

# **The need for translational bioethics within perinatal healthcare and policy making: a COVID-19 case study**

## **Abstract**

The COVID-19 pandemic highlighted many issues that can occur due to lack of translation between the spheres of bioethics and clinical practice. In this paper, we examine how mothers and newborn infants were inappropriately separated during the initial stages of the pandemic due to inconsistent application of ethical principles in determining policy. One of the significant challenges that translational bioethics faces is the complexity regarding its implementation into the health service environment. As outlined in the literature, it may be postulated that responsibility for translating bioethics from philosophical concepts into practice is the duty of those training in philosophical theory and reasoning (1). However, the use of bioethics in informing clinical practice is not just the case of needing a translator, but rather requires an interpreter in the widest sense: professionals attuned to both bioethics and clinical practice, who can communicate with both groups effectively. A two-way dialogue needs to be more cohesively established to ensure clinical practice is guided by ethical principles and to focus academic debate toward the pragmatic issues that require ethical exploration. Utilising the translational bioethics model described by Bærøe (2) and applying it to our perinatal COVID case study, we examine how an integrated translational bioethics approach could have prevented the harm and disruption to mother-infant dyads during the initial phase of the pandemic in 2020.

## **Main Article**

### **Context for our Case Study**

The spread of COVID-19 was officially declared a pandemic on 11th March 2020 by the World Health Organisation (WHO) (3). During this pandemic, the disconnect between clinical reality and well-meaning academic papers was felt acutely by many clinicians working in patient-facing roles. Reflecting as clinicians, there were times where we felt an interjection from an ethicist could have prevented some questionable

practice, as our case study (below) will demonstrate. To select COVID-19 as an example is not without its difficulties - this was a time of acute crisis, where clinical practice changed at a fast pace. Clinicians were faced with ethical dilemmas outside of their normal practice (4), whilst previously straightforward clinical interaction was suddenly awash with additional considerations. During this period there was a need for rapid ethical guidance. We could be criticised for choosing this as our example due to how abnormal the situation was; however, we feel COVID-19 encapsulates the problem well. The pandemic highlighted that when ethically complex decisions and policy development needed to happen at speed, the mechanisms and working relationships between the academics and clinicians on the ground were not in place to do so. That is not to say there were no relationships – ethicists were indeed included in SAGE, but the pandemic demonstrated a clear need to reinvigorate these relationships and two-way dialogues.

In the initial stages of the pandemic explicitly ethical national guidance was lacking (5). However, in the coming months a glut of guidelines was published by professional groups, individual Trusts, and the various colleges (6). Some of these were offering explicitly ethical advice, whilst others, although not explicit, gave guidance that was value laden and contained ethical suggestions (even if this wasn't their primary aim). As one could expect, when multiple bodies were suggesting clinicians to act in one way or another, there was both overlap and conflict between principles (6). This was felt on the ground by clinicians in various professions, as seen in a study commissioned by the Professional Standards Authority researchers found clinicians felt under-supported in their day-to-day decisions (4). There was unease that some areas of ethical concern were given a huge amount of attention (for example resource allocation) whereas others were ignored completely. Participants also felt that some of the guidance that had been detrimentally rushed and were promoting wrong decisions and/or offering unethical guidance.

The COVID-19 pandemic contained numerous ethical issues, many of which were reacted to by frontline clinicians who took initial decisive action and formed policies which have since been found to be ethically unsound. In some cases, these policies were formed in the absence of robust ethical frameworks and lacked academic input from ethicists, whose contributions emerged later, too late to be impactful during the

early stages of the pandemic. Appreciating the changing understanding of the disease within the context these decisions were made, and the fact that many such publications have been subsequently withdrawn, only serves to confirm the dubious ethical scaffolding upon which they were originally constructed. We will now draw upon our case study example of the suboptimal treatment provided to newborn infants born to COVID-positive mothers<sup>1</sup> to illustrate how, through competing priorities, misinformed policy was able to be created, actioned and have global uptake without timely or sufficient translation of ethical principles.

### **The mother-infant dyad**

The natural pattern of mother-infant behaviour after birth is for the infant to be placed skin-to-skin on the mother's chest and for the umbilical cord to be allowed to continue to pulsate for at least one minute, a process known as deferred cord clamping (DCC). This close physical contact between mother and infant has distinct physiological advantages, such as reduction in maternal blood loss, promotion of breastfeeding, improved infant thermoregulation and DCC has been shown to improve neurodevelopmental outcomes and reduce infant mortality rates (7–9). To disrupt this normal process of close physical and emotional interaction between mother and infant and in doing so, remove the significant advantages to both parties, there must be compelling grounds. In the context of COVID-19, mothers and infants were failed due to a lack of translation of ethical principles into clinical policymaking and practice.

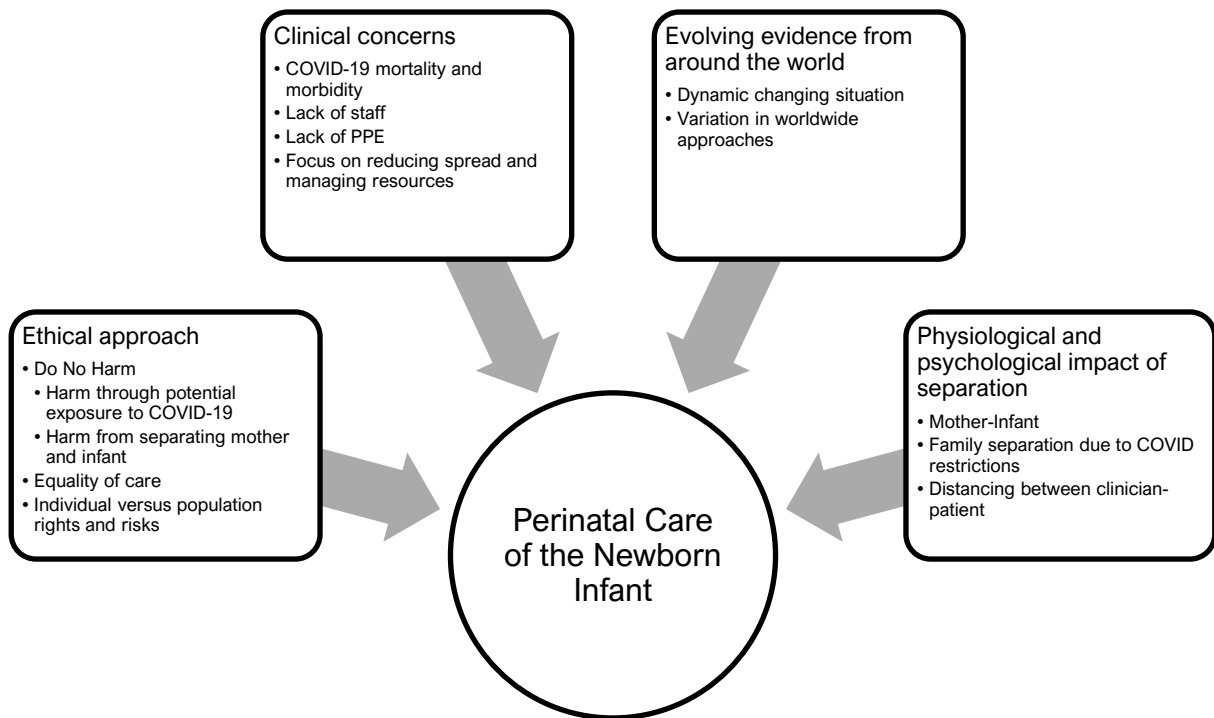
In February 2020, the Chinese Expert Consensus Group published their recommendations for perinatal and neonatal management in the context of COVID-19 (10). They recommended routine separation of infants from COVID-19 positive mothers, despite acknowledging in their own consensus statement that there were no known cases of vertical transmission, no neonatal deaths secondary to COVID-19 at that time and recognising the risk of maternal anxiety and depression due to the impact of mother-infant separation. This expert consensus statement also recommended that deliveries involving COVID-19 positive mothers should not have delayed cord

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<sup>1</sup> In this paper we use the term 'Mother' to refer to the birthing parent. We use this term as that is the language used in the guidelines which we are discussing but recognise that not all parents who give birth will use term 'Mother' and not all 'Mothers' will be the birthing parent.

clamping and that infants should receive donor or formula milk rather than breastmilk. There was, and still is, no evidence of transmission of COVID-19 through breastmilk (11).

In April 2020, the American Academy of Paediatrics (AAP) followed suit, issuing a statement advocating for separation of well newborn infants from their COVID-19 positive mothers (12). This position was also adopted by many countries, including several individual Trusts across the UK (13,14). This policy was based on understandable fear of the virus, despite an absence of robust evidence of vertical transmission or harm to the infant and with inadequate consideration of the risks to the infant-mother dyad of separation itself (15). This policy was subsequently reversed by the AAP in July 2020 (16). The Royal College of Paediatrics, UK allowed Trusts to make individual decisions initially, only issuing official guidance - to keep mothers and well babies together – later, in April 2020 (17). Given that COVID-19 was first officially reported in December 2019 and the official classification of COVID-19 as a pandemic by the WHO was in early March 2020, the delay in official national guidance from the RCPCH contributed to initial inconsistencies in postnatal ward separation policies between NHS Trusts and consequent injustice and trauma for parents who were needlessly separated from their newborns during this period. Additionally, despite the released RCPCH guidance, inconsistencies between Trusts persisted throughout the pandemic in relation to visiting policies for infants admitted to neonatal intensive care units (NICU) with continued reports of parents who had tested negative, or were awaiting test results, being denied access to their infant on NICU (18).



**Figure 1. Competing factors influencing perinatal care of the newborn infant during the COVID-19 pandemic**

### **Complexity of clinical practice and healthcare**

The case study (above) illustrates the need for a robust framework to integrate ethics with clinical practice. Bioethics as a discipline is multifaceted with its scope encompassing translational bioethics where there is a focus on applying theories and principles to concrete issues. Evans outlines this succinctly in his description of bioethics through a sociological lens, where he highlights the bioethicists' role in healthcare ethics consultations and development of public policies(19). In the development of public policies there need to be acknowledgement of the complexity of working in the real-world. As Bærøe summarises in her 2024 article, 'real-world actions and practices are subject to the influences of a complex conglomerate of political orders, social institutions and psychological motivations shaped by social

structures and interactions' (2). Effecting change within a complex systems requires evaluation of the issue from all these multiple perspectives and with input from all stakeholders – not just those with the most power over policy development (2)(20). In the case study described there were multiple stakeholders and numerous contributing components to the decision-making process and context (Table 1). Current conceptual frameworks proposing translational bioethics often fail to address context and implementation in an integrated way. For those papers where these are addressed, the focus remains on organisational context, and implementation concerned with specific outcomes (21), rather than incorporation into routine clinical care. This could be achieved using the framework described by Pfadenhauer, et al (22) which outlines that context reflects a set of characteristics, social rules, inter-relationships and circumstances within which the item of implementation is embedded. The Pfadenhauer framework conceptualises context as comprising seven domains: epidemiological, ethical, geographical, legal, political, socio-cultural and socio-economic (22). These domains can provide a structured approach to the consideration of contextual factors which add to the complexity of evaluating and integrating translational bioethics within ethically complex clinical situations, such as in our case study example (Table 1). Consideration of all contributing components and how these may impact each other could serve to maximise the relevance and impact of translational bioethics to patients, healthcare professionals and the lay public.

Effective integration requires a two-way dialogue to ensure that clinical practices are ethically sound and that academic debates address practical issues (2). A holistic and flexible framework, such as that proposed by Bærøe (2), is essential for successful bidirectional translation between bioethics and clinical practice. Greater adherence to and application of a clear ethical theoretical framework within clinical practice may have generated a more just and fair response to perinatal management worldwide in the early phases of the pandemic (Figure 2). Integrating bioethical approaches within clinical practice is essential to avoid further situations of ethically imbalanced, hasty decision-making from patient-facing staff and policymakers. Meaningful integration of bioethics into clinical practice needs to be achieved with sufficient depth that bioethics informs even unencountered clinical crisis situations, such as the pandemic, in a prompt and responsive manner. However, there is currently a disconnect between the reasoned debates taking place in academic literature and the reality of clinical practice

(23). A two-way dialogue needs to be more effectively established to ensure clinical practice is guided by ethical principles and to focus academic debate toward the pragmatic issues that require ethical exploration.

Epidemiological	<ul style="list-style-type: none"> <li>• This context refers to the distribution of disease, and the burden of disease across populations</li> </ul>
Ethical, Legal and Political	<ul style="list-style-type: none"> <li>• Ethical, legal, and political aspects are strongly interrelated. Within the United Kingdom, the initial response to the COVID-19 pandemic including national lockdowns, a reduction in travel enshrined in law, and increasing political pressure to ensure equitable access initially to treatment and then vaccination</li> </ul>
Geographical	<ul style="list-style-type: none"> <li>• Geographical context refers to the physical environment and resources. This could be different clinical settings (such as the ambulance service, or paediatric ward within a hospital)</li> </ul>
Socio-cultural	<ul style="list-style-type: none"> <li>• These include both the micro-, meso- and macro- levels and considers the individual in terms of their social characteristics and mobility, as well the group and behaviour patterns within the group they operate in, and the values of the organisation to which they belong (Sabatier, 2007).</li> <li>• Knowledge, customs and other habits or capabilities acquired by the group are also included in this domain. An example is the hero mentality adopted by healthcare workers at the height of the pandemic, enforced by the saviour mentality outlined in the British media during that time (Cox, 2020).</li> </ul>
Socio-economic	<ul style="list-style-type: none"> <li>• This context considers the social and economic resources of a community or the access of a population to these resources. This could, for example, comprise the potential loss of income among clinicians who were affected by the (revoked) mandatory vaccination legislation.</li> </ul>

**Table 1. Contextual factors outlined by domain based on the case study example**

## **The need for bidirectional translation**

Building from the work started by Bærøe (24), it is oftentimes accepted that the responsibility for translating bioethics from philosophical concepts into practice is the duty of those training in philosophical theory and reasoning. However, in order for bioethics to be effective in informing clinical practice, it is not just the case of needing a translator, but rather requires an interpreter in the widest sense: someone who is attuned to both bioethics and clinical practice, who can communicate to both groups effectively. It is crucial that there is harmonious integration across these two fields to ensure that care delivered to patients is ethically informed and practical to deliver. Lack of meaningful integration between bioethics and clinical practice can result in the two spheres becoming uncoupled during turbulent times, arguably precisely when an ethically informed approach is required.

The academic arguments put forth in the literature are often phrased in such abstract or hypothetical ways that the pragmatic clinician may stumble at the disconnection to their world (23,25). Connection between some clinicians and ethical argument is likely to be limited and may exist only through guideline updates, which amalgamate ethical and legal arguments into a few lines of professional guidance. Additionally, simply because clinical guidance has been issued by professional societies or government organisations does not mean said guidance has been ethically informed. When developing an ethically informed healthcare policy for use in clinical practice the policy needs to be clear, concise and pragmatic, whilst retaining flexibility in its application. This is a fine balance, between creating something which is both accessible but practical, and is perhaps where traditional bioethics have struggled to cross the gap between epistemological endeavour and pronesis within the clinical workforce. Indeed, most clinicians will be able to cite the heralded four principles by Beauchamp and Childress (28), however, in presenting only four principles of bioethics in clinical practice, the clinical workforce is ill-equipped to consider the wider and more nuanced implications of bioethics in practice. Whilst these four principles are widely adopted into healthcare guidance (such as NICE), policy, and regulatory standards, the lack of a behavioural model to account for the relevant situational factors not captured by



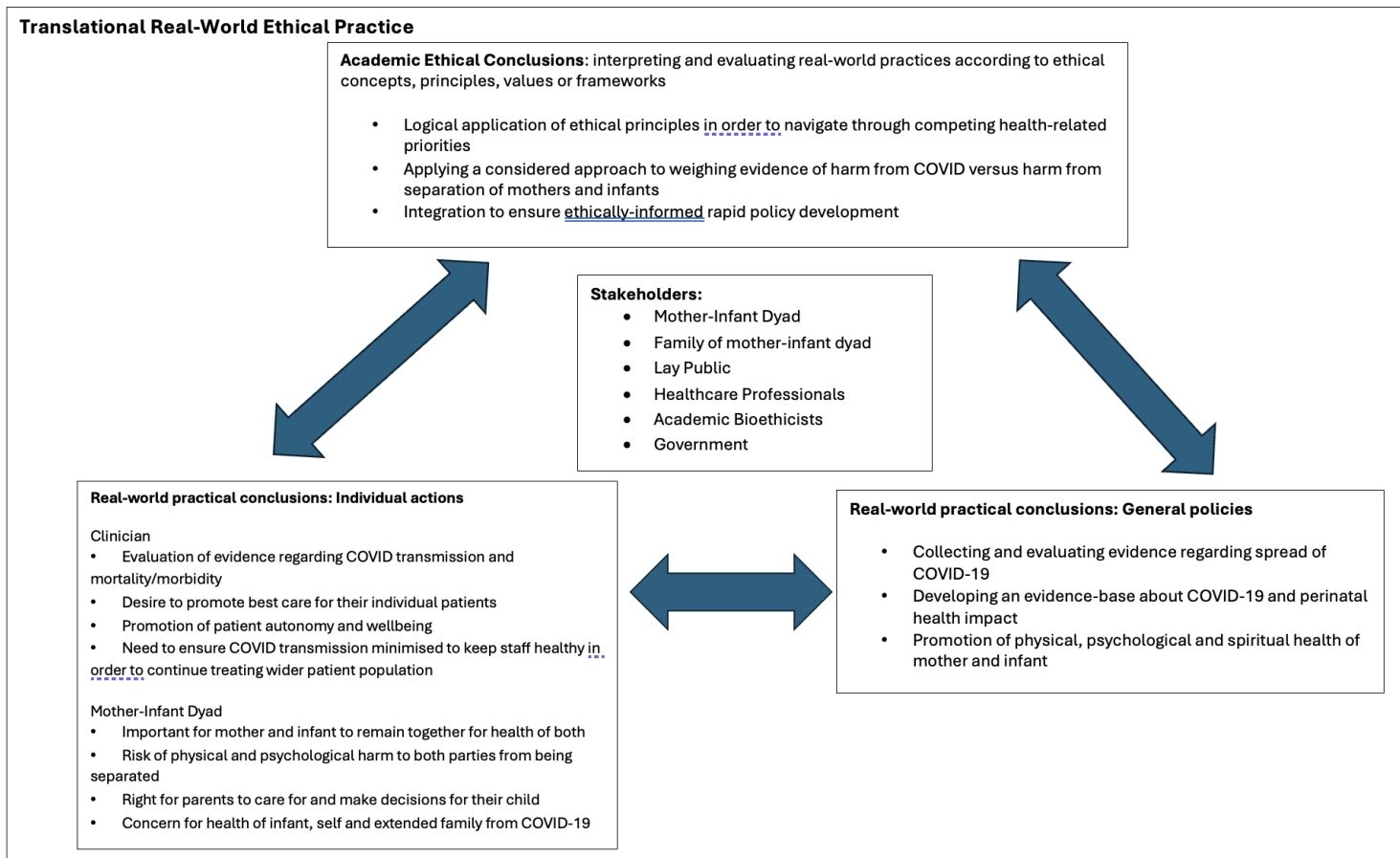
these four principles has been posited as a reason for the lack of uptake of these principles in every-day clinical decision making (26). Traditional medical ethics education often presents the four principles approach in narrow, repetitive scenarios, such as the well-worn vignette of a patient who is a Jehovah's Witness refusing blood products. By limiting discussion of bioethics to the four principles approach and blunt, stereotypical scenarios, the clinician is not equipped to consider bioethics a useful, adaptable, practical tool applicable in daily practice to inform clinical care. There is little integration within routine practice, and this has the potential to result in detrimental effects on care provision. For ethical policy to be successfully implemented, it must be created in an iterative process between policy makers and clinicians, with mechanisms to support feedback to enable the further development of policy and its application to patient care.

### **Bidirectional integration**

Ensuring that ethical principles can be effectively integrated into clinical practice empowers ethicists to translate theoretical concepts into meaningful changes within healthcare (2). Recent papers have considered the application of specific frameworks to support the bidirectional integration of translating ethical norms into practice (27), arguing that when formulating a specific norm, ethicists should consider its practical feasibility, as the resulting norm will directly influence the types of interventions that are subsequently developed and may have tangible real-world impact and influence.

For example, revisiting the contentious issue of mother-infant separation during COVID-19, the arguments made in defence of the recommendations by various professional bodies advocating for separation of mother and infant were that there was a paucity of knowledge about the COVID-19 pathogen - other than it was highly contagious and conferred significant mortality to those infected - and therefore, it was difficult to create guidelines in the absence of robust, peer-reviewed evidence. This position is illogical when a bioethics lens is applied. To assert there was a lack of evidence to guide policy, is to ignore the extensive evidence basis which supports and acknowledges the importance of the mother-infant dyad. The evidence for keeping mother and infant together was present and published. The data that was available in relation to COVID did not show clear evidence of vertical transmission and did not show clear evidence of neonatal morbidity or mortality secondary to COVID-19.

Applying the basic medical ethical tenet, *Do No Harm*, it seems clear that separation of mother and infant should not have been the default position that was implemented and then subsequently revised in light of further research. Rather, in the absence of evidence to the contrary, the status quo should have been maintained. Mothers and infants should have remained together with all the health benefits this dyad reciprocally provides. Separation should only have been considered had clear evidence of harm emerged. Proper application of basic medical ethical principles would have determined that evidence of increased harm is required before inflicting a change of approach which intrinsically comes with its own significant harms. To overrule a pre-existing body of evidence, there must be evidence of risk. Having translational bioethics embedded more effectively may have aided this process and avoided unnecessary separation of mothers and babies.



## **Figure 2. Application of the Bærøe translational bioethics model (2) to outline bioethical considerations within various contexts of perinatal COVID policy and care**

### **Summary**

In the same way that translational healthcare research aims to bridge the gap between laboratory bench research and bedside clinical practice, with a two-way dialogue between the two ends of the spectrum, with each informing the other's practice and priorities, translational bioethics needs to embed itself more prominently within the clinical world. Translational bioethics occupies a distinct space incorporating normative, empirical and foundational ethics research and has the potential to close the theory-practice gap between academic bioethical research and real-world clinical practice and policy development (2). As our case study illustrates, where a bioethics approach is not embedded within clinical practice and policy development, ethically questionable policies can be actualised to the detriment of patients. By acknowledging and embedding bioethicists within policy development, even in rapidly evolving clinical situations, true integration of a bioethical approach into clinical praxis seems feasible. Integration of bioethics and clinical practice encourages conceptual reconsideration by both clinicians and bioethicists. This bidirectional dialogue approach lends itself to evaluation of its effect on clinical practice and quality of service provision. Evaluation of measured evidence holds particular significance for clinicians and can be a useful tool to levy culture change. Additionally, collation of measurable evidence is key to sustained, funded change within any large-scale system. Ethical issues abound in clinical care and the care that is delivered is enhanced through considered academic ethical debate; the two sectors are enriched by interaction from the other. Therefore, both parties must actively work to craft a shared dialogic system, rather than two silent silos.

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