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Global scenarios in Maternal and Fetal Health  
Diagnostics Business in year 2030 – Analysis,  
Conclusions and Suggestions



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## Global scenarios in Maternal and Fetal Health Diagnostics Business in year 2030 – Analysis, Conclusions and Suggestions

In this development work the current landscape for the maternal and fetal diagnostics business was studied. Thesis aimed to answer to the question “what are the competitive advantages in the future for maternal and fetal health diagnostics business”. Thesis investigated the landscape from high to low-income settings and analyzed available data, drivers, trends, and silent signals from various sources with the aim to form a big picture of today's maternal and fetal health diagnostic business. Trends and other affecting factors were analysed both from external and internal dimensions. The information sources for the study were gathered from different articles, publications, and reports. Empirical findings were further analyzed using different strategic tools. These included PESTEL, SWOT and, Porter's five forces. The analysis of the findings was used to present four scenarios of the probable futures. In the conclusions and suggestions, reflections of the analyses were conducted to make the recommendations for maternal and fetal health diagnostic business competitive advantages against the potential futures.

Keywords:

PESTEL, SWOT, healthcare, access, equitability, sustainability, health economics, digitalization

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## Mahdolliset globaalit tulevaisuudet äidin ja sikiön terveyden diagnostiikan liiketoiminnassa vuonna 2030 – analyysi, johtopäätökset ja suositukset

Kehitystyössä tutkittiin äidin ja sikiön terveyden diagnostiikan liiketoiminnan nykyistä ympäristöä. Opinnäytetyön tavoitteena oli vastata kysymykseen "mitkä on tulevaisuuden kilpailuedut äidin ja sikiön terveys diagnostisessa liiketoiminnassa?". Tutkimus keskittyi sekä korkea- että pienituloisiin maihin. Opinnäytetyössä tutkittiin ja analysoitiin eri lähteistä saatavaa dataa, tekijöitä, trendejä ja hiljaisia signaaleja, tavoitteena muodostaa kokonaiskuva tämän päivän äidin ja sikiön terveydenhuollon diagnostiikan liiketoiminnasta. Suuntauksia ja muita vaikuttavia tekijöitä tutkittiin sekä ulkoisista, että sisäisistä ulottuvuuksista. Tutkimuksen tietolähteet koottiin erilaisista artikkeleista, julkaisuista ja raporteista. Empiirisiä havaintoja analysoitiin edelleen erilaisilla strategisilla työkaluilla. Niihin kuuluivat PESTEL, SWOT ja Porterin viisi voimaa. Löydösten analyysin avulla esitettiin neljä skenaariota todennäköisestä tulevaisuudesta. Johtopäätöksissä ja ehdotuksissa analyysien pohdintaa käytettiin suositusten tekemiseksi äidin ja sikiön terveyden diagnostiikan liiketoiminnan kilpailueduista mahdollisia tulevaisuuksia vastaan.

Asiasanat:

PESTEL, SWOT, terveydenhuolto, saatavuus, tasa-arvo, kestävyys, terveystalous, digitalisaatio

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## List of abbreviations

ACOG	American College of Obstetricians and Gynecologists
AFP	Alphafetoprotein
AHA	American Hospital Association
AMCHP	Association Of Maternal And Child Health Programs
AI	Artificial Intelligence
BMI	Body Mass Index
CA	Chromosomal Abnormalities
cfDNA	cell-free DNA
cffDNA	cell-free DNA of fetal origin
cFTS	combined First Trimester Screening
COVID-19	Corona Virus Disease
CRP	C-Reactive Protein
EU	European Union
ECL	European Climate Law
FDA	Federal agency that regulates food, drugs, medical devices
fFN	fetal Fibronectin
FIGO	The International Federation of Gynecology And Obstetrics
FNR	False-Negative Rate
FPR	False-Positive Rate

GBD	Global Burden Of Diseases
GDB	Gross Domestic Product
GDM	Gestational Diabetes Mellitus
GDPR	General Data Protection Regulation
HIC	High-income country
IL	Interleukine
IGFBP1	Insulin Growth Factor Binding Protein 1
IoT	Internet-of-Things
IP	Intellectual Property
IVD	In Vitro Diagnostics
IVDR	In Vitro Diagnostics Regulation
LIC	Low-income country
LMIC	Low- and middle-income country
MDG	Millenial Development Goals
MMR	Maternal Mortality Ratio
NGS	Next-Generation Sequencing
NICE	National Institute For Clinical Excellence
NIPT	Non-Invasive Prenatal Testing
NIPD	Non-Invasive Prenatal Diagnostics
NTD	Neural Tube Defect
PG	Prenatal Genetics

PESTEL	Political, Environmental, Social, Technology, Economical, Legal,
PIGF	Placental Growth Factor
PMNCH	Partnership for Maternal, Newborn and Child Health
POC	Point-Of-Care
POCT	Point-Of-Care Testing
PROM	Premature rupture of membranes
PTB	Preterm birth
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDG	Sustainable Development Goals
sFlt-1	soluble Fms-like tyrosine kinase-1
SWOT	Strengths, Weaknesses, Opportunities, Threats
TFR	Total Fertility Rate
T21	Trisomy 21, Down syndrome
T13	Trisomy 13, Patau syndrome
T18	Trisomy 18, Edward syndrome
UN	United Nations
VC	Venture Capital
WHO	World Health Organization

# 1 Introduction

Clinical practice recommendations and technologies in maternal and fetal health diagnostics are rapidly evolving and practices are not standardized over different countries. This is true especially between different high- and low-income geographical regions. Between companies, there is high competition on-going and the future with constantly evolving and newly introduced solutions is blurry. COVID-19 accelerated the implementation of new solutions, including digital and decentralized solutions. And the rapid shift to these solutions surprised many of the companies in this diagnostic business.

Do the new technologies replace the currently used methods? What will happen to the currently used methods, will they be used in future? How are the current trends affecting the business? Will diagnostic business be more centralized or decentralized? How will the population structure and statistics influence on diagnostics? What is the effect of public policy programs?

In today's business environment, anticipating the possible future is a key competence. Businesses must be able to continuously adjust their strategies in a changing environment. Envisioning the potential future scenarios can be beneficial when planning strategies and tactics for the future. There are numerous factors affecting to the possible future, like technological evolvement, competition tactics, politics, socio-economical factors, population structure and even environmental status. Thus, the one future and direction of maternal and fetal health diagnostics business is complicated to anticipate. However, there are several means to envision the future, like planning for different future scenarios.

The following chapters go through the following topics: the objectives of this thesis, the structure of this thesis, research methodology, background information, literature, and available information review. Empirical part of the thesis compiles the process following with the results of the thesis work. The last chapters consist of the analysis, reflections and conclusions of the findings and the suggestions as a summary of the thesis process

## 1.1 Objectives of the Thesis

Forecasting future changes in markets and business environment will be more and more important for companies. Geographical regions forming different landscapes for businesses in highly competed environment that is experiencing a technological development peak. The primary objective of this thesis is to present different plausible future scenarios for maternal and fetal health diagnostic business. Main research question is; what are the competitive advantages in the future for maternal and fetal health diagnostic business. The study examines what tools and methods to be utilized to anticipate the future.

This thesis aims to answer to the question “How to keep maternal and fetal health business at the top of the wave?”. The main goal is to find out if currently available information, data, research and study methods can be used to form plausible future scenarios for maternal and fetal health diagnostic business from high- to low-income settings.

Future scenarios are not predictions or forecasts, they are stories that provide insight into the potential future. Future scenarios give guidance when strategic decision are made that might have an impact on the future or might be affected by the future. The learnings from the scenarios can be then incorporated in strategies and plans and support when tactics needs to be altered.

To be able to provide the future scenarios, research to find the patterns and trends of the current with the already existing data is needed. This thesis will investigate and analyse available data, drivers, trends and silent signals from various sources with the aim to form a big picture of today’s maternal and fetal health diagnostic business and will use the information to present scenarios of the probable future.

## 1.2 Structure of the thesis

This thesis is divided into six chapters. In the first chapter the reader is introduced to the topic. Chapter gives background to the objectives and the research questions. The second chapter builds the knowledge base and theoretical background to the maternal and fetal health diagnostic business, the foundation for the thesis. The third chapter introduces the available information and data from literature. The analysis of the literature and its findings are presented in chapter four. Following with conclusions, learnings, and reflections of the study in the fifth chapter. Finally, the suggestions based on the research question are presented in the sixth chapter.

## 1.3 Research Methodology

To form a picture of today's maternal and fetal health diagnostic business, both internal and external landscapes will be studied. Data used in the analyses will be collected from various sources, such as scientific publications, market research reports, guidelines, legislation, reports, governmental publications, statistics, conference content, health technology trend reports.

Different strategic analysis methodologies like PESTEL, SWOT and Porter's Five Forces are used to analyze the data. In short, as PESTEL analysis can help businesses identify the trends and changes in the macro-environment that can create or reduce opportunities and threats for the business, and further considers a broader range of factors that may not be directly related to competition but can still impact, SWOT analysis is more focused on the internal factors that are within the control of the business, but can affect its strengths and weaknesses. Further, Porter's Five Forces is used to study the competitive landscape. Information from the analyses will be used to create a plausible and alternative futures through scenario planning.

## **2 Maternal and Fetal Health diagnostics and introduction to prenatal care business**

Current maternal and fetal health diagnostics, more widely called prenatal care, has its roots back in the 1800s. By the mid-1800s, European physicians were able to acquire several insights about what has come to be known as preeclampsia or eclampsia (“toxemia”), which provided the foundation for future prenatal interventions. The association of convulsions in pregnant women with proteinuria was established in 1843 by John Lever, working at Guy’s Hospital in London. He suggested that rapid delivery was the most effective method of action. In 1896, Italian physician Riva-Rocci developed a sphygmomanometer that could accurately measure blood pressure. Following that, physicians began to assert that hypertension may be an early indication of eclampsia. In 1901, Scottish physician John William Ballantyne established the first maternity ward with 23 beds to provide care for women with complications and to study maternal and neonatal diseases in pregnancy. In the early 20th century, the advancement of care in Europe and new data revealed high rates of infant and maternal mortality, leading to a greater emphasis on prenatal care. These discoveries culminated in the initial codification of a prenatal visit schedule in 1930 by the United States Children’s Bureau. This schedule had remained unchanged through the current recommendations published in the “Guidelines for perinatal practice, 8th edition,” in 2017. (Peahl et al., 2021, 340.)

Already in 1930, a quarter century before the identification of trisomy 21 it was recognized that Down syndrome was more common in older women and that advanced maternal age increase the risk of chromosomal abnormalities. (Lejeune et al., 1959, 1721-1722, Penrose, 1933, 220). Although, the first non-invasive prenatal screen was actually maternal age, screening for fetal anomalies and abnormalities as a part of maternal and fetal care started to develop in early 70s (Hezenberg et al., 1979, 1453-1455, Burke et al., 2011, 154-155). True biochemical screening started off with neural tube defects (NTD). In the early 1970s, researchers in the United Kingdom found an

association between elevated levels of alphafetoprotein (AFP) in maternal blood and fetal NTD.

In 1982, an association between low levels of AFP and increased risk for Trisomy 21 (T21, also known as Down Syndrome) was first reported. With this biochemical screening marker AFP, Down Syndrome screening started during the second trimester of pregnancy. Such observations offered increased rationale for maternal serum screening, as well as the opportunity to expand T21 screening to younger women. However, the method with maternal age and AFP had only limited predictive value to screen the risk for T21. (Strike and Smith, 1982, 1334-1339.)

Further research identified an additional panel of maternal serum measures that provided more reliable identification of pregnancies at increased risk of T21. And in the 90s, first trimester screening for T21 was introduced with discovery of additional markers and improvements in ultrasound equipment (Wald and Hackshaw, 1997, 812-829). Development of various prenatal screening models has been continued until to date and are introducing constantly improved methods to detect fetal chromosomal anomalies in a cost-efficient manner and with alternative resources available.

In 1990's, placental growth factor (PIGF) was first introduced for preeclampsia (Torry et al., 1998, 1541-1544, Schmidt et al., 2009, 96-98). Discovery of PIGF made possible to expand prenatal screening to preeclampsia already in early pregnancy, in first trimester. However, PIGF also shifted the focus from screening fetal anomalies and abnormalities to wellbeing of the mother and placenta.

The fetal DNA in maternal circulation was found already in 70s (Hezenberg, 1979, 1453-1455) and non-invasive prenatal testing (NIPT) technology was introduced in 1997 (Lo et al., 1997, 485-87). At the same time with preeclampsia screening developing, in 2010 the advancements with circulating fetal free DNA (cell free DNA, cfDNA) in maternal serum started a whole new chapter in fetal trisomy screening (Thomas et al., 1995, 645, Bustamante-Aragones et al.,

2010, 197-198). The development of NIPT improved the accuracy of screening further from biochemical testing. However, serum markers enable detection of many other severe pregnancy complications that are not detectable with cfDNA, of which many may have treatment options.

“The success of the pregnancy is dependent on three factors. The baby, the placenta and the mother. Every one of them has to be in absolutely good health to be able to have a healthy outcome for both the mother and the baby. If we want to improve the health of the mothers and babies, we need to devote time, effort, resources and energy into screening for placental health, because that is far more likely to improve pregnancy outcomes than anything else ” *Professor Ranjit Akolekar, Medway Maritime Hospital, UK.*

For decades, early prenatal screening was strongly focused on the fetal anomalies and abnormalities. Today, many screening tests are used routinely in pregnancy to assess the health of the mother and baby. Screening includes, for example, blood tests for gestation diabetes, hemoglobin levels and infections and ultrasound in second and sometimes third trimester is used to assess fetal growth and placental placement.

When technologies have evolved and information has increased, more is now possible. More precise methodologies and technologies are being introduced that are both complementing and replacing widely used old methods and standard care models. Although the technological evolving has been constant since 1970s, the speed we see improvements and development introduced today is accelerating and is exponential. Further, the coronavirus disease 2019 (COVID-19) pandemic forced healthcare systems to reconsider prenatal care delivery practices (Towsend et al., 2021, 1-19). It was necessary to reduce viral exposure during clinic visits and to conserve scarce healthcare resources. Introduction of new approaches also lead to some of the care models being introduced permanently.

As the ability to screen and intervene has improved over the last century, the issues to be assessed have expanded to include not only medical aspects of

care but also barriers to access, psychologic considerations, and patient education about general health, pregnancy, and childbirth. (Phelan, 2008, 339-353.)

This rapidly evolving landscape from the company perspective is rather challenging and is requiring full focus on scanning the signs, trends, and drivers happening in the surrounding environment. Information flow is coming both inside the business and affected by development outside. The competition how to keep the business profitable and “in” the game is demanding requiring strong and agile strategy, tactics, and capabilities. Ability to see a step further to the future and to prepare for the plausible scenarios is vital.

### **3 Current Environmental Landscape of Maternal and Fetal Health Diagnostics**

#### **3.1 Global trends and changes in health tech**

To adjust the strategy and tactics to a shifting landscape, and to plan for possible futures, diagnostic companies and organizations need to be aware of the current healthcare trends. The global healthcare is still facing challenges of continuing effects of the COVID-19 pandemic. One of the effects is the continuing increase of healthcare costs globally with health inequities through affordability and access of care being a genuine concern. Thus, there is a pressure to reduce costs and improve access to care. At the same time there is a shortage of skilled workers and clinicians with increasingly aging global population, disruption of supply chains because of geopolitical tensions, and an increase in diseases based on worsening climate conditions. This has driven some healthcare systems to adopt emerging technologies to fill the gaps and re-think the structures of healthcare. Healthcare organizations are adopting use remote technologies and telemedicine which were quickly introduced during the pandemic. While maintaining the quality and accessibility of healthcare, governments, payers, and providers are taking measures to control costs. Evolving strategies are designed to help ensure cost-effective healthcare delivery.

Advanced technology solutions are being invented by technology companies. These solutions are being introduced to fill the gaps and solve the challenges of the healthcare, such as high costs, access, with changing population, and constrained resources. Already in 2022 health technology trend report, Future Today Institute listed among the health tech trends the following: big tech, automation, wearables and sensors for remote diagnosis through telemedicine, home testing and artificial intelligence enabling cut medical costs. (Future Today Institute, 2022) Also here, the digitalization with remote testing at home

or decentralized is seen as a major new form of healthcare. During the past few years, the trends in health tech has remained quite similar.

Although technology is introducing increasing number of new innovations and approaches, there are some limitations that make timely solutions unrealistic and prohibit the use and adoption, especially in the public healthcare: fractured data landscape, lack of infrastructure, and lack of data ownership and sharing regulation. However, at the same time, increasingly sophisticated patients, are actively taking charge of their own health requiring high quality. Innovations are sold to private sector and / or directly to consumers.

### 3.1.1 Trends in health policy

Health policy is defined by the World Health Organization (WHO) as the decisions, plans, and actions that are undertaken to achieve specific healthcare goals within a society (O'Brien et al, 2020, 1). Governments worldwide have faced severe challenges in the last few years. External shocks, COVID-19 pandemic and Russia's invasion to Ukraine has impacted the world. Energy and food markets have been severely disrupted, inflation continues to surge, and economic growth is slowing (EuroStat 2023). To cope, governments must respond to these emerging threats while already grappling with issues such as climate change and digital disruption. As already concluded, the need to adapt has driven the governments to seek for alternative, innovative ways for ensuring equitable care. New approaches and methods, decisions, plans and actions have been made and new objectives are needed to keep people safe and healthy also in the future.

Most well-known policies to improve health, like Millennium and Sustainable Development Goals, has been published by international organization United Nations (UN). Additionally, different non-profit organizations like Bill and Melinda Gates Foundation together with other international organizations like

the International Federation of Gynecology and Obstetrics (FIGO) and WHO have published policies for pregnancy care. While advancements in development of global health through policy and programs can be seen, these advancements in global health and development are very slowly translating into best practices.

The trends, environment and global state are shaping the healthcare. Healthcare costs continue to be a burden and access to care and health equity remains as top issues for health policy experts and researchers. While there are, increasingly new health care technologies, pharmaceuticals, and innovations introduced, also new policies are needed. Legislators and regulators are responding to ensure safety and efficacy and access to new products and care (see for IVDR later in this thesis). At the same time, the reimbursement landscape is evolving, although relatively slowly. Inevitably, investment is needed and economic and societal value of using the new technologies needs to be evaluated. (Phillips et al., 2023, 1-8) Figure 1 below is visualizing the relationships between different influencing factors that are shaping the future of health.

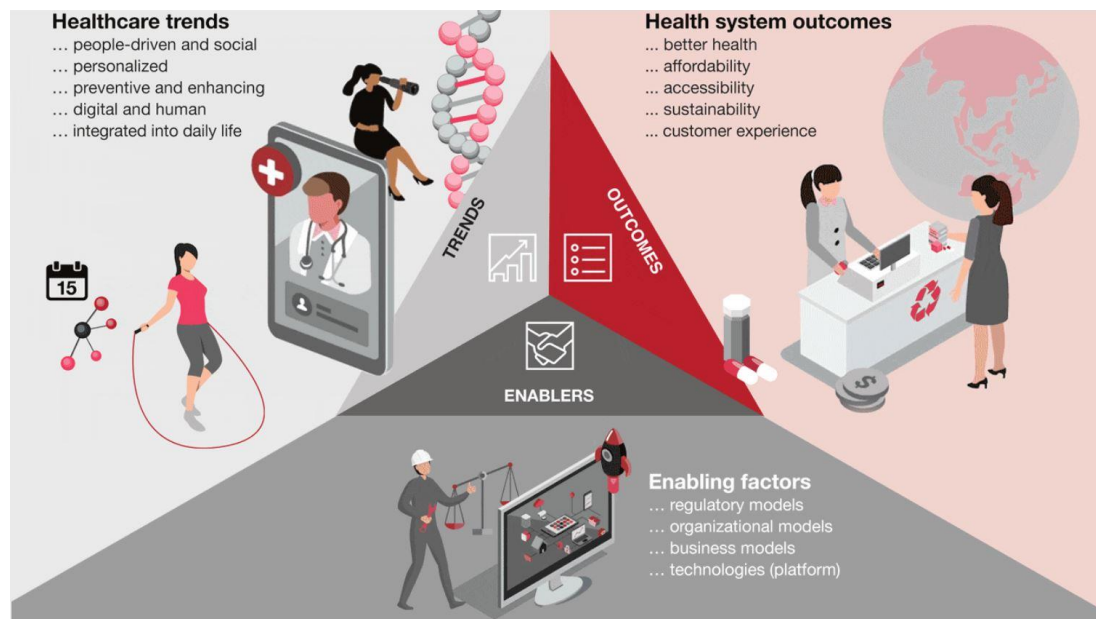


Figure 1. The future of health: different factors and their relations. (Strategy& Turkey (pwc.com) 2024)

### 3.1.1.1 Policies, regulations and guidelines in maternal and fetal health

Maternal and fetal health refers to the health of the unborn baby and woman during pregnancy, childbirth, and the postnatal period. To ensure high quality maternity care that is proactively identifying risk factors in clinical, behavioural, and social level, enhancing equity in care, reducing maternal morbidity and mortality, as well as prematurity and stillbirth, policies, guidelines, and regulations are needed both at international and national level.

Many of the maternal health policies and guidelines (like UNICEF, WHO, SDG and MDG) share similar high level goals to prevent maternal mortality and morbidity. Adverse outcomes of pregnancy and maternal deaths are mostly preventable (Figure 2) with timely management by skilled health professionals in supportive environments (Roser and Ritchie 2024). The investment to health systems is crucial. Strengthening quality, availability and resources in healthcare systems plays a pivotal role in reducing maternal mortality and improving overall maternal health. Ensuring all women have access to respectful and high-quality maternity care is essential to address inequalities.



Figure 2. Women could be save from dying in pregnancy and childbirth with better care. (Roser and Ritchie 2024)

In summary, maternal and fetal health policies should prioritize prevention, holistic care, health system strengthening, and equity to achieve positive outcomes for both mothers and babies. International organizations like WHO, UNICEF and FIGO and many national level organisations and foundations for

obstetric care (like the American College of Obstetricians and Gynecologists (ACOG) and National Institute for Clinical Excellence (NICE)) have published their own policies, guidelines, and recommendations on maternal and fetal health, defining the recommendations like safe childbirth, health system strengthening and respectful care. However, governments play a crucial role in shaping maternal and fetal health policies. Advocacy efforts, funding allocation, and legislative changes impact access to care, quality of services, and health outcomes. Policymakers need to collaborate to address disparities, to reduce maternal mortality, and to improve neonatal outcomes. Policies that promote access to care, prevention, affordability, and equity and consider cultural competence, respectful care, and community engagement are crucial.

### 3.1.2 Trends in health economics

Economic growth is central to shaping people's overall living conditions. Both poverty and inequity are dependent on the country's ability to substantially grow its economy. COVID-19 pandemic and Russia's invasion to Ukraine have disrupted global economy (EuroStat 2023). The global crisis has caused rise in energy prices, challenges in logistics of raw material and shortages of raw material and goods. These are seen in the rise of prices and overall costs. Since the beginning of this century, two types of essential categories have been increasing in price: healthcare and education (Routley 2023, Figure 3). According to International Monetary Fund's World Economic Outlook -report (International Monetary Fund 2023), global growth is forecasted to be slow from 3.5 percent in 2022 to 3.0 percent in 2023 and 2.9 percent in 2024. Global inflation is forecasted to decline steadily, but it is not expected to return to target until 2025. Several forces are holding back the recovery. There is little margin for error on the policy front. Central banks need to restore price stability while using policy tools to relieve potential financial stress when needed.

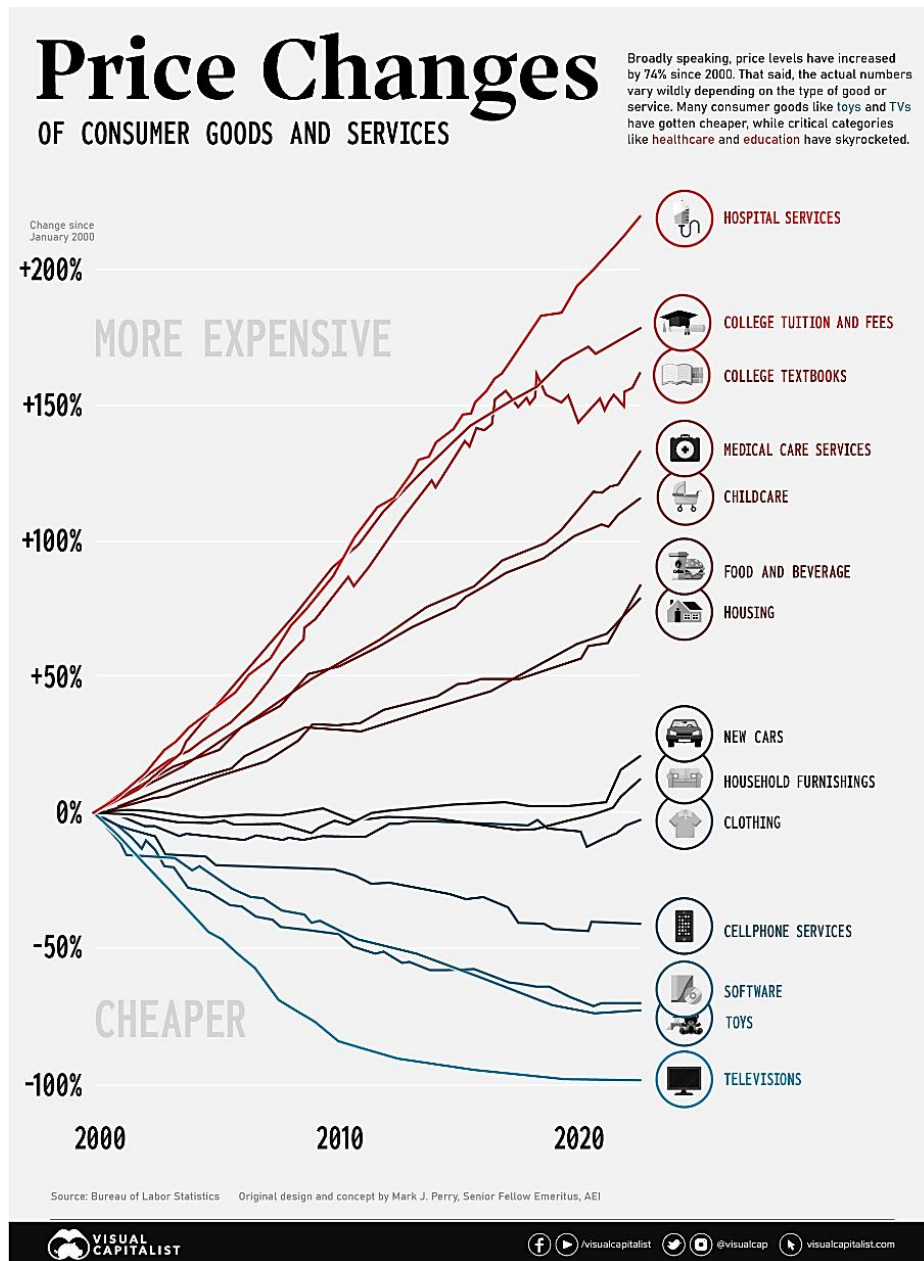


Figure 3. Consumer Price Inflation, by Type of Good or Service in years 2000-2022. (Routley 2023)

The global trend of general government debt has been in increase and have also been heavily influenced by COVID-19 pandemic and Russia's invasion to Ukraine. The debt-to-GDP ratio, often expressed as a percentage, is the metric comparing a country's public debt to its gross domestic product (GDP). The

amount of debt a government holds is a key indicator for the sustainability of its finances. The debt-to-GDP ratio, reliably indicates that particular country's ability to pay back its debts. If the debt is excessively high it may signal challenges in meeting financial obligations, potentially leading to economic instability. Rising government debt-to-GDP ratios need urgent response (Figure 4 and Figure 5). This is putting governments in a situation where they have limited options to make the right decisions to reduce their debt burdens without compromising elsewhere the commonwealth status of the country.

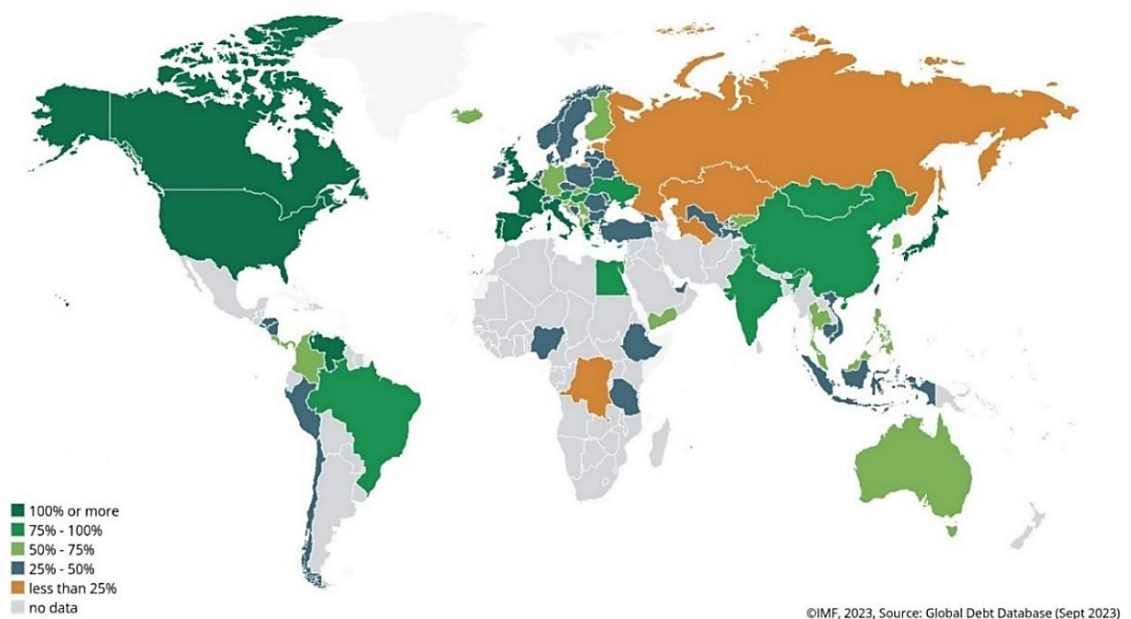


Figure 4. Global government debt-to-GDP ratios (percent of GDP) in 2022.  
(International Monetary Fund 2023)

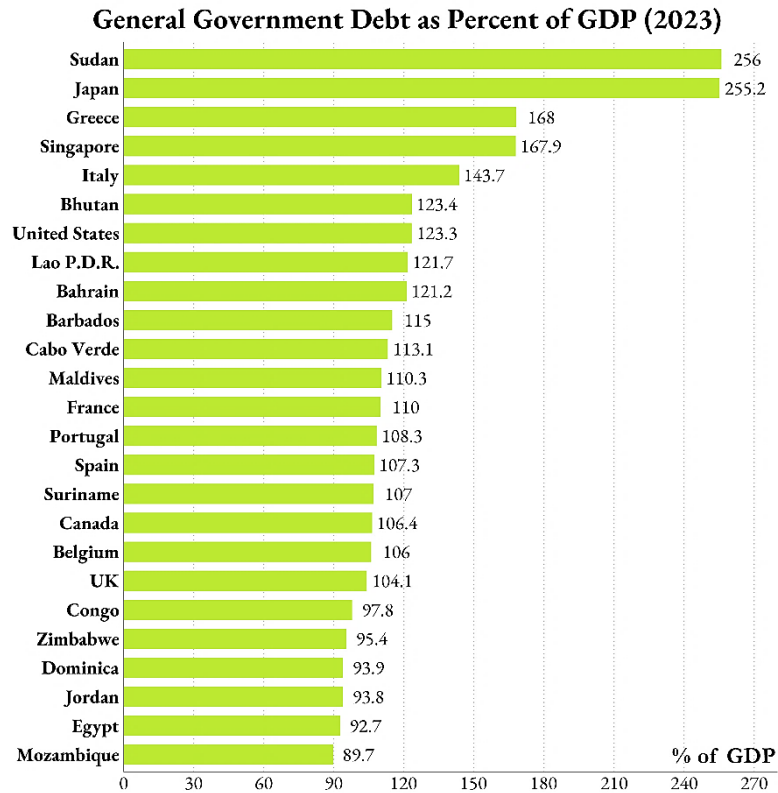


Figure 5. Global government debt-to-GDP ratios (percent of GDP) in 2023. (International Monetary Fund 2023)

Most nations, rich and poor, are facing the issue of per capita healthcare costs increasing faster than per capita gross domestic product (GDP). Global spending on health has increased over the past two decades (Ortiz-Ospina and Roser 2017, Figure 6). In 2023, WHO published a report 'Global spending on health: Coping with the pandemic'. According to this report, spending to healthcare in overall, was unequally distributed globally, with high-income countries (HICs) accounting for approximately 80% of the spend (Figure 7) (World Health Organization 2023b, 17).

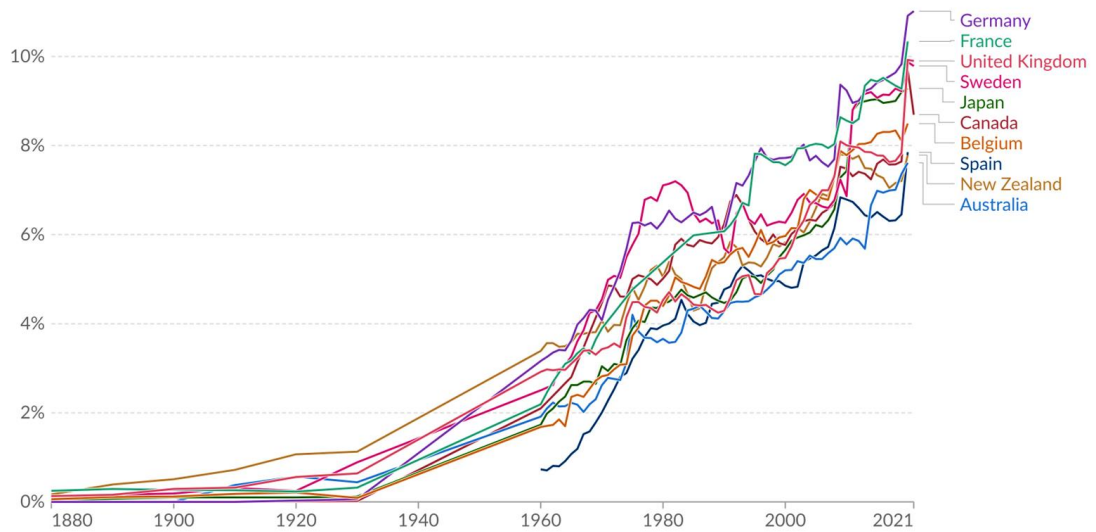


Figure 6. Government health expenditure as a share of GDP in years 1880-2021. (Ortiz-Ospina and Roser 2017)

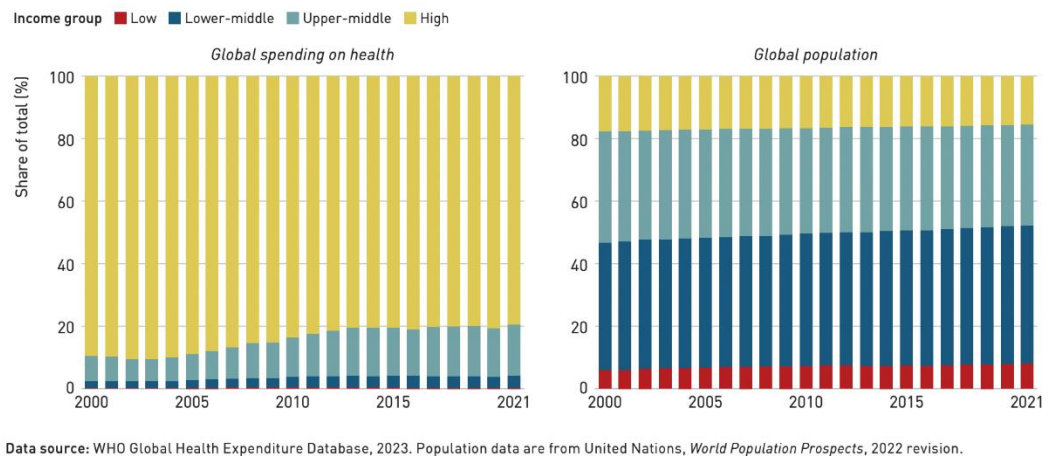


Figure 7. Health spending per income group in 2021. (World Health Organization 2023b)

In HICs, 70% of the expenditure was mainly financed by government. Higher government spending on health as a share of GDP is typically associated with a smaller proportion of out-of-pocket spending (OOPS) in total health expenditure. The low government spending on health was well seen in the low-income countries' (LICs') structure of health spending. Healthcare was primarily financed by OOPS (44%) and external aid (29%) with less than 30% was covered by governments (Figure 8). Although the out-of-pocket spending in low

income countries is on a relatively high level, OOPS fell during pandemic. (World Health Organization 2021, 8)

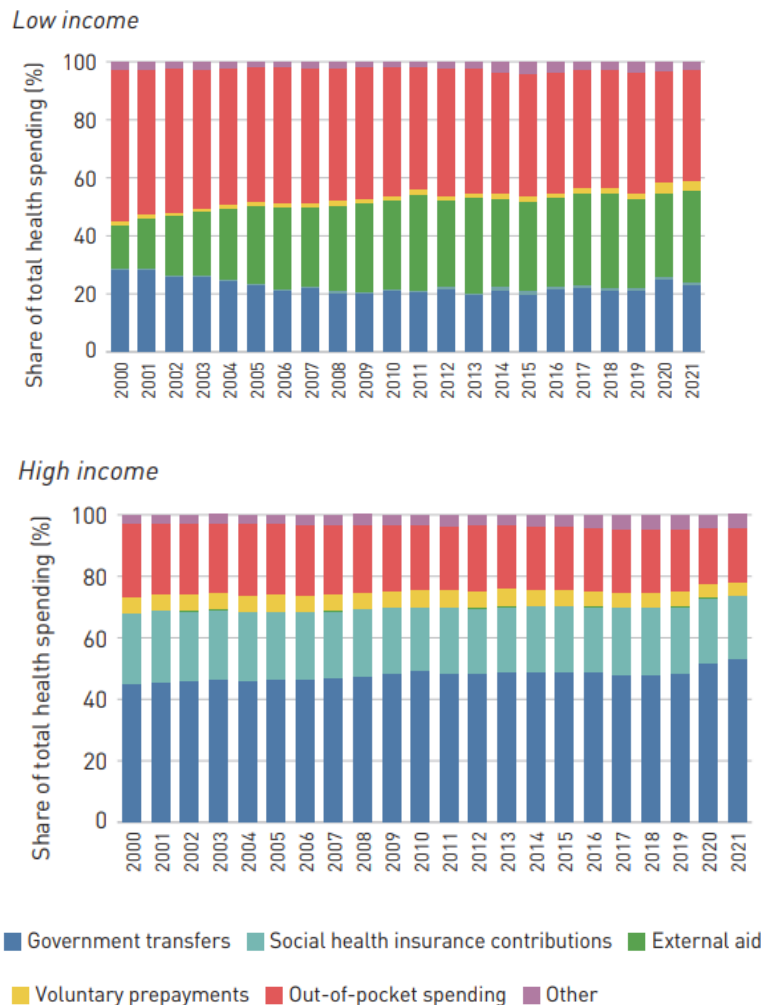


Figure 8. Global spending on health across low and high income groups. (World Health Organization 2023b, 24)

In addition, global average health spending per capita increased during the pandemic in 2021 in all income groups except LICs, where it fell. In 2021, spending increased to US\$ 9.8 trillion, which is 10.3% of the global gross domestic product (GDP). The growth in health spending in 2021 was a budgetary response to pandemic from governments. In high- and upper-middle-income countries, the increase in spending reflected higher prioritization of health within government budgets, while in low- and lower-middle-income

countries, the drop in spending reflected mainly an overall increase in general government spending. (World Health Organization 2023b, 11)

During COVID-19 pandemic, in 2021, annually increased external aid was crucial in supporting government spending in low- and lower-middle-income countries (Figure 9). At the same time, for many donating countries, sustaining government health spending and external aid levels during pandemic was challenging due to the deterioration in global economic conditions and the increase in debt-servicing obligations. (World Health Organization 2023b, 15, 26)

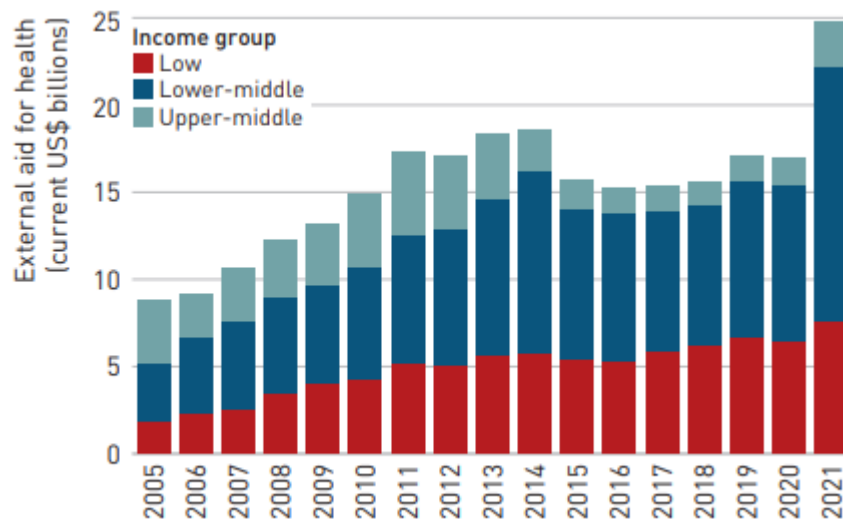


Figure 9. External aid for health 2005-2021. (World Health Organization 2023b)

### 3.1.2.1 Global increase in healthcare costs

The increasing cost of healthcare continues to define the quality, access, and affordability of health services worldwide. While healthcare providers are increasingly considering more affordable and efficient models for access, some of which are being delivered through technology and other innovations, companies are struggling with the increased cost of for example raw material, manufacturing, distribution, regulatory burden, and regulations.

While workforce expenses are a major driver of rising health costs, other factors also contribute. The cost of maintaining care facilities is one factor. We see countries closing smaller hospitals in rural areas and communities in favour of clinics that provide basic care (McIntyre et al., 2024, 8). As well as increasing trend in chronic diseases, the aging population will require more health care (Figure 10 and Figure 11). Aging populations increase demand for long-term care to treat chronic disease. (Alvarez, 2023.) Health care organizations globally are beginning to implement innovative technologies such as virtual wards and AI-enabled diagnostic tools and remote monitoring technology to reduce costs of age-related care. Providers also are investing in technologies to accelerate diagnoses and reduce treatment costs for chronic diseases.

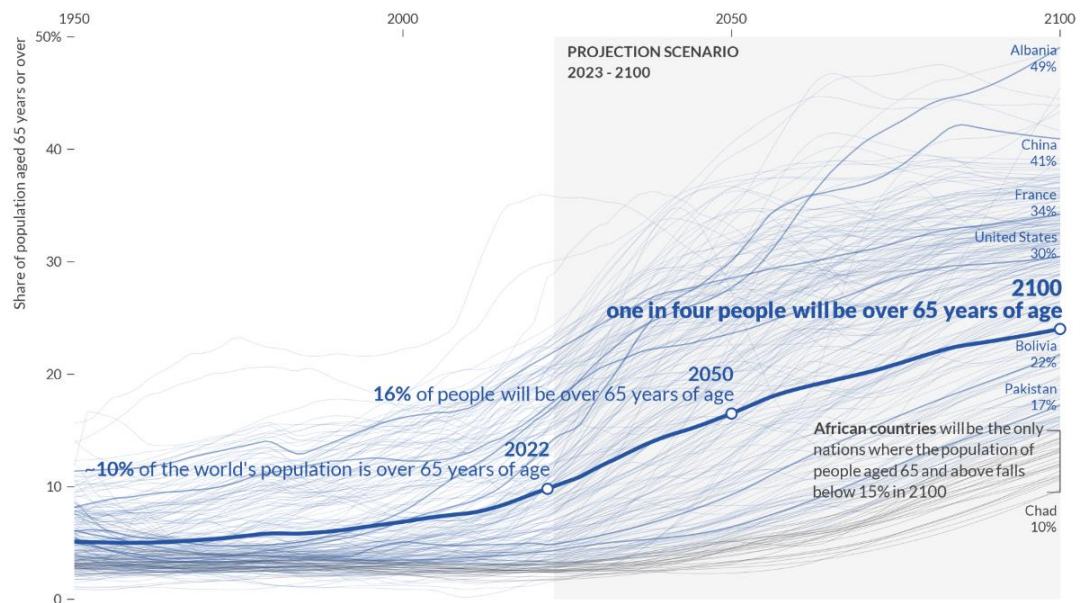


Figure 10. Share of over 65 years old in world's population between years 1950 and 2100. (Alvarez, 2023)

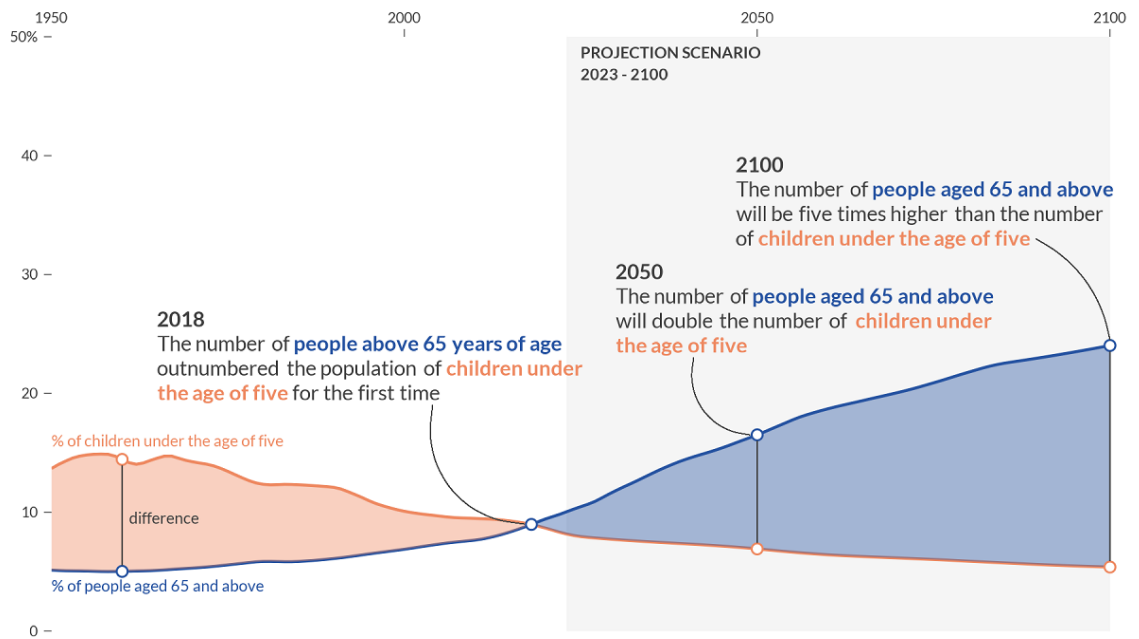


Figure 11. Share of under age of 5 versus over 65 years old in world's population between years 1950 and 2100. (Alvarez, 2023)

Paradoxically, the more the country has spent money to the healthcare, the longer is the lifetime expectancy (Figure 12) and the higher will the costs burden caused by the aging population be (Du, 2022).

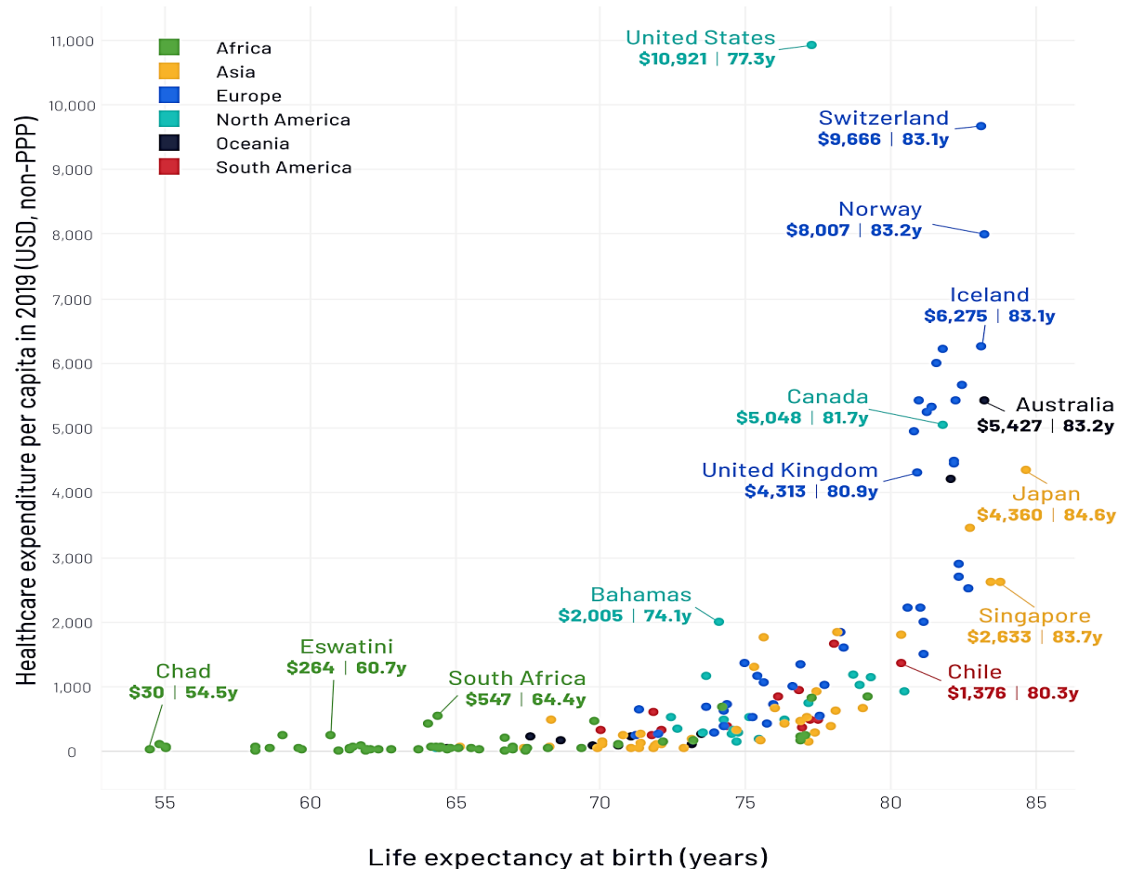


Figure 12. Healthcare expenditure per capita vs lifetime expectancy. (Du, 2022).

### 3.1.2.2 Investing to Women's health

Since in 1977 when the U.S. Food and Drug Administration excluded women of childbearing age from taking part in drug trials the health technology, research and development has ignored women (FDA, 2018). The technology is heavily behind and at the same time is introducing a significant market potential. Women represent half of the global population in women's health.

Today, there is a better realization of the unmet health needs of women and the awareness has increased fast during the past years. A vast number of apps and tech companies have been introducing in past years to meet the possible need women have. Products being introduced include for example apps and solutions for menstruation, hormonal cycle for fertility tracking, pregnancy, breastfeeding, and menopause. Regardless of the recent increased investments to address

the unmet needs, the solutions introduced have greatly leaned towards healthtech rather than life sciences. But not everything can be solved with an app or AI (with “digital biomarkers”). There has been a growing understanding that there is a gap in our knowledge with the clinical research and outcomes data available that would enable development of diagnostics, devices, and therapeutics (Alexe et al., 2024) to address women’s health issues. Past years, investors have increased their investment towards women’s health. However, the proportion of annual investment compared to overall healthcare investments is notably small (Figure 13). Although the definition of women’s health goes beyond the reproductive health, of the investments made to this area, pregnancy is still holding the top position.

Figure 14 below is showing how the investments are divided across the women’s health.

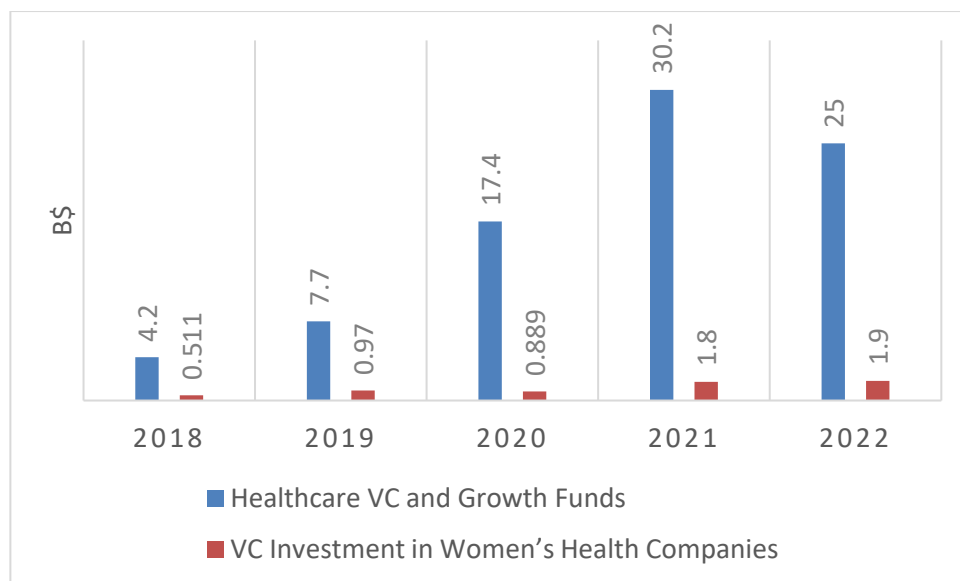


Figure 13. Healthcare VC and Growth Funds vs VC Investment in Women’s Health Companies (in US and Europe).(Silicon Valley Bank 2023)

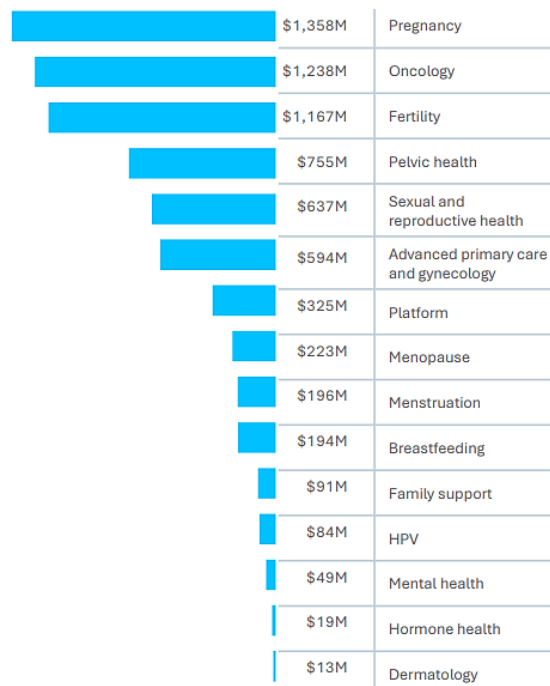


Figure 14. Venture Capital Investment Since 2019. (Silicon Valley Bank 2023)

### 3.1.3 Towards healthy motherhood

“Investing in women’s health will potentially contribute to economic and social development, not only for individual women but also for their families, communities, and societies.” Helen E. Clark in World Economic Forum 2023.

The concept of “healthy motherhood” covers the following areas under reproductive health: pre-pregnancy health, fertility planning, equitable and accessible antenatal care and postpartum follow-up. The range and use of telehealth technologies in the prenatal and postpartum periods have exploded since the COVID-19 pandemic. As with overall healthcare, telehealth services and solutions have shown to increase access to care, particularly for populations in underserved areas, at rural areas and with fewer resources, and has shown to produce comparable care with in-person care (DeNicola et al., 2020, 317-382, Society for Maternal Fetal Medicine, 2023 a,b, Wu et al., 2022, 1). Digital technologies (e.g. mobile phone and tablet apps and telehealth) have become vital health system strengthening tools globally. Studies have shown

improved outcomes with digital health interventions, including patients' timely access to health services and improvements in obstetric and gynecologic (Moise et al., 2023, 2,17).

The investment to women's health is showing both clinical, and technology-based advancements towards healthy motherhood. These advancements are outcome of guidance, solutions and actions with a goal to enable equitable care in high- and low-income settings, millennium development goals and sustainable development goals; development of clinical training programs, prenatal care expansion and potential, decentralized health systems, antiretroviral therapy for HIV, essential medicines, vaccines, mhealth/ehealth, ultrasonography, and obstetric haemorrhage management are concrete examples of the work done towards healthy motherhood. (Khorrami et al., 2019, 126-131, Hod et al., 2023, 6-8)

#### 3.1.4 Global inequality: high-income vs low-income countries

Despite statistics showing the maternal mortality rate has declined in the last 20 years, the number of maternal deaths worldwide is still unacceptably high. According to the WHO (World health organization, 2024a), an estimated 95% of maternal deaths occur in LMICs, and these two regions contained around 87% of the global maternal deaths in 2020 (Figure 15). WHO also states that "The high number of maternal deaths in some areas of the world reflects inequalities in access to quality health services." For expectant mothers living in rural or remote regions of the world – also called "medical deserts" due to limited access to health care facilities and services – their inability to access prenatal care and important diagnostic testing can pose a risk to their health and that of their baby (McIntyre et al., 2024, 8-10, Sonenberg et al., 2023, 1, March of Dimes Maternity care report, 2022, 6-30.) The deaths are caused due to complications during pregnancy, childbirth or postpartum period could be prevented in most cases.

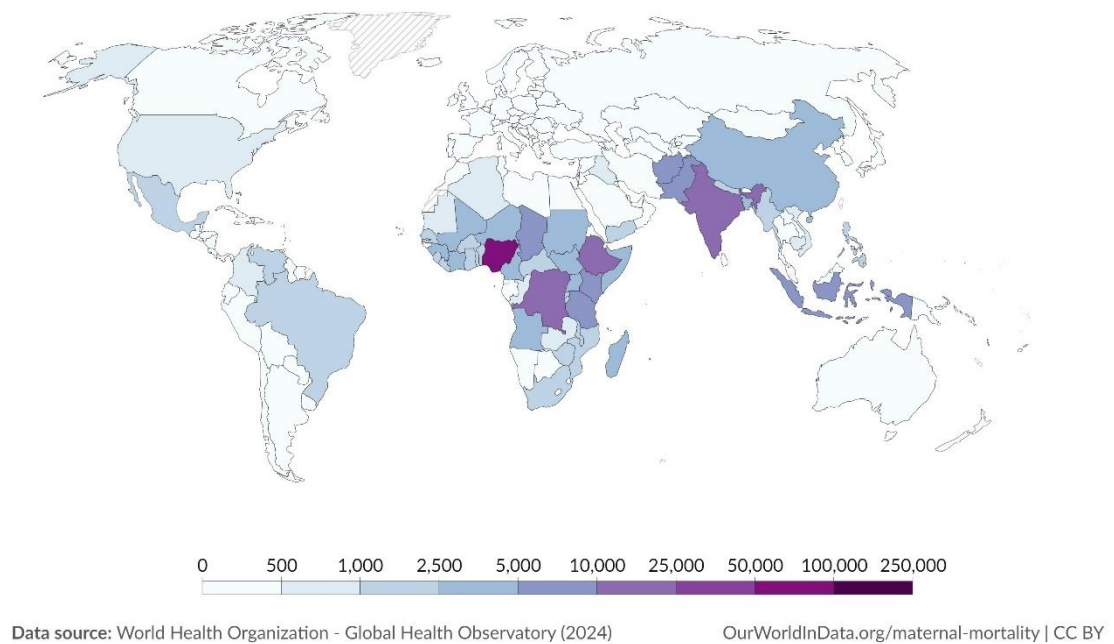


Figure 15. Maternal deaths in 2020. (Roser 2024).

In contrast to LMICs, current statistics suggest that in HICs very few women die from childbirth, due to universal maternal health care services (Yaya and Ghose, 2019, 151-153). In HICs, to address the known risks associated with pregnancy and birth implemented medical interventions have been largely successful and have resulted in very low levels of maternal and neonatal mortality (Chamberlain, 2006, 559-560, 563). Maternal mortality is disproportionately higher in LMICs compared to other parts of the world.

In LMICs, providing essential healthcare services throughout the pregnancy might be challenging and the care pathways or even the tools that are primarily developed for high-income settings are not a fit to these conditions. Studies have observed that the main challenges for promoting maternal health care utilization in resource-limited settings are linked to accessibility and affordability barriers (Yaya and Ghose, 2019, 146). To these are affecting various infrastructural, educational, technological, and financial issues at health systems level. Large disparities exist in a large number of countries across Asia

and Africa in the utilization of antenatal care and skilled birth assistance services (Yaya and Ghose, 2019, 151). Figure 16 shows the average utilization of antenatal care and the level of the trained personnel in different regions.

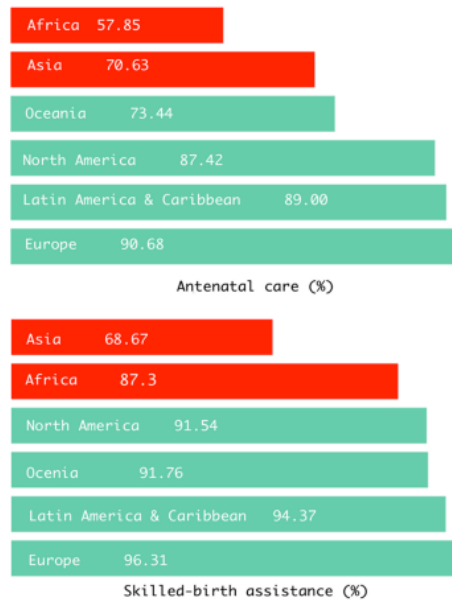


Figure 16. Regional inequity in the utilization of antenatal care and skilled birth assistance services. (Yaya and Ghose, 2019)

In recent years the diagnostics industry has moved towards technology-based healthcare interventions utilizing digital technologies like telemedicine and decentralized testing. The COVID-19 pandemic illuminated the need for decentralized testing with point-of-care testing (POCT) with health care services outside of traditional healthcare settings, such as offices, travel hubs, educational institutions, at home or even in rural resource limited locations. POCT and digital technologies have revolutionized healthcare delivery and holds potential in addressing the healthcare needs of women in LMICs.

Women in LICs lack access to adequate care (Dahab et al., 2020, 1-16). Introducing technology-based low-cost healthcare solutions to improve maternal and child health outcomes in LMICs has potential to increase access to care in such settings. One of the key benefits of digitalized and decentralized hybrid healthcare models is its ability to personalize medical case and allocate

resources strategically. It enables targeting the care to those who needs it the most. Digital, portable, and remote solutions can identify the patients who needs to be hospitalized from those who can still stay home. In LMICs this is critical when resources, including transportation to facilities are scarce. (Hod et al., 2023, 4-10.)

It is not only the LMICs that are benefitting from telehealth. March of Dimes released its 2022 report on maternity care deserts across the United States. The report found that there are up to 6.9 million women and almost 500,000 births across the U.S. that has low or no access maternity care, as there are no hospitals or birth centres offering obstetric care and no obstetric providers. In fact, March of Dimes are calling for policy recommendation to expand telehealth services to bridge gaps in health care, especially obstetric services where none exist and costs are considerable. USA has significantly higher maternal mortality rate than other comparable countries. In addition to location bound poor access to care, challenges with socioeconomic status and ethnic background are impacting the level and quality of care available (Tran et al, 2023, 1, 4). Several studies have provided data demonstrating the risks women of colour undergo because of lesser healthcare access and quality. Furthermore, women of colour have been reported to experience inequalities based on their age and level of education (Tran et al, 2023, 1). As an action to inequity in USA, the Association of Maternal and Child Health Programs (AMCHP), who drives to advance the health of women by strengthening governmental public health through a health equity lens, created a Birth Equity Ecosystem Map (Figure 17). A comprehensive vision of what the birth equity system needs in order to achieve equitable outcomes.

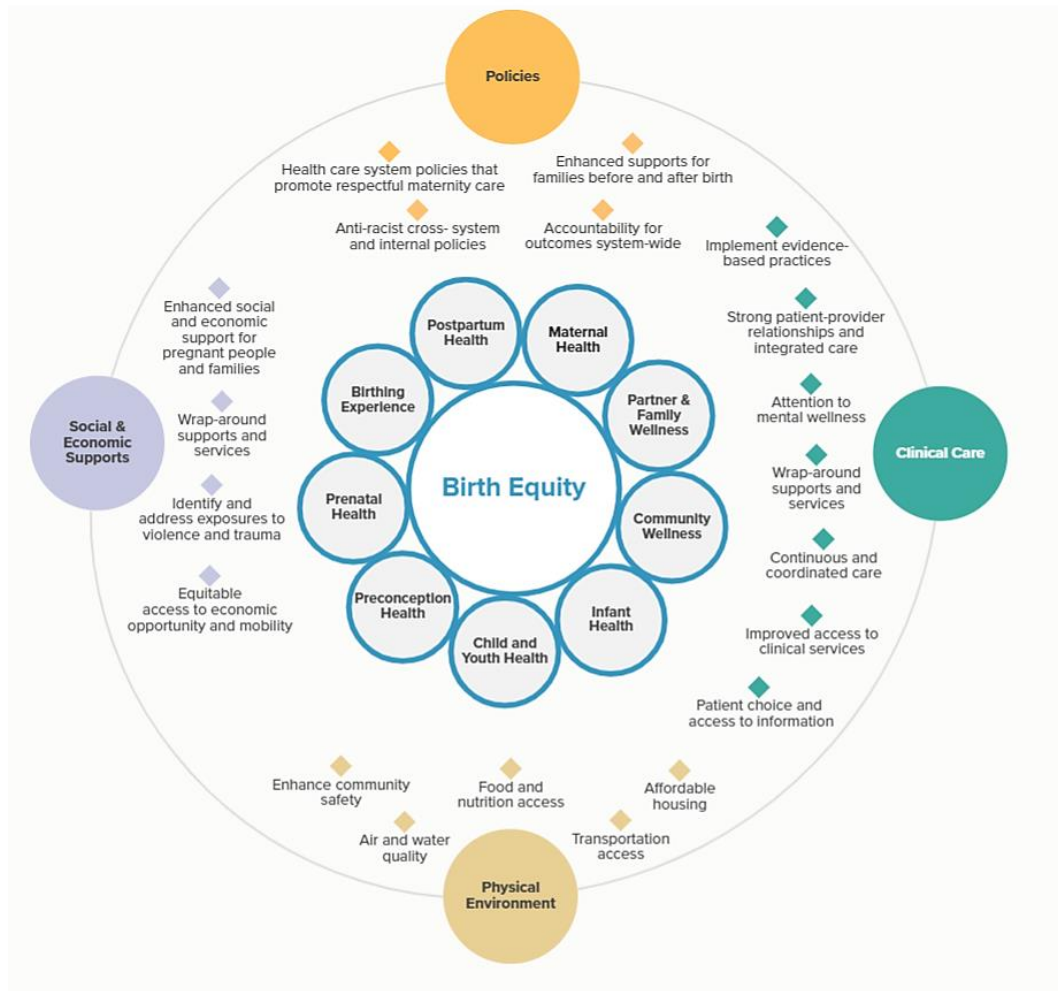


Figure 17. Birth Equity Ecosystem Map. (Simon, 2023)

### 3.1.5 Access to care

Access to care is directly linked to affordability. While higher costs reduce affordability of care, affordability can also reflect the level of investment in health and health systems. In many LICs, as few as one in seven individuals received all doses of the COVID-19 vaccination, while in high-income countries the same number was about three out of four in (Deloitte, 2024, 16). To improve access to care in developing regions, organizations are putting effort to improve the availability of medical supplies and treatments in developing regions.

However, access to and affordable care is a global issue (World Health Organization 2019b, 4,7) (Figure 18). Around half of the world's population still

lacks access to essential primary health care (World Health Organization, 2024b). As an action to seek access to and affordable care, medical tourism has become increasingly popular among businesses and insurance providers as a means of bringing down health care costs (Dalen et al., 2019, 9).

The current cost environment requires new strategies to transform healthcare organizations. Worldwide, providers are working to address inequities that inhibit access to and affordability of care through multiagency collaborative actions, networks of care and programs (Agyekum et al., 2023, 2). Healthcare organizations need to build new capabilities, relationships, and competencies.

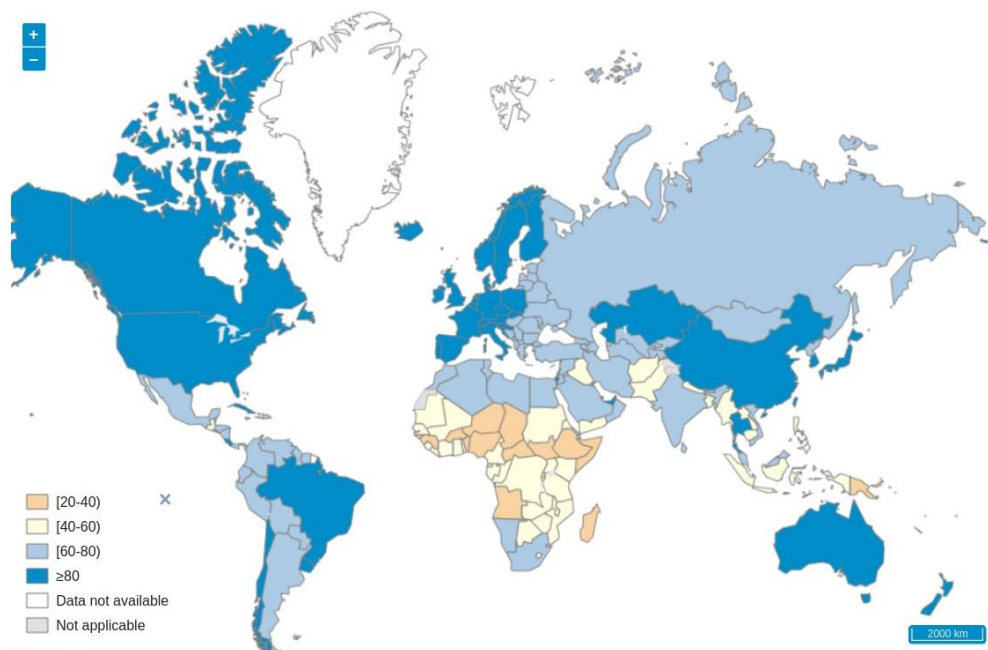


Figure 18. Proportion of the population that can access essential quality health services. UHC = Universal health coverage. (World Health Organization 2024b)

### 3.1.6 Urbanization and equity

Trends are showing that the already ongoing population urbanization is increasing (Figure 19). The projections by UN are showing that in 2050, 66% of the world's population will live in urban areas in upper-middle-income countries. In many low to lower-middle-income countries, the majority still live in rural areas (Kruk et al., 2016, 1-3). This development has both positive and negative

impact on the health. Living in cities bring important benefits, including high density of workplaces and active trade and infrastructure. In terms of healthcare urban areas offer shorter travel time and availability of services and trained providers. However, although these advantages are recognized, the gap between rich and poor in accessibility is big. Urbanization has led to a growing trend of mega sized slums where a proportion of individuals are living under poor conditions and lacking access to improved water, to improved sanitation, sufficient living area, and durability of housing (Kruk et al., 2016, 3). These individuals often cannot afford to pay for the quality care. Increasing urbanization with barriers to care poses new emerging challenges for health care services and for governments.

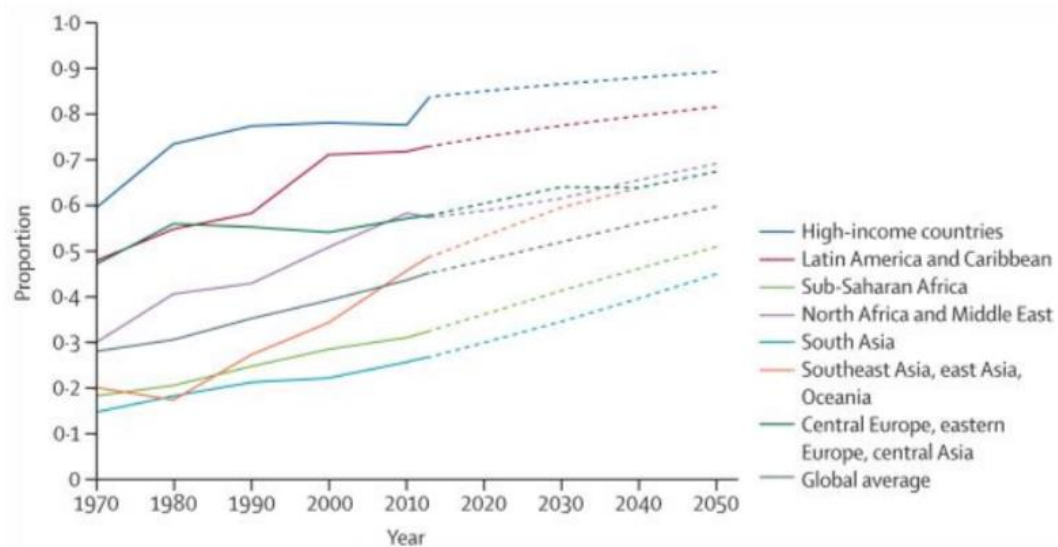


Figure 19. Urban and rural birth projections. Proportion of births in urban areas by region, 1970–2050. (Kruk et al., 2016)

### 3.1.7 Conflicts and disease outbreaks

The world has faced severe challenges in the last few years. External shocks like, COVID-19 pandemic and Russia's invasion to Ukraine has impacted the world.

The economic spillover effects by Ukraine war are affecting worldwide. War has introduced an additional shock to global and national economies still reeling

from the impacts of the pandemic. While the main affected countries of war are the ones in direct conflict, countries from other regions might be negatively affected through global effects due to their reliance on commodity imports, remittances, and tourism or through weak resilience due to pre-existing high levels of debt, inflationary pressures and poor governance.

In addition to the economical impact, war has its effects on the food security, to availability of goods and raw material, to energy availability and to the relationships between other countries (Figure 20). (Pantuliano, S. 2022)

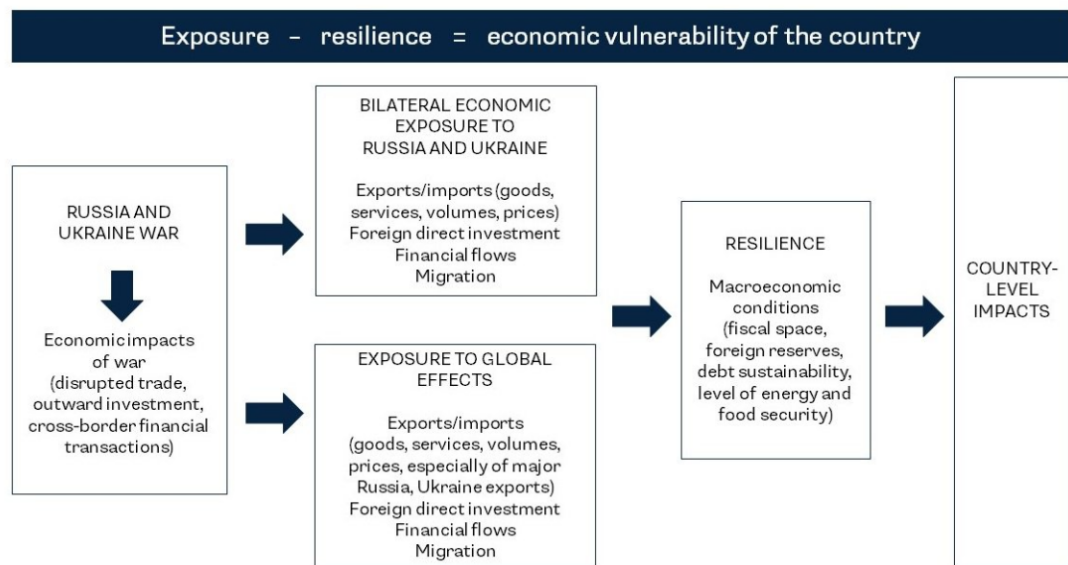


Figure 20. An example of the negative impact of the war (Pantuliano, S. 2022)

COVID-19 pandemic turned the lives of billions of people around the globe upside-down, and significantly affected the health, economic, environmental, and social domains. The global socio-economic impact of COVID-19 includes higher unemployment and poverty rates, oil prices, altered education sectors, changes in the nature of work, lower GDPs and heightened risks to healthcare workers. The impact on the energy sector includes increased residential energy demand due to a reduction in mobility and a change in the nature of work. However, restricted movement across the globe with people primarily at home, decreased industrial and commercial energy demand and waste generation, lead to substantial decreases in pollution. (Mofijur et al., 2021, 357.) COVID-19

had direct impact to many businesses. But the biggest impact was of course to the health and healthcare systems.

Despite advancements in healthcare lengthening lifetime expectancy across the world, in addition to unexpected disease outbreaks, there are many other diseases that has been showing growing trend (Figure 21). One of these growing and costly diseases is diabetes, one of the leading causes of death and disability globally. (International Diabetes Federation, 2021)

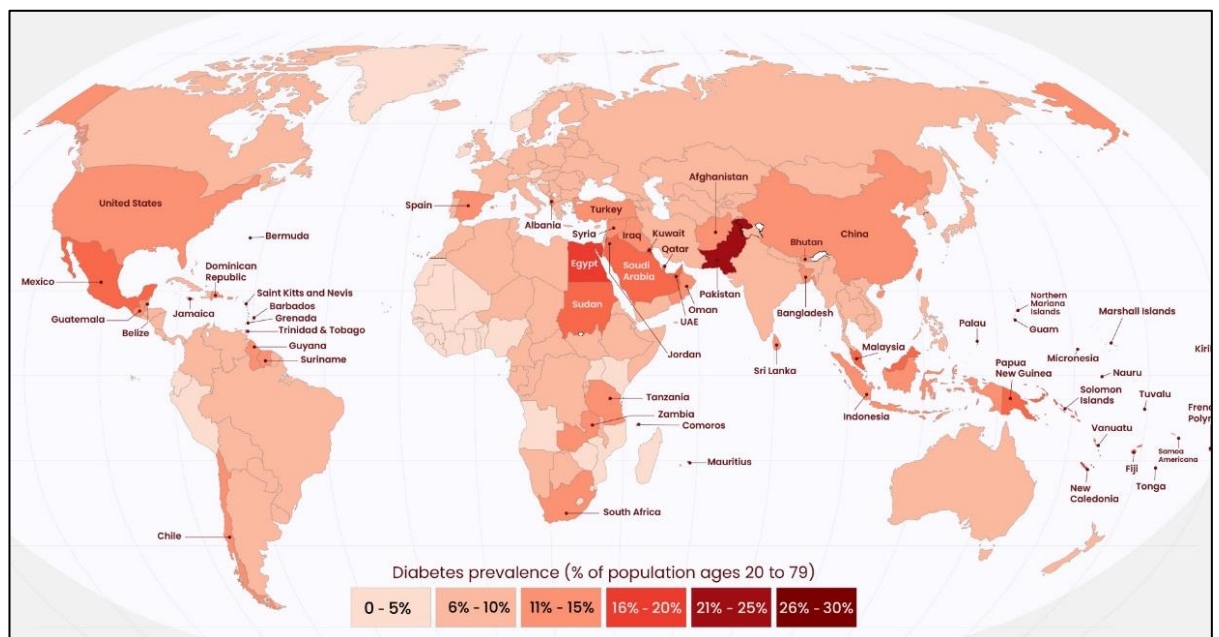


Figure 21. Map of diabetes rates by country, highlighting the countries with the highest rates of the disease. (Rojo Moro 2023)

Treating chronic diseases like diabetes that is used here as an example, is a huge burden to the healthcare organization. Caring these conditions that are increasing with the aging population bounds a significant amount of resources. Healthcare expenditures of chronic diseases worldwide has and will increase greatly with chronic conditions (Table 1).

Table 1. Global Diabetes data report 2000 — 2045. (International Diabetes Federation 2021)

At a glance	2000	2011	2021	2030	2045
<b>Diabetes estimates (20-79 y)</b>					
People with diabetes, in 1,000s	151,000	366,000	536,600	642,800	783,700
Age-adjusted comparative prevalence of diabetes, %	4.6	8.5	9.8	10.8	11.2
<b>Mortality attributable to diabetes (20-79 y)</b>					
Deaths attributable to diabetes	-	4,600,000	6,700,000	-	-
<b>Hyperglycaemia in pregnancy (HIP) (20-49 y)</b>					
Live births affected by HIP	-	-	21,060,499	-	-
<b>Diabetes-related health expenditure</b>					
Total diabetes-related health expenditure, USD million	-	465,000	966,000	1,027,600	1,053,700

### 3.1.8 global resource constrains and climate warming

Economical, physical, and political shortages of key resources increase and drive increasing tension between and within countries. As we exceed the Earth's natural thresholds, food and water receive as much focus as oil and gas, there is a need for intelligent solutions for more sustainable environment.

In relation to healthcare, global shortage of skilled workers and clinicians, especially in rural regions, has also impacted to the access and thus quality of care. The lack of resources due to the pandemic, COVID-19 demonstrated the world with the lack of educated healthcare workers. And it is estimated that even with the help of newly developed methods such as AI, the global

workforce shortage will increase. (World Health Organization, 2020). As concluded earlier, the global population is aging and there is increasing trend in many chronic diseases, even more resources will be required to provide healthcare. There is an increased need for transforming the healthcare structures, jobs and pathways, but also solutions to overcome the shortage.

There are already technological innovations that can close the gaps for the lack of educated healthcare workers. As introduced earlier, adapting digital technology healthcare models with wearables, devices, noninvasive sensors may offer cost savings and accessibility to care, while reducing the immediate need to access health care facilities and occupy resources (Hod et. al., 2023). By utilizing digital technologies and devices, patient health data can be shared outside of traditional health care settings. Remote patient monitoring is ensuring continuous communication between patients and their health care provider. In addition, to not only increase access to care, near patient, i.e. point-of-care (POC) diagnostics offer speed, and convenience. (Zhang et al., 2022, 30.)

In addition to work force shortage, world is facing a growing demand-supply gap for natural resources resource, a shortage in physical resources. Demand for food, water and critical metals and minerals is escalating. Access to many important resources is increasingly constrained, which is affecting to the price of the raw materials and logistics and eventually to cost of the products used in health care. Over the next decade, many resources are going to become more difficult to get hold of and may become more expensive. (World Economic Forum, 2023)

Climate change is increasingly recognized as one of the key global risks. Climate change will impact on all environmental determinants of health. Health providers are increasingly concerned with their own carbon footprint and taking active steps to reduce this impact. Healthcare organizations are adopting sustainable practices to reduce their carbon footprint and ensure responsible use of resources. This is becoming a quality requirement for the products companies are developing, producing and distributing. Organizations and companies have to use less material and produce less waste. A global

transition towards a carbon-neutral circular economy is an opportunity for all companies to develop new business, expand into new markets and create sustainable growth (SITRA, 2022, 29, 41). Resource-efficient, and energy-saving activities to help reduce the environmental impacts of operations is becoming one of the key performance metrics for health care organizations and industry (SITRA, 2022, 5-10). The underlying climate crisis has opened new opportunities for industry to develop solutions to decrease the environmental burden, such as smart technologies, smart factories and even smart cities and homes that are supporting the collective efforts towards zero emission and carbon neutrality (World Economic Forum, 2023).

Raised awareness on global constraints on resources and climate warming will lead to increasing number of innovations of new and more effective ways of creating energy, and resource-effective eco-friendly ways of manufacturing. In addition, the legislative changes will further drive innovations and investments to reduce our reliance on oil and gas and other constrained materials. However, despite these efforts, higher prices and shortages remain obstacles to transitioning to green energy. (World Economic Forum, 2023, SITRA, 2022, 21-23.)

For businesses, circular economy offers tools to create more value with fewer resources. It is also an opportunity to meet the changing needs of customers, cut expenses, minimise risks and make business more sustainable for the planet. A circular economy focuses on maximizing the value of existing resources, emphasizing smarter design, digital solutions, and a transition from product ownership to service utilization. (SITRA, 2022, 29)

### 3.1.9 Decentralization of care

With the growing financial and resource pressures on public health systems around the world, innovative new technology is allowing patients to access care better and to take their healthcare into their own hands. As in the overall healthcare trends, also pregnant women want to be more in control of their

health. With the technological solutions available there is constantly more options for care at home. Number of available wearables, home tests and apps are constantly increasing (Cheong et al., 2022, 2, 7-11, Attkinson et al., 2023, 7-14).

In countries where healthcare is expensive or otherwise restricted, remote care and home testing can provide a more easily accessible and affordable option for people to obtain a diagnosis quickly and efficiently. COVID-19 pandemic demonstrated also how decentralization of the care can help to allocate the resources better by treating in centralized care in hospital only the ones who really needs to be in the hospital. (Cheong et al., 2022, 2, 7-11, Attkinson et al., 2023, 1, Nichols, 2021, 143.)

In addition to remote care, decentralized care with supporting solutions has its benefits. These include such as customize care based on the specific needs. faster response time, local expertise, and flexibility with the location (Nichols, 2021, 142). Especially in low- and middle-income settings, where the infrastructure and education are not suitable for the centralized solutions. Decentralized tools, like point-of-care tests meets the needs of these conditions much better. In addition to telehealth as a decentralized solution, Covid-19 pandemic introduced the point-of-care quick tests. Almost the entire globe is now very confidently performing these tests without a formal education.

## 3.2 Trends In Maternal and Fetal Health

### 3.2.1 Fertility and birth rates

The fertility rate is the number of babies born for each female. Total Fertility rate (TFR) (births per woman) has shown declining trend since 1950 (GBD 2021 Fertility and Forecasting Collaborators, 2024, 2057). Fertility gradually declines as a woman matures, starting from 32 years of age and due to a decline in



Figure 22: Total fertility rate (TFR), globally and by region, 1950–2100. The dashed horizontal line indicates replacement TFR (2.1), and the dashed vertical line indicates the year 2022 (the first forecast year). (GBD 2021 Fertility and Forecasting Collaborators 2024)

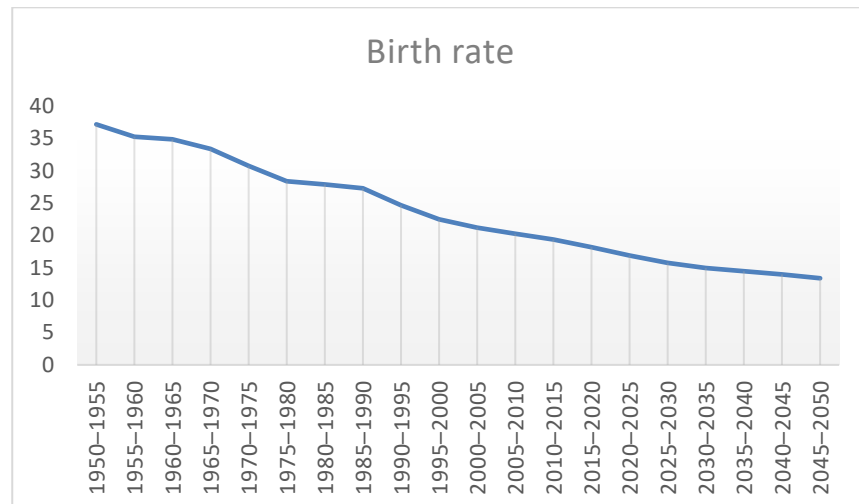


Figure 23. Average global birth rate (the number of live births a year per 1,000 of a population). (The World counts, 2024)

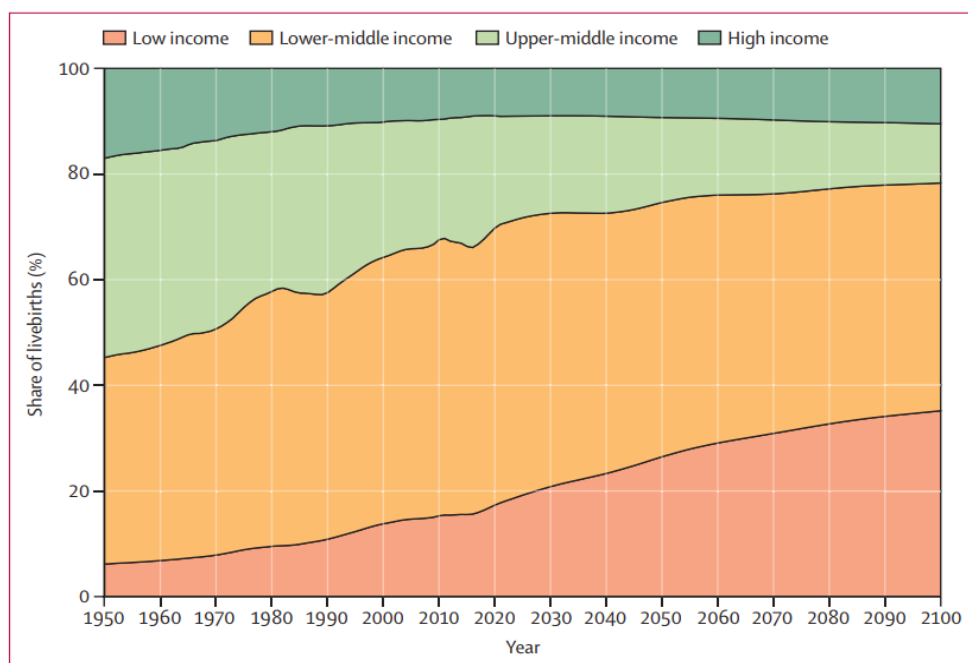


Figure 24. Share of livebirths by 2021 World Bank income group. (GBD 2021 Fertility and Forecasting Collaborators 2024)

Currently available data shows a sharp decline in birth rates in both Europe and the US during the final two months of 2020. The US Centers for Disease Control and Prevention and the National Center for Health Statistics reported a 4% decline in birth rates from 2019 to 2020. These findings suggest a net reduction in the number of children born in 2020 (International Federation of Fertility Societies' Surveillance (IFFS), 2022; 2, Torkamani et al., 2018, 2). Italy and Spain both noted a 20% decline in the number of births reported in December 2020 compared to December 2019. Similarly, in China the birth rates are declining (Figure 25). In 2023, the birth rate in China was approximately 6.39 births per 1,000 people, while it has previously been almost double (Statista, 2023). Also the neighboring country has suffered from very low birth rates during the past few years. Japan's population has been steadily decreasing (Figure 26).

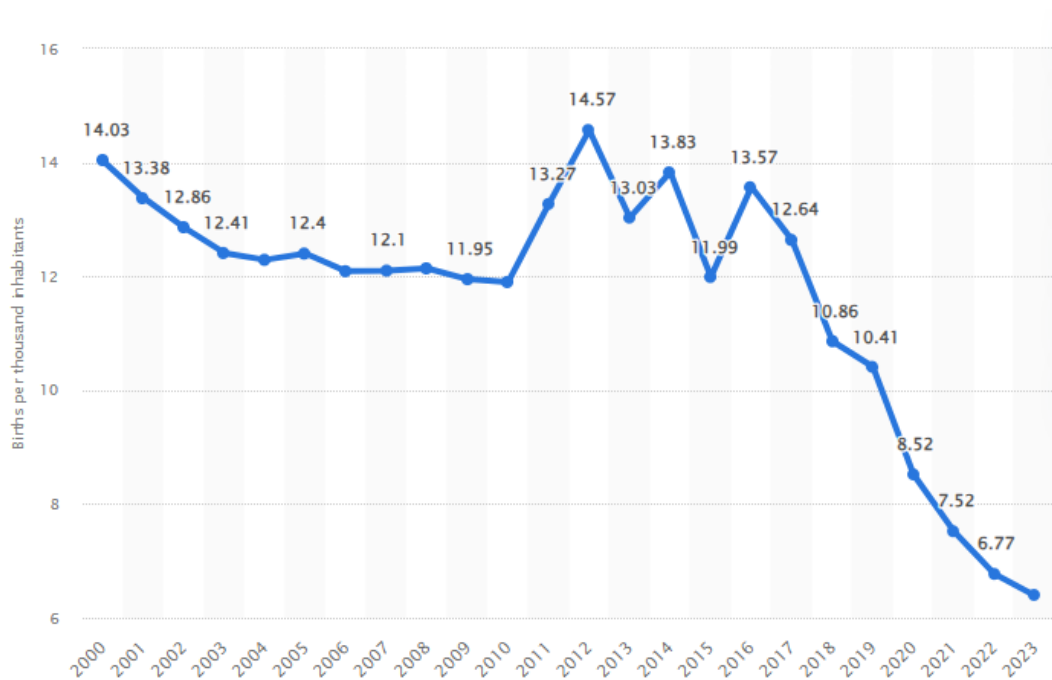


Figure 25. Birth rate in China from 2000 to 2023 (in births per 1,000 inhabitants) (Statista 2023)

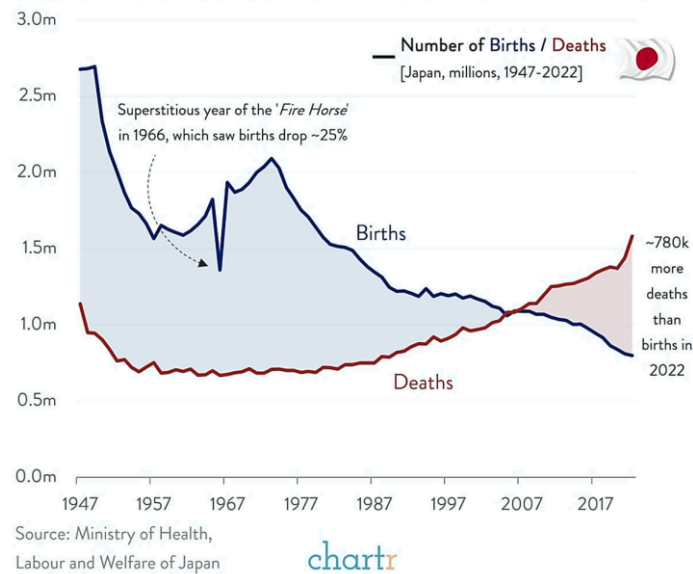


Figure 26. Japan's population growth. Births vs. deaths in years 1947-2022. (Chartr 2023)

### 3.2.2 Maternal mortality and morbidity

Maternal morbidity describes any short- or long-term health problems that result from being pregnant and giving birth. Maternal mortality refers to the death of a woman from complications of pregnancy or childbirth that occur during the pregnancy or within 6 weeks after the pregnancy ends. From 2000 to 2020, the global maternal mortality ratio (MMR) declined by 34 per cent – from 339 deaths to 223 deaths per 100,000 live births. This translates into an average annual rate of reduction of 2.1 per cent. (UNICEF, 2023.)

Globally, more than half of maternal deaths between 2003 and 2009 were due to haemorrhage, hypertensive disorders, and sepsis (Say et al., 2014).

Common causes of maternal mortality vary by region: in Northern Africa, 36.9% of deaths were due to haemorrhage compared with 16.3% in HICs. Deaths due to hypertensive disorders were most prevalent in Latin America and the Caribbean, accounting for 22.1% of deaths. The vast majority of deaths due to sepsis were in LMICs (Geller et al., 2018, 32).

Maternal mortality continues to be a factor in the public health, however, for each woman who dies as the direct or indirect result of pregnancy, many more women experience life-threatening complications. It is estimated that 50–100 women experience severe morbidity compared to every maternal death in the United States and the rate has more than doubled from 74 per 10,000 delivery hospitalizations in 1998–99 to 163 in 2010–11. (Geller et al., 2018, 32)

Consistently, both maternal mortality and morbidity rates are higher in LMICs than in HICs (Figure 27) (UNICEF, 2023). These alarming rates of poor maternal and infant outcomes with long term poor health consequences, highlight a critical need for surveillance with the goal of understanding how to prevent maternal morbidity.

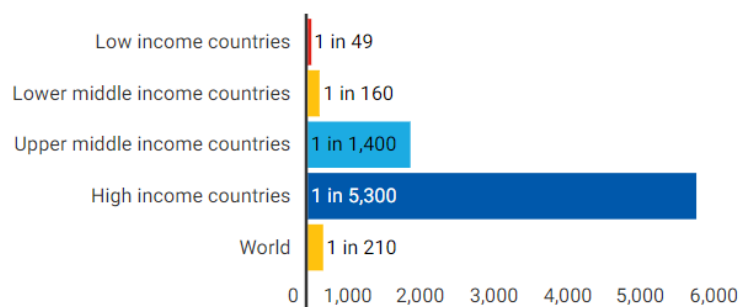


Figure 27. Trends in Maternal Mortality by Income groups\*: 2000 to 2020 (\*Income groups refer to World Bank income classification in 2018). (UNICEF, 2023)

Although the global maternal mortality trend has been decreasing (Figure 28, Table 2), according to WHO's trends in maternal mortality 2000 to 2020 report (World Health Organization 2023c, 14), maternal deaths are largely concentrated in the poorest parts of the world and in countries affected by conflict. In 2020, about 70% of all maternal deaths were in sub-Saharan Africa, and in nine countries facing severe humanitarian crises, maternal mortality rates were more than double the world average (World Health Organization 2023c, 30).

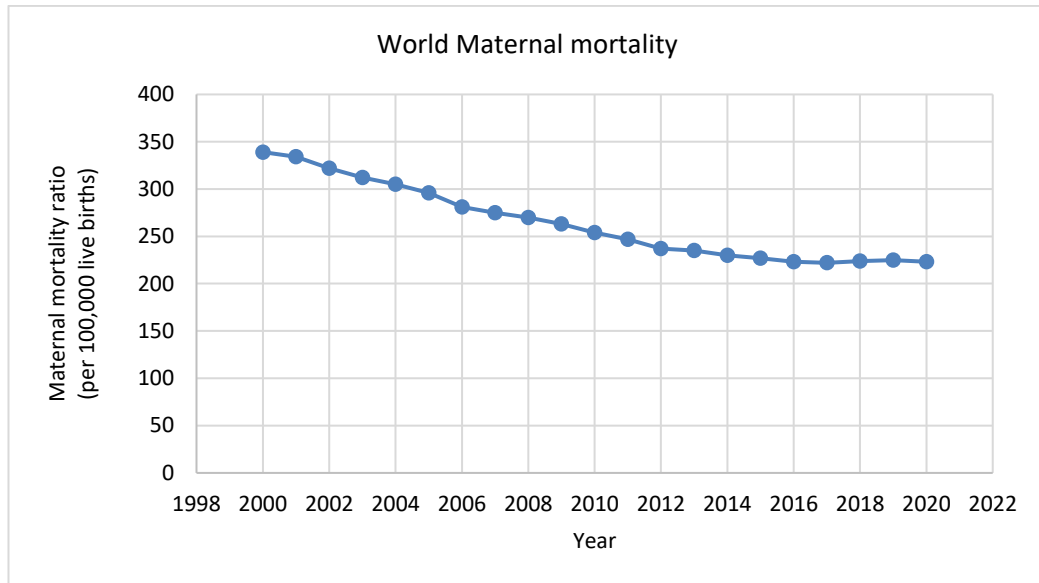


Figure 28. World maternal mortality Ratio 2000-2020. (World bank data 2024)

Table 2. World maternal mortality ratios per region. (Roser 2024)

Region	2000	2005	2010	2015	2020
East Asia and Pacific	121	106	84	73	74
Europe and Central Asia	27	20	16	13	13
Eastern Europe and Central Asia	43	32	23	17	19
Western Europe	9	8	7	6	6
Latin America and Caribbean	90	85	79	75	88
Middle East and North Africa	106	85	68	58	56
North America	12	13	14	17	20
South Asia	417	323	224	172	138
Sub-Saharan Africa	802	711	657	587	536
Eastern and Southern Africa	712	601	500	392	324
West and Central Africa	890	817	807	766	724
Australia/New Zealand	8	6	6	6	4
Central and Southern Asia	397	306	210	160	129
Eastern and South-Eastern Asia	121	105	83	72	74
Europe and Northern America	17	14	12	11	13
Latin America and the Caribbean	90	85	79	75	88
Northern Africa and Western Asia	159	130	102	86	84
Oceania (excluding Australia and New Zealand)	261	267	248	185	173
Sub-Saharan Africa	807	716	668	598	545
<b>World</b>	<b>339</b>	<b>296</b>	<b>254</b>	<b>227</b>	<b>223</b>

Global disparities exist between low-, middle- and high-income nations with low-income countries demonstrating the highest maternal mortality ratios (Small et al., 2017, 2). The intersection of equity and the COVID-19 pandemic was not just temporal; disparities in the rates of infection, vaccination, and access to care resulting from the social determinants of health were seen across the globe. Within nations, disparities in race and ethnicity have found to be influencing to maternal outcomes (Small et al., 2017, 2, Glazer et al., 2021, 1-3, Shah et al., 2021, 1). In United States maternal mortality ratios for non-Hispanic black women are 3–4 times higher and maternal morbidity risk is 2 to 5-fold increased than for white women (Louis et al., 2015, 690-692). Racial disparities are impacting to maternal adverse pregnancy outcome. Among these outcomes are preeclampsia and preterm birth (Leonard et al. 2019, 31).

### 3.2.3 Global trends in demographics of pregnant women: obesity, late child bearing age, hypertensive disorders, gestational diabetes

In the field of maternal and fetal health, population structure that has an impact to the maternal and fetal health has changed over time. Literature shows that there are some trending factors increasing over time with pregnant women demographics leading to increase in adverse outcomes.

#### 3.2.3.1 Advanced maternal age

One of these trends is increasing advanced maternal age (Pinheiro, et. al. 2019, 224, Driscoll et. al., 2020, 1-9, Li et al., 2021, 2-6, Attali & Yogev, 2020, 3). The average age of motherhood has gradually increased globally in recent decades, especially on high-income countries (Figure 29). Advanced maternal age is becoming an increasingly relevant issue (Figure 30). Although, delaying childbirth can have relevant and beneficial effects on children's education and women's economic and emotional ability, better preparing individuals to raise children, there are also clinical and public health risks (Ye et al., 2023b, 3).

Advanced maternal age with lower fertility is increasing the need for assisted reproductive therapy is increasing comorbidities, such as premature delivery, caesarean section, preeclampsia, postpartum haemorrhage, and gestational diabetes mellitus, are further increasing adverse maternal and fetal outcomes. (Attali & Yogev, 2020, 6)

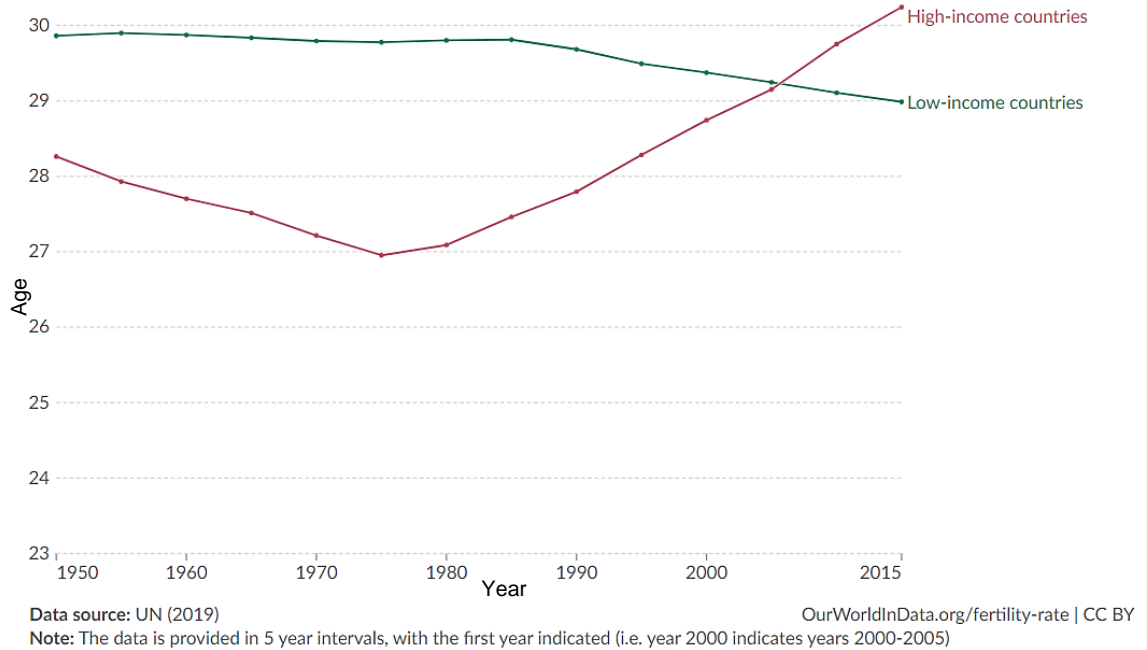


Figure 29. Average age at which women are having their first child in low- and high-income countries between years 1950 to 2015. (Roser 2024b)

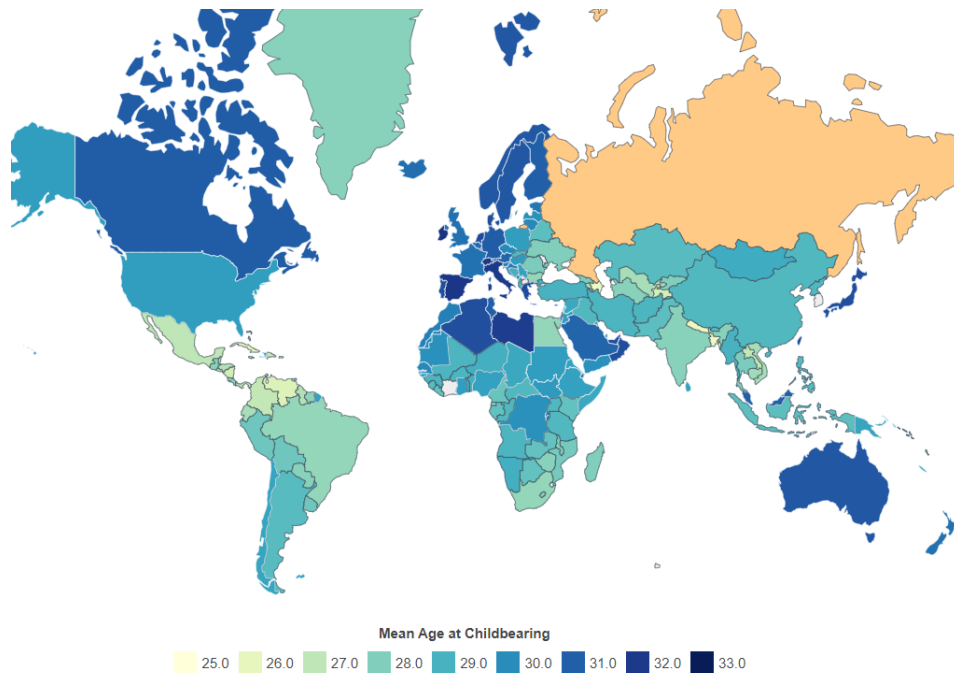


Figure 30. Average Age of Having First Child by Country in 2024 (World Population Review 2024)

### 3.2.3.2 Maternal weight

Similar trend is seen with maternal weight. Prevalence of obesity in women of reproductive age is increasing globally. Obesity reduces fertility and increases time taken to conceive and is associated pregnancy and perinatal complications. Obesity-related comorbidities (such as type 2 diabetes and chronic hypertension) heighten the risk of adverse outcomes for mother and child if the woman becomes pregnant. Pregnancy associated complications include GDM, preeclampsia, premature delivery and the risk of stillbirth. (Poston et al., 2016, 1, Lende et al., 2020, 1, 7, Strauss et al., 1757-1762). Obesity is no longer a problem exclusively affecting the western world. Worldwide, 11.5% of adults were obese in 2010 with nearly a tripling to 30% (2.1 billion) in 2020 (Figure 31).

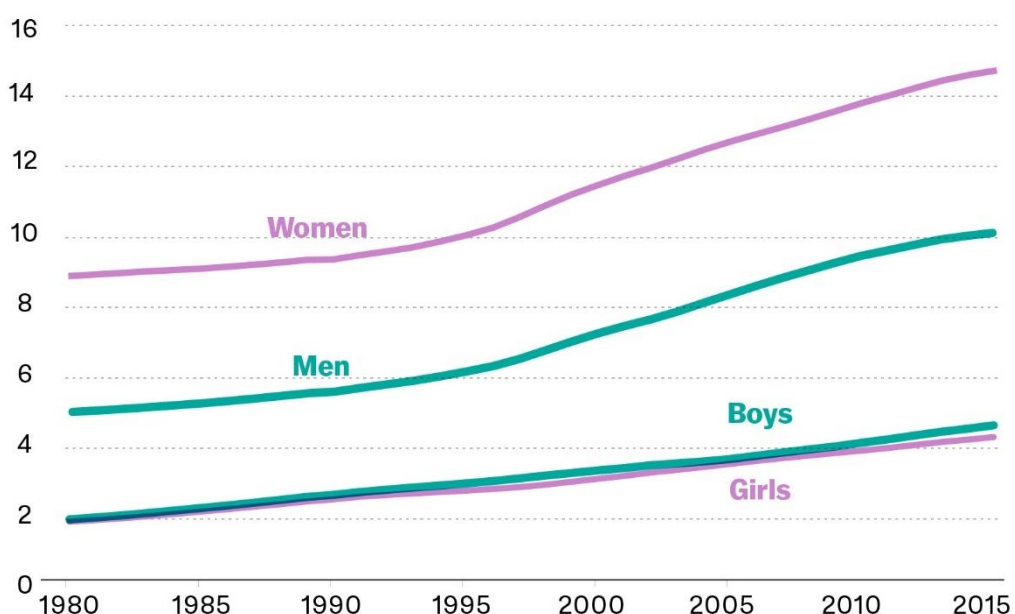


Figure 31. Increasing Obesity (GBD 2015 Obesity Collaborators, 2017)

In a publication from Germany, obesity in pregnant women was shown to be a major problem on health issues in obstetrics (Table 3; Strauss et al., 2021, 1761). It stated that both advancing maternal weight and increasing mother's age considerably complicate pregnancy and delivery. The impact of obesity on health and wellbeing of mothers and their offspring is profound.

Maternal obesity can result in both pregnancy and delivery complications for mother and child (e.g., placental insufficiency, stillbirth, fetal malformations). Furthermore, late maternity is associated with various risks to the mother and hazards to perinatal outcomes. Over the past decades, there has been not only a rising proportion of deliveries among mothers with advanced age but also with increased body weight (Strauss et al., 2021, 1761). Ongoing increase in the average maternal age as well as rising body weight and proportion of obesity will continue to challenge obstetrics also in the coming years.

Table 3. Prevalence of pre-obesity, obesity I–II° and obesity III° in German women of childbearing age (Strauss et al., 2021)

	<b>BMI 25.0–29.9 kg/m<sup>2</sup> % (95% CI)</b>	<b>BMI 30.0–39.9 kg/m<sup>2</sup> % (95% CI)</b>	<b>BMI ≥ 40.0 kg/m<sup>2</sup> % (95% CI)</b>
18–29 years	30.0 (25.9–34.5)	9.6 (7.2–12.7)	0.9 (0.3–2.7)
30–39 years	38.0 (32.8–43.5)	17.9 (14.0–22.7)	2.3 (1.1–4.6)
40–49 years	46.4 (42.1–50.8)	18.6 (15.6–22.2)	2.1 (1.2–3.6)

### 3.2.3.3 Hypertensive disorders and preeclampsia

Hypertensive disorders of pregnancy (HDP) are affecting approximately 5% to 10% of pregnant women globally (Fu et al., 2019, 1). Despite decreasing prevalence after years of interventions, HDP remain one of the leading causes of maternal and fetal morbidity and mortality globally, especially in LMICs (Wang et al., 2021, 216, Jiang et al., 2022, 761–762). HDP are responsible for an estimated 14% of maternal deaths globally (Figure 32). Despite a much lower maternal mortality in HICs than in LMICs, HDP remains one of the most common causes of maternal death worldwide (Say et al., 2014, 323, 326).

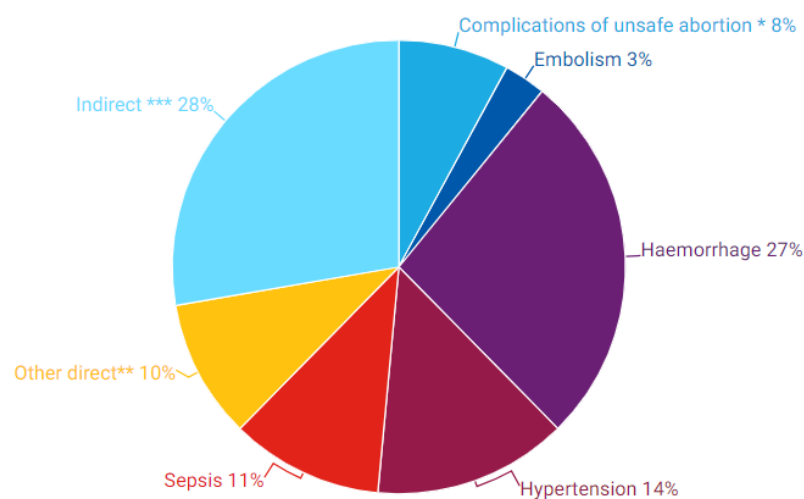


Figure 32. Global causes of maternal death. (Say et al., 2014)

The proportion of maternal deaths from HDP was 2.8% in the UK and Ireland (2011–2013), compared to 7.4% in the USA. In contrast, in LMICs, 10–15% of direct maternal deaths are associated with HDP (Jiang et al., 2022, 761). HDP has developed into a serious public health problem with short- and longer-term effects on the outcomes of pregnant women and their baby. Numerous studies have shown that pregnant women with HDP, have a significantly higher risk of morbidity and mortality from hypertension (especially pre-eclampsia), ischemic heart disease and stroke later in life. HDP increases the risk of preterm birth, stillbirth, and smaller gestational age fetus and causes an increased risk of mortality later in life, including perinatal diseases, cardiovascular diseases, and nutritional and metabolic diseases. (Fu et al., 2019, 1)

Preeclampsia is one of the leading causes of mortality and morbidity globally. It has been estimated that around 46,000 women are dying to preeclampsia and hypertensive disorders each year and in total it affects to around 10 million pregnancies each year. Although the deaths are mainly happening in LMICs, the prevalence of this condition is reasonably similar globally. The difference affecting the mortality numbers is in the care, access and quality. Along with the increasing obesity, infertility and maternal age, the numbers for preeclampsia are increasing. Preeclampsia is characterized with placental insufficiency and thus it is linked to other adverse outcomes in pregnancy, such as fetal growth restriction and preterm birth. (Kuklina et al. 2009, 1299-1305, Magee et al., 2022, 1817.)

As a response to the Sustainable Development goals for maternal mortality, preeclampsia as a major cause for preventable maternal mortality has received great attention. A vast amount of clinical data and finding the best clinical pathway for prediction, prevention and management has continued until today.

#### 3.2.3.4 Gestational diabetes mellitus

The prevalence of gestational diabetes mellitus (GDM) has increased dramatically over the past decades. Depending on the diagnostic criteria used,

prevalence of GDM is 9-25% of pregnancies annually. A great disparity exists between HICs and LMICs regarding the disease burden. (Jiang et al., 2022, 762.)

In recent years, GDM has become an increasing public health concern due to its adverse implications for maternal and child health (Zhou et al., 2022, 2, Ferrara, 2007, 141). In the short-term, GDM increases adverse pregnancy outcomes, and in the long-term, GDM carries an increased risk of developing type 2 diabetes for the mothers and an elevated risk of various cardiometabolic disorders in the offspring (Zhou et al., 2022, 2, Ferrara, 2007, 145).

There are studies showing several risk factors that contribute to the onset of GDM, like increased maternal Body Mass Index (BMI) and age were reported to be significantly higher in women diagnosed with GDM (Moody et al., 2020, 8). With the increasing epidemic of obesity and sedentary lifestyle, the global burden of GDM is predicted to increase, putting women of reproductive age and their babies at higher risk of type 2 diabetes later in life (Zhou et al., 2022, 2, Ferrara, 2007, 145. Jiang et al., 2022, 762). The literature on prevalence of GDM and the risk of exposure to pregnant women is sparse and varied, particularly in LMICs where there is no national policy on the diagnosis and management of the disease.

#### 3.2.3.5 Chromosomal abnormalities

Chromosomal abnormalities (CA) (also called aneuploidies) are common congenital abnormalities in human embryos and newborns, indicating numerical and structural chromosomal aberrations. The prevalence of CA is around 1 in 150 births, but vary depending on several factors such as race, age and ethnicity (AGOGs' Committee on Practice Bulletins—Obstetrics, Committee on Genetics, & Society for Maternal-Fetal Medicine, 2020, 49, European Commission Prevalence charts and tables, 2022).

Research has revealed an increasing trend of CAs, especially for numerical CA, in most parts of the world. There is also a well-established association between risk for CAs and advanced maternal age, which partially explains the elevated prevalence of CA worldwide. In addition to the advanced maternal age, the innovation of prenatal diagnosis tools might partly explain the increased CA statistics. More is being screened and registered. (Loane et al., 2013, 4; Berglund et al., 2020, 2)

The global trend of delayed childbearing and increasing assisted reproduction has become a significant concern in terms of CAs, genomic alternations characterized by deviations in the copy number of chromosomes. Over the last few decades, the proportion of women having their first child after the age of 35 has increased dramatically. See for figures in section of 3.2.3.1 Advanced Maternal age.

#### 3.2.3.6 Anemia

Anaemia is defined as haemoglobin concentration less than 120g/L for non-pregnant and lactating women, and less than 110 g/L for pregnant women. According to the statistic by WHO, the global anemia prevalence in women of reproductive age was 29.9% (equivalent to over half a billion women) and 36.5% in pregnant women (Figure 33). During pregnancy, iron deficiency anaemia is also associated with adverse reproductive outcomes such as preterm delivery, low-birth-weight infants, and decreased iron stores for the baby, which may lead to impaired development. (World Health Organization 2019a.)

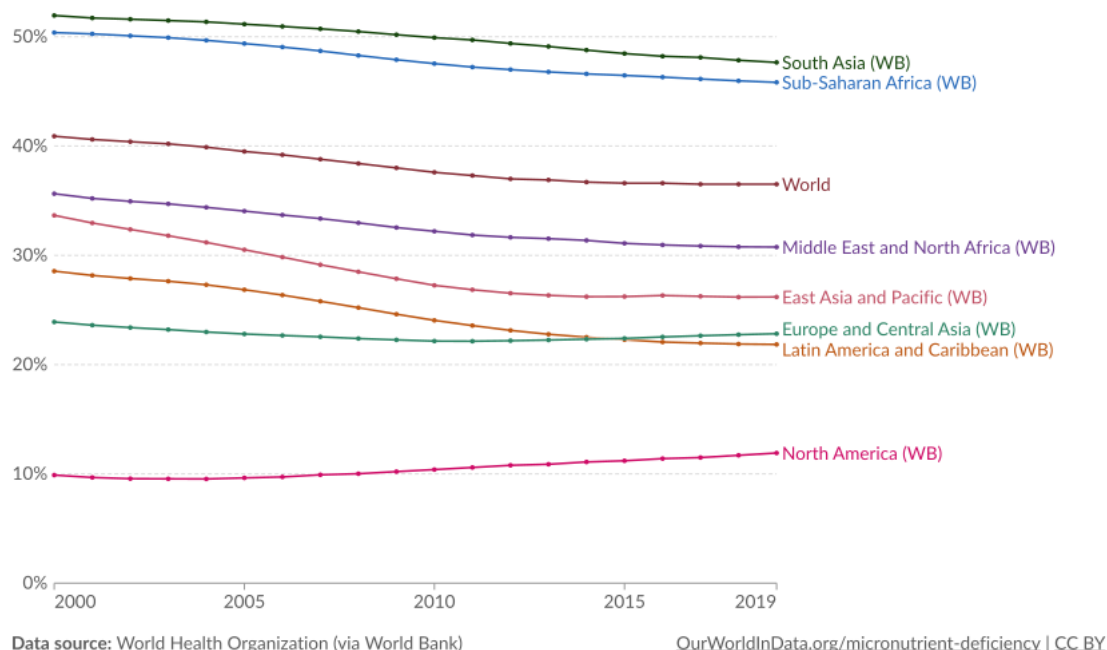


Figure 33. Prevalence of anemia in women in pregnant women between years 2000-2019. (World Health Organization 2019a)

### 3.2.4 Environmental factors: The impact of climate change to maternal, newborn and child health

Climate change is an urgent threat to pregnant women and children. In 2023, WHO published a document (World Health Organization 2023a) – Protecting maternal, newborn and child health from the impacts of climate change – about the effects of climate events on maternal and child health. While climate change will affect all populations physical and psychological health, it is critical to remember that women, newborns, and children are impacted disproportionately. Research shows that harm can begin even in the womb, leading to pregnancy-related complications, preterm birth, low birthweight, and stillbirth. For children, consequences can last a lifetime, affecting the development of their bodies and brains as they grow.

Evidence shows that poorer countries bear a significant financial burden from climate adaptation, requiring to make the biggest investments, given their lower capacity to adapt. Investing in women's, children's, and adolescents' adaptation and resilience to climate change, especially in low- and middle-income countries, is therefore critical. (The Intergovernmental Panel on Climate Change, 2023)

### 3.3 Technological Landscape

New technological advancements in the healthcare industry have impacted also the maternal and fetal health. Portable devices, wearables, noninvasive testing, AI with data, telemedicine and at home screening tests has started to change the care and management that has stayed since 1950s almost unchanged until very recent rapid revolutionizing. In addition to the technologies mentioned, some technologies have been advancing in past years rapidly and are briefly discussed below.

#### 3.3.1 Connectivity and Convergence: Big data, AI and automation

Solutions to overcome the challenges with accessibility are being solved with direct-to-consumer health care models and advancements in remote care. The care in remote settings is possible when an increasing amount of different telemedicine applications and wearables are being introduced. Frost & Sullivan in their Health & Wellness megatrends estimated that around 80% of the healthcare business models in 2025 will be driven by platform-based healthcare analytics and intelligence solutions. Development has already led to an increased number of connected devices through Internet-of-Things (IoT) network and through different apps and the increased volume of patient-generated data. As various personalized behavioural and physiological data is being collected through digital devices, there is an increased opportunity to develop personalized medicine solutions. Big technology companies like Microsoft, Amazon and Google have recognized this as a business opportunity and are

using their capabilities in data collection and are making this data available for other companies, enhancing the already to greater access to information.

Tailored healthcare solutions and treatment is made available with increasing amount of data that is collected. Different available solutions are creating an integrated ecosystem for collecting health information data. Such availability of big masses of data has increased the widespread adoption of artificial intelligence (AI). With AI, especially with generative AI (trained AI algorithms) patient-generated health data, a more comprehensive, real-time, and personalized view can be generated (Reddy, 2024, 2). This advancement has made possible to utilize genomic data from DNA for screening and diagnosing. The potential of AI for financial benefits, improved care delivery, and more efficient uses of resources is fostering enthusiasm for AI. AI has the potential in expanding access to care at a lower cost, in streamlining administrative processes and reducing expenses, in improving the quality of care with predicting patient outcomes.

AI and the vast amount of data has introduced an increasing number of new innovations. Digital technologies with AI are enabling the use of robotics in new applications like surgical theatres as well as a shift from reactive care to more proactive preventive healthcare. Also, AI together with virtual and augmented reality are opening new care models for healthcare. There is already good collected in pain management, mental care and rehabilitation. When taking this further, in future there are humans and robots working collaboratively through censored human-machine interfaces. Also, the decision making in healthcare is increasingly assisted or even done with AI.

The increased volume of innovations is creating new challenges. The regulatory climate around AI in general is changing rapidly. Cybersecurity concerns are on the rise, and the threat to health care organizations, information systems, and patient safety are substantial. Especially around patient-generated data, there is an increased demand for policymakers to revise regulations and policies of health data ownership and privacy. Governments worldwide are working to establish effective regulations (Madnick, 2022).

Trends in investments in health technology innovations has been focusing the past years to Digital care, wearables, and artificial intelligence (AI) (McCain 2022). Figure 34 below shows how the investments has been increasingly focusing to these top three areas. Although the innovations for utilizing the available data are evolving, the challenge with the process efficiency and data flowing through incompatible solutions from various healthcare technology providers are hindering the systems being effectively implemented. Automation will be the key in the use of AI in health care, making the use if data more efficient and reliable.

**VC investment in European healthtech startups**

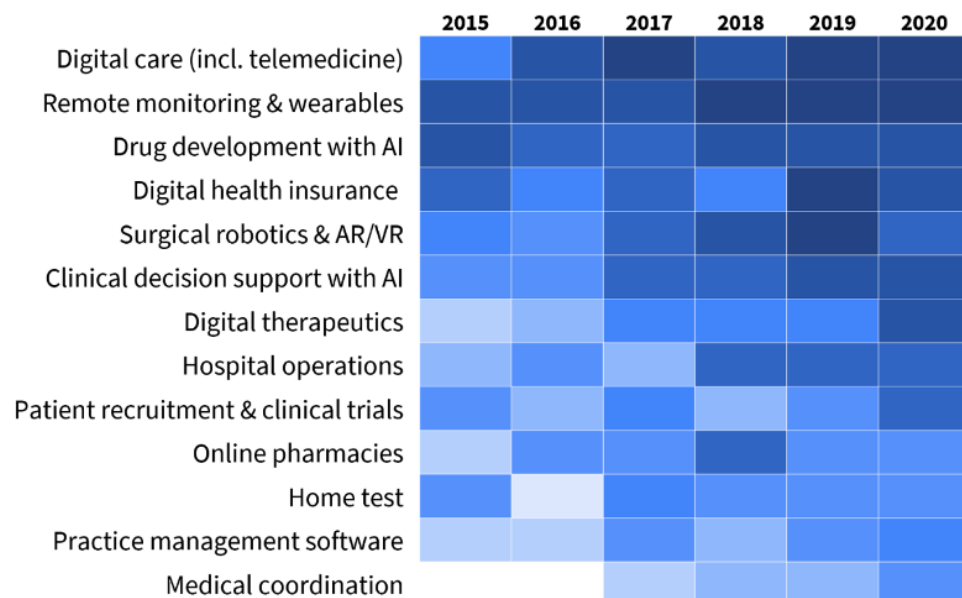


Figure 34. Venture capital investment activity. Focus is in AI, remote monitoring and digital therapeutics in addition to telehealth (McCain 2022).

### 3.3.2 Genetic testing

Globally, genetic technology has advanced dramatically has become increasingly used over the last two decades. (Jayashankar et al., 2023, 1-2) Major shifts has been taken in our technical ability to sequence genetic information at scale. Advances in sequencing technology have made it possible to undertake broad genetic testing on an individual patient basis within a clinically useful timeframe, via exome and genome sequencing. Along with the

development in the capabilities, genetic testing is also being used more extensively in the prenatal setting, in part because of developments in non-invasive prenatal testing (NIPT) and diagnosis (NIPD) to determine the fetal risk for genetic disorders, which allow genetic screening or testing of a developing fetus by doing a blood test for the mother. Cell-free DNA of fetal origin (cffDNA) is present in maternal bloodstreams, from which it can be sampled in noninvasive way and used for further analysis. The mainstream use today of NIPT is to screen for fetal aneuloidies; Trisomy 21, 18 and 13. The technology was first described by Lo et al in 1997.

Although NIPT using cell-free fetal DNA has increasingly been adopted as a screening tool for fetal aneuploidies, the introduction in clinical practice has opened a debate on the pros and cons of its use as a prenatal screening procedure. One of the undebatable advantages is its high sensitivity and specificity as a technology, which has decreased the need for unnecessary invasive diagnostic test. (Jayashankar et al., 2023, 2, Gadsbøll, et al., 2020, 732.) However, significantly higher cost of the NIPT compared to traditional biochemical aneuploidy screening has led to evaluation and implementation of different implementation models that are less expensive. It has been estimated that implementing NIPT as a primary screening method can increase the screening costs by 157%, while using it as an optional secondary test for high risk, the cost would increase only 21% (Ministry of Health Higher Health Council Higher Health Council Italy, 2015, 14).

Globally, the implementation of NIPT has been fast. In Europe many countries who adopted NIPT has also a national policy/program. Majority of the countries have implemented NIPT as an offer for higher risk women after first trimester traditional screening, only two countries, Belgium and the Netherlands offer NIPT for all pregnant women. In Australia, either combined first trimester screening (cFTS, i.e. biochemical screening) or NIPT is used as a primary prenatal screening test. In the USA, there are no national consensus policies on the use of NIPT.

Despite the availability and national programs NIPT is yet partially self-paid and partially reimbursed. (Jayashankar et al., 2023, 4-5,6,8, Gadsbøll, et al., 2020, 732) As the cost of the test is high, for families from lower-income class the cost of the test is too high financial burden. Pregnant women refrain from NIPT due to financial constraints. The cost has led to disparities. There is a disproportionate relationship between socioeconomic status and access to NIPT.

### 3.3.2.1 Next-Generation Sequencing

The introduction of affordable and rapid next-generation sequencing (NGS) technologies has revolutionized the practice of Medical Genetics and has been transformative for prenatal diagnosis, prenatal genetics (PG). NGS is one area of precision medicine that holds promise for the diagnosis and treatment of fetal congenital anomalies, genetic disorders, and other complications of pregnancy. NGS reduces time and costs needed to analyse nucleic acids as thousands of genes can be analysed at the same time, rather than testing one or a few genes at a time. (Mellis et al., 2018, 1-4, Almubarak et al., 2022, 1.)

Prenatal testing with NGS involves a procedure to obtain fetal DNA. This can be done either with an invasive procedure or by obtaining cell-free fetal DNA from maternal serum. Today, different NGS platforms are commercially available. Some of the available NIPT platforms utilizes whole-genome next-generation sequencing (NGS) technology. These tests analyses cfDNA fragments across the whole genome. (Mellis et al, 2018, 1-4, Vora et al., 2018, 791-792.)

Careful consideration is needed with introduction of these tools into prenatal care. The challenge now is to translate these approaches into mainstream use in the clinic as there are many ethical questions linked to this technology in prenatal stage. (Vora et al., 2018, 794) Guidance for the clinical implementation has been provided by several professional societies (Boon et al., 2013. 566).

### 3.3.2.2 CRISPR gene editing

Genome editing is a type of genetic engineering in which DNA is deliberately inserted, removed, or modified in living cells. Clustered regularly interspaced short palindromic repeat (CRISPR) and their associated protein (Cas-9) is the most effective, efficient, and accurate method of genome editing tool.

(Asmamaw et al., 2021, 1.) CRISPR/Cas-9 gene-editing technology works by utilizing the natural mechanisms of viruses to introduce DNA into genome and “fix” mutations in DNA. In nature CRISPR/Cas-9 system is used to protect prokaryotes from invading viruses by recognizing and degrading exogenous genetic elements. CRISPR technology has many potential applications from gene therapy to therapeutics, gene activation and silencing and agriculture. Today, CRISPR can be used to cure rare conditions like sickle cell disease. In fact, on December 8<sup>th</sup> 2023, the U.S. Food and Drug Administration (FDA) approved the first CRISPR treatments for sickle cell disease, Casgevy and Lyfgenia (FDA press release 2023). These are the first cell-based gene therapies. Therapeutics, utilize a type of novel genome editing technology and thus edits a gene involved in red blood cell shape and function.

### 3.3.3 3D printing

According to the American Hospital Association (AHA), the use of 3D printing techniques in healthcare has shown success in many ways in healthcare and is growing rapidly. The improvements include development of organ models, bone and joint implants, precision instruments, medicines and even skin tissue and organs. Current research is developing implants for the nervous system through neural 3D printed bioelectronic interfaces.

The number of hospitals with capabilities to 3D print is growing (Figure 35) and in 2019, 113 hospitals in US had centralized 3D facilities for point-of-care manufacturing. (Statista 2024)

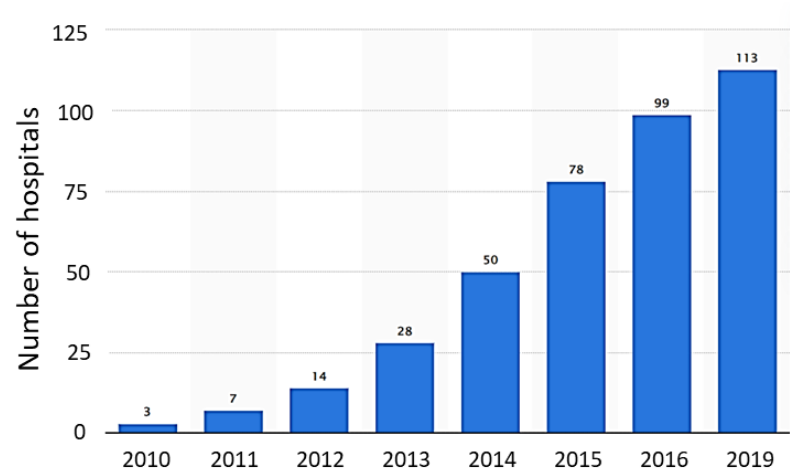


Figure 35. Number of US hospitals with a centralized 3D printing facility in years 2010-2019. The use of 3D printing techniques in healthcare is growing rapidly. (Statista, 2024).

#### 3.3.4 Rapid tests

COVID-19 pandemic together with other pandemics in human history have shown the world how infectious diseases have the ability to cause global threats to human life. Timely response is saving lives. However, traditional laboratory tests lack the flexibility and speed of testing. Thus, the rapid tests, also known point-of-care tests (POCT) were increasingly introduced and implemented during and after COVID-19. They also support the other trends in healthcare, such as telehealth and remote care. Hence, recent development has introduced new technologies to POCT. Today POCT have various recognition and detection strategies build into their design including nucleic acid amplification, optical POCT, electrochemistry, lateral flow assays, microfluidics, enzyme-linked immunosorbent assays, and microarrays (Figure 36). (Zhang et al., 2022 1-39.)

The rapidly growing market is increasingly demanding quantitative, reliable, high quality, and low-cost POCTs. The important specifications for the POCT, familiar from laboratories are today the limits of detection, time to result, portability, and specificity especially in resource-limited settings.

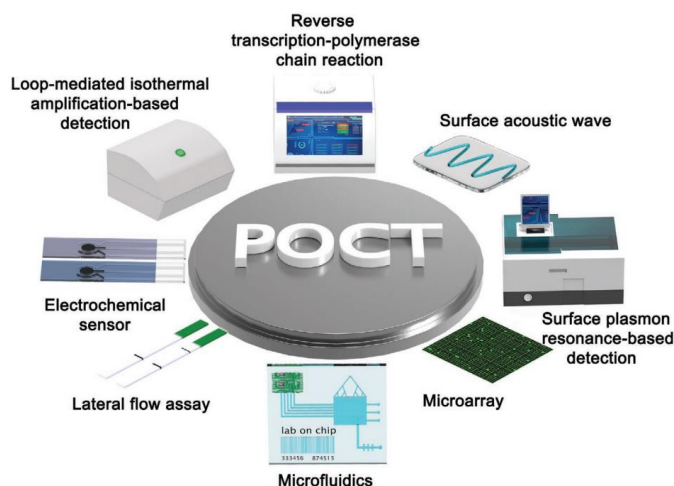


Figure 36. POCT technological designs. (Zhang et al., 2022)

### 3.3.5 Development of new drugs

Drugs to treat the clinical signs and symptoms that are indicating the development of an adverse outcome are widely used. Drugs for hypertension during the development of gestational hypertension, steroids to mature the lungs of the premature baby in threatening preterm labor and antibiotics administered to prevent infecting baby with Group B Streptococcus. Several novel strategies to treat the clinical signs and symptoms of conditions that are causing adverse outcomes are being investigated. These strategies may include injection of recombinant proteins, inhibition of protein production via RNA interference and small-molecule inhibitors and selective depletion of circulating proteins. These methods are in development for example for preeclampsia. (Phipps et al., 2019, 9-10)

### 3.4 Market landscape

There are constantly increasing amount of companies introduced for addressing the needs of maternal and fetal health. These companies vary greatly from their size and offering. In this chapter only the main players dominating the

competition and reasons with drivers, opportunities and challenges are discussed.

### 3.4.1 Biochemical screening market

As presented in the chapter 2, prenatal screening started to develop in early 1930's and first biochemical prenatal screening marker AFP was introduced already in early 70's. Since that, new markers with new models and indications have been introduced to prenatal screening and the sensitivity of the model has reached to very high values. There are a few key players in the prenatal screening biochemical providers. The following are the main competitors: Roche, Revvity, Thermo Fisher Scientific, Beckman Coulter, Siemens Healthineers and Snibe (Table 4). All of the providers are offering both instrumentation for different laboratory sample volume. In high level, Revvity is specialized to provide solutions mainly for reproductive health and screening for both during pregnancy and for newborns, while other companies are investing also to clinical chemistry and to big, centralized laboratory automation systems. The differences between manufacturers are very minimal. The competition of the markets is based on costs and in conjunction to other adjacent products (like preeclampsia) and services.

As the biochemical screening has been already available for a good period of time, the market itself is well established and quite stabile. Yet, there are some geographical differences in the markets. In Asia-Pacific region, majority of prenatal aneuploidy screening is still done during the second trimester of pregnancy, while in Europe, prenatal screening is primarily done at the first trimester of pregnancy. In Americas, the split is even. Differences in prenatal screening can partly be attributed to policies, provisions, and uptake of prenatal screening, socioeconomic background, awareness, and ethnic and religious beliefs. Differences between regions partially lead to wide variation in incidence and prevalence of Down's Syndrome (Chen et al., 2022, 4-5, 9).

Table 4. Different competitors in the biochemical screening market

Company	Product	Technology	Other Diagnostic Products
Revvity	prenatal panel for aneuploidy, open neural tube and preeclampsia screening and diagnosis, Risk Calculation Software	TRF	Instruments, NIPT, Neonatal screening, NGS, Dried Blood Spot assays, Molecular diagnostics
Thermo Fisher Scientific	prenatal panel for aneuploidy, open neural tube and preeclampsia screening and diagnosis, Risk Calculation Software	TRF	Automation, Clinical Chemistry, Information Management Tools, Immunoassays, Microbiology, Protein Chemistry, Urinalysis, Molecular diagnostics
Roche	prenatal panel for aneuploidy, open neural tube and preeclampsia screening and diagnosis	Chemiluminescence	Automation, Information Management Tools, Immunoassays, Protein Chemistry, Urinalysis, NIPT, Point-of-Care
Beckman Coulter	prenatal panel for aneuploidy, open neural tube	Chemiluminescence	Automation, Blood Banking, Clinical Chemistry, Information Management Tools, Immunoassays, Microbiology, Protein Chemistry, Urinalysis
Siemens Healthineers	prenatal panel for aneuploidy and preeclampsia diagnosis, Risk Calculation Software	Chemiluminescence	Automation, Clinical Chemistry, Information Management Tools, Immunoassays, Protein Chemistry, Urinalysis, Point-of-Care
Snibe	prenatal panel for aneuploidy and preeclampsia diagnosis, Risk Calculation Software	Chemiluminescence	Automation, Clinical Chemistry, Immunoassays, Protein Chemistry
Metabolomics Diagnostics	preeclampsia screening	Mass spectrometry Proteomics	
Mirvie	preeclampsia diagnosis	siRNA	
Sera Prognostics	preeclampsia screening and diagnosing	Mass spectrometry Proteomics	Preterm delivery solution PreTRM®

Preeclampsia, a condition with placental insufficiency can be screened with biochemical markers from maternal serum similarly to aneuploidy test. In fact, from the same sample. The markets of preeclampsia screening are mainly dominated by the same players as with aneuploidy biochemistry (Table 4). Some smaller players are being introduced in the past years. Some companies

and diverse groups are developing alternative tools for screening; DNA or RNA and mass-spec based. Also, platforms that are not competing with the laboratory devices but are more suitable to decentralized conditions and to LMICs like POCT are being developed (see for Table 7).

For the “traditional” biochemistry competition, the available clinical evidence and assay performance together with the complete and supporting offering has become the major competitive factors. Many countries require the cost efficiency analysis and population performance data, before creating national guidelines and making the decision to start national screening program. This is especially true for preeclampsia screening.

The same preeclampsia specific biochemical markers can be used for management of symptomatic women as are used for screening. As doctors have to face the challenges of diagnosing preeclampsia quickly, the advantages these markers bring to the quality of care has been easier to accept. Thus, the rationale of implementing these markers for diagnosing the pregnant women with symptoms is strong. For management the markers do not need a nationwide program, but a decision from the hospital management. Markers are already in use globally, but the utilization level is still low. Some advancement has already happened in terms of the nationwide programs. Programs are being implemented or planned at least in the following countries: Spain, Denmark, Estonia, Australia, Hong Kong, Sweden, Norway and France.

#### 3.4.1.1 Biochemical screening market drivers, opportunities and challenges

As the global number of advanced-age and high-risk pregnancies is increasing and fertility decreasing, the need for prenatal aneuploidy and preeclampsia screening increases. Although the increasing maternal age is seen as a driver, there are territorial and socio-economical factors influencing to the levels of the aneuploidy screening occurrence. The willingness to receive those tests is not the same everywhere. Aneuploidy screening uptake is higher with mothers in advanced age, than with younger mothers. Similarly, prenatal screening among

women with ethnic or religious origin is relatively low, and lower participation rates are common with women from lower socio-economic background.

(Jayashankar et al., 2023, 11-14.)

Implementation of NIPT into antenatal screening programmes is highly variable between countries, dependent on pre-existing prenatal testing and healthcare provisions. Also, biochemical screening is still considered to add value to clinicians over NIPT. Biochemical screening is well established and have additional benefits than detecting CAs (chromosomal abnormalities) (Figure 37). Serum markers enables detection of severe pregnancy complications, not detectable with cfDNA. In the absence of aneuploidy, these markers has shown the benefit in the identification of adverse obstetric outcomes. It also has synergy with placental insufficiency related conditions such as preeclampsia that are detected also with biochemical markers form maternal serum. In addition, biochemical screening is more cost efficient compared to NIPT. NIPT is highly expensive when chosen as the first-line screening approach for CAs. These factors may have impact to the implementation of NIPT as first-line screening approach (Ye et al., 2023a, 8). However, for those women who opt for screening, non-invasive prenatal testing (NIPT) is preferred by some pregnant women because of its high sensitivity and specificity as well as low false-positive rate (FPR) and false-negative rate (FNR).

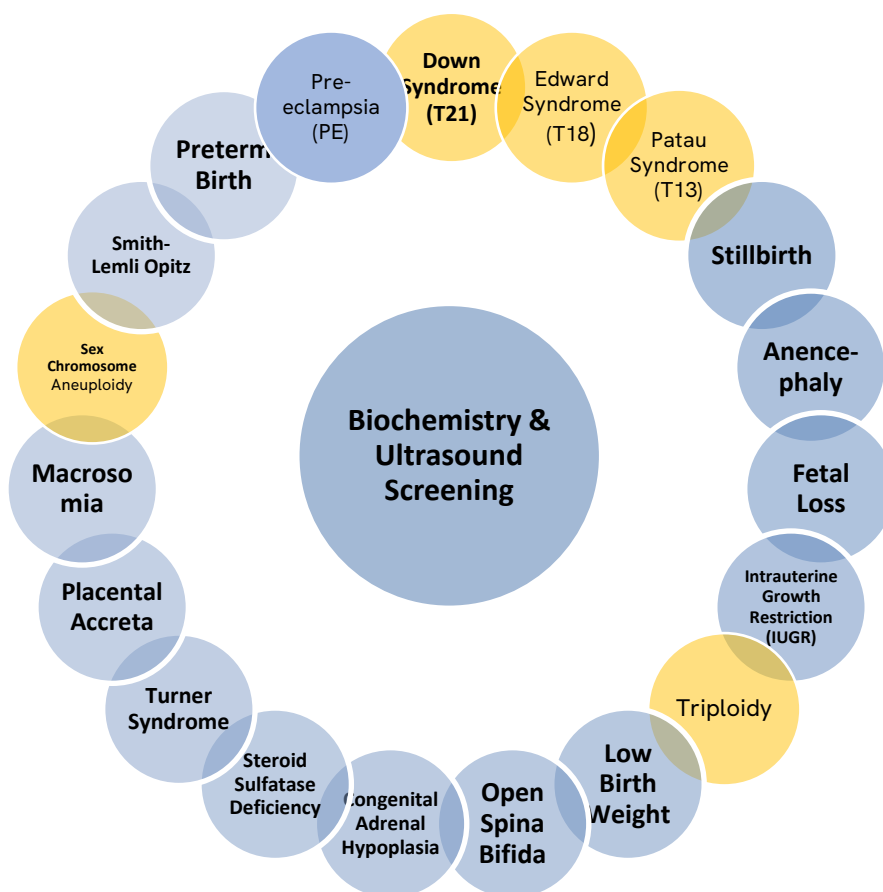


Figure 37. Prenatal screening with biochemistry and ultrasound. (Chart with courtesy of Professor Kypros Nicolaides)

The world is now in a momentum where both preeclampsia screening initiation and moving to NIPT are on a scale. Adding preeclampsia to the offering would be easy with the existing biochemistry solutions and workflows, but moving to NIPT would leave the instrumentation used for serum biochemical tests only with preeclampsia. Adding preeclampsia to the national screening programs is seen as an investment for the country's health system, but also NIPT would increase costs. Thus, keeping biochemistry aneuploidy screening as a primary screen and finding savings from preeclampsia screening could indeed be the most cost beneficial model.

### 3.4.2 NIPT market

As described earlier in this thesis, genetic technology has advanced dramatically and has become increasingly used over the last two decades. NIPT using cell-free fetal DNA has increasingly been adopted as a screening tool for fetal aneuploidies (Gadsbøl et al 2020, 723). The global implementation of non-invasive prenatal testing (NIPT) has been facilitated through collaborative research studies and consortiums, with governments and private authorities making significant efforts to integrate such testing into national healthcare programs. (Hui et al., 2023, 814) NIPT is the most accurate screening test for the common chromosomal aneuploidies, meaning trisomies 21, 13 and 18. Some providers are also offering microdeletions, sex chromosomal aneuploidy, triploidy and trisomies 9,16 and 22. (Figure 38)

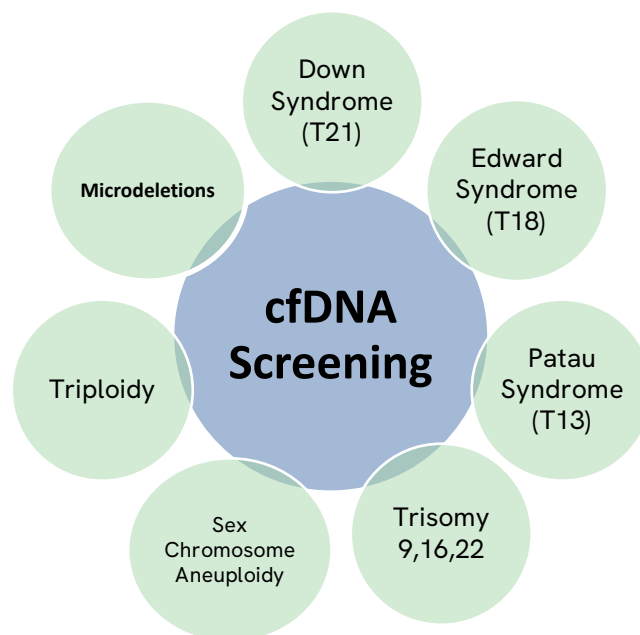


Figure 38. Cell free DNA screening and the most common chromosomal aneuploidy offering. (Chart with courtesy of Professor Kypros Nicolaides)

The introduction of NIPT has been rapid and in the beginning the test was available directly to patients through private channels. The growing market was seen as an opportunity and in a short time, there was a remarkable number of companies offering the test (Table 5) with minor differences over each other.

Table 5. List of different competitors in the NIPT markets.

Company	Product	Technology
Revvity	Vanadis® NIPT system	Rolling Circle Amplification - Imaging
Illumina	VeriSeq™ NIPT Solution v2	NGS-based noninvasive prenatal testing, PCR-free, whole-genome sequencing
Roche	Harmony®	Targeted PCR Microarray
Natera	Panorama®	Targeted PCR-based SNP Sequencing
BGI Health	Nifty®	NGS-based noninvasive prenatal testing, whole-genome sequencing (MPS)
Yourgene health (Novacyt)	IONA®	NGS-based noninvasive prenatal testing, PCR-free, whole-genome sequencing
LabCorp (former Sequenom)	MaterniT® 21 PLUS	PCR - NGS-based noninvasive prenatal testing, whole-genome sequencing
Quest Diagnostics	QNatal® Advanced	PCR- NGS-based noninvasive prenatal testing, whole-genome sequencing
Atila BioSystems	iSAFE™	Multiplex Digital PCR; ddPCR
BillionToOne	Unity™	Array based technology (Quantitative Counting Template (QCT))
GeneMind	NIGM	PCR - Low-pass whole genome sequencing
NIPTIFY	NIPTIFY	PCR - NGS-based noninvasive prenatal testing
GC Genome	G-NIPT	NGS-based noninvasive prenatal testing
Eurofins/Lifecodexx	PrenaTest®	NGS-based noninvasive prenatal testing
Arcedi	Evita test	Fetal Cells - trophoblasts
Luna Genetics	Luna Prenatal Test	Fetal Cells - trophoblasts
Igenomix	NACE	NGS-based noninvasive prenatal testing
Agilent	Clarigo	NGS-based noninvasive prenatal testing, PCR-free, whole-genome sequencing

The differences between the different tests are concentrated to the automation level and workflow simplicity, turn-around-time (time from sample to result), no call rate, sample tube and sample volume, sensitivity, offered panel, amount of available clinical data, cost, and regulatory status. Of the competing companies, Illumina is the market leader dominating the markets with its instrumentation installation base as many of the NIPT companies offer their test reagents to Illumina's platform.

#### 3.4.2.1 NIPT market drivers, opportunities and challenges

There are various factors that contribute towards the growth of the market such as: globally increasing average age of first-time mother, decreasing fertility, previous child with a chromosome abnormality, family history of chromosome abnormality, family history of single gene disorders, family history of neural tube defect and congenital structural abnormalities, and abnormalities identified during pregnancy among others. The availability of advanced screening technologies is a major factor for the growth and stability of the NIPT market. In addition, evolving government initiatives, adoption by a number of physicians, incorporation of tests into clinical care and allocation of reimbursement policies towards more genetic testing coverage are some of the major reasons which are driving the market. (Gadsbøl et al 2020; 723 Jayashankar, et al, 2023, 4-5, 6, 8.)

Non-invasive in nature, high accuracy and early detection, and rising awareness are some of the advantages offered by NIPTs as compared to invasive tests. Moreover, factors such as increasing market penetration in a number of countries in Europe and Asia and continuous rise in average maternal age are likely to fuel the growth of the global NIPT market. The risk of fetal chromosomal aneuploidies is directly related to the rise in advanced (>35 years) maternal age. Also, factors such as higher levels of education, higher income, and insurance coverage effect the uptake of NIPT in high-income countries (Jayashankar, et al, 2023, 14).

On the other hand, in LMICs both the cost of NIPT and its availability are limiting. The risk of ethical issues acts as a hindrance for the growth of the NIPT market in few regions. In the Middle Eastern countries also ethical and cultural norms are creating challenges. However, both in developing and in developed countries, women that the high sensitivity of the test can create a pressure to interfere with their overall reproductive autonomy. Lack of awareness among consumers is also a major restraint in developing countries of Asia, Africa, Central and South America. People are not aware about the benefits and the appropriate use of NIPT tests. At present, well established prenatal screening methods available in the market are maternal serum screening and ultrasound based which are used in the first and second trimester of pregnancy. These tests being cost effective may create hindrance in the growth of NIPT market to some extent. High pricing of screening tests along with the risk of accuracy creates obstacles in the growth of the market. (Jayashankar, et al, 2023, 11-21.)

### 3.4.3 Near patient rapid tests and acute diagnosis

Some conditions during pregnancy can develop rather quickly and lead to adverse outcome. There is a need for immediate diagnosing and management to both avoid unnecessary hospitalization and to enable fast triaging to hospital for further management and care. Among such conditions there are preterm birth (PTB), premature rupture of membranes (PROM) and preeclampsia. This chapter is to describe the landscape of rapid tests for these conditions.

There are more biochemical markers for PTB and PROM than there are for preeclampsia. For PTB/PROM Interleukin-6 (IL-6), IL-8, C-Reactive Protein (CRP), PAMG-1, insulin growth factor binding protein 1 (IGFBP1), Fetal Fibronectin (fFN), and AFP (Alpha fetoprotein) are offered with different combinations of markers and with different performance characteristic of the tests by different providers (Table 6). For preeclampsia as discussed previously, PIGF and sFlt-1 are found to be the main markers available. But there are also other markers like, glycosylated fibronectin (GlyFn) (Sokratous et al., 2023: 504-11) and endoglin (Levine et al., 2006, 992-1004) that has been found to be

indicative for preeclampsia. Similarly, these tests are offered by various providers (Table 7).

Table 6. List of different competitors in the rapid tests markets for PROM and PTB.

Company	Products	Biomarker	Availability/Status
Qiagen	PartoSure (PTL)	Placental alpha microglobulin 1 (PAMG-1)	CE-IVD, FDA
Qiagen	Amnisure (PROM)	PAMG-1	CE-IVD, FDA
Actim	Actim Partus (PTL)	phosphorylated form of insulin-like growth factor binding protein-1 (phIGFBP-1)	CE-IVD, FDA
Actim	Actim PROM	IGFBP-1	CE-IVD, FDA
Clinical Innovations	ROMPlus	Insulin-like growth factor-binding protein-1 (IGFBP-1) and alpha-fetoprotein (AFP)	FDA
Biosynex	PremaQuick (PTL)	IGFBP-1 Native & N Terminal plus IL-6	CE-IVD,
Biosynex	AmnioQuick Duo (PROM)	IGFBP-1	CE-IVD,
Biosynex	AmnioQuick Duo (PROM)	IGFBP-1/AFP	CE-IVD,
Hologic	Rapid fFNQ10 test	Fetal Fibronectin	CE-IVD, FDA

Table 7. List of different competitors in the rapid tests markets for preeclampsia.

Company	Biomarker	Products	Availability/Status
Gensure	PLGF, sFlt-1	PLGF/sFlt-1 test	CE-IVD
Lepzi	PLGF, sFlt-1	LEPZI® Quanti PLGF Test LEPZI® Quanti PLGF/sFlt-1 Test	CE-IVD
Toda Pharma	PLGF	Toda PLGF FIA®	CE-IVD
Revvity	PLGF	RONIA PLGF	Research use only
Momms Diagnostics	PLGF, sFlt-1	PreXclude	In Development
QuidelOrtho	PLGF	Triage PLGF	CE-IVD
Vacure	PLGF, sFlt-1	LYOFIA® PLGF & sFLT-1	CE-IVD
Intignus Biotech Ltd	Endoglin	Preeclampsia Screening Test	Research use only
Diabetomics Inc	Glycosylated Fibronectin	Lumella® PreeclampsiaTest	CE-IVD

### 3.4.3.1 Rapid test market drivers, opportunities and challenges

In terms of the conditions PTB, PROM and preeclampsia, the drivers, opportunities and challenges are similar to what has been described previously with laboratory offered tests. With these are available, there is an opportunity to save lives with the rapid availability of diagnosis regardless of the settings. The global high-risk pregnancies are increasing. And it is estimated that the global workforce shortage will increase. The global shortage of skilled workers and clinicians, especially in rural regions, will impact to the access and thus quality of care. In addition, the access to care is not equal.

The main advantages of these tests are discussed earlier in this thesis. The ability to provide fast and infrastructure free testing in any condition with relatively simple training are the main benefits. To low-income settings, the test with no sample transportation or need for laboratory is fundamental. Similarly in

high income settings, the ability to test at smaller clinics or even at home without sending to hospital is saving a lot of resources.

The challenge is that these tests need to give as well as the laboratory tests reliable and high quality results, which is affecting the manufacturing costs. The price expectation to these tests is demanding. The availability of quick tests in normal shops has lowered the bar to a very low level. With the current diagnostic landscape with licensing fees, regulatory and registration requirements, and logistics, the price per test is yet staying relatively high.

## **4 Analysis: Studies of Current And Future Forecasting**

In the previous chapter, the current landscape with trends and drivers was presented from the global perspective to healthcare in overall and more specifically to maternal and fetal health. Carefully conducted information gathering together with the analysis creates a sustainable base for all strategy work maternal and fetal health diagnostic business. This chapter analyses the information presented with different frameworks (PESTEL, SWOT and Porter's Five Forces) and use them for the basis of possible future scenarios presented as an output.

In short, as PESTEL analysis can help businesses identify the trends and changes in the macro-environment that can create or reduce opportunities and threats for the business. And further considers a broader range of factors that may not be directly related to competition but can still impact a company's operations, SWOT analysis is more focused on the internal factors that are within the control of the business, but can affect its strengths and weaknesses. Porter's five forces is more focused on direct competition and profitability.

### **4.1 PESTEL analysis**

PESTEL is a method widely used for analysing different dimensions of business, the letters referring to the words political, economic, social, technological, environmental, and legal. PESTEL analysis is a method that provides an oversight and helps to summarize the macro environment and external factors discussed in the earlier chapters. The macro environment is not something a company can usually impact. PESTEL is a useful tool in all industries at the strategic planning and decision-making process to assess current and future markets (MasterClass, 2022). The output from a PESTEL analysis is often used as an input for other tools such as a SWOT analysis. The following sections are summarizing the information presented in the global trends chapter.

#### 4.1.1 Political dimensions

As concluded earlier, governments worldwide have faced severe challenges in the last few years. COVID-19 pandemic and Russia's invasion of Ukraine has impacted the world. And these external shocks have accelerated some of the already existing trends, including the healthcare spending, which has been prioritized by governments. Yet, governments that have an increasing ratio of debt must cope with and respond to these emerging threats. The need to adapt has driven the governments to seek for alternative, innovative ways, new objectives are needed to keep the people safe and healthy also in the future. Many countries have committed to the sustainable development goals, and under the goals to ensure equitable care with access to everyone to reduce maternal mortality and morbidity. Healthcare costs continue to be a burden and access to care, and health equity remains a top issue for health policy experts. There is a the very slow implementation of actions and reluctance to establish new national programs. There would be a need to invest.

In HICs, where there is proper antenatal care established, maternal mortality is already in very low level. Majority of the deaths are happening in LICs. The biggest actions would be needed in LICs. In HICs, the actions are more related to the long-term health after pregnancy, to morbidity and to the high costs related to the care during and after pregnancy.

There is an increasing trend to move towards preventable healthcare. As new technological innovations are introduced to enable preventive care, there is an increasing need to put together new policies and regulations. Since the past years, European Union has decided to implement new In Vitro Diagnostic regulations to ensure safety and efficacy of the products available for the healthcare. Which has shown to slow down the introduction of new solutions. In addition, the fast digitalization that is happening in healthcare has also required new policies.

These new regulations and policies have an impact to maternal and fetal health diagnostic business. The regulations are creating new requirements and extra work to industry, making the introduction of new products slower and more costly. And challenging the access to affordable products. Creating a contracting affect to the maternal and fetal health policies.

As a new political dimension is the protectionism. Some countries have established an “in country for country”-policy. One great example of such is China. This has required companies to have local manufacturing site in China. This as such is seen problematic as when the proprietary manufacturing knowhow and information is transferred, the culture with lack of respect for IP can endanger the competitive advantage if the company. One form of protectionism are trade barriers, e.g tariffs on electric cars for China and tariffs on diagnostic products for at import. As an example of this is India. Both of the forms of protectionism are considered to protect local companies.

#### 4.1.2 Economical dimensions

The increasing cost of healthcare is heavily impacting the quality, access, and affordability of health services worldwide. There is now growing pressure on healthcare authorities to look for savings across the board through affordable and efficient models for access, delivered through technology and other innovations.

Although, to cope with COVID-19 pandemic, the healthcare was prioritized, with increasing depth-to-GDB ratios countries has started to look for new strategies to transform health care organizations are needed to build new capabilities, relationships, and competencies with reduced costs.

Workforce expenses and maintaining care facilities are a major driver of rising health costs. Countries closing smaller hospitals in rural areas/communities and centralizing the care to bigger hospitals to save costs. Healthcare organizations are also implementing remote monitoring technologies to close the gap after centralizing the care and to reduce costs of care.

While higher costs reduce affordability of care, affordability can also reflect the level of investment in health and health systems. Access to care is directly linked to affordability. To improve access, effort is needed. New strategies to transform health care organizations are needed to build new capabilities, relationships, and competencies.

The overall increase in health spend is partially caused by the increased out-of-pocket spend. While governments are not implementing and making care available for all under reimbursement, pregnant women have started to pay for the care out-of-pocket in private sector.

#### 4.1.3 Social dimensions

The population demographics has an impact to the maternal and fetal health. There is an increasing number of chronic diseases globally that are increasing the risk of adverse outcome of pregnancy. Together with poor lifestyle, advancing age to have first baby and thus, decreasing fertility, there is a decrease in global birthrates. Also, the numbers in global maternal mortality and morbidity are still unacceptable high. The mortality is not distributed evenly, but majority of the deaths are in low-income countries. The access to care is not equal, nor the quality of care is equal. There is infrastructure related constraints, but also educational, income, racial and regional differences. In addition, cultural and religious beliefs affecting the participation to maternal care. Consumer attitudes in places where care is available has changed. Many patients, and also pregnant women are seeking for personalized service from private sector and pay the care out-of-pocket.

#### 4.1.4 Technological dimensions

Technological advancements in the healthcare industry have impacted also the healthcare in maternal and fetal health, diagnostics and business. Genetic

testing, gene editing, portable point-of-care devices, wearables, noninvasive testing, 3D printing, AI, telehealth and at home testing are rapidly shaping the care and creating new opportunities to both healthcare providers, decision makers and to industry.

#### 4.1.5 Environmental dimensions

Global resource constraints and climate warming drive towards more sustainable solutions. The growing demand-supply gap for natural resources resource, a shortage in physical resources. Demand for food, water and critical metals and minerals is escalating. Access to many important resources is increasingly constrained, which is affecting to the price of the raw materials and logistics and eventually to cost of the products used in healthcare.

Climate change is increasingly recognized as one of the key global risks which will impact on all environmental determinants of health. Health providers and companies are increasingly adopting sustainable practices to ensure responsible use of resources. Climate change is an urgent threat to pregnant women and children leading to pregnancy-related complications, preterm birth, low birthweight, and stillbirth. The underlying climate crisis has opened new opportunities for industry to develop solutions to decrease the environmental burden.

#### 4.1.6 Legal dimensions

With the advancing technologies and care, also new laws and regulations will follow. An example of such regulations that was implemented in past and impacted the diagnostic industry is the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH"). Latest addition to impact the operations of diagnostic companies is the European Union In Vitro Diagnostics Regulation (IVDR). It is a new regulation ensuring a high level of

safety and performance of in vitro diagnostic (IVD) medical devices. On a contrary, additional burden of regulatory requirements are adding are also becoming a barrier to market access and implementation.

With big amounts of data generated and collected with current technologies, General Data Protection Regulation (GDPR) was introduced. GDPR is a law that protects the privacy and data of people in the EU and the EEA and applies to any organization that deals with their data. It gives people more control over their personal data. Now, with the era of digitalization, automation and AI governments are considering new laws and regulations. In fact, cybersecurity is a constantly evolving and growing field with emerging new threats, technologies, and laws. It deals with the legal and policy aspects of protecting data and systems from cyberattacks and is also influenced by global and national issues, such as Internet governance, privacy rights, cyberwarfare, and cyberterrorism.

For environmental legislation several hundred legal acts exist in the field of law and climate change, covering areas such as air quality, waste management, water protection, nature protection, industrial pollution control, chemicals management, noise and greenhouse gas emissions. And new laws are constantly been developed.

In 2021, the European Union (EU) adopted the so-called European Climate Law (ECL), enshrining in law the 2050 climate-neutrality objective and upgraded 2030 emission reduction target (Kulovesi et al. 2024). In 2022, the European Commission proposed a new law that would require large companies operating in the EU to verify that their global suppliers adhere to environmental standards and avoid using slave or child labour.

#### 4.1.7 PESTEL summary

As a summary of the environmental factors affecting in maternal and fetal health, a summary table is presented (Table 8). Also, the impact to the business with the degree of uncertainty was estimated.

Table 8. PESTEL. External factors and their impact to Maternal Fetal Health Business. Threat (T), Opportunity (O), Low (L), Medium (M), High (H)

Dimensions	Factors	Impact to business	Degree of Impact	Description	Degree of uncertainty
<b>P</b> <b>POLITICAL</b>	Conflicts between countries	T	H	Conflicts are affecting to business through international trade, altered logistics and through availability of raw material. Further, conflicts are affecting to the global economics and cost of goods.	L
	Governments looking for healthcare savings	O	H	The pressure to cut the costs of healthcare The investment is cost efficient and saving money and scarce resources and can be an opportunity for the business.	L
	2030 Sustainable Development Goals maternal and child health	O	M	This is clearly an opportunity. This is a strong commitment from several countries and organizations to put effort in maternal fetal health and as such an opportunity. Especially in low and middle-income countries.	L
	Increasing amount of national and international policies for improving maternal health	O	M	Strong commitment from country governments and organizations to put effort in maternal fetal health is an opportunity	L

(continue)

Dimensions	Factors	Impact to business	Degree of Impact	Description	Degree of uncertainty
E  ECONOMICAL	Increasing costs and saving pressure	T	H	Industry, private, investors and governments are holding back with investments. This is hindering the development and business	L
	Increase in health spend	O	H	This is an opportunity to implement soputions that are driving the current trends forward. Like equity in care and maternal mortality.	H
	Increasing out of pocket spend	O	M	There is an increasing amount of pregnant women seeking for care from private sector willing to pay for better care.	H
	Increasing depth-to-GDB ratios	T	H	This is againg driving the cost savings and can prevent implementing new programs to health care.	L
	Increasing investment money	O	H	Investors are increasing the funding of women’s health solutions development	M
S  SOCIAL	Population aging	T	M	Aging is increasing increasing the need for better care for elderly people with high prevalence of chronic diseases. Investmen for health care is directed to aging population.	L
	Decreasing fertility	T	H	The number of pregnancies in business is decreasing affecting the total market opportunity.	L
	Increasing age to have first baby	O	H	Aging is increasing the pregnancy related adverse outcomes, increasing the need for	L

(continue)

Dimensions	Factors	Impact to business	Degree of Impact	Description	Degree of uncertainty
				better care and implementing the solutions available.	
	High maternal mortality	O	M	The pregnancy related adverse outcomes are mostly preventable, high maternal mortality is increasing the need for better care and implementing the solutions available.	L
	Decrease in birthrates	T	H	Decrease in birthrate = decrease in total market size.	L
	Increasing chronic diseases and poor lifestyle	O	H	Increasing chronic diseases and poor lifestyle are increasing pregnancy related adverse outcomes which is increasing the need for better care and implementing the solutions available.	L
	Personal control on own health	O	L	An opportunity for new solutions and marketing the existing solution directly to consumers.	L
	Equitable care	O	L	Different geographical areas lack quality care, this is an opportunity to expand with solutions suitable for different needs. Also racial differences with increased need to better preventable actions during pregnancy are increasing the opportunity to offer solutions for care.	H
	Mobility and income: Access to care	O	L	This is an opportunity to grow business with solutions suitable for different needs	H
	Cultural and religious beliefs affecting the	T	M	Cultural and religious beliefs are impacting negatively the	L

(continue)

Dimensions	Factors	Impact to business	Degree of Impact	Description	Degree of uncertainty
	participation to maternal care			women's access and participation to antenatal care.	
	Low educational level	T	M	Low educational level impacting negatively to the women's participation to antenatal care. Lack of money, access and awareness	L
<b>T</b> <b>TECHNICAL</b>	Telehealth	T	L	Women may be treated home and participation to screening might be poor	H
	Wearables	O	M	Women may be treated home. There is a possibility to develop new solutions for home monitoring and to build ecosystems of different complementing diagnostics.	H

## 4.2 Porter's Five Forces

Porter's Five Forces is a method used in business strategy work, first introduced in Harvard Business Review article in 1979 (Porter, 2008). It is considering the impact of five different forces: industry rivals, customers, suppliers, potential entrants, and substitute products. Porter's five forces are used to identify and analyse an industry's competitive forces. Together, Porter's five forces shape the industry competition and future. Evaluating the competitive forces and assessing their positive and negative effects can be done only after the key players, and the related strengths for the selected industry has been defined and identified. (Porter, 2008.) As an outcome of the analysis of the competitive landscape, visual illustrations are presented in Figure 39, Figure 40 and Figure 41.

#### 4.2.1 Threat of New Entrants

When considering the new entrants there are few key questions to ask to evaluate the threat. Maternal and fetal health diagnostic business is very competed and dynamic business. There are constantly new competitors appearing, especially to the new areas like NIPT and preeclampsia that are in their early phases of the market lifecycle. However, in terms of the threat of new entrances, it is good to evaluate how expensive would it be, and how long would it take a new competitor or startup to enter your market. There are already big and small players on markets. Entering the growing business is easy. There is share left. The new entrants especially with a niche offering or big players with new content and strong capabilities are the biggest threats to the already available providers.

The testing of NIPT is dominated by private providers, thus switching provider is possible. However, the cost to switch can be relatively high, depending on the instrument base. But if there is a provider that is using a standard instrument and is only switching the reagents, the switch is easy. With niche offering the switch is costly.

With traditional biochemistry aneuploidy screening the relationships with customers are long term, especially in public side. There is strong customer loyalty in the industry. The first to implement preeclampsia are usually the customers having already biochemistry in use. Validating the systems to the laboratory is laborious. And when a supporting software that is needed for the screening is in use, configuring a new risk calculation software is a big effort. For a new competitor it would be difficult to persuade customers to switch away from existing products or services.

Additional barriers for a new player to enter the diagnostic markets are usually lack of clinical evidence and regulatory status and key opinion leader support. Diagnostic, medical device business is highly regulated. In addition to USA FDA and EU CE-IVD regulatory requirements, many countries have their own

regulatory agencies with requirements for performance and evidence to entry the markets.

Further, intellectual property is creating barriers for entry. For niche technologies and for companies having protection with IP is a true asset. Licencing from a company a right for the technology IP for a smaller company is not profitable. With low volumes, the increase in manufacturing costs is not profitable. The market price is an important aspect. For smaller companies with less sales, entry to markets with low prices can make the production of the low volumes not profitable.

#### 4.2.2 Bargaining Power of Suppliers

For both reagent products and instruments in medical device business, there are many raw materials classified as critical. It is undeniable that it is impossible to prevent the unavailability issues caused by the supplier entirely, but the starting point to mitigate the effect of supplier dependency is to have either multiple choices (minimum of two) or agreements to secure the for supply. For the material where there is no alternatives (like antibodies), the supply can be secured for example by transferring the production in-house. For instrument products the challenge with component obsolescence is not as straightforward, as there is a constant race to sustain the devices when the electronic components are facing their end of life.

It is broadly noticed that organizations are coping with the increasing complexity and engineering challenges of developing new products for the global competitive markets. The world has changed with the mobile phones that has caused a very short component lifecycle. The lifecycle of components has shifted from longer term to a two to four years. And for highly regulated devices this has caused a mismatch. Medical devices, along with other product sectors like airplanes, military find it difficult to adopt the rapidly changing technology. These products often “lag” the technology wave because of the high costs and expensive verification cycles required for design changes.

This is similarly true for a reagent product. Therefore, in case there is a need to change a critical component, the impact is critical. Both the cost to change and test a new supplier and raw material in a highly regulated product is enormous work and the probability that the product performance is altered (especially in reagent products) is big. In this light, it is crucial to ensure the availability of raw materials in this highly regulated business.

#### 4.2.3 Bargaining Power of Buyers

Although maternal and fetal health diagnostic business, especially screening related products are today sold for both private and public laboratories labs, the business has been traditionally in highly centralized on public laboratories. The centralization also enables selling bigger amounts to a single account, usually to university hospitals. When there is a national screening program, there is even a possibility to get the deal in the country level. For this reason, the number of accounts is relatively low.

Public laboratories have tenders open regularly by the hospital or the laboratory. The provider is selected with the basis of specifications set for the tender. Sometimes, the buyer wants to influence to the outcome and sets the specifications accordingly. The offering, the brand awareness and reputation, clinical performance and price are the main factors influencing.

#### 4.2.4 Threat of Substitute Products or Services

For non-invasive testing (NIPT) there are numerous players in the markets (see for table 5). Current, relatively high prices of the testing (compared to traditional biochemical testing) are so far keeping the providers profitable. Also, many of the competitors are only providing the reagents only and are utilizing the platform from other manufacturer, like Illumina. And some are offering their own test through a service in their service laboratories.

For Biochemical screening, a business that has been quite stable for many years, there are a few main players: Roche, Thermo Fisher Scientific, Revvity, Beckman Coulter, Siemens Healthineers, and a relatively new competitor Snibe. For Preeclampsia screening, the big players offering solutions for laboratories are mainly the same as for traditional aneuploidy biochemistry, excluding Beckman Coulter. There are also some companies offering solutions for preeclampsia testing that are not based on biochemistry, like Metabolomic Diagnostics, Mirvie and Sera prognostics. In addition to the big laboratory solution providers, there are number of small companies providing rapid tests for preeclampsia diagnosis Gensure, Lepzi and Intignus Biotech. Larger companied with known brands offering rapid tests include Revvity, QuidelOrtho and Diabetomics (see for table 7)

The similarity of the products/services from a functional standpoint is vast. For NIPT, most of the offering is screening for the common autosomal aneuploidies, meaning trisomies 21, 13 and 18, some providers are also offering microdeletions, sex chromosomal aneuploidy, triploidy and trisomies 9,16 and 22. The difference in tests are concentrated to the automation level and workflow simplicity, turn-around-time (time from sample to result), no call rate, sample tube and volume, sensitivity, offered panel, amount of available clinical data, cost and regulatory status. However, Revvity (divested from PerkinElmer) is has its own technology, which is not based on sequencing, but for rolling circle amplification (Dahl et al. 2018, 1-2).

For biochemical tests, the offering between laboratory solutions is relatively equal. There are only small nuances in performance, clinical data, validation status and registration status between the products. The competitive differentiator might come from analyte combination validated, instrument analyte portfolio and risk calculation software availability/features. Also, the availability of different sized platforms for different workflows and throughputs are seen as an asset.

What differentiates the products/services from substitutes is a key question. For some companies their proprietary niche portfolio, solutions for different sized laboratories and even rapid tests. Revvity has the full offering for prenatal and neonatal screening. Thermo Fisher Scientific is strong with its portfolio and preeclampsia test with broadest intended use and FDA approval. Roche has large analyte offering and installation base. In overall, differences are very minor.

Thus, price competition is high. There is a constant demand to press down the prices as there is also the external drivers that require the healthcare sector to cut the costs. The price level depends on the market greatly. In US markets the prices are higher due to the insurance company and reimbursement structure. Also, the offering mainly through private providers is affecting. In rest of the world, the price level is different, lower when screening is primarily offered through national screening programs.

As discussed above, when the laboratory is already having a fully functional screening program with population adjusted performance, it is highly costly to change the offering to a competitor's solution. This is mainly true with traditional biochemistry screening. When switching from biochemistry to NIPT, the system is completely separated and the need for population adjustments is irrelevant, the switch is possible with lower cost. However, the cost per test with NIPT is still remarkably higher. Thus the loss in cost efficiency of screening when switching to NIPT has been investigated to be at reasonable level with a contingent screening (biochemistry the first tier, NIPT for high risk).

For a substitute to become a market leader, a differentiating factor is needed. For screening, together with cost, performance and workflow/easy implementing is key factors. If there would be a new technology or a new marker, making screening cheaper, easier, or better, it could substitute the already available screening. This is partially why NIPT has been substituting in some level the existing biochemistry based screening. NIPT has better performance, accuracy. The higher cost is still hindering its implementation. Digital PCR is a potential

threat for NIPT– as the price per test is lower and it can be scaled to small numbers of samples to improve result turnaround time. However, sensitivity/specificity of the technology has not been proven as of now.

For preeclampsia screening, a biomarker that could replace the uterine arterial doppler needed for the risk assessment, could potentially be replacing the currently available model. However, also DNA and RNA based solutions are being investigated and can potentially be a threat to preeclampsia biochemical screening.

#### 4.2.5 Competitive Rivalry

As already described in earlier sections, the number of competitors in maternal fetal health business is high. For NIPT there are over 18 different providers offering NIPT solutions, some of them through laboratory service business. For traditional biochemistry aneuploidy screening, there are five main competitors offering laboratory solutions. For preeclampsia screening and diagnosis there are eight lab-based solutions. In addition, nine providers are offering rapid tests for quick diagnosing.

The biggest player in NIPT market is undoubtedly Illumina, also Roche's Harmony and Natera's Panorama are well established. For biochemistry screening Thermo Fisher Scientific, Roche, Revvity, Beckman Coulter and Siemens Healthineers are the main players. For preeclampsia Thermo Fisher Scientific, Roche and Revvity are equivalent and thus, evenly dividing the market share.

The challenge with biochemistry markets is that the products offered are very much alike. The differentiators are not actually the products, but what other assets the companies can offer. The screening software being one of the key competing factors, together with broader assay portfolio for the instrumentation and the instrument automation level. Cost driving the markets as well. At the moment Thermo Fisher Scientific is standing out with its FDA approved assay

and Roche is strong with its analyte portfolio and installation base in clinical chemistry and laboratory automation level. Revvity is strongest with its risk calculation software offering. Revvity is also mastering the markets with its capabilities to provide dried blood spot (DBS) sample format assays that are in low-income settings or in temperature demanding countries a true asset with more reliable sample stability.

For NIPT the Revvity solution is the only one that is based on to a different technique. It is said to be unique also to its robustness. The solution does not need a highly educated genetist to make the interpretation of the results. The system can be placed to a normal prenatal screening laboratory. However, having a differentiating solution is also a threat as the mainstream providers are formulating the clinical guidance and practises to support the majority. Also, the clinical evidence for a different solution need to be solid to compete against the mainstream solutions.

However, there are barriers preventing the customers from switching providers. At the moment, many barriers are keeping the customers with the provider they have chosen, until something better will be introduced. For biochemistry, the software used is definitely the glue that is keeping the customer with the provider. In addition, the cost and lack of reimbursement of NIPT is hindering the switch.

There are many future technologies that might have affect to the size of the industry in near future. There is no question that the NIPT markets are growing. The technology is constantly becoming cheaper enabling more and more providers to move into this solution making it also affordable for women. At the same time the size of the biochemical aneuploidy screening is slowly shrinking. Preeclampsia screening and testing is definitely a growing business. For the past two decades the clinical understanding, methods clinical practises and supporting guidelines of the use of biochemical markers in practice have evolved. The era of implementation is only starting. However, if a substitute technology like DNA based screening that could be done cost efficiently with

NIPT technologies, or a drug to treat when preeclampsia is about to developed are introduced, the cost benefit of screening might not be as profitable anymore as it is today.

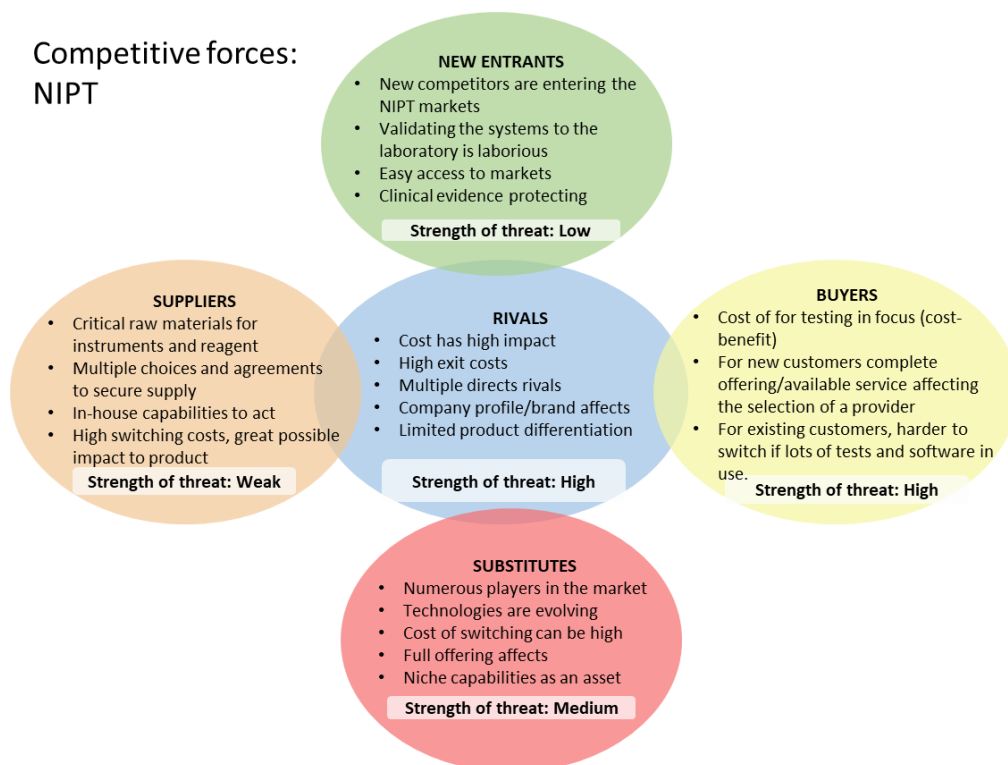


Figure 39. Competitive forces in NIPT landscape

## Competitive forces: Biochemistry

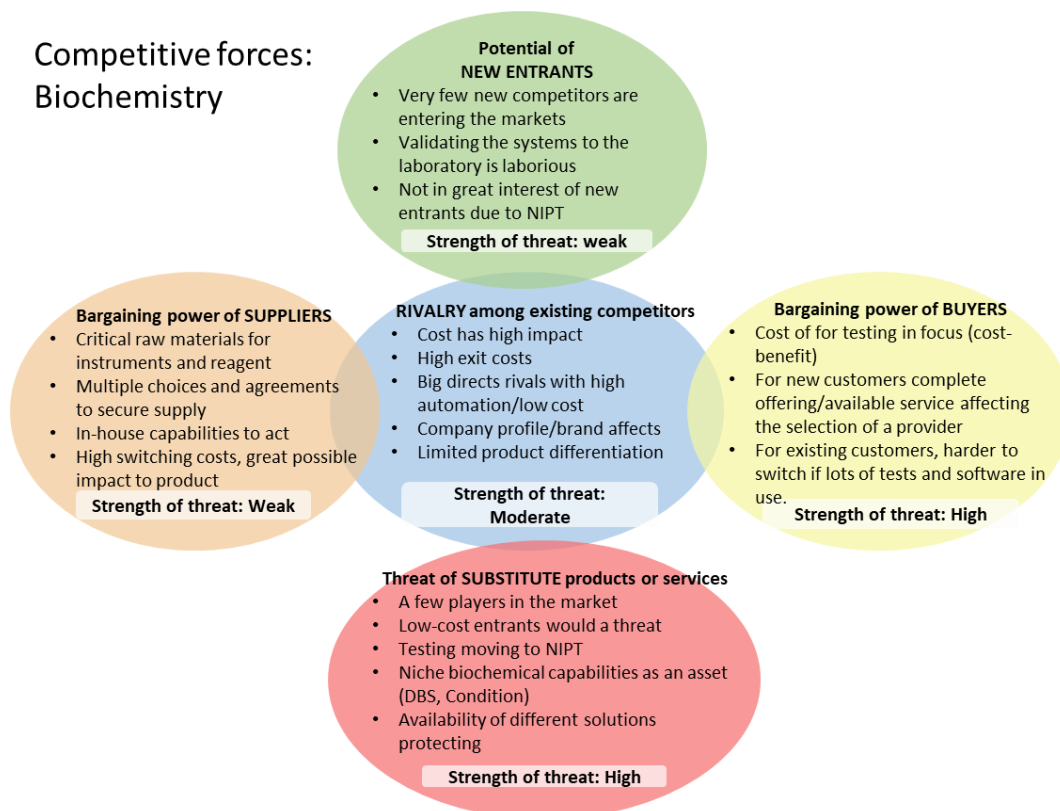


Figure 40. Competitive forces in traditional biochemical aneuploidy landscape

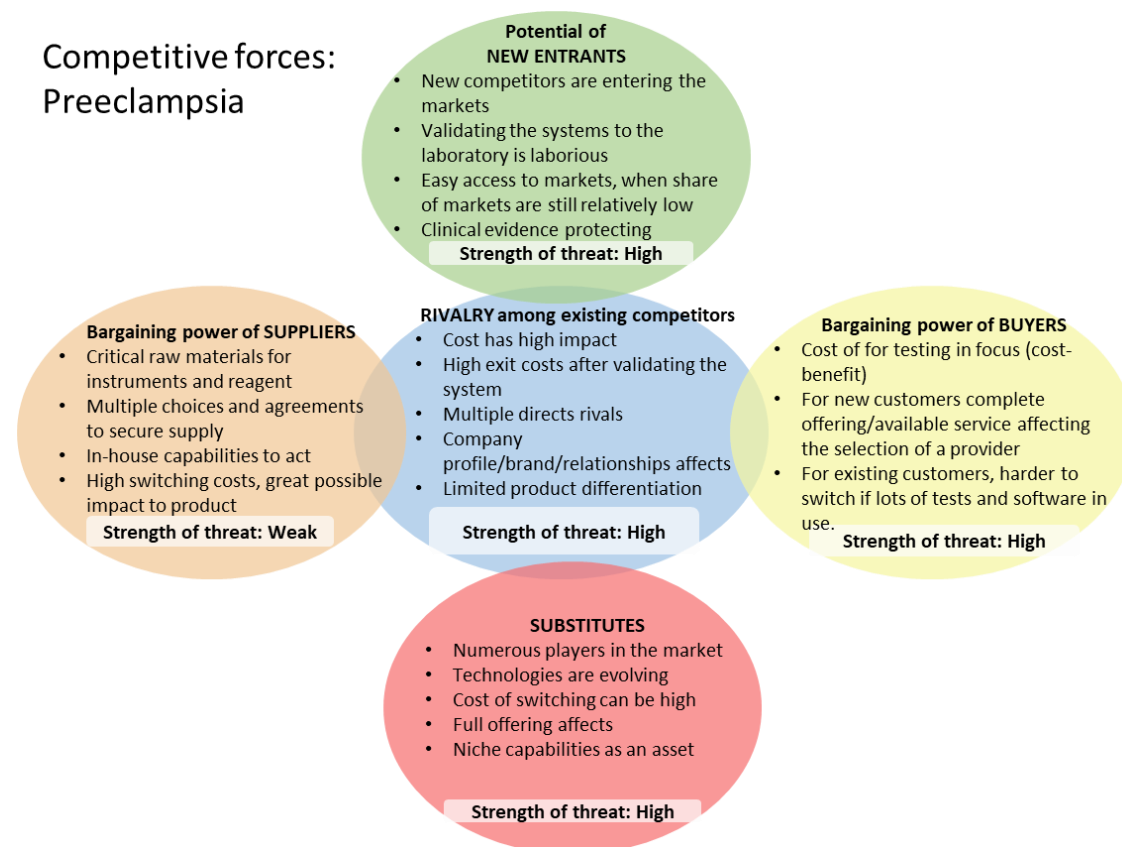


Figure 41. Competitive forces in preeclampsia screening landscape

### 4.3 SWOT analysis

SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis is one of most well-known strategy tools. SWOT is a strategic planning and strategic management technique used to help to identify strengths, weaknesses, opportunities, and threats related to business competition, internal operational efficiency, or project planning. The strategy tool SWOT is historically credited to Albert Humphrey in the 1960s (Gürel, 2017, 1, Toolshero, 2022). It is intended to identify the internal and/or external factors that are favourable and unfavourable to achieving the objectives.

How different factors affect on the objective, can be analysed with SWOT analysis tool. Here we use the maternal and fetal health diagnostic business as

an objective. Threats and opportunities for the SWOT (Table 9) are derived from the PESTEL analysis.

Table 9. Maternal Fetal Health Business SWOT

	Helpful (to achieving the objective)	Harmful (to achieving the objective)
Internal origin (attributes of the business)	<p><b>Strengths (S)</b></p> <ul style="list-style-type: none"> <li>•Portfolio for Maternal Fetal Health business</li> <li>•State of the Art software</li> <li>•Business highly focusing on Maternal Fetal Health</li> <li>•Strong relationships with academic key opinion leaders</li> <li>•Strong scientific evidence</li> <li>•Product offering / Menu for instrument</li> <li>•Automation level and connectivity</li> <li>•Instrument choices</li> <li>•Strong financial resources</li> <li>•Proprietary technology/ offering</li> <li>•Price advantage</li> <li>•Strong reputation</li> <li>•Agreement with strong financial resources.</li> <li>•Price advantage.</li> <li>•Longevity /commitment to Maternal and fetal health</li> <li>•Good company culture with</li> </ul>	<p><b>Weakness (W)</b></p> <ul style="list-style-type: none"> <li>•Unknown brand</li> <li>•Old technology</li> <li>•Limited product differentiation</li> <li>•Narrow portfolio</li> <li>•Lack of expertise/missing skills or competencies</li> <li>•Late to market</li> <li>•Vulnerable to competitive pressure (price/offering)</li> <li>•Below average marketing skills</li> <li>•Unable to finance needed strategic tactics.</li> <li>•Investment less than key competitors</li> <li>•Lack of scientific evidence</li> <li>•Lack of skilled salesforces</li> <li>•Internal operating challenges (managerial support, prioritizing)</li> <li>•Installed base in hundreds not thousands.</li> <li>•Proprietary biomarker / competency.</li> <li>•Poor strategic priority at corporate level</li> </ul>
External origin (attributes of the environment)	<p><b>Opportunities (O)</b></p> <ul style="list-style-type: none"> <li>•Sustainable Development Goals</li> <li>•Increasing amount of national and international policies for improving maternal health</li> <li>•Increase in health spend</li> <li>•Increasing out of pocket spend</li> <li>•Increasing investment money</li> <li>•Increasing age to have first baby</li> <li>•High maternal mortality</li> <li>•Increasing chronic diseases and poor lifestyle</li> <li>•Personal control on own health</li> <li>•Equitable care</li> <li>•AI</li> <li>•Genetic testing</li> <li>•Point-of-care</li> <li>•Climate change</li> </ul>	<p><b>Threats (T)</b></p> <ul style="list-style-type: none"> <li>•Conflicts between countries</li> <li>•Increasing costs and saving pressure/ Governments looking for healthcare savings</li> <li>•Increasing depth-to-GDB ratios</li> <li>•Aging population</li> <li>•Decreasing fertility</li> <li>•Decrease in birthrates</li> <li>•Income, cultural and religious beliefs affecting the participation to maternal care</li> <li>•New substituting technologies</li> <li>•New drugs</li> <li>•Shortage of raw materials</li> <li>•New regulations/laws</li> <li>•High competition</li> <li>•Leapfrogging technology</li> <li>•Focused competitors</li> <li>•New VC funded entrants</li> </ul>

#### 4.4 Plausible future scenarios of maternal and fetal health

Scenario planning is a practical tool for decision makers to create plausible views of the future of their business first developed by Shoemaker in 1995. Information that scenario planning provides is a crucial part of strategic management and decision making. There are several templates and formalized frameworks for scenario planning. Figure 42 shows the high-level steps for the scenario planning.

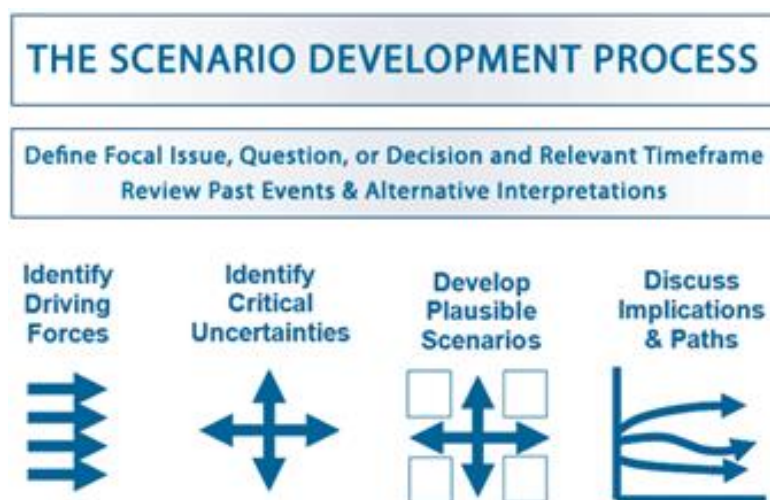


Figure 42. Scenario planning steps in short. (William 2022)

The objective of this thesis was to answer the question “what are the competitive advantages in the future for maternal and fetal health diagnostic business”. The objective is working as the focal question for scenarios. Since this thesis is not commissioned by a company, the scenarios for maternal and fetal health diagnostic business are created based on existing driving forces in health technology and maternal and fetal health discussed in detail in previous chapters of this thesis and analysed with different analysis frameworks. The key factors and external forces that could affect positively or negatively to the focal question were analysed with PESTEL, SWOT and Porter’s five forces. Impact of the factors to business as well as uncertainties were analysed.

To visualize the scenarios for maternal and fetal health diagnostic business in year 2030, the 2x2 matrix for four equally plausible scenarios in relation to two selected uncertainties were explored. For uncertainties the implementation and substitution force of new technologies and the investment source (payor) were selected due to them being strongly changing already. After the key descriptors for scenarios were selected, the four plausible scenarios was created (Figure 43).

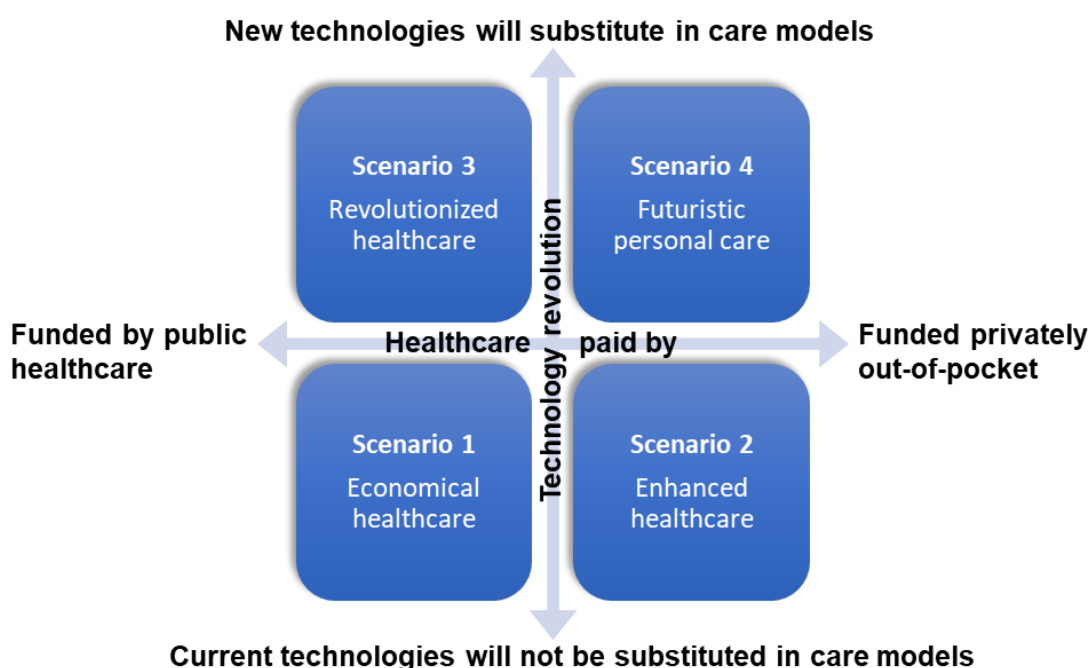


Figure 43. 2x2 matrix for scenarios

For each scenarios the same questions were evaluates and answered in terms to define how the future of Maternal and Fetal Health Business would look like in year 2030. The questions evaluated were:

- How will the population demographics affect to the economical burden of healthcare?
- How is the technology supporting the access and affordability of the care?
- How are the competing companies addressing the needs of healthcare?
- How will the regulations, laws and policies affect?
- How is are the environmental factors and policies affecting?

- How is the state of demographics of women and pregnant affecting the care?

#### 4.4.1 Scenario 1: Economical healthcare

Continuing increase of health care costs globally and increased spending on health because of the aging populations and chronic diseases (diabetes, obesity, and hypertensive disorders) are prioritizing investments done for healthcare. Lack of money drives to invest only to solutions that can create cost savings. New technologies are being selectively implemented to complement the care, to drive the access to care and to save the costs. Such solutions include the implementation of digitalized solutions like telehealth and remote care solutions that can increase the accessibility to care and are reducing the healthcare costs with the need for less healthcare resources. At the same time these technologies are supporting the attempts to improve the health outcomes.

Changes in the women's demographics with the decreasing birth rates, and decreased fertility, combined with the increasing maternal age and chronic diseases and lifestyle, puts more pressure to the scarce pregnancies. Companies are trying to get more out of the pregnancies and expand the business. Companies are offering supporting solutions like software and NIPT to improve the care, and to add value to the care providers. They also are expanding offering with the existing platforms to cover more conditions for care moving increasingly to preventative care. Solutions that are to identify the pregnancies at high risk for an adverse outcome (e.g. preeclampsia) are being funded and offered for all women. The expansion of the business is to target the geographical areas where there are high birth rates, but still very underdeveloped antenatal care and infrastructure. Yet, there is the real need for solutions that are able to reduce adverse outcomes. Increasing amount of point-of-care solutions to accompany the digitalized solutions has been introduced for pregnancy care. The consciousness of the climate change and the depletion of

some raw material has increasingly drove towards green values. Green values are being specified by the buyers in healthcare. Thus, companies that has created biodegradable products with low waste and carbon neutrality are having a competitive advantage. Implementation of digitalized solutions has increased the need for regulations, laws, and policies for data protection and for cybersecurity. Thus new requirements are to be met by the commercial companies.

#### 4.4.2 Scenario 2: Enhanced healthcare

Like in scenario 1, continuing increase of health care costs globally and increased spending on health because of the aging populations and chronic diseases are prioritizing investments to solutions creating cost savings. New technologies are implemented to drive cost savings like digitalized solutions with the need for less healthcare resources. And only a few countries have implemented new screening programs to the national level. At the same time these new solutions and technologies are advertised directly to consumers that have become increasingly sophisticated are taking charge of their own health. In many countries public healthcare is not yet offering the preventive solutions to improve the health outcomes because new drugs introduced to treat the symptoms for the affected pregnancies have been estimated to be a more cost beneficial choice. Changes in the women's demographics with the decreasing birth rates, and decreased fertility, combined with the increasing maternal age and chronic diseases and lifestyle has increased the risks for adverse outcomes and is putting pressure for women to have a healthy pregnancy. Women are increasingly investing to their own health. Thus, women are increasingly paying these preventive services out-of-pocket.

Women want to ensure that their pregnancy is well monitored. There are many different technologies that companies are offering to pregnant women both through clinicians and directly. Also in this scenario, companies are trying to get more out of the decreasing amounts of pregnancies. In addition to screening solutions (NIPT, preeclampsia screening, pre-pregnancy health package)

offered through private laboratories directly to consumers, companies are offering supporting solutions like software apps and wearables that can improve the care through support and monitoring and add value both to mother and to the care providers. Many companies are expanding the business with is introducing new conditions to the women's health area offering (like recently added endometriosis, polycystic ovaries). These conditions are not covered through public health but can be bought from private laboratories. The expansion of the business is also here geographical to areas where there are high birth rates or traditionally low level of solutions used in women's health due the cultural or religious reasons. The shift from aneuploidy only screening to pregnancy health opens new doors to business. In Middle East for example the out-of-pocket business is an opportunity for many companies. Increasing amount of point-of-care solutions has been introduced for pregnancy care, especially for clinicians to offer in their private business.

Also, in this model the green values of any product is preferred. For the solutions that are bought by the consumers directly, green value is a specification that can affect to the decision of the test choice. Thus, companies that has developed product that are environmentally friendly are having a true competitive advantage.

Implementation of digitalized solutions has increased the need for regulations, laws and policies for data protection and for cybersecurity in the healthcare system level, but for consumer directed solutions and apps, which are not considered as medical devices, the regulations are not affecting yet. Thus, new requirements are to be met only by the commercial companies providing medical devices for the use of healthcare.

#### 4.4.3 Scenario 3: Revolutionized healthcare

As in previous models, healthcare globally is increasingly facing the need to meet the challenge of the aging populations and chronic diseases, that are both costly to treat. However, in this scenario the structure of the healthcare has

changed which is enabling the wide use of the new technologies and digitalized technologies introduced. The price for the technologies due to the development has become affordable and thus, the care is widely covered by public healthcare in developed countries. Digital technologies with remote telehealth care have reduced the overall visits for antenatal care during pregnancy but has increased the participation and access to healthcare. While in this scenario the digitalized technologies have been widely implemented, also the laws, regulations and policies are being met by the manufacturers and healthcare organizations.

As the birthrates and fertility are decreased and demographics of women trying to reproduce are changed, there is increase in the risk of adverse outcomes during pregnancies. Thus, the care has moved to the preventable care. It is recommended to participate in pre-pregnancy care to ensure healthy pregnancy. To prevent adverse outcomes of pregnancy related to placental insufficiency, screening for placental insufficiency is in use and high-risk pregnancies are being treated with prophylactic medicine. The next generation sequencing solutions are in use to screen the fetus for some inheritable solutions like sickle cell disease and phenylketonuria and CRISPR technology is used to complement screening, to cure. NGS being a new area for companies to expand their capabilities in maternal fetal health.

In low and middle-income settings care during pregnancy is also implemented with digital technologies. When woman in LMIC traditionally has not been visiting the antenatal care clinics early or frequent enough, now the companies and different organizations supporting the set-up of care into these conditions have understood there is a need to adapt to the needs. Affordable and easily accessed care for every woman is implemented through bringing the hospital to the patient instead of patient to hospital. This means the use of portable technologies; wearables, apps and point-of-care tests.

This has opened a new segment for many of the companies in maternal and fetal health. While this is a new segment, new competitors (start-ups) are trying to get footprint in this space. However, new and increasing regulations and

registration requirements are not opening the doors to small companies without a collaboration with a big company in this space.

Point-of-care is an increasingly developing technology and business. However, it is also in high pressure to meet the needs for green values. The waste challenge produces with plastic test cartridges has been partly resolved by introducing bioplastics to the products. However, the solution is not feasible yet to all segments as bio plastic as a raw material is yet too expensive, increasing the product costs for LMICs.

While point-of-care is meeting the needs for LMICs these products have been widely implemented also in HIC. These tests are reducing significantly the need for infrastructure and resources when with one stop the examining, testing and treatment plan are all done without the next visits to laboratory and back to the doctor's appointment. This is also reducing the costs and is enabling the care for all women.

#### 4.4.4 Scenario 4: Futuristic personal care

Inevitable also in this scenario the population demographics have changed. The aging populations and chronic diseases is the new normal. Changes in the women's demographics with the decreasing birth rates and fertility, combined with the increasing maternal age and chronic diseases (obesity, high blood pressure, diabetes) and unhealthy lifestyle has increased the risks for adverse outcomes. On the other hand, everything is being monitored. Increasingly sophisticated consumers are taking charge of their own health. They have not only watches and rings to monitor their health, but also patches and sensors. They can monitor their blood glucose and blood pressure as well as heartrate. Together with AI that has been tuned to see patterns, it is possible to recognize and alert the patient before the condition is developed. In addition, screening and early prediction to prevent is available for all women through private labs. Further, prenatal NGS is available with a reasonable cost. Different providers having a variety of panels to screen. Early screening has become a business for

health insurance companies. Personalized packages are being offered by private clinics to women. Packages can have offering like pre-pregnancy care, assisted reproduction, early screening and prevention, pregnancy monitoring and postpartum care. Only sky is limiting, but this offering is mainly paid out-of-pocket. Women with fertility challenges and with advanced age are willing to pay.

The new personalized care is true business and thus companies have expanded their offering to cover the full path from pre-pregnancy to postpartum. This is also the first era when there is information available from the same woman for this whole cycle. The data is being utilized to develop the care even further. AI is playing a big role in this. This is also increasing the investment for women's health.

The development in HIC is taking further also the technologies for LMIC. AI is developing and the digitalized solutions are increasingly accessible also in LMICs. This together with the POC testing in remote settings are improving the health and pregnancy outcomes also in developing countries. Regulations and regulators have understood that the increasing number of regulations are actually worsening the introduction of solutions to make the care more accessible and equitable. Thus, there is a re-evaluation made to the regulations. Also, the countries that had added costly and laborious registrations submissions and fees to access the country have in the LMICs removing the high costs.

## **5 Conclusions – The Future of Maternal Fetal Health Business**

This chapter is summarizing the findings and learnings of the empirical research of this thesis studying the internal and external factors and reflects these against the research question “what are the competitive advantages in the future for maternal and fetal health diagnostic business”.

To answer the research question of this thesis was started with the literature and information research of the trends in health technology and maternal fetal health field. The information was gathered from different scientific publications, trend reports, reports from different forums and meetings held, from articles and web sources.

The thorough research included both external and internal factors affecting the landscape of maternal and fetal health. The aim was to identify the macro and micro trends and even silent signs to create the scenarios for the future. The research was performed with PESTEL analysis, SWOT analysis and the competitive landscape analysis using Porter’s five forces method as basis for the scenarios.

The frameworks to structure the research were found to be very important to keep the focus on the aspect under research. The external dimensions in PESTEL analysis, that are excluding technical dimensions, are easily forgotten in the strategic planning and decision-making process to assess current and future markets. This might be as they are not clearly dimensions that are a part of the business field. But as said are external. The work for strategy planning is very easily touching only the dimensions that are introduced by SWOT analysis. However, in this thesis, the author is considering PESTEL even more important to the future work than the SWOT. It was concluded earlier that PESTEL analysis is a method that provides an oversight and helps to summarize the

macro environment and external factors. These are the factors where the industry/business has very little influence. PESTEL is a tool to assess current and future markets. Without these dimensions, the business, company, industry cannot recognize its strengths and opportunities for the future. The output from a PESTEL analysis in this thesis was used as an input for the SWOT analysis.

As there was no commissioning company for the thesis the work was done from the overall business perspective. The SWOT analysis was very hard to create. It was basically collecting the findings through the empirical research work to form the possible strengths and weaknesses for the business, to any company. These were also overlapping with the Porter's five forces competitive rivalry. To form the competitive landscape with Porter's five forces, the different areas in the business (genetic testing/NIPT, biochemical traditional aneuploidy testing and preeclampsia) that are found to be in very different stage of their lifecycle and also in different competitive landscape, was resolved by splitting the business in three sections with their own competitive landscape models created.

The biggest findings affecting the current and future business from the studies were made through the PESTEL dimensions. The COVID-19 pandemic had enormous effects to the healthcare system, implementing of new tools and regulations and even reshaping it's structure. The speed of implementing new came with such a speed that the leap from the time before to after COVID-19 made more progress and changes to the healthcare than was made during the past decade. COVID-19 affected through the global economics, with physical barriers and though health crisis heavily to the current and future landscape. In addition, the Russian's invasion to Ukraine has increased the economic burden and costs, affecting to the businesses through changed access to the business regions, but also with changed availability of some raw material. The conflict is still true today and tensions between countries are constantly increasing. Thus, the future is not according to what we would like it to be. It needs to be created through the findings that are giving us a clue of the different possible future scenarios. These are mainly external factors and related uncertainties. If

PESTEL dimensions are not considered as a part of the strategy work to, the strategy will fail to understand and deal with the consequences of various business decisions in a way that leads to a good outcome.

The scenario building process was based on intuitive logics approach, where the whole scenario planning process was based on creating plausible futures and testing the business against them. The methodology used in the development part of this thesis was based on relatively widely used scenario planning with 2x2 matrix scenario building. The used scenario building method relies heavily on identifying the driving forces. The key drivers for the change were used to create the four possible scenarios together with guiding questions.

To create the four different scenarios, it was very hard to unlock your mind for the different futures. Some trends are inevitable happening and some are “the uncertainties”. And to keep your mind not trying to build the future you would like to see is hard. This would have been more fruitful with a facilitator asking the why questions, with a person that know very little of the business. Also, more time to try out even more different models with different uncertainties would have been beneficial. However, to create a scenario is always a “best guess”, and rarely the truth. This the uncertainty and not basing the scenario to true facts is something just to accept.

The aim of the thesis and the was to answer the research question “what are the competitive advantages in the future for maternal and fetal health business”. It started to become clear through the different analysis made through frameworks that the competitive advantages are the factors that are solving a gap in needs, are differentiating form the competition, are sustainable solutions for future and are aligned with the future trends. Some of these factors and solutions are presented in the Table 10 below.

Table 10. “what are the competitive advantages in the future for maternal and fetal health diagnostic business”.

Factor	Trend	Competitive advantages
Solving a gap in needs	<ul style="list-style-type: none"> <li>– Access to care</li> <li>– Equitable care</li> </ul>	<ul style="list-style-type: none"> <li>– Digital solutions</li> <li>– Portable solutions (not bound to place/infrastructure)</li> <li>– Point-of-care offering</li> </ul>
Differentiating from the competition	<ul style="list-style-type: none"> <li>– Offering</li> <li>– Complementing asset to offering</li> </ul>	<ul style="list-style-type: none"> <li>– Digital solutions</li> <li>– End-to-end portfolio</li> <li>– Software solutions</li> <li>– Level of service</li> <li>– Solutions tailored to needs</li> <li>– Quality</li> <li>– Price</li> <li>– Niche offering</li> <li>– Reputation/brand</li> </ul>
Are sustainable solutions for future	<ul style="list-style-type: none"> <li>– Environmentally sustainable</li> <li>– Low cost</li> <li>– Solution for different needs (LIC-HIC)</li> </ul>	<ul style="list-style-type: none"> <li>– Digital solutions</li> <li>– Carbon neutral / low waste offering</li> <li>– Low cost solutions for LIC</li> <li>– Portable solutions (not bound to place/infrastructure)</li> <li>– Point-of-care offering</li> </ul>
Aligned with the future trends	<ul style="list-style-type: none"> <li>– Changing demographics with chronic diseases</li> <li>– Advanced maternal age</li> <li>– Decreasing fertility and birth rate</li> <li>– Increasing adverse outcomes</li> </ul>	<ul style="list-style-type: none"> <li>– Digital solutions</li> <li>– End-to-end portfolio</li> <li>– Software solutions</li> <li>– Niche offering</li> </ul>

## 6 Suggestions

Future studies for the business are a fundamental exercise that would need to happen for any kind of the business. To create this level of comprehensive document with thorough studies is of course not possible in busy work life, but if the work is done throughout the year and updated periodically, it gives a strong foundation for the annual strategy work. From the framework tools used in this thesis, author would recommend using the PESTEL as the main landscape tool before going into the SWOT of the business/company. Future scenarios are done for the longer period of time. Thus, these would need to be updated if the PESTEL-SWOT landscape is having major changes during the periodically done iterative adjusting.

The research question “what are the competitive advantages in the future for maternal and fetal health diagnostic business” is relatively difficult to answer. The success in this business is of course dependent on the future landscape, but also of the actions the competitors are taking in relation the possible future scenarios. As concluded in the previous chapter, there were two major external shocks, COVID-19 pandemic, and Russia’s invasion of Ukraine, that unexpectedly affected globally. Such external factors together with factors out of the control may change the course rapidly and radically.

When taking the suggestions for the competitive advantages in the future for maternal and fetal health diagnostic business from this thesis and its conclusions, the most important fields to put effort would be right and competitive portfolio with niche offering, genetic testing, digitalized solutions and software, service, and accessible solutions (POC). These solutions are the most versatile and has footprint over all the scenarios. At its best with these solutions the business can prepare and adapt to unexpected and fast changes.

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