

Title: Reimbursing research participants in UK health research: ethical and policy implications

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Summary

This paper explores the ethics of reimbursing research participants in the East Midlands. Pertinent in the context of Governments targets to increase participation in health research and the UK welfare reform - the universal credit scheme triggering reform of payment systems for involvement in research. Internationally health research has relied on volunteers, influenced by the 1947 Nuremberg code of ethics. Under the UK collaborative research agenda, a survey was handed and disseminated by Patient and Public Involvement in research volunteers to health stakeholders in NHS Trusts. 251 responses statistically analysed were supplemented by thematic analysis. Four factors indicative of the values underpinning participants' motivation to participate in research emerged a) 'opportunity for self-development'; b) 'volunteering'; c) 'work and market forces'; and d) 'extra resources'. Stakeholders' values suggest a social shift in the meaning of the ethical values and principles underpinning research (i.e. from volunteering as moral obligation to market values).

Abstract

This paper explores the ethics of reimbursing research participants, looking at how health research stakeholders in the East Midlands perceive reimbursements for participation in research. This is particularly relevant in the context of Governments targets to increase participation in health research and the UK welfare reform - the universal credit scheme triggering reform of payment systems for involvement in research. Internationally health research has relied on volunteers, influenced by the 1947 Nuremberg code of ethics. In keeping

with the UK collaborative research agenda, a survey was distributed to Patient and Public Involvement in research (PPI) volunteers active in NHS Trusts to complete and disseminate to relevant health stakeholders. 251 responses were statistically analysed using descriptive, frequency based statistics and factor analysis (FA). Principal Component Analysis and Varimax Rotation with Kaiser Normalization used, supplemented by thematic analysis of open questions. Four factors emerged from the exploratory FA, indicative of the values underpinning participants' motivation to participate in research a) 'as an opportunity for self-development'; b) 'volunteering'; c) 'work and market forces'; and d) 'extra resources'. Results brought to light that stakeholders' values do not entirely accord with the priority given to volunteering in most NHS organisations i.e. respondents valued participation most as opportunities for self-development, skill acquisition and to be reimbursed as work. Findings suggest a social shift in the meaning of the ethical values and principles underpinning research (i.e. from volunteering as moral obligation to market values) indicative of the present socio-economic climate. This study contributes to a greater understanding of the use of reimbursements in health research with practical implications for policy makers, ethics reviews, ethics committees and researchers in the design of health research that both promotes ethical integrity and also maximises recruitment, critical for validity purposes.

Keywords

research, ethics, values, motivation, involvement, reimbursements

Introduction

Background:

In the United Kingdom, more than £8 billion a year is invested in health research. This mostly relies on 'volunteers' research participants or advisers (e.g. to test drugs or to share views about research direction and methodology). Research ethics are underpinned by the 1947 Nuremberg code. At times, both participants and advisers receive money or gifts (e.g. shopping vouchers) which is controversial for a variety of reasons (Risher, 2013). One is that it is perceived by some as encouraging a reckless approach to the risks involved, while others see it as a form of exploitation of the economically disadvantaged (in line, Fry, et al., 2006; Bentley & Thacker, 2004; Cryder, et al., 2010). Very importantly, payment may be seen as coercion and thus, generally opposed by research ethics committees - who stress volunteering in research as the ethical approach (Weindling, 2001). Additionally, participants who rely on means-tested benefits express concern that receiving payments may threaten their entitlements. On the other hand, when NHS trusts base their payment levels on welfare benefit regulations, they may then be viewed by non-claimant members of the public as insulting, paltry rates of remuneration.

To make matters worse, current national policy guidance is unclear, fractured, complex and incomplete. It tends to focus on the research advisers' circumstances, rather than on participants' issues and experiences generating local variation between NHS Trusts and a disjunction between policy and practice (Bates, 2013 & DWP, 2013). Recently, the Coalition Government redesigned the welfare benefits system and in 2013 piloted a new Universal Credit to be introduced in the near future. This policy introduction will trigger reform of payment systems for involvement in health research and current Governments aims to actively increase participation levels in research, as part of the 'transformational practice agenda' (Crisp &

Wilson, 2011, Arfken and Balon, 2011, DWP, 2013)). These reasons clearly highlight the importance of examining research reimbursements more closely (see further, Roca and Bates, 2014).

This exploratory study aims to assess and describe the experience and views of stakeholders involved in health research stakeholders based in the East Midlands of England (i.e. Patient and Public Involvement (PPI) volunteers, NHS users, finance staff from NHS Trusts, Chairs of Ethics Committees, members of a health steering group at a University, and researchers) regarding reimbursement for PPI in research activities. In addition, we aim to explore any dimensions along which these views fall, and whether there are any conceptual themes (i.e. sets of values and principles) which may underpin and explain these dimensions. A greater understanding of research stakeholders' attitudes and motivations towards reimbursements will help policy makers, ethics committees, Involve (an agency of the National Institute for Health Research and the body that supports public participation in health research) and researchers, to design studies that promote ethical integrity and maximise recruitment, critical for validity purposes (in line with Breitkope, et al., 2011).

Research questions:

- 1) What are the current payment arrangements to patients and the public involved in co-producing health research in the East Midlands, as perceived by a range of relevant stakeholders?
- 2) Are there sets of values and principles that underpin stakeholders' views of reimbursements for involvement in health research?
- 3) Is there a dominant theory of reward for participation in research?

- 4) Are there any differences in values and principles across different health stakeholders?

Methods

Participants

A variety of relevant stakeholders (purposive sample) from the East Midlands were identified as potential participants for this research, i.e. PPI volunteer representatives, NHS patients; finance staff from NHS Trusts, both with managerial and without managerial responsibilities; members of Ethics Committees; members of a health steering group at a University; and researchers, both main-investigators and co-investigators. The East Midlands location was chosen for being demographically representative of the wider UK according to the census data by the Office for National Statistics 2012 and Knowledge Transfer Network. 89 men and 149 women were selected, along with 13 who did not identify their gender. The sample had a minimum age of 20. Both gender and age bands reflected national trends, i.e. a predominance of females and participants in the age band 40-59 years and in the younger age band 20-39. According to the Census data by the Office for National Statistics (2012) and Knowledge Transfer Network (2012) in the UK, the female population is higher than male from 40 years onwards.

Questionnaire design rationale

Policy and guidance statements regarding payment for patient and public involvement were reviewed in the spring of 2013, by the second author. Reflection on this material and research in other fields, e.g. Hardill and Baines' (2007) work on the motives for community volunteering, generated a set of sometimes contradictory value statements that appeared to underpin policy. Those were categorised into four main propositions that seem to underpin informal commonsense explanations, which health service users and providers give for their social

behaviours. Such ideas are based on belief systems which may or may not be derived from scientific explanations, typically extrapolated from meanings attributed to life experiences, i.e. lay theories (Farr and Moscovici 1984; Shaw, 2002; Hughner and Klein, 2008). These four propositions are as follows:

1. PPI is volunteering as an active citizen. In this view, PPI activities are a freely given contribution driven by altruism with the goal of improving life chances and opportunities for other citizens and institutions.
2. Payments are fair wages for work done. PPI activities are one side of a mutual agreement in which payment or other benefits are exchanged for time, effort and expertise. Terms and conditions should, as far as possible, be like those pertaining to formal employment settings.
3. PPI activities are opportunities for self-development. PPI provides opportunities for the growth of confidence and skills in the individual. Each PPI rep should receive tailored support to enable them to both contribute and develop, including protection from harm where there are personal vulnerabilities.
4. It is a capitalist market. Each individual PPI arrangement is open to negotiation and both PPI reps and research teams will be driven by self-interest to achieve their goals with minimum cost and maximum benefit for themselves.

These value statements were in turn used to generate items for an on-line questionnaire that used a 1-5 response scale (1= strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree). In addition to these items, the questionnaire also included

demographic items, questions on respondents' experience of being paid for involvement in research, and open-ended questions to elicit qualitative data.

The survey was piloted for appropriateness with eight stakeholders (one NHS patient, one member of an ethics committee, one member of a university public engagement group, two social workers, one PPI member, one finance manager at an NHS trust and two academic researchers). Input from relevant health experts was also used in the survey design (e.g. researchers, members of ethics committees and finance managers).

Procedure

Collaboration, both with the questionnaire completion and dissemination within professional networks, was initially sought with PPI members via letter, distributed at a meeting of patient representatives and researchers in December, 2012. The design of the questionnaire and participant engagement conformed to the National Research Ethics Service (NRES) guidelines for user involvement. Voluntary prospective participants were then formally invited to participate in February 2013 via email, followed by phone call and e-mail reminders until February 27th. The survey was conducted over a five week period between February and March 2013. Participants were offered an incentive of entry into a prize draw for a £50 voucher

Data analysis

Both quantitative and thematic qualitative analyses were performed.

Descriptive and frequency statistics were computed. Questionnaire items were submitted to exploratory factor analysis to examine underlying patterns in the data.

To measure for a possible association of values and principles with each of the four theories, the items were submitted to factor analysis. That is, to observe whether the items grouped together in factors according to the four initial lay theories:

- 1) PPI is volunteering as an active citizen
- 2) Payments are fair wages for work done
- 3) PPI activities are opportunities for self-development
- 4) It is a capitalist market

To avoid over-fitting the data, and to obtain a better cases-per-variable ratio, the initial list of 46 variables was reduced to a set of 25 variables. To do this, the authors considered the conceptual underpinnings of the variables, and used judgements as to the appropriateness of the variables for factor analysis (FA).

This is the favoured approach to reduce variables according to the sample size (i.e. no more than 1 item per 10 participants); the alternative approach of hoping that FA can cope with the higher number of correlations and find some meaning in the data has the weakness of leading to a less generalisable model. Principal Components Analysis was used to extract factors, and varimax rotation with Kaiser normalization was used to rotate the factor matrix to obtain orthogonal factors. The primary aim of the factor analysis was to identify a simple and interpretable factor structure.

To examine whether different stakeholders varied in their value basis, crosstabs were carried out on the items comprising each of the factors. The five initial categories data was then averaged according to three main categories, i.e. 'agree', 'disagree' and 'neutral'. To achieve

this, the categories of 'strongly agree' and 'agree' were summated, as were the categories of 'strongly disagree' and 'disagree'. The findings are presented in Figure 1.

The content of the open questions was thematically analysed and included to supplement the quantitative analyses. Direct quotations from participants are presented in "inverted commas" to add validity to findings. Participants are mentioned in the results with pseudonyms for confidentiality purposes.

Ethics

An Ethics Committee chair in East Midlands was consulted on the ethics underpinning this research. The permissions obtained to perform this study conform to the 'Research Governance Framework for Health and Social Care: Second Edition' (2005-2008) and the National Research Ethics Service (NRES) guidelines on requirements for ethical review. For instance, based on informed consent and given that respondents were contacted via public databases and organisations membership lists and then chose to respond to an anonymous questionnaire, there was no need for approval from individual NHS Trusts.

Results

Demographics

We had 251 survey returns. It is not possible to establish a response rate, since PPI volunteers were recruited from across a range of East Midlands professional networks, using a widely disseminated invitation and collaborative engagement procedure. 59% of respondents were female (n=149), and 36% were male (n=89), whilst (n=13) opted for not revealing their gender. Ages were grouped, and groups ranged from 20-24 to 75+, with the highest proportion of respondents in the 50-54 age group (n=40, 15.9%).

The majority of participants described themselves as 'white' (86.6%). A high proportion 236 (94.4%) identified themselves as being of British nationality. The majority of respondents reported their employment status as "employed" (n=131, 52.19%), followed by "retired" (n=62, 24.7%).

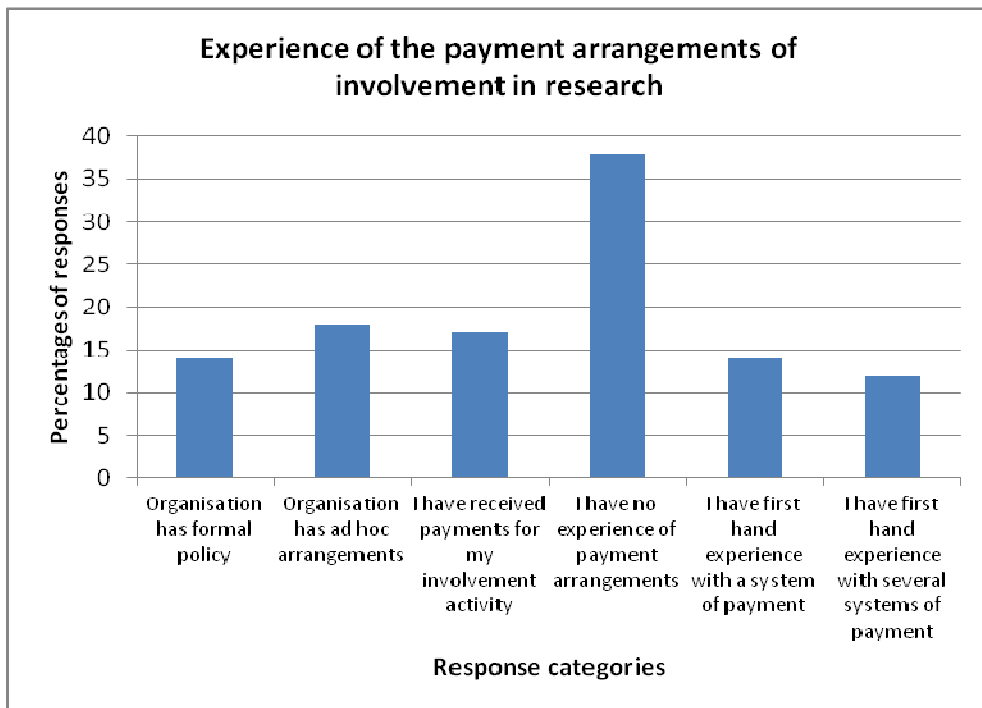
The largest proportion of respondents described themselves as "NHS patient/users" (n=108, 43.2%) or PPI representatives (n=44, 17.5%). A further 21% (n=53) were researchers and 8% (n= 20) were health or social care workers, with 25 (9.96%) respondents reporting multiple roles. For example, one respondent stated being an NHS patient/user, a doctor, a member of an ethics committee and a researcher. In the 'other' category, the predominant roles mentioned were carer, nurse, development officer, advocate, trusts manager, LINK member and drug worker.

From the review we have no knowledge of other similar project to contextualise the participants group in terms of their motivations to volunteer according to experiences and occupational status (i.e. participants involved in clinical trials tend to be paid for participation in research, some may do it for altruistic reasons to give back to community after negative health experience, others for the payments (Breitkopf, Loza, Viincent, Moench, Stanberry and Rosenbthal, 2011; Sikweyiya and Jewkes, 2013). For example it emerged from the analysis that a number of participants mentioned different payment ranges for participation in clinical trials (i.e. 19=15% suggested high payments and 89=36% answered 'don't know') - thus despite the low numbers mentioning high payments it is reasonable to extrapolate that experience may influence participants values and motivations regarding payments in research for different health stakeholders. This will be examined in an extension of this project.

Frequencies, Descriptive and Thematic Analysis

RQ1: *Payment Arrangements for Involvement in Research:*

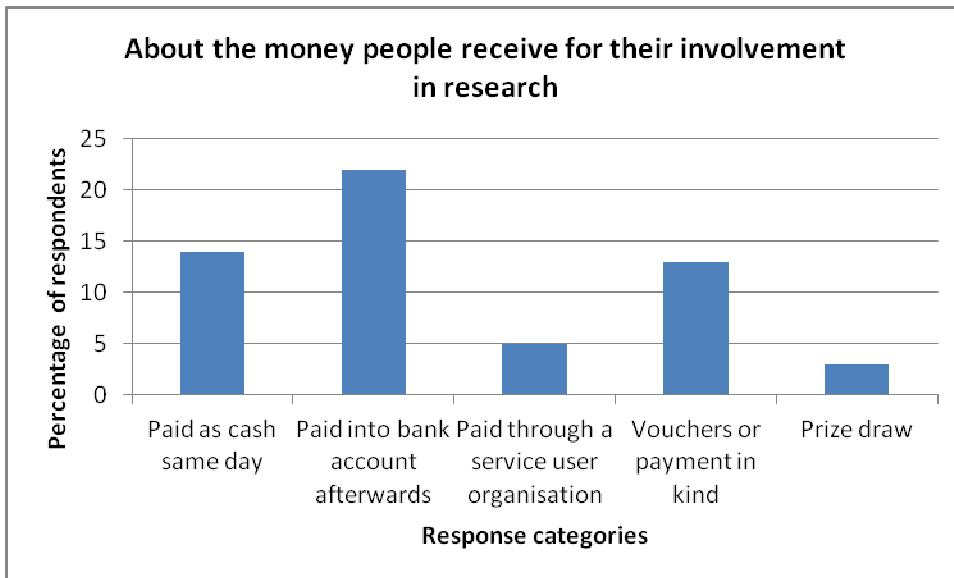
Results summary chart: 1



Forty-five (18%) respondents had experience of payment arrangements. However, the largest group of respondents (n=96, 38%) reported having no experience. 24 (approximately 10%) reported having received expenses only and a minority 2 (0.8%) mentioned expenses and a token voucher.

The predominant experience within respondent organisations was ad hoc payment arrangements (n=45, 18%) as opposed to a formal payment policy (n=34, 14%).

Results summary chart: 2



The predominant method of payment for involvement in research was via bank account after the collaboration had ended (n=54, 22%), followed by cash paid on the same day (n=35, 14%).

Other systems of reward also mentioned in the open questions included a goody bag, payment into a ward fund, meals, childcare provision, travel expenses, and an inconvenience allowance.

It is interesting to note that n=61 (24%) participants reported experience with multiple systems of rewards as exemplified by:

“A variety of the above depending on the company running the research. Sometimes it is vouchers and sometimes it is payment to us as an organisation for recruiting patients and at other times direct to the patients” (Alex).

Results summary table 1: Circumstances and expenses

| | Expenses | N= |
|--|-----------------|-----------|
|--|-----------------|-----------|

| Circumstances | £1-£10 N= % = | £11-£20 N= % = | £21-£80 N= % = | £81+ N= % = | D/Know N= % = | Total N= | Missing values |
|---|---------------------|----------------------|----------------------|-------------------|---------------------|-------------|-------------------|
| - Attend a two hour meeting and join in the discussion. | 23=9% | 47=19% | 25=10% | 2=0.8% | 55=22% | 152 | 99 |
| - Spend about 10 minutes filling in a short questionnaire. | 39=16% | 7=3% | 1=0.4% | 0=0% | 74=30% | 121 | 130 |
| - Be interviewed by a researcher for up to an hour. | 25=10% | 31=12% | 10=4% | 2=0.8% | 63=25% | 131 | 120 |
| - Attend a Board level meeting as a Patient Representative. | 6=2% | 24=10% | 19=8% | 7=3% | 80=32% | 136 | 115 |
| - Participate in a clinical trial. | 7=3% | 1=0.4% | 12=5% | 19=15% | 89=36% | 128 | 123 |
| - Other | 7=3% | 4=1.6% | 5=2% | 5=2% | 64=26% | 85 | 166 |
| Total N= 251 | | | | | | | |

NB The most typical amounts paid are coloured for clarity purposes

Respondents described the roles for which they have received payment, and the typical amounts for each of these roles were as follows:

- To attend a two hour meeting and join in the discussion, the most common amount received is £11-20 per hour (19%), followed by £21-80 per hour (10%) (Franki).
- To spend about ten minutes filling in a short questionnaire. Here the majority of respondents (n=39, 16%) receive £1-10. It was interesting to note that some explained that they were doing it for free since it required a minimal amount of effort, as illustrated by:

“I have not ticked an answer to 9.2 as the expectation would be no payment for such a short contribution. The others are answered on the basis of a sessional payment being made” (Andi).

"...For 9.2, I'd have ticked £0 if it was there" (Bernie).

- To be interviewed by a researcher for up to an hour, the most predominant experiences were payments of £11-20 (12%).
- To attend a Board level meeting as a Patient Representative, the greatest proportion of respondents (n=24, 10%) receive £11-20.
- To participate in a clinical trial, the largest proportion of respondents (n=19, 15%) reported receiving over £81. Different perceptions were expressed by respondents as follows:

"For participation in a clinical trial it will be dependent on what is involved, how many visits etc." (Danni)

"Participate in clinical trial- amount should vary depending on nature and demands of the study and what ethics panels' decision is" (Jerri).

"The amount all depends on what the trial has budgeted for" (Kel).

"Participant in a clinical trial - no payment" (Lou).

"I have been paid throughout the various levels by different bodies. Your 81+ payment is low as I am fairly regular paid £150 or more" (Max).

The amount of money received appears to relate to occupational status, skill base and knowledge basis as suggested in the open-response questions, illustrated by:

"We offer payment per hour and are very specific about how many hours we expect the involvement to take. Payment is also offered on skills set and what the involvement actually entails. It is difficult to gauge how much participants get paid to be involved in a trial as this is covered by the protocol itself Some get paid, others do not. In general, if it is just a quick questionnaire, we do not offer payment" (Mel).

But it was interesting to note that some respondents and organisations also believe that service users should be paid the same as professional experts (e.g. guest speakers at NHS Trusts and PPI meetings, GP's), as illustrated by:

"Pay participants the same as professional speakers" (Sall, service user).

"These payments can vary, for instance in our expert by experience programme we pay the same fees to service users as to professional speakers" (Mandi, service provider).

From the total of 107 participants who offered explanations for their involvement, 14 (13%) reported receiving only expenses, while 2 (2%) received expenses and a voucher (e.g. lunch voucher £3).

Overall the main messages were that each involvement is different and thus rewarded differently, as illustrated by:

"Each involvement is paid differently sometimes hourly sometimes as a session. Different involvements have different amounts paid to Patient/Carers involvement" (Taris).

"I have worked in a three units that have handled payments quite differently. Two were university departments and the third is a National Institute for Health Research unit. All have been based on ad-hoc arrangements on a per-study basis" (Sacha).

Concerns over tax and benefits implications

A number of respondents (i.e. service users, researchers) described concerns about the tax and benefits implications of payments.

"I am most aware from what service users have told me. My org will pay a small fee for expenses or receipted expenses if higher- because of issues around benefits. I believe there is a lot of fear on the part of payers around this, and a lot of discontent amongst users because they feel that they are unable to be paid properly- benefit system taking it back- and therefore they don't get involved with research" (Pat).

"Problematic mainly thanks to insane and inflexible benefits rules. I'm aware if I even turn payment down when it's offered I'm risking it being designated a 'notional payment' under rules presumably developed to discourage people from working for free for family while claiming to be unemployed, but which in fact deter and discourage volunteering or involvement while doing very little, at a guess, to penalise fraudsters who'll continue working and claiming regardless. As a result I feel guilty and nervous getting involved even when not claiming. This seems daft, especially as it's my volunteering that's the only way I'll ever get myself back fit for work again, seeing as there's bugger all out there

beyond facile literacy and numeracy courses and 'work first' one-size-fits-all schemes. I feel I'd be penalised less for sitting on backside doing nothing to help myself than I would getting out there and helping others as well as myself. Certainly if any involvement insisted on BACS payment (into my bank account) I'd get out of there fast, for my own protection" (Terri).

"Benefits payment rules need adjustment to reflect the existence of a research payment structure and so encourage support for research e.g. it should be mandatory across the whole country that payments received should be averaged over a 4 week period when adjusting down a benefit (i.e. if payment is being made for a monthly activity that should not all be treated as having all been received in that one week of the event). Moreover there should be no risk of research participants that present themselves to a research project being treated as if they are 'fit to work" (Oli).

Exploratory Factor Analysis

RQ2: Sets of values and principles underpinning reimbursement/payments for research

The original sets of values and principles were partially upheld, but also challenged, e.g. propositions two and four items merged into a factor categorised as 'work and market forces' (factor 2 in the matrix below). Interestingly a new factor emerged that was classified as 'extra resources' (factor 4).

Table 2: Factor analysis matrix

| Variables | Factors | | | |
|-----------|---------|---|---|---|
| | 1 | 2 | 3 | 4 |
| | | | | |

| | | | | |
|--|------|------|-------|-------|
| | | | | |
| Involvement expands important personal and social skills | .839 | | | |
| Involvement should help participants to develop their skills | .801 | | | |
| Involvement develops work-related skills | .796 | | | |
| Involvement really does help participants to develop skills | .756 | | | |
| The involvement system should promote wellbeing, independence and employment | .697 | | | |
| Involvement supports people to express their views, experiences and concerns | .646 | | | |
| Arrangements for getting people involved should support people... vulnerable to make a contribution alongside others | .583 | | | |
| Payments can coerce and distort motivation | | .716 | | -.319 |
| To contribute to society at large is good enough reward | | .698 | | |
| Unpaid people can challenge the system | | .618 | | |
| Paying for involvement may bring the 'wrong' people forward | | .576 | | -.354 |
| Volunteering is a way to give something back in exchange for the clinical care you have received | | .565 | | |
| Involvement is a leisure activity | | .564 | | |
| Pay as little as possible out of the public purse | | .559 | -.302 | |
| The amount of money paid should related to the actual tasks being done | | | .774 | |
| Payment levels should reflect the effort required | | | .770 | |
| Activities that are more intrusive (time consuming, invasive, dangerous or disruptive) should be paid at a higher rate | | | .674 | |
| Pay people according to the level of skill required | | | .665 | |
| It's work, so set out clear expectations | | | .561 | |
| Many people are poor so pay as much as possible | | | | .751 |
| Pay people their usual wage for the time they spend | | | | .708 |

Note: Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization. For clarity purposes the items with lower loadings (i.e. less than .3 were excluded from the results table. That is, a large loading indicative of a factor is classed as greater than .4 (Stevens, 1996). That is, when item loadings less than 0.30 were excluded, the factor analysis derived four factors on which 21 out of the 25 questionnaire items loaded. These factors accounted for 53% of total variation and had an eigenvalue = 1.8.

Reviewing the structure coefficient matrix suggests that the four factors group the items in a theoretically understandable way, as follows:

Self-development

Seven items loaded on to the first factor. These items all relate to the opportunities for personal development, skill acquisition and making a contribution that PPI activities provide, such as personal and social skills, work-related skills, wellbeing, independence and employment, and an opportunity to express their views, experiences and concerns and make a contribution. This factor was labelled 'self-development'.

Some illustrative quotes from respondents are:

"For those out of work, involvement should be seen as an opportunity to develop confidence and skills as part of their "return to work" programme..."(Sam).

"PPI means I can use some of my skills and see `both sides of the coin' now. I appreciate any payments I receive but I am not involved for the financial gain!!!! I gain much from being involved and it certainly enhances my retirement. I hope my contributions are of help and I do feel very appreciated by our particular group leaders" (Kell).

"Patients and carers make a valuable contribution to the ongoing improvement of cancer services. They attend formal meetings/discussion forums as well as undertaking a lot of reading in their own time to keep up to date with developments. They need to be properly supported through training, ongoing support and guidance and reimbursement of expenses as a minimum. A well thought out payment model to reimburse them for their time would be of value" (Micki).

Volunteering

Seven items load onto a second factor related to non-payment for PPI activities categorised as 'volunteering'. These items suggest that PPI activities ought to be freely given rather than paid for. This set of values and principles expresses concern over the impact of payment on motivation and/or in bringing unrepresentative groups forward such as individuals driven by material gains rather than altruistic values.

Responses to the open-ended questions illustrated this view as follows:

"People should contribute to research for altruistic reasons, not for payment. Their reward should be the satisfaction of furthering research into improved treatment for their condition" (Nat).

"...in principle do not support payments unless a role is being undertaken that is of required input as opposed to voluntary, or for a strategic purpose. Payments set a principle for involvement which, due to cost, would work against general involvement" (P).

"I have recently joined a PPI and have been offered expenses and payments. I asked that these should be reinvested in the research" (Robbi).

However, a number of respondents also suggested that expenses should be paid to volunteers so that involvement would not be taxing on their resources, for example:

“.... In my opinion payment for volunteering is quite controversial, paying travelling costs is acceptable” (P).

“I think that no public money should be spent on 'volunteers'. it is a choice for people to participate in NHS research and I think people should do it for the right reasons, to contribute to society. Paying people can distort results, and I think NHS money should be spent on necessary services, treatment, staff and equipment. There are always people that will aid with research for free, use them, not the ones just in it for the free voucher. I would still have answered this survey with or without the incentive, and, yes, I would be extremely happy if I won a voucher, but I answered this because I feel strongly about the subject. I have seen so many times people being paid by the NHS for participation in projects and so many of them have not actually helped patients/affected services - public money down the drain!” (Mandi).

Another respondent added as follows:

“I volunteered because my life had been saved by research and I wish to give something back. I will accept my expenses for attending meetings etc. so it does not cost me money out of my pension but I do not wish to be paid for my time out of the public purse. I would like to see this fed back into research funds”.

Some organisation representatives concurred as exemplified by:

“The minimum payment should at the very least cover expenses involved in getting to the place where research takes place in line with voluntary organisation and tax recommendations.

Payment should not equate to a wage as this would change the feel of 'volunteering' and possibly peoples motive for undertaking research" (Joey).

"I think volunteers should be encouraged where positive (taking into account their vulnerability) and they should be paid their expenses and a reasonable contribution for their support and this should be a free gift. Volunteers should be doing this for the right reasons and not just for monetary gain. Their support is invaluable to future service provision (Pat).

Work and market forces

The third factor that emerged had six items loading on to it, all of which reflect the view that PPI activities should be treated as a form of work, with payment commensurate to the nature of the tasks undertaken, and the skills or the effort required. This factor was labelled 'work and market forces'.

Illustrative quotes are:

"GPs get paid for 'everything', and research participation through 'good will' has been eroded. They are paid for recruiting the patients, so why the patients themselves shouldn't be paid? It is they who are subject to any clinical interventions; who have to fill in diaries; attend focus groups; travel back and forth to the research site on multiple occasions etc. Perhaps those designing research studies should be more sensitive to the unreasonable demands they put on some patients and put themselves in their shoes? A shame, but in this day and age I think most people expect to be reimbursed for their time (Terri)".

"I do feel that people should be paid for work that they do. their time is valuable and they are giving it up, as well as paying out for travel to and from wherever they have to go" (Ronni).

"My belief is everyone should be paid for their time (same rate as anyone else working on the project) and expenses and for any support/training and care arrangements that are needed (this is the only true way involvement can have the credential it deserves and if involvement truly valued this would be done) and if on benefits giving an equivalent payment to charity or non-profit group chosen by the person doing the work (the person themselves is not offered the payment only the choice about where a donation should go to) the person should always have all expenses paid. This includes child care, support, training, materials needed and access to resources and support" (Sal).

The above quotes suggest values as payment expected due to societal value changes with the meanings of work, however it is important to note that the next quote (see below) suggests that there may be differences in motivations from the different volunteer groups examined i.e. PPI's and volunteers for trials either seen as '*active participants in the research process*' as opposed to those with a preponderance of altruistic values derived from personal experiences and which will be examined closely in an extension of this project.

"I think that in order to attract participants to trials; they need to be remunerated appropriately and equitably for the work they do. Equally those who act as participants, in order to give academic expertise; the problem is they can be forced to become or assume the role of a volunteer, but really that title is wrongly appropriated to them, as they really are really active

research participants. This is especially important, if they are contributing to a programme of research, on behalf of a academic forum, i.e., by their 'casual' input,(e.g. their own researches e.g. their time at home, their photocopying , their printing, their travel, their time to write up the documents etc. These must be seen as costs pursuant to that research project, in just the same way as a paid employed researcher would expect in their work environment. They should be paid an hourly rate, similar to an academic junior researcher. They should then be seen as 'active paid participant researchers', as one cannot class them as straight "volunteers', in order to drive down research costs, and minimise on site facilities, i.e. office space, and other on-costs etc. These people have their own living expenses to deal with too. I think what may have been past expectations, by many academic bodies, societal changes have altered in the last twenty years, and thus many older volunteers have given way to new ways of being active paid participants, but not employees. Also, the ways of employment have changed, so many more 'informal' structures of working, and engagement opportunities, are coming into being. All of these are currently facilitating and supporting this sort of engagement that is required by commercial and academic bodies. It is important therefore, that appropriate reimbursement is implemented at the outset, in order that the best and most up to date academic participants' are engaged and recompensed for their contributions, whether or not that leads to a permanent position or employment by another organisation for that individual. If appropriate payments are not proffered, and then people may not be so ready to offer their time, as they may feel that they are just being used" (Sacha).

"It is really important for Patient to be treated as Partners in research and to be paid accordingly" (Jamie).

"I think we should be paid a remuneration that fits with the level of skills demonstrated. For example, I have had to go on a number of training courses to enable me to volunteer on certain projects and work plans. This should be the case but most often is not. If someone takes part in a clinical trial that could affect the outcome of their treatment they should get remuneration without question. They have to live with the consequences I sit on the Mid Trent cancer research steering group to offer the patient perspective but I am unpaid and I often feel undervalued and wonder how seriously the clinicians take me as an unpaid rep. We are professional in our input and contribute equally to the Healthcare professional" (Mike).

"I am finding the time taken to respond to e mails which are coming from all sorts of different sources now e.g. yours is an example taking up more and more of my time. I want to be a good PPI panel member and now am increasingly feeling there has to be some financial reward as this is a service that now is indispensable for research monies to be granted and so as such is as vital as the other research participants. Given that considerable amounts of money are granted the PPI element should be factored in. Nottingham seems to have a very frugal policy whereas other areas are generous. This needs to be equated across the country" (Morgan).

"Patients and carers make a valuable contribution to the ongoing improvement of cancer services. They attend formal meetings/discussion forums as well as undertaking a lot of reading in their own time to keep up to date with developments. They need to be properly supported through training, ongoing support and guidance and reimbursement of expenses as a minimum. A well thought out payment model to reimburse them for their time would be of value" (Shannon).

Extra resources

The fourth factor had four items loaded on to it, which expressed the view that payments were needed to supplement individuals' income. This factor was labelled 'extra resources'. Some corroborative quotes from respondents include:

"People who volunteer to get involved are often ill, disabled or have a mental health issue. Most are receiving welfare benefits and living on very little. They at least deserve to be reimbursed their expenses and given some payment for their time and effort..." (Tracy).

"I am retired, with a state pension. I get Disability living allowance for a disabling pain condition but i am an unpaid volunteer but would feel more valued with some remuneration for the more time consuming and difficult meetings that require most skills" (Jerry).

"It is good to receive a contribution to help ones income" (Jordan).

"Simply that a reasonable remuneration is only fitting as most subjects will be from a generally poor situation and simply looking to augment an already meagre income. Few will be full time workers on a decent salary/wage..." (Taylor).

"I used to consider accepting money for voluntary participation was wrong but, with increasing living costs, I'm now happy to accept whatever payment is considered appropriate and, also, it makes my efforts appear acceptable and a reward for giving up my time" (Hayden).

RQ3 Is there a dominant theory of reward for participation in research?

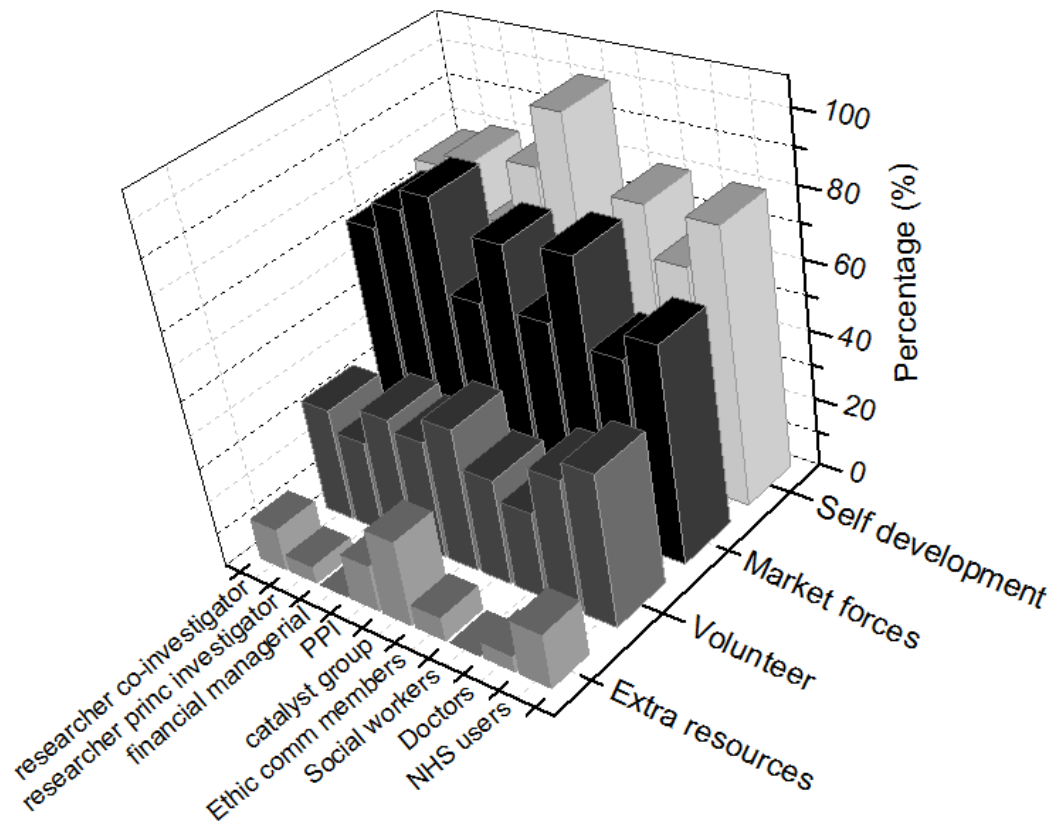
Table 3: prevalence of views on involvement in PPI activities

| Factors | Means % per categories |
|------------------------|----------------------------------|
| Self-development | Strongly agree=24% Agree= 48% |
| Work and Market Forces | Strongly agree=17% Agree=44% |
| Volunteering | Strongly agree= 5% Agree= 26% |
| Extra resources | Strongly agree=2% Agree=10% |
| Missing values | 6=2.4% |
| Total N | 251=100% |

The frequency based statistics suggested that the most prevalent view of PPI activities is that PPI contributes to self-development. There was a preponderance of respondents “strongly agreeing” and “agreeing” with the survey items that loaded onto the Self-development factor (see table 2).

RQ4 Are there any differences in values and principles across different health stakeholders?

The crosstabs statistics indicated differences in perceptions in the adherence to the sets of values and principles that emerged from the factor analysis by the different health stakeholders surveyed (please see Figure 1).



The results clearly show that the majority of health stakeholders subscribed to the main sets of principles described by the factors of 'self-development' (i.e. 79% of NHS users, 66% of Doctors, 83% of the PPI's, 80% of Social workers, 100% Catalyst group, 64% of Financial staff, 80% of Research Principal Investigators, 77% of the co-investigators and 50% of members of ethics committees) and 'market forces' (i.e. 62% of NHS users, 55% of Doctors, 80% of Social workers, 59% Catalyst Group, 59% PPI, 86% Financial staff, 78% Research Principal Investigators, 72% Research co-investigators and 59% of members of the Ethics Committees).

With the 'volunteering' factor the stakeholder representations included 44% of NHS users, 38% of Doctors, 25% of Social Workers, 42% of the Catalyst Group, 34% PPI's, 38% of Financial

staff, 27% of Researchers Principal Investigators, 34% of Research co-investigators and 31% of Members of the Ethics Committees.

The 'extra resources' factor, as with previous results, represented a higher number of participants who were neutral and or disagreed with the variables, ranging from 17% of Ethics Committees Members and Research co-investigators to 83% of Financial staff. The levels of agreement across the different stakeholders included 16% of NHS users, 5% of Doctors, 25% of the Catalyst group, 14% of PPI's, 5% of Research Principal Investigators, 13% of Research co-investigators and 7% of Members of Ethics Committees. A possible explanation is that this factor represents mainly research collaborators from underprivileged backgrounds, i.e. with disabilities and/or retired on low incomes. Overall more than 50% of all respondents agreed that participation in research should be compensated financially. However the low representation of some health stakeholders, i.e. Social Workers, Catalyst group, Finance staff, makes it difficult to derive strong representative conclusions. This study needs replication with a wider sample of each of the relevant health stakeholders.

Discussion

This study demonstrates that there is a variety of policies, views and practices regarding payments and reimbursements for PPI involvement in research and NHS services. Participants' common experiences of multiple systems of rewards to participate in research seem to indicate fragmented policies and understanding.

The exploratory factor analysis showed that these are underpinned by divergent values and principles that can be usefully subsumed into four broad sets of values and principles that

respondents regarded as an ethical approach to reward their participation in research, as follows:

1) 'Self-development' - PPI practices are perceived as opportunities for self-development, both in terms of social and personal skills and valuable skills that may promote full-time employment.

This is the most prevalent motivation underpinning involvement in PPI practices;

2) 'Work and market forces' - those involved in PPI activities should be financially rewarded for their time, skills and expertise and that reimbursement should reflect market value. By this view, both participating organisations and individuals ought to have financial gains and payment, which can be seen as ways of being valued. Payments were also perceived as contributing to fairness and equality and to prevent individuals' exploitation, as well as being a motivator. Thus, being paid for participation in research was considered by some to enhance the representativeness of the various interest groups that may be involved in PPI activities and research. However, this finding challenges the basis on which research involvement policies, practice and regulating ethical guidelines have been based in the UK (i.e. that it ought to be voluntary);

3) 'Volunteering' - PPI activities ought to be entirely voluntary, since the act of being paid may lead individuals to participate in research for the wrong reasons (e.g. to merely attain financial gain);

4) 'Extra resources' - being reimbursed for expenses provide a good way to supplement people's income in difficult financial situations, particularly people who are retired, disabled or unemployed. However, a constant theme within the qualitative analysis was the respondents' fear that participating in research, by being involved in PPI activities and disclosing payment, might threaten benefit claims (illustrated by: *"Volunteering must NOT be confused with work nor*

rewarded as work as not only benefits but tax liability issues arise."). 6 participants reported being benefit claimants, whilst 4 reported being unemployed and 11 omitted their working status, although some commented on concerns over benefit entitlements suggesting that a wider percentage of participants had benefit claims experiences and/or reported views and concerns on it.

These illustrate two different foci: a) a duty of care to the person; and b) a duty of care to the country's financial resources, reflecting a variety of health stakeholders', contexts and views on attaining healthcare quality.

There are two criteria by which the findings may be analysed and their implications interpreted. One is by making a simple comparison of the number of respondents who subscribed to the four factors, which places 'Personal Development' as the most often reported, followed by 'Work and Market Forces', and then 'Volunteering' and 'Extra Resources'. The other is to consider the power to drive the results, arising from higher loadings in more variables. In this case 'Personal Development' is still the strongest factor, but it switches the order of the other factors by placing 'Volunteering' second, 'Work and Market Forces' third and 'Extra Resources' fourth. The sequence of the second and third factors may reflect a shifting social and economic context. That is, within this study, work values and principles had more adherents, which indicates a shift in the values and principles that underpin research (likely to be associated with the present socio-economic climate), and 'Volunteering' values and principles which have long been driving the design of global and local policies and ethics since the Nuremberg ethics code, 1949, was less often advocated by this cohort.

From the detailed analysis of the results according to the different health stakeholders, it was very interesting to note that a higher percentage of members of ethics committees also subscribed to the lay theory of work and market forces. This suggests that despite the sets of values and principles in which the current ethics committees operate, these seem to be incongruent with some members' personal values and principles. Doctors were the stakeholder group that least subscribed to this lay theory. This calls for a longitudinal study with a wider number of respondents to track changes over time and to confirm whether this is indicative of wider social changes impacting on the values and beliefs of society at large, which is critical in informing policy makers, ethics reviews and ethics committees. Such findings together with this study also contribute to the current ethics review enquiries (e.g. Elliott and Hunter 2008; Vayena and Tasioulas, 2013; Kieran, et al., 2013; Hunter, 2013 and 2014).

Hardill and Baines' (2007) review of why people volunteer in activities that contribute to the welfare of individuals and their communities concurred that there is wide variation in what motivates individuals to volunteer. They identified four types of volunteering, which they named as "giving alms", "giving to each other", "getting on", and "getting by", and which motivate people to volunteer in the welfare and well-being of individuals and their communities. However, in their study of a disadvantaged community (also in the East Midlands, Hardill et al., 2007, p. 408), found that 'getting on', i.e. volunteering for "self-development reasons" to develop skills and derive experience of value in the labour market, were rarely provided as an explanation for volunteering within that community. In contrast, within our research cohort in the context of rewards to participate in health research, involvement and participation were predominantly perceived as contributing to self-development and gaining employability skills. This trend was observed across the socio-economically mixed respondent statuses, not just for comparable

disadvantaged volunteers who were less likely to be primarily motivated by career opportunities. Thus, this finding seems to reinforce our suggestion of changes in the socio-economic context (i.e. the global financial crisis initiated in 2007 by the banking industry, which hit the UK economy very hard and two major health and welfare reforms recognised by the Welfare Reform Act 2007 and Health and Social Care Act 2012, Hodson and Mabbett, 2009; Berthon, 2010; Benatar et al., 2011; and Bennett and Kottasz 2011), leading to a new conception of value creation, since Hardill *et al.* published their findings in 2007. Furthermore the finding that the factor 'Volunteering' had a strong loading on to the exploratory FA, also confirms that the values that derive from this motivation seem to be more entrenched within the public's general mental maps. However, when this finding is examined alongside the finding that a wider number of respondents subscribed to 'Workplace' values, respondents perceived as a 'fair and ethical approach to participate in research' it reinforces the argument of a values and motivations shift within the present socio-economic context.

A middle ground and possible way forward to resolve the controversies around conflicting values and principles that emerged from the overall analysis was that consistent and easy reimbursement of expenses along with an honorarium would make PPI members feel recognised and valued, and thus more likely to participate in health research. This would be welcomed by the majority of respondents and possibly counter the impact of different value systems and principles.

Ultimately, it was very gratifying to see that PPI activities contribute to enhancing the quality of life of many, whether or not they receive tangible financial gains. However, it also emerged that it is critical to support and recognise PPI members' activities by translating their inputs into practice - to build trust and engagement amongst PPI members, illustrated by:

“I contribute through patient involvement (PPG, PPRG, Networks, etc.) rather than through clinical trials. I have found that the 'value' placed on this work varies tremendously with some health professionals appearing resentful of 'patient interference' and others merely paying lip service to patient input. As a retired professional person, I expect some level of respect and value placed on my time, but this does not need to be monetary. I have already resigned as Chair of one NHS committee (Patient Participation Group) due to a lack of respect bordering on rudeness and apparently my and the groups work not being valued by the GP Practice”.

Implications and recommendations

The findings challenge conventional guidance on payments for participation in research focusing on the welfare benefit system, taxation, employment law and safeguarding arguing for the importance of rewarding people for their engagement in research in an ethical way that makes sense to them (Roca and Bates, 2014).

The emergent factors “Personal Development”, “Work and Market Forces”, “Volunteering” and “Extra Resources” also provide a framework for training and discussion amongst different stakeholders i.e. patient groups, policy makers, Boards of Governors and Research Ethics Committees in order to negotiate the best way forward. It moves the discussion away from ‘private morality’ as the basis of ethical approaches into a dialogue about how to respond to the specific drivers of diverse health stakeholders, who contribute to the improvement of the quality of health provisions -both as active participants and/or as advisors to develop sustainable policies and training that are more readily accepted. That is, recruitment and retention of both participants and advisors will be improved if policies and training are aligned to their motivations

for participation. Ultimately, increasing participation in research and the quality of services by deriving views from wider cohorts, who will not contribute their views on a purely voluntary fashion. Thus, the reach of consultation processes will be extended, if all the emerging core values and principles from this study are utilised to inform the design of research ethics and engagement strategies, rather than merely targeting those designing it for those who value volunteering.

Within the Personal Development 'lay theory' (Shaw 2002) suggesting that staff have a pastoral responsibility for the people who engage with researchers, to ensure that people are kept safe from exploitation and have opportunities to develop confidence, assertiveness, knowledge and skills. A system focusing on this agenda will establish mentoring relationships between researchers and lay advisers, will offer coaching in relevant skills, will attend to any safeguarding concerns and provide training and networking opportunities as the ultimate ethical approach to participation in keeping with scientific integrity.

Within the Work and Market Forces lay theory, a system focusing on this agenda will design research participation around defined work roles and performance and pay people on a scale starting at the National Minimum Wage or above, rising by increments of responsibility to consultancy rates.

With regard to the 'Volunteering' lay theory, patient and public involvement in research is a contribution to civil society, a way for people who have used health services to recompense the community that has helped them and something that should not be distorted through financial rewards. A system focusing on this agenda will advertise participation through volunteer

centres, emphasise flexibility rather than obligation, invest in showing appreciation to participants rather than paying for their time, in keeping with respect for what they perceive as the ethical approach to participation in research

Within the less represented “Extra Resources” theory, rewards need to be targeted at those who are experiencing financial, social and economic exclusion (e.g. individuals with mental or physical health issues characteristic of this theory), links with agencies that can offer social and psychosocial support, welfare benefits, budgeting and job search advice will be promoted, as well as pathways into self-employment, and entrepreneurial activities. Alongside this, considerable support may be offered to enable researchers to hear the voice of marginalised groups that are seldom listened to and increase their representativeness in research.

Another important implication is for advancing motivation organisation theory, since to have a deeper understanding of how societal value changes may impact on volunteers (Hardill et al., 2007; Mahoney, 2003 and Rueschneyer, 2003) and others motivations across different occupational settings at work is another distinct contribution of this initial work that needs further examination.

In conclusion, previous researchers working in other fields, such as Hardill et al., (2007) have also looked at the values and motivations that drive people to contribute to society. However, the work reported in this paper starts a novel approach to research in relation to the values that relevant health stakeholders hold regarding payments for participation in research and on the meanings of ethical behaviours and principles. Ethical principles and behaviours guiding research have come under scientific enquiry e.g. the recent research by Robertson, 2014 and

Hunter, 2013 and 2014. The insights gained exposed a pathway to work through the current welfare benefit reform by identifying procedures that are perceived as ethical, legal, and respectful of the values and priorities of individual participants, thus encouraging wider research participation. More research with wider cohorts is needed to substantiate and/or challenge these findings that certainly contribute to the current call of an ethical review of the core principles that underpin current scientific research.

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¹ INVOLVE is part of the National Institute for Health Research and has responsibility for promoting patient and public involvement in research

ⁱ Explanation on LINK provided at:

<http://www.nhs.uk/NHSEngland/thenhs/healthregulators/Pages/healthwatch-england.aspx>