

INTERGROWTH-21st

International Fetal and Newborn Growth Standards for the 21st Century

The International Fetal and Newborn Growth Consortium



**Correct measurement of fetal crown rump length
and standardization of ultrasonographers**

September 2010



Please read this manual carefully and refer to it throughout the study if any clarification is needed.

This Operations Manual was written by Aris Papageorghiou and prepared by the INTERGROWTH-21st Ultrasound Coordinating Unit.

INTERGROWTH-21st is a large-scale research project involving health institutions from eight geographically diverse countries. It is therefore essential that the participating institutions follow the same procedures.

This manual is designed to familiarize all staff involved in INTERGROWTH-21st with the techniques required to measure fetal crown rump length (CRL) uniformly. It also explains the procedures that should be followed for standardizing all participating ultrasonographers in CRL measurement.

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<p>THE REMAINDER OF THIS DOCUMENT SHOULD THEN BE DETACHED, COMPLETED AND SUBMITTED AS DESCRIBED ON PAGE 15 OF THE MANUAL</p>

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List of Abbreviations

CRL	Crown Rump Length
FGLS	Fetal Growth Longitudinal Study
LMP	Last Menstrual Period

AIMS OF THIS MANUAL

The aims of this manual are to ensure all ultrasonographers involved in measurements of fetal crown rump length (CRL) are familiar with:

- The standardized way this measurement should be taken for the purposes of the INTERGROWTH-21st study.
- The process of standardization, i.e. theoretical training, assessment and submission of a logbook.

This manual is **not** intended to teach those involved in ultrasound how to scan. It is recognized that local ultrasonographers already have a high standard of training and, in fact, this is a prerequisite for taking part. However, different sites and ultrasonographers may use different protocols for CRL measurement, different definitions of calliper placement, and a variety of ultrasound equipment. Therefore, to ensure uniformity, the factors that contribute to variation in measurements must be standardized.

This manual should be read in conjunction with the main Ultrasound Operations Manual, and Appendix C of the main INTERGROWTH-21st study protocol.

STANDARDIZATION PROCESS

The process involves ultrasonographers taking part in four steps:

1. Theoretical component: reading the manual
2. Confirming that you have read and understood the manual
3. Testing theoretical knowledge by filling out a simple questionnaire
4. Practical component: submission of a logbook of 5 images of relevant scans

The sections below explain each of these steps. The process of standardization is summarised on the last page.

1. THEORETICAL KNOWLEDGE

1.1 The importance of estimating gestational age at study entry

Establishing gestational age precisely is vitally important for constructing growth standards (in addition to clinical management) .

There are three ways to estimate gestational age early in pregnancy, by: a) LMP alone; b) ultrasound alone, or c) LMP and ultrasound. Dating by LMP and ultrasound is an assessment of different parameters. Although it has been suggested that ultrasound before 14⁺⁰ weeks may be better by an average of 2-3 days in predicting the date of delivery, in clinical practice, both are often used in combination. This seems sensible as, based on the 2004 Birth Cohort from the Brazilian Centre, 7% of women will not have a reliable LMP. In other studies in this socio-economic group, the figure may be as high as 20%.

Taking all these factors into consideration, we decided to base gestational age estimation on a combination of LMP and ultrasound. We use a standard gynaecological definition of LMP (1st day of the last menstrual period) as the initial stage in a two-stage process to calculate the gestational age; ultrasound is then used to confirm the LMP-derived gestational age estimation.

1.2 Measuring the crown rump length

(This part can also be found in the ultrasound operations manual, section 2.1)

All mothers have a transabdominal ultrasound scan between 9⁺⁰ to 13⁺⁶ weeks from the LMP.

1.2.1 Aims

- To confirm intrauterine pregnancy, viability and singleton gestation.
- To confirm gestational age.

1.2.2 Dating by LMP and confirming gestation by ultrasound

- **Gestational age is calculated from the LMP.**
To allow accurate assessment of gestational age, women need to have certain dates (a known LMP), regular menstrual cycles and a cycle length between 24 and 32 days), and they must not have used hormonal contraception or breastfed in the 2 months preceding the LMP. Only those with spontaneous conception should be included.
- **This gestation is confirmed by fetal crown rump length (CRL).**
The gestational age is confirmed by CRL measurement. The gestational age can be calculated by using the attached chart to look up the estimated gestation.

When the gestational age based on CRL is within 7 days of that calculated from the LMP, we consider the LMP to be reliable, and take it as the true biological date.

1.2.3 Features of a correct CRL measurement



Good magnification

The fetus fills almost the entire screen.

Mid-sagittal section

The profile, spine and rump are visible.

Neutral position

There is fluid visible between the chin and the chest of the fetus (see arrow).

Fetus is horizontal (90° to the ultrasound beam)

Crown and rump are clearly seen

Callipers are placed correctly

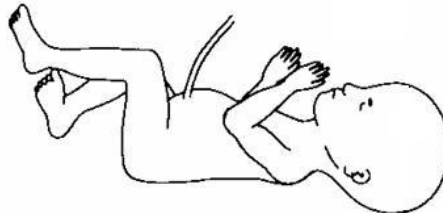
The intersection of the callipers should be placed on the outer borders of the skin over the head and rump (see image on next page).

1.2.4 Practical guide: How to do it

- Transabdominal ultrasound
- Lateral recumbent position

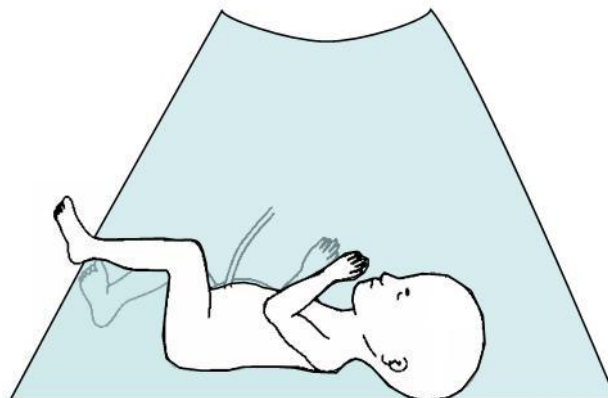
Step 1: Identify the fetus

- Viability?
- Intrauterine?
- Singleton?

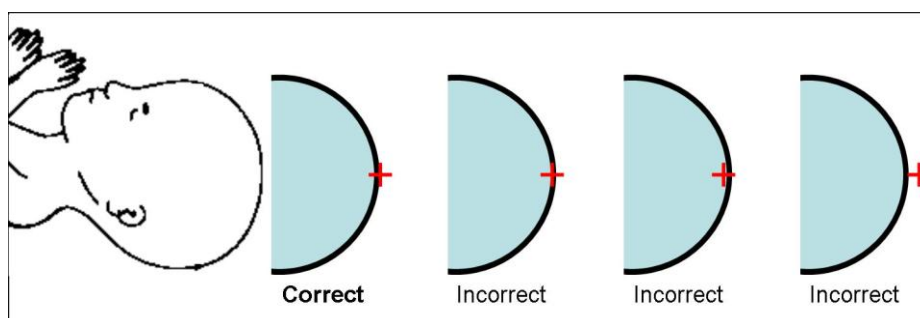


Step 2: Measure the CRL

- Find the mid-sagittal section of the fetus.
- The fetus should be horizontal (at 90° to the angle of insonation).
- The fetus should be in a neutral position (not hyperextended or flexed).
- The image should fill at least 30% of the monitor screen.
- Place the intersection of the callipers on the outer borders of the head and rump.

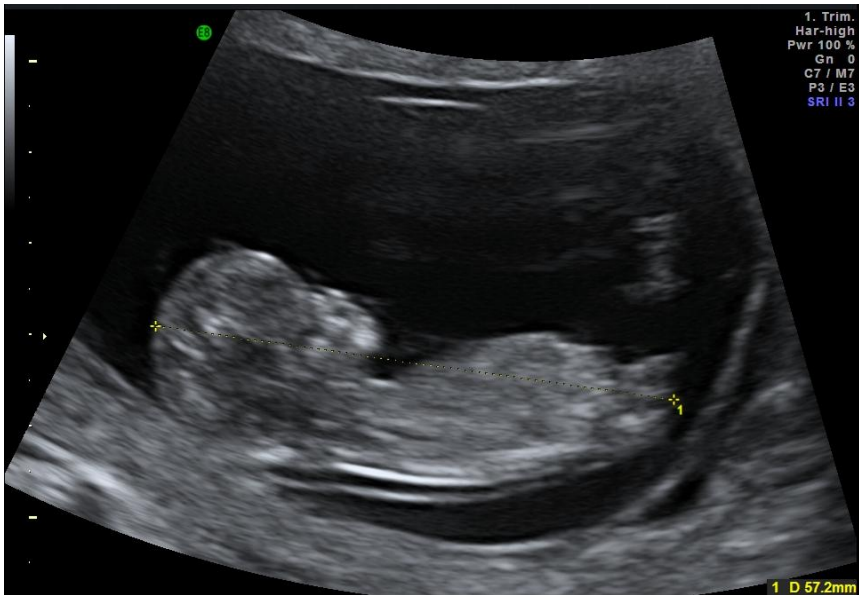


A mid-sagittal section of the fetus, in a horizontal position (90° to the angle of insonation), in a neutral position.



*The intersection of the callipers should be placed on the **outer** borders of the skin over the head and rump.*

1.2.5 Some examples



CORRECT:

- mid-sagittal section
- horizontal position
- neutral position
- good magnification
- correct calliper position



INCORRECT:

The section is not mid-sagittal
Magnification is poor



The section is not mid-sagittal
The fetus is flexed (not in a neutral position)
(It is also a twin pregnancy!)



The section is not mid-sagittal:
You can see the spine in the middle - this is a coronal section



1.2.6 Questions, answers and examples

- **It is not possible to obtain a good quality CRL**

Accurate measurement of CRL is obviously important to confirm that each mother is eligible to take part in the study. Every effort should be made to obtain the best possible measurement. This may require asking the mother to return for another scan later that day or on another day (but always in the 9⁺⁰ - 13⁺⁶ week window).

If, despite all attempts, it is not possible to obtain a CRL measurement that allows confirmation of gestational age, the mother is not eligible for the study.

- **The mother is over 13⁺⁶ weeks by LMP but CRL is within 9⁺⁰ - 13⁺⁶ weeks**

The mother is **NOT** eligible for the study.

- **The mother is less than 9⁺⁰ weeks by LMP**

The mother is not eligible for the study at present **BUT** should come back when she is 9⁺⁰ - 13⁺⁶ weeks as she may then become eligible.

- **The mother is 13⁺⁶ weeks by LMP but 14⁺⁶ weeks by ultrasound**

The discrepancy is 7 days exactly: this is OK and the mother is eligible for the study. Remember that dating is by LMP and the mother has to be 9⁺⁰ - 13⁺⁶ weeks **by LMP**. She is only excluded if the CRL suggests the gestation is more than 7 days discrepant.

- **The mother is 9⁺³ weeks by LMP but 8⁺⁴ weeks by ultrasound**

The discrepancy is 6 days: this is OK and the mother is eligible for the study. Remember that dating is by LMP and the mother has to be 9⁺⁰ - 13⁺⁶ weeks **by LMP**. She is only excluded if the CRL suggests the gestation is more than 7 days discrepant.

- **The discrepancy between LMP and CRL dates is more than 7 days**

The mother is **NOT** eligible for the study.

- **The discrepancy between LMP and CRL dates is exactly 7 days**

This is OK: the mother is eligible for the study.

- **This is a multiple pregnancy**

The woman is not eligible for the study, and should be managed according to the local multiple pregnancy protocol.

- **The fetus is not viable**

The woman can obviously not be enrolled in the study, and should be managed according to the local protocol for management of a non-viable pregnancy.

- **The fetus is not intrauterine**

The woman can obviously not be enrolled in the study, and should be managed according to the local ectopic pregnancy protocol.

1.3 Dating chart for fetal CRL in INTERGROWTH-21st

mm	GA [weeks]	GA [days]
10	7	2
11	7	3
12	7	4
13	7	5
14	7	6
15	8	1
16	8	2
17	8	3
18	8	3
19	8	4
20	8	5
21	8	6
22	9	0
23	9	1
24	9	2
25	9	3
26	9	3
27	9	4
28	9	5
29	9	6
30	9	6
31	10	0
32	10	1
33	10	2
34	10	2
35	10	3
36	10	4
37	10	4
38	10	5
39	10	6
40	10	6
41	11	0
42	11	0
43	11	1
44	11	2
45	11	2
46	11	3
47	11	4
48	11	4
49	11	5
50	11	5
51	11	6
52	11	6
53	12	0

mm	GA [weeks]	GA [days]
54	12	1
55	12	1
56	12	2
57	12	2
58	12	3
59	12	3
60	12	4
61	12	4
62	12	5
63	12	5
64	12	6
65	12	6
66	13	0
67	13	0
68	13	1
69	13	1
70	13	2
71	13	2
72	13	3
73	13	3
74	13	4
75	13	4
76	13	5
77	13	5
78	13	6
79	13	6
80	14	0
81	14	0
82	14	0
83	14	1
84	14	1
85	14	2
86	14	2
87	14	3
88	14	3
89	14	4
90	14	4
91	14	4
92	14	5
93	14	5
94	14	6
95	14	6
96	14	6
97	15	0

Please complete the remainder of this paper.

Please detach it from the manual and give it to your INTERGROWTH-21st data manager for entry onto the database.

The logbook of five images (see last page for instructions) should also be given to the data manager.

Keep pages 1-10 for reference.

Name / Code _____

Country / Code _____

Email address _____

0	1

2. CONFIRMING THAT YOU HAVE READ THE MANUAL

I have read and understood the CRL standardization manual.

Signature.....Date

D	D
---	---

 -

M	M
---	---

 -

Y	Y
---	---

3. TESTING YOUR KNOWLEDGE

Q1: In the INTERGROWTH-21st study the pregnancy is dated by:

(tick **one** of the following)

1. LMP only.
2. Ultrasound only.
3. LMP which is confirmed by a fetal CRL within 7 days.

Q2: When measuring fetal CRL:

(tick **all** that apply)

1. The fetus should be in mid-sagittal section.
2. The fetus should be horizontal to the ultrasound beam.
3. The fetus should be as curled up as possible.
4. Magnification is NOT important.
5. The intersection of the callipers should be on the outer borders of the

head and rump.

Q3: Look at this image:



(tick **one** of the following)

1. It is a correct image for measuring CRL because:
 - It is mid-sagittal.
 - The fetus is horizontal.
 - The fetus is in neutral position because there is fluid between the chin and the chest.
 - Magnification is good.
2. It is an incorrect image for measuring CRL.

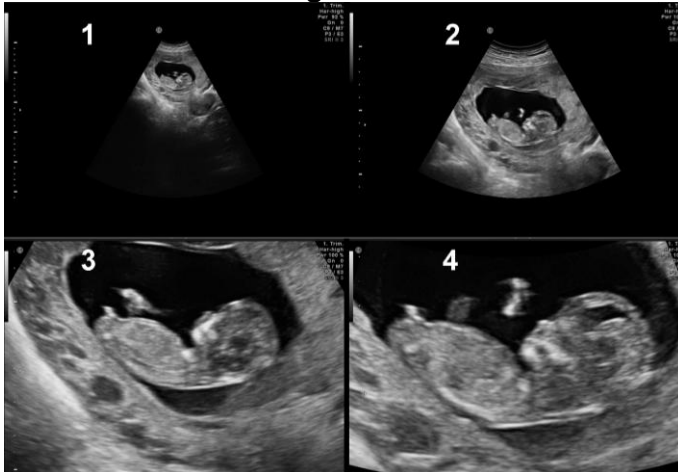
Q4: Look at this image in terms of the position / curling:



(tick **one** of the following)

1. The fetus is in a neutral position - It is a correct image and CRL will be accurate.
2. The fetus is too flexed (curled) because there is no fluid between the chin and the chest and CRL will be underestimated.

Q5: Look at these images:



(tick **one** of the following)

The best level of magnification is in image:

1.
2.
3.
4.

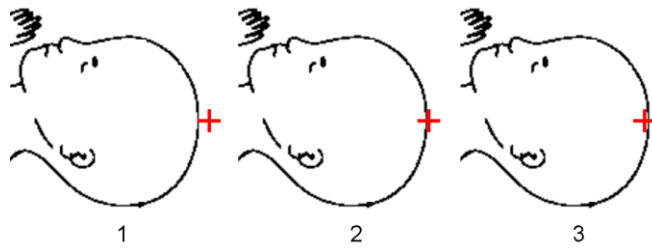
Q6: Look at this image:



(tick **one** of the following)

1. It is acceptable for measuring CRL if the baby is persistently in this position.
2. It is an incorrect image for measuring CRL because it is not mid-sagittal.

Q7: The correct way to place callipers is:



(tick **one** of the following)

1.
2.
3.

Q8: During a scan it is not possible to obtain a good quality CRL:

(tick **one** of the following)

1. The woman may need to return for the scan at a later time.
2. If the woman is sure of her LMP it does not matter and she can be recruited anyway.
3. A CRL should be taken anyway even if it is of poor quality.

4. GETTING A CERTIFICATE: THE PROCESS OF STANDARDIZATION AND INSTRUCTIONS ON SUBMITTING YOUR LOGBOOK

In order to be certified you will need to submit three items

1. The part you signed to confirm you have read the manual. (page 10)
2. The completed part entitled "testing your knowledge". (page 10-13)
3. A logbook of **FIVE** images showing fetal CRL measurements taken.

The logbook

To demonstrate your competence, please submit a logbook of **FIVE** images showing fetal CRL measurements taken:

- From 9⁺⁰ to 13⁺⁶ weeks of gestation.
- Taken according to the guidelines.
- Each image should be from a different pregnancy.
- For the logbook, thermal, printed or electronic images are all OK.
- Please submit all 5 images at the same time.
- Remember to label your logbook

How to submit the papers and logbook

Please include the following:

1. The part you signed to confirm you have read the manual.
2. The completed part entitled "testing your knowledge".
3. The logbook (thermal, printed or electronic images on CD/memory key).
4. **You must label your submission with your:**
 - Name (plus code)
 - Country name, alongside your pre-printed country code
 - Email address (for us to send you your results)

Please give this submission to the data manager who will forward it on to us.

What happens after you submit

The images will be scored and, if they are of good quality, you will receive a letter explaining the score and a certificate stating that you have successfully completed the standardization process for fetal CRL measurement for the INTERGROWTH-21st study.

Many thanks for your help and support.

15th September 2010