

## **Exploring the design and use of incentives for recruitment and retention in clinical trials: scoping review and stakeholder workshops**

### **Aims**

- 1) describe concepts underpinning design and use of incentives for recruitment and retention
- 2) explore the effects of incentives on patient experience, recruitment and retention, and bias
- 3) assess their acceptability to stakeholders

### **Achievements**

- We undertook a narrative review of the literature, summarising theory and empirical data around key questions relating to how incentives could be structured and designed.
- We searched PubMed and Econlit, securing 963 eligible studies, of which 123 were included.
- To complement the review, we conducted 2 workshops. These were designed to present our developing ideas about incentives in trials, and draw on the experience of all stakeholders (patients, funders, researchers, and ethics committee members) in the trial process to explore ideas, concerns and expectations concerning incentives.

We summarise key findings below:

- When designing an incentive system it is vital to consider the current incentives already operating in trials, and the current barriers to recruitment and retention
- For patients, the potential to gain access to new treatments before they become widely available, the prospect of receiving improved care due to trial protocol effects, accelerated take-up of new medicines, and altruism all act as incentives. For recruiters, clinicians, or other relevant trial staff, incentives may include job security or career advancement, improved care for their patients, altruism, and the opportunity to keep up to date with current research.
- The additional demands placed upon patients in terms of time-consuming activities (e.g. attending appointments, undergoing procedures), discomfort, and costs act as barriers. Recruiters face barriers including time and resources. Clinicians acting as recruiters also face concerns over the impact on doctor-patient relationships, and loss of professional autonomy
- Introducing incentives for recruitment and retention has the potential to induce unintended consequences. Incentives must be designed in such a way as to minimise the opportunities for individuals to engage in these undesirable behaviours
- The evidence is mixed about who incentives should be directed towards (patients, recruiters, clinicians or a combination)
- Incentivising processes (such as invitations to a trial) is likely to induce more effort than incentivising outcomes (e.g. recruitment and retention). However, there is a danger that changes in process do not translate to increased recruitment and retention

- However, there must be evidence of a strong relationship between the process and outcome to achieve the overall aim of increasing recruitment/retention
- Guaranteed payments are simple to implement and for recruiters, patients and health professionals to understand. They have been shown to have beneficial effects on incentivised activities, but can become expensive as most people receive payment
- Complex payment schemes can better direct incentives to increased activity, limiting costs. However, they take more time and effort to implement, and may fail to induce increased effort
- Prize draw or lottery incentives are simple and keep costs certain. Theory suggests that penalties should generate larger impacts than bonuses, but may not be acceptable
- More complex incentive structures may be suited for larger trials or where long-term arrangements exist with recruiters
- Monetary incentives are likely to have a larger direct price effect, but may have negative psychological effects (e.g. crowding out altruism)
- Other unintended consequences of incentives may include effects on the types of patients recruited and research integrity
- Stakeholders suggested that incentives were highly likely to be influenced by context
- Large incentives might make participants suspicious and could actually put people off participating. When discussing incentive size, people generally suggested amounts below £50
- Incentives less of an issue in retention than for recruitment. Concerns about coercion mainly revolve around the choice to participate in a trial in the first place. There was less concern with 'token of thanks' to be conditional upon meeting the requirements of the trial i.e. returning the necessary data

## **Next Steps**

- i. We will make our report available for the wider community, including an accessible summary. We have submitted an abstract at the International Clinical Trials Methodology Conference and we are currently working on editing the study draft report into a paper
- ii. We are going to set-up an 'Incentives in Trials' website to disseminate the ideas more widely and we are in discussion about the optimal place for this website, as there are a number of options (START, SWAT, TrialsForge, Hub)
- iii. We have identified areas which we think are most eligible for SWATS, and will submit these formally in due course
- iv. We will explore submitting 'dummy' ethics applications to a number of ethics committees in conjunction with the HRA to investigate the acceptability of our incentive models for trials