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National implementation of the first-trimester anomaly scan: benefits, opportunities and challenges

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Citation

Bronsgest, K. (2026, September 1). *National implementation of the first-trimester anomaly scan: benefits, opportunities and challenges*. Retrieved from <https://hdl.handle.net/1887/4308829>

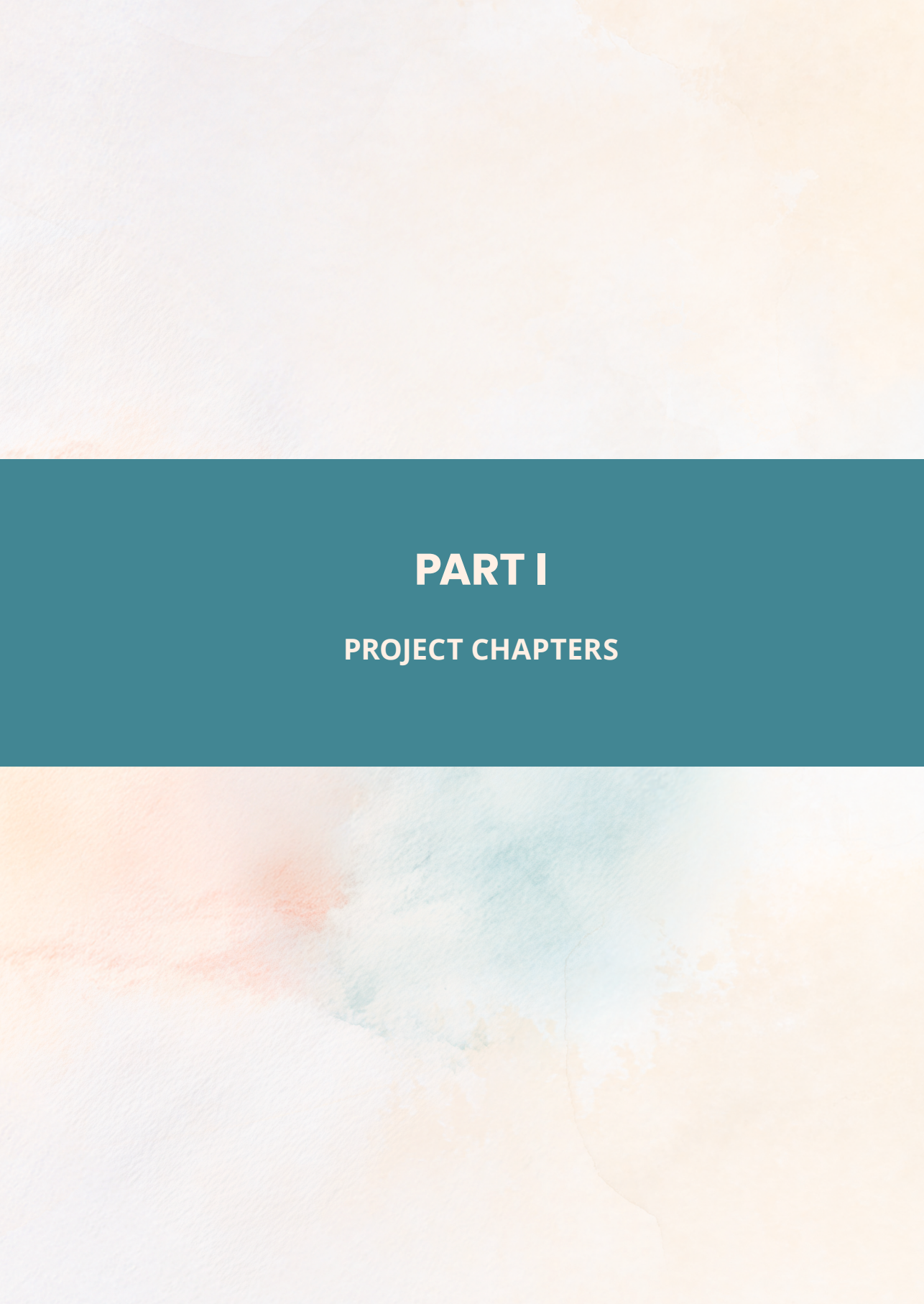
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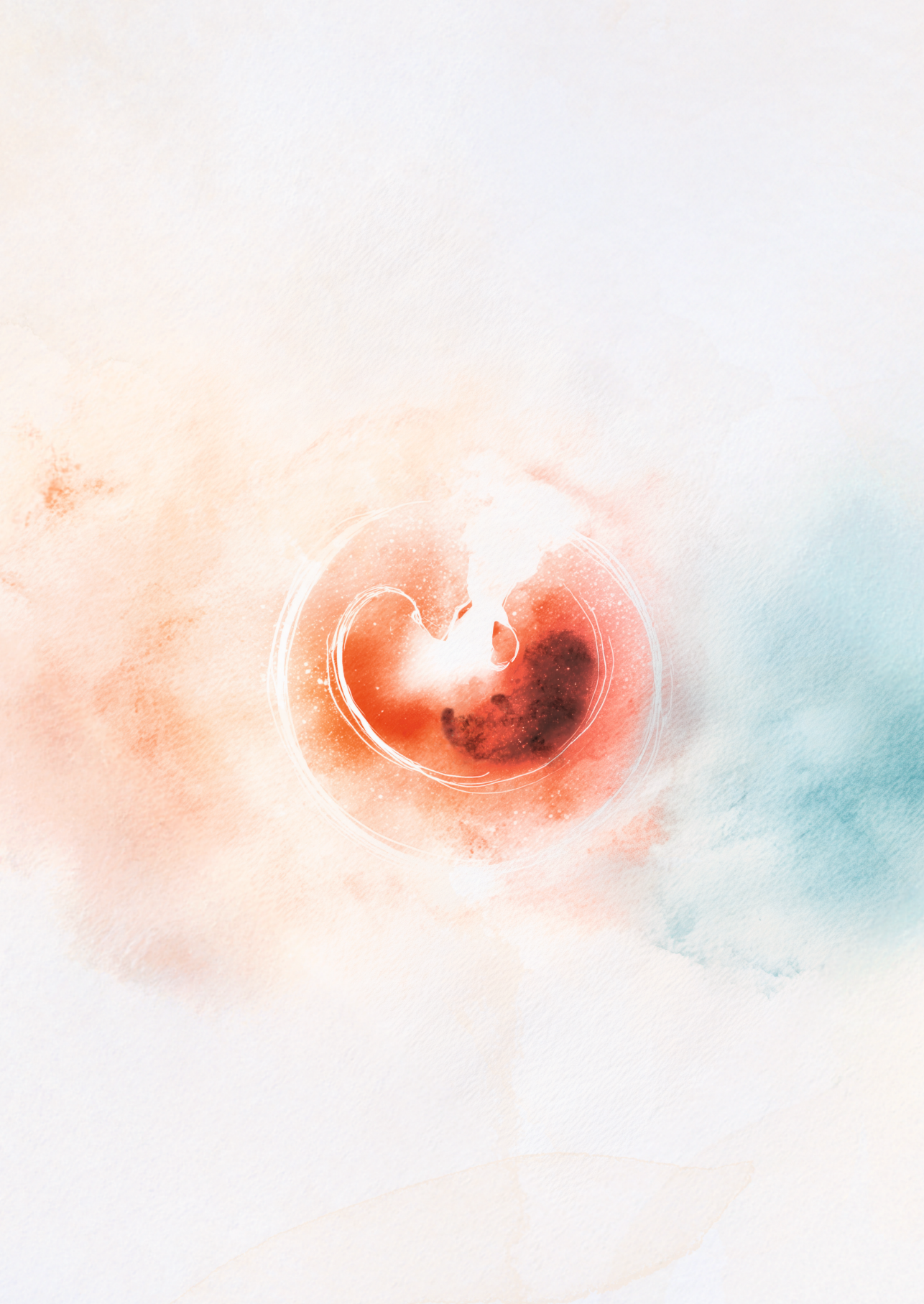
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PART I

PROJECT CHAPTERS



CHAPTER 2

Current practice of first-trimester ultrasound screening for structural fetal anomalies in developed countries

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Prenat Diagn. 2023 Jun;43(7):873-880

ABSTRACT

Objectives

First-trimester ultrasound screening is increasingly performed to detect fetal anomalies early in pregnancy, aiming to enhance reproductive autonomy for future parents. This study aims to display the current practice of first-trimester ultrasound screening in developed countries.

Method

An online survey among 47 prenatal screening experts in developed countries.

Results

First-trimester structural anomaly screening is available in 30 of the 33 countries and is mostly offered to all women with generally high uptakes. National protocols are available in 23/30 (76.7%) countries, but the extent of anatomy assessment varies. Monitoring of scan quality occurs in 43.3% of the countries. 23/43 (53.5%) of the respondents considered the quality of first-trimester ultrasound screening unequal in different regions of their country.

Conclusions

First-trimester screening for structural fetal anomalies is widely offered in developed countries, but large differences are reported in availability and use of screening protocols, the extent of anatomy assessment, training and experience of sonographers and quality monitoring systems. Consequently, this results in an unequal offer to parents in developed countries, sometimes even within the same country. Furthermore, as offer and execution differ widely, this has to be taken into account when results of screening policies are scientifically published or compared.

INTRODUCTION

A second-trimester scan to screen for fetal structural anomalies is available for pregnant women in most developed countries. Practice guidelines have been established by scientific societies in which standards are described, including the aim of the scan and targeted population, the timing and scan protocol ^{1,2}. Over the last years, screening for fetal anomalies in the first trimester is often advocated. Earlier detection of fetal anomalies provides future parents with more time for genetic testing and for considering their options, aiming to enhance reproductive autonomy. Treatment options are limited for most early diagnosed major anomalies, implying that parents have to choose between continuing or terminating the pregnancy. However, termination of pregnancy (TOP) is prohibited or restricted only to save a woman's life or preserve her health in 112/201 (55.7%) countries around the world³. Therefore, a country's jurisdiction on TOP may influence first-trimester screening policies. When first-trimester screening is available, the fetal anatomy is often assessed during the nuchal translucency (NT) scan as part of the combined test (CT), but not executed standardly. The CT is widely used and has the primary aim to detect fetal aneuploidy⁴. Adding anatomical evaluation to the CT in order to detect structural anomalies is feasible, but limitations include the need for trained and experienced operators and uncertain cost/benefit ratio⁵⁻⁷. Consequently, variation in the performance of first-trimester screening for structural anomalies between countries is likely. International variation has also been reported regarding the implementation of non-invasive prenatal testing for fetal aneuploidy, where differences were found in accessibility for pregnant women, uptake rates and screening protocols⁸. As the possibilities and potential of prenatal screening are evolving rapidly, we present an overview of current practice on the use of first-trimester ultrasound to detect fetal structural anomalies in developed countries. This may aid decision making of policy makers and care givers and consequently improve obstetric care for pregnant women.

METHOD

An online survey among national prenatal screening experts was conducted from July until September 2022 to explore the current international practice of ultrasound screening for fetal structural anomalies in the first trimester. The following topics were addressed: (estimated) uptake, availability of scanning protocols or guidelines, public versus private service, reimbursement, sonographer training and quality monitoring. Also, experts were asked about policies concerning TOP in their country.

The 36 countries included in the list of developed countries by the United Nations World Economic Situation and Prospects⁹ were the countries of interest for this study. (Inter)national recognized experts, who are involved in local, regional and/or national ultrasound screening, were selected from these countries and personally invited to participate in this survey study. The number of experts invited per country was based on the countries' population in 2020¹⁰. In case of countries' population of <11 million, 11-50 million, 50-100 million or >100 million we aimed to include one, two, three and four experts of the country. A few discrepancies in answers concerning *facts* between experts from the same country were assessed within the research team and adjusted based on additional questions via email to the experts or available checkable knowledge. *Opinions* from experts were never modified. Data were graphically presented in maps created with Mapchart.net (<https://mapchart.net/>). The Medical Ethics Review Committee granted a waiver since the Medical Research Involving Human Subjects Act (Dutch abbreviation: WMO) does not apply to this study.

RESULTS

We invited 93 medical specialists from 36 countries to partake in this survey study. In total 33 out of 36 countries participated. From these 33 countries, 47/93 (50.5%) experts completed the survey. No response was received from Luxembourg, Hungary and Slovakia. The number of responses reached the desired number in 26 countries. From seven countries, one to three respondents completed the survey. Of the 47 respondents, 46 respondents are maternal-fetal medicine (MFM) specialists and one is a clinical geneticist, with the majority of these experts (89.4%) having >10 years of professional experience.

First-trimester anomaly scan

According to the respondents, first-trimester screening for structural anomalies by ultrasound is available in 30 out of 33 countries. The remaining three countries (Ireland, Japan, United Kingdom (UK)) do not routinely offer screening for structural anomalies in the first trimester. However, the UK intends to formally implement screening for fetal anomalies at 11-14 weeks in the future. At this moment, Norway and the Netherlands undergo a regulated implementation since 2021 and are included in these results. In 27 of the 30 countries anatomical screening is part of the CT. In some of these countries, for example, Latvia, Lithuania, Sweden and parts of Australia, anatomical screening is additionally offered next to the CT, either during the dating scan or as a specific anomaly screening scan. In Belgium, Norway and the Netherlands the CT is not performed anymore. In these countries, first-trimester anatomy screening is offered as a stand-

alone offer, apart from aneuploidy screening. In 20/30 (66.7%) countries, the scan is performed between a gestational age (GA) of 11-14 weeks. In the other countries, the GA range is either variable within a country or different than GA 11-14 weeks, for example, GA 11-13 weeks in Canada, Cyprus and parts of Germany and Spain. Finland and some parts of Germany start earlier, from GA 10 weeks. Some regions in Germany start as early as GA 8 weeks. Denmark, the Netherlands, Sweden and some regions in Italy are the only exceptions where the end of the range exceeds GA 14 weeks for first-trimester screening, respectively at GA 14+2, 14+3 and 14+6.

Offer and uptake

In most countries, first-trimester screening is offered to all pregnant women, excluding Malta where this scan is only offered to women in private clinics and Poland where it is only offered to women with a high-risk profile. In Sweden, it depends on the district. Some respondents, however, mentioned that it is recommended in their country to offer the scan to all women, but practice variations exist, for instance, due to resource limitations or obstetric professionals being selective about who they offer the scan to. The uptake is estimated to be high in most countries, namely $\geq 70\%$ in 24/29 countries. Numbers from Norway are not available yet as they are still in an implementation process. The uptake varies from 20-66% in the remaining five countries: Austria, Germany, Malta, Poland and Romania. In Germany the uptake numbers are based on the age of the pregnant women: uptake for women older than 35 years is ca. 90% versus 50% for younger women, reflecting the fact that the purpose of the first-trimester scan is mainly to detect aneuploidy.

Scanning protocol or guideline

A national guideline on which anatomical regions to assess during the scan is available in 23/30 (76.7%) countries. However, some respondents argue that their protocols are sometimes more than ten years old or consist of very basic recommendations. In the seven remaining countries, there are three countries (Australia, Poland, Canada) with varying protocols throughout the country and four countries (Croatia, Cyprus, Czech Republic, Malta) without a protocol. In nearly all countries where a protocol is available, the guideline or protocol is developed by MFM specialists, sometimes based on Fetal Medicine Foundation publications or ISUOG guidelines.

The actual assessment during the scan may vary as not all items in the protocols are mandatory in all countries. In some countries, only NT measurement is obligatory, the other items are merely recommendations. Moreover, the extent of anatomy assessment may depend on the available time and experience of the sonographer, for instance an expert from Norway reported that many operators assess more than required by the protocol.

Public versus private service

Countries' healthcare system can be public, private, or mixed. A description of the healthcare system per country, reported by experts, is shown in Figure 1. We have identified four systems for reimbursement of first-trimester ultrasound screening within these healthcare systems, see Figure 2. The United States of America (USA) was not included due to the heterogeneous healthcare system with huge variations. Costs vary from 0 to 350 euros in some European countries and Australia (0-500 AUD). In 27/30 (90%) countries, first-trimester ultrasound is offered by, but not limited to, public hospitals. Furthermore, scans are executed in private hospitals/clinics (22/30; 73.3%) or midwifery practices (4/30; 13.3%). Scans can also be offered by commercial practice in Australia and the Czech Republic, private radiology practices in Australia or ultrasound centres in the Netherlands, Sweden and Canada. In Cyprus, Malta and Austria, first-trimester scans can only be performed in private clinics.

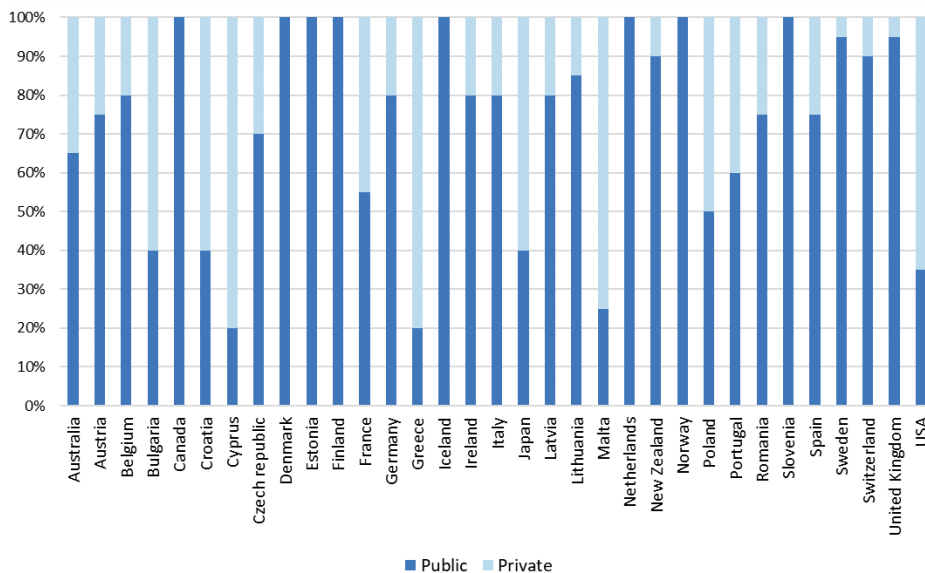


Figure 1. Organization of obstetric care per country estimated percentages of public and private obstetric care in developed countries reported by national experts

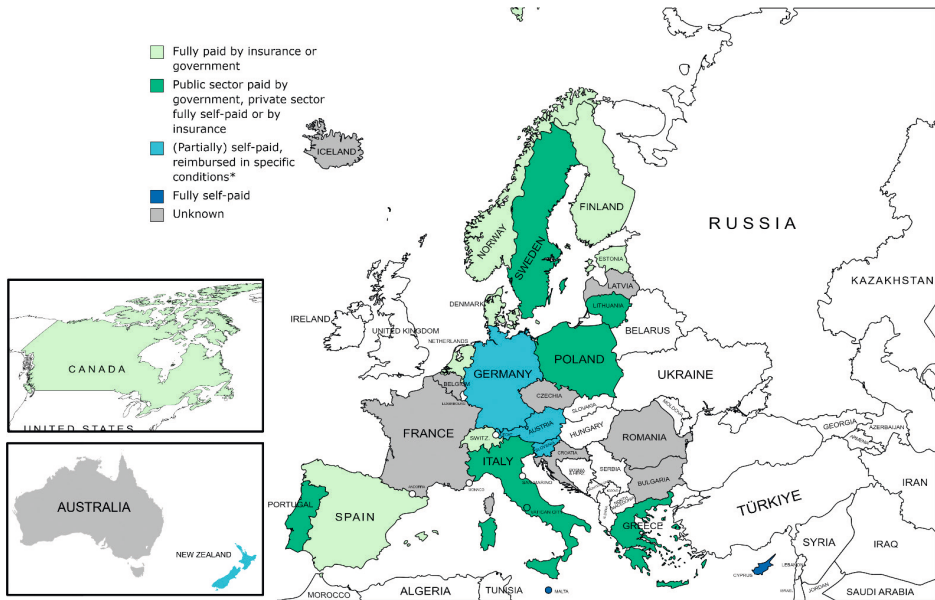


Figure 2. Reimbursement of first-trimester screening ultrasounds reported by national experts

*Austria and Slovenia: reimbursement depending on age; Germany: reimbursement depending on the type of insurance; New Zealand: partially self-paid, partially by government.

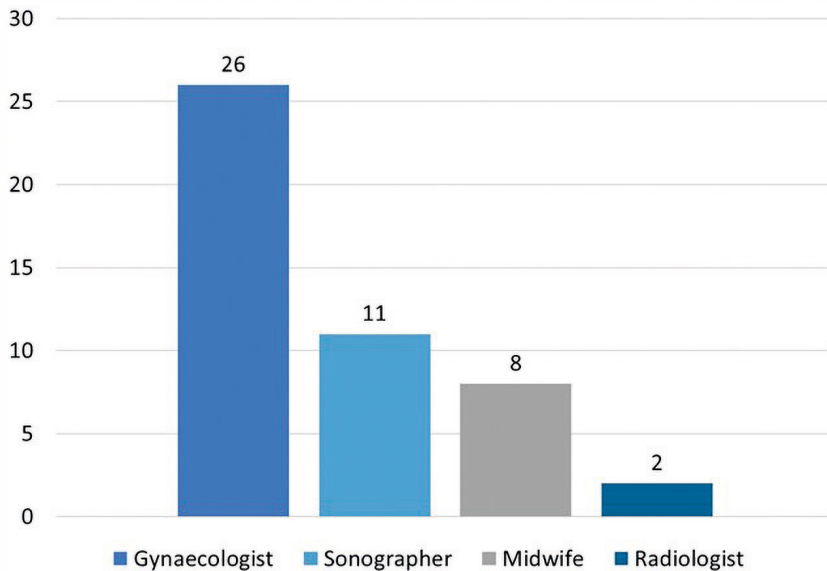


Figure 3. Professionals who perform first-trimester ultrasound screening according to national experts

As shown in Figure 3, the most frequently reported professionals performing scans are gynecologists (26/30; 86.7% of the countries), followed by professionals trained as sonographers (11/30; 36.7%), midwives (8/30; 26.7%) and radiologists (2/30; 6.7%). In half of the countries, only gynecologists execute the scan. In thirteen countries it is common to have two or three different professions to execute first-trimester ultrasound. Especially in Nordic countries, Belgium, the Netherlands, France, Spain, USA, Australia and Canada, other professions routinely perform the ultrasound. In the remaining two countries (Denmark and New Zealand), only sonographers execute the scan. In some countries, such as Finland and the Netherlands, the woman's risk profile determines the centre where the ultrasound takes place and the level of the sonographer, with MFM specialists scanning high-risk women and certified midwives or sonographers the low-risk women.

Training and quality monitoring

In 16/30 (53.3%) countries, training, license or certificate is obligatory to perform these first-trimester ultrasounds. Yet, for some of these countries this training or license applies to the NT-measurement only and is not mandatory for all providers. In four other countries, experts from the same country gave contrasting answers, possibly meaning that certification is not mandatory in all regions. Moreover, training methods are diverse, ranging from a theoretical course to a combination of theoretical and practical courses followed by an exam.

Quality monitoring occurs in 13/30 countries (43.3%); however, three respondents reported the monitoring to be limited to the NT measurement, not to other parts of the scan. Some respondents state that monitoring occurs but question the efficiency of the system. For instance in Portugal, where the internal quality of assessment is highly variable. Furthermore, quality monitoring is not always applicable to each clinic/hospital as for instance in Finland this only applies to the five university hospitals. In the Netherlands, the national health institute monitors the performance of first-trimester anomaly ultrasounds. Six out of eight countries with a completely public healthcare system have (national) monitoring in place, excluding Iceland and Slovenia. Furthermore, there is a strong link between full reimbursement and quality monitoring as in seven out of eight countries where costs are fully reimbursed by government or insurance, there is (national) monitoring as well. In Canada, however, the monitoring varies regionally.

On a 5-point Likert scale, 23/43 (53.5%) respondents (totally) disagreed with the statement that 'the quality of first-trimester screening ultrasound is equal in different regions of my country' compared to 16/43 (37.2%) respondents who (totally) agreed with this statement. See Figure 4 for an overview per country. From the 11 countries which (totally) agreed with

the statement, at least five countries do not have (national) quality monitoring in place. Reasons mentioned for differences in quality are, for example, absence of monitoring, no requirements for training; hence causing differences in quality depending on who performs the ultrasound, regional variation in access and quality (mostly higher quality in bigger cities or hospitals) and different types of imaging practices (general radiology, fetal medicine units). Apart from Canada, all countries with a completely public healthcare system consider the quality equal in all regions of their country.

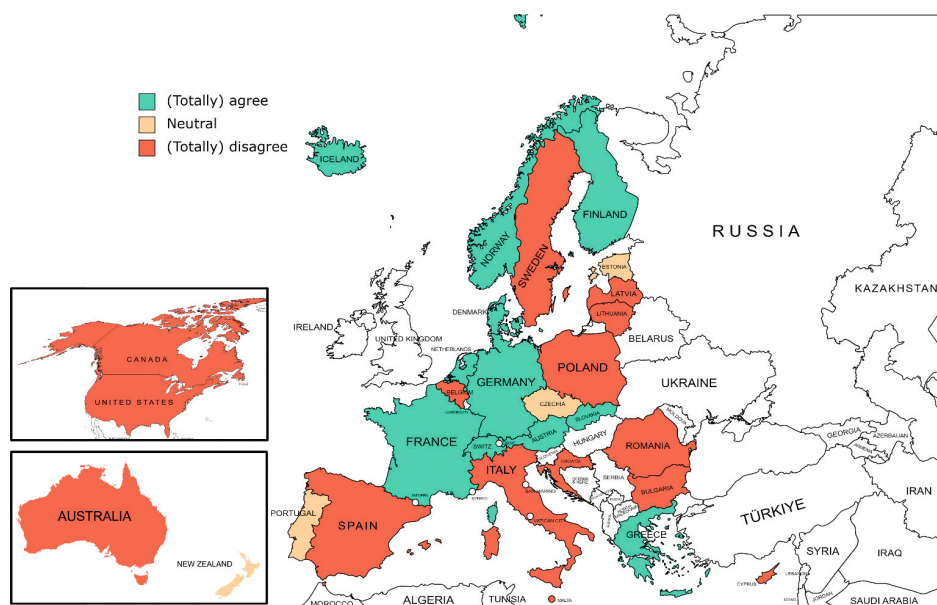


Figure 4. Response from experts to the statement 'The quality of first-trimester screening is equal in different regions of my country'

Termination of pregnancy

Countries' jurisdiction on TOP may influence first-trimester screening policies. In 32 out of 33 participating countries, TOP is legal, yet law, regulations and procedures vary per country. In Australia and USA, TOP jurisdiction is variable depending on the state. Since not all States of both countries were represented by an expert in our study, Australia and the USA are not depicted in Figure 5.

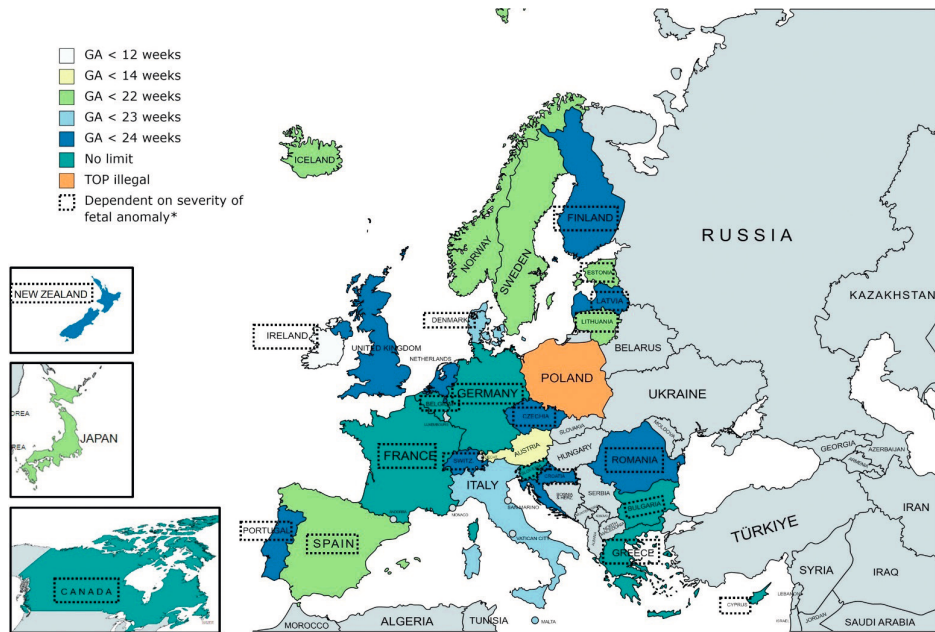


Figure 5. Gestational age (GA) limit for legal termination of pregnancy (TOP) on medical grounds reported by national experts

Furthermore, in the USA the right to undergo TOP is changing rapidly according to USA responding experts, as the Supreme Court's decision to overturn Roe v. Wade in June 2022 has led to abortion being banned in at least 10 states. Figure 5 shows an overview of the official GA limit for TOP reported by the national experts. A variety of conditions are, however, applicable in certain countries. In 21 of the 30 countries in which TOP is legal, the option to terminate the pregnancy within the reported GA range is dependent on the severity of the fetal anomaly. In Belgium, for example, there is no limit in GA, but after 14 weeks the fetal anomaly must lead to a substantial handicap or pose a serious threat to maternal health, as judged by a multidisciplinary panel. In Germany, termination can be requested by pregnant women until the term, but some centres will not perform termination after 24 weeks. In Cyprus, to terminate a pregnancy with fetal abnormality after GA of 10 weeks, permission from the Ministry of health is required. In other countries with an official limit, extension of the reported GA limits can be granted in case of lethal or severe anomalies or conditions representing a serious risk to the health of the pregnant woman. This is for instance the case in Ireland, the Netherlands, New Zealand, Norway, Portugal, Romania, Spain and the UK.

Per country it differs how the process leading to legal TOP is secured. Certain requirements should be met in order to allow TOP by law, such as multidisciplinary

consultation, consultation with own obstetric healthcare professional, second opinion, consultation with other healthcare professionals or a consideration period. Multidisciplinary panel decision is reported in 22/30 (73.3%) countries, followed by consultation with own obstetric healthcare professional 16/30 (53.3%), second opinion 12/30 (40.0%) and consultation with other healthcare professionals, for example, psychologists or social workers 12/30 (40.0%). A consideration period is mandatory in 11/30 (36.7%) countries. In some of these countries however, jurisdiction depends on the GA or may be regionally variable. Therefore, the reported percentages may be overestimated. Additionally, in some countries, specialized medical boards assess TOP requests including, but not limited to, obstetricians, geneticists, psychologists, ethicists and sometimes lawyers.

DISCUSSION

This study shows an overview of current practice of first-trimester structural ultrasound screening in 33 developed countries as reported by national prenatal screening experts. Most countries have implemented the assessment of the fetal anatomy as one of the aims of first trimester ultrasound screening, next to aneuploidy risk estimation, but execution strategies vary greatly between and even within countries. Furthermore, differences were found regarding monitoring, protocols and reimbursement. Also, the scan is not always offered to all pregnant women, which causes inequity in access to care and the possibility of early genetic testing.

The quality of anatomy screening is dependent on available protocols and their application, sonographers' experience, training and certification and the existence of a quality monitoring system. National protocols are available in most countries but are sometimes more than 10 years old or consist of very basic recommendations. In many countries, a uniform protocol for anatomy screening is missing, hence causing a lack of systematic anatomy assessment and dependence on the experience of the executing professional. The measurement of the NT is mostly the main goal of the scan and the extent and quality of the further fetal anatomical assessment depends on the expertise of the sonographer. As mentioned by some respondents, it is plausible that experienced sonographers will perform a more detailed scan, causing inequality within a country.

We found that in 16/30 (53.3%) countries, a license, certificate, or training is mandatory to perform first-trimester scans. However, training methods are diverse and in some of these countries only theoretical training suffices. According to multiple expert societies such as the American Institute of Ultrasound in Medicine and the Society for

Maternal-Fetal Medicine, physicians performing detailed fetal anatomy scans should either have acquired appropriate skills or keep a logbook under formal supervision of a qualified physician¹¹. Based on the available study data, it is not possible to judge on quality standards of all countries. Yet, for a nation to measure and verify the quality of the performed ultrasounds, monitoring can be implemented. According to the World Health Organization, monitoring and evaluating screening programmes at regular intervals is essential¹². Such evaluation can be used to inform policy-makers whether the screening programme is delivering the expected benefits and, if not, why this may be occurring and whether the screening programme needs to be modified in some way¹². However, our study showed that monitoring occurs in less than half (43.3%) of the countries. This percentage is even an overestimation as some respondents mention that their monitoring system is ineffective, does not cover all clinics/hospitals or is only limited to certain measurements, such as the NT. Because of diverse first-trimester screening strategies, the opportunity arises to learn from results in other countries. Whenever a study publishes detection rates in the first trimester, these rates should be carefully interpreted due to the large differences in training, protocols and monitoring as mentioned above.

In addition, different healthcare systems may contribute to the variation in the performance of first-trimester scan. This survey shows that experts from countries with a completely public healthcare system have national monitoring in place and consider the quality of the scan equal in different regions of their country. The healthcare system of 9/33 (27.3%) reviewed countries is completely public. However, Figure 1 shows merely a simplified overview as the healthcare systems and their financing are more complex. In the mixed healthcare systems, first-trimester screening can be offered either private, public or both, but equitable access to prenatal screening can be limited in countries where private healthcare dominates. Furthermore, the quality of health care in general may arguably be better in publicly funded and publicly provided healthcare systems¹³. Each country has its own, sometimes complex, healthcare system reflecting political, ethical, societal and financial differences. Diverse (inter)national implementation strategies may not directly imply problematic, as the quality of care could be similar and good. However, more than half of the respondents report inequity in the quality of first-trimester ultrasound screening in different regions of their country.

Another important factor in the offer of first-trimester screening is the country's jurisdiction on TOP, as a significant aspect to (future) parents' autonomy is the availability of legal termination of the pregnancy when they consider TOP to be the best option in their situation. TOP is illegal in Poland and the uptake of the scan is the lowest in comparison with the other countries, namely 20%. TOP is legal in all the other

participating countries TOP, however, the right to undergo TOP in the USA has been changing since June 2022. Courts must determine how to handle existing restrictions, and lawmakers in some states are expected to propose new laws to restrict abortion access. In others, abortion rights are protected by state law, and legislators may move to expand access. Moreover, there is great variation in the legal GA limits between countries, which can depend on the severity of the fetal anomaly. As a consequence, reproductive autonomy differs among developed countries, sometimes forcing parents to travel to different countries¹⁴.

Strengths and limitations

The strength of this study is the high response of experts from developed countries. One of the limitations of this study is that our findings are based on expert opinions. However, we have primarily invited specialists in the field with good track records in order to enhance reliability. To limit response bias, we invited multiple experts from the same country, stratified per population size. Nonetheless, we found some discrepancies between answers from experts in the same country, for example, concerning the availability of a protocol, monitoring or scan reimbursement. These discrepancies were evaluated within the research team and either assessed as possible regional differences or adjusted based on additional questions to the experts or available knowledge. Furthermore, the women's risk profile was not explicitly addressed in our survey, but some respondents clarified that in Finland and the Netherlands the first-trimester screening strategy is based on the women's risk profile: where and with whom the scan should be executed as well as the extensiveness of the ultrasound. This may be present in other countries as well and be underreported as it was not explicitly asked in the survey. Another limitation is that this study only reports on the current practice in developed countries, not in developing countries.

CONCLUSION

First-trimester anatomy screening is implemented in the majority of the studied developed countries with generally a high uptake. Countries have different performance strategies, often varying within the country itself, implying that access to prenatal care is not uniform. Differences were found in the availability of a national screening protocol, anatomy assessment, training and experience of sonographers, monitoring system and reimbursement. According to some respondents, these differences influence the quality of the scan within a country. Furthermore, variation in legal regulations concerning TOP among countries variably affect reproductive autonomy. Future studies should assess

how to combat inequity in the availability of first-trimester anatomy screening within and between countries.

Acknowledgements

We thank all experts who contributed to this survey study: Eugenia Antolin, Francesco D'Antonio, Edikai Arulaane, Sjanneke Beutler, Antoni Borrell, Miguel Branco, Daniel Challis, Rabi Chaoui, Petya Chaveeva, Helene Collinot, Mark Cordina, Themistoklis Dagklis, Charlotte Ekelund, Veronika Frisova, Daniela Gold, Anne Helbig, Lotta Herling, Hulda Hjartardóttir, Lisa Hui, Jacques Jani, Karl Kagan, İçten Kıvançlı, Biserka Knezic Frkovic, Sylvie Langlois, Wesley Lee, Liesbeth Lewi, Egle Machtejeviene, Fergal Malone, Nataša Tul Mandič, Alexandra Matias, Simon Meagher, Tim van Mieghem, Katie Morris, Anca Panaitescu, Federico Prefumo, Pran Pandya, Valentina de Robertis, Vedran Stefanovic, Katsuhiko Naruse, Peter Stone, Natalija Vedmedovska, Alexandre Vivanti, Neeta Vora, Marcin Wiechec, Louise Wilkins.

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