Participant remuneration for research — how much is enough?

To the Editor: Debate has emerged in South African health research circles regarding the appropriate remuneration for individuals participating in research studies.

Most international and national guidelines on health research ethics vaguely warn against unfair inducement of individuals to participate in research but are otherwise silent on this issue. The most comprehensive guideline referring to participant remuneration is that of the Council for International Organisations of Medical Sciences (CIOMS). This document has been developed in conjunction with the World Health Organisation (WHO) and refers specifically to research in developing countries. Guidelines 4 (1993 version) and 11 (2002 revised draft) refer to ‘inducement to participate’.

Guideline 4 states, inter alia, that ‘subjects may be paid for inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research’. Guideline 11 states, inter alia, that ‘subjects may be paid or otherwise rewarded for inconvenience and time spent’. The guideline also details acceptable and unacceptable recompense, remuneration of guardians of incompetent participants and remuneration in the event of withdrawal from a study.

The notion of participant remuneration ranges from the promotion of research as a socially responsible activity, with no payment at all but rather recognition for the time and effort of participants, to the view that a wage payment model should be used in which research subjects are paid an hourly wage based on that of unskilled workers.

The amount of money that participants should receive for their participation is therefore highly contentious. A balance has to be achieved between a rate of payment that is high enough not to exploit subjects and low enough that it does not create an irresistible inducement. Most ethics committees in South Africa allow an amount of R50 per visit to be paid for travel and food expenses incurred by the participant for the study visit, and some committees prefer that this amount not be reflected in the patient information leaflet. However, a recent recommendation by the Medicines Control Council (MCC) to investigators in South Africa requires that participants should receive R150 per visit for expenses incurred in participation in research and that this should be documented in the patient information leaflet read by the participant before deciding whether to participate in the research study.

The ethical concerns involved in participant remuneration have received attention in the international literature, yet surprisingly little research attention has been paid to this question in the South African context where research is frequently and unavoidably conducted on vulnerable populations. While many researchers have a strong opinion on the remuneration of study participants, there is little understanding of how participants themselves perceive remuneration for research.

To investigate this issue, we carried out a semi-structured cross-sectional study among 334 individuals from the Bishop Lavis and Elsies River communities in the Western Cape who had participated in two pharmaceutical industry-sponsored trials of an intranasal flu vaccine during 2001 and 2002. For their participation in these trials, participants received R50 at each of three scheduled study visits and an additional R20 for unscheduled ‘illness’ visits over a 12-month follow-up period. For this study, individuals were interviewed in their home language (English or Afrikaans) by an independent researcher 4 - 12 months after completing the vaccine trial. All participants gave informed consent before being interviewed. Ethical approval to conduct this study was granted by the Committee for Pharmaceutical Trials, University of Stellenbosch.

The mean age of the 334 participants was 68 years (range 60 - 80 years) and the majority were female, with a mean educational level of Standard 5 (the equivalent of Grade 7). All the participants received R50 per study visit (R150 altogether), although several received up to R200 for additional interim visits. The majority of those interviewed (N = 281, 84%) felt that the compensation they received for participation in the trial was adequate, although a minority (N = 36, 11%) recommended that the compensation per visit be increased to a median of R100 per visit (range R70 - R200 per visit). In open-ended questions regarding compensation, participants stated that they used the money received in a range of ways, primarily to purchase food for their families, to transport themselves or a family member to a clinic or hospital, or to meet cost-of-living expenses generally.

While drawn from a small sample within a particular community, these results indicate the complexity of a blanket compensation policy — as is being requested by the MCC — for participants in biomedical and epidemiological studies. In this setting, the standard of R50 per visit for three study visits spread over 12 months was deemed acceptable, yet it is likely that other communities may have substantially different standards — some greater, some lesser. And while there are sometimes concerns regarding the use of cash as compensation, these participants used their compensation to meet basic needs. Generally, identifying the most appropriate level of compensation for participation in a particular study, as well as what form it should take, is an important and sometimes daunting task for researchers. The establishment of a single
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. Globally, the last menstrual period (LMP) date is uncertain or unknown in the case of at least 20% of pregnant women. 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. It has, however, been postulated that women booking early for antenatal care have a more accurate recall of the LMP.

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). 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 = 0.86, 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.

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