Audit of neurodevelopmental outcomes at three years of age in very preterm infants

(< 31 weeks gestational age) or very low birth weight (< 1500 grams) admitted to single patient rooms compared to open bay neonatal intensive care unit (NICU)

Principal Investigator: Dr Michael Vincer

Protocol

Version 2, 15February2019

IWK Health Centre

PROJECT TITLE: Audit of neurodevelopmental outcomes at three years of age in very preterm infants (< 31 weeks gestational age) or very low birth weight (≤ 1500 grams) admitted to single patient rooms compared to open bay neonatal intensive care unit (NICU).

Principal Investigator: Michael Vincer

Co-Investigators: Darlene Inglis

Christy Woolcott

Tanya Bishop

Susan MacDonald

Jehier Afifi

David Simpson

Dora Stinson

Satvinder Ghotra

Walid El Naggar

Balpreet Singh

Souvik Mitra

Doug McMillan

Jon Dorling

BACKGROUND

Neonatal intensive care is vital to survival in preterm and critically ill neonates. As technology has advanced and the survival of very preterm infants has improved, NICUs became quite congested and very family unfriendly (figure 1). More recent trends have shown an improvement in the NICU environment (figure 2), but, there remained a great number of challenges for the families of critically ill neonates.

In the mid 1990s it was suggested that design features in NICUs should use the single patient room format to minimize parental separation as a result of intensive care (D. C. Stevens, Munson, & Khan, 2016). Current standards in the United States recommend a minimum of 15.3 square metres per room (White, Smith, Shepley, & Committee to Establish Recommended Standards for Newborn ICU Design, 2013). While there appear to be obvious advantages of the single patient room, there has been limited data showing the benefits of this design in comparison with the more traditional and current IWK design of an open bay including multiple beds in one large room in the NICU. There has only been one randomized controlled trial from Sweden comparing single

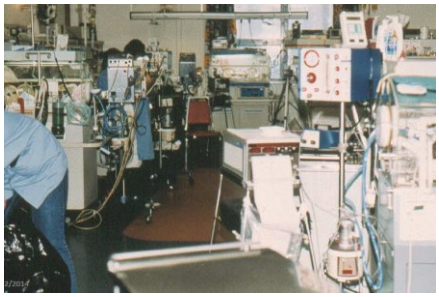

Figure 1: SNCU at the Grace Maternity Hospital, circa 1982

patient rooms with an open bay (Ortenstrand et al., 2010) which showed a significantly shorter length of hospital stay and a reduction in moderate or severe bronchopulmonary dysplasia in

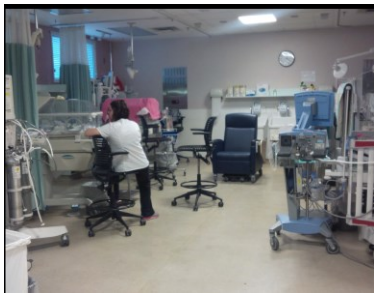

Figure 2: NICU at the IWK circa 2016

preterm infants $\geq$ 27 weeks cared for in the single patient room. Other outcomes such as stage 2-5 retinopathy of prematurity, sepsis and grades 3-4 intraventricular haemorrhage were not shown to be different. A number of cohort (non-random) study designs have shown a reduction in the number of apneas per day (Domanico, Davis, Coleman, & Davis, 2011), earlier oral feeds (Domanico et al., 2011), time to full enteral feeds (Erikson et al., 2011; D. C. Stevens et al., 2012), a reduction in the number of potentially harmful neonatal behaviors (Lester et al., 2014) and lower maternal postpartum depression (Erdeve et al., 2009).

Long-term outcomes have also been examined in cohort (non-random) study designs. In a study from St. Louis in which infants < 30 weeks gestational age were placed in either single patient rooms or an open bay, based upon room availability and nursing staff (Pineda et al., 2014), it was shown that language scores on the Bayley Scales of Infant and Toddler Development were significantly lower ($p<0.05$) in very preterm infants cared for in single patient rooms. This remained true when adjusting for more infants in the single patient rooms requiring Medicaid. There was a loss of follow up rate of 20% in this study. It is possible that low maternal involvement in the single patient room is a risk marker for poor long-term outcome, particularly due to a lack of language related sound (Lester et al., 2016). This contrasts with a study from Providence, Rhode Island which used historical controls of infants admitted to an open bay, a cohort born between January 2007 to August 2009, compared to infants admitted to single patient rooms born between January 2010 to December 2011 (Vohr et al., 2017). In this study, the authors showed that cognitive, expressive communication and fine motor skills on the Bayley Scales of Infant and Toddler Development were significantly better in single patient rooms. This study had a loss to follow up rate of 15% and the difference between the groups disappeared after adjusting for Medicaid usage. Therefore, studies exploring the effects of single room care on long-term

outcomes have shown mixed results and have been limited in their ability to control for confounders and subject to significant losses to follow up.

The NICU at the IWK is embarking on a redevelopment project that will see its current open bay design converted to a single room care environment. There will be a period during the redevelopment, called the "hybrid phase", when new single room care unit will coexist with an open bay unit. This provides a unique opportunity to explore the effect of the two different environmental designs on both short and long-term outcomes in a prospective fashion.

REASEARCH QUESTION

Do very preterm infants (< 31 weeks gestational age) and very low birth weight infants (≤ 1500 grams) admitted to a single patient room in the NICU have improved long-term neurodevelopmental outcomes when compared to very preterm infants admitted to an open bay in the NICU?

METHODS

Design: Currently all infants admitted to the NICU at the IWK are assigned to either the Red Team or the Green Team based upon a computer-generated weighted randomization. This weighted randomization was developed at a series of consensus meetings in 2015 of the NICU Allocation Administrative Group which included physicians, nurses and other health care professionals in the NICU to ensure that all infants admitted to NICU would have a fair chance of being admitted to either the Red Team or the Green Team. It was also designed to ensure relative balance in the workload between the two teams such that nursing staff allocation was relatively equal on either team. The concepts of fairness and relatively equal workload were reviewed with an Ethics Consultation on 19 May 2015 (Appendix 1) and the Family Leadership Council on 20 January 2016 (Appendix 2) and were accepted in principle. Further reviews by the Neonatal Care Committee and the Family Centred Care Committee also accepted these principles.

Mathematical computation for the weighted randomization: The computation of the weighted randomization involves defining the "effort level" for each team and using this effort level to weight the randomization so that the less busy team is more likely to receive the next admission to NICU. Mathematically, this involves taking 1/3 of the fraction of the patient census on each team and adding it to 2/3 of the fraction of the Winnipeg Assessment of Neonatal Nurses Need Tool (WANNNT) (Winnipeg Regional Health Authority, 2011). The nurses record the WANNNT calculation at the end of each 12 hour shift. Additional detail including an example of this computation is shown in Appendix 3.

Experience with the allocation algorithm to date: The allocation model began on 16 January 2017 and in the 448 days to 8 April 2018 there were 944 infants admitted to NICU and allocated to either Green Team or the Red Team. This is, on average, one admission every 11:24 hours.

There were 512 (54.2%) infants allocated to the Red Team and 432 (45.8%) infants allocated to the Green Team.

The hybrid phase: The NICU currently has two primary geographic locations (NICU-1 and NICU-2) and both are open bay units. The teams are geographically located such that the Green Team is located in NICU-1 and the Red Team is located in NICU-2. Upon completion of the first phase of the renovations of the NICU, the infants in NICU-1 (infants on the Green Team) will be relocated to the single patient rooms (to be called NICU North). Those infants in NICU-2 (infants on the Red Team) will remain in the open bay NICU-2 until the second phase of renovations is complete (NICU South) which will also be single patient rooms.

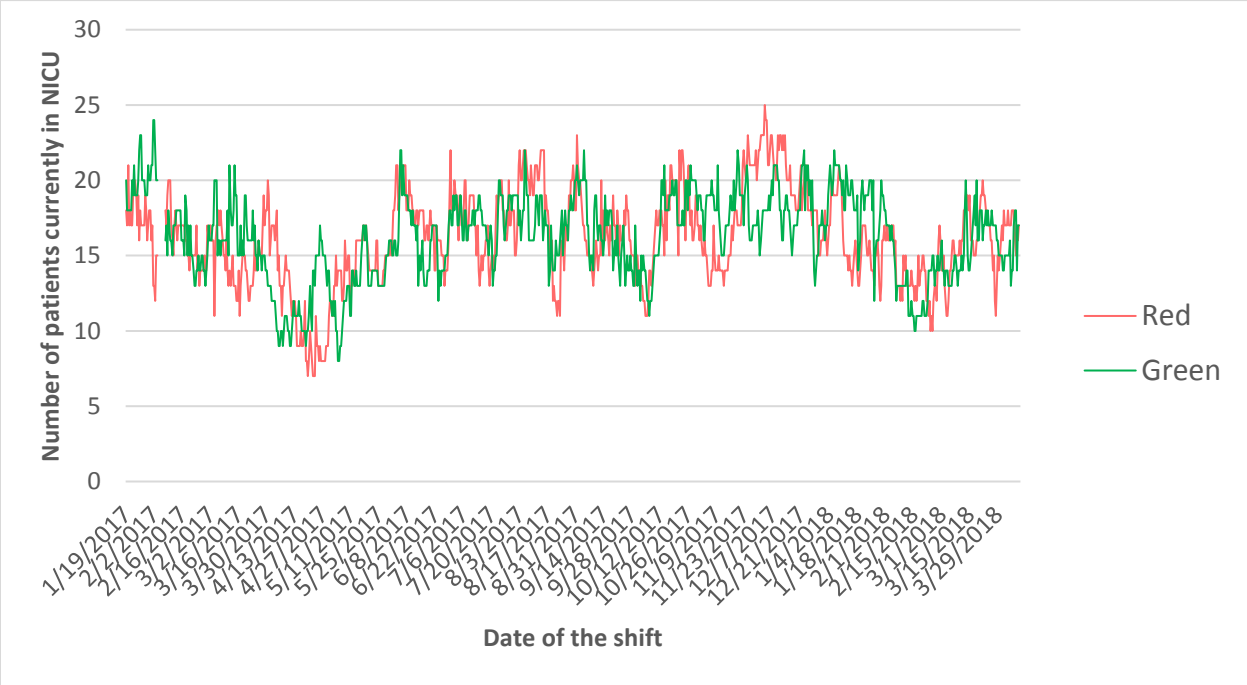

Figure 3: Patient allocation to each team 16 January 2017 to 4 February 2018

Since the allocation model was implemented it has provided relatively even distribution of patients to the teams (figure 3) and gives every incoming infant a fair chance of being allocated to either team. It is planned that this allocation model will continue. The estimated duration of completion of second stage of NICU is approximately 12-16 months.

Audit of very preterm infants and very low birth weight infants: All very preterm infants (< 31 weeks gestational age) and very low birth weight infants (≤ 1500 grams) admitted to the NICU at the IWK are routinely enrolled in the Perinatal Follow-Up Program of Nova Scotia and will be included in the audit of long-term outcome. These infants are evaluated in the Perinatal Follow-Up Program from 3-7 times up to three years corrected gestational age. At three years of corrected gestational age, all infants routinely have the Bayley Scales of Infant and Toddler Development - version 3 (Bayley, 2006) which evaluates cognitive, language and motor skills. These infants are also examined by a physician in the Perinatal Follow-Up Program to determine the presence or

absence of cerebral palsy. If present, its severity is assigned on a scale from 1 to 5 with level 1 being the mildest gross motor functional level to level 5 being the most severe gross motor functional level (Palisano et al., 1997). All infants have a hearing screen prior to discharge from NICU and if any concerns are expressed, they have additional hearing screens after discharge. All patient are also screened prior to discharge by an ophthalmologist specialized in newborn assessments and treatments. Infants known to have retinopathy of prematurity or any other risk factors for visual impairment are evaluated by the ophthalmologist usually at 9-12 months corrected gestational age.

Exclusions criteria for the clinical audit of long-term outcome include very preterm infants admitted from the delivery room for palliative care only and infants more than two weeks old upon admission to NICU.

Assignment of gestational age: Gestational age will be assigned to infants shortly after birth and is shown in Appendix 4. This algorithm was developed by Dr. Alexander Allen for the Reproductive Care Program of Nova Scotia.

Primary outcome: adverse neurodevelopmental outcome defined as: The clinical assessment at three years corrected gestational age will be used to assign adverse neurodevelopmental outcome. The primary outcome will be a composite of any one of the following outcomes: a) death before three years corrected gestational age; b) cerebral palsy of any degree of severity; c) blindness (vision < 20/200 in the best eye); d) deafness (bilateral) requiring hearing aids for correction; e) language score < 85 (<1 standard deviation below the mean) on the Bayley; or f) cognitive score <85 on the Bayley (<1 standard deviation below the mean) (Table 1).

Table 1: Severity of Disability	Minor	Major
Cerebral palsy	level 1-2	level 3-5
Cognitive scores	70-84	< 70
Language scores	70-84	< 70
Hearing	normal	bilateral deafness
Vision	normal	bilateral blindness

Secondary outcomes: Secondary outcomes will include the component outcomes of the primary outcome and because both language and the motor scores of the Bayley Scales of Infant and Toddler Development were significantly discrepant in the trial from St. Louis (Pineda et al., 2014), these two outcomes, as continuous variables, will also be examined. Additionally, all outcomes will be examined separately in infants 22-30 weeks gestational age.

Consent: Parents of infants enrolled in the Perinatal Follow-Up Program sign a consent to be enrolled in the Program and to allow staff to collect and use of data for their child (consent also available in French). It is made clear to each family that data for their child will never be disclosed to third parties and would never be used in publications that would allow the their identity to be known (Appendix 5). All parents of infants admitted to NICU, whether or not they have been

enrolled in the Perinatal Follow-Up Program will receive an information package explaining the single patient room NICU compared with the open bay NICU (Appendix 6).

Sample size: It is estimated that it will take approximately 14-16 months to complete phase 2 of NICU construction, after which time the entire NICU will be single patient rooms. When phase 2 of the renovations is complete, infants in NICU-2 will be relocated to NICU South which will draw the current audit to a close. During phase 2 construction, the NICU will be a "hybrid unit" in which half the beds in NICU will be open bay and the other half will be single patient rooms. It is estimated that between 130-160 very preterm or very low birth weight infants will be admitted to the NICU during the "hybrid time". The usual sample size calculation cannot be made because the sample size will be fixed by the duration of the construction. Therefore, a detectable difference given a fixed sample of approximately 65-80 infants in each group can be determined. Based upon evidence from the Perinatal Follow-Up Program for very preterm or very low birth weight infants born between 2002 and 2016 (15 year consecutive time period), approximately 41.0% of infants had either a disability (table 1) or died before reaching the age of three years. This means that assuming an α error of 0.05 with a power of 0.80, a detectable difference is approximately 55% (i.e. the primary composite outcome of 41.0% would be reduced to 18.5% or less to show a difference). For the major secondary outcomes, the language or motor domains on the Bayley Scales of Infant Development Toddler Development, a difference of 8 points (approximately 0.5 standard deviations) assuming and α error of 0.05 with a power of 0.80 can be detected.

Statistical analysis: The primary analysis (death or neurodevelopmental disability at three years of age) will be compared between groups using chi-square test and odds ratio with a 95% confidence intervals. Additional dichotomous outcomes will be analysed similarly with a Bonferroni correction and continuous outcomes will be analysed with two-sample two sided t-tests.

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Appendix 1: Ethics consultation, 19 May 2015

IWK Ethics Committee

This form is to be completed by the chair. The first section is completed in conjunction with the requestor; the second section is completed in conjunction with the ad hoc triaging group. This document is to be kept confidential and used only for the purposes of the organizational ethics consultation process.

Section One:

1. Briefly describe the situation or concern that has led you to request an organizational ethics consultation.

The Neonatal Intensive Care Unit (NICU) at the IWK Health Center is excited about our upcoming renovation for our newly designed "Single Family Room" unit. This new design will have included in the patient room a separate sleep space for families and a private bathroom. We believe this new structure will offer the architecture to support our philosophy of care delivery which has significantly changed over the years. Notable advances in neonatal care over the past few decades have resulted in preterm and ill infants being cared for within the highly technical environment of NICU. As a result of significant advances in science and technology, great improvements in survival rates have occurred. Unfortunately however, separation of mother and baby had been viewed as an inevitable trade off of providing such high tech neonatal care. We strive for not only greater survival but also for greatly improved long term outcome. Strong evidence supports better improvement in long term outcome for infants whose parents are intimately involved in providing care. Research confirms that parents as a result feel more confident and competent when they are involved in the care of their infant immediately after birth.

Our ultimate goal today is to keep babies and their families together soon after birth right through to discharge. The building of single family rooms will enable us to welcome the family in the NICU in a space that is significantly more comfortable and private compared to the open bay where neonatal intensive care is currently administered. The construction of this new unit will occur in stages. Beginning May 2015 construction for the new NICU North will commence. The plan is to move into NICU North in early summer of 2016. At such time half of the current neonatal population will be cared for in the "Single Family Room" fully equipped with a double sofa bed for parents and a full bathroom while the other half of the population will remain in NICU 2 which is the open bay design. This is expected to occur for a full year until NICU South is completed during the summer of 2017. In the open bay parents will not have a private place to sleep nor a private bathroom and shower. They will be offered a cot or chair at the bedside and a public bathroom and shower to share.

Our dilemma is how will we determine which patients are admitted to the NICU North with 22 private sleep rooms with a full bathroom as compared to the 16 open bay spaces in NICU 2?

2. What do you see as the ethical issue(s)?

We assume that families will feel that there is inequity in regards to the two options available upon admission.

3. Who are the concerned parties (e.g., who else is or could be involved)?

This decision impacts babies, families and all staff.

We also feel that the public will be very interested in our decisions.

4. What has been done so far to deal with the situation?

We have begun discussions within our team as to how challenging it will be for patients, families and staff during the construction phase. We will be consulting the Family Leadership Council to ask for family input and engagement; however we are requesting Ethics Consultation first. The predicament has also been presented to the Program Director, Michelle LeDrew and Jocelyn Vine, V.P. Patient Services who were also supportive of this consult.

Dr. Vincer presented the option of randomization. This option would have patients randomized at birth to either Single Family Room in the North or Open Bay Unit in NICU 2. This option sees the patient remaining in the site they were admitted to from admission to discharge.

The following two suggestions have also been brought forth: admit the longer term patients to the single rooms in the North while shorter term patients would go to the Open Bay Unit. The other option is a "first come, first served model". These options are concerning for a number of reasons, one being that when there would be a discharge from the North Unit families may possibly want to move over from the Open Bay Unit. In the current NICU patients are often moved as they progress from higher to lower acuity during the admission. We have found this to be costly but more importantly it is a potential patient safety concern as with every move there is potential for error to occur.

5. Additional Comments:

The NICU team welcomes your expertise in this very significant predicament.

Consultation requested by: *Darlene Inglis Manager NICU – 902 470-7819, Dr Krista Jangaard, Head, Division of Neonatal-Perinatal Medicine – 902 470-6643* March 18th, 2015
tp://www.ethics.ubc.ca/people/mcdonald/conflict.htm

Organizational Ethics Consultation
Intake Form

Name of Requestor	Darlene Inglis, Manager NICU
Date Received	
Reviewed by	Angela Arra-Robar

Action:

- ✓ proceed with ethics consultation
- ❑ refer to professional chief or manager
- ❑ refer to Dalhousie University Bioethics Department
- ❑ refer to IWK Risk Management
- ❑ other _____

Ethics Committee Consultants:

Angela Arra-Robar
Marika Warren
Julie Johnson

Meeting arranged (date/time/location):

May 19, 2015, 1400-1500 hrs, Classroom C

Record of Organizational Ethics Consultation Meeting

Date/Time	May 19, 2015 @ 1400
Requestor	Darlene Inglis, RN Manager NICU
Organizational Ethics Consultants	Angela Arra-Robar, Julie Johnson
Ethics Resource Person	Marika Warren
Recorder (if applicable)	Angela Arra-Robar
Present	Darlene Inglis, RN Manager NICU, Dr. Krista Jangaard, Dr. Mike Vincer, Brenda Hewitt, RN CNS, Tanya Bishop RN, CL and Michelle LeDrew, Director Women's and Newborn Health

Brief summary of case (e.g., what has lead to the consultation, what has been done previously to address the ethics issues, what the medical situation is as it relates to the ethics issue(s)):

The Neonatal Intensive Care Unit (NICU) at the IWK Health Center is excited about our upcoming renovation for our newly designed "Single Family Room" unit. This new design will have included in the patient room a separate sleep space for families and a private bathroom. This new structure will offer the architecture to support our philosophy of care delivery by providing an enhancement to our current family centered care.

Beginning May 2015 construction for the new NICU North will commence. The plan is to move into NICU North in early summer of 2016. At such time half of the current neonatal population will be cared for in the "Single Family Room" fully equipped with a double sofa bed for parents and a full bathroom while the other half of the population will remain in NICU 2 which is the open bay design. This is expected to occur for a full year until NICU South is completed during the summer of 2017. In the open bay parents will not have a private place to sleep nor a private bathroom and shower. They will be offered a cot or chair at the bedside and a shared bathroom and shower.

The NICU team has a redevelopment committee that has put careful thought into the options for room assignment. In addition to room assignment, the team is planning to perform a research study looking at the health outcomes based on whether the child was cared for in a private or open bay space.

Statement of ethics issue(s) (this may include any changes in what the identified issues are during the consultation and should be noted accordingly):

The NICU team has identified the following values as important throughout the discussion:

Fairness	Equity	Choice	Safety	Justice	Family	Support	Compassion
Patient and family centred care			Consistency	Transparency	Quality	Inclusion	

Short summary of the consultation (e.g., the major issues that were addressed, what the focus of the discussion was, what key values or ethics aspects were addressed):

While there is conflicting evidence to support the beneficial effect of single-family room care in the NICU on clinical outcomes (of which the proposed research study will help to address), there will almost

certainly be a perception among the public and possibly also staff (on the unit and elsewhere) that the single family rooms are “better” (although for some parents the open bay environment is preferable).

The NICU team provided an overview of the reconstruction plan and process, the current literature, and their dilemma regarding how to assign patients to rooms during the redevelopment. The group discussed the following options, all of which reflect a different conception of the value of fairness. Note that “benefit” in the description of the values refers to perception of benefit in this case

1. Assign patients to rooms at random (give all an equal chance of benefit)
2. Assign patients on a “first come, first serve” basis (allocate the most desirable resource, from the perspective of the parent(s), first)
3. Assign longer-term patients to single rooms (meet the greatest need first)
4. Assign patients to rooms by alternating (single, ward, single, ward) (give all an equal chance of benefit)
5. Assign patients to room based on acuity (allocate in response to medical needs)
    a. Which patients get the private room? The sickest? The most well?
6. Assign based on parental presence/absence (allocate to those who will make most effective use of the resource)
    a. Parent present 24/7 = private room?
7. Assign based on which NICU medical team is providing care, which is determined by balancing provider workload (give all an equal chance of benefit)

For all of these there will be a balancing mechanism for ensuring that the caseloads for staff are equitable in terms of amount of work and exceptions in the case of palliative patients, multiples, and readmissions.

A related question arose regarding what to do with existing space for families, the allocation of which has been a perpetual cause of distress for parents and staff. During renovation it is likely that it will need to be converted to storage space.

Recommendations (if applicable, arising from the consultation):

- Develop a clear articulation of the values that are reflected in the process that is used, including a description of the way that fairness is conceived.
- Continue involving stakeholders, especially parents and members of the public, in the process of designing the allocation procedure
- Involve PR at the outset to proactively engage with the public to explain what the process for allocating the single family rooms will be and how it reflects the IWK's organizational values. Insofar as possible, address questions proactively.
- Ensure that there is a robust implementation strategy including training for staff in addressing the concerns of parents who believe the allocation mechanism to be unfair or inappropriate (which is very likely, given how parents often respond to the experience of having a baby in NICU).
- Ensure that all of the above is well-documented, communicated and accessible to ensure transparency in the process.
- Explore either (a) closing off the existing family rooms or (b) using them as a trial run and devise allocation criteria for it that resemble what will be used for the single family rooms.
- The ethics consultants can be available for further discussion around the relevant values and how to reflect those in practice if that would be helpful.

_____ _____

Organizational Ethics Consultant Organizational Ethics Consultant

_____

Ethics Resource Person

Complete Evaluation form (below)

Evaluation of Consultation by Organizational Ethics Consultant

Consultant's evaluation of consultation:

How could such a consultation be improved in the future?

Does this case suggest a need for a Health Centre Ethics Committee initiative, e.g., educational program or new policy?

Appendix 2: Family Leadership Council Consult, 20 January 2016

Request for Family Leadership Council (FLC) Consultation

Thank you for taking the time to fill out this template. The Council meets monthly and typically carries a number of requests for consultation. Your information will enable our advisors to have time to reflect for broad patient/family perspective, and help prepare for focused discussion with valuable feedback.

What is the topic or title of your request?

We would like to come for consultationto discuss an option of how we may allocate patients to the Neonatal Intensive Care Unit while construction of the newly designed NICU. For at least one year we will be practicing within the newly designed the 22-Bed - Single Family Room NICU North and NICU – 2 a 16 Bed Open Bay Unit.

Please categorize the nature of your request.

- To seek advice or consultation from a centre-wide patient/family perspective

We are coming to the Council to seek advice on a proposed solution and gain feedback on what the council would suggest as any other acceptable options to consider.

If you are seeking advice or consultation, at what stage are you in the decision making process? This will help us better understand how to provide useable feedback, and help us prioritize FLC consults.

A. **Beginning/early stage of development** (i.e. committee has been struck, met once or twice, seeking patient/family perspective before advancing further)
B. Mid-way point (i.e. committee has met several times, have a plan established)
C. **End point** (i.e. work has been done, decision has been made, seeking advice on implementation)

Please briefly explain.

We believe us to be in the *Beginning/early stage of development* (i.e. committee has been struck, met once or twice, seeking patient/family perspective before advancing further). Leadership team has three times– to discuss options

- We have consulted Ethics
- We have met with a computer programmer to discuss the an option/plan
- We now are seeking feedback from Family Leadership Council
- In near future will be recruiting feedback from NICU current and past families

- We feel that we are still in the beginning stage as family and public feedback is imperative however we have established a proposal for a plan which meets the criteria of being at a Mid way Point of decision making. We felt that after going through the exercise with ethics the best way to proceed was to come with a plan to present to the council as it clearly will help to outline the complexity of our dilemma.

Could you please provide background information/context of your request? For example, what is the situation or purpose of this work? What has been accomplished so far? Who is this going to affect? How? Who has been involved? What is your timeline?

Situation or purpose of this work

Advances in neonatal care over the past few decades have resulted in preterm and ill infants being cared for within the highly technical environment of the neonatal intensive care unit (NICU). As a result of such advances in science and technology significant improvements in survival rates have occurred; however we continue to strive for such improvements in long term outcome. Preterm and ill infants have traditionally been separated from their mothers immediately after birth. They are placed into incubators where they are exposed to excessive noise, bright lights and are subjected to many painful procedures, at times without appropriate pain control. We know today that this is not optimal. Babies do much better when they are in very close contact with their parents who love them and want the very best for them.

It is not a new concept that babies thrive and do better in the presence of their mothers and fathers. As a result the NICU at the IWK Health Centre is scheduled to undergo a major re-development over the next three years and will be moving toward providing care in single family rooms. In order for parents to stay close to their babies as soon after birth as possible and throughout the entire NICU admission, we need to redevelop our unit so that parents are comfortable to stay for prolonged periods of time. In order to provide comfort we need to have bathroom and a comfortable sleep space. That is really difficult to achieve this in our current open baby design. We hear from families all of the time how difficult it is for them to leave their infants and go home when they are unable to gain access to a parent room. Our biggest growing pain at this point in time is how can we stay current with the new model of care provision in our current architecture. We already struggle with this concept each and every day. We believe this to become even more challenging however as beginning May 2015 construction for the new NICU North will commence. The plan is to move into NICU North in early summer of 2016. At such time half of the current neonatal population will be cared for in the “Single Family Room” fully equipped with a double sofa bed for parents and a full bathroom while the other half of the population will remain in NICU 2 which is the open bay design. This is expected to occur for a full year until NICU South is completed during the summer of 2017. In the open bay parents will not have a private place to sleep nor a private bathroom and shower. They will be offered a cot or chair at the bedside and a shared bathroom and shower.

Firstly, our number one concern is how will we fairly allocate patients to either NICU North or NICU Open Bay during the time of construction? It is our assumption that most families if given the choice would choose the single family room. This will not be an option for everyone until one year later.

We are proposing that we randomly assign patients to one of the two options. If we are able to randomly assign patients/families to one of the two options we would also be in the position to measure and collect data on the two different type of units which is very exciting to us as we would be able to add to the current literature about NICU design and care in two very different environments.

We also feel that if this project was successful we would be able to continue to use it to balance census and acuity in both sites of our newly designed single room care unit. This we feel to be advantageous as it would help to staff the units fairly equally which will help with work load, resource management and safe delivery of care as both units would be resourced with staff of appropriate number and competency requirements.

What has been accomplished so far?

The following is a methodology to assignment patients to either the green proxy for (North Unit – single room) or red teams (proxy for Open Bay sites). We are hoping to use a weighted random assignment based upon current number of patients on each team and the daily set workload measurements for each team. It requires data to be entered in a small database by the ward clerks for each admission and each discharge. At the end of the night shift, the charge nurse for each team assigns nursing workload for each patient. It is these measurements that will be used in the calculations found below. We may decide it best to enter this data twice a day rather than once as it would improve accuracy. Twins, triplets, etc will be randomized to the same unit.

We are proposing for those admitted from Labour& Delivery Room or through IWK transport who are palliative care patients they will be automatically assigned to the single rooms. Once there are no vacant single patient rooms left, these infants will go to the open bay unit until a single patient room becomes available. Of course this will be based upon parent preference as to open bay or single room for the palliative care population.

Who is this going to affect?

All patients, families, staff and physicians of the NICU

How? Who has been involved?

This idea has been presented to the team on a number of occasions. Conducted the ethics consult. Now in the process of gaining family and public feedback and ideas.

What is your timeline?

As soon as this project was to be complete we would put it into action in our current unit as a way to trial and work out any obstacles. We could potentially trial it for 1 year before moving into the new space. We would take the 2 open bay units and use the model to randomly assign the patients to one of the 2 open bay units. We could see if the randomization with the weighted processes will allocate patients to teams where census and acuity are balanced. We would then be able to work through any concerns before going live in the newly redeveloped unit. As I also indicated we would then recommend if the process worked to have this as our daily operation as to how to balance the 2 new single family room units.

Specifically, what kind of feedback, or where are you looking for feedback from IWK patients/families?The Family Leadership Council's Family Advisors will receive this template ahead of your consult in order to be prepared to provide the most helpful feedback possible.

We are looking for a critical assessment of what we are proposing and are willing to consider any options brought forth to us for discussion and consideration.

FOLLOW UP

The Family Leadership Council is interested in knowing if the information/feedback you obtained was helpful and met your objectives. We are interested in knowing the impact it had on your project/initiative? The Coordinator will contact the most appropriate person in 2 – 3 months time to discuss this with you. Please provide the name and contact information.

Please ensure your request is submitted a minimum of <u>one week</u> prior to an FLC meeting (held second Wednesday of each month, except July/Aug/Dec). We cannot guarantee late submissions will be added.Direct submissions or questions to Theresa Rogers at 470-6896.

Record of Family Leadership Council Consult

TITLE OF CONSULT: Neonatal Intensive Care Unit (NICU) Renovations

DATE OF CONSULT: January 20, 2016

PRESENTOR: Dr. Mike Vincer, Neonatologist
Darlene Inglis, Manager, Neonatal Care Team
Members of the NICU Team

BRIEF SUMMARY OF CONSULTATION: The NICU is undergoing a major redevelopment in the next three years and will be moving toward providing care in Single Family Room units. Before the completed renovation, there will be both a Single Family Room Unit and an Open Bay Unit. During this transition period, NICU is proposing that the decision about where babies will be admitted (Single Family Room Unit or the Open Bay unit) be determined by random assignment.

REQUEST TO THE FAMILY LEADERSHIP COUNCIL:

"We are looking for a critical assessment of what we are proposing and are willing to consider any options brought forth to us for discussion and consideration"

FAMILY LEADERSHIP COUNCIL COMMENTS/ SUGGESTIONS /RECOMMENDATIONS:

Comments:

- Appreciate having the 8 options presented as it helped shape the option chosen. A lot of thought went into this proposal.
- Randomization seems very logical. The care is the same regardless of Unit.
- Had experience with Open Bay and liked it because felt safe – everyone was around
- NICU has great staff – ensure all are on board when this is rolled out.
- The analogy of 'white marbles / black marbles" helped clarify how randomization works and may be useful if explaining this concept to other non-clinical folks in the future

Suggestions:

- "Out of town" patients be given preference for the Single Family Room unit. Would need to define what is considered 'out of town'
- NICU should reach out to existing parent groups (e.g. POMBA) for input
- Consideration should be given to how "Parents" will be defined. The person staying 24/7 with the patient may be a close relative or guardian, for example.

Recommendations:

- Committee agreed with random assignment to Single Family Room or Open Bay Unit
- Agree with palliative care babies being automatically assigned to Single Family Rooms

We are interested in knowing if the feedback you received was helpful and met your objectives. We would also like to know the impact it had on your project/initiative. The Coordinator will contact **Darlene Inglis in May, 2016** *for a status report.*

Appendix 3: Example calculation of the algorithm

Let us assume for the moment that the Green Team has 21 infants on the service and the Red Team has 17 infants on the service;

1. The Green Team has $^{21}/_{38} = 0.553$ (55.3%) of the census
2. The Red Team has $^{17}/_{38} = 0.447$ (44.7%) of the census.
3. Now let us assumed that the WANNNT indicates that the Green Team requires 8.9 nurses for the upcoming shift and that the Red Team requires 10.9 nurses for the upcoming shift;
4. The Green Team requires $^{8.9}/_{19.8} = 0.449$ (44.9%) of the nurses for NICU for that shift;
5. The Red Team requires $^{10.9}/_{19.8} = 0.551$ (55.1%) of the nurses for NICU for that shift.
6. Now the method of measuring the "effort level" for the Green Team is:

   $^{1}/_{3} \times 55.3\% = 0.184$ effort for census
   $^{2}/_{3} \times 44.9\% = 0.300$ effort for WANNNT

   Total = 0.484 (48.4%)

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7. Now the method of measuring the "effort level" for the Red Team is:

   $^{1}/_{3} \times 44.7\% = 0.149$ effort for census
   $^{2}/_{3} \times 55.1\% = 0.367$ effort for WANNNT

   Total = 0.516 (51.6%)

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8. This means that with a simple randomization that the Red Team would have a 48.4% chance of getting the next infant while the Green Team would have a 51.6% chance of getting the next infant admitted to the NICU (figure 3; simple randomization).
9. It was discovered very soon after implementing the above weighted randomization that the teams remained relatively unbalanced so it was felt that a modification to the simple randomization was required. Therefore, it was intuitively felt that an "S-shaped" curve in which the effort level was on the X-axis and the percent probability of allocation to one of the teams was on the Y-axis (the figure; weighted randomization). The NICU Allocation Administrative Group elected to use the following mathematical formula to define this "S-shaped" curve:

   $$\% \text{ allocation} = (e^{(8 \times \log10(x/(100-x)))})(1+e^{(8 \times \log10(x/(100-x)))})$$

   Where x was the computed simple randomization noted in points 7 and 8 above.

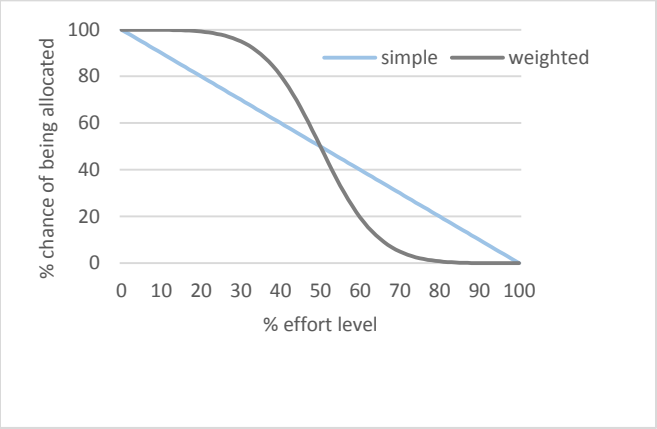

Figure (Weighted randomization): % effort level of a team vs % chance of next patient being allocated to that team

APPENDIX 4: Calculation for gestational age

(This version, revised 16 December 2008, was developed by Dr. Alexander Allen for the Reproductive Care Program of Nova Scotia and subsequently adopted by the Perinatal Follow-Up Program)

Algorithm for Estimation of Gestational Age in Canadian Perinatal Databases Introduction

Gestational age of a pregnancy and newborn is an important determinant of maternal and newborn outcomes. It is important in determining the timing of interventions as well as the understanding of perinatal issues within centres and in making comparisons between centres and provinces / territories. With the introduction of ultrasound dating of pregnancies, numerous methods are now used in Canada for estimating gestational age. Fetal ultrasound dating has become increasingly available and now is sufficiently common in Canada to be helpful in estimating gestational age in maternal and newborn research studies as well as descriptive studies of maternal and newborn health and disease. To this end, there would be considerable advantage in having a consistent method for estimating gestational age using the date of conception (when known), date of last menstrual period, fetal ultrasound dating, physical examination of the infant shortly after birth and obstetric best estimate before delivery. The purpose of this document is to achieve consistency in estimating gestational age for databases across Canada through consensus so that a standardised algorithm is used for clinical purposes, research and comparison studies. Note that in some situations the term, "completed weeks", is used because of the general inaccuracy of the estimate and, in this algorithm, "completed weeks" should be regarded as a block of 7 days[1]. However, except for certainty levels 5 and 6 below, all estimates of "Best Estimate" of gestational age are expressed in weeks and days. In developing the following algorithm as proposed, data would be recorded at the time of data entry and then a standard algorithm, using the best available evidence, would be applied to these data to give the "Best Estimate" of gestational age. Hopefully in the future, this will become the standard for estimating gestational age in Canada.

Data To Be Recorded in All Pregnancies, Including the Documentation of Unknown Values

1. Date of the last normal menstrual period, when known (LMP).
    a. Estimated date of delivery, commonly known as "EDC" = the date of the first day of the LMP 'plus' 280 days.

2. Usual cycle length, when known, is used to calculate the EDC corrected for cycle length (CorrEDC).
    a. CorrEDC = EDC 'plus' (aver cycle length in days) 'minus' 28 days.
    b. When not known, the CorrEDC is based on the EDC without correction.

3. Date of conception, only if determined by artificial reproductive technology (ART) measurement, when available.
    a. When correctly documented by ART, this provides the more reliable estimate of gestational age.
    b. ART-EDC = (date of conception) 'minus' 14 days 'plus' 280 days.

c. If the woman underwent *in vitro* fertilisation with embryo-transfer, then ART-EDC = (date of embryo-transfer) 'minus' (age of embryo at transfer) 'minus' 14 days 'plus' 280 days (see ref. 6).

4. Date, type of ultrasound procedure (i.e., vaginal or trans-abdominal), and gestational age at the time of the first (earliest) fetal ultrasound examination.
    a. If the first fetal ultrasound was done before 8 completed weeks (based on LMP) and was not vaginal, then in addition record the first fetal ultrasound after 8 completed weeks (based on LMP).
    b. If ultrasound exam was not done before 8 completed weeks, then record the first vaginal or transabdominal ultrasound between 8 and 24 completed weeks (based on LMP).

5. Neonatal clinical estimate of gestational age from neonatal physical exam at birth expressed in completed weeks (see refs. 1 and 9).

6. Obstetric clinical estimate of gestational age based on whatever clinical criteria are available before birth expressed in completed weeks.

Algorithm for Deriving the "Best Estimate" of Gestational Age at Birth Depending on Which of the Above Recorded Information Is Known and Available

As the algorithm moves from certainty levels (algorithm steps) 1 to 6 below, increasingly less information is available and, as a consequence, the "Best Estimate" of gestational age is increasingly less reliable. The level of certainty, as indicated by the step in the algorithm used to determine the gestational age, should be recorded.

Step 1: When the Date of Conception is known and correctly documented by ART, the "Best Estimate" of gestational age is computed as the (date of birth) 'minus' (date of conception) 'plus' 14 days.
    a) If the individual underwent *in vitro* fertilisation with embryo-transfer, then the gestational age is computed as the (date of birth) 'minus' (date of embryo-transfer) 'plus' (age of the embryo at the time of transfer) 'plus' 14 days.

Step 2: If the date of conception is not by ART and if the early fetal ultrasound[2] and the CorrEDC are available, the "Best Estimate" of gestational age is based on the LMP corrected for cycle length validated by the early fetal ultrasound dating, if:
    a) at <14 completed weeks (based on LMP), the CorrEDC is # 5 days of that computed from the fetal ultrasound measurement,
    b) at 14 to 17 completed weeks (based on LMP), the CorrEDC is # 7 days of that computed from the fetal ultrasound measurement,
    c) at 18 to 20 completed weeks (based on LMP), the CorrEDC is # 10 days of that computed from the fetal ultrasound measurement, or
    d) at 21 to 24 completed weeks (based on LMP), the CorrEDC is # 14 days of that computed from the fetal ultrasound measurement.

Otherwise, the "Best Estimate" of gestational age below 25 completed weeks is based on that gestational age computed from the fetal ultrasound measurement. Ultrasound dating after 24 weeks is not useful. In the case of multi-fetal pregnancies, the ultrasound measurement of the smaller fetus in one study was found to be more reflective of the gestational age of the pregnancy (see ref. 7). In conditions where fetal size is affected by the underlying disorder, such as hydrops fetalis, or where there are large differences in estimates of gestational age, ultrasound dating may not be appropriate.

Step 3: If early fetal ultrasound[2] is not available and if the gestational age based on the CorrEDC is within 20 days of the clinical estimate of gestational age from the neonatal physical exam, then the gestational age at birth based on the LMP corrected for cycle length is the best estimate. However, if the gestational age based on the CorrEDC is not within 20 days of that based on the neonatal physical exam, then the best estimate of gestational age is based on the clinical estimate of gestational age from the neonatal physical exam.

Step 4: If none of the above information is available and the estimate of gestational age by neonatal physical exam is known, then the "Best Estimate" is equal to neonatal clinical estimate of gestational age in completed weeks.

Step 5: If none of the above information is available and the obstetric clinical estimate of gestational age is known, then the "Best Estimate" is equal to the obstetric clinical estimate of gestational age in completed weeks.

Step 6 If none of the above information is available, then the estimate of gestational age is recorded as unknown.

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foot notes

1 For example, 40 completed weeks is a block of 7 days, 40 weeks 0 days to 40 weeks 6 days; less than 40 completed weeks is 39 weeks 6 days or less; and more than 40 completed weeks is 41 weeks 0 days or more.

2 "Early fetal ultrasound" is defined as the first vaginal fetal ultrasound before 8 completed weeks (based on LMP) or, if not available, the first vaginal or trans-abdominal fetal ultrasound at 8 to 24 completed weeks (based on LMP).

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APPENDIX 5: Consent for participation in the Perinatal Follow-Up Program

Participation in the Perinatal Follow Up Program

The purpose of the Perinatal Follow−Up Program has been explained to me in the information provided and from discussions with the Perinatal Follow−Up Program team. I understand that information collected during my child's visits to the Perinatal Follow−Up Program will be added to the Perinatal Follow−Up Program Database. This consent also authorizes the Perinatal Follow−Up Program team to access information from my child's home hospital health records and this information may also be included in the PFUP database. Information related to my pregnancy for my child may also be included.

I understand that all information collected about my child, in paper or electronic format, will be maintained confidentially, according to IWK Health Centre security and confidentiality standards. I understand that for research protocols, information from the Perinatal Follow−Up Program may be used for research only with the approval of the Research Ethics Board of the IWK Health Centre. I understand that information from the Perinatal Follow−Up Program may also be used to describe outcomes for children in general terms only, such as survival rate in premature infants, the average height in low birth weight infants, etc. No personal information will be released that would identify my child or family.

I understand that I may request and review any of the information collected about me or my child. I also understand that if I request to withdraw from the Perinatal Follow−Up Program, no further information will be added to the database. If I have any questions about the information collected about me or my child, the contact person in the PFUP is Dr. Michael Vincer.

I agree to have my child participate in the Perinatal Follow−Up Program, which includes the addition of information to the Perinatal Follow−Up Program database. I have read and agree with the above disclosure.

Signature (Parent or Legal Guardian)	Printed Name (Parent or Legal Guardian)	Relationship to the Participant

Signature (Person Obtaining Consent)	Printed Name (Person Obtaining Consent)	Date