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# Developing Morally Sensitive Policy in the NICU: Donation after Circulatory Determination of Death

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## Abstract

Policy development is an important activity for the practice of healthcare. Policies, after all, may cultivate common practices and ensure that best available evidence is employed in clinical decision making. Qualitative research and individuals with expertise in qualitative research methods have much to offer policy makers. We were confronted with the situation of developing policy for donation after circulatory death (DCD) for our newborn intensive care program. Due the moral-ethical complexities surrounding DCD, and the limited experience with DCD in this context, we approached policy development from an iterative design perspective employing qualitative methods. We describe our experience in employing this approach and the methodological implications of design as a method for policy development.

## Keywords

Design, Policy, NICU

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# Developing Morally Sensitive Policy in the NICU: Donation after Circulatory Determination of Death

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*Policy development is an important activity for the practice of healthcare. Policies, after all, may cultivate common practices and ensure that best available evidence is employed in clinical decision making. Qualitative research and individuals with expertise in qualitative research methods have much to offer policy makers. We were confronted with the situation of developing policy for donation after circulatory death (DCD) for our newborn intensive care program. Due the moral-ethical complexities surrounding DCD, and the limited experience with DCD in this context, we approached policy development from an iterative design perspective employing qualitative methods. We describe our experience in employing this approach and the methodological implications of design as a method for policy development.*
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Policies are fundamental for the provision of interdisciplinary healthcare:

> An explicit health policy can achieve several things: it defines a vision for the future which in turn helps to establish targets and points of reference for the short and medium term. It outlines priorities and the expected roles of different groups; and it builds consensus and informs people. (World Health Organization, 2015)

Procedures and guidelines are helpful, and while can be supported by explicit policy, are of a different order. Procedures typically detail steps, activities, and practices for a defined task as they represent the implementation of a policy to a specific situation (Lemer, Cheung, Viner, & Wolfe, 2015). Guidelines may be used to reflect a softer, gentler, or laxer requirement for adherence. In turn, existing procedures and guidelines may be used to help formulate policy (Brouwers et al., 2010).

Policies provide directives for members of an organization. Without policy the actions of healthcare practitioners may seem arbitrary, obscure, unaccountable, and, if things go wrong, indefensible. At the same time, sometimes people may hide behind policy. That is why, in healthcare, it is crucial that policy is clear and yet leaves room for professional discretion. For health professionals and patient-families, policies hopefully reflect thoughtful intent, careful deliberation, and best available evidence because they often serve as a starting point or even a guide towards professional practice (Ham, Hunter, & Robinson, 1995). Policy development for healthcare, however, can be challenging when dealing with a diversity of opinions and limited available evidence (Mahgoub, van Manen, Byrne, & Tyebkhan, 2014). The requirement for rigor in policy development is crucial for moral-ethically complex issues whereby transparency in the process of policy development may be as important as the ethics of the policy itself.

When policies are determined and imposed by central institutional administrators they may not be supported by the professional practitioners who must abide by them. That is why it is crucial that policy development in high-risk healthcare contexts is accomplished through a participatory design mode. Qualitative research has much to offer clinicians and policy-

makers (Tong, Morton, & Webster, 2016). As such, it is not simply that qualitative research studies may be critically reviewed in formulating policy; individuals with expertise in qualitative data collection and analytic methods may be called on to support policy development projects. In this article, we present our experience of using an iterative design method employing qualitative methods for policy development for donation after circulatory death (DCD) for our neonatal intensive care program. We begin with a brief review of existing methods for policy development and the challenges presented by DCD before presenting our experience of piloting this approach.

## Methods for Policy Development

In the medical literature and health practice, multiple methods exist for crafting policy (Mills, 2012). Consultation with expert or purposeful expert writing of policy is a common practice (Morgan, 2014). While an expert may contribute his or her judgement based on his or her background and experiences, review and integration of available evidence serve to support and strengthen the policy document (Cookson, 2005). If evidence is not available, qualitative and/or quantitative methods may be utilized. For example, methods such as interviews, focus groups, or surveys may be employed to elicit opinions and beliefs to inform the expert for policy development (Brownson, Chriqui, & Stamatakis, 2009).

Use of multiple experts in the form of an advisory or working group may further inform policy development. From a group milieu, the direction of policy development, in addition to the policy itself, may be informed by various experts' backgrounds and experiences (Lemer et al., 2015). Clearly, who participates in the panel will directly impact the crafted policy such that the constitution of an advisory or working group has methodological implications for the establishment of expertise, trust, support, and endorsement. In the context of group policy development, general discussion or formal consensus building techniques may be utilized. The Delphi method is perhaps the most frequently cited of the latter where the intention is to obtain unanimity or accord by means of a series of recursive discussion cycles (Hasson, Keeney, & McKenna, 2000; Joffe et al., 2001; Jones & Hunter, 1995). Issues where consensus is possible, and that lend themselves to group discussion, clearly are more suitable to this technique. As in the case of the lone expert, it is possible for an advisory group to become insular to the community that the policy is supposed to serve (Mahgoub et al., 2014).

Approaches exist for the appraisal of policy and the policy development process such as the AGREE II framework (Ham, Hunter, & Robinson, 1995). The AGREE II has multiple specific and global domains allowing rating of such issues as scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. In comparison, multiple strategies exist to evaluate, synthesize, and rate evidence to increase the validity of evidence-based policy statements (Centre for Evidence-Based Medicine, 2009; Guyatt et al., 2008). When evidence is lacking or an issue does not lend itself to evidence-based policy statements, good practice statements may be an appropriate alternative (Guyatt, Schünemann, Diulbegovic, & Akl, 2015).

## The Challenge of DCD for Policy Development

DCD specifies the situation of organ procurement for the purpose of organ donation following a medical determination of death based on the absence of intact circulatory function (Shemie et al., 2006). In other words, a DCD organ donor is declared dead based on the absence of heart rate, blood pressure, and other signs of life. DCD contrasts with organ procurement following a neurological determination of death ("brain death") where death

determination is made in the presence of an intact circulation (Nakagawa, Ashwal, Mathur, & Mysore, 2012).

In Canada and in other developed countries, DCD is increasingly being pursued as a method for organ procurement following a decision to withdraw medical treatments largely because the need for organ donors continues to rise (Shemie et al., 2006). In the neonatal population, the desire for DCD is being driven in part by the need for donor infant organs, and more specifically hearts, because infant heart-transplant recipients face high waitlist mortality due to scarcity of available donor hearts (Mah et al., 2009). Multiple reviewers have articulated the potential positive impact of neonatal DCD on the donor pool with the potential to save lives (Charles, Scales, & Brierley, 2014; Labrecque, Parad, Gupta, & Hansen, 2011; Mathur, Castleberry, & Job, 2011; Stiers et al., 2015).

The demand for DCD is tempered by moral-ethical concerns about the practice of DCD related to issues such as informed consent, conflicts of interest, premorbid interventions, social utility, transparency-openness, and declaration of death (Joffe et al., 2001). Organ donation may provide meaning to the loss of a loved one and even save a life. Yet, for particular patient-families or hospital staff DCD may not be "good" or "right." Various regulatory bodies have recommended local programs establish policies and procedures to support DCD in pediatric populations (Shemie et al., 2006; American Academy of Pediatrics, 2013), but there are limited reports of infants serving as DCD donors (Boucek et al., 2008; Kmietowicz, 2015), with variability between existent policies (Antommaria, Trotochaud, Kinlaw, Hopkins, & Frader, 2009).

It is imperative that the activity of policy development and the DCD policy itself should reflect the moral experience of front-line staff and other stakeholders. Moral experience encompasses a person's sense that the values that he or she deems important are being realized or thwarted in everyday life (Hunt & Carnevale, 2011). This includes a person's sense of a clinical practice that falls on spectrums of right–wrong, good–bad, or just–unjust.

Developing policy for moral-ethical issues such as DCD necessitates an iterative rather than a linear process of simply identifying issues, gathering information, consultation, drafting, and implementation. Methods for policy development must be flexible and sensitive to the realization that complete consensus is not possible for an issue like DCD (Dorst & Royakkers, 2006). Developing policy for DCD necessitates an integrated, collaborative approach engaging hospital staff, key stakeholders, and the public while recognizing the need for discretionary professional judgements and interventions (Shemie et al., 2006).

## Our Local Context for Policy Development

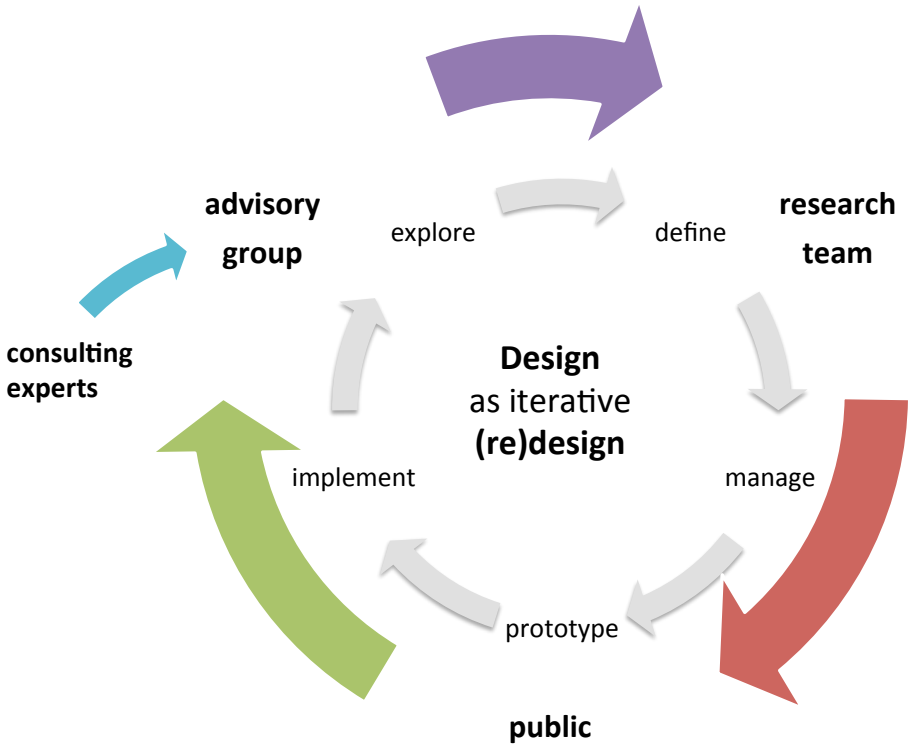
Our neonatal program includes two tertiary neonatal intensive care units (NICUs) affiliated with the University of Alberta Hospital in Edmonton, Alberta, Canada. One unit is linked to high-risk perinatology with specialized services in high-risk prematurity, refractory respiratory failure, and infant development with approximately 1300 admissions per year. The other unit has an active cardiosurgical service in addition to specialized pediatric services such as neurosurgery, general surgery, and otolaryngology with approximately 500 admissions per year. A multidisciplinary team inclusive of neonatologists, nurse practitioners, bedside nurses, respiratory therapists, dieticians, social workers, and trainees staff the NICUs. Pediatric subspecialists are consulted as needed. Clinical ethics, spiritual care, psychology, and other services are also available to patient–families.

Organ donation has been an exceptionally rare event in our NICU program. From reviewing all of the deaths that occurred from January 2009 to December 2013, only one patient was identified to have met criteria for neurological determination of death (Lam,

Kain, Joynt, & van Manen, 2016). Death tended to be a "naturalized event" whereby most dying infants were disconnected from cardiorespiratory monitors to be held by family members in a parent room or the NICU. The possibility of organ donation was not a routine part of end-of-life conversations of health professionals with patient-families. That being said, given our program's active cardiosurgical service, it was not an infrequent event that one of our patients was listed to receive a heart transplant. While some of these infants ultimately did receive organs, others died while waiting. It would seem our multidisciplinary team was aware of the benefits of organ transplantation, yet for the most part, unaccustomed with our patients serving as organ donors.

In response to the challenges associated with DCD, existent literature on policy design, and the cultural environment of our NICU, we used an iterative design approach to develop morally sensitive DCD policy for our neonatal intensive care program (Figure 1).

**Figure 1: Iterative Policy Design Framework**




## Piloting Design as a Method for Policy Development

Design may be conceptualized as a method for research whereby the researcher as designer is oriented towards a particular issue, problem, or solution (Dorst & Royakkers, 2006; Harrison & Laussen, 2008; Michel, 2007; Rodgers, 2015). A design orientation may be conceptually compared to the directedness of other methods that engage a research question or research hypothesis. What is defining to the method of design, compared to other methods, is the reliance on the designer's "creativity" to reframe or recast a design problem to imagine novel possibilities or solutions (Dorst & Cross, 2001; Kolko, 2010). The creativity of design remains enmeshed with other "designerly" activities such as *exploring, ideating*, and *testing* carried out in iterative fashion (Sless, 2008).

*Exploring* is a "nearing" activity undertaken so that the researcher can understand and expand upon a specific problem and existent solutions; can find patterns and exceptions; and,

can identify limitations and boundaries. In comparison, *ideating* involves a "distancing" on the part of the researcher to redefine problems, creating space for novel standpoints, alongside practices such as sketching, drafting, and modeling imagined possibilities for design. And finally, *testing* is an "experimental" activity addressing instrumental, technical, aesthetic, and ethical aspects of design in the form of prototyping and implementation. Testing recognizes that design inherently necessitates re-design because a solution for a given problem may actually change the nature of a design problem itself (Lawson, 2005). A NICU example of design necessitating re-design is the construction of single-family room units in place of open-ward environments. While these units may foster family-centered care and positive outcomes, when parents are absent, the rooms may be isolating for infants (Pineda et al., 2014). In effect, the design of single family rooms changes the traditional care environment for the NICU infant necessitating re-design such as the introduction of collapsible walls between adjacent rooms so hospital staff may maintain contact with multiple infants when parents are absent.

To pilot design as an iterative method for policy development, we took into consideration elements of an advisory group, frontline staff and stakeholders, and a research team as necessary for the policy development to proceed to address specific issues such as: To whom should we offer DCD? What ought the consent process for DCD look like? How do we manage conflicts of interest? Are modifications to palliative care appropriate for DCD donors? How and when should we declare death in the DCD donor? What ought after death care look like for the donor? What strategies are appropriate for quality assurance once the policy has been implemented? Our hope was that by exposing policy development to an iterative design process, the policy itself would be strengthened by cycles of scrutiny. This is quite different than the expectation that a policy will emerge from consensus as in a Delphi technique.

After discussion at interdisciplinary rounds and other venues for staff input, we obtained approval from the health ethics board and respective administrative authorities for this iterative design project. Informed consent was obtained from all participants. During the policy development project, we also presented lunchtime sessions to frontline staff on DCD. The presentations were given with the intent of providing more information about DCD and the policy project itself.

*Advisory Group*

An advisory group was formed of individuals "expert" in the care of NICU patient-families to serve as a venue to *explore* issues related to DCD in focus group fashion (Lawson, 2005; Pineda et al., 2014). Focus group method has the advantage of engaging, prompting, and sharing discussions between individuals (Kitzinger, 1995). Focus groups also served the purpose of promoting *ideating* as participants' disparate experiences and differing perspectives served to question taken-for-granted assumptions, to clarify existing opinions, and to formulate fresh perspectives (Krueger, 1994). The potential "novelty" that emerges from focus group discussions is congruent with the creative crux of design.

We felt that it would be valuable that various disciplines were included in the advisory group such that participants were purposefully chosen to include representation from medicine, nursing, respiratory therapy, social work, spiritual care, ethics, and law. Involvement of multiple disciplines benefited the aim to engage a spectrum of perspectives for policy design. We recognized, however, that advisory group members ultimately could not be representative given that within any practice group there is a spectrum of perspectives on DCD. As in other neonatal policy development projects, we also included parents who had

previously had a child cared for within the NICU to provide a parent perspective to policy development (Mahgoub et al., 2014).

The advisory group consisted of 18 members representing various backgrounds, experiences, and views pertaining to DCD. Members of the advisory group were invited to participate based on established practices of our program for approaching each disciplinary group. For example, information about the project was distributed to the nurse practitioner group with the group itself selecting an advisory group member. Groups were not obligated to participate yet all approached groups did offer a representative for the project. At the first advisory group meeting, we discussed the membership of the advisory group. Following this discussion, additional members were invited from spiritual care and pediatric neurology. The advisory group made the decision not to include members from transplantation services in order to keep the focus of the advisory group meetings on care of the potential neonatal intensive care donor-family rather than the potential transplant recipient.

A series of nine audio-recorded meetings took place from July 2014 through March 2015, including issues related to the processes surrounding DCD: eligibility criteria for DCD, consent process for DCD, pre-mortem interventions for the DCD donor, palliative care for the DCD donor-family, declaring death of the DCD donor, and post-mortem care for the DCD donor-family. Each meeting lasted between one to three hours. Video- and audio-conferencing was made available for advisory group members who could not be in physical attendance.

The advisory group and we, the research team, jointly set the agenda, intent, and scope for each meeting. We prepared discussion questions to prompt participants to individually reflect on issues related to DCD (see Table 1). The questions also served to spur discussion around issues related to DCD. We facilitated the focus groups to maintain the aim of the discussion; to encourage members to consider various and sometimes polarizing alternatives; and, to ensure each participant had an opportunity to contribute to discussion.

**Table 1: Example Discussion Prompts for Advisory Group**

| ***Ethics of Approaching Families for Organ Donation*** |
|---|
| • How ought we ensure separation of the decision to withdraw life-sustaining therapy and the decision for organ donation? |
| • When, who, and how ought we approach families regarding the possibility of donation after circulatory death? |
| • When ought we involve the organ transplant coordinator and services? |
| • How should assessment for eligibility for organ donation be woven into approaching families for organ donation? |
| • How ought we handle the situation of a family who asks to discuss organ donation prior to or during the discussion to withdraw life-sustaining therapy? |
| • Are there particular families that we should not approach to offer the possibility of donation after circulatory death? |

If the advisory group felt they lacked knowledge or needed additional information, we were tasked with either finding additional information or inviting consulting experts to attend advisory group meetings. Invited experts included parents who had experience with death and dying in a hospital setting and consideration of organ donation as well as health professionals with expert knowledge on medical or bioethical aspects of DCD. While the invited experts conveyed didactic knowledge, they also cultivated sensitivity and prompted reflective discussions in the advisory group. In other words, advisory group members gained insights into and questioned what the experience of DCD might be like for a particular patient-family

(see Table 2 for example anecdotes of invited parents) (van Manen, 1989). Although the length and focus of the advisory group meetings varied, each meeting fostered discussion, fulfilling the design mandate to *explore* and *ideate* around issues related to DCD.

**Table 2: Example Anecdotes from Invited Expert Parents**

| |
|---|
| The doctor said, "It's not looking good." I think we knew that in our hearts already. We had both said that there would be no more surgeries. We had decided that this would be it. And it was at that time when I said, "Well, what about her organs? Maybe we should donate her organs." Organ donation had not been brought up before. The doctor said in response, "She's been through a lot of surgeries already so you don't have to go that route." I felt grateful and relieved. I don't know what we would have done if he had just said, "Yes, that's a fantastic idea." She had been through so much already. For him to help to take it off the table, to say that it is not something you have to do. It was giving us permission to say no, to put our feelings for our child first.<br><br>– A parent who did not choose organ donation |
| I was remarkably surprised at how much time they gave us after they discontinued the life support. We had the time to say good-bye and I didn't feel like it was, "Okay, we're whisking her down the hall," and someone is standing there saying, "Okay, how much time?" Our experience was respected….although I did feel that I started putting that pressure on myself. It was actually one of the nurses that said, "Don't look at your watch." The time was ours.<br><br>– A parent who did choose organ donation |

* These anecdotes are based on transcriptions of focus group meetings. After being anonymized, they were reviewed with parent participants for iconic validity. See van Manen (1989) for discussion of the anecdote as a methodological device.

*Research Staff*

We, the research staff, included a neonatologist experienced in qualitative research and research assistant with background in nursing and public health. Our role was to facilitate the functioning of the advisory group. We also had administrative responsibilities for organizing meetings, providing refreshments, and so forth. Neither of us had previous direct experience with DCD.

Multiple *exploring* activities were completed in response to the advisory group meetings: literature reviews on topics related to pediatric DCD; an environmental scan for existing Canadian pediatric DCD policies; and, a retrospective review of our local program palliative care practices (Lam et al., 2016). These activities were completed outside of the advisory group meetings with gathered information brought back to the advisory group.

Audio recordings of each advisory group meeting were transcribed. Qualitative content analysis of focus group material was completed concentrating on the contextual meanings of the transcribed speech (Hsieh & Shannon, 2005; Lindkvist, 1981). As an *ideating* practice, drafts of policy statements and accompanying rationale were created. This drafting activity required us to deal with practical constraints, limitations in knowledge, and so forth. These statements and rationale were compiled into Research Electronic Data Capture (REDCap) as Survey-Briefings. REDCap is a secure, web-based application hosted at the University of Alberta and designed to support validated data capture and collection for research studies (Harris et al., 2009). The Survey-Briefings were then returned to the advisory

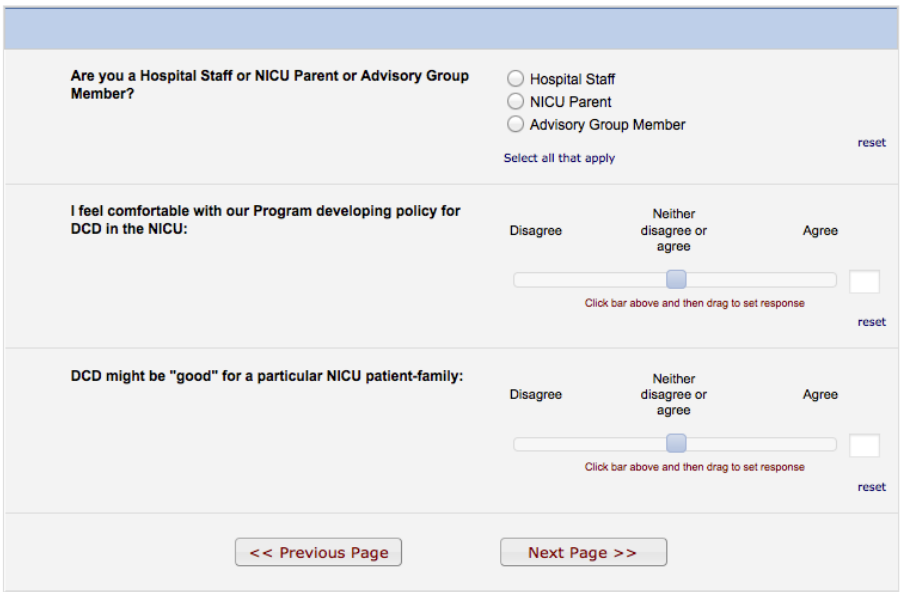
group as a validation measure to ensure that the policy statements and accompanying rationales accurately and appropriately reflected meeting discussions, offering an acceptable sketch of aspects of the proposed policy.

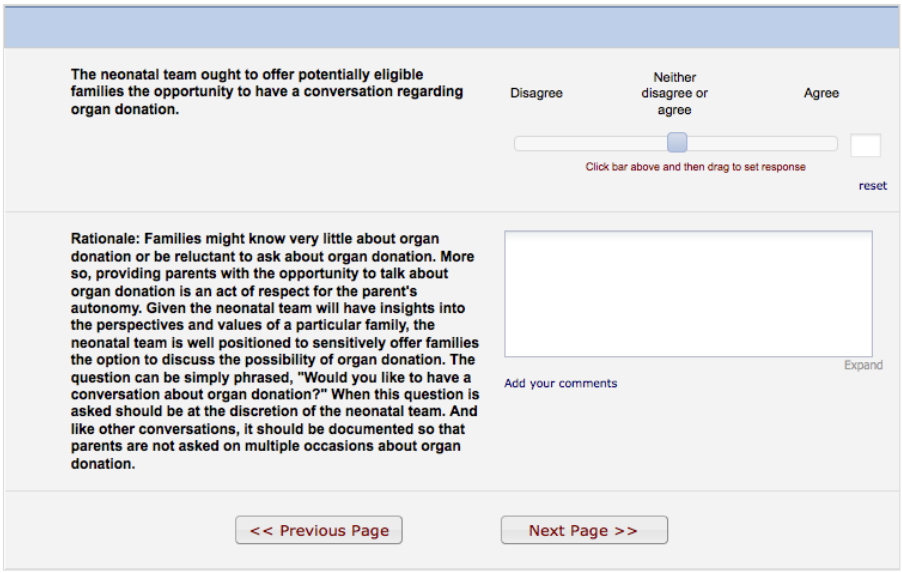
*Frontline Staff and Stakeholders*

After review by the advisory group, the Survey-Briefings (four in total) were shared with frontline staff associated with the NICU through hospital e-mail list-serves. Hospital staff included neonatologists, nurse practitioners, bedside and specialized nurses, neonatal subspecialty trainees, respiratory therapists, dieticians, pharmacists, and social workers. In addition, the survey was circulated to parents who had previously had a child in the NICU through the Family-Centered Care Network e-mail directory. Distribution of draft policy statements through anonymized Survey-Briefings functioned as a means of *testing* the moral acceptability of policy statements to the "public" or end-user of the DCD policy. In other words, the Survey-Briefings served as prototypes for the actual DCD policy statements that were to be produced.

Each Survey-Briefing began with giving participants the option to participate in the survey. Following, a general description of DCD and the specific purpose of the Survey-Briefing were detailed. This introduction was necessary to allow stakeholders an opportunity to consider their personal values and moral-ethical stance regarding DCD. Potential participants could either proceed or express that they did not want to participate. Following, there were single-answer multiple-choice fields for participants to indicate whether they were a health professional or NICU parent. Two slider/visual analog scales to ascertain participants' moral acceptability of DCD were also included. The purpose of all these fields were to track whether the Survey-Briefing was reaching professionals from all disciplines and from a variety of personal perspectives on DCD. The remainder of the Survey-Briefing included draft policy statements with rationale alongside slider/visual analog scale and paragraph text box fields (see Figure 2 for example screen shots of Survey-Briefing).

**Figure 2: Example Screen Shots of Survey-Briefing**






Approximately 4 to 6 weeks was given for response to each Survey-Briefing dependent on number of responses and timing of next advisory group meeting. Each Survey-Briefing received 60 to 100 responses. All disciplines were represented in responses. All data collected from the Survey-Briefings were shared with the advisory group including histograms for single-answer multiple-choice fields, scatter plots for slider/visual analog scales, and finally lists of the qualitative comments. We elected not to condense or summarize the qualitative comments such that the advisory group was exposed to each comment in its entirety. This step of returning survey data to the advisory group completed the iterative process of policy development to stimulate further discussion and revise policy statements dependent on received feedback and resulting discussion.

## Validity of Design as a Method for Policy Development

From our experience, design as a method for policy development is a promising approach with the benefit of subjecting a proposed policy to scrutiny in an iterative fashion. This iterative rigor is missing from linear policy development approaches, yet still allowed policy development to continue in the absence of complete consensus. Rigor for the development of the policy was also ensured by such *exploratory* practices as comprehensive literature reviews directed by the advisory group itself as well as research activities specific to the context of our neonatal intensive care program such as the retrospective review of local palliative care practices (Lam et al., 2016).

Stakeholders were involved throughout the DCD policy development process. For the advisory groups, we included individuals expert in neonatal intensive care: health professionals and parents whom had lived the neonatal intensive care experience. In comparison, the Survey-Briefings allowed policy statements to be informed in an inclusive fashion, involving health professionals and other parents not included on the advisory group. We believe that this kind of openness to seeking opinions, views, and perspectives brings transparency to the policy development process. More so, use of Survey-Briefings ensured that the advisory group did not operate in isolation from the larger hospital community. We suspect indirect benefits to this approach to policy development were raising awareness and staff education regarding DCD.

We formatted the DCD policy with the intention that it is easily read and understood by end-users, hospital staff, and potential DCD donor-families. By circulating these policy

statements to end-users we were able to discover and resolve possible ambiguity and other issues. The policy document was formatted into sections, based on an anticipated chronological order of events. It visually resembles other policies in our neonatal program. The document also includes multiple appendices that were crafted with the advisory group: Order of Events Flowchart; Process Safeguard Checklist; Eligibility criteria for Organ and Tissue Donation; Consent Conversation Checklist; Death Determination Checklist; End-of-life Resource Checklist; Warm Ischemic Time; and, Heparin Administration.

The DCD draft policy has been submitted to hospital administration, legal representatives, and other external experts and end-users that will have a direct impact on this policy being implemented. An issue that we are currently encountering is how to best engage and incorporate feedback from services such as transplant medicine that were kept at arm's length during policy development to mitigate potential conflicts of interests. While we still feel that this independence was crucial to ensure that the focus of the DCD was responsive to what is "right" for the potential donor-family, there are ethical considerations to DCD as far as the potential DCD recipient that also need to be respected.

Limitations of this method of policy development include amount of time and resources required for such an intensive and engaging process. As with any policy change, the implementation of DCD policy has the potential to cause unexpected repercussions. We hope that our process for policy development mitigates any such issues. We also realize that there likely are individuals who hold differing values and have opposing views. Clearly, the actual implementation of DCD policy will require ongoing monitoring from quality assurance and improvement perspectives.

## Conclusions

Policy development is an important component for the practice of healthcare, and perhaps even more so when developing policy for moral-ethically sensitive issues. The necessity for developing DCD policy for our neonatal program challenged us to utilize multiple methods to ensure that policy development was moral-ethically sound. We feel that design as a method for policy development proved to be a suitable and successful approach. We hope that our experience may inspire other programs and researchers to realize the promise of design for qualitative research.

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## Appendix

*List of abbreviations*

Donation after circulatory determination of death (DCD)

Neonatal intensive care unit (NICU)

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