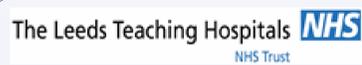


Bridging the non-invasive prenatal testing gap: accessing private screening in an NHS teaching hospital

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INTRODUCTION

Private access to non-invasive prenatal screening has been increasing across Yorkshire since 2013. No information regarding these patients has been collected by either the commercial companies or the NHS units at which they are booked, and it is not clear how many women across our region are accessing private NIPT or their reasons for doing so. Within the same time frame, increasing numbers of referrals for screen-positive results were received by the Leeds Fetal Medicine Unit. In the vast majority of cases, women had received inadequate pre- and post-test counselling and were unaware of the limitations of the NIPT, especially in the presence of a fetal structural abnormality. Increasing numbers of non-trisomy results were also causing concern.

The Leeds Fetal Medicine team felt strongly that an ethical and evidence-based NIPT service was urgently required in our region. In the absence of NHS funding, the challenge was to introduce a self-paying NIPT service, embedded within our maternity directorate and delivered by NHS staff.

KEY DRIVERS

- Perception of inadequate pre-test counselling offered by non-NHS providers
- Lack of support to choose the correct NIPT product – decisions based on cost alone were common
- Inappropriate counselling regarding the utility of NIPT for fetal structural anomalies.
- Lack of appropriately trained staff in private centres.
- Absence of appropriate follow up or support for women

BARRIERS TO IMPLEMENTATION OF THE SERVICE

- Cost to the patient
- Cost to the organisation of a send-away arrangement, especially staffing and logistics
- Anxiety regarding the blurring of boundaries between a private service and the NHS – the threat of a ‘two-tier service’ for users

Our choice of NIPT provider was based on accuracy, turnaround time and the limitation of false positive results. IONA tests for 13, 18 and 21 plus sexing, without the potential for detection of sex chromosome and other autosomal abnormalities with low positive predictive values. The IONA test is a CE-IVD ensuring high quality, safe, fast and accurate results. The IONA has a low re-draw rate and valid results are generated on samples with as low as 2% fetal fraction.

METHODS

- Cross-region engagement of midwives and obstetricians, with evening seminars and study days for screening co-ordinators, DGH clinicians and midwives.
- Patient information leaflets provided at booking with general information on NIPT, with a separate IONA-specific leaflet available for those women interested in accessing the test at LHHT
- Development of a standard operating procedure for access to NIPT, approved by the LHHT trust board, the Maternity CSU governance framework and patient and public representatives.



INCLUSION CRITERIA FOR ACCESSING NIPT AT LHHT:

- Structurally normal fetus on dating scan
- Screen positive on combined or quad test
- Maternal anxiety or wishes
- Past history of trisomy 13, 18, 21 or 45X
- Recurrent miscarriage, IVF and maternal infection
- Multiple pregnancies are referred to the Fetal Medicine Unit for further discussion of options

THE PATHWAY

- Women self-refer, or opt for IONA testing following positive first-trimester screening results.
- Specialist midwife appointment for full pre-test standardised counselling, including the limitations of NIPT.
- Charge to patient is £300, to cover the cost of send-away NIPT, all specialist midwifery time, counselling and phlebotomy, post-test support and immediate access to tertiary NHS fetal medicine if required. The service is cost-neutral for LHHT with no profits recorded
- Online access to the Premaitha results portal, MyNIPT for staff, with rapid turnaround time and emailing of results to women if desired.
- All women receive post-test counselling by FM specialist midwives, with full integration of NIPT results with combined screening, anomaly scanning and other NHS maternity pathways.

After launch of the service, we hosted Premaitha-sponsored educational events to improve knowledge and increase dissemination across the region.

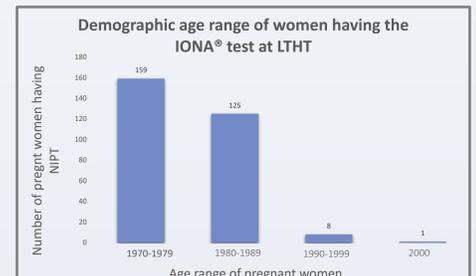
A full database of referral indications, patient demographics and results has been maintained.

RESULTS

Since March 2016, 293 IONA tests have been performed at LHHT.
Number of self-referrals 169/293.
Positive combined results 124/293.

Geographical referral:
240 / 293 Leeds
53 / 293 outside referrals

| Region | No of IONA® referrals |
|-------------|-----------------------|
| Calderdale | 20 |
| Mid Yorks | 8 |
| Bradford | 6 |
| Harrogate | 5 |
| York | 4 |
| Airedale | 3 |
| Bassetlaw | 2 |
| Windermere | 1 |
| North East | 1 |
| Sheffield | 1 |
| Cleethorpes | 1 |
| Workop | 1 |



Outcomes:

- 8 screen positive for T21 of which:
 - 3 continued pregnancy (1 had invasive, 2 declined) of these 2 have delivered term babies with T21 and 1 delivered 23 weeks and baby died
 - 4 confirmed on invasive testing – 3 TOP, 1 continued pregnancy
 - 1 declined invasive test – ruptured membranes at 20 weeks, premature labour and neonatal death at 26 weeks

Mean turnaround time is 3.6 ± 0.9 days.

Number of redraws 1/293.

PATIENT FEEDBACK

"Thankyou so much for your support and understanding over the last week you were amazing with very clear knowledge and detailed explanation of the screening process, clearly going above and beyond just doing your job."

"Just a little note to say thankyou for all your help yesterday. Just talking to you helped me process things so much more easily. You have given us so much more information than staff from anywhere else and we have decided to have the IONA. Thank you so much for your time it was very much appreciated."

DISCUSSION

This successful pathway has provided the women of Yorkshire with an alternative provider of NIPT. We feel that our service allows women to access NIPT with ethically-appropriate, high-quality pre- and post-test counselling. Choosing the IONA test prioritises screening for 13, 18 and 21, and avoids screening for conditions with very low PPVs such as microdeletions and sex chromosome anomalies.

Introduction of this service has allowed us to educate local midwives and clinicians about NIPT, improving the knowledge and counselling offered in our region's hospitals. Even if women seek NIPT from other providers, the increased knowledge has improved the support they receive from their local healthcare teams.

High levels of patient and clinical satisfaction have been noted following introduction of our service. Local clinicians feel empowered by access to a credible NIPT service, and we are increasingly receiving referrals from outside of Yorkshire as the reputation of the service spreads.

This is a low cost option for our trust, requiring no upfront investment. The majority of additional staffing cost is taken up by self-referring patients with normal first trimester scans, who wish to pay for advanced screening tests. Women who test positive on first trimester screening can opt to pay for NIPT, and their counselling is part of the routine pathway. This limits the potential for miscommunication and patient harm.

CONCLUSION

Until the national rollout of NIPT, expected in 2018, a private send away service is a viable option for NHS trusts who wish to provide ethically appropriate access to NIPT for their patients

ACKNOWLEDGEMENTS

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FURTHER INFORMATION

For further information on the IONA® test please visit www.Premaitha.com or email iona@Premaitha.com