

## **Exploitation, Justice, and Parity in International Clinical Research**

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*ABSTRACT* Consensus is lacking among research ethicists on the question of how broadly to understand the requirements of non-exploitation in international clinical research. Two types of principles have been proposed, minimalist and non-minimalist, grounded in two opposing conceptions of exploitation, transactional and systemic. Transactionalists have offered principles, which, it has been argued, are satisfied by minimal gains to vulnerable subjects measured against an unjust status quo. Systemicists have advanced principles with decidedly non-minimal mandates but only by conflating the obligations of clinical research with those of First World citizenship. My aim here is to break this deadlock by offering grounds for a non-minimal requirement of international research ethics grounded in a transactional conception of exploitation. I do this by arguing that a subject's gains must be measured not only within the transaction, relative to her own starting point and to the share of gains enjoyed by her co-transactor, but also across transactions, so as to ensure parity of benefit to trial participants whenever, and wherever, parity of burden is assumed.

### **Introduction**

For several decades now research ethicists have asked whether the moral standards appropriate for evaluating domestic research on human subjects are adequate in an international context. This question has arisen in response to a number of clinical cases in which First World pharmaceuticals (and in some cases state agencies) appear to have taken unfair advantage of desperate test subjects in the developing world, exposing them to the risks of medical research without eliciting their consent or providing them with fair benefits.<sup>1</sup> There is now a general consensus that at least one new ethical safeguard is required in contexts where poverty, low education levels, and a lack of health care resources make research populations acutely vulnerable to exploitation. But while agreement exists that such a principle is needed, consensus is lacking on the matter of scope, or on how broadly to understand the duties of non-exploitation in international clinical research.

A number of competing principles have been proposed, grounded in two opposing accounts of exploitation. Both accounts agree that exploitation consists in the taking of unfair advantage, yet each has quite a different understanding of what this involves. The transactional account holds that exploitation occurs when the distributive outcome of an exchange is such that the less well situated Party B fails to benefit relative to her starting point, or benefits too little relative to Party A. Principles grounded in this account have been referred to as minimalist in scope, as they can be satisfied by small gains measured against B's unjust pre-transaction baseline. The most outspoken critics of minimalism

have appealed alternatively to a systemic account of exploitation, according to which the relevant moral wrong occurs when A takes advantage of, profits from, or fails to redress the systemic injustice of B's pre-transaction baseline. Principles grounded in this account of exploitation have been deemed non-minimalist, as they rest the duties of developing world researchers in the rectification owed to the global poor by citizens of the developed world who profit from and thereby uphold global injustice.

I argue here that non-minimalist principles of international research ethics grounded in systemicism face two interrelated problems: they hold researchers more responsible for satisfying the duty of rectification than other First World citizens and at the same time deny that researchers derive any particular duties to their subjects from their specific interaction. Nonetheless, I concede the systemicist's worry about the minimalism of existing transactional principles. My aim is therefore to address the inadequacies of minimalism without endorsing systemicism. I propose to expand the transactional understanding of a just benefit share, and thus provide grounds for a more exigent, non-minimalist requirement of international research ethics, without appealing to the systemic account of exploitation.

My strategy will be to reject the transactionalist assumption that B's gains need only be measured within the transaction, relative to her own starting point and to the share of gains enjoyed by A. I will argue instead that true transactional justice demands not only the performance of *intra* but *inter* transactional distributive comparisons, whereby B's gains are assessed relative to those enjoyed by other Party Bs engaged in similar transactions in more developed regions. An appropriate transactional principle of non-exploitation in international research must, on my account, contain an *inter transactional parity condition*.

I do not try to advance a self-standing, fully articulated principle of non-exploitation in international clinical research here, but merely to sketch the normative foundations of a necessary condition that any such principle must contain. Whatever principle ultimately espouses the parity condition, as I call it, will be transactional in foundation, and thereby focus on the distributive duties A derives with respect to B from their specific interaction, yet at the same time be non-minimal in mandate, as the inter transactional comparative benchmark at its core will prevent the injustice of B's baseline from being used as grounds for denying her a just share of the research benefits she helps produce. I will conclude by showing, in response to potential challenges to the parity condition, that it is properly viewed as a requirement of non-ideal justice.

## 1. Transactional Exploitation and Minimalist Principles

Transactional accounts of exploitation hold that a moral wrong occurs when one party to an exchange takes unfair advantage of the other to secure for herself a greater share of the cooperatively produced surplus. According to Alan Wertheimer, a full account of transactional exploitation depends on an understanding of both its normative content and its normative force. The normative content of an exploitation claim, on this view, is that: A exploits B when A takes unfair advantage of B.<sup>2</sup> Unfair advantage is taken when there is a failure in either the transactional process (consent condition) or the transactional outcome (justice condition).

With respect to the consent condition what matters is whether A coerces B. If A takes advantage of some fact about B's circumstances to coerce B to transact with her,

A takes unfair advantage of B and exploits her. According to Wertheimer, A coerces B if A threatens to violate B's rights (to make her worse off than she otherwise would have been) if B does not agree to transact with A on A's terms. Where an exploitation claim is substantiated by the fact that A has coerced B, the claim carries adequate normative force to warrant the transaction's prevention.<sup>3</sup>

But how should we understand the taking of unfair advantage with respect to the transactional outcome, or justice condition? For Wertheimer, in order for A to take unfair advantage of B with respect to the distribution of benefits and burdens, there obviously has to be some benefit to A. But we also have to consider the effect on B. If B is harmed, in the sense that she loses as a result of the transaction (is rendered worse off by it than she would otherwise have been), then A has taken unfair advantage of B and exploited her. Once again where an exploitation claim is substantiated on these grounds, it carries adequate normative force to warrant prevention of the transaction. But what if B also benefits?

Mutually advantageous transactions are ones in which both A and B gain as a result of their interaction, relative to where each began. These can be exploitative if A manages to secure an unfairly greater share of the cooperative surplus for herself.<sup>4</sup> But it is not clear, according to Wertheimer, how we should determine whether A's share is unfairly large relative to B's, nor therefore when such transactions carry adequate normative force to warrant their prevention. The task of the transactionalist concerned to adduce a duty of non-exploitation in international clinical research is to provide a metric for assessing the fairness of A and B's relative shares, and thereby some account as to when mutually advantageous research transactions nonetheless warrant prevention.

#### *1A. The Principle of Fair Benefit (PFB)*

Emanuel *et al.* first made the novel and compelling move to identify research trials in the developing world as instances of mutually advantageous exploitation.<sup>5</sup> On their view, while the researchers (Party A) certainly benefit from the transaction in terms of the knowledge acquisition they require to license, patent, and market a new treatment, the participants and host community (Party B) also benefit in terms of gaining access to medical resources and treatments they require but could not otherwise afford or access. Party A might certainly be said to enjoy greater benefits than Party B, but it can hardly be denied that B herself gains from the transaction. That A gains more than B is not morally troubling, according to Emanuel *et al.*, provided that: (1) the consent condition is satisfied (B is not coerced by A); (2) there is mutual benefit (B is not harmed by A); (3) B receives a fair share of benefits, where fairness is determined according to whether B's own preferences regarding the content and scope of her share are satisfied.<sup>6</sup>

For Emanuel *et al.*, clinical research trials in the developing world qualify as mutually advantageous exploitative transactions, but are not normatively problematic (do not warrant prevention) so long as the previous conditions are satisfied. It is the moral duty of the researcher to ensure satisfaction of these conditions when conducting trials involving vulnerable developing world subjects. Their trials will then not be exploitative in the prohibited sense, because A's share will not qualify as unjustly greater than B's, provided that B herself is satisfied by the scope and content of her share.<sup>7</sup> For Emanuel

*et al.*, what matters from the point of view of justice is not that B receive any particular type of benefit, or some objectively determined share thereof, but whether B's benefits reflect B's values.

### *1B. The Principle of Permissible Exploitation (PPE)*

Wertheimer derives a slightly different principle of international research ethics from his transactional account of exploitation. On his view, the justice of a mutually beneficial distributive outcome is difficult to ascertain. In theory, he suggests, we could appeal to a hypothetical market model, whereby a fair distribution is one that would be arrived at in an ideal market by equally situated, rationally informed bargainers.<sup>8</sup> In theory, this would allow us to say that A exploits B, despite the fact that B gains all things considered from the transaction, whenever A takes advantage of B's circumstances to secure for herself a larger share than she could if B were ideally placed to bargain.

However, while Wertheimer thinks this is most likely the right metric of justice ideally speaking, he goes on to argue that the correct principle of international research ethics must be applicable under non-ideal conditions. He contends, therefore, that while the type of scenario above, wherein A gets more than she would if B were better placed to bargain, is indeed exploitative, it doesn't carry the right kind of normative force non-ideally speaking. Why? Because the prevention of a research transaction on the grounds that A gains more than A would under ideal conditions denies B the small gain the transaction would have afforded B had it been permitted.

The Principle of Permissible Exploitation (PPE) allows mutually beneficial exploitative transactions where the following conditions obtain:

1. A is under no obligation to transact with B on any terms.
2. A proposes to transact with B on terms X.
3. A's transaction with B on terms X is to A's benefit and also serves B's *ex ante* and all things considered interests.
4. B makes a voluntary, informed, rational decision to transact with A on terms X.
5. If A is not allowed to transact with B on terms X, A will choose not to transact with B on terms that are more favourable to B.
6. Preventing A from transacting with B on terms X will not have any significant positive consequences for anyone else.<sup>9</sup>

If A has no particular obligation to transact with B it is hard to demand that she do so on specific terms, claims Wertheimer. If we set these terms in an exigent way — say, what A might owe B in a hypothetically ideal market — A is more likely not to transact with B at all than to transact with her more fairly. B then stands to lose even the meagre gains she could otherwise have enjoyed.<sup>10</sup> If we accept that First World researchers have no pre-existing duty to transact with any particular subjects in the developing world, insisting that they do so on specified terms may deprive their potential subjects of any gains at all.<sup>11</sup> Thus, in a non-ideal world, Wertheimer says, justice must be seen to lie in Pareto improvements, as secured by the PPE.

### *1C. Challenges to Minimalism*

The PPE and the PFB are insistent that any transaction in which developing world research subjects are coerced or all things considered harmed are wrongfully exploitative

and must be prevented. Both principles also identify the subjects of the research as the appropriate beneficiaries thereof and conceive of benefits in terms broad enough to be consistent with the subjects' specific needs and interests, be they for such things as life saving medications, long term care, training, education, or infrastructure. In these regards, the term 'minimalist' seems highly disingenuous. Yet both principles are subject to a serious challenge — indeed, the one that earned them the moniker of minimalism.

According to the systemic challenge, no principle can hope to generate just outcomes so long as it takes injustice as its starting point. Measuring gains relative to the grossly unjust pre-transaction baselines of developing world research subjects cannot possibly, it is argued, be a recipe for fairness.<sup>12</sup> On the transactional account, we are supposed to measure gains enjoyed by the parties relative to each other, and relative to where each began. But if B had a grossly unjust starting position relative to A, we are inevitably going to carry that injustice over to the distributive outcome because almost anything is going to count as a gain relative to where B began. Minimalists thereby accept not only pitiful gains, according to their critics, but the moral validity of a horribly unjust status quo. If we truly want to provide a just benefit share to B, we should not measure her share relative to her own baseline. Thus, according to the systemic challenge, we should not be minimalists.

## **2. Systemic Exploitation and Non-Minimalist Principles**

For systemicists, the failure of minimalism stems from the belief that exploitation is a mere micro level feature of particular agreements that can be considered apart from the background conditions of global injustice. On the systemic view, the background conditions of a transaction determine the injustice of its distribution so long as they remain unchanged by it. A rejection of minimalism, on this view, thus necessitates a rejection of transactionalism. For systemicists, when clinical researchers conducting studies in the developing world provide a meagre benefit to their subjects relative to the conditions in which they found them (say, no benefits post-trial for subjects randomised to the placebo wing on the grounds of their having benefited from seeing a clinician for once) they not only thereby profit from the existing injustices of their subjects' condition, but from injustices they helped cause.

The systemic account of exploitation finds pedigree in Marx, who held that the institutional structure of capitalism is such that the proletariat has no choice but sell his labour power, from which the bourgeoisie is thereby able to extract surplus value for which the proletariat cannot be adequately compensated.<sup>13</sup> The solution to the problem of systemic exploitation is a change to the system itself. A more recent version of the systemic view is found in the work of Thomas Pogge, according to whom the global institutional order is such that the First World uses more than its per capita share of global resources, for which it fails to compensate those in the developing world who under-consume their rightful share thereof.<sup>14</sup> Members of the First World thereby owe a duty of redress to the global poor, and where instead of satisfying this duty they seek to profit from their deontic failure, they commit the gross injustice of exploitation.

Systemic exploitation, like transactional exploitation, is said to occur when developing world research subjects are taken unfair advantage of by First World researchers. But unfair advantage on this view is thought to occur in the following three ways: (1) gains

are measured relative to where the parties began rather than where the parties ought to have begun, (2) the cooperative surplus of the transaction is regarded as the only appropriate object of distribution, as opposed to the share of goods and capacities that constituted the parties' pre-transaction baselines, and (3) both (1) and (2) occur in conjunction with a prior deontic failure on the part of one party to satisfy duties of redress it owes to the other.

#### 2A. *The Human Development Approach Principle (HDAP)*

Alex John London argues that researchers have an obligation to improve the status quo in developing nations because of their own complicity, as First World citizens, in producing and benefiting from the conditions of poverty-related ill-health. We can't deny, he argues, that poverty-related ill-health in the developing world is the product of an unjust global institutional order that works to the advantage of members of the First World precisely because it disadvantages members of the developing world.<sup>15</sup> Members of the First World have a duty to rectify this injustice. If they do not comply, they fail in their moral obligation. If they also seek to profit from this — say by exposing desperate subjects to the risks of research for their own gain, when the subjects' desperation is a direct product of their own previous moral failure — they exploit their subjects.

London argues for the Human Development Approach Principle (HDAP) by appeal to three distinct premises. The first asserts that 'Duties of rectification . . . apply to medical researchers insofar as they are citizens of . . . nations that have contributed to and benefited from [global poverty].'<sup>16</sup> The second holds that the progress of human development is impeded by the ill-health of developing world communities. The third maintains that the social determinants of health in such communities must be addressed in the name of human development. And the conclusion of this argument, which consists in his articulation of the HDAP, is that medical researchers, as First World citizens with duties of rectification, must address the health related human development needs of the members of their subjects' communities.<sup>17</sup>

#### 2B. *The Relief of Oppression Principle (ROP)*

James Lavery *et al.* agree that the morality of research conducted in the developing world cannot be evaluated apart from the systemic conditions of injustice against which it occurs. They conceptualise this injustice in terms of oppression, or the absence of real freedom that characterises the lives of the global poor.<sup>18</sup> They therefore propose that researchers working in the developing world must be committed to relieving oppression by providing benefits that address the background conditions of injustice, or more specifically, that remove barriers to their subjects' fundamental freedoms. And, in doing so, Lavery *et al.* argue, 'elevate the priority of these benefits, in relation to any other types of benefit that might be considered and negotiated with participants, according to the degree to which the participating communities are constrained in their realisation of fundamental freedoms.'<sup>19</sup>

The ROP rests on two normative claims. The first holds that exploitation occurs when the benefits of a cooperative arrangement are enjoyed by one party and not the other, due to structures of oppression that govern the lives of the global poor. The second holds that oppression is undermined when the material, social, and political barriers to the

enjoyment and exercise of real freedom by the global poor are removed. The ROP thus demands that to avoid exploitation, clinical researchers in the developing world must provide benefits geared to enhancing the real freedom (by removing barriers thereto) of the members of their subjects' communities.

### 2C. Challenges to Systemicism

It seems uncontroversial to concede that micro transactions are affected by the nature of background macro injustices.<sup>20</sup> It is also fairly straightforward to count as an injustice the current distribution of wealth, resources, and freedoms across the developed and the developing world, and even to accept that members of the First World bear some significant duty to address this injustice. But none of these claims lead, even cumulatively, to the notion that the duty of non-exploitation incumbent on the clinical researcher boils down to a duty to rectify global inequality in the way that the HDPA and ROP demand. There are three interrelated challenges these principles face, all pertaining to their systemic derivation of a researcher's duties from those of her First World citizenship.

It is widely acknowledged that we err in research ethics when we conflate the obligations of the researcher with those of the doctor, given the different aims of clinical research and medical practice. We should not assume that in her role as researcher the individual has the same duties of care to her subjects that she owes her patients in her role as their physician.<sup>21</sup> Isn't it also equally a misconception to conflate the obligations of the researcher with that of the First World citizen? While the researcher may have duties as a First World citizen to redress the conditions of global injustice, it is unclear why this should have any more bearing on the duty she owes her subjects *qua* researcher than on the duties she owes her patients *qua* doctor, or for that matter, on the duties she owes her children *qua* mother, or her neighbours *qua* homeowner, etc.

More importantly, when we conflate the duties of research with those of First World citizenship we demand both too much and too little of clinical researchers. On the one hand, the researcher is expected to address the vast institutional structures that permit over-consumption and under-compensation simply as way of discharging her obligations to her subjects and conducting her clinical work. This is simply too much to ask. But it also raises concerns of practicality — how qualified is the clinical researcher to do this? And finally, it seems to smack of what we might call duty-dumping: the rest of us who bear duties of redress can wash our hands of them and/or berate researchers for failing to discharge our duties for us.

On the other hand, resting the duties of the researcher in those of First World citizenship seems at one and the same time to demand too little of her. On the systemic account, the researcher seems to be exonerated from any specific obligation to the actual subjects of her research. Since her duty to them pre-existed their interaction, or rather, since her exploitation of them depends on a previous deontic failure, she could just discharge her First World duties and thereby claim non-exploitation of her subjects. In other words, she could donate large sums to MSF, thereby addressing the health related human development needs of her subjects' communities, and be freed of any obligation whatsoever to the actual subjects of her clinical trials.<sup>22</sup> The conflation of these two duties therefore seems, albeit counter intuitively, to ask too little of the researcher while at one and the same time asking too much.

Finally, if the duties of the researcher are grounded in those of First World citizenship, on what basis are researchers more responsible for discharging this duty than the rest of us? One answer might be that they are profiting more directly from their previous deontic failure. Yet, London and Lavery *et al.* appeal, respectively, to the greater proximity of researchers to poverty related ill-health. Proximity to suffering does awaken an important obligation, whereby we are called upon to help non-specific others in need when we can do so at little or no moral cost to ourselves.<sup>23</sup> As such, researchers working in the developing world may seem to have a duty the rest of us do not. But this move grounds their duty in one of nearby rescue rather than rectification, and thereby makes all of us traveling in the developing world just as responsible for alleviating the poverty related ill-health of the subjects of a research trial as the researchers conducting it, and even more so than the sponsors miles away who will most profit from it.

### 3. Transactional Exploitation and Non-Minimalism

Non-minimalist principles of research ethics grounded in a systemic conception of exploitation are highly problematic. Systemic accounts see exploitation as avoidable only through systemic change, a duty to undertake which is borne by all those who profit from the existing systemic structure. Principles grounded in such an account cannot but see the researcher's duty of distributive justice to her developing world subjects as arising from the conditions of global injustice which she herself as a First World citizen supports. But this mistakes one duty for another, thereby both overstating and understating the distributive obligations of the international clinical researcher.

Nonetheless, the systemic critique of minimalism is extremely compelling. Can we really take an existing injustice as a normatively acceptable baseline against which to measure distributive shares and expect to produce a *just* outcome, as opposed to one that is merely 'better than nothing'? While a state of affairs (X) in which both parties gain at no cost to others is surely superior to a state of affairs (Y) in which no one gains whatsoever, this does not mean that state of affairs (X) is superior because it is more *just*. Of course the gain to B is a good thing, but that doesn't necessarily make her share a fair one. This leaves us in a situation where we should endorse the systemic critique but deny systemicism. What I propose to do in the remainder of this paper is supply *transactional* grounds for a *non-minimalist* requirement of justice in international clinical research.

Wertheimer's transactional account of exploitation identifies the respective obligations of the parties who enter a transaction — obligations not to coerce, harm, or deprive the other of a rightful share of the cooperative surplus. To determine the rightfulness of benefit shares, on his view, we must perform two types of comparative evaluations. First we must compare the gains (and losses) accrued to each party relative to their respective pre-transaction baselines. Then we must assess how much A gained relative to her baseline as compared to B. Both sets of evaluations (on the non-ideal account Wertheimer offers in defence of the PPE) involve taking B's starting point, no matter how unjust, as a basis from which to measure her gains; both thereby invite the systemic challenge.

But there is a third type of transactional comparative analysis we could perform that does not take B's baseline for granted. This third type of comparative analysis is *inter* transactional, as opposed to *intra* transactional. In other words, it is a type of comparative

analysis that is performed across transactions of a relevantly similar sort. We actually engage in this type of transactional comparison frequently in colloquial discussions of exploitation, and it plays a large role in our considered judgments as to when exploitation has occurred. When we evaluate the justice of a transactional distribution we find it relevant to know not only how well the parties did relative to each other and to where they began, but also how well they did relative to other parties engaged in similar transactions elsewhere. Thus we find ourselves *comparing gains not just within transactions but also across them*.

Take a common example, which many of us consider a quintessential case of international exploitation. Ford Motor Company operates a plant outside Mexico City and pays its workers there a fraction of the wage it pays to its employees in Detroit. We would not be surprised to hear it said that Ford is exploiting its Mexican workers. This claim doesn't so much point to the concern that Ford is deriving all the benefits from this transaction, because a wage to someone otherwise unemployed has obvious value.<sup>24</sup> What is really being pointed to when such labour practices are decried as exploitative is that Ford is taking unfair advantage of its Mexican employees by denying them the wages, union rights, medical benefits, safety standards, pensions, etc., that it provides to its American employees, despite the fact that both sets of employees do the same work.

Consider another example. Infertility is affecting many individuals and couples in the developed world, and prospective parents are turning in growing numbers to commercial surrogacy clinics in India. Global surrogacy may be mutually beneficial, as the parents gain a child and the surrogate a wage. But the real moral concern becomes apparent when we compare the wages and working conditions of Indian and American surrogates. The latter are typically college graduates who earn between \$25,000 and \$40,000, claim to prefer the work to other equally remunerable options, enjoy legal protections, an opt out clause and the possibility of a long-term relationship with the adoptive family.<sup>25</sup> Gujarati surrogates live below the poverty line, are typically uneducated and illiterate, earn on average \$3000, are compounded during their pregnancy so that their meals and activities can be monitored by a clinical matron, and are denied legal protections or recourse.<sup>26</sup> The inter transactional injustice here is stark.

Take yet one more example. Respiratory Distress Syndrome (RDS) can be fatal in premature infants who are born with insufficient surfactant in their lungs. Treatment initially consisted in ineffective ventilator therapy, but since the 1980s synthetic surfactants have been manufactured and employed as a matter of course in the developed world. In 2000, the American drug manufacturer Discovery Labs (DL) wanted to conduct a randomised trial for a new surfactant, Surfaxin. DL did not expect Surfaxin to be superior to existing surfactants and wanted to use ventilator therapy as a control. DL was told by the FDA that it could not conduct this trial in the United States where ventilator therapy was inferior to that which patients would otherwise receive. DL thus proposed using premature infants born to poor families in South America with no access to surfactants, and where ventilator therapy remained the standard treatment.<sup>27</sup> The wrong here lies in the discrepancy between what North and South American subjects could have expected from trial participation.

Our considered judgments suggest, in each case, that exploitation depends not only on intra but also inter transactional distributive injustice. To determine if a particular transaction is exploitative we must begin by asking whether the vulnerable party has all things considered been harmed or benefitted by their co-transactor, but we do not, and

should not, stop there. We must also ask whether the vulnerable party has been deprived of the share of benefits that a less vulnerable party to a similar transaction elsewhere has enjoyed, or would have enjoyed, for taking on the same burdens. If we do not demand such inter transactional comparisons as part of the justice condition of non-exploitation, we ignore a central instruction issued by our considered judgments on the matter.

But in what moral imperative might this judgment be grounded? It could be grounded in a number of different comprehensive doctrines, and our intuitive convergence on this point may itself generate normativity as an object of overlapping consensus.<sup>28</sup> But this judgment can also most certainly be grounded in the moral doctrine which says that two moral agents, identical in all other non-arbitrary respects, are deserving of equal concern and respect. Why should this mean that the distribution of benefit shares ought to reflect a commitment to parity? Because an agent who helps produce a cooperative good but is, on arbitrary grounds such as gender, race, class or geographical location, denied the share of benefits enjoyed by another who made the same contribution is thereby denied the same concern and respect.<sup>29</sup> Compensation when it is just, like consent when it is valid, makes the use of one agent by another permissible because it exhibits the right kind of concern and respect.

### *3A. The Parity Condition*

I do not intend in the limited space remaining to articulate a robust principle of research ethics meant to serve as an alternative to those canvassed thus far. Nor, moreover, do I think that a concern for inter transactional parity generates grounds for an altogether new principle. What I have tried to do is suggest that there are good reasons for both endorsing transactionalism and at the same time resisting minimalism. The arguments I offered in the previous section instruct the transactionalist to compare gains not simply within trials but across them. What I will now suggest is that a parity requirement must be included in any transactional principle of non-exploitation in international clinical research if such a principle is to resist the charge of minimalism.

The transactionalist account holds that in order to assess whether A has exploited B we must ask whether A has coerced B and whether A has all things considered harmed B. I propose, on the basis of the arguments for inter transactional parity offered in the previous section, that we ought also assess whether *A has denied B the benefits that A has provided as compensation to a less vulnerable party B1 with whom A is engaged in a similar transaction in a more developed part of the world.* Note that if there is no B1 with whom A is engaged, we must assess whether A has provided B the benefits she would have provided to B1. Let us call this the parity condition, and let us say, on the basis of the preceding arguments, that it ought to be a component of any transactional principle of non-exploitation in international clinical research.

The parity condition would not undermine the transactionalism of any principle to which it is attached, as it spells out the specific duties a researcher acquires to her subjects when she enlists them, and thus demands its own satisfaction as distinct from redress or rectification more generally. However, the parity condition also allows for the moniker of minimalism to be shaken off existing transactionalist principles, as it renders impermissible the use of a vulnerable party's unjust pre-transaction baseline as an acceptable benchmark from which to determine the justice of her benefit share. Instead of measuring a developing world subject's gain relative only to her own starting point,

the parity condition demands that it also be measured relative to the gains enjoyed by a less vulnerable party to a similar transaction in the developed world, whose baseline is decidedly less unjust.

### 3B. Parity and Non-ideal Justice: Objections and Replies

In the space remaining I hope to offer some further clarification and defence of the parity condition in the process of responding to potential challenges. The first challenge is whether my view implies that First World research subjects cannot be exploited except via coercion, that is, cannot be exploited with respect to the transactional outcome. For how could we evaluate whether they are exploited with respect to the distributive outcome of a transaction if there is no better-situated Party B against whom to evaluate their benefit shares? To answer this challenge we must appeal to the distinction between ideal and non-ideal justice. To determine whether First World clinical trials fail the justice condition we would have to consider an ideal form of this type of transaction, which might be established either by an enumeration of the kinds of goods commensurable with the kind of good a subject provides, or by appeal to the share of benefits ideally placed transactors would agree to under perfectly just conditions.

I think the latter is possibly the necessary move to determining the genuine justice of various types of arrangements. But we don't need to make this move in order to claim that developing world research trials are unjust. As a claim of non-ideal theory it is enough to say that they are quite obviously *less just* than First World arrangements (as the Surfaxin case, among myriad others, makes plain). Although First World subjects may receive less than they should ideally speaking, they typically enjoy a share of benefits considerably closer to the ideal, whatever it may be. The parity condition, insofar as it is concerned to address not a deviation from an ideal, but instead an arbitrary discrepancy in real world benefit shares, therefore issues a demand of non-ideal justice.

A second challenge is one that Emanuel *et al.* might raise in response to the claim that the parity condition should be added to existing transactional principles. They might argue that the transparency condition they impose on the PFB already satisfies a concern for inter transactional parity. According to this condition, the results of similar transactions must be made a matter of accessible public record, where the idea is that, in learning of the distributive results of other trials, developing world research subjects will thereby be better placed to demand similar benefits.<sup>30</sup> But knowing what someone else received and being in a position to demand it are two very different things. Bargaining power does not depend on information alone.

It may well be true that transparency better respects local autonomy, as it leaves it up to the subjects to assure parity for themselves if they want it, or to ask for something else that they feel better addresses the needs of their community. This is in many regards the most admirable aspect of the PFB. But it is also the very move that makes the PFB susceptible to the systemic challenge: we cannot rest the justice of a distribution on the bargaining power of such unequally situated parties unless we are prepared to do something to address not just the inequity of information but the inequity of material condition. Again, let me reiterate that while the systemic project is problematic, its critique of principles like the PFB is surely correct. The most urgent demand of justice in a non-ideal world is that of securing the preconditions of autonomy, by ensuring that vulnerable individuals get what they need so that they

might thereby be enabled to ask for what they want. And in this respect parity promises what transparency only permits.

I have suggested, in the course of responding to the previous two challenges, that the parity condition can be seen as issuing a demand of non-ideal justice. However, the most troubling challenge remains to be addressed and this challenge takes issue specifically with the condition's claim to non-idealism. According to the challenge, in the very non-ideal world in which global research transactions are carried out, the distributive exigencies of the parity condition may result, not in greater benefit sharing, but in non-compliance. If added as a rider to the PPE, for example, Wertheimer might object that the parity condition would act as a disincentive to A to transact with B; since if A owes to a developing world subject what she owes to a First World subject, A might as well just stay home, enlist some more First World subjects and save herself the travel costs. The result would thus not be greater gains for B but no gains for B at all. If the parity condition is indeed a requirement of non-ideal justice, surely it must be able to contend with the non-compliance worry. How might we respond to this worry?

We can begin by questioning Wertheimer's conception of non-ideal justice. In general terms this project is one of identifying the minimum requirements of any reasonable ideal theory so that we might begin institutionalising those minimums here and now, in response to the urgency of real world needs.<sup>31</sup> But it is not clear that this is how Wertheimer understands the project. He agrees that consensus on ideal justice is a long way off and compliance unlikely in the here and now. But his solution is to ground principles in the existing motivations of reluctant duty-bearers. Their non-compliance isn't treated as a problem to be solved by non-ideal principles, but as the very normative basis thereof. Even if we accept that non-ideality must deal with self-interest, why build it into the very normative structure of non-ideal theory, ignoring that a reasonable alternative could involve, for example, the institutional restructuring of incentives so as to align corporate interests more closely with the needs of the global poor?<sup>32</sup>

Of course none of this denies that a lack of incentive is a serious impediment to the achievement of justice, ideal or otherwise. So how might we defend parity as consistent with non-idealism, or rather, how might we understand the parity condition so as to lessen, if not to eradicate, its vulnerability to this concern? I have two tentative suggestions to make here, both of which require more elaboration than I will be able to provide in the remaining pages. Yet, even in their tentative formulations, they offer means by which to understand the parity condition so that it might resist non-compliance worries to a certain extent whilst remaining consistent with the task of rescuing transactional principles from the charge of minimalism.

To begin with, we could understand parity in its economic as opposed to its moral sense, as equivalence not identity. Indeed the term parity is most often used in discussions of global justice in its economic sense. Purchasing Power Parity (PPP) is a technique used to determine the relative value of currencies. It asks how much money would be needed to purchase the same goods and services in two countries as a way of calculating an appropriate exchange rate for those countries' currencies. It has also come to be used as a strategy for measuring quality of life in different countries by asking whether individuals in different nations are able to achieve the same level of functioning (whether they are able to access equivalent goods and services and achieve relevantly similar things with them) from unequal incomes. Applied to the question of justice in

global research, the parity condition could, in this sense, require that subjects across transactions receive, not identical bundles of resources, but benefit shares that promise to enable equivalent levels of functioning.

Second, we could slightly moderate the parity condition as it has been articulated thus far. As it stands, the parity condition asks us to measure the justice of B's benefit share relative to the share of gains enjoyed by B1, where B1 is a non-vulnerable (or less vulnerable) party to a similar transaction in the developed world. But on a more moderate version we might instead measure B's benefit share not against the benefit share enjoyed by a non-vulnerable party, but against the pre-transaction baseline from which that non-vulnerable party began. The developing world subject would not therefore have to receive the same share of gains as her First World counterpart, but she would have to receive something that would still qualify as a gain to her First World counterpart. The point here is that while principles like the PPE and PFB are satisfied with mere Pareto improvements for developing world subjects measured against their own pre-transaction baseline, the moderate version of the parity condition would insist that these Pareto improvements be measured instead against their developed world counterpart's pre-transaction baseline.

Both strategies promise to lessen the costs associated with the satisfaction of the parity condition for research teams and their sponsors, and thus to lessen its potential for generating their non-compliance, or for incentivising them to 'just stay home'. In the first case, where parity is to be understood in economic terms, the provision of various types of benefits to developing world subjects, ranging from follow-up care to training to infrastructure, would cost decidedly less in the developing world given the purchasing power of First World currencies. And in the second case, where the parity condition is moderated in strength, the demand is not for identity in resource shares across transactions, but for identity with respect to the baseline used to measure gains to parties across transactions. Satisfying parity in the moderate sense, where developing world subjects need only gain something relative to a First World standard, but not necessarily what first world subjects could themselves expect, may in this regard be far less costly than 'just staying home'.

Both of these suggestions require further elaboration and exploration. Both need to be considered more fully in application to a number of different trials and case studies and evaluated by the recommendations they issue in these cases. I leave this task to future work. For now, I think they both provide responses to the non-compliance worry, rescuing the parity condition from the charge of idealism whilst remaining consistent with the normative underpinnings of parity itself. And both are equally consistent with the larger project here, which has been to rescue the transactional account of exploitation from the systemic challenge by proposing a condition that will prevent a developing world research subject's unjust pre-transaction baseline from being used as an acceptable benchmark against which to evaluate the fairness of her post-trial benefit share.

## **Conclusion**

I argued in this article that principles of developing world research ethics founded in systemicism hold researchers more responsible for satisfying a duty of rectification than other First World citizens, and at the same time deny that they derive any unique duties

to their subjects from their specific interaction. I also argued that transactional principles accept justice as done, and exploitation as avoided, so long as developing world research subjects gain, however minimally, relative to their unjust starting point. I went on to show that true transactional justice demands not only the performance of intra but inter contractual distributive comparisons, and that the fairness of the benefit share enjoyed by developing world research subjects must be determined relative not to their own meagre starting point, but to that of their less vulnerable counterparts in the developed world.

The parity condition I proposed captures this normative mandate. The principle to which it would be attached would remain decidedly transactional, by identifying the distributive duties derived by parties to a specific interaction. Yet at the same time it would be non-minimal in scope, by preventing the injustice of a developing world research subject's starting point from being used as a normatively acceptable baseline against which to determine the fairness of her benefit share. Certainly much remains to be said by way of substantiating the practical requirements of the parity condition, but my aim here has been primarily the normative one of showing that a commitment to parity can enable research ethicists to embrace non-minimalism without endorsing systemicism.

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## NOTES

- 1 For a good discussion of a variety of such cases, see James V. Lavery, Christine Grady, Elizabeth R. Wahl & Ezekiel J. Emanuel (eds), *Ethical Issues in Biomedical Research: A Casebook* (New York: Oxford University Press, 2007).
- 2 Alan Wertheimer, *Exploitation* (Princeton NJ: Princeton University Press, 1999), pp. 3–35.
- 3 Wertheimer op cit., pp. 247–277, note 2. See also Alan Wertheimer, 'Exploitation', *Stanford Encyclopaedia of Philosophy* <http://plato.stanford.edu/entries/exploitation> (accessed 17 July 2013).
- 4 Wertheimer op cit. pp. 18–32, note 2.
- 5 Ezekiel J. Emanuel *et al.*, 'Moral standards for research in developing countries: From "reasonable availability" to "fair benefit"', *Hastings Center Report* 34,3 (2004): 17–28.
- 6 Ezekiel J. Emanuel, 'Addressing exploitation: Reasonable availability versus fair benefits' in J. S. Hawkins & E. J. Emanuel (eds) *Exploitation and Developing Countries: The Ethics of Clinical Research* (Princeton NJ: Princeton University Press, 2008), pp. 286–314, at pp. 298–303.
- 7 Emanuel *et al.* (op cit., pp. 19–22, note 5) are responding to the mandate outlined by the Council for the International Organization of Medical Sciences (CIOMS) known as Reasonable Availability, which demands that developing world subjects be assured access to the fruits of the research. See CIOMS, *International Ethical Guideline for Biomedical Research Involving Human Subjects*, Guideline 10, 2002. According to Emanuel *et al.*, this construes "benefit" too narrowly, as the fruits of the research may not in fact be the type of medical intervention most needed or desired by the community, and perhaps more importantly, the research may yield no fruits whatsoever.
- 8 Wertheimer op cit., pp. 230–236, note 2.
- 9 Alan Wertheimer, 'Exploitation in clinical research', in J. S. Hawkins & E. J. Emanuel (eds) *Exploitation and Developing Countries: The Ethics of Clinical Research* (Princeton NJ: Princeton University Press, 2008): 63–104, at pp. 73–4.
- 10 Wertheimer op cit., pp. 70–76, note 9.
- 11 Public agencies may well have obligations to transact with vulnerable research subjects in the developing world, which would impose more stringent duties of care and compensation. See Douglas MacKay's, 'Standard of care, institutional obligations, and distributive justice', forthcoming in *Bioethics*.

- 12 John D. Arras, 'Fair benefits in international medical research', *Hastings Center Report* 34,3 (2004): 3.
- 13 Karl Marx, *Capital, volume 1: A critique of political economy* (1867). Available at: <http://www.marxists.org/archive/marx/works/1867-c1/> (accessed 17 July 2013).
- 14 Thomas Pogge, 'Eradicating systemic poverty: Brief for a global resources dividend', *Journal of Human Development* 2,1 (2001): 59–77. Note, however, that Pogge does not himself employ the term 'exploitation' to conceptualise this systemic problem.
- 15 Alex John London, 'Justice and the human development approach to international research', *Hastings Center Report* 35,1 (2005): 24–37.
- 16 London op cit., p. 30, note 15.
- 17 London op cit., pp. 31–35, note 15.
- 18 James V. Lavery et al. "Relief of Oppression": An organizing principle for researchers' obligations to participants in observational studies in the developing world', *BMC Public Health* 10 (2010) 384 <http://www.biomedcentral.com/1471-2458/10/384> (accessed 17 July 2013)
- 19 Lavery et al. op cit., p. 4, note 18.
- 20 Although I refer to these accounts of exploitation throughout as the transactional and systemic, they have also been referred to as the micro and macro, respectively. Note also that these are not exhaustive of the forms of exploitation that may occur in clinical research, nor is my proposed strategy exhaustive of the means by which these two approaches might be reconciled. See Jeremy Snyder, 'Exploitations and their complications: The necessity of identifying the multiple forms of exploitation in pharmaceutical trials', *Bioethics* 26,5 (2012): 251–58.
- 21 Jennifer S. Hawkins, 'Justice and placebo controls', *Social Theory and Practice* 32,3 (2006): 467–496 at pp. 479–84
- 22 Imagine if a doctor claimed to have satisfied her professional duties to a patient by donating (her money or her time) to a charity that addressed the latter's poverty-related health needs. This might be admirable, or even obligatory insofar as her patient is among the disadvantaged of the doctor's community, and insofar as improving social determinants may be the best means of promoting the patient's long-term health. But to claim that in giving to, or working for, this charity, the doctor would be freed of the duties she owes as a physician to her patient would be entirely misplaced. And the same must presumably be said of the clinical researcher.
- 23 Hawkins op cit., p. 482, note 20. See also Richard W. Miller, 'Beneficence, duty, and distance', *Philosophy and Public Affairs* 32,4 (2004): 357–83, and Peter Singer, 'Famine, affluence, and morality', *Philosophy and Public Affairs* 1,3 (1972): 229–43. Singer argues compellingly that proximity is in fact irrelevant to the duty of rescue.
- 24 Matt Zwolinski, 'Sweatshops, choice, and exploitation', *Business Ethics Quarterly* 17,4 (2007): 689–727.
- 25 Karen Busby & Delaney Vun, 'Revisiting *The Handmaid's Tale*: Feminist theory meets empirical research on surrogate mothers', *Canadian Journal of Family Law* 26,1 (2010): 13–93.
- 26 Amrita Pande, 'Not an "angel", not a "whore": Surrogates as "dirty" workers in India', *Indian Journal of Gender Studies* 16,2 (2009) 141–173.
- 27 See 'Case 9' in Lavery et al., op cit.' pp. 151–170, note 1.
- 28 John Rawls, *Political Liberalism* (New York: Columbia University Press, 1996).
- 29 Ronald Dworkin, *A Matter of Principle* (Cambridge MA: Harvard University Press, 1985), pp. 125–27.
- 30 Emanuel et al. op cit., pp. 300–303, note 5.
- 31 Gopal Sreenivasan, 'Health and justice in our non-ideal world', *Politics, Philosophy and Economics* 6,2 (2007): 218–236
- 32 Thomas Pogge, 'Testing our drugs on the poor abroad', in J. S. Hawkins & E. J. Emanuel (eds.) *Exploitation and Developing Countries: The Ethics of Clinical Research* (Princeton NJ: Princeton University Press, 2008): 105–142. Also, Thomas Pogge, 'Human rights and global health: A research program', *Metaphilosophy* 36,1–2 (2005): 182–209.