What members of the public think about taking part in medical research during a pandemic of an influenza-like illness: a study across four European countries

REPORT FOR STUDY PARTICIPANTS

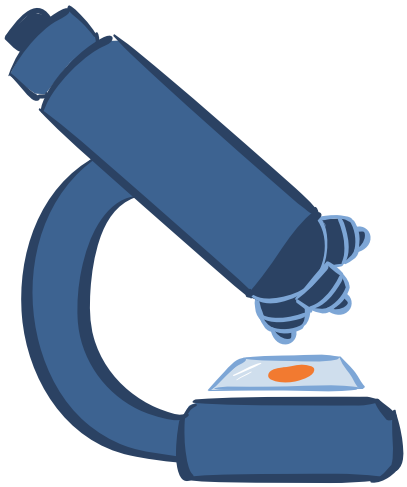
Introduction

We spoke with members of the public to understand how they would feel about taking part in medical research during a pandemic flu outbreak.

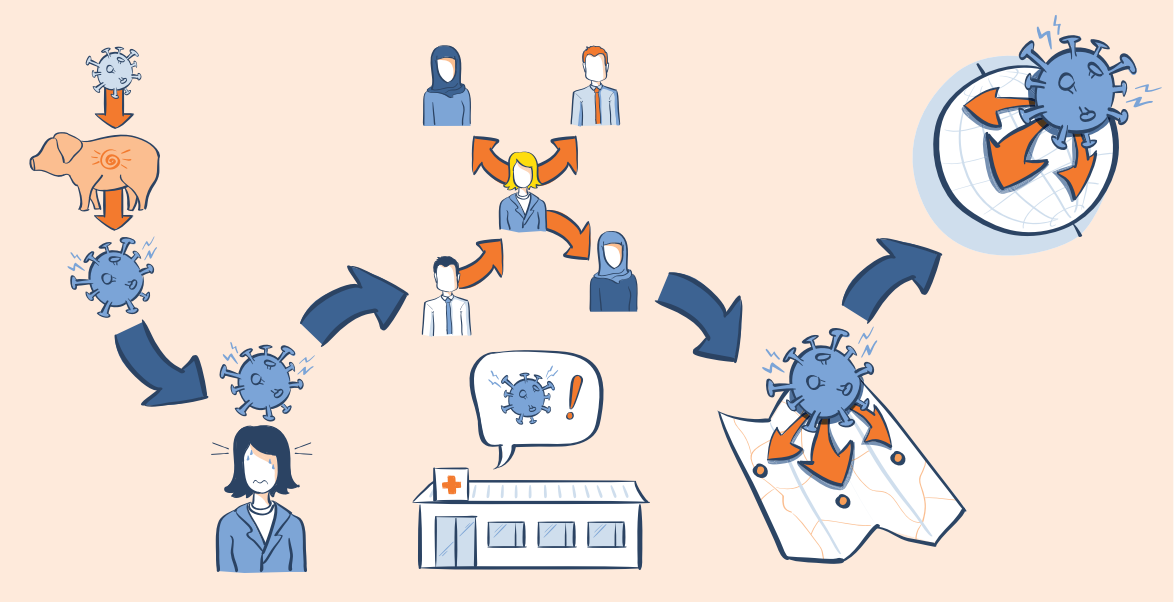
Pandemic flu happens when a new type of the flu virus develops. Because it is new, people have little or no immunity to it. We need to do research quickly to understand how the virus works and how to treat people when they get ill with it.

Once a disease outbreak happens there is very little time to set up research and get all the necessary approvals before a study can start. In the last flu pandemic in 2009, scientists weren't able to do much research mainly because it took too long to get research studies up and running. It is important that we are prepared to do research long before the pandemic starts and spreads. We also need join up with other countries to do pandemic research. Infectious bugs don't stop at borders and can spread quickly and easily.

We start this report with some background and information about what a pandemic is and how we did this research and then present our main findings.



What is a pandemic?



How pandemic bugs spread

A pandemic of an infectious disease happens when a new bug, or a new version of an existing bug, spreads quickly across the world. When the spread happens across a particular region but is not global, it is called an epidemic. Epidemics start from a disease outbreak. An infectious disease outbreak happens when more people in a community become ill than is expected in a community or during a season.

What causes a pandemic?

The bugs that can cause epidemics or pandemics often start in animals first. Sometimes the bugs then mutate so they can be passed from the animals to humans and from human to human. For example, Ebola passed from bats to humans, the Middle East Respiratory Syndrome (known as MERS-CoV) passed from camels to humans. The last pandemic flu happened in 2009 and was known as Swine flu because it transferred from pigs to humans. One the infectious bug has transferred from animals to humans, they can transfer between humans.

How do pandemics spread?

Different bugs spread in different ways and some are easier to control. Flu can spread easily from person to person because it travels through the air, for example through sneezing and coughing. This makes it very difficult to control. The flu virus can cross countries and continents easily too because of the way in which we live for, example, with frequent air travel.

How ill do people get when there is a pandemic flu?

Pandemics can cause different strengths of illness. For example, the 2009 swine flu pandemic caused fairly mild illness for many people whereas the flu in 1918 made many people severely ill. A pandemic flu bug can affect different groups of people differently too. So it might cause mild illness among some groups of people whereas others would become more severely ill if becoming infected. Even if a pandemic flu causes mild illness in most people, such as the 2009 swine flu outbreak, there is still has a significant impact on health services. This is because

many people become ill. A portion of people will develop additional infections and will need medical treatment.

Who is most at risk?

We tend to think of children, the elderly or people with existing health conditions as most vulnerable. But this is not always the case. In the 2009 swine flu pandemic young, healthy people were at most risk. At the start of an outbreak everyone is potentially at risk because we don't know enough about the new kind of flu. Finding out who is most at risk in any new outbreak is a top priority for researchers, doctors and people working in public health to help them make decisions about how best to deal with the outbreak.

Who decides when a disease outbreak becomes a pandemic?

The World Health Organisation monitors disease outbreaks across the world through disease surveillance programs. The World Health Organisation member countries are legally required to notify the World Health Organisation of disease outbreaks that are of international importance. Global flu surveillance is highly developed and new strains are closely monitored. World Health Organisation uses pandemic phases to alert governments to the threat of a pandemic outbreak. For example, they will declare a lower level (level 1-2) when monitoring viruses in animal populations and a higher level (level 3) once sustained human-to-human transmission has been observed. You can find out more about the WHO pandemic levels here: http://ecdc.europa.eu/en/healthtopics/pandemic_preparedness/basic_facts/pages/who_pandemic_phases.aspx

How do governments keep their citizens safe during a pandemic?

Public health authorities are responsible for keeping citizens safe in a pandemic. Public health plans will involve working with many different sectors of society. The health sector will be at the front line of caring for people who become ill, but other sectors such as schools and the police will also be closely involved. Public health authorities will have a plan for gathering information about the pandemic and communicating this with key stakeholders. For example, they will inform citizens of what symptoms to look out for, what to do if they become ill and what they can do to prevent the spread of the disease. Public health plans need to be joined up with clinical research plan so that what we learn through research can help public health authorities make good decisions.

Why did we do this study?

This study was done as part of a much larger project, called PREPARE (www.prepare-europe.eu). PREPARE is funded by the European Commission to do medical research if there is a disease outbreak that could lead to a pandemic. Results from PREPARE research studies would be used by clinicians and public health agencies to help them make evidence-based decisions. PREPARE has studies in primary care, in hospitals and in intensive care in many locations across Europe. These studies are being set up to run during seasonal flu times. This means that much of the work and time usually spent setting up studies and gaining the approvals needed before the research can start, will have already been done. If a pandemic were to be declared, the studies would then be ready to go into emergency response mode.

We did this study to understand what the members of the public think about taking part in research during a pandemic if they became ill. This will help us design research that best suits patients' preferences.

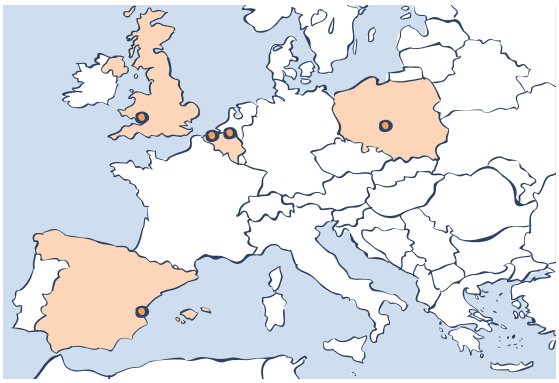
The aim of this report

We have written this report to feedback our research findings. We also hope to share our findings with a wide range of stakeholders including further members of the public, clinicians, researchers, public health agencies and government departments.

What we did

We spoke with 80 members of the public in major cities in four European countries:

- Cardiff, Wales (northern Europe)
- Barcelona, Spain (southern Europe)
- Lodz, Poland (eastern Europe)
- Antwerp and Bruges (western Europe)



Countries where we ran our study

We spoke with members of the public face-to-face in small focus groups. We chose this method because the subject of a pandemic can be complicated and we wanted to be able to speak with people directly to understand their thoughts. A few days after running the focus group, we then interviewed two members from each focus group to explore their thinking a bit more. Using these different research methods allowed us to get richer information about what people think.

Two focus groups were held in each country, except for Cardiff Wales where four focus groups were held. The first two groups in Cardiff were pilot groups where we tested our research processes.

Before running the focus groups, researchers from the four countries met in Cardiff to talk about the study, plan how we would do it in our different countries and to look together at the questions we were asking. This helped us to be sure we would be working in a similar way as far as possible.

Researchers in each country advertised for members of the public who were interested in taking part in the study. Interested members of the public contacted researchers and filled in a short questionnaire. We then invited people who had expressed interest to attend a group. We made sure we had at least one person in each focus group who was a parent or a carer and tried to make sure we had at least one person who had experience of an Intensive Care Unit. Focus groups ran for two hours and were held at different times of the day in community venues.

We asked participants:

- What they knew about pandemics and pandemic clinical research.
- What they think we should be researching during a pandemic outbreak.
- How they would feel about taking part in clinical research that was happening at their GP surgery if they were ill during a pandemic outbreak.
- How they would feel about taking part in clinical research if they were critically ill and admitted to an Intensive Care Unit during a pandemic outbreak.
- How they would feel about their routinely collected clinical samples being used for research during a pandemic.
- How they would feel about taking part in research that was designed using a new method.

We translated all our study materials, audio-recorded the discussions and then analysed our findings by looking for themes that were common across the focus groups.

A research ethics committee in each country gave us approval to run this study.

We ran these groups between July and November 2016.

Key findings

- The people who took part in our study saw a pandemic as an exceptional circumstance. They see the need for pandemic research and think it is important to do. For example, they want researchers to find out which treatments work best for which groups of people so that the people who do get ill can get better faster. They also think different rules should apply to doing research in a pandemic so that it can be done.
- The people who took part in our study think the sign up process for research in a pandemic should be quick and simple. Sign-up processes are so common in everyday life that they have lost their meaning. In a pandemic they would want to know the most important bits of information, usually about benefits to themselves and others and about risk.
- The people who took part in our study thought that researchers could use other ways of signing people up to studies, especially if taking part in the research meant that patients were exposed to the same kind of risk as when they got usual treatment. For example, for some research everybody could be automatically included with an option to opt-out.
- People use different strategies when making decisions about taking part in research. Most people seem to have a default position: either generally for taking part in research or generally against it. People need opportunities to think about their default position and to share these thoughts with people close to them.
- It is essential to maintain public trust in research. There are some common misunderstandings about research that we need to clear up so that people know what taking part will and won't involve.
- Members of the public are interested in this topic and were willing to discuss it with us in detail. They wanted more opportunities to talk about the topic and spoke of the need for public campaigns in order to raise awareness among the general population.

Our findings

What did our participants know about pandemics and pandemic research?

Why we asked about this

People's understanding of what a pandemic is will likely influence their decisions about whether or not to take part in research during a disease outbreak. There is not usually much discussion about pandemics until there is an outbreak. There is also often not much discussion about research until people are invited to take part in it. We wanted to understand how our participants developed an understanding of pandemics and research. This will help us plan how to share practical information about pandemics and pandemic research in the future.

We also had a practical reason for asking about this: we wanted to be sure that everyone had a similar understanding of pandemics and of research before asking about how they might feel about taking part.

What we found

Participants knew different amounts about what a pandemic is, including that:

- A bug that spreads quickly across the world causes a pandemic.
- A pandemic is declared once the spread is global.
- The pandemic bug comes from an animal source, for example, Ebola from bats.
- A pandemic outbreak can cause a lot of disruption to everyday life. For example, schools may need to close to prevent the pandemic spreading or hospitals may need to stop helping patients unless it is an emergency.

People's knowledge and ideas about what a pandemic is came from:

- Their personal experiences. For example, being ill with swine flu in 2009 or being vaccinated for smallpox.
- History. For example, people talked about the Black Death plague, and the 1918 flu pandemic.
- The media. For example, the way swine flu was reported in 2009 or films and TV programmes that can paint a sensationalised and stereotypical image of pandemics.

In general people felt that pandemic outbreaks were a time of national emergency. They anticipated much uncertainty and felt this could be a very fearful time for people. Participants also spoke about the 2009 Swine Flu pandemic, which was relatively mild. They had some concern the next time a pandemic outbreak happens people might not take it as seriously.

Participants identified some key priorities for researchers to focus on. These include:

- Ways of identifying disease outbreaks early so we can be prepared for a potential pandemic.
- Planning for research well before a pandemic outbreak.
- Research to understand how a bug works, how it spreads, what the symptoms of illness are, when people are infectious, and which groups of people might become most severely ill.
- Research to understand best treatments.
- Research that would give public health authorities rapid and reliable information to use in communication with the public.
- Research on the best ways to communicate with the public.

Scientists and public health experts, including at the World Health Organisation, have already identified many of these priorities.

What makes people take part in research during a pandemic?

Why we asked about this

We have some ideas about what makes people take part in research in general. But we know less about what might make people want to take part in research during a pandemic. The more people that take part in research during a pandemic, the quicker we might be able to produce results. We need to anticipate people's concerns and to design research in a way that might help address those concerns upfront.

What we found

- Participants wanted to take part in research if they thought benefits outweighed the risks or burdens of taking part. People seemed to have a default position about whether or not they would want to take part in research. They then looked at the benefits and risks to help them decide whether to stick with their default position or whether to go against it. They also said they would trust a doctor to help them make a decision. Some people thought they might refuse to take part because they deciding would be too stressful.
- Participants were also willing to take part in research to help others. Older participants, in particular, felt they had a duty to help society. Parents of young children were a bit more cautious and felt they couldn't necessarily afford to take risks with their health. If they were to take part, our participants wanted to know what the studies found. When they don't receive that feedback, they may be less inclined to want to take part in research again.

When talking about taking part in research, our participants showed a common misunderstanding about what taking part in research means.

- Most people thought that taking part would mean they would get better treatment. In fact it would be unethical for researchers to do a study if they knew one treatment was better than another. Researchers only do a study to see whether a treatment they think might work better does in fact work better than other treatments. If people took part in a study thinking that the treatment they received was better, they might be unhappy and upset if they found it didn't work. It is important for researchers to find ways of explaining this to people so that trust in research doesn't get undermined. However, in the longer term patients would get better treatment as doctors would have research evidence to help them make the best decision.
- People also misunderstood that agreeing to take part in research didn't automatically mean they would receive the experimental treatment. People might also think that any experimental treatment would be better than routine treatment. In reality, if a new treatment became available and was considered potentially effective and safe for widespread use, public health agencies might decide to make it available to everyone. Research on the effectiveness of the new treatment may only start later once there was greater uncertainty about whether it worked as well as they thought it did or not.

What do people think are reasonable adjustments to the sign-up process in a pandemic?

Why we asked about this

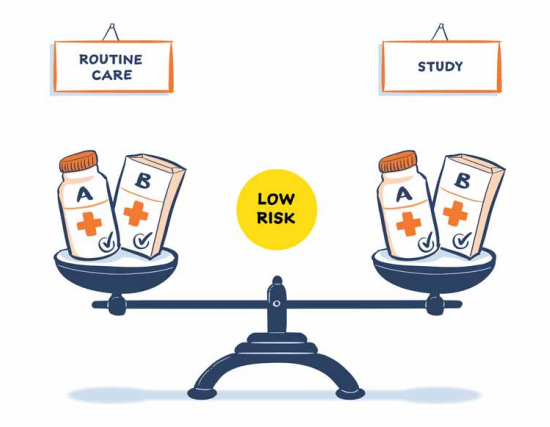
Before it can get started, all research must be reviewed and approved by a research ethics committee. A research ethics committee is made up of people with different backgrounds including doctors, researchers, ethicists and members of the public. To approve the research, they must be satisfied that it will be done ethically. For example, researchers must demonstrate that they are doing the research to benefit patients and not other undisclosed interests, like wanting to make money. Participants' rights to confidentiality and to privacy must be protected and researchers must make sure participants have all the information they need before they make a choice about whether or not they want to take part in the research.

Signing people up to research can take time. During a pandemic outbreak, there may not be the time or staff to follow these procedures in the same way we might if there were no outbreak. We need to think about other ways of signing people up to research so that it can still be done and so that the people who want to take part still can. For example, information sheets and forms where people sign that they are happy to take part in a study can be simplified. Some kinds of low risk studies could be done with different ways of taking consent, for example using opt-out models like for organ donation. We wanted to understand how members of the public feel about this.

What we found

- Participants who wanted to take part in research said the process for them to sign-up to it might put them off. They appreciated that the regulations for research are designed to protect them but some felt that the protections were more for the researchers than for the patients. They talked about signing 'terms and conditions' for lots of transactions, for example when booking a holiday, so they don't always pay attention to what they're signing up to especially if there is a lot for them to read before signing.
- Participants thought that being ill in a pandemic would be stressful and frightening. They didn't think it was fair for them or their family members to have to make a decision about taking part in research, especially if there wasn't much risk to them. They also questioned how much information they were really taking in when feeling ill or worried. Some participants felt that there were risks and uncertainties with routine clinical treatment. For example, GPs have a choice to prescribe many different treatments for a health condition and decide based on their judgment and experience. They saw little difference between receiving routine treatment and receiving that treatment as part of a research study.

This tells us that for low risk research, where the risks of taking part are no greater than the risks of receiving routine care, we might consider different ways of signing people up to it.



Taking part in research on treatments that are already used routinely everyday by doctors has the about same risk as just receiving the treatments without being in a study.

- Our study participants who were interested in taking part in research during a pandemic said we should make it quicker and easier for them to sign up to it. They said they would want to know the most important information, usually about the risks, benefits and requirements of taking part.
- Some people said they would be happy to give their permission to be included in the study verbally and others suggested mobile phones could be used to record patient consent on video. Not everyone was happy with these suggestions though. In general, participants wanted a record of their consent for taking part in any research that might present a higher risk than routine care.
- Some participants thought a register could be held where people could sign up in advance to taking part in pandemic research. Others thought it better to have an opt-out process particularly for lower risk research, so that participants would be automatically signed up and be given the option to 'opt-out' if they wanted to. In Belgium and the UK this system works for organ donation and participants thought it would be a good idea for research too.
- Participants thought existing rules for research in the Intensive Care Unit were a good idea. These rules say that a family member or a doctor might give permission for a person to be signed up to research. Some participants felt that they would not want their relative to have to make a decision like that in a pandemic and would prefer it to be made by a doctor. Participants who had had experience of Intensive Care Units talked about trusting the emergency medical teams because they see them as very experienced in caring for people who were critically ill.
- Not everyone felt their family would know their wishes about whether or not they would want to take part in research. People who said their family would know their wishes had usually had the conversation after someone they knew had become critically ill or had died. People also spoke of how the organ donation campaigns had encouraged people to talk more openly about their wishes and thought a similar campaign regarding involvement in research would be important.

What do people think about researchers using routinely collected clinical samples for pandemic research?

Why we asked about this

In many settings (e.g. General Practice surgery or hospitals) clinical samples, like blood tests, are taken as part of everyday clinical care. Any left over samples are usually destroyed once they are used. If researchers wanted to store

and use the leftover samples for research, patients need to give their permission or consent. During a pandemic outbreak, public health practitioners can use these samples to do research without asking patients permission, for example, to understand how the virus works. Researchers might want to do additional research, for example, by working with genetic material, to understand why the virus affects people differently. Any information that might identify someone personally (e.g. name, address) would be removed. Other information might still be attached to the sample though, for example, gender or age.

Once the pandemic outbreak is over, researchers would not be able to use the clinical samples for any other pandemic research without patients' permission. This means that a lot of research that could be done after the pandemic cannot be done easily. Researchers might want, for example, to understand if another virus or bacteria may also be involved so they know how best to treat this kind of illness if another pandemic happens in the future.

What we found

- Participants were generally very willing to allow the left overs from their routinely collected clinical samples to be used for pandemic research, especially if it could help researchers answer questions about how the pandemic bug worked.
- Many participants did not see clinical samples, such as snot or blood samples, as being part of their body. Rather they saw the samples as waste and were happy for them to be used rather than be thrown away.
- Some participants were worried that DNA could be taken from samples that could identify them. They also questioned if any samples could really be made anonymous.
- Participants felt that the main risks with donating left over clinical samples were a loss of privacy in the event that the sample could be identified. They wanted to be sure that their identity would be protected.
- Participants also generally wanted to be assured that the samples wouldn't be used irresponsibly. They thought it more acceptable for the samples to be used by researchers from a publically funded institution and wanted to be sure they could trust how their samples would be used. They spoke about public scandals where pharmaceutical companies had acted unethically and used these stories as a reason that they might not allow their samples to be used. Some participants felt that pharmaceutical companies were not all the same, that some could be trusted and that it was important for them to invest in new medicines and products.

What do people think about taking part in an adaptive clinical trial?

Why we asked about this

A newer research design is recommended for pandemic clinical research. This design, called an adaptive design, allows researchers to analyse their findings at certain times in the study rather than just at the end of the study. They can then make adjustments to how they do the study. For example, they may add new treatments once they become available. In some adaptive studies, the longer the study is going on for the more information researchers can work with. This means that people who sign-up to the study once it has been running for a while will have a better chance of getting an effective treatment. The chance of getting the better treatment is greater than the flip of a coin (i.e. randomly, which is the normal standard). Rather, it is like the flip of a weighted coin. We wanted to know what people thought about taking part in a study like this during a pandemic outbreak.

What we found

- Participants who liked the idea of an adaptive trial thought the flexibility of the design made sense for pandemic research. The potential to get a more effective treatment was seen as an important advantage of the new design.
- Participants were accepting of the fact that signing up earlier in the study would mean that researchers knew less about which treatment was effective.
- Participants who did not like the design said that, because researchers could make adjustments during the course of the study, it might give the impression that researchers didn't know what they were doing. Some also felt that newer was not necessarily better.
- With regard to what information participants would want before taking part in an adaptive study, most did not necessarily think it was important for them to know about the design. They did not think the design would influence their decision about taking part and prioritised information about risk and side effects.
- Participants did want to know what impact the adaptive nature of the design would have on them.

What we will do next

This study has helped us understand more about what people think regarding taking part in research during a pandemic flu outbreak and how they might make decisions about taking part.

The way we designed this study allowed us to have detailed conversations with people in different countries about their thoughts. What we don't know at this stage is how many other people agree with the things raised by the people who took part in our group discussion. To try and understand how widespread some of these ideas and opinion are, we have developed a short survey that will be sent to members of the public in Europe (Belgium, Poland, Spain, Ireland, the UK), Canada, Australia and New Zealand. We will get answers from 850 people in each of these countries, 6800 in total. We plan to make sure that the people answering us reflect the structure of the population in each of the countries we are surveying. This will allow us to see how common our findings are in the general population. Findings from both studies will be used to help us design research for pandemic outbreaks.

What do you think?

We welcome discussion about any of the issues raised in this report whether you agree or disagree with our results.

Opportunities for feedback

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