

WELCOME TO THE GBS3 TRIAL

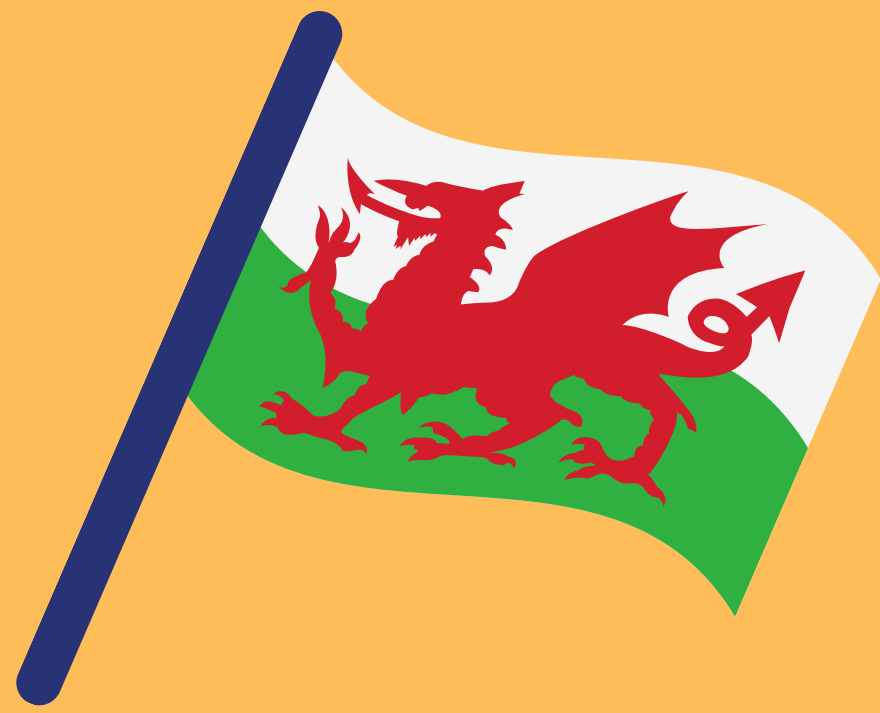




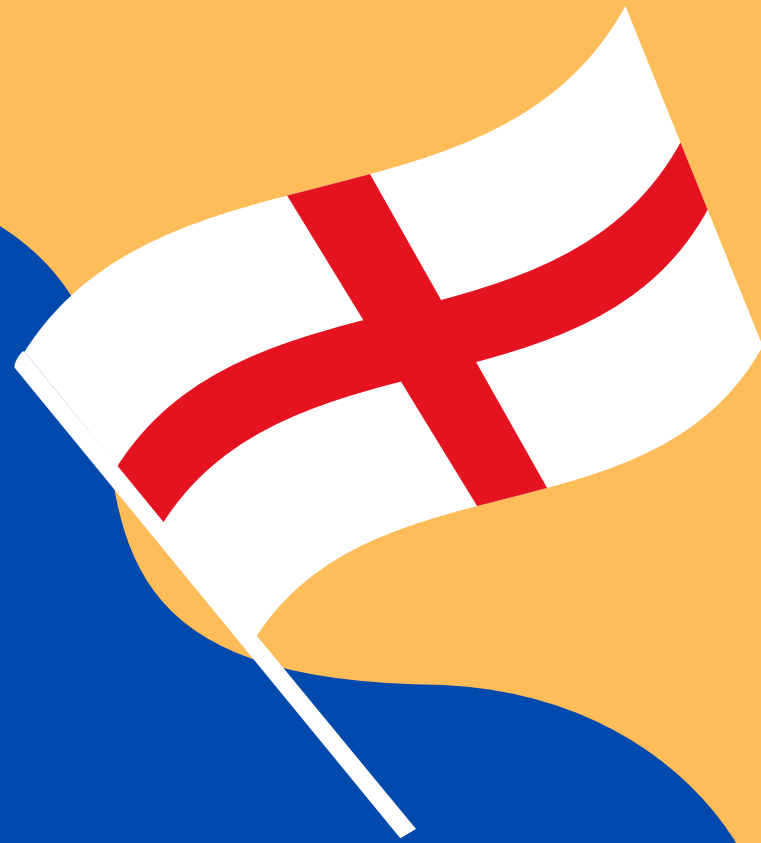
ROUTINE TESTING
FOR GROUP B STREP

What is the GBS3 Trial?

A Randomised Controlled Trial



Involving 80 NHS
sites across
England, Scotland
and Wales





320,000 pregnant women !



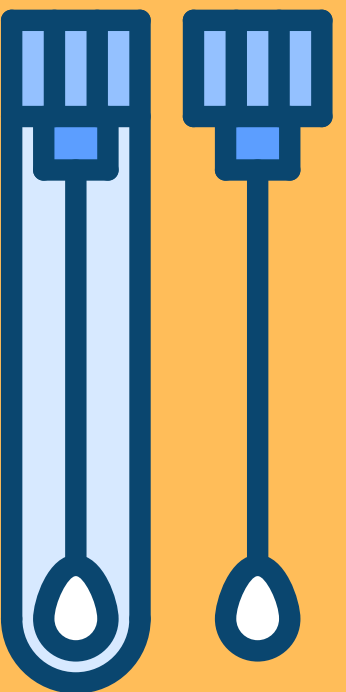


What question is GBS3
asking ?





Does routine testing for
GBS reduce early onset
neonatal sepsis?



Why is GBS3
asking the question ?

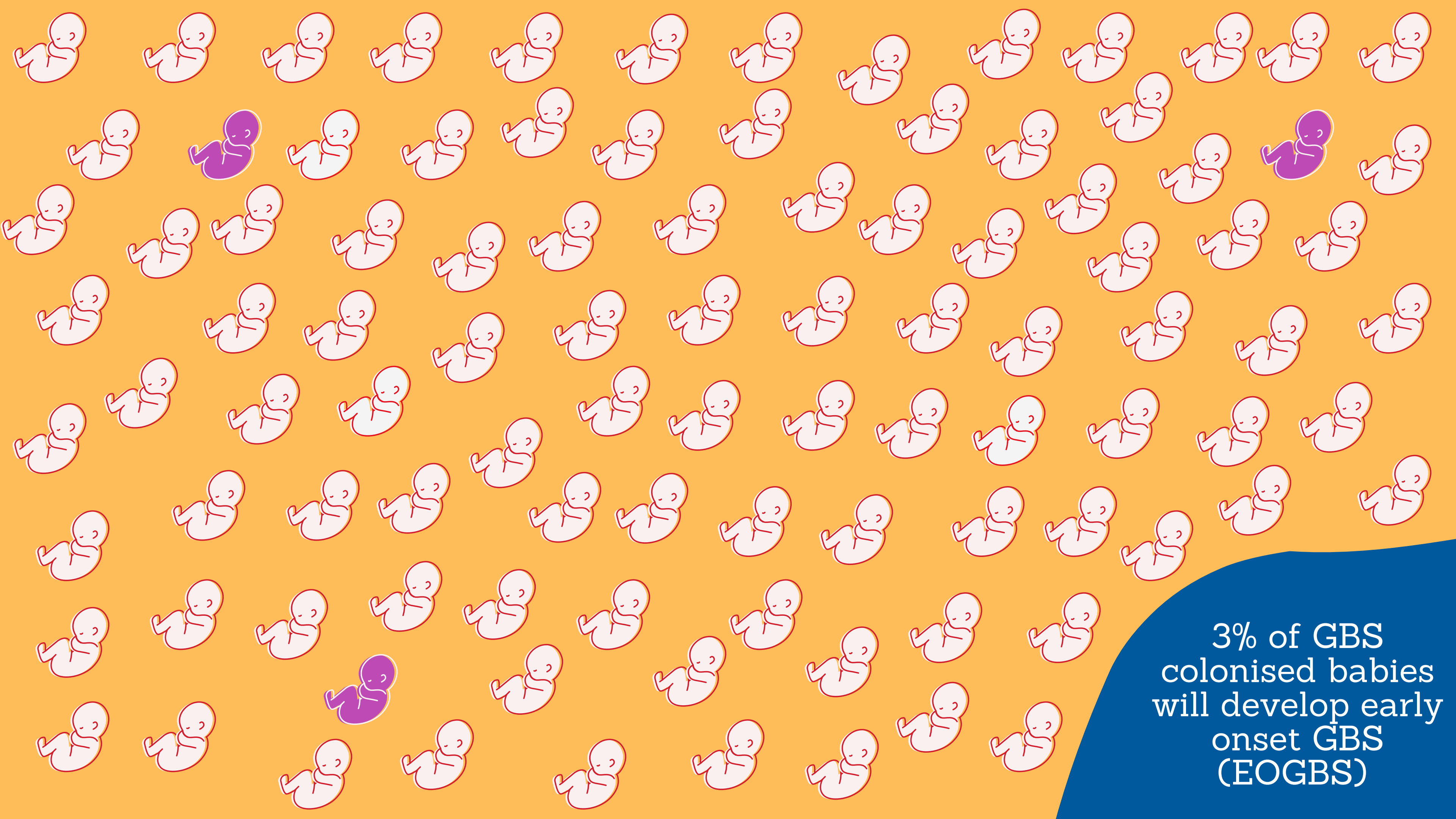




One in four
pregnant women
carry GBS in their
gut and/or genital
tract



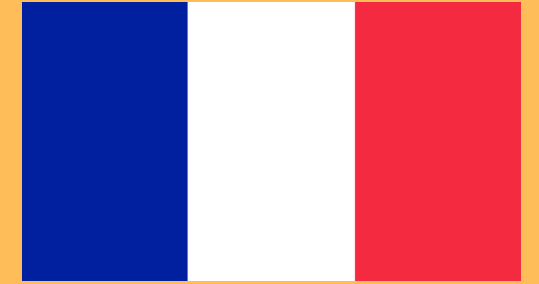
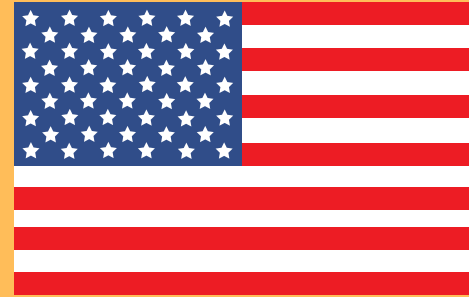
50% of babies of
GBS colonised
mothers will also
be colonised with
GBS



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

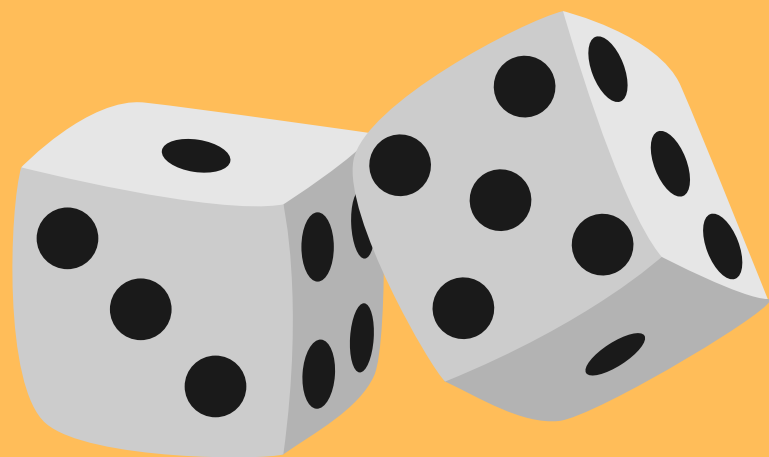
And thus the GBS3
Trial was born ...



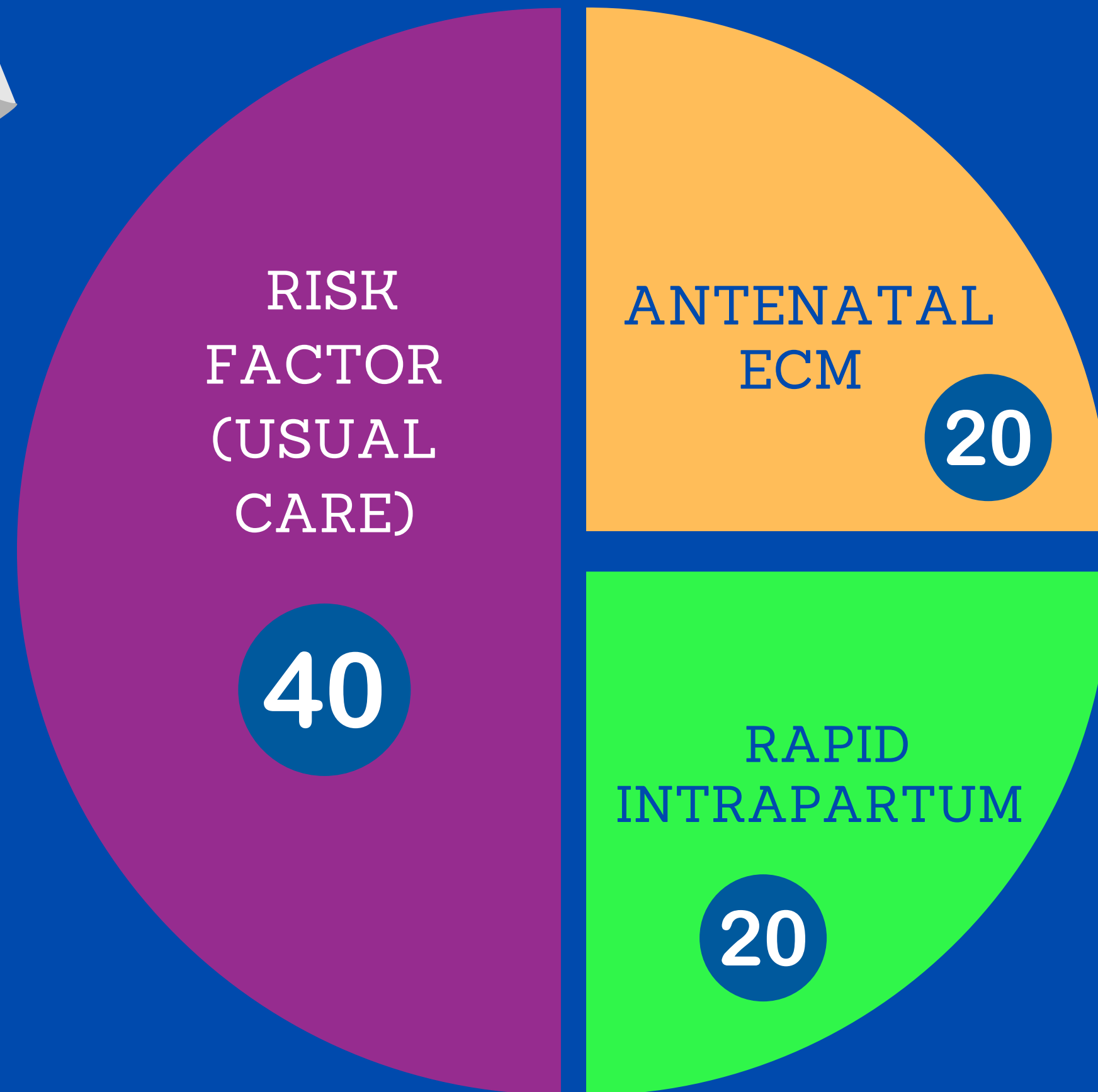
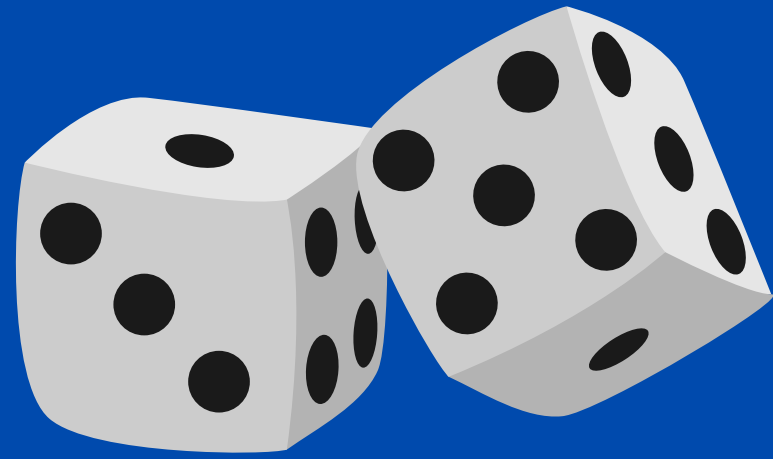


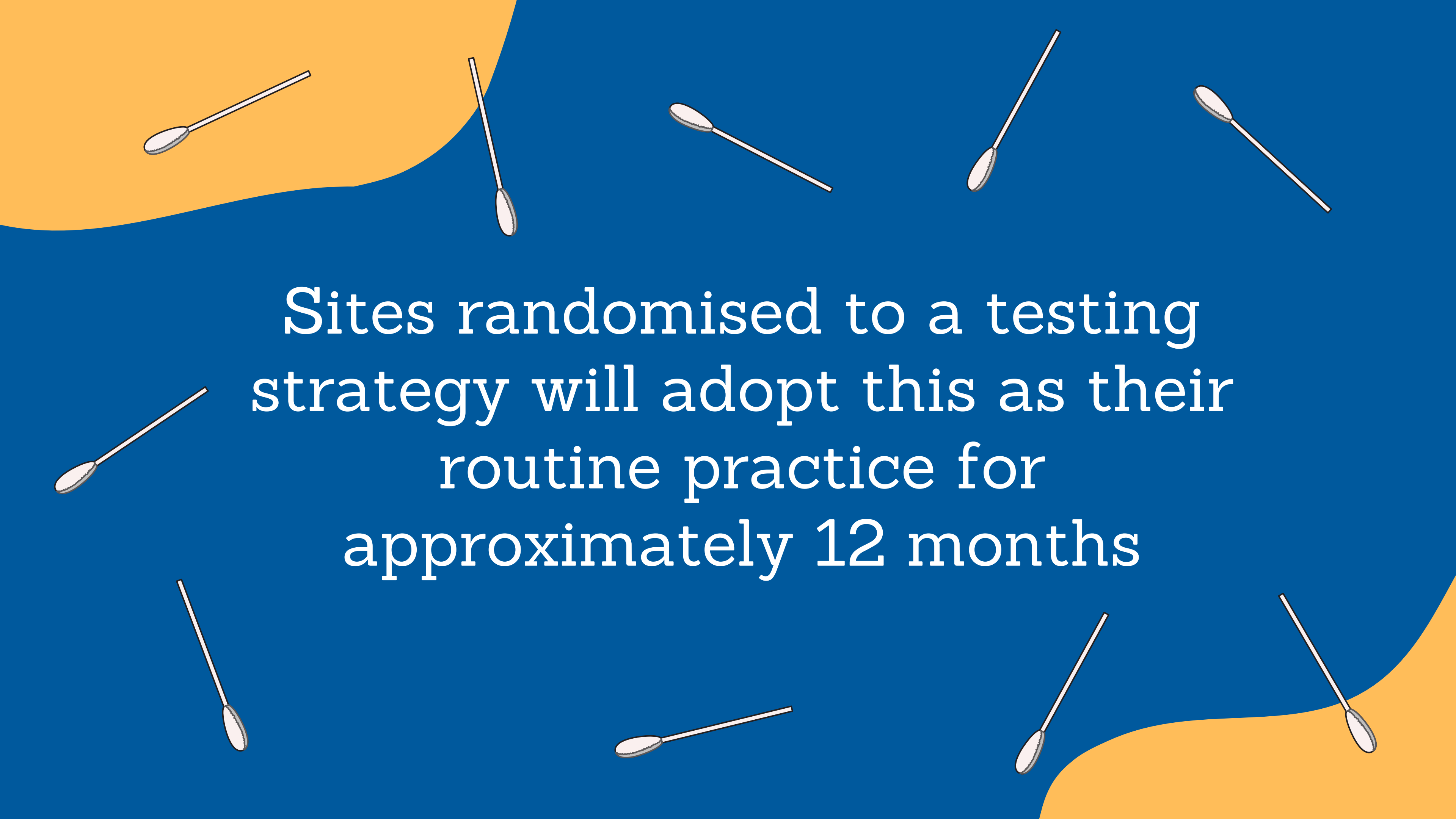
So how will GBS3 work?





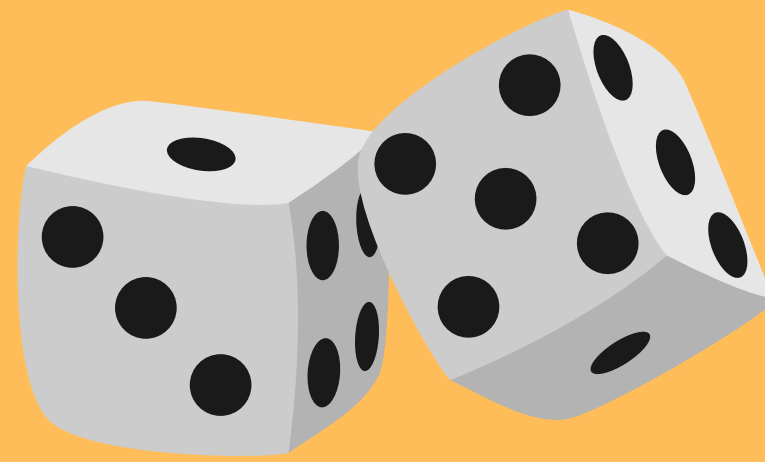
80 sites will be
randomised to
three different
trial strategies







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

Your site has been randomised to
Risk Factor (Usual Care)



Sites randomised to risk factor
(usual care) will be open as
part of the GBS3 trial for 10
months





This means your Trust will
continue with its' current practice
regarding GBS detection and
offering of IAP



Which should be in line with the
RCOG Green Top Guideline 36 (2017)



Royal College of
Obstetricians &
Gynaecologists

Which involves testing women and/or
offering Intrapartum Antibiotic
Prophylaxis (IAP)

...based on the identification of
maternal risk factors for having a
baby with EOGBS...

The background consists of a solid orange field with two large, flowing, organic shapes in a vibrant blue color. One shape is located in the top right corner, and the other is in the bottom left corner, creating a sense of movement and depth.

A quick reminder of these risk
factors....

1

Having had a baby previously with GBS infection (these women are automatically offered IAP)

2

Detection of GBS carriage in this pregnancy (via swab or in a urine sample) - these women are offered IAP and UTI's are treated at the time

3

Preterm labour (offered IAP regardless of any known GBS status)

4

Pre-labour rupture of membranes
(IOL and IAP if known GBS carrier in
this pregnancy)

5

Carriage of GBS in previous pregnancy
but baby not affected (discuss IAP
options, offer GBS swab in late pregnancy
and offer IAP if positive)

6

Women who are pyrexial in labour should be offered broad-spectrum antibiotic cover which should include GBS cover

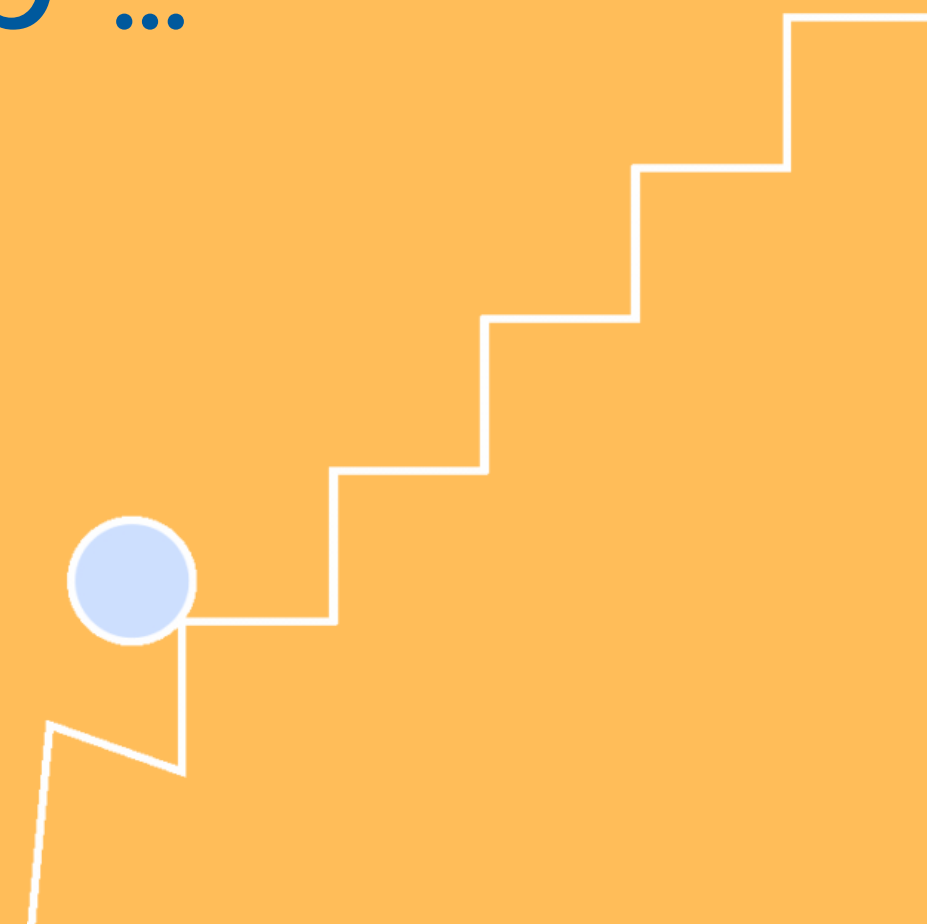


So ...what will maternity teams
have to do for GBS3?





Let's take it step by step ...





Before 28 weeks gestation
community midwives/antenatal
teams inform women that your site
is taking part in the GBS3 trial

But that your Trust will not be
changing its practice because you
have been randomised to 'Usual Care'

Which means continuing with the
current UK guidelines regarding
detection and treatment of maternal
GBS

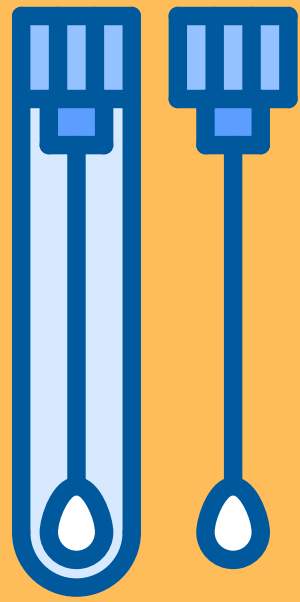


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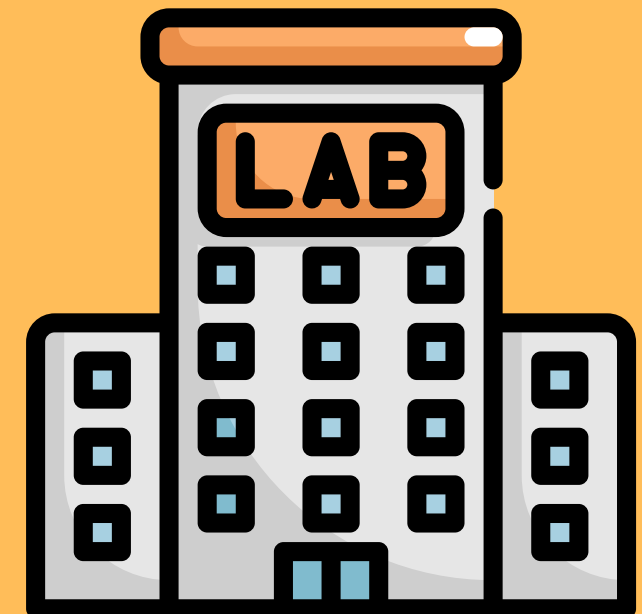
And... in line with RCOG guidelines -
provide all women with the
RCOG/GBSS leaflet...



This leaflet is also
available in 14
languages - in
electronic format :
gbss.org.uk



Label and process any swabs that
you take as you would in your
normal practice....





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





Delivery Suite Teams....





Follow your usual GBS practice....





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





If GBS positive or symptomatic of infection offer and commence IAP (Intrapartum Antibiotic Prophylaxis) as per your Trust guidelines....





Complete clinical records as per
your usual practice....



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







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



Q&A

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



THIS UNIT IS INVOLVED IN THE GBS3 TRIAL
For more details go to www.GBS3trial.ac.uk, speak to your local team (details below), ask for an information sheet or scan the QR code in the bottom right.



Limited data from the relevant part of your medical notes are being collected by researchers for an important trial on preventing potentially life-threatening Group B Strep Infection in newborn babies.

You have the right to opt out of your data being used.
To find out how visit: www.nhs.uk/your-data-matters or speak to your GP.

STICKER HERE



GBS3_Patient England_Flowchart_20200421

Q&A

And a GBS3 Patient Information Sheet will be available upon request..along with a 'participant card' that gives women the GBS3 Trial contact details



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FOR GROUP B STREP

For more information on the trial

Visit www.GBS3trial.ac.uk

Email: GBS3@nottingham.ac.uk



@GBS3Trial

..and you can simply 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 ?



No...the beauty of the GBS3 Trial is that it is very simple for clinical staff...let women know about the GBS3 trial but continue with your current GBS practice



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/>



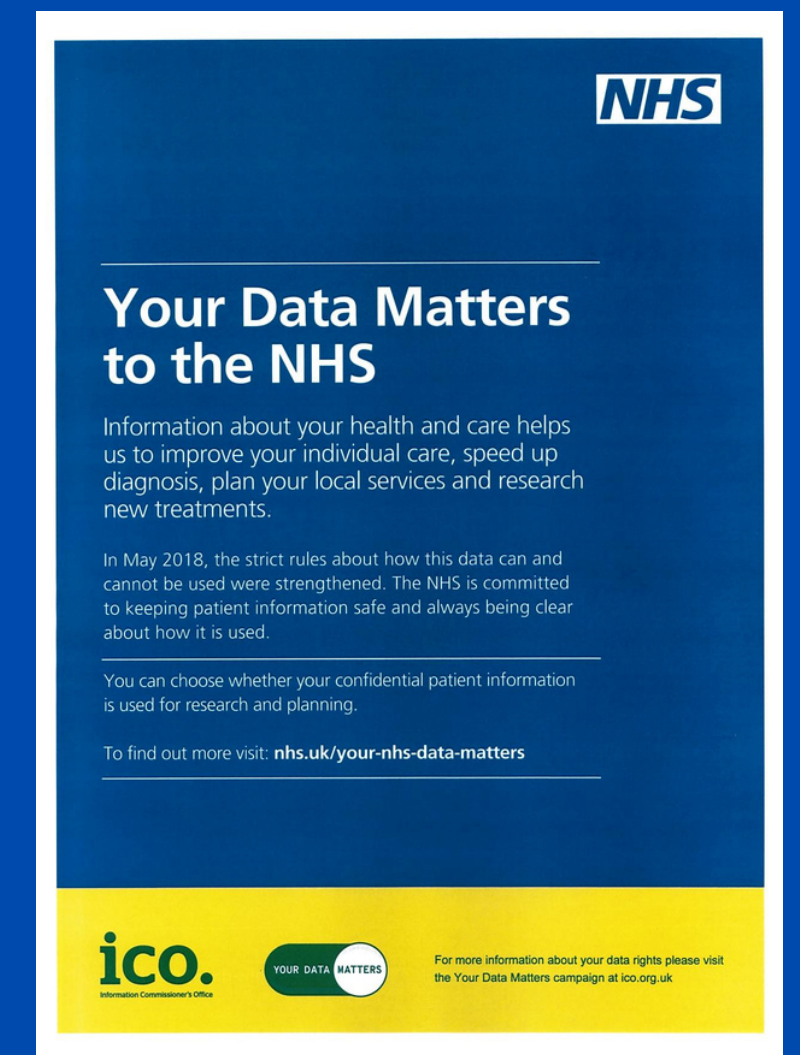


They will have to follow the
instructions to opt-out





Your Research Midwife will ensure the NHS 'Your Data Matters' poster is displayed in appropriate patient and clinical areas



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





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

Trial Manager



Ellie

Baz



Trial Co-ordinators



Jo

Trial Administrator



Lixiao

And the GBS3 Chief Investigators...

Jane



Kate



We are all here to help ...

Email us:

GBS3@nottingham.ac.uk

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