**The Ethics of Public Policy RCTs: The Principle of Policy Equipoise**

New York City’s Department of Homeless Services recently authorized a randomized controlled trial (RCT) to evaluate the effectiveness of its Homebase Community Prevention (HCP) program, a program which aims to prevent households from entering the shelter system.[[1]](#footnote-1) HCP, in place since 2004, provides households at risk of homelessness with assistance in maintaining their housing, including limited financial assistance to pay rental or utility arrears, moving costs, or security deposits, benefits advocacy, employment assistance, and legal referrals. Between June and September 2010, applicants to HCP were randomly assigned to either receive or not receive HCP services. The trial proved controversial as critics argued that it was unethical to deny applicants access to HCP, which, they claimed, had been effective in reducing shelter entry.[[2]](#footnote-2)

For bioethicists, this line of criticism is familiar. The AZT trials of the mid 1990s, designed to evaluate the effectiveness of a preventive intervention for maternal-fetal HIV transmission, were criticized on similar grounds. In these RCTs, participants from a number of low-income countries were not given access to the proven AZT regimen – considered standard of care in high-income countries – but were instead randomized to receive either a less costly and complex version of this intervention, or placebo.[[3]](#footnote-3)

However, although critics of the HCP RCT and the AZT trials shared a similar ethical concern, critics of the latter trial had available a rich set of ethical concepts and principles to express their concerns, and to structure their discussion with other commentators. In particular, critics argued that the AZT trials violated the principle of clinical equipoise since the proven AZT regimen was known to be superior to placebo;[[4]](#footnote-4) and subsequent discussions regarding these and other similarly designed trials have concerned the appropriate interpretation of this principle.[[5]](#footnote-5) By contrast, critics of the HCP RCT did not have such a rich set of ethical concepts and principles to appeal to, in part because the literature regarding the ethics of RCTs in the public policy context is largely under-developed. This is worrying since scholars and policy-makers increasingly use RCTs to evaluate the effectiveness of different types of social and economic policies.[[6]](#footnote-6)

In this paper, I ask whether a principle analogous to the principle of clinical equipoise should govern the design and conduct of RCTs evaluating the effectiveness of policy interventions. I answer this question affirmatively, and introduce and defend the principle of *policy equipoise*. According to this principle, all arms of a policy RCT must be, at minimum, in a state of equipoise with the best proven policy that is also morally and practically attainable and sustainable. For all arms of a policy RCT, policy experts must either (1) reasonably disagree about whether the trial arms are more effective than this policy, or (2) know that they are.[[7]](#footnote-7)

I shall use the principle of clinical equipoise as a platform to develop and justify the principle of policy equipoise. I therefore begin in part 1 with a discussion of the former principle, identifying the ways in which this principle does and does not provide a basis for the latter. In part 2, I present and justify the principle of policy equipoise. In part 3, I outline the implications of this principle for investigators working in non-ideal circumstances. In part 4, I apply the principle of policy equipoise to the HCP RCT. Finally, in part 5, I consider an objection.

1 FROM CLINICAL TO POLICY EQUIPOISE

The norm of clinical equipoise holds that a biomedical RCT comparing experimental treatment A against standard of care treatment B is ethical only if there is an honest, professional disagreement within the expert medical community about relative efficacy of A and B.[[8]](#footnote-8) Put simply, investigators should only enroll subjects in an RCT, in which some will receive A, and some will receive B, if expert clinicians reasonably disagree about whether A or B is the preferred treatment for the condition in question.

The foundation for clinical equipoise is widely understood to reside in the *therapeutic obligation* of clinician-investigators.[[9]](#footnote-9) Since clinician-investigators occupy the professional role of physician, they possess a fiduciary obligation to act in the best medically-related interests of their subjects. They may only therefore enroll subjects in an RCT evaluating the effectiveness of a non-standard of care treatment A, if there is reasonable disagreement within the expert medical community about whether the standard of care treatment B is superior to A. If the expert medical community agrees that B is superior to A then clinician-investigators have an obligation to provide their subjects with B, and so may not enroll them in an RCT evaluating A. If, in the course of a trial, enough evidence is gathered to convince the expert medical community that A is superior to B, clinician-investigators likewise have an obligation to stop the trial, and provide all participants with A.

More formally, the line of argument supporting the principle of clinical equipoise is as follows:

1. Clinician-investigators possess a therapeutic obligation to research participants to act in their best medically-related interests, usually by providing them with the standard of care treatment.
2. By enrolling subjects in an RCT, clinician-investigators randomly assign participants to receive treatments or non-treatments that are not the standard of care treatment.
3. Clinician-investigators may only conduct an RCT if there is reasonable disagreement amongst the expert medical community about whether the non-standard of care treatments or non-treatments offered to participants are superior to the standard of care treatment (from 1 and 2).

As commentators have noted, this argument contains a number of ambiguities that need to be resolved if clinical equipoise is to act as an action-guiding norm for investigators. First, what level and/or kind of disagreement amongst the expert medical community regarding the merits of treatments A and B is necessary for clinical equipoise to obtain?[[10]](#footnote-10) Second, how should the idea of “standard of care” be interpreted? Is the standard of care treatment the treatment that the *local* expert medical community considers to be standard practice, or the *global* expert medical community?[[11]](#footnote-11) Is it the treatment that is *actually* available to research participants outside of the trial – i.e. the *de facto* standard of care – or that *ought* to be available to them – i.e. the *de jure* standard of care?[[12]](#footnote-12)

An account of policy equipoise will also need to address these ambiguities. However, the chief problem for the project of developing and justifying a principle of policy equipoise is that social scientists, not clinicians, conduct policy RCTs. Social scientists, in virtue of their professional role, do not possess a therapeutic obligation to research participants, and so it is unclear that they possess a duty to provide participants with a certain level of “care.” While clinicians’ therapeutic obligation provides the basis for the principle of clinical equipoise, one might wonder what obligation could play the same grounding role for a principle of policy equipoise.

Fortunately, some commentators have raised a similar objection to the above argument for the principle of clinical equipoise, pointing out that not all investigators occupy the professional role of clinician,[[13]](#footnote-13) and even arguing that this role is irrelevant in the context of research.[[14]](#footnote-14) In response to this objection, some scholars have defended the relevance of investigators’ role as clinicians.[[15]](#footnote-15) Others, by contrast, have identified *alternative* obligations investigators have, namely, obligations of justice, that may be capable of grounding something like a principle of equipoise, thus offering a possible solution to the above-mentioned problem.[[16]](#footnote-16)

Rebecca Kukla offers what is arguably the most prominent account on offer. According to Kukla, investigators, qua human beings, have duties of justice, respect, and welfare protection to research participants.[[17]](#footnote-17) As such, investigators may not ‘knowingly prevent research participants from receiving care that they are morally entitled to receive as ordinary residents.’[[18]](#footnote-18) On the basis of these duties, Kukla defends the *minimum standards principle (MSP)*:

MSP: Investigators ‘should not run studies unless, *to the best of their knowledge*, every trial arm receives care that is at least as good as the local *de jure* standard of care.’[[19]](#footnote-19)

The local de jure standard of care, Kukla claims, includes the ‘kinds of health care services and protections the inhabitants of a region ought to have access, given that region’s material conditions, but regardless of its actual policies and politics.’[[20]](#footnote-20) The purpose of MSP, Kukla claims, is to ensure that research participants do not receive care that is worse than the care they are otherwise entitled to receive.[[21]](#footnote-21)

Kukla argues that MSP is not a principle of equipoise since such a principle ‘demands some specific form of uncertainty.’[[22]](#footnote-22) However, it is not difficult to see how Kukla’s account of investigators’ duties of justice can be used to ground a reformulated version of MSP that includes a form of uncertainty. One way to ensure that research participants do not receive care that is worse than the local de jure standard of care, after all, is to ensure that the different arms of the trial are in a state of equipoise with this intervention:

MSP\* Investigators may only conduct an RCT if there is reasonable disagreement amongst the expert medical or social scientific community about whether the non-standard of care interventions or non-interventions offered to participants are superior to local de jure standard of care intervention.

Importantly, for our purposes, MSP\* constitutes a principle of equipoise that applies to all RCTs since all investigators possess the above mentioned duties of justice. As well, it is analogous to the principle of clinical equipoise in purpose and content, constituting a principle designed to ensure that participants are not subjected to an intervention that is known to be worse than the standard of care treatment.

The problem with Kukla’s argument, as I see it, is that it only implies either MSP or MSP\* in *ideal* circumstances, that is, circumstances in which people can access the care to which they are morally entitled. Only in these circumstances would an investigator *prevent* participants from accessing the local de jure standard of care by conducting an RCT that included an intervention or non-intervention known to be worse than this standard. If people are otherwise unable to access the care to which they are morally entitled, conducting such an RCT does not prevent or interfere with their ability to access this care since they couldn’t access it in any case. To justify MSP or MSP\* in non-ideal circumstances, Kukla needs to attribute a stronger obligation of justice to investigators, not merely the *negative* duty not to interfere with people’s access to the care to which they are morally entitled, but rather the *positive* obligation to provide it.[[23]](#footnote-23) Unfortunately, the claim that investigators, qua human beings, possess such a duty is highly contentious. Individuals of course have duties of justice to aid those in need, but justice would be extremely demanding if it required people – qua human beings – to provide others with the services and benefits to which they are entitled.

Fortunately for our purposes, there are agents that possess such demanding duties of justice: governments.[[24]](#footnote-24) Governments have duties of justice to provide their residents with access to particular types of goods, and/or to realize particular outcomes.[[25]](#footnote-25) These goods may include liberty, personal security, health care, and education; outcomes may include particular health or educational outcomes, or specific levels of wellbeing. I shall use the term *justice outcomes* to refer to specifications of the type and amount of goods to which governments have a duty to provide their residents with access, and the outcomes that governments have a duty to bring about. Justice outcomes may therefore include specific levels of health insurance coverage, a certain level of personal security, specific educational outcomes, or certain housing and nutritional standards.

In addition to having duties to realize justice outcomes, governments play a normatively relevant role in the conduct of policy RCTs. First, government agencies often directly conduct policy RCTs and employ social scientists to design and carry them out. Second, even in cases where government agencies do not directly conduct policy RCTs, governments often *authorize* them, that is, grant specific permission or approval to an agent to conduct a particular RCT. Because policy RCTs involve subjecting residents to experimental policy interventions, whether in the sphere of education, housing, public health, or poverty alleviation, such experiments often require explicit government permission. Additionally, governments also implicitly authorize particular policy RCTs by funding them.

Governments are therefore agents who are (1) involved in the conduct of policy RCTs, and (2) possess duties of justice to ensure that research participants possess a certain level of care – i.e. possess those goods or inhabit those states of being specified by justice outcomes. Governments therefore offer a solution to the problem we identify above, namely, identifying some agent that possesses duties to provide research participants with a certain level of care. As such, governments provide a foundation for a principle of policy equipoise.

2 POLICY EQUIPOISE

A principle of policy equipoise must of course require that the arms of a policy RCT are in a state of equipoise with some policy. How might we ground such a principle on the basis of the claims established above, namely, that governments have duties to realize justice outcomes and are often involved in the conduct of policy RCTs?

Consider first that because governments have a duty to realize certain justice outcomes for their residents, they also have a duty to implement policies to realize them. Policies, after all, are the means by which governments provide their residents with access to goods and services; and a duty to realize some outcome implies a duty to take up the necessary means to do so.

Consider second, however, that because it is reasonable to think that governments have a duty to realize *multiple* justice outcomes, there are constraints on the policies governments can adopt to realize any *particular* justice outcome. Governments may not implement policies that, though expected to realize justice outcome A, are either so costly that they are unable to fully realize justice outcomes B, C, or D; or that involve employing means that prevent them from realizing some other justice outcome *at all*. For example, the protection of residents’ basic civil rights is likely to be a justice outcome for any government, and so governments may not adopt policies to realize other justice outcomes that involve violating these rights.

For any particular justice outcome that they have a duty to realize therefore, governments possess a duty to implement the policy that is (1) known to be most effective in realizing that particular outcome; and (2) consistent with the realization of other justice outcomes. With respect to any particular justice outcome therefore, governments have a duty to implement the policy that is *best proven*, and, to borrow a concept from Alex John London, *morally and ‘practically attainable and sustainable*.’[[26]](#footnote-26) As I shall use the term here, a policy is morally and practically attainable and sustainable if and only if:

1. It is consistent with residents’ rights; and
2. Government could implement it long-term, given a just system of resource procurement and allocation.[[27]](#footnote-27)

The best proven, morally and practically attainable and sustainable (BPA) policy is thus the most effective policy government could implement to realize a particular justice outcome if it acted justly and effectively in the procurement and allocation of resources.[[28]](#footnote-28)

I recognize here that the task of identifying the BPA policy for any particular justice outcome is likely to prove a challenging one. To fulfill this task, after all, one must not only work through the relevant empirical literatures to identify the policies likely to be effective in the context in question. One must also make difficult judgments about the justice outcomes governments have a duty to realize, and what the just share of resources is that particular government agencies should have to realize the outcomes they are responsible for.[[29]](#footnote-29) The latter judgments are likely to prove particularly challenging to make, given that people reasonably disagree about the demands of justice.

However, the fact that a task is difficult does not imply that it can be justifiably avoided. As I explain above, if we accept that governments have duties of justice to their residents, it follows that governments have duties to implement BPA policies. And, as I explain below, this has important implications for the treatment of research participants in policy RCTs. We must therefore meet the above-mentioned task head on, not pretend we can avoid it and still conduct policy research ethically.[[30]](#footnote-30)

With respect to justice-related areas of their legitimate jurisdiction therefore, governments have a duty to subject their residents to BPA policies. With respect to their involvement in public policy research, this entails that governments may not conduct or authorize others to conduct justice-related policy RCTs that subject residents to policies that are known to be less effective than the BPA policy. If governments do not comply with this latter principle, they fail to realize justice outcomes for these residents to the extent that is required by justice. Governments must therefore comply with the following principle of policy equipoise:

Policy Equipoise: Governments may conduct or authorize others to conduct a justice-related RCT only if each arm of the trial is either:

* 1. In a state of equipoise with the BPA policy, or
  2. Known to be more effective than the BPA policy.

By a *justice-related* RCT, I mean an RCT evaluating policies that aim to realize one or more justice outcomes. Since the principle of policy equipoise is grounded in governments’ duty to realize justice outcomes, it does not apply to RCTs evaluating policies that are not justice-related in this sense – e.g. an RCT evaluating regulations concerning traffic flow.[[31]](#footnote-31) The reason for (2) is that it is not always unjust for governments to subject residents to policies that are known to be more effective than the BPA policy in the context of research, but that may, for example, be too costly to implement society-wide. First, doing so is consistent with governments’ duty to realize justice outcomes for all residents to the greatest extent possible, given constraints of cost and knowledge. This is so since the policies in question are known to be superior to the BPA polices. Second, governments have legitimate reasons for evaluating such policies in the context of RCTs. For example, government may want to know *how much* better a particular policy is than the BPA policy for the purposes of deciding whether it makes sense to put resources into making it more affordable. Or, government may want to determine if the policy is practically attainable and sustainable, and see the RCT as a way to gather information to help make this determination.[[32]](#footnote-32) Since such RCTs promise to inform government decision-making, conducting them is a legitimate use of public resources.

We can express the line of argument supporting the principle of policy equipoise in more formal terms as follows:

1. Governments possess a duty to realize justice outcomes for their residents to the extent promised by BPA policies.
2. Justice-related policy RCTs involve subjecting residents to one or more policies that are not the BPA policy.
3. Governments may only conduct or authorize a justice-related RCT if all arms of the RCT are – at minimum – in a state of equipoise with the BPA policy (from 1 and 2).

The principle of policy equipoise implies that for all arms of a justice-related policy RCT, policy experts must either (1) have no evidence regarding the relative efficacy of the policy arms; (2) reasonably disagree – given existing evidence – about whether the policy arms are more effective than the BPA policy; or (3) know that they are more effective than the BPA policy.[[33]](#footnote-33)

One might question the usefulness of the principle of policy equipoise on the grounds that prior to conducting an RCT, investigators simply have *no evidence* regarding the effectiveness of the policy they wish to evaluate. All policy RCTs, on this line of thinking, would therefore necessarily satisfy the principle of policy equipoise, making its consideration redundant.[[34]](#footnote-34)

In response, consider first that investigators may have evidence regarding the effectiveness of a particular policy intervention from other RCTs. While one should not assume that a particular intervention will work the same way in different contexts, evidence regarding the effectiveness of an intervention in one context, can, under certain conditions, help investigators make judgments regarding its likely effectiveness in another.[[35]](#footnote-35) Consider second that although RCTs are widely understood to offer the highest quality evidence regarding the effectiveness of interventions, other types of social scientific research also produce this type of evidence, including the use of econometric methods.[[36]](#footnote-36) Prior to conducting an RCT therefore, investigators may have access to a variety of forms of evidence that allow them to make reasonable judgments regarding the likely effectiveness of the interventions they wish to study. On the basis of this evidence, investigators may judge that it would violate the principle of policy equipoise to test a particular intervention against no intervention, as opposed to some other intervention for which there is similar evidence regarding its effectiveness.

Although the argument for and content of the principle of policy equipoise is analogous to the argument for and content of the principle of clinical equipoise, there is an important difference. First, because the foundation for the principle of policy equipoise is governments’ duty to realize justice outcomes, whereas the foundation for the principle of clinical equipoise is clinician-investigators’ therapeutic obligation, the principle of policy equipoise applies primarily to government decisions to conduct or authorize policy RCTs, not individual investigators. As I explain below, this does not mean that policy equipoise has no implications for the actions of investigators conducting government authorized RCTs. But, it does mean that my analysis has no immediate implications for policy RCTs that are not conducted, authorized, or funded by government. Such RCTs are likely to be rare, but not impossible. For example, it strikes me as a realistic possibility that a well-funded NGO could conduct an RCT testing a cash transfer intervention without needing explicit government permission or funding. Determining the principles to govern such RCTs is an important project, but beyond the scope of this paper.[[37]](#footnote-37)

3 POLICY EQUIPOISE AND NON-IDEAL CIRCUMSTANCES

The principle of policy equipoise applies to government, placing conditions on the policy RCTs it conducts and authorizes. However, in non-ideal circumstances – i.e. circumstances in which government does not fulfill its duties of justice – other agents involved in the conduct of policy research will also face questions regarding the level of care they must provide to participants. In this part of the paper, I consider two types of non-ideal circumstances and ask whether the relevant agents are also subject to a principle of policy equipoise.

3.1 Policy Equipoise and the Duties of Investigators

Suppose government does not comply with the principle of policy equipoise, demonstrating a willingness to authorize justice-related policy RCTs that do not require that each arm is either in a state of equipoise with the BPA policy, or known to be more effective than it. Must investigators conducting these RCTs nonetheless comply with a similar principle of policy equipoise? I argue here that they must. Since the investigators in question are conducting RCTs authorized by government, I shall refer to them as *government-authorized investigators* (GAIs). GAIs include investigators who receive funds and/or permission from government to conduct an RCT.

GAIs stand in a normatively significant institutional relationship with government, receiving authorization to carry out a public purpose – policy research. As such, there is an important sense in which GAIs act as *agents* of government in carrying out their research, even if they are not government employees. This matters, I suggest, since agents of government – qua agents – have an obligation to only act in ways that government may authorize. By receiving authorization or accepting public funds to carry out a public purpose, GAIs are bound to carry out this purpose in a way that is accountable to the public. Since governments may not authorize GAIs to conduct a justice-related RCT that involves subjecting participants to a policy known to be less effective than the BPA policy, GAIs may not do so.

One might grant that there is an important institutional relationship between government and GAIs, but argue that GAIs only have a responsibility to comply with the *actual authorizations* of government and so need not concern themselves with considerations of which actions governments may or may not authorize. This line of argument has counter-intuitive implications however. It would seem to follow from this position that prior to the passage of the Civil Rights Act of 1964, public colleges – colleges operated by government or operated wholly or partly through government funds – did not act wrongly by discriminating against applicants having particular religious identities.[[38]](#footnote-38) At least in jurisdictions lacking legislation prohibiting such discrimination, public colleges that discriminated against students on religious grounds complied with the *actual* authorizations of government.

One might object that the wrong in question here has nothing to do with the public colleges acting in ways that the U.S. government may not authorize, but is rather a matter of all colleges – public or private – having a duty not to discriminate amongst applicants on the basis of religious identity. But, this can’t be the explanation. After all, it is reasonable to think that it is morally permissible for private colleges to discriminate on the basis of religious identity – i.e. for Catholic universities to favor Catholic students.[[39]](#footnote-39) These institutions have a legitimate purpose in creating a certain type of religiously infused educational environment for their students and so may discriminate amongst applicants to achieve this purpose.[[40]](#footnote-40)

The duty of government agents to only act in ways government may authorize is relevant to the question of whether GAIs must comply with a principle of policy equipoise. Since governments may not subject residents to policies that are known to be less effective than BPA policies, so too they may not authorize GAIs to do so in the conduct of their research. As well, since GAIs may not act in ways government may not authorize, in designing their RCTs, GAIs may not subject participants to policies that are known to be less effective than BPA policies, even in cases where government does not explicitly forbid them from doing so. In designing their RCTs therefore, GAIs are also subject to a principle of policy equipoise. They may only conduct a justice-related RCT if all participants are subject to policies that are – at minimum – in a state of equipoise with the BPA policy.

3.2 Policy Equipoise and Non-BPA Policies

A second type of non-ideal circumstance occurs when governments do not subject their residents to BPA policies. In these cases, must GAIs still comply with a principle of policy equipoise, even though participants are not subject to the BPA policy outside of the trial?

Whether residents are subject to the BPA policy or not, GAIs still act wrongly by conducting a justice-related RCT in which participants are subject to an intervention known to be less effective than the BPA policy. As agents of government, GAIs have a duty to only act in ways that government may authorize; and, since government may not authorize its agents to subject residents to policies known to be less effective than BPA policies, GAIs may not conduct justice-related RCTs in which participants are subject to such policies. In this second type of non-ideal circumstance therefore, GAIs are still subject to a principle of policy equipoise analogous to the principle I define above.

However, this does not mean that it is always on balance impermissible for GAIs to conduct justice-related RCTs that violate this principle. Instead, there are conditions under which it is in principle permissible, on balance, for GAIs to conduct such RCTs.[[41]](#footnote-41) In these cases, GAIs commit a pro tanto wrong against participants, but this wrong is outweighed by competing considerations, namely, the value of the research. The case I have in mind is one where GAIs would like to evaluate the effectiveness of a policy known to be worse than the BPA policy, but that may be more effective than the de facto policy. An RCT evaluating this policy would be in principle on balance permissible, in my view, when the following conditions are satisfied:

1. Subjecting participants to a non-BPA policy is scientifically necessary – i.e. there is no alternative study design that will yield evidence of sufficient quality.
2. All participants are subject to a policy that is – at minimum – in a state of equipoise with the de facto policy;
3. It is unlikely that residents will be subject to the BPA policy in the near future; and
4. It is likely that the intervention being evaluated will be implemented if proven to be more effective than the de facto policy.

In cases that satisfy these conditions, participants are wronged since they are subject to a policy known to be worse than the BPA policy. However, because they are not subject to a policy that is known to be worse than the de facto policy, and the RCT offers the prospect of an improvement to the de facto policy, it is reasonable to think that such RCTs are in principle on balance permissible. The research is valuable to residents, and participants are worse off than they would otherwise be outside of the trial.

Government agencies may also wish to conduct such RCTs when residents are not subject to the BPA policy, and I would suggest that this same line of reasoning applies to them. Provided conditions 1-4 are satisfied, it is in principle on balance permissible for government agencies to conduct and/or authorize an RCT in which participants will be subject to a policy known to be worse than the BPA policy. The only condition I would add is that the government agency conducting or authorizing the RCT must lack the authority, resources, and/or resource procurement powers necessary to implement the BPA policy. If a government agency has the authority and resources/resource procurement powers to implement the BPA policy, it ought to do so, not conduct or authorize an RCT evaluating a policy known to be less effective.

4 CASE: HOMEBASE COMMUNITY PREVENTION RCT

I want now to return to the HCP RCT to illustrate how the principle of policy equipoise might be applied in practice. My goal here is *not* to render a final, comprehensive judgment on the permissibility of this RCT, only to illustrate how one might use the principle of policy equipoise to evaluate it.

HCP is a New York City Department of Homeless Services (DHS) program that aims to prevent homelessness from occurring. Households at risk of homelessness but who are not in the process of applying for shelter or currently residing in a shelter are eligible for the program. Eligible households are assigned a case manager who acts to help them preserve their housing and develop a plan for maintaining housing in the future. Assistance can involve limited financial assistance to pay rental or utility arrears, moving costs, or security deposits, benefits advocacy, employment assistance, or legal referrals. In 2008, DHS directed Abt Associates, a private research firm, to conduct an RCT to (a) evaluate the effect of HCP on the rate of shelter use; and (b) determine whether the cost of operating HCP is offset by the savings resulting from its impact on reductions in shelter costs. Program applicants were recruited between June and September 2010. After they were deemed eligible for HCP services, they were offered the opportunity to give informed consent to the study; those who did not consent were not eligible to receive HCP services during the enrollment period. 415 households enrolled in the study, with 208 randomly assigned to receive HCP services and 207 assigned to not receive HCP services. Because not all eligible applicants receive HCP services due to funding constraints, no greater number of eligible applicants were denied access to HCP in 2010 due to the RCT. [[42]](#footnote-42)

To determine whether this RCT is consistent with policy equipoise, it is first necessary to identify the relevant justice outcome. For simplicity’s sake, I shall stipulate here that the justice outcome in question is universal access to adequate, permanent housing. This outcome is clearly a goal of the program, and realizing it is prima facie a moral responsibility of government.

Next, one must identify the BPA policy, that is, the policy that is (1) best proven; and (2) morally and practically attainable and sustainable. Answering this question decisively is beyond the scope of this paper, requiring housing policy expertise and knowledge of DHS’s legitimate funding constraints and commitments. However, for our purposes here, it is worthwhile exploring some of the considerations relevant to the question of whether HCP is the BPA policy.

With respect to (1), there is evidence that HCP has been effective in promoting access to permanent housing in the New York City context. First, between 2004 and 2007, DHS piloted six HCP programs in community districts with the highest homelessness rates. DHS also set up a control group of six community districts having similar economic characteristics. DHS found that the communities in which HCP operated showed a lower rate of increase in shelter entry – 10 percent – than control communities.[[43]](#footnote-43) The results of this study, as a non-randomized observational study with a control, are not as high-quality as the results of an RCT. But, it doesn’t follow from this that its conclusions do not constitute evidence.

Second, the HCP program was designed in part on the basis of a study conducted by the Vera Institute of Justice on the population entering shelters in New York City and the underlying causes motivating them to do so, as well as planning sessions featuring input from community-based organizations, landlords, and shelter providers and clients.[[44]](#footnote-44) It is likely therefore that DHS policy-makers have a reasonably accurate understanding of the causal mechanisms underlying homelessness, and that HCP has been designed with these causal mechanisms in mind. Additionally, between 2004 and 2009, over 90 percent of households did not enter shelters within one year of service.[[45]](#footnote-45) These facts are important, since, as Nancy Cartwright and Jacob Stegenga have argued, a well-grounded causal model of the relevant phenomena can serve as evidence of the effectiveness of a policy intervention.[[46]](#footnote-46) The success rate of HCP, I would suggest, is evidence that the causal model of homelessness DHS policy-makers are working with is reasonably accurate.

With respect to (2), the relevant question is whether HCP is affordable, given New York City’s responsibilities for promoting other justice outcomes. There are two reasons to think that DHS may have legitimate concerns that it may not be. First, as mentioned above, DHS has not had sufficient resources in the past to provide HCP to all eligible applicants, with 5500 households receive HCP each year, and 1500 being turned away.[[47]](#footnote-47) Second, one aim of the RCT was to determine HCP’s cost-effectiveness, suggesting that DHS doubts whether HCP is affordable, given its other commitments. Neither of these reasons is decisive however. As I note above, whether a particular policy is practically attainable and sustainable does not depend on the amount of resources a particular government agency *in fact* has to fund the policy; instead, it depends on the amount of resources it *ought* to have. Even though DHS does not have the funds to provide HCP to all eligible applicants, HCP may still be the BPA policy if the funding shortfall is due to injustice in the procurement and allocation of tax revenue.

HCP would count as the BPA policy therefore, if: (1) given the existing evidence regarding its effectiveness, policy experts could not reasonably doubt that it is more effective than nothing; and (2) given a just procurement and allocation of resources, DHS would be able to offer HCP benefits to all eligible applicants. Since determining whether (1) and (2) hold is beyond the scope of this paper, it is worthwhile considering the HCP RCT in light of my analysis above on the assumption that it is the BPA policy, and that it is not.

First, if HCP is *not* the BPA policy (and there are no alternative, affordable policies known to be more effective than nothing at promoting the justice outcome in question), then the HCP RCT does not violate the principle of policy equipoise. In this case, HCP is not a policy DHS has a duty to implement. The mere fact that DHS *has* implemented HCP in the past is irrelevant – what matters is whether residents have a *claim of justice* to be subject to this policy.

If, second, HCP *is* the BPA policy however, for example, because the New York City Government *ought* to provide DHS with the resources necessary to adequately fund it, then DHS acts wrongly by authorizing the RCT, and Abt Associates acts wrongly by conducting it. Both DHS and Abt Associates violate their duty to only act in ways government may authorize by subjecting participants to a policy known to be less effective than the BPA policy.

As I note above, this does not mean that DHS and Abt Associates act wrongly *on balance*. However, it is difficult see how the HCP RCT could satisfy the above-mentioned conditions. The problem here is that the HCP RCT does not evaluate the effectiveness or affordability of some novel policy that, though known to be less effective than the BPA policy, may be superior to the status quo policy. Instead, it investigates the effectiveness and affordability of the BPA policy itself. In other words, if HCP is the BPA policy, the HCP RCT has very little value since, as the BPA policy, policymakers already know enough about HCP to justify extending it to all eligible applicants.

5 AN OBJECTION

One might argue that government conducted or authorized policy RCTs need not comply with the principle of policy equipoise to be ethical. Instead, it is sufficient for investigators to secure the informed consent of participants. If government requires investigators to disclose to participants that a particular trial arm is not in a state of equipoise with the BPA policy, and if participants nonetheless consent to participation, it doesn’t seem as though these participants have been wronged.[[48]](#footnote-48)

In response, consider first that the central reason for not relying solely on informed consent in the context of biomedical RCTs – namely, that participants’ decision-making capacities are deficient – would seem to apply in the context of public policy RCTs as well.[[49]](#footnote-49) Potential clinical research participants often lack knowledge regarding the nature of the research enterprise and the specific area under research; and they often reason and judge poorly regarding whether participation is a good idea for them, given their values and circumstances.[[50]](#footnote-50) Potential policy RCT participants are likely to exhibit these same deficiencies.

Additionally, even if informed consent is *sufficient* for a policy RCT to be ethical, there are reasons to think that it is not *necessary* in all cases, and further reasons to think that requiring informed consent in all circumstances might prevent valuable social scientific research. Even if it were possible to sufficiently protect research participants by relying solely on informed consent, doing so, at least in some cases, may be neither ethically required nor desirable. In these cases it may therefore be morally permissible and best from the standpoint of research to set informed consent aside and rely instead on policy equipoise – amongst other principles – to protect research participants.

First, some scholars argue that informed consent is not necessary to ensure that policy RCTs are ethical, either because the risks to research participants are low, or because the institutions conducting such RCTs – e.g. governments or hospitals – have the authority to change rules and policies without the explicit consent of those subject to them, and possess an implicit mandate to conduct research for quality improvement reasons.[[51]](#footnote-51) This latter reason is arguably the justification for why, in the U.S. context, federal regulations governing human subjects research exempt from federal regulation – including the requirement of informed consent – research and demonstration projects concerning public service programs.[[52]](#footnote-52) Second, many scholars argue that securing participants’ informed consent in the context of some RCTs can disrupt scientific validity, for example, because informing people of their participation in research may alter their behavior.[[53]](#footnote-53) For these reasons therefore, even if informed consent were sufficient to protect research participants, there may be good reasons to rely on other sorts of protections such as policy equipoise.

CONCLUSION

My aim in this paper has been to contribute, in a small way, to the ethics of policy RCTs. I have argued that a principle analogous to the principle of clinical equipoise – the principle of policy equipoise – should govern justice-related RCTs conducted or authorized by governments.

Many questions concerning the interpretation and application of this principle must be addressed by future work. For example, by what procedure might investigators identify justice outcomes and BPA policies, given reasonable disagreement about the requirements of justice? More broadly, much work on the ethics of public policy RCTs remains to be done. As I hope to have demonstrated in this paper, such research cannot simply involve the mechanical application of ethical principles developed for the context of biomedical research to the context of policy research. Instead, such principles should be used as a resource to help identify the problems investigators are likely to encounter in the course of policy research, and to develop a set of concepts and principles investigators, IRBs, and government agencies can use to resolve them.

1. For an overview of the trial and results, see H. Rolston, J. Geyer & G. Locke. 2013. *Final Report: Evaluation of the Homebase Community Prevention Program*. Available at: https://www.ippsr.msu.edu/research/evaluation-homebase-community-prevention-program [Accessed 10 July 2017]. [↑](#footnote-ref-1)
2. See C. Buckley 2010. To Test Housing Program, Some Are Denied Aid. *The New York Times* 8 December. [↑](#footnote-ref-2)
3. For an overview of this trial and the ensuing controversy, see J.S. Hawkins & E.J. Emanuel 2008. Why Exploitation? In *Exploitation and Developing Countries: The Ethics of Clinical Research* J.S. Hawkins & E. J. Emanuel, eds. Princeton: Princeton University Press: 1-7 [↑](#footnote-ref-3)
4. See M. Angell. The Ethics of Clinical Research in the Third World. *N Engl J Med* 1997; 337: 847-849. [↑](#footnote-ref-4)
5. For example, see R.A. Crouch & J.D. Arras. AZT Trials and Tribulations. *Hastings Cent Rep* 1998; 28: 26-34; and A.J. London. Equipoise and International Human-Subjects Research. *Bioethics* 2001; 15: 312-332. [↑](#footnote-ref-5)
6. For discussion of, and advocacy for, this trend, see A.V. Banerjee & E. Duflo. 2012. *Poor Economics: A Radical Rethinking of the Way to Fight Poverty.* New York: Public Affairs; and L Haynes et al. 2012. *Test, Learn, Adapt: Developing Public Policy with Randomised Controlled Trials*. London: Cabinet Office Behavioral Insights Team. [↑](#footnote-ref-6)
7. I am not the first scholar to argue for a principle of equipoise to govern public policy RCTs. See R. Kukla. Resituating the Principle of Equipoise: Justice and Access to Care in Non-Ideal Conditions. *Kennedy Inst Ethics J* 2007; 17: 171-202. As I explain below however, my account differs markedly from Kukla’s. [↑](#footnote-ref-7)
8. B. Freedman. Equipoise and the Ethics of Clinical Research. *N Engl J Med* 1987; 317: 144. See also P.B. Miller & C. Weijer. Rehabilitating Equipoise. *Kennedy Inst Ethics J* 2003; 13: 93-118. [↑](#footnote-ref-8)
9. See R.J. Levine. 1986. *Ethics and Regulations of Clinical Research*. Second ed. New Haven: Yale University Press: 185-212; and T.L. Beauchamp & J.F. Childress. 2009. *Principles of Biomedical Ethics*. Sixth ed. New York: Oxford University Press: 317-324. [↑](#footnote-ref-9)
10. See F. Gifford. Freedman’s “Clinical Equipoise” and “Sliding-Scale All Dimensions-Considered Equipoise.” *J Med Philos* 2000; 25: 399-426; and S. Gelfand. Clinical Equipoise: Actual or Hypothetical Disagreement? *J Med Philos* 2013; 38: 590-604. [↑](#footnote-ref-10)
11. A.J. London. The Ambiguity and the Exigency: Clarifying “Standard of Care” Arguments in International Research. *J Med Philos* 2000; 25: 382. [↑](#footnote-ref-11)
12. Ibid: 382-384. [↑](#footnote-ref-12)
13. Kukla, *op. cit.* note 7, p. 172. [↑](#footnote-ref-13)
14. See F.G. Miller & H. Brody. A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials. *Hastings Cent Rep* 2003; 33: 19-28. [↑](#footnote-ref-14)
15. P.B. Miller & C. Weijer. Equipoise and the Duty of Care in Clinical Research: A Philosophical Response to Our Critics. *J Med Philos* 2007; 32: 117-133. [↑](#footnote-ref-15)
16. See Kukla, *op. cit.* note 7, p. 176; A.J. London. Two Dogmas of Research Ethics and the Integrative Approach to Human-Subjects Research. *J Med Philos* 2007; 32: 99-116; and D. MacKay. Standard of Care, Institutional Obligations, and Distributive Justice. *Bioethics* 2015; 29: 262-273. [↑](#footnote-ref-16)
17. Kukla, *op. cit.* note 7, p. 176. [↑](#footnote-ref-17)
18. Ibid. [↑](#footnote-ref-18)
19. Ibid: 178. [↑](#footnote-ref-19)
20. Ibid: 177. [↑](#footnote-ref-20)
21. Ibid: 178-179. [↑](#footnote-ref-21)
22. Ibid: 179. [↑](#footnote-ref-22)
23. MacKay, *op. cit.* note 16, p. 269. [↑](#footnote-ref-23)
24. For simplicity’s sake, I shall understand government here as a unitary agent. I recognize however that (1) governments are not always unitary agents – e.g. in federations; and (2) all levels of government have duties of justice – e.g. federal, state/provincial, and municipal. For justification of this latter claim in the context of health, see D. MacKay & M. Danis. Federalism and Responsibility for Health Care. *Public Aff Q* 2016; 30: 1-29. [↑](#footnote-ref-24)
25. I use the term *resident* rather than *citizen* to indicate that governments have robust duties of justice not only to citizens but also to non-citizens living within their territory – e.g. legal permanent residents. I also acknowledge that governments may have different duties to different types of residents – e.g. citizens, legal permanent residents, temporary workers, and undocumented immigrants. Finally, I don’t deny that governments also have duties to realize justice outcomes for non-residents – e.g. tourists or citizens of low-income countries. I focus on residents here for simplicity’s sake. [↑](#footnote-ref-25)
26. London, *op. cit.* note 5, p. 327. [↑](#footnote-ref-26)
27. Ibid: 327-329. [↑](#footnote-ref-27)
28. The BPA policy is thus roughly the same as Kukla’s notion of the local de jure standard of care – the level of services people in a particular jurisdiction ought to have access given its material circumstances. Kukla, *op. cit.* note 7, p. 177. I use the above concept of a BPA policy since I think it better details the factors that make a policy the local de jure standard. [↑](#footnote-ref-28)
29. I am grateful to an anonymous reviewer for pressing this concern. [↑](#footnote-ref-29)
30. In future work, I plan to develop an account of how investigators, IRBs, and policymakers can identify BPA policies in cases where there is reasonable disagreement about the demands of justice. Unfortunately, developing such an account is beyond the scope of this paper, and so I assume below that it is possible to justifiably identify BPA policies. My working idea is that investigators working in the context of legitimate liberal states should look to the decisions and structures of these institutions, e.g. constitutional documents, statutes, policies, and court decisions, as resources by which they can identify principles of justice that are relevant to their specific area of research. This proposal presupposes an understanding of liberal democratic states as fair and impartial institutions by which residents can resolve their reasonable disagreements about the demands of justice. For questions of global justice, democratically formulated international agreements and institutions could play a similar role. To develop this idea further, I shall rely on the work of Andrea Sangiovanni who has formulated an interpretive procedure for identifying the principles of justice that underlie current practices, laws, and policies. See A. Sangiovanni. Justice and the Priority of Politics to Morality. *J Polit Philos* 2008; 16: 137-164. [↑](#footnote-ref-30)
31. Thanks to an anonymous reviewer for raising this possibility, and for the example. [↑](#footnote-ref-31)
32. Thanks to an anonymous reviewer for this suggestion. [↑](#footnote-ref-32)
33. Kukla also defends a “new version of the principle of equipoise” (PE\*) that applies to policy RCTs, not only biomedical RCTs. According to PE\*, ‘in order to begin or to continue human subjects research, 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 falls under the scope of research.’ Kukla, *op. cit.* note 7, p. 180. The purpose of PE\* is not to ensure that participants receive care that is no worse than the standard of care; but rather to ensure that particular RCTs are socially valuable. Ibid: 182. Since my aim in this paper is to develop a principle of policy equipoise that is analogous to the principle of clinical equipoise, and so functions to achieve the former goal, I shall not discuss Kukla’s new version of the principle of equipoise. Kukla’s PE\* addresses a different question than the principle of equipoise I develop here, and it is in principle consistent with Kukla’s PE\*. I need not therefore reject it for my principle of policy equipoise to offer an alternative to Kukla’s PE\*. [↑](#footnote-ref-33)
34. I thank an anonymous reviewer for raising this objection. [↑](#footnote-ref-34)
35. For an excellent discussion of this issue, see N. Cartwright & J. Hardie. 2012. *Evidence-Based Policy: A Practical Guide to Doing it* Better. New York: Oxford University Press: 62-88. [↑](#footnote-ref-35)
36. Ibid: 38-40; and J.D. Angrist & J.S. Pischke. 2015. *Mastering Metrics: The Path from Cause to Effect*. Princeton: Princeton University Press. [↑](#footnote-ref-36)
37. See MacKay, *op. cit.* note 16 for further discussion of how the obligations of investigators might depend on their institutional affiliation. [↑](#footnote-ref-37)
38. The Civil Rights Act of 1964, 42 U.S.C. 21. [↑](#footnote-ref-38)
39. This is also legal in the U.S. context. [↑](#footnote-ref-39)
40. This line of argument also explains why non-GAIs do not necessarily possess the same obligations as GAIs. [↑](#footnote-ref-40)
41. I say ‘in principle’ permissible here to note that other features of the RCT would affect its permissibility – e.g. whether subjects are selected fairly etc. [↑](#footnote-ref-41)
42. For an overview of this RCT, see Buckley, *op. cit.* note 2, and Rolston et al., *op. cit.* note 1. [↑](#footnote-ref-42)
43. HUD Exchange. 2009. Community Spotlight: Homelessness Prevention Homebase in New York City, NY. Available at: https://www.hudexchange.info/resource/1140/community-spotlight-homelessness-prevention-homebase-in-new-york-city/ [Accessed 10 July 2017]. [↑](#footnote-ref-43)
44. Ibid. [↑](#footnote-ref-44)
45. Ibid. [↑](#footnote-ref-45)
46. N. Cartwright & J. Stegenga. 2011. A Theory of Evidence for Evidence-Based Policy. In *Evidence, Inference and Enquiry*. P. Dawid, W. Twining, & M. Vasilaki, eds. Oxford: Oxford University Press: 292-321. [↑](#footnote-ref-46)
47. Buckley, *op. cit.* note 2. [↑](#footnote-ref-47)
48. For a formulation of this objection in the context of biomedical RCTs, see R.M. Veatch. The Irrelevance of Equipoise. *J Med Philos* 2007; 32: 167-183. [↑](#footnote-ref-48)
49. F.G. Miller & A. Wertheimer. Facing Up To Paternalism In Research Ethics. *Hastings Cent Rep* 2007; 37: 24-34. [↑](#footnote-ref-49)
50. See S. [Joffe et al.](https://www.ncbi.nlm.nih.gov/pubmed/?term=Joffe%20S%5BAuthor%5D&cauthor=true&cauthor_uid=11734235) Quality of Informed Consent in Cancer Clinical Trials: A Cross-Sectional Survey. *Lancet* 2001; 358: 1772-1777; and C.W. [Lidz et al.](https://www.ncbi.nlm.nih.gov/pubmed/?term=Lidz%20CW%5BAuthor%5D&cauthor=true&cauthor_uid=14990370) Therapeutic Misconception and the Appreciation of Risks in Clinical Trials. *Soc Sci Med* 2004; 58: 1689-1697. [↑](#footnote-ref-50)
51. See J. Sim & A. Dawson. Informed Consent and Cluster-Randomized Trials. *Am J Public Health* 2012; 102: 480-485. [↑](#footnote-ref-51)
52. Protection of Human Subjects, 45 CFR 46 January 15, 2009. [↑](#footnote-ref-52)
53. For a good discussion of this issue, see D. Teele. 2014. Reflections on the Ethics of Field Experiments. In *Field Experiments and Their Critics: Essays on the Uses and Abuses of Experimentation in the Social Sciences*. D. Teele, ed. New Haven: Yale University Press: 124-128. [↑](#footnote-ref-53)