In general, health research ethics guidelines regard the issues of participant remuneration as residing fairly in the domain of the research ethics committee involved. In South Africa, however, a regulatory agency, namely the MCC, has decided to take this matter unilaterally into its domain. Is it the mandate of the MCC to review the patient information leaflet and informed consent documents, especially where participant remuneration is concerned, or is this a role of the local ethics committee? Participant remuneration in South Africa — how much is enough, and who should decide?

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Accuracy of menstrual history in early pregnancy

To the Editor: Dating of pregnancy relies traditionally on the menstrual history using Naegele’s rule, and on uterine sizing. Uterine sizing is fraught with inconsistency.1 Globally, the last menstrual period (LMP) date is uncertain or unknown in the case of at least 20% of pregnant women.2 This seems especially true in developing countries where more women are more likely to be uncertain about the LMP and more likely to be late attendees for antenatal care.3 It has, however, been postulated that women booking early for antenatal care have a more accurate recall of the LMP.4

In view of the uncertainty of both the menstrual history and the clinical assessment of uterine size, the sonographic correction of the error margin between the menstrual history-established gestational age (MHGA) and the clinical sizing should be corrected by the ultrasound-established gestational age (USGA).5 This, however, is hardly feasible in developing world settings devoid of sonographic facilities. It is, therefore, important to establish the accuracy of menstrual history in such settings. This is especially relevant to primary health care (PHC) facilities providing reproductive health care to antenatal women and to clients seeking a termination of pregnancy (TOP).

The aim of this study was to establish the accuracy of menstrual history in a rural setting using sonography as the gold standard. In addition, it was investigated whether there was a difference in the accuracy of the menstrual history between confirmation of pregnancy (COP) and TOP seekers.

A total of 2 627 women entered the study after having given verbal consent to participate. The following information was recorded: age, parity, and menstrual history. Only a precise date of the first day of the LMP was considered to compute the MHGA. A standard deviation of ± 1 week was considered compatible with the USGA.

Immediately after history taking and abdominal palpation a trans-abdominal ultrasound was performed using a 3.5 MHz transducer. The following parameters were used to establish the USGA: crown-rump length (CRL) up to 12 weeks’ gestation, biparietal diameter (BPD) between 12 and 18 weeks, and femur length (FL) after 18 weeks.

Statistical evaluation was carried out with Statmate and Prism Version 2 from GraphPad (GraphPad Software Inc., San Diego, Calif.). Proportions were compared using 95% confidence intervals (95% CI), Pearson’s chi-square for categorical variables, and odds ratio (OR) for association. A p-value < 0.05 was considered statistically significant.

Results

Of the 2 627 participants, 2 124 (80.9%) sought a TOP and 503 (19.1%) a COP. Among the TOP seekers, 385 (18.1% (95% CI 16.5, 19.8)) were actually not pregnant, and 133 (26.4% (22.7, 30.6)) COP seekers were not pregnant (X² = 17.8, p < 0.0001; OR = 1.6 (1.3, 2.1)). The menstrual history was known by 1 486 (70.0% (67.9, 71.9)) COP seekers and by 358 (71.2% (67.0, 75.1)) TOP seekers (X² = 0.28; p = 0.58, OR = 0.94 (0.76, 1.17)).

More than half of the clients in each group were in the third decade of life. The proportion of teenagers was significantly higher among the TOP seekers. Among TOP seekers, nulliparous and primiparous women predominated. COP seekers were more likely to be nulliparous.

The MHGA correlated with the USGA by ± 1 week in 588 (39.6% (37.0, 42.0)) out of the 1,486 TOP-seekers with known LMP, and in 116 (32.4% (27.6, 37.5)) of 358 COP-seekers with known menstrual history ($\chi^2 = 6.28; p = 0.01; OR = 1.37 (1.01, 1.75)).

Overall, for the two groups together, the discrepancy between MHGA and USGA was ± 2 weeks in 9.4%, ± 3 weeks in 5.9%, ± 4 weeks in 4.6%, and ± 5 weeks in 4.4% of the participants with known LMP. The discrepancy was ≥ 6 weeks in 37.5% (35.4%, 39.8%) ($\chi^2 = 0.14; p = 0.71; OR = 1.03 (0.90, 1.17)) of the clients. As shown in Table I, TOP seekers tended to underestimate the true gestational age, whereas COP seekers were more likely to overestimate the real gestational age ($\chi^2 = 46.35; p < 0.0001, OR = 4.13 (2.68, 6.36)).

### Table I. Patients’ estimates of gestational age

<table>
<thead>
<tr>
<th>Variable</th>
<th>TOP seekers</th>
<th>COP seekers</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MHGA&lt; USGA</td>
<td>39.6 (37.0, 42.0)</td>
<td>32.4 (27.6, 37.5)</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>MHGA= USGA</td>
<td>18.3 (15.3, 21.3)</td>
<td>48.0 (38.0, 58.2)</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>MHGA&gt; USGA</td>
<td>81.7 (78.7, 84.5)</td>
<td>52.0 (41.9, 62.0)</td>
<td>&lt; 0.05</td>
</tr>
</tbody>
</table>

### Discussion

According to reports from the developed world, the date of delivery can be predicted reliably from the menstrual history in between 75% and 85% of pregnancies. The present study confirms other data indicating that menstrual history is uncertain or unknown in a non-negligible proportion of pregnant or presumed pregnant women. The magnitude was similar in the studied population. Contrary to expectations, the reason for the consultation (TOP or COP) did not affect the proportion of known versus unknown LMP. What could have been expected, however, is the fact that TOP seekers tended to underestimate the true gestational age. One could speculate that perhaps the fear of being disqualified on grounds of excessive gestational age (viz. beyond the legal requirements) might motivate women, consciously or not, to report wrong dates.

It is not clear to what extent the absence of dates or inaccurate menstrual history can be compensated for by clinical sizing of the uterus. For some practitioners the matching of uterine size and menstrual history data means that there is a good prediction of the estimated date of confinement to within 2 weeks. For others, however, the lack of consistently described methods for sizing the uterus is a clear indication that the clinical assessment is not reliable. This not to say that the sonographic estimate of gestational age has no measurement error. According to Heringa, the measurement error for the CRL and FL leads to a systematic underestimation in 63% of cases, and BPD and head circumference leads to an overestimate in 56% of pregnancies after 12 weeks’ gestation. In the present study, 49.3% of the pregnancies were 12 weeks’ or less.

In conclusion, this study shows that, in keeping with other reports, the LMPs known with precision by 70.9% of rural women. The correlation with the USGA, however, is poor — 38.2% of known dates. In other words, the MHGA could be established with accuracy in only 26.8% of all women seeking a diagnosis of pregnancy. Since the correct diagnosis of gestational age influences the management of pregnancy, the shortcomings of alleged known menstrual history and the pitfalls resulting from (over-)reliance on the menstrual history should be borne in mind.

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