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ORIGINAL ARTICLE

Fractional exhaled nitric oxide-based asthma management: The feasibility of its implementation into antenatal care in New South Wales, Australia

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Background: The use of fractional exhaled nitric oxide (FeNO)-based asthma management during pregnancy can significantly reduce asthma exacerbations in non-smoking pregnant women. The feasibility of implementing this strategy into antenatal care has not been explored.

Aims: To examine the feasibility of implementing FeNO-based asthma management into antenatal clinics in New South Wales (NSW) Australia.

Materials and Methods: Semi-structured face-to-face interviews with video elicitation were conducted with healthcare professionals (HCPs) providing antenatal care in one of two hospital-based antenatal clinics in NSW, Australia. The video shown demonstrated the use of the FeNO instrument and other aspects of the management strategy, in antenatal care. Interviews were recorded, transcribed and analysed using qualitative content analysis.

Results: A total of 20 interviews were conducted with 15 midwives, four obstetricians, and one general practitioner. Two main themes and ten sub-themes arose: Getting a number (sub-themes: engaging, technically easy, objective, predictive, reassuring); and Resourcing (sub-themes: time and timing, systems, staff, education and cost). Comments included: 'It's easy, fast and effective' and 'the main barrier is time'. All HCPs felt capable of facilitating the FeNO-based management strategy, with appropriate education, and were willing to undertake this strategy, saying: '…it would be perfectly acceptable for a midwife or doctor to do it'; also, 'they don't necessarily need to see a physician, it's something that midwives would take on generally…'.

Conclusion: Participants in this study considered FeNO-based asthma management for pregnant women to be a feasible addition to antenatal care following appropriate provision of resources and education.

KEYWORDS

asthma, feasibility, FeNO, management, pregnancy

The participants for this study were recruited from the John Hunter Hospital (JHH), Newcastle, and the Royal Hospital for Women (RHW), Randwick NSW Australia. Authors participating in the FeNO demonstration video are Karen McLaughlin and Dr Vanessa Murphy.

INTRODUCTION

Asthma complicates 12.7% of pregnancies in Australia.[1] The increased risk of maternal complications (gestational diabetes, pregnancy-induced hypertension and preeclampsia) and adverse fetal outcomes (low birth weight and premature birth) for pregnant women with asthma is well documented.[2-5] Several outcomes are further increased with asthma exacerbations.[2,4] Therefore, optimising asthma control and reducing asthma exacerbations during pregnancy is an important goal of antenatal asthma management.[6]

Modern asthma management primarily utilises inhaled corticosteroids (ICS) as preventer medication, with or without long-acting bronchodilator therapy. While these medications are considered,[7] women and their physicians express concern as to optimal dosing and safety of these medications during pregnancy, which can lead to low prescription rates and non-adherence of medications.[8,9]In adults with asthma, biomarker-guided therapy is an effective way to reduce exacerbations and minimise medication exposure.[10] Fractional exhaled nitric oxide (FeNO) is a marker of T helper Type-2 (T2) eosinophilic airway inflammation in asthma and is used to guide titration of the dose of ICS required to reduce airway inflammation.

The Managing Asthma in Pregnancy (MAP) study[11] was a double-blind, parallel-group randomised controlled trial of the efficacy of FeNO-based management for reducing exacerbations in 220 non-smoking pregnant women with asthma.[11] Women were randomised prior to 22 weeks gestation into a control or intervention group. Treatment was adjusted in the control group according to asthma symptoms and lung function, assessed with the Asthma Control Questionnaire (ACQ).[12] The intervention group had ICS treatment adjusted according to their FeNO level, and long-acting beta agonist according to the ACQ. Treatment was adjusted monthly, and participants in both groups received free medications and self-management education. There was a significant 50% reduction in exacerbations in the FeNO group compared to the control group (0.288 vs 0.615 exacerbations per pregnancy; incidence rate ratio 0.496, 95% CI 0.325–0.755; $P = 0.001$).[11] FeNO-based asthma management also reduced ICS dose, and use of oral corticosteroids and short-acting beta agonists while maintaining asthma control. This is an important outcome as many pregnant women and some physicians are concerned about the use of asthma medications during pregnancy and will sacrifice asthma control for minimal medication use.[9]

Follow-up of the children from the MAP cohort found those born to mothers in the FeNO group, versus the control group, were less likely to have recurrent bronchiolitis in infancy[13,14] and less likely to have doctor-diagnosed asthma at age 4–6 years[13,14] suggesting a long-term benefit of FeNO-based asthma management during pregnancy, to the health of the offspring.

Following on from the MAP study, the Breathing for Life Trial (BLT),[15] is testing whether FeNO-based antenatal asthma management, compared to usual care, reduces the prevalence of adverse perinatal outcomes in babies born to 1200 women with asthma.[15] Those pregnant women randomised to FeNO-based asthma management receive regular review of their asthma by a research nurse or midwife, including measurement of their FeNO level via a simple breathing test. The FeNO measurement, along with the results of the ACQ, current medication use and smoking status are entered via an iPad, into an algorithm (Appendix S1), developed for BLT.[15] The electronic algorithm determines the need for changes in asthma medication. This trial has an expected completion date of early 2020.

Although the efficacy of FeNO-based antenatal asthma management has been established in one population group and continues to be studied, whether clinicians consider FeNO an acceptable measurement tool and whether they consider it is feasible to implement the strategy in the hospital-based antenatal clinic setting, is yet to be examined.

This study aims to assess the acceptability (defined as the perception among stakeholders that an intervention is agreeable[16]) and feasibility (the extent to which an intervention can be carried out in a particular setting or organisation[16]) of a FeNO-based asthma management strategy for pregnant women, by healthcare professionals (HCPs) currently providing hospital-based antenatal care in Australia.

MATERIALS AND METHODS

This study employed a qualitative descriptive study design, including video elicitation.[17] A purposive sample of HCPs currently providing antenatal care were recruited from two tertiary referral hospitals in metropolitan areas of New South Wales, Australia, providing services to a similar number of pregnant women per year, with antenatal clinics (ANC) seeing approximately 50 women per day. The ANCs are managed by a midwifery unit manager, a midwifery team leader who co-ordinates clinics on a daily basis and staffed by practitioners including obstetricians, obstetric trainees, general practitioners (GPs) and midwives.

This study was approved by the Human Research Ethics Committees of the Hunter New England Local Health District (16/09/21/4.01) and the University of Newcastle (h-2019-0010).

Data collection occurred from March to October 2018. All HCPs involved in the provision of antenatal care at the two sites were eligible to participate. Potential participants were given oral and written information about the study during regular staff meetings. Those agreeing to participate provided written consent and completed a face-to-face interview with the researcher (KM), focusing on the participant's current knowledge of FeNO-based asthma management, and their thoughts on the acceptability and feasibility of implementing the strategy into antenatal clinical practice. A video (Appendix S2) demonstrating the BLT intervention (including FeNO measurement, completion of the ACQ, and use of the algorithm on an iPAD) was shown to each participant

TABLE 1 Demographics of healthcare professionals

Code	Profession	Years of experience	Current position
†M1	Midwife	18 years 12–14 in antenatal clinic (ANC)	Team leader antenatal clinic
†M2	Midwife – clinical midwife consultant (CMC)	19 years	Currently informatics CMC previously group practice midwife and antenatal clinic manager
†M3	Midwife	21 years	Manager of outpatient services for maternity and gynaecology. Manage antenatal clinic
†M4	Midwife	15 years	Clinical practice and outpatients and research midwife
†M5	Midwife	30+ years	Antenatal clinic last 10 years
M6	Midwife	3 years	Two months in antenatal clinic
M7	Midwife	25+ years	Works in all departments of maternity
M8	Direct entry midwife	4 years	Antenatal clinic for two years
M9	CMC	40 years	Perinatal research
M10	Midwife	6 years	MAPS – Midwifery, antenatal and postnatal group practice
M11	Midwife	7 years	Midwifery group practice
M12	Midwife	14 years	Antenatal clinic and research recruitment
M13	Midwife	5 years	Three months in antenatal clinic
M14	Midwife	3 years	Antenatal clinic
M15	Midwife	40 years	Team leader antenatal clinic
GP1	General practitioner	30 years	Two clinics per week in large tertiary referral hospital antenatal clinic
Ob1	Obstetrician	14 years	Director of obstetrics. Large antenatal load
Ob2	Obstetrician/gynaecologist	32 years	Provide antenatal care for both private and public women
Ob3	Obstetrician	34 years	Medical maternity co-director. Participate in two ANCs per week
Ob4	Obstetric registrar	2 1/2 years	Four sessions in antenatal clinic per week

†Identifier for interviewees (M1 refers to: M = midwife, 1 = 1st midwife interviewed).

during the interview to stimulate thoughts about the management approach and to ensure consistency of information being provided. An interview schedule (Appendix S3) provided a guide for discussion about FeNO-based asthma management and issues relevant to participants and the clinical setting in which they worked. Interviews were digitally recorded and transcribed verbatim. Recruitment continued until data saturation was reached.[18]

A conventional approach to content analysis was undertaken using the four-stage process described by Morse and Field.[19] Data comprehension was gained through data immersion and reflection on field notes taken during the interviews. Initial codes generated from the transcripts were arranged into preliminary themes and sub-themes, which were discussed among the research team and cross-checked against the original data.

Rigour was ensured by documenting an audit trail, using a well-established research method, thoroughly describing the study setting to aid in transferability, illustrating the origin of the findings in the data by using participant quotes, and peer review of the analysis. Member checking occurred with all participants receiving a copy of their interview transcript with an opportunity to comment on, or make amendments to, the data prior to inclusion in the dataset.[20]

RESULTS

Interviews were conducted with 15 midwives (M), four obstetricians (OB) and one GP with a range of experiences (2.5–40 years, average 16.5 years, Table 1). Participants were employed in a range of roles in the maternity services and various models of hospital-based antenatal care were represented.

Thematic analysis identified two themes with ten sub-themes (Fig. 1): Getting a number (sub-themes: Engaging, Technically

easy, Objective, Predictive and Reassuring) and Resourcing (sub-themes: Time and Timing, Systems, Staff, Education and Cost).

Getting a number

Having a process that can provide a tangible result for women with asthma (ie the numerical FeNO measurement), and being able to share this with them immediately, had positive appeal to participants from all three professional groups (Table 2). Participants perceived the FeNO measurement as easy to perform and were excited about using this management strategy with pregnant women.

Participants felt that the process helped provide more holistic and individualised care for pregnant women with asthma. They considered FeNO-based management included the woman in her care and decision-making, since she would be able to understand the meaning of the numerical FeNO measurement and could be more informed about the need for medication.

Most participants commented on the perceived ease of the process and liked that it was a non-invasive test that didn't take long to do. The objectivity of the test was highly regarded. The algorithm was considered a benefit to both the clinician and the woman in order to guide joint decision-making.

The possibility of the FeNO measurement predicting when a woman was heading for an exacerbation of her asthma symptoms, was suggested to also help women to become more involved in their self-management during pregnancy. The reassuring nature of the process for both health professionals and pregnant women was an acceptable element of this process.

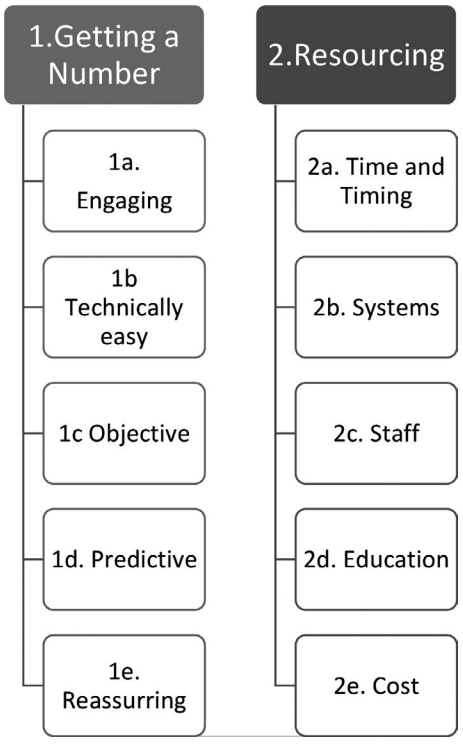

FIGURE 1 Themes and sub-themes.

Resourcing

Resourcing emerged as the main theme around feasibility (Table 3). Participants felt that some organisational and operational changes would be required to enable the implementation of FeNO-based asthma management into routine antenatal care. Time was a factor mentioned by many participants. Despite consensus that the process did not take too long, participants felt that having to add an extra process to an already full clinic visit could present challenges. There was also discussion about the optimal time during the pregnancy to perform the measurements.

Other implementation concerns included room availability, if the assessment was conducted as a separate visit, and what model of care the pregnant woman would need to receive. There was also discussion about firm policy and guidance surrounding the process, embedding prompts and the algorithm into information systems.

Participants discussed which staff would be responsible for the process and staff availability to perform the assessment. Some participants felt that a lack of staff could be a barrier; others felt that a dedicated person to perform this procedure would be required. Participants discussed whether this process should be performed by midwives or medical staff, with most suggesting that both would be suitable. The model of care the woman received was a consideration, as was the inability of the majority of midwives to prescribe asthma medications.

One participant felt that it would work best in a medical clinic, because doctors were required to prescribe medications. Alternatively, one midwife felt that midwives would like to take it on as part of the holistic care of women.

Training and education for clinicians about the FeNO-based process and the importance of well-controlled asthma in pregnancy was suggested as an essential aspect of implementation, due to limited knowledge about FeNO-based asthma management among staff. It was also suggested that women with asthma would require further education about asthma in pregnancy and the use of FeNO-based management which could aid implementation.

Overall, participants were uncertain about the effect of cost on the feasibility of the process, due to the cost of the equipment, and possible additional costs related to staffing and staff time.

DISCUSSION

This is the first study to examine the acceptability and feasibility of a novel, efficacious management strategy for asthma in pregnancy for implementation into antenatal care. All HCPs were accepting of the FeNO-based asthma management strategy, due to the ease of use of the equipment and minimal time required to obtain a measurement. The inclusion of this process into current antenatal care was deemed possible once common barriers such as time, education and training were addressed.

TABLE 2 Getting a number

Sub-theme	Illustrative quotes
Engaging	'I like that it's tailored for the individual person'(M1) and 'It's providing more holistic care' †(M10) 'They [the women] are actually being a participant in their care as well, so they're being an active member of their care' (M1) 'I think this could really support women and enable them to take care of their own health' (M1) 'It shows the women very clearly, a number, and they can understand therefore, what they need to do' (M13) It was also suggested that once women are armed with this knowledge it could, 'enable them in taking care of their own health, not only in pregnancy' (M1)
Technically easy	'I thought it was easy to do, easy to see quick results' (M1) 'It's simple…just to breathe in and out…with simple instruction anyone could do it.' (OB1); 'it seems quite easy' (M5) 'The iPad makes it really easy, the questions for the women are really easy and it's [the FeNO and ACQ process] not long' (M11) 'It's not invasive and it does not take long to do' (M15)
Objective	'I like that it's actually really objective, that it's providing guidance and it takes that subjective nature out of it' (M2) 'I like that it uses a measurement tool to give a woman a score, so it's not something that's going on information that she's necessarily giving you but something that you can do with her…I also like the algorithm that is digital to tell you what to do next' (M14)
Predictive	'It would help to identify women, more closely, who are needing adjustment to medication' (M13) 'I assume by monitoring these FeNO levels that patients will have fewer attacks' (OB2)
Reassuring	'It will give women a lot of reassurance that they're being managed well….and that it [their asthma] will be well monitored throughout the pregnancy' (M7) 'I've seen the benefit to women who will have their medication changed and come back the next appointment and go, 'wow that's what it's like to breathe normally', I like getting that feedback from women' (M9) 'It enables us to ensure that we're optimising management without increasing the risks of steroids' (OB4)

FeNO, fractional exhaled nitric oxide; ACQ, Asthma Control Questionnaire; OB, obstetrician.
†Identifier for interviewees (M1 refers to: M = midwife, 1 = 1st midwife interviewed).

After viewing the video demonstration of the FeNO-based process, participants unanimously regarded it as technically easy. Participants considered all clinicians would be able to carry out the process after receiving appropriate training. A previous study investigating the acceptability and ease of use of FeNO measurement among 37 patients with asthma (22 adults, 15 children), presenting to two nurse-led GP asthma clinics in the south-west of England, had similar findings.[21] Despite asthma nurses only receiving brief and basic training in the use of the FeNO equipment, they rated its ease of use as 'easy' or 'very easy' in most children (79%) and adults (75%). It was deemed acceptable to patients, with 96% stating that the process was 'acceptable' or 'completely acceptable' and none finding it 'unacceptable'. Furthermore, a Spanish study of the feasibility of measuring FeNO in 151 asthmatic children in a primary care setting,[22] concluded that the technical use of the FeNO device was feasible and acceptable to both staff and children. This was determined by perceived ease of operation and number of attempts required to gain a valid measurement. Most (98.7%) of the children were able to perform the FeNO manoeuvre using a hand-held device, and nurses considered the overall procedure to be 'very easy' or 'easy' in more than 86% of children. Thus, our data adds to previous work in other populations supporting the acceptance of FeNO assessment in clinical practice.

Providing an objective measure (FeNO) that could be shared with the pregnant woman immediately, was a positive feature of the process, since holistic, individualised, woman-centred care is the basis of antenatal care,[23] and therefore appealed to the clinicians in our study. It was also suggested that women may benefit from being more involved in their own asthma management during pregnancy. Several participants thought that this may continue following their pregnancy and lead to ongoing improvement in self-management. It was thought that as the pregnant woman could see the effect her current treatment was having on the inflammation in her lungs, she would continue her prescribed medication to ensure a consistent, or improved, measurement.

Moving forward, the inclusion of FeNO-based asthma management into antenatal clinical practice may require guideline review and development, and consideration of how the FeNO process could be implemented across different settings and models of care. Staff would require education and training, and there may be a need for extra staff (and therefore resources) to facilitate the change in practice. The involvement of consumers (pregnant women with asthma) in the development and implementation of this process would be an essential element in ensuring acceptability and sustainability of the intervention.

Strengths and limitations

This is the first qualitative study examining the acceptability and feasibility of FeNO-based asthma management in antenatal care, from the perspective of maternity health professionals. The

TABLE 3 Resourcing

Sub-theme	Illustrative quotes
Time and timing	'Antenatal care is changing all the time and the amount of things we are expected to do in an antenatal appointment is much more.... so time would be a factor' (OB1) 'The main barrier is time... there's only so much time to see someone' (M5)† 'My only concern is how will it fit into normal antenatal visits' (M4) 'We are quite tight for time in the appointments so I think we would have to add maybe 15 minutes more to the appointments' (M10) 'The biggest barrier will be timing of when it is required...if it is required to be done at booking, I think it's pretty much a no-go area because they can't fit in the stuff that they've got to do in a booking, into the time allocated' (M3) 'It's another thing to add to the booking visit or could it be done at 20 weeks?' (M9)
Systems	'Room availability is always a challenge' (OB4) 'Having a room to actually attend the test could be a barrier' (M12) 'It needs to be reproduceable in all our models of care' (OB1) 'A tight guideline around who we would screen...standard prompts in the system would be good' (M3) 'Putting the algorithm and pop-ups into e-Maternity' (M14)
Staff	'Changes to staff or staffing enhancements would be required' (OB1) 'Would need a designated person to do this' (GP1) 'Need a dedicated asthma midwife' (M4) 'Need someone available to call...someone that doesn't have a patient load' (M5) 'An extra midwife that could provide more support' (M10) 'A support person who does this on a regular basis, who can instruct the midwives' (M1) 'Champions to actually facilitate the process in the clinics, maybe a respiratory midwife' (M2) 'I think most midwives and doctors would be open to it' (M4) 'I would find it interesting' (GP1) 'It would require a fair bit of education for all midwives to be comfortable with it, but GPs would be another good avenue and, this might help them give better scripts for medications' (M9)
Education	'A little bit more education around general asthma management and more about the medications' 'Maybe a little information pack in the booking so that women know that we're going to be doing the test if they have asthma' (M6) 'Women who have asthma just need to be told about it and generally they would see this as a very efficient and intelligent way to tailor their treatment and the uptake would be great' (OB3)
Cost	'I don't think cost is a barrier...I don't think the machines and mouthpieces are going to break the bank' (M6) 'The cost would surround mainly time, the midwives' time on how to do it, the educators time on educating and paying a support person to come down' (M1)

GP, General Practitioner; OB, obstetrician.
†Identifier for interviewees (M1 refers to: M = midwife, 1 = 1st midwife interviewed).

knowledge gained will inform an implementation strategy including the development of educational resources surrounding FeNO-based antenatal asthma management.

Limitations may include limited transferability of results outside metropolitan tertiary referral hospital-based ANC and into different models of antenatal care, such as midwifery continuity of care. Although all professional groups working in the study settings were given the opportunity to participate and were represented, only small numbers of each group participated. Selection bias may further affect generalisability of results. Further research among larger numbers of health professionals from different antenatal care settings is required to improve generalisability.

The personal features of the participants that might influence their acceptability of this process, such as years of practice, previous experience implementing new strategies into clinical practice or preference for the use of technology in clinical care, was not examined in this study, but could be studied via a questionnaire in a larger sample size. The use of appreciative inquiry methods such as positive inquiry and emotional touch points[24] could further explore the positive aspects of implementing a new clinical practice rather than the limited 'barriers and enablers' approach. The involvement of stakeholders including consumers, in the development of implementation strategies will ensure the sustainability of clinical change.

A group of HCPs providing antenatal care in Australia regard the proposed inclusion of a FeNO-based asthma management strategy as acceptable to their practice, their clinical colleagues and pregnant women.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Fractional exhaled nitric oxide (FeNO) algorithm with cut points and suggested inhaled corticosteroids (ICS) dose changes based on Asthma Control Questionnaire (ACQ) results and FeNO measurement.

Appendix S2. Video link.

Appendix S3. Proposed interview schedule.