Stool Colour Chart -
A Qualitative Study on its use as Passive Screening & Educational Reference for Neonatal Cholestasis in the Well Child Tamariki Ora Framework

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Aim

To conduct a qualitative study on the implementation of a home-based Stool Colour Chart (SCC) to improve the current opportunistic screening for neonatal cholestasis. Better awareness of acholic stools by families and health professionals is expected to lead to earlier diagnosis and intervention for time-urgent neonatal liver diseases such as Biliary Atresia.

Introduction

Lead Maternity Carers (LMC) and Well Child Providers (WCP) have special relationships with families and their new-borns. These health professionals are in a unique position to help raise health literacy and awareness within families regarding a wide range of neonatal issues, especially neonatal liver disease.

There are multiple causes of neonatal liver disease that will lead to cholestasis and liver dysfunction. Biliary Atresia (BA) is a rare congenital, progressive cholestatic condition leading to hepatobiliary fibrosis and eventual liver failure in early childhood. Around 80 percent of infants with BA are healthy and anicteric at birth, but if the condition is not diagnosed early and untreated, it is usually fatal by early childhood. [1]

The exact aetiology of BA is unknown, and although BA cannot be prevented, the devastating consequences of this condition could be alleviated by timely diagnosis and intervention. As a result, a screening test and education on the signs of neonatal liver disease can help with the earlier diagnosis of time-urgent neonatal cholestasis such as BA to lower morbidity and mortality. Empowerment and raising health literacy could lead to greater engagement with primary care as well as referral to secondary and tertiary services.
Presentation of Biliary Atresia

The classic triad of BA signs include:

i. Jaundice which is conjugated and prolonged (lasting beyond second week of life)

ii. Acholic stools

iii. Hepatomegaly

As bile flow continues to be obstructed leading to liver dysfunction and cirrhosis, further signs may present, e.g. splenomegaly, pruritus, failure to thrive, ascites, or coagulopathy.

Since hyperbilirubinaemia or jaundice is a very common feature in neonatal life, evident in >50 percent in term infants and 80 percent in preterm infants, it is not until the jaundice becomes prolonged (>2 weeks in duration) or there are other features of concern, that a serum bilirubin level would be checked, delaying investigations and diagnosis. [2] Detecting clinical jaundice can be challenging in some infants, especially those with darker skin tones. [3, 4] Similarly, hepatomegaly may not be picked up clinically unless the child presents to health care services within the first few weeks of life. Meanwhile, acholic stools appear in infants with BA in 95 percent of reported cases and usually by four weeks of life. [5-7]

It has been shown acholic stools are often unrecognised as a sign of serious pathology in neonates by caregivers and health professionals alike. [8] Having a reference for stool colour can be an inexpensive and easy preliminary screen for BA and other neonatal cholestasis disorders.[9]

Importance of Timely Diagnosis of Biliary Atresia

If BA is diagnosed early enough, a Hepatopportoenterostomy (HPE) or Kasai Procedure can be performed to restore bile flow towards the intestines, preserving liver function, delaying cirrhosis and the need for liver transplant. [10] Early diagnosis and surgery (before 60 days of life), can improve survival from the operation,
the success of the operation and also survival post-operation with the native liver and delaying need for transplant. [11] If there is successful bile flow after surgery, 10 year survival rates without liver transplant can be as high as 90 percent. [12, 13] The age at which a HPE is performed has been found to be a major prognostic factor for survival in cases of BA. Some research has shown, that an HPE performed before 45 days of life, can increase survival rates by 15 percent. [14] Currently, the average age of presentation of BA in New Zealand to tertiary services is 50.37 days of life (±37.3), with HPE on 61.7 days of life (±25.7). [15]

**Biliary Atresia in New Zealand**

Incidence of BA varies around the world and sits at 1 per 10,000-20,000 live births in New Zealand, roughly equating to three to six new cases each year, with preponderance in Māori and Pacific Island ethnicities. [15, 16] Internationally, there are high rates of BA within South East Asian communities. [16] Barriers to care such as difficult access to primary care and poor health literacy have been known to act further to delay potential diagnoses of serious medical problems in these ethnic groups in New Zealand. [17-19]

**Impact on Māori**

Historical data in 1989 puts incidence of BA of 3 in 10,000 Māori and Pacific Island births in New Zealand. [20] More recent census data in New Zealand and cases at Starship Hospital, Gastroenterology & Hepatology, estimates the incidence of BA in Māori to be 1 in 7000, more than double that of the general population, and closer to incidences of Japan and Taiwan. There is also evidence to show an extremely high incidence of BA within a North Island iwi, indicating a possible genetic predisposition in Maori. [21] Raising awareness with the SCC could help monitor and deliver quality health care to Māori for a condition that affects Māori in disproportionate numbers.
Biliary Atresia Screening & Education in New Zealand

Currently, there is informal opportunistic screening for neonatal cholestasis in New Zealand with a simple question being asked of families by LMC/WCP regarding stool colour during scheduled visits without a robust process in terms of follow-up or quality assurance. Prompt presentation and diagnosis then relies upon self-referral by families or their LMC/WCP.

The Well Child Tamariki Ora (WCTO) Programme is a Ministry of Health initiative to ensure families and their children are offered support, information and clinical assessments throughout the first five years of the child’s life. The WCTO - My Health Book is given to all families at the birth of a child, and is used as a reference as well as a record of interactions with different primary care services. There is a wide range of neonatal and childhood topics covered by the My Health Book as well as scheduled visits with medical professionals with suggested topics for discussion and clinical assessments. The book makes reference to abnormal neonatal stool as “pale like putty,” and normal stool as “yellow or brown.” There is no visual reference and is only part of suggested discussion topics at the 2-6 Week Check and 4-6 Week Checks. [22]

As an accompanying tool, the Ministry of Health also provides the Your Health Website as part of its Health.org.nz domain. Further information is provided on different health topics for adults and children. A section on new born bowel motions discusses the range of normal stool colours as well as the need for medical review if the bowel motion was “white or cream coloured.” [23]

Further health promotion and literacy has been targeted by the Paediatric Society of New Zealand and the Starship Foundation with their collaboration on the Kidshealth Website. The website aims to provide accurate and reliable information for families/whānau on child health and safety issues. The website has sections dedication to both Jaundice and BA, and both sections contain the Beware Yellow Campaign which is aimed at educating families with jaundiced babies that if the stools are pale and/or the urine is dark, that they should seek medical attention. Although the campaign uses a photo of acholic stool and an example of a jaundiced
infant, it does not offer any other visual reference on normal stool colour or the range of acholic stool colours. [24]

From March 2014 to June 2014, “jaundice babies,” was the 20th most searched term on the Kidshealth Website, with over 10,000 hits to the Jaundice section, while “Biliary Atresia,” was the 51st most searched term with over 2000 hits to the BA section. [25] Although this is a rough estimate of online information demand, there does seem to be a desire for more information on both jaundice and BA, above what is provided in the WCTO Programme.

**Screening for Biliary Atresia**

BA is a relatively rare condition, but the ability for corrective intervention and potential savings with timely diagnosis makes this condition an attractive candidate for screening. There is also possibility of diagnosis of other neonatal liver diseases such as Alpha-1 Antitrypsin Deficiency, Hypothyroidism, Urinary Tract Infections, or other cholestatic disorders. [26]

Previous attempts at screening for BA have been modest in their success. Dried blood spots on universal Guthrie Card screening have been trialled with tandem mass spectrometry of bile salts, but lacked sensitivity and specificity. [27] Although it is known that serum levels of conjugated bilirubin are elevated in BA from the first 6-10 days of life, a practical universal screening biochemical test has not been found due to its reliance on liquid blood testing. [28]

Universal in-home monitoring for acholic stools in new-borns has been piloted in several countries including Taiwan, Japan, Argentina, Brazil, France, Switzerland, Canada and the United States. There have been long running programmes in Japan since 1992 and in Taiwan since 2004. [29, 30] Both programmes involve a
reference SCC for parents to mark the colour of stool on the card then the SCC is posted back to a central registry office at around 30 days of age. Medical services are then mobilised if the stool colour is abnormal. A routine 30 day infant check with a medical professional was another reporting time and opportunity for the SCC to be sent back to the registry centre. Although rates of SCC return were variable, in Taiwan, the sensitivity of this universal screening is 97.1 percent with a specificity of 99.9 percent, leading to earlier diagnosis and intervention. [30, 31] As a positive consequence of earlier diagnosis, more successful HPE operations have been seen in Taiwan and the five year survival rate with the child’s native liver increasing from 55.7 percent to 89.3 percent. [32] In Japan, the mean age at time of HPE was 58 days in the screening programme, compared to 84 days without the programme. [33]

It is difficult to ascertain whether the SCC screening or better public awareness has led to the increased pick-up rates, but nonetheless, the implementation of a SCC has led to improved outcomes for BA. In this study, a combined initiative has been adopted, so the SCC is used as a passive screening tool but also as a means to open up dialogue and raising awareness between families and health professionals in order to ensure all infants with acholic stools are identified in a timely fashion. The Children’s Liver Disease Foundation (UK) has found that parents whose children were diagnosed with BA after 90 days of life felt they had lacked enough information to empower them to ask for referral earlier. [34] The Yellow Alert Campaign was started in order to support families and health professionals alike to ensure important information, especially about acholic stools is distributed. [9] A more consistent and better quality implementation of a SCC in the WCTO framework may help disseminate this information and allow for greater empowerment and autonomy amongst families.
Cost-Effectiveness of Screening

A cost-effectiveness modelling study on screening with SCC alone in United States showed potential savings of USDS9 million, three fewer associated deaths and 11 fewer liver transplants. [35] This study probably far underestimates the potential savings of a SCC programme as it can help with earlier diagnosis of other neonatal liver diseases e.g. neonatal hepatitis, Cystic Fibrosis, paucity of biliary ducts in Alagille Syndrome, or Alpha-1 Antitrypsin Deficiency.

Furthermore, Schrieber et al. in Canada have found a passive SCC reporting system; much like the one implemented in Japan and Taiwan, was most cost effective and also resulted in fewer liver transplants and more HPE being performed. Despite, having a SCC return rate of 55-63 percent, the use of more intensive follow-up systems, e.g. follow-up phone calls, posted reminder cards, only led to nominal increases in return rates and exponential increase in costs. [36]

This study plans to utilise established WCTO frameworks with the LMC as primary contact for passive screening and education. There will be agreed contact where the SCC is reviewed with health professionals so as to capture any families that may not have utilised their cards independently in a passive home-based programme. The cost in time and financial terms for families and LMC/WCP is estimated by the Investigators as minimal as it is incorporated into already scheduled routine interactions with the families.

The main cost would be instituting and distributing the SCC itself, although there may be increased laboratory costs as the positive SCC screening infants will be required to undergo blood tests as well as possible review by medical professionals. The cost of unnecessary investigations and assessments due to false positives is reduced by an expected high SCC specificity. [31] Nonetheless, with any report of acholic coloured stools, the current standard of care should be for further investigations and clinical assessment by medical professionals. The SCC raises awareness of acholic stools and the study protocol is aligned with local best practice guidelines. [37]
Areas of Concern

With any potential screening tool the risk of generating anxiety and unnecessary testing is present. With the SCC, the specificity is very high and the study protocol aligns with usual practice. [32] The SCC seeks to increase awareness and improve caregivers’ and health professionals’ knowledge of normal stool colours. Being a qualitative study this study aims to uncover the true utility and everyday implications of an SCC to the lives of caregivers of new-borns.

There is an undoubtedly large amount of information for caregivers at a time of immense change and emotion. Adding more information in the form of a SCC may lead to dilution of the message and educational performance. However, this study seeks to meld together with information already readily given to caregivers via the WCTO – My Health Book, in a logical and understandable reference. The qualitative assessments with caregivers at the end of the observation period will elucidate any issues regarding message uptake.

Using LMC as primary contact for any positive SCC findings may lead to increased workload for already busy services. However, as stated previously, any report of acholic stools should be taken seriously and lead to further investigations as per best practice. With the sensitivity and specificity of the SCC, the Investigators feel that if a stool colour was in the abnormal palette on the SCC, any and all assessments and investigations are important, so that not only BA but other neonatal liver diseases can be ruled out.
Areas of Gain

This is the first time a formal screen and educational tool for BA and neonatal liver diseases has been trialled for its implementation and usefulness to families and health professionals in New Zealand. It utilises established WCTO frameworks and provides both a reference for home-based screening, but also as a cue for dialogue and education.

In established universal passive screening programmes, gains have been made in the form of earlier referrals to Tertiary Gastroenterology Services, earlier HPE and more successful HPE being performed, as well as delaying the need for liver transplants in children with BA. [30] The financial and life year gains have been found to be significant in cost-effectiveness modelling in the United States and Canada. [35, 36]

The aim of this study is to show the potential for passive screening and increasing health literacy in the general population regarding BA and acholic stools so that early diagnosis and treatment can be instigated. There will also be gains in earlier diagnosis of other neonatal liver diseases and possibly other disorders causing abnormal stool colour. The potential implications would be direct incorporation of the SCC into WCTO – My Health Book as well as other resources such as the Kidshealth Website, and Your Health Website.

Families will be compensated for their time and participation in the study in the form of a small gift.
Principles of Screening

The Ministry of Health has been advised on screening by the National Screening Advisory Committee (NSAC) on principles and assessment criteria for suitable screening programmes. Applying the principles to the SCC for BA screening would satisfy all eight criteria. [38]

<table>
<thead>
<tr>
<th>NSAC Principles of Screening and Screening Assessment Criteria</th>
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<tr>
<td>The condition is a suitable candidate for screening.</td>
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<tr>
<td>There is a suitable test.</td>
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<tr>
<td>There is an effective and accessible treatment or intervention for the condition identified through early detection.</td>
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<tr>
<td>There is high quality evidence, ideally from randomised controlled trials, that a screening programme is effective in reducing mortality or morbidity.</td>
</tr>
<tr>
<td>The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment).</td>
</tr>
<tr>
<td>The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation.</td>
</tr>
<tr>
<td>There is consideration of social and ethical issues.</td>
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<tr>
<td>There is consideration of cost-benefits issues.</td>
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Protocol for Qualitative Study
Protocol for Qualitative Study

There is a clear opportunity for improvement in New Zealand for earlier investigation and diagnosis of BA, using a SCC screening and education tool which can be incorporated into existing WCTO frameworks for parents/caregivers. The aim of the study is for the use of a standardised reference card to serve as a cue for dialogue between families and their LMC/WCP about stool colour. This would raise awareness of acholic stools and increase vigilance amongst the public and health professionals and prompt referral for investigations.

Study Population

10-15 term new-borns and their families from the Wellington and Hutt Valley regions, between 01 February 2015 and 30 April 2015) will be selected using a convenience sampling method. Ideally, the cohort of 10-15 families will be made up evenly in four groups of families identifying as New Zealand European/Pākehā, Māori, South East Asian and Pacific Islander. The ethnic proportionality acknowledges the fact that BA has increased incidence amongst South East Asians and Pacific Islanders and the need to ensure the SCC would be an acceptable intervention to these families in particular.

Outline of Methodology

After informed consent, the LMC will undertake an initial questionnaire with families will take place, and then a visual reference card with six colour palettes, three normal stool colours and three abnormal acholic stool colours would be given to families of new-borns and the LMC. The LMC would discuss with the families using the SCC as a reminder of normal stool colour at the initial visit at home in the first week of life, then again at the check between 2-6 weeks of life. As a final screen, there will be another chance for intervention at the Six Week Check, either with the LMC or WCP, with direct questioning using the SCC regarding stool colour. The head investigator will undertake a final exit interview with the families and the health professionals will take place inquiring about the usefulness and ease of use of the SCC and education process. If at any stage there is an abnormally coloured stool, the Protocol for Further Testing if SCC Screen Positive will be instigated.
The SCC’s colour palette is adapted from a colour chart from Johns Hopkins Children’s Centre. Language and syntax for stool colour is that already in use in the WCTO – My Health Book.
Protocol for Further Testing if SCC Screen Positive

Families will be instructed that if at any time the stool colour falls into the abnormal colour palette, or outside the normal colour palette, they should contact their LMC. The recommendation would be that if the colour is acholic, the infant’s conjugated and unconjugated bilirubin (Split Bilirubin, SBR) level is checked by the LMC and this algorithm is followed:

a. SBR proportion is $\geq 10\%$ direct (conjugated) bilirubin - Urgent paediatric referral (within 12 hours) will need to be made for further investigation for possible BA or other causes of neonatal cholestasis. This threshold of $\geq 10\%$ is lower than the traditional definition (>20% direct bilirubin) for conjugated jaundice. [41] However, with the combination of a positive screen for acholic stool colour, there is a high index of suspicion for cholestasis or liver dysfunction, needing urgent referral to Paediatrics.

b. SBR proportion is $< 10\%$ direct (conjugated) bilirubin - Risk of BA is low and the risk of other neonatal liver diseases is also lowered. Prolonged Jaundice will need to be considered if the infant is older than two weeks of age and usual practice guidelines regarding investigation and referral will apply. It is important to have continuing vigilance of stool colour, worsening jaundice, poor growth and other clinical signs by the LMC or General Practitioner (GP).

Serum direct bilirubin levels have been found to be elevated soon after birth in infants with BA and steadily rise during neonatal life. Testing for elevated portion of direct bilirubin has been found to 100 percent sensitive and 99.6 percent specific for neonatal liver disease. [41] If at any stage, there is concern regarding prolonged jaundice, best practice guidelines for investigations and assessment should be undertaken as per local best practice. Clinical review for weight gain or signs of sepsis should take place as well as consideration of further investigations such as full blood count with blood film, urine dipstick and culture, liver function tests, and thyroid function tests. Review of maternal blood group, booking serology and Rhesus status along with Direct Antiglobulin Testing should also be considered. [37]
If there has been a history of acholic stool at any stage, but the LMC was not notified at the time, even if the stool colour has normalised, a SBR level should be taken and algorithm followed. There is potential for stool to be abnormally coloured but not acholic, e.g. fresh blood, melaena, or meconium. If there is a stool colour which falls outside of the normal colour palette set out on the SCC, the LMC is to be contacted and further assessments be made just as usual practice would dictate.

**Figure 2- Protocol for Further Testing if SCC Screen Positive**

- **Normal Stool Colour**

- **Acholic Stool Colour**

- **SBR Check by LMC**
  - $\geq 10\%$ Direct Bilirubin
    - Urgent Paediatric Referral
  - $<10\%$ Direct Bilirubin
    - LMC/GP Review +/- Referral

- **Abnormal Stool Colour**
  - (not acholic e.g. black, bloody)

- **SCC based discussions:**
  - 1st week check
  - 2-6 week check
  - 6 week check

SCC & Education

Families & LMC monitor stool colour (0-6wks)
Protocol for Qualitative Data Collection on SCC

A translation of the consent form, SCC and the questionnaires into other languages will be offered to the families. All LMC and WCP will have contact details of the Investigators in case there are any concerns or questions regarding the use of the SCC.

Study will be terminated if there are any unforeseen circumstances causing hardship to any family or health professional. This is deemed to be unlikely by the Investigator as the study aligns with usual practice with everyday care for new-borns and LMC/WCTO interactions.

Data Collection Process:

1) Anonymised data collection will take place at time of consent, including demographics of the family, the gravidity and parity of the mother, name of LMC and the likely WCP that will perform the Six Week Check.
2) A questionnaire asking consented caregivers their perception of normal neonatal stool colour will be performed at the start of the intervention.
3) SCC with instructions will be distributed to the families along with their WCTO - My Health Book. The LMC will also have a copy of the SCC for reference. The family will notify the LMC at any stage if the stool colour is abnormal and Protocol for Further Testing will be implemented.
4) First conversation utilising the SCC between the LMC and family will take place within the first week of life to reinforce the normal stool colour and the sign of acholic stools.
5) At the scheduled WCTO assessment by the LMC between 2-6 weeks of age, there is already a list of suggested topics of conversation which include stool colour. [22] At this point the family and LMC should refer to the SCC and ensure there have not been any abnormal stool colours.
   a. If this is the final LMC visit, an exit interview with the LMC will be performed seeking qualitative data regarding the utility of the SCC in helping with the education and dialogue with families on normal neonatal stool colours.
6) There will be a *Six Week Check* by WCP. A final interaction using the SCC will take place between families and the health professional.
   
a. Practitioners performing the *Six Week Check* will be interviewed. The Investigator will coordinate with families to ensure the Six Week Check takes place in a timely manner as the window for effective HPE closes rapidly beyond this point.

7) The families will then be interviewed regarding their experiences with the SCC, compliance with SCC led discussions during WCTO interactions and whether this aided or changed their perceptions of normal and abnormal neonatal stool colour. A repeat question regarding the colour or normal neonatal stool will be asked again of all caregivers.

8) Analysis of pre-intervention perceptions of normal stool colour and the post-intervention understanding of acholic stools will be performed. Satisfaction with the SCC as a screening and educational tool will be assessed with interview results with health professionals and families.
Figure 3 - Initial Questionnaire Form for Families

Stool Colour Chart
Questionnaire for Families

Congratulations on the birth of your baby!!
Thank you for taking part in our study. This questionnaire should only take 5 minutes.
This information is confidential and will be anonymised.
Your contact details will only be kept to arrange future appointments then will be deleted.

Information about you, your baby and your family:

<table>
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<tr>
<th>Baby’s Date of Birth</th>
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<td>Baby’s Gender</td>
<td></td>
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<tr>
<td>Suburb where you live</td>
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<tr>
<td>Midwife’s Name</td>
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</table>

Who do you plan to see for Baby’s Six Week Check?
[ ] Dr Your Family Practitioner
[ ] Midwife

[ ] Mother’s Age
[ ] Father’s Age

[ ] How many other children have you had?
[ ] Mobile Number or how your Midwife will contact you
[ ] Email (optional)

Would you like the final study report emailed to you?

Information about your baby’s poo:

<table>
<thead>
<tr>
<th>What colours (1-7) do you think NORMA Lbaby poo should be – you can put down as many as you want</th>
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<tr>
<td>At birth</td>
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<td>In 1st week of life</td>
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<td>Between 2nd - 3rd week of life</td>
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<td>After 6 weeks of life</td>
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Stool Colour Chart
Exit Interview + Repeat Questionnaire

Thank you for taking part in our study. We would appreciate if you could let us know your thoughts on the Stool Colour Chart and what you found useful or not useful. If you have any suggestions or comments that would be greatly appreciated as well.

Discussion topics:
How did you feel about using the Stool Colour Chart?
How did the Stool Colour Chart change the way you think about your baby’s health?
How did the Stool Colour Chart change the way you interact with families/your midwife?
What would make the Stool Colour Chart more helpful?

Questionnaire for Families
Information about your baby’s poo:

<table>
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<tr>
<th>What colours (#1-7) do you think NORMAL baby poo should be – you can put down as many as you want</th>
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References