# Curds in the Way:

**Establishing Normal Sonographic Appearances of neonatal bowel on Fortified Breastmilk Feeds.**

Your baby will soon start or has recently started feeds with expressed breast milk. When your baby tolerates a few millilitres per feed, the NICU team plan to add fortifier (extra nutrition) to the expressed breast milk. Fortifier is added because it contains important extra nutrients, such a calcium and protein. This helps your preterm baby to grow and develop strong bones.

Your baby is invited to take part in a study. This study aims to get more information about what the bowel looks like on ultrasound scans of the tummy. 2 ultrasound scans will be done. The first is when your baby is tolerating breast milk. The second scan will be done after your baby has been on fortifier (extra added nutritional support) for several days. We want to examine babies that were born before 37 weeks and/or had a birthweight of less than 1,800 g.

Very rarely, a baby doesn’t digest the fortifier well, which can lead to a so-called ‘milk curd obstruction’ in the bowel. This curd is a cheesy substance that can partly or completely block the bowel tube. Such a complication is extremely rare. Your baby only has a very tiny chance of such an obstruction. Although we know the condition is extremely rare, the exact likelihood is unknown. It was first recognised in 1969 when it was more common with the very early types of formula feeds, after which 40 cases were reported in the worldwide literature up to the year 2000 (Lohn et al, 2000). The incidence decreased over time, with more babies being encouraged to have breastmilk. As we now fortify breastmilk of premature babies in NICU with extra nutrients (for very good reason as we know this helps them recover best from an early birth and low birth weight), there has been a tiny increase in milk curd obstruction worldwide. It is still rare enough that there are no studies available to provide exact numbers, and the risk is so very low that there is no question that fortified breastmilk is still clearly recommended as the best way to nutritionally support premature NICU babies.

 If the doctor thinks a baby might have a milk curd obstruction, they will order an x-ray of the belly. The x-ray doesn’t always give enough information and it does expose the baby to a small amount of radiation. Ultrasound is the safest imaging for babies and children and it involves no radiation. Ultrasound is used during pregnancy, so you and your baby will most likely have already had ultrasound scans. We can also use ultrasound for diagnosing problems with the bowel but it can be hard to work out if milk curd is the cause of the problem.

This study aims to give us a better understanding of what healthy bowel looks like on an ultrasound. This is important because it might help us to recognise sick bowel or bowel with a milk curd obstruction in the future.

***What will this study involve?***

We will be doing 2 ultrasounds for each baby. The first is when the baby is on expressed breast milk only. The second will be when the baby has been on expressed breast milk with fortifier for 10-14 days.

The ultrasound will take 10 to 20 minutes. An ultrasound is not painful.

The scans will not interfere with normal medical care.

If some previously unrecognised condition is revealed through this scan, your treating team will be advised and any required management of this will be discussed with you by the doctors looking after your baby. This is highly unlikely to happen as we are limiting the scan to the bowel only.

***Who is funding this study?***

This is a non-funded study with no conflicts of interest to declare. There are no financial costs to you associated with your participation.

***What are your rights?***

It is your decision if you would like to give permission for your baby to enrol in this study. Your decision will not affect the care your baby is receiving. If you decide to enrol your baby in this study, you can also withdraw consent at any time without affecting normal cares – no questions asked. Any information gathered up to the time of withdrawal would be deleted.

If you agree, we will ask you to sign a consent form on the last page of this document. You will receive a copy of this information sheet and the consent form.

Please note that He Kamaka Waiora Maori Health Provider Service is also available on call at Auckland City Hospital and are happy to help with questions or concerns about this study – see contacts.

***Where are images stored?***

All images will be safely stored in a password protected hospital intranet folder under the Radiology department. Only 4 doctors will have access to this (see contact information below).

Once the images are analysed and the study completed, they will be kept for 10 years in this secure location in accordance with the directions of the Health and Disability Ethics Committee. A few may be used as illustrations in the study report, but there will be no NHI number or name to identify any of these.

***What if something goes wrong?***

Ultrasound is the safest imaging available, it is non-invasive, and uses no radiation. If your baby were injured in this study, which is not likely, you would be eligible to apply for compensation from ACC just as you would if you were injured in an accident at work or at home. This would take time to assess and would not automatically be accepted. If accepted, you would receive funding to assist in any recovery.

***Who do I contact for more information?***

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Dr David Perry Dr Samantha Gerrie

Radiology Consultant Radiology Consultant

Starship Radiology Starship Radiology

On-call Maori Cultural Support Health and Disability Ethics Committee

He Kamaka Waiora hdecs@moh.govt.nz

Auckland City Hospital 0800 4 38442

(09) 307 4949 ext 29200

The Nationwide Health and Disability Advocacy Service

advocacy@advocacy.org.nz

0800 555 050

# Participation Consent Form: Curds in the way

**Parent/Caregiver Statement:**

* I have read and understand the participant information sheet
* I have had time to consider whether to allow my child to take part
* I have had the opportunity to discuss the study and am satisfied with any answers given
* I have had the opportunity to use whanau/family support or speak with friends to help me ask questions and understand the study
* I understand that participation is confidential, and no identifying names or numbers will be used in study reports or images
* I know who to contact if I have any concerns or questions about the study in general
* I understand that there is no payment for participation and no financial cost to me
* If I decide to withdraw my child from the study, I understand that my child’s care will not be compromised and that any information about my child gathered up to that point will be deleted

**Declaration:**

I hereby consent to my child taking part in this study.

Participant’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/caregiver’s name:

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Signature: Date:

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