# Guidelines and Recommendations on the use of Ultrasound in Obstetrics and Gynecology

## 1. Guidelines for the Assessment of Ductus Venosus in Obstetrics

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Ductus venosus (DV) is the main distributor of placental blood and directs well oxygenated blood from the umbilical vein to the cerebral and coronary circulations, across the foramen ovale toward the left atrium[1,5] (Fig. 1). This Y-shaped jet is arranged spatially in two pathways:

*Via sinistra (dorsal and left side stream)*: Thirty percent (at mid-gestation) and 20% (at term) of umbilical blood is accelerated to the left atrium through the *foramen ovale* shunted from the DV and left hepatic veins.

*Via dextra (ventral and rightward stream)*: Seventy percent of less oxygenated blood enters the right ventricle through the tricuspid valve, originating from the inferior vena cava.

The DV is located in the fetal abdomen, connecting the intra-abdominal ventral portion of umbilical sinus to the left side of the inferior vena cava, and streams caudo-cranially and ventrodorsally. Due to this architectural arrangement (sphincter-like), a pressure gradient is produced between the umbilical vein and the atrium, resulting in the acceleration of the blood flow in the DV and producing a triphasic high velocity waveform.[1]

A characteristic anterograde triphasic waveform is produced with a S-wave (ventricular systole), a D-wave (early diastole) and a A-wave (late diastole) evaluated by pulsed Doppler (Fig. 2). This latter wave presents the lowest velocity but always with forward flow. The peak velocity attained in the A-wave is about 3 to 4 times the velocity in the umbilical vein.[4] Unlike the second and third trimester, where the flow during the atrial contraction is always forward in normal pregnancies, one must take in consideration that in the early 1st trimester the A-wave can be null or reversed even in normal fetuses. However, after 11 weeks the presence of a reversed A-wave is considered abnormal (Fig. 3). Therefore, an easy qualitative assessment can be performed in routine clinical practice classifying the A-wave as positive, absent or reversed.[3]

However, in order to quantify blood flow in the DV, several authors have suggested different indexes, such as pulsatility index for veins (PIV), S/D index, the ductus venosus index (DVI) defined as (S-a)/S or (S-a)/D, and the perfusion index (PFI) defined as Tamx/S.[6]

Strict methodological principles should be adopted in order to obtain a reproducible and clinically relevant waveform (Table 1). There is obviously a learning curve that implies the performance of 100 scans. The Doppler evaluation of DV is based on a right parasagittal plane obtained by B-mode, taking care to avoid contamination by neighboring vessels (hepatic veins, inferior vena cava and umbilical vein) (Fig. 4). The identification of the DV is greatly aided by using color Doppler putting the gate directly on the aliasing zone. The DV is distinguishable from the UV by a distinctly higher velocity.

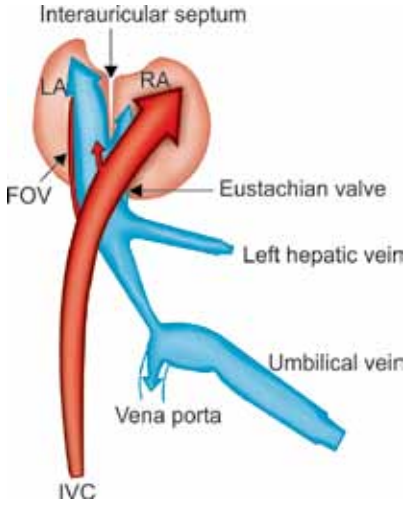


**Fig. 1:** Venous return is arranged in a Y-shaped inferior vena cava–foramen ovale unit with two different pathways (*Courtesy*: Prof Torvid Kiserud)

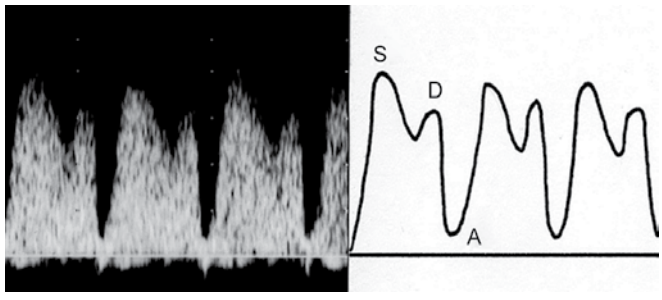


**Fig. 2:** Schematic representation of a typical waveform obtained by pulsed Doppler in the ductus venosus. S-wave: ventricular systole; D-wave: early distole; A-wave: atrial contraction

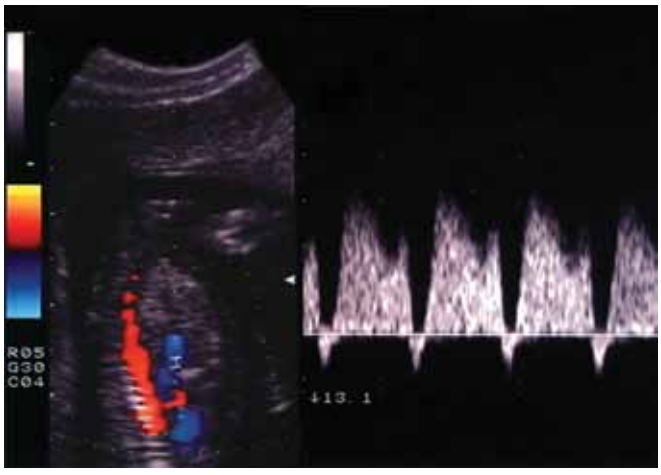


**Fig. 3:** Example of a reversed A-wave in the DV representing an abnormal waveform after 10 weeks of gestation

**Table 1:** Methodological guidelines for Doppler assessment of blood flow in the DV (Montenegro et al 1997)[2]

| |
|---|
| • Pulsed Doppler |
| • Color Doppler (helpful) |
| • Right parasagittal plane |
| • Magnification: fetal abdomen and thorax fill the majority of the image |
| • Pulsed Doppler gate 0.5 to 1 mm |
| • Caliper on DV isthmus (‘aliasing’) |
| • Adjust PRF |
| • Adjust high-pass filter (50 MHz) |
| • Avoid contamination |
| • Det insonation angle below 30º (respect to the longitudinal axis of the DV) |
| • Obtain regular waves |
| • Increase sweep speed |
| • Maximum exposure time (30 seconds) |


**Fig. 4:** B-mode image of venous return in a fetus of 12 weeks of gestation. UV: Umbilical vein; DV: Ductus venosus; IVC: Inferior *vena cava* and color Doppler with aliasing representing the turbulence due to the increased velocity in the inlet of the ductus venosus

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## 2. Rational use of Ultrasound in Normal and Abnormal Early Pregnancy

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Ultrasound scan is part of the antenatal care, most frequently offered to the patients during the second trimester of pregnancy. Thanks to the improvement in the ultrasound equipment and the resolution of the probes, a first-trimester scan is now routinely offered, depending on the resources of each particular health system. This scan must be performed by adequately trained and accredited professionals.

In the countries where it is available, pregnant women should be offered an early ultrasound scan between $10^{+0}$ and $13^{+6}$ weeks to establish an accurate gestational age.[1] Before this gestational age, there is no justification for scanning an asymptomatic woman: the likelihood for the diagnosis of a pregnancy of unknown location (PUL) would be higher thus increasing the anxiety of the patient, the risk for iatrogenic interventions and also the cost of repeated interventions. However, in cases of bleeding or abdominal pain, a scan must be done to rule out an ectopic pregnancy or a trophoblastic disease.

### BASIC OBJECTIVES

- *Patient's background*: Before starting the ultrasound scan, we should retrieve some data from the patient's background, such as the patient's age, parity, last menstrual period (LMP), mode of conception, previous gynecological diseases and other medical conditions.
- *Probe*: Some doctors will choose the transabdominal (TA) probe in the first place and only try the transvaginal (TV) approach in case the scan cannot be completed transabdominally. Others will systematically use both probes as complementary.
  - *Transabdominal*: Curvilinear transducer (4-7 MHz probe) to obtain a global view of the pelvis and exclude any pelvic pathology.
  - *Transvaginal*: Curvilinear high-frequency transducer (9-12 MHz probe). Closer proximity of the transducer to the fetus results in a better display of the anatomy.
- *Survey scan*: Before assessing the fetal anatomy, a global view of the uterine wall and both adnexa must be obtained in both longitudinal and transverse planes, in order to rule out pathology such as fibroids or ovarian cysts.[1]
  - Look for any obvious myometrial or cervical pathology.
  - Describe any uterine malformations.
  - Scan both adnexa entirely, excluding any obvious ovarian pathology or adnexal masses.
- *Viability*: Locating the embryo or the fetus inside the uterus is quite easy during the first trimester. This, along with the visualization of the body movements and the heart beating in the fetal chest, confirms viability (in terms of ongoing intrauterine pregnancy). The fetal heart rate can be measured by implementing the pulsed Doppler, positioning the gate over the point where the fetal heart activity is seen.
- *Number of fetuses*: Early scanning will easily confirm fetal number and the position of each fetus in the case of a multiple pregnancy.
- *Chorionicity and amnionicity*: The number and position of placentas should be determined, in particular by examining the placental-membrane junction for the presence or absence of the lambda sign. In monochorionic twins, the amniotic membranes should be assessed to determine if the fetuses are in separate amniotic sacs or not.
- Placental position[1]:
  - In the first weeks of pregnancy, the implantation of the embryo will determine the site of the uterus where the placenta will be located.
  - Usually the placental echo-structure is homogeneous and hypoechoic. At the $11\text{-}13^{+6}$ weeks scan it is possible to notice sonolucent cystic areas within the placenta, which would raise the suspicion for a partial or total molar pregnancy. Large subchorionic fluid collections should also be noted and followed up.
  - The position of the placenta with respect to the *internal os* is still provisional, since it will be modified by the uterus growth therefore it is not recommendable to document a 'previous' or a 'low set' placenta during the first trimester.
- *Placental cord insertion site*: The insertion site of the cord can be easily spotted on the fetal surface of the placenta and may be confirmed with the adjunct use of color Doppler.
- *Estimation of gestational age*[1]: Establishing an estimated date of delivery by ultrasound is one of the main objectives of the first-trimester scan. This is achieved by measuring the crown-rump length (CRL) (Fig. 1):
  - Mid-sagittal section of the fetal body (small degrees of rotation will cause shortening of the CRL).
  - Fetus in a neutral position with its head and body neither flexed nor extended.

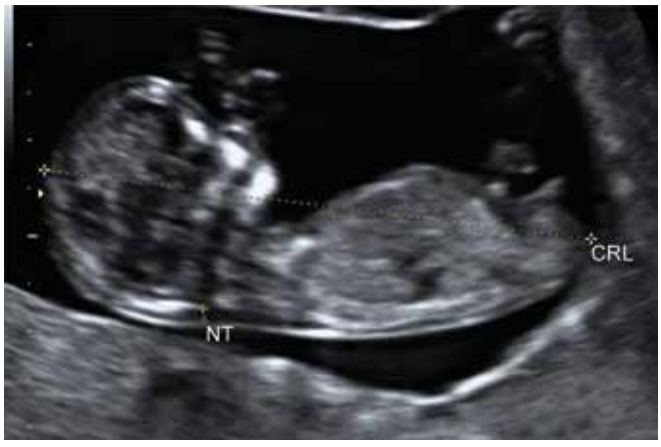


**Fig. 1:** Mid-sagittal view of the fetus and measurement of the crown-rump length

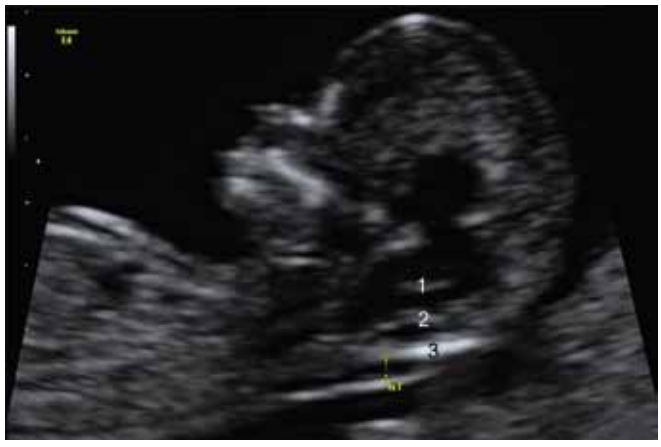


**Fig. 2:** Profile of the fetal head, visualization of the nasal bone and the brain midline and measurement of the nuchal translucency. The three parallel lines described for the assessment of the posterior fossa correspond to: (1) posterior part of the brainstem, (2) choroid plexus of the fourth ventricle and (3) occipital bone

- The calipers are placed in a straight line, measuring the largest distance between the top of the fetal head and the rump of the fetus.

## SCREENING FOR CHROMOSOMAL ABNORMALITIES

A marker is a sonographic finding in the fetus or the placenta that raises the suspicion for the presence of an aneuploidy. It does not have to be a malformation itself.

### Nuchal Translucency

Nuchal translucency (NT) is the sonographic appearance of the subcutaneous accumulation of fluid behind the fetal neck in the first trimester of pregnancy.[2] It is the best isolated marker for aneuploidy and it increases with CRL. Nuchal translucency is above the 95th centile in 72% of fetuses with trisomy 21. The way NT must be measured has been described in detail.[3] Briefly, it must be assessed at 11-13$^{+6}$ weeks (fetal crown–rump length 45-84 mm) on a mid-sagittal section of the fetus in the neutral position, with only the fetal head and upper thorax included in the image. The measurement of the maximum thickness of the subcutaneous translucency between the skin and the soft tissue overlying the cervical spine must be taken, with the callipers placed on the lines that define the NT thickness (ON-to-ON) (Fig. 2).

For a false positive rate of 5%, screening by a combination of (1) the a priori maternal age-based risk, (2) sonography for fetal nuchal translucency and (3) maternal serum biomarkers (free β-hCG and PAPP-A) can potentially identify more than 90% of trisomy 21 pregnancies. Adding the nasal bone assessment to this first trimester screening (maternal age + NT + maternal serum fβ-hCG and PAPP-A) can potentially increase detection rate to more than 95% of trisomy 21 pregnancies, for a FP rate of 5%.[4]

An abnormal waveform in the ductus venosus (DV)[5] and/or the presence of tricuspid regurgitation (TR)[6] can be used as a marker for aneuploidies and also for cardiac malformations. One of the main contributors to a thickened NT in the presence of a normal karyotype is a fetal cardiac defect. There are many others ultrasound markers for the detection of chromosomal abnormalities[7-10] although the most useful ones for the screening of aneuploidies have been described above.

The main limitations of the markers as predictors for aneuploidy are:[11]

- Impossibility to examine the marker:
  - Maternal factors.
  - Fetal factors.
- Wrong measurement of the marker.
- Wrong interpretation of the marker.
- What markers should we use?[12]
  - Maternal age + nuchal translucency: Detection rate (DR) = 80%, false positive rate (FPR) = 5%.
  - Maternal age + NT + PAPP-A and fβ-hCG (combined screening): DR = 90%, FPR = 5%.
  - Combined screening + nasal bone or ductus venosus or tricuspid regurgitation: DR = 93 to 96%, FPR = 2.5%.

## ANATOMY

Thanks to the continuous advances in equipment and technology, a very complete assessment of the fetal anomaly is nowadays possible during the first trimester of pregnancy. Different conditions can be early diagnosed, the ones incompatible with life being the most important to be detected.

The following eight planes are proposed as an example of a good exploration of the fetus at 11-13$^{+6}$ weeks. This is not too time-consuming, since some of the planes are already needed for the measurement of the CRL and the NT:

1. *Mid-sagittal plane of the fetus (Figs 1 and 3)*: This view is mandatory during the ultrasound examination

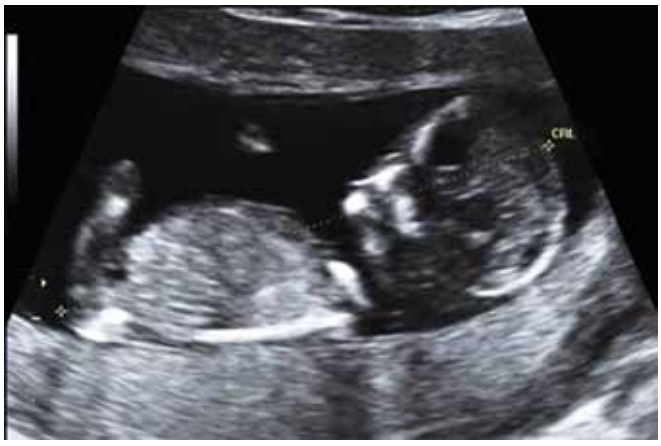


**Fig. 3:** Mid-sagittal view of the fetus. The bladder can be seen

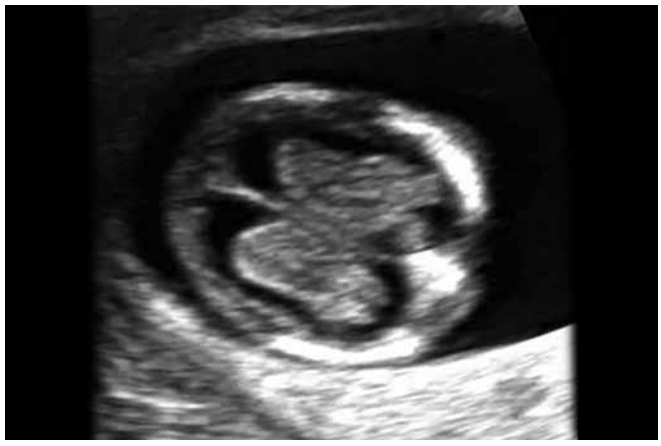

**Fig. 4:** Axial view of the fetal head: 'butterfly sign'

because is the plane where the CRL can be measured, thus an accurate estimation of the gestational age can be made.[1] A lot of information can be obtained in this view, regarding the anatomy of the fetus: the bladder can be visualized; it is the most helpful direct view of the spine to discard, at least, the most severe defects during the first trimester; the diaphragm can be seen, separating the abdominal from the thoracic contents; the integrity of the abdominal wall can be confirmed. Even fetal gender can be predicted with an accuracy of approximately 80%[13] by looking at the direction of the genital tubercle with respect to the spine (perpendicular for males, parallel for females).

2. *Profile of the fetal head*[14]: The same mid-sagittal view that is used to measure the NT and to assess the NB is also important for assessing normal fetal head anatomy. Several midline structures of the CNS can be identified on this view: thalamus, midbrain, brain stem, cisterna magna.

   In this sagittal plane, a '3-parallel-line sign' has been described to ascertain a normal posterior fossa (Fig. 2). Of these 3 lines, the most important one seems to be the mid one, which would represent the choroid plexus of the 4th ventricle (the other two lines being quite constant). According to Chaoui et al,[15] the intracranial translucency (IT) corresponds to the future fourth ventricle and would be delimited by the posterior part of the brainstem and the line corresponding to the choroid plexus. The inability to image the IT has been described as an ultrasound marker for the early diagnosis of open spina bifida.

   The fetal profile alone is also useful to suspect certain facial abnormalities. Nasal bone, palate and mandible can be seen in the sagittal plane; cases of micrognathia and other irregularities of the fetal profile can be detected.

3. *Axial plane of the fetal head* (Fig. 4):
   - Initial transverse plane, scanning through from the top of the fetal head to the fetal neck.
   - A transverse section of the mid-portion of the cranium should be recorded in a still image.
   - Assessment of cranial anatomy:
     - Developing fetal skull: hyperechoic rim around the outside of the fetal head (ossification progresses from the frontal to the occipital bones).
     - Absence of the cranial vault, either partial or complete, as seen in cases of cephalocele or acrania, becomes evident in this view.
     - The shape of the skull may be characteristic in certain pathologies, such as the strawberry-shaped skull found in cases of trisomy 18 or certain dysplasias.
   - Cerebral anatomy. An echogenic division between the two hemispheres, representing the falx cerebri, must be seen. The echogenic plexues, on either side of the midline, resemble the wings of a butterfly. This 'butterfly' sign[16] is very useful to rule out cases of holoprosencephaly.
   - The orbits and the lenses can be seen in an axial or a coronal plane (their visualization is very recommendable but not mandatory during the first trimester).

4. *Thorax (Fig. 5)*: A transverse view of the normal fetal thorax shows a circular structure of medium echogenicity containing the fetal heart, more hypoechoic and slightly orientated to the left of midline. Fetal heart beat is easy to ascertain and measure in this view. The fetal lungs at 11 to 13 weeks of gestation are slightly more echogenic than the abdominal contents and should be homogenous in echotexture.

   *Heart*[1,17]: When the conditions are favorable, standard images of the four-chamber view and ventricular outflow tracts could be obtained at 13 to 14 weeks. These images alone exclude many major heart defects and therefore may be considered as part of the first-trimester fetal anatomy scan, at least in high risk cases. Fetal echocardiography, when indicated, can

be successfully accomplished at 13 to 14 weeks of gestation in a high proportion of cases.

Cystic masses in the thorax or pericardial or pleural effusions are abnormal and in these cases, the exact location of the fetal stomach should be demonstrated to rule out the possibility of a diaphragmatic hernia.[1]

5. *Abdomen (Fig. 6)*: Visualization of the stomach as an econegative structure under the diaphragm on the left side of the abdomen is very useful to ascertain situs solitus and it practically rules out the possibility of a huge diaphragmatic hernia. More inferiorly, the bladder can be seen in the fetal pelvis, both in sagittal and axial planes. Megacystis can be diagnosed at this point, since the longitudinal diameter of the bladder should not exceed 10% of the CRL at any given gestational age. Fetal kidneys[1] can be visualized in the transverse or coronal plane as two slightly echogenic paraspinal structures in the fetal abdomen, slightly below to the plane where the fetal stomach is located (their visualization is not mandatory during the first trimester, though).
6. *Abdominal wall (Fig. 7)*: The insertion site of the umbilical cord into the abdominal wall is seen on the way between the stomach and the bladder and a continuous unbroken line on either side of the cord insertion should be seen.

   Any irregularity in the continuity of the abdominal wall or any thickening of the cord at the fetal insertion site are not consistent with normal anatomy and a diagnosis of gastroschisis or omphalocele, respectively, must be ruled out.
7. and 8. *Limbs (Figs 8 and 9)*: It is feasible and important to demonstrate, at early gestational ages if possible, the presence of the four limbs (with 3 segments on each of them). Since, the fetus can be very mobile, it is important, when assessing the fetal limbs with ultrasound, to make sure which limb we are assessing. Not only the upper or the lower limb but also be sure whether it is the left or the right.

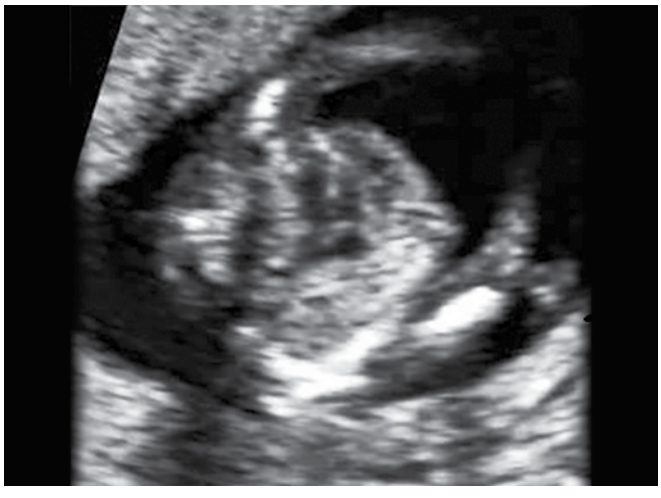

**Fig. 5:** Axial view of the fetal thorax, with the heart in the center, slightly to the left

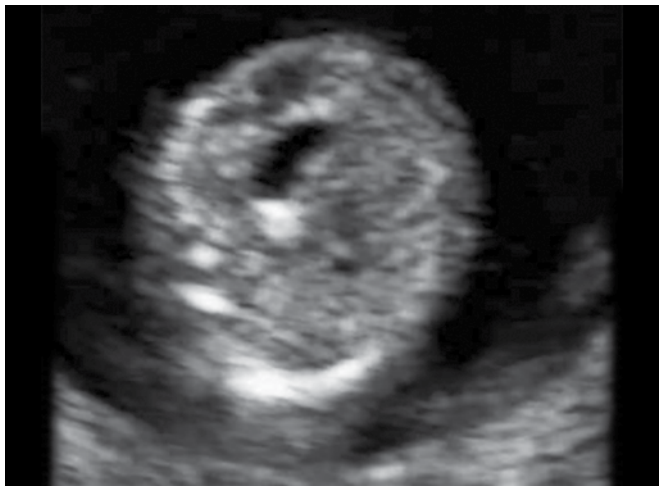

**Fig. 6:** Axial view of the fetal upper abdomen, with the stomach to the left

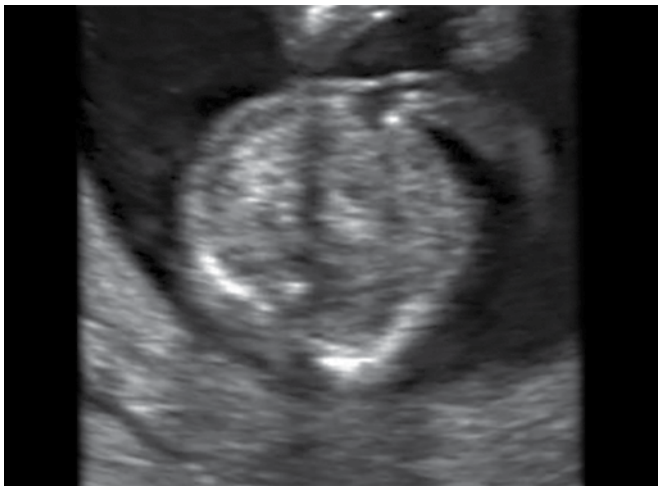

**Fig. 7:** Axial view of the fetal mid-abdomen, where the cord insertion can be visualized

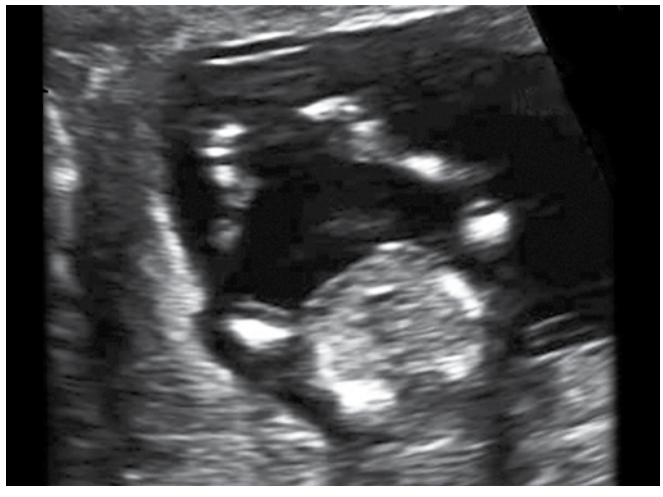

**Fig. 8:** Fetal upper limbs

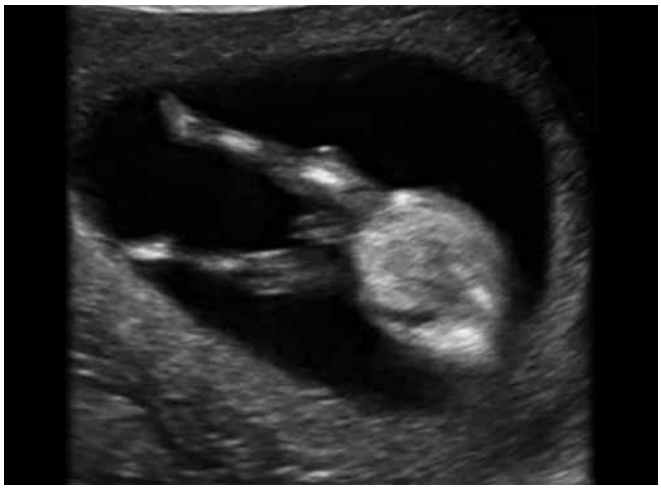

**Fig. 9:** Fetal lower limbs

## IMAGE RECORD AND REPORTS

An examination report should be produced as an electronic or paper document; such document should be stored locally and made available to the patient and referring healthcare provider.[1] Images should also be obtained and printed/stored as part of the document.

## SAFETY CONSIDERATIONS

Fetal exposure time and power output should be minimized according to the as low as reasonably achievable (ALARA) principle[1]. For safety reasons, color Doppler should not be used for routine scan, but can be useful in dedicated studies.

## THE FUTURE OF THE FIRST TRIMESTER SCAN

During the first trimester of pregnancy, the patients can be identified as being at low or high risk for pregnancy complications.[18] The surveillance of the pregnancy can be therefore programmed on the basis of this first classification.

The first-trimester scan will be useful for this purpose, in combination with other parameters (physical, biochemical) in different algorithms.

The study of cell free fetal DNA in maternal blood will eventually change the method for the detection of aneuploidies in the first trimester of pregnancy, although ultrasound will continue to be a very important source of information on this respect.

Finally, the early assessment of fetal anatomy will remain a paramount objective of the first-trimester scan.

## SUMMARY: OBJECTIVES FOR THE FIRST-TRIMESTER SCAN

- For basic scan:
  - — Viability
  - — Estimation of gestational age
  - — Number of fetuses:
    - – Chorionicity
    - – Amnionicity
  - — Assessment of:
    - – Placenta
    - – Uterus
    - – Adnexa
- Recommendations for anatomical survey: Routine assessment of at least the 8 planes described above for a correct evaluation of the fetal anatomy during the first trimester of pregnancy.
  - – Mid-sagittal view of the fetus
  - – Profile of the fetal head
  - – Axial plane of the fetal head
  - – Thorax
  - – Abdomen
  - – Abdominal wall
  - – Upper and lower limbs.
- Recommendations for screening of aneuploidies.[12]
  - – A priori maternal-age based risk.
  - – Routine: Nuchal translucency + early anomaly scan.
  - – If possible: Nasal bone + DV or TR.

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# 3. Guidelines for the Assessment of Gestational Age

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## Importance

Accurate assessment of gestational age is invaluable for the management of pregnancy. Avoidance of the complications of postmaturity is dependent upon accurate assessment of gestational age. Knowledge of gestational age is required to determine if a fetus in the third trimester is large for gestational age or growth restricted. Accurate dating is essential for the avoidance of iatrogenic prematurity when planning scheduled cesarean delivery or induction of labor and may also decrease the need for post-term induction of labor.[1] Survival near the limit of viability is highly dependent on gestational age, thus this information is important for both clinical decision-making and counseling patients. Furthermore, specific screening tests in pregnancy are dependent on accurate gestational age assessment. Biochemical screening for aneuploidy or neural tube defects is highly dependent on gestational age.

Multiple methods for assessing gestational age are available. The methods differ in accuracy, cost, and need for resources and trained personnel. Where available, the history and physical exam have been supplanted by ultrasound.

## History

The estimated date of delivery is 266 days from the date of conception and generally assumed to be 280 days from the LMP. Gestational age can be estimated by history. The most traditional method for determining gestational age is 'Naegele's rule' which obtains the EDC by adding 7 days to the last menstrual period and counting back 3 months. Accurate assessment of gestational age in this way requires patient's knowledge of her LMP, regular cycles, adjustment for a longer or shorter cycle length, and absence of first trimester bleeding (which could be mistaken for menstruation.) Furthermore, large studies have questioned the accuracy of the rule and use of Naegel's rule increases post dates induction.[2] While dating by history may provide useful clinical information, it should NOT be the only method for determining EDC when ultrasound is available.

## Clinical Assessment

Physical examination is an important part of pregnancy care and a crude estimation of gestational age can be made by pelvic exam in the first trimester or assessment of fundal height thereafter. At approximately 12 weeks, the uterus can be palpated above the pubic symphysis, at 16 weeks the uterus is midway between the pubic symphysis and the umbilicus, at 20 weeks the uterus is at the umbilicus and afterward gestational age corresponds to the measurement of fundal height in centimeters from the pubic symphysis.[3] While such measurements help approximate gestational age the error is between 2 and 8 weeks and is therefore unreliable for dating a pregnancy.[4]

## First Trimester Ultrasound

It is well established that fist trimester ultrasound assessment of gestational age by crown rump length is the most accurate ultrasound tool. It is more accurate than dating by LMP, clinical dating or dating in the second trimester.[5] Both the Society of Obstetricians an Gynecologists of Canada and the British National Institute for Health and Clinical Excellence guidelines recommend routinely offering first trimester ultrasound for dating to reduce the incidence of induction of labor for prolonged pregnancy.[3,6] However, the American College of Obstetrics and Gynecology guidelines state that in the absence of an indication for a first trimester ultrasound, ultrasound for dating may be performed between 18 and 20 weeks.[7,8] Because of the value in early determination of twin pregnancy, determination of chorionicity in twin pregnancy, and screening for aneuploidy by nuchal translucency there is often value in a first trimester ultrasound. In these cases, an assessment of gestational age should be part of the routine examination.

First trimester ultrasound may be performed either transvaginally or transabdominally. Landmarks may be easier to visualize transvaginally. However, in the presence of visualization of landmarks transvaginal ultrasound is not more accurate.[9]

The first trimester CRL is the most accurate measurement of gestational age and should be used as soon as the embryonic pole is identified until 14 weeks or the CRL reaches 84 mm.[8] A mean sac diameter is not as accurate and should not be used to date a pregnancy when a CRL is available. The CRL is obtained by imaging the fetus in a mid sagittal plane and placing calipers to measure the longest distance (Fig. 1). Three measurements should be obtained and averaged. The software on most ultrasound machines will also provide an estimate of gestational

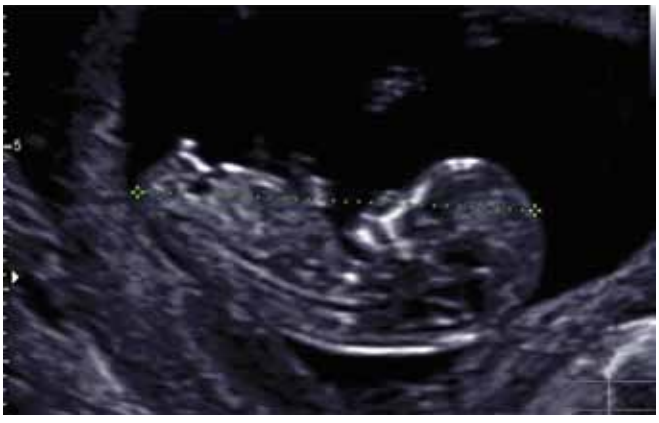


**Fig. 1:** Crown rump length demonstrating assessment of gestational age

age based on CRL. Alternatively, the gestational age can be calculated by referencing a table. When the CRL is less than 25 mm, the gestational age in days may be approximated by the CRL +42.[10]

## Second Trimester Ultrasound

After 14 weeks, gestational age is typically calculated by measurement of four biometric parameters. The parameters which are traditionally measured to calculate gestational age are the biparietal diameter (BPD), head circumference (HC), femur length (FL) and abdominal circumference (AC).

The measurements of head circumference and BPD should be obtained in the same plane (Figs 2A and B). The thalami and cavum septum pellucidum should be visualized; however the cerebellum should not be in the imaging plane. The calvarium should appear smooth and symmetrical. The head circumference is obtained by placing calipers on the outer edges of the calvaria and adjusting an ellipse to fit around the head without the scalp. The BPD is measured by placing calipers on the outer edge of the proximal wall of the calvarium and the inner edge of the distal wall and measuring the straight line between them.[11]

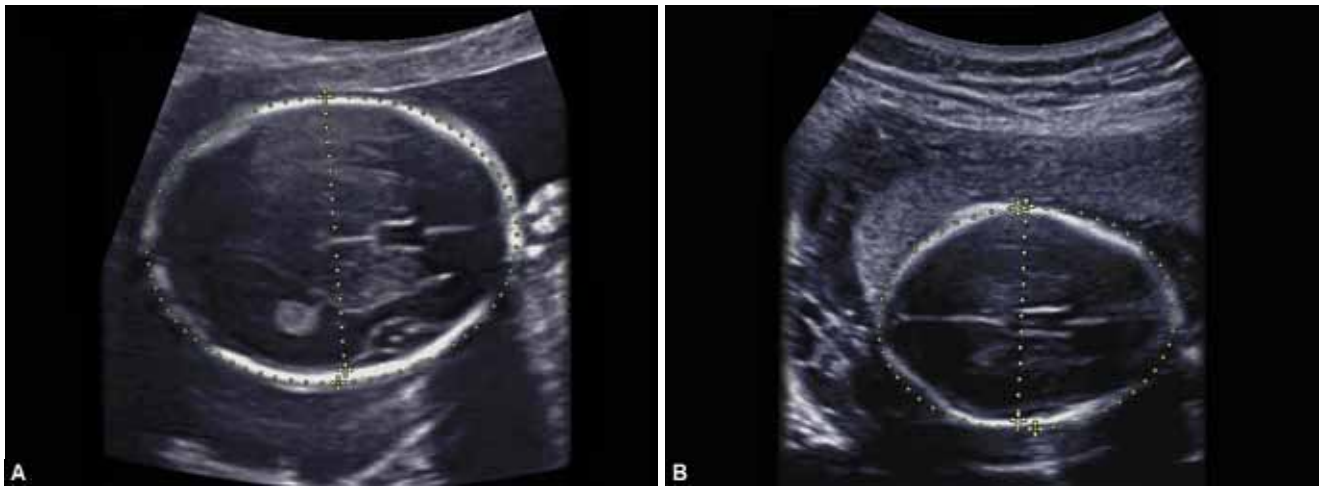
The femur length is measured by aligning the long axis of the femur with the transducer. The calipers are placed with both ends of the ossified metaphysis visible[11] (Figs 3A and B). Measurement of the distal femur may provide an anomalously short measurement (Fig. 3A). Although femur length correlates with gestational age within 1 week prior to 22 weeks, it correlates less well as gestation progresses and has a large ethnic variability later in gestation.

The abdominal circumference is measured by adjusting an ellipse to fit around a transverse section of the abdomen in a plane in which the liver, stomach, and umbilical vein is visualized at the level of the portal sinus[11] (Figs 4A to C). The image should be as circular as possible and should not be deformed by pressure form the ultrasound probe.

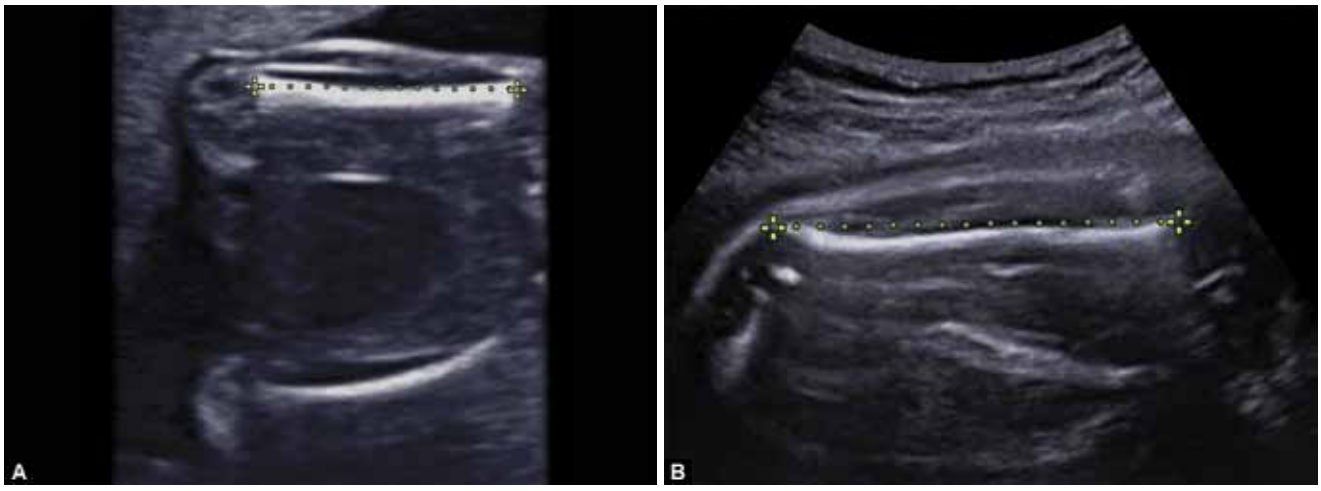
When measurements are properly performed the gestational age should be accurate to within 7 days prior to 22 weeks. The head circumference is the most reliable measurement of gestational age. However, accuracy is improved when measurements are used in combination.[12]

## Third Trimester Ultrasound

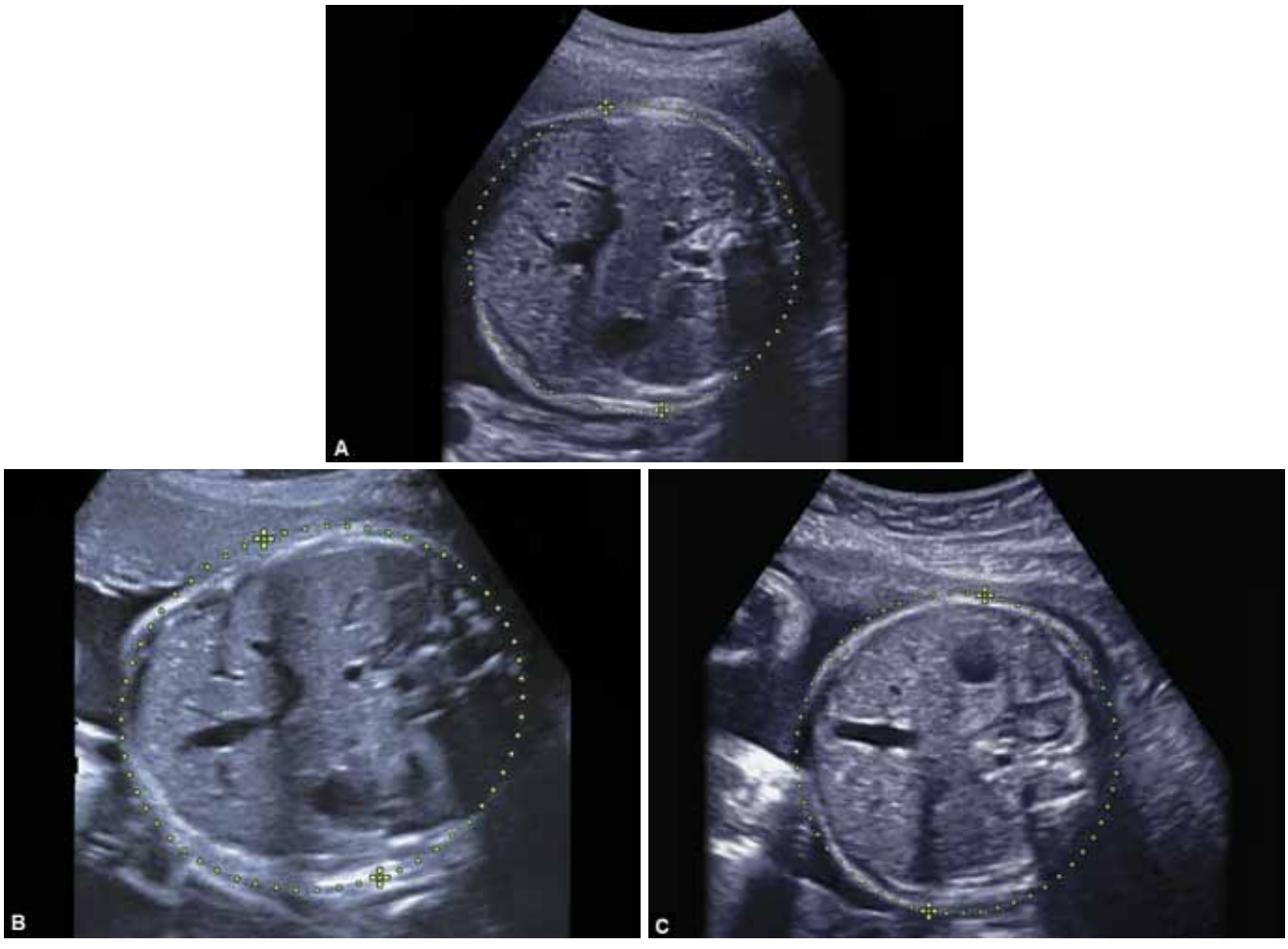
Due to both biologic variability and risk of anomalous fetal grow, ultrasound later in pregnancy correlates less well with gestational age. The gestational age is assigned by assuming the fetus is at the mean size. Therefore, error is introduced by biologic variability and fetuses that are either SGA or LGA. In the third trimester, assessment of gestational age by ultrasound may be differed from gestational age by up to 3 weeks.[13] When an EDC must be assigned in the late second or third trimester, a follow-up ultrasound should be performed at least 2 weeks later to ensure appropriate interval fetal growth. Furthermore, other measurements may be included to help assign gestational age late in gestation. The transverse cerebellar




**Figs 2A and B:** Measurement of HC and BPD demonstrating symmetric contour, cavum septum pellucidum and thalami and (B) this measurement is too superior. The thalami are not visualized




**Figs 3A and B:** (A) Measurement of femur length demonstrating caliper placement on osseous portions of diaphysis. Artifactual bowing of the distal femur can be seen in this image and (B) overmeasurement of femur length due to not clearly identifying the metaphysis




**Figs 4A to C:** (A) Abdominal circumference at a plane in which the liver, stomach and junction of portal veins are visualized, (B) in this oblique image the spine is not transverse and (C) in this image the umbilical vein is too close to abdominal wall and cord insertion site. This image is inferior to the appropriate plane

diameter is one such measurement which has been shown to perform well correlating within 5 days of actual gestational age up to 36 weeks. This measurement is taken by imaging the cerebellar hemispheres in an oblique plane through the posterior fossa that includes the midline thalamus and cisterna magna. The calipers are placed on the outer edges of the cerebellum and a published nomogram is used to determine gestational age.[14]

## Redating a Pregnancy

The EDD obtained by a patient's known LMP corrected for cycle length is a reasonable estimate of gestational

age. However, when the gestational age differs by greater than 5 days in the first trimester or 7 days prior to 22 weeks, the pregnancy should be redated based on ultrasound criteria.[15] The pregnancy should not be redated by a subsequent ultrasound as biologic variability only increases (Flow Chart 1).

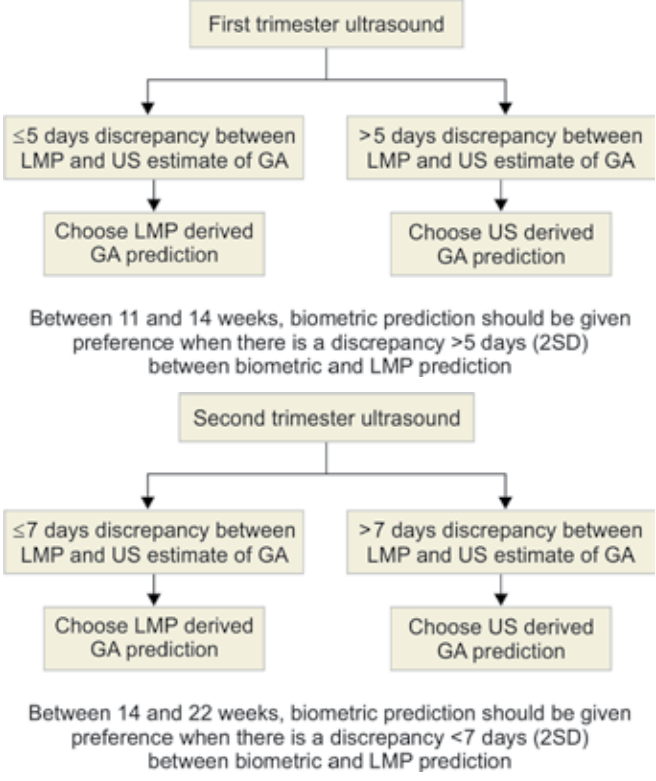
### Other Considerations

When the date of conception is known as with use of artificial reproductive technologies the EDD should be calculated based on this date. Accuracy requires knowledge of the age of the embryo and the date of transfer.[1]

### Recommendations

- Ultrasound should be used to determine or confirm EDC.
- Patients should not be redated by ultrasound after an ultrasound determination of EDC has been made.
- First trimester ultrasound for dating with CRL should be obtained for patients who meet any of these criteria:
  - Undergoing ultrasonography in the first trimester.
  - Uncertain dating by history due to irregular or unknown menstrual dating.
  - Discrepancy between dating by LMP and dating by physical examination.
  - Patients at risk for growth restriction due to medical illness (chronic hypertension and diabetes).
- For patients who do not meet the above criteria dating may be obtained at an 18 to 20 weeks ultrasound.

**Flow Chart 1:** Algorithm for determining the best gestational age in the first and second trimester




- Head circumference is the single best measurement to assign gestational age.
- In the first trimester ultrasound is accurate to within 5 days. In the second trimester ultrasound is accurate to within 7 days.

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# 4. Ethics in Prenatal Ultrasonographic Diagnosis

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## INTRODUCTION

According to various research groups working under the auspices of the World Health Organization (WHO), prenatal diagnosis refers to any prenatal method aimed at detecting and/or diagnosing a congenital defect, i.e. any anomaly present at birth (although it may appear later) in relation to the morphological, structural, functional or molecular development, which can be external or internal, steady or sporadic, hereditary or otherwise, and unique or multiple'. Chromosomal impairments and malformations therefore fall within the scope of prenatal diagnosis, as does any other type of disorder affecting fetal development and functionality.

In practice, a distinction should be made between 'suspicion', 'detection' and 'diagnosis'. While the first term only refers to the presence of indirect and presumptive signs of fetal impairments, detection is related to the location (by ultrasound, biochemistry, etc.) of a specific impairment, and diagnosis to the identification of a determined congenital defect.

We now have the technology to detect and diagnose most congenital defects. However, even though the diagnostic ability approaches 100% in many areas, it is sometimes much more limited. Such methods can be accompanied by a series of difficulties arising from the current disproportion that exists between diagnostic capacity and the actual therapeutic possibilities (insufficient at present).

This report is only concerned with the ultrasonographic techniques which make it possible to suspect, detect and/or diagnose those morphological anomalies that present sufficient ultrasonographic evidence. The report also deals with the ethical and legal issues related to the performance of such invasive tests.

Several reasons account for the fact that so many ethical, social and legal conflicts have developed in this area; these reasons are the complexity of the issue at stake (there are thousands of different congenital defects), the degree of sophistication of the technology required (which involves heavy investments by hospitals), the need for specialists in prenatal diagnosis (which not all gynecologists are), the social exclusion of people suffering from a deficiency and, above all, the ideological background underlying the decision-making process.[1]

## LEGAL ISSUES

Based on the premise that any prenatal diagnosis procedure is a 'medical act', it may only be legally permitted provided that it complies with the three basic requirements described below:

1. The physician who carries out the test must hold the appropriate qualification.
2. The specialists (obstetricians, radiologists, etc.) must also have undergone sufficient training in carrying out such tests, which involve a degree of risk to the mother and to the fetus that lies within the normal range.
3. The consent of the patient must be obtained. The notion of 'informed consent' should not be regarded solely as an ethical requirement, but also as a legal requisite.[2,3]

In some countries, ultrasonographic examination may be performed (either in whole or in part) by non-medical staff. However, the specialized physician (either a gynecologist or a radiologist) in charge of overseeing the scan is ultimately responsible for the examination and issuing a diagnosis, which he/she must also sign.

## GENERAL ETHICAL PRINCIPLES

There is a general consensus about the following principles:[4,5]

- In prenatal diagnosis, good practice should be guided by three basic principles: beneficence, autonomy and justice.
- All pregnant women (and their partners) are entitled to have access to objective information about the congenital defect risk and the possibilities of prenatal diagnosis.
- The information about current prenatal diagnosis methods should include the indications related to such methods, as well as any specific risks and alternative options available.
- The physician should not attempt to impose his own views on patients. He should inform them of all reasonable options.
- All ultrasonographic examinations should be carried out according to lex artis (sufficient experience, appropriate technology and suitable environment). If this is not possible, the patient should be referred to another level of care.
- The results of the explorations must be kept confidential and access to such results must be restricted.
- The physician's task does not end once diagnosis has been completed or, where appropriate, following termination of pregnancy. In fact, the physician

should endeavor at all times to provide relevant genetic counselling to the couple to help them in deciding between the options available.
- The physician should abide by any decision that the couple may make.

Ethical dilemmas normally arise at five different stages, which are all linked to prenatal diagnosis:
1. Upon disclosing the information.
2. Upon establishing the indication.
3. Upon performing the test.
4. Upon communicating the diagnosis.
5. Upon making any subsequent decision.

We will now set out to analyze the accepted method of practice, inappropriate practice and recommendations for situations of potential conflict, with regard to each of the stages mentioned above.

## INFORMATION

### Accepted Practice

- All preconception and pregnancy consultations should include information about the individual risks to the couple (or to each member of the couple) regarding the conception of a child with a congenital defect, as well as the existing means of prevention and the possibilities of prenatal diagnosis (ultrasonography, invasive tests, etc.) As a rule, the information given should be adapted to the age and the personal and family history of the couple.
- The preconception risk is chiefly assessed according to the age of the couple, their personal history (such as having another child affected by a congenital defect, balanced translocation in parents; etc.), their family history (affected first-degree relatives) and their environment. The risk during pregnancy is calculated (risk index) according to the above factors and to the results of screening tests, especially biochemical screening and ultrasound screening (nuchal translucency and other ultrasonographic signs). It should be stressed that the definitive diagnosis regarding the presence or absence of chromosomal disorders in the fetus is carried out by means of an invasive test designed to determine the fetal karyotype.
- Information given should include a list of the various methods available for detection and prenatal diagnosis together with a detailed explanation of the methods advisable in each particular case.
- The sonologist should advise, about the existence of maternal blood test capable of detection of chromosomal anomalies.
- The content of the information should be clear; comprehensive, easily understandable and consistent with the patient's personal characteristics (idiosyncrasy, culture, etc.).

### Inappropriate Practice

The following should be avoided:
- Failing to inform the patient about congenital defect risks and about the prenatal tests available for detecting such risks, whether on ideological grounds (such as for religious reasons) or simply because of professional negligence.
- Providing biased information (such as underestimating congenital defect risks or overestimating the risks linked to the tests).
- Providing partial or incomplete information on the actual possibilities of each test (what it does and what it does not do).

### Recommendations for Situations of Potential Conflict

If the couple expressly state their refusal to resort to prenatal diagnosis methods, the physician must respect their choice, provided that he has previously made sure that it is based on a free and informed decision. This, however, should not stop the physician from requesting the patients to sign a 'non-consent' statement.

Any medical information about the genetic disease of a patient is absolutely confidential and cannot be disclosed to any member of the family without the patient's explicit consent. However, the physician should advise the affected couple to inform those members of the family that play a crucial role in ensuring that the prenatal diagnosis is carried out appropriately.

## INDICATIONS FOR THE TESTS

### Accepted Practice

- Both the number and the chronology of the ultrasonographic examinations to be performed are determined according to the indication and outcome of each case.
- For ethical reasons, a policy of excessive indications should be avoided. In general, the protocols and/or recommendations of the country concerned should be complied with.
- In assessing the risk of a chromosomal anomaly, the indication for a particular test (for detection and/or diagnosis purposes) depends basically on the age and the history of the pregnant patient. If the pregnant patient has a low risk (patients under 35 years of age and with no personal or family history), a non-invasive test is suggested (biochemical or ultrasound test) for evaluating the risk index. Only if the risk

index is greater than 1/270 would an invasive test be justified. If the pregnant patient is considered a high-risk individual, i.e. over 35 to 38 years of age with a proven history, or if the risk evaluation tests point to an index greater than 1/270, an invasive test would be indicated.
- The choice of a specific method (amniocentesis, chorionic biopsy or cordocentesis) is made on the basis of the indication, the age of the patient and the experience of the physician.

### Inappropriate Practice

The following should be avoided:
- Indicating a method (ultrasonography, etc.) which is not the most suitable due to personal limitations (lack of experience) or to poor resources in the medical facility (single-member private medical care, low standards, etc.).
- Indicating invasive tests without any specific indication (unethical policy regarding indications). The reasons for this are multiple: they may be related to economic motives (especially in the private medical sector), incomplete information given to the patient (inappropriate balance of risks/benefits), erroneous indications (such as an indication due to teratogens), or a masked study.
- Failing to recommend invasive tests in cases where they should be indicated on the basis that a 1/100 or 1/200 index is a low risk. The threshold point should not be modified because of opinions of the physician (in which case inaccurate information would be provided).
- Unduly delaying the diagnosis (through negligence, ideological convictions, etc.) until the legal time limit for abortion has been reached, thus increasing the level of risk in connection with late abortion.

### Recommendations for Situations of Potential Conflict

The indication of maternal anxiety to perform a prenatal diagnostic test will only apply where, after providing accurate information to the patient, the state of anxiety persists. If the anxiety suffered is severe, the intervention of a specialist might be required.

As a rule, invasive prenatal diagnostic tests should not be carried out unless there are strictly medical indications. Except in the case of genetic diseases, any request for a test to determine the sex of the fetus should be rejected, especially if there is a strong suspicion that the patient might request an abortion depending on the results of the tests. Choosing the sex of a fetus infringes the principle of equality between genders.

Only in exceptional cases (judiciary order, severe pathological situations, etc.) will a request for a prenatal paternity test be satisfied.

If a test is required as a result of a correct medical indication, it must be carried out even if the couple states that they will only use the results for information purposes, and that under no circumstances will they decide to terminate the pregnancy. The couple is entitled to be informed of their situation, regardless of what decision they make afterwards.

The standards of each country will serve as a basis for determining the threshold point (age, risk index, etc.) at which invasive tests become justified.

## PERFORMING THE TESTS

### Accepted Practice

- The operator (a sonographer or sonographist) should be sufficiently qualified and experienced to obtain as much information as possible from the ultrasonographic examination.
- The technique must be performed with an appropriate level of care. The standards of ultrasonographic safety must be observed in all cases.
- The ultrasonographic examination must be carried out in an appropriate environment (with privacy, peace of mind, reduced family pressure, etc.), under the supervision of a suitable technical team and using an appropriate screening method (following a specific protocol). The overall structure of the care center should provide the time and resources necessary while respecting the dignity of patients at all times.
- Invasive prenatal diagnosis, given the specific risk it involves, can only be carried out by skilled professionals working within a suitable technological infrastructure and medical environment. In fact, most hospitals have a dedicated prenatal diagnosis section or unit.
- The decision to use a particular method must be made on the basis of the objective characteristics of each case (age of the pregnant patient, indication, etc.), and not solely on the basis of the technical experience of the physician. A series of semi-objective criteria (number of test carried out, etc.) are now available for assessing the physician's experience.
- If the physician does not have the required experience and/or if the appropriate technology is not available, the patient should be referred to a prenatal diagnosis center with proven experience. Such a referral should be decided on the bases of health considerations, and not on economic grounds.
- Before carrying out the test, the physician should have a conversation with the couple to explain to them

the reason for performing the test, the possible risks involved and the precautions that should be taken. He should also comply with the appropriate procedure.

### Inappropriate Practice

The following should be avoided:

- Carrying out the test without the necessary experience, as this could increase the level of risk.
- Carrying out the invasive test in a negligent manner or with scant diligence (incomplete asepsis, etc.).
- Failing to take the steps required to ensure the safety and confidentiality of the testing and of the ensuing results (promiscuity between patients, verbal information given in public, mistakes, interchanging results, backing up the information in an inappropriate way, etc.).

### Recommendations for Situations of Potential Conflict

It is absolutely right for a care center to carry out invasive prenatal diagnosis even when it cannot provide patients with legal abortion facilities afterwards (such as religious hospitals or hospitals whose practitioners have declared their conscientious objection to abortion), provided that such a restriction has been previously notified to the couple.

Invasive prenatal diagnosis must only be performed in those hospitals, whether public or private, that have the appropriate equipment to ensure maximum safety for the patient and the fetus. Accordingly, the staff must be trained to carry out the tests and resolve any problem that may arise in the process.

## COMMUNICATING THE DIAGNOSIS

### Accepted Practice

- In addition to being duly notified in writing, the diagnosis (normal and/or pathological) must be communicated verbally to the patient, in person, by a member of the medical staff. It is desirable that the person responsible for informing the patients of the diagnosis be the obstetrician in charge of the case, since he knows all the aspects of the case, including the idiosyncrasy of the patients.
- The practitioner should be adequately trained in this area, and if this is not the case, he should seek the assistance of a specialist more skilled in informing patients.
- The information should be communicated in a way that can be easily understood by the couple, particularly in the case of a pathological diagnosis. In other words, the information should take their personal circumstances into account while being explained in plain language.
- In some cases, the prognosis and the options available should not be confirmed until all necessary additional screenings have been carried out.
- Where necessary, special psychological support should be provided. Including social services assistance in some cases, in addition to the assistance and emotional support given by the attending physical.
- In any case, the focus should be on ensuring that the patients are treated by the same member of staff throughout their stay in hospital (to avoid mistakes and any possible disagreement), while allowing them to have a second opinion (from a list of specialist physicians or centers).

### Inappropriate Practice

The following should be avoided:

- Untimely communication of the diagnosis by unqualified staff, or by members of staff who do not know the particulars of the case in question.
- Communicating the information by telephone or fax, via third parties or by any other indirect means, thereby increasing the chances of a misunderstanding while jeopardizing the confidentiality of the diagnosis.
- Communicating the diagnosis with too much haste, without previously analyzing and examining the case, a situation which Is likely to five rise to errors in terms of diagnosis.
- Failing to provide the appropriate psychological support, thus increasing the chance of chronic grief.

### Recommendations for Situations of Potential Conflict

Wherever possible, it is recommended that the specialist physician (sonographer, geneticist, etc.) avoid making any additional diagnosis related decision (such as carrying out an invasive test following the detection of an ultrasound marker) and/or any therapeutic decision without the opinion and approval of the treating obstetrician.

It is desirable that the obstetrician in charge of the patient's care be informed as soon as possible of any pathological diagnosis, so that he can inform the patient of the results, in person and in due time.

The results of the prenatal diagnosis must be treated as confidential, just like the rest of the hospital records. Furthermore, each care center and practitioner must take any steps necessary to restrict access to this information to the authorized staff only.

## DECISION-MAKING FOLLOWING DIAGNOSIS

### Accepted Practice

- Before issuing any diagnosis and suggestion alternative options to the couple with a view to helping them make their decision, all the different possibilities available for reaching a consistent diagnosis and for indentifying the strategy to be followed must be explored.
- The case must be examined by all the specialists involved (geneticist, sonographer, obstetrician, neonatologist, etc.), where possible, within the framework of a hospital committee. The aim is to examine the results of the tests carried out while evaluating the risks and advantages of any decision and option.
- It is needless to say that the information provided to the couple regarding the issues mentioned above should be easily understandable, clear, complete, and suited to their personal circumstances. This information is designed to help the couple decide freely and in accordance with their needs and beliefs. The information will be provided within the scope of genetics or reproductive health and, as such, must include relevant information about the reproductive health outlook for the couple (possibilities and options).
- The couple should be reminded of the need to carry out an autopsy study in case of fetal death or legal abortion to confirm the prenatal diagnoses, and the need to follow-up the case in an appropriate manner.
- After explaining the diagnosis, prognosis and available options, the physician must, within the limits of the law, fully respect the decisions made by the patient (or the couple). If the hospital or its practitioners have duly stated their conscientious objection, the case must be referred to another hospital or practitioner which has not declared any conscientious objection. In all cases, the patients should be able to seek a second opinion. The psychological assistance provided to patients should be aimed at supporting their final decision.

### Inappropriate Practice

The following should be avoided:

- Unduly delaying the decision as to whether to terminate pregnancy, thereby giving rise to an increase in the risk of complications, given that late abortion (in particular, illegal abortion) is more dangerous.
- Giving one-sided advice that emphasizes one single option (legal abortion), without discussing any other alternatives with the couple.
- Causing the patient to opt for termination on the basis of mere conjecture (absence of any relevant prenatal study), or for trivial reasons (such as an alleged exposure to teratogens).
- Failing to recommend legal termination in cases of severe fetal pathology, while underestimating the problems caused to the child in the future.
- Providing inaccurate or negligent information regarding the outcome and prospects of the necropsy study.
- Carrying out legal termination of pregnancy without taking the samples necessary for carrying out a subsequent study of the product (necropsy and cytogenetic study). Such practices will make it impossible to confirm the prenatal diagnosis or provide adequate counselling to the couple.

## RECOMMENDATIONS FOR SITUATIONS OF POTENTIAL CONFLICT

The information provided regarding any possible options must not be based on the ideology and/or religious beliefs of the physician, or indeed on those of the patient or couple. If the patient wishes to obtain information about specific religious criteria, she must be asked to request it from the relevant authorities (priests, etc.). Ultimately, it is the patient's sense of right and wrong that will determine any subsequent moral decision. Accordingly, the patient's principles should be respected at all times, and no attempt whatsoever should be made to manipulate the patient whether directly or indirectly.

## THE DECALOGUE OF PRENATAL ULTRASONOGRAPHIC DIAGNOSIS

As a conclusion, we recommend the following commandments of prenatal ultrasonographic diagnosis:

- All pregnant women should be examined by ultrasonography.
- All fetuses have some congenital structural defects, unless evidence is provided to the contrary. This evidence can only by provided carring out a systematic examination of fetal phenotype.
- The results obtained are depend upon working conditions and, above all, the experience and training of the sonologist.
- The sonologist who does not know what he is looking for, does not know or understands what he doing.
- Sonologists should not be satisfied with merely having detect a malformation. It is necessary to establish a possible syndromic diagnosis (look for other anomalies) and carry out complementary tests (cytogenetic biochemical studies).

- A quality ultrasound should always be preformed.
- Sonologists working in a hospital should have the support of a multi disciplinary team.
- Sonologists should always consider the psychological state of the pregnant women, as well as the ethical al legal aspects of each case.
- Decisions should not be made without having first, clearly defined, the disorders of the fetus. If the congenital defect is compatible with life, parents would be advised to obtain consultation from pediatric specialists.
- A detailed post-mortem examination should be carried out. The purpose of course is to provide appropriate counselling and the control of quality.

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