

Updated DEGUM Quality Requirements for the Basic Prenatal Screening Ultrasound Examination (DEGUM Level I) between 18 + 0 and 21 + 6 weeks of gestation

Aktualisierte Qualitätsanforderungen an die Ultraschall-Screeninguntersuchung in der pränatalen Basisdiagnostik (=DEGUM-Stufe I) im Zeitraum 18+0 bis 21+6 Schwangerschaftswochen

Authors

Christiane Kähler¹, Thomas Schramm², Rainer Bald³, Ulrich Gembruch⁴, Eberhard Merz⁵, Karl-Heinz Eichhorn⁶

Affiliations

- 1 Obst Gyn, Practice of prenatal medicine Erfurt, Germany
- 2 Ultrasound, Prenatal Medicine München, Germany
- 3 Prenatal Medicine, Klinikum Leverkusen gGmbH, Leverkusen, Germany
- 4 Obstetrics and Prenatal Medicine, University-Hospital, Bonn, Germany
- 5 Center for ultrasound and prenatal medicine, Frankfurt am Main, Frankfurt, Germany
- 6 Gynecology and Obstetrics, Practice of prenatal medicine Weimar, Germany

Key words

prenatal diagnosis, second trimester, level I examination, quality requirements

received 08.05.2019

accepted 11.09.2019

Bibliography

Ultraschall in Med 2020; 41: 499–503

Published online: January 3, 2020

DOI 10.1055/a-1018-1752

ISSN 0172-4614

© 2020. Thieme. All rights reserved.

Georg Thieme Verlag KG, Rüdigerstraße 14,
70469 Stuttgart, Germany

Correspondence

Dr. Christiane Kähler

Obst Gyn, Practice of prenatal medicine Erfurt, Anger 81,
99084 Erfurt, Germany

Tel.: ++49/3 61/64 43 05 40

kaehler@praenatalmedizin-erfurt.de

ABSTRACT

A precondition for the early detection of fetal abnormalities is the high quality of prenatal basic ultrasound (screening examination). The objective of ultrasound screening is the recognition of abnormal fetal growth and fetal anatomical anomalies. The prenatal detection of fetal abnormalities enables detailed

prenatal counselling of parents, improved care at birth and potentially a reduction in morbidity and mortality. In the guidelines for maternity care in Germany (“Mutterschaftsrichtlinien”), the performance of basic ultrasound in pregnancy is not clearly defined. The required image documentation includes a few biometric measurements only. Therefore, adherence to a standard technique and the possibility of audit are limited, thus not necessarily resulting in high screening quality. In this update of the DEGUM quality requirements for level I screening ultrasound examination between 18 + 0 and 21 + 6 weeks of gestation, the required parameters, standard planes and required documentation are described in detail. The greater experience of gynecologists in the field of sonographic screening examinations and the use of a modern ultrasound technique allow improvement of the screening quality. This will improve the standard of basic ultrasound screening. Due to the enhanced standard of the DEGUM I examination, more pregnant women may benefit from a detailed ultrasound examination and specialized therapy in DEGUM level II and III centers. The required fetal structures are described in detail. This update of the requirements for level I DEGUM basic ultrasound examination between 18 + 0 and 21 + 6 weeks of gestation goes far beyond the guidelines for maternity care in Germany (the “Mutterschaftsrichtlinien”) thereby elevating standards.

ZUSAMMENFASSUNG

Eine hohe Qualität der pränatalen Basisdiagnostik in den Ultraschall-Screeninguntersuchungen ermöglicht eine Steigerung der Qualität der Untersuchung und somit die frühzeitige Erkennung fetaler Störungen. Aufgabe des Screenings ist die Detektion von Hinweiszeichen auf fetale Erkrankungen, Entwicklungsstörungen oder Fehlbildungen. Deren pränatale Diagnose führt in vielen Fällen zu einer Verbesserung der Therapiemöglichkeiten, der Lebensqualität der betroffenen Kinder und Senkung der perinatalen Mortalität und Morbidität. In den deutschen Mutterschaftsrichtlinien sind die Leistungsinhalte der Ultraschall-Screeninguntersuchungen nicht klar definiert. Die geforderte Bilddokumentation umfasst lediglich die Biometrie. Dies erschwert das Erreichen und die Ein-

haltung einer hohen Qualität sowie die Qualitätskontrolle. In den aktualisierten Empfehlungen für die DEGUM-Stufe-I-Untersuchung zwischen 18 + 0 und 21 + 6 Wochen werden die Inhalte dieser Untersuchung und deren Dokumentation dagegen detailliert beschrieben. Die gestiegene Erfahrung der Untersucherinnen und Untersucher und die Verwendung einer modernen Ultraschalltechnik bereits im Screening ermöglichen eine Steigerung der Qualitätskriterien und somit eine Stärkung der pränatalen Basisdiagnostik. Durch die Erhöhung der Qualität der DEGUM-Stufe-I-Untersuchung können

mehr Schwangere von einer gezielten weiterführenden Diagnostik und Therapie in Stufe-II- und -III-Zentren profitieren. Die vorliegenden DEGUM-Empfehlungen entsprechen deshalb wesentlich besser den heutigen Möglichkeiten und Erfordernissen einer Ultraschalluntersuchung im zweiten Trimenon. Sie ermöglichen eine hochwertige Ultraschall-Screeninguntersuchung, die sich durch die genaue Definition der darzustellenden fetalen Strukturen qualitativ und quantitativ von den Mindestanforderungen der derzeit gültigen Mutterschaftsrichtlinien abhebt.

Significant advances in quality assurance (minimum requirements) have been achieved on a high level as a result of concrete quality requirements and their subsequent update for secondary differentiated DEGUM level II ultrasound examinations in the first and second trimester [1–3].

In many cases, early prenatal diagnosis of fetal diseases, developmental disorders and malformations results in improvement of treatment options and the quality of life of affected children and in a decrease in perinatal mortality and morbidity. Since more than 80% of affected pregnant women do not belong to a risk group, early diagnosis can only be achieved by means of thorough ultrasound screening.

The minimum requirements defined in the guidelines for maternity care in Germany (“Mutterschaftsrichtlinien”) (appendix 1a, 2b) [4] correspond to the quality requirements for DEGUM level I from 2006 [5]. “IIb screening” includes the visualization of deviations from the normal sonoanatomy of fetal structures, documentation of abnormalities, and initiation of any necessary secondary examinations. The lack of clear definitions of the tasks to be performed and the lack of a documentation requirement are decisive disadvantages of IIb screening. This complicates quality control for the own further development and performance record.

Advanced ultrasound screening experience – particularly with respect to the most common fetal malformations, i. e., heart defects and urological anomalies [6–9] – as well as a modern ultrasound technique allow us, even when using today’s “basic equipment”, to elevate our quality criteria in modern screening according to the requirements for strengthening basic prenatal diagnostic assessment (Institute for Quality and Efficiency in Health Care) [10].

The present study provides gynecologists in Germany performing ultrasound screening in the second trimester as DEGUM level I examiners with a template including an updated definition of the tasks to be performed and the necessary documentation.

Abnormal screening findings are clarified in collaboration with specially trained and qualified examiners (DEGUM levels II and III) (multilevel concept) [11]. A major requirement for the success of this concept is high quality of DEGUM level I ultrasound screening examinations particularly in the period from 18 + 0 to 21 + 6 gestational weeks.

The updated recommendations for DEGUM level I examinations correspond significantly better to today’s options and requirements regarding ultrasound examinations in the second trimester. They

allow qualified DEGUM level I examiners to perform high-quality ultrasound screening examinations that achieve better quality than in the case of the minimum requirements of the currently valid guidelines for maternity care in Germany as a result of the exact definition of the fetal structures to be visualized.

The requirements for counseling pregnant women as part of ultrasound examinations are also defined in these recommendations.

The present updated quality requirements replace the DEGUM level I quality requirements from 2006 [5].

Objective

The concrete quality and qualification requirements for secondary differentiated ultrasound screening examination in the second trimester are formulated as minimum requirements for DEGUM level I [1, 2, 5, 11]:

- Improvement of the diagnostic assessment of signs of fetal anomalies and diseases as a result of systematic processing of a defined checklist.
- Strengthening of intradisciplinary collaboration with DEGUM level II and III examiners in secondary diagnostic assessment as part of the multilevel program (consultations, case conferences) [1, 11].
- Qualification of level I examiners to perform follow-up examinations of certain fetal anomalies depending on their experience and the ultrasound technique being used. This applies in particular to the third trimester since the guidelines for maternity care in Germany do not define any basic diagnostic procedures here. As a result, care can be provided by the same person in such cases.
- Target qualification for those learning prenatal diagnostic procedures and basis for subsequent DEGUM level II qualification
- Knowledge of the appropriate use of the 3 D/4 D technique in multiplanar imaging and 3 D surface rendering.
- Recording and observation of relevant risk factors in the patient’s history (including appendix 1c of the guidelines for maternity care in Germany) [4]

DEGUM level I examinations should continue to be performed as prenatal screening examinations, but, in contrast to ultrasound screening examinations according to the guidelines for maternity care in Germany, they should examine for concretely defined signs of fetal diseases, developmental disorders and malformations.

Tasks to be performed as part of diagnostic ultrasound assessment in obstetrics (checklist)

1. General (► Table 1)

- Vitality (cardiac activity)
- Multiples
 - Determination of the chorionicity and amnionicity (if still possible at this time and not already performed in the first trimester)
Detection of signs of twin-to-twin transfusion syndrome (amniotic fluid and bladder discrepancy, biometric discrepancy)
- Determination of the location of the placenta and structure of the placenta
Detection of placenta previa
Optional: Detection of velamentous cord insertion and/or vasa previa
- Cervical length – in case of suspicion of shortening (abdominal ultrasound < 35 mm) [12]: Transvaginal control
- Number of umbilical cord vessels
- Amount of amniotic fluid
Detection of oligohydramnios
- Fetal movement
Detection of restrictions like intrauterine constraint

2. Biometry (► Table 2)

Head

Biparietal (BPD) and fronto-occipital diameter (FOD) or head circumference (HC)
Cerebellum (transverse diameter)

Torso

Abdominal transverse diameter (ATD) and abdominal sagittal diameter (ASD) or abdominal circumference (AC)

Extremities

Femur length (FL) and humerus length (HL)
Optional: Measurement of the bones of the lower legs and forearms

Biometry interpretation

- Detection of disproportions
- Correction of due date ambiguities based on measured values (if the gestational age was not already confirmed in the first trimester)
- Detection of signs of fetal growth restriction and fetal macrosomia (particularly asymmetrical macrosomia)

3. Sonoanatomical tasks to be performed and detection of abnormal structural changes (signs) (► Table 3)

Head/brain

- Head shape
 - Detection of deviations from a normal head shape (e.g. brachycephaly or “lemon sign”)

► **Table 1** Checklist for DEGUM level I examination: General parameters.

- vitality
- determination of the location of the placenta and structure of the placenta
- cervical length (measurement if applicable)
- umbilical cord vessels
- amount of amniotic fluid
- fetal movement
- multiples: Chorionicity and amnionicity (if not already diagnosed in the first trimester)

► **Table 2** Checklist for DEGUM level I examination: Biometry.

- biparietal diameter (BPD) and fronto-occipital diameter (FOD) or head circumference (HC)
- cerebellum (transverse diameter)
- abdominal transverse diameter (ATD) and abdominal sagittal diameter (ASD) or abdominal circumference (AC)
- femur length (FL) and humerus length (HL)
- optional: Length of the bones of the lower legs and forearms

- Visualization of the falx cerebri with the cavum septi pellucidi
- Assessment of the ventricular width (measurement if needed)
Detection of liquid intracranial masses
- Visualization of both cerebellar hemispheres and the cerebellar vermis
Detection of deviations from the normal size and shape of the cerebellum (e.g. “banana sign”)
- Optional: Median sagittal section of the profile and coronal section of the upper lip

Neck

- Transverse section of the contour

Thorax

- Heart [13, 14]
 - Normal cardiothoracic ratio
 - Size (1/3 of the thorax area)
 - Position (2/3 of the heart is in the left half of the thorax, 1/3 in the right)
 - Cardiac axis tilted to the left approximately 45° (+/-15°)
 - Rhythm and contractility
 - Normal four-chamber view
 - Size of the atriums in relation to one another (approximately the same size)
 - Chambers in relation to one another (detection of the right ventricle with moderator band and increased trabeculation)
 - Position and function of the AV valves (the tricuspid valve inserts 1–2 mm more apical on the ventricular septum than the mitral valve)
 - Continuity of the ventricular septum

► **Table 3** Checklist for DEGUM level I examination: Sonoanatomy.

head/brain
<ul style="list-style-type: none"> ▪ ovoid head shape ▪ falx cerebri with the cavum septi pellucidi ▪ ventricular width (measurement if applicable) ▪ cerebellum: Hemispheres/cerebellar vermis ▪ <i>optional: Median sagittal section of the profile/coronal section of the upper lip</i>
neck
<ul style="list-style-type: none"> ▪ Transverse section of the contour
thorax
<ul style="list-style-type: none"> ▪ heart [13, 14] <ul style="list-style-type: none"> ▪ normal cardiothoracic ratio ▪ rhythm and contractility ▪ normal four-chamber view ▪ <i>optional: Normal left and right outflow tract</i>
<ul style="list-style-type: none"> ▪ lungs <ul style="list-style-type: none"> ▪ uniform echogenicity of both lungs
<ul style="list-style-type: none"> ▪ abdomen <ul style="list-style-type: none"> ▪ transverse section of the contour ▪ location of the stomach in the left upper abdomen ▪ evaluation of the echogenicity of the abdominal organs
<ul style="list-style-type: none"> ▪ kidneys <ul style="list-style-type: none"> ▪ longitudinal and transverse ▪ renal pelvis in the ap diameter
<ul style="list-style-type: none"> ▪ bladder <ul style="list-style-type: none"> ▪ ability to be visualized, size
<ul style="list-style-type: none"> ▪ back <ul style="list-style-type: none"> ▪ transverse and longitudinal section of the contour ▪ sagittal section of the spinal column

- Optional: Normal left and right outflow tract
 - Continuity of the ventricular septum in the outflow region
 - Ability to visualize the two great arteries and their crossing
- Lungs
 - Uniform echogenicity of both lungs
 - Detection of intrathoracic cystic structures, stomach and/or bowel dislocated into the thorax

Abdomen

- Transverse section of the contour
Detection of abdominal wall defects
- Determination of the location of the stomach in the left upper abdomen
- Evaluation of normal echogenicity of the abdominal organs
Detection of atypical fluid collection in the abdomen (ascites, cysts)

Urogenital tract

- Kidneys
 - Longitudinal and transverse visualization
Detection of atypical shape, size or atypical echo pattern of the kidneys
 - Visualization of the renal pelvis in the ap diameter
Detection of urinary tract obstruction
- Bladder
 - Visualization of the bladder, estimation of the size
Detection of megacystis

Back

- Transverse and longitudinal section of the contour
- Sagittal section of the spinal column

In the case of signs of fetal diseases, developmental disorders or anomalies or in the case of fetal structures that cannot be exactly visualized, quick transfer of the pregnant woman to a DEGUM level II or DEGUM level III center is expected (DEGUM multilevel concept).

Image documentation

Quality assurance and control require exact documentation of findings and images. Such documentation also serves as a performance record.

The following parameters should be recorded as standard image documentation (► **Table 4**):

- Biometry
 - Transventricular plane
 - Transcerebellar plane
 - Transverse section of the abdomen with stomach
 - Femur or humerus
- Sonoanatomy
 - Cerebellum
 - Four-chamber view (visualization of at least 1/3 of the image section)
 - Optional: Left and right outflow tract
 - Stomach
 - Kidneys and renal pelvis (ap)
 - Bladder
 - Spinal column (sagittal)

Any abnormalities detected during the examination are to be documented separately. The inability to visualize parameters should be documented in writing and secondary diagnostic procedures should be initiated.

Counseling pregnant women

Counseling prior to ultrasound examination

According to the quality standard for DEGUM level I diagnostic assessment, prior to expanded ultrasound screening examinations, patients must be informed of the possibilities and limitations of

► **Table 4** Checklist for DEGUM level I examination: Image documentation.

- biometry
 - transventricular plane
 - transcerebellar plane
 - transverse section of the abdomen with stomach
 - femur or humerus
- sonoanatomy
 - cerebellum
 - four-chamber view (visualization of at least 1/3 of the image section)
 - optional: left and right outflow tract
 - stomach
 - kidneys and renal pelvis (ap)
 - bladder
 - spinal column (sagittal)

the ultrasound screening examination [4]. It should be emphasized that these examinations are not secondary differentiated diagnostic ultrasound examinations.

During the informed consent discussion, the examination conditions should also be assessed and if applicable the significance of unfavorable viewing conditions should be explained (adipose or scarred abdominal wall, insufficient amniotic fluid, unfavorable fetal position). This informed consent discussion should be individualized and carefully documented.

Counseling following ultrasound examination

In the case of detection of signs of a fetal malformation or diagnosis of fetal diseases, developmental disorders or a malformation, in the case of difficult examination conditions or in the case of other indications for secondary differentiated diagnostic ultrasound examination, the pregnant woman should be informed of the options regarding secondary differentiated DEGUM level II or III ultrasound examination [1]. The informed consent discussion should also be documented.

Qualification requirement/general requirements/certification/recertification (DEGUM level I)

Refer to the detailed description of the qualification requirements, general requirements and the procedure for certification/recertification on the DEGUM homepage (gynecology and obstetrics section (www.DEGUM.de)).

Conflict of Interest

The authors declare that they have no conflict of interest.

References

- [1] Merz E, Eichhorn KH, von Kaisenberg C et al. Aktualisierte Qualitätsanforderungen an die weiterführende differenzierte Ultraschalluntersuchung in der pränatalen Diagnostik (=DEGUM-Stufe II) im Zeitraum 18+0 bis 22+6 Schwangerschaftswochen. *Ultraschall in Med* 2012; 3: 593–596
- [2] Rempfen A, Chaoui R, Häusler M et al. Quality Requirements for Ultrasound Examination in Early Pregnancy (DEGUM Level I) between 4+0 and 13+6 Weeks of Gestation, Qualitätsanforderungen an die Ultraschalluntersuchung in der Frühschwangerschaft (DEGUM-Stufe I) zwischen 4+0 und 13+6 Schwangerschaftswochen. *Ultraschall in Med* 2016; 37: 579–583
- [3] von Kaisenberg C, Chaoui R, Häusler M et al. Quality Requirements for the early Fetal Ultrasound Assessment at 11–13+6 Weeks of Gestation (DEGUM Levels II and III). Qualitätsanforderungen an die weiterführende differenzierte Ultraschalluntersuchung in der pränatalen Diagnostik (DEGUM-Stufen II und III) im Zeitraum 11–13+6 Schwangerschaftswochen. *Ultraschall in Med* 2016; 37: 579–583
- [4] Richtlinien des Bundesausschusses für Ärzte und Krankenkassen über die ärztliche Betreuung während der Schwangerschaft und nach der Entbindung („Mutterschaftsrichtlinien“) in der Fassung vom 10. Dezember 1985 (veröffentlicht im Bundesanzeiger Nr. 60a vom 27. März 1986) zuletzt geändert am 21. April 2016 veröffentlicht im Bundesanzeiger AT 19.07.2016 B5 in Kraft getreten am 20. Juli 2016.
- [5] Eichhorn KH, Schramm T, Bald R et al. Qualitätsanforderungen an die DEGUM-Stufe I bei der geburtshilflichen Ultraschalldiagnostik im Zeitraum 19 bis 22 Schwangerschaftswochen, DEGUM Grade I Quality Standards in Obstetric Ultrasound Diagnosis During the 19th – 22nd Week of Pregnancy. *Ultraschall in Med* 2006; 27: 185–187
- [6] Holland BJ, Myers JA, Woods CR. Prenatal diagnosis of critical congenital heart disease reduces risk of death from cardiovascular compromise prior to planned neonatal cardiac surgery: a meta-analysis. *Ultrasound Obstet Gynecol* 2015; 45: 631–638
- [7] Hindryckx A, de Catte L. Prenatal diagnosis of congenital renal and urinary tract malformations. *ObGyn* 2011; 3: 165–174
- [8] Van Velzen CL, Haak MC, Reijnders G et al. Prenatal detection of transposition of the great arteries reduces mortality and morbidity. *Ultrasound Obstet Gynecol* 2015; 45: 320–325
- [9] Dolk H, Loane M, Garne E. The prevalence of congenital anomalies in Europe. *Adv Exp Med Biol* 2010; 686: 349–364
- [10] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Ultraschallscreening in der Schwangerschaft: Testgüte hinsichtlich der Entwicklungsrate fetaler Anomalien. Abschlussbericht S05 – 03. IQWiG. Köln. 2008
- [11] Hansmann M. Nachweis und Ausschluss fetaler Entwicklungsstörungen mittels Ultraschallscreening und gezielter Untersuchung – ein Mehrstu-fenkonzept. *Ultraschall* 1981; 2: 206–220
- [12] Pandipati S, Combs CA, Fishman A et al. Prospective evaluation of a protocol for using transabdominal ultrasound to screen for short cervix. *Am J Obstet Gynecol* 2015; 213: 99.e1–13
- [13] Berg C, Geipel A, Gembruch U. Der Vier-Kammer-Blick in der fetalen Echokardiografie. *Ultraschall in Med* 2007; 28: 132–157
- [14] Berg C, Gembruch U, Geipel A. Die Ausflusstrakt-Schnittebenen in der zweidimensionalen fetalen Echokardiografie – Teil I. *Ultraschall in Med* 2009; 30: 128–149