

WHO antenatal care recommendations for a positive pregnancy experience

Maternal and fetal assessment update: imaging ultrasound before 24 weeks of pregnancy



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Acronyms and abbreviations

ANC	antenatal care
CI	confidence interval
DECIDE	Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence
DOI	declaration of interest
ERG	External Review Group
EtD	evidence-to-decision
FIGO	International Federation of Gynecology and Obstetrics
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GRADE-CERQual	Confidence in the Evidence from Reviews of Qualitative research
GSG	Guideline Steering Group
LMIC	low- and middle-income country
MCA	Department of Maternal, Newborn, Child and Adolescent Health and Ageing (at WHO)
PICO	population, intervention, comparator, outcome
RCT	randomized controlled trial
RR	risk ratio
SRH	Department of Sexual and Reproductive Health and Research (at WHO)
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
US\$	United States dollar
USAID	United States Agency for International Development
WHO	World Health Organization

Executive summary

Evidence from a Cochrane systematic review on imaging ultrasound conducted before 24 weeks of pregnancy was evaluated as part of the World Health Organization (WHO) antenatal care guideline development process in 2016. The following recommendation was made by WHO: "One ultrasound scan before 24 weeks of gestation (early ultrasound) is recommended for pregnant women to estimate gestational age, improve detection of fetal anomalies and multiple pregnancies, reduce induction of labour for post-term pregnancy, and improve a woman's pregnancy experience".

The evidence on effectiveness that supported this recommendation was derived from high-income countries. Since the publication of the Cochrane review, the findings of a large cluster-randomized trial of an antenatal ultrasound intervention in low-income countries have been published; therefore, this recommendation was prioritized by the Executive Guideline Steering Group (GSG) for updating.

In March 2021, a WHO-convened Guideline Development Group (GDG) re-evaluated evidence on imaging ultrasound before 24 weeks of pregnancy, updating the recommendation on this intervention in accordance with the WHO Department of Sexual and Reproductive Health and Research (SRH) living guidelines approach.¹

Target audience

The target audience of this updated recommendation includes national and local public health policy-makers, implementers and managers of national and local maternal and child health programmes, concerned nongovernmental and other organizations, professional societies involved in the planning and management of maternal and child health services, health workers (including obstetricians, midwives, nurses and general medical practitioners), and academic staff involved in training health workers.

Guideline development methods

The updating of this recommendation was guided by the standardized operating procedures described in the *WHO handbook for guideline development*. This involved: (i) identification of the priority question and outcomes (done as part of the antenatal care [ANC] guideline development process); (ii) evidence retrieval and synthesis; (iii) assessment of the evidence; (iv) formulation of the recommendation; and (v) planning for the dissemination, implementation, impact evaluation and updating of the recommendation. The scientific evidence supporting the recommendation was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) and Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) approaches, for quantitative and qualitative evidence, respectively. An up-to-date systematic review was used to prepare an evidence profile for the recommendation prioritized for updating. The Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence (DECIDE) framework – an evidence-to-decision tool that considers research evidence on interventions according to the six criteria of effects, values, resources, equity, acceptability and feasibility – was used to guide the formulation and approval of the recommendation by the GDG, an international group of experts that was convened for this process, during an online GDG meeting on 22 June 2021.

Recommendations

The WHO meeting led to the retention of the 2016 recommendation on imaging ultrasound before 24 weeks of pregnancy (Table 1). The GDG had the option to recommend the intervention, not to recommend the intervention, or to recommend the intervention under certain conditions (in specific contexts, with targeted monitoring and evaluation, in the context of rigorous research). For this update, the GDG elaborated on the implementation considerations to facilitate appropriate implementation of the recommendation. Users of the guideline should refer to these considerations, as well as the GDG remarks and the evidence summary, for further information about the basis of this WHO recommendation.

This recommendation applies to pregnant women and adolescent girls within the context of routine ANC.

1 Vogel JP, Dowswell T, Lewin S, Bonet M, Hampson L, Kellie F, et al. Developing and applying a "living guidelines" approach to WHO recommendations on maternal and perinatal health. *BMJ Glob Health*. 2019;4(4):e001683. doi:10.1136/bmjgh-2019-001683.

Table 1. WHO recommendation on imaging ultrasound before 24 weeks of pregnancy

One ultrasound scan before 24 weeks of gestation is recommended for pregnant women to estimate gestational age, improve detection of fetal anomalies and multiple pregnancies, reduce induction of labour for post-term pregnancy, and improve a woman's pregnancy experience.
Remarks
<ul style="list-style-type: none">▪ The evidence on effects of routine imaging ultrasound before 24 weeks of pregnancy has not changed materially since the 2016 recommendation. A newly identified large-cluster randomized controlled trial (RCT) conducted in low-resource settings was reviewed but was not found suitable for inclusion in meta-analysis, because it evaluated the effect of two imaging ultrasounds conducted in both the second and third trimesters (i.e. it did not address the guideline's participants, intervention, comparator, outcome [PICO] question).▪ Implementation considerations associated with this recommendation have been significantly expanded based on the findings of a new qualitative evidence synthesis of the views and experiences of service users and health workers.^a▪ Ultrasound scan can guide subsequent care. When implementing or scaling up routine imaging ultrasound before 24 weeks of pregnancy, the purpose of imaging ultrasound should be to assess:<ul style="list-style-type: none">- location of pregnancy (e.g. intrauterine)- cardiac activity- fetal size- gestational age- fetal number- chorionicity and amnionicity for multiple gestation.▪ Where the skill set and health systems allow, the following, which are more informative after 18 weeks of pregnancy, may also be assessed:<ul style="list-style-type: none">- presence of normal head, neck, face, spine, chest, heart, abdomen, abdominal wall and extremities- placental appearance and location, and umbilical cord.▪ Those who perform obstetric ultrasound should have specialized training that is appropriate to the practice of screening ultrasound in pregnancy.▪ Many pregnancy complications, including fetal malformations, may develop later in pregnancy or may not be detectable without appropriate ultrasound training and equipment.▪ There remain some uncertainties around undesirable effects, including the risk of litigation, the potential for female feticide, the short- and long-term psychological impact of an inconclusive or adverse scan finding, and the potential for overuse of ultrasound scans (as a replacement for formal ANC contacts).

a Moncrieff G, Finlayson K, Cordey S, McCrimmon R, Harris C, et al. First and second trimester ultrasound in pregnancy: a systematic review and metasynthesis of the views and experiences of pregnant women, partners, and health workers. PLoS One. 2021;16(12):e0261096. doi:10.1371/journal.pone.0261096.

1 Introduction

1.1 Background

An imaging ultrasound scan is widely used to estimate gestational age, investigate suspected pregnancy complications and monitor complicated pregnancies when they occur. In 2016, the World Health Organization (WHO) added a single ultrasound scan before 24 weeks of pregnancy to its list of recommended interventions for routine antenatal care (ANC) (1). In most high-income countries, routine antenatal ultrasound screening has been standard practice for some time, often being conducted in both the first and second trimesters (2). When conducted in the first trimester (up to and including 13 weeks and 6 days of gestation), an imaging ultrasound scan is aimed at confirming fetal viability, identifying the location of the gestational sac, establishing gestational age, determining the number of fetuses and, in the presence of a multiple pregnancy, assessing chorionicity and amnionity; also, towards the end of the first trimester, nuchal translucency thickness is commonly measured in settings that offer screening for fetal chromosomal abnormalities (3). Second-trimester ultrasound scans conducted between 18 and 24 weeks allow for more detailed examination of fetal anatomy and detection of fetal anomalies, provide information on the number of fetuses present, identify the location of the placenta and enable an estimate of gestational age (4).

A 2015 systematic review on ultrasound scans before 24 weeks of pregnancy (5) and a qualitative review on women's views and experiences of pregnancy (6) informed the 2016 WHO recommendations on antenatal care for a positive pregnancy experience (7). The ultrasound recommendation (B2.4) is: "One ultrasound scan before 24 weeks of gestation (early ultrasound) is recommended for pregnant women to estimate gestational age, improve detection of fetal anomalies and multiple pregnancies, reduce induction of labour for post-term pregnancy, and improve a woman's pregnancy experience." In the context of a new cluster-randomized randomized controlled trial (RCT) evaluating the impact of routine ultrasound scans in low-resource settings (7), an independent Executive Guideline Steering Group (GSG) prioritized updating the 2016 recommendation. A new systematic review on routine ultrasound before 24 weeks of pregnancy has since been conducted (8).

1.2 Rationale and objectives

As part of WHO's normative work on supporting evidence-informed policies and practices and its living guidelines approach, the Department of Sexual and Reproductive Health and Research (SRH) and the Department of Maternal, Newborn, Child and Adolescent Health and Ageing (MCA) undertook the updating of this recommendation. As the focus of the guideline is on routine antenatal ultrasound scan before 24 weeks of pregnancy, the guideline does not include evidence on the use of Doppler ultrasound as a fetal surveillance technique for a growth-restricted fetus.

1.3 Target audience

The recommendations in this global guideline are intended to inform the development of relevant national- and local-level health policies and clinical protocols. Therefore, the target audience of this guideline includes national and local public health policy-makers, implementers and managers of national and local maternal and child health programmes, concerned nongovernmental and other organizations, professional societies involved in the planning and management of maternal and child health services, health workers (including obstetricians, paediatricians, midwives, nurses and general medical practitioners), and academic staff involved in training health workers. (The recommendations are also to guide future research and assess existing practice.)

1.4 Scope of the guideline

This updated recommendation is relevant to all pregnant women and adolescent girls receiving ANC in any health-care facility or community-based setting, and to their fetuses and newborns. The guideline question was prioritized during the WHO 2016 ANC guideline development process. In 2019, the recommendation was prioritized for updating in the context of WHO's living guideline commitment. The outcomes of interests are, therefore, the same as those prioritized for the ANC guideline relevant to ultrasound scan interventions (Box 1).

Box 1: Outcomes of interest in ANC ultrasound scan interventions

Maternal outcomes	Fetal/neonatal outcomes
Maternal mortality	Small for gestational age
Caesarean section	Low birth weight
Induction of labour	Preterm birth
Detection of multiple gestation	Neonatal mortality
Detection of fetal anomaly	Stillbirth
Termination of pregnancy for fetal anomaly	Perinatal mortality
Maternal satisfaction	Congenital anomalies
Side-effects	

2 Methods

This recommendation is an update of one of the 49 recommendations that were published in the *WHO recommendations on antenatal care for a positive pregnancy experience (1)*. The recommendation was developed initially using the standardized operating procedures described in the *WHO handbook for guideline development (9)*. In summary, the process included: (i) identification of priority question and outcomes; (ii) retrieval of evidence; (iii) assessment and synthesis of the evidence; (iv) formulation of recommendation; and (v) planning for the implementation, dissemination, impact evaluation and updating of the recommendation. This recommendation was identified by the Executive GSG as a high priority for updating in response to new evidence on this question.

2.1 Contributors to the guideline

Executive Guideline Steering Group

The Executive GSG is an independent panel of external experts and relevant stakeholders from the six WHO regions. This group advises WHO on the prioritization of new and existing questions in maternal and perinatal health for recommendation development or updating.

WHO Steering Group

The WHO Steering Group that managed the updating process comprised the same staff members from the Departments of SRH and MCA as the WHO ANC guideline of 2016 (see Annex 1 for the list of members). The WHO Steering Group drafted the key recommendation question in participants, intervention, comparator, outcome (PICO) format and identified individuals to be invited to participate as guideline methodologists, as well as in the Guideline Development Group (GDG) and External Review Group (ERG). In addition, the WHO Steering Group supervised evidence retrieval and synthesis, organized the technical consultation and finalized the guideline document. The WHO Steering Group, in collaboration with WHO regional offices, will oversee the dissemination of the updated recommendation.

Guideline Development Group

The WHO Steering Group identified and invited 13 external experts and stakeholders from the six WHO regions to constitute the GDG, ensuring geographic representation, gender balance and no important conflicts of interest. Most of these experts also served in the GDG for the WHO ANC guideline's recommendations of 2016. This was a diverse group of individuals with expertise in research, guideline development methods, and clinical policy and programmes relating to ANC interventions, and it included a patient/consumer representative. The GDG appraised the evidence used to inform the recommendation, advised on the interpretation of this evidence, and formulated the final recommendation during an online GDG meeting on 22 June 2021. In addition, the GDG members reviewed and approved the final guideline document before its submission to the WHO Guidelines Review Committee, WHO's quality oversight body, for approval. A list of GDG members can be found in Annex 1.

External Review Group

The ERG was a geographically balanced and gender-balanced group with no important conflicts of interest (see Annex 1 for ERG members). There were four members, including technical experts and other stakeholders with interests in the provision of evidence-informed ANC. This group peer-reviewed a preliminary version of the guideline document to identify any factual errors and comment on the clarity of the language, contextual issues and implications for implementation. The group ensured that the contextual values and preferences of persons affected by the recommendation, including pregnant women and adolescent girls, health workers and policy-makers, were considered and incorporated during the guideline decision-making processes. It was not within the ERG's remit to change the recommendation formulated by the GDG.

Systematic review team and guideline methodologists

The managing editors of the Cochrane Pregnancy and Childbirth Group coordinated the quantitative systematic review process and facilitated collaboration between systematic review authors and guideline methodologists. Working closely with the WHO Steering Group, methodologists from the Evidence-based Medicine Consultancy

Ltd. in the United Kingdom of Great Britain and Northern Ireland appraised the quantitative evidence using a standardized operating procedure for the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology (10). Three qualitative-evidence experts from the University of Central Lancashire in the United Kingdom systematically reviewed qualitative studies related to women's and health workers' views on ANC, and synthesized this evidence.

External partners and observers

Representatives of the International Federation of Gynecology and Obstetrics (FIGO), the International Confederation of Midwives (ICM), the United Nations Population Fund (UNFPA), the United States Agency for International Development (USAID), the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) and the Bill & Melinda Gates Foundation were invited to the final GDG meeting to serve as observers. All these organizations are potential implementers of the proposed guideline with a history of collaboration with WHO in guideline dissemination and implementation. Observers do not participate in the formulation of recommendations.

2.2 Declarations of interests by external contributors

WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to actual or ostensible conflict of interest. In accordance with the WHO guidelines for declarations of interests (11), all GDG members, ERG members and observers were asked to declare in writing any competing interests (whether academic, financial or other) at the time of the invitation to participate in the ANC guideline development process. The standard WHO form for declaration of interest (DOI) was completed and signed by each expert. The WHO Steering Group reviewed all the DOI forms before finalizing experts' invitations to participate. When any competing interests were declared, the WHO Steering Group determined whether they were serious enough to affect the individual's ability to make objective judgements about the evidence or recommendation. To ensure consistency, the WHO Steering Group applied the criteria for assessing the severity of a conflict of interest in the *WHO handbook for guideline development* (9).

All findings from DOI statements were managed in accordance with the WHO DOI guidelines on a case-by-case basis and communicated to the experts. Where a conflict of interest was not considered significant enough to pose any risk to the guideline development process or reduce its credibility, the expert was only required to declare such a conflict at the GDG meeting, and no further action was taken. A summary of the DOI statements and information on how conflicts of interest were managed are included in Annex 2. To strengthen public trust and transparency in connection with WHO meetings involving the provision of expert advice in developing technical norms and standards, the names and brief biographies of individuals considered for participation in this guideline, together with a description of the objectives of relevant meetings, were published online ahead of the first meeting planned, to allow time for public notice and comment.

2.3 Identifying priority questions and outcomes

The priority question and outcomes were aligned with those of the ANC guideline. This question and the outcomes were originally informed through an extensive scoping exercise of existing clinical practice guidelines relevant to routine ANC, supplemented by searching the Cochrane Database of Systematic Reviews for existing key systematic reviews relevant to ANC. Critical and important outcomes were informed by these reviews as well as by a WHO-commissioned scoping qualitative review of what women want during pregnancy (12). The findings of the latter revealed that pregnant women want a positive pregnancy experience, which is defined as maintaining physical and sociocultural normality, maintaining a healthy pregnancy and fetus, having an effective transition to positive labour and birth, and achieving a positive motherhood. The desire to achieve the composite outcome of a positive pregnancy experience became the overarching principle of ANC guideline recommendations (1).

2.4 Evidence identification and retrieval

Evidence to support this recommendation was derived from a number of sources by the methodologists working closely with the WHO Steering Group. A new systematic review was the primary source of evidence on effectiveness of antenatal imaging ultrasound before 24 weeks of pregnancy (8). A different systematic review

on the same topic supported the ANC guideline recommendation of 2016 (5). The up-to-date RevMan file² was retrieved from the Cochrane Pregnancy and Childbirth Group and customized to reflect the key comparisons, GDG-specified subgroup analyses, and outcomes relevant to the ANC guideline. Evidence was evaluated according to standardized operating procedures approved by the WHO Steering Group, and evidence profiles (in the form of GRADE tables) were prepared, including assessment of the certainty of the evidence, for comparisons of interest.

A 2021 qualitative systematic review commissioned by the WHO Steering Group informed the values, equity, acceptability and feasibility criteria of the evidence-to-decision (EtD) framework (13). Additionally, systematic reviews of cost-effectiveness were identified through PubMed searches of the literature.

2.5 Quality assessment and grading of the evidence

The GRADE approach (6) to appraising the certainty of quantitative evidence was used, meaning that the certainty of evidence for each outcome was rated as high, moderate, low or very low, based on a set of established criteria. As a baseline, the evidence from the Cochrane reviews was rated as high certainty, because it was derived from randomized controlled trials (RCTs); this rating was then downgraded according to considerations of risk of bias (design limitations), inconsistency, imprecision, indirectness, publication bias or other considerations.

Qualitative evidence was derived from a qualitative evidence synthesis (13) and subjected to quality appraisal using the Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) tool. The GRADE-CERQual tool, which uses a similar approach conceptually to other GRADE tools, rates the level of confidence that can be placed in qualitative evidence synthesis according to four components: methodological limitations of the individual studies, adequacy of data, coherence, and relevance to the review question of the individual studies contributing to a qualitative evidence synthesis finding (14).

2.6 Preparation of the evidence summary

The WHO Steering Group supervised and finalized the preparation of the evidence summary and profile, in collaboration with the guideline methodologists, using the Developing and Evaluating Communication strategies to support Informed Decisions and practice based on Evidence (DECIDE) framework. DECIDE is an EtD tool that includes explicit and systematic consideration of research evidence on interventions according to six criteria, namely: effects, values, resources, equity, acceptability and feasibility (15). These six EtD criteria were populated with the research evidence, where available; in addition, information from other sources was described in the "Additional considerations" subsection for each criterion. The graded evidence on intervention effectiveness was systematically interpreted according to guidance from the Cochrane Effective Practice and Organisation of Care Group (16).

2.7 Formulation of the recommendation

GDG members and other participants were provided with the evidence summary in advance of the online GDG meeting held on 22 June 2021, organized by the WHO Steering Group from Geneva, Switzerland. During the technical consultation, under the leadership of the GDG chair, GDG members reviewed, discussed and made judgements on the impact of the interventions for each of the EtD criteria. GDG judgements were summarized in a table before finalizing the recommendation and remarks. The intervention could either be recommended, not recommended, or recommended in specific contexts, namely in the context of rigorous research (including RCT, observational and implementation research) or targeted monitoring and evaluation, or in another GDG-specified context (e.g. age- or setting-specific).

2.8 Decision-making process

The online GDG meeting was guided by a clear protocol, designed to allow the recommendation to be formulated through a process of group discussion until consensus was reached. The final adoption of the recommendation and its context, if applicable, was confirmed by unanimous consensus (i.e. full agreement among all GDG members).

2 RevMan (Review Manager) is Cochrane's software for preparing and maintaining Cochrane-style systematic reviews.

2.9 Guideline preparation and peer review

Following the online GDG meeting, members of the WHO Steering Group – assisted by methodologists from the Evidence-based Medicine Consultancy – drafted a full guideline document to accurately reflect the deliberations and decisions of participants. A preliminary version of the document was sent electronically to participants and the ERG for final review and technical comments. The WHO Steering Group carefully evaluated the input of the peer reviewers for inclusion in the guideline document and revised the guideline draft as needed. After the GDG meetings and peer review process, further modifications to the guideline by the WHO Steering Group were limited to corrections of factual errors and improvements in language to address any lack of clarity. The document was then submitted for executive clearance according to established WHO publication procedures.

3 Evidence and recommendation on ultrasound scan before 24 weeks of pregnancy

This section provides the evidence summary and WHO recommendation. Evidence on the effectiveness of an imaging ultrasound scan before 24 weeks of pregnancy is further detailed in GRADE tables in Annex 3. To ensure that the recommendation is correctly understood, additional remarks reflecting the summary of the discussion by the GDG are included along with the recommendation (Table 1).

3.1 The priority question

For pregnant women (population, P), does routine ultrasound scan before 24 weeks of pregnancy (intervention, I) compared with no routine ultrasound before 24 weeks of pregnancy (comparator, C) improve maternal and perinatal health outcomes (O)?

3.2 Assessment

Effects of the intervention

What are the anticipated effects of a routine versus no routine ultrasound scan before 24 weeks of pregnancy?

Research evidence

The following evidence was derived from a 2021 systematic review (8). The review included data from 12 individually randomized RCTs involving 37 719 women, along with a large cluster-randomized RCT including an additional 46 904 deliveries. The difference between the 2021 review and the 2015 review is that the 2021 review authors split the individual RCT data according to whether the ultrasound scan was done in the first or second trimester, whereas the 2015 review considered the data together irrespective of the timing of the ultrasound scans. No new individual RCTs were included in the 2021 review. The cluster RCT (7) included in the 2021 review compared the effects of two ultrasounds in pregnancy – the first between 16 and 22 weeks of pregnancy, and the second between 32 and 36 weeks of pregnancy – and is therefore outside the scope of this guideline, which is focused on scans before 24 weeks of pregnancy only. More details of the cluster trial can be found in the “Additional considerations” subsection under “Certainty of the evidence”.

Thus, two comparisons evaluated in the 2021 review are relevant to this guideline:

- routine first-trimester ultrasound scan (before 14 weeks of pregnancy) versus no routine ultrasound scan
- routine second-trimester ultrasound scan (at 14–24 weeks of pregnancy) versus no routine ultrasound scan.

Comparison 1: Routine versus no routine first-trimester ultrasound scan (before 14 weeks of pregnancy)

This comparison included four trials (2244 women) reported between 1990 and 2006. Trials were conducted in Australia (648 women), Canada (218 women), the United Kingdom (463 women) and the United States of America (USA) (915 women).

Maternal outcomes

Maternal mortality: This outcome was not reported.

Caesarean section: A first-trimester ultrasound scan may make little or no difference to the number of women undergoing caesarean section (three trials, 1253 women; risk ratio [RR] 1.27, 95% confidence interval [CI] 0.99–1.61; *low-certainty evidence, downgraded due to study design limitations and imprecision*).

Induction of labour: A first-trimester ultrasound scan may make little or no difference to induction of labour for post-term pregnancy (three trials, 1474 women; RR 0.83, 95% CI 0.50–1.37; *low-certainty evidence, downgraded due to study design limitations and imprecision*) or to induction of labour for any reason (one trial, 463 women; RR 0.73, 95% CI 0.49–1.09; *low-certainty evidence, downgraded due to study design limitations and imprecision*).

Detection of multiple pregnancy: It is not known whether a first-trimester ultrasound scan improves the detection of multiple pregnancy before 24–26 weeks of gestation or before labour, as these outcomes were

reported in a single trial and event rates were very low (*very low-certainty evidence, downgraded due to study design limitations and very serious imprecision*).

Positive pregnancy experience: Maternal anxiety was reported in one trial. The evidence suggests that women undergoing first-trimester ultrasound scans are probably less worried about their pregnancy after the scan (634 women; RR 0.80, 95% CI 0.65–0.99; *low-certainty evidence, downgraded due to study design limitations and indirectness*).

Fetal/neonatal outcomes

Perinatal mortality: First-trimester ultrasound scans may make little or no difference to perinatal mortality (two trials, 1472 newborns; RR 0.73, 95% CI 0.23–2.31; *low-certainty evidence, downgraded due to study design limitations and imprecision*).

Stillbirth: This was reported in a single trial, and the evidence was very uncertain (463 pregnancies; RR 2.96, 95% CI 0.12–72.32; *very low-certainty evidence, downgraded due to study design limitations and serious imprecision*). Two trials reported fetal loss before 20 weeks of pregnancy; evidence suggests that a first-trimester ultrasound scan may make little or no difference to miscarriage before 20 weeks of pregnancy (two trials, 1111 pregnancies; RR 0.84, 95% CI 0.57–1.24; *low-certainty evidence, downgraded due to study design limitations and imprecision*).

Low birth weight (less than 2500 g): A first-trimester ultrasound scan may make little or no difference to low newborn birth weight (one trial, 594 newborns; RR 2.01, 95% CI 0.99–4.08; *low-certainty evidence, downgraded due to study design limitations and imprecision*).

Congenital anomalies: Detection of congenital anomalies and termination of pregnancy for major anomalies were not reported in trials of first-trimester ultrasound.

Comparison 2: Routine versus no routine second-trimester ultrasound scan (14–24 weeks of pregnancy)

Eight trials (35 324 women) contributed data for this comparison. Most were reported in the 1980s and 1990s; one was reported in 2007. Trials were conducted in Finland (one trial), Norway (two), Sweden (one), South Africa (two), the United Kingdom (one) and the USA (one).³ Timing of routine second-trimester ultrasound scans varied. In three trials, the intervention also included a third-trimester ultrasound scan at approximately 32 weeks.

Maternal outcomes

Maternal mortality: This outcome was not reported in these trials.

Caesarean section: A routine second-trimester ultrasound scan probably makes little or no difference to caesarean section (five trials, 22 193 women; RR 1.05, 95% CI 0.98–1.12; *moderate-certainty evidence, downgraded due to study design limitations*).

Induction of labour: A routine second-trimester ultrasound scan may reduce the number of labour inductions for post-term pregnancy (six trials, 24 174 women; RR 0.48, 95% CI 0.31–0.73; *low-certainty evidence, downgraded due to study design limitations and high heterogeneity between studies*). The evidence for the effect of ultrasound on induction of labour for any reason was very uncertain.

Detection of multiple pregnancy: A routine second-trimester ultrasound scan probably reduces the number of undetected multiple pregnancies before 24–26 weeks of gestation (six trials, 285 multiple pregnancies; RR 0.06, 95% CI 0.02–0.16; *moderate-certainty evidence, downgraded due to study design limitations*).

Detection of fetal anomaly: A routine second-trimester ultrasound scan probably increases the detection of fetal anomaly before 24 weeks of pregnancy (two trials, 17 158 women; RR 3.45, 95% CI 1.67–7.12) and pregnancy termination for fetal anomaly (four trials, 26 893 women; RR 2.36, 95% CI 1.13–4.93; *moderate-certainty evidence, downgraded due to study design limitations*). Evidence suggests that there may be little or no impact on the number

3 This comparison includes a single study from 1982 involving 1062 women that evaluated the effects of concealing the results of an ultrasound scan at 16 weeks of pregnancy from health workers versus revealing the results to them. Data from this trial have subsequently been analysed in a separate comparison in the review. Sensitivity analysis showed that excluding this trial from this comparison made very little difference to the findings.

of pregnancy terminations for any cause (four trials, 30 516 women; RR 1.30, 95% CI 0.85–1.96; *low-certainty evidence, downgraded due to study design limitations and imprecision*).

Positive pregnancy experience: Maternal anxiety and satisfaction with care were not reported in these trials.

Side-effects: This outcome was not reported in trials contributing to this comparison.

Fetal/neonatal outcomes

Perinatal mortality: Routine second trimester-ultrasound scans may have little or no impact on perinatal death (eight trials, 34 973 newborns; RR 0.90, 95% CI 0.71–1.14; *low-certainty evidence, downgraded due to study design limitations and imprecision*).

Stillbirth: Routine second-trimester ultrasound scans may make little or no difference to stillbirth (four trials, 30 646 newborns; RR 0.99, 95% CI 0.68–1.44; *low-certainty evidence, downgraded due to study design limitations and imprecision*).

Neonatal mortality: A routine second-trimester ultrasound scans may make little or no difference to neonatal death (four trials, 26 458 newborns; RR 0.83, 95% CI 0.52–1.32; *low-certainty evidence, downgraded due to study design limitations and imprecision*).

Neonatal morbidity: A single large trial reported this outcome; a routine second-trimester ultrasound scan may make little or no difference to the number of newborns with serious morbidity (one trial, 15 281 newborns; RR 1.03, 95% CI 0.78–1.36; *low-certainty evidence, downgraded due to study design limitations and imprecision*). Six trials reported on the number of newborns admitted to neonatal intensive care or special care facilities; a routine second-trimester ultrasound scan may make little difference to the number of admissions (six trials, 17 484 newborns; RR 0.92, 95% CI 0.84–1.01; *moderate-certainty evidence, downgraded due to study design limitations*).

Low birth weight: A routine second-trimester ultrasound scan may make little or no difference to low newborn birth weight (six trials, 17 728 newborns; RR 0.92, 95% CI 0.74–1.14; *low-certainty evidence, downgraded due to study design limitations and imprecision*) or to the number of small-for-gestational-age newborns (one trial, 964 newborns; RR 1.47, 95% CI 0.92–2.35; *low-certainty evidence, downgraded due to study design limitations and imprecision*).

Preterm birth: This outcome was not reported in trials contributing to this comparison.

Summary of effects

The evidence suggests that routine first-trimester ultrasound scans may reduce women’s anxiety about their pregnancies but may have little or no impact on other reported guideline outcomes. Routine second-trimester ultrasound scans may reduce the risk of induction of labour for post-term pregnancy and probably increase the detection of multiple pregnancies and fetal anomalies before 24 weeks of pregnancy; however, the available evidence suggests there may be little or no impact on other reported maternal and newborn outcomes.

Desirable effects

How substantial are the desirable anticipated effects of routine versus no routine ultrasound scans before 24 weeks of pregnancy?

Judgement					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Don't know	Varies	Trivial	Small	Moderate	Large

Rationale for judgement: The GDG considered the absolute effect sizes shown in the evidence profile table and judged them to be relatively small.

Undesirable effects

How substantial are the undesirable anticipated effects of routine versus no routine ultrasound scans before 24 weeks of pregnancy?

Judgement					
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Don't know	Varies	Large	Moderate	Small	Trivial

Rationale for judgement: The evidence was sparse, and the GDG considered that undesirable effects could potentially include medico-legal costs associated with missed or incorrect diagnoses, female feticide, a psychological impact of an inconclusive finding on parents, and overuse of and over-reliance on ultrasound scans at the expense of formal ANC contacts.

Certainty of the evidence

What is the overall certainty of the evidence of effects of routine versus no routine ultrasound scans before 24 weeks of pregnancy?

Judgement				
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No included studies	Very low	Low	Moderate	High

Additional considerations

- The systematic review also compared data on ANC utilization; however, the evidence was very low certainty (8).
- A large multicentre cluster RCT was conducted in five low-income countries, namely Pakistan, Kenya, Zambia, the Democratic Republic of the Congo and Guatemala, between 2014 and 2016. The intervention strategy of training health workers to use ultrasound scans to routinely screen pregnant women for complications during the second and third trimesters at primary ANC clinics and refer them if indicated did not demonstrate an impact on maternal mortality, mode of birth, low birth weight, neonatal mortality or stillbirth compared with usual ANC (7).
- Accurate estimation of gestational age may have the greatest impact on newborn health in low- and middle-income countries (LMICs), where the prevalence of small newborns (preterm and small for gestational age) is extremely high and low birth weight is associated with 80% of neonatal deaths (17-19).
- Accurate gestational age dating is critical for the appropriate delivery of time-sensitive interventions in pregnancy, as well as for management of pregnancy complications, particularly pre-eclampsia and preterm birth, which are major causes of maternal and perinatal morbidity and mortality in LMICs (20). Good-quality ultrasound scans can enable accurate estimation of gestational age, which may facilitate more robust national and global estimates of the prevalence of preterm birth (19).
- Ultrasound assessment of the fetus in the first trimester is considered the most accurate method to establish or confirm gestational age (21). Up until 14 weeks, gestational age is assessed by measurement of the crown-rump length, with an accuracy to about 5-7 days; second-trimester dating is based on measurement of the biparietal diameter and head circumference, femur length and abdominal circumference; in the first part of the second trimester (up to 21 weeks and 6 days of pregnancy) ultrasound has an accuracy to +/- 7-10 days, and up to 28 weeks it has an accuracy to approximately +/- 10-14 days (21).

Values

Is there important uncertainty about, or variability in, how much women (and their families) value the main outcomes associated with an ultrasound scan before 24 weeks of pregnancy?

A scoping review of what women want from ANC informed the outcomes for the WHO ANC guideline (12). Evidence showed that women from various resource settings valued having a positive pregnancy experience comprising three equally important components – namely effective clinical practices (interventions and tests), relevant and timely information, and psychosocial and emotional support – each provided by practitioners with good clinical and interpersonal skills within a well-functioning health system (high confidence in the evidence).

Judgement

<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability

Rationale for judgement: The GDG considered that women are likely to agree that the outcomes associated with routine antenatal ultrasound, such as the detection of multiple pregnancy and of abnormalities, are important.

Balance of effects

Does the balance between desirable and undesirable effects favour routine versus no routine ultrasound scans before 24 weeks of pregnancy?

Judgement

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Don't know	Varies	Favours no routine ultrasound	Probably favours no routine ultrasound	Does not favour routine or no routine ultrasound	Probably favours routine ultrasound	Favours routine ultrasound

Rationale for judgement: The GDG considered that, as the only new RCT was not suitable for inclusion, the evidence in favour of routine ultrasound has remained the same since the 2016 decision.

3.3 Resources

How large are the resource requirements (costs) of routine versus no routine ultrasound scans before 24 weeks of pregnancy?

Research evidence

A 2002 systematic review on cost and cost-effectiveness of ultrasound screening in ANC for fetal abnormalities concluded that the training of staff was a key factor, with the skill of the sonographer having a significant influence on the cost-effectiveness of an ANC ultrasound screening programme; it also concluded that the clinical evidence of effectiveness on which to base economic studies was poor at that time (22). Almost two decades later, there continues to be a lack of literature on the cost-effectiveness of routine antenatal ultrasound scans. In the 2016 ANC guideline it was noted that the cost of ultrasound equipment had decreased (23), and portable units were available for less than US\$ 10 000 (24). A WHO-commissioned scoping review in 2021 suggests that the cost of handheld ultrasound devices may now be lower than US\$ 2000 (25). However, the introduction of ultrasound scans can have considerable cost implications extending well beyond the cost of the devices.

Additional considerations

- The use of ultrasound technology for various applications in low-resource settings has been increasing due to the development of low-cost portable equipment, training programmes and task-shifting (26). Documentation on the use of ultrasound for the management of obstetric and non-obstetric conditions that may impact decisions about cost-effectiveness is needed.
- Given the financial investment required for performing ultrasound scans for antenatal screening, it may be advisable to use ultrasound equipment for other indications, such as obstetric emergencies, or to make equipment available to other departments (27). For resource-limited settings, less expensive options for ultrasound gel have been explored (28).
- It is important to note the variability in the functionality of machines. In addition, the cost of handheld devices does not always include the cost of the viewing device, for example the phone or tablet, or equipment needed to protect equipment from damage due to surges in electrical power.
- Women and families may be burdened with additional out-of-pocket payments, such as for transport costs to facilities that offer ultrasound scans.

Resources required

How costly are the resources required to perform routine versus no routine ultrasound scans before 24 weeks of pregnancy?

Judgement						
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Don't know	Varies	Large costs	Moderate costs	Negligible costs or savings	Moderate savings	Large savings

Rationale for judgement: The GDG considered that costs include not only the cost of the equipment, but also the cost of training, extra personnel, referrals, equipment repair and maintenance, quality assurance and monitoring, equipment security and supplies, including gels, print media (e.g. thermal paper) and others.

Certainty of evidence on required resources

What is the certainty of the evidence on costs?

Judgement				
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No included studies	Very low	Low	Moderate	High

Rationale for judgement: The GDG noted the dearth of evidence, and identified costs and cost-effectiveness of ultrasound in pregnancy as a research gap.

Cost-effectiveness

How cost-effective are routine versus no routine ultrasound scans before 24 weeks of pregnancy?

Judgement						
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Don't know	Varies	Favours no routine ultrasound	Probably favours no routine ultrasound	Does not favour routine or no routine ultrasound	Probably favours routine ultrasound	Favours routine ultrasound

Rationale for judgement: There was not enough evidence to decide for or against the intervention.

3.4 Equity

What would be the impact of routine versus no routine ultrasound scans before 24 weeks of pregnancy on health equity?

Research evidence

Evidence from a qualitative systematic review exploring key stakeholders' views of ultrasound during pregnancy suggests that an unequal distribution of ultrasound equipment and/or sonographers in some LMICs may lead to inequitable access (*moderate confidence in the evidence*) (13). In some contexts, the lack of equipment in the public sector may be offset by private clinics offering ultrasound scans to those who can afford them (*moderate confidence in the evidence*).

The same review also highlights social and family preference for a male baby in certain contexts (*high confidence in the evidence*). Carrying a fetus identified as being of an undesirable sex can have severe consequences in some cultural contexts, where women report that ultrasound can lead to female feticide (*high confidence in the evidence*). Health workers in these contexts are also aware of the potential for female feticide and, in some settings, advocate for a policy of non-disclosure of fetal sex following an ultrasound scan (*high confidence in the evidence*).

Additional considerations

- Evidence also highlights the importance of effective communication between the health worker and the pregnant woman to explain reasons for performing the ultrasound and related results (29).
- In some settings, ultrasound has been used as a tool to dissuade pregnant women from obtaining abortion. However, research has suggested that such use is not medically necessary, does not alter decisions of most women who are certain that abortion is the appropriate decision, and functions as an attempt to undermine women's bodily autonomy (30).

Judgement

<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Don't know	Varies	Reduced	Probably reduced	Probably no impact	Probably increased	Increased

Rationale for judgement: In addition to the issues discussed above, the GDG considered that equity may be negatively impacted if access to ultrasound is not universal.

3.5 Acceptability

Would routine ultrasound scanning before 24 weeks of pregnancy be acceptable to key stakeholders?

Research evidence

Evidence from a qualitative systematic review exploring key stakeholders' views of ultrasound during pregnancy suggests that pregnant women trust ultrasound technology and value the reassurance it offers (*high confidence in the evidence*) (13). For many women, the ultrasound image legitimizes their pregnancy and frames their fetus as a person (*high confidence in the evidence*). The ultrasound scan presents an opportunity for couples to bond with their baby and experience feelings of joy and relief when the scan result is normal (*moderate confidence in the evidence*). In many contexts the ability of ultrasound to determine fetal gender is appreciated by couples, although in some settings a societal preference for male newborns may have negative implications that sometimes lead to female feticide (*high confidence in the evidence*).

For some women, the opportunity to visually monitor fetal development leads to increased demand for scans and, occasionally, a reliance on the scan as the sole arbiter of ANC quality (*high confidence in the evidence*). Findings from health workers largely support these views, although some health workers also think that over-reliance on ultrasound may have a detrimental impact on their clinical skills, and, in certain contexts, where women replace formal ANC with scans, there is potential for harm (*high confidence in the evidence*). In some settings, women's beliefs about the benefits (or otherwise) of ultrasound are shaped by partners, friends and families and/or by traditional or societal beliefs that sometimes overestimate the capacity of ultrasound or, alternatively, mis-assign harmful properties to the technology, which may affect uptake (*moderate confidence in the evidence*).

The same review (13) also indicates that some women and couples believe ultrasound is an obligatory aspect of ANC, rather than a choice, and may be unaware of the purpose of a scan, viewing it as a social occasion rather than a clinical assessment (*high confidence in the evidence*). An anomalous scan is therefore an unexpected shock for some couples, and difficulties in dealing with the uncertainty may shift perspective away from experiencing pregnancy as a positive state (*moderate confidence in the evidence*). For some women, this uncertainty may lead to detachment from the pregnancy or increased anxiety about the newborn after birth, even when the anomaly on the scan is found to be benign (*moderate confidence in the evidence*). For other women, an anomalous scan provides an opportunity to prepare (emotionally and financially) and to make decisions about the potential management of complications (*moderate confidence in the evidence*).

In a few settings, health workers expressed feelings of anxiety if they thought they might have missed something, and, in some high-income country settings, these anxieties were enhanced by the potential for censure (or even litigation) in the event of an abnormality going undetected (*low confidence in the evidence*).

In addition, some women and couples highlighted their interactions with staff and the importance of feeling welcomed, informed and engaged in the scan. Some women experienced anxiety as a result of a lack of

communication from health workers, being excluded from conversations about their scan, or not being able or allowed to view the ultrasound screen (*moderate confidence in the evidence*).

Additional considerations

- Another systematic review of qualitative research exploring women’s views and experiences of ANC suggests that they tend to view ANC as a source of knowledge and information, and generally appreciate interventions that may lead to a healthy baby and a positive pregnancy experience (*high confidence in the evidence*) (6).
- The same review explored health workers’ views of ANC, and suggests that health workers are keen to offer general health-care advice and specific pregnancy-related information (*low confidence in the evidence*), but sometimes think they do not have the appropriate training and lack the resources and time to deliver the service in the informative, supportive and caring manner that women want (*high confidence in the evidence*) (6).
- Routine imaging ultrasound may expose the sonographer or health system to medico-legal challenges, especially if a congenital malformation evident after birth is not detected during ultrasound, and claims may be enormous. For this reason, some medical insurance companies require clinicians (including sonographers) to pay special indemnity rates before they will insure the clinician. This may contribute to sonographers and clinicians declining to do antenatal imaging ultrasound scans.

Judgement

<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Don't know	Varies	No	Probably No	Probably Yes	Yes

Rationale for judgement: The GDG noted that many factors could impact acceptability for both women and health workers.

3.6 Feasibility

Would routine ultrasound scanning before 24 weeks of pregnancy be feasible to implement?

Research evidence

Evidence from a qualitative systematic review exploring key stakeholders’ views of ultrasound during pregnancy (13) suggests that a lack of ultrasound equipment in some LMIC contexts limits routine use (*moderate confidence in the evidence*). In some rural LMIC contexts, where an ultrasound scan is only accessible by referral to a secondary facility, the availability (and cost) of transport, women’s lack of autonomy and time away from essential domestic responsibilities may inhibit uptake of the intervention (*moderate confidence in the evidence*).

The shortage of appropriately trained staff may also be an issue in some LMIC settings, resulting in the need to train (formally or informally) other health workers in ultrasonography (*moderate confidence in the evidence*). Some health workers also highlighted the need for more time during an ultrasound appointment to establish a rapport with parents with differing expectations, and to offer empathic and compassionate care when needed (*high confidence in the evidence*).

The same review also indicates that sonographers require regular training and support, not only with the technical aspects of their job but also with counselling skills, communication skills, and the moral and ethical responsibility of their role (*moderate confidence in the evidence*). Some health workers identified regular peer engagement as an important source of personal and professional support, particularly when they experience emotional stress and/or loneliness (*moderate confidence in the evidence*).

Additional considerations

- Other evidence from a qualitative evidence synthesis conducted to support development of the WHO ANC guideline shows that where there are likely to be additional costs to pregnant women associated with health care, women may be less likely to engage with services (*high confidence in the evidence*) (6). In addition, in several LMIC settings, health workers thought that a lack of resources, both in terms of the availability of recommended interventions such as ultrasound scanning and the lack of suitably trained staff to perform the scans, is an issue which may limit the implementation of this intervention (*high confidence in the evidence*).

Judgement					
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Don't know	Varies	No	Probably No	Probably Yes	Yes

Rationale for judgement: The GDG noted that many factors could affect the feasibility of this intervention.

3.7 Summary of GDG judgements on routine versus no routine ultrasound scans before 24 weeks of pregnancy

Desirable effects	<input type="checkbox"/> Don't know	<input type="checkbox"/> Varies		<input type="checkbox"/> Trivial	<input checked="" type="checkbox"/> Small	<input type="checkbox"/> Moderate	<input type="checkbox"/> Large
Undesirable effects	<input checked="" type="checkbox"/> Don't know	<input type="checkbox"/> Varies		<input type="checkbox"/> Large	<input type="checkbox"/> Moderate	<input type="checkbox"/> Small	<input type="checkbox"/> Trivial
Certainty of the evidence on effects	<input type="checkbox"/> No included studies			<input type="checkbox"/> Very low	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Values				<input type="checkbox"/> Important uncertainty or variability	<input type="checkbox"/> Possibly important uncertainty or variability	<input checked="" type="checkbox"/> Probably no important uncertainty or variability	<input type="checkbox"/> No important uncertainty or variability
Balance of effects	<input type="checkbox"/> Don't know	<input type="checkbox"/> Varies	<input type="checkbox"/> Favours no routine ultrasound	<input type="checkbox"/> Probably favours no routine ultrasound	<input type="checkbox"/> Does not favour routine ultrasound or no routine ultrasound	<input checked="" type="checkbox"/> Probably favours routine ultrasound	<input type="checkbox"/> Favours routine ultrasound
Resources required	<input type="checkbox"/> Don't know	<input type="checkbox"/> Varies	<input checked="" type="checkbox"/> Large costs	<input type="checkbox"/> Moderate costs	<input type="checkbox"/> Negligible costs or savings	<input type="checkbox"/> Moderate savings	<input type="checkbox"/> Large savings
Certainty of evidence of required resources	<input type="checkbox"/> No included studies			<input checked="" type="checkbox"/> Very low	<input type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Cost-effectiveness	<input checked="" type="checkbox"/> Don't know	<input type="checkbox"/> Varies	<input type="checkbox"/> Favours no routine ultrasound	<input type="checkbox"/> Probably favours no routine ultrasound	<input type="checkbox"/> Does not favour routine ultrasound or no routine ultrasound	<input type="checkbox"/> Probably favours routine ultrasound	<input type="checkbox"/> Favours routine ultrasound
Equity	<input type="checkbox"/> Don't know	<input checked="" type="checkbox"/> Varies	<input type="checkbox"/> Reduced	<input type="checkbox"/> Probably reduced	<input type="checkbox"/> Probably no impact	<input type="checkbox"/> Probably increased	<input type="checkbox"/> Increased
Acceptability	<input type="checkbox"/> Don't know	<input checked="" type="checkbox"/> Varies		<input type="checkbox"/> No	<input type="checkbox"/> Probably No	<input type="checkbox"/> Probably Yes	<input type="checkbox"/> Yes
Feasibility	<input type="checkbox"/> Don't know	<input checked="" type="checkbox"/> Varies		<input type="checkbox"/> No	<input type="checkbox"/> Probably No	<input type="checkbox"/> Probably Yes	<input type="checkbox"/> Yes

3.8 Conclusions

RECOMMENDATION: One ultrasound scan before 24 weeks of gestation is recommended for pregnant women to estimate gestational age, improve detection of fetal anomalies and multiple pregnancies, reduce induction of labour for post-term pregnancy, and improve a woman's pregnancy experience.

Remarks

- This recommendation updates and supersedes the WHO recommendation found in the WHO ANC guideline (1).
- The evidence on effects of routine imaging ultrasound before 24 weeks of pregnancy has not changed materially since the 2016 recommendation. A newly identified large cluster RCT conducted in low-resource settings was reviewed but not found suitable for inclusion in meta-analysis, because it evaluated the effect of two imaging ultrasounds conducted in both the second and third trimesters (i.e. it did not address the guideline's PICO question).
- Implementation considerations associated with this recommendation have been expanded based on the findings of a new qualitative evidence synthesis of the views and experiences of service users and health workers (13).
- Ultrasound scans can guide subsequent care. When implementing or scaling up routine imaging ultrasound before 24 weeks of pregnancy, the purpose of imaging ultrasound should be to assess:
 - location of pregnancy (e.g. intrauterine)
 - cardiac activity
 - fetal size
 - gestational age
 - fetal number
 - chorionicity and amnionicity for multiple gestation.
- Where the skill set and health systems allow, the following, which are more informative after 18 weeks of pregnancy, may also be assessed:
 - presence of normal head, neck, face, spine, chest, heart, abdomen, abdominal wall and extremities
 - placental appearance and location, and umbilical cord.
- Those who perform obstetric ultrasound should have specialized training that is appropriate to the practice of screening ultrasound in pregnancy.
- Many pregnancy complications, including fetal malformations, may develop later in pregnancy or may not be detectable without appropriate ultrasound training and equipment.
- There remain some uncertainties around undesirable effects, including the risk of litigation, the potential for female feticide, the short- and longterm psychological impact of an inconclusive or adverse scan finding, and the potential for overuse of ultrasound scans (as a replacement for formal ANC contacts).

Implementation considerations

General considerations

- When implementing ultrasound use, policy-makers should consider the financial implications of: creating/ updating national policies and standards for ultrasound use, including which cadres will perform it; standardized training of relevant health personnel (initial and refresher); extra personnel; understanding power supply and availability (including surge protection and environmental upgrades); infection control supplies and processes; providing routine maintenance and repair; replacing trained staff lost through attrition; and monitoring and evaluation for quality assurance.
- Policy-makers should be aware of the potential for overuse of ultrasound and restrict the number to that recommended according to the woman's condition.

- Policy-makers and health system managers should work with front-line health workers to design systems that allow gestational age information derived from ultrasound to be available in all settings where women (especially those in preterm labour) may present for care, thus facilitating clinical decision-making that considers the most appropriate interventions and setting for birth, given estimated gestational age.
- Policy-makers need to consider the diversion of resources from other health-care needs. Also, and in countries where maternal and perinatal mortality is very high, priority may be given to interventions that improve survival. Use of ultrasound equipment for non-obstetric purposes should also be reflected when calculating overall costs.
- Policy-makers should also consider health worker/facility capacity for consultations and referral upon suspicion or detection of complications.
- Functional obstetrical ultrasound programmes include strong systems to ensure safe management of conditions requiring urgent intervention (e.g. extrauterine pregnancy, placenta praevia, placenta accreta spectrum).

Logistical considerations

- Extra space and seating may be required to facilitate women bringing partners and other family members to ultrasound scans.
- Ideally, the room (or environment) where the scan and related counselling take place should be in a private location, away from the waiting room, to ensure privacy and confidentiality. Addressing privacy, comfort and needs of women is important. Where possible, sonographers should ensure that women (and their partners) can see the image on the screen when discussing fetal well-being.
- In some locations (e.g. isolated or rural areas), portable ultrasound equipment may be useful, especially in communities that may not have the resources to engage with formal maternity services or where poor infrastructure limits access. These settings are often poorly equipped to charge and protect devices – which needs to be considered, as well as building capacity to consult via phone, etc. In addition, it is important to ensure that the portable ultrasound equipment is of adequate quality for the task.
- While new devices may increase accessibility, some may require: additional viewing devices, such as a compatible phone or tablet; the downloading of specific applications (apps), which may be subject to regulatory constraints; recharging (for rechargeable devices); connectivity to built-in consultation functionality; and device security.
- Expanding the scope of practice for health workers can have both positive and negative consequences. While the opportunity to acquire new skills such as for ultrasound scans may be welcome and rewarding for some health workers, others may find new requirements burdensome and/or distracting from their current duties. Policy-makers should also be mindful of the potential negative impact of shifting skilled birth attendants to performing scans in settings with shortages.

Training and education considerations

- Policy-makers at national and local levels should promote evidence-based standards and training for health workers (physicians, nurses, midwives and sonographers). Health workers should have had comprehensive training on the use and maintenance of equipment, on how to perform standard components of ultrasound screening, how to record and counsel women regarding results, and how to manage any abnormalities diagnosed by ultrasound.
- Health workers should make women aware of the availability of ultrasound, its purpose, benefits and limitations, and potential out-of-pocket costs.
- In settings where the availability or supply of sonographers is limited, policy-makers could consider training other cadres (e.g. midwives, obstetricians or nurses) to perform antenatal ultrasound, provided they have been trained to use the equipment competently and safely.
- Consideration should be given to training new ultrasound providers on: infection control measures; proper cleaning and disinfection of equipment and of care areas between scans; appropriate methods for adjusting ultrasound system controls to optimize images; calculation of best obstetric estimate of gestational age; when and when not to re-date pregnancies; and special counselling considerations related to fetal loss and anomalies. Training should include communication and a relational approach during the conduct of the scan.

- Sonography (when conducted by sonographers) can be emotionally challenging. The role may require additional training (e.g. in counselling, medical ethics and communication skills) and regular opportunities for peer support.
- In communities where there may be misunderstandings about the potential benefits or harms of ultrasound, community education programmes should be considered. These should be inclusive (also open to partners and family members), culturally sensitive and flexible.
- Prior to the first ultrasound appointment, parents should be provided with clear information about the clinical purpose of an ultrasound scans, along with details of the potential consequences of detecting fetal anomaly. Parents should also be informed that an ultrasound scan is a choice and not compulsory.
- Ultrasound findings should be communicated in a timely and clear manner that the woman and her partner can understand. Opportunities to ask questions should be provided.
- Attention should also be paid to helping health workers and women understand the limitations of ultrasound in predicting fetal weight, that a positive fetal heartbeat does not rule out the possibility of future pregnancy loss, and that some anomalies may not be apparent, especially early in pregnancy.

Counselling and other considerations

- In some contexts, health workers should be aware of the potential implications of revealing fetal sex following an antenatal scan. In these contexts, health workers should consider whether disclosure of fetal sex is appropriate.
- Since ultrasound may detect fetal abnormalities, the provision of associated support services for parents is important. Parents may require counselling and access to social support networks if an abnormal diagnosis is possible or confirmed.
- To keep fetal exposure to ultrasound as low as possible, the as low as reasonably achievable (ALARA) principle should be applied, with scans conducted in the shortest possible time and with the lowest power levels that are compatible with obtaining relevant diagnostic information.
- Health system managers must be aware of the risk of medico-legal exposure and develop mechanisms to protect the clinicians performing imaging ultrasound. One way of doing this could be through the provision of a consent form explaining the limitations of imaging ultrasound before it is performed. Limitations may include the fact that confirming a viable fetus does not rule out the possibility of future pregnancy loss or other pregnancy complications, fetal anomalies cannot always be identified, and fetal weight estimation may not be accurate.

4 Dissemination of the recommendation

This updated global guideline will be available online for download. Online versions will be available via the WHO websites and other online platforms developed by the WHO Departments of SRH and MCA and the WHO ANC portal.⁴ The updated recommendation and updated associated products, in particular the *WHO antenatal care recommendations adaptation toolkit* and its instruction manual, will be disseminated during meetings and scientific conferences attended by WHO staff.

The policy brief on ultrasound examination will be updated with expanded implementation considerations to inform country policies and programming.

To increase awareness of the updated recommendation, a short commentary will be published in a peer-reviewed journal, and social media channels will also be used.

The executive summary and recommendations from this publication will be translated into the six United Nations languages for dissemination through the WHO regional offices and during meetings organized or attended by WHO staff.

⁴ Available at: <https://www.srhr.org/antenatalcare>

5 Research implications

The GDG agreed that more research on antenatal ultrasound before 24 weeks of gestation is warranted and noted the following research gaps:

- What are the undesirable effects of imaging ultrasound in pregnancy, including non-detection of fetal abnormalities and litigation?
- How does the performance of handheld and other portable devices compare with that of stationary machines, in terms of image quality?
- How cost-effective is imaging ultrasound before 24 weeks of pregnancy?
- Can routine imaging ultrasound scans in pregnancy be effectively shared among different cadres of health workers?
- What is the impact of the introduction of routine obstetric ultrasound on the timing of women's entry to ANC services, the quality of ANC services, and on retention of pregnant women in ANC services?
- What are the optimal strategies to facilitate use of ultrasound data for appropriate clinical decision-making in antenatal, intrapartum and postnatal care?
- To what extent does imaging ultrasound contribute to misdiagnosis, for example of preterm birth and small-for-gestational-age newborns?
- What are the views and experiences of antenatal imaging ultrasound among women and health workers in South America, Central America and Caribbean countries? (The qualitative systematic review identified few studies from these countries.)

6 Updating the guideline

WHO convenes the Executive GSG biannually to review the current WHO portfolio of maternal and perinatal health recommendations, and to advise on the prioritization of new and existing questions for recommendation development and updating. Any concern about the validity of the recommendation will be promptly communicated via the guideline website,⁵ and plans will be made to update the recommendation as necessary. WHO will prioritize its independent normative guidance informed by the strategic shifts embedded in its Constitution and the Thirteenth General Programme of Work 2019–2023.

⁵ Available at: <https://www.who.int/publications/i/item/9789241549912>

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Annex 2. Summary of declarations of interest from Guideline Development Group members and how they were managed

Name (with title)	Gender	Expertise	Disclosure of interest	Conflict of interest and management
Dr Niveen Abu-Rmeileh	F	Community and public health, statistical epidemiology	None declared	Not applicable
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Professor Tippawan Liabsuetrakul	F	Epidemiology, obstetrics and gynaecology	None declared	Not applicable
Professor James Neilson	M	General obstetrics, perinatology, gynaecology, systematic reviews, evidence synthesis and guideline development using GRADE	None declared	Not applicable
Dr Lisa Noguchi	F	Midwifery, delivery of care, implementation science	Employer anticipated research funding from Bill & Melinda Gates Foundation relating to studying introduction of innovations and improving quality of care in antenatal and perinatal care	The conflict was not considered serious enough to affect GDG membership or participation in the technical consultation
Professor Nafissa Osman	F	Obstetrics and gynaecology, implementation research	None declared	Not applicable
Professor Erika Ota	F	Midwifery, nutrition, evidence synthesis, guideline development	None declared	Not applicable
Dr Tomas Pantoja	M	Family medicine, evidence synthesis, policy and programming	None declared	Not applicable
Professor Robert Pattinson	M	Obstetrics and gynaecology, delivery of care, evidence synthesis	None declared	Not applicable
Dr Charlotte Warren	F	Nursing, maternal and perinatal health, health systems, policy and programming, implementation research	None declared	Not applicable
Professor Charles Shey Wiysonge	M	Health systems, systematic reviews, delivery of care	None declared	Not applicable

Annex 3. Antenatal ultrasound before 24 weeks of gestation: GRADE¹ tables

Question: Should first-trimester routine versus no routine ultrasound be used in fetal assessment before 24 weeks of gestation?

Settings: First-trimester studies carried out in Australia, Canada, the United Kingdom of Great Britain and Northern Ireland and the United States of America (USA). Second-trimester studies in Finland, South Africa (two), Sweden, the United Kingdom and the USA.

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Comparison 1: First-trimester routine scan (before 14 weeks of pregnancy) versus no routine scan

Maternal outcomes

No. of studies	Design	Quality assessment						No. of participants		Effect		Certainty	Importance
		Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	First-trimester routine versus no routine ultrasound	Control	Relative (95% CI)	Absolute			
Caesarean section													
3	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	serious ^b	none	125/633 (19.7%)	96/620 (15.5%)	RR 1.27 (0.99-1.61)	42 more per 1000 (from 2 fewer to 94 more)	⊗⊗○○ LOW	CRITICAL	
Induction of labour for post-term pregnancy													
3	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	serious ^b	none	52/739 (7%)	60/735 (8.2%)	RR 0.83 (0.5-1.37)	14 fewer per 1000 (from 41 fewer to 30 more)	⊗⊗○○ LOW	CRITICAL	
Induction of labour for any reason													
1	randomized trial	serious ^c	no serious inconsistency	no serious indirectness	serious ^b	none	34/233 (14.6%)	46/230 (20%)	RR 0.73 (0.49-1.09)	54 fewer per 1000 (from 102 fewer to 18 more)	⊗⊗○○ LOW	IMPORTANT	

1 GRADE: Grading of Recommendations Assessment, Development and Evaluation

Maternal outcomes (continued)

No. of studies	Design	Risk of bias	Quality assessment					No. of participants		Effect		Certainty	Importance
			Inconsistency	Indirectness	Imprecision	Other considerations	First-trimester routine versus no routine ultrasound	Control	Relative (95% CI)	Absolute			
Detection of multiple pregnancy by 24–26 weeks of gestation (number not detected)													
1	randomized trial	serious ^c	no serious inconsistency	no serious indirectness	very serious ^d	none	0/2 (0%)	2/7 (28.6%)	RR 0.53 (0.03–8.19)	134 fewer per 1000 (from 277 fewer to 1000 more)	⊗○○○ VERY LOW	IMPORTANT	
Detection of multiple pregnancy before labour (number not detected)													
1	randomized trial	serious ^c	no serious inconsistency	no serious indirectness	very serious ^d	none	0/2 (0%)	1/7 (14.3%)	RR 0.89 (0.05–16.36)	16 fewer per 1000 (from 136 fewer to 1000 more)	⊗○○○ VERY LOW	IMPORTANT	
Maternal anxiety (mother worried about pregnancy)													
1	randomized trial	serious ^c	no serious inconsistency	no serious indirectness	no serious imprecision	none	98/310 (31.6%)	128/324 (39.5%)	RR 0.8 (0.65–0.99)	79 fewer per 1000 (from 4 fewer to 138 fewer)	⊗⊗⊗○ MODERATE	IMPORTANT	

RR: risk ratio

- a. Studies contributing data had design limitations.
- b. Wide 95% confidence interval (CI) crossing the line of no effect.
- c. Single study with design limitations.
- d. Low event rate and wide 95% CI crossing the line of no effect.

Fetal and neonatal outcomes

No. of studies	Design	Risk of bias	Quality assessment					No. of participants		Effect		Certainty	Importance
			Inconsistency	Indirectness	Imprecision	Other considerations	First-trimester routine versus no routine ultrasound	Control	Relative (95% CI)	Absolute			
Perinatal death													
2	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	serious ^b	none	5/725 (0.69%)	7/747 (0.94%)	RR 0.73 (0.23-2.31)	3 fewer per 1000 (from 7 fewer to 12 more)	⊗⊗○○ LOW	CRITICAL	
Stillbirth (intrauterine fetal demise after 20 weeks)													
1	randomized trial	serious ^c	no serious inconsistency	no serious indirectness	very serious ^d	none	1/233 (0.43%)	0/230 (0%)	RR 2.96 (0.12-72.32)	-	⊗○○○ VERY LOW	CRITICAL	
Serious neonatal morbidity (admission to neonatal intensive care unit)													
1	randomized trial	serious ^c	no serious inconsistency	no serious indirectness	serious ^b	none	25/404 (6.2%)	31/420 (7.4%)	RR 0.84 (0.5-1.39)	12 fewer per 1000 (from 37 fewer to 29 more)	⊗⊗○○ LOW	CRITICAL	
Low birth weight (less than 2500 g)													
1	randomized trial	serious ^c	no serious inconsistency	no serious indirectness	serious ^b	none	22/296 (7.4%)	11/298 (3.7%)	RR 2.01 (0.99-4.08)	37 more per 1000 (from 0 fewer to 114 more)	⊗⊗○○ LOW	CRITICAL	

RR: risk ratio

a. Studies contributing data had design limitations (B studies).

b. Wide 95% CI crossing the line of no effect.

c. Single study with design limitations.

d. Low event rate and wide 95% CI crossing the line of no effect.

Comparison 2: Second-trimester routine scan (between 14 and 24 weeks of pregnancy) versus no routine scan

Maternal outcomes

No. of studies	Design	Quality assessment					No. of participants		Effect		Certainty	Importance
		Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Second-trimester routine versus no routine ultrasound	Control	Relative (95% CI)	Absolute		
Caesarean section												
5	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	no serious imprecision	none	1537/11151 (13.8%)	1455/11042 (13.2%)	RR 1.05 (0.98-1.12)	7 more per 1000 (from 3 fewer to 16 more)	⊗⊗⊗⊗ MODERATE	CRITICAL
Induction of labour for post-term pregnancy												
6	randomized trial	serious ^a	serious ^b	no serious indirectness	no serious imprecision	none	198/12176 (1.6%)	339/11998 (2.8%)	RR 0.48 (0.31-0.73)	15 fewer per 1000 (from 8 fewer to 19 fewer)	⊗⊗⊗⊗ LOW	IMPORTANT
Induction of labour for any reason												
6	randomized trial	serious ^a	serious ^b	no serious indirectness	serious ^c	none	2313/12209 (18.9%)	2401/12120 (19.8%)	RR 0.79 (0.63-1)	42 fewer per 1000 (from 73 fewer to 0 more)	⊗⊗⊗⊗ VERY LOW	CRITICAL
Detection of multiple pregnancy by 24-26 weeks of gestation (number not detected)												
6	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	no serious imprecision	none	2/150 (1.3%)	55/135 (40.7%)	RR 0.06 (0.02-0.16)	383 fewer per 1000 (from 342 fewer to 399 fewer)	⊗⊗⊗⊗ MODERATE	IMPORTANT
Detection of multiple pregnancy before labour (number not detected)												
3	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	very serious ^d	none	0/70 (0%)	3/65 (4.6%)	RR 0.1 (0.01-1.74)	42 fewer per 1000 (from 46 fewer to 34 more)	⊗⊗⊗⊗ VERY LOW	IMPORTANT

Maternal outcomes (continued)

		Quality assessment					No. of participants			Effect		Certainty	Importance
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Second-trimester routine versus no routine ultrasound	Control	Relative (95% CI)	Absolute			
Detection of fetal abnormality before 24 weeks of gestation													
2	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	no serious imprecision	none	33/206 (16%)	8/181 (4.4%)	RR 3.45 (1.67-7.12)	108 more per 1000 (from 30 more to 270 more)	⊗⊗⊗○ MODERATE	CRITICAL	
Termination of pregnancy for fetal abnormality													
4	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	no serious imprecision	none	23/13549 (0.17%)	9/13344 (0.07%)	RR 2.36 (1.13-4.93)	1 more per 1000 (from 0 more to 3 more)	⊗⊗⊗○ MODERATE	IMPORTANT	
Termination of pregnancy for any cause													
4	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	serious ^e	none	51/15321 (0.33%)	39/15195 (0.26%)	RR 1.3 (0.85-1.96)	1 more per 1000 (from 0 fewer to 2 more)	⊗⊗○○ LOW	IMPORTANT	

RR: risk ratio

- a. Studies contributing data had design limitations (most weight from B studies).
- b. High heterogeneity between studies.
- c. Wide 95% CI reaching the line of no effect.
- d. Low event rate and wide 95% CI crossing the line of no effect.
- e. Wide 95% CI crossing the line of no effect.

Fetal and neonatal outcomes

No. of studies	Design	Risk of bias	Quality assessment					No. of participants		Effect		Certainty	Importance
			Inconsistency	Indirectness	Imprecision	Other considerations	Second-trimester routine versus no routine ultrasound	Control	Relative (95% CI)	Absolute			
Perinatal death													
8	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	serious ^b	none	127/17590 (0.72%)	139/1738 (0.8%)	RR 0.9 (0.71-1.14)	1 fewer per 1000 (from 2 fewer to 1 more)	⊗⊗○○ LOW	CRITICAL	
Stillbirth													
4	randomized trial	serious ^a	no serious inconsistency ^c	no serious indirectness	serious ^b	none	54/15389 (0.35%)	54/15257 (0.35%)	RR 0.99 (0.68-1.44)	0 fewer per 1000 (from 1 fewer to 2 more)	⊗⊗○○ LOW	CRITICAL	
Neonatal death													
4	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	serious ^b	none	32/13323 (0.24%)	38/13135 (0.29%)	RR 0.83 (0.52-1.32)	0 fewer per 1000 (from 1 fewer to 1 more)	⊗⊗○○ LOW	CRITICAL	
Serious neonatal morbidity (admission to neonatal intensive care unit)													
6	randomized trial	serious ^a	no serious inconsistency	no serious indirectness	no serious imprecision	none	767/8815 (8.7%)	819/8669 (9.4%)	RR 0.92 (0.84-1.01)	8 fewer per 1000 (from 15 fewer to 1 more)	⊗⊗⊗○ MODERATE	IMPORTANT	
Serious neonatal morbidity													
1	randomized trial	serious ^d	no serious inconsistency	no serious indirectness	serious ^b	none	99/7685 (1.3%)	95/7596 (1.3%)	RR 1.03 (0.78-1.36)	0 more per 1000 (from 3 fewer to 5 more)	⊗⊗○○ LOW	IMPORTANT	

Fetal and neonatal outcomes (continued)

		Quality assessment						No. of participants		Effect		Certainty	Importance
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Second-trimester routine versus no routine ultrasound	Control	Relative (95% CI)		Certainty	Importance	
									RR	OR			
Low birth weight (less than 2500 g)													
6	randomized trial	serious ^a	no serious inconsistency ^c	no serious indirectness	serious ^b	none	336/8931 (3.8%)	354/8797 (4%)	RR 0.92 (0.74-1.14)	3 fewer per 1000 (from 10 fewer to 6 more)	⊗⊗○○ LOW	IMPORTANT	
Small for gestational age													
1	randomized trial	serious ^d	no serious inconsistency	no serious indirectness	serious ^b	none	41/490 (8.4%)	27/474 (5.7%)	RR 1.47 (0.92-2.35)	27 more per 1000 (from 5 fewer to 77 more)	⊗⊗○○ LOW	IMPORTANT	

RR: risk ratio

- a. Studies contributing data had design limitations (most weight from B studies).
- b. Wide 95% CI crossing the line of no effect.
- c. Moderate heterogeneity but not downgraded.
- d. Single study with design limitations.



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