TE WHARE WĀNANGA O TE ŪPOKO O TE IKA A MĀUI VICTORIA UNIVERSITY OF WELLINGTON

Centre for Women's Health Research | Te Tātai Hauora O Hine

Participation Information Sheet for Practices

Study title:	**He Korowai Manaaki – A Wrap Around Approach**		
Locality:	**Wellington**	Ethics committee ref:	17/STH/112
Lead investigator:	**Bev Lawton**	Contact phone number:	021 0237 5264

Wairoa General Practices and midwifery practices are invited to take part in the research project He Korowai Manaaki. He Korowai Manaaki involves practices offering added clinical visits and referral pathways to allied services for pregnant women.

This information sheet will help you decide if your practice would like to take part in this research and explains why we are doing the study, what participation by your practice would involve, what the benefits and risks to the practice might be and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not your practice will participate in this study.

If your practice agrees to participate your practice will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet for Practices and the Consent Form to keep.

WHAT IS THE PURPOSE OF THE STUDY?

This research is testing whether an augmented maternal care pathway with additional clinical appointments, additional supports and referrals to allied services during pregnancy improves maternal and infant outcomes. Additional supports include patient transport and free contraception.

The primary outcomes include timely vaccination and avoidable hospital admissions for the infant and secondary outcomes include timely contraception and enrolment and attendance to services (including oral health, Early Childhood Education (ECE) and Well Child Tamariki Ora (WCTO)) and smoking prevalence.

Results will be obtained from the Ministry of Health (MoH) using data matching through multiple national databases (e.g. MOH, ANZNN, NIR, NMDS) up until the infant is 1-2 years of age to source clinical and demographic data to provide a combined data source. All data provided to the research team will be encrypted and de-identified. The NHIs of women and infants will be known only to the practice providers.

Comparisons will be made between a retrospective cohort and the study cohort. If this augmented maternity care model is successful it will inform policy and system changes.

This study is based at the Centre for Women's Health Research, Victoria University of Wellington and is funded by the Health Research Council of New Zealand.

WHAT WILL PARTICIPATION IN THE STUDY INVOLVE?

Training will be provided on the augmented maternal care pathway (table 1) and during the study period the research team will provide on-going support.

Women will need to be consented to join the study. Women will be entitled to the augmented maternal care pathway regardless of whether they consent to their outcome data being collected.

Table 1:

LESS THAN 20 WEEKS (optimally <12 weeks)	**"First Touch"** Extended first antenatal appointment – this is carried out by the first practitioner that the pregnant women has contact with and is based on the recommendation of the NZ Perinatal and Maternal Mortality Committee and includes: • opportunity to offer screening for congenital abnormalities, sexually transmitted infections, family violence and maternal mental health, with referral as appropriate • education around nutrition, smoking, alcohol and drug use and other at-risk behaviour • recognition of underlying medical conditions, with referral to secondary care as appropriate • identification of at-risk women (maternal age, obesity, maternal mental health problems, multiple pregnancy, socioeconomic deprivation, maternal medical conditions) • navigation to midwife **Whānau focus needs assessment** – a checklist to assess whether help is required for transport to appointments, safe housing, finances and oral health, refer to family start or whānau ora
	Follow-up appointment - best practice to follow up tests that have been ordered and make sure all appropriate referrals have been made.
THIRD TRIMSTER	**Additional GP appointment** this is routinely offered for vaccination and will also include best practice information re child health and planning for postnatal contraception - appointment open to midwife to attend
POST-NATAL	**Additional whānau visit at 6 weeks postnatal with GP** to provide free contraceptive, address any concerns, screen for infections family violence and maternal mental health with referrals as appropriate, education around nutrition, smoking alcohol & drug use and other at-risk behaviour **Active navigation** - "connecting the dots" to services such as Family Start, Well Child/Tamariki Ora, oral health and ECE services.

To identify the retrospective control cohort your practice will be asked to provide NHIs of infants registered aged between 18-30 months of age to the MoH and these will be matched to the maternal NHI. Their health outcome data will be requested by MoH through national and local DHB databases and provided to the research team de-identified and encrypted.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The benefits of this study are that this augmented maternal care pathway will offer additional funded appointments for pregnant women and foster communication between maternity care providers and other allied services. The Whānau Focus embedded in this pathway will support GPs and midwives to navigate women to services supporting non-health needs.

We will be able to find out whether this augmented model impacts on maternal and infant health outcomes and from this inform the Ministry of Health about changes that could improve the outcomes for future mothers, babies and whānau.

WHO PAYS FOR THE STUDY?

Your practice group will receive a fee-for-service from the Centre for Women's Health Research (CWHR) for each additional intervention appointment attended by the woman and your practice will receive additional koha to support the relevant training and administration work. Practice groups will be provided with details of the individual costings and invoice process during the study training. The study is funded by the Health Research Council of New Zealand.

WHAT IF SOMETHING GOES WRONG?

In the unlikely event that something that does go wrong we will work with a practice to find a suitable solution.

WHAT ARE MY RIGHTS?

Your practice's participation in the study is entirely voluntary and you are free to decline to participate or withdraw from the study at any time without experiencing any disadvantage.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

The usual maternal care pathway will resume after the study is completed. Once the study is complete a summary of results will be sent to your practice if you would like to receive it. The study is expected to be completed in 2021.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

The Principle Investigator, Professor Bev Lawton

Tel +64 4 463 5497 Mobile +64 21 463762 Bev.lawton@vuw.ac.nz

The Project Manager, Francesca Storey

Mobile +64 21 0237 5264 Francesca.storey@vuw.ac.nz

You can contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Practice Consent Form

Please tick to indicate you consent to the following:

I/we have read, or have had read to me in my first language, and I understand the Practice Information Sheet for Practices	Yes ☐	No ☐
I/we have been given sufficient time to consider whether or not our practice will participate in this study	Yes ☐	No ☐
I/we have had the opportunity to use a legal representative, colleague, service leader to help me ask questions and understand the study	Yes ☐	No ☐
I/we am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet	Yes ☐	No ☐
I/we understand that taking part in this study is voluntary (my choice) and that my practice may withdraw from the study at any time	Yes ☐	No ☐
If I/we decide to withdraw from the study, I/we agree that the information collected up to the point when I/we withdraw may continue to be processed	Yes ☐	No ☐
I/we agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative checking the accuracy of the information recorded for the study	Yes ☐	No ☐
I/we know who to contact if I have any questions about the study in general	Yes ☐	No ☐
I/we understand my responsibilities as a study participant	Yes ☐	No ☐
I/we wish to receive a summary of the results from the study	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Name: _____

Role in Practice: _____

Name of practice group: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the practice understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____