UNIVERSITÀ DEGLI STUDI DI TRIESTE

XXXV CICLO DEL DOTTORATO DI RICERCA IN

SCIENZE DELLA RIPRODUZIONE E DELLO SVILUPPO

A CO-DESIGN APPROACH FOR THE DEVELOPMENT OF A MHEALTH SOLUTION TO SUPPORT THE FIRST 1000 DAYS OF LIFE

Settore scientifico-disciplinare: **MED/40**

DOTTORANDA

DR.SSA LAURA BRUNELLI

COORDINATORE

PROF. PAOLO GASPARINI

SUPERVISORE DI TESI

PROF.SSA TAMARA STAMPALIJA

ANNO ACCADEMICO 2021/2022

Summary

The issue

The first 1000 days of life as a foundation for the future

The importance of the first 1000 days of life, the period from conception to the child's second year, has been widely recognized by international organizations and institutions such as the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), and the World Bank Group (1). A child's early exposure to a variety of health determinants during this period is critical, so much so that this period has been identified as a crucial window of opportunity for a child's development, growth, and future physical and mental health (2). As highlighted in the 2015 Minsk Declaration, the course of human life is influenced by genetic, epigenetic, and intrauterine hereditary factors; environmental exposures; family and social relationships that can support and promote growth; behavioural choices; social norms; opportunities for future generations; and historical, cultural, and structural context (3). Exposure to risk or protective factors related to the physical and psychosocial environment during a critical and vulnerable period of plasticity such as the first 1000 days (4) can therefore lead to potentially adaptive responses (depending on the duration and timing of exposure) that can alter the brain architecture and endocrine-metabolic programming of the individual, sometimes permanently and with intergenerational effects when germ cells are involved. This favours the occurrence of pathologies and disorders in childhood or adulthood when risk factors are involved, whereas better child development can be promoted by protective factors. Knowledge and management of the main risk and protective factors and their mechanisms of action in the first 1000 days are therefore becoming a public health priority, also in view of the potential synergistic effect due to possible interactions between these factors and genetic susceptibility, which may determine medium- and long-term consequences (5). Indeed, this first window of child development is characterized by the developmental phase of organs, especially the brain and its functions, whose plasticity is influenced by a variety of positive and negative factors that can also be partially controlled. For example, some metabolic defects and obesity in adulthood can be strongly influenced by poor nutrition during pregnancy, non-breastfeeding, or even exposure to toxic substances or environmental pollutants. As reported by Burgio et al, maternal nutrition during pregnancy can alter the metabolic phenotype of offspring through epigenetic regulation of certain genes, and this can be passed on to the next generations (6). In addition, the development of the child's cognitive and socio-relational skills is highly dependent on the quality of the relationship with the parents and the environment in which the child grows up (5).

As recently urged by international institutions, in Figure 1 are shown the five components of nurturing care that enable children to reach their full potential: good health, adequate nutrition, responsive caregiving, security and safety, and opportunities for early learning (1).

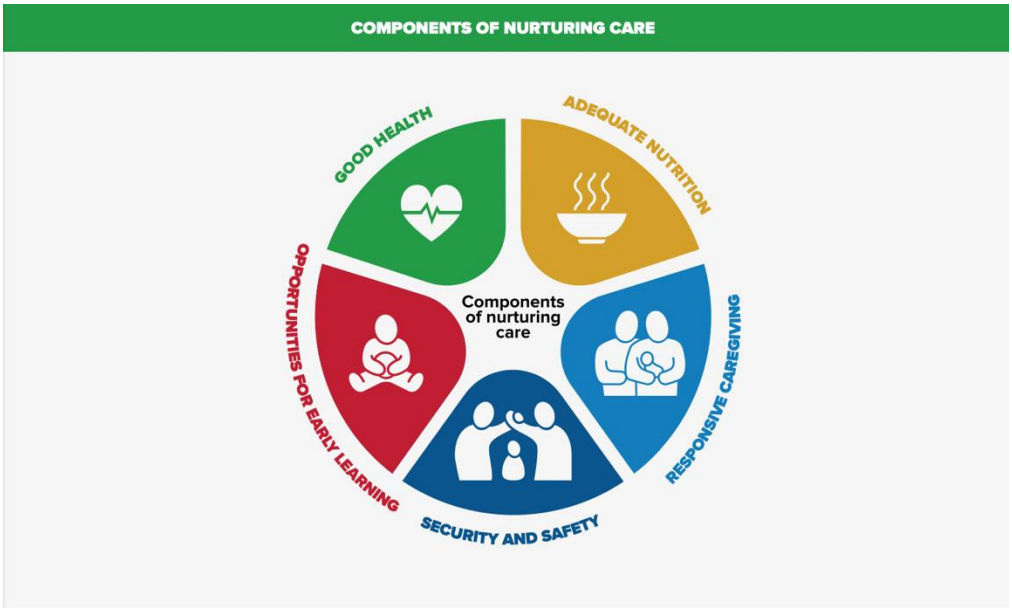


Figure 1. The five components of nurturing care, WHO (1).

Therefore, it is essential to strengthen maternal and child health services in the first 1000 days of life to provide the greatest opportunity for the child (7). However, given the principles of the Ottawa Charter, this goal would benefit greatly from empowering the mother, who is the first and most important determinant of offspring health, as well as the entire family and community surrounding the new life (8). Drawing on the thinking behind the seminal Dahlgren-Whitehead's rainbow model (9), WHO identifies a number of determinants for infant and nurturing care that include caregiver capability, community empowerment, improved supportive services and enabled policies (Figure 2)(1).

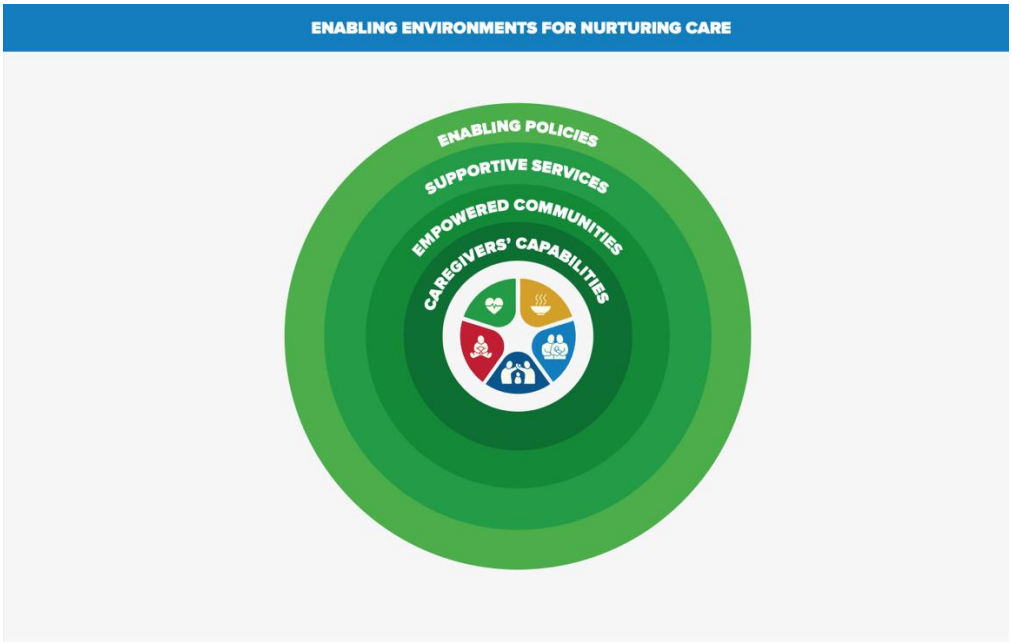


Figure 2. Determinants and enabling environments for nurturing care, WHO (1).

At the same time, pursuing the goal of ensuring the best first 1000 days of life also provides an opportunity to work in line with the Sustainable Development Goals (SDGs) set out in the United Nations 2030 Agenda (10), especially when considering SDGs No. 2.2 - End all forms of malnutrition, No. 3.1 and 3.2 – Reduce global maternal, newborn and child mortality, No. 4.2 - Ensure access to all girls and boys to quality early childhood development, and others. In this view, the SDGs represent an opportunity to link early childhood development with efforts to achieve equity, prosperity, and sustainable growth in our society.

For these reasons, many international and national institutions are working to implement policies and interventions to support this crucial stage, in both low- and high-income countries (11–14).With this in mind, in 2016 the Italian Ministry of Health established a technical group focused on protecting and promoting health in the first 1000 days of life. This group produced a guidance document for parents, health professionals, and policy makers on protecting and promoting the health of children and future generations, entitled “Investing in health early: Actions and strategies in the first thousand days of life” (Investire precocemente in salute: azioni e strategie nei primi mille giorni di vita) (5). The aim of this policy paper was to focus on the main evidence-based preventive actions that can be taken by parents and health professionals as well as in national and local policies to minimise the main risk factors and strengthen protective factors in the first 1000 days of life. In addition, this document analyses the different periods that make up the first 1000 days of life (pre-conceptional; first, second, and third trimesters of pregnancy; labour-delivery and birth; baby’s first month of life; and child’s first and second year of life) in terms of the five components of nurturing care. The 11 main topics examined are parenting knowledge and skills, food and nutrition, other lifestyles, drugs, diseases and screening/exams, genetic diseases, mental health, infections and immunizations, fathers’ role and health, environmental factors, and social factors and access to services. Table 1 summarizes the key risk factors that should be addressed in each of these time periods to promote maternal and child health.

Area	Risk factor	Pregnancy				Birth	After-birth	
		Pre-conceptional	1st trimester	2nd trimester	3rd trimester	Labor-delivery and birth	Baby's 1st month	Child's 1st and 2nd year
Parenting knowledge and skills	Poor/no knowledge about pre-conception health and prevention	x						
	Lack of knowledge about prenatal care		x	x	x			
	Insufficient or no participation in childbirth classes			x	x	x		
	Lack of knowledge about labor/delivery/birth and the services offered					x		
	Lack of information about the possible mode of delivery, including in the case of a previous cesarean delivery					x		
	Lack of information about umbilical cord blood donation					x		
	Lack of knowledge and skills related to the newborn health, prevention, and care						x	
	Lack of knowledge about shaken baby syndrome						x	x
	Inadequate parental support (in terms of quality and time commitment)							x
	Inadequate/lack of access to scheduled paediatrician visits and lack of adherence to counselling offered							x
	Inadequate/lack of knowledge of best prevention practices							x
	Use of inadequate sources of counselling on infant health status							x
Food and nutrition	Inadequate varied and balanced diet	x	x	x	x			
	Underweight/overweight	x	x	x	x			
	Inadequate folic acid intake	x	x	x	x			
	Inadequate iodine intake	x	x	x	x			
	Exposure to methylmercury	x	x	x	x			
	High exposure to vitamin A	x	x					
	Foods and toxoplasmosis		x	x	x			
	Insufficient fluid and nutrient intake					x		
	No early latch-on to promote breastfeeding					x		
	Failure to give breast milk or donated milk						x	x
	Exposure to allergenic factors that may be present in breastmilk substitutes or lack of information on breastmilk substitute preparation						x	
	Use of bottles and teats that have not been disinfected or do not comply with industry general and technical regulations						x	
	Early introduction of complementary feeding							x
	Late introduction of solid foods							x
	Overweight							x
	Vitamin D deficiency							x
	Zinc deficiency							x
	Vegan diet							x
	Fluoride deficiency							x
	Use of honey							x
Other lifestyles	Sedentaritiness	x	x	x	x		x	x
	Smoking	x	x	x	x		x	
	Maternal smoking and exposure to secondhand smoke							x
	Alcoholic beverages	x	x	x	x		x	x
	Drugs	x	x	x	x			x
	Other inappropriate behaviors		x	x	x			
	Lack of oral health care	x						

	Failures to care for child's oral health							x
	Unsafe sleep						x	
	Sudden and unexpected death							x
	Insufficient hours of sleep							x
	Inadequate sleep environment							x
	Accidents and trauma						x	x
	Failure to identify and treat women with substance abuse, alcohol, smoking					x		
	Exposure to television/tablets or other screens							x
	Excessive exposure to the sun and high temperatures							x
Drugs	Inappropriate use of risky medications during pregnancy	x	x	x	x			
	Taking contraindicated or inappropriate medications					x		
	Inappropriate use of medications when breastfeeding						x	
	Inappropriate use of medications in the newborn						x	x
	Uncontrolled use of homeopathic or alternative treatments							x
	Inappropriate use of sugary drinks for healing purposes							x
Diseases and screening/exams	Obesity	x	x	x	x			
	Thyroid dysfunction	x	x					
	Diabetes	x	x	x	x			
	Chronic hypertension	x	x	x	x			
	Epilepsy	x	x					
	Pathologic obstetric-gynecologic history	x						
	Failure to perform preconceptional examination	x						
	Obstetric complications related to chronic diseases or occurring during labor/delivery					x		
	Failure to perform the examinations prescribed in the LEA (Livelli Essenziali di Assistenza) in the pregnancy trimester		x	x	x			
	Inappropriate management of fever					x		x
	Failure to perform screening for inherited metabolic diseases (extended newborn screening)						x	
	Delayed/failed diagnosis and treatment of congenital malformations detectable in the first month of life						x	
	Delayed/failed diagnosis and/or intake for diseases that can be diagnosed in the first month of life: rare diseases						x	x
	Respiratory syncytial virus (RSV) infections							x
	Urinary tract infections							x
	Gastroenteritis							x
Genetical diseases	Genetic risk	x						
	Pregnancy at an advanced age	x						
	Lack of information on genetic risks and available prenatal testing		x	x	x			
	Lack of identification and treatment of genetic diseases and malformations in the newborn					x		
	Lack of newborn screening for early detection of congenital deafness						x	
	Lack of newborn screening for congenital cataract						x	
Mental health	Presence of psychological problem in the woman/couple	x	x	x	x	x		
	Psychiatric disorders in the mother or father	x	x	x	x		x	
	Postpartum depression						x	
	Missing/insufficient mother-child relationship						x	
	Inadequate parental role in mental health problems, alcoholism, drug addiction, social problems							x
	Missed or delayed diagnosis of neurodevelopmental disorders							x

Infections and vaccinations	Rubella	x	x	x	x	x		
	Measles	x	x	x	x			
	Chickenpox	x	x	x	x			
	Hepatitis B	x	x	x	x	x		
	Sexually transmitted infections	x	x	x	x	x		
	Toxoplasmosis		x	x	x	x		
	Mumps		x	x	x			
	Cytomegalovirus		x	x	x			
	Group B β-hemolytic streptococcus			x	x	x		
	Omission of recommended vaccinations during pregnancy		x	x	x			
	Partial or complete refusal of vaccinations for mother and child						x	x
	Increase of infections related to preventable infectious diseases							x
	Neglect of hand hygiene							x
Fathers' role and health	Lack of attention to healthy lifestyles and health among men of childbearing age	x		x	x			
	Lack of father's involvement in pregnancy and potential exposure to behavioral and environmental risk factors		x	x	x			
	Lack of father's involvement and participation					x		
	Unhealthy lifestyles and behavioral risk factors (e.g., absent father)						x	x
Environmental factors	Exposure to air pollution (outdoor and indoor)	x	x	x	x		x	x
	Exposure to endocrine disruptors	x	x	x	x		x	x
	Exposure to electromagnetic fields	x	x	x	x		x	x
	Exposure to ionizing radiation		x	x	x			
	Exposure to noise		x	x	x			
	Exposure to heat waves			x	x		x	x
Social factors and access to services	Vulnerabilities by age, socioeconomic status, education level, geographic origin, and immigrant status	x	x	x	x	x	x	x
	Domestic violence	x	x	x	x	x	x	x

Table 1. Risk factors affecting specific developmental stages in the first 1000 days of life (5).

To provide all children with the best developmental opportunities and ensure their right to survive and thrive, countries are expected to invest in local research to strengthen the implementation of nurturing-care interventions, strive for family-centred care, apply a whole-of-government action, and move to a whole-of-society approach (1).

Parental needs and information seeking behaviour

The transition to parenthood is undoubtedly one of the most drastic and critical life events (15), the impact of which on the physical and mental health of parents cannot be overlooked. Indeed, the birth of a child is associated with profound changes that require mothers and fathers to adapt to their new roles. New responsibilities arise that shake their comfortable, controlled lives in which they were 'experts' and force them to face the unknown world of parenthood (16). These changes have recently been described for the mother as perinatal stress, which goes beyond depression and anxiety and encompasses the entire period of the first 1000 days of life, but from the mother's perspective (17). Indeed, as described by Professor Wilkins (16), the path to intuitive motherhood passes through several stressful moments: it begins with feelings of inadequacy, then progresses to feelings of avoidance, isolation and disconnection from reality, until the new role is reconciled with the previous life and, finally, self-confidence is gained (see Figure 3).

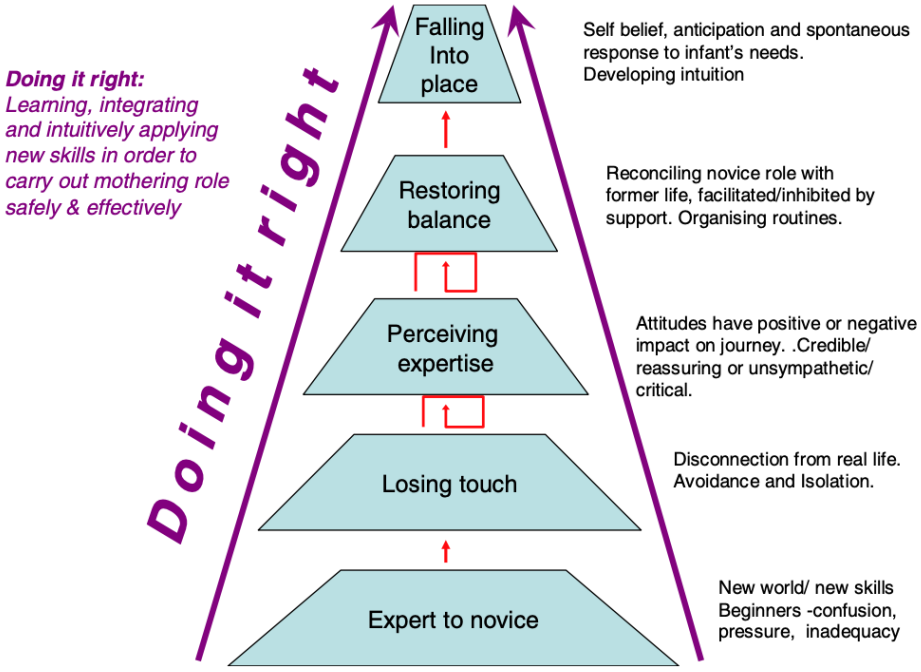


Figure 3. The journey towards intuitive mothering. An illustration of the core and supporting categories, from Wilkins (16).

Although parents often feel inadequately prepared for this new situation, the ultimate quality of parenthood seems to depend on the processes underlying family formation, such as the desire to have a child, the involvement of both parents in child care, and the quality of parenting, although the presence or absence of a genetic link does not seem to matter depending on the mode of conception (18). Nonetheless, the need for adequate preparation remains a concern for both parents and health professionals (19), especially when social, cultural, or economic vulnerabilities and weaknesses exist (20,21). Indeed, the top priority is to give every child a good start in life. This in turn requires, as a minimum, adequate social and health protection for women, expectant mothers, and young families, as well as a significant progress toward a universal, high-

quality, and affordable system of early childhood education and care (21). Although the inclusion and participation of pregnant women in maternity-related research can be challenging due to the transient nature of pregnancy and the potential underrepresentation of minor women and ethnic minority groups (22), the main categories of needs summarised by Slomian et al (23) include the need for information, the need for psychological support, the need to share experiences, and the need for practical and material support. The mix of these needs has been referred by some authors as the concept of pregnancy ecology, a structured concept that takes into account informational, physical, emotional, and social needs (15). In addition to this, it is time to include fathers in this journey from the beginning (15,24,25) as their greater involvement can positively influence overall outcomes for both mother and child in the first 1000 days of life.

Parents are aware of their needs and feel the pressure of the future that is soon to come. A Swiss study (26) found that almost all of them (91%) use digital media to search for information about their child's health and development, especially search engines (55%) and websites (47%); the high proportion of e-health searchers has been confirmed by other authors (27,28). Although other more professional sources of information such as paediatrician (67%) and midwives (91%) were also indicated, they were accompanied by family and friends (79%) and, again, websites (78%) and apps (61%) (26,28). Despite the heavy use of digital sources of information, likely chosen primarily for their 24/7 availability, there were concerns among the majority of users about the trustworthiness and reliability of the information presented (26,28,29). Several authors and institutions have called for addressing the quality of health advice on the Internet and better guiding users to trustworthy sources of information (30–33), including in light of what has happened in recent years with COVID-19 pandemic (34). Although some recommendations and strategies have been proposed (32,35,36), including practical tools to assess the quality of Web sites (37–39), "infodemic" will remain a public health problem to be addressed in the years ahead. However, as several colleagues point out, the problem lies not only in the reliability and accuracy of sources but also in health literacy (35,40–42) and in the electronic or digital health literacy of individuals (43). The less the individual is able to evaluate online health information, the greater the risk that he or she will trust the information found, regardless of its actual reliability (40). In fact, health literacy includes the ability to seek, find, and obtain health information (*access*); understand the retrieved health information (*understand*); interpret, filter, assess and evaluate that health information (*appraise*); and communicate and use the information to make a decision to maintain or improve health (*apply*). Looking at the issue from a broader perspective, health literacy itself is an additional and critical determinant of individual and community health (41), as outlined and visually represented in the review by Sørensen et al. (44) in Figure 4.

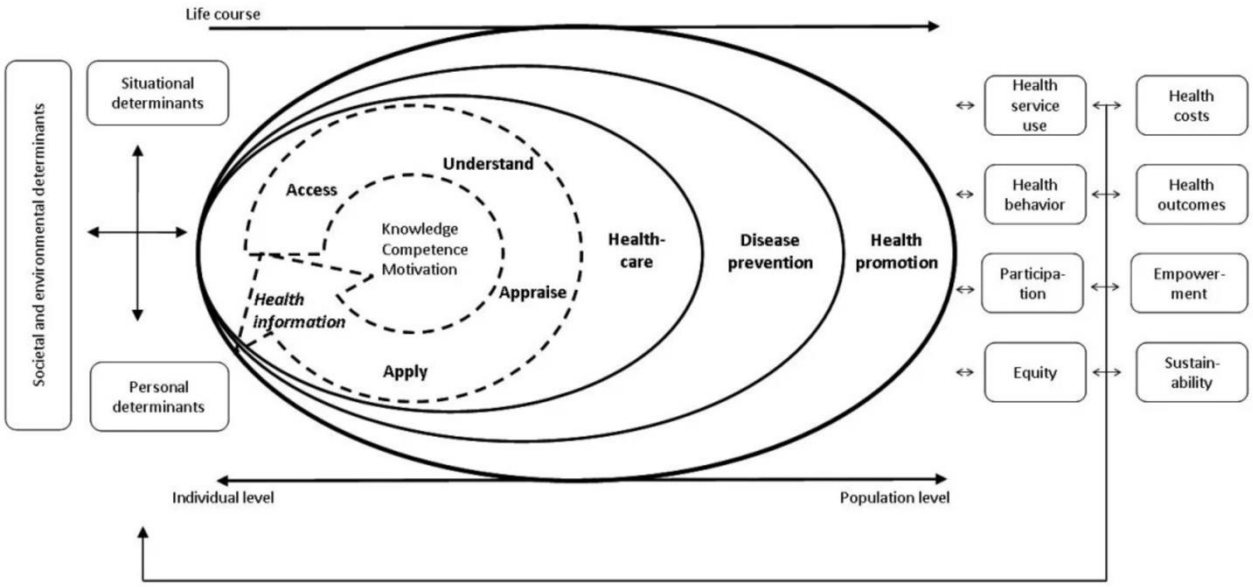


Figure 4. Integrated conceptual model of health literacy, from Sørensen et al. (44).

The increasing complexity of healthcare for the first 1000 days of life

The target population for health promotion and prevention interventions in the first 1000 days of life is changing from many aspects. These included the age of parents, particularly pregnant women, who are generally getting older both nationally and internationally (45–47), but also the presence of comorbidities (e.g., maternal obesity, diabetes, or a history of chronic disease or neoplasia) (48,49), the variety of ethnic and cultural backgrounds (47), changes in family structure, and increased societal demands associated with rapid changes in parents' reproductive behaviour and lifestyles. In addition, disparities within persons of childbearing age remain strongly related to the economic and employment situation, as reported for the European Region (21) and specifically for our national context (50). The WHO report on the state of health equity in Italy analysed the five main areas that need to be addressed to achieve health equity: health services, income security and social protection, living conditions, social and human capital, employment and work situation. Specifically, the analysis examined the role and weight of each of these areas in determining inequalities within the country (Figure 5), provided further details for each identified area, and examined the gaps to be closed (Figure 6 a, b, c, d, e).

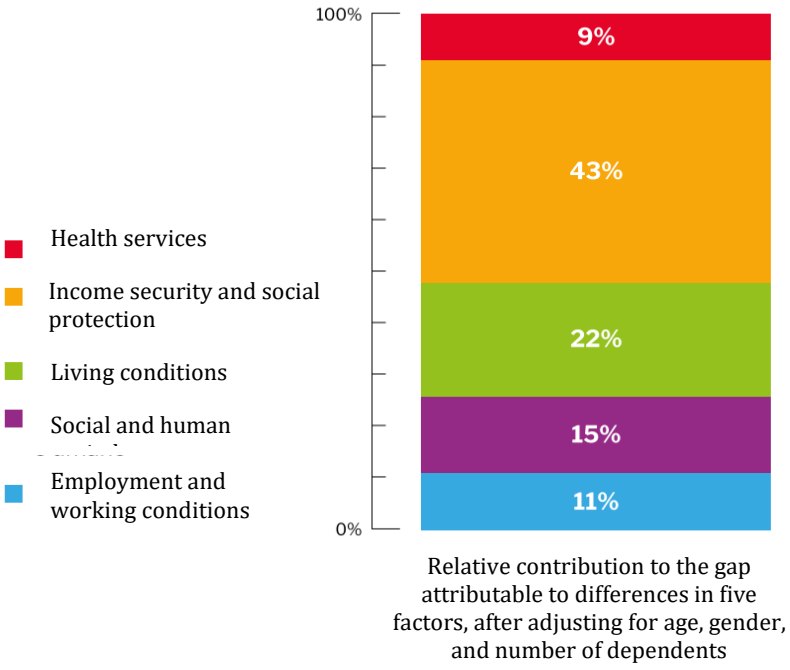
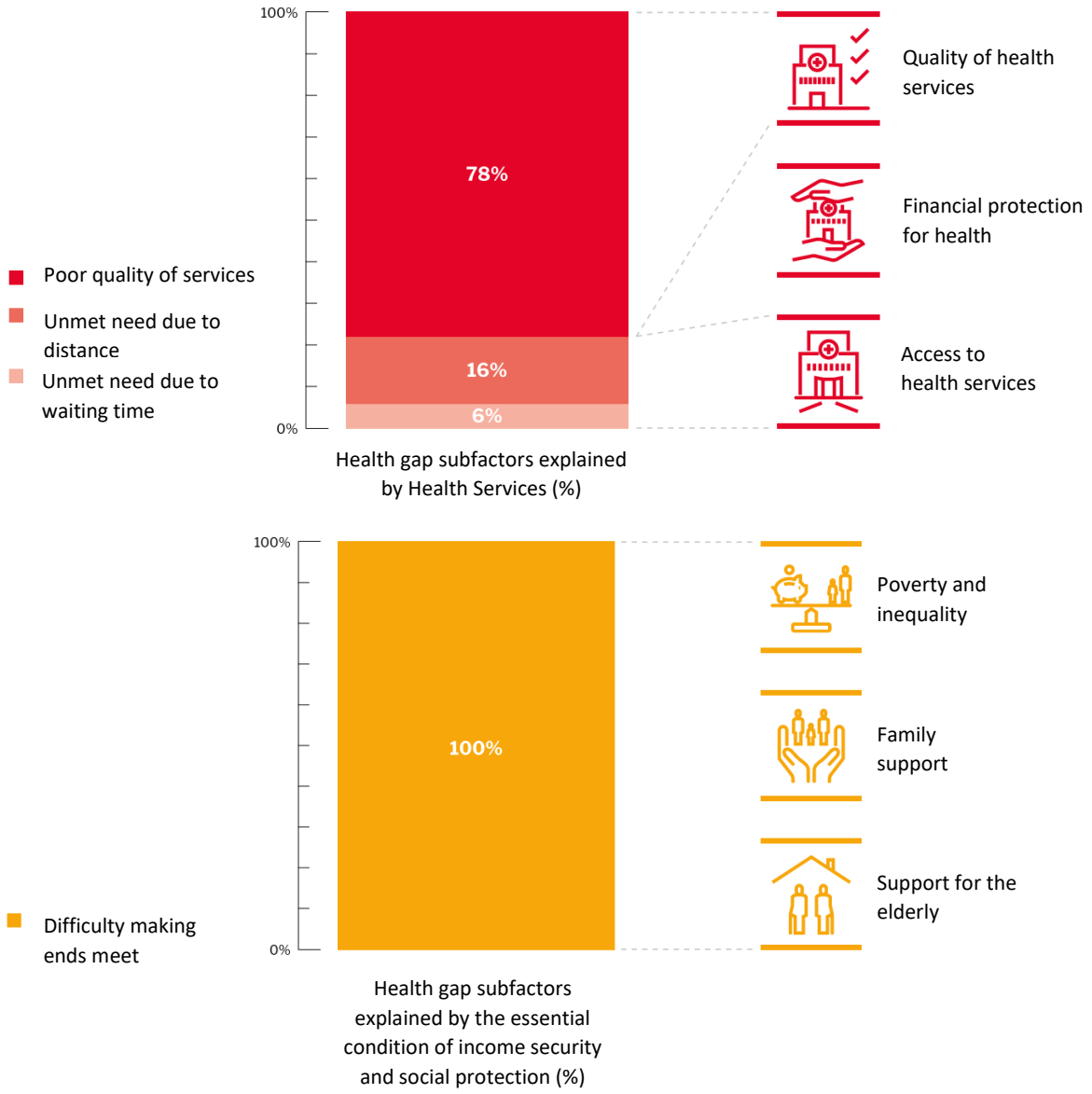


Figure 5. Impact decomposition of the five most important conditions influencing the difference in health status between the richest and poorest 40% of people in Italy (50).

While the problems were quite evident in some areas (i.e., 100% economic insecurity and 93% too many hours for employment and working conditions), more sophisticated patterns emerged in other areas. Disparities in quality and access to health services accounted for 9% of the total contribution to the health gap between higher and lower income groups, and these inequalities were reported to be mainly due to poor quality of health services. In relation to living conditions (22% of the total), gaps in food security and household heating have been steadily widened since the 2008 recession, accounting for 28% and 16% of the

health gap attributable to living conditions, respectively. This may have led to harmful dietary behaviours among disadvantaged households, that over-rely on low-cost, high-energy foods influenced by the marketing and commercialization techniques of commercial food companies. Inequalities in social and human capital accounted for 15%, with lack of trust accounting for the overwhelming majority at 43%. Within all of these areas, education remains a strong predictor of health inequalities (50).



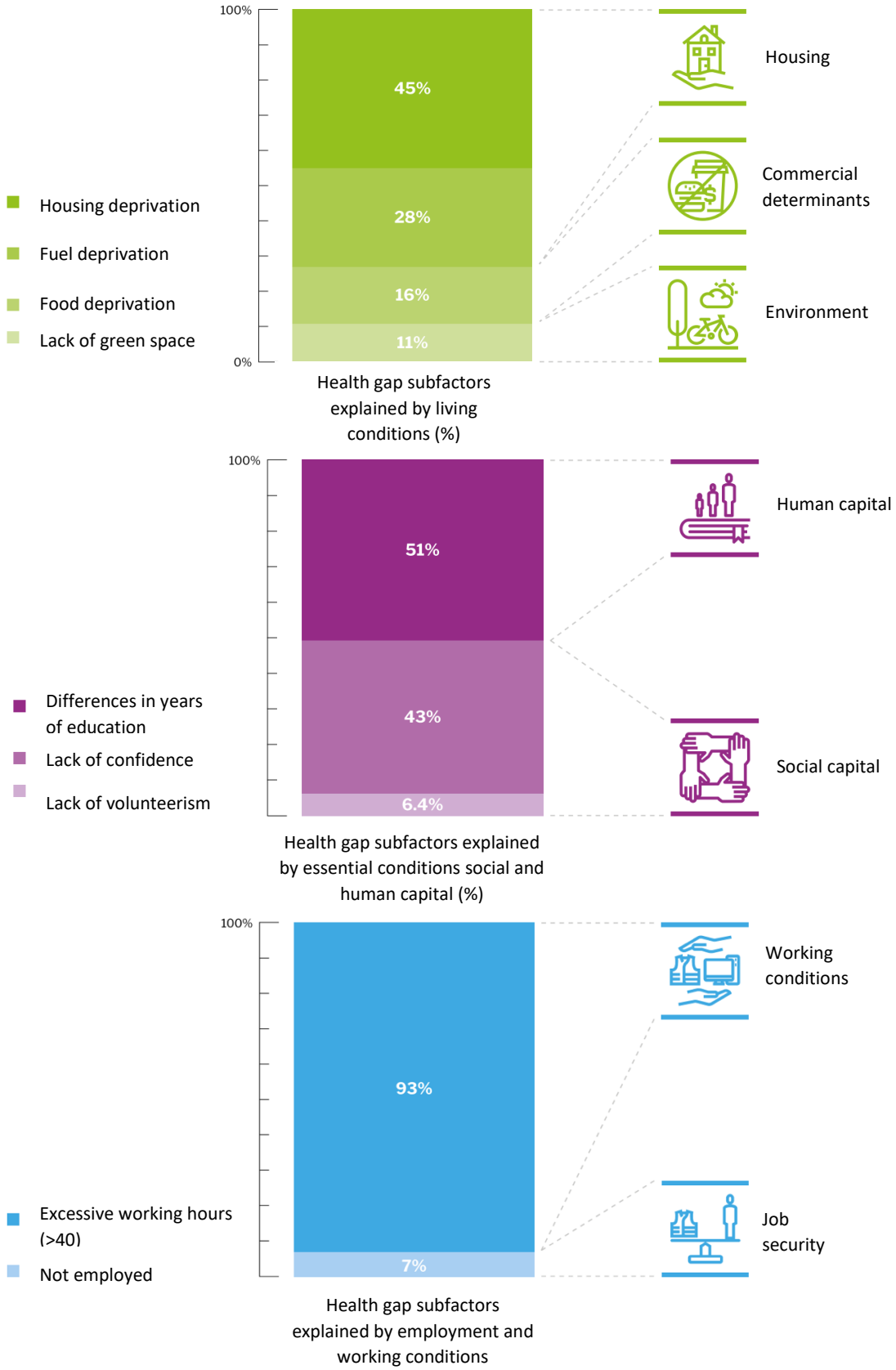


Figure 6. Decomposition of the components of the factors health services (a), income security and social protection (b), living conditions (c), social and human capital (d), employment and working conditions (e), from WHO (50).

The level of trust towards both other people and institutions is particularly worrying in Italy, where trust is significantly lower than in many other countries in the WHO European Region (50), but this phenomenon has also been observed at a global level (51). As reported by Gualano et al. (52), lower confidence among health professionals, people with anxiety, and people in economic difficulties has worsened significantly in recent years: citizens who feel the impact of the pandemic and its constraints strongly may no longer be able to weigh and understand the risk of the disease and the measures that need to be taken to cope with COVID-19. A central role in this recent loss of trust may have been pandemic fatigue, a demotivation that occurs gradually over time and likely increases as people experience the personal, social, and economic impact of the restrictions (53). Nevertheless, such an analysis should not overlook the pervasive and disruptive role that social media has played in public health communication in recent years (31,54). From a broader perspective, as Italy begins to recover from the acute early phase of the COVID-19 pandemic, there is an increased risk that young people in particular will face increasing inequalities in trust, sense of belonging, opportunities to have a voice, and a sense of future and hope (50), as they face a future of social distancing and have a very different vision of their individual destiny.

Looking at the situation more broadly, a summary of new evidence shows how COVID-19 exacerbates existing inequalities in health and in the essentials for healthy and prosperous living and highlights new risks of inequality and new vulnerabilities (51,55). Italy entered the COVID-19 pandemic with numerous preexisting inequalities in the prevalence of noncommunicable diseases, overweight and obesity, mental health problems, and health-risk behaviors (50). Early evidence suggests that COVID-19 and its containment measures may have exacerbated some of these existing inequalities and created new, multifaceted vulnerabilities. In particular, a social gradient have been observed in COVID-19 exposure, disease outcomes, and non-COVID-19 healthcare disruption (55,56). This calls for priority health and intersectoral strategies that can mitigate the exacerbation of existing and emerging inequities and promote recovery that leaves no one behind because of poor health and unsafe living conditions (10). There is growing evidence that there is an accumulation of advantages and disadvantages over the life course. To harness this phenomenon and reverse its effects, a life-course approach to health equity is needed. Such an approach begins by looking at the important early stages of life – pregnancy and early childhood development – and continues with school, transition to work, employment and working conditions, and circumstances affecting older people, as shown in Figure 7 (21). Measures that address the first 1000 days of life are therefore beneficial not only for society but also for the future of new generations, as they set in motion the development of a virtuous circle.

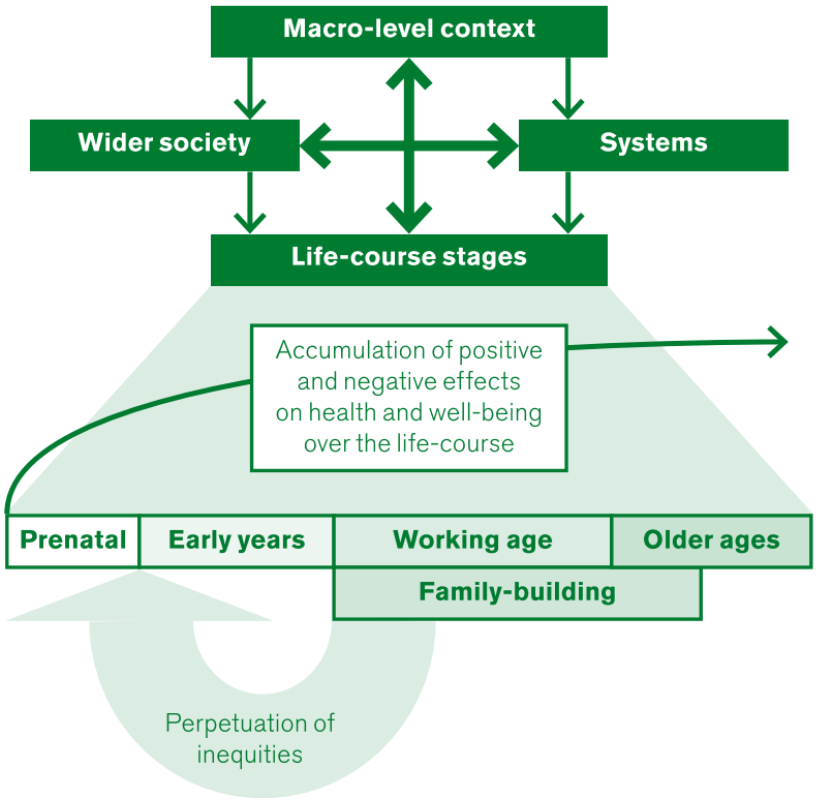


Figure 7. Social determinants of health and strategies to promote health equity – key elements to address the perpetration of inequities (21).

Therefore, given the increasing complexity of the particular health contexts of the first 1000 days of life (57), greater specificity of public health interventions is required to move towards a complex systems approach that allows for creative self-organization. This can be achieved by removing the structural boundaries between institutions, health professionals and patients/citizens, aligning their goals, and enabling experimentation (58).

Telehealth as part of the solution

The development of information and communication technologies in recent years has enabled a ground-breaking expansion of electronic health (eHealth) and mobile health (mHealth) services. These developments, together with the introduction of technological innovations in clinical practice such as telemedicine, telemonitoring, and remote screening, are considered essential elements of "game-changing innovations" in reproductive, maternal, newborn and child health in the coming decades (59).

Cisco, a leading manufacturer and supplier of networking equipment, estimates that by 2023 there will be 388 million Internet users (78% of the population) and 404 million mobile phone users (81% of the population) in Europe (60). According to Statista (61), the smartphone penetration rate in Europe is estimated at 78% and is projected to reach 84% by 2025. In 2020, 2.5 billion Internet-of-Things (IoT) connections were already being tracked in Europe, and the forecast for 2025 expects IoT connections to increase by more than 70%. With the exponential growth of connected devices and systems, data processing and analytics are becoming the driving force behind the digitalization of our economy, society and environment. As devices become smarter in collecting data, processing and transmitting information, and triggering actions in real-time, the IoT space is being considered, along with artificial intelligence (AI) and Big Data, from institutions (i.e., the European Commission) (62), researchers (63), and health professionals (64) to be at the center of the current healthcare digital transformation, integrating devices, data, computing power, and connectivity.

In 2017, 325,000 health-related apps (i.e., health and fitness apps and medical apps) were already available in all major app stores, with an estimated app download volume of 3.7 billion (64). Still, the field is highly fragmented: less than 4% of mHealth app vendors manage to achieve more than 1 million downloads per year for their app portfolio, and at the other end of the scale, 55% of mHealth app vendors report fewer than 5,000 downloads across their entire app portfolio in one year (65). Many of these health apps are designed to address specific female body experiences, such as menopause or pelvic floor problems, and solely to enable effective management of women's self-care, such as during pregnancy and after childbirth (66). Regarding the latter two public health issues, despite the impressive number of apps available, there is generally a lack of continuity beyond birth (67) and attempts to scientifically and clinically prove their effectiveness (68–72). Virtuous examples are mHealth interventions to improve knowledge, attitudes, and behaviours (73), such as breastfeeding (74) and short- but not long-term eating behaviour and food intake (75), but much remains to be done. Nonetheless, patients and health professionals acceptance of mHealth appears to be high (76), and the potential for such integration into standard care should be further explored.

In this already rapidly evolving scenario, the COVID-19 pandemic has made an additional positive contribution to the acceleration and improvement of telemedicine (77). This leverages the benefits of remote medical care by avoiding unnecessary hospitalizations (78), reducing costs and the risk of hospital-acquired

infections, and positively impacting patients' quality of life by keeping patients and caregivers in their familiar environment (i.e., home care) (79), lowering also the carbon footprint by reducing transportation to healthcare services (80). In addition, the use of mobile health applications could positively influence communication and the relationship between patients and health professionals, making it easier for patients to take an active role in managing their health (81). In fact, digital technology offers the opportunity to cost-effectively improve the delivery of information at a time, place, and pace that is most convenient for the patient (68,73). Indeed, colleagues reported that during the pandemic, more than three-quarters of women used mobile applications related to pregnancy, and almost all of them found it useful (82).

As noted earlier, recent years have seen advancements in telehealth capabilities in reproductive, maternal, newborn and child settings. A comprehensive analysis of potential applications included the following areas: prenatal and postpartum care, ultrasonography, fetal echocardiography and genetics, maternal-fetal medicine consultation, and fetal monitoring. Indeed, the latter seems to be the most controversial area because of the risk of overuse, leading to an increase in false-positive alarms and unnecessary medical interventions that cannot be performed quickly on-site when needed (83). Because the adoption of these new solutions comes with some concerns, including potential gaps in content quality, software functionality, and the app development process itself (84), a recommendation document from the American College of Obstetricians and Gynaecologists (ACOG) has been published (85). ACOG recommends that obstetricians and gynaecologists and other physicians become familiar with and proficient in this new technology, but also points to quality of care and patient safety, as well as the need to maintain and enhance the patient–physician relationship in the treatment plan. Indeed, it is critical that health professionals participate in the development of eHealth and mHealth solutions to meet the information needs of today's generation of parents (28), who even need to be helped to browse health websites more safely (29). To help telemedicine reshape how care is delivered during the first 1000 days of life and to ensure the safety, effectiveness, and reliability of solutions, it is imperative that all stakeholders (i.e., patients, caregivers, health professionals, and healthcare institutions) be involved in more rigorous and focused research to best design, implement, and evaluate interventions (68,71,72,84).

The project

With these premises in mind, and considering the issues and perspectives of all stakeholders, a participatory design method was chosen for our project that included the four phases described by Clemensen et al. (86): 1) identification and analysis of needs; 2) generation of ideas and development of prototypes; 3) testing and refinement of prototypes; and 4) evaluation.

Research group, funding, and aims

The research group of the project is composed of professionals from the Institute for Maternal and Child Health-IRCCS Burlo Garofolo, the public research institution of Area Science Park, and the University of Trieste. Right at the beginning, Area Science Park received funding for the complex project 'ARGO system' thanks to a protocol agreement signed in 2018 between the Friuli-Venezia Giulia Region, the Italian Ministry of Education, University and Research, and the Italian Ministry of Economic Development. Within this project, Area Science Park was asked to develop an integrated information ecosystem that includes both a web-based platform and a mobile app service to support mother-child care. The first two areas in which this protocol was developed and implemented were maternal and child healthcare during pregnancy and perioperative pediatric care. The project required the development of public-private partnerships and was supported by academia. The research presented here was supported by the Italian Ministry of Health through contributions to the Institute for Maternal and Child Health, IRCCS Burlo Garofolo, Trieste, Italy, and by the University of Trieste. Regarding the maternal and child pregnancy pathway, the aim was quickly identified: to develop an ecosystem that supports the first 1000 days of life. This ecosystem should represent a helpful tool for citizens/patients, health professionals and the public health institution. Under these administrative and legal conditions, a research group was formed, composed of health professionals from IRCCS Burlo Garofolo (obstetricians, pediatricians, midwives, nurses, supporting staff), health and research staff of the University of Trieste (public health specialists, specialists in gynecology and obstetrics), and personnel from the Area Science Park (psychologists, sociologist, clinical engineers, specialists in ergonomics). These researchers discussed the general framework for the project and the potential impact, identified the relevant stakeholders (Table 2), and pointed out the main research questions that should accompany the whole project.

General issue	The first 1000 days of life		
Specific care pathway	Pregnancy and postnatal care and counselling		
Stakeholders	Primary users	Secondary users	Tertiary user
	Expectant and new parents	Health professionals	Healthcare institution

Table 2. General framework for the participatory research project.

The main research questions were:

- Question 1 (Q1) – What is the perspective of the healthcare institutions as a tertiary user of such an ecosystem? What are the expected benefits of implementing this tool in clinical practice?
- Question 2 (Q2) – What is already available to primary users? Are these tools sufficient to support the first 1000 days of life? What are the key gaps that need to be addressed?
- Question 3 (Q3) – What are the needs and expectations of primary and secondary users for an app to support the first 1000 days of life?
- Question 4 (Q4) – How can a digital tool be developed to effectively support primary users during pregnancy and the postnatal period?

Q1. The perspective of the healthcare institution

Understanding and responding to the requests and needs of the healthcare institutions (tertiary user) is necessary to develop solutions that integrate effectively into a hospital's care, management and organizational processes. IRCSS Burlo Garofolo has a privileged observatory on maternal and child health and is aware of the need for primary users to rely on trustworthy information, as it provides highly qualified inpatient and outpatient services for minors, pregnant women, women in post-partum period and pediatric care. As a highly specialized hospital providing complex and specialized maternal-child, the Institute is aware of the needs of parents, health institutions and the entire community (87). The vision of IRCSS Burlo Garofolo aims to ensure an equally high level of health for all children, adolescents and women, while promoting research and innovation as well as teaching and training for the maternal-child sector.

The development of a mHealth solution would enable a more reliable and accountable delivery of information to citizens, patients, and caregivers, which could simultaneously improve communication between the latter and health professionals and increase the efficiency of service delivery. In addition, the development of a digital ecosystem could help track activities that are currently conducted informally between users and health professionals, as well as within the healthcare institution. Nonetheless, the introduction of a new technology entails in the relationships among individuals and between individuals and the environment due to the interaction between the technology and the characteristics of the social, institutional, and cultural context in which it is developed and embedded. By reconstructing the dynamics of interaction within a well-defined context of action, social impact assessment is an inherently action-oriented research activity that aims to provide information useful for highlighting and correcting potential dysfunctions while enhancing the intervention through valorization of what is new and what can be used as a resource (88,89). Social impact is usually defined in terms of four key elements: the value created as a result of an activity, the value experienced by beneficiaries and all others affected, an impact that includes both positive and negative effects, an impact that is judged against a benchmark of what the situation would have been like without the proposed activity (88). Although the social dimension and impact are often overlooked in the context of technological innovation, the research group decided to include this additional and innovative assessment in the digital ecosystem project.

To explore the expected benefits of implementing this ecosystem in clinical practice in terms of social impact, focus groups and semi-structured interviews were conducted with various stakeholders of IRCCS Burlo Garofolo in September 2020 and April-June 2021, respectively. The professionals who participated in these interviews included members of the hospital management, public relations staff, obstetricians, gynecologists, midwives, and the heads of the midwife department. The discussions were conducted both remotely and in person and lasted between 50 and 100 minutes. The potential dimensions impacted by the technology implementation are presented in a social impact matrix and will be assessed using the predictive social return

on investment – (SROI) method, which aims to predict the social value of a future intervention by establishing benchmarks for assumed public health outcomes (90). This method proved to be very useful in the design phase of the intervention, as it allows to identify what social impact should be achieved and to understand how to maximize that impact. This particular evaluation was conducted by Quolity, an innovative start-up in partnership with Area Science Park that engages in research and experimental development in social sciences and humanities.

Data collection through focus groups with stakeholders was based on the construction of a group interview track, a tool that allows for "in-depth exploration" of the content being interviewed. This track aims to identify three fundamental aspects of the mapping carried in the context of the digital ecosystem: i) the specific professional activities of the sampled stakeholders; ii) the impact on the operational dynamics of the service offer; and iii) the impact on the behavior of the end users. Based on the results, the development of a social impact matrix allowed us to assign to each identified stakeholder the impact dimensions selected through the analysis of the primary and secondary available sources. The primary sources were data and information collected through an ad hoc evaluation (focus groups, semi-structured interviews). As for secondary sources, the documentation prepared by the work team for the project (synoptic frameworks, information content, research questionnaires, etc.) was comprehensively analyzed using the qualitative approach of textual source analysis starting from four main areas: information, organization, empowerment, and wellbeing. These areas were selected based on the exploratory survey conducted at the beginning of the project activities, which included semi-structured interviews with privileged witnesses. For each dimension, Table 3 lists all stakeholders potentially impacted by the dimension itself. This selection was made based on the intensity of the impact revealed by the textual analysis of the primary information collected. Based on the identified dimensions, a set of indicators was developed to measure the social impact of each dimension on stakeholders.

Area	Dimension	Stakeholder						
		Primary users	Secondary users				Tertiary users	
		Family	Outpatient clinic	Delivery room	Prenatal diagnosis	Obstetric ward	Healthcare leadership	Public relations office
INFORMATION	Time dedicated to the woman	x	x	x	x	x		x
	Reliability and validity of medical and health information	x	x	x	x	x		x
	Research of information	x	x	x	x	x		
	Volume of information content on a single platform	x						x
	Diversification of information content on a single platform	x					x	x
	Awareness about the use of vaccines	x	x				x	

	Choice of communication channels with Burlo by the woman/family unit	x	x					x
	Communication between health professionals and foreign family	x	x		x			
ORGANIZATION	Sharing of operational dynamics among healthcare professionals		x	x	x	x	x	
	Streamlining of appointments for the woman	x	x		x			
	Identification of admission pathways by the woman/family unit	x					x	x
	Access to emergencies (pediatric emergency department and pediatric emergency room)	x	x				x	
	Telephone contacts for information requests		x				x	x
	Access to hospital facilities for information requests	x					x	x
	Accesses to outpatient clinics for information requests	x	x				x	
	User complaints	x					x	x
	Standardization of information given to the woman/family unit		x		x	x	x	x
	Gaining of a common information base by health professionals		x	x	x	x	x	
	Women's compliance with administrative prescriptions for appointments, visits, and instrumental examinations	x	x		x		x	
	Compliance with hospitalization regulations			x		x	x	x
	Substitution of on-site childbirth classes	x		x			x	
	Management of the digitalization of information						x	x
	Compliance with anti-COVID-19 regulations		x		x			x
	Institutional reputation						x	x
EMPOWERMENT	Information sharing with the family	x	x	x	x	x		x
	Involvement of partners in planned activities	x	x	x	x	x		x
	Involvement of partners in childbirth preparation classes	x	x	x				
	Information about anonymous birth	x					x	x
	Integration of birth preparation classes on site	x	x	x				
	Raising awareness of maternity issues among the general population	x	x				x	x
WELLBEING	Risks of using non-certified sources	x	x	x	x	x		
	Anxiety of the woman	x	x	x	x	x		
	Anxiety of family members	x	x	x	x	x		
	Prevention of violence against women	x	x					
	Management of the birth pathway (pregnancy and postpartum) by the woman	x	x					
	Aggressiveness of the woman	x	x	x	x	x		x
	Aggressiveness of the family	x	x	x	x	x		x

Table 3. Matrix and stakeholders and dimensions potentially affected by the implementation of the digital ecosystem.

Q2. Assessment of tools available to primary users

As mentioned above, we were interested in assessing the mHealth tools available in Italy for pregnancy and postnatal care in the first 1000 days of life to highlight the main gaps to be addressed. To this end, we conducted a systematic search of the Apple App Store and Google Play Store, which are the first two European digital market leaders (61), to identify all potential apps addressing this crucial life stage. This search was conducted independently by six researchers under the age of 45, working in equal number on both stores between June 15 and July 3, 2020. Specifically, we searched the stores for the Italian terms for pregnant, mother, 9/nine months, birth, newborn, baby, obstetrics, pregnancy*, new baby*, my baby* and child* (*for these terms, the English translation was also used). Based on these terms, an initial group of 684 apps was identified. The basic set of information collected for all these apps allowed us to deduplicate the datasets (399 were duplicated) and exclude those related to games, photos and videos, shopping, commercial apps, calculators, fertility or menstruation tracking apps, as well as apps aimed for health professionals and apps that were not available with a Latin alphabet. To further select the apps, we decided to apply additional inclusion criteria by excluding those that were not available in Italian (n=158), that were not available without payment (n=21), and that were only available in one of the two stores (n=71). The total number of excluded apps was 250. After downloading the apps and checking these criteria, another 13 apps were excluded. The app selection process is shown in Figure 8.

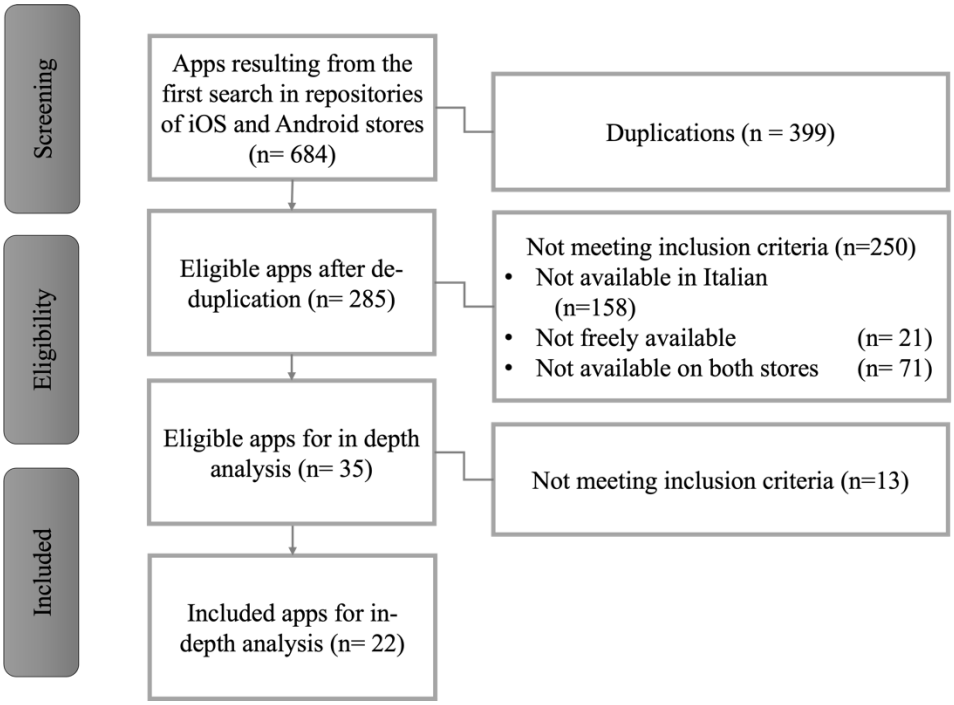


Figure 8. App selection process, from Brunelli et al. (91).

At the end of this screening and eligibility selection process, we downloaded and evaluated 22 apps on both iOS and Android devices. For this assessment, the researchers developed a 71-item questionnaire that examined the desirable content and features of an app to support the first 1000 days of life. They drew on

their experience and the available thematic literature (5), and were inspired by similar work for the postnatal period (92). Given the complexity of the topic of healthcare (57), the development of such instrument was possible thanks to interdisciplinary discussions that continued until agreement was reached among researchers (93). As shown in Table 4, the 71 items were divided into six main domains:

- *Pregnancy care and counselling*
- *Postnatal care and counselling for both mother and child*
- *Reminders and push notifications*
- *Notes and records*
- *Social support*
- *App technical features*.

Domain	Item
Pregnancy care and counselling	1. Does the application provide information about pregnancy? 2. Does the application provide information about the woman rights during the pregnancy (e.g., at work, at school, economical support)? 3. Are prenatal risks and life-threatening conditions identified in the application? 4. Does the application inform about maternal physiological and metabolic changes occurring during pregnancy? 5. Does the application inform about the immunizations that the mother needs to be administered? 6. Does the application provide information about maternal or child services accessibility and contacts? 7. Does the application provide information about available prenatal diagnostic tests? 8. Does the application include physical exercises and workouts for women during pregnancy? 9. Does the application provide pregnancy nutritional counselling for mothers? 10. Does the application include personal hygiene practices for women during pregnancy? 11. Does the application provide information about delivery? 12. Does the application provide information about pre-delivery courses? 13. Does the application provide month/trimester-related tips for pregnant women? 14. Does the application provide a list of essentials for the hospital-luggage? 15. Does the application provide a list of free-of-charge and upon payment exams during pregnancy?
Postnatal care and counselling for both mother and child	16. Does the application provide a list of essentials for the first welcome of mother and baby at home? 17. Does the application inform about maternal physiological and metabolic changes occurring during the postpartum period? 18. Does the application include information about manifest neonatal complications and warning signs? 19. Does the application offer information about postpartum mental disorders such as postpartum depression and baby blues (e.g., symptoms, coping strategies)? 20. Does the application inform about the immunizations that mothers or newborns need during the first 1000 days? 21. Does the application provide tips for the postpartum recovery process? 22. Does the application provide practical tips on how to take care of the newborn (e.g., hygiene, diaper changing, burping)? 23. Does the application provide postnatal nutritional counselling for mothers? 24. Does the application provide a breastfeeding guide and support? 25. Does the application report personal hygiene practices in the postnatal period? 26. Does the application encompass methods for postpartum family planning and birth spacing?
Reminders and push notifications	27. Does the application allow to set reminders for medical appointments (e.g., prenatal and postnatal check-ups, pediatric visits, immunizations)? 28. Does the application include push notification reminders for scheduled medications/immunizations? 29. Does the application include push notification reminders when the pregnancy month/trimester begins? 30. Does the application allow to schedule reminders for routine activities (e.g., drinking, diapering, feeding, pumping, sleeping)? 31. Does the application allow users to change reminders and notifications settings?
Notes and records	32. Does the application require specifying the latest period date or the expected delivery date?

	33. Does the application allow the user to modify the expected delivery date following medical re-evaluation? 34. Does the application allow to record physiological values of the mother (e.g., pressure, temperature, mood)? 35. Does the application allow to record contractions or kicks? 36. Does the application allow to record routine activities of the mother or the newborn (e.g., drinking, steps, diapers changes, bottle feeding, sleeping patterns/times)? 37. Does the application allow to take note of the medical care the mother or the newborn have received (e.g., medications and vaccination shots)? 38. Does the application allow to track the newborn's developmental milestones? 39. Does the application record anthropometric measurements of the fetus (e.g., height, weight and head circumference)? 40. Does the application record anthropometric measurements of the newborn (e.g., height, weight and head circumference)? 41. Does the application record measurements of the mother's weight at baseline and during pregnancy? 42. Does the application record measurements of the mother's weight in the postnatal period? 43. Does the application allow the mother to create a sleep diary for herself? 44. Does the application allow the mother to create a sleep diary for the newborn?
Social support	45. Is the application integrated with social networks (e.g., Facebook, Twitter)? 46. Is there a FAQ page in the application? 47. Does the application provide users with social mechanisms to interact with each other and share experiences (e.g., Community, forum, chat)? 48. Does the application provide users with social mechanisms to interact with healthcare staff (e.g., Community, forum, chat)?
App technical features	49. Does the application ask users for authentication? 50. Does the application present a privacy policy? 51. If present, is that privacy policy properly written in Italian? 52. Are all app contents freely available to the users (without any payment)? 53. Are there specific inclusion criteria for full app usage (e.g., national health service card, place of living, certification by a health professional)? 54. Does the application require to "sign" an informed consent for the application usage? 55. Does the application provide references about contents provided? 56. Does the application include a glossary of most used medical terms? 57. Does the application identify the scientific responsibility of provided contents? 58. Is there the possibility to back-up/restore data within the application? 59. Is there the possibility to download data collected through the application? 60. Does the application have a multi-language support? 61. Does the application geolocate the user to provide more detailed information? 62. Does the application allow users to book visits, vaccination, checkups? 63. Does the application allow users to update their account preferences? 64. Does the application use a tone that is simple, informal and friendly? 65. Does the application adapt to screen orientation (both portrait and landscape)? 66. Does the application learn user's preferences over time? 67. Does the application implement intuitive and predictable navigation patterns? 68. Are the application contents validated by an institutional source (local, regional or national)? 69. Is the application a certified medical device according to Italian law? 70. Does the application provide contents throughout different ways (e.g., text, video, audio)? 71. Does the application ask for the user satisfaction?

Table 4. Tool for evaluating available Italian apps to support the first 1000 days of life, from Brunelli et al. (91).

In addition to these items, we decided to evaluate the quality of the apps using the Mobile Application Rating Scale (MARS) (94), including the dimensions of engagement, functionality, aesthetics, and information quality. Because it was impossible for researchers to assess these aspects without actually using the app in a real pregnancy situation, as reported by colleagues (95), we decided not to use the subjective quality subscale and the perceived impact section. The features of the 22 apps were first assessed independently, and then the results were compared and disagreements discussed among the researchers to reach agreement. The data were merged and analysed using Microsoft Excel for Office 365 ProPlus (Microsoft Corp). The fulfilment of the desirable criteria for each app was expressed as a number and percentage for each domain and for each item with descriptive statistics. The results, presented below, were published in 2021 by Brunelli et al (91).

Initially 328 apps were identified, of which 180 were available in the Apple Store and 148 in the Google Play Store. Apps available simultaneously in both stores totalled 285. Most of these apps were actually freely available, especially for Android (99%), but many offered additional content for payment (53% and 34% for iOS and Android, respectively). Most apps presented users with a privacy policy, but only about half of them were actually available in Italian (57% for iOS and 42% for Android). The presence of advertising within the apps was quite different for the two operating systems, and there were also large differences in terms of the mean size (MegaBytes, MB). Only one of the apps was certified as a medical device with the European CE mark. The characteristics of the apps after initial screening and deduplication are shown in Table 5.

Apps characteristics	**iOS (n=180)** n (%) or value	**Android (n=148)** n (%) or value
Freely available	148 (82)	146 (99)
Further contents upon payment	95 (53)	50 (34)
Available in Italian	103 (57)	62 (42)
Privacy policy	141 (78)	122 (83)
Advertisement	10 (6)	89 (60)
Mean size (MB)	52	21
Some age restriction	106 (59)	11 (7)
Mean users' rating (stars/5)	3.9	4.2
Medical device European mark	1	1

Table 5. Characteristics of the first 285 apps for pregnancy and postnatal care, from Brunelli et al. (91).

The in-depth analysis was then conducted for the following 22 apps: Bebe+, iMamma, La mia gravidanza (Aleksei Neiman), Autosvezzamento ricette veloci, Gravidanza+, Mamma 2.0, Vera mamma, Yoga in Gravidanza: la guida, VITA: prodotti in gravidanza, Dalla nascita, Gravidanza Sprout, Mamma in salute, Calendario WomanLog Baby, La mia gravidanza (Doctissimo), Non Da Sola (Emilia Romagna Region-specific app), iBimbo, SOS bimbi, Happy mamma (Toscana Region-specific app), Mustela per me, Seimammaeuganea, Pregnancy, and eMyBaby, respectively.

In general, these apps met a mean of 20.9 items (29%), ranging from a minimum of 6 items (8%) to a maximum of 37 items (52%), with only one app achieving at least 50% of the desired characteristics (i.e., iMamma). More than half of the apps included general information about pregnancy (n=14, 64%) and nutritional advice for the mother (n=11, 50%), required entry of the last date of the period or expected delivery date (n=12, 55%) and allowed its modification after medical reevaluation (n=12, 55%), and 12 apps offered the user a FAQ page (55%). In addition, most apps presented a privacy policy (n=17, 77%), most frequently in Italian (n=13, 59%), and offered free content (n=14, 64%), but half of them asked users to authenticate (n=11). All apps used a simple, informal, and friendly tone, and 86% of them (n=19) employed intuitive and predictable navigation patterns. Nonetheless, the majority of the remaining content was not addressed in a sufficient number of apps: women rights during pregnancy, immunizations needed by mother and newborn, information about maternal and child health services, free or paid exams during pregnancy, manifest neonatal complications and warning signs, postpartum recovery for the mother, practical tips for caring for the newborn, nutritional counseling and hygiene practices for the mother in the postnatal period, and postpartum family planning and birth spacing.

Regarding reminders and push notifications, most apps did not offer user-settable alerts, except for medical appointments (i.e., prenatal and postnatal checkups for the mother and newborn). In addition, many features that allow the mother to store notes and records, such as maternal health parameters, maternal anthropometric measurements (weight before and during pregnancy and in postpartum), maternal health parameters, fetal/newborn length and weight, and developmental milestones, as well as a maternal and infant sleep diary, were mostly unavailable. Virtually all apps did not provide primary users with social mechanisms to interact with peers or health professionals to share experiences (e.g., community, forum, chat), and only six of them (27%) were integrated with a social network. Regarding other features, most apps lacked credentials or scientific responsibility for the content (27% and 23%, respectively) and certification of the app as a medical device (none; the only app met exclusion criteria and was therefore not analyzed further). In addition, basic requirements for digital tools were not met, including the ability to backup and restore (23%) or download data (14%), the availability a multilingual version (14%), or adaptability to screen orientation in portrait or landscape (18%). Finally, none of the apps was able to interact with the local healthcare provider to book exams/visits, while some were able to locate the user to provide more detailed information about services available in the area (14%). Full results of the analysis of the 22 apps can be found in Table 6.

Domain	Item	Bebe+	iMamma	La mia gravidanza (Aleksei Neiman)	Autosvezzamento ricette veloci	Gravidanza+	Mamma 2.0	Vera mamma	Yoga in Gravidanza: la guida	VITA: prodotti in gravidanza	Dalla nascita	Gravidanza Sprout	Mamma in salute	Calenodario WomanLog Baby	La mia gravidanza (Doctissimo)	Non Da Sola	iBimbo	SOS bimbi	happy mamma	mustela per me	seimammaeuganea	pregnancy	eMyBaby	yes, n (%)	no, n (%)	Y/N, n (%)	P, n (%)
Pregnancy care and counselling	1	N	Y	N	N	Y	N	Y	N	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y	Y	N	14 (64)	8 (36)	0 (0)	0 (0)
	2	N	Y	N	N	N	N	N	N	N	Y	N	N	N	Y	Y	N	N	Y	Y	Y	N	N	7 (32)	15 (68)	0 (0)	0 (0)
	3	N	N	N	N	Y	N	N	N	Y	N	Y	Y	N	Y	Y	N	N	Y	Y	Y	N	N	9 (41)	13 (59)	0 (0)	0 (0)
	4	N	Y	N	N	Y	N	Y	N	Y	N	Y	Y	N	Y	Y	N	N	N	Y	N	N	N	9 (41)	13 (59)	0 (0)	0 (0)
	5	N	P	P	N	N	N	N	N	N	N	P	Y	N	Y	Y	N	N	Y	N	N	N	N	4 (18)	15 (68)	0 (0)	3 (14)
	6	N	N	N	N	N	N	N	N	N	Y	N	Y	N	N	Y	N	P	Y	N	Y	N	N	5 (23)	16 (73)	0 (0)	1 (5)
	7	N	Y	N	N	Y	N	Y	N	N	Y	Y	Y	N	Y	Y	N	N	Y	P	Y/N	N	N	9 (91)	11 (50)	1 (5)	1 (5)
	8	N	Y	N	N	Y	N	Y	Y	Y	N	N	N	N	Y	N	N	N	Y	Y	N	N	N	8 (36)	14 (64)	0 (0)	0 (0)
	9	N	Y	N	N	Y	N	Y	N	Y	Y	Y	Y	N	Y	Y	N	N	Y	Y	N	N	N	11 (50)	11 (50)	0 (0)	0 (0)
	10	N	Y	N	N	Y	N	N	N	Y	Y	N	Y	N	Y	N	N	N	N	Y	Y	N	N	8 (36)	14 (64)	0 (0)	0 (0)
	11	N	Y	N	N	Y	N	N	N	Y	Y	Y	Y	N	Y	Y	N	N	Y	P	Y	N	N	10 (45)	11 (50)	0 (0)	1 (5)
	12	N	Y	N	N	Y	N	N	N	N	Y	Y	Y	N	N	Y	N	N	Y	Y/N	Y	N	N	8 (36)	13 (59)	1 (5)	0 (0)
	13	N	Y	Y	N	Y	N	Y	N	Y	N	Y	Y	N	Y	P	N	N	N	Y	Y	N	N	10 (45)	11 (50)	0 (0)	1 (5)
	14	N	Y	Y	N	Y	N	Y	N	Y	Y	Y	Y	N	Y	N	N	N	N	P	N	N	N	9 (41)	12 (55)	0 (0)	1 (5)
	15	N	Y	P	N	P	N	P	N	N	P	P	Y	N	P	Y	N	N	P	N	Y/N	N	N	3 (14)	11 (50)	1 (5)	7 (32)

Postnatal care and counselling for both mother and child	16	N	N	Y	N	N	N	Y	N	Y	N	Y	N	N	Y	P	N	N	N	N	N	N	N	5 (23)	16 (73)	0 (0)	1 (5)
	17	Y	N	N	N	Y	N	N	N	Y	N	N	P	N	Y	P	N	N	Y	N	Y	N	N	6 (27)	14 (64)	0 (0)	2 (9)
	18	N	N	N	N	N	N	N	N	Y	N	N	Y	N	Y	N	N	Y	Y	N	N	N	N	5 (23)	17 (77)	0 (0)	0 (0)
	19	Y	N	N	N	Y	N	Y	N	Y	N	Y	Y	N	Y	Y	N	N	Y	N	Y/N	N	N	9 (41)	12 (55)	1 (5)	0 (0)
	20	P	N	N	N	N	N	P	N	N	N	N	Y	N	P	P	N	P	Y	N	N	N	N	2 (9)	15 (68)	0 (0)	5 (23)
	21	P	N	N	N	N	N	Y	N	Y	N	N	N	N	Y	N	N	N	N	N	Y	N	N	4 (18)	17 (77)	0 (0)	1 (5)
	22	Y	N	N	N	Y	N	Y	N	Y	N	N	Y	Y	N	N	N	N	N	N	N	N	N	6 (27)	16 (73)	0 (0)	0 (0)
	23	N	N	N	N	N	Y	Y	N	Y	Y	N	N	N	Y	N	N	N	N	N	N	N	N	5 (23)	17 (77)	0 (0)	0 (0)
	24	Y	N	N	N	Y	N	N	N	Y	Y	Y	Y	N	Y	Y	N	Y	Y/N	N	P	N	N	9 (41)	11 (50)	1 (5)	1 (5)
	25	N	N	N	N	N	N	N	N	P	Y	N	N	N	Y	N	N	P	N	N	N	N	N	2 (9)	18 (82)	0 (0)	2 (9)
	26	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	Y/N	N	N	N	N	1 (5)	20 (91)	1 (5)	0 (0)
Reminders and push notifications	27	Y	Y	N	N	N	N	N	N	Y	Y	Y	Y	N	P	N	N	N	N	Y	Y	N	Y	9 (41)	12 (55)	0 (0)	1 (5)
	28	N	Y	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	Y	N	N	N	3 (14)	19 (86)	0 (0)	0 (0)
	29	N	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	3 (14)	19 (86)	0 (0)	0 (0)
	30	N	N	N	N	N	N	N	N	N	N	Y/N	Y	N	N	N	N	N	N	Y	N	N	N	2 (9)	19 (86)	1 (5)	0 (0)
	31	Y	Y	Y	N	Y	N	N	N	N	N	N	N	Y	N	N	N	N	Y/N	Y	N	Y	N	7 (32)	14 (64)	1 (5)	0 (0)
Notes and records	32	N	Y	Y	N	Y	N	Y	N	N	N	Y	Y	N	Y	Y	N	N	N	Y	Y	Y	Y	12 (55)	10 (45)	0 (0)	0 (0)
	33	N	Y	Y	N	Y	N	Y	N	Y	N	Y	Y	N	Y	N	Y	N	N	Y	Y	Y	N	12 (55)	10 (45)	0 (0)	0 (0)
	34	N	Y	N	N	N	N	N	N	N	N	N	P	N	N	N	N	N	N	Y	N	N	Y	3 (14)	18 (82)	0 (0)	1 (5)
	35	N	Y	Y	N	Y	N	Y	N	N	N	Y	Y	N	Y	N	N	N	N	N	N	Y	Y	9 (41)	13 (59)	0 (0)	0 (0)
	36	P	P	N	N	N	N	N	N	P	N	N	P	Y	N	N	Y	N	N	Y	N	N	N	3 (14)	15 (68)	0 (0)	4 (18)

	37	P	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	2 (9)	19 (86)	0 (0)	1 (5)
	38	Y	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	P	N	N	Y	N	N	N	3 (14)	18 (82)	0 (0)	1 (5)
	39	N	P	Y	N	P	N	Y	N	Y	N	N	N	N	N	N	N	N	N	Y	N	Y	Y	6 (27)	14 (64)	0 (0)	2 (9)
	40	Y	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	Y	N	N	Y	N	N	Y	5 (23)	17 (77)	0 (0)	0 (0)
	41	N	Y	Y	N	Y	N	Y	N	N	N	Y	Y	N	Y	N	N	N	N	Y	N	Y	Y	10 (45)	12 (55)	0 (0)	0 (0)
	42	Y	Y	Y	N	Y	N	Y	N	N	N	Y	N	N	N	N	N	N	N	Y	N	N	N	7 (32)	15 (68)	0 (0)	0 (0)
	43	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	1 (5)	21 (95)	0 (0)	0 (0)
	44	Y	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	Y	N	N	Y	N	N	N	4 (18)	18 (82)	0 (0)	0 (0)
Social support	45	N	Y	N	Y	N	Y	N	N	N	N	Y	Y	N	N	Y	N	N	N	N	N	N	N	6 (27)	16 (73)	0 (0)	0 (0)
	46	Y	Y	N	N	Y	N	Y	N	N	P	N	Y	N	Y	Y	Y	Y	Y	Y	N	Y	N	12 (55)	9 (41)	0 (0)	1 (5)
	47	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	1 (5)	21 (95)	0 (0)	0 (0)
	48	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	1 (5)	21 (95)	0 (0)	0 (0)
App technical features	49	Y	Y	N	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	Y/N	N	Y	Y	N	Y	Y	11 (50)	10 (45)	1 (5)	0 (0)
	50	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	N	Y	Y	Y	N	Y	17 (77)	5 (23)	0 (0)	0 (0)
	51	Y	Y	Y	Y	Y	N	Y	Y	N	N	N	N	N	N	Y	Y	NA	Y	Y	Y	NA	Y	13 (59)	7 (32)	0 (0)	0 (0)
	52	Y	Y	Y	N	N	Y	Y	N	N	Y	Y/N	Y	N	Y	Y	Y/N	Y	Y	Y	Y	N	Y	14 (64)	6 (27)	2 (9)	0 (0)
	53	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	1 (5)	21 (95)	0 (0)	0 (0)
	54	N	Y	Y	N	Y	N	N	N	N	N	N	N	N	Y	Y	N	N	Y/N	N	N	N	Y	6 (27)	15 (68)	1 (5)	0 (0)
	55	N	N	N	N	N	N	N	N	N	Y	N	Y	N	Y	Y	N	Y	Y	N	N	N	N	6 (27)	16 (73)	0 (0)	0 (0)
	56	N	N	N	N	N	N	N	N	N	Y	N	Y	N	Y	N	N	P	Y	N	N	N	N	4 (18)	17 (77)	0 (0)	1 (5)
	57	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	Y	N	Y	Y	N	Y	N	N	5 (23)	17 (77)	0 (0)	0 (0)

	58	Y	N	N	N	Y	N	N	N	N	N	N	N	Y	N	N	Y/N	N	N	N	N	Y	Y	5 (23)	16 (73)	1 (5)	0 (0)
	59	Y	N	N	N	Y	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	3 (14)	19 (86)	0 (0)	0 (0)
	60	N	N	N	Y	N	N	N	N	N	N	N	N	Y/N	N	Y/N	N	N	N	N	N	Y	Y	3 (14)	17 (77)	2 (9)	0 (0)
	61	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	Y	Y/N	N	N	N	N	3 (14)	18 (82)	1 (5)	0 (0)
	62	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0 (0)	22 (100)	0 (0)	0 (0)
	63	Y	Y	Y	N	Y	N	N	N	Y	N	N	N	Y	Y	N	Y/N	N	N	Y	N	Y	N	9 (41)	12 (55)	1 (5)	0 (0)
	64	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	22 (100)	0 (0)	0 (0)	0 (0)
	65	N	N	N	Y/N	N	Y	N	Y	N	N	Y/N	Y/N	Y	N	N	N	N	N	N	N	Y	N	4 (18)	15 (68)	3 (14)	0 (0)
	66	N	Y	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	2 (9)	20 (91)	0 (0)	0 (0)
	67	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y	Y	19 (86)	3 (14)	0 (0)	0 (0)
	68	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	Y	N	Y	Y	N	Y	N	N	5 (23)	17 (77)	0 (0)	0 (0)
	69	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0 (0)	22 (100)	0 (0)	0 (0)
	70	N	Y	N	N	N	N	N	Y	N	N	Y/N	N	N	N	Y	N	Y	N	N	N	N	N	4 (18)	17 (77)	1 (5)	0 (0)
	71	Y	N	Y/N	N	Y	N	N	N	N	N	Y	N	Y	N	N	N	N	N	N	N	N	N	4 (18)	17 (77)	1 (5)	0 (0)
tot yes, n (%)		21 (30)	37 (52)	18 (25)	6 (8)	32 (45)	8 (11)	25 (35)	7 (10)	26 (37)	18 (25)	22 (31)	33 (46)	14 (20)	34 (48)	26 (37)	10 (14)	11 (15)	26 (37)	33 (46)	21 (30)	15 (21)	16 (23)				
tot no, n (%)		46 (65)	31 (44)	50 (70)	64 (90)	37 (52)	63 (89)	44 (62)	64 (90)	43 (61)	51 (72)	43 (61)	34 (48)	56 (79)	34 (48)	40 (56)	56 (79)	55 (77)	39 (55)	34 (48)	46 (65)	55 (77)	55 (77)				
tot yes/no, n (%)		0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 (6)	1 (1)	1 (1)	0 (0)	1 (1)	4 (6)	0 (0)	5 (7)	1 (1)	3 (4)	0 (0)	0 (0)				
tot partially, n (%)		4 (6)	3 (4)	2 (3)	0 (0)	2 (3)	0 (0)	2 (3)	0 (0)	2 (3)	2 (3)	2 (3)	3 (4)	0 (0)	3 (4)	4 (6)	1 (1)	4 (6)	1 (1)	3 (4)	1 (1)	0 (0)	0 (0)				

Table 6. Results of the analysis of the content, functionalities, and technical features of the 22 apps, from Brunelli et al (91).

MARS rating for global app quality ranged from a minimum score of 1.9 to a maximum score of 4.5, with 68% of apps scoring above 3. Ratings for engagement ranged from 1.6 to 4.1 (median 3.0), for functionality from 2.5 to 4.9 (median 4.0), for aesthetics from 1.8 to 4.3 (median 3.7), and for information from 1.7 to 4.8 (median 3.5). Mean MARS ratings for all 22 apps analyzed is shown in Table 7.

App	MARS domain				
	Engagement	**Functionality**	**Aesthetics**	**Information**	**App quality**
Bebe+	3.8	3.9	4.2	4.0	4.0
iMamma	3.5	3.6	3.7	3.5	3.5
La mia gravidanza	2.5	4.3	3.3	2.1	3.0
Autosvezzamento ricette veloci	2.2	4.8	3.5	2.9	3.3
Gravidanza+	3.5	4.5	4.0	3.9	3.9
Mamma 2.0	1.6	2.5	1.8	1.8	1.9
Vera mamma	3.6	4.1	3.3	3.7	3.7
Yoga in Gravidanza (la guida)	3.4	3.9	4.2	3.3	3.7
VITA: prodotti in gravidanza	3.9	3.3	3.8	3.6	3.7
Dalla nascita	2.9	4.5	3.6	3.8	3.7
Gravidanza Sprout	3.5	3.6	3.8	2.9	3.5
Mamma in salute	4.0	4.9	4.3	4.8	4.5
Calendario WomanLog Baby	2.4	2.9	2.3	2.3	2.5
La mia gravidanza (Doctissimo)	4.1	4.4	4.0	3.5	4.0
Non Da Sola	2.5	2.8	2.8	3.7	2.9
iBimbo	2.4	4.4	3.7	2.4	3.2
SOS bimbi	2.3	4.5	4.0	3.8	3.6
Happy mamma	3.0	4.4	3.7	4.0	3.7
Mustela per me	3.1	3.6	3.9	2.8	3.3
Seimammaeuganea	2.9	4.1	3.7	3.6	3.6
Pregnancy	2.6	3.7	2.4	1.7	2.6
eMyBaby	2.0	3.7	2.9	2.2	2.7

Table 7. MARS ratings for the 22 apps analyzed, from Brunelli et al. (91).

Q3. Users' needs and expectations

Between November 2021 and August 2022, health professionals (November 2021 – March 2022) and expectant parents in all three trimesters of pregnancy and new parents (May – August 2022) were recruited as a convenience sample to participate in a cross-sectional study. Health professionals included physicians (i.e., gynecologists, neonatologists and pediatricians), midwives, nurses, supporting staff, and residents working and studying at the Institute for Maternal and Child Health - IRCCS Burlo Garofolo. Expectant and new mothers and fathers were enrolled during scheduled consultations and check-ups or in the postnatal period during hospitalization at IRCSS Burlo Garofolo. Expectant and new parents with cognitive impairment or with poor understanding of Italian were not included. All participants were informed of the purpose of the study and were asked to provide informed consent in order to be able to participate to the survey. Participants completed the survey with paper and pencil in approximately 15 minutes and with the assistance of a researcher who was available to answer any questions. To ensure confidentiality, the consent form and completed questionnaire were linked to a random code. The study was approved by the Institutional Review Board of the Institute for Maternal and Child Health, IRCCS Burlo Garofolo, Trieste (Italy) (Code: IRB-BURLO 08/2021).

Based on the items included in the Q2 of this project (91), we made slight modifications to make some items more explicit, obtaining a questionnaire with 83 items covering the same six domains: 1) *Pregnancy care and counselling* (26 items); 2) *Postnatal care and counselling for both mother and child* (or *Mother and child postnatal care and counselling* (13 items); 3) *Reminders and push notifications* (4 items); 4) *Notes and records* (13 items); 5) *Social support* (4 items); and 6) *App technical features* (23 items). A 5-point Likert scale was used: 0-not important at all, 1-of little importance, 2-of average importance, 3-very important, 4-absolutely essential. In addition, health professionals were asked about the sources of information most frequently used by their patients, the improvements they expected to see in a dedicated mHealth app to support the first 1000 days of life, the settings and situations in which pregnant women typically receive information and advice, and the main barriers health professionals experience or perceive in communicating effectively with pregnant women. Sociodemographic data of the participating health professionals were collected to describe the participants, including professional profile, working area, and years of working experience. Expectant and new parents were also asked about the sources/tools they most frequently use to learn about pregnancy and postpartum period, as well as the improvements they expected to see from using a mHealth app designed specifically to support the first 1000 days of life. In addition, the following data were collected: sociodemographic characteristics such as age, place of residence (zip code), country of origin, mother language, level of education, working conditions and hours, if they were health professionals, marital status, and family income; data on current and previous pregnancies; and data on the partner (age, biological

paternity of the coming child, country of origin, mother language, level of education, working conditions and working hours).

Descriptive statistics (mean, standard deviation (SD) and frequency) were obtained for Likert ratings given by all participants. Health professionals and parent responses, and items with more than five missing values were excluded. After exclusion of almost completely non-responding participants and/or due to typing errors in the questionnaire, 81 items from 145 health professionals and 159 expectant and new parents were available for analysis. The health professionals' and parents' datasets were managed separately, with the former 64 and the latter 48 missing total values filled with multivariate imputation via chained equations MICE function with five imputed data sets and ten maximum interactions. The domain score was assigned as the average score of the items in the domain. Ward hierarchical clustering was used to classify respondents according to their response patterns. The number of different clusters was examined based on the ability of the clusters to meaningfully describe the respondent behavior in relation to the six question domains. The final number of clusters was selected by the authors based on the meaningful description of the respondents' answers. The means of each item between health professionals and parents, and between father and mother were compared using a two-sample z-test. Data were analyzed in R using the R packages: mice, ggplot2, dplyr, pvclust, and Hmisc (96).

The point of view of health professionals

In our cross-sectional study, 145 health professionals were enrolled. Their characteristics in terms of professional profile, working area, and years of working experience are shown in Table 8.

		Working area			**Years of working experience** *(missing 4)*		
		Obstetrics and Gynecology	Nursery and neonatology	Pediatrics	< 3	3-5	> 5
Physician	33 (23)	17	4	12	1	3	28
Medical resident	43 (30)	23	0	20	20	21	1
Midwife	30 (21)	21	9	0	7	3	19
Nurse	24 (16)	10	2	12	1	7	16
Supporting staff	15 (10)	11	0	4	0	1	13
Total, n (%)	145	82 (57)	15 (10)	48 (33)	29 (20)	35 (24)	77 (53)

Table 8. Characteristics of health professionals who participated in the survey.

Regarding their opinion on the sources of information most frequently used by their patients, health professionals indicated social media (83%), practice communities (70%), and live communities (66%). In terms of their expectations for implementing a mHealth app to support the first 1000 days of life, they focused primarily on improved communication (69%) and increased knowledge and awareness among women (61%), with more than a third of them also expecting a reduction in the amount of time spent providing information to patients as well (35%). See Table 9 for the full responses from health professionals.

Patients most used sources of information*	**n (%)**
Social media (e.g., Facebook, Twitter)	120 (83)
Community of practice (e.g., blog, forum, online platforms, websites)	102 (70)
Digital communication tools (e.g., WhatsApp)	64 (44)
Live communities (e.g., peer groups, training groups)	96 (66)
Certified information (e.g., guidelines, services chart)	15 (10)
Other	10 (7)[§]
Expected improvements from the use of a dedicated mHealth app*	
Improved communication between pregnant women/new mothers/couples and health professionals	100 (69)
Optimization of time spent providing information by health professionals	51 (35)
Use of a common language	42 (29)
Increased preparation of pregnant women/new mothers	88 (61)

*Table 9. Summary of opinions and expectations of 145 health professionals. * multiple responses allowed; § private practitioners, family, friends.*

According to health professionals, the most important opportunities to inform and educate their patients are individual counselling (n=127; 88%), prenatal classes (n=107; 74%), and ultrasound examinations (n=91; 63%), as well during prenatal screening (n=52; 36%). Three out of four health professionals (physicians, midwives, and supporting staff) mentioned three of these educational opportunities, whereas medical residents and nurses mentioned only two on average. Health professionals cited the negative impact of fake

news (n=123; 85%), language difficulties (n=100; 69%), and low patient's education levels (n=57; 39%) as the main barriers from sharing information and education during professional activities.

Regarding the desirable characteristics of a mHealth app for the first 1000 days of life, the distribution of the mean scores assigned by health professionals for the domains of desirable content, functionalities, and technical features is shown in Figure 9. Overall, higher values were given for the domains of *Pregnancy care and counselling*, *Postnatal care and counselling for both mother and child* and *App technical features*, as shown by the left-skewed diagrams of a), b), and f).

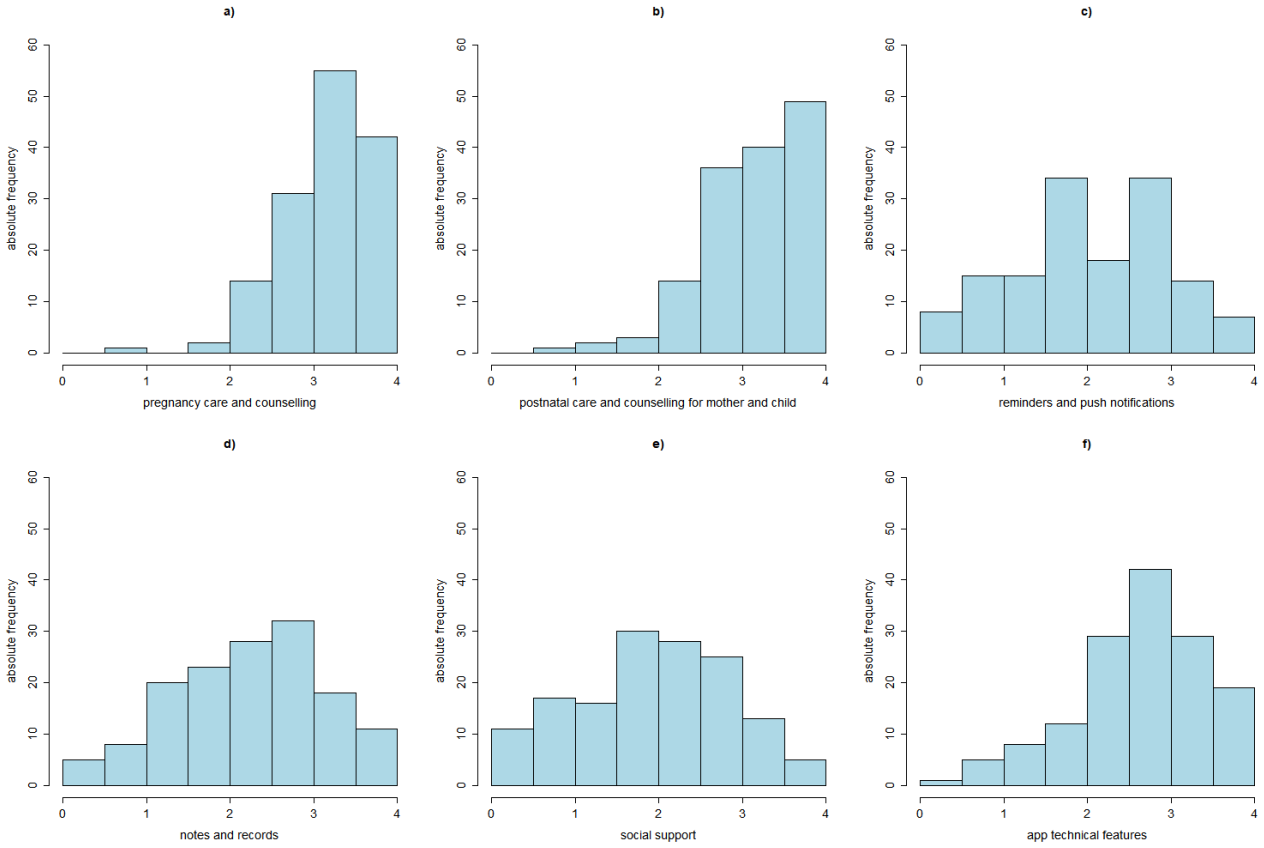


Figure 9. Distribution of health professionals' opinions regarding the content, functionalities, and technical features of a mHealth app to support the first 1000 days of life, grouped by the six domains.

In terms of content (*Pregnancy care and counselling*, and *Postnatal care and counselling for both mother and child* domains), items such as infections that may occur during pregnancy (rating: mean±SD, 3.6±0.7), information about pregnancy in general (3.5±0.7), manifest neonatal complications and warning signs (3.5±0.8), immunizations that the mother needs to receive during pregnancy (3.4±0.8), fetal movements (3.4±0.9), labor (3.4±0.9), delivery (3.4±0.8), postpartum mental disorders (3.4±0.9), and immunizations needed during the first 1000 days of life (3.4±0.9), reached the highest mean rates. In general, 85% of the items (33/39) scored from at least of average importance up to absolutely essential. Based on their experience in clinical practice, three health professionals suggested that the topic of sexuality during pregnancy and after birth should be included in the content. Lower scores were given to items describing the

possible functions of the app (*Reminders and push notifications*, *Notes and records,* and *Social support* domains), all of which were rated as of little or no importance (20/20). On the other hand, very low scores were given to functionalities such as the app's integration with social networks (1.5±1.2), the ability to schedule reminders (1.7±1.3) or record routine activities of the mother or the newborn (1.73±1.2), the ability to create a sleep diary for the mother (1.7±1.2) and the newborn (1.8±1.3), and the presence of social network mechanics that allows users to interact with each other and share experiences (1.8±1.2). Among the *App technical features*, the presence of multilingual support was rated highest (3.4±0.9), and the app's ability to locate users geographically to provide more detailed information was rated lowest (1.8±1.2). The list of health professionals' ratings of the content, functionalities, and technical features can be found in Table 10.

Domain	Item	Rating	
		Mean	SD
Pregnancy care and counselling	General information about pregnancy (e.g., nutrition/weight gain, fitness, oral health, travel health)	3.5	0.7
	Information about drugs that can be taken during pregnancy	3.4	1.0
	Information about vitamin supplement during pregnancy	2.8	1.0
	A list of free-of-charge and upon payment examinations to be carried out during pregnancy	3.4	0.8
	Information about infections that can occur during pregnancy (e.g., toxoplasmosis, cytomegalovirus)	3.6	0.7
	Information about the immunizations that the mother needs to receive during pregnancy	3.4	0.8
	Information about voluntary termination of pregnancy	3.2	1.0
	Information about spontaneous miscarriage	3.1	1.0
	Information about violence/abuse during pregnancy	3.1	1.1
	Information about possible problems related to pregnancy	3.2	0.9
	Information on fetal development	3.2	0.9
	Information about fetal movements	3.4	0.9
	Information about prevention measures during pregnancy (e.g., home accidents, car accidents)	3.2	0.9
	Information about labor	3.4	0.9
	Information about delivery (e.g., epidural anesthesia, caesarean section)	3.4	0.8
	Information about cord blood donation	2.7	1.0
	Information about pre-delivery courses	3.2	0.9
	Information about in-hospital stay for mother and newborn at the time of delivery	2.9	0.9
	Information about the woman's rights during pregnancy (e.g., at work, at school, economical support)	3.3	0.9
	Information on prenatal risks and life-threatening conditions for both the mother and the fetus during pregnancy	3.3	0.8
	Information about maternal physiological and metabolic changes occurring during pregnancy	3.0	0.9
	Information about maternal or child services accessibility and contacts	3.2	0.9
	Information about available prenatal diagnostic tests	3.3	0.8
	Information on physical exercises and workouts for women during pregnancy	2.9	0.9
	Month/trimester-related tips for pregnant women	3.1	0.9
	A list of essentials for the hospital luggage	2.2	1.2
Postnatal care and counselling for both mother and child	A list of essentials for the first welcome of the mother and baby at home	2.8	1.1
	Information about maternal physiological and metabolic changes occurring during the postpartum period	3.0	1.0
	Information about manifest neonatal complications and warning signs	3.5	0.8
	Information about postpartum mental disorders, such as postpartum depression and baby blues (e.g., symptoms and coping strategies)	3.4	0.9
	Tips for the postpartum recovery process	3.1	0.9
	Information on breastfeeding practices	3.3	0.9
	Information on mother's nutrition after childbirth and during breastfeeding	3.0	0.9
	Information about drugs compatible with breastfeeding	3.3	0.8
	Practical tips on how to take care of the newborn (e.g., hygiene, diaper changing, and burping)	3.2	0.8
	Information about neonatal screening procedures	3.1	0.9
	Information about the immunizations needed during the first 1000 days	3.4	0.9
	Information about risk prevention measures regarding the newborn	3.2	0.9
	Information on methods for postpartum family planning and birth spacing	3.0	1.0
Reminders and push notifications	App's ability to send push notification reminders when the pregnancy month/trimester begins	2.3	1.2
	App's ability to schedule reminders for routine activities (e.g., drinking, diapering, feeding, pumping, and sleeping)	1.7	1.3
	App's ability to change reminders and notifications settings	2.4	1.1
Notes and records	App's ability to record the latest period date or the expected delivery date	2.5	1.2
	App's ability to change the expected delivery date following medical re-evaluation	2.7	1.1

	App's ability to record physiological values of the mother (e.g., pressure, temperature, and mood)	2.4	1.1
	App's ability to record contractions or kicks	2.3	1.3
	App's ability to record routine activities of the mother or the newborn (e.g., drinking, steps, diapers changes, bottle feeding, and sleeping patterns/times)	1.7	1.2
	App's ability to record the medical care the mother or the newborn has received (e.g., medications and vaccination shots)	2.6	1.1
	App's ability to track the newborn's developmental milestones	2.3	1.2
	App's ability to record anthropometric measurements of the fetus (e.g., height, weight, and head circumference)	2.4	1.2
	App's ability to record anthropometric measurements of the newborn (e.g., height, weight, and head circumference)	2.4	1.1
	App's ability to record measurements of the mother's weight at baseline and during pregnancy	2.4	1.1
	App's ability to record measurements of the mother's weight in the postnatal period	2.0	1.1
	App's ability to create a sleep diary for the mother	1.7	1.2
	App's ability to create a sleep diary for the newborn	1.8	1.3
Social support	Integration of the app with social networks (e.g., Facebook, Twitter)	1.5	1.2
	Presence of a FAQ (frequently asked questions) page in the app	2.5	1.1
	Presence of social mechanisms allowing the user to interact with each other and share experiences (e.g., community, forum, and chat)	1.8	1.2
	Presence of social mechanisms allowing the user to interact with healthcare staff (e.g., community, forum, and chat)	2.4	1.1
App technical features	Authentication request to the user	2.6	1.3
	Presence of a privacy policy in the app	2.8	1.2
	If present, availability of a privacy policy properly written in Italian	2.7	1.2
	Ability for the user to access all app content for free (without any payment)	3.3	1.0
	Access to full app usage based on specific inclusion criteria (e.g., national health service card, place of living, and certification by a health professional)	2.4	1.3
	Requirement for the user to sign an informed consent to use the app	2.4	1.3
	Presence of references about the contents provided through the app	2.7	1.1
	Presence of a glossary of the most used medical terms	2.9	1.1
	Declaration (through the provision of specific references) of the scientific responsibility of the contents provided through the app	2.4	1.1
	Possibility to back-up/restore data within the app	2.4	1.2
	Possibility to download data collected through the app	2.6	1.1
	Presence of multilanguage support	3.4	0.9
	App's ability to geolocate the user to provide more detailed information	1.8	1.2
	App's ability to book visits, vaccinations, and checkups	3.1	1.1
	App's ability to update users' account preferences	2.7	1.1
	Use of a simple, informal, and friendly tone by the app	2.9	1.1
	App's ability to adapt to screen orientation (both portrait and landscape)	2.6	1.2
	App's ability to learn user's preferences over time	2.2	1.3
	App's ability to implement intuitive and predictable navigation patterns	3.1	1.0
	Presence of app contents validated by an institutional source (local, regional, or national)	3.0	1.1
	Presence of certification of the app as a medical device according to Italian law	2.3	1.3
	App's ability to provide contents through different ways (e.g., text, video, audio)	2.7	1.1
	App's ability to ask about user satisfaction	2.5	1.2

Table 10. Ratings for the content, functionalities, and technical features of the proposed app to support the first 1000 days of life by health professionals.

Health professionals were then grouped in clusters according to their responses: a section of the cluster tree with three clusters was deemed by the researchers to be meaningful to the domains of the items, as it clearly identified those with high, medium, and low scores, as shown in Figure 10. *High demanding cluster* narrowly grouped respondents who answered giving very high average score (e.g., very important or absolutely essential) to questions on *Pregnancy care and counselling*, *Postnatal care and counselling for both mother and child*, *App technical features*, and *Notes and records* domains. *Medium demanding cluster* responses were also highly scored for the same four domains, but with a median rate closer to average importance) and a broader distribution. In contrast, *low demanding cluster* was characterized by a more skeptical attitude toward all items, especially the domains of *Reminders and push notifications*, *Notes and records*, and *Social support* domains.

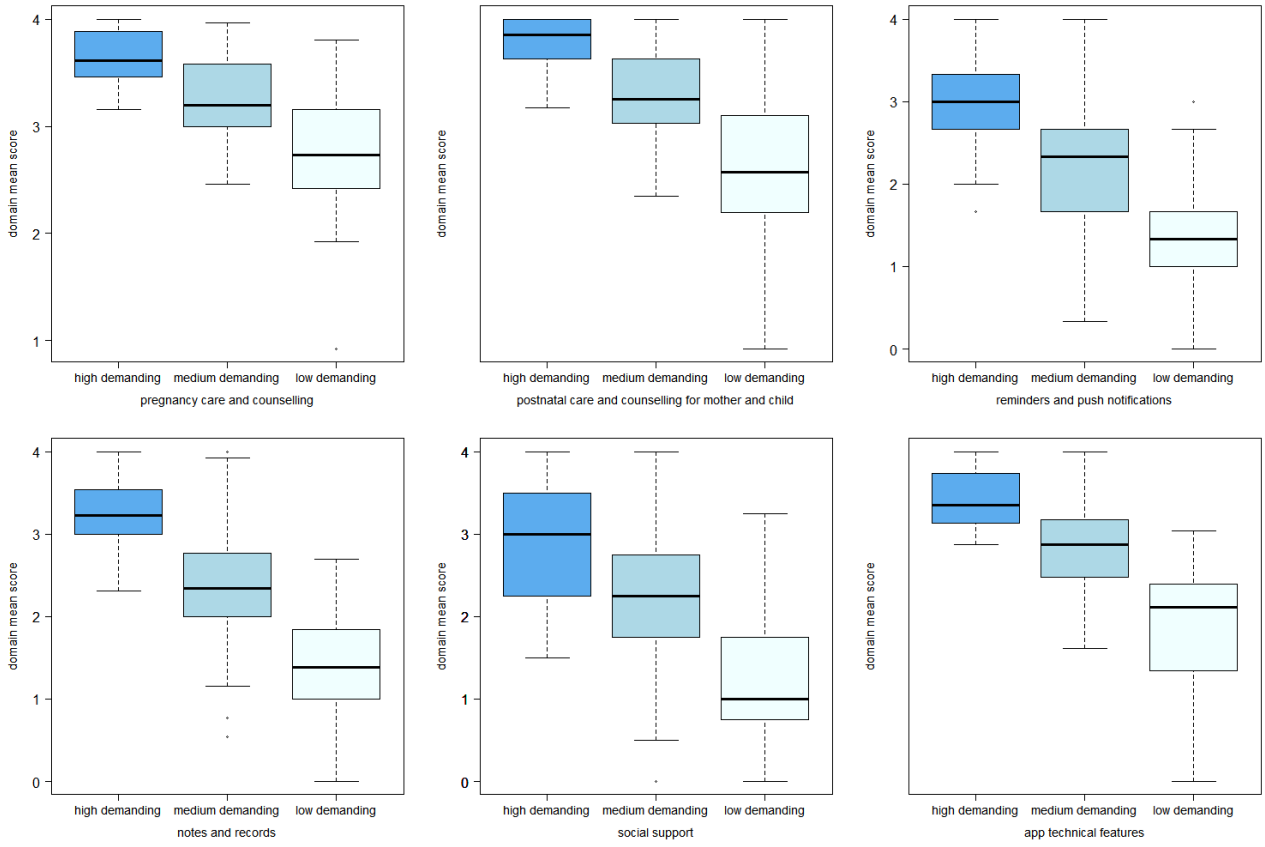


Figure 10. Distribution of health professionals' responses by cluster for each domain.

In terms of the number of the components of clusters, *medium demanding cluster* was the most represented with 51% (74/145) of all respondents, while *high demanding* and *low demanding clusters* comprised 20% (29/145) and 29% (42/145) of respondents, respectively. When analyzing the detailed composition of the three clusters, we found that *high demanding cluster* was evenly composed of health professionals' profiles (21% physicians, 17% medical residents, 14% nurses, 21% midwives), with supporting staff slightly outnumbered (28%). In contrast, *medium demanding cluster* consisted of a larger number of medical residents (35%), a smaller number of supporting staff (8%), and similar proportions of physicians (16%),

nurses (18%), and midwives (23%). Finally, *low demanding cluster* consisted mostly of physicians (36%) and medical residents (29%), while again supporting staff made up a very small proportion (2%) and midwives and nurses each accounted for 17%. Looking at the distribution of health professionals within their professional profiles in clusters, the majority of medical residents (60%), midwives (57%) and nurses (54%) belonged to *medium demanding cluster*, while 53% of all supporting staff belonged to *high demanding cluster* (Figure 11 a). This distribution of health professional profiles among clusters was significantly different (p=0.02). Looking at the distribution of professionals by their working area in clusters (Figure 11 b), 49% of those working in obstetrics/gynecology, 87% of those working in nursery/neonatology, and 44% of those working in the pediatric area were grouped in *medium demanding cluster*. There were no health professionals working in nursery/neonatology who belonged to *low demanding cluster*. The difference in clusters compositions by working area was statistically significant (p=0.02). When examining the allocation of health professionals to clusters according to their working experience (Figure 11 c), no statistically significant difference was found.

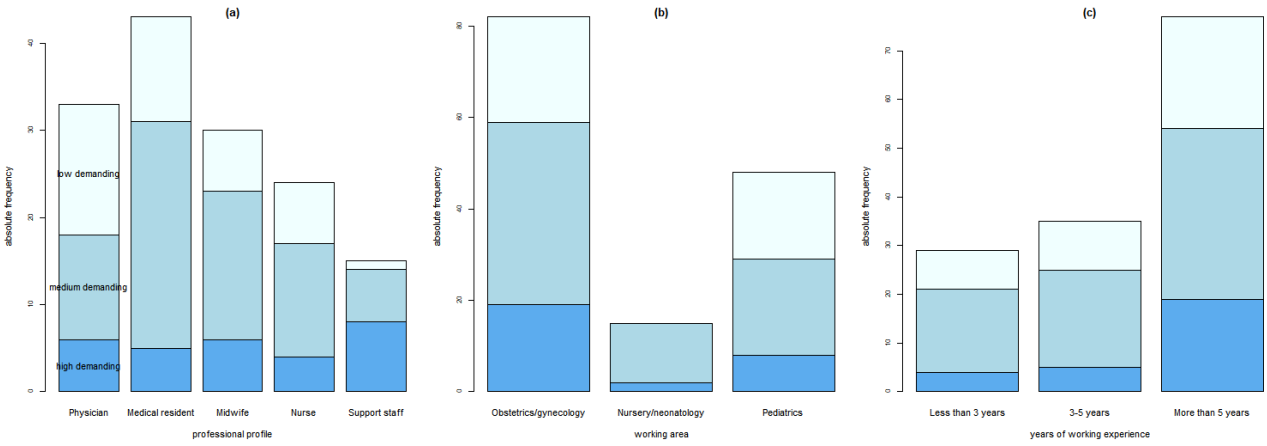


Figure 11. Distribution of clusters of health professionals regarding content, functionalities, and technical features of the mHealth app, grouped by professional profile, working area, and years of working experience.

The expectations of health professionals (i.e., secondary users) involved in the care of pregnant women and new mothers with their babies for a mHealth app to support the first 1000 days of life are currently being reviewed for publication.

The point of view of expectant and new parents

The expectant and new parents who participated in our cross-sectional study were 94 women (19 in the first trimester of pregnancy, 21 in the second trimester, 36 in the third trimester, and 16 in the postpartum period; missing data for one mother) and 69 men partners (17 in the first trimester of pregnancy, 18 in the second trimester, 16 in the third trimester, and 16 in the postpartum period; missing data=2). The mean age of the women was 33.2±10.4 years, whereas the mean age of the men was 36.1±8.5 years. Most participants were Italian (79% women, 91% men) and expecting their first child (52% women, 65% men). The sociodemographic characteristics of all participants are shown in Table 11.

Variable		**Respondent**			
		Women (N=94)		**Men (N=69)**	
		Women	**Partners**	**Men**	**Pregnant partners**
Age (years); mean ± SD		33.2±10.4	35.7±5.3	36.1±8.5	32.8±4.5
		n (%)	**n (%)**	**n (%)**	**n (%)**
Place of residence	Trieste - city center	53	/	36	/
	Trieste – suburbs	29	/	23	/
	Other	10	/	8	/
	(missing)	*2*	/	*2*	/
Country of origin	Italy	74 (79%)	77 (82%)	63 (91%)	65 (94%)
	Other	20 (21%)	17 (18%)	6 (9%)	0
	(missing)	*0*	*0*	*0*	*4*
Mother language	Italian	75 (80%)	76 (81%)	64 (93%)	66 (96%)
	Other	19 (20%)	18 (19%)	5 (7%)	0
	(missing)	/	/	/	*3*
Level of education	Primary school	0	1 (1%)	0	0
	Lower secondary school	5 (5%)	9 (10%)	5 (7%)	3 (4%)
	Upper secondary school	35 (37%)	49 (52%)	36 (52%)	29 (42%)
	University	45 (48%)	27 (29%)	22 (32%)	32 (46%)
	Post-university	9 (10%)	8 (9%)	6 (9%)	5 (7%)
Working condition	Manager, Businesswoman/businessman	7 (7%)	6 (6%)	5 (7%)	4 (6%)
	Freelance professional	5 (5%)	12 (13%)	10 (14%)	4 (6%)
	Employed	51 (54%)	44 (47%)	32 (46%)	42 61%)
	Worker	8 (9%)	30 (32%)	22 (32%)	8 (12%)
	Housewife/ housemaker	11 (12%)	0	0	4 (6%)
	Unemployed	10 (11%)	1 (1%)	0	7 (10%)
	Other non-specified	2 (2%)	1 (1%)	0	0
	(missing)	/	*1*	/	/
Working hours (only for working participants)	Full-time	50 (68%)	90 (96%)	69 (100%)	47 (81%)
	Part-time	23 (32%)	2 (2%)	0	11 (19%)
	(missing)	*0*	*1*	/	*0*
Healthcare professional	Yes	19 (20%)	/	4 (6%)	/
Pregnancy	Singleton	89 (95%)	/	67 (97%)	/
	Multiple - 2 twins	3 (3%)	/	1 (1%)	/
	(missing)	*2*	/	*1*	/
Type of conception	Planned	26 (28%)	/	35 (51%)	/
	Spontaneous	62 (66%)	/	31 (45%)	/
	Assisted reproduction	5 (5%)	/	3 (4%)	/
	(missing)	*1*	/	*0*	/

Professional caregiver assisting current pregnancy	Midwife (public service)	26 (28%)	/	19 (28%)	/
	Private gynecologist	50 (53%)	/	42 (61%)	/
	Other	18 (19%)	/	8 (12%)	/
Other children	None	49 (52%)	/	45 (65%)	/
	One	30 (32%)	/	17 (25%)	/
	Two	11 (12%)	/	7 (10%)	/
	Three or more	4 (4%)	/	0	/
Marital status	Married or with a partner	93 (99%)	/	68 (99%)	/
	(missing)	*1*	/	*1*	/
Family income	Upper	3 (3%)	/	5 (7%)	/
	Middle	63 (67%)	/	51 (74%)	/
	Sufficient	23 (24%)	/	12 (17%)	/
	Insufficient	1 (1%)	/	0	/
	(the respondent preferred not to answer)	*4 (%)*	/	*1 (1%)*	/
Biological father of the coming baby as current partner (only for mothers)	Yes	92 (98%)	/	/	/

Table 11. Sociodemographic characteristics of the expectant and new parents who participated in the study and their partners, from Brunelli et al (97).

As shown in Table 2, expectant and new parents reported as the most frequently used sources of pregnancy and postpartum information: communities of practice (55%), certified information (39%), and live communities (36%). Despite some differences in the frequency of responses between expectant and new mothers and fathers (i.e., mothers relied more on live communities and fathers on communities of practice), the ranking of most frequently used sources of information was similar. However, 33% of women reported using social media to get the information they need in this area. Other sources that were cited by expectant and new mothers included health professionals (i.e., gynecologist or midwife), friends, apps, relatives and friends who already have children, and the Internet. For their part, the expectant and new fathers mentioned their mother and mother-in-law, scientific articles, books, health professionals, and friends who already have children as additional sources of information consulted. As for their expectations regarding the improvements they hoped to see from implementing a mHealth app for the first 1000 days of life, these focused primarily on increased knowledge and awareness (65%), improved communication with health professionals (56%), and reduced time spent on education by health professionals (49%). Expectations expressed by participants are listed in Table 12.

	Expectant and new parents (N=163)	Expectant and new mothers (N=94)	Expectant and new fathers (N=69)
Most used information sources*	n (%)	n (%)	n (%)
Community of practice (e.g., blog, forum, online platforms, websites)	90 (55%)	48 (51%)	42 (61%)
Live communities (e.g., peer groups, training groups)	58 (36%)	38 (40%)	20 (29%)
Certified information (e.g., guidelines, services chart)	63 (39%)	36 (38%)	27 (39%)
Social media (e.g., Facebook, Twitter)	46 (28%)	31 (33%)	15 (22%)
Digital communication tools (e.g., WhatsApp)	11 (7%)	8 (9%)	3 (4%)
Other	26 (16%)	14 (15%)§	12 (17%)°
Expected improvements from the use of a dedicated mHealth app*			
Increased preparation of pregnant women/new mothers	106 (65%)	61 (65%)	45 (65%)
Improved communication between expectant/new parents and health professionals	91 (56%)	51 (54%)	40 (58%)
Optimization of time spent providing information by health professionals	80 (49%)	45 (48%)	35 (51%)
Use of a common language	15 (9%)	9 (10%)	6 (9%)

*multiple answers allowed; § private practitioners and midwives, family, friends, google, apps; ° family, books

Table 12. Most frequently used sources of information and expected improvements from using an app to support the first 1000 days of life, from Brunelli et al (97).

Regarding the desirable characteristics of a mHealth app for the first 1000 days of life, the distribution of the average score given by expectant and new parents in the domains of desirable content, functionalities, and technical features is shown in Figure 12. In general, higher scores were attributed to the domains of *Pregnancy care and counselling*, *Postnatal care and counselling for mother and child* and *App technical features*, as can be seen from the left skewed distributions of charts a), b) and f).

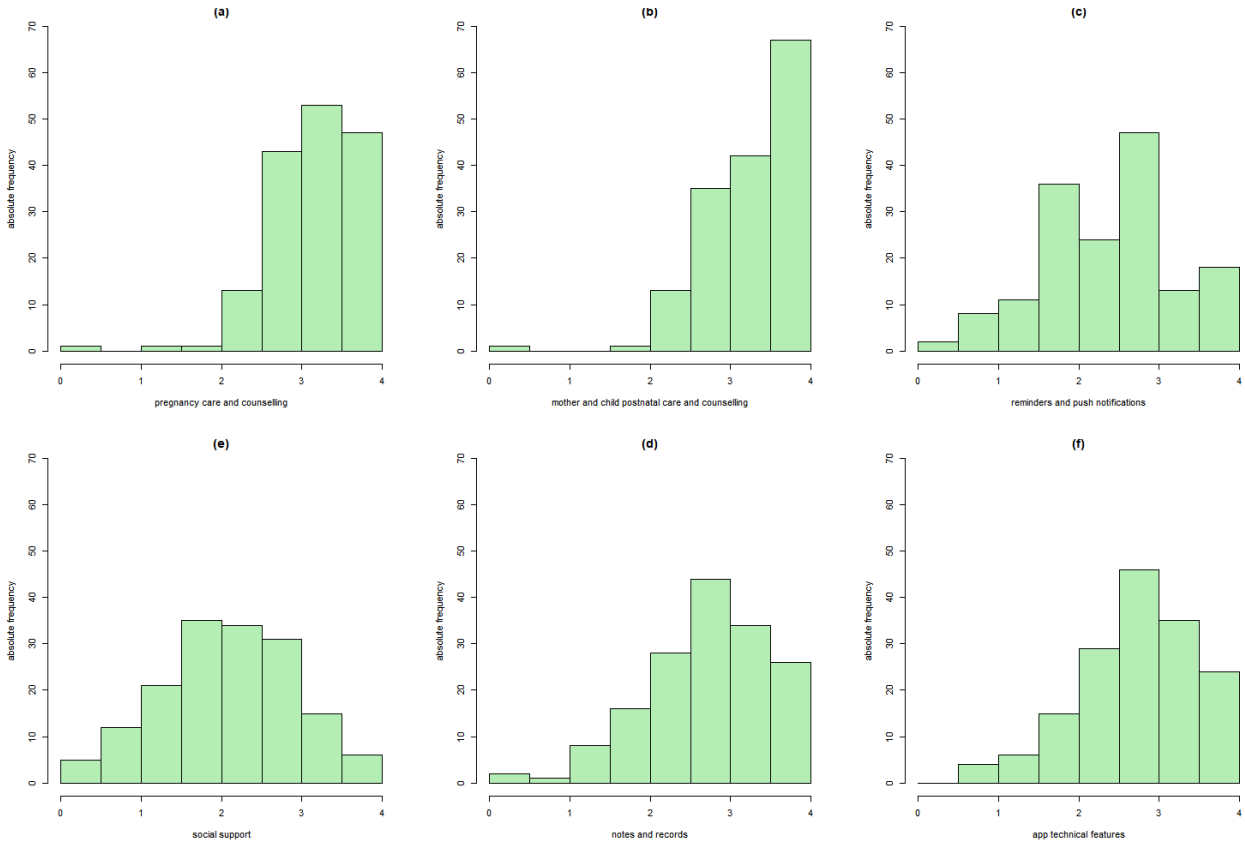


Figure 12. Distribution of opinions of expectant and new parents about the content, functionalities, and technical features of a mHealth app to support the first 1000 days of life, grouped by the six domains, from Brunelli et al (97).

In relation to content (*Pregnancy care and counselling*, and *Postnatal care and counselling for both mother and child*), the items with the highest mean parental rates were information about manifest neonatal complications and warning signs (rating mean±SD; 3.7±0.6), delivery (3.6±0.8), pregnancy in general (3.5±0.8), infections that may occur during pregnancy (3.5±0.8), fetal development (3.5±0.7), and labor (3.5±0.8). Overall, 82% of items (32/39) achieved a mean rating of "at least of average importance" up to "absolutely essential". Exceptions were information about voluntary termination of pregnancy, which was rated as not important or of little importance by expectant and new parents (2.5±1.3), as well as methods of postpartum family planning and birth spacing (2.5±1.1), and content about violence/abuse during pregnancy, although responses here also varied more (2.6±1.3). Lower needs were expressed for items describing the app's potential functionalities (*Reminders and push notifications*, *Notes and records,* and *Social support*), most of which were rated as "of little" or "no importance" on average (76%, 16/21). The app's ability to create a sleep diary for the mother was rated very low (1.4±1.2). Regarding the *App technical features*, the ability to provide content in multiple ways (3.5±0.8), a privacy policy (3.4±0.9), and multilingual support (3.4±0.9) were rated highest. The ratings assigned by expectant and new parents for content, functionalities, and technical features are shown in Table 13.

Domain	Item	Expectant and new parents (N=163)		Expectant and new mothers (N=94)		Expectant and new fathers (N=69)		p-value
		Rating		Rating		Rating		
		M	SD	M	SD	M	SD	
Pregnancy care and counselling	General information about pregnancy (e.g., nutrition/weight gain, fitness, oral health, travel health)	3.5	0.8	3.4	0.8	3.6	0.7	*
	Information about drugs that can be taken during pregnancy	3.3	0.9	3.3	0.8	3.3	1.0	*
	Information about vitamin supplement during pregnancy	3.0	0.9	3.1	0.9	3.0	0.8	*
	A list of free-of-charge and upon payment examinations to be carried out during pregnancy	3.4	0.7	3.4	0.8	3.5	0.7	*
	Information about infections that can occur during pregnancy (e.g., toxoplasmosis, cytomegalovirus)	3.5	0.8	3.4	0.9	3.6	0.6	*
	Information about the immunizations that the mother needs to receive during pregnancy	3.2	1.0	3.2	1.0	3.0	0.9	*
	Information about voluntary termination of pregnancy	2.5	1.3	2.5	1.3	2.4	1.2	*
	Information about spontaneous miscarriage	3.0	1.0	3.0	1.0	2.9	1.0	*
	Information about violence/abuse during pregnancy	2.6	1.3	2.6	1.3	2.4	1.2	*
	Information about possible problems related to pregnancy	3.3	1.0	3.3	1.0	3.2	0.8	*
	Information on fetal development	3.5	0.7	3.5	0.8	3.5	0.5	*
	Information about fetal movements	3.3	0.9	3.4	0.9	3.1	0.9	*
	Information about prevention measures during pregnancy (e.g., home accidents, car accidents)	3.0	1.0	2.9	1.1	3.0	0.9	*
	Information about labor	3.5	0.8	3.6	0.9	3.5	0.7	*
	Information about delivery (e.g., epidural anesthesia, caesarean section)	3.6	0.8	3.6	0.8	3.5	0.7	*
	Information about cord blood donation	2.9	1.0	2.9	1.0	2.8	1.0	*
	Information about pre-delivery courses	3.1	0.9	3.2	0.9	2.9	0.9	*
	Information about in-hospital stay for mother and newborn at the time of delivery	3.1	0.9	3.2	0.9	3.0	0.9	*
	Information about the woman’s rights during pregnancy (e.g., at work, at school, economical support)	3.3	0.9	3.4	0.8	3.1	1.0	*
	Information on prenatal risks and life-threatening conditions for both the mother and the fetus during pregnancy	3.4	0.8	3.4	0.8	3.3	0.7	*
	Information about maternal physiological and metabolic changes occurring during pregnancy	3.1	0.8	3.1	0.8	2.9	0.8	*
	Information about maternal or child services accessibility and contacts	3.2	0.9	3.3	0.8	3.0	0.9	*
	Information about available prenatal diagnostic tests	3.3	0.9	3.3	0.9	3.1	0.8	*
	Information on physical exercises and workouts for women during pregnancy	2.8	0.9	2.9	0.9	2.7	0.9	*
	Month/trimester-related tips for pregnant women	3.2	0.8	3.3	0.8	3.0	0.8	*
	A list of essentials for the hospital luggage	2.7	1.1	2.9	1.1	2.5	1.2	0.02538
Mother and child postnatal care and counselling	A list of essentials for the first welcome of the mother and baby at home	3.3	0.9	3.4	0.8	3.1	0.9	*
	Information about maternal physiological and metabolic changes occurring during the postpartum period	3.3	0.8	3.4	0.8	3.1	0.8	*
	Information about manifest neonatal complications and warning signs	3.7	0.6	3.7	0.7	3.7	0.6	*
	Information about postpartum mental disorders, such as postpartum depression and baby blues (e.g., symptoms and coping strategies)	3.4	0.8	3.5	0.8	3.2	0.8	*
	Tips for the postpartum recovery process	3.4	0.7	3.5	0.7	3.1	0.8	0.01278
	Information on breastfeeding practices	3.4	0.8	3.5	0.7	3.1	0.8	0.01073
	Information on mother's nutrition after childbirth and during breastfeeding	3.2	0.9	3.3	0.8	3.1	0.9	*

	Information about drugs compatible with breastfeeding	3.4	0.7	3.5	0.7	3.1	0.8	0.03293
	Practical tips on how to take care of the newborn (e.g., hygiene, diapers' changing, and burping)	3.3	0.7	3.5	0.6	3.0	0.8	<0.05
	Information about neonatal screening procedures	3.4	0.7	3.5	0.7	3.3	0.7	*
	Information about the immunizations needed during the first 1000 days	3.4	0.7	3.5	0.7	3.2	0.8	*
	Information about risk prevention measures regarding the newborn	2.8	1.0	2.9	1.0	2.6	1.0	*
	Information on methods for postpartum family planning and birth spacing	2.5	1.1	2.7	1.1	2.3	1.0	<0.05
Reminders and push notifications	App's ability to set reminders for medical appointments (e.g., prenatal and postnatal check-ups, pediatric visits, and immunizations) and scheduled medications/immunizations	2.2	1.1	2.2	1.1	2.1	1.2	*
	App's ability to send push notification reminders when the pregnancy month/trimester begins	2.8	1.0	2.9	1.0	2.6	1.1	*
	App's ability to schedule reminders for routine activities (e.g., drinking, diapering, feeding, pumping, and sleeping)	2.9	1.0	3.1	1.0	2.6	0.9	<0.05
	App's ability to change reminders and notifications settings	3.0	1.0	3.1	0.9	2.7	1.0	<0.05
Notes and records	App's ability to record the latest period date or the expected delivery date	2.9	1.0	2.9	1.0	2.9	1.0	*
	App's ability to change the expected delivery date following medical re-evaluation	3.0	1.0	3.1	1.0	2.7	1.1	<0.05
	App's ability to record physiological values of the mother (e.g., pressure, temperature, and mood)	2.3	1.1	2.4	1.1	2.3	1.1	*
	App's ability to record contractions or kicks	2.8	1.0	2.9	1.0	2.8	0.9	*
	App's ability to record routine activities of the mother or the newborn (e.g., drinking, steps, diapers changes, bottle feeding, and sleeping patterns/times)	2.9	0.9	2.9	1.0	2.8	0.8	*
	App's ability to record the medical care the mother or the newborn has received (e.g., medications and vaccination shots)	3.0	0.9	3.1	0.9	3.0	0.9	*
	App's ability to track the newborn's developmental milestones	3.1	0.9	3.1	1.0	3.0	0.9	*
	App's ability to record anthropometric measurements of the fetus (e.g., height, weight, and head circumference)	2.7	1.0	2.8	1.0	2.5	0.9	*
	App's ability to record anthropometric measurements of the newborn (e.g., height, weight, and head circumference)	2.5	1.0	2.6	1.0	2.3	0.9	*
	App's ability to record measurements of the mother's weight at baseline and during pregnancy	2.3	0.9	2.3	1.0	2.2	0.9	*
	App's ability to record measurements of the mother's weight in the postnatal period	2.5	1.0	2.6	1.0	2.4	0.9	*
	App's ability to create a sleep diary for the mother	1.4	1.2	1.6	1.1	1.1	1.2	<0.05
	App's ability to create a sleep diary for the newborn	2.4	1.0	2.5	1.1	2.4	0.9	*
Social support	Integration of the app with social networks (e.g., Facebook, Twitter)	2.1	1.2	2.3	1.2	1.8	1.1	<0.05
	Presence of a FAQ (frequently asked questions) page in the app	3.1	1.0	3.1	1.0	3.0	0.9	*
	Presence of social mechanisms allowing the user to interact with each other and share experiences (e.g., community, forum, and chat)	2.9	1.2	2.8	1.2	2.9	1.2	*
	Presence of social mechanisms allowing the user to interact with healthcare staff (e.g., community, forum, and chat)	2.8	1.1	2.8	1.1	2.8	1.2	*
App technical features	Authentication request to the user	2.7	1.2	2.7	1.1	2.7	1.2	*
	Presence of a privacy policy in the app	3.4	0.9	3.5	0.8	3.3	1.0	*
	If present, availability of a privacy policy properly written in Italian	2.7	1.1	2.7	1.1	2.7	1.1	*
	Ability for the user to access all app content for free (without any payment)	2.6	1.2	2.7	1.2	2.3	1.2	<0.05

	Access to full app usage based on specific inclusion criteria (e.g., national health service card, place of living, and certification by a health professional)	2.6	1.1	2.7	1.0	2.5	1.3	*
	Requirement for the user to sign an informed consent to use the app	2.9	1.1	2.8	1.1	3.0	1.0	*
	Presence of references about the contents provided through the app	2.5	1.1	2.5	1.1	2.5	1.1	*
	Presence of a glossary of the most used medical terms	2.5	1.1	2.5	1.1	2.4	1.0	*
	Declaration (through the provision of specific references) of the scientific responsibility of the contents provided through the app	2.7	1.0	2.7	1.1	2.7	0.9	*
	Possibility to back-up/restore data within the app	2.8	1.2	2.8	1.2	2.7	1.1	*
	Possibility to download data collected through the app	2.0	1.3	2.0	1.4	1.9	1.1	*
	Presence of multilanguage support	3.4	0.9	3.4	0.9	3.4	0.8	*
	App's ability to geolocate the user to provide more detailed information	2.9	0.9	2.9	1.0	2.9	0.8	*
	App's ability to book visits, vaccinations, and checkups	2.9	1.0	2.9	1.1	2.8	1.0	*
	App's ability to update users' account preferences	2.4	1.2	2.4	1.2	2.4	1.1	*
	Use of a simple, informal, and friendly tone by the app	2.3	1.2	2.4	1.2	2.1	1.1	*
	App's ability to adapt to screen orientation (both portrait and landscape)	3.2	0.9	3.2	0.9	3.0	0.9	*
	App's ability to learn user's preferences over time	2.9	1.0	2.9	1.1	2.8	0.9	*
	App's ability to implement intuitive and predictable navigation patterns	2.7	1.1	2.7	1.2	2.8	1.0	*
	Presence of app contents validated by an institutional source (local, regional, or national)	2.7	1.0	2.7	1.1	2.7	0.9	*
	Presence of certification of the app as a medical device according to Italian law	2.4	1.1	2.5	1.2	2.3	1.1	*
	App's ability to provide contents through different ways (e.g., text, video, audio)	3.5	0.8	3.4	0.8	3.6	0.7	*
	App's ability to ask about user satisfaction	3.3	0.9	3.3	0.8	3.3	1.0	*

Table 13. Ratings for the content, functionalities, and technical features of the proposed app to support the first 1000 days of life by expectant and new parents, from Brunelli et al (97)*; *>0.05.*

Expectant and new parents were grouped in three clusters based on their responses identifying high, medium, and low ratings (Figure 13). *High demanding cluster* grouped respondents who gave a very high average score (i.e., very important or absolutely essential) to questions about *Pregnancy care and counselling*, *Postnatal care and counselling for both mother and child*, *Notes and records*, and *App technical features*. *Medium demanding* and *low demanding clusters* gradually grouped responses with lower scores.

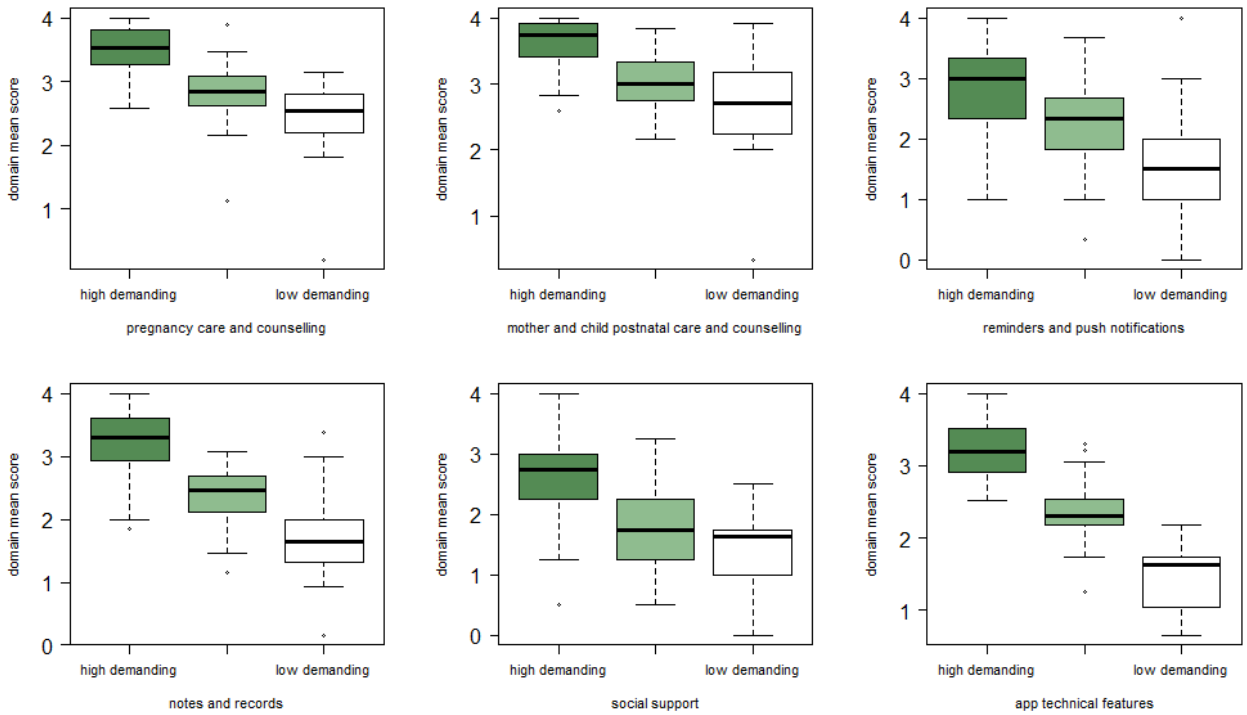


Figure 13. Distribution of responses from expectant and new parents by cluster for each domain, from Brunelli et al (97).

Analyzing the numerousness of clusters, *high demanding cluster* included 56%, *medium demanding cluster* included 31%, and *low demanding cluster* included the remaining 13% of expectant and new parents. Women were more likely to be found in *high demanding cluster* (62%), while men were more evenly distributed between *high demanding* and *medium demanding clusters*, but without reaching statistical significance ($p>0.05$). The likelihood of being classified in *low demanding cluster* was low for both expectant and new mothers and fathers (see Figure 14 a)). No significant differences were found between the three clusters in terms of the average family income or education ($p>0.05$), see Figure 14 b), c).

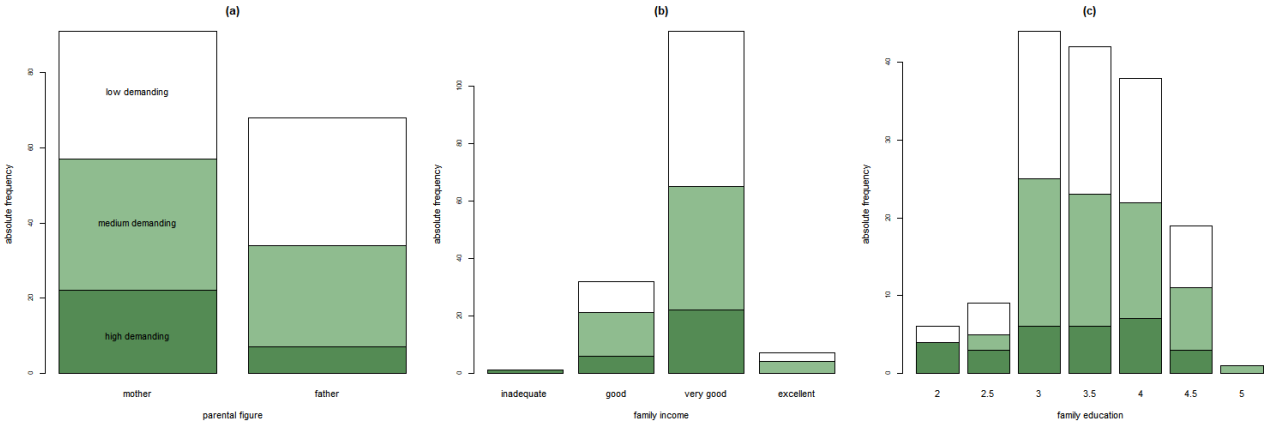


Figure 14. Distribution of clusters of expectant and new parents in relation to content, functionalities, and technical features of the mHealth app, grouped by parental profile, family income, and family education (97).

Correlation analysis revealed associations between some parental or family characteristics (e.g., sex, family income, mean family education, and educational gap between parents) and ratings of the six domains. In addition, statistically significant correlations also emerged between the ratings of the different domains, as shown in Table 14.

Parental characteristic/domain rating	Domain rating	correlation
Parent (mother as baseline)	*Postnatal care and counselling for both mother and child*	-0.24
	Social support	-0.17
Family income	*Reminders and push notifications*	-0.24
	Notes and records	-0.22
Family education divide (education gap between woman and man)	*Social support*	-0.19
Family average education	*Social support*	-0.20
Pregnancy care and counselling	*Reminders and push notifications*	0.45
	Notes and records	0.58
	Social support	0.40
Postnatal care and counselling for both mother and child	*Reminders and push notifications*	0.49
	Notes and records	0.53
	App technical features	0.59
	Social support	0.38
Reminders and push notifications	*Social support*	0.45
	App technical features	0.42
Notes and records	*Social support*	0.50
Social support	*App technical features*	0.62

Table 14. Correlation between parental characteristics and scores in the six domains, and between scores in the domains.

Expectations of primary users (expectant and new parents) for a mHealth app to support the first 1000 days of life were published in early 2023 (97).

The comparison between the perspectives of primary and secondary users

To comprehensively understand the needs and expectations of health professionals and their patients (i.e., secondary and primary users, respectively), Table 15 shows a comparison of the mean scores assigned to each item by the two groups of stakeholders. When different, health professionals' scores for content related to pregnancy were higher than expectant and new parents' ones, while the opposite was generally true for content about the postnatal period, reminders and push notifications, notes and records, social support and app's technical features.

Domain	Item	Expectant and new parents (N=163)		Health professionals (N=145)		p-value
		mean	rank	mean	rank	
Pregnancy care and counselling	General information about pregnancy (e.g., nutrition/weight gain, fitness, oral health, travel health)	3.5	2	3.5	5	*
	Information about drugs that can be taken during pregnancy	3.4	11	3.3	17	*
	Information about vitamin supplement during pregnancy	2.8	43	3.0	35	*
	A list of free-of-charge and upon payment examinations to be carried out during pregnancy	3.4	5	3.4	7	*
	Information about infections that can occur during pregnancy (e.g., toxoplasmosis, cytomegalovirus)	3.6	1	3.5	6	*
	Information about the immunizations that the mother needs to receive during pregnancy	3.4	6	3.2	28	<0.05
	Information about voluntary termination of pregnancy	3.2	18	2.5	70	<0.001
	Information about spontaneous miscarriage	3.1	29	3.0	39	*
	Information about violence/abuse during pregnancy	3.1	26	2.6	65	<0.001
	Information about possible problems related to pregnancy	3.2	25	3.3	21	*
	Information on fetal development	3.2	19	3.5	4	<0.05
	Information about fetal movements	3.4	9	3.3	22	*
	Information about prevention measures during pregnancy (e.g., home accidents, car accidents)	3.2	23	3.0	40	*
	Information about labor	3.4	7	3.5	3	*
	Information about delivery (e.g., epidural anesthesia, caesarean section)	3.4	4	3.6	2	*
	Information about cord blood donation	2.7	47	2.9	45	*
	Information about pre-delivery courses	3.2	24	3.1	32	*
	Information about in-hospital stay for mother and newborn at the time of delivery	2.9	38	3.1	30	*
	Information about the woman’s rights during pregnancy (e.g., at work, at school, economical support)	3.3	13	3.3	18	*
	Information on prenatal risks and life-threatening conditions for both the mother and the fetus during pregnancy	3.3	16	3.4	10	*
	Information about maternal physiological and metabolic changes occurring during pregnancy	3.0	36	3.1	33	*
	Information about maternal or child services accessibility and contacts	3.2	21	3.2	26	*
	Information about available prenatal diagnostic tests	3.3	17	3.3	24	*
	Information on physical exercises and workouts for women during pregnancy	2.9	39	2.8	51	*
	Month/trimester-related tips for pregnant women	3.1	32	3.2	27	*
	A list of essentials for the hospital luggage	2.2	72	2.7	59	<0.05
Mother and child postnatal care and counselling	A list of essentials for the first welcome of the mother and baby at home	2.8	42	3.3	23	<0.001
	Information about maternal physiological and metabolic changes occurring during the postpartum period	3.0	33	3.3	19	<0.05
	Information about manifest neonatal complications and warning signs	3.5	3	3.7	1	*
	Information about postpartum mental disorders, such as postpartum depression and baby blues (e.g., symptoms and coping strategies)	3.4	8	3.4	11	*
	Tips for the postpartum recovery process	3.1	30	3.4	14	<0.05
	Information on breastfeeding practices	3.3	15	3.4	12	*
	Information on mother's nutrition after childbirth and during breastfeeding	3.0	37	3.2	25	*
	Information about drugs compatible with breastfeeding	3.2	22	3.4	15	*

	Practical tips on how to take care of the newborn (e.g., hygiene, diapers' changing, and burping)	3.1	27	3.3	20	*
	Information about neonatal screening procedures	3.4	12	3.4	9	*
	Information about the immunizations needed during the first 1000 days	3.2	20	3.4	13	*
	Information about risk prevention measures regarding the newborn	3.0	35	2.8	53	*
	Information on methods for postpartum family planning and birth spacing	2.3	70	2.5	66	*
Reminders and push notifications	App's ability to set reminders for medical appointments (e.g., prenatal and postnatal check-ups, pediatric visits, and immunizations) and scheduled medications/immunizations	1.7	80	2.2	78	<0.05
	App's ability to send push notification reminders when the pregnancy month/trimester begins	2.4	58	2.8	54	<0.05
	App's ability to schedule reminders for routine activities (e.g., drinking, diapering, feeding, pumping, and sleeping)	2.5	55	2.9	42	<0.05
	App's ability to change reminders and notifications settings	2.7	50	3.0	38	<0.05
Notes and records	App's ability to record the latest period date or the expected delivery date	2.4	59	2.9	43	<0.05
	App's ability to change the expected delivery date following medical re-evaluation	2.3	71	3.0	37	<0.05
	App's ability to record physiological values of the mother (e.g., pressure, temperature, and mood)	1.7	79	2.3	75	<0.05
	App's ability to record contractions or kicks	2.6	51	2.8	50	*
	App's ability to record routine activities of the mother or the newborn (e.g., drinking, steps, diapers changes, bottle feeding, and sleeping patterns/times)	2.3	68	2.9	46	<0.05
	App's ability to record the medical care the mother or the newborn has received (e.g., medications and vaccination shots)	2.4	62	3.0	36	<0.05
	App's ability to track the newborn's developmental milestones	2.4	65	3.1	31	<0.05
	App's ability to record anthropometric measurements of the fetus (e.g., height, weight, and head circumference)	2.4	63	2.7	62	*
	App's ability to record anthropometric measurements of the newborn (e.g., height, weight, and head circumference)	2.0	74	2.5	69	<0.05
	App's ability to record measurements of the mother's weight at baseline and during pregnancy	1.7	78	2.3	77	<0.05
	App's ability to record measurements of the mother's weight in the postnatal period	1.8	76	2.5	67	<0.05
	App's ability to create a sleep diary for the mother	1.5	81	1.4	81	*
	App's ability to create a sleep diary for the newborn	2.5	56	2.4	73	*
Social support	Integration of the app with social networks (e.g., Facebook, Twitter)	1.8	75	2.1	79	<0.05
	Presence of a FAQ (frequently asked questions) page in the app	2.4	60	3.1	34	<0.05
	Presence of social mechanisms allowing the user to interact with each other and share experiences (e.g., community, forum, and chat)	2.6	53	2.9	49	<0.05
	Presence of social mechanisms allowing the user to interact with healthcare staff (e.g., community, forum, and chat)	2.8	44	2.8	52	*
App technical features	Authentication request to the user	2.7	46	2.7	56	*
	Presence of a privacy policy in the app	3.3	14	3.4	8	*
	If present, availability of a privacy policy properly written in Italian	2.4	67	2.7	60	<0.05
	Ability for the user to access all app content for free (without any payment)	2.4	64	2.6	64	*
	Access to full app usage based on specific inclusion criteria (e.g., national health service card, place of living, and certification by a health professional)	2.7	48	2.6	63	*
	Requirement for the user to sign an informed consent to use the app	2.9	40	2.9	44	*
	Presence of references about the contents provided through the app	2.4	61	2.5	68	*
	Presence of a glossary of the most used medical terms	2.4	66	2.5	71	*

	Declaration (through the provision of specific references) of the scientific responsibility of the contents provided through the app	2.6	52	2.7	61	*
	Possibility to back-up/restore data within the app	3.4	10	2.8	55	<0.001
	Possibility to download data collected through the app	1.8	77	2.0	80	*
	Presence of multilanguage support	3.1	31	3.4	16	<0.05
	App's ability to geolocate the user to provide more detailed information	2.7	45	2.9	41	*
	App's ability to book visits, vaccinations, and checkups	2.9	41	2.9	47	*
	App's ability to update users' account preferences	2.6	54	2.4	74	*
	Use of a simple, informal, and friendly tone by the app	2.2	73	2.3	76	*
	App's ability to adapt to screen orientation (both portrait and landscape)	3.1	28	3.2	29	*
	App's ability to learn user's preferences over time	3.0	34	2.9	48	*
	App's ability to implement intuitive and predictable navigation patterns	2.3	69	2.7	57	<0.05
	Presence of app contents validated by an institutional source (local, regional, or national)	2.7	49	2.7	58	*
	Presence of certification of the app as a medical device according to Italian law	2.5	57	2.4	72	*
	App's ability to provide contents through different ways (e.g., text, video, audio)	3.5	2	3.5	5	*
	App's ability to ask about user satisfaction	3.4	11	3.3	17	*

*Table 15. Comparison between health professional and parental ratings, *>0.05.*

We compared the first ten ranked characteristics for the two groups, showing slight differences in the perspectives of primary and secondary users (see Table 16).

Health professionals	Ranking	Parents
Information about infections that can occur during pregnancy	1	Information about manifest neonatal complications and warning signs
General information about pregnancy	2	Information about delivery
Information about manifest neonatal complications and warning signs	3	Information about labor
Information about delivery	4	Information on fetal development
A list of free-of-charge and upon payment examinations to be carried out during pregnancy	5	General information about pregnancy
Information about the immunizations that the mother needs to receive during pregnancy	6	Information about infections that can occur during pregnancy
Information about labor	7	A list of free-of-charge and upon payment examinations to be carried out during pregnancy
Information about postpartum mental disorders, such as postpartum depression and baby blues	8	Presence of a privacy policy in the app
Information about fetal movements	9	Information about neonatal screening procedures
Possibility to back-up/restore data within the app	10	Information about postpartum mental disorders, such as postpartum depression and baby blues
		Information on breastfeeding practices
		Information on prenatal risks and life-threatening conditions for both the mother and the fetus during pregnancy

Table 16. Top ten ranked content for health professionals and parents.

Q4. Development of a telehealth solution for the first 1000 days of life

To meet the needs and expectations of primary, secondary, and tertiary users, an integrated digital ecosystem was developed to support the first 1000 days of life, including features and functionalities that make this mHealth tool potentially scalable and applicable to different medical specialties by adapting it to specific clinical and care needs. In order to shorter the planned timeline, a telehealth solution “CGM CARE MAP (H&S HealthPlatform)” (hereinafter referred to as “CGM CARE MAP”) already on the market and developed by H&S SpA - CGM TELEMEDICINE Business Unit of CompuGroup Medical Italia, was used and adapted. The customized ecosystem that has been developed was named “AreaBurlo” by the project partners and represents de facto a first prototype.

An importance was given for digital solutions to provide value-based healthcare, that address patient needs, promote patient empowerment, support clinical activities, and ensure data confidentiality, availability, and integrity. For that reason, three critical features of the AreaBurlo ecosystem developed under the project including the provision of certified information, content customization and user profiling, and interactivity. The phases of design and development of the AreaBurlo digital ecosystem included:

- Phase 1: Analysis of needs and identification of functional and technological requirements, definition of experimental designs, methodological and formal tools to the construction of summary tools for content creation.
- Phase 2: development and implementation of the digital solution based on the results of the assessment of the needs and expectations of the primary, secondary and tertiary users, the design of the digital platform, the preparation of the content in a format suitable for insertion into the tools and the digitization of the methodological tools created, initial and beta testing of the system.

Content review by expert health professionals

Considering the lack of validated and evidence-based contents both online and in the apps for iOS and Android, the heterogeneous level of health literacy among the target population prompted stakeholders to summarize evidence-based content regarding the first 1000 days of life, particularly for the pregnancy and the postnatal period. Therefore, a group of expert health professionals from IRCSS Burlo Garofolo with expertise in this area reviewed the available literature, national and international recommendations, and guidelines to obtain and summarize the most recent evidence-based information. Content preparation also required a summary of all documents, brochures, posters, and social media messages distributed by the IRCCS Burlo Garofolo to the target population, including specific and up-to-date guidance on prevention and control of COVID-19 pandemic. Nonetheless, lessons learned from previous phases of research (exploration to answer questions 1, 2, and 3) were used to adapt the content to the needs and expectations of users.

The content was reviewed to ensure that all basic guidance from the Ministry of Health recommendations for parents, health professionals, and policy makers on protecting and promoting the health of children and future generations was included (5). Table 17 shows synoptically all topics addressed.

Domain	Topic
Preconception period	Folic acid intake
	Alcohol and drugs
	Smoking
	Effects of smoking
	Smoking cessation
	Recommendations for couples trying to conceive
	Medications intake during pregnancy
Prenatal screening and diagnosis	Embryo and fetal development
	Brochure on prenatal diagnosis
	Options of prenatal diagnosis
	Prenatal diagnosis – explanations for expectant parents
Medical history	Medical history: What is it?
	Personal medical history
	Obstetric-gynecologic anamnesis
	Family history
Nutrition, dietary supplements, weight gain	Nutrition in pregnancy
	Useful tips on nutrition for pregnant women
	Energy requirements during pregnancy
	Macronutrients and micronutrients
	BMI and weight gain in pregnancy
	Dietary supplements in pregnancy
	Folic acid and folates in pregnancy
	Important minerals in pregnancy
	The most important vitamins in pregnancy
Wellness and health in pregnancy	Physical activity in pregnancy
	Seat belt use in pregnancy
	Common problems in pregnancy
	The risks of alcohol consumption in pregnancy
	Alcohol and substance abuse in pregnancy

	Smoking during pregnancy
	Effects of smoking in pregnancy
	Smoking cessation in pregnancy
	Infections and vaccinations in pregnancy
	Vaccinations in pregnancy
	Anti-COVID vaccine in pregnancy
	Travel in pregnancy
	Week-by-week of pregnancy
Screenings tests and health assessments in pregnancy	Health assessments
	Diagnoses and examinations in pregnancy
	Examinations and screening in pregnancy
	RH incompatibility in pregnancy
	Information about the low risk course of pregnancy
	Examination package 14th, 19th, 24th, 28th, 33rd gestational week (gw)
	Examination package 1st trimester before 13th gw
	Application for exemption from co-payment during pregnancy
	Self-administration of enoxaparin
	Cardiotocography
	Urine collection
	Midwife assessment in low risk pregnancy
Women's rights and safeguard of maternity and labor	Maternity and protection
	Protection of pregnant workers
	Protection of pregnancy and breastfeeding
	Rights and protection for female employees
	Rights and protection for self-employed women
	Maternity leave and early maternity leave
	Parental leave
	Paternity leave
	Measures to reconcile work and family life
	One-time allowance for dependent children
	Maternity benefits
	World Day of Social Service
	Guide for victims of violence
	Violence against women and gender-based violence
	Burlo's position statement against gender-based violence
	Respectful care of women in pregnancy, childbirth and puerperium
	Consolidated Labor Protection Law (Testo Unico Tutela Lavoro)
Diabetes during pregnancy	Diabetes during pregnancy
	Delivery and treatment of the newborn baby of diabetic woman
Hypertension in pregnancy	Hypertension in pregnancy
	Chronic hypertension in pregnancy
	Gestational hypertension
	Pre-eclampsia
Infections in pregnancy	Infections in pregnancy
	Hepatitis
	Gonorrhea
	COVID-19 vaccination
	Herpes simplex
	HIV
	Cytomegalovirus
	Sexually transmitted infections
	Rubella
	Syphilis
	Toxoplasmosis
	Human papilloma virus and cervical cancer
	COVID-19 vaccination during breastfeeding

	Varicella
	Zika virus
Immunizations in pregnancy, childhood and adolescence	Infection prevention and vaccine in pregnancy
	Immunizations and herd immunity
	The immunization schedule in pregnancy
	COVID-19 vaccination in pregnancy
	COVID-19 vaccination during breastfeeding
	The childhood immunization schedule
	Regional immunization plan for childhood and adolescence
	Information on mandatory pediatric immunizations
	Self-declaration on mandatory pediatric immunizations
	MMR vaccine
	DPT vaccine
	Hepatitis B vaccine
	HIB (Haemophilus influenzae type B) vaccine
	Meningitis B vaccine
	Meningitis C vaccine
	Polio vaccine
	Varicella vaccine
	Pneumococcus vaccine
Domestic accidents	Domestic accidents
	Incidence of domestic accidents
	Risk factors for domestic accidents
	Causes and prevention of domestic accidents
	The most common domestic accidents
	Causes of risk for domestic accidents
	Types of injuries caused by domestic accidents
	Decalogue of domestic accident prevention
	Injuries to housewives - an under-recognized phenomenon
	Safe children at home
	Checklist of domestic risks
	How to protect your baby from domestic accidents
	Prevention of household accidents in children between 0 and 4 years of age
Vaginal bleeding	Vaginal bleeding in pregnancy
	Nonpathological vaginal bleeding in the first trimester
	Pathological vaginal bleeding in the first trimester
	Vaginal bleeding in the second and third trimester
	Vaginal bleeding at the end of pregnancy
Labor and delivery	Labor and delivery
	Examinations and screening at term of pregnancy
	Prodromal period: when to go to the hospital
	Labor: when and why it begins
	The cephalic or breech presentation
	Suitcase for hospitalization
	Midwifery practices for labor and delivery
	Low-risk labor and delivery management
	Analgesia in labor
	Natural analgesia in labor
	Epidural analgesia in labor
	Active labor
	Pain control in labor
	Protected and/or anonymous delivery
	Premature rupture of membranes
	Cesarean section
	Postpartum period
	Puerperium and rooming-in

	Who can access the department during the hospital stay
Cord blood donation	Cord blood donation
	How to perform a cord blood donation
	Collection of cord blood
	Autologous or dedicated donation
	Legislation on cord blood donation
	The 7 points of cord blood donation
	Brochure on cord blood donation
	Clamping the umbilical cord
	Insights into cord blood donation
Burlo Garofolo children's hospital	Welcome to the Maternal and Child Care Institute – IRCSS Burlo Garofolo
	Best practices for patient safety
	Our institute
	Charter of services for pregnancy and postnatal care
	Where we are, parking
	The road to birth
	The hospital stay
	The delivery room
	How to access freelance services
	Cultural mediation
	Neonatology and neonatal intensive care unit (NICU)
	Rooming-in mother and baby always together
	Presentation of the nursery
	Gynecological-obstetrical admission service
	Social services
	Obstetrics-gynecology urgencies and emergencies: when to come
	Neonatology and pediatric urgencies and emergencies: when to come
	Access in our department: when to come
	Rules for access in epidemiological emergencies - COVID-19
BFHI - Baby-Friendly Hospital Initiative and Mother-Friendly Care Accreditation (98)	Baby-Friendly Hospital Initiative and Mother-Friendly Care
	10 steps for BFHI
	Facility and health care professionals
	Mother-Friendly Care
	Baby Friendly Communities and the 7 steps
	BFHI: an accreditation to grow
	WHO and UNICEF joint statement on breastfeeding
	BFHI corporate policy
	Respectful Maternity Care Charter (99)
	Global and local strategy on infant and young child feeding
ASUGI (Giuliano Isontina Healthcare University Trust): the territorial network supporting mother and baby	Information for working mothers
	Breastfeeding, a choice for life
	Breastfeeding at work
	Complementary feeding
	Birth pathway – District 1
	Birth pathway – District 2
	Birth pathway – District 3
	Birth pathway – District 4
Breastfeeding and neonatal feeding	Breastfeeding
	Insights into breastfeeding
	The international code of marketing of breastmilk substitutes
	Breastfeeding and medications
	Tips for a peaceful breastfeeding
	Disorders and diseases of the breast
	Breastfeeding management in case of SARS-CoV-2 infection
	Assessment of infant growth

	Manual breast squeezing
	The newborn suckling
	The preparation and initiation of breastfeeding
	The infant's instinctive milestones
	When to give the feeding addition?
	Recognizing the newborn's feces
	Biological nurturing: a new approach to support breastfeeding
	Tips for preventing food ingestion
	Excerpt from the 0-4 EDITEAM guide (100)
	A guide to safety at the table
	Baby feeding "I eat well with you"
	Swallowing maneuvers in the baby
	Swallowing maneuvers in the toddler and child
Puerperium	The puerperium: what it is and how long does it last?
	Psycho-emotional difficulties in the post-partum
	The puerperium during hospital stay and after discharge
	Return of the body to pre-pregnancy conditions
	Maternity care certificate and birth certificate
	Birth declaration
	Informative about the birth of the municipality of Trieste
	Pelvic floor
	Rehabilitation of the pelvic floor
	Pelvic floor rehabilitation clinic
	Handover letter for mother and child care
	Midwifery education in the postpartum period
Health and care of the newborn	The newborn
	The first days of the newborn's life
	Infant hygiene
	Car seats and transport
	Care of the umbilical cord
	Vaccination calendar for the baby
	Vaccinations in the FVG region
	Herd immunity
	Reading to infants
	The head of the newborn
	Dressing the umbilical stump
	Protect your baby
	The newborn's heartbeat and respiratory rate
	The infant's body temperature
	The crying of the newborn
	Crying due to pain
	Crying due to hunger
	Crying request for attention
	The infant's cry: from Darwin to Chomsky
	Measures that help to calm the crying baby
	The shaken baby syndrome: what it is and how to avoid it
	The shaken baby syndrome: symptoms and damages
	The magic of tummy time
	Sudden infant death syndrome (SIDS) – the "cot death"
Glossary of terms	Glossary of terms related to pregnancy, childbirth and post-partum from A to Z

Table 17. Synoptic overview of contents of the pregnancy and postnatal care validated by health professionals of the Institute for Maternal and Child Health - IRCCS Burlo Garofolo.

Subsequently, the contents were organized based on their relevance for the related trimester of pregnancy, and a chronological sequence was established based on the content outline of the ministerial

document “Investing in health early: Actions and strategies in the first thousand days of life” (5). Some contents were assigned to the entire pregnancy or postnatal period (i.e., women's rights and safeguard of maternity and labour), whereas other contents were specifically assigned to the corresponding gestational week (e.g., prenatal screening and diagnosis; screening testing and health assessments in pregnancy). In each case, all contents were made available for free consultation throughout the usage period of the app. Links to relevant institutional websites or other validated sources of information were provided, as well as a FAQ section, with the most frequently asked questions collected during recent years by the staff of the IRCCS Burlo Garofolo.

To improve comprehensibility for primary users, the content has been revised by Fablab, the business unit of CompuGroup Medical Italia (CGM) dedicated to the conception and design of digital and multichannel communication campaigns in the healthcare sector. The aim was to remove overly technical scientific terms, reword sentences, and use a simple, informal, and friendly tone. In addition, some content was enhanced by illustrations and videos to facilitate understanding of the topics (Figure 15).

Figure 15. Examples of content taught using figures about the increase in volume of the uterus and the correct use of the seat belt.

Design and development of a digital ecosystem

The “CGM CARE MAP”, on which the AreaBurlo ecosystem was developed, is a modular telehealth solution for health professionals to support home-based patient management, telemonitoring, and telemedicine. Building on its structure, the “Area Burlo” telehealth ecosystem includes two components that connect the different users of the service:

- A web-based platform that is the web interface for health professionals and a database to provide access to patient data, profiled and personalized by role.
- A mobile application that allows managing the primary user's appointment calendar, sending reminders, accessing informational and educational content, and communicating with health professionals (via chat and video call), as well as monitoring and sharing vital signs by integrating specific medical devices.

To enrich the integration of these two components, the ecosystem is also designed to connect with third-party systems, such as electronic health records, pharmacy management software, general practitioners’ medical records and other external applications. In addition, the solution integrates tools to collect, extract, and analyse patient utilization data. A graphical representation of the overall architecture of the “CGM CARE MAP” telehealth solution including the web-based platform and the mobile application is shown below (Figure 16).

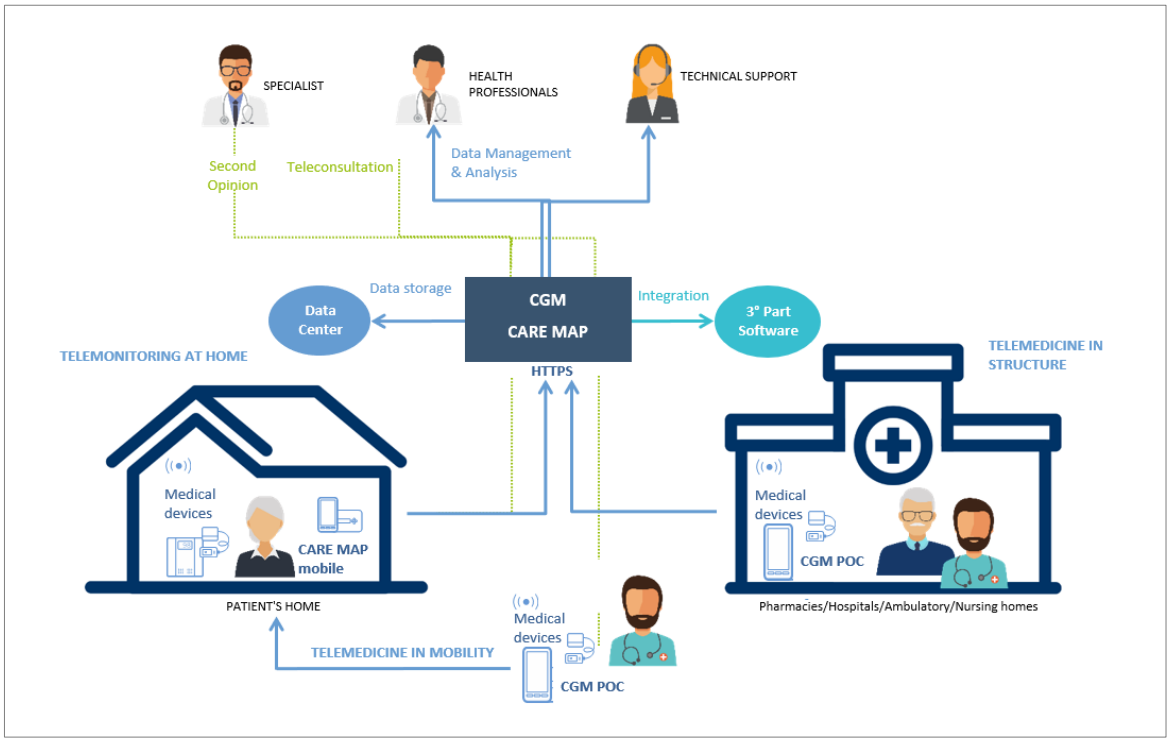


Figure 16. “CGM CARE MAP” telehealth solution overview.

The ecosystem and all related services have been developed according to the rules of the Three-Year Plan for Information Technology for Public Administration (2019/2021), as far as they are applicable, and according to the "Cloud First" principle. In addition, this ecosystem stands out for being compliant with the latest certifications (Class IIA Medical Device for both the web-based platform and the mobile application), IT security and privacy regulations. All detailed technical characteristics of the AreaBurlo ecosystem will be reported in a dedicated paper.

In this first phase, we have chosen to enable only a part of all the features of the digital ecosystem, as shown in Figure 17; the full potential will be implemented after the testing phase.

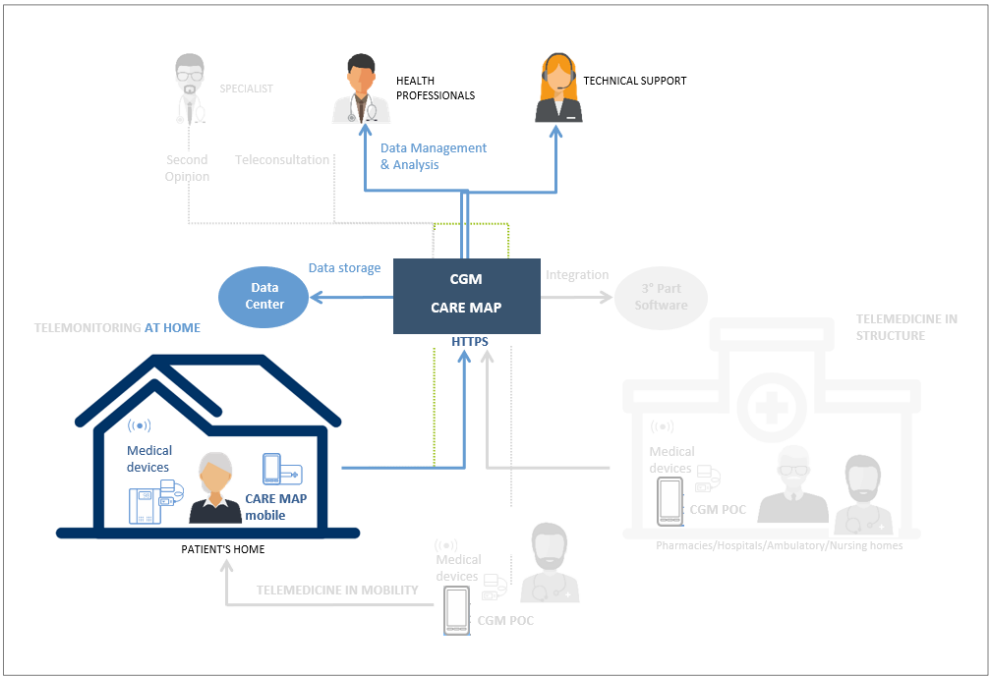


Figure 17. AreaBurlo features enabled in the pilot and the full potential of the digital ecosystem.

The web-based platform allows health professionals to enrol patients with different health needs, assign predefined or customized telemonitoring programs, generate clinical reports including storage of exams, schedule appointments in the patient's agenda, monitor patient activity and vital signs when the case and medical devices are paired, develop and deliver surveys to the patient and, when enabled, enable remote communication between the patient and health professionals.

The AreaBurlo ecosystem mobile app is designed to promote a tailored patient education and empowerment, manage the patient's daily activities and appointments, and when enabled, capture and monitor vital signs and overall health condition. To this end, the app provides:

- an agenda that can be implemented by both the patient and the health professional
- notifications for upcoming scheduled activities

- content storage for both educational materials provided by the health professionals and personal documents uploaded by the patient
- survey function
- tracking of measures (e.g., blood pressure, weight) – not enabled
- chat for asynchronous and synchronous communication between patient and health professionals – not enabled.

The AreaBurlo mobile application homepage is shown in Figure 18.

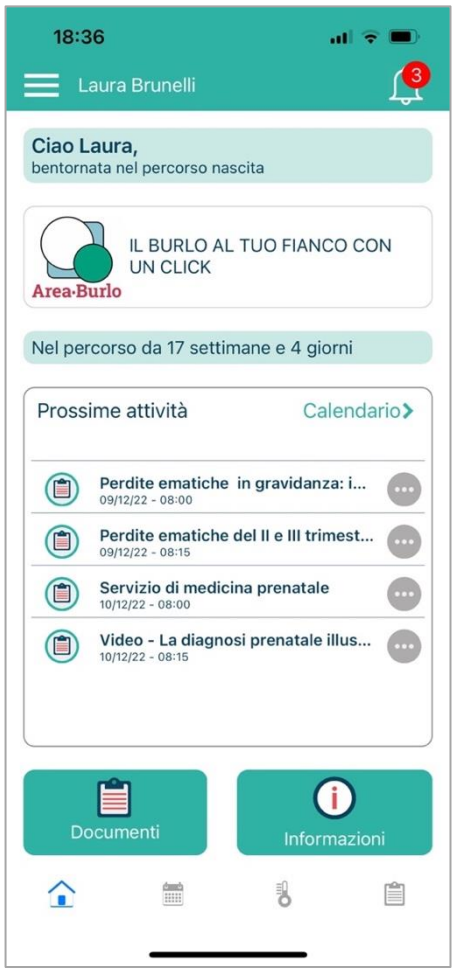


Figure 18. Example of the AreaBurlo mobile application homepage.

Evaluation of the developed app according to the tool of Q2. The developed mobile application met 59% of the items included in the evaluation of available Italian apps for pregnancy and postnatal care responding to Q2 (91). Specifically, 73% for content (88% for *Pregnancy care and counselling* domain, and 50% for *Postnatal care and counselling for mother and child*), 40% for *Reminders and push notifications* domain, 38% for *Notes and records* domain, 0% for *Social support* domain, and 16% for *App technical features* domain. According to the preferences expressed by primary and secondary users, some functionalities and technical features were not developed or implemented, such as those related to social support between peers and with health professionals via social media.

Pilot test on the digital ecosystem

To test the effectiveness of the implementation of the digital ecosystem designed to support the first 1000 days of life, a randomized, open-label, controlled trial was designed to prospectively evaluate the superiority of care delivered with the support of the mHealth app compared with standard care: "CARE 1000: Randomized controlled trial for the evaluation of the effectiveness of a mHealth app for supporting the first 1000 days of life". The study protocol was approved by the FVG Regional Ethics Committee (CEUR-2022-Sper-59) and registered on ClinicalTrials.gov (Trial identifier: NCT05500339). The study protocol was published in early December 2022 (101).

The results of this study will be important for improving the developed app to promote health and prevention and to support the first 1,000 days of life of mother and child. Our findings will be relevant to the future expansion of such mHealth app to promote positive health-related outcomes among primary users, and to support the organization of health services during the first 1000 days of life (secondary and tertiary users).

With this study, we seek to answer the following research questions:

- Is a mHealth app a potential tool to bridge information and communication gaps between patients and institutions during the first 1000 days of life?
- What are the health and social implications of a patient- and family-centred mHealth application for a Maternal and Child Health Institute?
- Could such a tool be useful for supporting pregnant women and new mothers in the first 1000 days of life?
- Could such a mHealth tool be used at a regional or national level to improve the relationship between citizens and healthcare providers?

The primary aim of the study is to evaluate the effectiveness of the mHealth app in supporting women in the first 1000 days (the study focuses on the period from the first echography to the first month after birth, i.e., pregnancy and postnatal care and counseling) and in improving health behaviours such as immunization during pregnancy, weight gain during pregnancy, abstention from smoking and alcohol consumption, and adherence to the routine childhood immunization schedule. In addition, the study aims to understand the level of appreciation of this mHealth app as a tool to overcome information and communication gaps between patients and institutions. The study is ongoing.

Pregnant women who visit the Unit of Fetal Medicine and Prenatal Diagnosis of IRCSS Burlo Garofolo for first-trimester ultrasound during their pregnancy (around 12 gestational week) are asked to participate in this study if they are >=18 years old, have a good understanding of the Italian language, have a smartphone for app download, and are willing to deliver at the IRCCS Burlo Garofolo. Individuals with cognitive impairment

or who are unable to give consent in person are excluded from the study. Participants are asked to provide informed consent for study participation, and data collection and management in accordance with the European General Data Protection Regulation and Italian Law D.Lgs. 101/2018.

Participating women are randomly assigned in a 1:1 ratio to the intervention group (use of the mHealth app, group A) or to the control group (standard care, group B). Assignment to the two groups is based on PC-driven randomization of enrolment days to help researchers to provide information and training to women in group A to download and initialize the app. In case of intrauterine death, severe foetal malformation, miscarriage, or therapeutic termination of pregnancy during the study period, the study will be stopped by the researchers. Enrolment is conducted by health professionals from the IRCCS Burlo Garofolo and Area Science Park researchers.

Both groups of women (A and B) are asked to complete a questionnaire at baseline to collect data at time zero (T0) in order to describe the population and potential confounders (e.g., age, country of origin, marital status and composition, socioeconomic level, educational level) as well as risk/protective factors (e.g., smoking and alcohol consumption before pregnancy, data on current pregnancy). This questionnaire also includes questions on health literacy, knowledge, and attitudes about prevention and health-promoting behaviours. During the study period, women in group A are able to use the app, with all the features and content now available, while women in group B undertake standard care consisting of usual education by health professionals about preventive health and health promotion (e.g., to improve their preventive behaviours such as vaccinations during pregnancy, weight gain during pregnancy, abstention from smoking and alcohol consumption, and adherence to routine childhood immunization schedule). Three additional questionnaires are collected from both groups of women during the study period at the end of the second and third trimesters (T1-2) and during the postpartum period (T3). The second and third questionnaires are distributed in printed form to women when they visit the institute, the fourth questionnaire will be made available online on the IRCCS Burlo Garofolo platform and in the app itself. Figure 19 shows a visual representation of the data collection schedule for both groups. A version of the questionnaires translated into English can be found in the Appendix. Women will be reminded to complete the questionnaires via the app's calendar function, as well as via email and phone reminders. At the end of the testing period, women will also be asked to rate their appreciation of the app features and content by providing feedback in digital format and participating in focus group sessions. With the support of the digital ecosystem and regional health information systems, data on app use will also be collected, such as frequency of app access, content consultation, references consultation, use of app features, along with access to and use of health services and vaccination adherence during pregnancy.

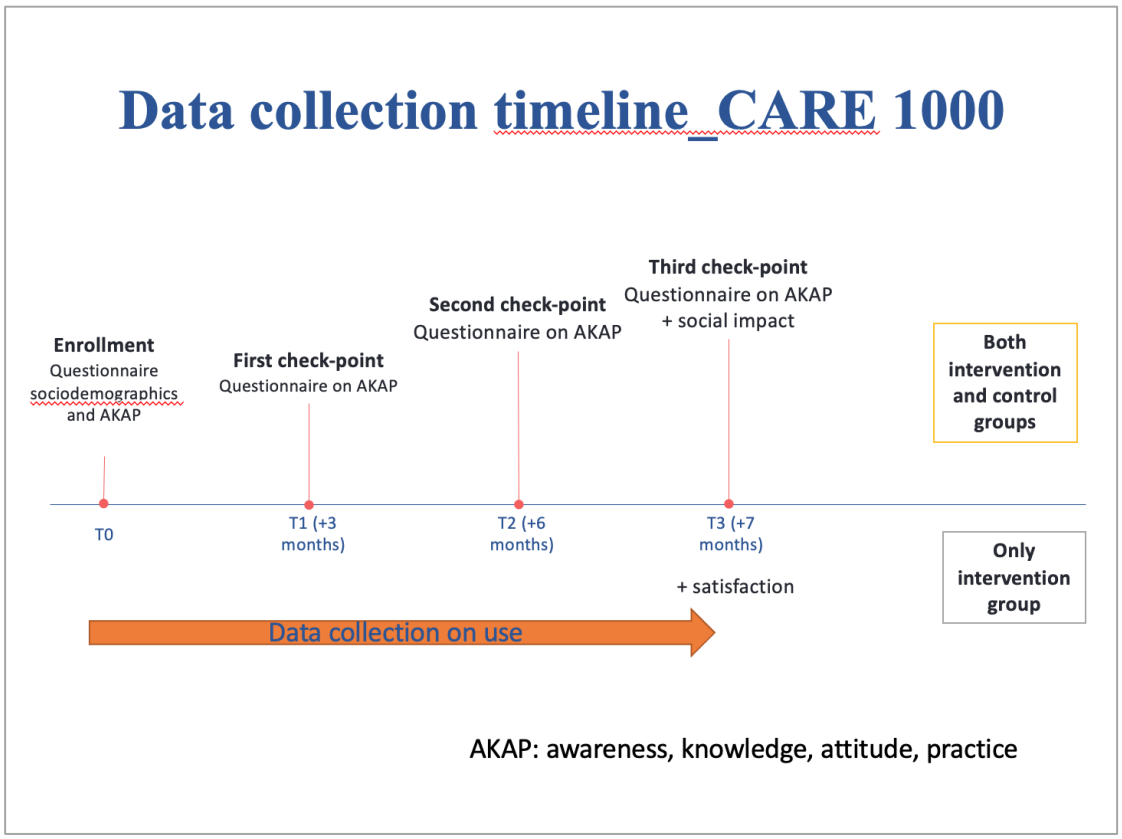


Figure 19. Schedule for CARE1000 RCT data collection.

The primary study outcome is to assess the differences between the experimental and control groups in adherence to diphtheria-tetanus-pertussis (DPT) vaccination in pregnant women. The choice of this outcome is due to the clear evidence of the need for maternal vaccination, particularly against pertussis, which can be a life-threatening infection for the newborn. In addition, available data on DPT vaccination coverage of pregnant women in Trieste in recent years show an unsatisfactory percentage of women vaccinated with DPT (only 55%).

Secondary study outcomes will include differences between the experimental and control groups in terms of:

- knowledge and behaviours related to health prevention and promotion, especially regarding folic acid intake, weight gain during pregnancy, smoking and alcohol consumption, breastfeeding, adherence to routine childhood immunization schedule (questionnaires; evaluation at T1- end of second trimester, T2- end of third trimester, T3);
- level of health literacy (Italian version of the 16-item European Health Literacy Survey Questionnaire HLS-EU-Q16; evaluation at T1, T2, T3);
- Evaluation of social and health impact of the introduction of a mHealth app for a mother and child hospital (questionnaire; evaluation at T3).

As with the experimental group, the final evaluation will include:

- the appreciation of such a tool to bridge the information gap between patients and healthcare institutions (qualitative satisfaction questionnaire, freely modified from the Italian version of the Mobile Application Rating Scale (MARS) (102); evaluation at T3 for experimental group-A only);
- the analysis of data on app use collected by the app itself throughout the study period.

Sample size calculation. Given that 55% of pregnant women in Trieste received the DPT vaccine during pregnancy in 2018, and assuming that this rate will increase to 70% after app use, a sample size of 163 women per group (326 women in total) with an alpha-error of 0.05 and a beta-error of 0.2 is required. Considering the possibility of spontaneous abortion and the possibility of drop-out during the follow-up period, the investigators decided to recruit a total of 360 women (180 per group). Recruitment is expected to last 3.5 months and began on November 22, 2022; the study will continue until the required sample size is reached.

Discussion

This project aimed to explore the potential of telehealth in maternal and child health, with a focus on supporting the first 1000 days of life. It then moved from theory to practice with the development and testing of a digital ecosystem for IRCCS Burlo Garofolo.

With several embedded researches, we tried to answer the four main questions that arose at the beginning of this journey. To this end, we adopted a participatory design approach inspired by the three-cycle framework for the design of scientific research (i.e., relevance, rigor, and design cycle) proposed by Hevner (103) and subsequently implemented by colleagues for the design of telehealth services (104). In summary, this participatory design approach was conducted as follows:

- Exploring the perspective of the public health institution (i.e., IRCSS Burlo Garofolo);
- Exploring the information needs of primary users (i.e., expectant and new mothers and fathers);
- Exploring the perceptions of secondary (i.e., health professionals within the maternal and child care field) and primary users' information and care needs;
- Analyzing the match between mHealth solutions already available to primary users and identified information and technical needs;
- Analyzing evidence-based content from the literature, national and international recommendations, and guidelines to identify aby issues that need to be addressed;
- Investigating the preferences and expectations of primary and secondary users regarding the technical features and functionalities of the digital ecosystem to be developed;
- Sharing findings with the digital technology provider to adapt the digital ecosystem in an iterative process;
- Designing a randomized controlled trial to test the effectiveness of the implementation of the digital ecosystem.

The research method

Similar approaches have been theorized and described by colleagues (86,105–108). Common steps include i) a preliminary design phase to identify needs, information sources, and best practices, ii) a generative and prototyping phase to design and develop the tool, iii) a pilot testing phase to implement the tool in a real situation, and iv) an evaluation and refinement phase to adapt and address problems or gaps identified by end users. Considering the guidelines proposed by Noorbergen et al. (106), we could have benefitted from the privileged observatory of IRCCS Burlo Garofolo that has been monitoring pregnant women and their babies in Trieste for decades and has developed a strong and valuable relationship between families and health professionals (28): these features represent the key to understanding vulnerabilities and diversity. Nonetheless, the already available public health experience for health promotion and disease prevention

interventions in the first 1000 days, was linked to the research group's expertise in psychology, sociology, and ergonomics. In addition, the involvement of the Area Science Park provided the necessary facilitator role to engage stakeholders in a trustworthy, meaningful, and effective manner. Nevertheless, the childbearing age of most of the professionals involved in the research project contributed to understanding the real-world experiences of primary users. Moreover, the involvement of the University of Trieste allowed for early engagement of all stakeholders who needed to contribute to the study design, including appropriate ethics approval that allowed for recognition and prioritization of primary users' needs. The crucial post-design advocacy step was fostered by a strong media information campaign about the project, targeting the general public, and the involvement of health professionals from IRCCS Burlo Garofolo. However, the beta testing conducted before the release of the ecosystem has allowed us to offer women a tool as ready and complete as possible. Further improvements will come from the women's feedback during and after the randomized controlled trial, along with data on app use and the results of impact analyses and clinical evaluations.

Despite debates about wording (109) and the extent to which public and patient participation is implemented at different stages of healthcare innovation (110), in our project we used different methods of user participation as defined in the IAP2 Public Participation Spectrum and presented by Wiles et al (111) under a co-creative guiding principle (112). Indeed, we strongly believe that patient engagement is essential for better patients and providers information (113), and, thus, we chose to consider the family as a whole. Moreover, it is our believe that such a family-centred approach - where policies, procedures, and practices are tailored to the needs, beliefs, and cultural values of children and families - is the only effective and valuable way to empower families and recognize and build on their strengths. To broaden the view of the mother-child dyad, we included the father/partner as a key stakeholder in the research from the phase of exploring needs and expectations to his consideration as the main user of the theoretical digital ecosystem and mHealth solution. Bringing the role of the father back into the consciousness of the health system is extremely important for several reasons, but above all to mark out that his marginality during the first 1000 days of life must be rejected at the conceptual level and fought against at the practical level (5,24,25,114). In fact, it must not be forgotten that, at the biological level, the father contributes significantly to the health of the unborn child, starting from his own genetic background, the presence of diseases, age, to the adoption of lifestyle habits, especially in relation to alcohol consumption, smoking, and obesity; all these factors are well known to influence health from conception. The father/partner's contribution to the child's health inevitably continues through all subsequent stages, both practically and emotionally and affectively. The importance of paternal presence is fundamental to the child's physical and mental health and is expressed not only in the direct relationship but also through protection from second-hand smoke, attention to safe sleep, shaping the home environment to prevent accidents, traffic safety, active participation in the health budget, and sharing immunizations. On the psychological and neurological level, the father's participation in the bonding process (formation of the bond between parent and child) is particularly important. This is done

by exposing the child to the new, physical contact, stimuli, interactive play, music, storytelling, and reading in the family since pregnancy and in the first months, representing essential moments to build an intense affective relationship and maximize the plasticity of the child's brain and promote the best emotional and cognitive development. Establishing and developing mindful parenting not only leads to positive child development, but also allows the mother-father-child triad to grow together (5). In summary, we have followed Clemensen's recommendations and given a voice to health professionals and expectant and new mothers and fathers in this telehealth research (86), without also neglecting the institutional perspective (73), thus overcoming the gap highlighted by Wang et al. concerning the lack of multiple perspective during design (108).

Research questions and findings

Q1. Exploring the perspective of IRCSS Burlo Garofolo has allowed us to highlight the urgent need to better inform and promote the empowerment of patients and families, improve the work organization and recognize the highly skilled work of health professionals, and promote the wellbeing of both primary and secondary users. These main goals are deeply rooted in the values of public health institutions to ensure that quality, safety, equity, privacy, accountability and appropriateness of care are always pursued.

Given the complexity of the context in which healthcare services operate and trying to address the generally low level of the population health literacy, several authors have started to think about what is known as organizational health literacy (OHL). This system-level health literacy refers to organization-wide efforts to make it easier for people to explore, understand and use information and services to take care of their health (115,116). The ten described attributes of health literate healthcare organizations theorized by the Institute of Medicine in 2012 are shown in Figure 20.

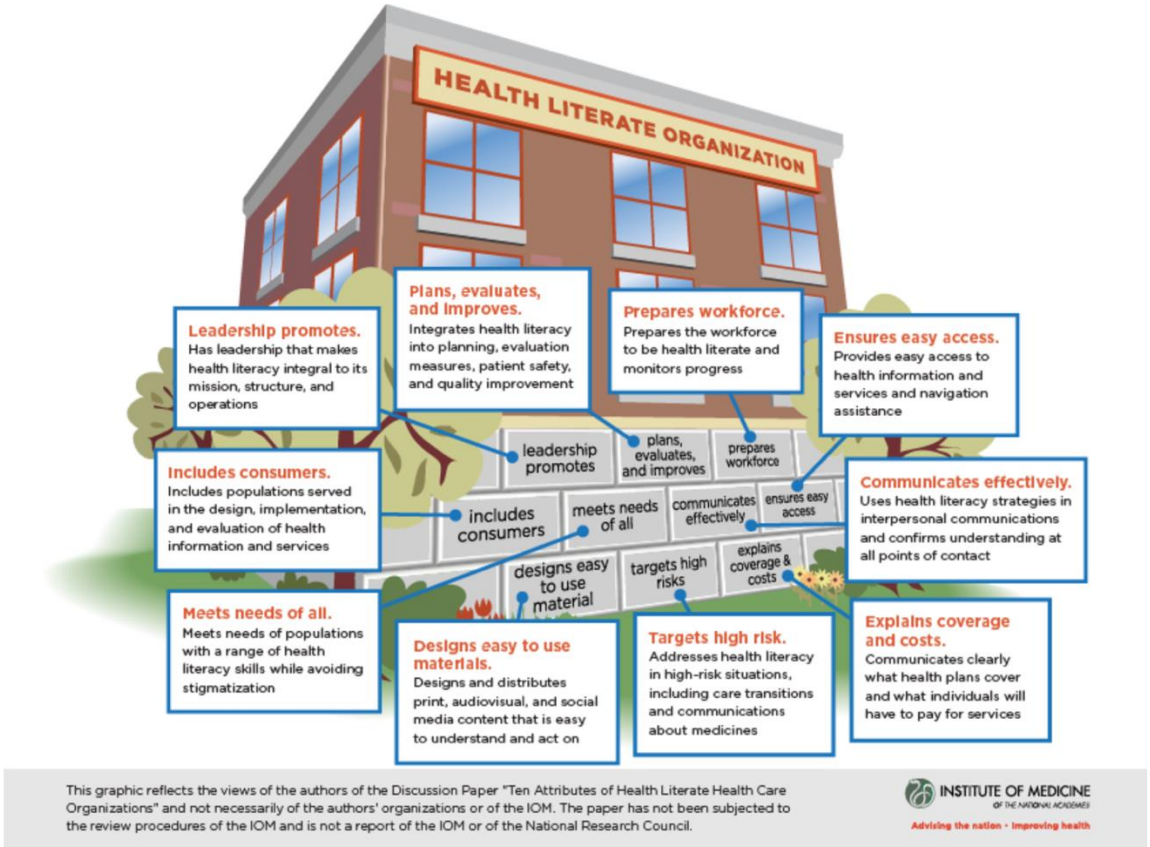


Figure 20. Ten attributes of health literate organizations, from IOM (116).

OHL is necessary to break the vicious cycle of negative health outcomes and limited health literacy, which in turn is perpetuated by patients' inability to explore health systems and difficulty understanding communication tools. Similarly to health literacy, many theories, operational frameworks, and implementation guides have been developed on OHL (117). Despite some differences, all of the guides focus on addressing the lack of health literacy by reducing the complexity of healthcare, improving patient

understanding of health information, and enhancing support for patients at all levels of health literacy (117). Recently, some additional considerations and suggestions have been made, but a comprehensive and consensus-based conceptual framework for OHL is still lacking (118). Be that as it may, many criteria and attributes of health literate healthcare organizations have continued to include communication with users, ease of access and navigation, integration and prioritization of OHL, assessment and organizational development, engagement and support of service users, and information and skill development of staff (118).

Nonetheless, in some ways, OHL represents the healthcare effort towards patients and users, that is in addition to the concurrent work of improving their health literacy. Indeed, the development and implementation of the digital ecosystem and its testing will allow IRCSS Burlo Garofolo to improve its OHL by involving the target population in the design, implementation, and evaluation of health information and services; meeting the needs of primary users with a range of health literacy skills; providing easy access to health information and services and navigation assistance; and clearly communicating which services are free (116).

Q2. The systematic search of the Apple and Google Play stores provided an overview of the pregnancy and postnatal care apps available in Italy, taking into account both content and technical features. This helped the researchers to identify the main gaps to be addressed by the upcoming development of the digital ecosystem. We strongly believe that such an assessment was critical in providing initial data to inform and guide subsequent steps. In particular, the presence of a single app containing more than half of the theoretically desirable items made it clear that there is significant room for improvement in this area. Although the market has an extremely rich supply of apps for women (64) and a large proportion of them are focused on reproductive health (66), many authors have expressed concerns about their reliability and trustworthiness (91,119–121) and also stated that most of them should not be recommended (122).

In particular, postnatal care and counselling for mother and child was the least considered area among the apps analysed, suggesting that most of them focus only on pregnancy and neglect the postpartum period as its natural continuation. This gap in conceptualising the first 1000 days of life as a whole has been reported previously (67) and is similar to the objection raised by both primary and secondary users to stand-alone apps that disregard the complex context of use reported in mental health telehealth (123). Moreover, information about immunizations that both mother and child need was largely absent. This is a very concerning public health issue in a context of suboptimal vaccination coverage rates nationwide (124), with awareness still widespread, but not prevalent (125,126), and misinformation about risks associated with vaccines, including fake news about autism and other serious side effects (127). Although the COVID-19 pandemic appears to have positively influenced pregnant women's knowledge and beliefs about vaccination (128), much remains to be done to address vaccine hesitancy. In addition, most apps did not provide information about free and paid clinical examinations during pregnancy, which may be a barrier to equal access to preventive or

diagnostic medical practices for all pregnant women. In addition, less than one-third of the apps studied were able to provide references or designate scientific responsibility for the content included, a concern previously acknowledged by Bert et al (120). Finally, aesthetic features were rated higher than content, suggesting a possible misdirection toward hedonistic motivation rather than information quality, validity, and usefulness (129), especially among expectant and new mothers with low health literacy (130), who might be attracted by a simple, informal, and friendly tone and by intuitive and predictable navigation patterns.

Q3. The survey, conducted to explore the views of health professionals, found a general agreement with the proposed content for both *Pregnancy care and counselling* and *Postnatal care and counselling for mother and child*. There was also good consensus on *App technical features*. Health professionals' awareness about the importance of patient information and education and the relevance of combating infodemic and fake news is undisputed. At the same time, they seemed to be clear about what technical features a mHealth solution should have, which is probably related to their first-hand experience in everyday life. However, attitudes toward the remaining three - *Reminders and push notifications*, *Notes and records*, and *Social support* - were quite clear. Contrary to what the study group originally suspected (91), they did not seem overly interested or willing to integrate such an app into their social media to support social interaction with patients remotely. This attitude could be explained by health professionals' reluctance to be available to their patients 24/7, which may underscore their need to find a better work-life balance and protect themselves from burnout. Indeed, work-life imbalance and burnout have been described as a pandemic affecting a significant proportion of the workforce (131,132). Nevertheless, it cannot be ruled out that some health professionals' concerns about the risk of anxiety in patients due to a constant monitoring, overdiagnosis, and overtreatment play a role (83). This could also be related to the fact that there is a generation of health professionals or a health system that is not yet ready to change their practice and adopt telehealth.

The survey conducted to explore the perspectives of expectant and new parents found a general agreement with the proposed content and indicated that they are aware of numerous issues that characterize the complexity and diversity of their needs in the first 1000 days of life. In addition, expectant fathers reported a high level of interest in general information about pregnancy, confirming their need and desire to learn about what is happening in the uterus and to visualize the unborn child, as previously described in the literature (24,25). A systematic review has shown that their involvement is effective in promoting breastfeeding (133), and therefore this engagement should be supported and further encouraged to counteract the sense of alienation that these partners may feel (15). Nonetheless, expectant and new parents paid little attention to immunization during pregnancy. This finding is particularly concerning given the recent renewed phenomenon of complacency about routine vaccination, along with public concerns and misconceptions about the safety and efficacy of vaccines recommended for pregnant women (127), which worsened after the COVID-19 pandemic (134). Even before the pandemic, some colleagues found an association between vaccine hesitancy and economic hardship (135), which was not confirmed in our study.

In this regard, any opportunities to promote the importance and safety of vaccination could help increase trust in public health interventions for disease prevention and health promotion measures (136), especially if the information is communicated in a trustworthy and reliable manner (137). Interest in content about violence and abuse in pregnancy was low. This finding may be indicative of parental complacency, although this phenomenon is unfortunately widespread: more than 5% of all pregnant women have been physically abused during at least one pregnancy worldwide (138). In Italy, it was reported that for 11.8% of women intimate partner violence has continued during pregnancy, with an increasing frequency or debuting in 11.3% and 5.7% of women, respectively (139).

Empowering patients, citizens, and communities to take charge of their own health has been a key goal since the 1986 Ottawa Charter for Health Promotion (8). However, as early as 2013, WHO reported on the growing problem of low health literacy and digital health literacy among individuals and the potential impact on people's ability to actively manage and promote their health and wellbeing (41). With this in mind, the information sources most frequently used by expectant and new parents raise some questions about reliability and trustworthiness, as well as their ability to effectively identify a certified information source (84). In addition to social media, expectant and new mothers also interestingly mentioned apps as additional sources of information, confirming that the suggestion of developing an app to support the first 1000 days may indeed meet their needs, especially for the first pregnancy (28). Furthermore, their expectations regarding improved communication with health professionals after gaining knowledge through the use of the app seem to confirm that this mHealth solution could be a useful tool to bridge the potential gap between expectant and new parents and their health professionals (81).

As noted in the analysis of health professional responses, participants generally rejected the proposed functions for the app that provide reminders for routine activities and sleep habits, likely expressing disagreement with the app controlling their lives. Indeed, the burden of the intrusiveness of information that is not explicitly desired may add to the stress levels that expectant and new parents already experience during the drastic and critical life stage of early parenthood (140). As with health professionals, primary users were generally dismissive of the possibility of integrating the proposed mHealth solution into their social media, confirming the report by Peyton et al (15) and possibly requiring a sharper distinction between fun or social support and formal healthcare. Another reason may be awareness of the potential unreliability of information shared in these online communities, as described by Goetz et al (141). Although participants' interest in the technical features of the apps was lower than expected, some technical elements can be considered as minimum standards for any app, such as adaptability of screen orientation, ability to learn user preferences over time, or geolocation. However, skepticism about geolocation is a different matter, as it involves personally identifiable and sensitive user information that can be stored, transmitted, and accessed outside of the user's control, thus creasing distrust (142). Despite these negative perceptions, the constant

app monitoring of geolocation may offer potential benefits in terms of identifying and connecting with health and social services in a given geographic area.

Overall, the readiness and openness for the telehealth revolution appears to be quite high among the primary and secondary users who participated in this study, confirming the findings of other studies (76,143). Involving primary and secondary users from the beginning of the design and development process, as also recently noted by Tran et al (144), was critical to meet their information needs, align with gender-sensitive parenting frameworks and ultimately ensure maximum participation and empowerment of both parents for the best child outcomes.

Q4. Because the pilot study is still ongoing, no definitive thoughts can yet be made about the effectiveness of the digital ecosystem in supporting the first 1000 days of life. Nevertheless, similar experiences targeting specific pregnancy issues such as gestational weight gain, healthy eating, smoking cessation, infection and asthma management (69), and maternal mental health and pregnancy knowledge have been shown to be effective (145). These findings suggest a great potential for mHealth solutions to improve maternal behaviour and wellbeing, aspects that we are currently testing further with a randomized controlled trial. The fact that we addressed reliability issues by reviewing all content by the experts from IRCCS Burlo Garofolo reinforces our belief that we are on the right track. Moreover, we addressed concerns about the low health literacy of the general population (130,146) by translating technical content into language that can be understood by the general public and by providing information in a variety of formats, ultimately providing a digital ecosystem and an app meeting many of the desired characteristics from the Institution, primary and secondary users' perspective.

The role of telehealth and mHealth in maternal and child care

As reported in a 2019 review by Chen et al (72), recent years have seen a rapid increase in the number of published studies on mHealth interventions for reproductive, maternal, newborn, and child health, most of which are based on the use of apps and targeted at primary users. Although they are becoming de facto a new standard, concerns and challenges related to security and privacy (129), patient safety (84), and other practical and technical issues (68,147) have yet to be fully addressed. For these reasons, we agree with our colleagues' call for strengthened legal and ethical institutional and systemic oversight frameworks and guidelines for telehealth implementation at both the international and national levels.

Meanwhile, the workforce of health systems is also changing, as new generations have new expectations, and most health professionals seek a better work-life balance. As a result, public health systems need to invest in digital health technologies, including genomics, digital medicine, artificial intelligence, and robotics (148). According to 2017 Research2Guidance, the cost of developing mHealth apps has increased significantly in recent years. In the initial app economy of 2011, the typical project size for developing an app - not just for healthcare – was between $30,000 and $40,000. By early 2018, the average total cost of developing a mHealth app to its initial launch was already around $425,000, with top apps costing up to several million USD (149). Public health systems should not view these costs merely as increasing, but rather should view them as health investments and new means to address the major health challenges of the 21st century (148). To close the skills gap between healthcare and digital health start-ups or investors, public health systems need to work with academia and industry with a clear partnership strategy, aligned expectations, and efficient decision making from the start to avoid the most common breaking points (65).

The complexity of data management requirements should not be a reason for inaction. Most importantly, mechanisms are in place to ensure that patients remain at the centre of our mission. While technological advances will improve efficiency, they should never replace human interaction. Therefore, mHealth should not be seen as a substitute for healthcare and interpersonal relationships, but as a useful tool that can be used alongside conventional services that retain paper-based tools (28,120,150,151).

For these reasons, Topol's independent study (148) suggests three principles to support the use of digital health technologies:

1. Engage patients as partners and inform them about health technologies, with special attention to vulnerable/marginalized groups to ensure equitable access.
2. Health professionals need expertise and guidance to evaluate new technologies, using processes based on real-world evidence.
3. The gift of time: wherever possible, the introduction of new technologies should enable staff to devote more time to care and promote more intensive interaction with patients.

There is a need to raise awareness of digital literacy among the health and social care workforce, which requires the development of individual skills, attitudes, and behaviours to become digitally competent and confident. Levels of digital literacy, awareness among health workers of the skills needed, access to training and support, and the skills to enable patients and citizens to improve their health and wellbeing using technology will all need to be improved as the balance of workforce skills fundamentally changes over the next two decades. At the same time, the development and implementation of digital medicine will also provide new opportunities for leadership careers for some health professionals (148).

Limitations

This research project has several limitations that must be acknowledged in order to better contextualize the findings and recommendations that follows. First, due to the unexpected COVID-19 pandemic, at the very beginning of the project, we were unable to conduct focus groups with primary and secondary users because of restrictions and massive disruption to researchers, health professionals and healthcare services. This might have prevented us from gaining firsthand knowledge of their perspectives, which we were actually exploring with surveys. Although we were forced to use this method, we always gave the opportunity to express free thoughts and suggestions in addition to multiple-choice questions. Secondly, the results of the systematic search for apps available in Italian for pregnancy and post-partum are highly dependent on the timing of the research, since this scenario evolves very quickly. Moreover, we were not able to evaluate the full potential of regional apps, as access to them was limited by the registration of users by local health services. Nonetheless, our interest was mainly focused on free and ready-to-use mHealth solutions for any user without restrictions based on geographic affiliations. Third, when selecting primary and secondary users for our survey we included participants from the IRCCS Burlo Garofolo from Trieste, whose characteristics may not be representative of national groups and therefore may be influenced by a selection bias whose burden is unknown to the researchers. Finally, we restricted access to all phases of research to participants with a good knowledge of Italian and excluded expectant and new parents who spoke other languages from this initial assessment. This may have prevented us from enriching our findings with the perspective of ethnic and cultural groups that were not as integrated in the local context.

Future perspectives

Considering the last limitation, a first improvement should certainly be the adaptation of all content and the user interface of the app to the most represented ethnic groups and their languages. In addition, full accessibility to all content related to the 1000 days to the child's second year should be ensured as soon as possible, also considering the possible expansion to regional levels of the digital ecosystem. To address fathers' need for more direct involvement in the first 1000 days of life and believing that there is no one-size-fits-all solution, customized (15) and gender-specific (24,114) versions of the same ecosystem should be developed to strengthen the family unit for health and wellbeing. Future applications and feature development should also be considered in light of the investments Europe and Italy are pursuing with the National Recovery and Resilience Plan (PNRR) (152) under the NextGenerationEU fund (153), which could breathe new life into all telehealth projects with the goal of making our world green, digital, healthy, strong, and equal.

Conclusions

The results of this participatory co-design approach, which involved expectant and new parents - both mothers and fathers - health professionals, and the public health institution, allowed us to better tailor the digital ecosystem and app to support the first 1000 days of life to the needs and expectations of all users. We strongly believe that such an approach is essential for the development of appropriate and tailored mHealth solutions in maternal and child health, but also in all other public health areas. Nonetheless, the close synergy between the expertise of public health institutions and their professionals with technology developers and innovation accelerators and promoters is critical to develop mHealth tools capable of effectively supporting all stakeholders during the crucial period of the first 1000 days of life. Efforts to design and develop such tools can be seen as steps toward improving information, education, culture, and organizational processes, to achieve effective integration and implementation of telehealth into normal health practice and, ultimately, into better and more equal outcomes for the mother and her child.

References

1. World Health Organization, United Nations Children's Fund, World Bank Group. Nurturing Care for Early Childhood Development. A framework for helping children survive and thrive to transform health and human potential. Geneva: World Health Organization; 2018.

2. UNICEF. The first 1,000 days: a singular window of opportunity [Internet]. 2017 [cited 2022 Aug 26]. Available from: https://blogs.unicef.org/blog/first-1000-days-singular-opportunity/

3. World Health Organization. The Minsk Declaration. 2015.

4. Berg A. The importance of the first 1 000 days of life. J Child Adolesc Ment Health. 2016;28(2):iii–vi.

5. Ministero della Salute. Investire precocemente in salute: azioni e strategie nei primi mille giorni di vita [Internet]. 2019 [cited 2023 Jan 9]. Available from: https://www.salute.gov.it/imgs/C_17_pubblicazioni_3120_allegato.pdf

6. Burgio E, Lopomo A, Migliore L. Obesity and diabetes: From genetics to epigenetics. Mol Biol Rep. 2015;42(4):799–818.

7. Indrio F, Dargenio VN, Marchese F, Giardino I, Vural M, Carrasco-Sanz A, et al. The Importance of Strengthening Mother and Child Health Services during the First 1000 Days of Life: The Foundation of Optimum Health, Growth and Development. Vol. 245, Journal of Pediatrics. Elsevier Inc.; 2022. p. 254-256.e0.

8. World Health Organization. Ottawa Charter for Health Promotion: An International Conference on Health Promotion: The Move Towards a New Public Health. Ottawa; 1986.

9. Dahlgren G, Whitehead M. The Dahlgren-Whitehead model of health determinants: 30 years on and still chasing rainbows. Public Health. 2021;199:20–4.

10. United Nations. TRANSFORMING OUR WORLD: THE 2030 AGENDA FOR SUSTAINABLE DEVELOPMENT. 2015.

11. Government of India. Journey of The First 1000 Days Foundation for a Brighter Future [Internet]. 2018 [cited 2023 Jan 9]. Available from: https://nhm.gov.in/images/pdf/programmes/RBSK/Resource_Documents/Journey_of_The_First_1000_Days.pdf

12. FHI Solutions. Thousanddays [Internet]. 2010 [cited 2022 Aug 26]. Available from: https://thousanddays.org/

13. European foundation for the care of newborn infants. Why the first 1000 days of life matter

[Internet]. 2018. Available from: www.efcni.org

14. 1 000 days, think babies. Nutrition in the first 1,000 days: A Foundation for Brain Development and Learning [Internet]. [cited 2023 Jan 9]. Available from: https://thousanddays.org/wp-content/uploads/1000Days-Nutrition_Brief_Brain-Think_Babies_FINAL.pdf

15. Peyton T, Poole E, Reddy M, Kraschnewski J, Chuang C. "Every pregnancy is different": Designing mHealth for the pregnancy ecology. Proceedings of the Conference on Designing Interactive Systems 2014. New York: Association for computing machinery; 2014. p. 577–86.

16. Wilkins C. A qualitative study exploring the support needs of first-time mothers on their journey towards intuitive parenting. Midwifery. 2006;22(2):169–80.

17. Rallis S, Skouteris H, McCabe M, Milgrom J. The transition to motherhood: Towards a broader understanding of perinatal distress. Women and Birth [Internet]. 2014;27(1):68–71. Available from: http://dx.doi.org/10.1016/j.wombi.2013.12.004

18. Zanchettin L, Tallandini MA, Gronchi G, Zito G, Ricci G, Russo LR. The quality of parenting in reproductive donation families: A meta-analysis and systematic review. Reprod Biomed Online [Internet]. 2022;00(0):1–17. Available from: https://doi.org/10.1016/j.rbmo.2022.08.099

19. Deave T, Johnson D, Ingram J. Transition to parenthood: The needs of parents in pregnancy and early parenthood. BMC Pregnancy Childbirth. 2008;8:1–11.

20. Bolte G, Tamburlini G, Kohlhuber M. Environmental inequalities among children in Europe - Evaluation of scientific evidence and policy implications. Eur J Public Health. 2010;20(1):14–20.

21. WHO Regional Office for Europe. Review of social determinants and the health divide in the WHO European Region. Final report [Internet]. 2017. Available from: http://www.euro.who.int/en/publications/abstracts/review-of-social-determinants-and-the-health-divide-in-the-who-european-region.-final-report

22. Goodwin L, Skrybant M, Kenyon S. Involving and engaging pregnant women in maternity-related research: reflections on an innovative approach. Res Involv Engagem. 2021 Dec 1;7(1).

23. Slomian J, Emonts P, Vigneron L, Acconcia A, Glowacz F, Reginster JY, et al. Identifying maternal needs following childbirth: A qualitative study among mothers, fathers and professionals. BMC Pregnancy Childbirth. 2017 Jul 3;17(1).

24. Johnsen H, Stenback P, Halldén BM, Crang Svalenius E, Persson EK. Nordic fathers' willingness to participate during pregnancy. J Reprod Infant Psychol. 2017 May 27;35(3):223–35.

25. Alio AP, Lewis CA, Scarborough K, Harris K, Fiscella K. A community perspective on the role of fathers

during pregnancy: A qualitative study. BMC Pregnancy Childbirth. 2013 Mar 7;13:60.

26. Jaks R, Baumann I, Juvalta S, Dratva J. Parental digital health information seeking behavior in Switzerland: A cross-sectional study. BMC Public Health. 2019;19(1):225.

27. Bert F, Gualano MR, Brusaferro S, De Vito E, De Waure C, La Torre G, et al. Pregnancy e-health: a multicenter Italian cross-sectional study on internet use and decision-making among pregnant women [Internet]. Vol. 67, Journal of Epidemiology and Community Health. 2013. Available from: https://www.jstor.org/stable/43281662

28. Vogels-Broeke M, Daemers D, Budé L, de Vries R, Nieuwenhuijze M. Sources of information used by women during pregnancy and the perceived quality. BMC Pregnancy Childbirth. 2022 Dec 1;22(1):109.

29. Battineni G, Baldoni S, Chintalapudi N, Sagaro GG, Pallotta G, Nittari G, et al. Factors affecting the quality and reliability of online health information. Vol. 6, Digital Health. SAGE Publications Inc.; 2020. p. 2055207620948996.

30. Dalhaug EM, Haakstad LAH. What the Health? Information Sources and Maternal Lifestyle Behaviors. Interact J Med Res. 2019;8(3):e10355.

31. Naeem S Bin, Bhatti R, Khan A. An exploration of how fake news is taking over social media and putting public health at risk. Vol. 38, Health Information and Libraries Journal. Blackwell Publishing Ltd; 2021. p. 143–9.

32. Tangcharoensathien V, Calleja N, Nguyen T, Purnat T, D'Agostino M, Garcia-Saiso S, et al. Framework for managing the COVID-19 infodemic: Methods and results of an online, crowdsourced who technical consultation. J Med Internet Res. 2020 Jun 1;22(6).

33. Zarocostas J. How to fight an infodemic. World Rep [Internet]. 2020;395:676–676. Available from: www.thelancet.com

34. Eysenbach G. Infodemiology: The Epidemiology of (Mis)information. Am J Med. 2002 Dec 15;113:763–5.

35. Eysenbach G. How to fight an infodemic: The four pillars of infodemic management. Vol. 22, Journal of Medical Internet Research. JMIR Publications Inc.; 2020.

36. Winker MA, Flanagin A, Chi-Lum B, White J, Andrews K, Kennett RL, et al. Guidelines for medical and health information sites on the Internet: Principles governing AMA Web sites. Jama. 2000;283(12):1600–6.

37. Team Health On the Net. Health On the Net [Internet]. Available from:

http://www.hon.ch/en/certification.html

38. Charnock D, Shepperd S. Learning to DISCERN online: Applying an appraisal tool to health websites in a workshop setting. Health Educ Res. 2004;19(4):440–6.

39. Conte A, Brunelli L, Moretti V, Valdi G, Guelfi MR, Masoni M, et al. Can a validated website help improve university students' e-health literacy? Ann Ig. 2022;

40. Diviani N, Van Den Putte B, Giani S, Van Weert JCM. Low health literacy and evaluation of online health information: A systematic review of the literature. J Med Internet Res. 2015 May 1;17(5):e112.

41. World Health Organization. Regional Office for Europe. Health literacy: the solid facts [Internet]. Copenhagen; 2013 [cited 2023 Jan 9]. Available from: https://apps.who.int/iris/bitstream/handle/10665/128703/e96854.pdf

42. Covolo L, Guana M, Bonaccorsi G, Brunelli L, Castaldi S, De Donno A, et al. Exploring the Online Health Information-Seeking Behavior in a Sample of Italian Women: The "SEI Donna" Study. Int J Environ Res Public Health. 2022 Apr 1;19(8):4745.

43. Giudice P Del, Bravo G, Poletto M, De Odorico A, Conte A, Brunelli L, et al. Correlation between ehealth literacy and health literacy using the ehealth literacy scale and real-life experiences in the health sector as a proxy measure of functional health literacy: Cross-sectional web-based survey. J Med Internet Res. 2018;20(10).

44. Sørensen K, Van Den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy and public health: A systematic review and integration of definitions and models. BMC Public Health [Internet]. 2012;12(1):80. Available from: http://www.biomedcentral.com/1471-2458/12/80

45. Eurostat. Women in the EU are having their first child later [Internet]. European Union. 2021. Available from: https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20210224-1

46. Euro-Peristat Project. European Perinatal Health Report. Core indicators of the health and care of pregnant women and babies in Europe from 2015 to 2019 [Internet]. 2020. Available from: https://www.europeristat.com/images/Euro-Peristat_Fact_sheets_2022_for_upload.pdf

47. Boldrini R, Cesare M Di, Basili F, Gaia C, Rossana M, Romanelli M, et al. Certificato di assistenza al parto (CeDAP). Analisi dell'evento nascita - Anno 2020 [Internet]. 2021. Available from: www.salute.gov.it/statistiche

48. Attali E, Yogev Y. The impact of advanced maternal age on pregnancy outcome. Best Pract Res Clin Obstet Gynaecol [Internet]. 2021;70:2–9. Available from:

https://doi.org/10.1016/j.bpobgyn.2020.06.006

49. Pinheiro RL, Areia AL, Pinto AM, Donato H. Advanced maternal age: Adverse outcomes of pregnancy, a meta-analysis [Idade materna avançada: Desfechos adversos da gravidez, uma meta-análise]. Acta Med Port [Internet]. 2019;32(3):219–26. Available from: https://www.scopus.com/inward/record.uri?eid=2-s2.0-85064198024&doi=10.20344%2Famp.11057&partnerID=40&md5=02ca1823a5bfb55fa7692a37c2e041c1

50. WHO RO for E. Una vita sana e prospera per tutti in Italia. Rapporto sullo stato dell'equità in salute in Italia. Relazione nazionale [Internet]. Copenhagen; 2022. Available from: http://apps.who.int/bookorders.

51. McKee M, European Observatory on Health Systems and Policies. Drawing light from the pandemic. A new strategy for health and sustainable development. A review of the evidence [Internet]. 2021. Available from: https://www.euro.who.int/en/health-topics/health-policy/european-programme-of-

52. Gualano MR, Lo Moro G, Voglino G, Bert F, Siliquini R. Is the pandemic leading to a crisis of trust? Insights from an Italian nationwide study. Public Health [Internet]. 2022;202:32–4. Available from: https://doi.org/10.1016/j.puhe.2021.10.015

53. WHO Regional Office for Europe. Pandemic fatigue. Reinvigorating the public to prevent COVID-19. Policy framework for supporting pandemic prevention and management. [Internet]. Copenhagen; 2020. Available from: https://apps.who.int/iris/bitstream/handle/10665/335820/WHO-EURO-2020-1160-40906-55390-eng.pdf

54. Focosi D, Navarro D, Maggi F, Roilides E, Antonelli G. COVID-19 infodemics: the role of mainstream and social media. Vol. 27, Clinical Microbiology and Infection. Elsevier B.V.; 2021. p. 1568–9.

55. The Independent Scientific Advisory Group for Emergencies (SAGE). COVID-19 and health inequality [Internet]. 2020. Available from: https://www.independentsage.org/wp-content/uploads/2020/11/Inequalities-_i_SAGE_FINAL-draft_corrected.pdf

56. Gustafsson PE, San Sebastian M, Fonseca-Rodriguez O, Fors Connolly AM. Inequitable impact of infection: social gradients in severe COVID-19 outcomes among all confirmed SARS-CoV-2 cases during the first pandemic wave in Sweden. J Epidemiol Community Health. 2022;76(3):261–7.

57. Plsek PE, Greenhalgh T. The challenge of complexity in health care. BMJ [Internet]. 2001 Sep 15;323(7313):625–8. Available from: https://www.bmj.com/lookup/doi/10.1136/bmj.323.7313.625

58. Lipsitz LA. Understanding health care as a complex system: The foundation for unintended

consequences. JAMA - J Am Med Assoc. 2012 Jul 18;308(3):243–4.

59. Engmann CM, Khan S, Moyer CA, Coffey PS, Bhutta ZA. Transformative Innovations in Reproductive, Maternal, Newborn, and Child Health over the Next 20 Years. PLoS medicine. 2016.

60. Cisco. Cisco Annual Internet Report (2018–2023). Cisco [Internet]. 2020;1–41. Available from: http://grs.cisco.com/grsx/cust/grsCustomerSurvey.html?SurveyCode=4153&ad_id=US-BN-SEC-M-CISCOASECURITYRPT-ENT&KeyCode=000112137

61. Statista. Empowering people with data. Insights and facts across 170 industries and 150+ countries [Internet]. Available from: https://www.statista.com

62. European Commission. Shaping Europe's digital future. The next generation Internet of Things [Internet]. European Commission website. 2022. Available from: https://digital-strategy.ec.europa.eu/en/policies/next-generation-internet-things

63. Islam SMR, Kwak D, Kabir MH, Hossain M, Kwak KS. The internet of things for health care: A comprehensive survey. IEEE Access. 2015;3:678–708.

64. Pohl M. mHealth app economics. Res 2 Guid [Internet]. 2017;(November 2017). Available from: https://research2guidance.com/wp-content/uploads/2017/11/R2G-mHealth-Developer-Economics-2017-Status-And-Trends.pdf

65. Shivkova M, Jahns R. Partnerships in Digital Health. What are the breaking points and how to successfully build partnerships? Results of R2G's global study on innovation management via partnerships [Internet]. 2019. Available from: https://research2guidance.com/product/partnerships-in-digital-health-breaking-points-and-success-factors/

66. Research2Guidance. Digital Health Market Watch: Women's Health. 2019.

67. Zhang P, Dong L, Chen H, Chai Y, Liu J. The rise and need for mobile apps for maternal and child health care in China: Survey based on app markets. JMIR mHealth uHealth. 2018;

68. Tsai Z, Kiss A, Nadeem S, Sidhom K, Owais S, Faltyn M, et al. Evaluating the effectiveness and quality of mobile applications for perinatal depression and anxiety: A systematic review and meta-analysis. J Affect Disord [Internet]. 2022;296(October 2021):443–53. Available from: https://doi.org/10.1016/j.jad.2021.09.106

69. Overdijkink SB, Velu A V., Rosman AN, van Beukering MDM, Kok M, Steegers-Theunissen RPM. The usability and effectiveness of mobile health technology–based lifestyle and medical intervention apps supporting health care during pregnancy: Systematic review. JMIR mHealth and uHealth. 2018.

70. Mildon A, Sellen D. Use of mobile phones for behavior change communication to improve maternal, newborn and child health: A scoping review. J Glob Health. 2019;9(2).

71. Daly LM, Horey D, Middleton PF, Boyle FM, Flenady V. The effect of mobile app interventions on influencing healthy maternal behavior and improving perinatal health outcomes: Systematic review. Vol. 6, JMIR mHealth and uHealth. JMIR Publications Inc.; 2018.

72. Chen H, Chai Y, Dong L, Niu W, Zhang P. Effectiveness and appropriateness of mhealth interventions for maternal and child health: Systematic review. Vol. 6, JMIR mHealth and uHealth. JMIR Publications Inc.; 2018.

73. Schnitman G, Wang T, Kundu S, Turkdogan S, Gotlieb R, How J, et al. The role of digital patient education in maternal health: A systematic review. Patient Education and Counseling. Elsevier Ireland Ltd; 2021.

74. Qian J, Wu T, Lv M, Fang Z, Chen M, Zeng Z, et al. The value of mobile health in improving breastfeeding outcomes among perinatal or postpartum women: Systematic review and meta-analysis of randomized controlled trials. Vol. 9, JMIR mHealth and uHealth. JMIR Publications Inc.; 2021.

75. Bijlholt M, Ameye L, Van Uytsel H, Devlieger R, Bogaerts A. The inter-act e-health supported lifestyle intervention improves postpartum food intake and eating behavior, but not physical activity and sedentary behavior—a randomized controlled trial. Nutrients. 2021 Apr 1;13(4).

76. Bjelica D, Bjelica A, Despotović-Zrakić M, Radenković B, Barać D ĐM. Designing an IT Ecosystem for Pregnancy Care Management Based on Pervasive Technologies. Healthcare. 2020;9(1):12.

77. Perrone G, Zerbo S, Bilotta C, Malta G, Argo A. Telemedicine during Covid-19 pandemic: Advantage or critical issue? Med Leg J. 2020 Jul 1;88(2):76–7.

78. Peters GM, Kooij L, Lenferink A, Van Harten WH, Doggen CJM. The effect of telehealth on hospital services use: Systematic review and meta-analysis. Vol. 23, Journal of Medical Internet Research. JMIR Publications Inc.; 2021.

79. WHO Regional Office for Europe. Home care in Europe. The Solid Facts. 2008.

80. Purohit A, Smith J, Hibble A. Does telemedicine reduce the carbon footprint of healthcare? A systematic review. Futur Healthc J. 2021;8(1):e85–91.

81. Qudah B, Luetsch K. The influence of mobile health applications on patient - healthcare provider relationships: A systematic, narrative review. Vol. 102, Patient Education and Counseling. Elsevier Ireland Ltd; 2019. p. 1080–9.

82. Özkan Şat S, Yaman Sözbir Ş. Use of Mobile Applications by Pregnant Women and Levels of Pregnancy Distress During the COVID-19 (Coronavirus) Pandemic. Matern Child Health J. 2021 Jul 1;25(7):1057–68.

83. Kern-Goldberger AR, Srinivas SK. Telemedicine in Obstetrics. Vol. 47, Clinics in Perinatology. W.B. Saunders; 2020. p. 743–57.

84. Akbar S, Coiera, E, Magrabi F. Safety concerns with consumer-facing mobile health applications and their consequences: A scoping review. Vol. 27, Journal of the American Medical Informatics Association. Oxford University Press; 2020. p. 330–40.

85. Denicola N. Implementing Telehealth in Practice: ACOG Committee Opinion Summary, Number 798. Obstet Gynecol. 2020;135(2):493–4.

86. Clemensen J, Rothmann MJ, Smith AC, Caffery LJ, Danbjorg DB. Participatory design methods in telemedicine research. J Telemed Telecare. 2017 Oct 1;23(9):780–5.

87. IRCSS Burlo Garofolo. Atto aziendale [Internet]. 2016. Available from: https://www.burlo.trieste.it/sites/default/files/generali/Atto_Aziendale_10nov20161.4.pdf

88. OECD. Policy Brief on Social Impact Measurement for Social Enterprises: Policies for Social Entrepreneurship [Internet]. 2015. Available from: https://data.europa.eu/doi/10.2767/427680

89. Social Impact Investment Taskforce. Measuring Impact – Subject Paper of the Impact Measurement Working Group [Internet]. UK's Presidency of the G8. 2014. Available from: https://gsgii.org/wp-content/uploads/2017/07/Measuring-Impact-WG-paper-FINAL.pdf

90. Banke-Thomas AO, Madaj B, Charles A, Van Den Broek N. Social Return on Investment (SROI) methodology to account for value for money of public health interventions: A systematic review. BMC Public Health [Internet]. 2015;15(1):1–14. Available from: http://dx.doi.org/10.1186/s12889-015-1935-7

91. Brunelli L, De Vita C, Cenedese F, Cinello M, Paris M, Samogizio F, et al. Gaps and future challenges of Italian apps for pregnancy and postnatal care: Systematic search on app stores. J Med Internet Res. 2021;23(8):e29151.

92. Sardi L, Idri A, Readman LM, Alami H, Bezad R, Fernández-Alemán JL. Mobile health applications for postnatal care: Review and analysis of functionalities and technical features. Comput Methods Programs Biomed [Internet]. 2020;184:105114. Available from: https://doi.org/10.1016/j.cmpb.2019.105114

93. D'Amour D, Ferrada-Videla M, San Martin Rodriguez L, Beaulieu MD. The conceptual basis for

interprofessional collaboration: Core concepts and theoretical frameworks. Vol. 19, Journal of Interprofessional Care. 2005. p. 116–31.

94. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile App Rating Scale: A New Tool for Assessing the Quality of Health Mobile Apps. JMIR mHealth uHealth. 2015;

95. Knitza J, Tascilar K, Messner EM, Meyer M, Vossen D, Pulla A, et al. German mobile apps in rheumatology: Review and analysis using the mobile application rating scale (MARS). JMIR mHealth uHealth. 2019;7(8):1–13.

96. R Core Team. R: A language and environment for statistical computing [Internet]. Vienna, Austria: R Foundation for Statistical Computing; 2021. Available from: https://www.r-project.org/

97. Brunelli L, Bussolaro S, Dobrina R, De Vita C, Mazzolini E, Verardi G, et al. Exploring the Needs and Expectations of Expectant and New Parents for an mHealth Application to Support the First 1000 Days of Life : Steps toward a Co-Design Approach. IJERPH. 2023;20:1227.

98. UNICEF. BFHI - Baby-Friendly Hospital Initiative [Internet]. Available from: https://www.unicef.it/italia-amica-dei-bambini/insieme-per-allattamento/ospedale-amico-bambini/

99. Bernstein SL. Respectful Maternity Care. MCN Am J Matern Nurs. 2022;47(4):227.

100. Squicciarini M, Vania A, Troiano E, Acquaviva A, Marocco G, Lombardi A, et al. Zeroquattro: bambini a tavola in sicurezza, nessuno escluso [Internet]. 2018. Available from: https://www.manovredisostruzionepediatriche.com/wp-content/uploads/2019/12/ESTRATTO-da-GUIDA-ZeroQuattro.copiryght-EDITEAM-2.pdf

101. Brunelli L, Bussolaro S, Dal Cin M, Ronfani L, Zanchiello S, Cassone A, et al. CARE 1000: randomized controlled trial for the evaluation of the effectiveness of a mHealth app for supporting the first 1000 days of life. Trials [Internet]. 2022;23(1007). Available from: https://doi.org/10.1186/s13063-022-06953-y

102. Morselli S, Sebastianelli A, Domnich A, Bucchi C, Spatafora P, Liaci A, et al. Translation and validation of the Italian version of the user version of the Mobile Application Rating Scale (uMARS). J Prev Med Hyg. 2021;62(1):243-E248.

103. Hevner AR. A Three Cycle View of Design Science Research. Scand J Inf Syst [Internet]. 2007;19(2):87–92. Available from: https://www.researchgate.net/publication/254804390_A_Three_Cycle_View_of_Design_Science_Research

104. Schnall R, Rojas M, Bakken S, Brown W, Carballo-Dieguez A, Carry M, et al. A user-centered model

for designing consumer mobile health (mHealth) applications (apps). J Biomed Inform. 2016 Apr 1;60:243–51.

105. Jackson DN, Sehgal N, Baur C. Benefits of mHealth Co-design for African American and Hispanic Adults: Multi-Method Participatory Research for a Health Information App. JMIR Form Res. 2022 Mar 1;6(3):e26764.

106. Noorbergen TJ, Adam MTP, Teubner T, Collins CE. Using co-design in mobile health system development: A qualitative study with experts in co-design and mobile health system development. JMIR mHealth uHealth. 2021 Nov 1;9(11).

107. van Hierden Y, Dietrich T, Rundle-Thiele S. Using participatory design to design an ehealth well-being program. Int J Environ Res Public Health. 2021 Jul 2;18(14).

108. Wang T, Giunti G, Melles M, Goossens R. Digital Patient Experience: Umbrella Systematic Review. Vol. 24, Journal of Medical Internet Research. JMIR Publications Inc.; 2022.

109. Masterson D, Areskoug Josefsson K, Robert G, Nylander E, Kjellström S. Mapping definitions of co-production and co-design in health and social care: A systematic scoping review providing lessons for the future. Heal Expect. 2022;25(3):902–13.

110. Cluley V, Ziemann A, Feeley C, Olander EK, Shamah S, Stavropoulou C. Mapping the role of patient and public involvement during the different stages of healthcare innovation: A scoping review. Vol. 25, Health Expectations. John Wiley and Sons Inc; 2022. p. 840–55.

111. Wiles LK, Kay D, Luker JA, Worley A, Austin J, Ball A, et al. Consumer engagement in health care policy, research and services: A systematic review and meta-analysis of methods and effects. Vol. 17, PLoS ONE. Public Library of Science; 2022.

112. Vargas C, Whelan J, Brimblecombe J, Allender S. Co-creation, co-design and co-production for public health: a perspective on definitions and distinctions. Public Heal Res Pract. 2022 Jun 1;32(2):3222211.

113. Bombard Y, Baker GR, Orlando E, Fancott C, Bhatia P, Casalino S, et al. Engaging patients to improve quality of care: A systematic review. Vol. 13, Implementation Science. BioMed Central Ltd.; 2018.

114. Darwin Z, Galdas P, Hinchliff S, Littlewood E, McMillan D, McGowan L, et al. Fathers' views and experiences of their own mental health during pregnancy and the first postnatal year: A qualitative interview study of men participating in the UK Born and Bred in Yorkshire (BaBY) cohort. BMC Pregnancy Childbirth. 2017 Jan 26;17(1):45.

115. Roundtable on Health Literacy, Board on Population Health and Public Health Practice, Institute of

Medicine. How Can Health Care Organizations Become More Health Literate? National Academies Press (US). Washington (DC); 2012.

116. Brach C, Keller D, Hernandez LM, Baur C, Parker R, Dreyer B, et al. Ten Attributes of Health Literate Health Care Organizations [Internet]. 2012. Available from: https://nam.edu/wp-content/uploads/2015/06/BPH_Ten_HLit_Attributes.pdf.

117. Farmanova E, Bonneville L, Bouchard L. Organizational health literacy: Review of theories, frameworks, guides, and implementation issues. Inq (United States). 2018;55.

118. Bremer D, Klockmann I, Jaß L, Härter M, von dem Knesebeck O, Lüdecke D. Which criteria characterize a health literate health care organization? – a scoping review on organizational health literacy. BMC Health Serv Res. 2021;21(1):1–15.

119. Musgrave LM, Kizirian N V., Homer CSE, Gordon A. Mobile phone apps in australia for improving pregnancy outcomes: Systematic search on app stores. JMIR mHealth uHealth. 2020 Nov 1;8(11):e22340.

120. Bert F, Passi S, Scaioli G, Gualano MR, Siliquini R. There comes a baby! What should i do? Smartphones' pregnancy-related applications: A web-based overview. Health Informatics J. 2016;22(3):608–17.

121. Lee Y, Moon M. Utilization and content evaluation of mobile applications for pregnancy, birth, and child care. Healthc Inform Res. 2016;22(2):73–80.

122. Muñoz-Mancisidor A, Martin-Payo R, Gonzalez-Mendez X, Del Mar Fernández-Álvarez M. Content, behavior change techniques, and quality of pregnancy apps in Spain: Systematic search on app stores. JMIR mHealth uHealth. 2021;9(11):1–9.

123. Aryana B, Brewster L. Design for mobile mental health: Exploring the informed participation approach. Health Informatics J. 2020 Jun 1;26(2):1208–24.

124. Ministero della Salute Italiano. Vaccinazioni dell'età pediatrica. Anno 2021 (coorte 2019). [Internet]. 2022. Available from: https://www.salute.gov.it/imgs/C_17_tavole_20_10_0_file.pdf

125. Bragazzi NL, Barberis I, Rosselli R, Gianfredi V, Nucci D, Moretti M, et al. How often people google for vaccination: Qualitative and quantitative insights from a systematic search of the web-based activities using Google Trends. Hum Vaccines Immunother [Internet]. 2017;13(2):464–9. Available from: http://dx.doi.org/10.1080/21645515.2017.1264742

126. Giambi C, Fabiani M, D'Ancona F, Ferrara L, Fiacchini D, Gallo T, et al. Parental vaccine hesitancy in Italy – Results from a national survey. Vaccine. 2018 Feb 1;36(6):779–87.

127. Rosso A, Massimi A, Pitini E, Nardi A, Baccolini V, Marzuillo C, et al. Factors affecting the vaccination choices of pregnant women for their children: a systematic review of the literature. Hum Vaccines Immunother [Internet]. 2020;16(8):1969–80. Available from: https://doi.org/10.1080/21645515.2019.1698901

128. Bruno S, Nachira L, Villani L, Beccia V, Di Pilla A, Pascucci D, et al. Knowledge and beliefs about vaccination in pregnant women before and during the COVID-19 pandemic. Front Public Heal. 2022;10.

129. Lupton D, Pedersen S. An Australian survey of women's use of pregnancy and parenting apps. Women and Birth [Internet]. 2016;29(4):368–75. Available from: http://dx.doi.org/10.1016/j.wombi.2016.01.008

130. Meldgaard M, Gamborg M, Terkildsen Maindal H. Health literacy levels among women in the prenatal period: A systematic review. Sex Reprod Healthc [Internet]. 2022;34(August):100796. Available from: https://doi.org/10.1016/j.srhc.2022.100796

131. Humphries N, McDermott AM, Creese J, Matthews A, Conway E, Byrne JP. Hospital doctors in Ireland and the struggle for work–life balance. Eur J Public Health. 2020;30:IV32–5.

132. Schwartz SP, Adair KC, Bae J, Rehder KJ, Shanafelt TD, Profit J, et al. Work-life balance behaviours cluster in work settings and relate to burnout and safety culture: A cross-sectional survey analysis. BMJ Qual Saf. 2019;28(2):142–50.

133. Mahesh PKB, Gunathunga MW, Arnold SM, Jayasinghe C, Pathirana S, Makarim MF, et al. Effectiveness of targeting fathers for breastfeeding promotion: Systematic review and meta-analysis 11 Medical and Health Sciences 1117 Public Health and Health Services. BMC Public Health. 2018;18(1):1–14.

134. He K, Mack WJ, Neely M, Lewis L, Anand V. Parental Perspectives on Immunizations: Impact of the COVID-19 Pandemic on Childhood Vaccine Hesitancy. J Community Health. 2022 Feb 1;47(1):39–52.

135. Bertoncello C, Ferro A, Fonzo M, Zanovello S, Napoletano G, Russo F, et al. Socioeconomic determinants in vaccine hesitancy and vaccine refusal in Italy. Vaccines. 2020;8(2):1–9.

136. van Zoonen K, Ruijs WLM, De Melker HE, Bongers MEJ, Mollema L. How to increase awareness of additional vaccinations; the case of maternal pertussis vaccination. BMC Public Health. 2021 Jun 29;21(1):1257.

137. Januszek SM, Faryniak-Zuzak A, Barnaś E, Łoziński T, Góra T, Siwiec N, et al. The approach of pregnant women to vaccination based on a covid-19 systematic review. Med. 2021;57(9):977.

138. Garcia-Moreno C, Jansen HAFM, Ellsberg M, Heise L, Watts C. WHO Multi-Country Study on Women's Health and Domestic Violence Against Women: Report on the First Results. World Health Organization. 2005.

139. ISTAT. La gravità e le conseguenze della violenza [Internet]. 2014. Available from: https://www.istat.it/it/violenza-sulle-donne/il-fenomeno/violenza-dentro-e-fuori-la-famiglia/gravita-e-conseguenze

140. Segers S, Mertes H, Pennings G. An ethical exploration of pregnancy related mHealth: does it deliver? Med Heal Care Philos. 2021 Dec 1;24(4):677–85.

141. Goetz M, Müller M, Matthies LM, Hansen J, Doster A, Szabo A, et al. Perceptions of patient engagement applications during pregnancy: A qualitative assessment of the patient's perspective. JMIR mHealth uHealth. 2017 May 1;5(5):e73.

142. van Haasteren A, Gille F, Fadda M, Vayena E. Development of the mHealth App Trustworthiness checklist. Digit Heal. 2019;5:2055207619886463.

143. Shi J, Yan X, Wang M, Lei P, Yu G. Factors Influencing the Acceptance of Pediatric Telemedicine Services in China: A Cross-Sectional Study. Front Pediatr. 2021 Oct 18;9.

144. Tran S, Smith L, El-Den S, Carter S. The Use of Gamification and Incentives in Mobile Health Apps to Improve Medication Adherence: Scoping Review. Vol. 10, JMIR mHealth and uHealth. JMIR Publications Inc.; 2022.

145. Chan KL, Chen M. Effects of social media and mobile health apps on pregnancy care: Meta-analysis. JMIR mHealth uHealth. 2019;7(1):1–13.

146. Chen Q, Carbone ET. Functionality, Implementation, Impact, and the Role of Health Literacy in Mobile Phone Apps for Gestational Diabetes: Scoping Review. JMIR Diabetes. 2017;

147. MacKinnon AL, Simpson KM, Salisbury MR, Bobula J, Penner-Goeke L, Berard L, et al. Building Emotional Awareness and Mental Health (BEAM): A Pilot Randomized Controlled Trial of an App-Based Program for Mothers of Toddlers. Front Psychiatry. 2022 Jun 24;13.

148. NHS. The Topol Review: Preparing the healthcare workforce to deliver the digital future. An independent report on behalf of the Secretary of State for Health and Social Care [Internet]. Nhs. 2019. Available from: https://topol.hee.nhs.uk/the-topol-review/

149. Research2Guidance. mHealth Developer Economics Survey 2017-18 [Internet]. 2018. Available from: https://research2guidance.com/wp-content/uploads/2018/03/R2G-mHealth-Developer-Economics-2017-How-To-Monetize-Mobile-Health-Apps.pdf

150. Goto R, Watanabe Y, Yamazaki A, Sugita M, Takeda S, Nakabayashi M, et al. Can digital health technologies exacerbate the health gap? A clustering analysis of mothers' opinions toward digitizing the maternal and child health handbook. SSM - Popul Heal. 2021 Dec 1;16:100935.

151. Fisher K, Magin P. The telehealth divide: health inequity during the COVID-19 pandemic. Fam Pract. 2022 May 28;39(3):547–9.

152. Italian Council of Ministers. Italian Recovery and Resilience Plan [Internet]. Italian Council of Ministers. Rome; 2021. Available from: https://www.mef.gov.it/en/focus/documents/PNRR-NEXT-GENERATION-ITALIA_ENG_09022021.pdf

153. European Commission. Recovery plan for Europe [Internet]. European Commission, Directorate-General for Communication. 2021. Available from: https://commission.europa.eu/strategy-and-policy/recovery-plan-europe_en#documents

Appendix

CARE1000 questionnaires

(T0 only) General information

- In what year were you born? _____
- What week of pregnancy are you currently in? _____week + _____days
- What is the zip code of the place where you live? _____
- In which country were you born? Italy / Other (please specify _____)
- Your mother language is: Italian / Other (please specify _____)
- To which of the following ethnic groups do you feel you belong? Italian / Greek / Iberian / North and West European / North African / Balkan / Asian / Other (please specify _____)
- What is the highest level of schooling you have achieved? None (not yet) / Elementary school / Junior High School / High school / University / Postgraduate (Master's/Doctorate) / Other (please specify _____)
- How many years did you attend school? _____ years
- What is your current occupation? Executive Businesswoman / Freelancer / Employee / Worker / Housewife / Student / Not employed or unemployed / Other (please specify _____)
- Your occupation is: Full-time / Part-time or part-time
- Are you currently: Single / Married or cohabiting / Divorced / Widowed
- Your current economic situation is: Excellent / Good / Sufficient / Insufficient / I do not want to answer
- What was your weight before your pregnancy? _____kg
- What is your height? _____m
- Did you smoke during your pregnancy? Yes/No
- Did you smoke in the months before you became pregnant? Yes / No
- Have you had alcoholic beverages in the past? (Yes even if it was only half a glass of wine/small beer/alcoholic aperitif) Yes / No
- Have you been vaccinated against papillomavirus (HPV)? Yes / No
- Is your current partner(s) the biological father of the child? Yes / No / I prefer not to answer
- Your current partner is: Male / Female / I prefer not to answer
- In what year was your partner born? _____
- Where was your partner born? Italy / Other (please specify _____)
- Your partner's native language is: Italian / Other (please specify _____)
- To which of the following ethnic groups does your partner feel he/she belongs? Italian / Greek / Iberian / North and West European / North African / Balkan / Asian / Other (please specify _____)
- What is the highest level of schooling your partner has completed? None (not yet) / Elementary school / Junior High School / High School / University / Post-university (Master's/Doctorate) / Other (please specify _____)
- How many years has your partner/partner attended school? _____ years
- What is your partner’s current occupation? Executive Entrepreneur / Freelancer / Employee / Worker / Homemaker / Student / Not employed or unemployed / Other (please specify _____)
- What is your partner's occupation: Full-time / Part-time or part-time
- Does your partner smoke? Yes / No

- This pregnancy was: Planned / Spontaneous / Occurred after medically assisted reproductive techniques / Other (please specify _____)
- This pregnancy is: Singleton / Twin (2 twins) / Twin (3 or more twins)
- During this pregnancy, you plan to be cared for: By your midwife as part of the physiological pregnancy pathway / By your private gynaecologist / Other (please specify _____)
- Do you already have other children? No / 1 / 2 / 3
- Have you ever heard of folic acid? Yes / No
- Did you take folic acid before pregnancy? Yes / No

(T0, T1, T2, T3) Monitoring habits and behaviours

- Has your work situation changed since the onset of pregnancy? No, situation has not changed / I have lost my job / I am currently on maternity leave / Other (please specify _____)
- (T3 only) What is your current occupation? Businesswoman / Freelancer / Employee / Worker / Housewife / Student / Not employed or unemployed / Other (please specify _____)
- (T3 only) Your occupation is: full-time / part-time
- (T3 only) Your current economic situation is: Excellent / Good / Sufficient / Unsatisfactory / Would not like to answer
- What is your current weight? _____kg
- (T3 only) Are you taking any medications? Please specify_____
- Do you currently smoke? Yes/No
- How many cigarettes do you smoke per day? _____no
- Are you exposed to second-hand smoke? Yes / No
- (T3 only) Does your partner currently smoke? Yes / No
- (T3 only) Did you smoke during pregnancy? No / Yes / 2-3 times/week / 4 or more times/week
- How often have you had alcoholic beverages during your pregnancy so far? (Consider even half a glass of wine/small beer/alcoholic aperitif) Never / 1-2 times/month / 3-4 times/month / 2-3 times/week / 4 or more times/week
- During your pregnancy so far, how often did you drink 4 or more units of alcoholic beverages at one time? (By alcohol unit, we mean one glass of wine or one can of beer or one aperitif or one shot of liquor) Never / 1-2 times/month / 3-4 times/month / 2-3 times/week / 4 or more times/week
- The following are considered alcoholic units: a glass of wine, a can of beer, a shot of liquor). According to this definition, you are currently: a teetotaller / Stopped drinking alcohol when you found out you were pregnant / Take 1-2 alcohol units per week / Take 1 alcohol unit per day / Take 1-3 alcohol units per day / Take more than 3 alcohol units per day
- Have you taken folic acid in the last few months? Yes / No
- (T3 only) Have you taken any other supplements in the last few months? Yes / No
- Do you plan to have your son/daughter vaccinated in the future? Yes, for all vaccinations / Yes, but only for some vaccinations / Have not decided / Have not thought about it yet / No
- (T1, T2, T3 only) Have you been vaccinated against pertussis during this pregnancy (DPT vaccine: diphtheria, tetanus, pertussis)? Yes/No
- (T3 only) Are you currently breastfeeding? Yes, exclusively / Yes, but with supplemental feeding of breast / No / Other (please specify _____)

(T0, T1, T2, T3) Current knowledge and opinions

Select the applicable answer (true/false) for each of the statements:

- Maternal breastfeeding
    - May prevent obesity in infants
    - Should be discontinued if infant colic occurs

    - Promotes “mother's return to form"
    - prevents early respiratory tract illnesses in the baby/child
- Alcohol consumption during pregnancy
    - can lead to changes in the development of the foetus
    - can have harmful effects already at conception
    - if you limit yourself to moderate amounts of alcohol (e.g., half a glass per meal), there is no risk of harm
- Smoking during pregnancy
    - may influence the occurrence of severe malformations in the child
    - may influence the premature birth of the child
    - may affect low birth weight of the child
    - may affect the occurrence of some early respiratory diseases of the child
- The intake of folic acid
    - may reduce the risk of premature birth
    - may reduce the baby’s risk of developing certain heart defects
    - may reduce the baby’s risk of developing certain neural tube defects such as spina bifida
- In your opinion, what is the recommended maximum weight gain during pregnancy for a normal-weight woman? ___kg
- How long is it recommended to exclusively breastfeed your baby (i.e., without adding solid foods or liquids)? There is no specific time / No. months_____ / Do not know
- Until what age do you think it is desirable for your child to be breastfed? Until the time slid foods are introduced / Up to 1 year / Up to 2 years or even beyond

On a scale of 1 to 5, please indicate how much you agree with the following statements, where 1=not at all agree and 5=very much agree

- The disease being vaccinated against is less dangerous than the vaccine itself
- Too many vaccines are given together
- It is important to vaccinate children because the diseases that are vaccinated against can have very serious consequences
- If people stop vaccinating, many diseases that are now very rare could come back into circulation
- Healthy lifestyles can prevent disease without vaccinating children

(T0, T1, T2, T3) Health literacy assessment. Italian version of the 16-item European Health Literacy Survey Questionnaire HLS-EU-Q16

(T3 only) Social impact assessment

- On a scale of 1 to 10, how adequate was the time in attendance given to you by Burlo's medical/nursing staff during your pregnancy? (1. not at all; 10. very much) _____
- During your pregnancy, on average, how many hours per week did you consult the web (search engines, sites, social media, blogs, etc.) to search for medical/health information? never occurred to me/ less than 1 hour / between 1 and 3 hours / between 3 and 5 hours / between 5 and 7 hours / more than 7 hours
- During your pregnancy, on average, how many hours per month did it take you to schedule appointments (visits, instrumental examinations, tests, etc.) at the Burlo facility? less than 1 hour / between 1 and 2 hours / between 2 and 4 hours / between 4 and 6 hours / more than 6 hours
- Using a scale of 1 to 10, how easy was it to find information regarding the course of your pregnancy at the Burlo facility? (1. not at all; 10. very much)

- During your pregnancy, how often did you need to use the obstetrics-gynaecology reception or the paediatric emergency room at Burlo? _____ number of times
- During your pregnancy, how often did you happen to call the Burlo for information? never happened to me / between 1 and 5 times / between 6 and 10 times / between 11 and 20 times / more than 20 times
- During your pregnancy, how often did you visit Burlo facilities/outpatient clinics for information (other than scheduled appointments)? It never happened to me / Once / 2 to 5 times / 6 to 10 times / more than 10 times
- Using a scale of 1 to 10, how much did the information you received from Burlo enable you to show up for scheduled appointments (examinations, instrumental examinations, tests, etc.) with all the necessary documentation/preparation? (1. never; 10. always)
- During your pregnancy, could you tell us if and how many complaints you have made to Burlo? (in case of no complaints made write 0)
- Using a scale of 1 to 10, how well did the information you received from the Burlo enable you to arrive prepared for the day of delivery (delivery suitcase, specific procedures for admission, etc.)? (1. not at all; 10. very much)
- On a scale of 1 to 10, how successful were you in sharing information regarding your pregnancy within your household? (1. not at all; 10. very much)
- On a scale of 1 to 10, how successful were you in sharing information regarding the postpartum period within your household? (1. not at all; 10. very much)
- Were you able to involve your partner in pre-partum classes? Yes / No / I don't have a partner
- If yes, on a scale of 1 to 10, how easy was it for you to involve your partner in the pre-natal classes? (1. not at all; 10. very much)
- During the pregnancy period, on a scale of 1 to 10, how well did you feel you were able to manage your health? (1. not at all; 10. very much)
- Upon returning home after giving birth, on a scale of 1 to 10, how well did you feel you were able to manage your son/daughter's health? (1. not at all; 10. very much)
- Upon returning home after childbirth, on a scale of 1 to 10, how well did you feel you were able to manage your home life? (1. not at all; 10. very much)

(T3 only) Satisfaction questionnaire

- Do you think the information conveyed by the app is complete? Not at all / Slightly / Somewhat / Very / Completely
- Do you think the information conveyed by the app is useful? Not at all / Slightly / Somewhat / Very / Completely
- Do you think the information conveyed by the app is easy to understand? Not at all / Slightly / Somewhat / Very / Completely
- Which of the topics offered by the app did you find most useful? _____
- Among those proposed by the app, are any of the topics covered in an unclear way? Yes/No
- If yes, which ones? _____
- Are there any topics not offered by the app that you would have liked to have explored? Yes/No
- If yes, which ones? _____
- How often have you searched the web (search engines, social media, social networks, blogs, sites, etc.) for information because you were not satisfied with the information offered by the app? Never / Rarely / Sometimes / Often / Always
- Have you experienced any issues while using the app? Yes/No
- If yes, which ones? _____

Express your degree of agreement/disagreement with each of the following six statements on a scale of 1 to 5, where 1 = Strongly disagree to 5 = Strongly agree.

- This app has increased my awareness of the importance of adopting behaviours for my health and the health of my child(ren) during pregnancy and puerperium.
- This app has increased my knowledge/understanding of behaviours for my health and that of my child(ren) to take during pregnancy and puerperium.
- The app has changed my attitude by improving behaviours for my health and that of my child(ren) during pregnancy and puerperium.
- The app increased my intentions/motivation to engage in behaviours for my health and that of my child(ren) during pregnancy and puerperium.
- This app encouraged me to seek further help to undertake behaviours for my own health and that of my child(ren) during pregnancy and puerperium (if there was a need).
- Using this app has increased my behaviours for my health and that of my child(ren) during pregnancy and puerperium.
- Overall, how satisfied are you with the app? Not at all / Slightly / Somewhat / Very / Completely