

Video Explaining Randomisation

A link to the animation can be found here: <https://youtu.be/NB47BEwoTQU>

In this short animation, we'd like to explain Randomisation

Visual of neonatal unit

Narrator: "Meet Farah, whose baby, Abdi, was born preterm. Abdi is in the neonatal unit so he can receive the extra care needed for babies born preterm"

Farah (thinks): "I really hope Abdi gets better soon and I can take him home."

Narrator: "When Abdi is admitted to the neonatal unit, Farah is encouraged to express milk as he is too premature to go directly to the breast.

Farah: I really want to express milk for Abdi as I know this is the best food for him. But I'm finding it really hard. I'm just so tired and anxious about Abdi.

Narrator: After a few days, Abdi is able to take more milk and Farah finds she doesn't have enough.

Nurse: While your milk supply is picking up, we can give Abdi pasteurised donor milk.

Narrator: The nurse asks for Farah's consent. Farah says she will discuss it with her family.

Farah: I discussed this with my cousin Sadia, who had a preterm baby in another hospital. Sadia told me that in her hospital they used preterm formula when there wasn't enough milk from a baby's own mother. I was really confused by this; why would one hospital choose pasteurised donor milk and another hospital choose formula?

Visual: Making choices

Narrator: Both pasteurised donor milk and preterm formula are used in neonatal units in the UK. The problem is we don't know which is best AS A SUPPLEMENT when a SUPPLEMENT IS NEEDED.

In the UK about a third of babies receive pasteurised donor milk and about two-thirds receive formula.

When there's uncertainty about the best treatment, we need research to find the answer. But in the meantime, a decision has to be made. So the clinical team makes a recommendation based on their own opinions. However, even though they mean well, this may be the wrong decision.

The only way to give every baby an equal chance of getting the best treatment when we don't know what this is, is called randomisation

Visual: Why ensuring every patient has an equal chance of getting the best treatment is important

Doctor: An example of why giving every patient an equal chance of getting either treatment is important in antenatal steroid treatment for Mum's at risk of delivering a preterm baby. In the 1980s and 1990s some doctors wondered if this might increase infection in Mums and have other side effects. Other doctors thought it would be beneficial. It wasn't possible to give reliable advice.

So, in clinical studies many thousands of Mums agreed to have the decision of receiving steroid treatment or not, made by randomisation. As a result, we now know for certain that antenatal steroids reduce the likelihood by up to half, of a preterm baby dying, or suffering life-long impairment. If the treatment hadn't been tested fairly, there would still be uncertainty, and many

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Commented [BD1]: check you agree, the word 'fair' was removed from some places but not all - maybe that was intentional?

Commented [AB2R1]: Yes I read it in the REC response that they had said it was fine to call the process of randomisation 'fair' but not best choice. So I left it here but also happy to remove if you prefer Rahi.

Commented [JR3R1]: Happy with Daphne's changes

millions of babies would have died or been harmed because their Mums would not have been given the treatment.

Farah: I had antenatal steroids and I know Sadia did too. Our babies benefited from this. I suppose the reason why Abdi's neonatal unit uses pasteurised donor milk, and Sadia's uses formula is because no one knows which is best.

Doctor: So, in my hospital we are recommending taking part in COLLABORATE. This is a study to find out whether we should use pasteurised donor milk or formula if there isn't enough milk from a baby's own mother. In COLLABORATE the decision will be made fairly, by randomisation.

Narrator: You can find out more about the COLLABORATE study here: QR code / collaborate@imperial.ac.uk

We'd like to thank Alima, Louise and Rafika. Parents of babies born either preterm or sick for helping make this video.