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A pragmatic stepped wedge cluster randomised implementation trial assessing the effect of a quality improvement programme on the proportion of infants achieving delayed cord clamping for more than 60 seconds in infants <37 weeks gestation: Statistical analysis plan for the Wait a Minute or More (WAMM) trial

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update

Keywords: stepped wedge cluster randomised trial, neonatal, statistical analysis plan

Posted Date: March 5th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-8876192/v1

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Additional Declarations: No competing interests reported.

A pragmatic stepped wedge cluster randomised implementation trial assessing the effect of a quality improvement programme on the proportion of infants achieving delayed cord clamping for more than 60 seconds in infants <37 weeks gestation:

Statistical analysis plan for the Wait a Minute or More (WAMM) trial

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Preparing to submit to: Trials

ABSTRACT

The Wait a Minute or More (WAMM) trial is a pragmatic stepped-wedge cluster randomised implementation trial designed to increase the proportion of preterm infants receiving delayed cord clamping for at least 60 seconds (DCC60) across Australian maternity hospitals. This statistical analysis plan prespecifies primary, secondary, and exploratory analyses prior to accessing outcome data. The primary analysis will use mixed-effects modelling to estimate the effect of a locally adapted quality improvement programme and accurate data sharing, on achieving DCC60, accounting for clustering and secular trends. By detailing our approach, this SAP ensures transparency, reproducibility, and rigorous evaluation of the WAMM intervention.

KEY WORDS

stepped wedge cluster randomised trial, neonatal, statistical analysis plan

BACKGROUND

The Wait a Minute or More (WAMM) study is designed as a pragmatic stepped wedge cluster randomised trial (SW-CRT) aimed at integrating delayed cord clamping (DCC) practices for preterm infants. A total of 18 Australian maternity hospitals (sites) commenced recruiting infants on 15 July 2024, and the last infant will be recruited into the sustained implementation period on 19 April 2026 (Figure 1). The WAMM study will utilise the updated, integrated-Promoting Action on Research Implementation in Health Services (i-PARIHS) framework [1] to strategize both the intervention and its implementation, and will integrate a robust process evaluation. The trial is described in detail in the published protocol,[2] and registered prior to the first recruited patient (ACTRN12624000035527).

In this paper, we describe the statistical analysis plan (SAP) of the WAMM study. This SAP complies with the recommended reporting guidelines [3] and the completed checklist is provided in the supplementary materials. The final report will follow the updated Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting randomised controlled trials and the CONSORT extension for stepped-wedge cluster randomised trials.[4, 5] This SAP specifies the procedures to be applied to the primary and secondary analyses of the study participants, once the data are complete. The SAP was finalised during the study, prior to any analyses being undertaken.

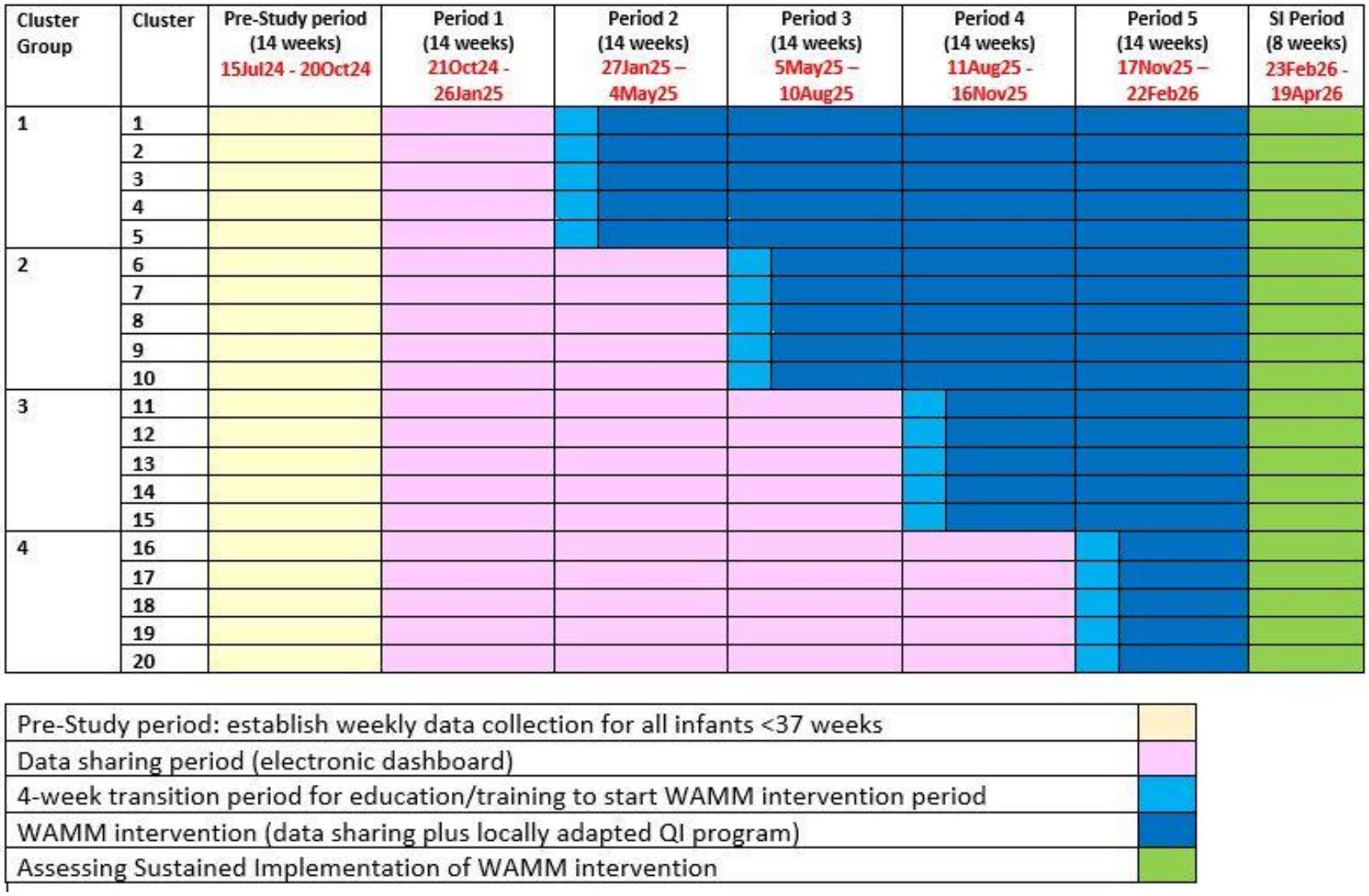


Figure 1: Schema for the Wait a Minute or More (WAMM) Study - a stepped wedge cluster randomised trial

STUDY DESIGN

The WAMM study is a pragmatic, superiority, cross-sectional, stepped wedge cluster randomised trial (SW-CRT), which involves a sequential crossover of clusters (sites) from the control to the WAMM intervention so that every cluster begins in the control condition and eventually receives the intervention, with the order of crossover randomly determined. This trial will be conducted across 18 Australian sites (clusters), which are grouped into 4 sequences (cluster groups). At the end of the pre-study period, baseline data will be collected at each site, to inform the stratification factors for randomisation. The WAMM study will be conducted over 5 periods of 14 weeks duration, with a 4-week transition period at the start of each sequence moving into the WAMM intervention. At the end of Period 5, the sustained implementation period commences for 8 weeks, where there is no further funding for the WAMM intervention. The specific terminology used for this design is provided in Table S1.

Primary objective

To evaluate in (*Population*) infants <37 weeks' gestation who do not need resuscitation, if (*Intervention*) the WAMM intervention (sharing of anonymised data on DCC60, together with a locally adapted quality improvement (QI) programme), compared with (*Control*) sharing of anonymised data on DCC60 alone, increases the proportion of (*Primary Outcome*) infants receiving DCC60.

Population

Site eligibility criteria: Tertiary or non-tertiary Australian maternity hospitals willing and able to comply with all study requirements including intervention, timing and/or nature of required assessments for the duration of the study. There were no exclusion criteria.

Infant eligibility criteria: All liveborn infants born at participating sites before 37 weeks gestation for whom active care is planned. Infants born before 37 weeks gestation and not needing immediate resuscitation will be eligible to receive DCC. Infants requiring immediate resuscitation (except at sites with facilities to provide resuscitation with an intact umbilical cord) are ineligible to receive DCC.

Control

Sites will be provided with access to an electronic dashboard to view their DCC data for all infants born at <37 weeks gestation. Sites will also be able to see anonymised data of all other participating sites in their own cluster group. This sharing will commence during Period 1.

Intervention

Once a site commences their WAMM intervention, further funding will be provided for a nurse and/or midwife to support it for the duration of their intervention period (up until the end of Period 5). The WAMM intervention comprises an electronic dashboard (control) and a locally adapted QI programme. This programme is multifaceted, and involves QI team building, education, and the implementation of local change ideas. To facilitate the implementation of the WAMM intervention components, the study team uses collaborative QI strategies. These are detailed in the protocol. [2]

Randomisation and blinding of sites

Sites will be randomised at the end of the pre-study period. Randomisation will be performed by minimisation, using a computer-generated algorithm, stratified by hospital type (tertiary versus non-tertiary), number of infants expected in the 14-week period, and average baseline number of seconds of cord clamping (NSCC) (both as determined during the pre-study period; less than the median versus greater than or equal to the median). Sites will be allocated to commence the QI programme in Period 2, 3, 4, or 5, with a ratio of 1:1:1:1 (i.e. equal chance of allocation to each period). As there is no sequential order, sites will be randomly selected for the order of randomisation. Only the WAMM statistician and trial manager will be unblinded immediately following randomisation. Allocation will be blinded to sites and other central trial operations staff until 14 weeks prior to the transition period for the allocated step for that cluster group, at which point up to two to three essential personnel nominated by the site will be informed to allow for staffing arrangements. All other participating staff at each site will be informed on the first day of the transition period.

Primary outcome

The primary outcome is whether an infant achieves a delay in cord clamping of 60 seconds or more (DCC60; yes vs no).

Secondary outcomes

The clinical effectiveness outcome is the number of seconds until cord clamping (NSCC). The balancing outcomes are inadvertent hypothermia, and death at 28 days or discharge (whichever occurs earlier). Process outcomes include the key process outcomes of fidelity, dose, reach, and acceptability, as well as mechanisms of impact and barriers and enablers of implementation.

Sample size

In hospitals in the Australian Placental Transfusion Study (APTS) [6], DCC60 was achieved in 73% of infants assigned to delayed cord clamping. The primary hypothesis for WAMM is that implementing the WAMM intervention will increase DCC60 by 10% (e.g. from 50% to 60%, or 60% to 70%) adjusted for secular trends (trends over time).

We assumed a (best case) scenario of 10 tertiary sites and 10 non-tertiary sites, and a birth rate of 5,000 per year for the 10 tertiary sites and 2,500 per year for the 10 non-tertiary sites, which yielded a total of 75,000 births per 52 weeks, or 75,000 x (14 weeks * 5 periods)/52 = ~100,000 births in 70 weeks. Assuming that 10% are born at <37 weeks gestation yields approximately 10,000 preterm births, or ~100 (1000 ÷20 ÷ 5) preterm births at each site within each cluster-period of 14 weeks.

Therefore, WAMM will have ~10,000 infants (~100 per site (cluster) per time period), in four steps with up to five clusters per sequence (Fig 2), yielding >99% power to detect whether the WAMM intervention results in an 10% improvement in DCC60 (from 50% to 60%) after adjusting for secular trends with a 2-sided p value of 0.05, assuming a Intra Cluster Coefficient (ICC) of 0.02, and unequal cluster sizes with a coefficient of variation of 0.8. If the number of infants is half of that estimated (i.e. 5000 total preterm births) over 18 sites (~55 preterm infants within a 14-week period), we still have >95% power to detect a 10% improvement from 50% to 60%, assuming ICC of 0.02, and coefficient of variation of 0.8. Given that the variability in a proportion is highest at 50%, any rates higher than this (e.g. from 60% to 70%) will have higher power. If the number of infants is ~10 000, but the

improvement in DCC60 is 5% rather than 10% (e.g. 50% to 55%) , the trial will have 80% power keeping other assumptions the same. Calculations were performed via the Shiny CRT calculator. [7]

Study procedures

The full study procedures are detailed in the published protocol. [2] A total of 18 geographically representative Australian maternity hospitals have commenced the trial. This includes a mix of tertiary (delivering all infants, from 22 weeks' gestation) and non-tertiary hospitals (delivering only infants ≥32 weeks). Each participating site is considered a cluster (**Figure 1**). An initial pre-study period of 14 weeks will establish the process for weekly data collection including the number of seconds of cord clamping in all infants <37 weeks. All sites will then enter a 14-week data sharing period (control period, period 1). After 14 weeks, cluster groups (groups of up to 5 sites) will be randomised to the WAMM intervention (period 2-5) in a stepwise manner (**Figure 1**).

GENERAL STATISTICAL METHODOLOGY

Objectives of the analysis plan

This SAP covers the analysis of outcomes detailed in Table 1. The secondary outcomes of acceptability, mechanisms of impact, and barriers and enablers of implementation are outside the scope of this SAP. Additionally, the correlation of local QI programmes with DCC60 are outside this SAP. Subsequent analyses of an exploratory nature may also be requested from within the WAMM team or by journal editors or reviewers, and journal editors or reviewers may also request additional analyses not mentioned in this protocol. When possible, analyses will be performed consistently with the principles outlined in this SAP.

Table 1: WAMM Outcomes covered within this SAP

Outcome	Outcome type	Unit of measurement
Primary outcome		
Delayed cord clamping of 60 seconds or more (DCC60)	Binary	Infant
Clinical effectiveness outcome		
Number of seconds of delay before the cord is clamped (NSCC)	Continuous	Infant
Balancing outcomes		
Hypothermia	Binary	Infant
Death at 28 days of age or discharge	Binary	Infant
Key process outcomes (Fidelity, dose, and reach)		
Delivering the QI education programme within the transition window (Fidelity)	Binary	Site
Establishment of local QI teams in the transition window (Fidelity)	Binary	Site
Creating and implementing one or more local change idea(s) in transition window (Fidelity)	Binary	Site
Ongoing check-in monitoring meetings between central and local QI teams (Fidelity)	Binary	Site
Participation in at least one virtual meeting of sites in the intervention ecosystem (Fidelity)	Binary	Site
Number of check-in monitoring meetings between central and local QI teams (Dose)	Continuous	Site
Number of completed PDSA cycles (Dose)	Continuous	Site
Number of clinical staff engaged with local QI team to design local change ideas (Reach)	Continuous	Site
Exploratory analyses		
Primary outcome: before vs after data sharing	Binary	Infant
Primary outcome: secular trends	Binary	Infant
Primary outcome: sustained implementation period	Binary	Infant

Analysis software

Data will be extracted from the REDCap study databases and imported into R version 4.4.0 for analysis. Packages that we expect to use include tidyverse,[8] gtsummary,[9] lme4, [10] gamlss, [11] rmarkdown[12] and targets [13].

Data cleaning

The data will be checked and cleaned on an ongoing basis by the WAMM data manager and trial statisticians. Data analysis will not commence until all relevant data are entered, cleaned, and the data are locked. We expect this to be completed for all data from June 2026.

Analysis populations

The WAMM trial has several analysis populations. First, the *primary analysis population* will comprise all infants less than 37 weeks of gestation recruited during periods 1 to 5 (21 October 2024 to 22 February 2026, inclusive), *who did not require immediate resuscitation*. Infants born within the 4-week transition period between control and WAMM intervention will also not be included. Next, a *sensitivity analysis population* will include all infants less than 37 weeks gestation recruited during periods 1 to 5 (21 October 2024 to 22 February 2026, inclusive), except for those in transition periods, therefore including those that require immediate resuscitation. Third, the *before-after analysis population* will contain all infants recruited in the pre-study period and period 1 only (see Figure 1, when all sites are not receiving the WAMM intervention). Finally, the *sustained implementation analysis population* will include all eligible infants born in Periods 1-5 except for those in transition periods, and the sustained implementation period, *that did not require immediate resuscitation*.

Interim analyses

As the study examines the implementation of an established intervention, there is no independent data and safety monitoring committee (IDSMC) and no formal interim analyses for safety, efficacy or futility have been performed. Therefore, there is no adjustment for interim analyses.

Handling of missing data

While we have provided resources and support to sites to collect accurate data on the number of seconds until the cord was clamped, we understand that in some cases, only the estimated number of seconds was provided in the database. There are also instances when the time is not documented at all. We will summarise the proportion of actual data, the proportion of estimated data and the proportion of missing data. At the time of writing this SAP (February 2026), the amount of missing data is low at

3%. We do not plan to undertake multiple imputation if the percentage of missing data is <5% at the completion of the study.

Statistical principles

There will be no formal adjustments to constrain the type I error for planned secondary and exploratory analyses. All analyses will be conducted at p=0.05. All estimates will be provided with 95% confidence intervals.

Timing of analyses

This SAP will be approved by both the WAMM study co-chairs and the head of Biostatistics at the National Health and Medical Research Committee Clinical Trials Centre (NHMRC CTC), in accordance with the NHMRC CTC standard operating procedures. The SAP will be submitted for publication before any analyses are undertaken. If the primary analysis data is cleaned and locked prior to the sustained implementation analysis population, and the SAP is approved, the primary analysis may occur at this time.

TRIAL SUMMARY

Recruitment and follow-up

The number of infants born within each period, within each cluster group (sequence) will be reported, along with the average cluster size and the variance of the cluster sizes, following guidelines for Consort diagrams for SW-CRT.[14]

Cluster-group characteristics prior to Period 1

The characteristics of the 4 cluster groups will be summarised at the end of the pre-study period (time of randomisation, before Period 1 commenced). This will include both infant characteristics (number of infants born, gestational age, multiple birth status, Apgar scores, mode of delivery), baseline measures of delay (NSCC, DCC60) and site characteristics (tertiary site, state in Australia, metropolitan versus regional).

Cluster group characteristics over time

The characteristics of the infants born in the 4 cluster groups will also be summarised over the 5 study periods. Graphical summaries may be used.

Adherence to WAMM intervention

The adherence to the WAMM intervention will be summarised through the reporting of secondary outcomes, specifically dose and reach. Here we will summarise any other QI programmes that were conducted over the 18 sites.

ANALYSES OF THE PRIMARY OUTCOME

Definition of the primary outcome

The primary outcome is the binary outcome of whether an infant achieves a delay in cord clamping of at least 60 seconds or more (DCC60). If the delay before cord clamping is 60 seconds or more, then the infant will be assigned as DCC60=Yes; if the delay is 59 or fewer, then DCC60=No.

Primary analysis

First, the raw (unmodelled) proportion of DCC60 will be summarised descriptively and graphically for each period, site and cluster group.

The estimand for the primary analysis is detailed in Table 2, based on a template by Kang et al. [15] The primary analysis will be performed at the infant level. For the primary outcome, a linear mixed model with an identity link will be used, therefore estimating the risk difference in proportions with a 95% CI. A clustering term will account for the clustering of infants within sites (as required for cluster randomised trials) and a time effect (period) will be incorporated for secular trends, as follows:

$$\mathbb{E}[Y_{ijt}] = \beta_0 + \beta_1 Intervention_{jt} + \beta_2 Time_t + u_{site(j)} \qquad \text{Equation 1}$$

where

the link function is the identity link (so the expected value is modelled directly);

Y_{ijt} is the outcome for individual *i* at site *j* in period *t* ;

$u_{site(j)} \sim N(0, \sigma^2)$: a random intercept for each site, accounting for the clustering of infants within each site;

β_1 is the effect of the intervention, given as a risk difference (absolute difference in probability between the intervention and control); and

β_2 is the effect of the time period on the outcome (adjustment for the secular trend).

This model will be fit with the lme4 package in R. [10] Model assumptions will be checked and the ICC from these analyses will be reported in line with guidelines. [5] The proportion achieving DCC60 for each treatment will also be given from the averages over time from the primary analysis model.

Given the trial simulation studies we have conducted on the basis of our design, it is expected that the identity link model for risk differences will be stable, given that the DCC60 rates are expected to be in the range of 50%-70%. However, if the primary model does not converge or predictions are outside the bound of [0,1], a logit link will be used to provide an odds ratio rather than a risk difference as the population-level summary measure. Generalised estimating equations (GEE) with an identity link, exchangeable correlation structure and robust (sandwich) standard errors may also be used in this instance. This approach is robust to correlation and variance misspecification.

Table 2: Primary outcome for the WAMM trial, presented in the estimand framework

Objective:	Reduce the gap between the evidence and practice by integrating timely collection and reporting of cord clamping data with Evidence-based Practice for Improving Quality (EPIQ) methods to increase the proportion of preterm infants receiving DCC for 60 seconds or longer (DCC60)
Estimand:	The risk difference in DCC60 rates between the presence of the WAMM intervention plus basic accurate data sharing, compared to the presence of basic, accurate data sharing alone in Australian infants born <37 weeks' gestation who do not need resuscitation, under a treatment policy approach.
Treatment:	WAMM intervention (a funded locally adapted QI programme)
ESTIMAND	**ANALYSIS**
Target population	**Analysis set**
Infants born less than 37 weeks' gestation that do not require immediate resuscitation at given Australian sites	Infants at randomised sites who do not require immediate resuscitation, born <37 weeks' gestation in periods 1-5. Infants born within the 4-week transition periods between control and WAMM intervention, within the pre-study period and within the sustained implementation period will not be included.
Variable	**Outcome measure**
Delayed cord clamping of 60 seconds or more (DCC60)	
Handling of intercurrent events	**Handling of missing data**
A treatment policy approach is taken, where any delays in the commencement of the WAMM intervention (or commencement of alternative QI activities) are considered part of the intervention, in alignment with the intention to treat principle.	The amount of missing data is expected to be <5%, therefore imputation is not planned.
Population level summary measure	**Analysis approach**
Risk difference between WAMM intervention and control, averaged over the periods in each (averaged treatment effect)	Adjusted risk difference (with 95% CI), between treatment and control periods using binary regression (a generalised linear multivariable model with an identity link function and binomial distribution), adjusted for the clustering of infants within sites and time.

Sensitivity analyses

Given we have a waiver of consent for infants, we cannot identify infants born to the same individual.

A sensitivity analysis will therefore adjust for multiple birth status (yes vs no). The second sensitivity

analysis will use the sensitivity analysis population, which includes infants who received resuscitation. All other aspects of the estimand given in Table 2 will be the same.

Subgroup analyses

Interactions between the prespecified subgroups and the intervention will be incorporated into the main analysis model of the primary outcome of DCC60 in the primary analysis population. This includes site, gestational age (<32 weeks versus ≥32 weeks), mode of birth (caesarean versus vaginal) and multiple birth (yes versus no). For the model assessing the interaction between site and treatment, site will be fit as a fixed effect. In the case of convergence issues, tests for interaction will be performed in a model with a logit link, rather than an identity link, in line with the analysis for the primary outcome.

ANALYSES OF THE SECONDARY OUTCOMES

The secondary outcomes are separated into clinical effectiveness, balancing measures and process outcomes (see Table 1).

Clinical effectiveness outcome

The clinical effectiveness outcome is the number of seconds before cord clamping (NSCC), from which the primary outcome was categorised. Given that NSCC is unlikely to follow a normal distribution, the best distributional fit will be assessed prior to any formal analysis by treatment, i.e., prior to the primary outcome analysis and the knowledge of any treatment effects. The candidate distributions will be limited to those that estimate parameters such as the mean and median, and will be performed with the generalised additive models in the location shape and scale (GAMLSS) package in R. [11] Once the distribution is selected, the treatment effect will be modelled in the mean/median parameter only, in a similar fashion to that given in equation one. Again, the model assumptions will be checked.

A sensitivity analysis may explore treatment effects on other parameters (e.g. scale).

Balance Measures

Hypothermia and death at 28 days after birth or discharge (whichever occurs earlier) will be recorded as balancing measures. These are collected at the infant level. Hypothermia is defined as the first recorded temperature at admission of <36.5 degrees Celsius. Analyses will be performed on the primary analysis population.

First, both will be summarised graphically by DCC60, over each period, site, and cluster group. These measures will be analysed and summarised by DCC60 and an ordinal measure of delay (0-60, 61-119 and 120 seconds or more). The analysis will use a similar model to that of the primary outcome, but with DCC60 or the ordinal measure of delay included rather than allocated treatment. Given that this is not an intention-to-treat analysis and the size of the trial, any observed associations will be interpreted cautiously to ascertain if they may be clinically meaningful, rather than merely statistically significant differences. Explorations of any warming techniques used (towel drying or plastic wrapping), and infants at lower gestations may also be undertaken.

Key process outcomes

Definitions

Fidelity will be evaluated in relation to the delivery of the WAMM intervention as intended. It will be measured by the following individual components:

a) Delivering the QI education programme within the 4-week transition window. The date of the first meeting must be within these 4-weeks, with a window of 7 days either side.

b) Establishment of local QI teams of 6-8 members in the 4-week transition window. The date the team member joined the QI team must be within these 4-weeks, with a window of 7 days either side.

The members of each team will also be summarised (e.g. parent representative, lead obstetrician, lead neonatologist/paediatrician etc).

c) Creating and implementing one or more local change idea(s) in the 4-week transition window. The date of the change idea implementation must be within these 4-weeks, with a window of 7 days either side.

d) Ongoing check-in monitoring meetings between central QI facilitators and local QI teams on a 4-6 weekly basis after the first 4 weeks. Over the intervention period for the given site, a total number of meetings will be expected at 6-weekly intervals (e.g. cluster group 1 has 52 weeks of intervention, and therefore expects at least 8 check-in meetings). At least this number of meetings will determine those sites who to have achieved this outcome.

e) Participation in at least one quarterly virtual meeting of the study sites in the intervention ecosystem to discuss progress and share ideas. This is based upon at least one QI team member representing the site at one or more meetings.

Dose will be measured by:

a) The number of check-in monitoring meetings between central QI facilitators and local QI teams. This is based upon at least one QI team member representing the site at each meeting.

b) The number of completed PDSA cycles for individual sites. The dates of PDSA cycles must fall within the intervention period for that site.

Reach will be measured by:

a) The number of clinical staff who engage with the local QI team to design local change ideas.

These data will be extracted from the QI database, based on data collected from WAMM check-in forms completed by local QI teams or central QI facilitators.

Analyses

These outcomes will be summarised overall, and by cluster group using means (or medians as appropriate) for continuous data and proportions for categorical data. We will also report summaries by tertiary vs non tertiary hospital status, and by the median births per year (above or below the median).

EXPLORATORY ANALYSES

Effect of data sharing

A before-after model will incorporate time and cluster (site) terms to quantify the effect of the introduction of data sharing, which commences in the data sharing period (period 1). This analysis will be performed in the before-after analysis population, following the same principles as the primary analysis. The model will look like so,

$$\mathbb{E}[Y_{ijt}] = \beta_0 + \beta_2 Time_t + u_{site(j)} \qquad \text{Equation 2}$$

Where;

The link function is the identity link (so the expected value is modelled directly);

Y_{ijt} is the outcome for individual *i* at site *j* in time period *t* ;

$u_{site(j)} \sim N(0, \sigma^2)$: a random intercept for each site, accounting for the clustering of infants within each site; and

β_2 is the effect of the time period on the outcome, the effect of interest. Note that *t* is 0 or 1, denoting the pre-study period (period 0) compared with period 1.

Secular trends

Our primary model assumes a homogenous secular trend across all clusters. In this analysis, we plan to explore secular trends that vary across clusters in two manners, analogous to Model extensions 1 and 2 in Hemming *et al.* [16] First, we will explore secular trends based upon by our stratification factors used in the randomisation of the clusters (e.g. tertiary versus non-tertiary), and second, we explore random variability across clusters. The secular trend of the best fit (final secular trend model) will be determined by the lowest value of the Bayesian information criterion (BIC).

Our primary model also assumes a constant treatment effect over the intervention period. Given that the WAMM intervention may have been refined over time, it is possible that the treatment effect is not constant over time, particularly as International Liaison Committee on Resuscitation (ILCOR) and

Australian and New Zealand Committee on Resuscitation (ANZCOR) guidelines have recently been updated. [17, 18] Therefore, we plan to undertake analyses to examine how the treatment effect for the primary outcome changes over time by fitting an interaction term between treatment and time. This interaction term will be explored in the final secular trend model.

Sustained implementation

The sustainability of any increase in DCC60 will be explored using a model that incorporates the final period of the study (the sustained implementation period). The population will be the 'sustained implementation period population' from above. First, we will provide graphical summaries over time. Next, we will extend the primary outcome model to include an additional time period. Finally, if appropriate, we will explore extending the final secular trend model to include the sustained implementation period effect.

CONCLUDING REMARKS

In summary, this Statistical Analysis Plan outlines the predefined analytical methods for evaluating the effectiveness of the WAMM intervention in improving delayed cord clamping practices for preterm infants across Australian maternity hospitals. By specifying primary, secondary, and exploratory analyses in advance, this SAP supports transparency, reproducibility, and rigour in the conduct and reporting of the WAMM trial. Adherence to this plan will ensure that the final trial outcomes are interpreted in accordance with contemporary methodological standards for stepped wedge cluster randomised trials and will provide high-quality evidence on the impact of a structured quality improvement programme on optimising neonatal care practices.

If the WAMM intervention is proven effective, scaling up our intervention will result in increased average uptake of DCC in all ~250 Australian maternity hospitals, and globally. This will reduce mortality, childhood anaemia, disability in preterm infants and their associated long-term costs.

DECLARATIONS

Ethical approval and consent to participate

This study protocol was approved by the Lead HREC, Hunter New England Human Research Ethics Committee (2023/ETH01558, Version 2, 24 October 2023) and was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007, updated 2018).

Consent for publication

Not applicable

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed.

Competing Interests

The authors declare that they have no competing interests.

Funding

The study has been funded through the Medical Research Future Fund (MRFF) – Clinical Trials Activity Initiative - 2021 Clinical Trials Activity Grant Opportunity – Stream 5 (MRFF2022801).

Kristy Robledo is funded by NHMRC grant 2033081.

Authors contributions

Kristy P. Robledo: Conceptualization (lead), Methodology (lead), Writing – original draft (equal), Writing – review & editing (equal), Project administration (supporting).

Himanshu Popat: Methodology (supporting), Formal analysis (supporting), Writing – original draft (equal), Writing – review & editing (equal).

Isabel Li: Data curation (lead), Software/Statistical programming (lead), Writing – original draft (equal), Writing – review & editing (supporting).

Sarah Finlayson: Project administration (lead), Investigation (supporting), Writing – review & editing (supporting).

Melinda Cruz: Project administration (supporting), Investigation (supporting), Resources (supporting), Writing – review & editing (supporting).

Angela Cavallaro: Project administration (supporting), Investigation (supporting), Writing – review & editing (supporting).

Naomi Spotswood: Investigation (supporting), Writing – review & editing (supporting).

Amy Keir: Investigation (supporting), Writing – review & editing (supporting).

Christoph Lehner: Investigation (supporting), Writing – review & editing (supporting).

Sailesh Kumar: Investigation (supporting), Writing – review & editing (supporting).

Graeme Polglase: Investigation (supporting), Writing – review & editing (supporting).

Adrienne Gordon: Investigation (supporting), Writing – review & editing (supporting).

Khalid Aziz: Investigation (supporting), Writing – review & editing (supporting).

Kei Lui: Investigation (supporting), Writing – review & editing (supporting).

Ian Marschner: Methodology (senior oversight), Supervision (supporting), Writing – review & editing (equal).

William Tarnow-Mordi: Conceptualization (supporting), Supervision (supporting), Writing – review & editing (equal).

Acknowledgements

We would like to thank the 18 sites who have undertaken the WAMM study: Gosford Hospital, Canberra Hospital, Royal Darwin Hospital, Monash Medical Centre, Joondalup Health Campus, The Northern Hospital, Gold Coast University Hospital, Westmead Hospital, Tamworth Rural Referral Hospital, Mackay Base Hospital, Alice Springs Hospital, Flinders Medical Centre, Fiona Stanley Hospital, Nepean Hospital, Royal Hobart Hospital, Sunshine Coast University Hospital, Royal Brisbane and Women's Hospital, Blacktown Hospital.

In particular, we would like to thank the local QI teams at each of the sites, and their parent partners: Haliyat Alliu, Bryley Conley, Stephanie Endycott, Jennifer Brown, Zenna D'Ortona, Lihn Pham, Fariha El Nachar, Emma Snowden, Felicity Dowdell, Courtney Scott, Tae Viri, Amy Ellis, Tayla Micallef and Nathanael Yates.

Although this study operates with a waiver of consent, we gratefully acknowledge the parents of all infants whose data have been provided. Their infants' contributions make this research possible, and we recognise the importance and value of the data entrusted to us.

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