



Health Innovation  
West of England



Gloucestershire  
**Local Maternity  
and Neonatal  
System**

# Protocol for Real World Evaluation of Anya

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## 1. Background

Breastfeeding is recommended by the World Health Organisation (WHO) as the exclusive source of feeding for the first six months of an infant's life<sup>1</sup>. Moreover, WHO recommend this is initiated within the first hour of a baby's life. This is supported in a Cochrane review which notes the substantial health benefits to both women and babies of exclusively breastfeeding for the first six months<sup>2</sup>.

The UK has one of the lowest breastfeeding rates worldwide, despite the well-documented benefits to both women and infants<sup>3</sup>. Recent governmental data<sup>4</sup> reveals the aggregate rate of breastfeeding in England at 6-8 weeks for 2021-22 was 49.3%.

A substantial number of interventions have been developed to increase the rate of breastfeeding, with arguably mixed evidence of success. One systematic review of breastfeeding interventions<sup>5</sup> concluded that interventions were more effective than usual care, although the authors qualify this by stating "it is questionable whether these trivial effects have any real-world effect" (p.570). A Cochrane review<sup>6</sup> found evidence for improved rates of breastfeeding initiation across interventions undertaken by professionals from healthcare and non-healthcare backgrounds. However, they found no evidence of improved initiation rates from multi-media educational interventions. A further Cochrane review<sup>7</sup> found no conclusive evidence from the studies they reviewed that antenatal breastfeeding education improved the initiation or duration of breastfeeding.

A review of breastfeeding interventions<sup>8</sup> between 2004-2008 identified three e-based interventions and 18 provider-based (peer or professional support-based) interventions. The author found that e-based interventions had an odd's ratio two times greater than provider-based interventions, suggesting that e-based interventions are potentially more effective. Of interest in the discussion of the literature is the statement that there is "strong evidence to support the development of interventions that offer provider support in addition to breastfeeding education" (p.649); a recommendation of the U.S. Preventive Services Task Force. In other words, breastfeeding interventions need to combine the practical support of healthcare providers with educational elements of breastfeeding.

## 2. Anya in Gloucestershire

Anya is a smartphone app that is available on Android and iOS platforms. The app aims to provide around-the-clock breastfeeding support through the LatchAid module which offers visual information on latching technique. Anya also provides access to virtual parenting groups and 1:1 support from real-life specialists.

Gloucestershire Local Maternity & Neonatal System (LMNS) purchased 500 licences for Anya and Health Innovation West of England has been commissioned to conduct a real-world evaluation following implantation and deployment across the breastfeeding care pathway in the local region. The LMNS would like to understand the deployment of these licences in areas where breastfeeding rates in the county are lowest. These are areas that have been identified as more deprived with higher birth rates among younger women. The system has previously struggled to engage with such populations. To this end, the evaluation will focus on deployment Anya in Gloucester City and the Forest of Dean.

### 3. Terminology

In this protocol, we have deliberately avoided using the terms “mothers” or “patients” as these terms can convey a multitude of other meanings for people. In this protocol, for the sake of clarity and consistency we will use terms such as “women” or “women staff support” to refer to those who Anya is aimed at.

### 4. Evaluation Aims

This evaluation aims to identify the impact of implementing Anya in two social-economically deprived areas on breastfeeding outcomes, NHS staff and health resource use. The evaluation will identify insights into the experiences of healthcare professionals involved in implementing the delivery of Anya with women who have recently given birth.

### 5. Evaluation Objectives

The evaluation will address the following objectives which are framed as questions:

1. What can we **learn** from healthcare staff about breastfeeding support and technology that can be applied to **support the implementation** of Anya?
  - a) What are their views on the current provision of breastfeeding support and information?
  - b) How confident are staff in using smartphone apps?
  - c) What are staff beliefs about the potential benefits and challenges of using breastfeeding apps?
  - d) What do staff think and feel about implementing a breastfeeding app specifically in their routine clinical practice?
2. Does the introduction of Anya to women who have recently given birth in socio-economic deprived areas support them to achieve better breastfeeding **outcomes and experiences**?
  - a) What are the demographics of women initiating breastfeeding using Anya?
  - b) How many women using Anya are still breastfeeding at 6-8 weeks?
  - c) How have women used Anya?
  - d) How has Anya helped women with breastfeeding and parenting?
  - e) What difference has Anya made to the confidence of women to breastfeed?
  - f) How has Anya impacted how women seek help from professionals?
3. What is the **impact of implementing** Anya on health visitors, midwives and service utilisation?
  - a) What impact do staff believe Anya has made to their workload?
  - b) What do staff believe is the added value of using Anya?
  - c) What impact do staff believe Anya has had on patient contacts with staff?
  - d) How has Anya impacted the delivery of postnatal care to women and babies?
4. Is Anya considered an **acceptable** breastfeeding support tool by women who have recently given birth, health visitors and midwives?
  - a) How did women experience using Anya?
  - b) Have there been any unintended or adverse outcomes from using Anya?

- c) What were staff experiences of the Anya training?
- d) How did staff experience implementing Anya with patients?
- e) Were staff able to introduce Anya to women?
- f) Would staff recommend using Anya to colleagues and the women they support?

## 6. Methods Overview

To achieve the evaluation objectives, a mixed methods approach will be used. These are captured in a process timeline described in Appendix 1:

1. An insights survey of NHS staff to guide the implementation of Anya.
2. Two surveys of women using Anya at weeks 1 and 6 postpartum.
3. Usage data of Anya from the company.
4. Anya signposting and breastfeeding data from NHS Trusts.
5. A survey of NHS staff at the end of the project.
6. Interviews of key NHS staff at the end of the project.

### 6.1. Methods: Implementation Survey

To understand the perspective of staff working in the maternity services, we have undertaken an insights survey to shape the implementation of Anya.

Staff from the Evaluation & Insights (E&I) team in Health Innovation West of England designed a staff survey. This was delivered to NHS staff in roles including Health Visitors, Community Midwives and Community Feeding Support, employed across two Trusts: Gloucestershire Hospitals NHS Foundation Trust and Gloucestershire Health and Care NHS Foundation Trust. The survey was sent by staff in the two Trusts to their colleagues.

Whilst demographic data was collected, we did not actively collect personal data (IP addresses were inadvertently collected by the survey system and will be deleted) and participants remained anonymous. The survey was run via a secure website with data returning to E&I staff at Health Innovation West of England. Appendix 2 contains a copy of the survey.

#### *Resources*

- i. Online staff survey

### 6.2. Methods: Anya Survey of Mothers

#### 6.2.1. Recruitment of Women in Community

Community midwives will be asked to share information about the evaluation at Week 28 with women. This is the same point at which the midwives will discuss Anya as part of the breastfeeding conversation.

Note, it is possible that the Week 28 contact point will not always be used as the first introduction to Anya. For instance, some women may miss this appointment; the project may seek to include women who have gone past this contact point up until Week 8 of the baby's birth.

Community Midwives will share information about Anya to all women living in Gloucester City and Forest of Dean who are 18 years or over. They may draw on the information sheet in Appendix 3 to do this. They will also share information about the evaluation. **Community Midwives will seek permission from women to share the woman's name and contact details from the evaluators.** They will record the woman's decision using the Badgernet form. Appendix 3 offers a guide to how to complete this.

The number of women to be recruited will depend on the number of live births. It will also depend on the needs of the commissioners with respect to gathering sufficient evaluation data to allow an adequate evaluation of Anya.

The two districts where Anya will be introduced are Gloucester and the Forest of Dean. Data from 2021 indicates that between the two districts, a total of 2227 live births occurred in that year<sup>10</sup>. This equates to 185 live births each month. The company behind Anya anticipate a 20% uptake of the app suggesting 37 women each month may take part.

We propose a flexible timeline of data collection dependent on the success of sufficient women using the App and completing the survey. Ideally, we will have baseline and six-week data on 75-100 women.

## 6.2.2. Inclusion & Exclusion Criteria

Women are eligible for the evaluation if they live in the Forest of Dean or Gloucester City areas, are pregnant or have had a baby who is no older than 8 weeks old. Women who do not use Anya but who wish to participate in the evaluation will be included.

We will exclude from the evaluation:

- i. women under 18 years old (to avoid complications of consenting individuals legally considered children).
- ii. women whose babies are on the Neonatal Intensive Care Unit (NICU) (given that experiences of breastfeeding premature babies will complicate the evaluation data).
- iii. women who cannot speak English or do not have access to someone who can speak English (given the app is only available in English).
- iv. women whose babies are older than 8 weeks old.

The evaluation team will be responsible for final confirmation of eligibility prior to consent.

## 6.2.3. Consent of Women

Once the contact details of women have been sent over from Badgernet, a member of the Evaluation Team will make contact with the woman. They will explain the evaluation to them (see suggested script in Appendix 4) and ask them if they would like to consent. An information sheet (see Appendix 5) can be posted or emailed to the woman. An easy-read version is available (see Appendix 6).

When the woman agrees to take part, they can complete the consent form (see Appendix 7) in a number of ways: by post, by email, by Whatsapp, by an online Zoho form or, face-to-face. An easy-read version is also available (see Appendix 8).

A QR code and link to the online form are printed at the bottom of the participant information sheet. The QR code takes women to a form hosted on Zoho Survey. This form has a link to download the latest Participant Information Sheet. We ask women for their first and last name. We ask them to confirm their identity by telling us their mother's maiden name and their postcode.

On all formats of the consent form, we ask women for their first and last name, and the due date or birth date of their baby. This will enable us to contact the woman at the most appropriate time.

#### **6.2.4. Data Collection**

A member of the Evaluation Team will contact the woman a week before the woman's due date. They will arrange with the woman a convenient time to contact them the following week to check if they have had their baby. This contact arrangement will go on until the woman has had their baby or they withdraw from the study. We aim to undertake the survey between 1-14 days postpartum. The survey can be done on the phone, by video call, on the internet, by post or face-to-face with an evaluator.

The survey will collect demographic information, data around delivery method and breastfeeding, how women heard about Anya, use and intention to use Anya, and completion of the Breastfeeding Self-Efficacy Scale Short-Form<sup>9</sup>. If the participant does not complete the week 1 survey, we will still endeavour to collect data from the week 6 survey.

Between weeks 6-8, a member of the Evaluation Team will contact the woman and complete a further survey. This will establish whether the woman is still breastfeeding, use and intention to use Anya, and a (comparison) score on the Breastfeeding Self-Efficacy Scale Short Form. Women will be asked about their experience of using Anya (or if not using Anya, a different set of questions). Questions will be designed to elicit numerical and textual data. See Appendix 9 for a copy of the survey.

As personal identifiable information and special category information (within the meaning of GDPR legislation) is being collected, we have completed a Data Protection Impact Assessment (DPIA).

#### *Resources*

- *Evaluation Team contacting Anya users*
- *Zoho Survey hosts data collection.*

#### **6.2.5. Safeguarding**

All evaluators involved in working with Anya users have permanent NHS contracts with the RUH Bath, and have a DBS check and have undergone safeguarding training.

We have liaised with staff from the LMNS and Trust partners to develop a safeguarding protocol. This will be followed if during the process of interacting with Anya users, we become concerned about a safeguarding or potential safeguarding issue. Appendix 10 details our safeguarding processes.

Where face-to-face visits are taking place, the evaluators will following lone working processes set out by their NHS employer.



Where risk is identified in the referral from the community midwife, we will liaise with them further. We are routinely sharing consenting participants with the health visiting team. This is a further safeguard to protect vulnerable participants and ensure the evaluators are appropriately informed prior to undertaking the week 6 contact.

### **6.3. Methods: App Usage Data**

LatchAid Ltd. will provide anonymous data to Health Innovation West of England for all users of Anya, regardless of whether they participate in the evaluation. This is specified in Appendix 11. Where Anya users have consented to the evaluation and to the sharing of data between Latchaid Ltd and Health Innovation West of England, identifiable data will be securely shared by Latchaid Ltd with Health Innovation West of England in a way that identifies the user; also specified in Appendix 11. To enable LatchAid Ltd to identify evaluation participants, Health Innovation West of England will share with LatchAid Ltd, limited personal details (name, postcode, baby's birth date/due date) of those women who have used Anya and consented to this information being shared. We may share evaluation consent forms with LatchAid Ltd securely.

To ensure data is appropriately shared and processed, a Data Protection Impact Assessment has been completed. Data will be securely shared between Health Innovation West of England and LatchAid Ltd using a secure portal and secure email.

### **6.4. Methods: NHS data**

We will be collecting breastfeeding, Anya referrals, names and contact details and risk information from Gloucestershire Hospitals NHS Foundation Trust and Gloucestershire Health & Care NHS Foundation Trust. Using NHS numbers, we propose to link data sets between the Trusts. Some of the NHS data will be anonymous, much of it will be identifiable, special category data. As a result, we have completed a DPIA to ensure data is securely stored and processed and shared between organisations. See Appendix 12 for a list of data points proposed. Data sharing agreements between the Health Innovation West of England and the project partners are in place.

### **6.5. Methods: Staff Survey**

Towards the end of the implementation of Anya, a survey will be sent to staff in the two NHS Trusts in roles including Health Visitors, Community Midwives and Community Feeding Support. Data will be managed directly by the Evaluation and Insight team.

Demographic data including personally identifiable information will be collected. The exact questions of the survey are still to be decided but will cover a range of topics and are listed in Appendix 13.

A range of maternity staff from the two Trusts will be recruited for the end of project survey. Staff will be informed participation is voluntary. Ideally, we will have a minimum of 15 responses. Introductions to the survey will be made through contacts in the NHS Trusts. A DPIA has been completed to ensure data is securely handled.

## *Resources*

- v. Online staff survey

## **6.6. Methods: Staff Interviews**

Interviews will be conducted by members of the E&I team with NHS staff from Gloucestershire Hospitals NHS Foundation Trust and Gloucestershire Health and Care NHS Foundation Trust. The purpose of the interview is to facilitate deeper exploration of staff experiences of implementing Anya.

A range of staff will be sought for interview, including frontline community midwives, health visitors and feeding support staff; team leaders; senior staff such as Matrons and Heads of Service. We will be looking to recruit a minimum of 3 staff members. Staff will be informed participation is voluntary and staff will be contacted via a member of staff in the organisation. Staff in the NHS will be asked to facilitate introduction between staff and evaluators from the E&I team.

Prospective participants will be given a participant information sheet (see Appendix 14) and will be asked to sign a consent form (see Appendix 15) prior to interview. Interviews will be conducted either on Microsoft Teams or in person and will be recorded and transcribed. The final interview schedule is still be drafted. However, interviews will typically explore area such as:

- vi. The process and impact of implementing Anya.
- vii. The positive and negative impact of Anya on staff, women and babies.
- viii. Lessons that could be learned.

The data will be analysed using Thematic Analysis by staff from the E&I team. Basic information about the participant's job role and years working in maternity services will be collected, although consideration will be given as to how confidentiality will be maintained when presenting data alongside job roles in the end report.

## *Resources*

- *Recording & transcribing software*
- *Voice recorders*
- *Interview rooms*

## **7. Data Analysis**

Data will be analysed by evaluators from the E&I team. Numerical data will be analysed, with descriptive statistics produced (such as mean and range). In some instances, inferential statistics will be applied, for example, to establish if there is a significant change in breastfeeding self-efficacy between the two data points. Textual data will be analysed using Thematic Analysis. Where appropriate, data analysis will be checked by a colleague in the E&I team.

## 8. Governance

Within the Health Innovation West of England, the evaluation is overseen by a steering group consisting of Senior Programme Managers and clinical staff from the LMNS. Evaluation progress is also reported to the Evaluation & Insight board.

The main organisations involved in this evaluation are:

- Gloucestershire Local Maternity and Neonatal System (LMNS);
- Health Innovation West of England
- Gloucestershire Hospitals NHS Foundation Trust;
- Gloucestershire Health and Care NHS Foundation Trust;
- Maternity Voices Partnership;
- Partners within One Gloucestershire; and
- Anya.

Information will be shared between a number of these organisation. To ensure this is done under appropriate legal frameworks, Health Innovation West of England has registered the evaluation with the R&D departments at Gloucestershire Hospitals NHS Foundation Trust and Gloucestershire Health and Care NHS Foundation Trust, in compliance with research governance.

Data workshops have been held with Anya and the clinical systems to provide workshop into the data that is collected. Data sharing agreements are in place and Data Protection Impact Assessments (DPIA) have been completed and shared with the participating NHS Trusts for approval.

## 9. Project Assumptions

- Sufficient NHS staff and women agree to participate in the evaluation.
- The survey will be acceptable to women. The birthing woman's survey has been piloted with a member of the Maternity Voices Partnership group.
- All data sharing agreements will be in place and agreed.
- All project governance that is required will be done in sufficient time to allow the evaluation to proceed successfully.

## 10. Causality Considerations

- This evaluation has been set up as a real-world evaluation. It does not have a control group. There will therefore be strong limitations on the ability to make causal inferences about Anya. For instance, it will not be possible to say that Anya has increased breastfeeding initiation or continuation rates. Nor will it be possible to say that Anya has increased breastfeeding self-efficacy.
- Although Anya is being targeted in a population that is more deprived, we anticipate that end users are likely to be more interested in breastfeeding than those who do not use Anya. We also anticipate the end users will be better educated and from a less deprived area. Should this be the case, it may limit what conclusions can be made about the use of Anya in more socio-economically deprived areas.

- The evaluation is designed to provide a level of confidence to support future commissioning decisions of Anya. The end report will provide data that will enable the generation of hypotheses around particular causal inferences (e.g. the data suggests that Anya may be more useful in this specific population).

## 11. Report

The E&I team will produce a final report at the conclusion of the project. This will feature the evaluation methodology, key findings and analysis and where appropriate, recommendations. Should key stakeholders have specific requirements for the report, this should be outlined to the E&I team at the earliest stage possible.

## 12. Work Product

The Evaluation & Insights team will work independently to provide an evaluation of the Anya alongside the operational delivery provided by the Health Innovation West of England project team. Initial findings will be shared internally to ensure that a draft evaluation report reflects the requirements of the project team and to provide an opportunity for feedback. A dissemination and communications plan will be agreed collaboratively with the project team and E&I function and may include (but is not limited to) dissemination via conference presentations, evidence repositories and peer-reviewed publications, where appropriate.

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<https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/datasets/birthsummarytables>

## 14. Appendices Contents

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Appendix 2	Pre-implementation survey
Appendix 3	Information for staff to share with potential evaluation participants
Appendix 4	Suggested script for initial contact
Appendix 5	Participant information sheet (birthing women)
Appendix 6	Easy-read participant information sheet (birthing women)
Appendix 7	Consent form (birthing women)
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Appendix 9	Surveys at weeks 1 and 6
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Appendix 11	Summary of LatchAid Ltd app usage data
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