Establishing a Preterm Birth Clinic/Advisory Service

Standard Operating Procedure

Purpose

This document describes what is required to set up and run a preterm birth clinic/advisory service. It predominantly refers to preterm birth clinics, but the majority of recommendations may be applied to a preterm birth advisory service as well.

This document has been developed to support hospitals and healthcare professionals to operationalise the recommendations of Taonga Tuku Iho, the Best Practice Guide for Preterm Birth Care in Aotearoa. The background and summary of evidence to support these recommendations and the tools and resources to enable its implementation are available in Taonga Tuku Iho on the Carosika Collaborative website **www.bestpracticeguide.carosikacollaborative.co.nz**

Background

A preterm birth clinic is a specialised service providing dedicated and coordinated care for wāhine/people at high risk of spontaneous preterm birth. Care is predominantly provided during the second trimester of pregnancy but may also be offered after pregnancy loss and in preparation for pregnancy.

Preterm birth clinics provide up-to-date and evidence-based care in a multidisciplinary setting aiming to reduce second trimester miscarriage and spontaneous preterm birth.[1,2] Care includes a full risk assessment with clinical history, vaginal examination and cervical length measurement; individualised counselling and shared formation of a management plan, including addressing modifiable risk factors; cervical length surveillance; use of interventions such as cervical cerclage and vaginal progesterone; and preparing for imminent preterm birth when indicated.[2,3] Care is provided in partnership with a Lead Maternity Carer and is usually in addition to routine pregnancy care provided by general antenatal clinics and other health care providers.

Preterm birth clinics are now considered standard care in many countries including the United Kingdom[3] and Australia,[4] and more recently in Aotearoa. Taonga Tuku Iho, the Best Practice Guide for Preterm Birth Care in Aotearoa recommends that all Te Whatu Ora hospitals providing secondary level pregnancy care or above should have a preterm birth clinic or specialist preterm birth advisory service. Smaller units may be more suited to an advisory service whereby a few obstetricians and midwives with a specialist interest in spontaneous preterm birth, support a service that may be run through a general antenatal clinic, often with ultrasound services support rather than a more defined specialist clinic. The Carosika Community of Practice has been established as a 12-month programme (from September 2024) funded through research, to provide education and peer support via a network of clinicians in preterm birth clinics and advisory services across the country. If successful, this Community will be maintained and the network developed will be well positioned to facilitate referrals and shared care for wāhine/people at highest risk who may benefit from tertiary level care.

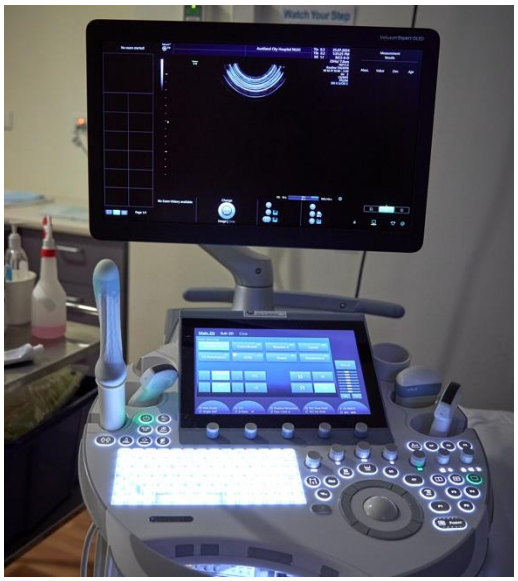
Resources required

Resources required include personnel, equipment, and consumables. Exact requirements will depend on the size/capacity of the preterm birth clinic.

Personnel

A multidisciplinary team, which may include:

- Consultant obstetricians
- Midwives
- Health care assistants
- Obstetricians in training e.g. fellow or registrar (aim for trainees to be scheduled for at least a 6-month placement)
- Sonographers
- Allied health e.g. social work or other counselling support (these may not be part of the clinic, but referral pathways should be clear)
- Interpreters as required.



Equipment

- Private room with an ultrasound machine, with easy access to a bathroom for emptying the bladder before the scan
- Transvaginal ultrasound probe with sterilising facility e.g. Tristel wipes or Trophon
- Transabdominal probe
- Private counselling room with space for whānau
- Access to QUiPP app (free download for smartphone on Apple and Android, or available on QUiPP website https://quipp.org)
- Access to a computer to review clinical records, write reports and provide electronic prescriptions
- System for writing a report/recording notes, as per the local hospital system e.g. Viewpoint, Badgernet, other.

Consumables

- Transvaginal ultrasound probe covers
- Ultrasound gel
- Lubricant
- Gloves
- Tissues
- Speculums and light source
- Vaginal swabs for sexually transmitted infection screen
- Swabs for HPV vaginal swab for national cervical screening programme (if due)
- Specimen containers and preparatory kit for midstream urine collection
- Laboratory request forms for midstream urine, vaginal swabs, HPV testing etc
- Whānau Information sheets e.g. Preterm Birth Clinic, Treatment Options to Prevent Preterm Birth, Transabdominal Cervical Cerclage, Exiting the Preterm Birth Clinic
- Resources for smoking cessation e.g. Quitline information
- Prescription pads (if no e-prescription facility)
- Surgical booking and consent forms (if not done electronically).

Referral criteria

There are many known risk factors for spontaneous preterm birth, but not all of these are amenable to modification through a preterm birth service. Preterm birth clinics aim to care for wāhine/people at the highest risk of spontaneous preterm birth, for whom their risk factors require specialist assessment and cervical length surveillance and/or interventions such as vaginal progesterone and cervical cerclage may be effective. During the establishment phases and/or due to resource constraints, there may be some differences in referral criteria between services, but each service should aspire to include the same referral criteria (see box over page).

Criteria for referral to a preterm birth clinic/advisory service

- Previous spontaneous preterm birth or preterm prelabour rupture of membranes (PPROM) <36^{+0} weeks
- Previous spontaneous miscarriage ≥16^{+0} weeks
- Previous large loop excision of the transformation zone (LLETZ) procedure with depth of excision ≥10 mm, in primiparous wāhine/people, or since the last term birth for multiparous wāhine/people
- Previous knife cone biopsy or trachelectomy or more than one LLETZ procedure (of any depth of excision), in primiparous wāhine/people, or since the last term birth for multiparous wāhine/people
- Known uterine or cervical anomaly, such as unicornuate or didelphic uterus
- Previous caesarean section at full cervical dilatation, or complicated caesarean section with tear into the cervix or vagina in labour, in most recent pregnancy >16 weeks
- Previous uterine instrumentations ≥2 procedures including surgical termination of pregnancy, evacuation of retained products of conception and dilatation and curettage in primiparous wāhine/people, or since the last term birth for multiparous wāhine/people
- Previous pregnancy requiring ultrasound-indicated or rescue cerclage, or treatment with vaginal progesterone due to a short cervix (without preterm birth)
- Known collagen or connective tissue disorder e.g. Ehlers-Danlos syndrome
- Short cervix in the current pregnancy ≤25 mm at ≤24^{+6} weeks
- Rescue cerclage in the current pregnancy

Wāhine/people with twins or higher order multiple pregnancies as their only risk factor for spontaneous preterm birth should not be reviewed through a preterm birth service (due to lack of evidence on benefit of cervical length surveillance, and use of cerclage or progesterone). However, wāhine/people with a multiple pregnancy and other referral criteria should be reviewed.

Referral process

How to refer

Each service should provide local information to all Lead Maternity Carers regarding the availability of their service with clear guidance on who, how and when to refer. As a clinic/service is established dissemination of this information should include hospital or departmental newsletters, meetings and educational sessions. Wherever possible, systems should be in place to reduce reliance on human factors to remember criteria and need for referral e.g. incorporation into e-referral systems within and between hospitals.

Each service should develop their own referral pathway that aligns with local practice. A dedicated referral form can be utilised (Taonga Tuku Iho provides an exemplar template for preterm birth clinic referral). Referrers should be encouraged to complete all fields of the referral form to limit delays in review/triage and support timely assessment for wāhine/people. A midstream urine and vaginal swabs for sexually transmitted infection screen arranged by the Lead Maternity Carer in the current pregnancy may be encouraged as a prerequisite of the referral process.

Wāhine/people should be contacted directly via usual hospital scheduling systems regarding appointment details with offers to support attendance as required e.g. transport. Wāhine/people should be provided with written information in advance of their first appointment. The Carosika Whānau Information Sheet 'Preterm Birth Clinic' is available from Taonga Tuku Iho and can be sent as hard copy or emailed PDF with the appointment letter. This written information describes the role of the clinic, why they may have been referred, and what they can expect to happen during clinic visits.

Referrers should be notified if the criteria for review are not met and advice for appropriate ongoing care with regards to their risk for preterm birth provided.

Timing of referral

- **In pregnancy -** wāhine/people should be referred as early as possible in pregnancy aiming for a first visit consultation at 10-12 weeks gestation. This allows for a full assessment to be made in early pregnancy, provides opportunity for risk modification where able, and history-indicated cervical cerclage at 12-14 weeks where this is recommended. The majority will then have subsequent visits arranged from 16 weeks. If a referral is made for a new finding of a short cervix, urgent same day specialist review is recommended for an open or very short cervix <10 mm, and referral for specialist review within 24-48 hours recommended if cervical length 10-25 mm prior to 24^{+6} weeks.[5]
- **Pre-pregnancy** - Wāhine/people with major risk factors for spontaneous preterm birth may be referred for a pre-pregnancy consultation if this may influence their decision to proceed with pregnancy or if therapy prior to pregnancy may be advantageous e.g. consideration of transabdominal cervical cerclage.
- **Pregnancy loss review** – Wāhine/people who have had a pregnancy loss due to extreme prematurity or a second trimester miscarriage may be considered for a pregnancy loss review. In general, it is recommended that wāhine/people are initially seen (including review of all investigations) by the team caring for them at the time of birth to provide opportunity for an initial debrief by clinicians who were involved in their care.

Referral pathway for complex cases

The Carosika Community of Practice will support upskilling of clinicians across Aotearoa and provide peer support to enable consistent care which is close to home for the majority. It will also facilitate a network to enable referral of wāhine/people at very high risk for spontaneous preterm birth who may benefit from tertiary preterm birth service review. This will usually be at the nearest tertiary hospital but will also be dependent on services available at that unit which may vary over time. Secondary units should have clear referral pathways to their local tertiary hospital to enable timely review when required.

Indications for tertiary review (or clinical opinion) may include:

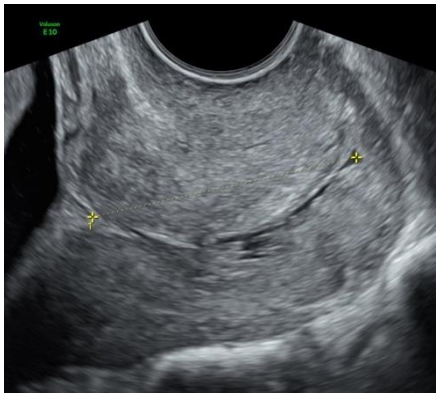
- Consideration and placement of transabdominal cervical cerclage:
  - Following a pregnancy managed with a history- or ultrasound-indicated transvaginal cerclage (but not rescue cerclage i.e. with cervical dilatation), and birth occurs <28 weeks gestation
  - Following extensive cervical surgery with a very short cervix e.g. trachelectomy, deep or multiple cone biopsies or LLETZ
- Where the fetal membranes have prolapsed through a cervical cerclage and a repeat, 'rescue' cerclage is being considered
- Where there is a high risk of birth close to the limits of survival and level 3 neonatal services may be required
- Other complex cases outside the clinical expertise of the local preterm birth service.

Consultations and frequency of review

First visit: It is recommended that approx 45 minutes should be allocated and include:

- Full clinical history with focused questions on modifiable risk factors for spontaneous preterm birth
- Digital vaginal examination to assess the length and contour of the vaginal portion of cervix
- Swabs for sexually transmitted infection screen (if not done by referrer and if pregnant) +/- HPV testing if due
- Transvaginal ultrasound assessment of the cervix (if pregnant) (see 'Transvaginal ultrasound assessment of cervical length Standard Operating Procedure' available from Taonga Tuku Iho)
- Counselling and information regarding individualised risk for preterm birth
- Discussion regarding potential interventions including lifestyle and behaviour change e.g. smokefree referral; serial cervical length assessment; and cervical cerclage and vaginal progesterone
- Review of social circumstances and how this may impact on preterm birth care and preterm birth e.g. need for transport to clinic. Referral for social work support as required
- An individualised plan of care including relevant written information. Carosika Whānau Information Sheets 'Treatment Options to Prevent Preterm Birth' and 'Transabdominal Cervical Cerclage' are available from Taonga Tuku Iho.

Follow-up visits: These will usually occur regularly from 16-24 weeks and require less allocated time (recommended 15 minutes). The frequency should be individualised considering level of risk (see below). Follow-up visits should include:



- Review of pregnancy progress including signs and symptoms of preterm labour
- Transvaginal ultrasound assessment of the cervix, see 'Transvaginal ultrasound assessment of cervical length Standard Operating Procedure' available from Taonga Tuku Iho
- Plan of care including interventions such as cervical cerclage, vaginal progesterone and rarely, hospital admission and antenatal corticosteroid use
- Review of lifestyle and behaviour as required, e.g. progress to becoming smokefree
- Review of social circumstances including referral to social worker as required.

There is limited evidence to guide the frequency of follow-up visits and ultrasound surveillance of cervical length. The following is recommended as a guide and may vary between services during their establishment phases and due to resource constraints:

Moderate risk

First visit at 10-12 weeks, follow-up visits at 16, 20 and 23 weeks

- Previous spontaneous preterm birth/PPROM 34^{+0} to 35^{+6} weeks
- Single LLETZ procedure with histological evidence of 10-15 mm depth (for primiparous wāhine/people, or since last term birth for multiparous wāhine/people)
- Uncomplicated caesarean section at full dilatation in most recent pregnancy reaching >16 weeks
- ≥2 uterine instrumentations for primiparous wāhine/people, or since last term birth for multiparous wāhine/people)
- Congenital uterine and/or cervical anomaly, including corrected/resected anomalies (for wāhine/people with a previous term birth)
- Known collagen or connective tissue disorders

High risk

First visit at 10-12 weeks, follow-up visits at 16, 18, 20, 22 and 24 weeks

- Previous spontaneous preterm birth/PPROM $<34^{+0}$ weeks
- Previous spontaneous miscarriage $\geq 16^{+0}$ weeks
- LLETZ with histological evidence of >15 mm depth of excision or >1 procedure (for primiparous wāhine/people, or since last term birth for multiparous wāhine/people)
- Knife cone biopsy or trachelectomy (for primiparous wāhine/people, or since last term birth for multiparous wāhine/people)
- Congenital uterine and/or cervical anomaly, including corrected/resected anomalies (for primiparous wāhine/people)
- Complicated caesarean section with tear into the vagina and/or cervix in labour in most recent pregnancy reaching >16 weeks
- Rescue cerclage in current pregnancy

Individual risk assessment

- Short cervix in current pregnancy ≤25 mm at $\leq 24^{+6}$ weeks
- Previous pregnancy requiring ultrasound-indicated or rescue cerclage, or treatment with vaginal progesterone due to a short cervix (without preterm birth)

Consideration on when interventions are indicated should follow recommendations as provided in the Prevention of Spontaneous Preterm Birth section in Taonga Tuku Iho. Clinicians within the preterm birth service should be responsible for organising/performing these interventions i.e. cervical cerclage insertion and prescription of vaginal progesterone.

Final visit: Wāhine/people will generally be seen and discharged from the preterm birth service at 23-24 weeks, as preventative therapies are rarely indicated beyond 24 weeks and there is no role for ongoing routine assessment of cervical length.

At the final visit an overall risk assessment of very early preterm birth should be made and include:

- Review of initial risk factors for referral
- Review of pregnancy progress including signs and symptoms of preterm labour
- Transvaginal ultrasound assessment of the cervix, see 'Transvaginal ultrasound assessment of cervical length Standard Operating Procedure' available from Taonga Tuku Iho
- Any use of interventions (cervical cerclage, vaginal progesterone)
- Wāhine/people should be provided with an individualised ongoing risk assessment for spontaneous preterm birth, including information on the signs and symptoms of concern for preterm labour and PPROM, and need to report these to their Lead Maternity Carer early to allow time for further assessment. This should include written information, Carosika Whānau Information Sheet 'Exiting the Preterm Birth Clinic' available from Taonga Tuku Iho.

Where there is concern for significant ongoing risk of very early preterm birth, and in particular in the next 1-2 weeks, a more formal calculation of risk should be considered using the QUiPP calculator to guide further interventions such as consideration of admission to a unit with tertiary neonatal services, neonatal consult and administration of antenatal corticosteroids. Further recommendations and good practice regarding birth at the limits of survival is available in Taonga Tuku Iho.

Clinic reports

A written report should be generated, included in the main clinical record (Badgernet) and sent to the Lead Maternity Carer, referrer (if not Lead Maternity Carer) and GP after each visit. As required a telephone call to the update Lead Maternity Carer should be considered when a new intervention/ management plan including hospital admission is required.

Practice review

Each unit should regularly review the care provided in their preterm birth service. This will include audit of practice and outcomes, consideration of new evidence as it becomes available, and appraisals of patient satisfaction.

Audit tools will be developed and made available in Taonga Tuku Iho. We strongly recommend that units audit their local practice including by ethnic group to allow for objective assessment of equity in practice.

References

1. Dawes L, Groom K, Jordan V, Waugh J. The use of specialised preterm birth clinics for women at high risk of spontaneous preterm birth: a systematic review. BMC Pregnancy and Childbirth. 2020;20(1):58. DOI: 10.1186/s12884-020-2731-7.
2. Vernet G, Watson H, Ridout A, Shennan A. The role of PTB clinics: A review of the screening methods, interventions and evidence for preterm birth surveillance clinics for high-risk asymptomatic women. Women's Health Bulletin. 2017;4(4):2-9. DOI: 10.5812/whb.12667.
3. UK Preterm Clinical Network. Reducing Preterm Birth: Guidelines for Commissioners and Providers 2019. Available from: https://www.tommys.org/sites/default/files/Preterm%20birth%20guidelines.pdf.
4. Australian Preterm Birth Prevention Alliance. Available from: https://www.pretermalliance.com.au..
5. Ministry of Health. New Zealand Obstetric Ultrasound Guidelines 2019. Available from: https://www.health.govt.nz/publication/new-zealand-obstetric-ultrasound-guidelines

For more information including access to Taonga Tuku Iho (national best practice guide), you can access the Carosika Collaborative website ***www.carosikacollaborative.co.nz*** *or by using the QR code.*

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