

Jan 16, 2020

Algorithm for gestational age assessment at birth

DOI

dx.doi.org/10.17504/protocols.io.bawbifan



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Protocol Citation: Zilma Reis, Juliano de Souza Gaspar, Sara Oliveira Elias, Regina Amelia Lopes Pessoa De Aguiar 2020. Algorithm for gestational age assessment at birth. **protocols.io** <https://dx.doi.org/10.17504/protocols.io.bawbifan>

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Protocol status: Working

We use this protocol in our group, and it is working to enroll newborns according to the clinical trials registers: "Prematurity detection evaluating interaction between the skin of the newborn and light: protocol for the preemie-test multicentre clinical trial in Brazilian hospitals to validate a new medical device"; Register number RBR-3f5bm5. "Premature or small for gestational age? International multicenter trial protocol for classification of the low birth weight newborn through the optical properties

Created: December 31, 2019

Last Modified: January 16, 2020

Protocol Integer ID: 31395

Keywords: Gestational age, Ultrasound, Pregnancy dating, Information Systems, Preterm birth, algorithm for gestational age assessment, gestational age assessment, best estimative of the gestational age, protocol for the preemie, obstetric ultrasound, available in the birth scenario, birth this protocol, birth scenario, enrollment of newborn, gestational age, international multicenter trial protocol for classification, test multicentre clinical trial in brazilian hospital, prematurity detection, newborn, low birth weight, new medical device, small for gestational age, preemie, international multicenter trial protocol, birth, good clinical practice protocol, clinical trial, accordance with the good clinical practice protocol, brazilian hospital, reliable last menstrual period



Abstract

This protocol presents an algorithm for gestational age assessment when a reliable last menstrual period or an obstetric ultrasound are available in the birth scenario. A software was developed to automatically process data entries into the best estimative of the gestational age at birth.

It shall be used by the multicenter team of researchers, duly trained in accordance with the Good Clinical Practice Protocol, during the enrollment of newborns. Also, this protocol is complementary documentation for the scientific publications related to the clinical trials:

"Prematurity detection evaluating interaction between the skin of the newborn and light: protocol for the premie-test multicentre clinical trial in Brazilian hospitals to validate a new medical device"; Register number **RBR-3f5bm5**.

"Premature or small for gestational age? International multicenter trial protocol for classification of the low birth weight newborn through the optical properties of the skin"; Register number **RBR33rnjf**.

Guidelines

The scientific references for the best recommendation to assist gestational age calculation at birth were:

1. Committee on Obstetric Practice, the Society for Maternal-Fetal Medicine. Committee Opinion No 700: Methods for estimating the due date. Obstet Gynecol. 2017;129(5):e150-4. PMID: 28426621. DOI: [10.1097/AOG.0000000000002046](https://doi.org/10.1097/AOG.0000000000002046).

2. Papageorgiou AT, Kennedy SH, Salomon LJ, et al. International standards for early fetal size and pregnancy dating based on ultrasound measurement of crown-rump length in the first trimester of pregnancy. Ultrasound Obstet Gynecol 2014;44:641-8. doi: [10.1002/uog.13448](https://doi.org/10.1002/uog.13448)

3. Nguyen TH, Larsen T, Engholm G, et al. Increased adverse pregnancy outcomes with unreliable last menstruation. Obstet Gynecol 2000;95(6 Pt 1):867-73. DOI: [10.1016/s0029-7844\(99\)00639-0](https://doi.org/10.1016/s0029-7844(99)00639-0)

Materials

Standardized Clinical Trial Data Collection Form and tablet for recollecting data of the study

Troubleshooting

Safety warnings

- ! Ask permission to obtain a digital image of the sources of data: the reference ultrasound and the personal clinical report of the pregnancy, where the last menstrual period is reported, as well as are described all of the ultrasound assessments of pregnancy.

Before start

The researchers should identify the sources of data to assist in determining gestational age at childbirth: antenatal obstetric ultrasound reports with their images, medical records from prenatal care. They have to be prepared to interview the woman if she is conscious and agrees to participate in the study.

Menstrual cycle reference

1 The last menstrual period reference

The interview aims to qualify the information about the last menstrual period, in terms of its reliability.

- 1.1 The last menstrual period assessment to assist gestation age calculation is based on an interview with women and documentary analysis. To achieve a reliable last menstrual period reference, the researcher will interview the woman using the questions as follows, adapted from Nguyen et al. 2000 report:

Question 1: When did your last menstrual period occur? Please, confirm if it was the first day of menstruation. Question 2: Are you sure about this date?

Question 3: Are your menstrual cycles regulars? Clarify her that it was when the duration of the cycles did not change for more than one week. Question 4: Two months before your last menstrual period, did you use any contraceptive method, like pills, injections, Mirena IUD, skin implant, vaginal ring? Question 5: Two months before your last menstrual period, had you an abortion or delivered a child?

- 1.2 For further double-check, take a picture of the personal prenatal care book where the last menstrual period is reported. Make sure she permitted you for this step.

Make sure the informed date is the same reported in the personal prenatal care book, to avoid memory recall bias.

Ultrasound reference

2 The first obstetric ultrasound reference

This step aims to assess the best antenatal ultrasound record to assist the gestational age calculation at birth. When the assessment occurred between 7w+0d and 13w+6d of pregnancy, the crown-rump-length (CRL) measurement of the embryo is the primary reference. The research should certify the source of information, preferably the value of CRL.

- 2.1 Chronologically organize the antenatal obstetric ultrasound reports.

Select the first gestational assessment with an available CRL measurement, among 7w+0d and 13w+6d of pregnancy.

Take note of the assessment date and the reported gestational age at this time. When gestational age is incomplete as 7/8 weeks, consider 3 days: 7w+3d.

Take note of the CRL measurement, when available even in the embryo image.



Crown-rump-length (CRL) measurement

Gestational age will be adjusted according to Intergrowth's 21st standard curve for ultrasound CRL measurements using the International Fetal Size in Early Pregnancy from 7 weeks and 3 days up to 13 weeks and 6 days (Papageorgiou AT et al., 2014).

- 2.2 Take a picture of the reference ultrasound report if available or the personal prenatal care book where the ultrasound result is reported. Make sure she permitted you for this step.

Automated algorithm

3 Gestational age assessment, according to an automated algorithm

For this step, we developed software to process pregnancy dating at birth following the best practice for gestational age calculation. The algorithm automates methods like the following scientific references recommendations:

Adjustment of CRL to the Intergrowth-21st reference: PapageorgiouAT, Kennedy SH, Salomon LJ, et al. International standards for early fetal size and pregnancy dating based on ultrasound measurement of crown-rump length in the first trimester of pregnancy. Ultrasound Obstet Gynecol 2014;44:641–8. DOI:[10.1002/uog.13448](https://doi.org/10.1002/uog.13448)

Reliable last menstrual period concept: Nguyen TH, Larsen T, Engholm G, et al. Increased adverse pregnancy outcomes with unreliable last menstruation. Obstet Gynecol 2000;95(6 Pt 1):867–73. DOI:[10.1016/s0029-7844\(99\)00639-0](https://doi.org/10.1016/s0029-7844(99)00639-0)

Gestational age at birth assisted by the CRL measurement or the last menstrual period: Committee on Obstetric Practice, the Society for Maternal-Fetal Medicine. Committee Opinion No 700: Methods for estimating the due date. Obstet Gynecol. 2017;129(5):e150–4. PMID: 28426621. DOI: [10.1097/AOG.0000000000002046](https://doi.org/10.1097/AOG.0000000000002046).

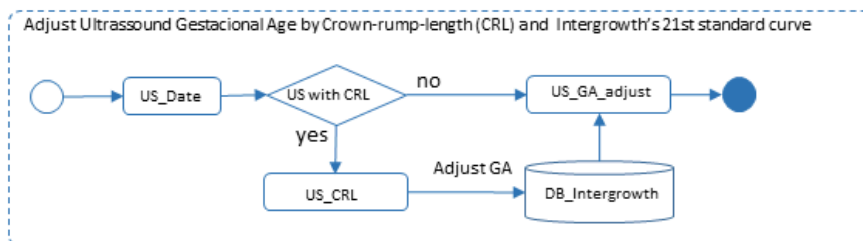
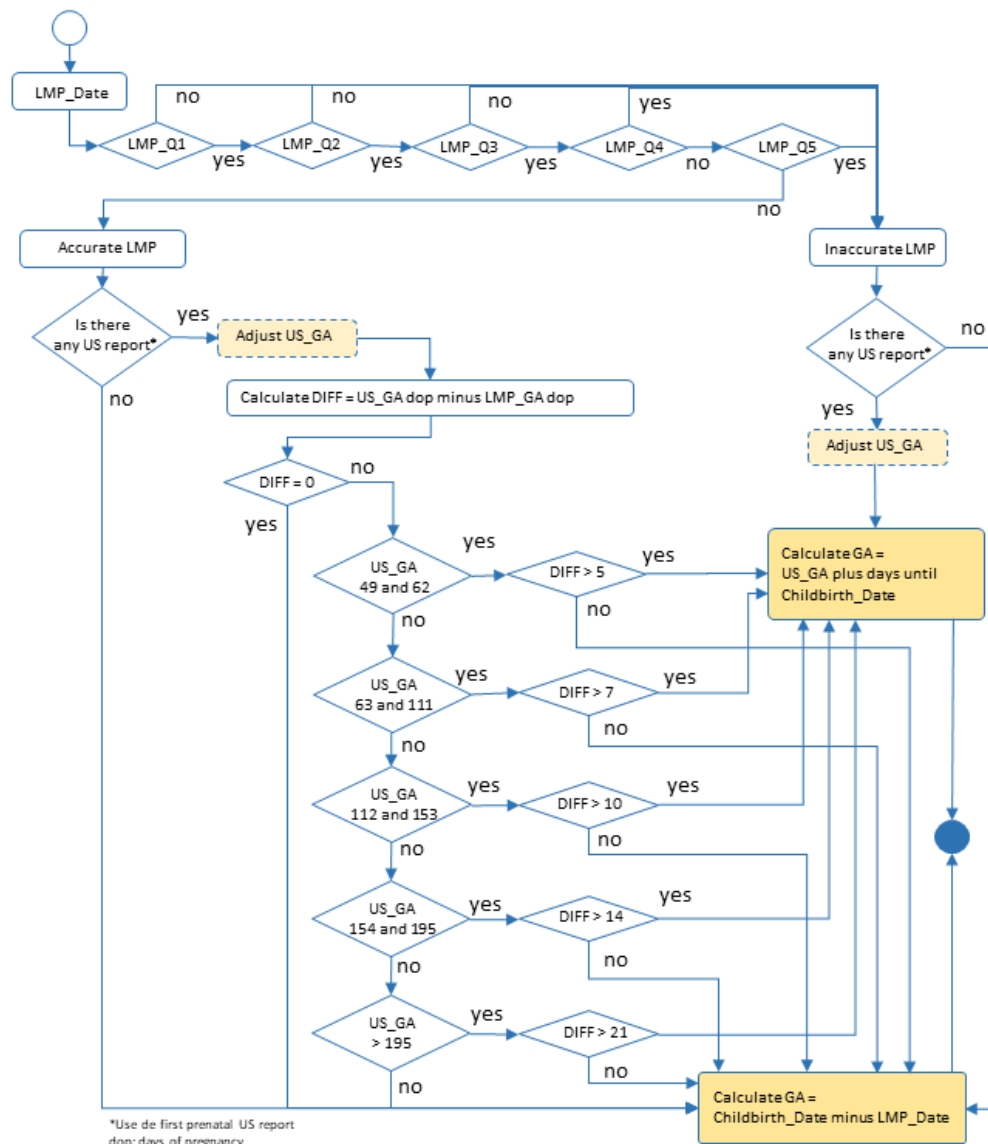
3.1 DetailsInsert data in the information system entries:

Variable	Data	Details
LMP_Date	Date of the last menstrual period	Date
LMP_1	Question 1	Yes/No
LMP_2	Question 2	Yes/No
LMP_3	Question 3	Yes/No
LMP_4	Question 4	Yes/No
LMP_5	Question 5	Yes/No
LMP_GA_Days	Number of days between the LMP_Date and the Childbirth_Date	Date
US_CRL	Crown-rump-length (mm) reported in the ultrasound	Value
GA_CRL	Gestational age reported in the reference ultrasound (days)	Value
Childbirth_Date	Date of the childbirth	Date



US_Date	Date of the reference obstetric ultrasound	Date
US_GA	Gestational age reported in the reference ultrasound (days)	Value
DIFF	Day difference calculated by the LMP and US days of pregnancy	Value
DB_Intergrowth	Database with Intergrowth's 21st standard curve for US CRL	Reference values

3.2 Decision-tree details



Experts checking and adjustments

- 4 A team of researchers-experts has a role in rechecking the data, according to sources as photos of ultrasound reports, the digital image of the CRL, the digital copies of the personal prenatal care book. This procedure demands access to the database simultaneously with the digital images. After one-by-one of the newborns' data double-checking, gestational age obtained at birth should be adjusted to mirror the registered information when the original data was recollected.

Once more, the algorithm will process the optimal dating gestational age at birth.

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Expected result

We expect the best accuracy for the gestational age assessment at birth.