps. The English interview guides were translated to Arabic and back-translated to English by an external person.

### Sampling and data collection process

We purposively selected seven public primary healthcare clinics where both pregnant women and healthcare providers were invited to participate in the study. Women, who attended ANC at the day of data collection, were asked to take part in the study by means of convenience sampling. We obtained oral informed consent from all informants. In total, four trained female nurses conducted 15 in-depth interviews in a private room, and three phone-interviews with pregnant women who never returned for ANC to the public primary healthcare clinic where they were first registered. The interviewers also conducted in-depth interviews with four MCH doctors and four nurses/midwives. We stopped further interviews

after reaching theoretical saturation. All interviews were audio-recorded.

### Data analysis

We transcribed the interviews and translated them to English. NVivo 12 software (QSR International Pty Ltd. Version 12, 2018) was used for all data management and subsequent analyses. We performed thematic analyses according to HBM constructs. First, we categorized the texts into nodes, referring to the HBM constructs, and then performed line-by-line coding. The main themes were developed and named from codes under each node. We also thematically analyzed information unrelated to the HBM. Three researchers participated in defining the themes based on the data.

### Composing and evaluating the text messages

We used the results of the in-depth interviews to compose the TCC content to be sent via SMS. The TCC content was developed to fill the major awareness and knowledge gaps related to the three HBM constructs (Table 2). The prioritized conditions were linked with the recommended timing of screenings at each of the five sentinel ANC visits, according to the national guidelines (Additional file 1). We used the Model of Actionable Feedback [36] and concepts of social nudging and Enhanced Active Choice [11] to compose the TCC content (Additional file 2). We did not state the recipient's risk factors to ensure confidentiality. The TCC content was composed in English, translated to Arabic, and independently back-translated to English. We gathered feedback on the TCC content in a stepwise manner, and incorporated comments prior to the next round of feedback. The first consultation with national health education experts on the TCC content suggested further contextualization such as using local expressions. We interviewed healthcare providers and pregnant women to assess the TCC content's understandability and acceptance, in addition to the preferred time of the day to receive the text messages. The final text message library was created after considering all comments.

### Technology platform

We wrote algorithms to trigger each text message types in the text message library after determining the parameters that characterize the eligibility of who should receive which specific text message. All these parameters are available as a data point in the MCH eRegistry, to mention a few that are included, gestational age, date of scheduled visit, various risk factors, risk conditions, and assent to receive the text message. The algorithms run at each interaction with the data points and sends or schedules messages accordingly after inserting the name, scheduled date, and the name of clinic in to the

pre-designed message template. The scheduler is set to run automatically at agreed up on time with the users on daily basis to send the scheduled messages after linking to the recipients' phone number. We use the DHIS2 Tracker App [25] to send messages from the MCH eRegistry through a local telecom service provider's SMS gateway, as per agreement with the Ministry of Health.

## Results

We first present the findings from the in-depth interviews with pregnant women and healthcare providers and second, how we utilized these findings in iterative rounds of development and evaluation of the TCC intervention with users.

### Part I: findings from in-depth interviews

Among 18 interviewed pregnant women, seven had a high-risk condition in the current pregnancy, and seven were primigravida. The participants mean age was 26 years, ranging from 20 to 33 years. All interviewed women had formal education and seven of them held a college degree or above.

We present pregnant women's perceptions of the prioritized high-risk conditions (anemia, HDP, GDM, and FGR) and untimely ANC attendance using the HBM (Table 1). We also present results from healthcare providers' perspectives and experiences, where relevant.

### Perceptions of high-risk conditions and timely attendance

#### *Perception of susceptibility and severity*

Pregnant women, in general, perceived that they had low susceptibility to the high-risk conditions, and that these had low severity. Women with knowledge of the high risk conditions, a history of pregnancy complications, or knew someone with a history of pregnancy complications, perceived greater susceptibility to the high-risk conditions compared with their peers. Women engaged in self-care activities, such as healthy diet, exercise, and regular checkups, perceived themselves as less susceptible to pregnancy complications compared with women not engaged in self-care activities. Most pregnant women knew the general consequences and complications of anemia, diabetes, and hypertension as chronic diseases for the general population, but not their effects in pregnancy on maternal and fetal outcomes (Table 1).

#### *Perceived benefits of timely ANC attendance*

Pregnant women recognized the benefits of attending ANC on wellbeing, both for their baby and themselves. However, they had little awareness of the importance of timely ANC attendance for appropriate screening and management. The pregnant women's perceived benefits of attending ANC for screening and management of high-risk conditions were affected by individual background

characteristics. Women identified with a high-risk condition or with a history of a pregnancy complication, attended ANC more often than women without any current or previous complications. These women were also more aware of what to expect during ANC visits and the importance of timely attendance. Primigravida women were eager to attend ANC, but had low awareness of what to expect regarding screening and management activities, and the importance of timely attendance. Healthcare providers reported that they provided attractive ANC services to women that contributed positively to women's ANC attendance (Table 1).

#### *Perceptions about barriers, cues-to-action, and self-efficacy*

In general, women's perceptions of barriers, lack of cues-to-action, or lack of self-efficacy were not main factors preventing women from attending ANC services. Among women interviewed, the majority reported that accessibility and lack of support from the husband and/or other family members were not a problem. However, a few women with young children stated that lack of support in childcare was a barrier for them to attend ANC. Low perceived benefits from ANC attendance, along with low perceptions of susceptibility to, and severity of, the high-risk conditions, were the main barriers to timely ANC attendance.

Most women attended ANC despite the lack of cues-to-action, such as a formal appointment reminder system. However, both healthcare providers and women indicated that healthcare providers sometime contact women with a missed appointment via phone or through social networks including family members. Healthcare providers pointed out that these approaches are time consuming and done irregularly. Women diagnosed with a high-risk condition and perceived this as severe, attended ANC due to their concerns. As one midwife pointed out, "...they feel it is important for them, they write the date on their mobile so that they don't forget it".

Regarding self-efficacy, almost all women said that they independently decided to attend ANC, and that they were confident about their choice. They also reported that they have adequate social capital to do so. One interviewee said, "*Inshalah, since I am educated, I can do the right thing.*"

#### *Pregnant women's awareness, health information sources, and counseling*

All pregnant women had heard of anemia, HDP, GDM and FGR. However, their awareness and descriptions of causes and consequences, varied based on the level of education, parity, personal history and knowing someone with at least one of the conditions. Women diagnosed with a condition were more aware of that condition and followed its progress more closely, compared to women

**Table 1** Health Belief Model constructs including the main themes with quotes from the participants, Palestine

Model constructs	Description of the themes	Example excerpts
Perceived susceptibility	Knowledge: Susceptibility is perceived as higher among women who know the complications that can develop in pregnancy	"I don't know about the disease, so how can I know if I am susceptible to it or not." - a <i>primigravida</i>
	Self-care: Women perceive lower susceptibility as they engage in preventive self-care (e.g. healthy diets) and follow recommendations of care providers (e.g. ANC and screening)	"No, because I came to the clinic every time, and they [healthcare providers] reassured me that I didn't have anything worrying. Also, in fact, I do not like sweets and sugar." - a <i>primigravida</i> "I do not think so, because I am eating a good diet. As long as you have a good diet and milk and your hemoglobin is 12 and you are at the end of your pregnancy..." - a <i>low risk woman</i>
	Pregnancy history: Women with complications in previous pregnancies perceive themselves as more susceptible	"Yes, I had it [hypertension] in my first pregnancy and I recovered after delivery. Yes, I am susceptible because..." - a <i>woman who had a history of hypertension</i>
	Family history: Women with a family history of pregnancy complications or chronic conditions perceive themselves as more susceptible	"No I don't worry, and there is nobody in my family who has diabetes" - a <i>hypertensive woman</i> "I don't know exactly, my parents don't have hypertension and my husband's parents have hypertension, so may be my children will have hypertension in the future." - a <i>pregnant woman who had miscarried five times</i>
Perceived severity	Chronic conditions, not pregnancy complications. Women relate their perception of severity to the conditions as chronic conditions, but not their potential for complicating pregnancy	"I know that diabetes delays healing of the wound and this may cause amputation of limbs..." - a <i>woman attending a high-risk clinic</i> "Heart problems and increase heart rate, dizziness and loss of consciousness" - a <i>low-risk woman</i> "I do not know if it affects [the baby]" - a <i>primigravida with moderate anemia</i>
	History of friends/relatives: Women who know friends/family with a history of pregnancy complications perceive complications as more severe	"...hypertension is dangerous for pregnant women and leads to preeclampsia, I know a friend who had eclampsia at the end of the eighth month" - a <i>multigravida</i> "My sister had anemia and her hemoglobin became 5, and she needed two units of blood..." - a <i>grand multipara</i>
	Being affected by a complication: Women diagnosed with a high risk condition, often articulate clearly the potentially severe consequences of the condition	"Premature baby, low birth weight or IUGR" - a <i>pregnant woman in a high-risk clinic</i> "It can cause early labor, bleeding and thrombosis" - a <i>woman with coagulation disorder</i>
Perceived benefit	Expectations to care content: Advance knowledge of purpose and what tests each scheduled visit would include, affects the women's perception of benefit	"I found that [private] doctor and [public] clinic providing the same services, such as weight, height, blood pressure measurements, so I decided to follow up in the [public] clinic" - a <i>pregnant woman at low-risk clinic trying out services in Gaza</i> "I have to come. It is my duty to come for ANC visit" - a <i>primigravida</i>
	Being affected by a complication: Women diagnosed with a high risk condition perceive the importance of visiting the clinics according to the schedule, but only for the specific condition they are diagnosed with	"...examine the level of sugar and control..." - a <i>woman attending a high-risk clinic</i> "I follow my periodic check-ups every month ...I receive the anticoagulant injections..." - a <i>woman with coagulation disorder</i> "Of course it is beneficial, since I get the anti-hypertensive drugs, iron and vitamins" - a <i>woman diagnosed with HDP</i>
Perceived barrier	Perception of benefits: The better the perceived benefit the woman have, the less perceived barrier to attend the scheduled visits	"I think that there are no obstacles, and I should follow the right things for my benefit." - a <i>primigravida</i> "I think, there are no difficulties, and the most important thing is having personal will" - a <i>grand multipara</i>
	Family logistics: Women with small children and little family support, report this as a barrier to attend ANC	"In the first and second pregnancies, I attended regularly, but when the number of my children increased, it became less often

**Table 1** Health Belief Model constructs including the main themes with quotes from the participants, Palestine (Continued)

Model constructs	Description of the themes	Example excerpts
		<p>than before.”</p> <p>- a mother of three</p> <p>“...my children are small and my husband works in military and he comes back at night...”</p> <p>- a multipara</p>

not diagnosed with any of the high-risk conditions. Most of the diagnosed women remembered lab results, such as hemoglobin levels over time (Additional file 3<sup>a</sup>).

Healthcare providers, especially MCH doctors, were the main trusted sources of pregnancy related information. Several women also use the internet or ask their mothers if they need the information immediately. If they do not understand or find contradictory information, they prefer to confirm it with a doctor (Additional file 3<sup>b</sup>).

Most women felt that they received adequate health information during ANC visits (Additional file 3<sup>c</sup>). Women diagnosed with one of the high-risk conditions received information regarding that specific condition. Healthcare providers stated that they spent less time on counseling and health education than desired, due to the high patient load (Additional file 3<sup>d</sup>). Some pregnant women who were diagnosed with a high-risk condition (Additional file 3<sup>e</sup>) confirmed this.

#### Attendance at ANC

Almost all women stated that they visited the health facility when they missed a period, and most healthcare providers had observed an increasing trend in early initiation of ANC. Most women were committed to scheduled ANC visits, but the degree of adherence differed based on their background characteristics, such as education, parity, and previous adverse pregnancy outcomes (Additional file 3<sup>f</sup>). Healthcare providers also said that most women are committed to scheduled ANC visits, including those with low-risk pregnancies. Women showed an interest in more frequent visits than currently recommended (Additional file 3<sup>g,h</sup>).

In sum, the in-depth interviews indicated that many women had limited knowledge about pregnancy related anemia, HDP, GDM, and FGR, and perceived the susceptibility to, and severity of, such conditions as low. While the general motivation to attend ANC was high, awareness of the importance of timely attendance to be appropriately screened and managed for such conditions was low. Women with high exposure to information about such pregnancy-related complications and the role of ANC (i.e. complications in current or prior pregnancy, knowing someone who experienced it, etc.) had

high awareness of both the susceptibility to and severity of the conditions, as well as the benefits of timely ANC.

#### Part II: Composing the text messages

We used the findings from the in-depth interviews above to identify gaps in information and awareness, across the HBM constructs, to be addressed in the TCC intervention. The national ANC guidelines recommend specific interventions towards the prioritized pregnancy related conditions in ANC visits at specific gestational ages (Additional file 1). We identified the five sentinel visits, corresponding to the specific time windows, as an opportunity to provide timely and actionable text messages based on the Model of Actionable Feedback. Actionable reminders of scheduled sentinel visits were combined with information about the susceptibility to and severity of the prioritized pregnancy related condition to be addressed, and the benefits of attending this sentinel visit. The text messages were co-designed iteratively with users. The Enhanced Active Choice, nudging theories and the Model of Actionable Feedback guided the framing, composition and timing of each text message.

#### Intervention structure: target condition, frequency, timing and intensity

We developed text messages to be delivered in concert with the five sentinel recommended visits (gestational week < 16, 18–22, 24–28, 32 and 36) [34] in addition to a welcome message sent at the time of enrollment. The content of the text message corresponding to each sentinel visit was, among other factors, determined by the prioritized pregnancy related condition to be addressed through a screening test at that visit (Additional file 1). We applied the following message types and frequencies per visit:

1. One week before a scheduled sentinel visit: Women with a scheduled sentinel visit within an appropriate gestational age window, described above, receive this message. The message content addresses the benefit of attending ANC and the susceptibility to and, severity of the specific high-risk condition to be screened for, at that visit, according to national guidelines.

- Three days before scheduled sentinel visit: Women with a scheduled sentinel visit and only with risk factors for the high-risk condition receives this message. The content addresses the increased susceptibility to, and the benefit of ANC attendance to be screened for timely. We use “scaled intensity” to intensify the intervention for those with the highest needs.
- 24-h before any scheduled visit: All women with a scheduled visit irrespective of the gestational age receive this simple reminder.
- 24-h after missed appointments for a sentinel visit: Only women with a missed appointment for a sentinel visit receive this reminder to re-schedule the appointment.

The package of text messages included continuity of care and postpartum care messages (Fig. 1). To illustrate, a woman above 34 years of age without a diagnosed high-risk condition, will receive 19 text messages if she starts ANC before gestational week 15, and is scheduled for and attends all five sentinel visits (Fig. 1). Missed appointment reminders would be additional.

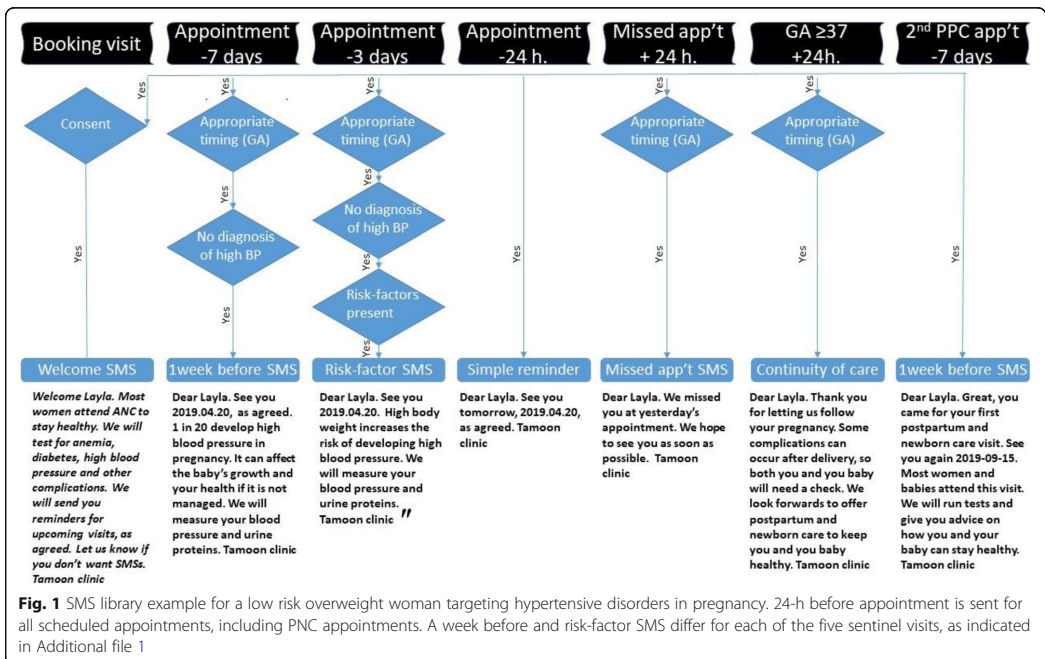
**Content and framing of the text messages**

The content in the text messages addressed key themes within the HBM constructs identified in Part I (Table 2).

To address gaps in perceived susceptibility, the text messages included information about a woman’s relative chance of getting each high-risk condition (Table 2). We followed message-framing concepts and expressed proportions in an “x in y” format. For women with risk factors, we stated the risk factor and the increased susceptibility to the corresponding high-risk condition.

We stated the consequences of each high-risk condition to both the woman and her baby to address the perceived severity, given that most women knew the general population consequences of the chronic disease, but not the specific adverse effects during gestation. We avoided serious and grave consequences, such as death or malformation, to prevent unwarranted worries in pregnancy. We presented the potential screening tests that could detect each high-risk condition to address the perceived benefits (Additional file 1).

The Model of Actionable Feedback [36] and concepts of social nudging and Enhanced Active Choice [11] were used to structure the text messages, and make them action oriented while addressing knowledge gaps, beliefs and perceptions (Fig. 2, Additional file 2). Concepts from the Model of Actionable Feedback, including timeliness, non-punitiveness, customizability, and individualization, were among the guiding principles at each stage of the TCC content development, evaluation, and implementation. See Additional file 2 for details on





**Table 2** Content creation for the identified constructs of the Health Belief Model and the application of selected concepts to structure and frame messages, an example

Targeted HBM constructs	Gaps and considerations	Source of information	Example phrases
Perceived Susceptibility	<ul style="list-style-type: none"> <li>• Specifying risks to pregnancy</li> <li>• Statistics</li> <li>• Scaled intensity: more messages to those with risk-factors</li> </ul>	<ul style="list-style-type: none"> <li>• Finding from part I</li> <li>• Nudging concept</li> <li>• MAF</li> <li>• Nudging concept</li> </ul>	1 in 20 develop high blood pressure in pregnancy.
Perceived Severity	<ul style="list-style-type: none"> <li>• Consequences to the baby and the women herself</li> <li>• No mentioning of severe/grave consequences</li> </ul>	<ul style="list-style-type: none"> <li>• Findings from part I</li> <li>• EAC and MAF</li> </ul>	This can affect the baby's nutrition and growth. If not measured and managed, it can affect your health too.
Perceived Benefits	<ul style="list-style-type: none"> <li>• Guideline based available screening services at the PHCs</li> <li>• Specifying beneficial test beforehand</li> <li>• Personalization</li> <li>• Timed to the benefit</li> </ul>	<ul style="list-style-type: none"> <li>• Mapping: ANC guideline</li> <li>• Findings from part I</li> <li>• EAC</li> <li>• MAF and EAC</li> </ul>	We will measure your blood pressure and proteins in your urine that can be a sign of high blood pressure.

HBM Health Belief Model, MAF Model of Actionable Feedback, EAC Enhanced Active Choice

the application of the Model of Actionable Feedback and Enhanced Active Choice in composing the text messages.

#### Evaluation of the draft text messages

Generally, the content of the text messages was understandable and acceptable after evaluation by health educators, healthcare providers, and pregnant women. Minor changes to a few messages were made based on comments from stakeholders. Contextualized translation into Arabic was preferred over literal translation. Regarding the timing, women preferred to receive the text messages after working hours when they are free to read the text messages.

#### Discussion

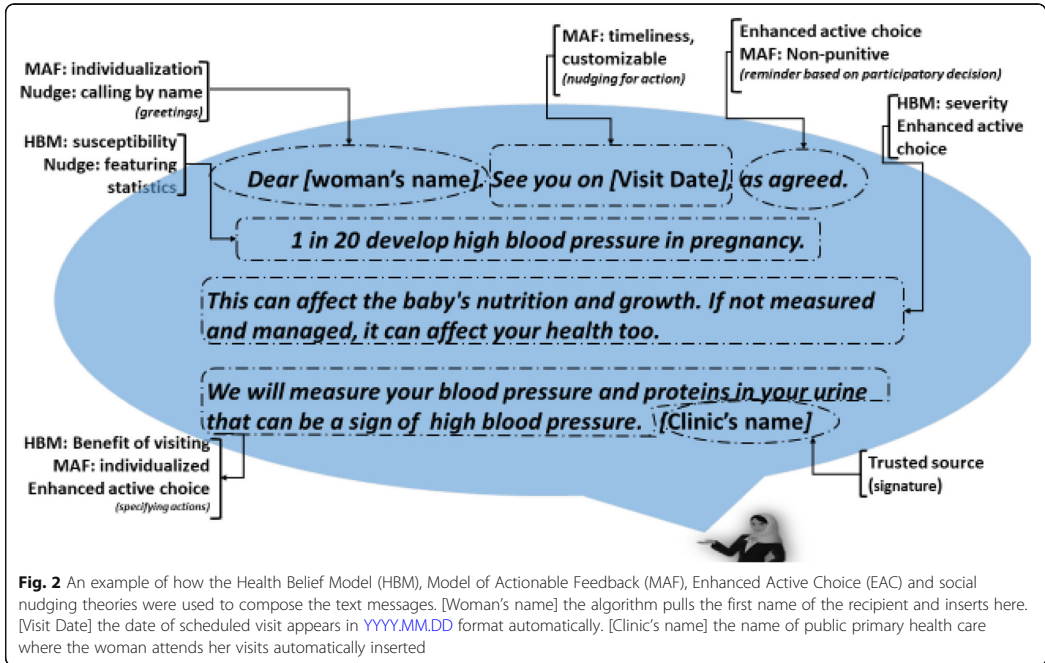
In co-design with users, we developed a TCC intervention tailored to individuals to be sent via SMS. We underpinned our intervention with behavior change theories and recommendations from systematic reviews [13, 14, 17, 18], and composed messages following recommended framing models [11, 37]. The message development process was iterative, and we involved end-users from the beginning. The MCH eRegistry [26, 27] presents a unique opportunity for an individually tailored and automated TCC intervention development.

Our qualitative findings revealed that perceived susceptibility, severity, and benefits are the main HBM constructs affecting whether or not pregnant women attend ANC for screening and management of high-risk conditions (anemia, HDP, GDM, and FGR) in a timely fashion. This is in line with systematic reviews of ANC service utilization, reporting that women's perceptions of risks (perceived susceptibility and severity) and the ANC

service's potential to identify and manage risks (benefits), affect timely attendance [38, 39]. Access to health care facilities was not reported as an important barrier to attend ANC in our sample. However, it has been reported that the presence of checkpoints restricted access to health facilities in Palestine [40], and one of the major factors in other settings [38, 39].

Analyses guided by the HBM assisted us in identifying information targets to be addressed in the TCC intervention. Our TCC intervention directly targets perceived susceptibility, severity, and benefits, and indirectly targets perceived barriers, cues-to-action and self-efficacy. Through SMS, we aim to improve the awareness of personal susceptibility to, and severity of high-risk conditions, and the benefit of timely attendance to ANC for screening and management. We believe that these text messages from the eRegistry can serve as cues-to-action and affect self-efficacy by empowering women.

Among behavior change theories used for similar interventions [22], we selected the HBM as theoretical framework based on its common use in similar resource-limited settings [24]; the nature of our behavior change goal; the scope of our intervention; and our target audience [22]. The HBM served as a lens to understand the context and to identify the major gaps to be addressed. We also used social nudging, a concept derived from behavioral science, and the Enhanced Active Choice model for framing the text messages [11, 37]. We wanted women to make a conscious decision regarding ANC attendance. Information about the gains and losses of timely attendance was used to nudge women to attend timely scheduled visits [11]. The Model of Actionable Feedback was used to help transition women from intention to actual performance of the expected behavior [36]. It guided, for example, the insertion of the scheduled date right after the personalized



greetings, since the action or targeted behavior change goal, is to attend the facility in a timely manner. All the different components in a text messages were created based on the concepts and theory we used (Fig. 2).

Limited information exists regarding the best processes for designing the content of a TCC intervention. It is recommended to publish the development process, as well as the effectiveness of digital health interventions [41], to increase scientific discussions and improve the quality of digital health interventions including TCC. We have considered learning points from previous development processes despite the differences in technologies used [23, 41, 42]. Communicating back to the client from the registries is one of the functions which can be utilized better [26]. We demonstrate how longitudinally collected digital data can be harvested to deliver more personalized health education and promotion messages in the growing field of mobile technology for health, in an integrated way with the health systems infrastructure.

### Strengths and limitations

Our text messages are based on modifiable factors among the recipients by our digital intervention, such as gaps in knowledge and awareness. We have refrained from sending condition-specific messages to woman

diagnosed with the same high-risk condition, i.e. a woman with hypertensive disease in pregnancy will not receive messages about her susceptibility to develop hypertension in pregnancy. This includes avoiding sending messages that included recommendations for action to women with high-risk conditions managed in high-risk clinics, where management may be highly individualized and not determined solely by guideline-driven algorithms.

We addressed confidentiality issues concerning the TCC content throughout the design process. Women might share their phones with other family members, and someone other than herself might therefore see the text messages. We have therefore de-sensitized the TCC content by not indicating that the receiver has a specific risk factor. For example, for a woman with high BMI, we phrased the message as "...High weight increases the risk of diabetes. We will measure your..." without directly stating that she is obese.

The main project, aimed at assessing the effectiveness of automated TCC in improving ANC and PNC attendance, pioneers the use of the DHIS2 Tracker software to send tailored text messages on specific dates and times at national scale. This involves scheduling of messages based on data, a functionality that did not exist in the software at the outset of the project, and therefore



required longer development and enhancement time than first anticipated. Future projects should take the readiness of the technology and the time needed for software development into account when planning the overall timeline. It is a challenge to express necessary and personalized information in a clear and understandable way within the limitations of SMS messages (size of screen, acceptability, and cost increasing by “one SMS” for each 160 characters in Latin letters [43] and 70 characters in Arabic). The fact that several of our messages have over 140 Arabic characters (i.e. cost as for three messages), may affect the sustainability if used in a national system. We have not utilized the full potential of the current technology due to development needs, but further tailoring to various static and dynamic personal characteristics should be possible with the MCH eRegistry. Additionally, two-way communication has been shown to be more effective than a one-way messaging [44]; this feature is not yet routinely available in the software.

There is no one-size-fits-all approach for deciding the ideal ‘dosage’ of text messages to be delivered to an individual to change behavior. The threshold is likely to vary according to the richness of the content, intervention type, and target group [45, 46]. We have chosen our dosage after discussing with the local experts, but have not put the final quantity under formal evaluation. We selected the timing by considering the balance between the time needed to prepare for a visit (one week ahead as a cue to action and enable reflection and planning of practicalities) and not forgetting the date of that visit (24 h before as a simple reminder). However, most untailored TCC interventions in the field of maternal and child health, has reported sending more text messages per week than we propose [13, 15, 47].

## Conclusions

The stepwise iterative process revealed elements critical to an effective TCC intervention, which otherwise could have been easily missed. The theory served as a lens through which we assessed gaps in anticipated behavior, a focus in composing the text messages, and a guide in overall designing and implementation of the TCC intervention. Behavioral science concepts made us value each word and its relative position in the text. The co-design with users improved the relevance, understandability, and acceptability of the text message content. The MCH eRegistry can serve as a unique platform through which to tailor communication. Reporting on the development process of our TCC intervention will improve transparency and contribute to scientific dialogue to improve its effectiveness.

## Supplementary information

**Supplementary information** accompanies this paper at <https://doi.org/10.1186/s12911-019-1002-x>.

**Additional file 1.** The timing and services provided according to the Palestinian national antenatal guidelines and the corresponding high-risk conditions addressed in the tailored Targeted Client Communication (TCC) intervention

**Additional file 2.** Theories and concepts used in the design of the Targeted Client Communication (TCC) intervention

**Additional file 3.** Quotations from the pregnant women and healthcare providers from the in-depth interviews, Palestine

## Abbreviations

ANC: Antenatal Care; FGR: Fetal Growth Restriction; GDM: Gestational Diabetes Mellitus; HBM: Health Belief Model; HDP: Hypertensive Disorders of Pregnancy; MCH: Maternal and Child Health; mHealth: Mobile Health; PNC: Postnatal Care; SMS: Short Message Service; TCC: Targeted Client Communication; WHO: World Health Organization

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## Availability of data and material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

## Authors' contributions

Conceptualization, J.F.F.; Methodology, J.F.F., K.M., and B.B.; Investigation, B.B., B.G., I.A.W., K.A.K., M.B., T.H. T.A.; Software, B.O., B.B., M.F., M.B., Y.R.; Writing-original draft, B.B., K.M., J.F.F.; Writing- Review and Editing, all; Funding Acquisition, J.F.F. All authors have read and approved the final version of the manuscript.

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## Ethics approval and consent to participate

We secured oral informed consent from the participants prior to the in-depth interviews. In the study setting, women prefer an oral consent and are hesitant to sign any document, and their willingness to participate in the study is confirmed through the interviews. The recruitment and consent procedure was stated in the research protocol, for which we obtained an ethical approval from the Palestinian Health Research Council (04/06/2018, ref: PHRC/HC/401/18), and an exemption from ethical review from the Regional Committee for Health Research Ethics (REK) - Section South East B, from Norway (05/06/2018, ref: REK sør-øst 2018/1148) as health systems research falls outside of the mandate for ethical review in Norway.

**Consent for publication**

Not applicable.

**Competing interests**

The authors declare that they have no competing interests.

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## Additional file to Paper II

### Additional file 3: Quotations from the pregnant women and healthcare providers, from an in-depth interview, Palestine.

#### Reference in the text

#### Quotations

- a “My hemoglobin is now 9.1 g/dl, and my ferritin level is low. I am currently taking iron tablets, but, I can’t feel that I am benefiting from them”  
- *A multigravida from the West Bank*
- b “I will follow my doctor’s opinion because she has more experience than others” *A primigravida woman*
- c “Of course, they [healthcare providers] provide all the information and advices I need during pregnancy, including how to deal with any problem when it happens. In addition, they gave me the appropriate medications.”  
- *A multigravida in a low-risk clinic*
- d “We counsel them, but when I have 20 pregnant women in a day ... I try to explain quickly, but I feel that there is not enough time per client for counseling”  
- *A doctor*
- e “There is no enough time because of the overload of pregnant women in the clinic, in general, but when I need important information, I ask the doctor in the clinic and I get what I need”  
- *A multigravida in a high-risk clinic*
- f “...Previously, they used to come when they were two or three months pregnant. As a doctor, [I know that] they miss a very important period in their pregnancy. Now women come early and they are aware of the importance of early booking”  
- *MCH doctor*
- g “Yes, they feel that it is important for them, they write the date on their mobile so that they cannot forget it, and they [pregnant women] complain of the new guidelines since there is a distance between each visit for normal pregnancies.”  
- *A midwife*
- h “Yes, thank God, but the timing between the visits are long. It is long to wait for one month to see your health professional”  
- *A multigravida woman*

# PAPER III

**The effect of a digital targeted client communication intervention on pregnant women’s worries and satisfaction with antenatal care in Palestine – a cluster randomized controlled trial**

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## Abstract

### **Background:**

The eRegCom cluster randomized controlled trial assesses the effectiveness of targeted client communication (TCC) via short message service (SMS) to pregnant women, from a digital maternal and child health registry (eRegistry) in Palestine, on improving attendance and quality of care. In this paper, we assess whether this TCC intervention could also have unintended consequences on pregnant women's worries, and their satisfaction with antenatal care (ANC).

### **Methods:**

We interviewed a sub-sample of Arabic-speaking women attending ANC at public primary healthcare clinics, randomized to either the TCC intervention or no TCC (control) in the eRegCom trial, who were in 38 weeks of gestation and had a phone number registered in the eRegistry. Trained female data collectors interviewed women by phone from 67 intervention and 64 control clusters, after securing informed oral consent. The Arabic interview guide, pilot-tested prior to the data collection, included close-ended questions to capture the woman's socio-demographic status, agreement questions about their satisfaction with ANC services, and the 13-item Cambridge Worry Scale (CWS). We employed a non-inferiority study design and an intention-to-treat analysis approach.

### **Results:**

A total of 454 women, 239 from the TCC intervention and 215 from the control arm participated in this sub-study. The mean and standard deviation of the CWS were 1.8 (1.9) for the intervention and 2.0 (1.9) for the control arm. The difference in mean between the intervention and control arms was -0.16 (95% CI: -0.31 to -0.01) after adjusting for clustering, which was below the predefined non-inferiority margin of 0.3. Women in both groups were equally satisfied with the ANC services they received.

### **Conclusion:**

The TCC intervention via SMS did not increase pregnancy-related worries among recipients. There was no difference in women's satisfaction with the ANC services between intervention and control arms.

## Introduction

Targeted client communication (TCC) using Short Message Service (SMS), is among the most common digital health interventions [1]. The most effective digital TCC interventions are co-designed with users, underpinned by behavior change theories, tested, and iteratively improved [1-3]. Pure appointment reminders have shown moderate effectiveness in improving attendance to maternity services [1, 4, 5]. However, digital health communication interventions tailored to the individual recipient are more likely to lead to behavior change compared with generic communication [6, 7]. Health education and promotion messages via SMS can empower women to make informed health choices, which may contribute to a positive pregnancy experience [1, 2, 4, 8, 9]. While tailoring based on individual-level risk factors has advantages, it may also result in potential unintended consequences, such as, the triggering of worries among the message recipients. Documenting and preventing potential unintended consequences have generally been given little attention in the field of health education and promotion interventions [10].

TCC intervention studies often report the effectiveness as a main outcome, and seldom include a robust study design to assess its potential negative effects, such as adverse psychological outcomes and clients' satisfaction [1, 11]. In their guidelines for digital interventions for health system strengthening, the World Health Organization (WHO) highlights the importance of assessing any unintended consequences of, and client's satisfaction with digital health interventions, in addition to the effectiveness among others [12, 13].

Pregnancy is a period when women are more vulnerable to worries and anxiety, which are often highest in early and late stages of pregnancy [14, 15]. The variabilities in the definition and the psychometric measurement tools used across studies, hamper the understanding of worries and anxiety in pregnancy [15-17]. Nevertheless, the psycho-social environment, and previous and current obstetric and medical status were among the risk-factors causing worries in pregnancy [14]. Generic antenatal health education and promotion utilizing digital health technology can reduce pregnancy-related concerns and worries [18-20], but there is limited information on the potential adverse effects [21].

In a client-centered maternity care model, women's satisfaction is an integral part of the quality of services [22, 23]. Well-informed pregnant women are more likely to make informed health choices, and they are often satisfied with the antenatal care (ANC) services they receive. A well-designed TCC intervention using SMS, in addition to the routine antenatal education program, may improve women's satisfaction [20].

We have previously reported low effective coverage of essential interventions of ANC in Palestine, mainly attributed to untimely attendance in public primary healthcare center (PHC)[24]. An electronic registry that includes systematic, uniform, and longitudinal client information entered at the point-of-care, such as the Maternal and Child Health (MCH) eRegistry in Palestine, provides a unique opportunity for tailored TCC via SMS to each woman to improve attendance [25-27]. We have developed a theory-based, co-designed, and user tested TCC intervention to pregnant women automated from the MCH eRegistry [25]. The aim of



the TCC intervention was to increase the awareness of individual-level susceptibility to, and severity of, prioritized pregnancy-related high-risk conditions, specifically, anemia, hypertension, diabetes, and growth restriction, and thus improve timely attendances for screening and management of the high-risk conditions. This digital health intervention is under assessment for its effectiveness in a four-armed cluster randomized trial (eRegCom: Trial registration number: ISRCTN10520687).

Efforts to minimize potential worries were made during the design of the TCC intervention; however, we cannot exclude the potential increase in pregnancy-related worries. This might be particularly relevant for pregnant women receiving text messages with tailored information about their risk factors, such as high body mass index, high or low age, and a history of pregnancy complications; and the link to one of the prioritized pregnancy-related high risk conditions [25].

The objective of this sub-study of the eRegCom trial was to assess whether this TCC intervention via SMS, automated from the Palestinian MCH eRegistry, could affect pregnant women's worries and satisfaction with ANC services.

## **Methods**

### **Trial design and participants**

This was a non-inferiority two-armed parallel cluster randomized trial, sub-sampled from the four-armed eRegCom trial (Trial registration number: ISRCTN10520687), described in detail elsewhere [28]. In short, the four arms include one arm with Quality Improvement Dashboards (QID) for healthcare providers; one with TCC via SMS to women; one with both QID and TCC via SMS; and one control arm. The 138 clusters (one closed after randomization) in the eRegCom trial are public PHC offering both antenatal and postnatal care services, active users of the MCH eRegistry, and served 45 to 3000 new pregnancies in 2016.

For this sub-study, the TCC intervention arm (69 clusters) includes both arms with TCC intervention in the eRegCom trial, and the control arm (68 clusters) includes both arms without it. Additional inclusion criteria for this sub-study were that the women had registered a phone number in the eRegistry, were in the 38<sup>th</sup> week of gestation, and spoke Arabic.

### **Intervention**

The development process and content of the TCC intervention are described elsewhere [25]. In short, the TCC intervention in the eRegCom trial includes training of healthcare providers on how to enroll women in the TCC program, which sends a series of individualized and automated text messages. Routine clinical data captured by the healthcare provider at the point-of-care are applied in algorithms that identify the correct text message to each individual woman. The woman's name, the date of her next appointment and the name of the PHC are automatically inserted into one of the 56 unique predesigned text message templates stored in the library. The text messages that include information about one or two of the prioritized pregnancy-related high-risk conditions, are sent at the time these conditions are screened for, namely at the 16, 18-22, 24-28, 32- or 36-weeks' gestation routine ANC visits. Women receive a welcome text message to the mobile

number registered during the first ANC visit (booking) or any visit where they assent to take part in the text message program; one week, three days, and 24 hours before a scheduled appointment; 24 hours after a missed appointment; and 24 hours prior to an appropriate time window without any timely scheduled routine visit in the future.

### **Data collection**

We used the 13-item Cambridge Worry Scale (CWS) [29] which utilizes a six-point Likert-type scale ranging from 0 (not a worry) to 5 (extremely worried). In addition to the CWS, the interview guide included close-ended questions to capture the women's socio-demographic status, and agreement scale questions (0 = strongly disagree to 5 = strongly agree) about satisfaction with ANC services. Two researchers, fluent in English and Arabic, translated the English version to Arabic, which was back translated by a third individual prior to a pilot test in January 2019.

Four trained and experienced female data collectors conducted the phone interviews while being blinded to the allocation and primary outcome, fluent in the Arabic language and familiar with the local context, including ANC terminologies. The data collectors received a password-protected document with a list of eligible women and their registered phone numbers on a weekly basis. The lists were deleted after one week. A data manager oversaw the preparation and distribution of lists, including the safe storage of the allocation key. The data collectors entered the response in a pre-designed Google Form while interviewing, and the data quality and completeness were monitored daily. The data collectors tried to reach each woman on a maximum of three different occasions.

### **Outcomes**

The primary outcome of this sub-study was the difference in mean total CWS score between the intervention and control arms with the one-sided confidence interval (CI) considering the non-inferiority margin. The mean and standard deviation (SD) of the total 13-items CWS score were calculated for each study arm. A higher mean score suggests higher levels of worries. We categorized the 13-items into the four predefined components, namely socio-medical, socio-economic, health, and relationship [29-35].

We also measured pregnant women's satisfaction with ANC services, computed as the mean difference of each question on an agreement scale.

### **Sample size**

The power of the study was estimated using PASS software for sample size calculation for a non-inferiority cluster randomized trial design [36]. We hypothesized that there was no statistically significantly increased difference in the mean total CWS score between women in the intervention and control arms with a given non-inferiority margin. We were more than 90% powered to detect a non-inferiority margin of a one-point increase of every third questions on the CWS (corresponding to an increase of 0.3 in the CWS mean score), with standard deviation (SD) of 1.1, assumed intra-cluster correlation coefficient (ICC) of 0.01, a one-sided

significance level of 2.5% for 137 clusters with equal cluster size of four. The SD and a pooled mean score of 1.5 [95% CI: 1.09-1.92] were computed from a meta-analysis of relevant literature and a pilot study (n=41) conducted in the same study site in January 2019.

### **Randomization**

An independent statistician performed the randomization for the eRegCom trial [28], where PHCs were randomized to the TCC; QID; TCC and QID; or control arm with equal allocation. The randomization was stratified by the national implementation phase of the eRegistry, and constrained on laboratory availability, ultrasound availability and the size of the PHCs.

### **Statistical Methods**

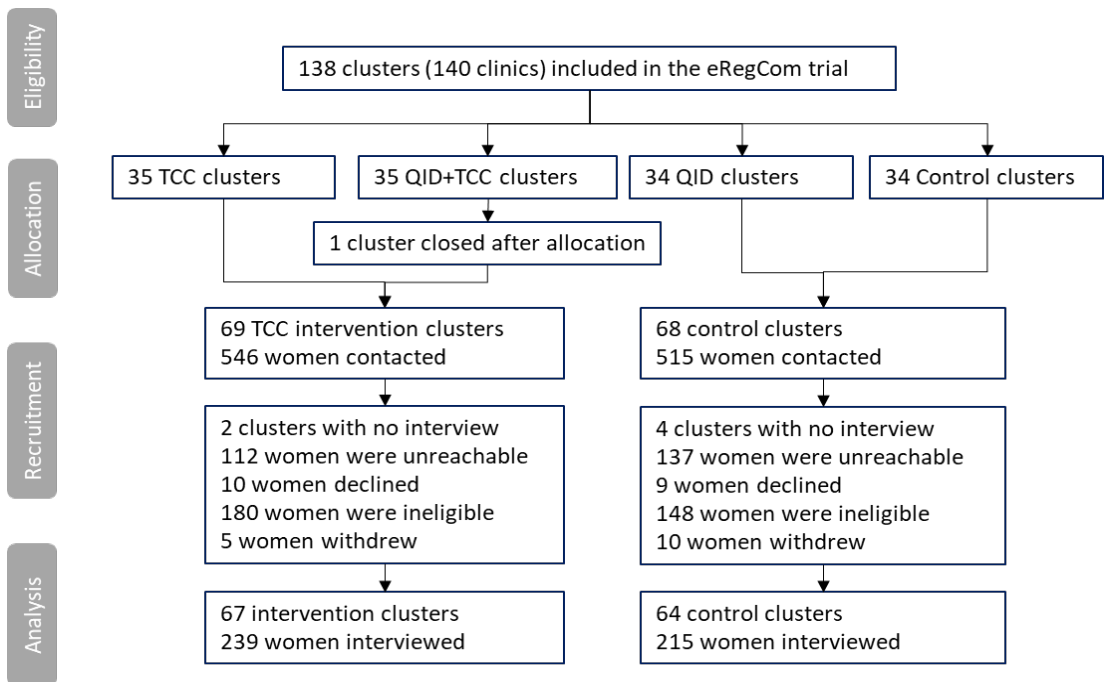
We applied an intention-to-treat analysis and used R software with the lme4 package for the Mixed Effect Linear Regression Model to consider the cluster effect for the computation of the difference in the mean total CWS score between the intervention and control arms. We used an unstructured covariance model to impose the fewest assumptions. In exploratory analyses, we found that this resulted in the best fitting model. We performed an exploratory analysis to assess any imbalances across the groups in potential confounders for the CWS like women's educational status, previous adverse pregnancy outcomes, age, and parity. We also used a previously established four factor structure for the CWS to analyze the unadjusted difference in mean scores. The ICC for the difference in mean CWS score and Cronbach's Alpha to see the internal consistency of the measurement were calculated. A statistician blinded for the allocation performed the final analysis.

### **Ethics approval**

The data collectors read out the information sheet and secured oral informed consent from all participants before conducting the phone interview. We obtained ethical clearance from the Helsinki Committee for Ethical Approval in Palestine (ref. no.: PHRC/HC/670/19) and an exemption from ethical review from the Regional Committee for Health Research Ethics (REK) - Section South East B, from Norway (ref.: REK sør-øst 139204) as health systems research falls outside of the mandate for ethical review in Norway.

### **Results**

We interviewed 239 women from 67 TCC intervention clusters, and 215 women from 64 control clusters in February and March 2020 (Fig 1). This was in total 83% of the calculated sample size. The data collection did not continue to the full sample size (estimated four women per cluster) as the TCC intervention was discontinued in March 2020 due to the COVID-19 situation in Palestine, and women in the intervention arm would no longer have received the full intervention after this point.



**Fig 1. Participant flow chart**

There were no statistically significant imbalances in background characteristics between the intervention and control arms. The majority of women were between 25-29 years of age (Table 1). About half of the women had a college or university level education, and only one woman reported no formal education. In control arm PHCs, 35% were primiparous and 74% of the women had their first ANC visit in the first trimester. About 80% attended regular ANC and 90% ultrasound services in private/Non-Governmental Organization/United Nations clinics, in addition to the public PHC they were registered to. More than 85% in each arm had their own mobile phone.

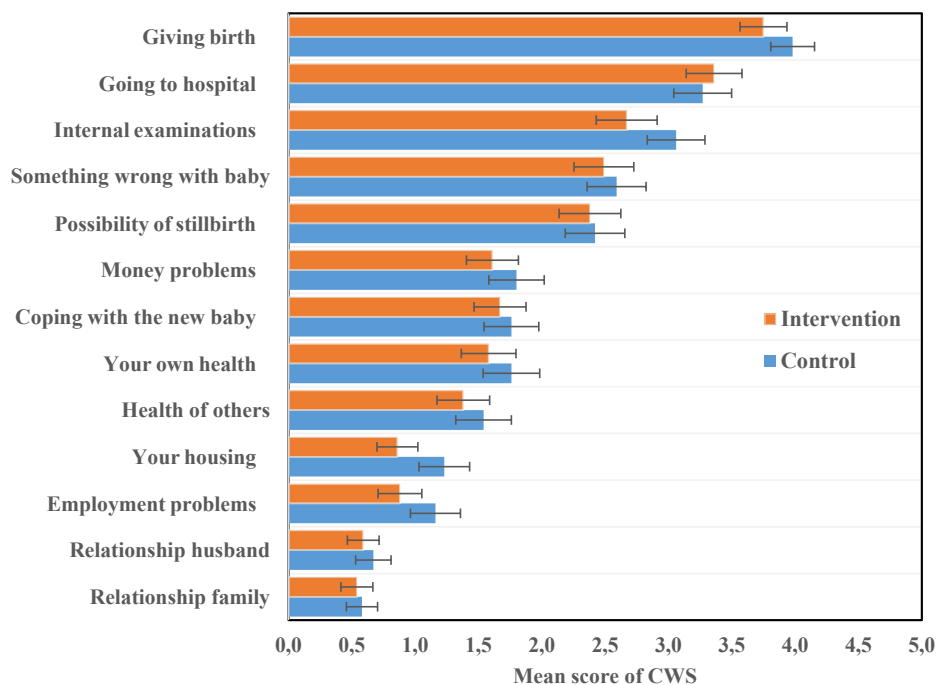
**Table 1. Background characteristics of the study participants in intervention and control arms**

Background characteristics	Intervention arm (clusters = 67, n = 239)	Control arm (clusters = 64, n = 215)
	n (%)	n (%)
<b>Women's age</b>		
<20	21 (9)	16 (8)
20-24	57 (24)	59 (28)
25-29	84 (35)	74 (35)
30-34	49 (21)	56 (26)
35-39	22 (9)	6 (3)
≥ 40	5 (2)	3 (1)
<b>Educational status</b>		
Primary	3 (1)	1 (1)
Secondary	114 (48)	113 (53)
College or University	117 (49)	96 (45)
After college or University	5 (2)	4 (2)
No formal education	0 (0)	1 (1)
<b>Work status</b>		
Work outside the home	26 (11)	33 (16)
No work outside the home	211 (89)	180 (85)
<b>Parity</b>		
Primipara	69 (29)	74 (35)
Multipara	169 (71)	140 (65)
<b>Gestational age at booking</b>		
< 4 months	160 (70)	160 (74)
4 - 6 months	67 (28)	46 (21)
> 6 months	12 (5)	8 (4)
<b>Referral to high-risk clinics</b>		
Yes	35 (15)	31 (14)
No	204 (85)	184 (86)
<b>Attended ANC in another clinic</b>		
Yes	203 (85)	170 (79)
No	36 (15)	45 (21)
<b>Attended for ultrasound in another clinic</b>		
Yes	211 (90)	189 (88)
No	23 (10)	26 (12)

n: number of women

### Worries in pregnancy

Generally, women in the intervention clusters scored lower on the CWS than their counterparts in the control clusters, but the difference was not statistically significant. Items directly related to the pregnancy (giving birth, going to hospital, and internal examinations), along with items related to the baby had the highest scores of worries in both arms. Fig 2 presents a crude mean value per intervention and control arms without adjusting for clustering effect.



**Fig 2. Ranking of women’s mean worry score with 95% confidence interval for intervention and control arms**

There was no item in the CWS that none of the women in our sample were not worried about, although the most frequent response was “no worry at all”. The unadjusted total mean CWS score and SD were 1.8(1.9), and 2.0(1.9) in intervention and control arms respectively (Table 2). The previously established socio-medical and health factor structures comprised the highest worries in both arms. The reliability of the CWS was satisfactory (Cronbach’s Alpha = 0.74).

**Table 2. Unadjusted summaries of the Cambridge Worry Scale for the total sample, and across study arms**

Cambridge Worry Scale items	Freq (n)	Level of worry (%) <sup>e</sup>						Intervention (clusters = 67 n = 239)	Control (clusters = 64 n = 215)	Difference in Mean score (95% CI)
		0	1	2	3	4	5	Mean (SD)	Mean (SD)	
<i>Your housing</i>	449	53	26	1	10	6	5	0.9 (1.3)	1.2 (1.6)	-0.4 (-0.7, -0.1)
<i>Money problems</i>	451	38	21	2	19	12	8	1.6 (1.7)	1.8 (1.8)	-0.2 (-0.5, 0.1)
<i>Your relationship with your husband/partner</i>	448	62	27	1	6	2	1	0.6 (1.0)	0.7 (1.1)	-0.1 (-0.3, 0.1)
<i>Your relationship with your family and friends</i>	449	64	28	0	4	2	2	0.5 (1.1)	0.6 (1.0)	-0.0 (-0.2, 0.2)
<i>Your own health</i>	446	41	19	2	15	15	8	1.6 (1.8)	1.8 (1.8)	-0.2 (-0.5, 0.2)
<i>The health of someone close to you</i>	449	45	25	1	8	14	7	1.4 (1.7)	1.5 (1.8)	-0.2 (-0.5, 0.2)
<i>Employment problems</i>	451	55	25	1	7	7	5	0.9 (1.4)	1.2 (1.6)	-0.3 (-0.6, 0.0)
<i>The possibility of something being wrong with the baby</i>	447	26	14	2	14	27	17	2.5 (2.0)	2.6 (1.9)	-0.1 (-0.5, 0.3)
<i>The possibility of stillbirth</i>	447	28	16	2	13	21	19	2.4 (2.0)	2.4 (1.9)	0.0 (-0.4, 0.3)
<i>Going to hospital</i>	448	16	9	1	10	30	34	3.4 (1.8)	3.3 (1.8)	0.1 (-0.3, 0.4)
<i>Internal examinations</i>	451	21	13	2	13	24	26	2.7 (2.0)	3.1 (1.8)	-0.4 (-0.7, 0.0)
<i>Giving birth</i>	449	7	4	3	12	29	45	3.8 (1.5)	4.0 (1.4)	-0.2 (-0.5, 0.1)
<i>Coping with the new baby</i>	451	36	22	6	16	13	8	1.7 (1.7)	1.8 (1.7)	-0.1 (-0.4, 0.2)
<i>Total CWS (13- items)</i>								<b>1.8 (1.9)</b>	<b>2.0 (1.9)</b>	<b>-0.2 (-0.3, -0.1)</b>
<i>Socio-medical<sup>a</sup></i>								2.9 (1.9)	3.0 (1.9)	-0.2 (-0.3, 0.0)
<i>Socio-economic<sup>b</sup></i>								1.1(1.5)	1.4 (1.7)	-0.3 (-0.5, -0.1)
<i>Health<sup>c</sup></i>								2.0 (1.9)	2.1(1.9)	-0.1 (-0.3, 0.1)
<i>Relationship<sup>d</sup></i>								0.6 (1.0)	0.6 (1.1)	-0.1 (-0.2, 0.1)

<sup>a</sup>(Worry of giving birth, internal examinations, going to hospital, coping with the new baby), <sup>b</sup>(money problems, housing problems, employment problems), <sup>c</sup>(possibility of stillbirth, something wrong with the baby, own health, others' health), <sup>d</sup>(relationship with the family, relationship with partner); ; Level of worry (0= not a worry, 5= extremely worried) n: number of women

After adjusting for the clustering effect, the difference in mean score was -0.16 (95%CI: -0.31 to -0.01), where the upper limit of the confidence interval was -0.01 (taking 2.5% confidence level on each end), which was lower than the predefined non-inferiority margin of 0.3 for the hypothesis testing. The ICC for the difference in mean CWS score was 0.01.

### Satisfaction with ANC services

In both groups, three of four women moderately or strongly agreed to the statement “I am satisfied with the antenatal care services I have received”, and an equal majority responded that they would come back to the same PHC, if become pregnant again, and would recommend it to others. Most of the pregnant women were moderately or strongly satisfied with the information and communication from their care providers, and there was no difference between the groups (Table 3).

**Table 3. Women’s satisfaction with ANC services among TCC intervention and control arms in Palestine**

	Trial arm	Total	Level of agreement (%) <sup>a</sup>					Mean (SD)	Mean Difference (95% CI) <sup>b</sup>	
			0	1	2	3	4			5
<i>I am satisfied with the antenatal care service I have received</i>	<b>Control</b>	214	3	2	3	18	33	41	4.0 (1.2)	0.1(-0.1, 0.3)
	<b>Intervention</b>	237	3	0	3	16	33	46	4.1 (1.1)	
<i>I would recommend the services to a friend</i>	<b>Control</b>	214	3	5	1	6	42	44	4.1 (1.2)	0.1 (-0.1, 0.3)
	<b>Intervention</b>	235	2	3	0	7	43	45	4.2 (1.0)	
<i>I would come back if I become pregnant again</i>	<b>Control</b>	212	3	3	1	5	35	53	4.2 (1.2)	0.1 (-0.1, 0.3)
	<b>Intervention</b>	237	2	3	1	5	38	52	4.3 (1.0)	
<i>I am always confident of when my next antenatal care visit is</i>	<b>Control</b>	214	3	1	1	6	27	64	4.4 (1.0)	0.0 (-0.2, 0.1)
	<b>Intervention</b>	237	2	3	0	3	31	60	4.4 (1.0)	
<i>The health staff take my questions and concerns seriously</i>	<b>Control</b>	210	2	2	1	9	37	49	4.2 (1.0)	0.1 (-0.1, 0.3)
	<b>Intervention</b>	236	2	8	0	6	34	56	4.4 (1.0)	
<i>I am well informed about the purpose of the tests the health staff run</i>	<b>Control</b>	213	3	8	5	6	38	40	3.9 (1.4)	0.1 (-0.1, 0.4)
	<b>Intervention</b>	235	3	8	3	4	36	46	4.0 (1.3)	
<i>I am well informed of when (gestational age) to do the tests</i>	<b>Control</b>	213	5	6	4	5	39	42	3.9 (1.4)	0.1 (-0.2, 0.3)
	<b>Intervention</b>	235	3	8	3	5	40	43	4.0 (1.3)	

SD: Standard Deviation; CI: Confidence Interval; <sup>a</sup> Level of agreement (0= strongly disagree, 1= moderately disagree, 2= slightly disagree, 3= slightly agree, 4= moderately agree, 5= strongly agree); <sup>b</sup>unadjusted for the cluster effect



## Discussion

We have demonstrated that pregnant women receiving digital tailored text messages with health content during pregnancy, were not more worried compared to women in the control clusters, measured by the CWS. Even though not statistically significant, both the total and single item mean CWS scores were consistently lower for women in the TCC intervention arm compared to their counterparts in the control arm. Women in both arms were equally and generally satisfied with the ANC services they received from their public PHCs.

Most effectiveness trials of digital health interventions fail to report potential unintended consequences of the interventions [1, 4, 5]. This research gap is highlighted by WHO in its first digital health guideline [13]. The majority of health messaging interventions using mobile technologies, have up until now, included generic health promotion content [4]. Such content is generally acceptable and have most likely been considered as safe, which might explain the low attention towards unintended consequences of public health intervention in general [37], and health promotion in particular [10]. Precautions in composing individually tailored messages, which are increasing, are warranted to avoid harmful consequences. Furthermore, the communication of individualized risk factors to pregnant women needs special attention [38]. Co-designing theory-based interventions in an iterative process with users is recommended to secure the safety and effectiveness of messages [1-5]. We have followed these recommendations, and findings from a systematic review recommending identifying the sender, using a positively framed tone, and including content with solutions in a structured and focused manner [39].

Maternal age, previous adverse pregnancy outcomes, education, and employment status are known predictors of worries in pregnancy [14]. These can also affect the acceptance and understanding of the TCC intervention, hence be potential confounders to the main outcome of the study. However, we did not identify any statistically significant imbalances of these variables between intervention and control arms, and they were therefore not included in the final model. We took the cluster effect into account, but it did not markedly change the point estimate or the confidence interval of the estimate.

The mean CWS score for pregnant women in Palestine did not differ from other studies reported using the CWS [29-34]. The items, such as, giving birth, hospital visits, internal examinations, something might be wrong with the baby, and the possibility of stillbirth, were in line with other studies, recoded with the highest mean scores [31]. Similarly, pregnant women in both the intervention and control arms were more worried about the socio-medical and health components compared to the socio-economic and relationship components of the CWS. We did not aim to validate the CWS (has not been validated in Arabic language); however, the good internal consistency score (Cronbach's alpha = 0.74) might indicate that the CWS can be used for pregnant women in Palestine. Since this study is a non-inferiority trial, it does not intend to measure any benefit of the TCC intervention in terms of reducing pregnancy-related worries.

Due to the closure of PHCs and disruption of the TCC intervention in response to the COVID-19 pandemic, we ended the data collection period earlier than planned to ensure that we only included women who had been eligible for the full intervention. This resulted in the loss of six clusters and we only reached 83% of the planned sample size. However, we have no reason to believe that this has affected the main findings, nor that the emerging epidemic of COVID-19 in Palestine unequally affected the worries among women across arms. Our ethical clearance did not cover merging the sub-sample data with the data in the eRegistry. We have therefore no information about the number of timely scheduled ANC visits, the number of text messages, nor which text messages each woman in the sub-sample have received. Two in three women attended their first ANC visit in their first trimester and would be eligible to receive the full sequence of messages, a service that started in June 2019.

We interviewed women towards the end of their pregnancy and prior to delivery to ensure that they had been eligible for the full intervention and avoid any recall bias. Women who delivered or had an abortion prior to 38 weeks of gestation were not included. Our trained data collectors were not affiliated with the primary healthcare services to reduce the social desirability bias. The data collectors were blinded for the allocation to reduce the potential selection bias. The main strength of this sub-study was the study methodology including the design, the use of the validated CWS, and that we conducted a pilot test of the entire study tool.

## **Conclusion**

Our TCC intervention via SMS to improve attendance to ANC did not have any unintended consequences in increasing pregnancy-related worries among recipients. There was no difference in women's satisfaction with the ANC services between intervention and control arms.

## **List of abbreviations**

ANC: Antenatal Care; CI: Confidence Intervals; CWS: Cambridge Worry Scale; ICC: Intra-cluster Correlation Coefficient; MCH: Maternal and Child Health; PHC: Primary Healthcare Center; PNIPH: Palestinian National Institute of Public Health; QID: Quality Improvement Dashboard; SD: Standard deviation; SMS: Short Message Service; TCC: Targeted Client Communication

## **Availability of data and materials**

Anonymized data will be available from the authors upon request, given appropriate approvals from the responsible authorities.

## **Competing interests**

The authors declare that they do not have any competing interests.

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#### **Authors' contributions**

Conceptualization, J.F.F.; Design and Methodology, B.B., J.F.F., K.M. B.G., T.H., Z.N.; and Investigation, B.B., B.G.,I.A., I.A.W., M.I., S.K.,S.I, T.H.; Analysis, B.B., F.A., M.I., S.K.; Writing- original draft, B.B.; Writing- Review and Editing, all ; Funding Acquisition, J.F.F.

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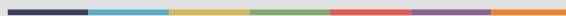
## Errata

Page 37 “Clarification as requested by the committee: Addition to the first paragraph, page 37):

At the implementation of the General Data Protection Regulation (GDPR) in May 2018, the eRegistries project’s data collection and management was reviewed and discussed with the Data Protection Ombudsman of the NIPH to ensure compliance with the GDPR and Norwegian research legislation. Since we have no identifiable personal data, the conclusion was that it falls outside the scope of the GDPR. The eRegistries project is registered in the internal database at NIPH used for monitoring, audits and Data Protection Impact Assessments.



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