

BMJ Open Midwife or doctor local opinion leader to implement a national guideline in babies on postnatal wards (DesIGN): protocol of a cluster-randomised, blinded, controlled trial

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To cite: Alsweiler JM, Crowther CA, Harding JE. Midwife or doctor local opinion leader to implement a national guideline in babies on postnatal wards (DesIGN): protocol of a cluster-randomised, blinded, controlled trial. *BMJ Open* 2017;7:e017516. doi:10.1136/bmjopen-2017-017516

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2017-017516>).

Received 31 July 2017
Revised 26 October 2017
Accepted 27 October 2017



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ABSTRACT

Introduction Neonatal hypoglycaemia is a common condition that can cause developmental delay. Treatment of neonatal hypoglycaemia with oral dextrose gel has been shown to reverse hypoglycaemia and reduce admissions to neonatal intensive care for hypoglycaemia. An evidence-based clinical practice guideline was written to guide the use of dextrose gel to treat neonatal hypoglycaemia in New Zealand. However, it is unclear what clinical discipline might most effectively lead the implementation of the guideline recommendations.

Objective To determine if midwife or doctor local opinion leaders are more effective in implementing a clinical practice guideline for use of oral dextrose gel to treat hypoglycaemia in babies on postnatal wards.

Methods and analysis A cluster-randomised, blinded, controlled trial. New Zealand maternity hospitals that care for babies born at risk of neonatal hypoglycaemia will be randomised to having either a local midwife or doctor lead the guideline implementation at that hospital. The primary outcome will be the change in the proportion of hypoglycaemic babies treated with dextrose gel from before implementation of the guideline to 3 months after implementation.

Ethics and dissemination Approved by Health and Disability Ethics Committee: 15/NTA/31. Findings will be disseminated to peer-reviewed journals, guideline developers and the public.

Trial registration number ISRCTN61154098.

BACKGROUND

Neonatal hypoglycaemia is a common condition affecting 50% of babies with risk factors such as infants of diabetic mothers,¹ and small and preterm babies.² Neonatal hypoglycaemia has been associated with developmental delay,² reduced visual motor and executive function³ and impaired school performance.⁴ Treatment of neonatal hypoglycaemia with oral dextrose gel has been shown to be more effective than feeding alone in reversing hypoglycaemia and also reduced both the rate of neonatal intensive care (NICU) admission for hypoglycaemia and

Strengths and limitations of this study

- This is the first randomised controlled trial to investigate whether a local midwife or doctor opinion leader is most effective for implementation of a clinical practice guideline.
- A blinded cluster trial; clinical staff at local hospitals are blinded to the study allocation.
- A national study including all maternity hospitals in New Zealand.
- Some hospitals in New Zealand have already begun to use oral dextrose gel to treat neonatal hypoglycaemia, which may reduce the detectable impact of guideline implementation.

the rate of formula feeding at 2 weeks of age.⁵ Use of the gel was therefore recommended for first-line treatment of hypoglycaemia in late preterm and term babies. These are the majority of babies who experience neonatal hypoglycaemia, and they may potentially avoid NICU admission if this new treatment were widely adopted, with substantial benefits in terms of family separation, costs of care and breastfeeding rates. A New Zealand evidence-based clinical practice guideline has been written as a first step in implementing this new treatment approach, as a change in midwifery and neonatal practice is unlikely to occur rapidly without an active implementation strategy.⁶

There is often a large gap between research knowledge and clinical practice. Knowledge synthesis and guideline development have been shown to be effective at translating research findings into clinical practice but are often not sufficient in themselves to lead to a change in practice. Prospective identification of barriers to change is crucial to achieve better adoption of intervention and improve implementation.^{7,8} Multi-faceted interventions including audit with feedback are helpful, but local opinion leaders

have been shown to be the most effective method of implementing obstetric guidelines.⁷ Most evidence on implementation has come from studies of implementation of guidelines for treatment of adults. However, previous cluster-randomised trials of implementation of treatments for extremely preterm babies in NICU have shown that multi-faceted active implementation strategies improve care of preterm babies.^{9 10}

There are few data on the most effective strategy to implement new treatments for otherwise well babies on the postnatal wards, who are usually under midwifery care. New Zealand has a unique healthcare system where lead maternity carers (LMCs), the majority of whom are midwives, provide most primary neonatal care. LMCs are responsible for ensuring that neonates in their care who are at risk are screened for neonatal hypoglycaemia. In New Zealand, midwives have prescribing rights and have experience in implementing strategies to improve breast feeding.¹¹

Dextrose gel, a new treatment not currently in routine use, offers a unique opportunity to investigate effective implementation strategies for management of babies on postnatal wards, a group of babies usually under the care of midwives. Although local opinion leaders have been shown to be important in the implementation of guidelines,¹² it is not known from which discipline the opinion leader should be drawn in the implementation of cross-disciplinary guidelines. Typically, in New Zealand, doctors would be approached to implement a guideline for a neonatal treatment. However, doctors usually only become involved in hypoglycaemic babies' care once they receive a referral from a midwife/LMC because of a low blood glucose concentration. It is unclear if midwives or doctors are best placed to lead a practice change involving babies on the postnatal wards. We propose a randomised controlled trial to determine if midwives or doctors are more effective local opinion leaders for implementing a clinical practice guideline for oral dextrose gel to treat neonatal hypoglycaemia.

Hypothesis

Midwives are the most effective opinion leaders for implementing a guideline for use of oral dextrose gel to treat neonatal hypoglycaemia in babies on postnatal wards.

Aim

To determine if midwives or doctors are the most effective local opinion leaders for implementation of a national guideline for use of oral dextrose gel for the treatment of neonatal hypoglycaemia.

METHODS AND ANALYSIS

Study design

Multi-centre, cluster, blinded, randomised controlled trial.

Inclusion and exclusion criteria

Maternity hospitals in New Zealand where babies at risk of neonatal hypoglycaemia (infant of a diabetic, late

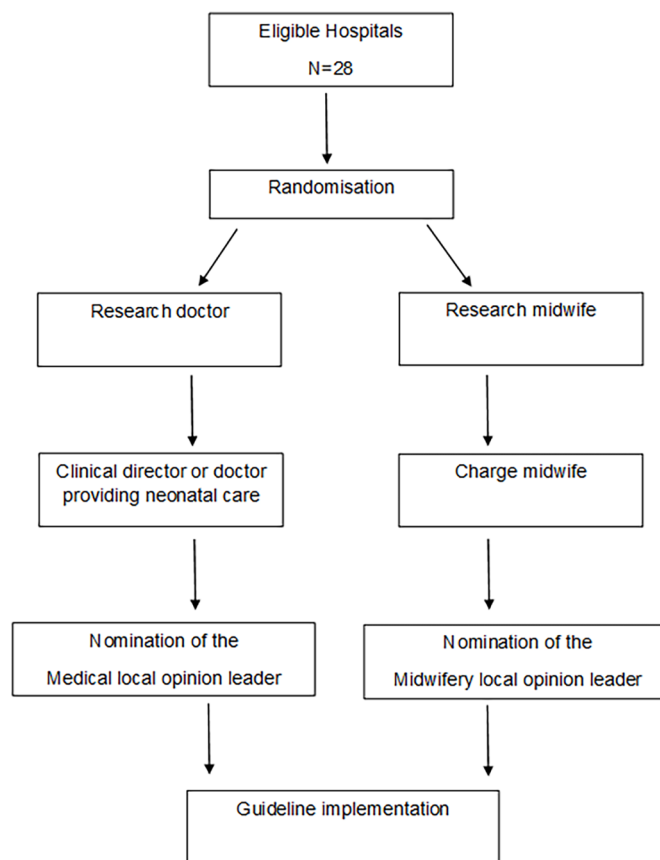


Figure 1 Strategy to determine local opinion leader.

preterm, small or large for gestational age) are born, including hospitals where oral dextrose gel is currently in use, will be eligible to take part in the study. Hospitals will not be eligible if there is no doctor (paediatrician or general practitioner) available to provide medical treatment or no midwifery care for newborn babies. Primary maternity hospitals that base their neonatal guidelines on the practice of their local secondary or tertiary maternity hospital will not be eligible.

Trial setting

The trial will be coordinated by Department of Paediatrics: Child and Youth Health, the University of Auckland, Auckland, New Zealand.

The study will have three phases: (1) hospitals are randomised to having a midwife or doctor opinion leader to implement the clinical practice guideline; (2) the midwife or doctor opinion leader implements the 'Oral Dextrose gel to treat neonatal hypoglycaemia' guideline using the implementation tool kit; (3) outcome data related to the use of dextrose gel are collected for the preimplementation and postimplementation periods (figure 1).

Randomisation and blinding

The study team will include a research doctor and a research midwife who will follow a standard predetermined strategy to identify the key opinion leader at each maternity hospital.

The allocation sequence will be generated by a statistician using computer-generated random numbers. All hospitals will be stratified by type of maternity hospital (primary, secondary, tertiary) and by current use of oral dextrose gel to treat hypoglycaemic babies (yes, no). Eligible hospitals within each stratum will be randomly allocated in a 1:1 ratio to either (1) the research midwife identifying and recruiting a key midwife based at the hospital to lead the implementation or (2) the research doctor identifying and recruiting a key doctor based at the hospital to lead the implementation. The allocation sequence will be distributed by password-protected email to the research midwife and research doctor.

Intervention

For hospitals randomised to a midwife opinion leader, the research midwife will contact the charge midwife and introduce the plans for the implementation of the guideline. The research midwife will ask the charge midwife to nominate a senior midwifery staff member to be the local opinion leader for the guideline implementation.

For hospitals randomised to a doctor opinion leader, the research doctor will contact the clinical director of newborn services in tertiary hospitals, the clinical director of paediatrics in secondary hospitals or the doctor providing neonatal care in primary hospitals. The research doctor will introduce the plans for the implementation of the guideline and will ask the local doctor to nominate a senior medical staff member to be the local opinion leader for the guideline implementation (figure 1).

If the charge midwife or the doctor contacted by the research team offers an opinion leader who is not of their specialty, that is, if a doctor offers a midwife or *vice versa*, then the research doctor or midwife will respond again requesting that a doctor or midwife as appropriate is the key clinician. If the contacted charge midwife or doctor then insists on an opinion leader of a different discipline, this will be accepted. If the offer of implementation in their hospital is declined for any reason, they will then be asked to participate in an audit of oral dextrose gel use to treat neonatal hypoglycaemia, and the data from the audit will be included in the intention-to-treat analysis.

The trial intervention is blinded to all staff in participating hospitals, including the trial participants, care providers and outcome assessors. There will be no circumstances in which unblinding is permissible.

Implementation of the guideline

An implementation tool kit using the barriers and enablers identified from a national survey of stakeholders¹³ will be used in the implementation of the guideline. The tool kit will include: copies of the 'Oral Dextrose gel to treat neonatal hypoglycaemia' guideline,⁶ educational materials including a PowerPoint presentation, health professional and consumer information, flow charts, posters and pocket-cards. Once the local opinion leader (midwife or doctor) has been identified and has agreed to be involved

in implementation of the dextrose gel guideline, they will be offered an opportunity to attend an education day and be given the implementation tool kit. The education day will provide education on neonatal hypoglycaemia, dextrose gel, availability of support from the research team and recommended implementation strategies. The research team will provide support to the local opinion leader, for example, visiting speakers and local education sessions as requested. The local opinion leader will then identify local stakeholders and implement the guideline in their hospital.

Study outcomes

Primary outcome of the trial will be the change in the proportion of babies eligible to receive dextrose gel (blood glucose concentration <2.6 mmol/L, ≥ 35 weeks gestational age, diagnosed in the first 48 hours after birth and not in NICU) who are actually treated with dextrose gel from before implementation of the dextrose guideline to 3 months after implementation.

Secondary outcomes will be: the proportion of eligible babies admitted to NICU (including special care baby units (SCBUs)) for at least 4 hours; proportion of eligible babies given formula as a treatment for hypoglycaemia; amount of dextrose gel used in the hospital during the study period from pharmacy records; successful treatment of hypoglycaemic babies with oral dextrose gel (blood glucose concentration ≥ 2.6 mmol/L on the blood test taken immediately following dextrose gel treatment (maximum of 2 doses)); eligible babies who are breast feeding at discharge; initial uptake of dextrose gel (change in proportion of eligible babies treated with dextrose gel from before implementation of the guideline to 1 month after implementation); and sustained use of dextrose gel (change in proportion of eligible babies treated with dextrose gel from 1 month to 3 months after implementation) and adherence to the 'Oral Dextrose gel to treat neonatal hypoglycaemia' guideline.

Data collection

Data for all babies at risk of neonatal hypoglycaemia (infants born to diabetic mothers, preterm (35–36 completed weeks' gestation) and small or large for gestational age as defined by local guidelines) will be identified from hospital databases or delivery unit records. Clinical records will be reviewed by the local opinion leader or their research assistant to identify babies born at the hospital in whom neonatal hypoglycaemia (blood glucose concentration <2.6 mmol/L) was diagnosed in the first 48 hours after birth, who were not in NICU at the time of the hypoglycaemia and who were eligible to receive oral dextrose gel according to the 'Oral Dextrose gel to treat neonatal hypoglycaemia' guideline.

Data for hypoglycaemic babies identified as eligible for dextrose gel born in three periods will be collected: 1 month prior to the start date of the implementation period and 1 month after and 3 months after the date of the end of the implementation period, defined as a

6-week period from the date the local opinion leader received the implementation tool kit. Each baby will be assigned a unique study number by the local opinion leader, and the data sent to the coordinating centre will be de-identified. The local opinion leader will maintain a list of study numbers with the baby's national health index number in a secure location at the local hospital for the duration of the trial.

Neonatal history will be collected for each eligible baby and will include the date, time and mode of birth, estimated date of delivery, multiple birth, sex, gestational age, ethnicity, birth weight, type of maternal diabetes (if applicable), admission to NICU/SCBU and whether breast feeding at discharge. A description of each episode of neonatal hypoglycaemia will include the date and time when hypoglycaemia occurred, blood glucose concentrations and treatment received.

Data on the method of blood glucose analysis, definition and screening criteria for hypoglycaemia, the strategies used to implement the guideline and whether the implementation strategies were considered useful will be collected from a survey sent to the local opinion leader 8 weeks after the end of the implementation period.

Single data entry will be done by trained data entry technicians on a secure database.

Sample size

Assuming an intraclass coefficient of 0.05, 20 maternity hospitals, with 20 babies recruited at each hospital, will allow us to detect an increase in the proportion of eligible babies who are treated with dextrose gel from 40% to 60%, with 80% power and an alpha level of 0.05. There are 5 tertiary, 19 secondary and 57 primary hospital-based maternity facilities in New Zealand.¹⁴ All of the tertiary and secondary facilities, as well as several of the primary facilities, care for babies at risk for neonatal hypoglycaemia.

Statistical analysis

Analysis of the data will be by intention to treat. The primary outcome will be analysed by generalised linear mixed models with a random cluster effect. Secondary analyses will adjust for potentially confounding variables: reason for risk of hypoglycaemia (infant of diabetic, late preterm, small or large for gestational age), sex, gestational age, mode of birth (vaginal vs caesarean section) and if oral dextrose gel was being used at the hospital prior to implementation of the guideline. A *per protocol* secondary analysis will also be performed, analysing the data by the professional discipline of the local opinion leader who actually carried out the implementation of the guideline. A P value of <0.05 will be considered statistically significant.

Dissemination of findings

The trial began on 22 May 2015 and is ongoing; we expect data collection to be completed by 31 March 2018. The results of the trial will be published in an international

peer-reviewed journal. The results will also be disseminated via presentations at local and international conferences to researchers and clinicians, guideline developers and also the public.

Registration: the trial is registered with ISRCTN registry (ISRCTN61154098) from 20 May 2015.

DISCUSSION

There are currently no data available on the characteristics of the most effective local opinion leader for implementation of guidelines aimed at improving the health of babies on postnatal wards. In the past, a doctor opinion leader would implement new clinical practice guidelines in their hospitals. Having a local leader to implement guidelines can lead to better uptake due to close interpersonal relations and in-person communication with the local staff, which accelerates behaviour change and knowledge uptake.^{15 16} Although identifying local opinion leaders might be difficult because they often change over time in some areas,¹⁷ this is unlikely to happen in this study as the number of specialists who work in the field of neonatal medicine in New Zealand is small.

In many countries, including New Zealand, midwives are central to the care of healthy mothers and newborn babies, while doctors care for mother and babies who are unwell. Midwives are frequently involved with the implementation of guidelines for the mothers and babies they care for.^{11 18 19} Midwives, nurses and doctors have a different approach to communication and knowledge exchange.²⁰ For example, nurses are more likely to prefer in-person communication with colleagues and patients to share and receive knowledge rather than electronic resources than are doctors.^{21 22} Further, nurses' information-seeking behaviours are more concentrated on policy and procedures, while doctors concentrate more on information related to diagnosis.²³ Therefore, having midwives or doctors as local opinion leaders of guideline implementation may lead to different outcomes as the knowledge provided by the research team is received and shared in a different manner.

Babies at risk of neonatal hypoglycaemia are often cared for by midwives on the postnatal wards with input from doctors as required. Therefore, it is unclear if midwives or doctors would be most effective at implementing a clinical practice guideline on oral dextrose gel for neonatal hypoglycaemia, a treatment that midwives can prescribe and administer under appropriate guidelines.

This study will determine if midwife or doctor opinion leaders provide the most effective pathway for implementation of guidelines to change clinical practice for babies on the postnatal wards.

Acknowledgements The authors thank Sonja Woodall and Nataliia Burakevych for valuable contributions to the study design and manuscript.

Contributors JMA conceived and developed the study design, drafted the article and approved the final version of the study protocol. CAC contributed to the study design, critically revised the article and approved the final version of the study

protocol. JEH contributed to the study design, critically revised the article and approved the final version of the study protocol.

Funding This work was supported by Gravida: National Centre for Growth and Development, grant number STF-14-04. The funder had no role in the study design and will have no role in collection, management, analysis and interpretation of the data; writing the report or the decision to submit a report for publication.

Competing interests None declared.

Ethics approval New Zealand Health and Disability Ethics Committee: 15/NTA/31.

Provenance and peer review Not commissioned; externally peer reviewed.

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