

Flawed recommendation issued by the Norwegian Directorate of Health concerning the determination of fetal age

In October 2014 the Norwegian Directorate of Health issued its recommendation that one specific ultrasound method, the *eSnurra* obstetric wheel, must be used throughout the country to determine gestational age and predict pregnancy term. We hold the opinion that this recommendation is medically flawed and that the Directorate has conducted a muddled investigation process.

The autumn of 2014 saw public debate about the appropriate threshold for abortion and gestational age. Gestational age can be determined in a number of ways and ultrasound examination represents an important contribution. In Norway, two methods are in use: the *Terminhjulet* obstetric wheel, developed in Bergen (the Bergen method) by a group that includes some of the authors of this article, and the *eSnurra* obstetric wheel, developed in Trondheim (the Trondheim method).

Because it was deemed desirable to implement a uniform approach for the whole country, the Norwegian Directorate of Health decreed in a letter to the nation's health enterprises (1) that the Trondheim method must be the sole tool used to predict pregnancy term and fetal age in Norway. We feel the process has been muddled, and that the Directorate's decision has been made on grounds that fail to instil confidence. This is not how the Norwegian Directorate of Health should be working.

Running roughshod over medical expertise

The Norwegian Society of Gynaecology and Obstetrics recently reviewed available knowledge about the determination of gestational age. They gave their resulting recommendations in a revised edition of their birthing guidelines for the medical profession, *Veileder i fødselshjelp 2014* (2). They recommend routine ultrasound examination in the second trimester, and that the gestational age in cases of in-vitro fertilisation be based on the time of conception. They also recommend that if the gestational age has been determined earlier in the pregnancy, this should never be changed as a consequence of later ultrasound examinations. This is entirely in line with international guidelines – and both Norwegian methods are included.

The Directorate of Health has opted to disregard these guidelines by recommending that all pregnancies be dated by applying the Trondheim method in weeks 17–19 of the pregnancy. By doing so, they ignore current national and international medical guidelines. During their investiga-

tion process, the Directorate of Health requested the opinion of the Norwegian Knowledge Centre for the Health Services. The centre was unable to contribute to an assessment of the methods and instead referred to a PhD thesis published by the Trondheim Group (3), apparently without first having reviewed the documentation or

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the criticisms raised (4). The Directorate of Health should have left this job to the medical experts – the patients deserve as much.

Erroneous use of term prediction for fetal age

The Norwegian Directorate of Health chose the Trondheim method, the *eSnurra*, because they found that this demonstrated the least bias with respect to term prediction – according to the Trondheim Group's own validation study (3). The group used the size of the fetus at the time of the routine ultrasound examination, and the remaining gestation period, in a model that predicts the date of birth (5). However, the issue at stake is not the accuracy of the predicted date of a normal delivery, it is the accuracy of the *fetal age*, which is an essential factor in clinical situations throughout the pregnancy.

In order to make an assertion about fetal age it is necessary to know how old the fetus was at the time of the ultrasound examination – an issue which has not been documented by the Trondheim Group.

However, they admit that «Our primary focus in this paper has been on prediction of term. It is interesting to note that the approach also provides estimates for gestational age at the time of the ultrasound examination. This can be done by assuming a typical length of pregnancy of, for instance 282 days. For a given BPD or FL value, one can then subtract the predicted remaining time from the total length of 282 days and thus obtain an estimate of gestational age» (5). However, the basis for determining gestational age is not the end of the pregnancy, but its beginning.

This was exactly what the Bergen Group looked at in a prospective study in which they employed internationally recommended standards for design and analysis (6, 7) and compiled reference values for age determination and growth (8–11). This study has been internationally rated as one of the very best (12).

Yet this is not enough for the Norwegian Directorate of Health. Paradoxically, they prefer the Trondheim Group's retrospective population-based study – which did not determine gestational age – when looking to determine gestational age. The epidemiological Trondheim study included 40,000 pregnancies and the object was to calculate the median date of delivery. The prospective Bergen study included 650 pregnancies and the object was to determine fetal age and growth. The objectives were different, and so the methods were different: epidemiological studies need high numbers, while prospective, longitudinal studies should never include more participants than the number dictated by the strength calculation. The Directorate of Health appears to have been blinded by the large data sample to the extent that they have failed to see the difference between the scientific methods and definitions.

Fetal age, fetal size, length of pregnancy and date of delivery are obviously all related data. However, it is impossible to deduce fetal age routinely from the predicted date of delivery. Only 4 per cent of women give birth at their estimated due date; in order to determine gestational age, it is clearly necessary to take account of the time of

conception. The Directorate of Health have demonstrated their lack of understanding of these differences, and they have failed to appreciate that the Trondheim Group looked only at term prediction (3).

Validation deficiencies ignored

For many years, the precursor to today's eSnurra, the 1984 Snurra, was the only ultrasound method used in Norway to determine gestational age and predict pregnancy term. It was clear at an early point, however, that this method was encumbered with serious deficiencies with respect to the period before the 17th week of pregnancy. For example, women who were examined in the 14th week of pregnancy would have to return after the 17th week in order to have the gestational age determined. The method was nevertheless disseminated throughout the country for years, without attention being directed to this weakness. The Bergen Group pointed to this problem in 1999 and published their objections to the method (13), and the Norwegian Research Council gave the go-ahead for establishing new reference values for fetal age determination and growth.

The PhD thesis published by the Trondheim Group compares the Trondheim method to the Bergen method, and the authors go out of their way to demonstrate the advantages of the eSnurra (3) obstetrics wheel. The Trondheim Group makes use of their own population, in which their own method has been established, in order to gauge the accuracy of their term predictions. They then go on to use the same population to test the results of the Bergen method.

This procedure provides a flawed basis for comparison of the two methods. It is to be expected that the due date predicted by means of eSnurra and communicated to the women will influence their expectations, treatment and attitudes, as well as those of the health service, so as to converge towards this prediction. Yet we know nothing about the age of the fetus, only about the expected due date.

The two methods are also based on different ultrasound measurements. The Bergen Group recommends head circumference as the preferred parameter when determining fetal age, yet the Trondheim Group has never tested this method. The Bergen method calculates the fetal femur length as an average of three measurements, while the eSnurra uses the longest of three measurements. The two methods are nevertheless made the subjects of a comparison.

The Trondheim Group has altered the expected duration of pregnancy from 282 to 283 days in the eSnurra (3). If the Bergen method had also been tested for 283 days, the difference between the two methods' term predictions would have been minimal (for this was indeed the object of compa-

ison, not the determination of age). The Trondheim Group defines over-term pregnancy as 283 (or 282) + 14 days (3), which is wrong – this should be 294 days or 42 + 0 weeks (14).

We hold the opinion that the comparison conducted by the Trondheim Group suffers from conflicts of interest, but the Directorate of Health appears not to have realised that the comparative evaluation of the two methods really amounts to comparing apples to pears. The Directorate of Health also ignores the criticism raised against the Trondheim study (4): selection bias before and after weeks 18–20 of gestation; unclear exclusion criteria for fetuses with potentially hampered growth; and failing to account for the inclusion of fetuses with an elongated head whose biparietal diameter was adjusted based on the longitudinal axis of the skull.

Flawed and biased emphasis on ultrasound dating

The Directorate of Health has sought to ensure that the same method is used for age and term determination throughout the country, and they have given the impression that routine ultrasound examinations constitute the only solution. We have the impression that users of the Trondheim method have been routinely using the 18-week routine measurements to calculate the pregnancy term and overrule any fetal age determination based on known time of ovulation, in-vitro fertilisation or first-trimester ultrasound. The noise around these matters has subsided in the course of this autumn's debate, but unilateral reliance on routine ultrasound examinations is unwarranted.

If this procedure were to be implemented, the sickest fetuses would suffer the most from incorrect predictions, as they are often small for their age. Ultrasound measurements taken in the second trimester will therefore suggest a lower than true age. We argue that critical mistakes may follow from the failure to include all available information when fetal age is assessed. Had the Directorate of Health listened to the expert opinion expressed by the Norwegian Society of Gynaecology and Obstetrics (2), the recommendation would have been better balanced and based on sound knowledge.

We all support the aim of securing equal treatment irrespective of geographic circumstances – provided it is based on sound knowledge. In this instance we feel that the Directorate of Health has acted beyond their competence and that they have simplified the issues beyond all understanding.

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