Deterioration in pediatric patients can have serious adverse consequences including morbidity and death. Evidence indicates prevention is possible with early identification, mitigation, escalation. Child Health BC, with Health Authority partners, are implementing and evaluating a pediatric early warning system (PEWS) in 15 hospital sites provincially. Evaluation will assess the ability to implement a standardized system of PEWS to reduce serious adverse events and improve processes of care. Through mixed methods accessing a range of data sources, indicators of process, quality, and outcomes will be measured.

Evaluation Plan

Provinical Pediatric Early Warning System Implmentation-Phase 1

McElroy, Theresa & Nahdi, Suud

CHILD HEALTH BC
LEAD BENEFACTOR
save on foods

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TABLE OF ABBREVIATIONS

BCCH	BC Children's Hospital
CHBC	Child Health BC
CNE	Clinical Nurse Educators
CNL	Clinical Nurse Lead
CPA	Cardiopulmonary arrest
FGD	Focus Group Discussion
HA	Health Authority
HCP	Health Care Provider
ICU	Intensive Care Unit
L&D	PHSA Learning and Development
LOS	Length of Stay
PACU	Post-anesthetic Care Unit
PCC	Patient Care Coordinator
PEWS	Pediatric Early Warning System
PICU	Pediatric Intensive Care Unit
PTN	Patient Transfer Network
PRISM	Pediatric Risk of Mortality Score
SAE	Serious Adverse Events
SBAR	Situation, Background, Assessment, Recommendation
UNSAFE	Unrecognized Situational Awareness Failure Events

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I. Background

The need: Deterioration of pediatric patients

The incidence of cardiopulmonary arrest (CPA) in hospitalized children is relatively low (Berg et al. 2008, North America) with incident rates described in the literature ranging from 0.7-3% for pediatric inpatients (Tucker et al. 2009, Chapman et al. 2010). However, when arrest does occur an estimated 63 to 89% of children do not survive the event (Tucker et al. 2009, McLellan et al. 2013). In addition to child death, morbidity in survivors remains high, despite advances in resuscitation training, technology and treatment (Tibballs et al. 2005). The devastating consequences of CPA on both child and family are well documented (Meert et al., 2009, Balluffi et al., 2004). There are also substantive financial costs to the healthcare system for 'failing to rescue' deteriorating children in hospital (Duncan & Frew, 2009).

Can deterioration be prevented?

There is evidence indicating that prevention is possible. A detailed confidential panel review of 126 child deaths in the UK concluded that 63 of the 89 deaths (71%) occurring in hospital were avoidable or potentially avoidable (Pearson GA, 2008 CEMACH). This suggests an urgent need to improve early identification and mitigation of deterioration in hospitalized children.

Research in adults has demonstrated CPA and other serious adverse events (SAE) are often preceded by a period of physiological instability that, when recognized earlier, offer a window of opportunity for the health-care team to intervene to improve outcomes (Kause et al. 2004, Hodgetts et al., 2002, Buist et al. 1999 & Franklin C et al. 1994). Pediatric patients also demonstrate physiologic and behavioural symptom deterioration 24 hours prior to CPA (Robson et al, 2013; McLellan et al. 2013). Thus, a similar window of opportunity likely exists within which to identify children at risk of SAE (Haines C 2005, Tusker RC 2005, Tume L & Bullock I 2004). However, there are a number of issues that make this more complex than with adult populations including variation in physiologic norms for pediatric patients, developmental limitations to communication; compensatory mechanisms, and limitations of health provider knowledge, skill or focus (Haines et al, 2006 in Lambert et all, 2004).

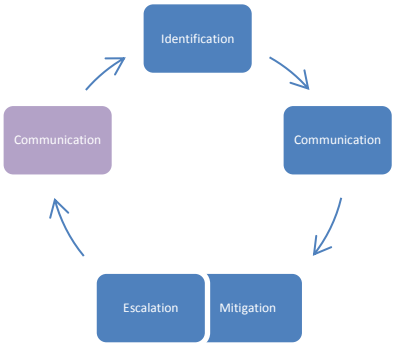
Pediatric Early Warning Systems (PEWS)

Internationally, Pediatric Early Warning Systems (PEWS) have been implemented to improve safety for hospitalized children; these are particularly common throughout the USA, England, Australia, Canada and Wales (Chapman et al. 2010, Lambert et al, 2014). PEWS are implemented in healthcare facilities that admit pediatric patients under the age of 18 years.

The majority of implementation occurs in inpatient pediatric units but modifications of PEWS have been developed for use in emergency departments (ED), cardiac units, post-anesthetic care units (PACU), and for pediatric transfer (Lambert, 2014).

The aim of the PEW system

- ✓ ***Identify*** pediatric patients who are at risk of deterioration
- ✓ ***Mitigate*** the risk (through clinical and procedural response)
- ✓ ***Escalate*** to a higher level of care if mitigation is unsuccessful



The effectiveness of PEW systems- what does the evidence tell us?

- ✓ The effectiveness of PEWS cannot be concluded definitively due to a lack of level-one evidence and diverse results from other levels of evidence such as quasi-experimental studies.
- ✓ The existing evidence suggests there are positive directional trends with the use of PEWS improving clinical outcomes (e.g. earlier intervention, reduced cardiopulmonary arrest rates, reduced mortality rates, reduced UNSAFE (unrecognized situational awareness failure events) transfer to PICU)
- ✓ There are positive outcomes in relation to "enhanced multi-disciplinary team work, communication and confidence in recognizing, reporting and making decisions about child clinical deterioration" (p.10, Lambert et al 2014)- *This finding was supported by the Vancouver Coastal Pews Pilot sites*
- ✓ There are no negative outcomes reported in the literature related to the use of PEWS
- ✓ There is limited evidence to support any particular system (Lambert et al, 2004). Studies have shown different levels of sensitivity (the ability of the score to correctly identify patients who are deteriorating) and specificity (the ability of the score to correctly identify patients who are not deteriorating) with different PEW detection systems.
- ✓ There is limited uniformity in the age-delineated norm ranges for physiological measurement. This makes it challenging to conclude optimal parameters for identification of deterioration.

While the evidence is not definitive, the trends suggest the use of PEWS is associated with critical outcomes including saving lives and other significant clinical outcomes as noted in the literature. Thus, from the perspective of pediatric experts at BC Children's Hospital, health providers across multiple tiers of service in British Columbia, and Child Health BC, the implementation of PEWS will proceed to provincial implementation, with plans for on-going monitoring and evaluation to ensure positive outcomes are observed.

PEWS in British Columbia

All health facilities (Tiers 1 to 4) providing care to children in the province will implement PEWS through a staged introduction. Child Health BC will lead this provincial roll out, including developing the resources needed for its successful implementation and providing a provincial coordinator to oversee the process and deal with barriers that arise. **Child Health BC**, an initiative of BC Children's Hospital (BCCH), is a network which includes all health authorities, key child-serving ministries (MOH MCFD & MOE), health professionals, and provincial partners dedicated to improve the health status and health outcomes of British Columbia's children and youth.

PEWS is not new to BC. A system of PEW was introduced in 2009 at BCCH, the Tier 4 pediatric facility serving the province. The system was tested, modified and operationalized in BCCH and has undergone 3 iterations of improvements and refinement. It will be evolving to a 4th iteration with the provincial roll out to ensure provincial standardization; scheduled for Fall 2015. Other sites have also used versions of PEWS; Royal Columbian Hospital used a version of the BCCH system called the Escalation of Patient Care (EoPC) and Victoria General Hospital used the proprietary BPEWs system.

When the idea of provincial implementation of PEWS was brought forward to Child Health BC by clinical leaders at BCCH, pilot testing occurred at Tier 3 (Lions Gate Hospital), Tier 2 (Richmond Hospital) and Tier 1b (Sechelt Hospital) facilities in the Vancouver Coastal Health Region in August 2014. Following this successful pilot, in December 2014, a provincial working group of 43 stakeholders with representation from 5 of the health authorities (CHBC Regional project Coordinators, Regional, Medical

& Program Directors, CNEs, PPCs, Informatics reps, HCP (physicians, RNs) met to begin working through a plan for province.

Implementation of PEWS provincially will promote:

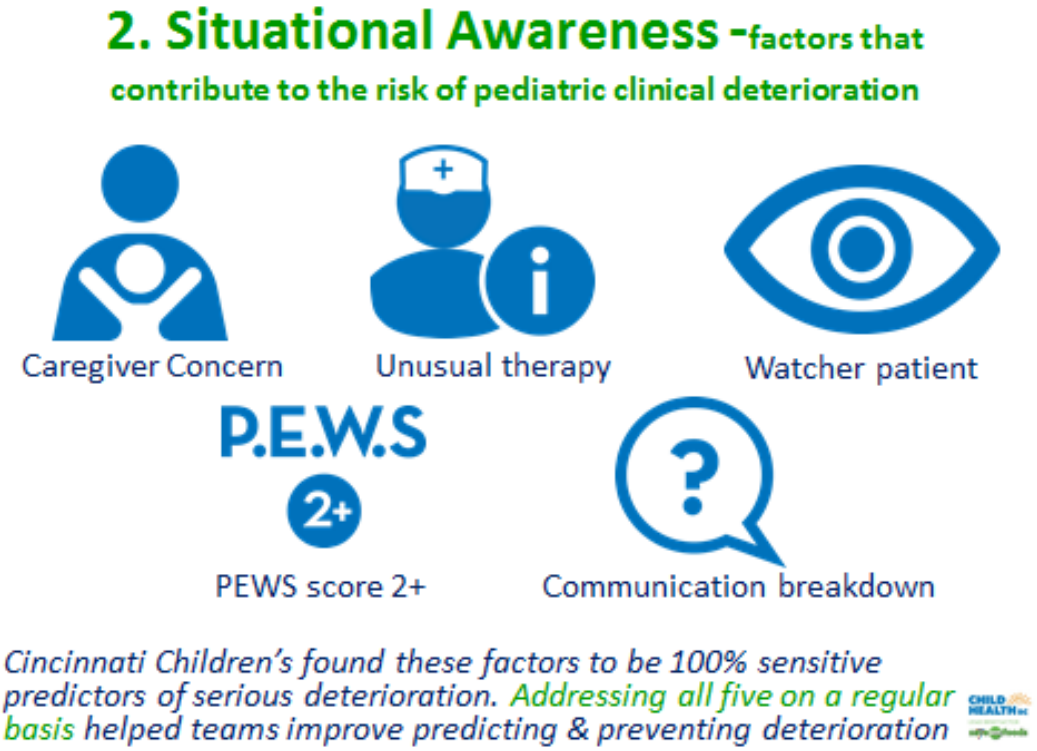
- ✓ **Standardized assessment and measurement**
- ✓ **Standardized communication processes & expectations for responses and care**

The Components of PEWS

In BC, we are adopting a provincial PEW system based on the Brighton PEWS score (Monaghan, 2005) and the Cincinnati Situational Awareness Model (Brady et al, 2010) (see Figure 2 below for details). The provincial PEW system has the following components which together guide the identification, mitigation and escalation of pediatric care:

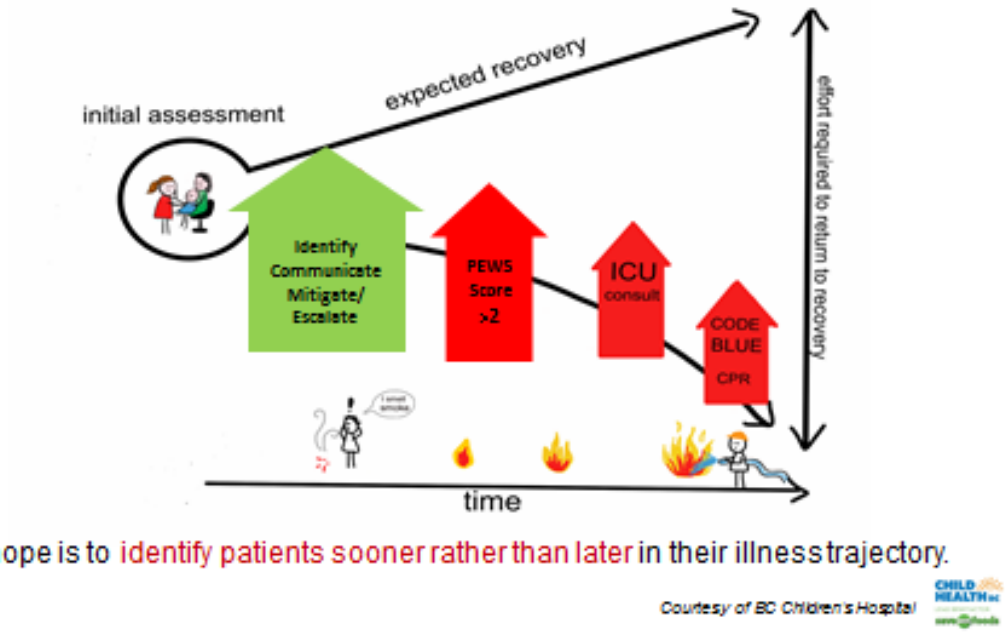
- risk score based on physiological findings incorporated into paediatric flow sheet,
- provincial escalation guide
- tools to promote situational awareness (evidence based risk factors illustrated in Figure 2 below)
- communication framework: SBAR (Situation-Background-Assessment-Recommendation), which promotes a method of communication between members of the health care team about a patient's condition. SBAR is an easy-to-remember, concrete mechanism useful for framing any conversation, especially critical ones, requiring a clinician's immediate attention and action.

Figure 2: Situational Awareness



When a similar system was put in place at Cincinnati Children's hospital, they were able to decrease UNSAFE (unrecognized situational awareness failure events) by almost 50% (Brady et al, 2013). By putting a system in place in BC, our goal is to improve outcomes for children and reduce the efforts required to attain recovery (Figure 3):

Figure 3: Goal of the project



How does the PEWS score work?

One component of the PEW system is the calculation of a PEWS score. Frontline healthcare providers assess multiple physiologic systems at defined intervals with primary focus on cardiovascular and respiratory system, and basic neurological assessment. At each assessment they assign a score which is monitored across time for trends. If deterioration is noted (by an increasing score), then procedures are followed to communicate, mitigate the risk and escalate to a higher level of care. In BC, a guideline has been developed for escalation of care, and each facility in the province will use this to create their own escalation protocol based on local resources.

FIGURE 4
The stated purpose for using PEWS score differs across settings e.g. screening of acutely ill children, identification of children at risk of deterioration, activation of rapid response teams (RRT).

A challenge has been determining which PEWS scoring criteria to use provincially. Globally, there is high heterogeneity of PEW scoring criteria with no widely accepted standard (Lambert et all, 2004). Numerous scoring systems have been developed and modified for local usage, but many are developed by expert opinion and working groups in varied contexts and remain un-validated. For the provincial roll out, the decision has been made to use the Brighton PEWS score, the original score which has been validated in numerous settings. Brighton is also congruent with the provincial roll out of electronic records as it is the scoring system available in

CERNER. The Brighton PEWS score is a maximum of 13 points and patients are given point for each of the following:

Figure 5: Brighton PEWS scoring criteria

	0	1	2	3	Score
Behaviour	Playing/appropriate	Sleeping	Irritable	Lethargic/confused Reduced response to pain	
Cardiovascular	Pink or capillary refill of 1-2 sec	Pale or capillary refill of 3 sec	Grey or capillary refill of 4 seconds. Tachycardia of 20 above normal rate	Grey and mottled or capillary refill of 5 seconds. Tachycardia of 30 above normal rate or bradycardia	
Respiratory	Within normal parameters, no resuscitation of tracheal tug	>10 above normal parameters, using accessory muscles, 30+ %FiO2 or 4+ litres/min.	>20 above normal parameters, recessing, tracheal tug. 40+ %FiO2 or 6+ litres/min.	5 below normal parameters with sternal recession, tracheal tug or grunting. 50 %FiO2 or 8+ litres/min.	
Score 2 extra for ¼ hourly bronchodilator or persistent vomiting following surgery					

II. Description of Implementation & Evaluation methods

Implementation & Education strategy

The PEWS system is an extensive undertaking with multiple phases being conducted by stakeholders throughout the province. The following bullets outline what has been completed to date and the plan for rolling out site implementation moving forward:

- A literature review was completed to look at the evidence for PEWS and to better understand its international use in March 2015. This is available through CHBC.
- The CHBC PEWS project charter was completed in June 2015.
- A provincial flow sheet was developed integrating the pediatric nursing assessment documentation with the PEW system (the PEW score and situational awareness factors). Clinicians from all health authorities provided feedback on this flow sheet throughout multiple iterations, and the first order of forms went to print May 2015. A second version was printed in September 2015 in response to feedback received and a third began distribution in September 2016. This flow sheet is being integrated into the new electronic health records in all health authorities.
- The standardized provincial PEWS education strategy was planned at a meeting of clinical educators from across the province on April 16, 2015. A toolkit of resources to support this strategy was finalized and included two online modules for frontline staff, power point presentations for various audiences, a short online video for physicians, edu-quicks, case studies, and awareness tools (lanyards for staff, situational awareness posters). Health authority "train the trainer" workshops for phase 1 site's champions and educators occurred throughout fall 2015 led by a CHBC provincial educator who supported site leads and regional coordinators for successful implementation.

- The clinical implementation of Phase 1 of PEWS occurred September 2015- January 2016 with a phased approach beginning at 15 inpatient units across all health authorities (Phase 1 sites are outlined below). Phase 2 sites went live in 2016. Implementation will continue to expand in a third phase as experience is gained, as the approach is refined in response to feedback, and as CHBC and partners build capacity to support a safe, high-quality implementation.

- ED implementation will be carefully considered and is not yet planned province wide. We will seek to understand the unique clinical environment and educational needs of EDs while learning from the inpatient implementation experience. Additionally Richmond Hospital launched a pilot of PEWS in the ED in December 2015 and their experience will help to inform a provincial strategy. The evaluation of the RH pilot is outlined in a separate evaluation (UBC REB#H15-02236)

How will frontline health care providers be trained?

Nurses and physicians were supported by CHBC to receive training in the PEW system, with all 5 components. The composition of who is trained at each facility will be determined by the tier of service and availability of providers but will include RNs, LPNs and physicians at each site.

Baseline training has been standardized provincially through two online learning modules available on the Provincial Health Services Authority Learning Hub: https://learninghub.phsa.ca (see figure 6 below). A community of practice website was launched for PEWS which houses the BC PEWS toolkit: https://www.clwk.ca/communities-of-practice/bc-pediatric-early-warning-system-bc-pews/

Figure 6: The Online training modules for PEWS

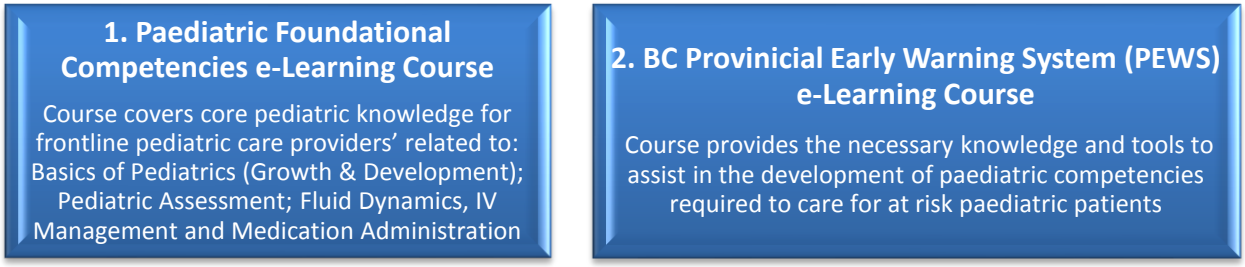
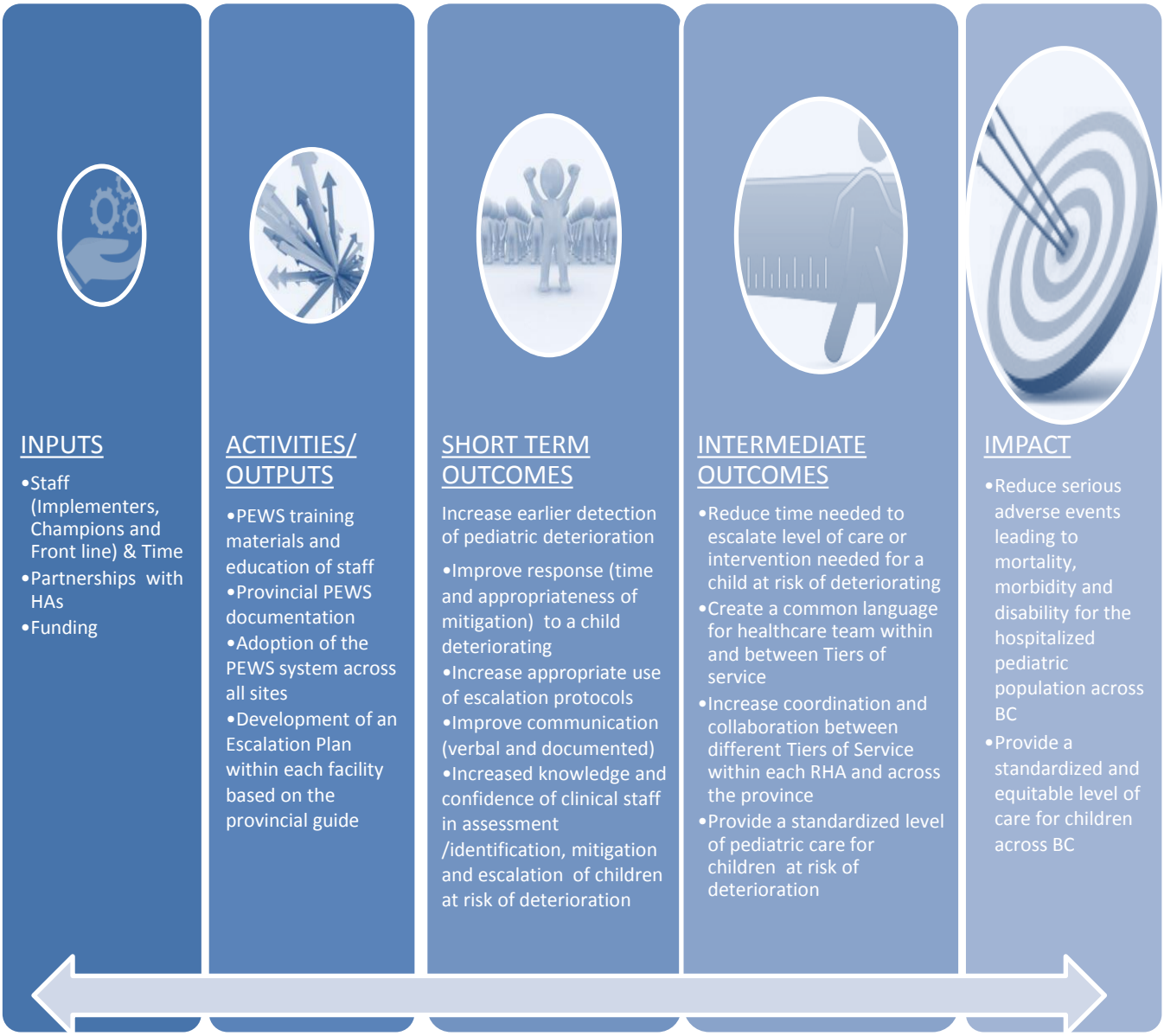


Figure 7: Logic model of provincial implementation of PEWS



Timeline for Provincial Implementation

The provincial roll out occurred in stages (dependent on site readiness). Richmond Short Stay Unit went live first in July 2015. Thirteen sites across the province followed from September 2015-December 2015 and the last phase 1 site to go live was BC Children's Hospital in February 2016. Phase 2 sites launched throughout the first half of 2016 (completed in September 2016).

Evaluation Framework Design

The framework chosen for this evaluation is the Triple Aim Evaluation Framework that was created by the Institute for Health Care Improvement: http://www.ihi.org/Topics/TripleAim/Pages/Overview.aspx.

As outlined on this web resource, the framework has three areas of focus: *Applying integrated approaches to simultaneously improve care, improve population health, and reduce costs.* Our evaluation will focus on the first two of these primarily with an underlying assumption (outlined in Figure 3) that improving the care of the hospitalized child and intervening earlier to prevent deterioration leads to improved health outcomes and less effort required to return child to baseline of functioning. This has both short and long term cost reduction for the health care system. As highlighted in the literature, the cost savings of implementing a PEW system (detection and response) are met by prevention of CPA (Bonafide et al. 2014) and other clinical deterioration events (Duncan & Frew, 2009) that require substantive financial resources from the healthcare system.

Evaluation Goals and Objectives

Evaluation Goal

To evaluate the ability of PEWS to reduce serious adverse events leading to mortality, morbidity and disability in hospitalized (inpatient wards) pediatric patients (population health) through earlier identification, mitigation, escalation and improved systems (situational awareness) (improve care) within a year of implementation.

**The evaluation strategy is based on the assumption that improving care and answering the following research questions will address our population health goal of reducing serious adverse events leading to mortality, morbidity and disability.*

Outcome Evaluation Questions

1. Can PEWS increase identification of pediatric deterioration within a year of implementation?
2. Can PEWS provide earlier identification of pediatric deterioration within a year of implementation?
3. Can PEWS decrease time to mitigation of pediatric deterioration within a year of implementation?
4. Can PEWS increase usage of appropriate responses for mitigation including the appropriate usage of escalation protocols (improved timing, following of escalation protocols) within and between facilities at all tiers of service within a year of implementation?
5. Can we identify the 'active ingredients' (most helpful, usable elements) of PEWS in identifying, mitigating and escalating children at risk?
6. Can PEWS enhance communication (clarity & thoroughness of verbal & written communication) related to identification, mitigation, escalation within a year of implementation?

Process Goal

To evaluate if PEWS can be implemented provincially at all tiers of service in a standardized manner (improve care) to provide equitable levels of care for children across BC (population health).

**The evaluation strategy is based on the assumption that answering the following research questions will address our process goal as stated above.*

Process Evaluation Questions

In addition to these outcomes evaluation questions, we have set a number of process evaluation questions to assist us in establishing achievement of our process goal.

1) **How was PEWS implemented in phase 1, year 1?**
    a. How many hospitals /departments have implemented PEWS (by tier, by geographic/ health authority location)?
    b. What proportion of implementing sites have an individualized (written) escalation protocol based on the provincial PEWS escalation aid?
    c. What proportion of nurses completed the online training courses (1) Foundational Competencies and 2) BC PEWS, prior to site launch date?
    d. What proportion of sites have trained PEWS educators?
    e. What is the proportion of nurses who attended PEWS training sessions per facility? What proportion of physicians attended PEWS orientation per facility
    f. What proportions of nurses within implementing departments are using PEWS clinically?
    g. What proportions of pediatric inpatient charts have a PEWS form (per facility)?

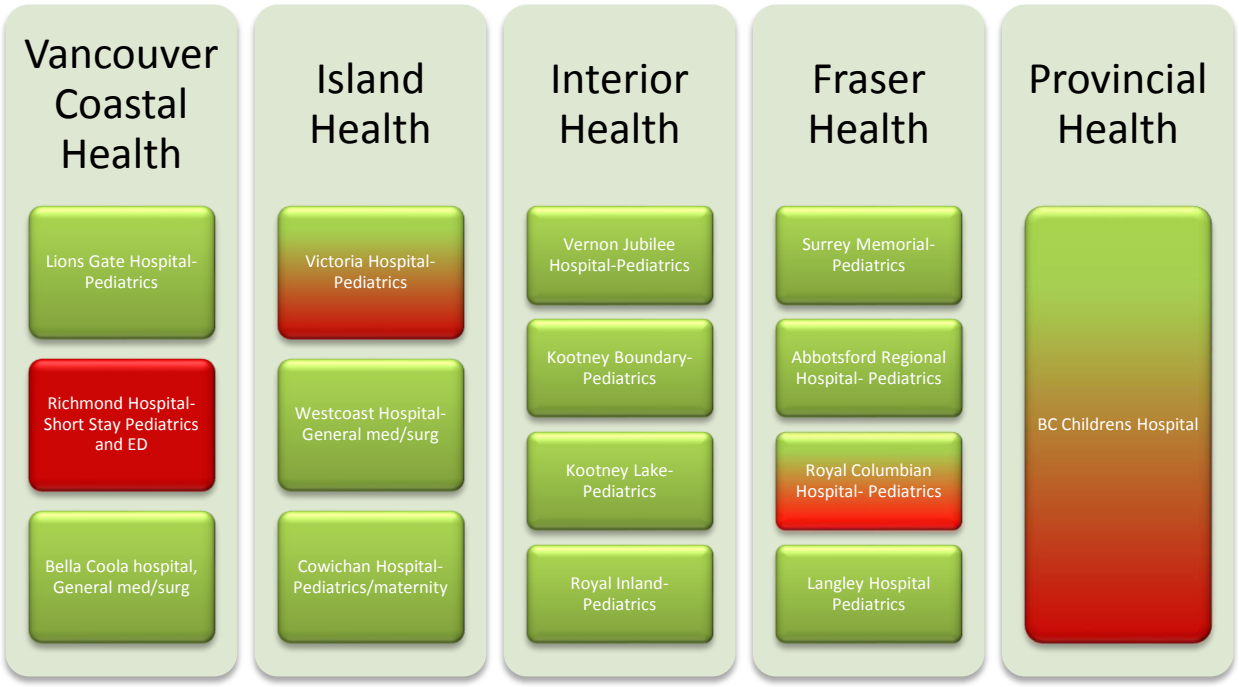
2) **How well (accuracy, fidelity, care provider satisfaction) was PEWS implemented in phase 1 year 1?**
    a. What proportion of charts have completed PEWS scores i.e. at least one PEW score at admission and each time vital signs assessment is completed?
    b. What proportion of charts have an accurate PEWS score?
    c. In what proportion of cases were the PEWS escalation guidelines followed?
    d. In what proportion of cases were Situational Awareness Factors identified in PEWS flow sheet and documented in nurses notes?
    e. How satisfied are health care providers with online training modules?
    f. How satisfied are health care providers with training tool packages?
    g. How satisfied are clinicians and leaders with the PEW system (score and situational awareness)?
    h. What are the barriers and facilitators to using a PEW system?
    i. What changes are reported to have occurred following the introduction of PEW system re: identification, mitigation and deterioration (i.e. utility, documentation, etc.)?
    j. What proportion of HCPs report communications are clear and provide the necessary information?
    k. What proportion of HCPs report increased confidence in identifying, mitigating and escalating a deteriorating pediatric patient?

Evaluation Population / Data Sources

The source population of this provincial evaluation is PEWS implementation sites in Phase 1 inclusive of all health authorities (see chart below):

Care environments

The following BC hospitals will be in phase 1 of provincial PEWS implementation. However, it should be noted that BC Children's Hospital, Victoria General and Royal Columbian had pre-existing PEWS systems in place. Thus, they will have individualized data collection tools applied to their pre-PEWS evaluation and are not included in this proposal. Additionally, Richmond hospital is implementing PEWS in their Emergency Department (and short stay pediatrics unit – within the ED) and will therefore undergo a separate evaluation.



Patient/Care population (for chart audit) - *no direct contact with patients or families*

- Children up to the age of 16 years 364 days admitted in sites/wards implementing PEWS
- Children who experienced deterioration or risk (as this is the population that PEWS targets for improvement). Because we have no electronic data sources on indicators of risk/deterioration, proxy indicators associated with risk/severity were used to select our population:
    - death
    - transfer to higher level of care
    - consult call to higher level of care
    - prolonged length of stay in hospital

Health care provider population (for survey, interview and FGD)

- Health Care Providers
    - Nurses/ LPN
    - Physicians
- HCP leaders (CNLs, CNEs, PCCs)
- Hospital Administration/operations (Directors, Managers)

Sample selection

Patient/care population (for chart review only): In order to understand how PEWS functioned within and between sites and situations, charts were selected in two broad groupings:

1) Children who required transfer to a higher level of care (external mitigation), and
2) Children who were mitigated internally (as defined by consult call to higher level of care without transfer and prolonged length of stay)

The inclusion/exclusion criteria outlined below were applied to determine an appropriate sample of each population…

Inclusion/Exclusion criteria:

The chart audit sample included charts selected by the following inclusion criteria:

Externally mitigated:

- Children age birth to 16 years 364 days, who were transferred to BCCH or VGH for higher level of care (BCCH ED, ICU or WARD).
  - For T1a/1b sites, transfer may have occurred from any location child was admitted (ED, ICU or ward) to BCCH T4 /VGH T3b (T1a/b sites will implement PEWS with any admitted pediatric patient regardless of where in the hospital they are admitted).
  - For T2/T3a sites, transfer will have occurred from the pediatric ward to BCCH/VGH (as T2/T3a will only implement PEWS on pediatric inpatient wards to begin).

  - *Exclude direct ward transfers to BCCH mental health units i.e. CAPE, APU, EDI as these children are deemed medically stable prior to admission on these units.*

Internally mitigated:

- Children age birth to 16 years 364 days, who were either:
  - Transferred internally to a higher level of care (ED, ICU), OR
  - Transferred within the health authority to higher level of care facility
- OR, received a critical care consult phone call from BCCH but were not transferred externally.
- OR, died in facility
- OR, if none of the above proxy indicators of deterioration exist or are insufficient in number to meet sample size, then: child had a LOS in their facility of 4 to 14 days (LOS has been demonstrated to correlate with higher risk of deterioration or poorer health status. 4 days was selected due to natural inflections seen in the available data and 14 days for feasibility of conducting the audit).
  - *Exclude LOS charts where there was no evidence of risk or deterioration.*

From this population, the following sample was selected for audit:

- 100% of charts of patients meeting the external mitigation criteria
- Equal number of charts meeting the internal mitigation criteria. To attain this sample:
  - 100% of charts meeting the internal mitigation criteria except LOS.
  - For LOS, stratified random sample of charts by PEWS flow sheet age categories until we obtained a number of charts equal to the external mitigations.

  A number of internally mitigated charts were excluded at the point of audit if the auditor determined after chart review that the child had no indication of deterioration. These charts were not replaced, thus the numbers from the internally mitigated sample were less than the externally mitigated sample.

Health Care providers: The entire population of HCPs involved in the implementation of PEWS will be invited to participate in evaluation activities online. Lists of HCPs with workplace contact emails will be compiled by the CHBC Regional Coordinators for each site/health authority.

From the population of HCPs who complete an online survey, we will purposively select a sample of practitioners who self-identify. We will select participants based on heterogeneity of experience, and across tiers of service delivery. There will be a total of 2 to 4 FGDs (16-32 participants total).

Leaders: From the population of leaders, we will purposively select a sample of 1 to 2 leaders from each site - targeting those who were most involved with the implementation and oversight of PEWS. The titles/positions of these leaders will vary from site to site (dependent on size, resources, availability of staff, etc.).

Conduct of Evaluation

Data Collection Methods

Mixed methods (both quantitative and qualitative) were chosen to allow for depth and breadth of exploration of PEWS implementation and to assist us in understanding the what, why and how of the PEW system. PEWS is a complex system spanning across all tiers of pediatric health services with potential for serious health impact, thus requires exploration from a number of angles.

Qualitative methods

- **Interviews**: One to one interviews will be held with health care leaders such as hospital administration, and clinical leads on participating wards involved in implementing the PEW system one year following its launch. Interviews will last approximately 25 minutes and will be conducted in private locations on site or via teleconference or tele health. Focus will be on the utility of the PEW system, the active ingredients, barriers and facilitators to implementation (see appendix for interview tool).

- **Surveys (mixed quantitative and qualitative questions):** Online survey will be conducted with health care practitioners involved in implementing the PEW system one year following its launch. We have separated the survey into two respondent groups: 1) RNs and allied health and 2) physicians. Questions are similar, but the physician survey has far fewer questions as physicians are not as involved in the assessment of PEWS, etc. Survey will take approximately 20-30 min (10-20 min for physicians) to complete. Focus will be on exploring perceptions related to knowledge and skill development, attitudes (satisfaction, confidence), perceptions regarding the most useful aspects of PEWS, implementation experiences and practice changes noted. Survey question include: open-ended, forced choice, ranking and select all applicable. The two surveys are loaded on to Fluid survey accessible through the following links:

    - HCP survey: phsa.fluidsurveys.com/surveys/child-health-bc/provincial-pews-provider-survey-tmokh/
    - Physician survey: http://phsa.fluidsurveys.com/surveys/child-health-bc/provincial-pews-physician-survey-pxjdk/

- **Focus group discussion (FGD)**: FGDs with 4 to 8 people and lasting ~ 60 minutes will be held with HCPs as a follow up to the survey and interviews. These will be held in private spaces within healthcare facilities (e.g. meeting rooms) or Telehealth. The focus will be on validating preliminary findings and gaining clarity on issues raised throughout the evaluation. All questions will be open-ended and question themes will be determined based on surveys, interviews and audit findings.

Quantitative methods

- **Pre & Post PEWS chart audit (mixed quantitative and qualitative):** Audit of pediatric charts will be conducted by an experienced pediatric RN. Audit will cover a sample of ~200 charts from a year pre-PEWS implementation and an additional 200 from a year post PEWS implementation. Audit will extract data on the component parts of the PEW system including identification, mitigation and escalation. Audit data will be put directly into a fluid survey (on a Canadian-based server) but identifiers will be removed and a unique study code will be generated for each patient. Questions will be mix of text boxes, multiple choice, checkboxes, calculations based on available information,

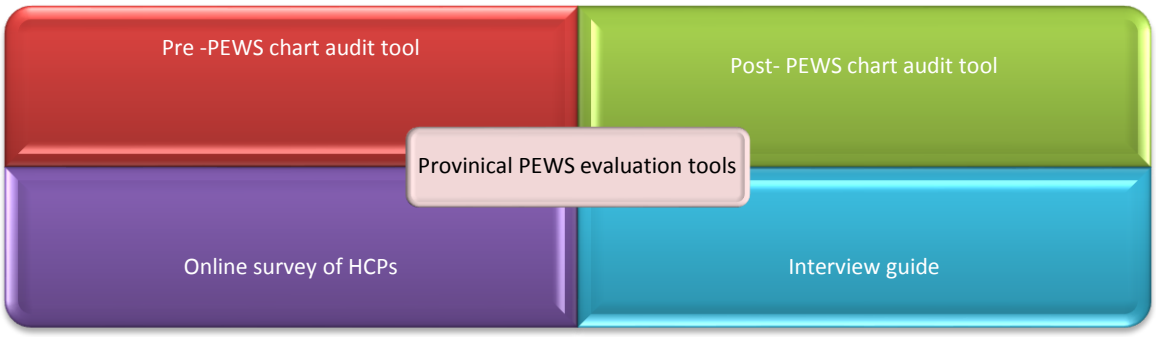
and some questions will require expert interpretations or judgment for instance, would the PEWS score have reflected the clinical picture?

While many of the questions will be the same in the pre and post audit to allow for comparison, audit of post-PEWS implementation will also focus on quality and fidelity of implementation i.e. accuracy of documentation, use of the system, scope and reach of the program, etc. Audit tools are loaded on to FluidSurvey and are accessible through the following links:

- Pre- PEWS audit tool: http://phsa.fluidsurveys.com/surveys/child-health-bc/provinical-pews-eval-pre-pews-chart-audit-tool-akvyf/
- Post PEWS audit tool: phsa.fluidsurveys.com/surveys/child-health-bc/provinical-pews-eval-post-pews-chart-audit-ajoej/

Data Collection Tools

All tools (see diagram below) were based on tools used at the provincial site (BC Children's Hospital) or previous studies (Waller, 2006), examples from the literature, expert opinion, and were tailored to reflect the scope and indicators of this evaluation (appendix A). All were modified to fit the context and unique challenges of provincial implementation and cross –tier focus. An extensive review process was applied to incorporating stakeholder feedback from across the province on all tools during the development phase.



Validity/trustworthiness & inter-rater reliability (review, pilot testing and data checking)

Review and Pilot testing: All audit tools have undergone extensive review by members of the research team and pilot testing at a number of sites throughout the province (Victoria, Nanaimo, North Vancouver and Richmond), to ensure they captured the relevant data in an accurate fashion. Modifications were made as necessary to ensure the tools were clear and captured the relevant information. If issues are identified in early data collection, further adjustments will be made.

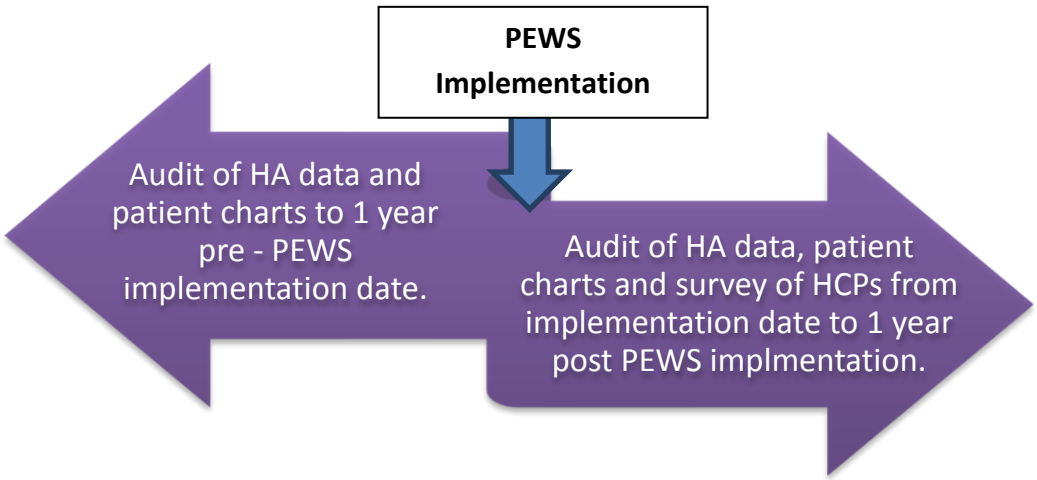
Survey tools have been reviewed by members of the research team and will be sent out for pilot testing prior to data collection starting (i.e. once PEWS implementation has begun and participants can effectively answer the questions).

Establishing inter-rater reliability on audit tools: To test the inter-rater reliability of the chart audit tool (housed on *FluidSurveys*), the RA/auditor test audited 3 sample charts. The same charts were audited by two additional subject experts and results were compared to ensure inter-rater reliability of the audit tool. This also allowed for further examination of validity/trustworthiness of the content of the tool. Small wording issues that arose were addressed prior to launching the official data collection.

Data checking: For validation of interview results, the interviewer will be mirror responses from participants and summarize to confirm information is collected accurately at the end of the interview session.

For validation of the audit results, at the end of the audit, a random sample of 10 charts will be re-audited by a subject expert as a check on the trustworthiness of collected data.

Timing of Data Collection



Evaluation Data Collection Team

- The research team, as listed on page 1, is composed of individuals with diverse pediatric health care and research experiences offering triangulation of perspectives.

Chart Audits: A nurse with pediatric acute care experience and experience applying the PEW system at BCCH was hired to conduct the provincial chart audit. After testing reliability of the tool and auditor, this skilled Research Assistant travelled to all phase 1 sites across the health authorities to collect data in order to ensure consistency.

- Analysis will be completed by members of the research team; there is also the potential of hiring data analysts for quantitative analysis of audit findings.

Privacy and Ethics

Data monitoring (Security and access controls in place for the project/initiative)

Please refer to the provincial PEWS Information Sharing Plan for details on secure collection, transmission and storage of information

Chart Audit: Patients will be identified by chart number on the master randomization schedule only. A master list of patients fitting the inclusion criteria (including patients from VCH, FHA, IHA, and VIHA) will be compiled by PHSA's Decision Support (Performance Measurement and Reporting) from the following data sources:

- The PHSA Critical Care Database (BCCH), which contains data on clinical work done by the ICU at BCCH to advise on transports and consultations where the ICU is contacted by external health care workers, or via the Patient Transfer Network. PHSA's Discharge Abstract Database (DAD) to identify PHSA patients meeting the inclusion criteria.
- Data from the participating Health Authority's central Decision Support on children who died prior to any consult with the Patient Transfer Network. This list is anticipated to be small and potentially nil from each HA.
- Data from VIHA's Decision Support on patients from the VIHA PEWS sites meeting the PEWS criteria. Victoria General Hospital is the only other BC site with a Pediatric ICU and internal transfers or transfers from West Coast General Hospital or Cowichan Hospital to VGH would not be captured by PHSA's Critical Care Database, as generally they would not require a consult with the Patient Transfer Network.

After randomized sampling is done, chart numbers will be forwarded to the various phase 1 facility health records departments in order to pull the charts (please refer to the ISP for details).

Audit of the charts will be conducted on site by a single auditor (a Child Health BC (PHSA) employee). The auditor will assign a unique study code to each chart number on the master randomization list (excel spread sheet stored on PHSA server) and will then enter data from the audits directly into a FluidSurvey on the PHSA approved FluidSurvey account (housed on a Canadian server) identified only by the unique study code. This unique study code will also be on any exported reports or excel spreadsheets used in the analysis of data.

Surveys: Surveys are anonymous unless participants choose to give their names and business contact information at the end either to be approached to participate in the FGD, and/or to be entered in the draw. Exported data from this survey will not include participants names and no identifiers will be used on any reports or results shared from this study (even if participants choose to self identify for further study participation or the draw).

FGD/ Interviews: Participants will be identified by unique study code and a general role descriptor i.e. RN, health care leader, but will not be linked to names or titles in order to protect confidentiality.

During interview and FGD, two research assistants will be present. The second assistant will type notes (with the permission of the interviewees gained during consent). These data collection sessions will also be audio recorded for reference using a Sanyo ICR-1000 digital voice recorder. The interviewer will get consent for the recording at the beginning of the interview.

While recording will occur for reference, recordings will not be transcribed due to issues of time and feasibility, thus limiting the detail and nuance that may be captured. However, the participants will have the opportunity to review notes taken either at the end of the session or at a later date, to ensure data is representative of their key ideas. They will also be permitted to add to their information or change it if they choose in order to accurately represent their experiences, knowledge, perceptions.

Ethics and Privacy Review

This proposal was submitted through:

- BC Ethics Harmonization Initiative (The Board denied review of the application, September 21, 2015- deeming it to be evaluation)
- Information Access and Privacy Office Review (PHSA, VCH, FHA, VIHA and IHA --- VCH as the Board of Record)

Analysis and Interpretation of Evaluation Data

Qualitative data analysis

Analysis will be ongoing throughout data collection (reviewing notes, adding probes as required) to ensure data collected meets study objectives and to give opportunity for exploration of themes/ideas important to the topic of study that emerge during data collection. There will be attention paid both to ideas which repeat throughout the data and to unusual or different responses that may suggest further areas of consideration for analysis or probing. This ongoing analysis will be conducted by the research assistants with input from members of the research team, in particular Theresa McElroy and Gary Hoyano.

Once all the data is collected, it will be coded. Initially, codes at a low level of inference (single or very similar ideas) will be generated and applied to the data. Coding will be facilitated by the analysis function within fluid survey which allows for the application of codes to particular responses in the text. Should a more detailed analysis be required, the use of qualitative software will be considered. If this occurs, codes will be applied to raw data reports generated through fluid survey.

Codes will be sorted or categorized into larger encompassing themes as appropriate. This process will be done by multiple members of the research team to enhance trustworthiness of the data. When interpretations are required, key informants will be approached to assist (i.e. through FGD or key informant interviews). Prominent themes will be described in reports with quotes to explain the theme in the words of the study participants.

Quantitative Data Analysis

Chart audits (Appendix B & C) will generate quantitative data for analysis. A broad overview of the statistical analysis to be done is outlined in the table below:

Summary Table of Evaluation Indicators with methods and analysis plan

Indicators were chosen initially based on literature review and previous evaluation protocols. A comprehensive list was compiled, and was then brought to expert clinicians, researchers, quality and safety leads, Health Authority operations and frontline care representatives. Their input assisted us to focus the potential indicators, decide which were feasible, most useful and would provide the best measures. In total 20 stakeholders were involved in the indicator selection process with final decisions made by the research team.

TABLE 1: Evaluation Outcome Indicators

Outcome Evaluation Questions	Indicators	Data Collection Methods	Analysis
1) Can PEWS increase identification of pediatric deterioration	a) Post PEWS introduction, ≥80% of children will have a critical pews score of ≥4 or 3 in one domain at the time of transfer	• Pre and Post PEWS chart audit by expert research	• Depending on normality tests, we will conduct t-tests if the data is

within a year of implementation?	b) PEW system reflects clinical picture of deterioration (i.e. score comparison to patient status, actions taken, situational awareness factors) c) As a result of the project, HCPs (RN, MD Respiratory Therapists(RT)) report better knowledge and skills related to identification (i.e. of abnormal pediatric vitals parameter, situational awareness factors)	assistant. • Post PEWS HCP survey	normally distributed or Mann-Whitney U tests if not, to determine significance. • Qualitative analysis as described.
2) Can PEWS provide earlier identification of pediatric deterioration within a year of implementation?	a) Decrease in time between documented markers of identification (identification by nurse, notification of MRP, MRP orders written/care plan documented) b) Summary of barriers and enablers of early identification of deterioration reported by RN, MD, RT	• Pre and Post PEWS chart audit by expert research assistant. • Post PEWS HCP Survey	• Comparison of mean & median time between documented markers of identification of deterioration in the pre-PEWS and post-PEWS group. • Qualitative analysis as described.
3) Can PEWS decrease time to mitigation of pediatric deterioration within a year of implementation?	a) The introduction of PEWS will increase leeway time (time from identification to transfer to higher level of care) by ≥2 hours. b) Decrease in length of time between the 5 indicators of deterioration: MRP orders written/care plan documented); intervention given (fluid IV, antibiotics, O2 administered, 02 saturation monitoring); transfer within or between facilities to higher	• Pre and Post PEWS chart audit by expert research assistant. • Post PEWS Key informant interviews • Post PEWS HCP survey	• Depending on normality tests, we will conduct t-tests if the data is normally distributed or Mann-Whitney U tests if not to determine significance. • Comparison of mean & median time between documented markers of

	level of care c) HCPs report that PEWS aided prioritization of transport AND with faster identification of transfer decision		mitigation of deterioration in the pre-PEWS and post-PEWS group. • Qualitative analysis as described.
4) Can PEWS increase usage of appropriate responses for mitigation including the appropriate usage of escalation protocols (improved timing, following of escalation protocols) within and between facilities at all tiers of service within a year of implementation?	a) ≥45% reduction of UNSAFE (vasoactive initiated, 3 or more fluid boluses, ventilation (invasive and non-invasive) and/or late transfers resuscitation (resuscitation intensity scale) any time before arrival or within 60 min of arrival at ICU b) Mean PRISM III (Pediatric Risk of Mortality Score) on arrival in PICU will be less 1 year post PEWS c) Healthcare team (both within and between facilities) who are notified through the escalation of patient care pathway respond as per roles and responsibilities d) As a result of the project, HCPs (RN, MD and RT) report better knowledge and skills related to mitigation of deterioration including the selection of appropriate escalation actions e) Increase in proportion of charts indicating the appropriate escalation (increased rate of assessment & documentation, increased nursing ratios, consultations	• Pre and Post PEWS chart audit by expert research assistant. • BCCH/Patient transfer network database • Post PEWS HCP survey	• Depending on normality tests, we will conduct t-tests if the data is normally distributed or Mann-Whitney U tests if not to determine significance. Comparison of mean & median PRISM III scores in pre and post PEWS groups • Qualitative analysis as described.

	and other actions taken as outlined in escalation protocol) f) HCPs report that PEWS aided escalation and de-escalation decisions. g) HCPs (RN, MD and RT) report increase confidence related to identification , deterioration and mitigation of pediatric patients		
5) Can we identify the 'active ingredients' (most helpful, usable elements) of PEWS in identifying, mitigating and escalating children at risk?	a) Ranking of what aspects of PEWS are useful in identifying children at risk	• Post PEWS HCP survey • Post PEWS key informant interviews	• Descriptive statistics • Qualitative analysis as described.
6) Can PEWS enhance communication (clarity & thoroughness of verbal & written communication) related to identification, mitigation, escalation within a year of implementation?	a) Improved (completeness and frequency) of documentation b) Improved rates of documentation of situational awareness factors c) HCPs report improved communication (instances, timing, understanding and results) d) Proportion of HCPs reporting SBAR communication method used.	• Pre and Post PEWS chart audit by expert research assistant. • Post PEWS HCP survey	• Comparison of proportions of documentation accuracy and thoroughness in the pre-PEWS and post-PEWS group. • Qualitative analysis as described.

Because Child Health BC is seeking to implement a standardized process of care which crosses tiers of service and enhances equalization of access to health care, two process evaluation questions will further focus the evaluation on understanding the implementation of PEWS in scope, reach, and quality. Some

of these will be used for on-going quality monitoring, with data compiled for full evaluation one year post PEWS.

TABLE 2: Process Evaluation Questions

Process Evaluation Question	Sub -questions	Data Collection Methods	Analysis
How was PEWS implemented in Phase 1 year 1?	How many hospitals /departments have implemented PEWS (by tier, by geographic/ health authority location)?	• CHBC RPC tracking	• Descriptive statistics
	What proportion of implementing sites have an individualized (written) escalation protocol based on the provincial PEWS escalation aid?	• CHBC RPC tracking	• Descriptive statistics
	What proportion of nurses completed the online training courses (1) Foundational Competencies and 2) BC PEWS?	• Learning hub analytics	• Descriptive statistics
	What proportion of sites have trained PEWS educators?	• CHBC RPC tracking	• Descriptive statistics
	What is the proportion of nurses attended PEWS training sessions per facility? What is the proportion of physicians attended PEWS orientation per facility?	• Site tracking	• Descriptive statistics
	What proportion of nurses within implementing departments are using PEWS clinically?	• Site tracking	• Descriptive statistics
	What proportion of pediatric inpatient charts have a PEWS form (per facility)?	• Site tracking/ comparing form numbers to admission numbers	• Descriptive statistics
	What the demographics on age of children transferred to higher level of care when comparing pre and post PEWS implementation?	• Pre and Post PEWS Chart Audit	• Descriptive statistics
How well	What proportion of charts have completed	• Post PEWS	• Descriptive

(accuracy, fidelity, satisfaction) was the PEWS strategy implemented in Phase 1, year 1?	PEWS scores i.e. at least one PEW score at admission and each time vital signs assessment is completed?	Chart Audit	statistics
	What proportion of charts have an accurate PEWS score?	• Post PEWS Chart Audit	• Descriptive statistics
	In what proportion of cases were the PEWS escalation guidelines followed?	• Post PEWS Chart Audit	• Descriptive statistics • Comparison of proportion of charts with mitigation actions that correspond to the provincial escalation aid pre-PEWS and post-PEWS group.
	In what proportion of cases were Situational Awareness Factors identified in PEWS flow sheet and documented in nurses notes?	• Post PEWS Chart Audit	• Descriptive statistics • Comparison of proportion of charts with documentation of situational awareness factors in the pre-PEWS and post-PEWS

			group.
	How satisfied are health care providers with online training modules?	• HCP feedback survey: Pop-up survey at the end of the modules	• Descriptive statistics • Qualitative analysis as described
	How satisfied are health care providers with training tool packages?	• Evaluation forms at end of trainer training	• Descriptive statistics • Qualitative analysis as described
	How satisfied are clinicians and leaders with the PEW system (score and situational awareness)?	• Post PEWS Interviews, survey	
	What are the barriers and facilitators to using a PEW system?	• Post PEWS Interview, survey	• Qualitative analysis as described
	What changes are reported to have occurred following the introduction of PEW system re: identification, mitigation and deterioration (i.e. utility, documentation, etc).	• Post PEWS interview, survey	• Qualitative analysis as described
	What proportion of HCPs report communications are clear and provide the necessary information?	• Post PEWS HCP feedback survey	• Descriptive statistics
	What proportion of HCPs report increased confidence in identifying, mitigating and escalating a deteriorating pediatric patient?	• Post PEWS HCP feedback survey	• Descriptive statistics

Strengths and Limitations of Data Collection Methods

PEWS is a multi-faceted complex system aiming to have impact on a varied population of children being cared for in varied health facilities with varied resources across a diverse province. It is very difficult to measure the direct impact of the system as there are a multitude of possible confounding factors.

Our sampling strategy will likely miss children who do deteriorate but who are identified and mitigated internally and for whom no consult is made. Aside from length of stay, we have no proxy for identifying these children, and it is not feasible to audit every child with a prolonged LOS- thus we need to acknowledge that this is a limitation of our sampling strategy.

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APPENDIX : Key Informant Interview Guide

PEWS Key Informant Interview Guide

Unique study code: _____

PLEASE READ TO PARTICIPANT: During these data collection sessions we will take notes and will audio record for reference only. Recordings will not be transcribed due to issues of time and feasibility, thus limiting the detail and nuance that may be captured. However for validation, the interviewer will mirror your responses and summarize their understanding to confirm information is collected accurately at the end of the interview session. If you choose, you will have the opportunity to review notes taken either at the end of the session or at a later date, to ensure data is representative of your key ideas. You will also be permitted to add to your information or change it if you choose in order to accurately represent your experiences, knowledge, perceptions.

I agree to allow notes to be taken: _____(please tick of respondent agrees)

I agree to be audio recorded: _____(please tick of respondent agrees)

Background information:

Health authority:

Facility:

Interviewee's position/title/roll in PEWS implementation:

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1. **Describe any changes in practice (positive or negative) which you attribute to the introduction of a pediatric early warning system (PEWS)**
    a. Please include stories of 'PEWS in action' if possible....

2. Please describe how the components of the PEW system are implemented in your hospital? (refer to situational awareness)

Probe:

a. How are each of the components functioning in the hospital?
b. Processes for situational awareness? i.e. Scoring sheets by the bed? Visual cues?
c. SBAR usage?
d. Are they all used as expected?
e. What components needed adjusting?

3. What are the active (or most useful/effective) ingredients of the PEW system? Probe: situational awareness factors, flow sheet, escalation protocol, SBAR

4. What is your experience of the general thoughts/attitudes of the healthcare team responsible for caring for children with the PEWS system?

Probe for:

a. Did they resist or accept the PEWS system?
b. How did you address any challenges?

5. Since the implementation of PEWS, what are your perceptions of the outcomes on pediatric care?

Probe for: Examples

a. Improvements in care for children in general?
b. Systematic process of escalating care?
c. Improved confidence and knowledge of staff caring for children?
d. Less or more transfers?
e. Less or more clinical deterioration?

6. What are some of the facilitators to using PEWS?

Probe for: Resources, Champions etc.

7. What are some of the challenges/gaps in using PEWS?

Probe for: Resources, staff, timing, competing projects etc. If you could change something what would it be?

8. Any final comments about the PEWS system in your hospital?

Thank you for your input. It is greatly appreciated.