

Incentive payments and research related risks – No reason to change

The paper by Fernandez Lynch et al argues that payments to research participants in biomedical research can be divided into three different categories, reimbursement, compensation, and incentive and that guidelines for each can be developed specifying what factors to take into account when deciding the amount to be paid to participants (Fernandez Lynch et al 2020).

This comment focuses primarily on incentive payments and whether it is acceptable to incentivise healthy research participants to take on research related risks. It will show that the traditional position in research ethics that we should not offer risk payments is fully justified. This will further show that the current public health emergency created by the Covid-19 pandemic provides no reason to change that position. Covid-19 related research projects should, as Fernandez Lynch et al also argue be treated exactly as any other research projects involving the same procedures, risks and projected benefits.

In the first paragraph of their section on incentives the authors write ‘Incentives are paid as needed to address anticipated or actual recruitment and retention shortfalls, **including those that may stem from the risks and uncertainty associated with research.**’ (Fernandez Lynch et al 2020, p. 14, my emphasis). If there is a recruitment shortfall that ‘stem from the risks [...] associated with research’ it can only be because many prospective participants think that the risks involved in this particular research project are too large to be worth taking in a situation where they are fully reimbursed for costs incurred, fully compensated for time and burden, and adequately insured if any research related risk eventuates. The incentive payment will thus be directly aimed at overcoming their risk based reluctance to participating in the research! This means that any empirical research showing that people are unwilling to trade off risk against payment is a double edged sword in this context. If the findings are true, then incentive payments for risk will not work, if they are not true an important empirical premise in arguments that payment for risk are not ethically risky because they do not entice people to take on risk will no longer be available.

Furthermore, for the poorest prospective participants with the lowest incomes there will already be a de facto incentive element if the time element of compensation is calculated fairly on an ‘equal pay for equal work’ (Fernandez Lynch et al 2020, p 12) basis. It is probably better to state this neutrally as equal pay for equal time commitment or equal participation, since labelling research participation as ‘work’ smuggles in a number of unargued for assumptions, and some potentially worrying implications (Boye 1940).

What arguments do the work in the authors' justification of incentive payments for research risk? The first is based on the claim that independent research ethics approval ensures that 'research participation represents a reasonable offer' and that this means that 'research risks and burdens are acceptable' (Fernandez Lynch et al 2020, p.12). Let us first note that there is an in principle difference between research involving healthy research participants and research involving participants who suffer from the condition that is being researched. Healthy research participants cannot derive any personal "medical" benefit from participating, except in the very attenuated sense that they will get the same benefit as every other citizen gets from the research being performed. What makes the offer 'reasonable' in terms of risk is thus only the balance between the social value and the risks, but deeming that balance to be 'reasonable' is not the same as being able to conclude that the risks are 'acceptable'. First, both sides of the balancing equation are matters of judgment and the outcome of the balancing not an objective fact. This makes the term 'acceptable' liable to equivocation. If there is no upper limit on risks that can form part of a reasonable offer, then it becomes rather obvious that many of these risks are unacceptable from the perspective of most and perhaps all prospective participants unless accompanied by incentive payments (e.g. a significant risk of death or long-lasting disabling illness). So, the offer it is reasonable to make under the logic that it balances social value and risk when social value is very high, is in the absence of incentive payments unacceptable to prospective participants. Its reasonableness might show that it is acceptable to make, but not that it is acceptable to accept from the point of view of participants.

Second, there may be research risks that are simply unacceptable *per se*, no matter how important the research is in terms of social value. This position is, for instance reflected in Article 5 of the Nuremberg Code (see more below):

"No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects."

The second argument is an analogy to payment for risk in other areas of activity. The authors acknowledge that the US (and in fact most other countries) do not allow payments for risk in relation to living organ donation, and that their own search of recent challenge studies has found none that involved explicit incentive payments. So the analogies have to be found outside of health care, primarily in the context of paid employment. But, this casts doubt on the relevance of these analogies for three different reasons. The first is that research participation is not work, and is not generally promoted as paid employment. The organisation 1 Day Sooner, who has funded Fernandez Lynch and her co-authors does, for instance not portray participation in Covid-19 challenge studies

as work. The front page of its web-site has the header 'We Advocate on Behalf of COVID-19 Challenge Trial **Volunteers**' (1 Day Sooner 2020, my emphasis). The second and related reason is that we have no *a priori* reason to believe that the societal rules of justice that apply or should apply to research participation are the same as those that apply to work (Walzer 1983). And, the third reason is that there is an important disanalogy between risky research participation and risky work that is often overlooked when the work analogy is invoked. Probably the most common specification of the analogy point to people employed by the fire service and the higher salary they receive than people employed in other occupations involving the same level of skill and training, but less risk. If this or similar examples is what the analogy is based on it is problematic. Research ethics approval is essentially the issuance of an event license (Dove 2020), research participation is participation in an extended event, and payment for risk will be payment for event risk. However, firefighters are not paid for event risk. We do not assess the dangers of entering a specific burning building and then offer payment that is predicted to be sufficient to entice enough firefighters to enter the building and save lives. The more convincing analogy would be with event specific hazard pay which is much more ethically contested (Bailey 2020).

The third argument is a straightforward pragmatist/consequentialist argument. Challenge studies are important, they have high social value and we should therefore allow incentive payments for risk if they are necessary for recruitment or retention. The problem with this argument is that it ignores the history of human experimentation in medicine and the reasons for instituting a research ethics system that sets the protection of research participants lexically higher than the social value of the research. The medical researchers in the US and the UK who performed the research analysed by Beecher and Pappworth in the 1960s did not set out to harm their research subjects and probably believed the research risks to be reasonable when balanced against the social value of the research (see for the recently reprinted book by Mellanby (Rasmussen 2020)), but they were simply wrong in many cases (Beecher 1966, Pappworth 1967). The issue was not just that there was often no consent to this research, but that the risks subjects were subjected to were manifestly excessive in themselves and could not be made acceptable by any amount of social value. Even if we accepted that hyper-altruistic people should be allowed to accept any level of research risks for what they perceive as the greater good, that is not an argument for paying people to accept significant risks that they are not willing to accept without payment.

It is of course possible to argue on pragmatist/consequentialist grounds that '... there are no moral limits on the amount of risk or money participants should be allowed to accept to take part in clinical trials.' (Anomaly and Savulescu 2019), but that is simply because a pragmatist/consequentialist analysis could never justify hard moral limits on anything if the benefits of breaching those limits is

just projected/imagined to be large enough (see also Holm and Takala 2007 on automatic escalator arguments).

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