



Determining the feasibility of randomising children and young people to invasive and non-invasive urine sampling techniques

Lay summary of study results

Background:

When doctors and nurses think a child may have a urinary tract infection (UTI), they usually need to test a sample of the child's urine. This can help them decide whether the child needs antibiotics.

The usual way to collect urine is called a "clean-catch". This means waiting for the child to pass urine and catching some of it in a clean container.

UK guidance recommends non-invasive clean-catch urine collection as the first approach. Clean-catch urine collection does not hurt the child, but it can take a long time to collect the urine. Bacteria from the child's skin or nappy area can also get into the sample. This is called "contamination". If this happens, it can be difficult to tell whether the child really has a UTI. The urine test may need to be repeated, and some children may receive antibiotics they do not need.

There are other ways to collect urine. A catheter is a small, soft tube that is passed into the bladder through the opening where urine comes out. Another method, called suprapubic aspiration, uses a needle passed through the lower part of the tummy into the bladder.

These methods may collect urine more quickly and may be less likely to give a contaminated sample. However, they can cause pain or distress to the child.

We do not yet know which way of collecting urine is best:

A large research study is needed to compare the different methods. Before doing a large study, the FROG team wanted to find out whether such a study would be possible.

We wanted to know:

- whether enough families would agree to take part
- whether the different ways of collecting urine could be used in hospitals
- what information we should collect to compare the methods



Why did we do the FROG study?

FROG was a small study carried out to help us decide whether a larger study comparing different ways of collecting urine from children would be possible.

What did we do?

The FROG study had three parts.

Part 1 - Comparing ways of collecting urine

Children were recruited from hospitals in the UK. They could take part if they needed a urine test because doctors thought they might have a UTI and they could not provide a urine sample themselves.

Families who agreed to take part could be asked to have their child's urine collected using clean catch or a catheter. At some hospitals, collecting urine using a needle through the lower tummy was also considered.

We recorded information including:

- whether a urine sample was successfully collected
- how long collection took
- whether the child experienced pain or distress
- whether the child needed further hospital care.

Part 2 - Finding out what parents and healthcare professionals thought

Parents completed questionnaires and some took part in interviews. Healthcare professionals also took part in group discussions. We asked them what they thought about the study and the different ways of collecting urine.

Part 3 - Deciding what a future study should look like

Parents and healthcare professionals then took part in an online meeting. Together, they discussed the findings and agreed what should be included in a future larger study.



Results and Findings

The researchers had decided before the study that at least one-third of families would need to agree to randomisation for a larger study to be possible. Of the 170 families asked, 64 (about 38%) agreed. This was more than the minimum needed. Hospitals also recruited enough children each month to show that a larger study was possible.

Of the 64 children who were randomly allocated:

- 32 were allocated to clean catch
- 32 were allocated to catheter urine collection.

No families agreed to take part when the needle method was one of the possible options. This suggests that a future study could compare clean catch with catheter urine collection, but should not include the needle method.

The study was able to collect information about how often urine was successfully collected, how long collection took and how much pain or distress children experienced. Not every urine sample was sent to the laboratory for further testing because this is not always needed during normal hospital care. The researchers will need to take this into account when deciding how to measure contaminated urine samples in a future study. No problems or unexpected harms related to the study were reported.

What did parents and healthcare professionals think?

Most parents thought the way families were approached about the study was appropriate and that the study information was clear. Some parents thought the information sheet should be shorter. Parents and healthcare professionals felt that both clean catch and catheter urine collection could be included in a future study.

When thinking about the two methods, people considered the balance between getting a urine sample quickly and reliably and the possible pain or distress caused to the child. The needle method was not widely available, and no families agreed to randomisation when this method was included. For this reason, the researchers decided it should not be included in a future larger study.

What should happen next?

Thirteen healthcare professionals and six parents took part in a final meeting to discuss what a larger study should look like.



They agreed that a future study should:

- include children under 18 months old who come to hospital with a suspected UTI
- compare clean catch with catheter urine collection
- not include the needle method.

They thought the most important question was whether each method provides an accurate urine result and what happens when a sample is contaminated.

What does this mean?

FROG showed that a larger study comparing clean catch with catheter urine collection appears to be possible.

FROG was not large enough to tell us which method is best. A larger study is now needed to find out which method gives the most reliable urine sample while causing the least pain and distress for children.