Quality-Based Procedures Clinical Handbook for Hyperbilirubinemia in Term and Late Pre-Term Infants (≥35 weeks)

Provincial Council for Maternal & Child Health & Ministry of Health and Long-Term Care

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## List of Abbreviations

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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AAP</td>
<td>America Academy of Pediatrics</td>
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<tr>
<td>CEAG</td>
<td>Clinical Expert Advisory Group</td>
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<td>CPS</td>
<td>Canadian Paediatric Society</td>
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<tr>
<td>DAT</td>
<td>Direct Anti-Globulin Test</td>
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<tr>
<td>HCP</td>
<td>Health Care Provider</td>
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<tr>
<td>NICE</td>
<td>National Institute for Clinical Evidence</td>
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<tr>
<td>TcB</td>
<td>Transcutaneous Bilirubin</td>
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<tr>
<td>TSB</td>
<td>Total Serum Bilirubin</td>
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1.0 Purpose

Provided by the Ministry of Health and Long-Term Care

This clinical handbook has been created to serve as a compendium of the evidence-based rationale and clinical consensus driving the development of the policy framework and implementation approach for the Quality Based Procedure (QBP) for Hyperbilirubinemia in Term and Late-Pre-Term Infants (≥ 35 weeks).

This document has been prepared for informational purposes only. This document does not mandate health care providers to provide services in accordance with the recommendations included herein. The recommendations included in this document are not intended to take the place of the professional skill and judgment of health care providers.
2.0 Introduction

Provided by the Ministry of Health and Long-Term Care

Quality-Based Procedures (QBP) are an integral part of Ontario’s Health System Funding Reform (HSFR) and a key component of the Patient-Based Funding (PBF). This reform plays a key role in advancing the government’s quality agenda and its Action Plan for Health Care. HSFR has been identified as an important mechanism to strengthen the link between the delivery of high quality care and fiscal sustainability.

Ontario’s health care system has been living under a global economic uncertainty for a considerable period of time. At the same time, the pace of growth in health care spending has been on a collision course with the provincial government’s deficit recovery plan.

In response to these fiscal challenges and to strengthen the commitment towards the delivery of high quality care, the Excellent Care for All Act (ECFAA) received royal assent in June 2010. ECFAA is a key component of a broad strategy that improves the quality and value of the patient experience by providing them with the right care at the right time, and in the right place through the application of evidence-informed health care. ECFAA positions Ontario to implement reforms and develop the levers needed to mobilize the delivery of high quality, patient-centred care.

Ontario’s Action Plan for Health Care advances the principles of ECFAA reflecting quality as the primary driver to system solutions, value and sustainability.

2.1 What Are We Moving Towards?

Provided by the Ministry of Health and Long-Term Care

Prior to the introduction of HSFR, a significant proportion of hospital funding was allocated through a global funding approach, with specific funding for some select provincial programs and wait times services. A global funding approach reduces incentives for Health Service Providers (HSPs) to adopt best practices that result in better patient outcomes in a cost-effective manner.

To support the paradigm shift from a culture of ‘cost containment’ to ‘quality improvement,’ the Ontario government is committed to moving towards a patient-centred funding model that reflects local population needs and contributes to optimal patient outcomes (Figure 1).

Internationally, PBF models have been implemented since 1983. Ontario is one of the last leading jurisdictions to move down this path. This puts the province in a unique position to learn from international best practices and lessons learned by others to create a funding model that is best suited for Ontario.

PBF supports system capacity planning and quality improvement through directly linking funding to patient outcomes. PBF provides an incentive to health care providers to become more efficient and
effective in their patient management by accepting and adopting best practices that ensure Ontarians get the right care, at the right time and in the right place.

Figure 1: The Ontario government is committed to moving towards patient-centred, evidence-informed funding that reflects local population needs and incents delivery of high quality care

<table>
<thead>
<tr>
<th>Current State</th>
<th>How do we get there?</th>
<th>Future State</th>
</tr>
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<tbody>
<tr>
<td>Based on a lump sum, outdated historical funding</td>
<td>Strong Clinical Engagement</td>
<td>Transparent, evidence-based to better reflect population needs</td>
</tr>
<tr>
<td>Fragmented system planning</td>
<td>Current Agency Infrastructure</td>
<td>Supports system service capacity planning</td>
</tr>
<tr>
<td>Funding not linked to outcomes</td>
<td>System Capacity Building for Change and Improvement</td>
<td>Supports quality improvement</td>
</tr>
<tr>
<td>Does not recognize efficiency, standardization and adoption of best practices</td>
<td>Knowledge to Action Toolkits</td>
<td>Encourages provider adoption of best practice through linking funding to activity and patient outcomes</td>
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<tr>
<td>Maintains sector specific silos</td>
<td>Meaningful Performance Evaluation Feedback</td>
<td>Ontarians will get the right care, at the right place and at the right time</td>
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2.2 How Will We Get There?

Provided by the Ministry of Health and Long-Term Care

The Ministry has adopted a three-year implementation strategy to phase in a PBF model and will make modest funding shifts starting in fiscal year 2012/13. A three-year outlook has been provided to the field to support planning for upcoming funding policy changes.

The Ministry has released a set of tools and guiding documents to further support the field in adopting the funding model changes. For example, a Quality-Based Procedure (QBP) Interim list has been published for stakeholder consultation and to promote transparency and sector readiness. The list is intended to encourage providers across the continuum to analyze their service provision and infrastructure in order to improve clinical processes and where necessary, build local capacity.

The successful transition from the current, ‘provider-centred’ funding model towards a ‘patient-centred model’ will be catalyzed by a number of key enablers and field supports. These enablers translate to actual principles that guide the development of the funding reform implementation strategy related to QBPs. These principles further translate into operational goals and tactical implementation, as presented in Figure 2.

Figure 2: Principles guiding the implementation of funding reform related to Quality-Based Procedures

<table>
<thead>
<tr>
<th>Principles for developing QBP implementation strategy</th>
<th>Operationalization of principles to tactical implementation (examples)</th>
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<tr>
<td>• Cross-Sectoral Pathways</td>
<td>• Development of best practice patient clinical pathways through clinical expert advisors and evidence-based analyses</td>
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<td>• Evidence-Based</td>
<td>• Integrated Quality Based Procedures Scorecard</td>
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<tr>
<td>• Balanced Evaluation</td>
<td>• Alignment with Quality Improvement Plans</td>
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<tr>
<td>• Transparency</td>
<td>• Publish practice standards and evidence underlying prices for QBPs</td>
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<td>• Sector Engagement</td>
<td>• Routine communication and consultation with the field</td>
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<td>• Knowledge Transfer</td>
<td>• Clinical expert panels</td>
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<td></td>
<td>• Provincial Programs Quality Collaborative</td>
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<tr>
<td></td>
<td>• Overall HSFR Governance structure in place that includes key stakeholders</td>
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<td></td>
<td>• LHIN/CEO Meetings</td>
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• Applied Learning Strategy/ IDEAS
• Tools and guidance documents
• HSFR Helpline; HSIMI website (repository of HSFR resources)
2.3 What Are Quality-Based Procedures?

Provided by the Ministry of Health and Long-Term Care

QBPs involve clusters of patients with clinically related diagnoses or treatments. Hyperbilirubinemia in Term and Late-Pre-Term Infants (35≥ weeks) was chosen as a QBP using an evidence and quality-based selection framework that identifies opportunities for process improvements, clinical re-design, improved patient outcomes, and enhanced patient experience and potential cost savings.

The evidence-based framework used data from the Discharge Abstract Database (DAD) adapted by the Ministry of Health and Long-Term Care for its Health Based Allocation Methodology (HBAM) repository. The HBAM Inpatient Grouper (HIG) groups inpatients based on the diagnosis or treatment responsible for the majority of their patient stay. Day Surgery cases are grouped within the National Ambulatory Care Referral System (NACRS) by the principal procedure they received. Additional data was used from the Ontario Case Costing Initiative (OCCI). Evidence such as publications from Canada and other jurisdictions and World Health Organization reports were also used to assist with the patient clusters and the assessment of potential opportunities.

The evidence-based framework assessed patients using four perspectives, as presented in Figure 3. This evidence-based framework has identified QBPs that have the potential to both improve quality outcomes and reduce costs.

Figure 3: Evidence-Based Framework
1. **Practice Variation**

The DAD has every Canadian patient discharge, coded and abstracted for the past 50 years. This information is used to identify patient transition through the acute care sector, including discharge locations, expected lengths of stay and readmissions for each and every patient, based on their diagnosis and treatment, age, gender, co-morbidities and complexities and other condition specific data. A demonstrated large practice or outcome variance may represent a significant opportunity to improve patient outcomes by reducing this practice variation and focusing on evidence-informed practice. A large number of ‘Beyond Expected Days’ for length of stay and a large standard deviation for length of stay and costs, were flags to such variation. Ontario has detailed case costing data for all patients discharged from a case costing hospital from as far back as 1991, as well as daily utilization and cost data by department, by day and by admission.

2. **Availability of Evidence**

A significant amount of research has been completed both in Canada and across the world to develop and guide clinical practice. Working with the clinical experts, best practice guidelines and clinical pathways can be developed for these QBPs and appropriate evidence-informed indicators can be established to measure performance.

3. **Feasibility/ Infrastructure for Change**

Clinical leaders play an integral role in this process. Their knowledge of the patients and the care provided or required represents an invaluable component of assessing where improvements can and should be made. Many groups of clinicians have already formed and provided evidence and the rationale for care pathways and evidence-informed practice.

4. **Cost Impact**

The selected QBP should have no less than 1,000 cases per year in Ontario and represent at least 1 per cent of the provincial direct cost budget. While cases that fall below these thresholds may in fact represent improvement opportunity, the resource requirements to implement a QBP may inhibit the effectiveness for such a small patient cluster, even if there are some cost efficiencies to be found. Clinicians may still work on implementing best practices for these patient sub-groups, especially if it aligns with the change in similar groups. However, at this time, there will be no funding implications. The introduction of evidence into agreed-upon practice for a set of patient clusters that demonstrate opportunity as identified by the framework can directly link quality with funding.
2.4 How Will QBPs Encourage Innovation in Health Care Delivery?

Provided by the Ministry of Health and Long-Term Care

Implementing evidence-informed pricing for the targeted QBPs will encourage health care providers to adopt best practices in their care delivery models, and maximize their efficiency and effectiveness. Moreover, best practices that are defined by clinical consensus will be used to understand required resource utilization for the QBPs and further assist in the development of evidence-informed prices. Implementation of a ‘price X volume’ strategy for targeted clinical areas will incent providers to:

• Adopt best practice standards;

• Re-engineer their clinical processes to improve patient outcomes; and

• Develop innovative care delivery models to enhance the experience of patients.

Clinical process improvement may include the elimination of duplicate or unnecessary investigations, better discharge planning, and greater attention to the prevention of adverse events, i.e. post-operative complications. These practice changes, together with adoption of evidence-informed practices, will improve the overall patient experience and clinical outcomes, and help create a sustainable model for health care delivery.
3.0 Description of the QBP for Hyperbilirubinemia in Term and Late-Pre-Term Infants (≥ 35 weeks)

3.1 Population Group

Hyperbilirubinemia in the newborn, also referred to as neonatal jaundice, is a result of the diminished ability to conjugate and excrete an excess of bilirubin in the blood of the neonate (Mosby, 2009). Hyperbilirubinemia is a common condition affecting approximately 60% of term and 80% of pre-term babies in the first week of life (National Institute for Health and Clinical Excellence, 2010); (American Academy of Pediatrics Provisional Committee for Quality Improvement and Subcommittee on Hyperbilirubinemia, 2004). In most of these infants the condition will resolve without any need for intervention. However, for some, there is a risk of developing severe hyperbilirubinemia which can lead to acute bilirubin encephalopathy (kernicterus). Severe hyperbilirubinemia has been on the rise in North America and Europe, with increasing frequency in term and near-term infants (Manning D, 2007). This is a troublesome finding as severe hyperbilirubinemia is largely preventable.

This QBP, unlike intervention specific QBPs, is addressing a diagnosis. As mentioned above, the diagnosis of hyperbilirubinemia is one that affects a large number of neonates. Hyperbilirubinemia is often mild and can be managed without medical intervention. Medical intervention is required for serious cases of hyperbilirubinemia, some of which can be prevented when early screening and systematic monitoring are in place.

Population Definition

Defining a population for the management of paediatric hyperbilirubinemia can be likened to an inverted triangle. The screening process starts will all infants born, and then funnels down to those infants who are diagnosed with hyperbilirubinemia and require/receive treatment. The Paediatric Hyperbilirubinemia Clinical Expert Advisory Group (CEAG) recommends defining the population for this QBP as all newborns which includes ‘Normal Newborns’, AND/PLUS a subset of infants which will have been diagnosed with hyperbilirubinemia. Newborns with significant morbidities should be excluded as the costs of care for these infants will more directly reflect their other conditions.

The technical definition is as follows:

Inpatient Cases

‘Normal Newborns’ – All newborn babies, born at 35 weeks 0 days gestation or greater either in hospital or at home

Defined as:

- Z38 Liveborn Infants According to place of birth
  - Z38.0 Singleton, born in hospital
  - Z38.1 Singleton, born outside hospital
  - Z38.100 Singleton, born outside hospital, product of both spontaneous (NOS) ovulation and conception
- Z38.101 Singleton, born outside hospital, product of assisted reproductive technology (ART)
- Z38.2 Singleton, unspecified as place of birth
- Z38.200 Singleton, unspecified as to place of birth, product of both spontaneous (NOS) ovulation and conception
- Z38.201 Singleton, unspecified as to place of birth, product of assisted reproductive technology (ART)
- Z38.3 Twin, born in hospital
- Z38.4 Twin, born outside hospital
- Z38.400 Twin, born outside hospital, product of both spontaneous (NOS) ovulation and conception
- Z38.401 Twin, born outside hospital, product of assisted reproductive technology (ART)
- Z38.5 Twin, unspecified as to place of birth
- Z38.500 Twin, unspecified as to place of birth, product of both spontaneous (NOS) ovulation and conception
- Z38.501 Twin, unspecified as to place of birth, product of assisted reproductive technology (ART)
- Z38.6 Other multiple, born in hospital
- Z38.7 Other multiple, born outside hospital
- Z38.700 Other multiple, born outside hospital, product of both spontaneous (NOS) ovulation and conception
- Z38.701 Other multiple, born outside hospital, product of assisted reproductive technology (ART)
- Z38.8 Other multiple, unspecified place of birth
- Z38.800 Other multiple, unspecified place of birth, product of both spontaneous (NOS) ovulation and conception
- Z38.801 Other multiple, unspecified place of birth, product of assisted reproductive technology (ART)

Diagnosis Type:
M: Most responsible diagnosis on main patient service

- Age range: Birth to 14 days
  - Newborn, 0 days, 1 day, 2 days, 3 days, 4 days, 5 days, 6 days, 7 days, 8 days, 9 days, 10 days, 11 days, 12 days, 13 days, 14 days

PLUS

‘Infants with Jaundice’ – All newborn babies, born at 35 weeks 0 days gestation or greater diagnosed with Jaundice

Defined as:

- P57 Kernicterus
  - P57.0 Kernicterus due to isoimmunization
  - P57.8 Other specified kernicterus
- P57.9 Kernicterus, unspecified
- P58 Neonatal jaundice due to other excessive haemolysis
  - P58.0 Neonatal jaundice due to bruising
  - P58.1 Neonatal jaundice due to bleeding
  - P58.2 Neonatal jaundice due to infection
  - P58.3 Neonatal jaundice due to polycythaemia
  - P58.4 Neonatal jaundice due to drugs or toxins transmitted from mother or given to newborn
  - P58.5 Neonatal jaundice due to swallowed maternal blood
  - P58.8 Neonatal jaundice due to other specified excessive haemolysis
  - P58.9 Neonatal jaundice due to excessive haemolysis, unspecified
- P59 Neonatal jaundice from other and unspecified causes
  - P59.0 Neonatal jaundice associated with preterm delivery
  - P59.1 Inspissated bile syndrome
  - P59.2 Neonatal jaundice from other and unspecified hepatocellular damage
  - P59.3 Neonatal jaundice from breast milk inhibitor
  - P59.8 Neonatal jaundice from other specified causes
  - P59.9 Neonatal jaundice, unspecified

Diagnosis Type:
M: Most responsible diagnosis on main patient service
1: Pre-admit comorbidity
2: Post-admit comorbidity
W: Service transfer diagnosis
X: Service transfer diagnosis
Y: Service transfer diagnosis

- Age range: Birth to 14 days
  - Newborn, 0 days, 1 day, 2 days, 3 days, 4 days, 5 days, 6 days, 7 days, 8 days, 9 days, 10 days, 11 days, 12 days, 13 days, 14 days

EXCLUSIONS:

- Any cases that fall into a HIG other than:
  - 585 – Newborn/Neonate 1500-1999 grams, Gestational Age 35+ Weeks
  - 587 – Newborn/Neonate 2000-2499 grams, Gestational Age 35-36 Weeks
  - 588 – Newborn/Neonate 2000-2499 grams, Gestational Age 37+ Weeks
  - 594 – Newborn/Neonate 2500+ grams, Jaundice
  - 602 – Newborn/Neonate 2500+ grams, Haemolytic Disease

NOTE: These codes for Jaundice capture only cases of hyperbilirubinemia that require intervention (such as phototherapy or exchange transfusion). At this time, data coding in the Discharge Abstract Database (DAD) does not assure the coding for cases of jaundice that do not require medical intervention, thus it is not possible to define these with any confidence. All infants with jaundice not requiring medical intervention are therefore captured in the ‘normal newborn’ group.
Readmission Cases

‘Readmissions’ – Infants born at 35 weeks 0 days gestation or greater, readmitted to the hospital within 14 days of birth

Defined as:

- ‘Infants with Jaundice’ – as above
- Those diagnosed with adult jaundice diagnosis codes
  - E80.6 Other disorders of bilirubin metabolism
  - E80.7 Disorder of bilirubin metabolism
  - R17 Unspecified jaundice
- Those diagnosed with haematological diagnosis codes
  - P55 Haemolytic disease of fetus and newborn
    - P55.0 Rh isoimmunization of fetus and newborn
    - P55.1 ABO isoimmunization of fetus and newborn
    - P55.8 Other haemolytic disease of fetus and newborn
    - P55.9 Haemolytic disease of fetus and newborn, unspecified
  - P61.4 Other congenital anaemias, not elsewhere classified
  - D58.9 Hereditary haemolytic anaemia, unspecified
- Those diagnosed with dehydration and feeding problems diagnosis codes
  *Include only those cases where phototherapy was administered (procedure code 1YZ12JADQ)*
  - E86.0 Dehydration
  - P74.1 Dehydration of newborn
  - P92.2 Slow feeding of newborn
  - P92.3 Underfeeding of newborn
  - P92.5 Neonatal difficulty in feeding at breast
  - P92.8 Other feeding problems of newborn
  - P92.9 Feeding problem of newborn, unspecified
  - R63.3 Feeding difficulties and mismanagement

Diagnosis Type:
M: Most responsible diagnosis on main patient service

- Age range: Birth to 14 days
  - Newborn, 0 days, 1 day, 2 days, 3 days, 4 days, 5 days, 6 days, 7 days, 8 days, 9 days, 10 days, 11 days, 12 days, 13 days, 14 days
Outpatient (Emergency Department) Cases

Any infant who visits the Emergency Department with Jaundice

Defined as:

- P57 Kernicterus
  - P57.0 Kernicterus due to isoimmunization
  - P57.8 Other specified kernicterus
  - P57.9 Kernicterus, unspecified
- P58 Neonatal jaundice due to other excessive haemolysis
  - P58.0 Neonatal jaundice due to bruising
  - P58.1 Neonatal jaundice due to bleeding
  - P58.2 Neonatal jaundice due to infection
  - P58.3 Neonatal jaundice due to polycythaemia
  - P58.4 Neonatal jaundice due to drugs or toxins transmitted from mother or given to newborn
  - P58.5 Neonatal jaundice due to swallowed maternal blood
  - P58.8 Neonatal jaundice due to other specified excessive haemolysis
  - P58.9 Neonatal jaundice due to excessive haemolysis, unspecified
- P59 Neonatal jaundice from other and unspecified causes
  - P59.0 Neonatal jaundice associated with preterm delivery
  - P59.1 Inspissated bile syndrome
  - P59.2 Neonatal jaundice from other and unspecified hepatocellular damage
  - P59.3 Neonatal jaundice from breast milk inhibitor
  - P59.8 Neonatal jaundice from other specified causes
  - P59.9 Neonatal jaundice, unspecified
- Those diagnosed with haematological diagnosis codes
  - P55 Haemolytic disease of fetus and newborn
    - P55.0 Rh isoimmunization of fetus and newborn
    - P55.1 ABO isoimmunization of fetus and newborn
    - P55.8 Other haemolytic disease of fetus and newborn
      - P55.9 Haemolytic disease of fetus and newborn, unspecified
  - P61.4 Other congenital anaemias, not elsewhere classified
  - D58.9 Hereditary haemolytic anaemia, unspecified
- Those diagnosed with dehydration and feeding problems diagnosis codes
  *Include only those cases where phototherapy was administered (procedure code 1YZ12JADQ)*
  - E86.0 Dehydration
  - P74.1 Dehydration of newborn
  - P92.2 Slow feeding of newborn
  - P92.3 Underfeeding of newborn
  - P92.5 Neonatal difficulty in feeding at breast
  - P92.8 Other feeding problems of newborn
  - P92.9 Feeding problem of newborn, unspecified
- R63.3 Feeding difficulties and mismanagement

Diagnosis Type:
Main Problem

- Age range: Birth to 14 days
  - Newborn, 0 days, 1 day, 2 days, 3 days, 4 days, 5 days, 6 days, 7 days, 8 days, 9 days, 10 days, 11 days, 12 days, 13 days, 14 days

Population Definition

In fiscal year 2014/15, QBP funding will be provided for Inpatient cases that meet the definition outlined on pages 12-14 of this Clinical Handbook. QBP Funding for Outpatient (Emergency Department) Cases will be explored for future years.
3.2 Evidence-Based Rational

The key objectives of this QBP are to:

- Ensure all newborns receive bilirubin screening between 24-72 hours of life (if not clinically indicated and performed earlier)
- Ensure infants receive systematic bilirubin monitoring as per the treatment graph and risk nomograms recommended by evidence-based guidelines
- Utilize health care resources responsibly through avoidance of unnecessary/excessive testing, timely discharge, appropriate outpatient follow-up and minimization of preventable readmission
- Reduce the incidence of severe hyperbilirubinemia and acute bilirubin encephalopathy

Application of the Evidence-Based Framework

Figure 3: Evidence-Based Framework
1. Practice Variation

*Is there variation in clinical outcomes across providers, regions and population?*

While there are recent guidelines from paediatric societies in Canada, the United States and the United Kingdom, practice variation in how these guidelines are implemented and followed exists. Experience and observations by the CEAG demonstrate that inconsistent application and interpretation of the guidelines affects infant length of stay, frequency of blood sampling and risk of readmission with severe hyperbilirubinemia.

The average length of stay for an infant with hyperbilirubinemia ranges across LHINs from 2.5 days to 4.5 days. See Figure 4. Readmission rates also vary across LHINs, from 6% to 13%, and the length of stay for these readmissions ranges from 2 to 5.9 days. See Figure 5.

Figure 4: 2011/12 Average Hyperbilirubinemia LOS (Days) by LHIN

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1 Hyperbilirubinemia Cases data from CIHI Portal. Definition as per “Infants with Jaundice” definition in Chapter 3.
Figure 5: 2011/12 Hyperbilirubinemia Readmissions and Readmit LOS (Days) by LHIN\(^2\)

![Graph showing percentage of cases readmitted and average LOS (days) by LHIN.]

Emergency Department lengths of stay show a variance ranging from 2.6 to 4.5 hours across LHINs. See Figure 6.

Figure 6: 2011/12 Average Emergency Department LOS (Hours) by LHIN\(^3\)

![Graph showing average LOS (hours) by LHIN.]

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\(^2\)Hyperbilirubinemia Cases data from CIHI Portal. Definition as per “Infants with Jaundice” definition in Chapter 3.

\(^3\)Hyperbilirubinemia Cases data from CIHI Portal. Definition as per “Infants with Jaundice” definition in Chapter 3.
Is there a high-degree of observed practice variation across providers or regions in clinical areas where a best practice or standard exists, suggesting such a variation is inappropriate?

According to the Health Insurance Reciprocal of Canada (HIROC), the leading provider of healthcare liability insurance in Canada, common themes seen in HIROC claims related to hyperbilirubinemia include: systematic assessments not performed; poor understanding/compliance with guidelines; inappropriate medical directives for assessments and testing; failure to interpret total serum bilirubin (TSB) levels according to the hour specific nomograph, and failure to document assessments, decisions and information provided to parents. (Health Insurance Reciprocal of Canada, 2012)

This is echoed by the experience and observations by the CEAG which suggests that in spite of the publication of the Canadian Paediatric Society’s clinical practice guidelines for infant hyperbilirubinemia (Canadian Paediatric Society, Fetus and Newborn Committee, 2007), there can be a lack of knowledge of the guidelines (or about universal screening in general), or where knowledge is had, there is still variation in the bilirubin screening and monitoring of newborns, and in the screening, monitoring and treatment of infants with hyperbilirubinemia.

2. Availability of Evidence

Is there a clinical evidence base for an established standard of care/or care pathway? How strong is the evidence?

Evidence-based clinical practice guidelines for the management of hyperbilirubinemia in term and late pre-term infants have been developed by the Canadian Paediatric Society (Canadian Paediatric Society, Fetus and Newborn Committee, 2007), the American Academy of Pediatrics (American Academy of Pediatrics Subcommittee on Hyperbilirubinemia, 2004), and the NHS National Institute for Health and Clinical Evidence (National Institute for Health and Clinical Excellence, 2010).

These guidelines incorporate the best available evidence, however, randomized controlled trials are rare in this area and many of the recommendations are based on lower levels of evidence, including expert opinion. The high degree of congruence between the three guidelines, however, suggests a relatively good agreement between experts as to the recommended surveillance and treatment.

Is costing and utilization information available to inform development of reference costs and pricing?

Costing and utilization information is available. Inpatient costs per case can be determined using the HBAM Inpatient Groups (HIGs). Case costing data is also available for those hospitals who participate in the Ontario Case Costing Initiative (OCCI). Emergency department costs are also available, however, costs pertaining to other outpatient follow-up such as visits to clinics or primary care cannot be captured.

What activities have the potential for bundled payments and integrated care?

Bundled payments could be considered for those infants in the normal newborn categories which would cover routine screening, both within the hospital and in community settings. A separate level of bundled payment could be considered for infants with a true jaundice diagnosis who will require medical therapy and have increased inpatient costs.
3. Feasibility/Infrastructure for Change

Are there clinical leaders able to champion change in the area?

Knowledge of the guidelines is widespread. Many clinicians, however, are struggling with their implementation and interpretation. A QBP such as this may help clinicians and administrators to focus their efforts in achieving best practice. As hyperbilirubinemia is such a common condition, and all newborns require screening, it is readily identified as a priority and finding clinical leaders and champions is not predicted to be difficult.

Is there data and reporting infrastructure in place?

Data and reporting infrastructure is in place, however, it does not accurately capture all cases of neonatal hyperbilirubinemia. Currently, cases of hyperbilirubinemia are captured in the Discharge Abstract Database (DAD) and the National Ambulatory Care Reporting System (NACRS). The data capture, however, is inconsistent and currently only captures the most serious cases of hyperbilirubinemia which require phototherapy or more intensive treatment including exchange transfusion. In addition, there is currently no mechanism to capture the severity of hyperbilirubinemia, bilirubin screening information, lab results (important to the determination of severity and treatment) or feeding details such as exclusive breastfeeding or supplementation (indications of feeding difficulties which are a risk factor for hyperbilirubinemia).

The BORN Ontario Information System (BIS) captures some hyperbilirubinemia-related information pertaining to the birth occurrence such as use of phototherapy, whether severe hyperbilirubinemia is present (but does not include a scale of severity) and feeding related data such as breastfeeding and supplementation. BORN Ontario has agreed to consider updating and improving the BIS to capture some of the proposed evaluation metrics, such as occurrence of bilirubin screening, severity of hyperbilirubinemia, and will also consider the possibility of adding lab results. The addition of this data to the BIS would be of enormous benefit to the province, both for the monitoring and evaluation of this QBP and for the health of infants in Ontario.

Finally, there is currently no method available to capture follow-up visit data for infants who are assessed in post-natal clinics, lactation clinics, by midwives or other multidisciplinary teams where physicians may not be providing the primary care and hence no OHIP billing is generated. This is a large gap in assessing the appropriateness of care and in assessing the overuse of physician consultations when cases could be addressed by other disciplines.

Can we leverage other initiatives or reforms related to practice change (e.g. Wait Time, Provincial Programs)?

Other programs that could be leveraged to improve hyperbilirubinemia screening and monitoring include the Healthy Babies Healthy Children Program (Ministry of Children and Youth Services), the Healthy Kids Strategy (Ministry of Health and Long-Term Care), and the Ontario Baby Friendly Initiative.
4. Cost Impacts

*Does the clinical group contribute to a significant proportion of total costs?*

Hyperbilirubinemia is a common condition affecting approximately 60% of term and 80% of pre-term babies in the first week of life (National Institute for Health and Clinical Excellence, 2010) (American Academy of Pediatrics Provisional Committee for Quality Improvement and Subcommittee on Hyperbilirubinemia, 2004)

Based on average costs per case, in fiscal 2011/12 there was a total of 9,884 cases of hyperbilirubinemia in Ontario. Of these cases, 6,521 had ‘jaundice’ as a main diagnosis accounting for $12.3Million and 3,363 cases had ‘jaundice’ as a secondary diagnosis, which accounted for $40.3Million. (Health Analytics Branch, Ministry of Health and Long-Term Care, 2013). In addition, HIROC ranks the failure to identify/monitor hyperbilirubinemia as the 14th highest risk in terms of cost. This represents 1.5% of all claims costs, some of which have gone as high as $8Million. (Health Insurance Reciprocal of Canada, 2012)

It is important to note that the costs per case focus strictly on infants diagnosed and treated for hyperbilirubinemia and do not include screening well babies for hyperbilirubinemia and the costs incurred with screening (such as the laboratory and health care provider costs). While the costs per patient in the well baby group will be lower than in those who require treatment for hyperbilirubinemia, the numbers of patients, and therefore the associated cost to the healthcare system, are large. There are approximately 140,000 births annually in Ontario (Statistics Canada, 2013), of which approximately 95% are 35 weeks or greater gestation (BORN Ontario, 2013). Over 130,000 babies therefore require screening and monitoring in order to identify the nearly 10,000 requiring treatment.

*Is there significant variation across providers in unit costs/volumes/efficiency?*

There is variation in costs related to, and volumes of hyperbilirubinemia across the province.

Hyperbilirubinemia volumes vary by LHIN from a low of 3% of total LHIN births up to 8% of total LHIN Births. See Figure 7.
Cost data provided by the Ministry of Health and Long-Term care show that 2011/12 estimates for infants diagnosed and treated for hyperbilirubinemia, using HBAM Acute Inpatient Unit Costs, demonstrate a range of Costs Per Weighted Case across the LHINs from $4,945 in North Simcoe Muskoka LHIN to $6,313 in Toronto Central LHIN. (Health Analytics Branch, Ministry of Health and Long-Term Care, 2013)

Limiting comparison to cases with the HIG 595 (‘jaundice’ as a main cause, removing many other comorbidities) the variance is less, however, estimated average costs still range from $1,648 in the Central LHIN to $2,242 in Toronto Central. (Health Analytics Branch, Ministry of Health and Long-Term Care, 2013)

Is there potential for cost savings or efficiency improvement through more consistent practice?

There is potential for cost savings and efficiency improvement through the application of this QBP. Anecdotally, patients are being tested excessively leading to increased laboratory costs as well as hospital outpatient charges. Ideal implementation, with increased community based services, also has the opportunity to reduce unnecessary consultation fees dependent on the model of care.

In addition, a recent study of the cost-effectiveness of a systems-based approach to managing neonatal hyperbilirubinemia (such as those recommended by the CPS and the AAP, and this QBP), versus traditional practice, has shown that system-based approaches are only slightly more expensive per patient (three dollars) than traditional approaches, and that these costs are more than offset by fewer emergency room visits, fewer hospital readmissions and fewer cases of kernicterus (Xie B, 2012).

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Footnote:

**How do we peruse quality and improve efficiency?**

Implementation of the QBP will improve efficiency by standardizing the timelines for clinical and laboratory follow-up, and there is an opportunity to link bilirubin screening with the current newborn screening protocol. Recommendations are also made for care to be provided in the community and home setting. The proposed quality indicators will allow for the evaluation of the QBP and measurement of improved quality.

**Are there potential areas for integration across the care continuum?**

There is significant potential for integration of hyperbilirubinemia follow-up care across the care continuum. Much of the follow-up and screening required post discharge from hospital could be done by care providers in the community. There is also potential for home based treatments such as home phototherapy. This approach, however, is problematic as most community-based providers are not available seven days per week and often do not have access to newborn blood collecting or laboratory services. Communities are struggling with the best way to ensure high quality integrated services across the continuum of care. In many communities hospitals have found no suitable alternative so have undertaken the follow-up of these infants.

5. **Impact on Transformation**

If community-based care is achievable, it will align with and impact the transformation priorities as outlined below.

**Is this aligned with Transformation priorities?**

Following Ontario’s Action Plan for Health Care, this QBP is aligned with:

- Item #2 Faster Access and a Stronger Link to Family Health Care – Recommendation of post discharge screening and follow-up to a primary care provider, will promote having 'Family Health Care at the Centre of the System', and will prevent visits to the ED and readmissions to the hospital.
- Item #3 Right Care, Right Time, Right Place – Ensuring consistent screening recommendations and consistent following of guidelines will promote ‘High Quality Care’, providing evidenced based care, and getting it right the first time

**Will this contribute directly to Transformation system-redesign?**

This quality based procedure will support and promote the Transformation system-design in so far as it will require:

- ‘Faster Access’, Item #2 Faster Access and a Stronger Link to Family Health Care
- ‘Local Integration of Family Health Care’, Item #2 Faster Access and a Stronger Link to Family Health Care
- ‘Timely Access to Care’, Item #3 Right Care, Right Time, Right Place
- ‘Care as Close to Home as Possible’, and in the most appropriate setting, Item #3 Right Care, Right Time, Right Place
3.3 Expert Panel and Clinician Engagement

The Clinical Expert Advisory Group (CEAG) for the paediatric QBP on Hyperbilirubinemia in Term and Late Pre-Term Infants was composed of both clinical experts and researchers in the field of hyperbilirubinemia. Members included paediatricians, neonatologists, family physicians, advance practice nurses, midwives, researchers and analysts from across the province. See Chapter 10 for the list of membership.

Over the course of five months the CEAG held 4 in-person meetings and a number of teleconferences with smaller working groups. When required, CEAG members sought feedback and input from others within their networks of expertise. CEAG decisions were made by general consensus.
4.0 Best practices Guiding the Implementation of the QBP for Hyperbilirubinemia in Term and Late Pre-Term Infants (≥35 weeks)

4.1 Definition of Best Practices

To date there have been at least three national guidelines for the treatment of hyperbilirubinemia in term or near-term infants:

- Canadian Paediatric Society (CPS) (Canadian Paediatric Society, Fetus and Newborn Committee, 2007) and

These guidelines are currently the recommended practice for managing hyperbilirubinemia in their respective countries.

The proposed clinical pathway for the management of hyperbilirubinemia in term and late-pre-term infants has been informed by these guidelines, the evidence informing them and the expert opinion of the CEAG. Where further evidence was required it was sought in a systematic manner. Where evidence was not available the CEAG based their recommendations on the consensus of the group.
4.2 Clinical Pathway for the Management of Hyperbilirubinemia in Term and Late Pre-Term Infants (≥35 weeks)

Figure 8: Clinical Pathway for the management of Hyperbilirubinemia in Term and Late Pre-Term Infants (≥35 weeks)

This pathway uses Total Serum Bilirubin (TSB) measurement. If using Transcutaneous Bilirubin (TcB) measurement, refer to the recommendations regarding Transcutaneous Bilirubin Screening on page 39.

Total Serum Bilirubin (TSB) = Unconjugated/Indirect Bilirubin + Conjugated/Direct Bilirubin
DAT = Direct Anti-Globulin Test
HCP = Health Care Provider
## Clinical Pathway Instructions and Recommendations

**Legend:**

- AAP = American Academy of Pediatrics Guidelines
- CPS = Canadian Paediatric Society Guidelines
- NICE = National Institute for Clinical Evidence Guidelines

For a description of the levels of evidence used in each guideline, please see Appendix A.

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<th>Instructions</th>
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<td><strong>UNIVERSAL SCREENING</strong></td>
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| 1 Identify newborns of mothers with red cell antibodies (isoimmunization) | - All mothers should be tested for blood type (ABO and Rh(D)) and screened for red cell antibodies during pregnancy  
- If mother not tested during pregnancy, cord blood should be sent for blood group and DAT  
- Significance of various antibodies differs  
- Consultation with a neonatologist or paediatrician suggested due to risk of bilirubin encephalopathy | AAP Guidelines (Quality B: benefits exceed harms), CPS Grade D |
| 2 Newborns of mothers with red cell antibodies should have blood group evaluation and direct anti-globulin test (DAT) | - Significance of various antibodies differs  
- Further evaluation, closer follow-up and earlier therapy may be required  
- Consultation with a paediatric haematologist or neonatologist suggested | CPS |
| 3 Measure cord blood for haemoglobin and TSB | - Measurement of haemoglobin and bilirubin from cord blood suggested as part of initial evaluation for DAT positive infants of mothers with red cell antibodies | CEAG Consensus |
| 4 If cord TSB level $\geq 100\mu mol/L$ | - Critical value, suggestive of need for exchange transfusion  
- Multiple intensive phototherapy should be initiated without delay, while continuing pathway (Step #17) and initiating consult (Step #18) | NICE |
| 5 If cord TSB level $<100\mu mol/L$ | - Plot bilirubin on Phototherapy Graph (Figure 9, Step #10), using time = 0 hours  
- Isoimmunization is a risk for bilirubin encephalopathy  
- If gestation 35-37+6 weeks, use the “high risk” line (lowest position on graph, brown line)  
- If gestation 38 weeks or more, use the “medium risk” line (middle position on graph, blue line) | |
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| 6 | Clinically assess for jaundice routinely during newborn care                 | - If visibly jaundiced at 24 hours of age or less, do a blood smear, blood group screen, DAT, and test for G6PD deficiency  
- Jaundice might appear clinically at any time in the newborn period  
- Jaundice in the first 24 hours is more likely to be significant/pathologic, so multiple clinical assessments in the first 24 hours are recommended  
- Clinical assessment of jaundice should continue at every well newborn check through the newborn period, before and after universal bilirubin screening  
- In case of early discharge (prior to 24 hours) parents need to be made aware of potential for jaundice and understand when to contact health care provider prior to universal bilirubin screening at 24-72 hours. | AAP (Quality D: benefits vs harms exceptional) (8-12 hours)  
NICE (every opportunity in the first 72 hours)  
CPS (repeatedly in the first 24 hours, at a minimum 24-48 hours)  
CEAG Consensus |
| 7 | Measure TSB in all newborns who appear clinically jaundiced in their first 24 hours of life | - Further evaluation may be required to determine etiology of early jaundice (see Step# 6) | AAP (Quality C benefits exceed harms), CPS (Grade D), NICE |
| 8 | If not required earlier because of clinical jaundice, TSB should be obtained (CPS Grade C) at the same time as newborn screening (between 24-72 hours of age) | - For early discharge babies, arrangements should be made for outpatient bilirubin measurement | CEAG Consensus |
| 9 | Assess for presence of any Bilirubin Encephalopathy Risk Factors (RF #1)     | - Bilirubin Encephalopathy Risk Factor (RF #1) determination, along with gestational age, is used to identify the low/medium/high treatment threshold lines on the Phototherapy Graph (Figure 9)  
- Assess for:  
  1. Isoimmune haemolytic disease  
     *Blood group evaluation and DAT Recommended*  
  2. G6PD deficiency  
     *At risk infants (ethnic origin, family history) and infants with severe jaundice should be screened for G6PD deficiency*  
  3. Asphyxia  
     *Apgar 0-3 beyond 5 min AND cord pH<7.0* | AAP (Reproduced in CPS)  
CPS (Grade D) |
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| 10. Plot TSB on **Phototherapy Graph** (figure 9) to determine need for phototherapy | - Determination of treatment line depends on gestational age at birth as well as presence of **Bilirubin Encephalopathy Risk Factors (RF #1)** from Step #9.  
  - Use the “high risk” line (lowest position on the graph, brown line) for 35-37 weeks plus 6 days gestation and one or more risk factors from **Step #9**  
  - Use the “medium risk” line (middle position on graph, blue line) for 35-37 weeks plus 6 days gestation and NO risk factors from **Step #9** OR baby was born at 38 weeks or greater gestation and one or more of the risk factors from **Step #9**.  
  - Use the “low risk” line (highest position on the graph, green line) if baby was born at 38 weeks or greater gestation and has NO risk factors from **Step #9**  
  - Plot on **Phototherapy Graph** (Figure 9) using TSB (unconjugated + conjugated) and age in hours at the time that the bilirubin was measured. | AAP (Reproduced in CPS)  

AAP
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<td><strong>PHOTOTHERAPY - YES</strong></td>
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<td>* If mom type O do a blood group screen and Coombs test</td>
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<td>CPS (Grade B)</td>
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<td><strong>11</strong> If phototherapy indicated determine if TSB is within 50µmol/L of the exchange transfusion line on <em>Exchange Transfusion Graph</em> (Figure 10)</td>
<td>- Plot TSB bilirubin on <em>Exchange Transfusion Graph</em> (Figure 10) and refer to same risk line as was used for the <em>Phototherapy Graph</em> (Figure 9)</td>
<td>NICE</td>
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<td><strong>12</strong> If no in Step #11, start Standard Intensive Phototherapy</td>
<td>- Use dose of 30 uW/cm²/nm minimum&lt;br&gt;- Irradiance does not need to be measured every time but regular calibration checks of equipment are required according to manufacturer’s instructions&lt;br&gt;- Expose maximal skin surface to the lights&lt;br&gt;- Diaper may be left on&lt;br&gt;- Using clinical judgment, short breaks (up to 20-30 minutes q3h) for breastfeeding and other care may be allowed&lt;br&gt;- If using a phototherapy blanket it should remain in place during breaks for feeding and care&lt;br&gt;- Continue lactation and breastfeeding support&lt;br&gt;- Weigh baby daily and monitor urine and stool output&lt;br&gt;- Supplementation of breastfed infants with water or dextrose water is not recommended.&lt;br&gt;- If supplementation is considered, preference is expressed breast milk</td>
<td>AAP, CPS (Grade D) AAP, CPS, NICE AAP, CPS AAP(Quality C: benefits exceed harms), CPS (Grade A), NICE, CEAG Consensus CEAG Consensus NICE NICE, CEAG Consensus AAP, CPS (Grade B), NICE CEAG Consensus</td>
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<td><strong>13</strong> Repeat TSB in 4-6 hours</td>
<td>- Use clinical judgment including consideration of <em>Severe Hyperbilirubinemia Risk Factors (RF #2)</em> and height of TSB to determine patient specific timing of repeat</td>
<td>AAP, NICE</td>
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<tr>
<td><strong>14</strong> If TSB is stable/falling continue to repeat TSB q8-24 hours while on phototherapy</td>
<td>- Use clinical judgment considering <em>Severe Hyperbilirubinemia Risk Factors (RF #2)</em>, response to therapy and height of TSB to determine patient specific timing of repeat</td>
<td>CEAG Consensus, considering: NICE (q6-12hr)</td>
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<td><strong>15</strong> Discontinue phototherapy when TSB is below threshold for phototherapy initiation</td>
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<td>CEAG Consensus</td>
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<td><strong>16</strong> Check TSB for rebound 12-24</td>
<td>- Patient does not need to remain in</td>
<td>CEAG Consensus,</td>
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<td>Instructions</td>
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| 17 If YES in Step #11, start Multiple Intensive Phototherapy | - Add a phototherapy blanket under the infant to increase exposed surface area (i.e. double surface phototherapy)  
- Remove diaper  
- Do not interrupt phototherapy for feeding or other care  
- Supplemental fluids, oral or IV, should be administered in infants at elevated risk of requiring an exchange transfusion  
- Continue lactation/feeding support  
- Weigh baby daily and monitor urine and stool output | CPS  
AAP, CPS  
AAP, NICE  
CPS (Grade A) |
| 18 Consider immediate consult with neonatologist (CPS Grade B) | - IVIG or exchange transfusion may be indicated  
- Exchange transfusion should only be performed in tertiary level NICUs | AAP(Quality B: Benefits Exceeds Harms, Quality D: Benefits vs Harms Exceptional), CPS (Grade A), NICE  
AAP (Quality D: Benefits vs Harms Exceptional), CPS |
| 19 Repeat TSB in 2-6 hours to confirm response to treatment | - Use clinical judgment including considering Severe Hyperbilirubinemia Risk Factors (RF #2) and height of TSB to determine patient-specific timing of repeat test | CPS, NICE (4-6 hrs) |
| 20 If TSB stable or decreasing continue to repeat q6-12h | - Use clinical judgment Severe Hyperbilirubinemia Risk Factors (RF #2), response to therapy and height of TSB to determine patient specific timing of repeat test | NICE |
| 21 When TSB is more than 50µmol/L below exchange transfusion threshold return to Step # 9 | | NICE |

**PHOTOTHERAPY - NO**

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| 22 If phototherapy not indicated, plot the TSB on the Hour-Specific Nomogram (See Figure 11) | - Use the infant’s age in hours at the time of blood draw  
- Use TSB (unconjugated + conjugated)  
- If (high-intermediate zone) and mom blood type O do a blood group screen and Coombs test | AAP, CPS (Grade D)  
CPS (Grade B) |
| 23 Assess for presence of any Severe Hyperbilirubinemia Risk Factors (RF #2) | - The following risk factors are used to determine timing of repeat testing and clinical follow-up in Step #24: | AAP (Quality C: Benefits Exceeds Harms)  
CPS |
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| 24 **Consult Follow-Up Algorithm (Figure 12) for management and follow-up according to pre-discharge TSB** | 1. Use algorithm to determine:  
   - If repeat TSB measurement is indicated  
   - Recommended timing of repeat TSB  
   - Recommended timing of clinical follow-up | AAP, CPS, Maisels |
<p>| 25 <strong>Arrange follow-up TSB measurement, if indicated</strong> | - Setting of follow-up may vary depending on community resources. Refer to recommendations regarding <em>Community Follow-Up Care and Monitoring</em>, page 40 | CPS AAP (Quality C: Benefits Exceed Harms), NICE, Maisels |
| 26 <strong>If appropriate follow-up cannot be ensured in the presence of elevated risk for developing severe hyperbilirubinemia, delay discharge</strong> | - Discharge should be delayed until appropriate follow-up can be ensured or the period of greatest risk has passed (72-96 hours.) | AAP (Quality D: Benefits vs Harms Exceptional) |
| 27 <strong>Provide lactation evaluation and support for all breastfeeding mothers</strong> | | CPS (Grade D) Maisels |
| 28 <strong>Any infant discharged before 24 hours should be assessed by an HCP within 24 hours</strong> | - Health care provider conducting the assessment needs to have access to testing and treatment facilities. | CPS (Grade D) |
| 29 <strong>The infant’s parent/guardian should be provided with written and verbal instructions regarding the infant’s follow-up and the timing of that follow-up (Refer to recommendations)</strong> | - Include general information regarding jaundice, the importance of repeat TSB (if indicated) and clinical follow-up. | Adapted from AAP (Quality D: Benefits vs Harms Exceptional) |</p>
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<td>regarding <em>Discharge Documentation</em>, page 40)</td>
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| **30** The follow-up assessment should include | - Expectations:  
- Infant’s weight and % change from birth weight  
- Adequacy of intake  
- Pattern of voiding and stooling  
- Presence or absence of visible jaundice | AAP (Grade C) |
| | - Weight loss should be no more than 10% of birth weight  
- 4 to 6 wet diapers and 3 to 4 stools per day by the fourth day  
- Stools in breastfed infants should have changed from meconium to mustard yellow  
- Consider observing breastfeeding to assess effectiveness | |
| | - If there is any doubt about the degree of jaundice, the TSB level should be measured.  
- Visual estimation of bilirubin levels can lead to errors, especially in darkly pigmented infants. | AAP (Grade C) |
| **31** Clinical judgment should be used to determine the need for TSB measurement | - To determine the need for phototherapy, need for further TSB measurements, and timing of clinical follow-up | |
| **32** Any repeat TSB measurements should be plotted in this algorithm in same manner as the initial TSB | | |
Related Figures

Figure 9: Phototherapy Graph

Adapted with permission from the Champlain Maternal Newborn Regional Program (Champlain Maternal Newborn Regional Program, 2012)
Figure 10: Exchange Transfusion Graph

Figure 3) Guidelines for exchange transfusion in infants of 35 or more weeks’ gestation. These guidelines are based on limited evidence and the levels shown are approximations. Exchange transfusions should be used when the total serum bilirubin (TSB) concentration exceeds the line indicated for each category.

Reproduced with permission from the Canadian Paediatric Society, (Canadian Paediatric Society, Fetus and Newborn Committee, 2007)
Figure 11: Hour Specific Nomogram

Based on data from Stevenson et al. (Stevenson DK, 2001)
Figure 12: Follow-Up Algorithm

Modeled on Maisels’ Algorithm (Maisels MJ, 2009), reflecting the findings of the Clinical Expert Advisory Group for the paediatric QBP on Hyperbilirubinemia in Term and Late Pre-Term Infants.
Other Considerations and Recommendations

Home Phototherapy

The CEAG considered whether a program of home phototherapy would be advantageous in treating hyperbilirubinemia. The Maternal-Child Screening Committee’s Severe Hyperbilirubinemia Task Force is currently undertaking a Rapid Review on Severe Hyperbilirubinemia. Based on the evidence reviewed to-date, and the experience of CEAG members with such programs in the community, the CEAG determined that there is insufficient evidence to recommend a home phototherapy program as a core part of this QBP or standard of care. While lacking strong evidence to recommend this service, there also does not appear to be strong evidence of harm associated with such programs and the CEAG can see potential benefits to a home phototherapy program in some circumstances. Such a program has the potential to save costs and address gaps in communities where accessing follow-up care could be burdensome to families. If skilled blood sampling for the neonate cannot be offered in the home, many of the benefits of home phototherapy would be negated.

- The CEAG therefore recommends that in any community implementing a home phototherapy program, a planned evaluation is essential.

Transcutaneous Bilirubin Screening

The CEAG would like to note that both total serum bilirubin (TSB) and transcutaneous bilirubin (TcB) are acceptable methods of bilirubin screening. The Maternal-Child Steering Committee’s Severe Hyperbilirubinemia Task Force’s Review on Severe Hyperbilirubinemia (currently underway) has found that there is generally a good correlation between TcB and TSB measures. In addition, it has found that TcB is relatively easy to perform, time saving, pain free for the infant and spares blood. Once the initial cost of the machine is accounted for, TcB can be less expensive than TSB depending on the model of machine used. It should be noted, however, that the accuracy of the TcB machine is dependent on regular maintenance and upkeep, thus a quality assurance program would need to be ensured.

If centres choose to use TcB for hyperbilirubinemia screening, the CEAG makes the following recommendations:

- The initial screening TcB should be done PRIOR to the time of the Newborn Screen so that, should a TSB be required, it can be done at the time of the Newborn Screen thus avoiding two blood draws
- If the TcB result is within 50 µmol/L of the phototherapy treatment line, a TSB should be performed immediately. This is recognized to be conservative, however, the evidence of correlation between TcB and TSB is variable and the TcB tends to underestimate TSB to a greater degree at higher (more dangerous) values
- A quality assurance program must be implemented and include calibration and return of the units to the manufacturer for quality assurance as required by the manufacturer’s recommendations
- TcB may not be used during or following phototherapy treatment, TSB is required
- **Use of TcB does not replace lab availability and it cannot be used without available laboratory backup**


Community Follow-Up Care and Monitoring

Infants discharged and requiring a visit to their health care provider for follow-up would be provided with the right care in the right place via a visit to their primary care provider, a follow-up clinic, or a community health care provider. Routine follow-ups do not usually require the consultation of a paediatrician specialist and should not generally take place in an Emergency Department, although this tends to happen frequently.

- The CEAG therefore recommends, where possible, the use of community health care resources to follow-up infants once discharged. Where community health care resources are not available and infants must return to the hospital, or other acute care facility, the CEAG recommends that protocols be in place to expedite the testing and to avoid infants waiting in general waiting rooms where they may be exposed to risk of infection.

Weekend and Community Lab Access

Access to lab services that will undertake blood work on weekends in the community is currently a major impediment to ensuring the timely screening and monitoring of bilirubin required to deliver the right care, at the right time, in the right place. In addition, most labs have limited experience taking blood samples from newborns.

- In communities where a blended model of hospital and community-based services are available, the CEAG recommends that the community-based services must meet the following criteria:
  - Skilled in obtaining blood from infants
  - Use appropriate pain management
  - Have the ability to deliver lab results within two hours of the blood draw

- Given the early discharge practices of maternal units, the need for standard testing in the newborn (newborn screening, hearing testing, bilirubin) and the fact that many community based services do not operate seven days per week, PCMCH should be asked to convene a task group that will make recommendations about the best way to achieve consistent high quality testing and timely results reporting in Ontario.

Discharge Documentation

It is important that the health care providers who will be undertaking the follow-up care of the infant be aware of their patient’s “bilirubin journey” and any actions taken while in hospital.

- CEAG therefore recommends that, upon discharge, the infant’s parents or guardian be provided with materials that document their child’s screening and treatment history so that this can be shared with subsequent health care providers (HCP) in order to facilitate care. It is expected that this will decrease the number of repeat bilirubin tests performed after discharge as HCPs will be able to see the trend of values. Refer to section 4.3 for more details.
4.3 **QBP Documentation**

For implementation, the CEAG recommends the clinical pathway and associated graphs/figures be made available as easily reproduced tools for use by front line clinicians.

In addition the CEAG recommends that the plotting of the TSB levels on the *Phototherapy Graph*, the *Hour-Specific Nomogram*, details pertaining to the action and outcome of any treatment decisions (and who they were made by), and the proposed follow-up plan be documented. This information about the infant’s “bilirubin journey” should then be provided to parents or guardians either on the discharge summary, or separately once the final bilirubin measure has been taken, as this information is important for infant follow-up care in the community. Examples of suggested discharge summaries will be made available.

4.4 **Patient Outcomes**

The QBP on Management of Hyperbilirubinemia in Term and Late-Pre-Term Infants will improve patient outcomes by ensuring universal screening of all newborns, standardizing the timing of repeat testing, improving the understanding of patient risk and subsequently ensuring that the appropriate risk line is used to determine the need for phototherapy, encouraging creative resource use to facilitate community follow-up after discharge, improving communication between in hospital and community care providers and reminding health care providers when consultation with a paediatrician or neonatologist may be required.
5.0 Implementation of Best Practices

How should best practices be implemented to ensure standardized and optimal patient care delivery? How can organizations/communities tailor the recommended patient clinical pathways and best practices to their local circumstances?

Organizations and communities will be able to identify the most appropriate health care provider for the various parts of the pathway for their situation. Of particular importance, successful implementation will require the development of partner relationships with all involved in the pathway (both within the hospital and between the hospital and community health care providers). In developing these relationships, roles and responsibilities should be clearly articulated and agreements should be drawn up if/as necessary, i.e. between inpatient units and community providers or other hospital units/clinics providing care.

Describe the roles of the clinicians and multi-disciplinary teams in implementing the best practices

Clinicians and multi-disciplinary teams will be critical in implementing the QBP. Their role is to determine the best way to implement the QBP in their unique environment, comparing current practice to the ideal and ensuring optimal environments for care. Team members can include (but are not limited to), perinatal nurses, lactation consultants, midwives and physicians. Much of the screening can be done by nursing staff (provided they have medical directives to order bilirubin screening) until the infant can be seen by a physician.

Describe data management implications (if applicable)

As mentioned previously in the Evidence-Based Framework, data collection data and reporting infrastructure is in place, however, neither the DAD or NACRS captures hyperbilirubinemia in a consistent manner, nor do they capture important details such as severity, bilirubin levels or feeding information.

The BORN BIS captures some hyperbilirubinemia-related information, however, it is not as comprehensive as would be ideal. BORN has agreed to consider updating their BIS to capture some of the evaluation metrics outlined in the evaluation metrics chapter.

Finally, there is currently no method available to capture follow-up visit data for infants who are assessed in post-natal clinics, lactation clinics and other locations by midwives or other multidisciplinary teams where physicians may not be providing the primary care. This is a large gap in assessing the appropriateness of care.
6.0 What Does It Mean For Multi-Disciplinary Teams?

Will the QBP have any implication for multidisciplinary teams? Describe the immediate and/or long-term impact on physicians, nurses, allied health, health records, etc.

Implementation of the QBP should not have a dramatic impact for those organizations that currently follow the Canadian Paediatric Society’s (CPS) guidelines for management of hyperbilirubinemia. In some organizations, however, there may be a significant change in clinician work flow if the QBP’s clinical pathway differs significantly from their current practice:

- Education may be required for clinicians not familiar with the use of the treatment graph or nomographs.
- There may be a change in physician/clinician responsibilities and in referral and consultation patterns as the pathway suggests moving towards follow-up care in community health settings. Community health care providers will likewise be impacted if this recommendation to move follow-up care to them is a change for a given community.
- There will be either more blood tests, in centres not already doing universal screening, or fewer blood tests, in centres not following standardized recommendations for repeat testing. This will have a direct impact on nursing, phlebotomy services and labs.
- The QBP funding should reduce specialist consultation for the interpretation of bilirubin results. Although this is more appropriate practice it will decrease fee-for-service income for some paediatricians.

How does it align with clinical practice?

The QBP care pathway is in alignment with the guidelines for the management of hyperbilirubinemia published by the CPS. Additional details intended to guide clinical practice are provided by the expert opinion of the CEAG. Use of the QBP will therefore promote further standardization of practice across hospital settings, reducing the areas for possible practice variance not addressed by the guidelines.

Will it change current clinical practice?

For those hospitals that do follow the CPS guidelines the change should not be dramatic, however, there may be changes regarding work flow and responsibilities for some health care providers.

In hospitals that do not follow the CPS guidelines the implementation of this QBP may be a significant change in clinical practice and may require change management strategies and education regarding the use of the nomograph and treatment graphs in order for it to be successful. There may also be changes to documentation following the recommendation for screening information to be provided to the patient’s parent or guardian.
7.0 Service Capacity Planning

The LHINs will work with their HSPs to ensure that as the funding reform is implemented, the overarching goals of ECFAA are followed. These include: managing access to care, promoting care closer to home and ensuring that the patients get the right care, at the right time, and at the right place.

HSPs wishing to change their current/ future volumes will discuss with the LHINs the feasibility of such changes from a system perspective and not just an individual organization’s perspective.
# 8.0 Performance Evaluation and Feedback

The following are the proposed evaluation metrics for the pediatric QBP on Management of Hyperbilirubinemia in Term and Late Pre-Term Infants (≥ 35 weeks). The metrics refer to the population as defined in Section 3 of this handbook.

<table>
<thead>
<tr>
<th>Evaluation Metric</th>
<th>Domain</th>
<th>Relevance</th>
<th>Rational</th>
<th>Feasibility/ Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Percent infants receiving a bilirubin measurement in the first 72 hours of life</td>
<td>Effectiveness</td>
<td>Clinicians Administrators LHINS</td>
<td>To determine if the QBP is being followed. With the QBP in place, all babies (100%) should receive bilirubin testing in the first 72 hours of life.</td>
</tr>
<tr>
<td>2a</td>
<td>Percent infants with severe hyperbilirubinemia</td>
<td>Effectiveness</td>
<td>Clinicians Administrators LHINS</td>
<td>Infants with severe hyperbilirubinemia are likely those who were missed by bilirubin screening/the QBP. This indicator will be most useful/prevalent in cases of readmission.</td>
</tr>
<tr>
<td>2b</td>
<td>Percent infants with critical hyperbilirubinemia</td>
<td>Effectiveness</td>
<td>Clinicians Administrators LHINS</td>
<td>See 2a. In addition, if linked with readmissions can be used for monitoring and tracking</td>
</tr>
<tr>
<td>3</td>
<td>Percent infants who require phototherapy</td>
<td>Appropriateness</td>
<td>Administrators LHINS</td>
<td>To determine baseline numbers of infants requiring phototherapy</td>
</tr>
<tr>
<td>4a</td>
<td>Length of Stay</td>
<td>Appropriateness</td>
<td>Administrators LHINS</td>
<td>To determine the initial LOS of infants who develop hyperbilirubinemia during their birth hospitalization prior to discharge</td>
</tr>
<tr>
<td>4b</td>
<td>Total Hospital Days LOS</td>
<td>Effectiveness Appropriateness</td>
<td>Administrators LHINS</td>
<td>To determine total LOS associated with a diagnosis of hyperbilirubinemia. Can also be a proxy for complex/serious cases, or those who may not have followed the QBP</td>
</tr>
</tbody>
</table>

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⁵ BORN could potentially add a bilirubin screening element to the BORN Information System (BIS)

⁶ BORN could potentially modify the current severe hyperbilirubinemia data element to >340umol/L (currently >475umol/L is collected)

⁷ BORN could potentially add a critical hyperbilirubinemia data element of TSB >425umol/L

⁸ BORN will explore the potential for lab data uploads to the BIS
<table>
<thead>
<tr>
<th>Evaluation Metric</th>
<th>Domain</th>
<th>Relevance</th>
<th>Rational</th>
<th>Feasibility/ Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5a  Number of readmissions within 14 days of birth for hyperbilirubinemia</td>
<td>Integration</td>
<td>Administrators LHINS</td>
<td>To determine total number of hospital admissions associated with a diagnosis of hyperbilirubinemia which may indicate proper use of the QBP</td>
<td>DAD?</td>
</tr>
<tr>
<td>5b  Number of readmissions within 14 days of birth for severe hyperbilirubinemia</td>
<td>Integration</td>
<td>Administrators LHINS</td>
<td>To determine total number of hospital admissions associated with a diagnosis of severe hyperbilirubinemia which may indicate failure of the system/cases that were missed by the QBP</td>
<td>DAD?</td>
</tr>
<tr>
<td>6    Per case direct cost</td>
<td>Efficiency</td>
<td>Administrators LHINS</td>
<td>To determine if costs are coming in at par with QBP</td>
<td>Ontario Case Costing Initiative (OCCI) Database</td>
</tr>
<tr>
<td>7    Percent infants requiring exchange transfusion or IVIG for hyperbilirubinemia</td>
<td>Effectiveness</td>
<td>Clinicians Administrators LHINS</td>
<td>Infants requiring exchange transfusion or IVIG therapy represent the most severe cases and may representing failure of the system/QBP</td>
<td>DAD?</td>
</tr>
<tr>
<td>8    Percent exclusive Breastfeeding versus Supplementation during phototherapy</td>
<td>Appropriateness</td>
<td>Patients Administrators LHINS</td>
<td>A measure of variation in practice across hospitals</td>
<td>BORN?</td>
</tr>
<tr>
<td>9a   Number of ED visits within 14 days of discharge</td>
<td>Effectiveness</td>
<td>Clinicians Administrators</td>
<td>To determine ED resource utilization by this population</td>
<td>NACRS linked with DAD or BORN BIS</td>
</tr>
</tbody>
</table>
| 9b   Number of walk-in clinic or other clinic visits within 14 days of discharge | Effectiveness    | Clinicians Administrators | To determine walk-in clinic resource utilization by this population                                | OHIP Billing Data Available? 
This indicator would only capture physician visits, not clinic or nursing visits. |
| 10   Number of follow-up physician visits or repeat visits?                     | Integration     | Administrators LHINS | To determine where patients are going for follow-up visits. May also determine physician over-use in areas where multidisciplinary or nurse-led clinics/services are available | OHIP Billing Data Available? |
9.0 Support for Change

The ministry, in collaboration with its partners, will deploy a number of field supports to support adoption of the funding policy. These supports include:

- **Committed clinical engagement** with representation from cross-sectoral health sector leadership and clinicians to champion change through the development of standards of care and the development of evidence-informed patient clinical pathways for the QBPs.

- **Dedicated multidisciplinary clinical expert group** that seek clearly defined purposes, structures, processes and tools which are fundamental for helping to navigate the course of change.

- **Strengthened relationships with ministry partners and supporting agencies** to seek input on the development and implementation of QBP policy, disseminate quality improvement tools, and support service capacity planning.

- **Alignment with quality levers such as the Quality Improvement Plans (QIPs).** QIPs strengthen the linkage between quality and funding and facilitate communication between the hospital board, administration, providers and public on the hospitals’ plans for quality improvement and enhancement of patient-centered care.

- **Deployment of a Provincial Scale Applied Learning Strategy known as IDEAS (Improving the Delivery of Excellence Across Sectors).** IDEAS is Ontario’s investment in field-driven capacity building for improvement. Its mission is to help build a high-performing health system by training a cadre of health system change agents that can support an approach to improvement of quality and value in Ontario.

We hope that these supports, including this Clinical Handbook, will help facilitate a sustainable dialogue between hospital administration, clinicians, and staff on the underlying evidence guiding QBP implementation. The field supports are intended to complement the quality improvement processes currently underway in your organization.
10.0 Membership

Provincial Council for Maternal and Child Health

Clinical Expert Advisory Group Paediatric QBP - Hyperbilirubinemia

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Organization</th>
<th>LHIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pervez Z. Faruqi</td>
<td>Paediatrician</td>
<td>Chatham-Kent Health Alliance</td>
<td>1</td>
</tr>
<tr>
<td>Paul Dick</td>
<td>Paediatrician, Chief of Paediatrics</td>
<td>Grey Bruce Health Services</td>
<td>2</td>
</tr>
<tr>
<td>Charlotte Etue</td>
<td>CNS, Childbirth Program, NICU Co-Chair</td>
<td>Grand River Hospital</td>
<td>3</td>
</tr>
<tr>
<td>Tamar Packer</td>
<td>Family Physician, Medical Director, Newborn Care</td>
<td>St. Joseph’s Healthcare Hamilton</td>
<td>4</td>
</tr>
<tr>
<td>Andrea Temple</td>
<td>RN, Manager, Paediatrics/NICU</td>
<td>William Osler health System</td>
<td>5</td>
</tr>
<tr>
<td>Jane Healey</td>
<td>Paediatrician</td>
<td>Trillium Health Partners</td>
<td>6</td>
</tr>
<tr>
<td>Luca Simonetto</td>
<td>Senior Analyst, Strategy Management Office</td>
<td>Trillium Health Partners</td>
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<tr>
<td>Michael Sgro</td>
<td>Paediatrician</td>
<td>St. Michael’s Hospital</td>
<td>7</td>
</tr>
<tr>
<td>Vibhuti Shah</td>
<td>Neonatologist</td>
<td>Mount Sinai Hospital</td>
<td>7</td>
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<tr>
<td>Charmaine van Schaik</td>
<td>Paediatrician, Chief of Paediatrics</td>
<td>Southlake Regional Health Centre</td>
<td>8</td>
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<tr>
<td>Robert Connelly</td>
<td>Neonatologist</td>
<td>Kingston General Hospital/Hotel Dieu Hospital</td>
<td>10</td>
</tr>
<tr>
<td>JoAnn Harrold</td>
<td>Neonatologist Co-Chair</td>
<td>Children’s Hospital of Eastern Ontario</td>
<td>11</td>
</tr>
<tr>
<td>Liz Darling</td>
<td>Midwife</td>
<td>Ottawa</td>
<td>11</td>
</tr>
<tr>
<td>Andrea Mills</td>
<td>Midwife</td>
<td>Royal Victoria Hospital, Barrie</td>
<td>12</td>
</tr>
<tr>
<td>Angie Wiwczor</td>
<td>Nurse Practitioner, Family Child Program</td>
<td>Health Sciences North</td>
<td>13</td>
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<tr>
<td>Linsey Mutch</td>
<td>Paediatrician</td>
<td>North Bay Regional Health</td>
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</tr>
<tr>
<td>Sandy Dunn</td>
<td>RN, PhD Knowledge Translation Specialist</td>
<td>BORN Ontario</td>
<td></td>
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<tr>
<td>Julian Little</td>
<td>Professor and Chair, Dept. of Epidemiology &amp; Community Medicine (Canada Research Chair in Human Genome Epidemiology)</td>
<td>Maternal-Child Screening Committee</td>
<td></td>
</tr>
<tr>
<td>Riffaat Mamdani</td>
<td>Program Consultant, Child Development Unit</td>
<td>Ministry of Children and Youth Services</td>
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Secretariat

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marilyn Booth</td>
<td>Executive Director</td>
<td>PCMCH</td>
</tr>
<tr>
<td>Doreen Day</td>
<td>Senior Project Manager</td>
<td>PCMCH</td>
</tr>
</tbody>
</table>
11.0 References


Canadian Paediatric Society, Fetus and Newborn Committee. (2007). Guidelines for detection, management and prevention of hyperbilirubinemia in term and late preterm newborn infants (35 or more weeks' gestation). Paediatric Child Health, 12, 1B-12B.


Health Analytics Branch, Ministry of Health and Long-Term Care. (2013, August). Newborn Hyperbilirubinemia (Jaundice) Quality Based Procedure (Definition Analysis). Toronto, Ontario, Canada.


## Appendix A – Description of Levels of Evidence

<table>
<thead>
<tr>
<th>Organization</th>
<th>Canadian Paediatric Society (CPS)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Guideline Name</strong></td>
<td>Guideline for Detection, Management and Prevention of Hyperbilirubinemia in Term and Late Preterm Newborn Infants</td>
</tr>
<tr>
<td><strong>Evidence Grading Method</strong></td>
<td>Oxford Centre for Evidence-Based Medicine – Levels of Evidence (Centre for Evidence Based Medicine, 2013)</td>
</tr>
<tr>
<td><strong>Grades</strong></td>
<td><strong>A: Consistent level 1 studies</strong> 1a – SR (with homogeneity) of RCTs 1b – Individual RCT (with narrow confidence interval) 1c – All or none <strong>B: Consistent level 2 or 3 studies</strong> 2a – SR (with homogeneity) of cohort studies 2b – Individual cohort study 2c – “Outcomes” research 3a – SR (with homogeneity) of case-control studies 3b – Individual case-control studies <strong>C: Level 4 studies</strong> 4 – Case-series (and poor quality cohort and case-control studies) <strong>D: Level 5 evidence or troublingly inconsistent or inconclusive studies of any level</strong> Expert opinion without explicit critical appraisal or based on physiology, bench research or “first principles”</td>
</tr>
<tr>
<td>Organization</td>
<td>American Academy of Pediatrics (AAP)</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>Guideline Name</td>
<td>Management of Hyperbilirubinemia in the Newborn Infant 25 or More Weeks of Gestation</td>
</tr>
<tr>
<td>Evidence Grading Method</td>
<td>AAP Steering Committee on Quality Improvement and Management (American Academy of Pediatrics Steering Committee on Quality Improvement and Management, 2004)</td>
</tr>
<tr>
<td>Grades</td>
<td></td>
</tr>
<tr>
<td>A:</td>
<td>Well designed, RCTs or diagnostic studies on relevant populations</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>B:</td>
<td>RCTs or diagnostic studies with minor limitations overwhelmingly consistent evidence from observational studies</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>C:</td>
<td>Observational studies (case control and cohort design)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>D:</td>
<td>Expert opinion case reports, reasoning from first principals</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>X:</td>
<td>Exceptional situations where validating studies cannot be performed and there is clear preponderance of benefit or harm</td>
</tr>
<tr>
<td>Organization</td>
<td>National Institute for Clinical Evidence (NICE)</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td><strong>Guideline Name</strong></td>
<td>Neonatal Jaundice</td>
</tr>
<tr>
<td><strong>Evidence Grading Method</strong></td>
<td>NICE Clinical Guideline Development Methods (National Institute for Clinical Evidence, 2013)</td>
</tr>
<tr>
<td></td>
<td><em>Used to rate studies, but not to assign a grade to a recommendation</em></td>
</tr>
<tr>
<td><strong>For Intervention Studies</strong></td>
<td></td>
</tr>
<tr>
<td>1++</td>
<td>High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High-quality systematic reviews of case–control or cohort studies; high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal</td>
</tr>
<tr>
<td>2+</td>
<td>Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytical studies (e.g. case reports, case series)</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion, formal consensus</td>
</tr>
<tr>
<td><strong>For Diagnostic Tests</strong></td>
<td></td>
</tr>
<tr>
<td>Ia</td>
<td>Systematic review (with homogeneity) of level-1 studies</td>
</tr>
<tr>
<td>Ib</td>
<td>Level-1 studies</td>
</tr>
<tr>
<td>II</td>
<td>Level-2 studies systematic reviews of level-2 studies</td>
</tr>
<tr>
<td>III</td>
<td>Level-3 studies systematic reviews of level-3 studies</td>
</tr>
<tr>
<td>IV</td>
<td>Consensus, expert committee reports or opinions and/or clinical experience without explicit critical appraisal; or based on physiology, bench research or ‘first principles’</td>
</tr>
</tbody>
</table>