P3-MumBubVax: Development of a multi-component antenatal intervention to promote maternal and childhood vaccine uptake in Australia

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Burden of disease for pregnant women and their infants

Influenza in pregnancy

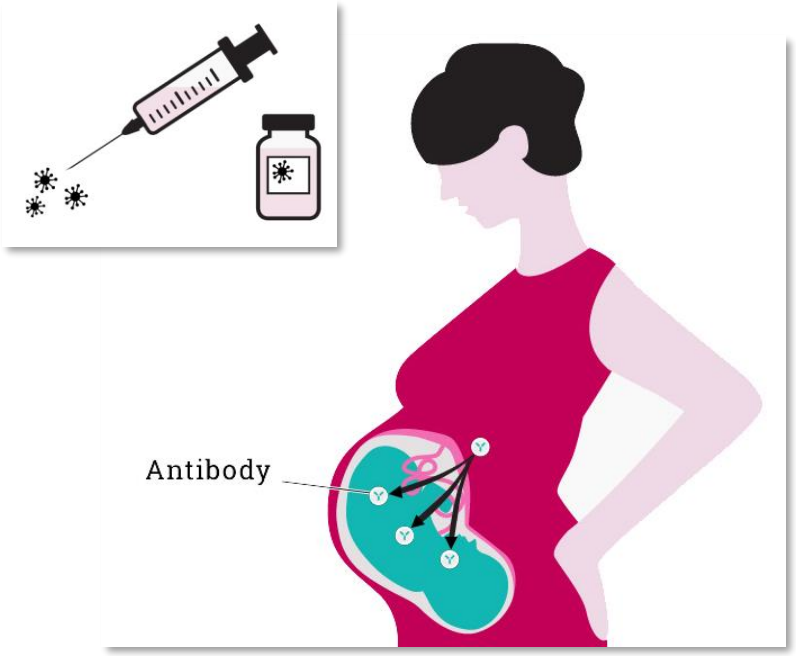
- Pregnant women and infants are a WHO high-risk priority group for influenza[1]
- Pregnant women are **more than twice as likely to develop serious complications** and be admitted to hospital than non-pregnant women, particularly if they have underlying illnesses
- **Infants <6 months old are at highest risk of death** or developing serious complications
- The rates of hospitalisation in infants 0-5 months are **4 times higher** than adults >75 years

Pertussis in pregnancy

- Risk to the pregnant woman herself is less than for influenza, but can be severe or life-threatening for babies under 6 months
- **Infants <3 months have the highest risk of pertussis-related death**

1. WHO Wkly Epi Rec 2012 2.Mertz et al, 2017 3. Fell et al, 2017 4. Li-Kim-Moy et al, 2016 5. Winter et al, 2015
6. Regan et al, 2016

Promotion of maternal and childhood vaccines in the antenatal period



- Need to increase and <u>sustain</u> acceptance and uptake of antenatal vaccination for influenza (40-60%)[6] and pertussis (65-80%)[7,8]
- Prepare for new maternal vaccines
- Expectant parents begin to decide about childhood vaccines, beginning with birth hep B[9]
- Midwives in public antenatal clinics are most frequently accessed and highly trusted regarding vaccination[9]
- A robust vaccine program needs high levels of vaccine acceptance, where people understand and have confidence in the purpose, value and effectiveness of vaccines.

6. Regan et al, 2016 7. Clinical Council Unit data 8. Rowe et al, 2018 9. Danchin et al, 2017

We need effective, scalable interventions to embed vaccination discussion and delivery into routine antenatal care

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Interventions to improve antenatal influenza vaccine uptake – what works?

- Interventions that primarily aim to change vaccine attitudes
  - generally not effective in isolation
  - content that reinforces benefit to infant shown greatest impact
- Provider recommendation strongest predictor of vaccine receipt for pregnant women
  - few interventions evaluated focus on **provider-patient interaction** OR **communication training for providers**

- Nudge-based interventions have shown good success
  - include **provider prompts** to vaccinate and record vaccination, **patient prompts** ie text messages AND **standing orders**
  - build on positive intentions to vaccinate without trying to change attitudes
- Provision of vaccines on site
  - most common barrier is financial; need to fund/stock vaccines on site

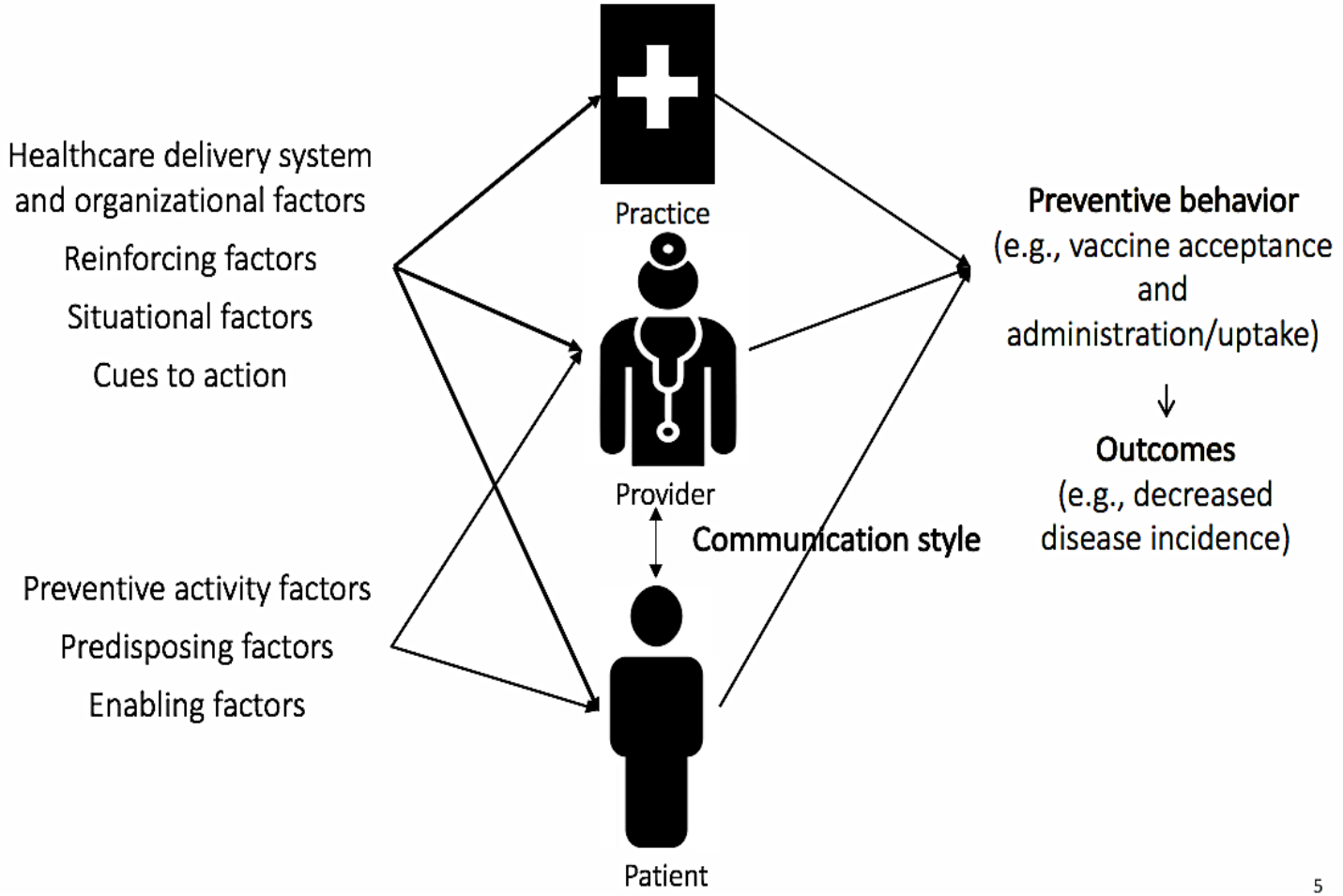
10. Ellingson et al, 2019

The P3 Model – a promising intervention model

Theory-based model of preventive health behaviour that incorporates practice-, provider- and patient-level factors[11]

Designed for the USA private obstetric antenatal setting targeting obstetricians to improve antenatal influenza and pertussis uptake

Trial underway; pilot study showed non-significant but promising results[12]



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11. Bednarczyk et al, 2018 12. Chamberlain et al, 2015

Aims and research plan

- **Design** multi-component intervention package with and for midwives to optimise vaccine discussions
  - "MidVaxCom" qualitative study, Nov 2017-Sept 2018, Victoria and Western Australia

- **Pilot** the intervention to assess its acceptability and feasibility
  - "MumBubVax" pilot study, Oct 2018-September 2019, Victoria

- **Evaluate** intervention efficacy in a national cluster randomised controlled trial
  - "MumBubVax" RCT, from 2020, national

MidVaxCom – qualitative study to inform intervention design

- **12 semi-structured interviews** with midwives
  - Royal Women's Hospital, Melbourne (no maternal vaccines delivered)
  - King Edward Memorial Hospital, Perth (maternal vaccines delivered)
  - Discussed attitudes and values, perceptions about their role, communication techniques, resources and training, record-keeping

- **2 focus groups**
  - Discussed preliminary intervention features, design, appropriateness, usefulness

the women's
the royal women's hospital
victoria australia

King Edward Memorial Hospital
Women and Newborn Health Service

Led by Dr Katie Attwell
Funded by WA Health

13. Kaufman et al 2019

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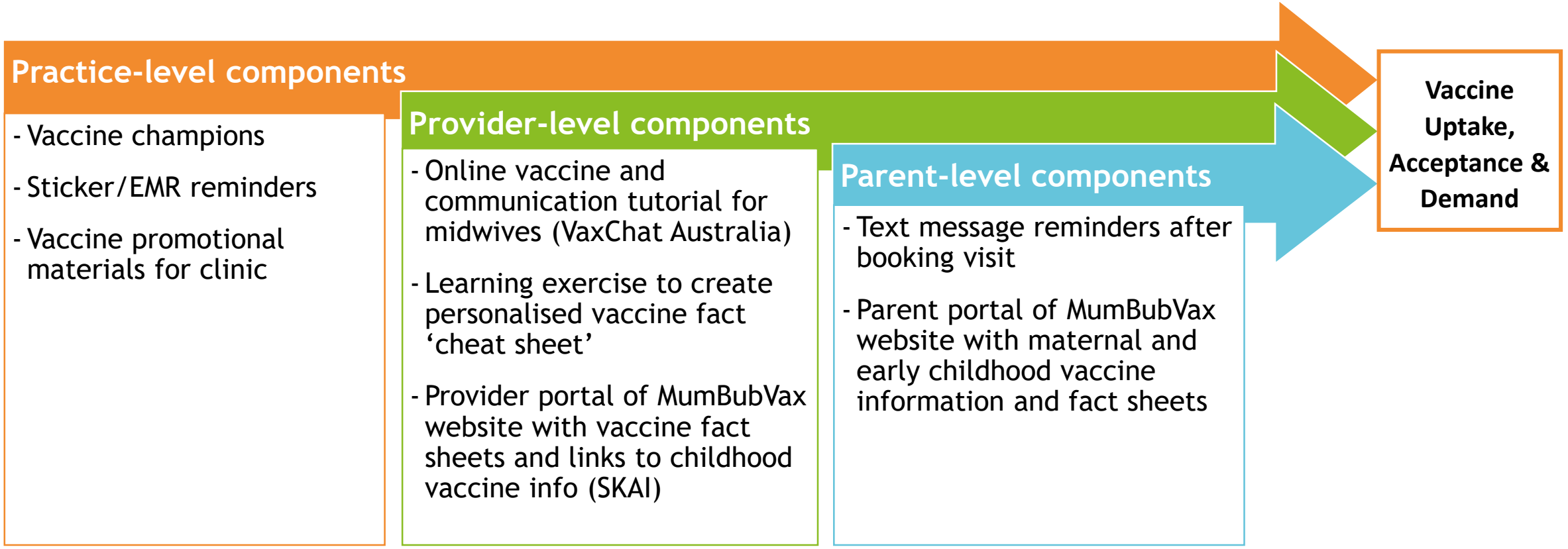
MidVaxCom - key findings

- Vaccination is part of a midwife's role, but limited time and competing priorities
- Roles and vaccine discussions vary when vaccines are available on site
- Very little/no specific vaccination training
- Generally comfortable recommending vaccination ("It is recommended") but not always confident answering questions
- Relationship with women is paramount, but most midwives respectfully ask parents' reasons for hesitancy or refusal
- Trustworthy online info and fact sheets are useful and valued
- Rarely discuss infant and childhood vaccines
- Midwives particularly interested in knowing key vaccine facts and how to debunk myths / misinformation
- Findings support and echo those in other Australian studies[14,15]

14. Frawley et al, 2019 15. Attwell et al, 2018

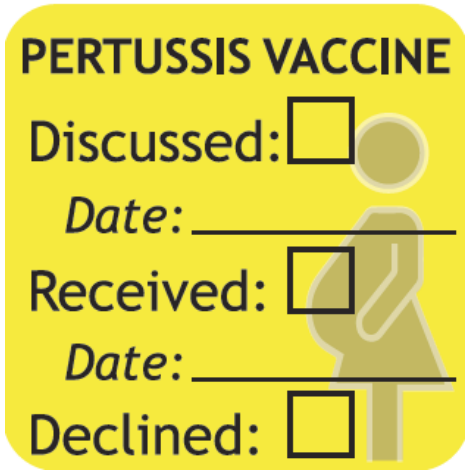
P3-MumBubVax intervention development

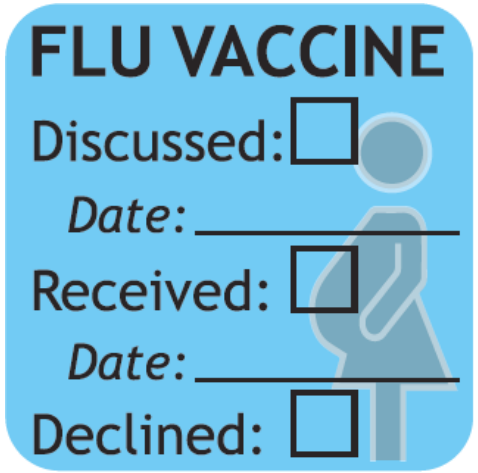
- **P3-MumBubVax intervention package** - design informed by MidVaxCom qualitative research and studies from the USA[11,12,16,17]

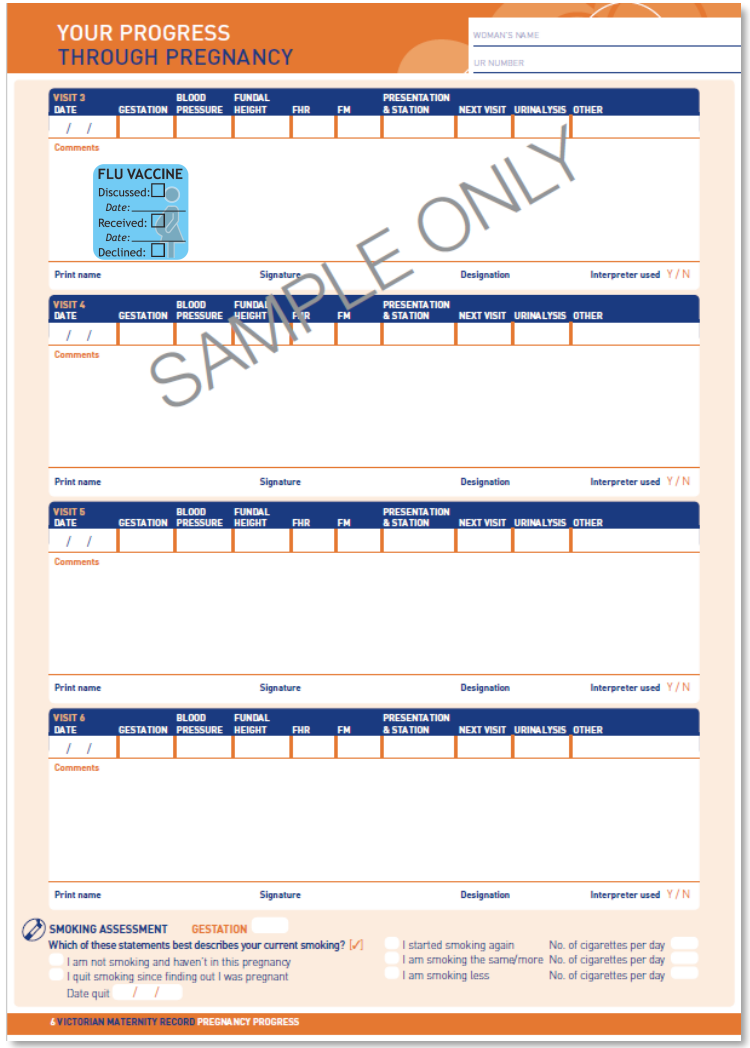


11. Bednarczyka et al, 2018 12. Chamberlain et al, 2015 16. Dempsey et al, 2018 17. Stockwell et al, 2014

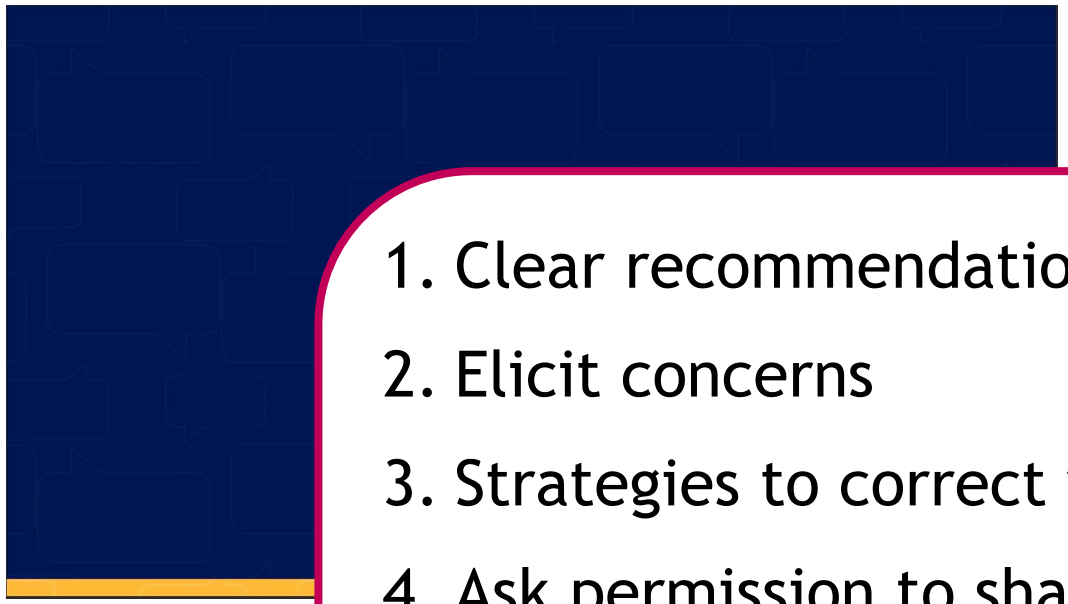
PRACTICE LEVEL: Stickers for paper records and vaccine champions

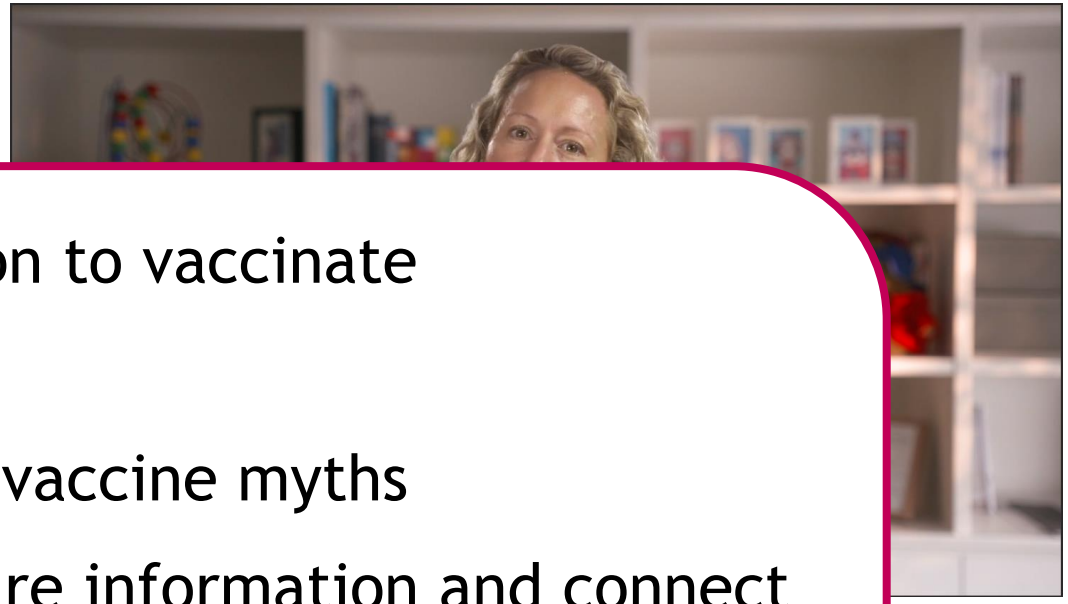




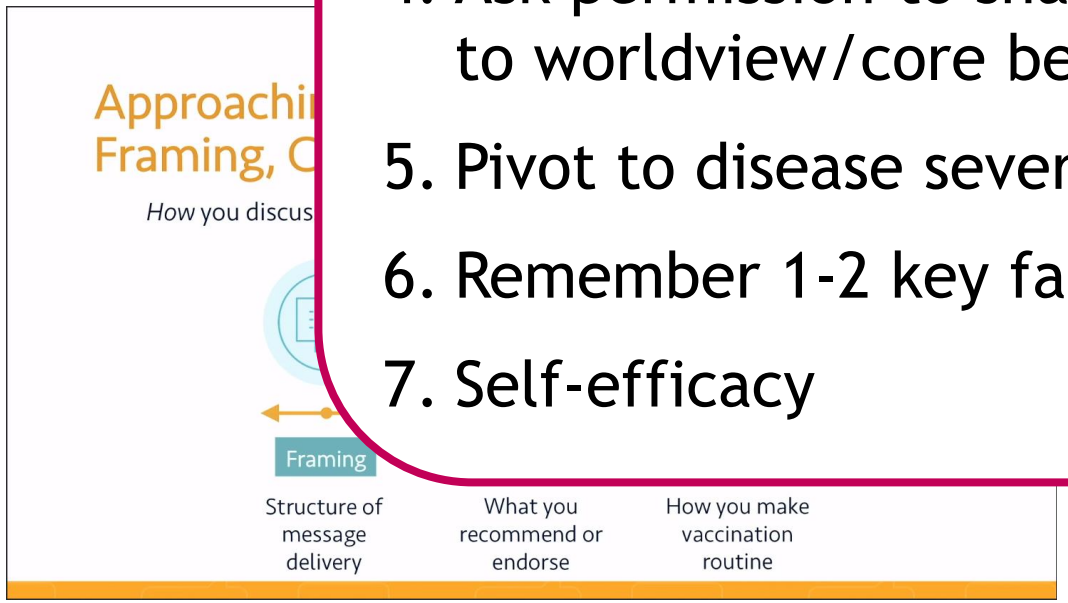


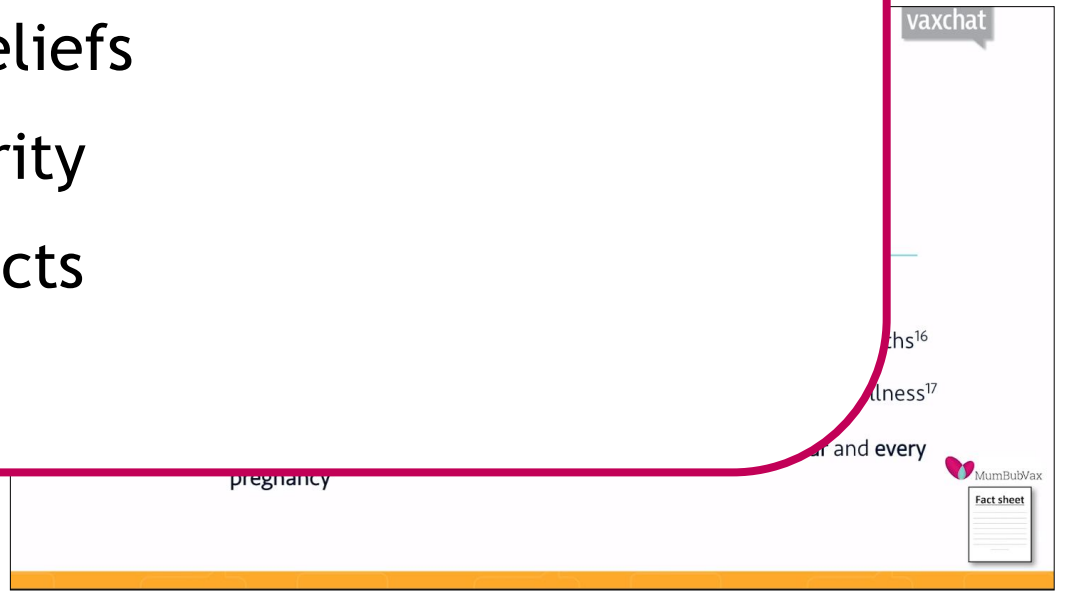
PROVIDER LEVEL: VaxChat online training video





1. Clear recommendation to vaccinate
2. Elicit concerns
3. Strategies to correct vaccine myths
4. Ask permission to share information and connect to worldview/core beliefs
5. Pivot to disease severity
6. Remember 1-2 key facts
7. Self-efficacy





PROVIDER LEVEL: Personalised vaccine fact ‘cheat sheet’

VaxChat Australia cheat sheet

In your conversations with expectant parents, it is helpful to have 1-2 key facts about maternal influenza and pertussis vaccines and the birth hepatitis B vaccine that you can share quickly and confidently with expectant parents.

In this short exercise, you will select the fact you think will be most memorable or useful in your discussions. At the end of the exercise, you will receive an email with your personalised fact cheat sheet, which you can print and insert into your ID lanyard for easy access. We will not use or store your email address or responses to any of the questions.

All the facts listed in this exercise are supported by reliable, recent evidence and are included on the MumBubVax website and in the VaxChat educational tutorial.

* Required

Email address *

Your email

First name

Your answer

GENERAL VACCINE SAFETY FACTS

In this question, you will select a key fact that you would like to remember about vaccine safety in general.

Choose 1 GENERAL vaccine safety fact

- ○ Maternal flu and pertussis vaccines are inactivated and can't cause disease
- ○ 11% of women have mild reactions (local reactions, headache, fever)
- ○ Vaccines are tested in 3 phases of clinical trials before use and adverse events are monitored
- ○ 1 in a million women have an anaphylactic reaction to vaccines

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Jess test, this is your personalised vaccine information ‘cheat sheet’. Please print this document, cut along the outside lines and fold down the centre. This small card is designed to fit in a plastic ID lanyard for easy access.

MumBubVax

This is a personalised ‘cheat sheet’ with key facts about maternal influenza and pertussis and infant hepatitis B vaccines for you to share with parents
mumbubvax.org.au

General vaccine safety fact:

- Vaccines are tested in 3 phases of clinical trials before use and adverse events are monitored

Flu facts:

- Flu complications include pneumonia, bronchitis, brain or heart inflammation & sepsis
- Maternal flu vaccination does not increase risk of stillbirth, premature delivery, or birth defects
- Flu vaccine effectiveness can vary each year, but vaccination is still the best way to protect mums & babies

Pertussis facts:

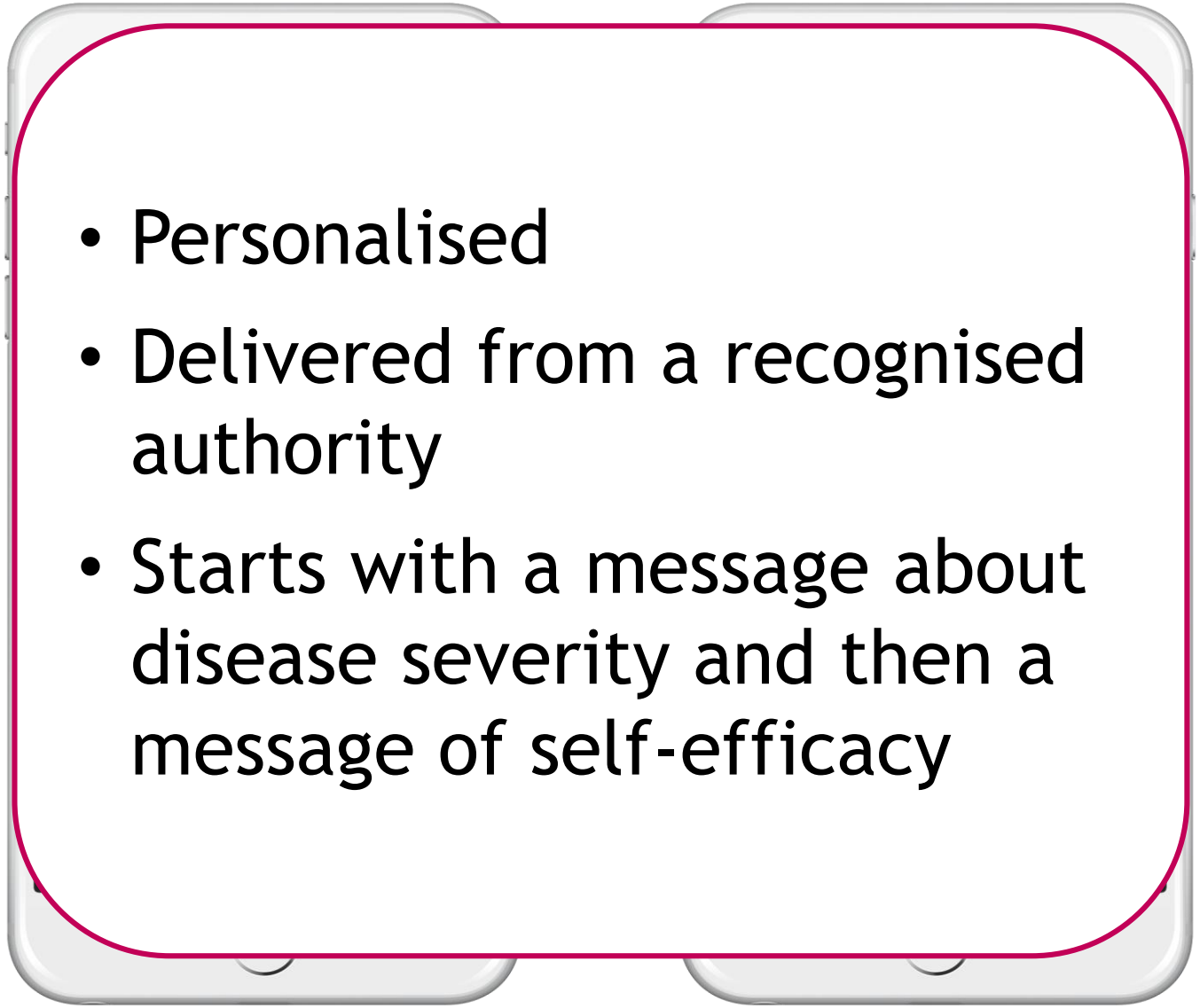
- Pertussis complications include pneumonia, organ failure, seizures & brain damage from lack of oxygen
- Previous anaphylactic reaction to vaccine is the only medical contraindication to maternal pertussis vaccination
- Protective antibodies transfer from mums to babies through the placenta after antenatal vaccination

Hepatitis B facts:

- Hepatitis B is very contagious & can be passed through birth, breastfeeding, biting & open sores
- No increased risk of Sudden Infant Death Syndrome (SIDS), autism, fever or infection from hepatitis B vaccination
- Premature babies are even more vulnerable to infection than full-term babies & should still be vaccinated on-schedule

Cut along this outside border ✂

PRACTICE LEVEL: Text message reminders for mothers



PROVIDER & PARENT LEVEL: MumBubVax website

Immunise Australia | SKAI Childhood Vaccination

MumBubVax

I AM VACCINATING | I HAVE QUESTIONS | RESOURCES | ABOUT MUMBUBVAX

TALKING ABOUT IMMUNISATION FOR MOTHERS AND BABIES

Answering your questions and giving you evidence-based information to make decisions about vaccination in pregnancy and for your baby after delivery

I AM VACCINATING

Vaccination during pregnancy is one of the best possible ways to protect your baby against disease during pregnancy and in the first few months after birth. Find out what vaccines are recommended during pregnancy and after delivery.

1st Trimester | 2nd Trimester | 3rd Trimester | At Birth | SKAI Childhood

Immunise Australia | SKAI Childhood Vaccination

MumBubVax

I AM VACCINATING | I HAVE QUESTIONS | RESOURCES | ABOUT MUMBUBVAX

< Back Home > Pertussis vaccine

PERTUSSIS VACCINE

RELATED

- Pertussis vaccine
- Flu vaccine
- How will the vaccines affect my baby?
- How will I feel after vaccination?

When you are pregnant, it is strongly recommended that you get vaccinated against pertussis (also known as 'whooping cough'). Women should have a pertussis vaccination in each of their pregnancies, ideally between 28 and 32 weeks. The pertussis vaccine will protect both your baby and you from this serious infectious disease. The vaccine is free for all pregnant women in Australia.

DOWNLOAD

What is pert

How can I pr

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Immunise Australia | SKAI Childhood Vaccination

MumBubVax

I AM VACCINATING | I HAVE QUESTIONS | RESOURCES | ABOUT MUMBUBVAX

< Back Home > Infographic: How does the vaccination protect my baby

INFOGRAPHIC: HOW DOES THE VACCINATION PROTECT MY BABY

HOW DOES THE VACCINATION PROTECT MY BABY?

1. Vaccine

Vaccines contain tiny fragments of the disease they are targeting. These are called 'antigens'. In vaccines given to pregnant women, the antigens are always inactivated which means they cannot reproduce or cause disease.

2. Antibodies

When you get the vaccine, your immune system detects the antigens and produces antibodies to fight the disease.

3. Vaccine during pregnancy

When you have a vaccine during pregnancy, the

PARENT LEVEL: Downloadable fact sheets

The pertussis vaccine

for pregnant women

MumBubVax Read more about immunisation for pregnant women and their babies at **MumBubVax.org.au**

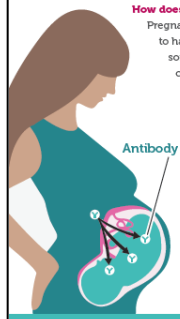
Pertussis or 'whooping cough' is a serious infection that can cause severe illness and even death in babies under six months. Getting vaccinated against pertussis during pregnancy is the most effective way to protect both you and your baby. It is recommended that you have a pertussis vaccination every time you are pregnant, ideally between 28 and 32 weeks. The vaccine is free for all pregnant women in Australia.

What are the risks of pertussis for my baby?

Commonly known as 'whooping cough', pertussis can cause life-threatening complications in babies, including pneumonia and brain damage. Pertussis is a bacterial infection of the nose, throat and lungs. It irritates the airways causing thick mucus and long, severe coughing fits that usually end with a gasping breath that can sound like a 'whoop'. Babies under three months of age who develop severe pertussis infection usually develop pneumonia, which can be complicated by low blood pressure and organ failure[1]. Babies under three months who develop pertussis have the highest risk of pertussis-related death[1-3].

How does pertussis affect pregnant women?

Pregnant women with pertussis are likely to have prolonged coughing fits, sometimes resulting in vomiting, cracked ribs, disturbed sleep, incontinence and fainting[4].



How effective is the vaccine?

The best way to protect your baby against pertussis is to get the vaccine during pregnancy, so that the protective antibodies your body produces can be passed on to your baby. These antibodies will protect your baby against pertussis for the first few months of life. You can read more about the effectiveness of the pertussis vaccine at MumBubVax.org.au.

Benefits for babies whose mothers were vaccinated against pertussis

less likely to catch pertussis during the first three months[5]

vaccine results in no greater risk of premature birth, low birth weight, small size for gestational age, stillbirth, neonatal death or congenital abnormalities[10]

MumBubVax

For more information, you can call the **National Immunisation Hotline** on **1800 671 811.**

- mild fever of around 38.5° or less.

A very small number of people have a severe allergic reaction to vaccines, called 'anaphylaxis'. Anaphylaxis can lead to swelling, hives, breathing difficulties, lowered blood pressure and, in severe cases, shock. Anaphylactic reactions to vaccination occur in about one in a million people. Midwives, nurses and GPs are trained to respond to anaphylactic reactions with adrenaline.

If you have any worries about how you feel after your vaccination, you can get help from your doctor, or your nearest emergency department, or by calling Health Direct on 1800 022 222.

References

For links to the references used in this factsheet, please go to MumBubVax.org.au.

Risk of a reaction serious enough to see a doctor or attend a hospital

Around 1 in 100 pregnant women vaccinated against flu had a reaction that required a visit to a doctor. Around 1 in 1000 attended hospital to recover from an adverse reaction to the pertussis vaccine[11].

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For more information, you can call the **National Immunisation Hotline** on **1800 671 811.**

The flu vaccine

for pregnant women

MumBubVax Read more about immunisation for pregnant women and their babies at **MumBubVax.org.au**

Getting vaccinated against influenza (also known as 'the flu') during pregnancy will protect both you and your baby from a highly contagious viral infection that can have serious complications. The vaccine is free for all pregnant women in Australia, and is recommended for every pregnancy.

What are the risks of influenza for my baby now?

Influenza can cause complications during pregnancy or at birth. If you get influenza while you are pregnant, your baby may be born prematurely or with a low birthweight[1].

What are the risks of influenza for babies after they're born?

Influenza can be life-threatening for your baby. Babies under six months of age are too young to get the influenza vaccine themselves. The only way you can protect your baby against influenza is to get the vaccine yourself during pregnancy. Babies who catch influenza, especially babies under six months of age, are more at risk of developing serious complications and are more likely than other children to end up in hospital as a result[2]. Those serious complications include pneumonia, bronchitis, inflammation of the brain or heart, bacterial infections and toxins in the blood stream (sepsis). It can even lead to death.

What are the risks of influenza for pregnant women?

Influenza can have very serious consequences for pregnant women. When you are pregnant, you are more likely to catch influenza than you would normally be. That's because being pregnant changes how your heart, lungs and immune system function. Pregnant women who catch influenza are more than twice as likely to be admitted to hospital[3], are more likely to be admitted to intensive care, and may even die. Complications caused by an influenza infection include pneumonia, bronchitis, inflammation of the brain or heart.

Benefits for babies whose mothers were vaccinated against the flu

less likely to catch flu at six months of age[13]

less likely to be admitted to hospital with the flu in the first six months[12]

Benefits for mothers

less likely to catch the flu[14-15]

MumBubVax

For more information, you can call the **National Immunisation Hotline** on **1800 671 811.**

- mild fever of around 38.5° or less.

A very small number of people have a severe allergic reaction to vaccines, called 'anaphylaxis'. Anaphylaxis can lead to swelling, hives, breathing difficulties, lowered blood pressure and in severe cases, shock. Anaphylactic reactions to vaccination occur in about one in a million people[11]. Midwives, nurses and GPs are trained to respond to anaphylactic reactions with quick delivery of adrenaline.

If you have any worries about how you feel after your vaccination, you can get help from your doctor, or your nearest emergency department, or by calling Health Direct on 1800 022 222.

References

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Risk of a reaction serious enough to see a doctor or attend a hospital

Around 1.5 in 100 pregnant women vaccinated against flu had a reaction that required a visit to a doctor. Around 3 in 1000 attended hospital to recover from an adverse reaction to the flu vaccine[16].

MumBubVax

For more information, you can call the **National Immunisation Hotline** on **1800 671 811.**

The hepatitis B vaccine

for newborns

MumBubVax Read more about immunisation for pregnant women and their babies at **MumBubVax.org.au**

Babies under one year who catch hepatitis B can develop chronic hepatitis B, which can lead to liver disease and liver cancer in adulthood. Babies are most at risk of catching hepatitis B at birth, which is why it is recommended that all babies are vaccinated against hepatitis B within 24 hours of being born. In Australia, the vaccine is free for all newborn babies.

How will hepatitis B affect my baby?

Hepatitis B is a serious infectious disease that mainly affects the liver[1]. Around 90 per cent of babies who catch hepatitis B at birth will develop chronic hepatitis B, a condition that can lead to liver disease and liver cancer[2]. There is no cure for chronic hepatitis B infection and people with the disease need long-term antiviral therapy to reduce the risk of developing liver cancer[3]. Around one in four babies who catch hepatitis B at birth or soon after will die of liver failure or liver cancer as an adult[4].

How does hepatitis B affect adults, including pregnant women?

The risk of developing chronic hepatitis B is far greater in babies than it is in adults[1]—less than 10 per cent of infected adults develop chronic hepatitis B. Most adults who are infected with the hepatitis B virus recover fully. While infected, they may have no symptoms at all or very mild flu-like symptoms, or they may suffer from fever, nausea and vomiting, pain in the liver, pain in the joints and yellowing of the skin (called 'jaundice'). Many people who are carrying hepatitis B don't know that they have the virus.

How effective is the hepatitis B vaccine?

Between 90 and 95 per cent of people under 40 who have had three doses of the hepatitis B vaccine, as recommended in the National Immunisation Program, are protected against the hepatitis B virus[5].

MumBubVax

For more information, you can call the **National Immunisation Hotline** on **1800 671 811.**

The vaccine works by training the baby's immune system to recognise and get rid of the hepatitis B virus. The vaccine contains 'antigens' which are tiny fragments of the hepatitis B virus. When a baby's immune system detects the antigens in the vaccine, it produces antibodies to fight them and get rid of them. The vaccine does not contain any blood products and is not a 'live' vaccine. The synthetic fragments cannot reproduce themselves or cause disease.

If you have any worries about how you feel after your vaccination, you can get help from your doctor, or your nearest emergency department, or by calling Health Direct on 1800 022 222.

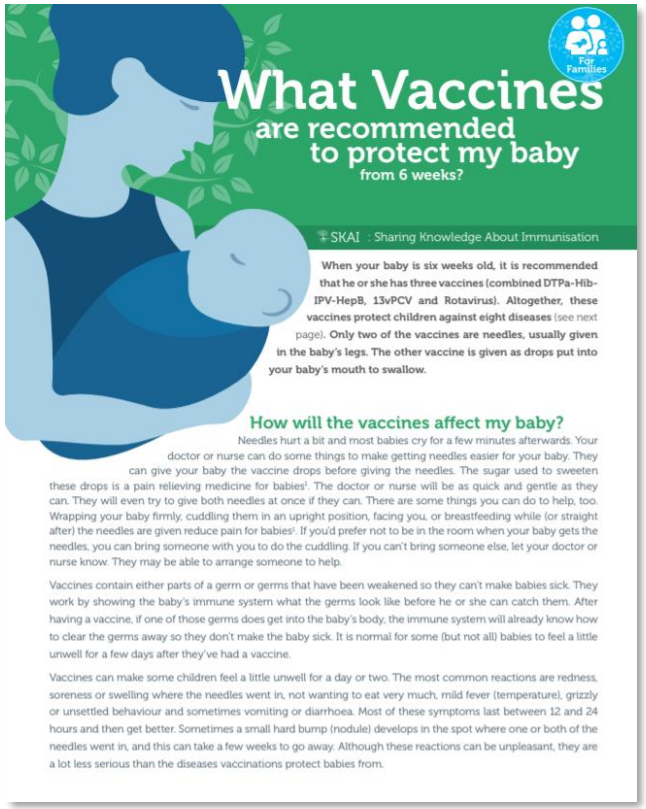
References

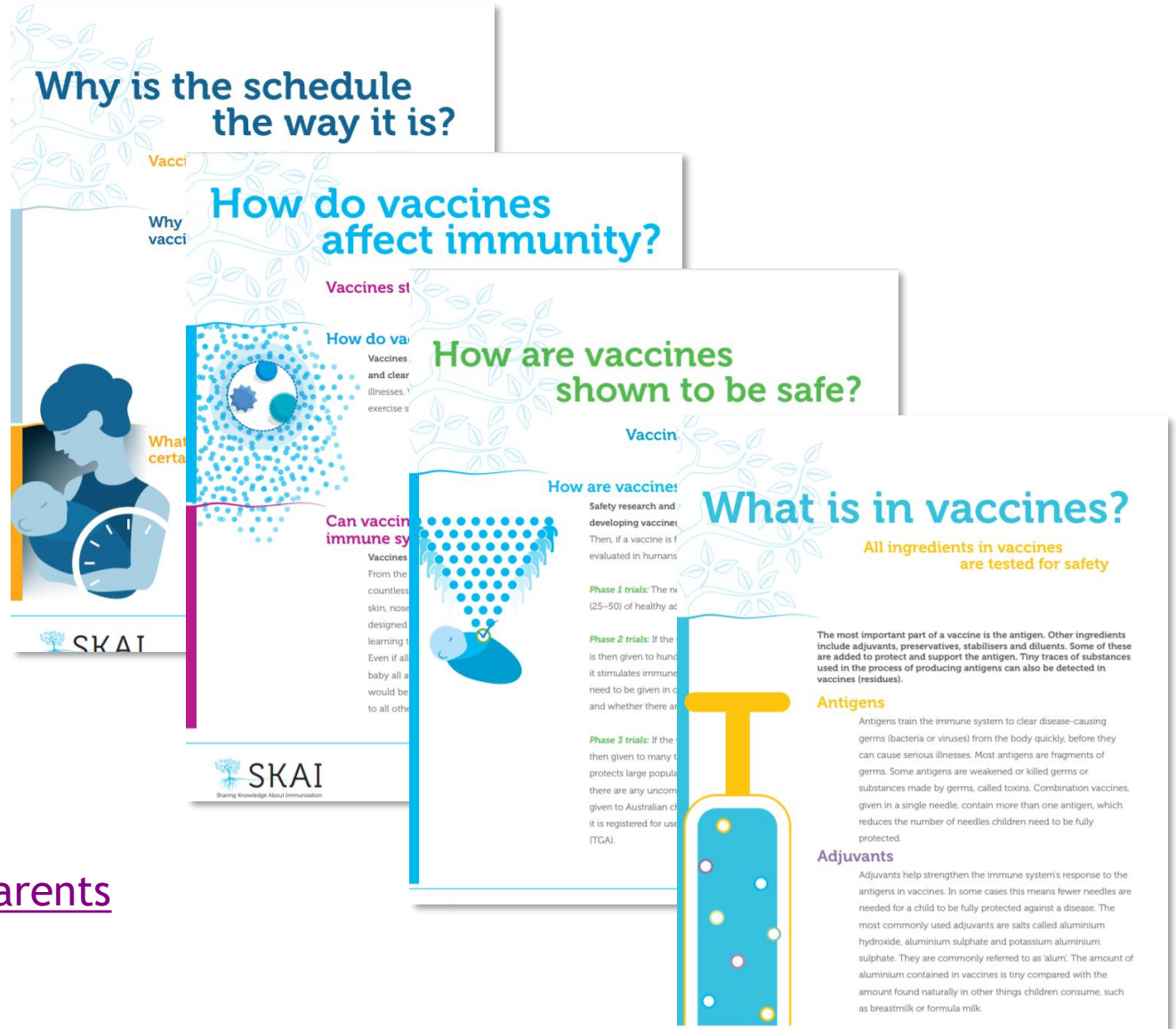
For links to the references used in this factsheet, please go to MumBubVax.org.au.

MumBubVax

For more information, you can call the **National Immunisation Hotline** on **1800 671 811.**

Links to existing Sharing Knowledge About Immunisation (SKAI) resources about childhood vaccination





http://www.talkingaboutimmunisation.org.au/parents

P3-MumBubVax intervention designed to…

- Fit with midwife values
- Increase efficiency of vaccine conversations without adding to time or workload
- Schedule vaccine discussions at set times in pregnancy
- Create a platform for new vaccines ie RSV, GBS
- Operate in combination with structural levers

MumBubVax pilot for feasibility and acceptability

- SETTING:
  - Royal Women's Hospital, Melbourne
- TIMELINE:
  - October 2018 – September 2019
- OUTCOMES:
  - Feasibility, acceptability, degree of intervention implementation
  - Uptake of maternal, infant and childhood vaccinations
- MIDWIVES:
  - n=25 midwives enrolled
  - n=18 completed VaxChat training (72%)
  - Median time to training completion = 13 days (range 5-53)
- MOTHERS:
  - n=62 expectant mothers enrolled (50% primipara)
- Data collection complete, analysis underway

Pilot data – quotes from midwives

Stickers are my favourite strategies!

It encouraged me to feel confident when discussing facts and figures with parents

Which skills from VaxChat did you use most?

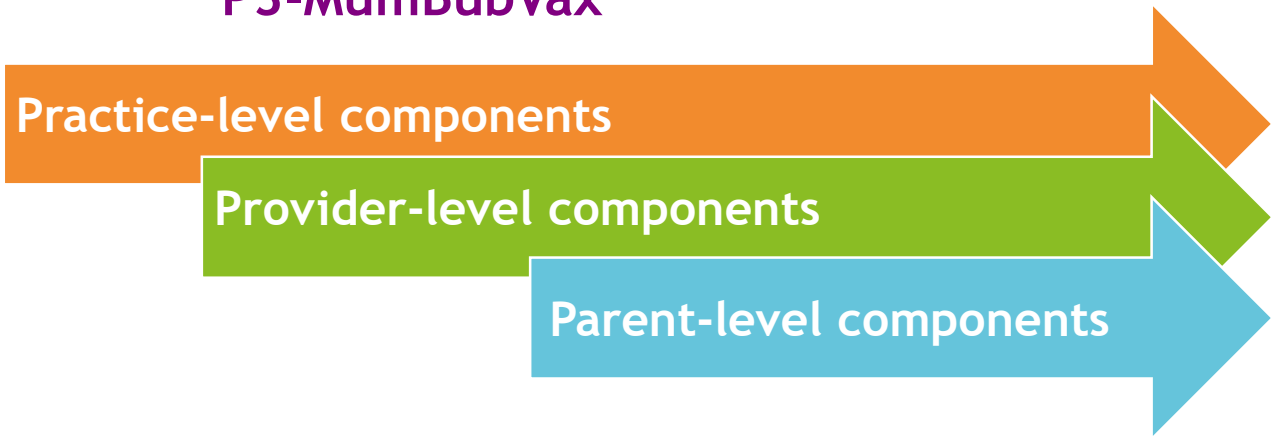
I took more time to get to the root of people's concerns and use more open ended questions when discussing vaccinations.

Sticking to one key point and making that relevant to the woman's situation

Really enjoyed the MumBubVax study. It increased my confidence in having these discussions and I have found the resources very helpful.

Next steps: national cluster RCT

P3-MumBubVax



PROPOSED TRIAL OUTCOMES:

1. Uptake of maternal influenza vaccine during pregnancy *(primary outcome)*
2. Uptake of maternal pertussis vaccine during pregnancy
3. Infant uptake of the birth dose of hepatitis B vaccine
4. Uptake and timeliness of primary series childhood vaccines to 12 months of age
5. Maternal knowledge and attitudes about maternal vaccines and hesitancy about childhood vaccines
6. Provider confidence in communicating about vaccination

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3. Fell DB, et al. Maternal influenza and birth outcomes: systematic review of comparative studies. BJOG. 2017;124(1):48-59
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