What Are the Implications of Applying Equipoise in Planning Citizens Basic Income Pilots in Scotland?

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We have been asked to consider the feasibility of piloting a Citizens' Basic Income (CBI): a basic, unconditional, universal, individual, regular payment that would replace aspects of social security and be introduced alongside changes to taxes. Piloting and evaluating a CBI as a Cluster Randomized Control Trial (RCT) raises the question of whether intervention and comparison groups would be in equipoise, and thus whether randomization would be ethical. We believe that most researchers would accept that additional income, or reduced conditions on receiving income would be likely to improve health, especially at lower income levels. However, there are genuine uncertainties about the impacts on other outcomes, and CBI as a mechanism of providing income. There is also less consensus amongst civil servants and politicians about the impacts on health, and substantial disagreement about whether these would outweigh other impacts. We believe that an RCT is ethical because of these uncertainties. We also argue that the principle of equipoise should apply to randomized and non-randomized trials; that randomization is a fairer means of allocating to intervention and comparison groups; and that there is an ethical case for experimentation to generate higher-quality evidence for policymaking that may otherwise do harm.

Introduction

We have been asked to consider the feasibility of piloting a Citizens' Basic Income (CBI): a basic, unconditional, universal, individual, regular payment that would replace aspects of social security and be introduced alongside changes to taxes.

According to the Citizens Income Trust, a Citizens Basic Income (CBI) is an unconditional, non-withdrawable income for every individual as a right of citizenship. It is usually described as having four core elements. First, it is a minimum payment that is sufficient to meet basic needs. This may be at a high level that would substantially increase the incomes of the poorest groups or at a lower level broadly equivalent to current benefits. Second, it is universal to the whole population based on residence. Third, it is paid without conditions irrespective of other sources of income. Finally, it is paid to individuals rather than households. The Scottish Government have funded a study to assess the feasibility

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of piloting a CBI in Scotland, involving partners across four local authorities (Fife, North Ayrshire, Edinburgh and Glasgow), NHS Health Scotland and the Improvement Service (which supports local government in Scotland). As part of this feasibility work, the team have been considering the ethical issues that would arise with piloting a CBI. Given that one of the aims of the feasibility work is to design pilots that would maximize the learning of the impacts of CBI across a number of different outcomes, a range of different evaluation designs have been considered, including controlled experiments and randomized controlled experiments.

One of the outcomes of interest for a pilot study is the potential for CBI to generate community-level impacts (e.g. increases in the formation of voluntary organizations, informal caring arrangements or new enterprises) that could not be captured with randomization at individual or household level because the mechanism proposed for the intervention requires the whole community to have the CBI (as was the case with the famous Dauphin experiment (Forget, 2011)). As such, the preferred design at this stage is for an entire community or communities to be the unit of intervention, and to minimize bias this is operationalized as a clustered randomized controlled trial, but with only one intervention site (Citizens' Basic Income Feasibility Study steering group, 2019). Note that there is guidance for the conduct of cluster randomized trials that is relevant for this pilot feasibility work, in particular relating to the need for informed consent for inclusion into the intervention area and the degree to which this is under the control of the researchers (Weijer *et al.*, 2012). This is not however the focus for this article and is not discussed further here.

During the feasibility study, researchers and policymakers at national and local level have been working very closely such that the researchers have had substantial influence in the potential design of any pilot study if it were to go ahead. This puts the researchers in a more influential position than is common when evaluating social or 'natural' experiments. However, policymakers remain the ultimate decision-makers on whether and how any pilot study would proceed.

Piloting and evaluating a CBI as a Cluster Randomized Control Trial (RCT) raises the question of whether intervention and comparison groups would be in equipoise, and thus whether randomization would be ethical. This article discusses the ethics of randomization, and in particular those concerning equipoise, that work on this project has raised. We argue that a cluster RCT of CBI would be ethical because of uncertainties amongst some of the outcomes of interest. We also argue that the principle of equipoise should apply to randomized and non-randomized trials; that randomization is a fairer means of allocating to intervention and comparison groups; and that there is an ethical case for experimentation to generate higher-quality evidence for policymaking that may otherwise do harm.

The Ethics of Equipoise

Equipoise can be defined as a state of genuine uncertainty of the relative merits between two courses of action, treatments or policies (Freedman, 1987). It originated from clinical research because of the duty on medical staff to ensure that they treat their patients fairly and with the best possible treatments at their disposal, arising from the Hippocratic Oath and (in the UK) the General Medical Council's 'Duties of a Doctor'. As such, it is argued that it is only ethically justified for a clinician to enrol patients into a randomized trial where there is no clear benefit of one course of action over another, as in this scenario no patients are being treated unfairly or being given an inferior treatment. In other words, the impacts of an intervention to be trialled should be sufficiently uncertain that an experimental design (i.e. where the populations receiving an intervention can be manipulated (Craig *et al.*, 2018)) is justified. This is sometimes judged by the extent to which there is disagreement amongst informed practitioners about the relative merits of the intervention and comparison, perhaps evidenced by there being varying practice amongst them. If it is certain that the intervention will be beneficial, there is no justification for denying this to part of the population in order to facilitate a more robust evaluation design.

It is also now argued that the equipoise principle should equally apply to policy experiments, and to researchers advising on such experiments, as well as to a wider range of outcomes than simply health (Verweij, 2009; Petticrew *et al.*, 2013; MacKay, 2018). Again, this is largely on the basis that no group should be disadvantaged in the course of the research, but there are other strong arguments in favour of this approach. It reduces the conduct of low-value research, and it minimizes the risks of harm to trial participants (Phillips Hey, et al., 2017).

However, others have argued against the application of equipoise for social research. Writing from an economics and development perspective, McKenzie has expressed concerns with suggestions of applying the principles of clinical equipoise to social interventions (McKenzie, 2013). His argument is that it is necessary

to take into account the financial costs of any intervention relative to the improvement in the outcomes rather than simply whether there is uncertainty in the direction of effect. This is because the policy question that the research should inform is not simply whether or how to implement the intervention, but whether this intervention represents better value than every other possible intervention. This generates substantial uncertainty in almost all circumstances and justifies randomization based on the principle of equipoise.

Kukla's position is similar to that of McKenzie on the basis that scarcity is common and most research takes place in a context in which most people are not in receipt of the best available intervention (Kukla, 2007). In this way, it is argued that researchers should not be bound to study only interventions compared to a 'gold standard' if that standard is not met, nor would it be ethical to trial interventions in which there was no prospect of introduction across the population of interest. As such Kukla (2007) proposes that, ". . .the principle of equipoise does not focus on equipoise with respect to the relative expected outcomes of trial arms, but rather on equipoise concerning the social value of the intervention being tested", and, ". . .one must be in a state of equipoise with respect to whether or the extent to which the intervention being tested should be made accessible to the population that. . . [the research findings would be generalised to]".

This is linked to the argument that randomization can be justified by the social value of research (i.e. the value of increased knowledge that is applicable to populations overall). This social value can be substantial if the knowledge generated informs policy and practice for larger populations for a long time period. However, this needs to be balanced against the risks to research participants of potential harm, and the risks of unintended consequences of what is believed to be an effective intervention (Phillips Hey *et al.*, 2017).

Finally, the lack of development over recent decades of any shared tools to assess whether equipoise is present (in particular, to assess whether and when there is substantial and genuine uncertainty), has been argued to be sufficient indication that this is highly unlikely to be achieved. That being the case, the application of the equipoise principle is likely to be variable across researchers, impractical to consistently implement and as a result be itself unethical (Shamy, 2017). This has led to alternative ethical decision-making frameworks being proposed instead of equipoise, including those based on non-exploitation (Buchanan and Miller, 2005) and on net risk (Rid and Wendler, 2011).

There does not appear to be specific or consistent guidance in the UK for the NHS, university or social research ethics committees on whether or how to assess and implement the principle of equipoise. Instead, there are principles to help researchers and ethics committees to identify and mitigate risks to research participants (ESRC, 2015). As a result, there is likely to be inconsistency on how equipoise is judged by any ethics committees that are asked for an opinion.

The evidence base for many social interventions across many disciplines is often less than we think and is less often based on carefully synthesized evidence than on expert opinion or individual studies of variable quality (Petticrew, 2001; Petticrew *et al.*, 2013). It is therefore vitally important to introduce (and remove) interventions in ways that can be evaluated such that we learn more about their general impact, their differential impacts across the population, and how they interact with contextual factors. If we do not do this then we run the risk of applying interventions and policies that are neither effective nor cost-effective, may have unintended consequences, or may even be harmful (Macintyre and Petticrew, 2000; Macintyre, 2011).

Generating a high-quality evidence base from evaluating social interventions and policies does not necessarily require randomization or even a control/comparison group, but the ability to reduce the risks of bias and confounding is substantially improved by their use (Craig *et al.*, 2012, 2017). It is usually the case that randomization is not possible with social interventions and policy changes because of competing political priorities, practical considerations (e.g. legislative changes impacting on an entire population at the same time) or a lack of influence of evaluators in the implementation process. These factors can also sometimes limit the availability and suitability of comparison groups leaving evaluators with designs such as interrupted times series or before-and-after studies which, although still valuable, are at high risk of confounding due to secular changes in other important factors over time. It is usually the case therefore that given the opportunity, and all other things being equal, evaluators will prefer randomized designs to minimize these risks and enhance the causal inference that the study can provide. There is already a skew towards there being more studies, and studies generally using more robust designs, for individualized interventions compared to social interventions (Tannahill, 2008). It is therefore even more important to take those less frequent opportunities to build the evidence base for social interventions (Petticrew *et al.*, 2013).

A question that does not seem to have been addressed in the equipoise debate thus far, is why equipoise should

apply to randomized trials but not non-randomized controlled studies. It seems that the same arguments, particularly the avoidance of inferior treatment or policy being applied to some people but not others, applies equally in a scenario where there is an intervention in one population but not in another (as might occur if an intervention is introduced in one particular community and evaluated in comparison to other communities), whether or not those people are selected randomly or otherwise. This is discussed further below.

Equipoise has been raised in relation to income experiments previously and has led some groups to decide against randomization (Thomson et al., 2004). As discussions of the relevance of equipoise for social research are ongoing we shall proceed on the assumption that it is a valid and relevant ethical issue.

Our conundrum incorporates many of the issues discussed here and has led us to closely consider whether a randomized pilot study, or indeed whether a non-randomized pilot study, of Citizens Basic Income is ethically justified on the basis of equipoise (other relevant ethical issues are not discussed in this article). We explain our position in the following sections in the spirit of provoking further discussion, debate and reflection on the issues our example has raised.

Equipoise as an Ethical Challenge to a CBI Pilot

Through our feasibility work, we have had a series of internal debates about the ethical issues raised. Given our own discussions and our reading of the relevant literature, we have identified a series of considerations in relation to equipoise which is laid out in Table 1. Other ethical considerations for any pilot are not discussed in this article.

Central to the argument against randomization of CBI in any pilot is that increasing the income of individuals, or removing the conditions for receiving income, is highly likely to be beneficial for health and other social outcomes (especially for those on low incomes), and therefore there is not the genuine uncertainty required for randomization (Kawachi *et al.*, 2010; Gunasekara *et al.*, 2011; Pega *et al.*, 2013; McAuley *et al.*, 2016; Pega *et al.*, 2017). Of course, how people get additional income and the context in which this happens is likely to have an impact on how positive this is for health outcomes, and there is uncertainty around the health impacts of CBI with some potential for harm (Gibson *et al.*, 2020). Nevertheless, at individual and household level, the increase in income and decrease in poverty that is likely to happen in a CBI pilot is highly likely to have positive health outcomes.

There are, however, genuine uncertainties for the non-health outcomes in relation to individuals and households gaining additional income, and many more uncertainties about the broader social impacts of CBI in general (Gibson *et al.*, 2020). More generally, it is unclear how to apply the principle of equipoise when there are several outcomes of interest, for which there are varying levels of pre-existing evidence and/or different likely directions of impact (i.e. some outcomes improving and some worsening) (MacKay, 2020).

Table 1 —Summary of the ethical arguments in relation to equipoise raised in this study.

Issue	Summary
Does equipoise only need to exist for one outcome?	There is good evidence for likely positive impacts of CBI on several important outcomes (e.g. health and poverty) but the evidence is less clear for other outcomes.
Is general evidence of impact sufficient or does it have to be context specific?	This relates to the potential interactions of CBI with other aspects of the social security system; the individual nature of the payment; the potential impacts on labour market participation, etc. This could mean that the impacts of income via a CBI are different to those of giving income via other routes.
Is randomization not a fairer way to identify intervention and comparison areas than the alternatives?	If equipoise is not present and this prevents randomization of the CBI, there may be a risk that the selection process of the intervention areas might not be fair or transparent.
Why is equipoise an issue for randomized experiments but not non-randomized controlled studies?	The risks of detriment seem to apply equally to intervention or control groups whether or not these are selected through randomization.

In a roll-out scenario, there are additional uncertainties regarding the impacts of the macroeconomic effects of the large changes to political economy that would likely arise if CBI was implemented due to changes to tax rates required to fund the CBI payments, income distribution and power relations in society. As this creates a somewhat false context for generating evidence around the impact of CBI, this might count against a study being ethically justified. However, there are research questions that could be answered by a pilot study. For example, the interaction of additional income provided via a CBI with the remaining parts of the social security system carries risks that some individuals (e.g. those on complicated combinations of disability benefits with particular household structures) may be at risk of inadvertent loss of income. The feasibility work is seeking to minimize these risks but this is another theoretical reason as to why there are genuine uncertainties about the impact of a CBI pilot, as opposed to the impact of a simple increase in income (Shaw and Paterson, 2019).

Another argument that we have discussed in this context is whether or not there is an ethical difference between a randomized or non-randomized pilot study. There is a real need to pilot CBI to understand the impacts across the full range of relevant outcomes and to identify unintended consequences in the Scottish context. The pilot will therefore include some of the population in the intervention group and many others in a comparison group. If we accept that additional income and/or reduced conditionality for receiving benefits (through CBI) is likely to be beneficial for health, even a non-randomized design will mean that some people do not receive these benefits and that this advantage will be allocated by design rather than randomly. A non-randomized design is likely to create lower quality evaluation evidence, so what ethical case can be made for this option over a randomized option? Additionally, if a pilot is to proceed, is randomization not fairer than the intervention groups being selected by an individual or groups, with the potential for conflicts of interest that this generates, as a way of deciding which communities receive the intervention and which are the controls? Or does the equipoise argument mean that we just need to live with all of the uncertainties about the broader impacts of CBI? We were unable to get to a consensus position within our group on this point. It is also worth noting that had we not been involved in the discussions about the design of the pilot at an early stage, we would have had no influence over the design and nature of the intervention and this would instead have been described as a natural experiment (i.e. where "[the intervention is] not under the control of a researcher that divides a population into exposed and unexposed groups" (Craig *et al.*, 2018)).

One further issue identified in Table 1 is that many of the uncertainties in the evidence base for CBI lie in the macroeconomic consequences of the policy. As such, a small pilot study of relatively short duration is not expected to generate all the macroeconomics impacts that might occur if a CBI were rolled out and therefore cannot be used to evaluate such effects. This is somewhat separate from the equipoise issue but does relate to the range and importance of the genuine uncertainties which a pilot study might address.

Discussion

There are clearly many arguments for and against the use of randomized design for the CBI pilot described here. If it is only the question of whether there is substantial and genuine uncertainty in the impacts of the intervention that matters in making a decision on the ethics of a randomized trial, then where genuine uncertainty exists, a randomized trial of a CBI pilot would be ethical. For our scenario, there are substantial uncertainties, but these concern only some of the outcomes of interest (e.g. labour market behavioural responses and community-level effects) whilst other outcomes, including poverty and health outcomes (drawing upon the wider literature not specific to CBI-like interventions), are highly likely to improve in the intervention group, especially if the pilot was of the higher level payment. It is likely that, based on there being little genuine uncertainty in the impacts of CBI on health and poverty, we should advise against a randomized pilot design.

However, if the 'trump card' of 'genuine uncertainty' is balanced against the other arguments, the case against randomization is less clear. There are uncertainties about increasing incomes, or removing conditionality, specifically through a CBI payment. The greatest uncertainties in the impact of a CBI would occur in a roll-out rather than pilot scenario, which would include commensurate tax and benefit changes to fund the CBI and generate substantial consequences for the economy and for the outcomes of interest.

There are several additional arguments that undermine the case against randomization. First, policymakers do not have the powers or resources at their disposal at present to introduce the intervention for the whole country. They are, however, interested in piloting a CBI to inform policymaking in a possible future scenario where there may be more flexibility in the opportunity to design a different approach to the welfare

state. The learning from any pilot will also be of great interest to other governments as the discussion on the relative merits of CBI policies is being widely debated. There are also genuine uncertainties about the impacts of CBI on non-health outcomes. As such, a pilot approach is clearly of interest and would have substantial social value.

Second, there is a very substantial and nuanced policy debate currently on whether CBI policies of different types are more or less likely to have positive impacts across a range of outcomes, not least in reducing poverty. With strong advocates on each side, and multiple models of CBI proposed, this represents the substantial and genuine uncertainty that might justify a randomized trial to evaluate CBI. However, the difficulties again are that the learning from such a pilot might not be able to evidence the main routes of impact (e.g. macroeconomic impacts) and few researchers working in the area of CBI argue that the current system (i.e. the comparison group in any pilot) is equally as likely as the CBI models to have positive impacts on health. Despite the views of the CBI research community, many political parties do argue that the current approach is better, mostly because of the changes to work incentives and on the grounds of competing political priorities such as lower taxes. Thus, there is genuine uncertainty about the merits of the policy both in terms of its likely impacts and also in terms of the balance of political priorities. This is similar to the points made by McKenzie that highlight that is not just whether something 'works' that matters, but about its cost-effectiveness and range of impacts (McKenzie, 2013). Indeed, where there are multiple outcomes of interest and variation in the strength of pre-existing evidence and directions of effect for those outcomes, how is the principle of equipoise to be applied?

Third, the case made for equipoise in relation to randomization seems to be equally applicable to non-random studies. If we are saying there is insufficient uncertainty in the impacts then the appropriate response would be to simply recommend full policy roll-out, not a non-randomized study. This risks policies with unintended consequences being introduced at scale before they have been properly evaluated. Even though there may be supporting evidence that recipients will benefit in various ways, there may be little or no evidence on the impact of rollout of a particular form of the policy at a societal level.

Finally, through our involvement in this feasibility work, we have raised the ethical question of equipoise. Had we or other similar researchers not been involved in the process, it is unlikely that the equipoise framework would have been applied to the planning of CBI pilots. It is therefore only because of the early involvement of researchers that this potential issue has been raised and as a result, somewhat paradoxically, our early involvement could mean that only a less robust (i.e. a non-randomized design) evaluation is implemented.[1]

Are these arguments suggesting that there is an ethical case for a randomized controlled design simply 'red-herrings' in the face of the equipoise 'trump'? If so, how much uncertainty is required in the evidence base, and amongst whom and for what range of outcomes, to claim that genuine equipoise exists and therefore to justify randomization? It is certainly true that most reasonable public health researchers are convinced that increasing the income of all individuals (as would be the case in the trial of a 'high level' CBI payment) improves health outcomes. However, this is not necessarily the case amongst economists or social researchers. There are also genuine uncertainties about other outcomes (e.g. in relation to labour market decisions and community-level impacts), and about CBI as a mechanism for increasing incomes and reducing conditionality. Do these evidence uncertainties provide sufficient genuine uncertainty? On balance, our view is that there is enough uncertainty to justify a pilot to be planned and evaluated using a randomized controlled design, but it could be argued the other way and in the absence of clear guidance different groups might arrive at different decisions using the same evidence. We believe it is time for further work to clarify this issue, possibly using public participatory methods, to guide research across the social sciences and to guide ethics committees.

Conclusions

We believe that most reasonable public health researchers would accept that additional income, or reduced conditions on receiving income through the social security system, would be likely to improve health. However, there are genuine uncertainties about the impacts on other outcomes including community-level impacts and macroeconomic impacts, and about the mechanism of giving incomes via a CBI. There is also less consensus amongst civil servants and politicians about the likely impacts of additional income or reduced conditionality, and the relative policy priority across outcomes. For these reasons, we believe that a randomized controlled trial is ethical and meets the principle of equipoise because of these uncertainties. We also find that there is no good reason why the principle of equipoise should apply only to randomized but not non-randomized trials, although we note that randomization

is not readily accepted by the public as a preferable approach. Randomization arguably is the fairest means of allocating individuals or communities to intervention and comparison groups where there is a risk that there is no clarity of why one area is selected over others and the decision is made by an individual or small group. Further work should be undertaken to provide clearer guidance to social researchers and ethics committees on how to apply the principle of equipoise in practice and to explore the public perceptions of randomized social policy experiments.

Notes

1. This might be akin to the final part of episodes of the popular cartoon 'Scooby Doo', where the villain is oft heard to say: 'we would have got away with it if it wasn't for those meddling kids!'.

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Conflict of Interest

None declared.

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