

# WELCOME TO THE GBS3 TRIAL

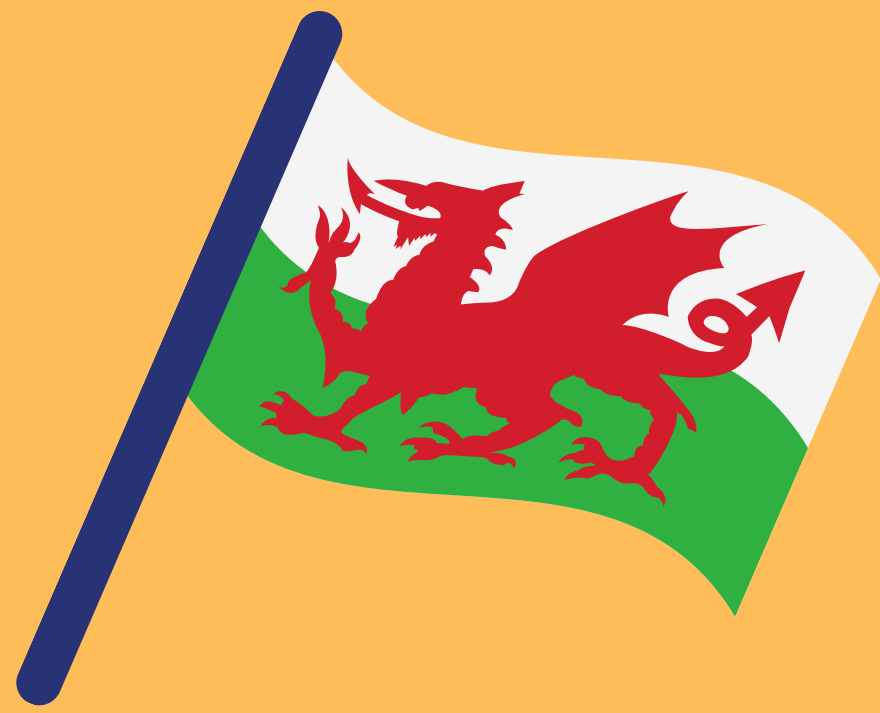




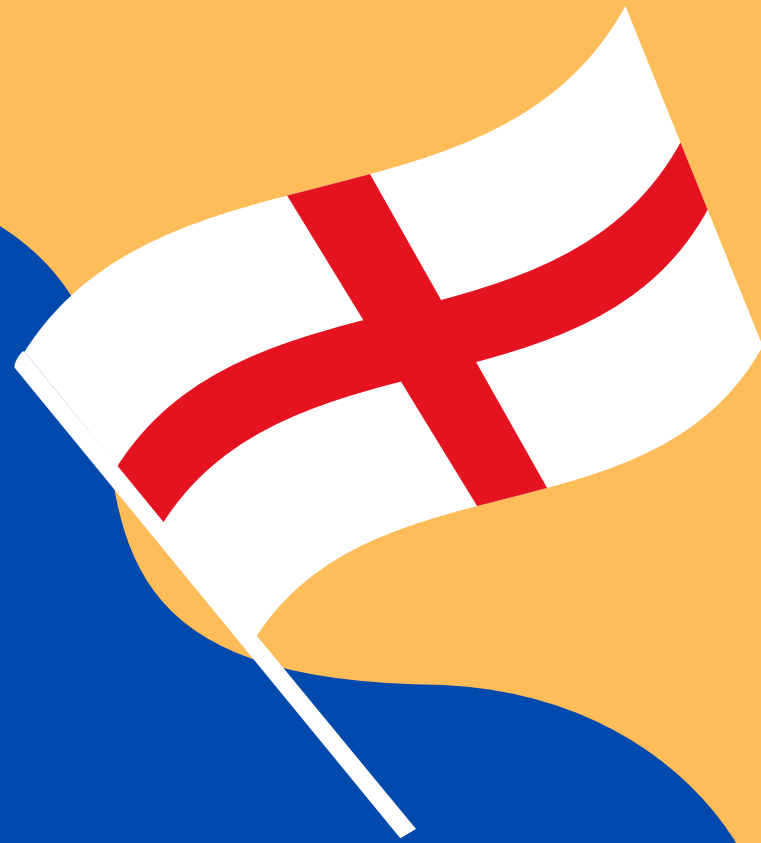
ROUTINE TESTING  
FOR GROUP B STREP

What is the GBS3 Trial?

# A Randomised Controlled Trial



Involving 80 NHS  
sites across  
England, Scotland  
and Wales





320,000 pregnant women !



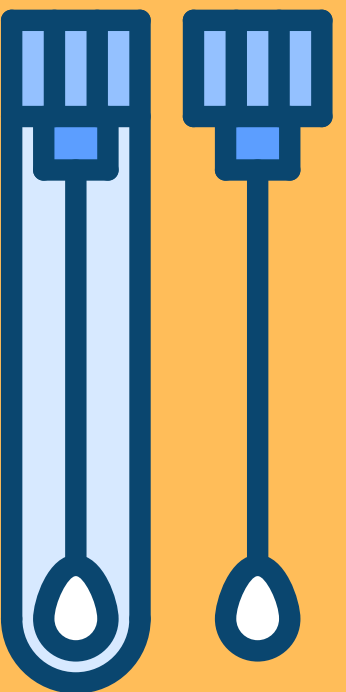


What question is GBS3  
asking ?





Does routine testing for  
GBS reduce early onset  
neonatal sepsis?





Why is GBS3  
asking the question ?

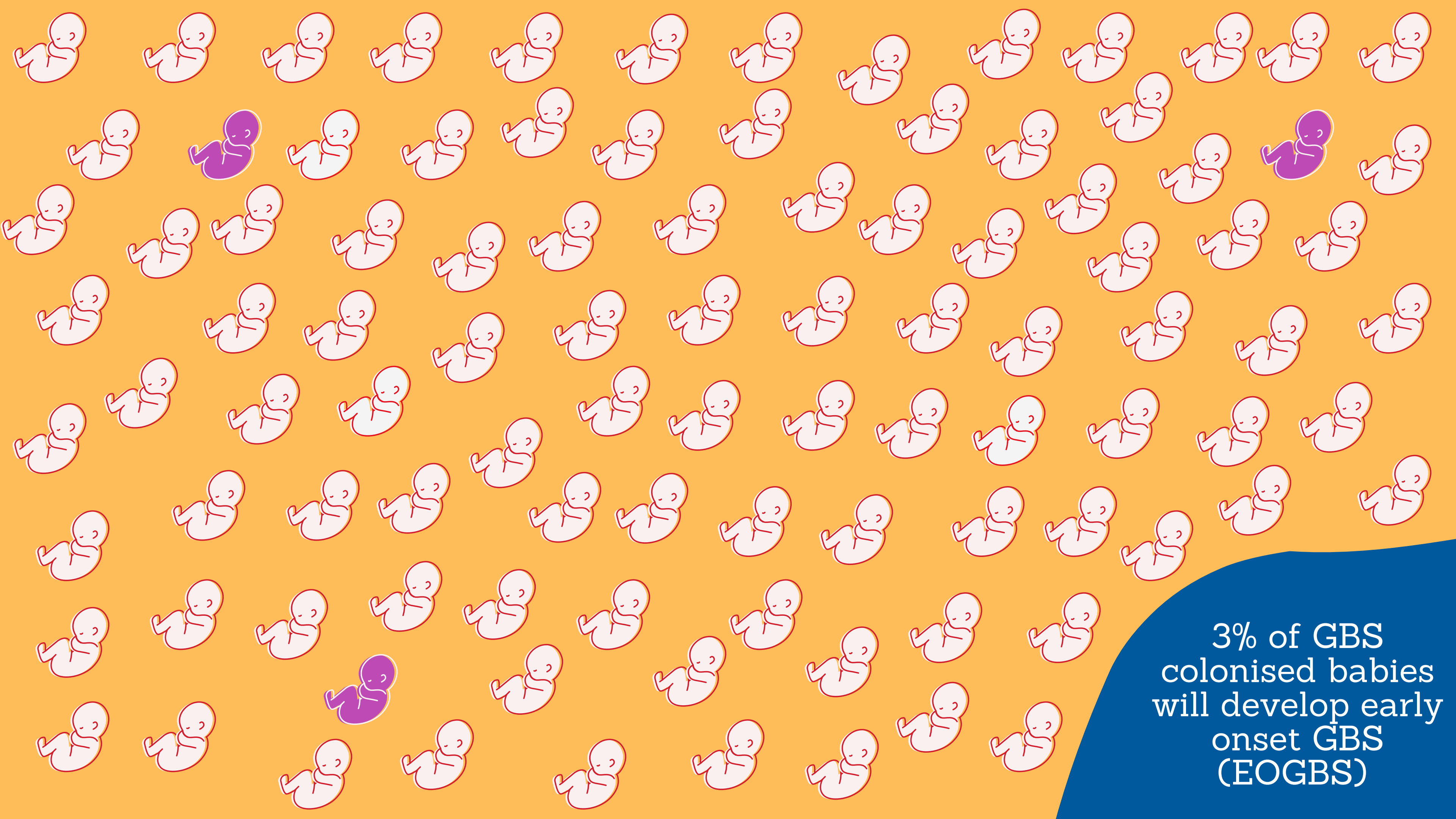




One in four  
pregnant women  
carry GBS in their  
gut and/or genital  
tract



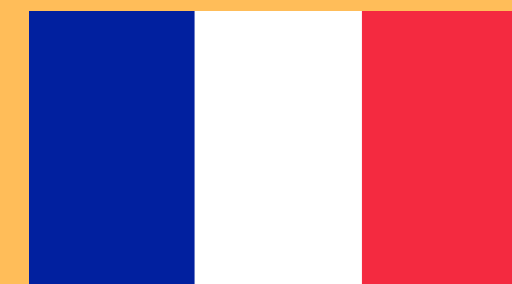
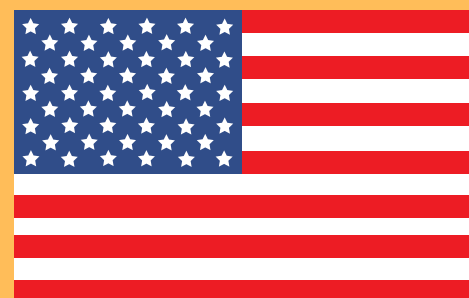
50% of babies of  
GBS colonised  
mothers will also  
be colonised with  
GBS



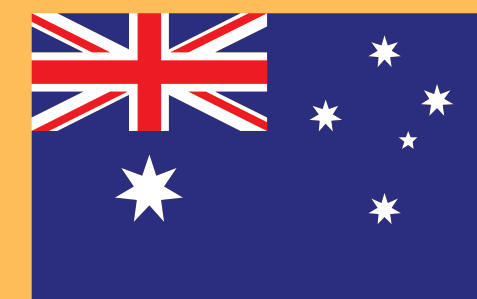
3% of GBS  
colonised babies  
will develop early  
onset GBS  
(EOGBS)



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

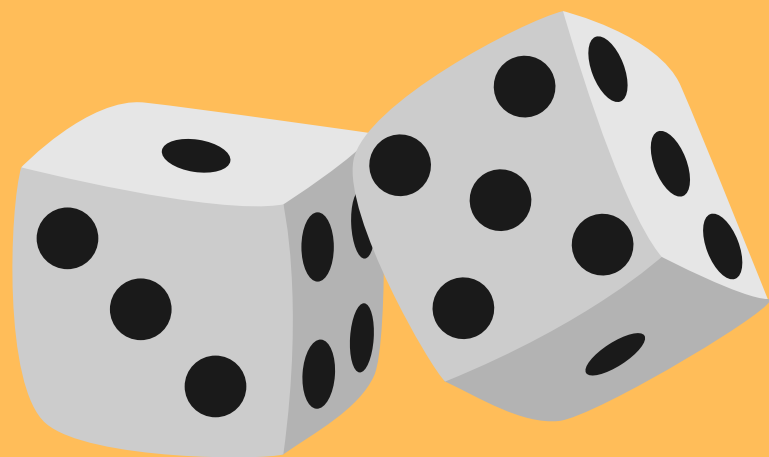
And thus the GBS3  
Trial was born ...



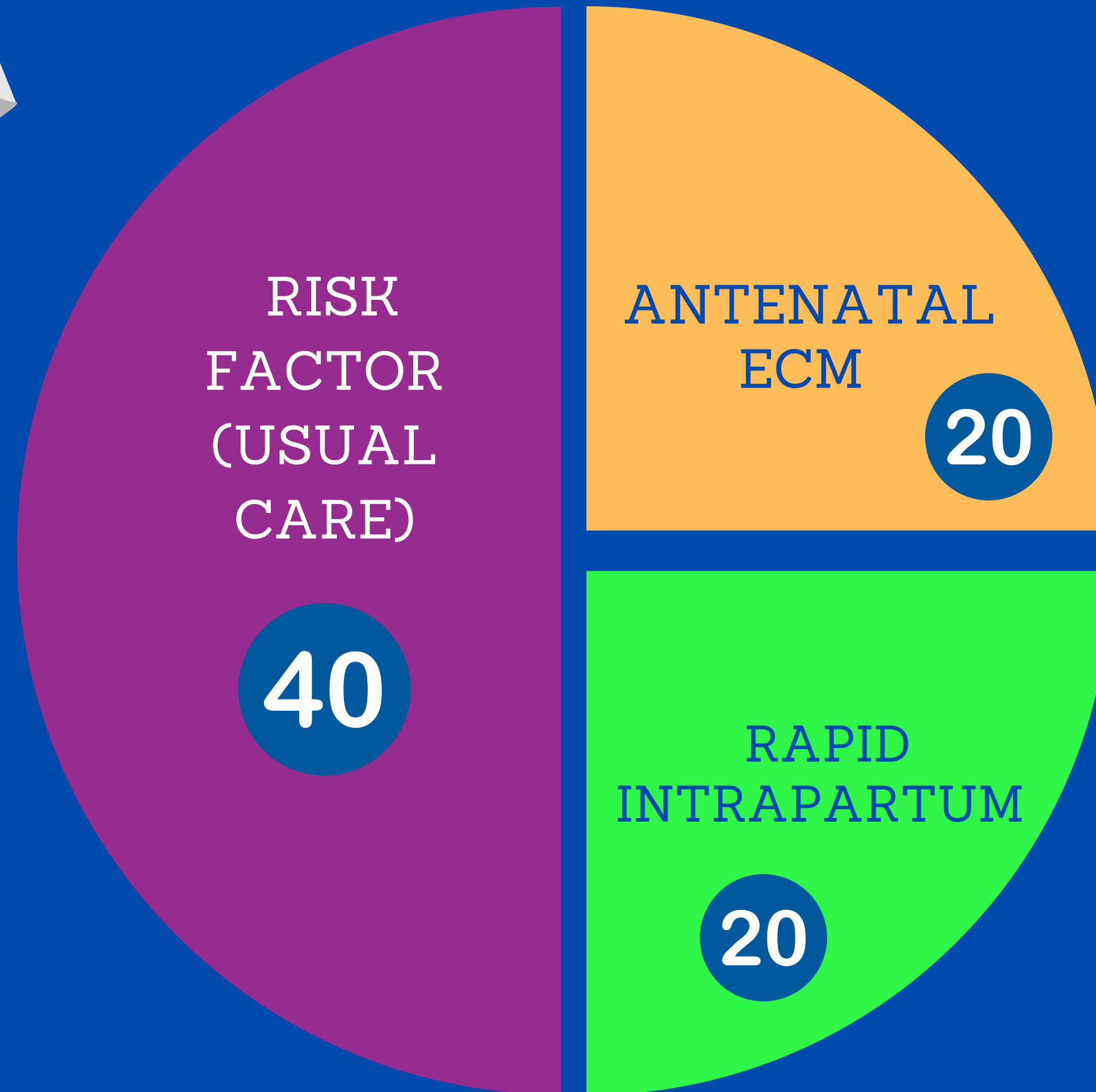
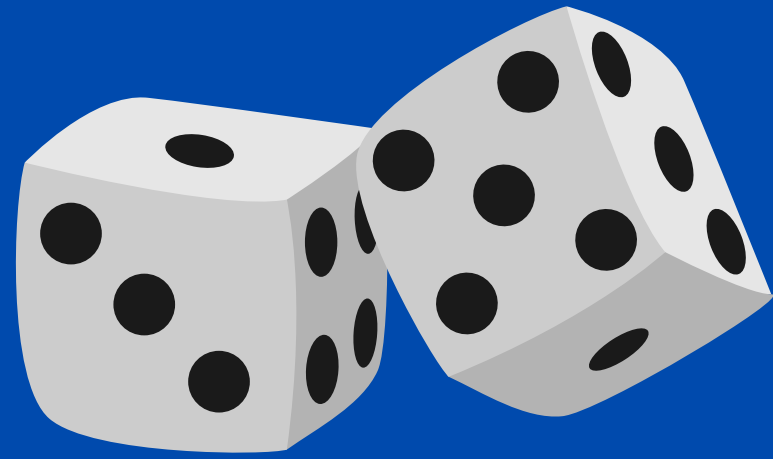


So how will GBS3 work?

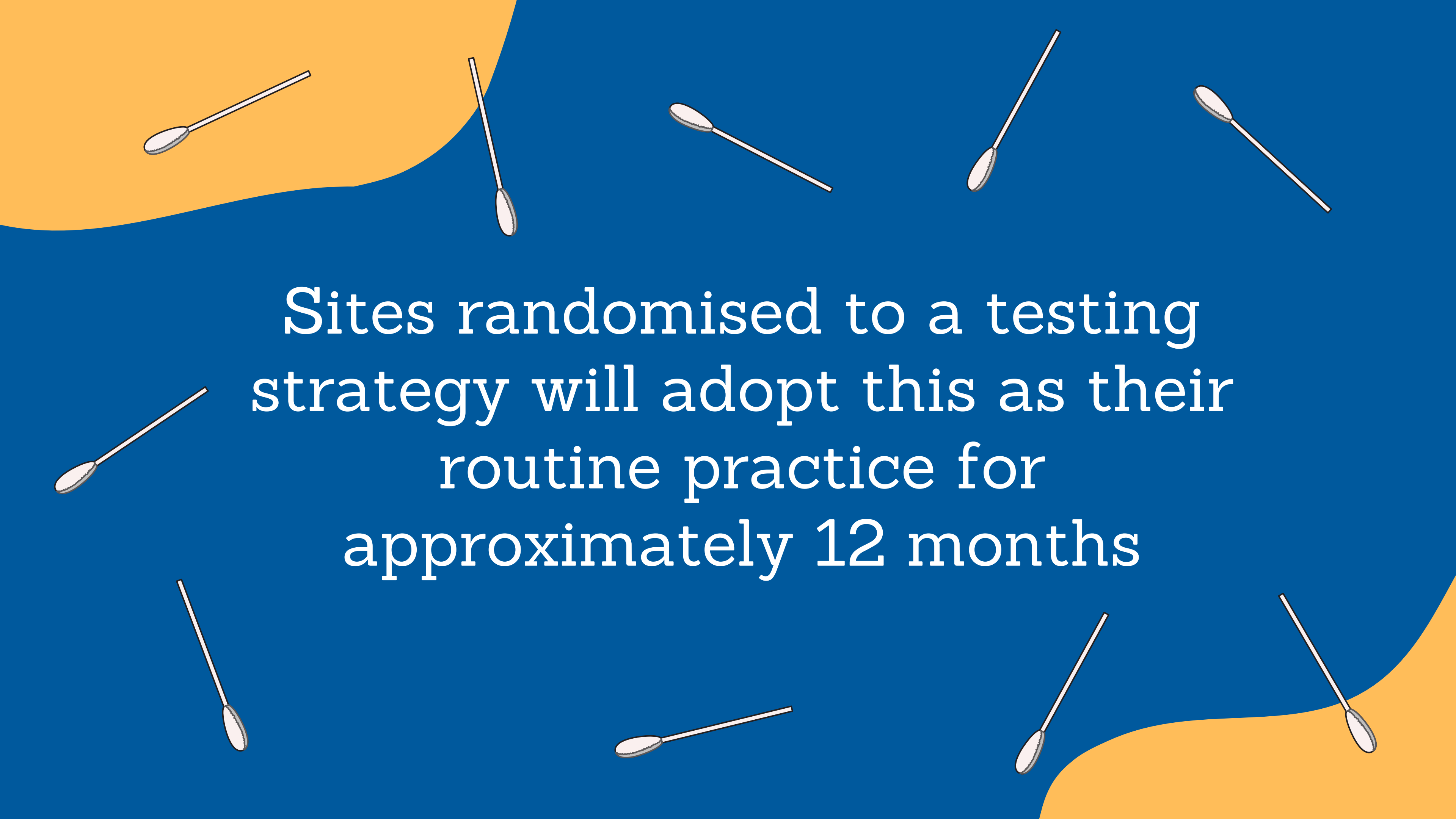




80 sites will be  
randomised to  
three different  
trial strategies

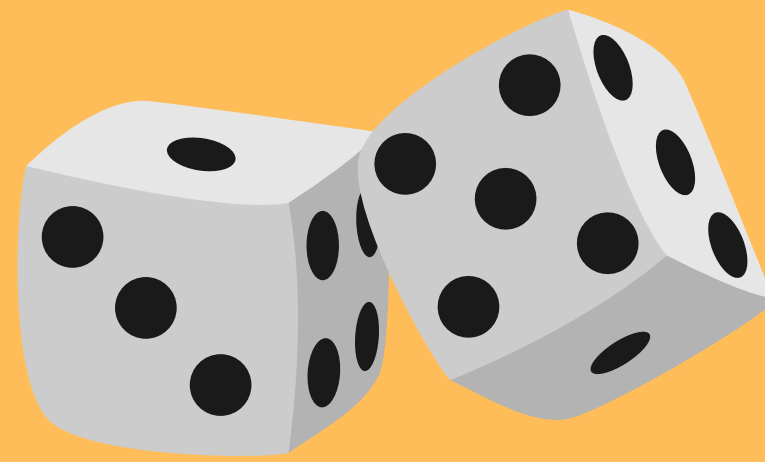




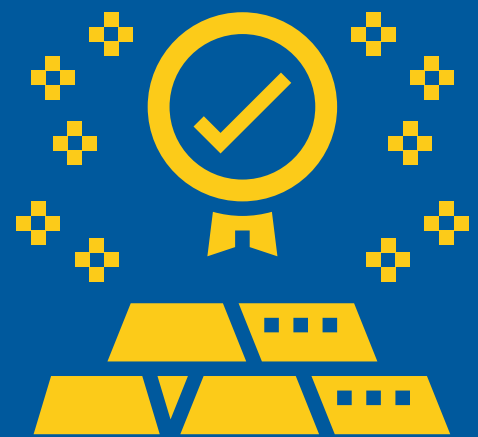


Sites randomised to a testing  
strategy will adopt this as their  
routine practice for  
approximately 12 months

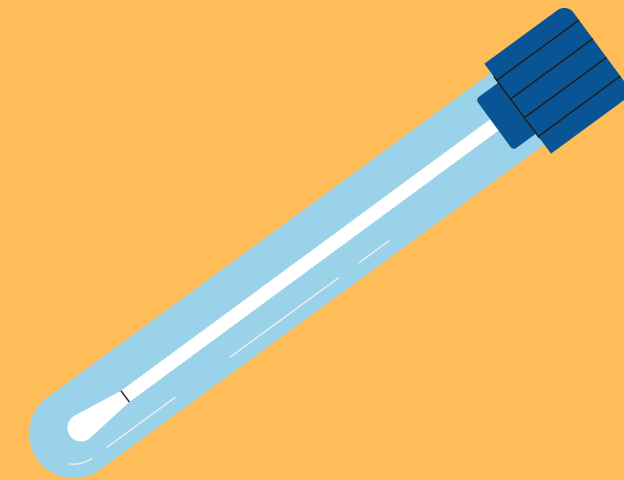
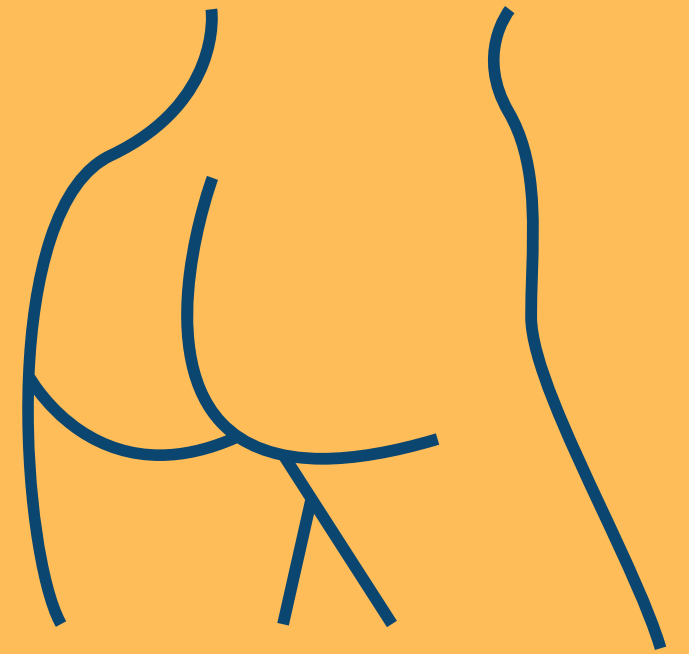
Your site has been randomised to  
Antenatal ECM (Enriched Culture Medium)  
testing



ECM is the international 'Gold Standard' for detecting GBS

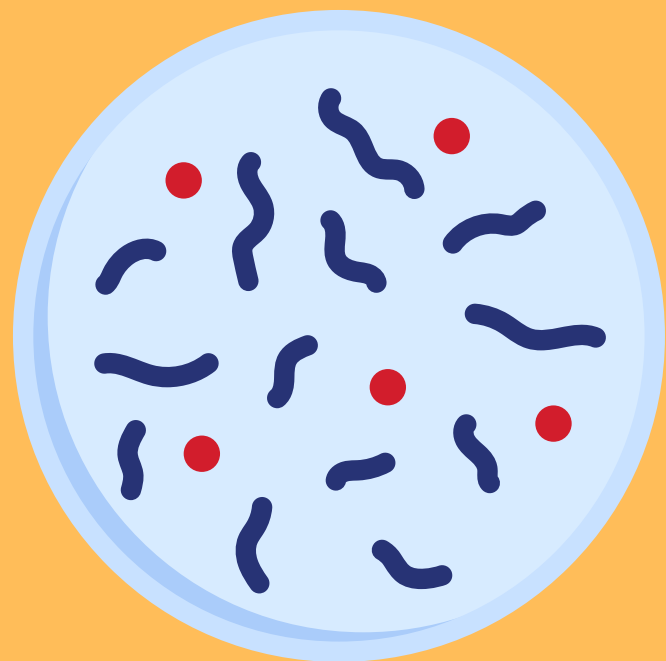


For the GBS3 Trial a  
single swab will be used  
to obtain a vaginal-rectal  
sample...



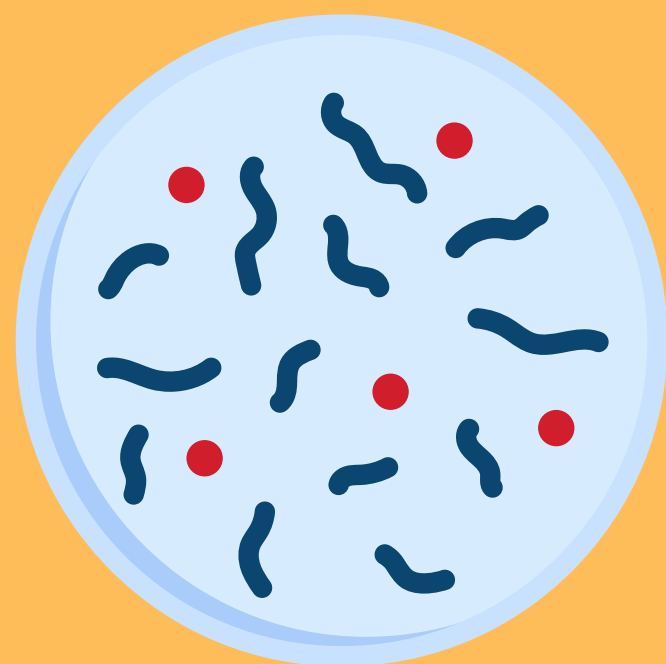


.... the swab is sent to your  
pathology lab where the sample  
is placed in a broth and cultured  
overnight....





The result is available  
within 48-72 hours



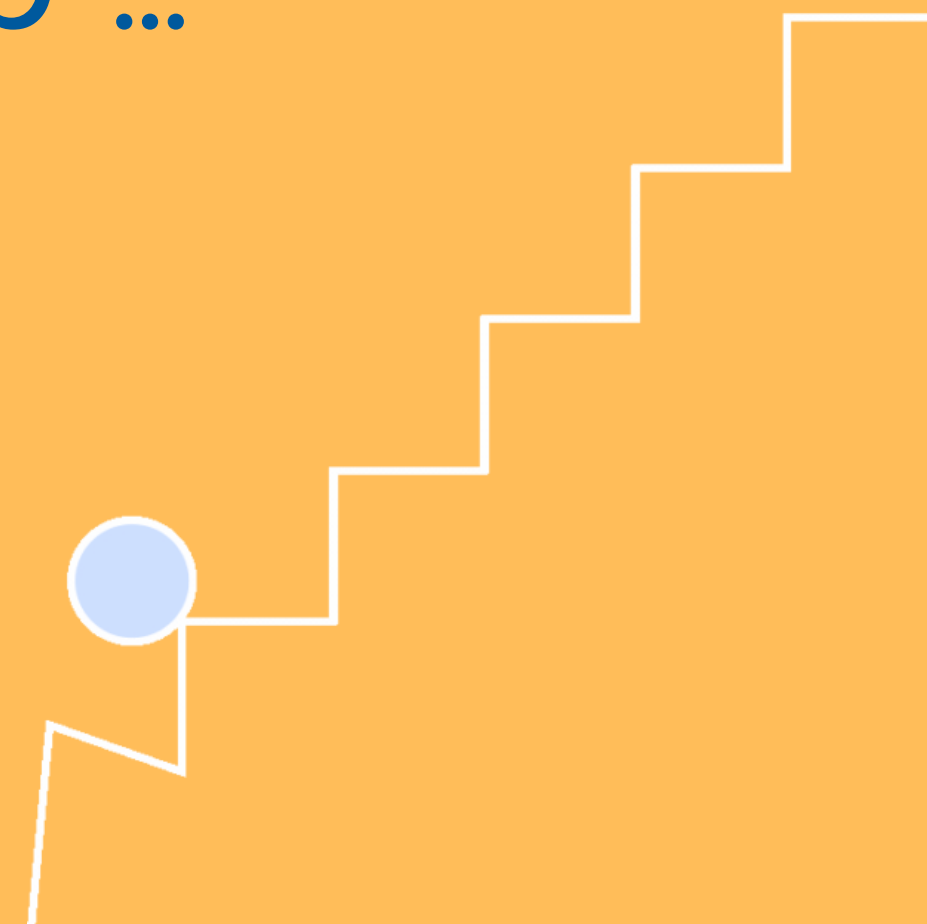


So ...what will maternity teams  
have to do?





Let's take it step by step ...







Before 28 weeks tell women that  
your site is taking part in GBS3 and  
you will offer a GBS swab 3-5  
weeks before their expected due  
date/induction date/elective section  
date

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



ROUTINE TESTING  
FOR GROUP B STREP

**For more information on the trial**

Visit [www.GBS3trial.ac.uk](http://www.GBS3trial.ac.uk)

Email: [GBS3@nottingham.ac.uk](mailto:GBS3@nottingham.ac.uk)



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



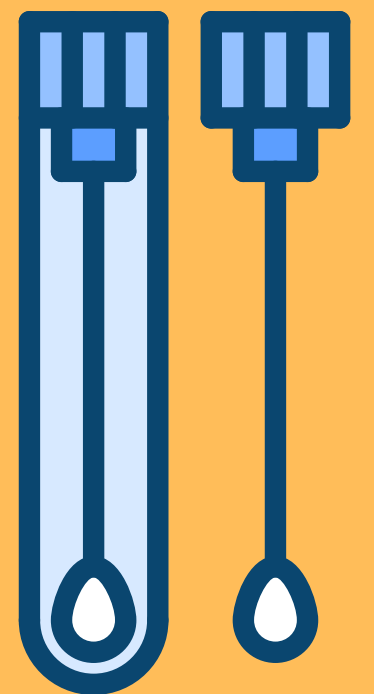
The leaflet  
has been  
adapted  
with info  
about the  
GBS3 Trial

35



37

At 35-37 weeks offer  
women the GBS vaginal-  
rectal swab



32



34

For Mums with twins+ offer the swab at around 32 - 34 weeks as we know many twins will arrive by 37 weeks



YES



NO



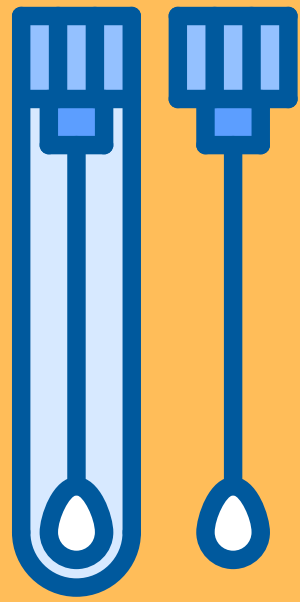
You don't need to take 'research consent' – just verbal consent as you would for any clinical procedure

you've  
GOT  
this!

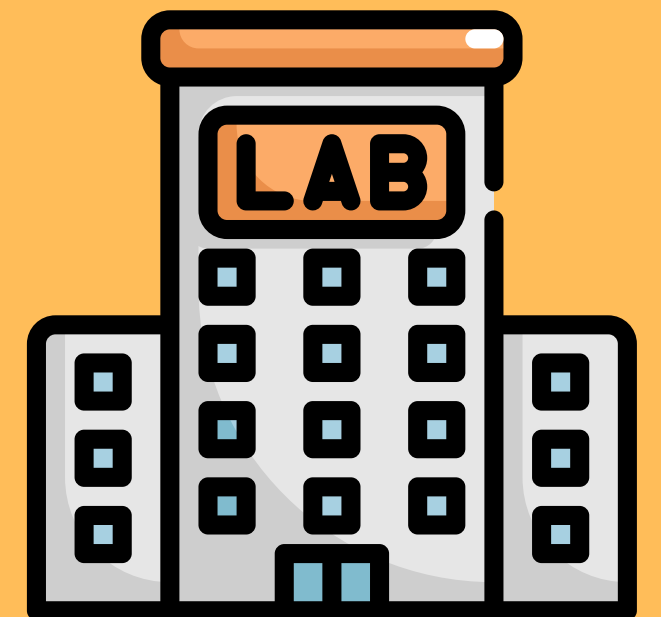
Women can take the swab  
themselves if they wish - a self  
swab leaflet will be available

(Please record in your clinical  
notes if the woman has self-  
swabbed)





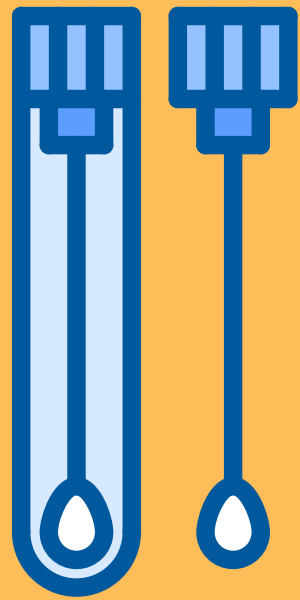
Label and process the swabs as per your usual system - adding 'for ECM GBS' (or the wording that has been agreed locally by your team) to your request





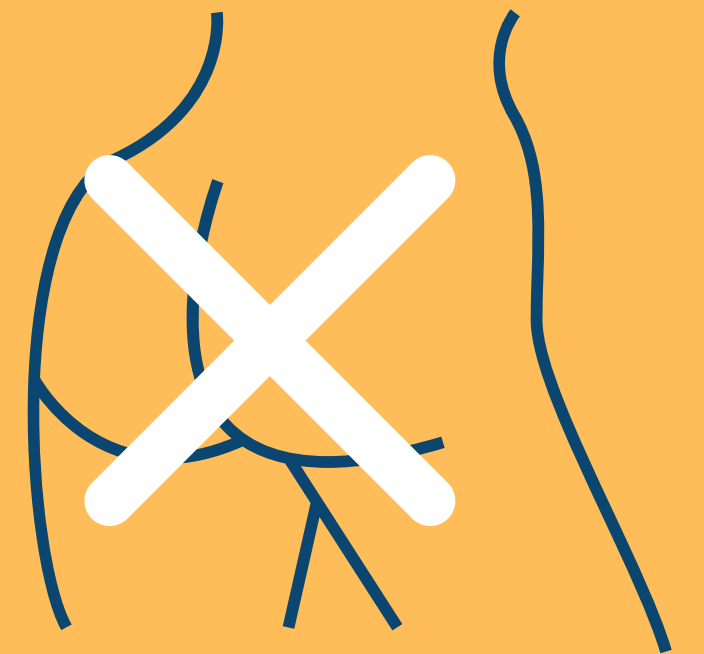


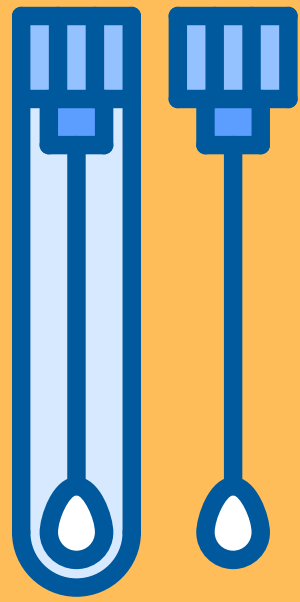
...and for all trial swabs remember to add an orange GBS3 sticker to the transport tube and the pathology form (these stickers will be provided)



DON'T FORGET

If women decline the rectal part of  
the swab - a few things to  
remember ...



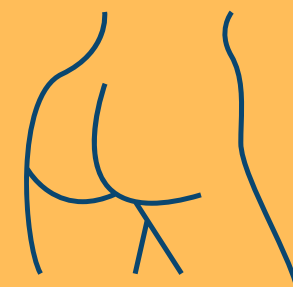


**IMPORTANT!**

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

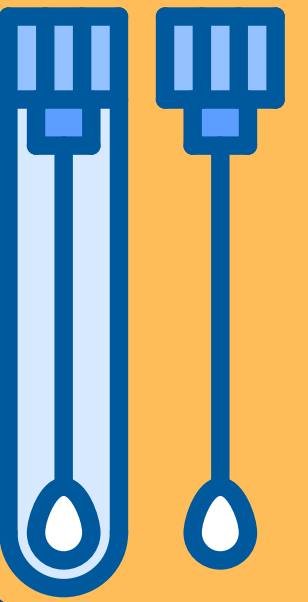


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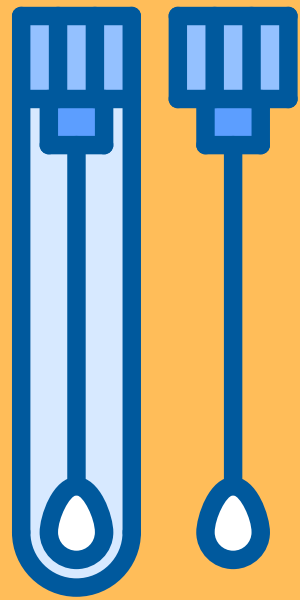


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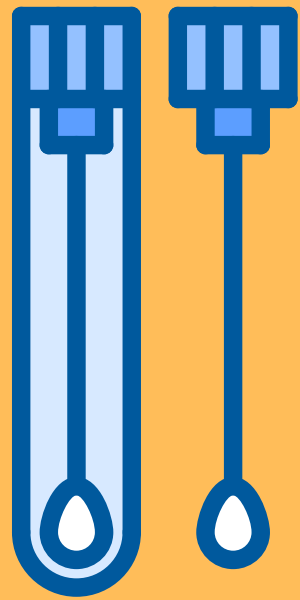
**More accurate  
test**



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

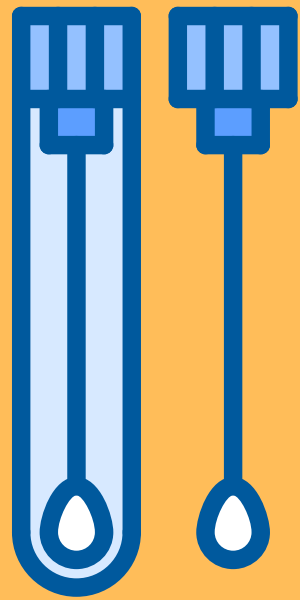


So a vaginal swab only may mean  
an opportunity to detect GBS in the  
GI tract is missed



But of course - the woman's choice  
is paramount ....





So.. if a vaginal swab only is obtained then please make sure you make a note of this in your clinical records and on the swab transport tube and lab request

(similarly, if a woman requests the rectal swab only, please record this)



A week after taking the swab  
check your patient  
record/pathology systems for  
the result







Inform women and clinical  
teams of results as per your  
normal practice





... and when a woman is GBS positive, if possible, place an alert on her notes

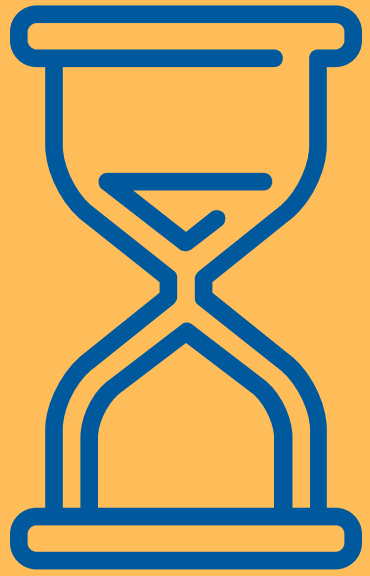




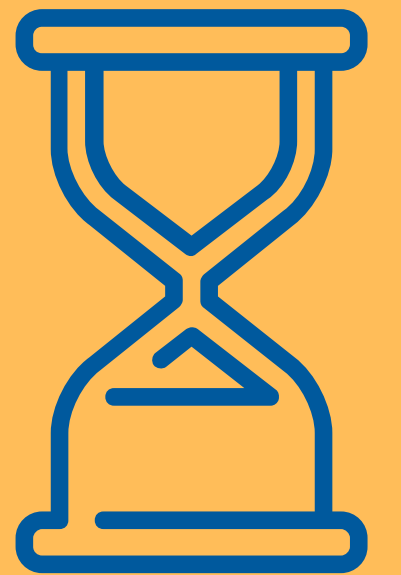
If the swab has not been taken  
between 35-37 weeks...

...take one as soon as possible

There is no 'cut-off gestation' for  
testing



If you can turn around a result  
before labour commences or  
I.O.L then get a swab done





# Delivery Suite Teams....





Check a woman's GBS status  
when she is admitted in labour or  
for induction....





If 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



# 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





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





Q&A

1.



Are all women offered a GBS swab?



Q&A



No, not quite...

Do not offer a GBS swab to ..





Women with a baby with a congenital abnormality 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)



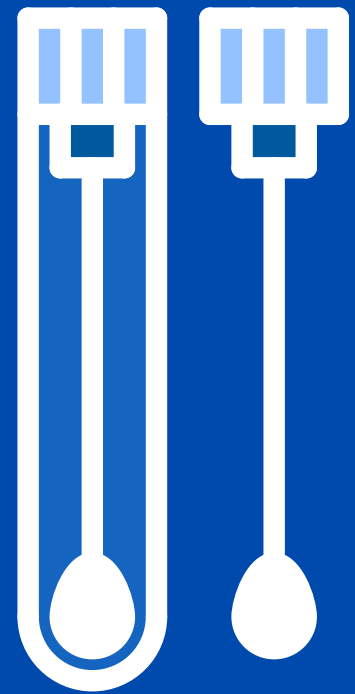
Q&A

And note  
that ..

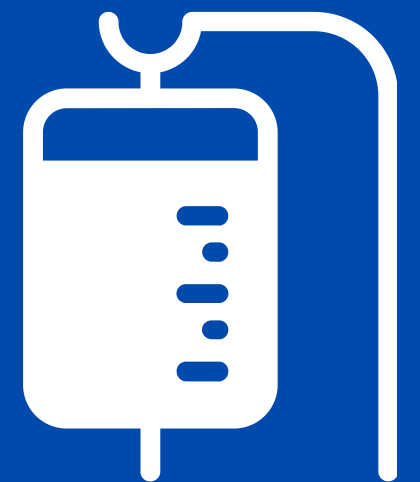


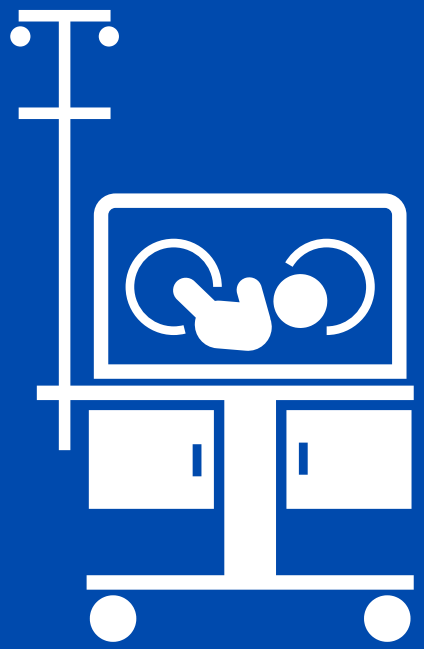
If a woman has previously had a  
baby with early or late onset GBS

Q&A



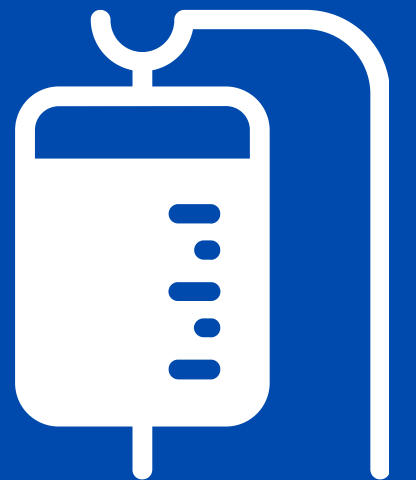
You can offer her an antenatal  
ECM test ...





Q&A

But reassure her that she can have  
IAP in labour regardless of the  
ECM 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](http://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 ?



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

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/>



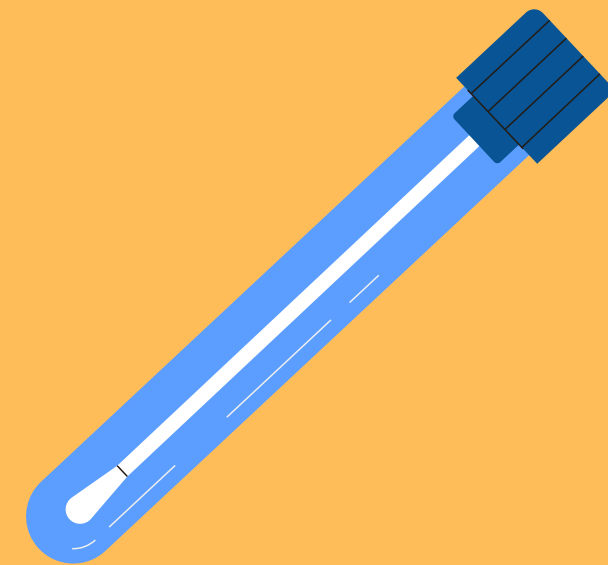


And explain this will not affect their care but it will remove their data for all research and planning – not just for GBS3





Is a special swab required for the  
ECM test?



Q&A



No ..your usual Trust swabs that you use for vaginal swabbing are fine





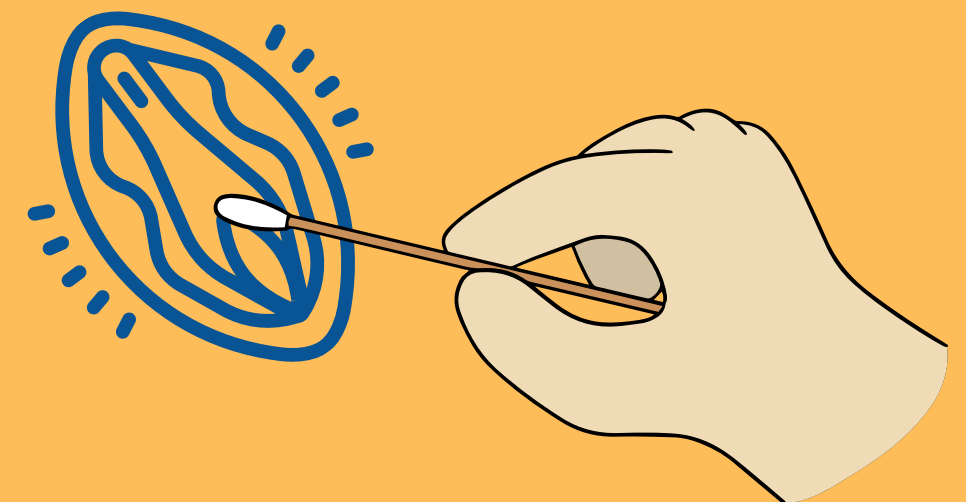
Can we have more detail on the vaginal-rectal swab process?





Swab the vagina first - a LVS no more than  
2-4cm into the vagina

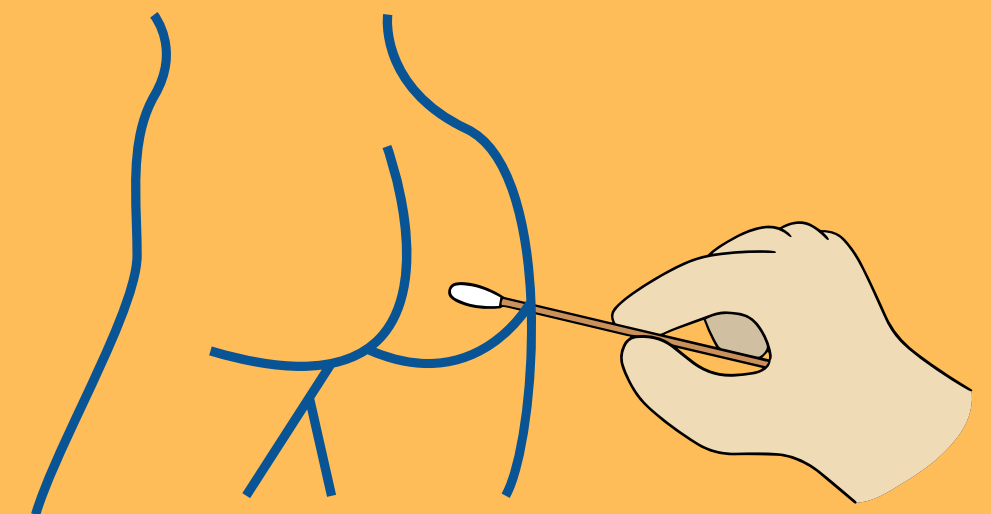
Rotating the swab around the lower vaginal  
wall for 10 - 15 seconds





Then insert the tip of the same swab into the rectum, just 1-2cm beyond the opening of the anus

And gently rotate the swab tip around the rectum wall as you slowly remove the swab



# Q&A

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





What about women booked for elective sections?

Do we still offer them an antenatal ECM swab?







Yes ..because a number of women booked for elective sections will go into labour and opt to progress to a vaginal delivery





What about women planning to have their baby at home or in a birth unit where it is not possible to have IAP?





Still offer them an antenatal ECM swab – if they are GBS positive they can then make an informed choice about their place of birth





More questions?

Take a look at the GBS3 website ...  
[gbs3trial.ac.uk](http://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...



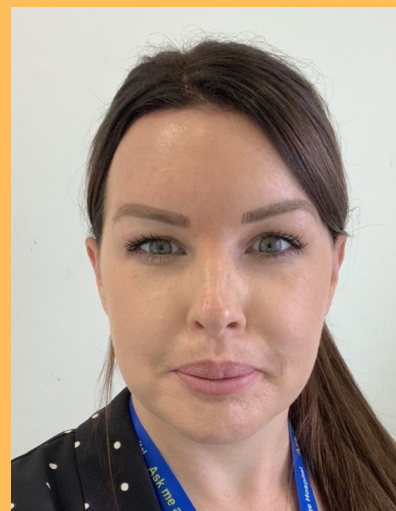
*Kerry*

## GBS3 Research Midwives...

*Jodi*



*Sophie*



*Heidi*





Senior Trial Manager



*Beki*

Trial Manager



*Ellie*



*Jo*

Trial Co-ordinators

*Baz*



*Lixiao*



Trial Administrator

And the GBS3 Chief  
Investigators...

*Jane*



*Kate*



We are all here to help ...

Email us:

[GBS3@nottingham.ac.uk](mailto:GBS3@nottingham.ac.uk)

Follow us on Twitter...

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