Provision and practice of specialist preterm labour clinics: a UK survey of practice

AN Sharp, Z Alfirevic

Department of Women and Children's Health Research, University Department, Liverpool Women's Hospital, Liverpool, UK *Correspondence:* Dr AN Sharp, Department of Women's and Children's Health Research, Liverpool Women's Hospital, Crown Street, Liverpool L8 7SS, UK. Email asharp@liv.ac.uk

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Objective To identify the current status of specialist preterm labour (PTL) clinic provision and management within the UK.

Design Postal survey of clinical practice.

Setting UK

Population All consultant-led obstetric units within the UK.

Methods A questionnaire was sent by post to all 210 NHS consultant-led obstetric units within the UK. Units that had a specialist PTL clinic were asked to complete a further 20 questions defining their protocol for risk stratification and management.

Main outcome measures Current practice in specialist preterm labour clinics..

Results We have identified 23 specialist clinics; the most common indications for attendance were previous PTL (100%), preterm

prelabour rupture of membranes (95%), two large loop excisions of the transformation zone (95%) or cone biopsy (95%). There was significant heterogeneity in the indications for and method of primary treatment for short cervix, with cervical cerclage used in 45% of units, progesterone in 18% of units and Arabin cervical pessary in 5%. A further 23% used multiple treatment modalities in combination.

Conclusions A significant heterogeneity in all topics surveyed suggests an urgent need for networking, more evidence-based guidelines and prospective comparative audits to ascertain the real impact of specialist PTL clinics on the reduction in preterm birth and its sequelae.

Keywords Cerclage, cervix, preterm birth, specialist antenatal clinic, transvaginal ultrasound.

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Introduction

Preterm birth affects up to 12.5% of all births¹ and remains a significant burden to healthcare services,² with an estimated health cost of more than £2.9 billion in the UK.³ Over the last 10 years, the identification of women at high risk of a preterm birth has been revolutionised by greater recognition of the impact of risk factors, such as cervical surgery,⁴ and the increased use of transvaginal ultrasound surveillance of cervical length during pregnancy.⁵

This advance in ultrasound detection of women at risk of preterm birth has occurred at a time when new treatment options have been identified, to such an extent that we now appear to have several treatment options for short cervix, namely cervical cerclage,^{6,7} progesterone^{8,9} and Arabin cervical pessary,¹⁰ all of which appear, at least from the limited comparative data currently available, to be similarly efficacious.¹¹ However, a note of caution must be

sounded because of the recent controversies over intramuscular 17α -hydroxyprogesterone caproate.¹²

A lack of formal guidance from bodies such as the Royal College of Obstetricians and Gynaecologists (RCOG) and the American College of Obstetricians and Gynecologists (ACOG) has hampered a clear approach to management. For example, RCOG suggests that high-risk women without a short cervix may be offered either serial sonographic assessment or expectant management, because of the high chance of delivery at >33 weeks in all high-risk groups.¹³

Although preventative treatment options are well defined, the indications for when to treat are still hotly debated, with cut-offs for cervical length of 25 mm¹⁴ or 15 mm¹⁵ and centile charts¹⁶ all being used. Further controversies exist over the effectiveness of other management options, including fetal fibronectin testing,¹⁷ treatment of bacterial vaginosis,¹⁸ vaginal pH testing,¹⁹ the use of vaginal probiotics,²⁰ aspirin²¹ and dietary advice, such as high oily fish intake.²² The increasing complexity of management of these pregnancies has naturally led some units to develop dedicated preterm labour (PTL) clinics. This has occurred despite a recent Cochrane review which states that there is a paucity of evidence to support the benefits of a specialist PTL clinic.²³

It is noteworthy that neither RCOG nor ACOG has made any recommendation on the use of specialist PTL clinics. However, Whitworth et al.²³ state that, despite a lack of proven cost-effectiveness, specialist clinics are here to stay, a statement which mirrors the introduction of a variety of specialised antenatal clinics in other areas (maternal medical disorders, multiple pregnancy).²⁴

This survey aimed to identify current practice within the UK, given the variety of management options and lack of good quality of guidelines. We hoped that clarification of the current provision would lead to the development of a more standardised approach to care, at least within the context of a social care system.

Methods

The survey (Appendix S1) with a covering letter was mailed to each of the 210 NHS hospitals with a consultant obstetric unit in the UK (England, Wales, Scotland, Northern Ireland, Channel Islands and Isle of Man). The first round of questionnaires was sent in November 2012 and this was followed up by a second round in February 2013 to those units which had not responded to the initial invitation. If the unit did not have a specialist PTL clinic, the responder was thanked for their time and no further questions were necessary.

For those units with a specialist PTL clinic, further questions established the frequency of clinics, staffing and local protocols. Particular emphasis was placed on risk stratification and management options, including the use of transvaginal ultrasound, treatment options for a short cervix and other complementary investigations and advice. Finally, each unit was asked whether their clinical data was regularly audited and made available for external scrutiny.

Results

Of the initial 210 units identified, 12 responses were excluded as the unit no longer provided acute obstetrics, or had merged with other hospitals, leaving 198 hospitals for consideration. The survey was sent in two rounds in November 2012 and February 2013, achieving an overall response rate of 144/198 (73%).

Of the 144 responders, 48 units (33%) reported a delivery rate of >5000 per annum, 73 (51%) between 2500 and 5000, and 23 (16%) of <2500, with 19, three and one specialist PTL clinic, respectively. All specialist PTL clinics were located within England.

One unit with a specialist PTL clinic provided information about staffing and frequency, but failed to provide any information about their management policy, and was therefore excluded from the later analysis of clinic management. One unit performed screening tests on both highand low-risk women, but was included in the analysis to demonstrate the range of clinical care offered. The staffing and skills mix is reported in Table 1.

All units invited women with a history of previous preterm birth, although there was significant heterogeneity in what gestation constituted a clinically significant previous preterm birth (Table 2). Other indications for referral to a PTL clinic included previous preterm prelabour rupture of membranes (PPROM) (n = 20, 95%), uterine anomalies (n = 19, 90%), recurrent first trimester miscarriage (n = 1, 1)5%), recurrent second trimester miscarriage (n = 20, 95%) and previous cervical surgery (n = 20, 95%). The significance given to cervical surgery also varied, with some considering a single large loop excision of the transformation zone (LLETZ) as significant (n = 11, 52%), whereas others invited women with two (LLETZ) procedures (n = 20,95%) or a cone biopsy (n = 20, 95%). The timing of appointments also varied significantly, with 11 (55%) clinics seeing women at <12 weeks for their initial appointment and all units seeing them before 20 weeks (Table 2).

Thirteen units (59%) initiated treatment with a cervical length of <25 mm, whereas two units used a cut-off of 15 mm (9%). A further four units (18%) used a variety of different cut-off measurements for treatment, and three units (14%) used a cervical normogram (Table 3).

The most commonly used primary treatment for asymptomatic women with ultrasound-detected short cervix was cervical cerclage (n = 10, 45%). However, both vaginal progesterone pessaries (n = 4, 18%) and Arabin cervical pessary (n = 1, 5%) were also used. Some units treated with multiple modalities (n = 5, 23%), which included a

 Table 1. Staffing and organisation of specialist preterm labour clinics

Staffing of preterm labour clinic	<i>N</i> = 23
Lead clinician-university staff	7 (30%)
Lead clinician-NHS staff	16 (69%)
Designated midwife	11* (55%)
Cervical length assessment operator	<i>N</i> = 22
Obstetric consultant	17 (77%)
Obstetric trainee	8 (36%)
Staff grade	2 (9%)
Research/clinical fellow	6 (27%)
Midwife	3 (14%)
Ultrasonographer	9 (41%)

*Two units did not answer this question.

Indication N = 21* (%) Initial clinic N = 20** (%) for referral appointment to PTL clinic Previous 21 (100) ≤12 weeks 11 (55) preterm birth Previous PPROM 20 (95) 12-14 weeks 3 (15) $1 \times LLETZ$ 11 (52) 15-16 weeks 2 (10) $2 \times LLETZ$ 20 (95) 17-18 weeks 2 (10) Cone biopsy 20 (95) 19-20 weeks 1 (5) Uterine anomalies 19 (90) As soon as 1 (5) referred Recurrent first 1 (5) trimester loss Recurrent second 20 (95) trimester loss Gestation N = 21* (%) N = 22 (%) Frequency of previous of follow-up preterm birth <37 weeks 3 (14) Every 2 weeks 4 (18) <35 weeks 1 (5) Every 4 weeks 1 (5) <34 weeks 10 (48) Based on clinical 17 (77) <32 weeks 5 (24) findings <28 weeks 2 (10)

 Table 2. Indication for referral and general management structure

 of specialist preterm labour (PTL) clinics

LLETZ, large loop excision of transformation zone; PPROM, preterm prelabour rupture of membranes.

*One unit excluded as perform screening test on all women.

**One unit excluded as stated 37 weeks for initial appointment; one unit excluded as perform screening test on all women.

 Table 3. Cervical length measurement deemed to be sufficiently significant to require primary treatment

Cervical length at treatment	<i>N</i> = 22
<25 mm	13 (59%)
<15 mm	2 (9%)
Centile charts	3 (14%)
Other	4 (18%)
Primary treatment choice	N = 22
Cervical cerclage	10 (45%)
Vaginal progesterone	4 (18%)
Intramuscular progesterone	0
Arabin cervical pessary	1 (4%)
Multiple therapies*	5 (22%)
Dependent on clinical picture	2 (9%)

*Two units used cervical cerclage and vaginal progesterone, one unit used cervical cerclage and intramuscular progesterone, one unit used cervical cerclage and rectal progesterone, and one unit used vaginal progesterone and Arabin cervical pessary.

combination of cervical cerclage with vaginal progesterone (two units), cervical cerclage with intramuscular progesterone (one unit), cervical cerclage with rectal progesterone (one unit) and vaginal progesterone with Arabin cervical pessary (one unit). If we include units that used multiple therapies, primary treatment involved cervical cerclage in 14 units (64%), vaginal progesterone in seven units (31%), Arabin cervical pessary in two units (9%) and rectal and intramuscular progesterone in one unit (5%) each.

Thirteen units (59%) regularly assessed vaginal flora, seven units (32%) used fetal fibronectin and three units (14%) utilised the cervical stress test, whereas no units routinely assessed vaginal acidity as part of their management strategy. If bacterial vaginosis was diagnosed, nine units (45%) treated with vaginal clindamycin, three units (15%) with oral clindamycin, seven units (35%) with metronidazole and two units (10%) did not treat bacterial vaginosis (Table 4).

An array of additional advice was given to women managed within specialist PTL clinics, which included restricting physical activity (n = 10, 46%), avoidance of sexual intercourse (n = 9, 41%), stopping work (n = 6, 27%) and dietary advice (n = 6, 27%) (Table 4). However, eight units (36%) did not routinely give any additional advice.

After a diagnosis of short cervix, women were followed up within the specialist PTL clinic until 24 weeks (n = 1, 5%), 28 weeks (n = 9, 41%), 30 weeks (n = 1, 5%), 34 weeks (n = 8, 36%), 37 weeks or until delivery (n = 3,

Table 4.	Other	assessments	and ad	ditional	advice	routinely
conducte	d with	in specialist p	oreterm	labour	clinics	

Other assessments	N = 22 (%)	Additional advice	N = 22 (%)
Vaginal flora	13 (59)	Restricting physical activity	10 (45)
Vaginal acidity	0	Sick leave	6 (27)
Cervical stress test	3 (14)	Refraining from sexual intercourse	9 (41)
Fetal fibronectin	7 (32)	Nutrition	6 (27)
None of the above	5 (23)	Bed rest	0
		No further advice given	8 (36)
Management of bacterial vaginosis	N = 20* (%)	Gestational age at discharge	N = 22 (%)
Vaginal clindamycin	9 (45)	24 weeks	1 (5)
Oral clindamycin	3 (15)	28 weeks	9 (41)
Oral metronidazole	7 (35)	30 weeks	1 (5)
We do not treat	2 (10)	34 weeks	8 (36)

*Two units did not respond to this question.

14%) (Table 4). Outcomes from women seen within the specialist PTL clinic were routinely audited by 17 units (77%), but the information from only four units (18%) was publicly available.

Discussion

Main findings

This is the first time that a structured assessment of the current provision and management of women at risk of PTL has been performed within the UK. Perhaps, not surprisingly, the majority of specialist PTL clinics were located within larger maternity units. This may reflect the larger number of high-risk women seen within these units, but also more clinicians with the expertise to establish and support such a clinic. Thirty-one per cent of specialist PTL clinics are led by university staff, which may reflect the traditional development of these clinics from a research focus. A high proportion of current clinics are led by an NHS clinician, which suggests migration of specialist clinics out of the research environment and into standard clinical care. It is also reassuring to note that the majority of units have a dedicated midwife available.

The most striking feature of this survey is the significant variation in clinical management between units in almost all aspects of the current identification and management strategies used for women at high risk of preterm birth within the UK.

This lack of consensus is perhaps most clearly shown by the lack of uniformity in cervical length measurement deemed to necessitate treatment. Although 59% of units used <25 mm, others used <15 mm, cervical centile charts and various other cut-offs, making a comparison of outcomes for treated women between individual units virtually impossible.

The common use of cervical cerclage as a primary treatment for short cervix is interesting. It reflects the significant amount of literature on efficacy, with some claiming a limited effect,^{7,15} whereas others claiming more substantial benefits.^{6,14} It is possible that, as evidence for the efficacy and safety of vaginal progesterone and cervical pessaries continues to grow, they may become increasingly accepted into clinical practice, particularly as they offer a less invasive alternative with a similar efficacy to cervical cerclage.¹¹

Of interest is the significant minority of units that use therapies in combination to treat women with short cervix. These units were approached to confirm that this was their actual practice. Although the use of multiple treatment modalities may be efficacious, it is not currently supported by the literature and makes any comparison of outcomes difficult to interpret.

Given the variation in practice with cervical length measurement and treatment for short cervix, it is unsurprising that there was even greater variation in other management strategies, such as vaginal flora or fetal fibronectin testing, treatment of bacterial vaginosis or additional advice given to high-risk women.

Strengths and limitations

Although the main focus of this survey was on specialist PTL clinics, clearly there are many other women who are managed in a similar way within the auspices of conventional antenatal or fetal medicine clinics. Although this could have led to a less complete picture, we chose this approach as a pragmatic decision to achieve maximum clarity in response from dedicated specialist PTL clinics, which may be more likely to have a dedicated protocol.

Interpretation

This survey highlighted the significant degree of heterogeneity in clinical practice with regard to the management of asymptomatic women at risk of preterm birth.

A means of addressing these issues could include nationalised audit of outcomes from specialist PTL clinics or the voluntary adoption of a universal protocol for the management of these high-risk women. We suggest that, with the continued expansion in specialist antenatal clinics of all types, it would be an opportune time to begin to collate the real-life outcomes from women managed within these clinics. We believe that such a national clinical outcome review will become increasingly important in the context of revalidation,²⁵ resource allocation and standar-dised outcome reporting.²⁶

Conclusions

We have demonstrated the wide variation in the management of high-risk women with a short cervix within specialist PTL clinics in the UK. The new trend in favour of specialised antenatal clinics appears to be here to stay, and PTL clinics are just another aspect of this continued growth. Nothwithstanding the need for an individualised approached in many cases, such variation in management strategies employed by these clinics remains of concern. Better collaboration between these specialist clinics would provide a real opportunity to generate practice-based evidence and improve the care offered to these high-risk women.

Disclosure of interests

The authors have no conflicts of interest to declare.

Contribution to authorship

The idea for the survey was conceived by AS; both AS and ZA wrote the manuscript.

Details of ethics approval

Ethical approval was not required as no patient information was involved.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Survey of practice in preterm labour clinics in the UK. ■

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