# Pursuing ethical coherence in the prevention of vertical transmission of HIV: justice and injustice in Option B+

Nathan Hodson<sup>1</sup>\* and Susan Bewley<sup>2</sup>

<sup>1</sup> Brighton and Sussex Medical School, UK <sup>2</sup> King's College London, UK

#### **Abstract**

Improved prevention of vertical transmission of HIV is an essential part of the global response to HIV. The Option B+ strategy took the extraordinary step of treating many non-pregnant women living with HIV (those with CD4 cell counts >350 cells/mm³) in the absence of evidence that they themselves would benefit from ART. This example of so-called AIDS exceptionalism reflects an understanding that the global response to HIV demands a different set of morals. This philosophical article explores a retrospective analysis of the ethical arguments made in support of Option B+ incorporating utilitarian, feminist and equity-based frameworks. A number of inconsistencies were found in the arguments made for the introduction of Option B+ well before results were available from the START and TEMPRANO trials. Although some people think 'the ends justify the means', we conclude that erroneous justifications were initially given in support of Option B+. We identify tensions that remain in light of these results and argue that future strategies would benefit from a community-focused, human rights-based approach.

Keywords: HIV, ethics, option B+, vertical transmission, human rights

#### Introduction

Improved prevention of vertical transmission of HIV is an essential part of the global response to HIV but the interaction between HIV prevention and individual rights is contentious [1,2]. Many public health measures to limit the transmission of HIV are focused upon HIV-negative people rather than those living with HIV. Option B+ took the extraordinary step of treating many non-pregnant women living with HIV (those with CD4 cell counts >350 cells/ mm<sup>3</sup>) in the absence of evidence that they themselves would benefit from ART. Although, under all treatment regimes (Option A, Option B and Option B+) treatment is initiated during pregnancy, Option B+ is unique in that treatment is continued after pregnancy ends irrespective of the woman's CD4 cell count. This means that women who would not receive ART if they had never been pregnant were now receiving ART purely because they had once been pregnant. This anomaly reflects a belief that the global response to HIV demands a different set of morals; so-called 'AIDS exceptionalism' [3].

Medical authority carries weight in society. To preserve the standing of the medical profession, arguments co-opting the notion of medical ethics deserve careful scrutiny. Thus, the claim that delaying Option B+ would have been 'unethical' must be critically analysed. This paper explores the philosophical rationale given for Option B+, a relatively recent development in the prevention of vertical transmission of HIV during pregnancy and breastfeeding, and offers a retrospective appraisal of the arguments using the dominant moral theories of the 20th century.

The word 'option' may mistakenly be assumed to indicate patient choice; rather it is the health-service provider that opts for and implements one programme, whether Option B or Option B+, for all women living with HIV under their care. Option B+ entails treating all women found during antenatal care to be living with HIV with antiretroviral therapy (ART) and (innovatively) maintaining them on ART for life thereafter [4,5]. This programme was developed in Malawi by simplifying Option B [4,5], a programme where antenatal ART was given but not continued after breastfeeding unless an end-of-pregnancy low CD4 cell count

\*Corresponding author: Nathan Hodson, Brighton and Sussex Medical School, Audrey Emerton Building, Eastern Road, Brighton, BN2 OAE, UK Email: n.hodson@doctors.uk.org indicated that the mother required continued ART for her own benefit.

Eight reasons were given between 2011 and 2013 in the published literature promoting Option B+ [4,6–8](shown in Table 1).

The START and TEMPRANO results released in 2016 reinforced reason 3 by providing evidence from randomised controlled trials (over 48 and 29 months respectively) that adults (median ages 36 and 35 years) with CD4 cell counts >350 cells/mm³ benefit from continuous ART, although long-term data is still lacking [5,9]. In this article, we appraise the rationale for Option B+ as it was initially made, in pursuit of a coherent ethical framework. The application of coherence might ensure the highest standards are maintained in the global response to HIV and other similar interventions.

## Unethical to delay?

Proponents of Option B+ presented this as an ethical issue, claiming that delay would 'not be ethical' [4] and elsewhere reiterating that it would be 'unethical not to choose Option B+' [8]. However, the literature promoting Option B+ made no direct appeal to any ethical theory, raising the question whether there was a coherent ethical argument that fitted an ethical framework or whether the idea of ethics was merely co-opted for rhetorical purposes.

UNICEF's document 'Options B and B+' was subtitled 'Key considerations for countries to implement an equity-focused approach' [6]. By emphasising 'equity', this publication implied a framework where justice was derived from the value of the individual.

Medical ethics, the professional ethics of doctors, emphasises the special moral status of the doctor—patient relationship. The doctor may allow the interests of their patient to override competing perceived benefits to society. The medical profession would fail if patients felt that presenting to a clinic was simply an opportunity for them to be processed in whatever way benefited others or society as a whole. Doctors must aim to benefit the patient in front of them. Thus, medicine acts as if 'each person possesses an inviolability founded on justice that even the welfare of society as a whole cannot override ... justice denies that the loss of freedom for some is made right by a greater good shared by others' [6,10].

Table 1. Reasons for Option B+ found in the published literature 2011-2013

- 1. Prevention of vertical transmission of HIV in index and future pregnancy
- 2. Integration of services
- 3. Protection of maternal health
- 4. Treatment as prevention
- 5. Simplicity
- 6. Stopping is a pointless interruption
- 7. Improved adherence
- 8. Wider access to ART

Equity means that an individual should not be denied treatment for the benefit of others and an individual should not be treated for the benefit of others; all people who will benefit from treatment have an equal right to treatment. Equitable access protects people from the tyranny of efficiency that often threatens to override the inviolability of the individual.

However, examination of the early arguments for Option B+ reveals that the authors admit inequity: 'Option B+ favours women rather than men in terms of ART accessibility, although we feel this inequality is acceptable in view of the policy's potential contribution to the elimination of paediatric HIV infection' [4]. Option B+ was intended to treat women rather than men, in order to protect future children, contrary to equity.

Furthermore, Option B+ favours a subset of women: giving ART to women who are pregnant now, not to women who have never had children or have completed their families. The policy's potential contribution to the prevention of new paediatric HIV acquisition is a greater good shared by others. Given the potential loss of freedom-as-health, faced by women who are not mothers, women who have completed their families, and men, the equity purported by advocates of Option B+ deviates from its usual meaning.

Perhaps the ethics referred to are actually utilitarian (the greatest good for the greatest number) and the unequal access was thought to be in the wider interests of society. A classical utilitarian approach, based on the idea that the right action is the one that leads to the greatest sum total of happiness among everyone affected, would be more consistent with this evident preference for efficiency over equity. For example, although the UNICEF document mentioned equity, it prioritised expeditious roll-out, as shown in the subtitle '[e]quity-focused roll-out strategy: approach roll-out with urgency' [6]. The priority was to maximise the greater good shared by others even if this was structurally skewed against certain groups.

The notion that it was unethical to defer roll-out, even until randomised controlled study results were available [4,8] implied a willingness to take risks (or impose risks on others) in the absence of persuasive efficacy and safety data. It did not demonstrate a scrupulous respect for patients' rights to access treatment based on high quality and agreed evidence, but on the balance of probability. This attitude is consistent with the utilitarian principle that the likelihood (or certainty) of an outcome is taken into account [11]. Utilitarians can weigh prospects and risk harmful outcomes on balance, whereas rights-based approaches are more cautious. The proponents of Option B+ could not know the outcome of future studies for certain, suggesting a utilitarian mindset.

However, a strong utilitarian argument would address the present quality, and potential future quality of the evidence and demand meticulous analysis of the scientific studies in order to accurately weigh the likelihood of various outcomes, an approach developed during the Enlightenment along with much modern mathematics. Thus, in contrast to the approach based on interpreting the implications of the patient's inviolability [12], utilitarian theories require scientific precision and analysis of statistical probability. Schouten et al. cited evidence of the benefit to women whose CD4 cell counts are >350 cells/mm<sup>3</sup> without mentioning that the particular study was only observational and that the authors had warned against generalising from their results [13]. Similarly, a treatment-as-prevention study was uncritically presented as supportive evidence, without acknowledgment of the poor validity and generalisability of the comparison arm [14].

The dissonance here is not that a utilitarian approach would necessarily have rejected Option B+. The problem is that, in the case made by proponents of Option B+, prospects were not weighed but overstated to suggest they already aligned with Option B+. Whereas a utilitarian argument would wrestle with the evidence seeking the most good, the proponents of Option B+ denied that there was any wrestling to do. To support the assertion that delay was unethical using utilitarianism, proponents of Option B+ should have provided a close analysis of current best evidence and demanded high-quality randomised controlled trial evidence at the earliest opportunity, rather than uncritically accepting an unclear observational picture.

In general, utilitarians may be open to the possibility that Option B+ is bad for women but justified on balance if it is good for fetuses. If this was their position Option B+'s proponents ought to have made that claim explicit. A principle of good science is falsifiability - this facilitates empirical study. In parallel, in the field of ethics one must make the premises of one's argument explicit in order to allow the argument to be criticised. If indeed the proponents of Option B+ were motivated by this utilitarian calculus, but decided to hide this fact (perhaps due to the prevailing current in medical ethics, which preferences living women over unborn fetuses), then they were not engaging properly and ought not to have invoked medical ethics in their reasoning. Future arguments from medical ethics must make controversial calculations explicit, so they may be challenged and defended.

There is fundamental discord between language emphasising equity and arguments from efficiency. Women who are pregnant are given ART preferentially (over women who are already mothers or who are not mothers) as this is thought to be the best way to ensure all babies are born without acquiring HIV. Simultaneously, justice-based arguments are made lauding an equal right to treatment for all.

The ethics referred to seem incompatible with any coherent moral theory [4,8]. During the initial roll-out, it appears Option B+'s proponents bundled several attractive ethical ideals together. This melange argument can be reconstructed: 'Not only does Option B+ demonstrate its efficiency through giving certain women preference, but also it is equity focused'. This constitutes a logical fallacy in that preferencing one group over another group with an equal claim is, by definition, not equitable.

Norman Fairclough explains that the use of the 'not only but also' device occurs where contrasting values are listed together as if complementary, observing 'it is easy to be carried along in the rhetoric'. He warns that it glosses over 'incoherence and contradiction' [15]. 'Not only but also' phrasing risks appearing disingenuous; presenting incompatible arguments as being perfectly reconciled. Although some may claim that health benefits across society outweigh ethical concerns, this line of thought fails to recognise that health benefits are contributory to, not competitive with, ethical considerations. The ethical argument could be based upon Option B+ being overwhelmingly beneficial (if it is), rather than upon rhetoric that risks obfuscation.

A utilitarian justification for Option B+ depends on the evidence of the overall good the policy would achieve. Equity-based arguments for Option B+ were being made at the same time, causing tension between the values of equity and efficacy. These values are not irreconcilable, but in this case they were contradictory and, therefore, to promote both (as advocates of Option B+ did) was incoherent. In public health crises marked by scarcity, conflicts between equity and efficiency are not just due to confused thinking by health policy committees. Indeed, tensions are real and inevitable, and no ethical theory can completely wish them away. The issue at hand was that proponents claimed that any alternative was unethical whilst themselves making two irreconcilable ethical arguments. This incoherence suggests that we must search for another approach. It would be unreasonable to criticise views attempting to incorporate elements of efficacy and equity, without suggesting an alternative. We outline below how a human rights-based approach might avoid these tensions.

## Treatment as prevention

The overarching reasoning given for Option B+ lacked consistency with the major moral theories. Feminist ethics focuses on the nurturing of virtuous, personal characteristics further developing Aristotelean ethics [16]. Noddings and Gilligan explore personal relationships and micropolitics in individual circumstances without seeking broad universal laws [17,18]. This framework is suited to appraisal of the reasons that were initially given for Option B+ in terms of imbalances in burdens of care and the imposition of responsibilities within the family unit: the arguments in favour of Option B+ implied that 'boys will be boys' and that women's bodies should be used to shield them from the consequences.

Insofar as it is a justification for Option B+, 'treatment as prevention' creates conflicts within personal relationships of the sort that concerns feminist ethics not least because in this context it refers specifically to 'treatment of [childbearing] women to prevent transmission to men'. The gendered ramifications of this deserve exploration.

Proponents of Option B+ claimed that 'HIV transmission in couples is an important contributor to overall transmission rates, and the use of ART greatly reduces the risk of HIV transmission to non-HIV infected partners' [4]. All HIV acquisition is important so the emphasis on discordant couples involving women living with HIV with CD4 cell counts >350 cells/mm<sup>3</sup> is perplexing. Importance may derive from transmission, number or difficulty preventing. Onward transmission via men in stable relationships is less likely than transmission via other groups (e.g. single men, men who use sex workers or men with multiple partners) and no evidence was given suggesting that couple relationships result in a disproportionate number of HIV acquisitions. Furthermore, technically, these are not difficult transmission events to avoid as couples can be provided with condoms. Revisiting the above quote reveals the implication that it is important to medicate women to protect men who do not use condoms. There is no suggestion any men should be medicated to protect women (who often cannot negotiate condom use). This inferred notion of using women's bodies to protect reckless men is gender stereotyped and distasteful. If the argument for Option B+ was already sufficient without, it ought to have been omitted from the policy.

The cited study [19] was limited by its distorting design [20]. The comparison arm delayed initiation of ART until a woman's CD4 cell count was <250 cells/mm³, whereas most programmes started ART from <350 cells/mm<sup>3</sup>. The British HIV Association (BHIVA) thus postulated that women in the research study with uncontrolled HIV and CD4 cell counts of 250–350 cells/mm<sup>3</sup> would be more likely to transmit HIV through sex than women under real-world conditions [20]. The study reported a 96% lower linked-transmission rate (relative risk reduction) in the early ART initiation group compared with the late ART initiation group [19]. Transmission events were reduced from 31/1000 couples over 5 years under late initiation to 1.2/1000 by early initiation. The absolute risk reduction is approximately 0.6 per 100 person years – undoubtedly important, but less impressive sounding than '96% reduction'. The human (and financial) cost of 1000 people taking medication over 5 years to avoid 30 transmissions should be considered, especially when a subsequent larger study found a smaller effect (from 1.6 to 1.3 transmission events per 100 person years, i.e. absolute risk reduction of 0.3 per 100 person years or 26% relative risk reduction) [21].

At this time BHIVA recommended 'if a patient with a CD4 cell count >350 cells/mm<sup>3</sup> wishes to start ART to decrease risk of transmission to partners, this decision is respected and ART is started.' By contrast, proponents of Option B+ advised giving lifelong ART to every woman living with HIV who became pregnant, despite evidential uncertainty [20]. All women living with HIV whose CD4 cell counts were >350 cells/mm<sup>3</sup> would be treated, even though they did not all have serodiscordant partners. Therefore, many more women proportionally would be treated for each man receiving this modest protection from a risk that could be mitigated through other means (e.g. condoms, circumcision). BHIVA suggested an autonomy-focused approach emphasising informed discussion of a moderate-quality evidence base, whereas Option B+ entailed a blanket policy extending beyond the evidence base.

Finally, it was found that 10 of the 38 total transmission events occurred outside the primary relationship [19]. So, while Option B+ justifies the use of lifelong daily medication for women in order to protect their male partners, a significant number of men still acquire HIV outside that relationship. This illuminates both the fundamental theoretical problem of treating one person in order to protect another and the practical, complex real-world interaction between personal relationships, power, and HIV.

#### Adherence

Poor adherence to ART increases the risk of antiretroviral resistance emerging – not simply a lost opportunity but a potential harm. One early aim of Option B+ was to increase ART adherence. In this domain also, women were used to benefit others.

Although it was hoped that Option B+ would increase medication acceptance among women living with HIV, evidence increasingly suggests the opposite [22]. WHO identified ART adherence within this programme as a 'challenge' [7] to which health authorities were failing to respond. It was suggested that patients' (correct) perception of being healthier may explain lower rates of initiation among women with higher CD4 cell counts [23]: maybe Option B+ does not increase adherence among women because ART is prescribed to women who are not convinced of benefits within the complicated contexts of their lives, which often include high levels of violence [24]. This suggests giving ART to women with higher CD4 cell counts without meaningful discussion of all possibilities is wasteful. In May 2014 Dr John Ong'ech, assistant director at Kenyatta National Hospital, warned 'If you have adherence problems among the HIV patients that you are already treating there is no need to roll out Option B+ because it will only get worse' [25].

Some claimed that Option B+ could increase adherence; not among women living with HIV but across the whole community. It sends 'a simple message to communities that, once ART is started, it is taken for life' [7]: women being used instrumentally, as role models, rather than solely as beneficiaries. However, this 'simple message' fails to recognise the more complex ethics concerning prescriber responsibility for medication non-adherence. The argument runs: women who are mothers have poor adherence to Option B+; men and children generally also have adherence issues with their ART regimens; without Option B+ some women miss out on benefits of ART and men and children continue to face the dangers of poor adherence; if Option B+ indeed sends a message to the rest of the community then these women face the dangers of poor adherence whereas men and children avoid these dangers. This boils down to a suggestion that the bodies of women living with HIV should be used to send a public health message. This offensive use, merely as a means, should not have been included in the rationale.

We have thus demonstrated that the proponents of Option B+ rejected efficiency-based (utilitarian) arguments and equity-based arguments to support our contention that there was no profound ethical grounding, just the co-option of a notion of ethics for rhetorical effect. We then outlined the risks women living with HIV are exposed to in order to protect men, concluding that women living with HIV are unfairly burdened. Before there was good medium- to long-term evidence for health benefits to women with CD4 cell counts >350 cells/mm³, the arguments for Option B+ were problematic in terms of feminist ethics, arguably, frankly sexist, and must be avoided in future. We would not accept such policies in other areas: treating HIV differently, AIDS-exceptionalism, leads into the trap of treating women living with HIV as vectors.

## Human rights-based approach

The START and TEMPRANO trials have now produced high-quality evidence supporting the notion that ART benefits people living with HIV irrespective of their CD4 cell count [5,9]. Before 2016, no such evidence existed. The case for Option B+ relied upon various inconsistent arguments including some that treated women merely as a means rather than as ends in themselves.

In order to achieve the 90-90-90 goals, an effective programme for the prevention of vertical transmission of HIV is required [26]. There are a number of problems that Option B+ must still negotiate including the many women living with HIV lost to follow-up early on. There is evidence to suggest that this is due to the mismatch between perceived need and perceived potential for positive outcomes from ART demanding careful personalised counselling and trusted relationship building [27]. Such strategies, sometimes described as 'human rights-based approaches' often involve localised care, mentoring from other women living with HIV, and inviting couples to participate in group sessions aimed at reducing stigma, improving understanding and empowering communities [28,29]. One way to implement interventions that are both acceptable and highly effective is to encourage women living with HIV to participate in every stage of development. The Meaningful Involvement of Women Living with HIV/AIDS (MIWA) begins with investment in women's leadership; at community level as well as policy-making [30]. One implication of MIWA is that women with experience of living with HIV can support more newly diagnosed women through peer mentoring, another is that through local leadership and advocacy women living with HIV can ensure that policies and trials protect their dignity and human rights. To ensure women's rights are fully safeguarded, the next advance in HIV care must be led by women living with HIV and enacted through community-level support networks.

Although it was a radical and ambitious innovation, the arguments for Option B+ were problematic and recognised as such [31]. Incompatible claims were presented as if perfectly reconciled. The arguments could not be supported by the major moral theories. Analysis of the interpersonal dimensions of reasoning in support of Option B+ shows women were subjected to excessive burdens and held to higher standards than men. In attempting to mitigate these issues, a ground-level community-focused approach holds much promise.

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