

WELCOME TO THE GBS3 TRIAL

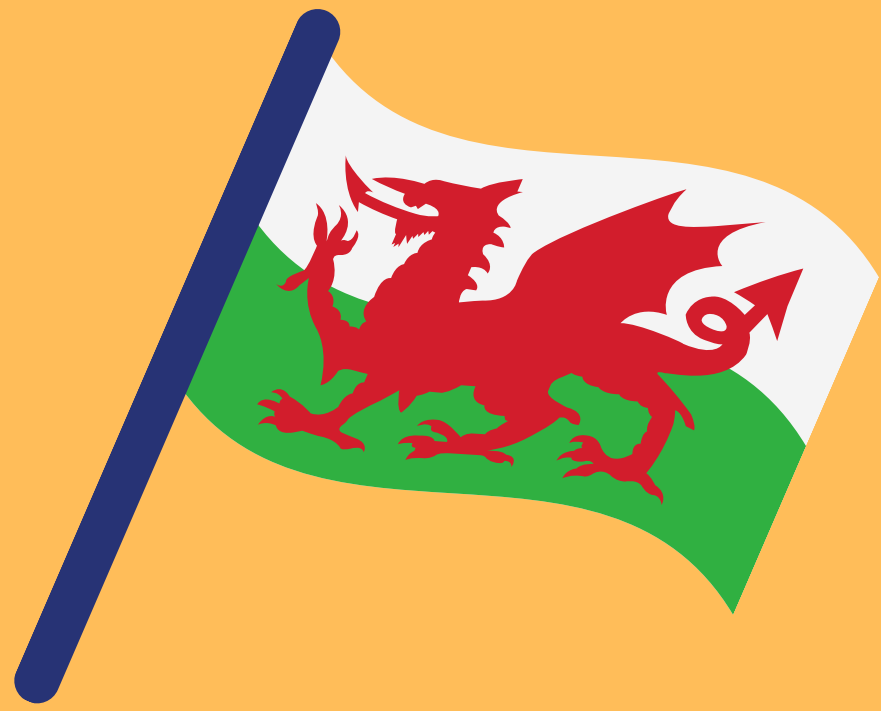




ROUTINE TESTING
FOR GROUP B STREP

What is the GBS3 Trial?

A Randomised Controlled Trial



Involving 80 NHS
sites across
England, Scotland
and Wales





320,000 pregnant women !



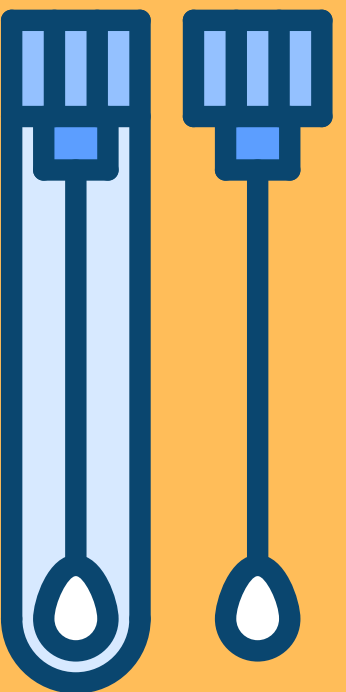


What question is GBS3
asking ?





Does routine testing for
GBS reduce early onset
neonatal sepsis?

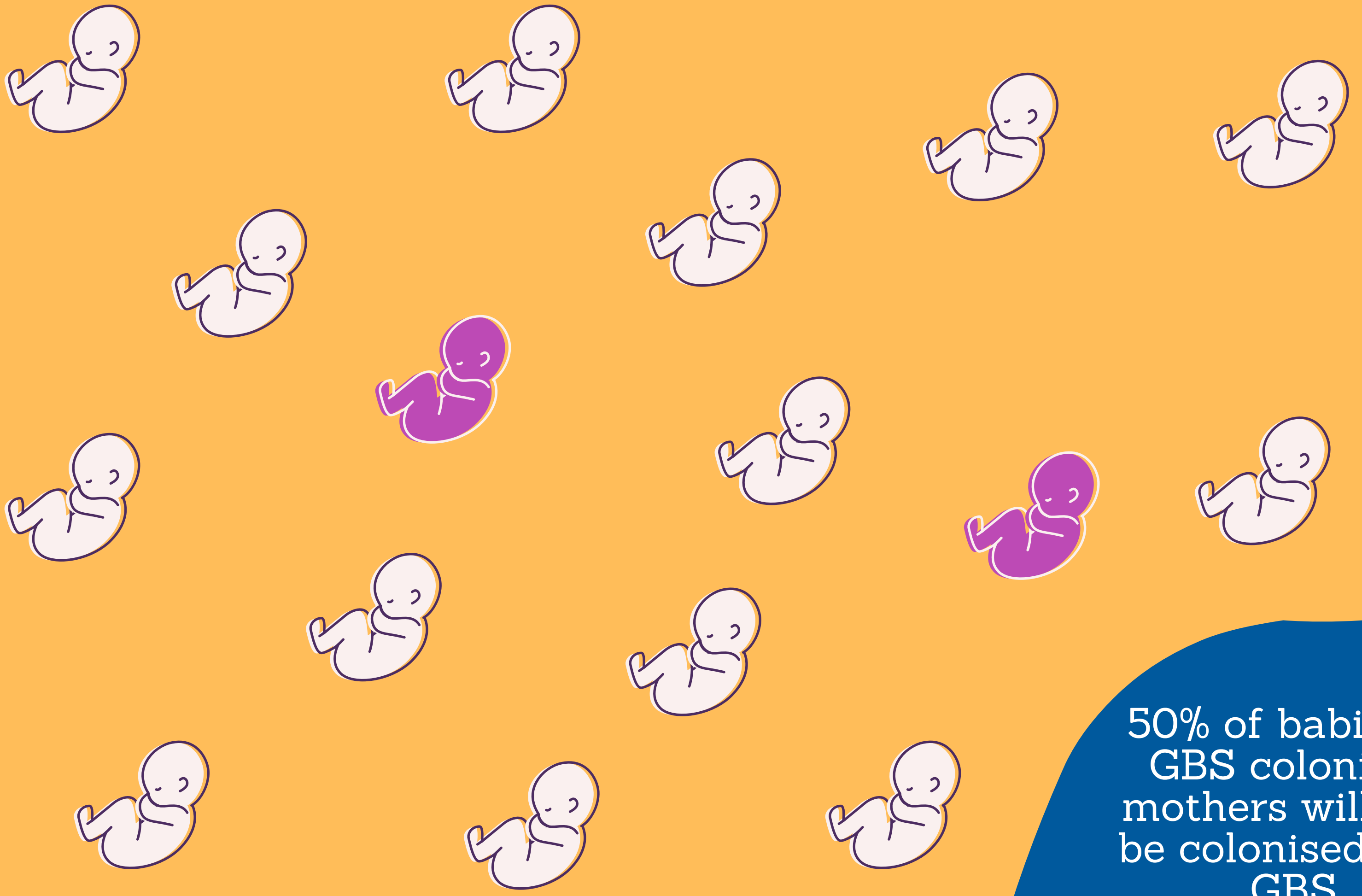


Why is GBS3
asking the question ?

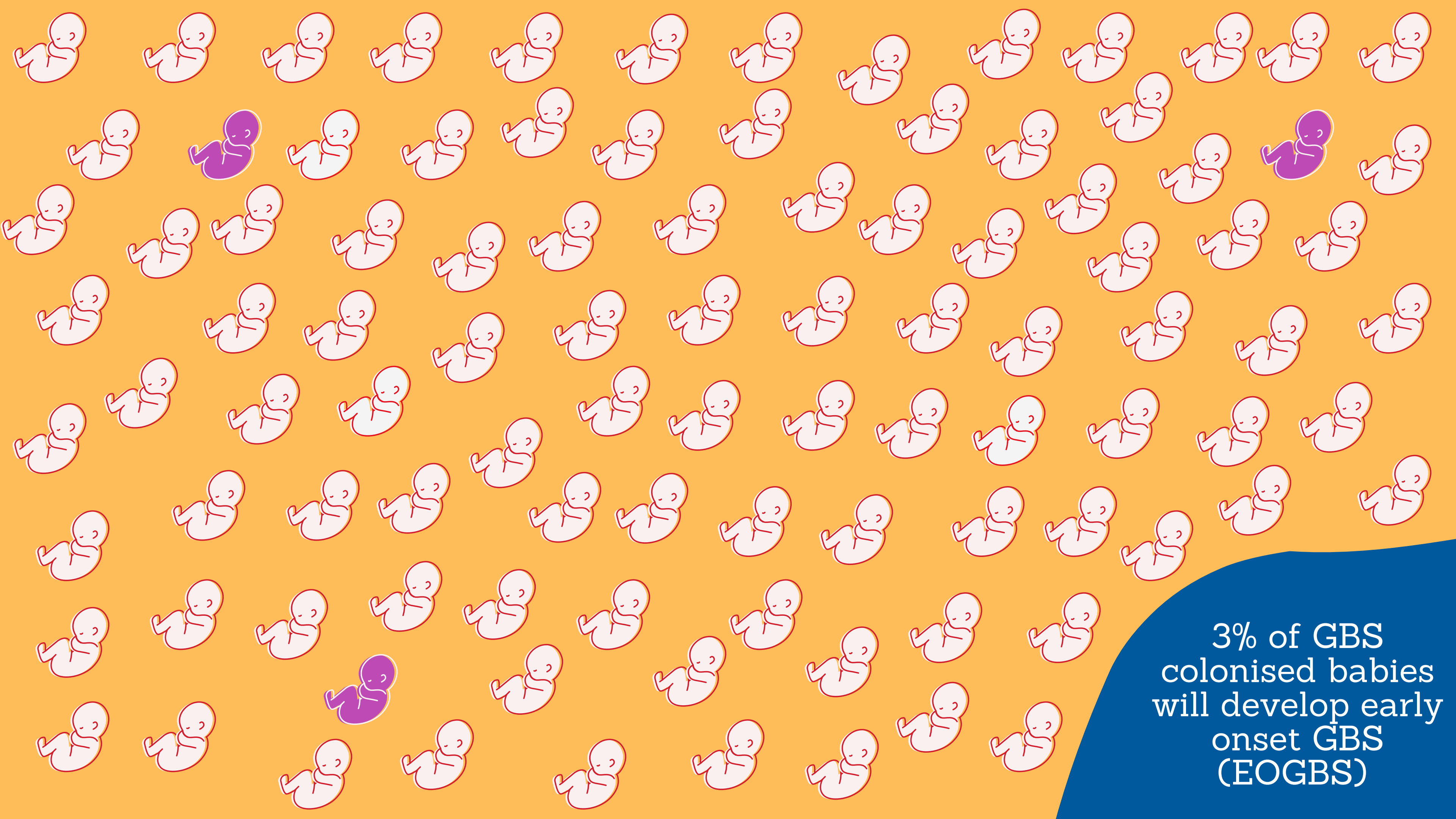




One in four
pregnant women
carry GBS in their
gut and/or genital
tract



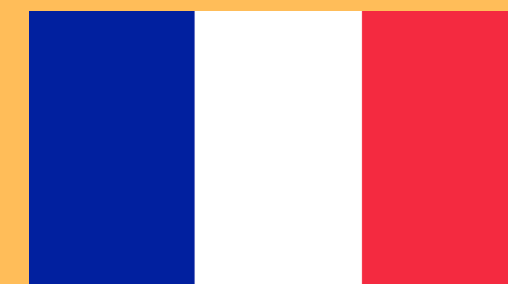
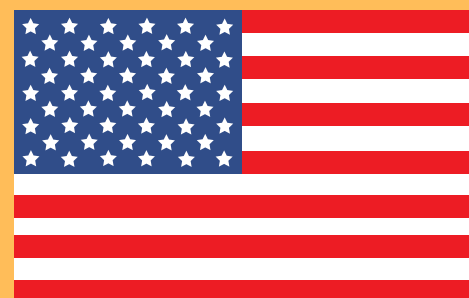
50% of babies of
GBS colonised
mothers will also
be colonised with
GBS



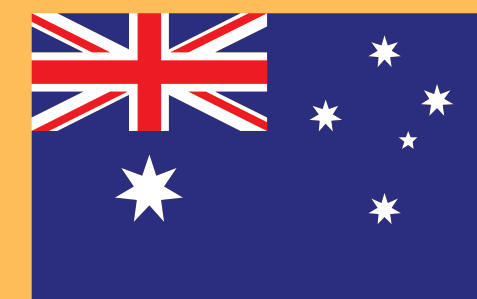
3% of GBS
colonised babies
will develop early
onset GBS
(EOGBS)



It is estimated that EOGBS
causes more than 40
neonatal deaths and around
25 cases of long term
disability each year in the UK



Routine testing takes
place in many developed
countries...



...and whilst routine testing
has been attributed to a
reduction in EOGBS in those
countries...



...there remains a lack of
randomised research data
on the clinical and cost
effectiveness of routine
GBS testing



This lack of research
evidence means that
we do not currently
routinely test for GBS
in the UK





Instead women are
tested/offered intrapartum
antibiotics (IAP) based on
maternal risk factors

It is important to provide evidence
on both clinical and cost
effectiveness before introducing
any new clinical testing strategy
across the NHS





The UK National Screening Committee recommended a randomised controlled trial to gather the required evidence



GOV.UK

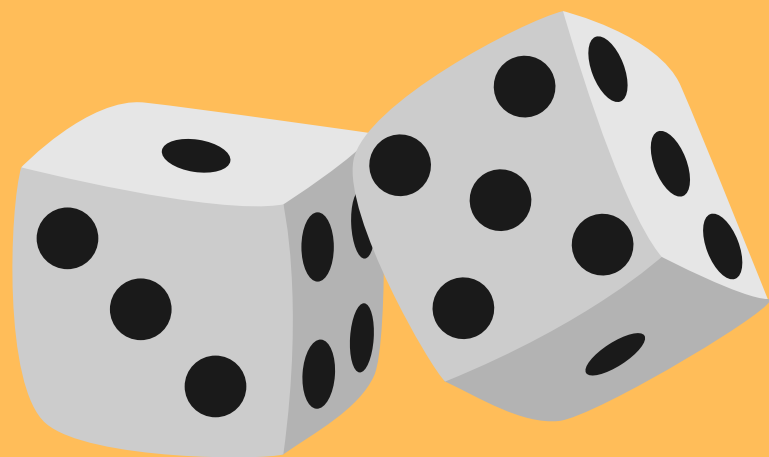
And thus the GBS3
Trial was born ...



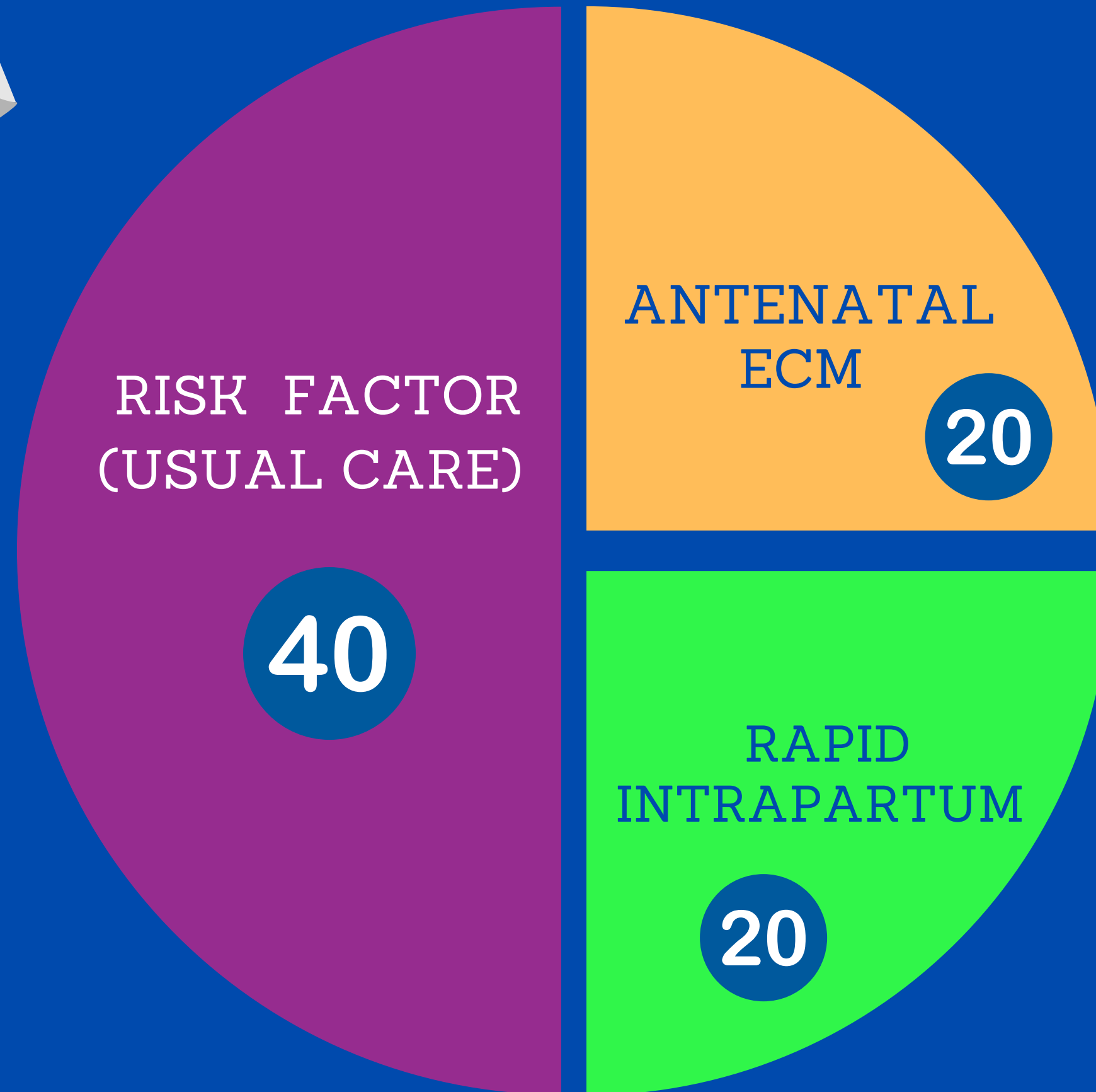
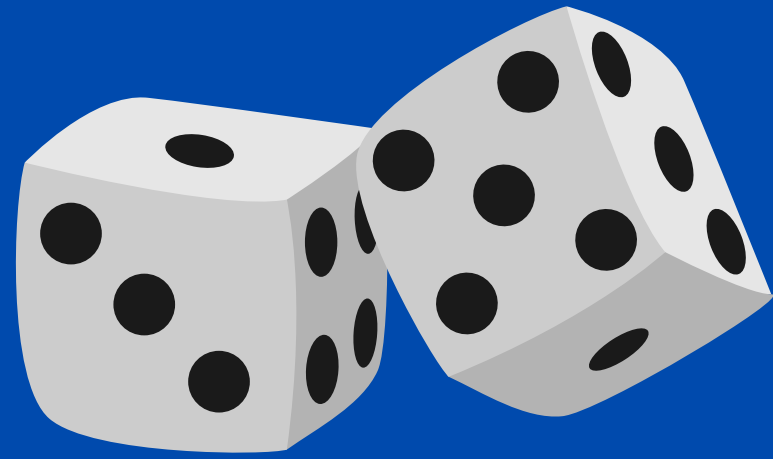


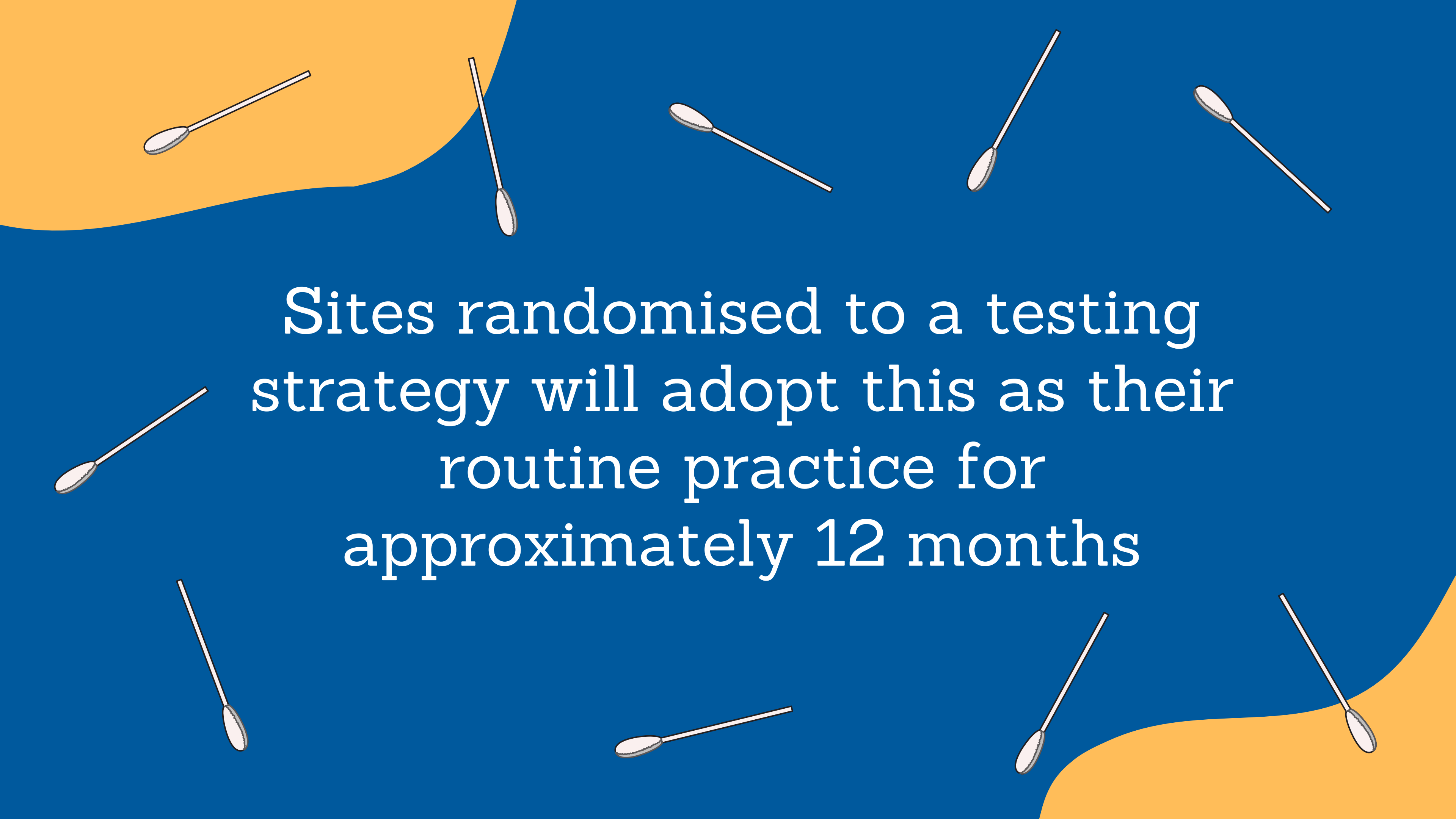
So how will GBS3 work?





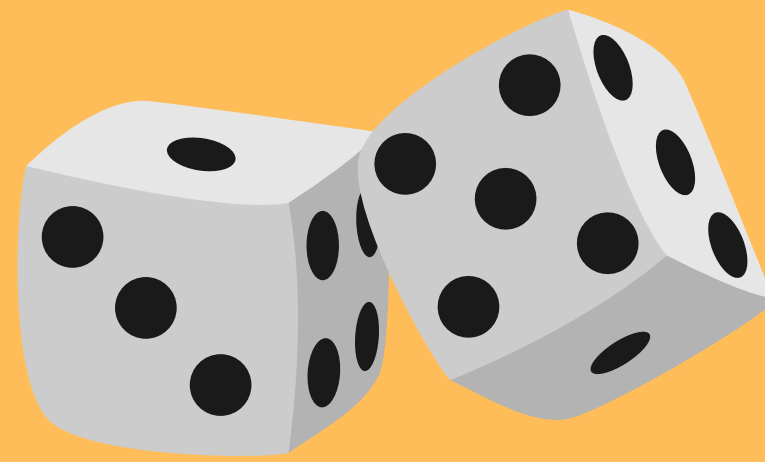
80 sites will be
randomised to
three different
trial strategies





Sites randomised to a testing
strategy will adopt this as their
routine practice for
approximately 12 months

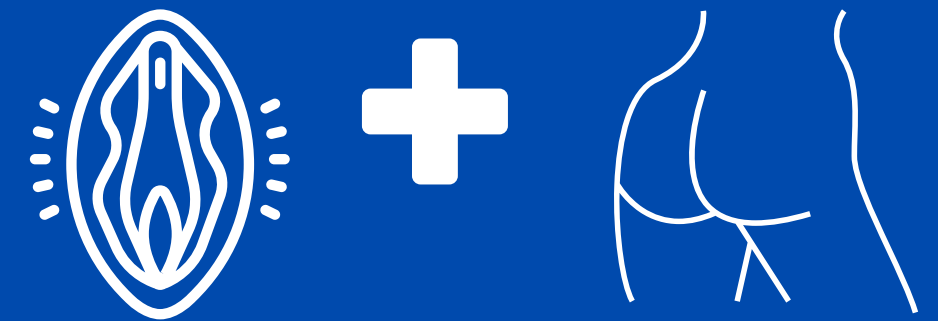
Your site has been randomised to
Intrapartum Rapid Testing



This is a PCR test processed on the ward
- results available within an hour



A vaginal-rectal swab when women are
admitted in labour or for IOL



A single, double head swab processed using
the GeneXpert device



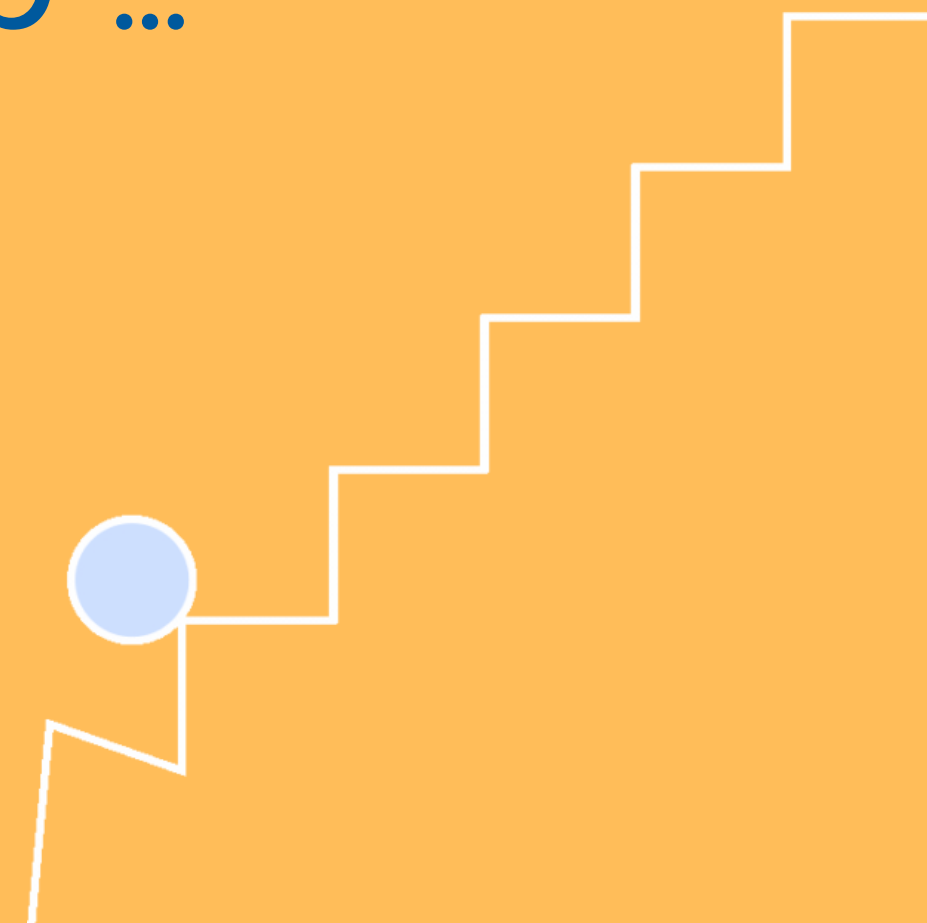


So ...what will maternity teams
have to do?





Let's take it step by step ...





Antenatal/Community Teams....





Before 28/40 weeks tell women that your site is taking part in GBS3 and she will be offered a GBS swab when she is admitted in labour or for I.O.L

A Patient Information Sheet will be available for women if requested and you will be provided with GBS3 'participant cards' to give to women if they would like one



And give
women the
RCOG/GBSS
leaflet by 28/40
- as per RCOG
guidance and
the GBS3
protocol



Your Research Midwife will make sure
you have supplies of the leaflet

The leaflet
has been
adapted
with info
about the
GBS3 Trial



Delivery Suite Teams....





Women will have been advised about the rapid test by 28 weeks - you will just need to remind women and request their consent to take the swab...



YES



NO



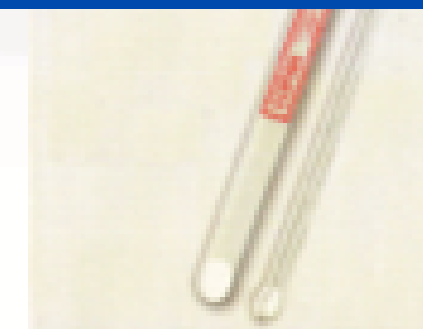
You don't need to take 'research consent' – just verbal consent as you would for any clinical procedure

You will be fully trained on the GeneXpert device and obtaining the sample but here is a quick run through of the process...



Materials Required

- Cepheid Collection Device (P/N 900-0370)



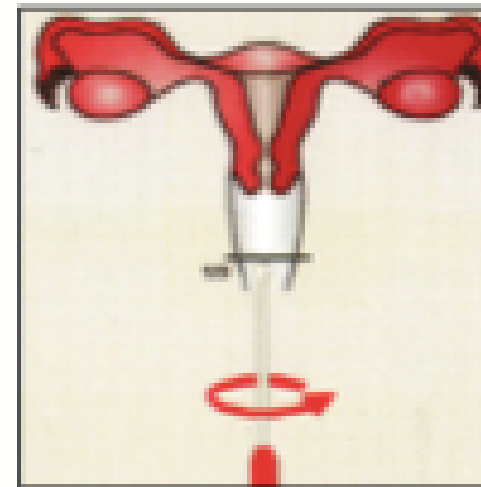
IMPORTANT: Perform the vaginal/rectal specimen collection prior to using a speculum or using a lubricant.

- 1 Use gauze to wipe away excessive secretion or discharge from the vaginal/rectal area.

NOTE: Wear gloves throughout the collection process.

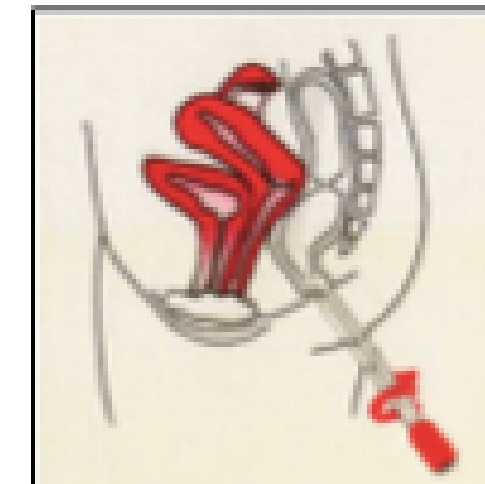


- 2 Carefully insert the double swab into the lower third of the patient's vagina and sample secretions from the mucosa. Rotate swab 3 times to ensure uniform sample on both swabs. Do not collect a cervical sample.

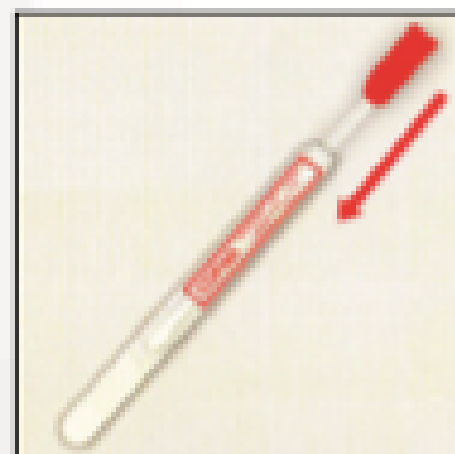


- 3 Using same double swab, carefully insert the swab approximately 2.5 cm beyond the anal sphincter and gently rotate to sample anal crypts.

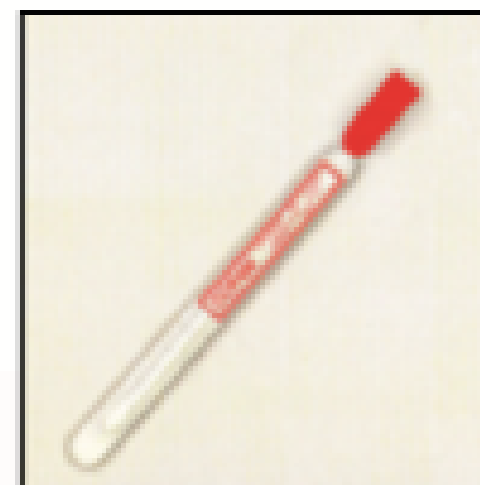
NOTE: Swabs must stay attached to the red cap throughout the procedure.



- 4 Remove and discard the cap on the transport tube and place swabs into the tube, pushing the red cap down completely.



- 5 Specimens that can be tested within 24 hours can be kept at room temperature; otherwise, specimens stored at 2-8 °C are stable for up to 6 days.



If lubrication is required you can use sterile water or normal saline to moisten the swab

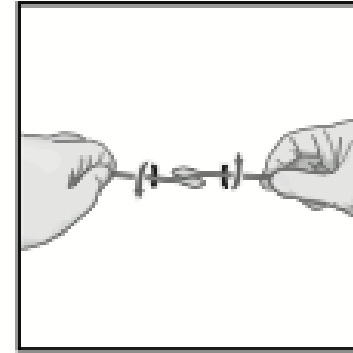


Quick Start Guide Xpert® GBS

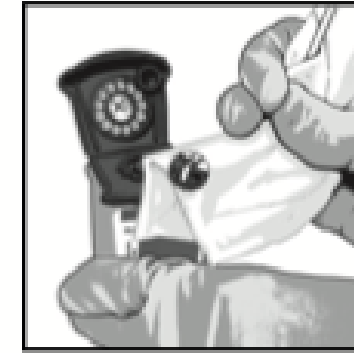
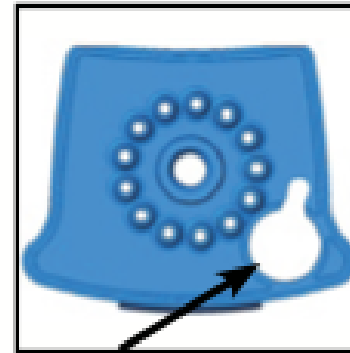
- 1 Use one cartridge for each sample. Open the cartridge lid.



- 2 Remove the swabs from the container. Gently brush the swabs together as shown in the first figure. Replace one swab in the collection/transport container. Insert the other swab in the cartridge. Break the swab at the score mark. Make sure the swab can float freely in the chamber.



NOTE: Do not hold the swab below the score mark.



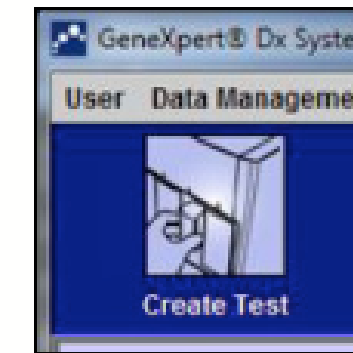
NOTE: Use tissue or an equivalent to minimize splashing.



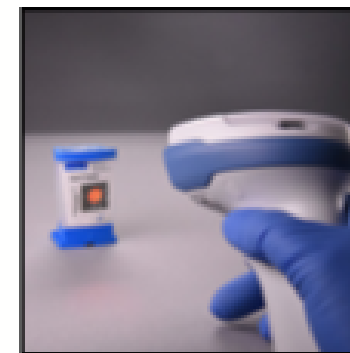
- 3 Close the lid firmly.



- 4 Click Create Test.



- 5 Scan the cartridge barcode.



- 6 Enter or scan the Sample ID.

Sample ID

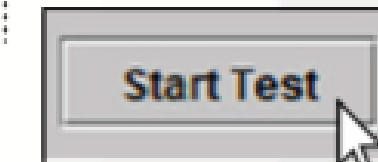
Name

Select Assay

Select Module

Reagent Lot ID Expiration Date

- 7 Click Start Test.



- 8 Load the cartridge in the module identified by the flashing green light. Close the module door until it latches and the green light stops flashing.

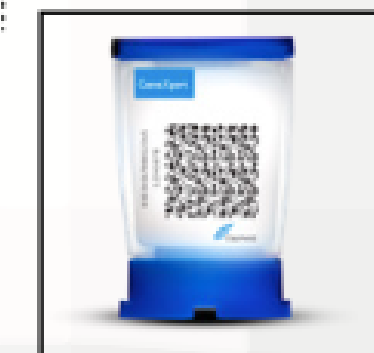


Results generated
≤ 56 Minutes

- 9 Click the View Results icon. Click on View Test from the bottom of the screen. Select the correct Sample ID.



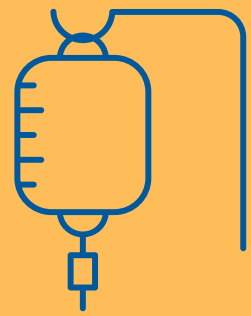
- 10 Dispose of used cartridge.





An appropriately trained healthcare professional must take the swab – a self swab is not possible due to the GeneXpert licence

Try and take the swab when the woman is in early labour or early IOL



This will ensure that if she is GBS positive you have the best chance to initiate IAP and optimise antibiotic cover throughout labour

If a woman has not delivered within 5 days of taking the swab consider repeating the swab

Once the swab has been placed in the GeneXpert cartridge the processing must begin within 15 minutes



Your Trust will have agreed which patient identifiers are to be used on the device - please be consistent in this.

Make sure you don't discard the second half of the double swab until you are confident you have obtained a result from the first half of the swab

ARE YOU
SURE

Occasionally the device may return an 'invalid' result and you will need to use the second half of the swab



Whether the second half of the swab is stored beside the device or taken back to the delivery room – make sure it is clearly and correctly labelled with the patient ID

Correct label = correct woman = correct treatment



Always wear gloves whilst
preparing
and putting the sample through the
device



If you are processing more than one
sample at a time it is essential to
use a clean pair of gloves for each
sample to avoid cross
contamination





The used cartridge must be disposed of in incinerator waste



The result will be available in just under an hour - you may want to set an alarm on your phone to check...



This means you can make sure you get the result in a timely fashion and also clear the cartridge from the machine so that it is available for more samples (4 samples can be tested at one time)

Communicate the result to the woman/
relevant clinicians asap and record the
result in your patient records



Results are stored on the GeneXpert device but
there is no results printout so you will need to
ensure results are accurately transferred to the
woman's records



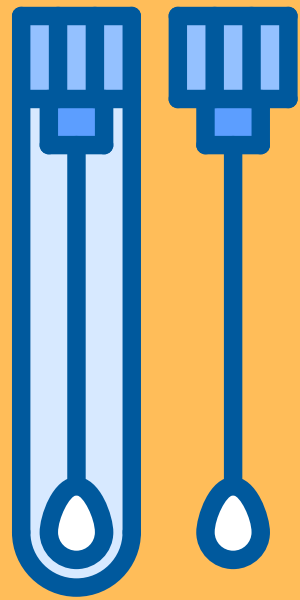
If the result is GBS positive offer
and commence IAP (Intrapartum
Antibiotic Prophylaxis) as per
your Trust guidelines....





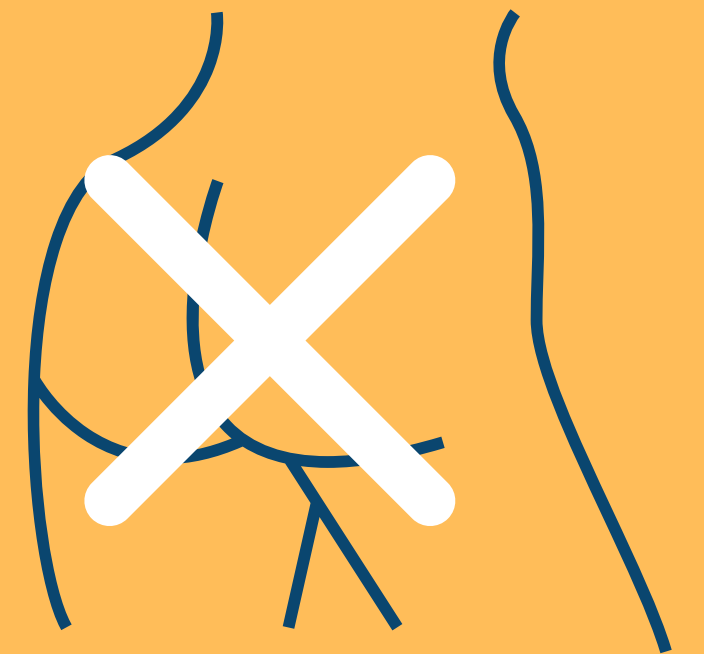
If no GBS result is available
revert to your Trust guidelines
regarding GBS risk factors and
IAP administration

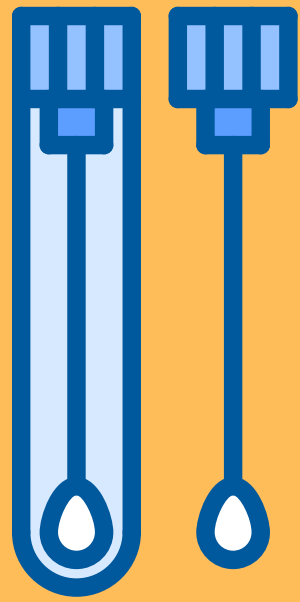




DON'T FORGET

If a woman declines the rectal part
of the swab - a few things to
remember ...



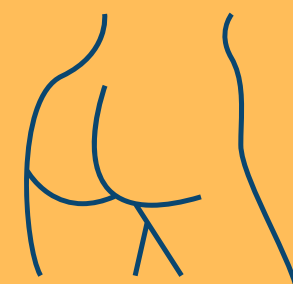


IMPORTANT!

Please speak with her about the importance of taking both vaginal and rectal samples



+



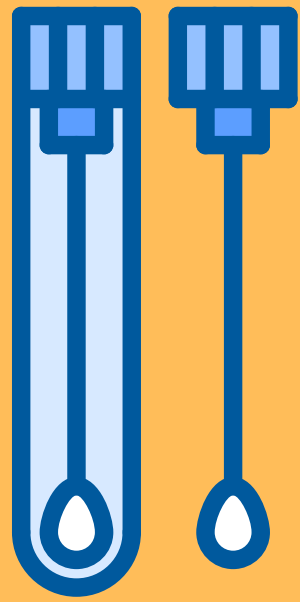
=

**More accurate
test**

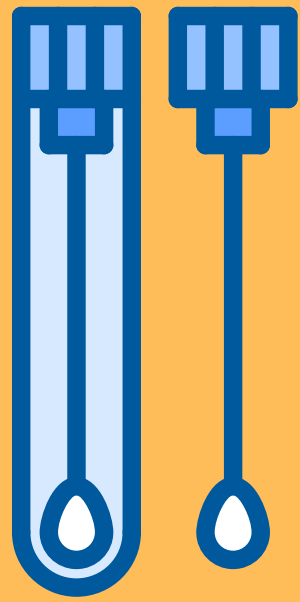


Because GBS may be in the GI tract/rectum but not in the vagina - and rectal GBS can still be transmitted to the baby



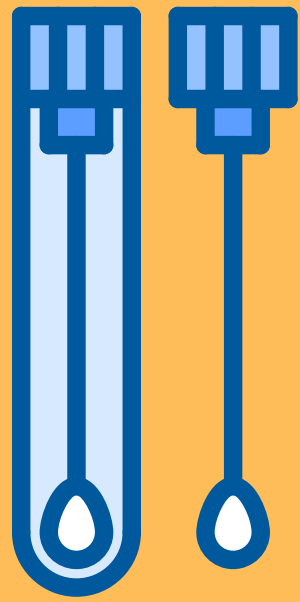


So a vaginal swab only may mean
an opportunity to detect GBS in the
GI tract is missed



But of course - the woman's choice
is paramount





.. if a vaginal swab only is obtained then please make sure you make a note of this in your clinical records

And....

If a woman experiences
anaphylaxis secondary to IAP



Please complete an incident
form/datix reporting the anaphylaxis
as we will be collecting this
information





Q&A

1.



Are all women offered a GBS swab?



Q&A



No, not quite...

Do not offer a GBS rapid test
to ..



Women with a baby with a congenital anomaly incompatible with life at birth



Women with a known prelabour intrauterine death in the current pregnancy

Women in preterm labour (as they will be offered IAP routinely)



Women admitted for an elective section (unless they go into labour)

Women not in labour and with intact membranes, who need an emergency section



Q&A

And note
that ..



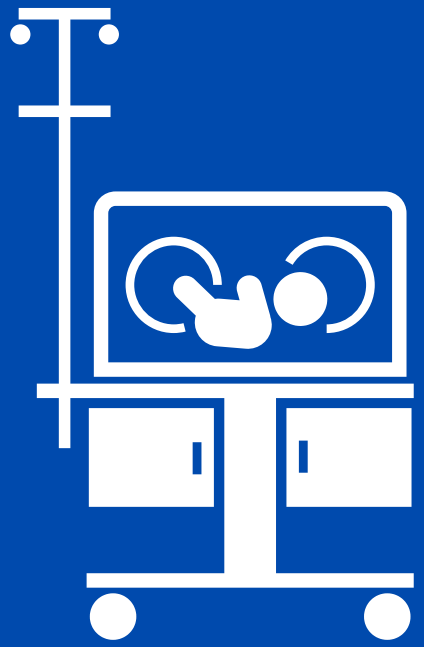
If a woman has previously had a
baby with early or late onset GBS

Q&A



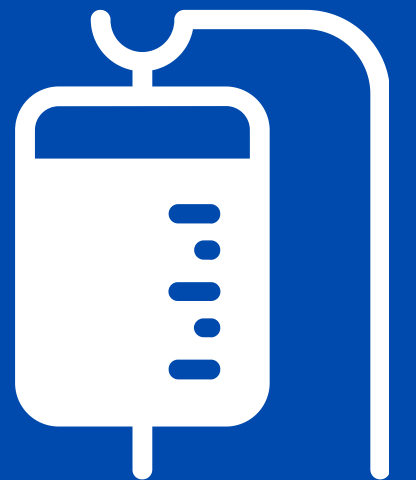
You can offer her an intrapartum
rapid test





Q&A

But reassure her that she can have
IAP in labour regardless of the
result





I am not confident about my research knowledge - how much do I have to tell women about the GBS3 Trial ?



Don't worry – we don't expect you to
know all of the ins and outs of the
GBS3 Trial



Your Research Midwife will make
sure GBS3 Trial posters are in all
relevant clinical/patient areas

And a GBS3 Patient Information Sheet will be available for women upon request

..and you can direct women to the
GBS3 website :

gbs3trial.ac.uk



I am so busy already .. do I have to make lots of additional notes about women being part of the GBS3 Trial ?

Q&A



No...the beauty of the GBS3 Trial is
that it is very simple for clinical staff



The GBS3 Team will collect most
of the data they require from
routine data sources



And routine GBS testing will become
your 'norm' for about a year so just
complete your clinical notes as usual

Q&A

Except ... just one really important
request please



Make a note
that you have
offered the
GBS swab

1

Record if the
woman
accepts or
declines

2

And if she
declines please
try and record
a reason

3



What if women say they don't want their information used for research?

No thank you



... direct them to the national data opt-out system at :

<https://www.nhs.uk/your-nhs-data-matters/>

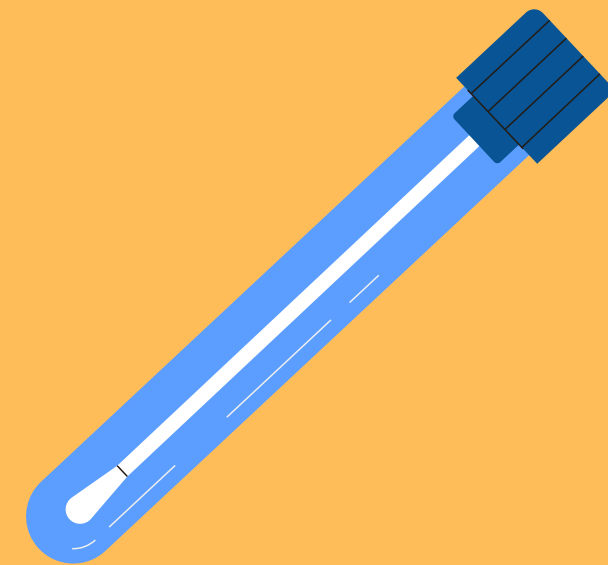


And explain this will not affect their care but it will remove their data for all research and planning - not just for GBS3





Is a special swab required for the rapid test?





Yes ..the double head single swab for use with the GeneXpert device will be purchased from Cepheid, the company that provide the device





What about women booked for
elective sections who come in
labouring ...



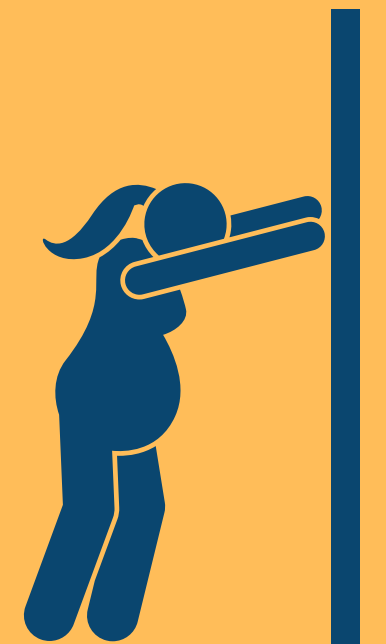


Offer these women an intrapartum swab –
in case they proceed to labour and deliver
vaginally





What about women planning to have their baby at home or in a birth unit where it is not possible to have IAP (or the unit does not have a GeneXpert device) ?





These women can be offered an antenatal rapid test swab - if they are GBS positive they can then make an informed choice about their place of birth





What if a woman has had a positive GBS result earlier in the pregnancy from a vaginal swab - do we still offer the rapid test or do we just offer IAP?



Offer the intrapartum rapid test – and the result should supersede an earlier result as we know that GBS carriage can and does change

HOWEVER – PLEASE NOTE !!

If a woman has been treated for TRUE GBS bacteriuria ($>10^5$ / ml) she should get IAP irrespective of the later test result



What if a woman's intrapartum test is negative but she is showing signs of infection such as pyrexia in labour?



It will then be a clinician's decision as to whether or not antibiotics are required and which ones should be prescribed



More questions?

Take a look at the GBS3 website ...
gbs3trial.ac.uk

Where you will find more FAQs



REMEMBER!

There is a lot of help available to
support sites taking part in this
really important research



Your local Research Midwife is
there to help you...

And the GBS3 Trial Team...



Kerry

GBS3 Research Midwives...

Jodi



Sophie



Heidi



Senior Trial Manager



Beki



Ellie Trial Manager

Baz



Trial Co-ordinators



Jo

Lixiao



Trial Administrator

And the GBS3 Chief Investigators...

Jane



Kate



We are all here to help ...

Email us:

GBS3@nottingham.ac.uk



Follow us on Twitter...

@GBS3Trial





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FOR GROUP B STREP