OPINION

Payment of trial participants can be ethically sound: Moving past a flat rate

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The South African Medicines Control Council (MCC) policy that trial participants be paid a flat rate of R150 per visit in clinical trials has been criticised in the press.[1] The literature argues that it is an excessive or inappropriate reward;[2] it neglects salient factors such as the design or nature of the study,[2,3] and non-industry-funded trials may not be able to afford it.[3] Also, this amount could be regarded as an 'undue inducement' for participants to enrol.

In our view, the main problem is that the MCC policy violates the ethical principle of justice in that participants are paid the same amount but do not do the same things or incur the same expenses.[4] It has been argued that it would be more appropriate to have a broad contextualised policy[5] and that participants should be paid for their time and expenses.[2] To take these recommendations forward, we apply two theoretical models of payment (the Wage Payment and Reimbursement models) for time, inconvenience and expenses (TIE). We recommend that participants be paid for their time at a rate similar to national unskilled labour rates, with increments for inconvenient procedures (determined nationally), and that they are refunded their direct expenses; this is operationally complex but ethically sound.

Our recommendations for stakeholders include that the National Health Research Ethics Council (NHREC) assumes control of payment norms and endorses payment for TIE.

A new payment approach may experience some resistance because of community expectations and researchers who have enjoyed a simple administrative procedure.

Types of payment

Four types of payment have been identified.[6] **Compensation payments** are intended to compensate for time, inconvenience, discomfort and other research-related burdens (not risks). **Reimbursement payments** are refunds to participants for direct research-related expenses. **Incentive payments** encourage participation either intentionally, when payment is given over and above compensation and reimbursement, or inadvertently, when payment unintentionally exceeds direct costs and burdens. **Appreciation payments** are bonuses given after participation to thank participants for their efforts.[6]

The debate about payment

Although a few hold that research participants should never be paid,[7] controversy centres largely on what should be paid for, and a sum that is appropriate. The principal justification for payment is that it **facilitates recruitment** of participants.[8] When research is scientifically valid, has a favourable balance of risks and benefits, and meets other ethical criteria,[9] recruitment is an ethically sound objective. Payment **reduces financial obstacles** to participation by making participation a 'revenue-neutral activity'[6,8,10] and respectfully acknowledges the burdens that participation in research involves.[6]

There are four main objections to payment. Firstly, payment to participants leads to the 'commodification' of what should be an altruistic venture.[8] However, people who contribute to society's welfare in other areas (e.g. fire-fighters) receive pay; therefore, receiving pay can be compatible with altruistic motives.[8,11,12] Research has long been commercialised,[12] so it is not clear why participants should be singled out as having to have altruistic motives. Participants are apparently motivated by many factors, including money.[2] It would be sensible to acknowledge this and to concentrate on reducing any negative effects of that influence.[13]

Secondly, payment could be more attractive to indigent participants, leading to their over-representation in research and to a disproportionate burden on them;[8] for example, poor people may be willing to undergo risks in return for rewards that better-off people would reject.[14] However, the logical response of decreasing payment amounts would make it even harder for poor people to participate.[8] It may be more logical to increase payment amounts to make participation more worthwhile to better-off people.[11]

Thirdly, payment could influence participants to be dishonest about information that would lead to their exclusion;[8,14] but more objective eligibility criteria would be more logical than eliminating payment.[8] While participants in lower-risk studies may be willing to conceal information, this does not seem to

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be associated with payment.[8] In any event, payment may not influence participants to conceal health information.[2]

Fourthly, payment may undermine the quality of participants' decisions[8] and can tend to be coercive.[8] However, coercion is decision-making *under threat of harm* and not in terms of limited options or a strong influence.[8] Payment is an offer and not a threat[8] and, while ethically complicated, is not coercive. Others assert that payment can be an 'undue inducement', but an inducement is merely an offer that encourages or changes a particular behaviour.[11] Payment may well be a financial inducement in research (better medical care may be a non-financial inducement) but is not necessarily ethically objectionable. An undue inducement is an excessive offer that distorts decision-making or impairs judgement by blinding research participants to potential study risks or causing them to minimise their concerns.[14] This definition includes participants who are led to enrol in potentially seriously harmful research[11] and acknowledges that payment becomes more controversial when there are doubts that an expert Research Ethics Committee (REC) has determined that the study risks are acceptably low.[11] A suitable response may be to put a reasonable cap on payment amounts,[8] improve consent processes regarding risks[11] and ensure that competent ethical review has reduced risks to acceptable levels.[8,11] There are no data confirming that payment leads to impaired judgement.[11]

Objections to paying patient-participants are that it makes the patient-provider relationship more complex, and that patients may receive a direct benefit that healthy volunteers will not. However, payment may actually reduce the 'therapeutic misconception', and some trial procedures do not confer direct benefit.[4]

Objections to payment for child participation include that payment can distort the judgement of parent and child, and that it seems unfair to pay parents when children bear the research burdens. Therefore, compensatory payments should be made to the party assuming the burden (usually the child) at rates comparable with what children would receive for similar activities. Payment should be in kind (e.g. vouchers) to protect children's assets from parents.[6] Reimbursement payments should go to the party incurring costs, and cash seems most appropriate.

Ethical guidance on payment

Many ethical guidelines raise the issue of payment to research participants as being potentially problematic, frequently because of concerns about informed consent or justice. South African guidelines are not completely concordant, but all South African ethical guidelines endorse reimbursement payments. Guidelines governing research funded by the Medical Research Council (MRC) endorse compensation payments for time and inconvenience, whereas the Department of Health tends to endorse incentive payments (payment may be a 'financial benefit').

Many international ethical guidelines are silent on payment (e.g. Belmont Report, Declaration of Helsinki). Those that address the topic endorse reimbursement payments and compensation payments for time and inconvenience but do not provide operational guidance on the latter (e.g. UNAIDS, 2007; CIOMS, 2002).

Models to operationalise payment for TIE

Two models go some way towards delineating payment in a way that broad ethical guidelines do not.[6,8,10,11]

Paying for time

The Wage Payment model[10] advocates compensation payment for time and inconvenience. Payment for time is calculated at an hourly rate commensurate with that for other unskilled but essential jobs.[8,10] While participants do not need any specific skills or training, participation does entail the expending of time and effort.[10] Therefore, to be fair, payments to research participants should be consistent with payments for other similar activities,[11] and participants should be paid the same for the same amount of 'work'.[8,10] The tendency for undue inducement is lessened as participants receive similar money-making opportunities in the community.[8,10] Also, standardisation of payment reduces inter-study competition.[8,10]

However, payment for time at these rates may not facilitate recruitment,[10] especially of higher wage earners.[15] Rate differentials between rural and urban settings or various sectors of unskilled labour[16] need to be considered. (In South Africa, sectoral unskilled labour rates are currently under review, and the general category of unskilled labour no longer exists. At present, domestic workers are paid approximately R5.00/hour when rural and urban sectors are averaged; and construction workers in certain urban regions get approximately R10.00/hour.) In their application of the wage payment model, Dickert and Grady[10] used a national average wage. It is possible that averages could exceed region-specific payments for similar activities (causing participants to conceal information or devalue risks). However, where rural-urban or sector differences are negligible, this is not likely, and a national average seems reasonable. Where stakeholders insist that it is fairer to implement rural-urban distinctions in payment for participants at different sites, the difference could be placed in a fund for community development activities. Even in settings with high unemployment, offering time-related payments at unskilled labour rates is arguably fairer and less likely to be an inappropriately high incentive than rates determined by a market model,[10] or even a flat rate.

Paying for inconvenience

The Wage Payment model advocates additional payments for inconvenient procedures[8,10] (which acknowledges that participation sometimes entails discomfort[10]) and may make

participation more attractive. However, this requires complex evaluation, for which there is little available guidance. Paying for inconvenience, but not for risk, can be problematic. Inconvenient procedures are trouble- or bothersome, or disturb routine.[17] Risky procedures hold the possibility of physical, psychosocial or economic harm. Consequences such as embarrassment could be viewed as either inconvenience or risk. These ramifications can probably be offset by further conceptual work defining the differences, and building the capacity of gatekeepers such as RECs, to apply the distinctions. While experiences of inconvenience will be subjective and differ among participants, the standard is to estimate what a 'reasonable person' would find inconvenient – a concept routinely applied by RECs when making risk estimations.[11]

Payment for inconvenience seems hard to apply without seeming arbitrary. According to the National Institutes for Health (NIH),[18] the study's principal investigator determines inconvenience rates. Dickert and Grady[10] suggest amounts for inconvenience but not how they classed procedures as such or how they arrived at the amounts. Determining rates for inconvenient procedures will always tend to be arbitrary or complex. This can be offset if legitimate institutions, through collective and informed decision-making, reach consensus and make preliminary recommendations on amounts paid for inconvenient procedures that can be adopted in trials by researchers and enforced by RECs.

Paying for expenses

The Reimbursement model[10] advocates payment for participants' direct expenses (e.g. transport costs, meals and child care). Participants are therefore not out of pocket. Because only actual costs are covered, concerns regarding participants' misrepresentation or failure to consider risks are minimised, and indigent people are not especially encouraged to participate.[8,10] However, since participation is not incentivised, it may be difficult to meet recruitment targets.[8,10] It must also be decided whether time away from work will be reimbursed and, if so, if participants are paid according to their income, which could cause researchers to target low-wage earners to reduce costs.[8] Therefore, it has been argued that this cost be excluded.

Since reimbursement will differ among participants, administration of this approach will be more complex. It may be difficult to prove what each participant has spent, as receipts may not be available. To simplify the procedure, and for budgeting purposes, researchers should engage in formative research and consult Community Advisory Boards (CABs) to assess expected costs to participants, e.g. transport to the research site.

Anecdotally, researchers already appear to implement this approach, as in the case of participants presenting for repeated unscheduled visits. Researchers could consider separating reimbursement payments from standardised time and inconvenience payments.

The MCC's payment policy for trials

The MCC policy does not fit the model of 'compensation for time or inconvenience' as participants are not paid according to time spent or inconvenience, e.g. participants who take 30 minutes to complete a simple questionnaire are paid the same as those who undergo hours of uncomfortable procedures – participants are paid the same but are not doing the same things or making the same contributions, which is unfair.[4]

The MCC flat rate does not fit the model of 'reimbursement of expenses' as participants are not reimbursed for their actual expenses, e.g. owing to differing transport costs, some participants may incur a loss while others may score financially. The flat rate could become an incentive if remuneration exceeds actual expenses or burdens. However, our primary concern is not with 'undue inducement' but with fairness.

Another concern is that the ruling on participant payment is beyond the MCC's mandate.[5] In South Africa, the mandate for setting norms and standards for research falls on the NHREC (s73, NHA, 2003),[19] which is more suited for setting standards for payment.

Conclusions

The MCC's policy of participants being paid a flat rate of R150 per trial visit has two apparent advantages: it is simple to administer and *appears* to be fair because all trial participants ostensibly receive the same amount; however, it is fundamentally unjust as participants are paid the same amount regardless of their differing inputs and outlays.[4,14] When research stakeholders acknowledge that paying participants the same amount for different contributions is unfair, alternative approaches should be seriously considered.

Participants should be paid for their actual expense and time outlays at a rate that approximates national unskilled labour rates, with additional payment for inconvenient procedures.

If TIE payment is implemented, trial payments will differ. A trial with fewer, shorter visits and less inconvenient procedures will pay participants less than one with many, longer visits and complex procedures. When participants are paid for their actual expenses, their remuneration will differ, which will require participants (and participating communities) to understand *what* is being paid for, so that the differences are understood to be fair. It is pertinent that participants are routinely expected to understand much more complex concepts (such as placebo/controls) than differing payment rates.

A new payment schedule that takes into account the nature of the study (length, procedures) and the individual costs to participants will not be seen as legitimate unless 'fair differences' are understood. Limiting payment to reimbursement of expenses and payment for time and inconvenience may also be the best way to keep financial inducements 'due'.[12] While this approach may involve logistical challenges and complex administration, it reflects a payment policy underpinned by thoughtful, ethical reflection.

Recommendations for stakeholders

1. The MCC should revoke its payment policy.
2. Research organisations, including their RECs, should audit the payment practices that prevailed prior to the flat rate.
3. The NHREC should adopt TIE payment, draft standardised rates for procedures, discuss these with stakeholders, recommend their implementation for a trial period, and ratify these rates.
4. South African guideline developers should revise ethical guidelines to endorse TIE payment and engagement with communities on aspects of payment.
5. Researchers should estimate expenses in consultation with communities and, using national time and inconvenience rates, prepare payment schedules for presentation to RECs.
6. RECs should implement TIE payment and stipulate that it be included in the consent process because it is material to volunteers deciding on participation. RECs should be familiar with rates for unskilled labour around the country.

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1. Govender P. Girls bunk school to cash in on HIV trials: School kids offered money to test gel product each time they have sex. *Sunday Times* 13 November 2005.
2. Burgess L, Sulzer N, Emanuel S. Clinical trial remuneration: the patients. *S Afr Med J* 2008; 98(2): 95-97.
3. Horn L. Payment of clinical trial participants. *S Afr Med J* 2008; 98(2): 93-94.
4. Dickert N, Emanuel E, Grady C. Paying research subjects: An analysis of current policies. *Ann Intern Med* 2002; 136(5): 368-373.
5. Moodley K, Myer L. Participant renumeration for research? How much is enough? *S Afr Med J* 2003; 93(9): 677-679.
6. Wendler D, Rackoff JE, Emanuel EJ, Grady C. The ethics of paying for children's participation in research. *J Pediatr* 2002; 141(2): 166-171.
7. McNeill P. A response to Wilkinson and Moore: Paying people to participate in research: Why not? *Bioethics* 2002; 11(5): 373-396.
8. Grady C. Payment of clinical research subjects. *J Clin Invest* 2005; 115: 1681-1687.
9. Emanuel E, Wendler D, Grady C. What makes clinical research ethical? *JAMA* 2000; 283(20): 2701-2711.
10. Dickert N, Grady C. What's the price of a research subject? Approaches to payment for research participation. *N Engl J Med* 1999; 341(3): 198-203.
11. Emanuel E. Undue inducement: Nonsense on stilts. *Am J Bioeth* 2005; 5: 9-13.
12. Pentz R. Spreading it around: money for researchers and research participants. *Mt Sinai J Med* 2004; 71(4): 266-270.
13. Heath E. On considering (what I might do for) money. *Am J Bioeth* 2001; 1(2): 63-64.
14. Macklin R. 'Due' and 'undue' inducements: On paying money to research subjects. *IRB* 1981; 3(5): 1-6.
15. Reid L. Nice work if you can get it. *Am J Bioeth* 2005; 5(5): 27-29.
16. Department of Labour. *Sectoral Determination*. Pretoria: Department of Labour. http://www.labour.gov.za/legislation/sectoral-determinations/sectoral-determination (accessed 2 May 2007).
17. Thompson D. Inconvenience. *The Concise Oxford Dictionary of Current English*. 9th ed. Clarendon: Oxford University Press, 1995.
18. NIH Clinical Center. *Are Clinical Studies for You?* Bethesda, MD, USA: National Institutes of Health (NIH). http://clinicalcenter.nih.gov/participate/studies.shtml (accessed 2 May 2007).
19. Strode A, Slack C, Mushariwa M. HIV vaccine research: South Africa's ethical-legal framework and its ability to promote the welfare of trial participants. *S Afr Med J* 2005; 95(8): 598-601.

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MEDICINE AND THE LAW

The Children's Amendment Act and the Criminal Law (Sexual Offences and Related Matters) Amendment Act: Duty to report child abuse and sexual offences against children and mentally disabled persons

David McQuoid-Mason

The Children's Amendment Act[1] and the Criminal Law (Sexual Offences and Related Matters) Amendment Act[2] (Sexual Offences Act) impose duties on medical practitioners and others to report child abuse and sexual offences against children and mentally disabled persons that go beyond those in the Child Care Act[3] and the Prevention of Family Violence Act.[4] The latter Acts will be repealed once the relevant provisions of the Children's Amendment Act come into effect.[5] The Sexual Offences Act came into effect on 16 December 2007.[6]

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Ill-treatment of children under the Child Care Act

Until the provisions regarding the duty to report ill-treatment of children in terms of the Child Care Act[7] are repealed, the existing provisions apply.