Resuscitation and Early Stabilization Improvement in Newborns (RESIN program)

1: APPLICATION FORM

Letter of support

2: EXECUTIVE SUMMARY

Preterm birth is the most important cause of perinatal mortality and long-term neurodevelopmental morbidity. It complicates 76 of every 1000 births in Canada, and its incidence has risen over 30% during the past 2 decades. The costs of preterm birth are estimated to exceed $1 billion annually in Canada and include Neonatal intensive care unit (NICU) care, which is complex, expensive and often prolonged.

This knowledge translation program aims to implement a 'resuscitation and early stabilization (Golden hour) care bundle' consisting of seven evidence based quality improvement interventions in preterm infants of ≤32 weeks gestational age (GA) and being born in McMaster University Medical Center (MUMC). Neonatal caregivers (approximately 240) and preterm infants born in MUMC (approximately 150/ year) will be the target population for these interventions. The interventions focus on adoption of state of the art practices, improving caregivers' education and training in teamwork and avoiding errors, strengthening monitoring and feedback processes on caregivers' performance and standardizing caregivers' roles during stabilization. Individual interventions will be led and supported by RESIN program's multidisciplinary team members. Effectiveness of implementation and impact of this program will be evaluated by comparing pre and post intervention outcomes. Based on preliminary work from RESIN team, this program is highly relevant to MUMC and appears feasible and sustainable. Mitigation strategies for foreseeable risks have been identified and stakeholder consensus and commitment have been established.

Implementation of this care bundle program will result in better clinical outcomes than implementing them individually. It will also lower the cost of care, enhance patient safety and quality of care, and improve provider and parent satisfaction. RESIN program interventions can easily be rolled out to other perinatal centers in our region as well as other centers across Canada.

3: RESEARCH PLAN

BACKGROUND

Preterm birth is the most important cause of perinatal mortality and long-term neurodevelopmental morbidity. It complicates 76 of every 1000 births in Canada, and its incidence has risen over 30% during the past 2 decades (1). The costs of preterm birth are estimated to exceed $1 billion annually in Canada and include Neonatal intensive care unit (NICU) care, which is complex, expensive and often prolonged(2).

Clinical care setting

MUMC is a high risk obstetric referral and delivery centre for a population of over 2 million in Central Southern Ontario. Nearly 150 out of 3000 deliveries/year in MUMC are $\leq$ 32 week preterm deliveries. A 47 bed NICU is situated across the hallway from labor and delivery suite. These preterm infants often require lifesaving therapies such as ventilation, chest compression, and medications to support heart rate at delivery [resuscitation] and are invariably transferred to neonatal intensive care for subsequent management. Management during first few hours [early stabilization period or Golden hour] involves performing multiple procedures and investigations, extensive handling, and invasive and non-invasive monitoring, and titrating treatment according to infant needs This period has been described as intense, chaotic and prone to error and miscommunication, and requiring coordination of multiple caregivers(3).

Preterm deliveries in MUMC are typically attended by the neonatal resuscitation team composed of a physician (neonatologists, fellows, and/or residents), nurse practitioner (NP), registered respiratory therapist (RRT) and registered nurse (RN). After resuscitation, the resuscitation team transfers the infant to NICU and collaborates with NICU caregivers in completing early stabilization. All neonatal caregivers are suggested to have a 2 yearly refresher course in American Academy of Pediatrics-Neonatal Resuscitation Program (NRP), which is a standard curriculum to teach caregivers about treating newborns in delivery room(4). There are 120 caregivers in the resuscitation team and 140 caregivers in NICU. Given the preterm infant's size and gestational age, deviation of treatment will have significant negative repercussions on infant's outcome. The organization of the teamwork and collaboration, ensuring consistency of care, and minimizing complications arising out of initial care are crucial for improving quality of care and outcomes in preterm infants.

Clinical problem or gap in care

Care practices during resuscitation and the early stabilization period have a significant impact on preterm infant's mortality, morbidity and long term neurodevelopmental outcomes (5-8). Ventilation, oxygen administration, team work, NICU and developmental supportive care (DSC) constitute the major care categories during this period. Significant gaps can exist in each of these practice categories:

Ventilation: Large volume inflations, repeated inflation of a collapsed lung due to lack of peak end expiratory pressure (PEEP), hypocarbia secondary to hyperventilation, inadequate ventilation due to face mask leaks and significant hemodynamic instability during intubation and surfactant administration, have all been associated with lung injury, poor response to resuscitation and adverse neurodevelopmental outcomes (9).

Oxygen administration: Free radical damage due to hyperoxemia with resultant BPD and ROP is well recognized (8, 9). NRP suggests using pulseoximetry in delivery room and using room air

to initiate positive pressure ventilation, neither does it specify the target SpO2 values or process of titrating oxygen administration resulting in inconsistency in practice(4)

Teamwork: Teamwork related factors have been correlated with poor quality of neonatal resuscitation, and perinatal deaths and injuries (10, 11). Deviation from NRP (12) and lack of teamwork and situational awareness (4) are common issues during resuscitation. Lack of teamwork and human error curriculum in NRP, inadequate simulation based learning, nonexistence of processes to identify and address errors systematically are often the root causes of poor teamwork

Standardization of roles and procedures: Unlike NRP, no standard curriculum exists for early stabilization of preterm infants. Lack of clarity on individual team member roles and prioritization of events lead to inconsistency in care.

Developmental supportive care (DSC): DSC has been shown to decrease length of hospital stay and costs, improve weight gain, time to full enteral feeding and neurodevelopmental outcomes. However guidelines as to how early and efficiently the practices should be initiated is not well defined (13, 14). This often results in delayed or inconsistent delivery of DSC practices in NICU

Data from MUMC on preterm infants' resuscitation, early stabilization and outcomes

Data from our own center demonstrates the existence of previously discussed clinical problems. The resource intensiveness of resuscitation and the early stabilization period, and the morbidity in this patient population are also significant.

A needs analysis survey was conducted in Jan 2010 in MUMC among neonatal resuscitation team members to estimate the extent of clinical problems related to resuscitation and stabilization of preterm infants. Significant deficits in standardization of procedures and roles, teamwork training and practice, and lack of monitoring and feedback processes were highlighted by majority of responders. Guidelines on important practices were unavailable, PEEP was not administered effectively and pulseoximeter use was inconsistent (Appendix 1). Previous years' data show that approximately 150, ≤ 32 weeks GA preterm deliveries occur every year in MUMC. Among them 98%, 95% and 60 % of them receive umbilical lines, ventilation and surfactant respectively, with a NICU stay of 14- 140 days (Appendix 2) (15). Five percent of these infants die before discharge and 3 -22% of them have one or a combination of major morbidity like bronchopulmonary dysplasia (BPD), Retinopathy of prematurity (ROP), intraventricular hemorrhage (IVH), Nosocomial infection (NI) or necrotizing enterocolitis (NEC) (15). The incidence of NI, IVH and mortality in MUMC are above national averages (16).

Criteria for appropriateness of care

Neonatal resuscitation program serves as the standard guideline for resuscitation practices. However abundant literature is available on newer ventilation devices, appropriate oxygen administration criteria, teamwork training, monitoring and feedback (9, 17, 18). Similarly there are many studies on care bundles during first hour of preterm infant's life leading to better clinical outcomes (19, 20). However the interventions in these care bundles are variable and are dependent on individual center's need. Thus quality improvement interventions need careful selection, customization and strategic implementation to achieve desired outcomes.

Evidence that the proposed problem to be addressed is an important issue to address by the team and the program involved

Data from MUMC NICU demonstrate that the volume of preterm infants is significant and these infants have significant morbidity. Our needs analysis survey highlights the existent gap in care

in our center. These gaps are likely to be compounded when a large number of caregivers are involved. If unaddressed, the persisting problems are a constant threat to patient morbidity and mortality, patient safety, excess resource utilization, and parent and provider satisfaction. Moreover they can affect our center's credibility and ratings during accreditation when compared to our peers.

PROPOSED KNOWLEDGE TRANSLATION (KT) SOLUTION

This knowledge translation program aims to implement a 'resuscitation and early stabilization care bundle' consisting of seven evidence based quality improvement interventions in preterm infants being born in MUMC. This care bundle has been specifically customized to MUMC setting. Neonatal caregivers and preterm infants born in MUMC will be the target population for these interventions. The interventions focus on adoption of state of the art practices, improving caregivers' education and training in teamwork and avoiding errors, strengthening monitoring and feedback on caregivers' performance and standardizing caregivers' roles and stabilization processes. These interventions are customizable to MUMC and can easily be integrated into existing care.

Hypothesis: The seven proposed interventions under RESIN program are either not practiced or practiced inconsistently in MUMC. Adopting these interventions and customizing them to suit MUMC context, is likely to produce a synergistic effect with measurable improvement in patient outcomes. However the end result will be dependent on effective implementation and demonstration of benefits of individual interventions

Rationale and evidence to support the KT solution: Executing a group of interventions (care bundles) will result in better outcomes than implemented individually (21, 22). This process allows bundling of education, training, change management and implementation strategies to lower costs and time spent in implementing individual interventions. We believe that implementation of RESIN program and developing a skilled-coordinated and collaborative care team, will produce better clinical outcomes, lower cost of care and enhance patient safety and quality of care.

The rationale and evidence for each intervention and a 'care bundle' to support adoption of these practices is provided in Table 1 and Figure 1. In brief these interventions have shown to improve teamwork, minimize lung injury and improve patient safety and quality of care. Well conducted clinical studies have shown significant reduction in incidence and severity of BPD, duration of mechanical ventilation and time to full enteral feeding by adopting care bundles (19,20)(36,37)

Target population: All MUMC resuscitation team members (approx 120), NICU bedside nurses (approx 120) and preterm infants of ≤ 32 weeks born in MUMC (approx 150/year)

RESIN program care bundle interventions: All resuscitation team members will receive: (i) in-service on using T piece resuscitator and pulse oximeter during resuscitation, (ii) training in team behavior and human error curriculum, (iii) feedback on actual neonatal resuscitation performance, (iv) education on individual member tasks, time to task completion and clinical practice guidelines related to resuscitation and early stabilization. All bedside nurses in NICU will receive: (i) education on individual member tasks, time to task completion and clinical

practice guidelines related to resuscitation and early stabilization, (ii) DSC practices that should be initiated immediately after early stabilization. All preterm infants will receive care in a setting where: (i) Ventilation pressures and oxygen administration are regulated and monitored, and (ii) resuscitation and initial care in NICU is closely monitored and well coordinated.

Milestones and timelines: RESING program projects will be implemented over three phases; Preparation, Go-live, Evaluation phases. Please refer to Appendix 3

Primary objective: Determine the effect of RESIN program on the proportion of preterm infants who remain extubated at 72 hours of life

Evaluation: The effect of RESIN program will be evaluated by comparing post intervention outcomes (2011-2012) with baseline outcomes (2009-2010).

Outcomes, collection and measurement (EVALUATION FRAMEWORK)
Primary: Proportion of preterm infants not intubated at 72 hours of life. Data will be collected by a research assistant at the bedside
Secondary:

- Global RESIN program outcomes
    - Patient outcomes: Incidence of death, BPD, ROP, NI, NEC and IVH before first discharge from NICU. Data will be obtained from existing Canadian neonatal network (CNN) database in the unit. Data is collected by CNN abstractors
    - Process outcomes: pCO2 at admission; first 24 hours data on Max pressure and FiO2 used, episodes of pCO2 < 40, hypoxia and hyperoxia duration, severity of illness and age at first extubation. Data will be collected by research assistant by reviewing patient flow sheets and discussing with bedside nurse.
    - Resource utilization: Length of NICU stay and mechanical ventilation, surfactant use. Data will be obtained from CNN database
    - Variation in practice patterns: Indication for surfactant, extubation, intubation: Data will be collected by research assistant at the bedside
    - Care givers' satisfaction: Feedback on education and training experience from care givers during training and debriefing sessions
    - Adverse events: Number of system issues/individual concerns identified and effectively addressed. These events will be collated from existing data collection forms and feedback given to RESIN team members by research assistant.
- Individual intervention in RESIN program outcomes:
    - Effect of individual interventions- Adherence to NRP guidelines, demonstration of team behaviors, time to task completion, adherence to clinical practice guidelines, pulseoximeter histogram, and number of pokes, handling and skin breakdown in first 24 hours
    - Effectiveness of implementation-Proportion of preterm infants where T-piece resuscitator/ pulseoximeter/ appropriate DSC were used/offered, educational experience of caregivers and extent of awareness of RESIN program.

  All evaluations will be based on data collected from RRTs, research assistant, participants' feedback and video recording assessment by instructors

Methodology/Implementation strategy: Individual project leads will collaborate with RESIN team members and other stakeholders in developing or modifying the published guidelines to suit the RESIN program in MUMC. They will develop knowledge translation dissemination and implementation strategies. On implementation of projects, the leads will supervise the implementation process, data collection, identify and address system issues and individual concerns as they arise. Finally progress will be shared among RESIN team members and CHORD steering group at regular intervals.

Video recording and audio video feedback of neonatal resuscitation performance (project 4):
A high definition video recorder will be permanently mounted above the radiant warmer in the main obstetrical operating room and one delivery room suite. It will be zoomed to provide a field of view that includes the entire infant and hands of resuscitation team members. The video recorder will be operated by RRT. All video recordings will be transferred to the HHS secure server by the research assistant once a week and no recordings on recorder will be erased. The video recording will be reviewed by a team of trained instructors from RESIN team. These instructors will also moderate a debriefing/feedback session every 2 weeks, which will be open for all NICU caregivers and learners (12, 23, 24).

Sample size calculation: We predicted that the RESIN program interventions would increase the proportion of preterm infants' not needing intubation at 72 hours by 10%. With a 80% incidence of preterm infants not needing intubation at baseline, an α value of 0.05, a β value of 0.2, we will have 80% power to evaluate the impact of RESIN program over 2 years

Statistical analysis: All outcomes will be noted at three time points; baseline, at the end of first year and second year. To answer the primary objective, we will use logistic regression with the probability of being intubated beyond 72 hours as the response, and time point as a covariate. We will also adjust for confounders. Logistic regression accounting for time point will also be used for those secondary outcomes that are binary. Linear regression, coupled with a non-parametric bootstrap should the residuals show evidence of non-Normality or heteroscedascity, will be used for outcomes that are ordinal or continuous. These regressions will be adjusted for confounders.

Safety and monitoring: System issues and individual concerns identified during training and education will be effectively addressed before launching the program. Program leads will review adverse events and safety concerns every 3 months related to their projects and report to RESIN team members and CHORD steering committee every 6 months.

Risks and mitigation: There are no anticipated risks in this program. However video recording of resuscitation may cause anxiety for care givers and family for breach of confidentiality and infringement of privacy. Caregivers may be worried about video recordings being used for medico legal or disciplinary purposes (23, 24). These issues will be addressed by educating care givers on the measures that will be followed to protect anonymity and allowing them to experience video recording during their training. Institutional support (senior executives, medical advisory committees, quality care committees, risk management committees) and medico legal privileges for quality improvement programs will be utilized. Importance of subjecting our performance to quality assurance activities will be stressed to care givers. If a caregiver refused

to participate, we plan not to make video recording of these deliveries. We plan to erase the records after debriefing meetings to mitigate the risk of disclosure.

Recruitment: All eligible care givers will be approached by RESIN team members and will be requested to participate in training and education related to RESIN program. Families will receive the information on video recording, as soon as they arrive in labor and delivery room. They will subsequently be contacted by a RESIN team member to take consent.

Consent: RESIN team member will prospectively seek parental permission where possible. Where impractical to do so, we would record the resuscitation, and subsequently explain the study to parents and seek their permission to view the recordings. Should they not permit us to view them; we propose to erase them without review. Should they permit us to view them; we propose to seek their written permission to retain recorded material for educational purposes.

Research ethics board: In a preliminary discussion, REB vice chair advised us that the approval was not necessary for this quality assurance activity. However we plan to take REB approval, in anticipation of a publication.

Personal health information: Direct identifiers of infant will be collected initially. However we propose to remove the patients' identifiers and replace them with codes after the debriefing meetings (2 weeks from birth date). These codes will be kept separate from the de identified patients' data till the data is safely destroyed after completion of this program

Storage and protection of information: All paper files will be stored in a secured, locked cabinet. All electronic files with identifiable information will be stored on a password protected computer on a secure network by taking help from HHS information and communication department. Video recording will be stored on HHS server. Access will be password protected and limited to RESIN team members.

How appropriateness criteria will be fulfilled

Neonatal resuscitation program (4), team behavior skills set (10,25), DSC practices core measures (14) and prescribed task completion times (26) and guidelines for ventilation and oxygen administration (27) described in standard curriculum and recent studies will be used to determine the appropriateness criteria and identify relevant indicators. Educational experience with training and debriefing process will be measured on previously validated tools (12).

Appraisal and consensus of interpretation of the clinical evidence for the HHS context

A body of evidence assessment matrix will be used to determine the appropriateness of adopting a practice to MUMC context (28). Only 'evidence that can be trusted to guide practice in most situations' has been selected in RESIN program. Individual project leads would work closely with relevant stakeholders to arrive at a consensus on customization of projects to suit HHS needs. The customized version of each project will be rehearsed to address system issues and individual concerns before going live.

EVALUATION FRAMEWORK- The effect of RESIN program will be evaluated by comparing post intervention outcomes (2011-2012) with baseline outcomes (2009-2010).

Please refer to section on outcomes, collection and measurement and Figure 1
Milestones and timelines- Please refer to Appendix 3

FEASIBILITY
In anticipation of this program, our teams of researchers have done important groundwork that makes it feasible for us to achieve the objectives of the proposal. These include;
Progress towards

1. Establishing a RESIN team by inviting experts from MUMC neonatal quality improvement, mock resuscitation, respiratory care and developmental supportive care.
2. Identifying data from our practice setting to demonstrate the existence and magnitude of clinical problems (Appendix 1: Needs analysis survey results)
3. Reviewing the body of evidence related to resuscitation and early stabilization and identifying practices appropriate for adoption in our setting in the form of a care bundle(45)
4. Building consensus and support among all stakeholders for proposed interventions (Support letters from neonatal division chief, Obstetric team, risk management, ICT department, McMaster Computer services unit, internal legal counsel, statistician, privacy officer, research ethics board are available on request)
5. Identifying evaluation tools to measure the extent of implementation, effect of individual interventions and 'care bundle'
6. The care bundle contains 7 projects integrated by the Promoting Action on Research Implementation in Health Services (PARIHS) framework which would ensure successful implementation of practice change (29).

POTENTIAL BENEFIT OF CARE:
This integrated program will result in meaningful reduction in the delivery of inappropriate practices like non provision of PEEP and unwarranted oxygen administration during resuscitation. RESIN care bundles will have a synergistic effect in reducing the level of sickness during initial stay in NICU. This would then translate into better patient outcomes and decrease length of hospital stay and duration of ventilation. Implementation of RESIN program care bundles will result in better clinical outcomes than implementing them individually. A 10% reduction in length of hospital stay in 25% of the preterm infants will translate into an estimated $300,000 savings per year for the hospital. A 10% increase in proportion of preterm infants being discharged from hospital without major morbidities will translate in to significant cost savings for health care system. Better teamwork achieved through this program would have a spill over effect on quality of resuscitation of all late preterm as well as term infants in MUMC. RESIN program care bundle is innovative and can easily be rolled out to other perinatal centers in our region as well as other centers across Canada.

SUSTAINABILITY
We anticipate establishing a well defined mechanism for training, monitoring and improving caregivers' performance during resuscitation and early stabilization. Interest and awareness generated during RESIN program will enable to integrate RESIN care bundles into existing NICU work groups; mock resuscitation, quality improvement and policies and procedures committees.

Figure 1: Evaluation framework

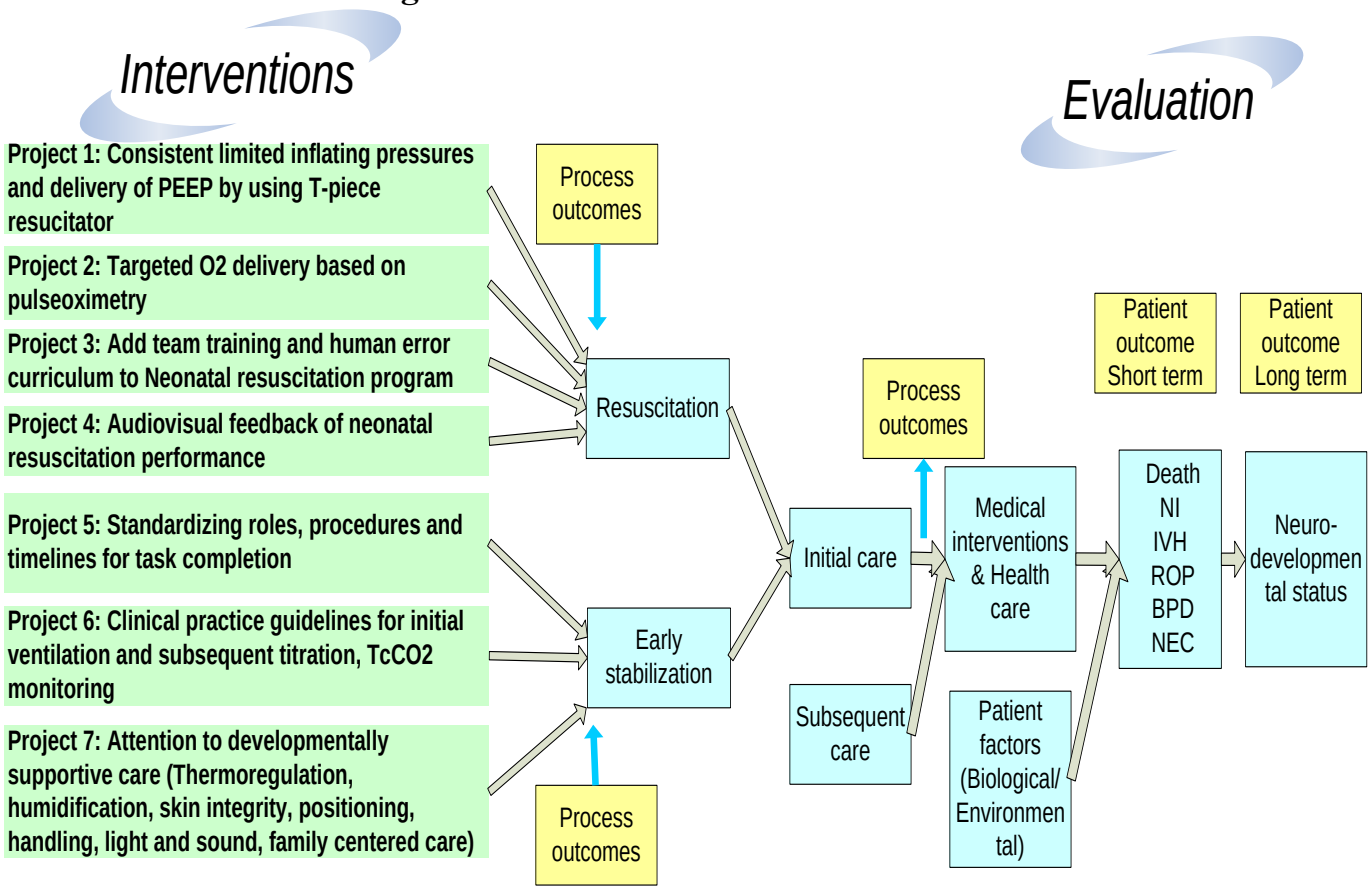

Table 1: Rationale and evidence for projects in RESIN program

Project	Rationale
1 (30-33)	Minimize lung injury, facilitate lung recruitment, prevent face mask leaks and facilitate controlled safer resuscitation
2 (8,27,34)	Avoid hyperoxia or hypoxia related organ injuries
3 (25,35,36)	Promote teamwork, minimize errors, improve emergency preparedness and improve quality of health care
4 (12,23,24,37,38)	Create positive effect on skill acquisition, retention, modification and application in real life situation. Identify and address management errors systematically
5 (26,39,40)	Allow delegation and channeling different caregiver roles to attain a common goal and covert chaotic environments into structured environment. Facilitate situational awareness, communication and team coordination. Minimize persistent handling of infants and reduce time to stabilization by clustering activities
6 (26,39,40)	Allow team members to adopt uniform approach for better outcomes. Allow easy identification of deviation of practice and facilitate discussion among members
7 (13,14)	Minimize potential short and long term complications associated with the hospital experience. Provide structured, care environment which supports, encourages and guides the developmental organization of preterm infants

References for 'care bundles during resuscitation and stabilization of preterm infants' (19, 20)

4: BUDGET TEMPLATE AND JUSTIFICATION

HAMILTON HEALTH SCIENCES
Office of Integrated Research Services - BUDGET FORM Template

CHORD Project Lead: Sandesh Shivanada Start date: July 2010						
Budget Details (insert or delete rows under sections as required)	START DATE DD/MM/YY	END DATE DD/MM/YY	CHORD CASH CONTRIBUTION	CHORD SUPPORT CONTRIBUTION	DEPARTMENT CASH CONTRIBUTION	DEPARTMENT SUPPORT CONTRIBUTION
A. PERSONNEL	Hours	Salary				
Review for this section is required by HHS Human Resources Mandeep Malhotra (malhotrm@hhsc.ca)						
Cash Costs:						
3 Nurse Practitioners	300	10,500	31,500			
Respiratory Therapist	100	7,500	7,500			
Research Assistant (salary plus benefits)	2000	55,000	50,000		5,000	
Program Support Contribution:						
QPSCRM:						
3 Nurse Practitioners	300	10,500		31,500		
PHRI:						
statistical analysis	400	20,000		20,000		
Other:						
Department of Pediatrics - Neotalogists (3	600	80,000				80,000
		Total Personnel	$89,000	$51,500	$5,000	$80,000
B. SUPPLIES (provide details and justification where relevant)						
Cash Costs:						
Supplies					5,000	
Neo puff circuits ($7 X 600 circuits)			4,200			
Program Support Contribution:						
		Total Supplies	$4,200	$0	$5,000	$0
C. EQUIPMENT (provide justification for equipment purchases of $600)						
Cash Costs:						
Audio visual recording equipment (2 sets)			45,000			
Computer and software			2,000			
Neo puff "T" piece resuscitator (4 @ $1500 ea.)			6,000			
Secure data storage			10,000			
Program Support Contribution:						
		Total Equipment	$63,000	$0	$0	$0
D. OTHER EXPENSES (eg. services, rental, etc.)						
Cash Costs:						
Stipends for resuscitation team members (120 memebers/6hrs each X$30.00/hr)			21,600			
Videos on Neonatal developmental care training (series - 6 CD's)			1,100			
Audio visiual teaching material production (2 large and 10 small scenerios)			20,000			
Program Support Contribution:						
Simulation lab rental fee (25 half day sessions @ $500/day)						12,500
Resuscitation and early stabilization workshops (QPSRM)				4,000		
		Total Other Expenses	$42,700	$4,000	$0	$12,500
		TOTAL CASH CONTRIBUTIONS	$198,900		$10,000	
		TOTAL SUPPORT CONTRIBUTIONS		$55,500		$92,500
TOTAL Project Cost			$356,900			
TOTAL CHORD REQUEST			$198,900	$55,500		
Budget Justification provided on Sheet 2 of this excel file						

Budget Justification

PERSONNEL

Primary investigator (0.1FTE X2years, 400 hrs) ($60000 for 2 years) [Department support contribution]

He will be in charge of program management, training, communications, database management, knowledge transfer and dissemination, interpretation and publishing of results. He will also be involved in planning and organization of the study and teams, literature review, establishing consensus among project leads and external stakeholders, managing funds and trouble shooting of problems. He will also be the lead for project 4

Neonatologist 2 (0.025 FTE X 2years, 100 hrs) ($10000 for 2 years) [Department support contribution]. He will lead the project 3.

Neonatologist 3 (0.025 FTE X 2years, 100 hrs) ($10000 for 2 years) [Department support contribution]. He will lead projects 1, 2 and 6

Nurse practitioner 1 (0.05 FTE X 2years, 100 hrs) ($10500 for 2 years) [CHORD cash contribution] She will lead project 5.

Nurse practitioner 2 (0.05 FTE X 2years, 100 hrs) ($10500 for 2 years) [CHORD cash contribution] She will lead Project 7.

Nurse practitioner 3 (0.05 FTE X 2years, 100 hrs) ($10500 for 2 years) [CHORD cash contribution] she/he functions as a knowledge broker.

Respiratory therapist (0.05 FTE X 2years, 100 hrs each) ($7500 each for 2 years) [CHORD cash contribution]

Research assistant (0.5FTE X 2years, approx 2000 hrs) ($55000) [CHORD cash contribution/Department cash contribution]

A research assistant will assist in taking consent (1 hour per patient=150 hrs/year), data collection (2 hr/patient=300 hrs/year), data entry into a database (1hr per patient==150 hrs/year), upload videos into secure server (0.5 hr per patient = 62 hrs/year)organize debriefing meetings (25 hrs per year), prepare project updates and newsletters monthly (100 hrs per year), collect and enter debrief meeting and team behavior training feedback from participants (35 hrs per year), prepare communication materials for training sessions, maintain an account of expenditure, liaise with all project leads, RESIN team members and stakeholders and will ensure completeness of data and data accuracy (100 hrs per year).

Resuscitation team members time to attend training sessions on team behaviors and human error curriculum (120 members, 6 hrs each = approx $ 21600)

Nurse practitioner 4, 5, 6 (0.05 FTE X 2years, 100 hrs each) ($10500 each for 2 years) [QPSRM contribution]. They will assist project leads in developing guidelines, protocols, training materials and literature reviews. They will act as instructors

Biostatistician (Hours to be determined but no less than 400) ($20,000 for 2 years) [PHRI contribution]. This quality improvement project requires a large volume of analysis using advanced statistical methods. An experienced biostatistician is needed to provide methodological expertise for all projects and to supervise data analysts. A constant stream of data analysis is required as results from each project feed into the next project for analysis. She/he will interface with project leads and research assistant and will assist in both methodological and analytic issues.

SUPPLIES ($5000 for 2 years) [Department of Pediatrics cash Contribution]

Materials, supplies and services

5: **APPENDICES**

Appendix 1: Needs analysis survey results related to RESIN program (Jan 2010)

	Description of current practices elated to preterm ≤ 32 weeks infants resuscitation and stabilization	Proportion of respondents
	Resuscitation practices in delivery room	
1	T piece resuscitator use for positive pressure ventilation	2 (4%)
2	T piece resuscitator mask CPAP use	3 (6%)
	Item 3-19 are based on likert scale assessment- Figures indicate proportion who reported disagree/strongly disagree	***disagree/strongly disagree***
3	Saturation probe is routinely applied	31 (57 %)
4	Guidelines exist on oxygen use	21 (39%)
5	Guidelines exist on CPAP use	31 (57 %)
6	Leader is identified routinely prior to resuscitation	33 (61%)
7	Member tasks are assigned routinely prior to resuscitation	29 (54 %)
8	Anticipated problems are discussed routinely prior to resuscitation	12 (22%)
9	Debriefing occurs routinely after every difficult resuscitation	33 (61%)
	Stabilization practices	
10	Optimal timelines for transferring infant to NICU is known	32 (59 %)
11	Optimal timelines for completing procedures is known	43 (80%)
12	Guidelines exist on mechanical ventilation and rescue surfactant use	27 (50%)
13	DSC is initiated routinely after stabilization	24 (44 %)
14	Transcutaneous CO2 monitoring occurs routinely	19 (35%)
15	Caffeine is administered routinely in < 1250g infants	26 (48 %)
	Training and feedback process	
16	Team behavior and error prevention training is routinely provided	23 (43%)
17	DSC training is routinely provided	23 (43 %)
18	Process to identify and address system issues and individual concerns during resuscitation and early stabilization exists	31 (57%)
19	Process to monitor and provide ongoing support in DSC practices exist	27 (50 %)

Total participants 54 (MD 5, RRT 13, NP 17, RN 19). 81% of respondents had >6 yrs of experience.
DSC=developmentally supportive care

Appendix 2: Annual data for preterm infants (≤ 32 weeks)*

Data	**Range**
No of deliveries in McMaster University medical Centre (MUMC)	120-150
No of calls for neonatal resuscitation team "To attend deliveries"	120-150
No of infants to be transferred to Neonatal Intensive Care Unit (NICU) from Labor and delivery (L&D)	120-150
No of infants who receive surfactant	70-90
No of infants who require intermittent positive pressure ventilation(IPPV) or Continuous positive airway pressure (CPAP) on Day 1	100-140
No of infants who require intubation and ventilation on day1	40-60
No of infants where umbilical line was established	120-150

***McMaster children Hospital NICU Fiscal year reports 2005-09**

Appendix 3: RESIN program milestones and timelines

Project	0-6months [Preparation phase]	7-12months [Go-Live phase]	13-18m	19-24months [Evaluation phase]
General (for all projects)	Develop/modify guidelines, curriculum, training material Consolidate RESIN team member roles and train instructors Create awareness of RESIN program among all stakeholders to ensure necessary support and active participation Collect baseline data Procure/install equipment Provide in-service to caregivers Identify and address system issues and individual concerns	Go-live with projects during resuscitation and early stabilization Identify and address system issues and individual concerns related to practice changes Compare outcomes with baseline		Compare pre and post intervention outcome changes and care providers experience
1	Procure 4 T-piece resuscitators	Go live with T piece resuscitator use		
2	Develop/modify guidelines on oxygen administration and target saturation levels in delivery room	Go live with mandatory saturation monitoring		
3	Develop scripts and produce teaching videos Develop a teaching curriculum	First session		Reinforcement session
4	Set up video recording device in delivery room Train instructors/team members	Go live with video recording and debriefing/feedback rounds		
5	Define member tasks and practice various scenarios to determine appropriate timelines for task completion			
6	Build consensus guidelines, disseminate widely	Go live		
7	Develop a short curriculum on initiating DSC immediately after early stabilization and its evaluation	Go live		

6: REFERENCES

(1) Canadian Perinatal Health Report - 2008 EDITION. 2008.
(2) Moutquin JM, Papiernik E. Can we lower the rate of preterm birth? Bull SOGC 1990(Sep):19-20.
(3) The Golden Hour, Implementing a Team Approach to Resuscitation of the Very Low Birth Weight (VLBW) Infant. The Preliminary Program for Association of Women's Health, Obstetric and Neonatal Nurses (June 21-25, 2008); 2008.
(4) Kattwinkel J, Short J, Shavell L editors. Text book of neonatal resuscitation. 5th ed. Elk Grove Village: American Academy of Pediatrics; 2006.
(5) Costeloe K, Hennessy E, Gibson AT, Marlow N, Wilkinson AR. The EPICure study: outcomes to discharge from hospital for infants born at the threshold of viability. Pediatrics 2000 Oct; 106(4):659-671.
(6) MacDorman MF, Munson ML, Kirmeyer S. Fetal and perinatal mortality, United States, 2004. National Vital Statistics Reports. 2004.
(7) Davis PG, Tan A, O'Donnell CP, Schulze A. Resuscitation of newborn infants with 100% oxygen or air: a systematic review and meta-analysis. Lancet 2004 Oct 9-15; 364(9442):1329-1333.
(8) Vento M, Moro M, Escrig R, Arruza L, Villar G, Izquierdo I, et al. Preterm Resuscitation With Low Oxygen Causes Less Oxidative Stress, Inflammation, and Chronic Lung Disease. Pediatrics 2009 Aug 10.
(9) Morley CJ, Davis PG. Advances in neonatal resuscitation: supporting transition. Arch.Dis.Child.Fetal Neonatal Ed. 2008 Sep; 93(5):F334-6.
(10) Thomas EJ, Sexton JB, Lasky RE, Helmreich RL, Crandell DS, Tyson J. Teamwork and quality during neonatal care in the delivery room. J.Perinatol. 2006 Mar; 26(3):163-169.
(11) Joint Commission. Sentinal Event Alert. 2004; Available at: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_30.htm. Accessed Feb 8, 2010.
(12) Carbine DN, Finer NN, Knodel E, Rich W. Video recording as a means of evaluating neonatal resuscitation performance. Pediatrics 2000 Oct; 106(4):654-658.
(13) Symington A, Pinelli J. Developmental care for promoting development and preventing morbidity in preterm infants. Cochrane Database Syst.Rev. 2006 Apr 19 ;(2):CD001814.
(14) Coughlin M, Gibbins S, Hoath S. Core measures for developmentally supportive care in neonatal intensive care units: theory, precedence and practice. J.Adv.Nurs. 2009 Aug 4.
(15) Seidlitz W. McMaster Children's Hospital neonatal intensive care unit, Fiscal 2007-08. 2009.
(16) Shah PS, Yoon W, Lee SK, Chan P, Maksimowska S. The Canadian Neonatal Network, Annual Report 2008. 2009; Available at: http://www.canadianneonatalnetwork.org/NewPortal/LinkClick.aspx?fileticket=YcqhZlFnB4E%3d&tabid=39. Accessed Feb 10, 2010.
(17) O'Donnell CP, Davis PG, Morley CJ. Resuscitation of premature infants: what are we doing wrong and can we do better? Biol.Neonate 2003; 84(1):76-82.
(18) Finer NN, Rich WD. Neonatal resuscitation: raising the bar. Curr.Opin.Pediatr. 2004 Apr; 16(2):157-162.
(19) Geary C, Caskey M, Fonseca R, Malloy M. Decreased incidence of bronchopulmonary dysplasia after early management changes, including surfactant and nasal continuous positive airway pressure treatment at delivery, lowered oxygen saturation goals, and early amino acid administration: a historical cohort study. Pediatrics 2008 Jan; 121(1):89-96.

(20) Birenbaum HJ, Dentry A, Cirelli J, Helou S, Pane MA, Starr K, et al. Reduction in the incidence of chronic lung disease in very low birth weight infants: results of a quality improvement process in a tertiary level neonatal intensive care unit. Pediatrics 2009 Jan; 123(1):44-50.
(21) Fulbrook P, Mooney S. Care bundles in critical care: a practical approach to evidence-based practice. Nurs.Crit.Care 2003 Nov-Dec; 8(6):249-255.
(22) Myburgh JA. Standardised terminology for guidelines, protocols, regimens, procedures and processes: the other side of the "bundle". Crit.Care.Resusc. 2008 Jun; 10(2):152-153.
(23) O'Donnell CP, Kamlin CO, Davis PG, Morley CJ. Ethical and legal aspects of video recording neonatal resuscitation. Arch.Dis.Child.Fetal Neonatal Ed. 2008 Mar; 93(2):F82-4.
(24) Gelbart B, Barfield C, Watkins A. Ethical and legal considerations in video recording neonatal resuscitations. J.Med.Ethics 2009 Feb; 35(2):120-124.
(25) Halamek LP, Kaegi DM, Gaba DM, Sowb YA, Smith BC, Smith BE, et al. Time for a new paradigm in pediatric medical education: teaching neonatal resuscitation in a simulated delivery room environment. Pediatrics 2000 Oct; 106(4):E45.
(26) Mickas N, Rhine W. The Golden hour. A gentle approach to resuscitation of the extremely premature infant. Available at: www.aap.org/nrp/pdf/TheGoldenHour.pdf. Accessed Feb 8, 2010.
(27) Dawson JA, Kamlin CO, Wong C, te Pas AB, O'Donnell CP, Donath SM, et al. Oxygen saturation and heart rate during delivery room resuscitation of infants <30 weeks' gestation with air or 100% oxygen. Arch.Dis.Child.Fetal Neonatal Ed. 2009 Mar; 94(2):F87-91.
(28) Coleman K, Norris S, Weston W, etal. NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. 2009; Available at: http://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/Stage%202%20Consultation%20Levels%20and%20Grades.pdf. Accessed Feb 8, 2010.
(29) Rycroft-Malone J, Kitson A, Harvey G, McCormack B, Seers K, Titchen A, et al. Ingredients for change: revisiting a conceptual framework. Qual.Saf.Health.Care. 2002 Jun; 11(2):174-180.
(30) Morley CJ, Dawson JA, Stewart MJ, Hussain F, Davis PG. The effect of a PEEP valve on a Laerdal neonatal self-inflating resuscitation bag. J.Paediatr.Child Health 2009 Nov 23.
(31) Roehr CC, Kelm M, Fischer HS, Buhrer C, Schmalisch G, Proquitte H. Manual ventilation devices in neonatal resuscitation: Tidal volume and positive pressure-provision. Resuscitation 2009 Nov 16.
(32) O'Donnell CP, Davis PG, Lau R, Dargaville PA, Doyle LW, Morley CJ. Neonatal resuscitation 2: an evaluation of manual ventilation devices and face masks. Arch.Dis.Child.Fetal Neonatal Ed. 2005 Sep; 90(5):F392-6.
(33) Bennett S, Finer NN, Rich W, Vaucher Y. A comparison of three neonatal resuscitation devices. Resuscitation 2005 Oct; 67(1):113-118.
(34) Stola A, Schulman J, Perlman J. Initiating delivery room stabilization/resuscitation in very low birth weight (VLBW) infants with an FiO (2) less than 100% is feasible. J.Perinatol. 2009 Aug; 29(8):548-552.
(35) Thomas EJ, Taggart B, Crandell S, Lasky RE, Williams AL, Love LJ, et al. Teaching teamwork during the Neonatal Resuscitation Program: a randomized trial. J.Perinatol. 2007 Jul; 27(7):409-414.
(36) Murphy AA, Halamek LP. Simulation based training in neonatal resucitation. NeoReviews 2005; 6:e489-e492.
(37) Dine CJ, Gersh RE, Leary M, Riegel BJ, Bellini LM, Abella BS. Improving cardiopulmonary resuscitation quality and resuscitation training by combining audiovisual feedback and debriefing. Crit.Care Med. 2008 Oct; 36(10):2817-2822.
(38) Oakley E, Stocker S, Staubli G, Young S. Using video recording to identify management errors in pediatric trauma resuscitation. Pediatrics 2006 Mar; 117(3):658-664.
(39) Reynolds RD, Pilcher J, Ring A, Johnson R, McKinley P. The Golden Hour: care of the LBW infant during the first hour of life one unit's experience. Neonatal Netw. 2009 Jul-Aug; 28(4):211-9; quiz 255-8.
(40) Hudson C, Oddie S. The Golden hour. Resuscitation and early care of the extremely preterm infant. 2005; Available at: http://www.yorkshireneonet.org.uk/guidelines_folder/TheGoldenHourversionafterrotherham.swf?POPUP_ENABLED=true. Accessed Feb 8, 2010.