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| **Dr edwina jenner – Immunologist**Teacher Guidance | **C:\Users\Felix\AppData\Local\Temp\Temp1_smallpox-logo(2).zip\smallpox-logo.jpg**  |

# NATIONAL CURRICULUM LINKS (ENGLAND)

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| **Upper KS2 (ages 9-11)** |
| **Working scientifically**Planning different types of scientific enquiries to answer questions, including recognising and controlling variables where necessary |

# KEY LEARNING OUTCOMES

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| **By the end of this activity children should be able to:** |
| * appreciate that all medicines and vaccines must undergo clinical trials
* explain simply why vaccines are tested on thousands of people over many years to ensure they work and are safe
* appreciate that the ethics of medical trials have changed since Dr Jenner’s time, and describe some of these changes
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# Lesson Activities

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| **Key questions** | How do scientists make sure a new vaccine works and is safe?How has the ethics of testing vaccines changed since Dr Jenner’s time? |
| **Overview** | **An introduction to the methods and ethics of modern vaccine testing**This is a teacher-led discussion activity. The lesson begins with a discussion of what the purpose of a vaccine trial is – what are people trying to find out? This is followed by a discussion of the main phases of a vaccine trial. Children then use their learning to complete a sorting activity. The lesson continues with further discussion about how vaccine trials make us confident that vaccines are safe. Finally, children compare the ethics of modern vaccine trials with those of Dr Jenner’s time. On page 4 you will find a list of questions to help guide discussion and answer common questions that children might ask. |
| **Teaching time** | 1 – 1.5 hrs |
| **Key vocabulary** | ethics | informed consent |  |  |

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| **Stage/summary** | **Running Notes** | **Resource**  |
| **Introduction** | Since Dr Jenner’s world-changing discovery, vaccines for many other diseases have been invented. For example, vaccines exist for polio, rabies, tetanus, mumps, chickenpox, measles, cervical cancer, Hepatitis A and B, influenza (flu)…When it comes to **developing and testing** **new vaccines**, things are done rather differently today compared to Dr Jenner’s pioneering work over 200 years ago.An immunologist is someone who studies the **immune system**. One of the things immunologists do is develop and test new vaccines. Once a new vaccine has been developed, it has to be **tested.** All medicines are tested according to a rigorous scientific procedure called a **clinical trial**. This is a type of **controlled scientific experiment**, done on a huge scale with many thousands of people. They can cost millions of pounds to run.**Ask the children what they think people need to find out when testing a new vaccine before it is made available to the general public**There are three main factors being investigated about the new vaccine – * Is it safe?
* Does it work?
* What is the best dosage and vaccination schedule (age or ages to give it to people)?

There are very strict rules about testing any medicine on humans. Scientists test the vaccine on human cells and animals first and then try out very small doses on a very small group of healthy people to check it is safe. All participants in medical trials are **volunteers** (although often people are paid for their time and inconvenience and any potential risk)**.** The purpose of the trial and the risks involved must be carefully explained to the volunteers, who must give their fully **informed** **consent**. All medical research in the UK has to first be approved by an **independent research ethics committee.** Their job is to protect the volunteers taking part in the trial. Bigger doses of the vaccine are then tested in successively larger groups to understand more about the possible **side effects,** to get a better idea of how well it works, and to try and work out the best **dosage** and **schedule** (what age to give it and if any **booster jabs** are required).It’s a long process: it takes around **ten years** **or more** for a vaccine to go from development to approval! Even after a vaccine is approved and becomes available, data is constantly gathered on its long-term effects and any possible new side-effects or safety concerns. The dosage or schedule can be adjusted accordingly. This long testing process and **continual** **monitoring** means the safety of vaccines is well understood and proven – especially ones that have been around for many years.For more information:<http://www.nhs.uk/Conditions/Clinical-trials> |  |
| **Discussion and sorting activity** | **Activity**: **trialling a new vaccine**Explain to children that new vaccines go through a long and rigorous process of testing to make sure they are **safe** and that they **work**.Discuss the importance of **ethics** in medical trials – how all participants must be volunteers giving **informed consent**. Why is this important?Explain that Dr Edwina Jenner is a modern-day immunologist in charge of testing a new vaccine for goose pox (both fictional!). Children help Dr Edwina Jenner by completing the sorting exercise either in groups or as a class. The table in the **Pupil Sheets** (PS1-2)describes the main stages of a vaccine trial. Children must match up the jumbled up boxes on PS3 to complete the **“Who the vaccine is tested on”** column in the tables. They should note that in each stage of the process the vaccine is tested on increasingly large numbers of people. | Pupil sheets |
| **Discussion questions on modern vaccine trials** | **How do we know that a new vaccine is safe?**Here are some questions to help guide discussion and provide answers to common questions from children.Why is a new vaccine tested on animals first?*To try and test its safety before giving it to humans. Also, to see if it works in animals and it’s worth proceeding with human trials.*Do you think it’s morally right to test on animals?*There are strict rules about testing on animals which say any suffering should be minimised and that alternatives should be used whenever possible. Without initial animal tests it would be too dangerous and risky to test a new medicine on humans. Nevertheless, some people feel that you can never justify testing on animals for any reason.*Why is the vaccine first given to a very small number of people in a very small dose?*Until a vaccine is given to a person, it is impossible to know for sure how the human body will react to it. Humans might well react differently to other animals. So you start off with a tiny bit of vaccine and if there are no nasty side-effects then you gradually give bigger doses.*Is it safe to take part in a vaccine trial?*Every effort is taken to make the trial as safe as possible, but there is a small degree of risk, mostly in the very first tests on humans. The risks must**be explained to volunteers before they take part in the trial. Severe adverse reactions are very rare indeed.*Why do you keep on increasing the size of the groups being tested?*Once you are confident that the vaccine is safe, you can test it on larger numbers of people.**There are mathematical equations that tell you how many people you need to test in order to be confident that a vaccine works or not. These equations say that you have to test many thousands of people. The more you test, the more confident you can be in your results. Also, different people will react to the vaccine in different ways, so you need to test lots and lots of people, preferably from a mix of ages and ethnic backgrounds and countries because all these factors might also affect the way people react to the vaccine and how well it works in them.*Why are only **half** the people in each group given the vaccine?*This is a vital part of making the vaccine trial a fair test****.*** *The half that are not given the vaccine are called the control group.**You have to compare the results from the group taking the vaccine with the control group. Otherwise you don’t know if the results you are seeing are actually caused**by the vaccine.* *For example, imagine that you were testing a flu vaccine on a thousand people. Imagine that during the trial, two hundred people became ill with flu. You might think that this means that the vaccine works in about 80% of people – which is quite good.**But now imagine that in your control group (i.e. another group of a thousand people who weren’t given the vaccine) only twenty people caught flu – much, much less than the vaccinated group. This would suggest that the vaccine actually didn’t do any good at all – in fact, it seems it might even make people more likely to catch flu! In this case, the control group suggests that the vaccine might well be worse than useless!*Why do people continue to monitor a vaccine after it is made available to the general public (Phase 4)?*This is to make sure the vaccine is safe and effective throughout a person’s lifetime, and also to check for any rare side-effects. Some vaccines have been in existence for decades, so because of this continued monitoring we can be extremely confident of their safety and have a very accurate understanding of any side effects. Children will investigate the example of the MMR vaccine (introduced in the 1970s) in the* ***MEASLES ALERT!*** *resource.*  |  |
|  | **Comparing today’s trials with Dr Jenner’s methods***Dr Jenner was working over two hundred years ago. Since then scientists have developed a standard way of testing new medicines that is a lot more* ***rigorous*** *and* ***reliable*** *– and much more* ***safe*** *and* ***ethical*** *for the* ***volunteers*** *taking part in the tests.*Did Dr Jenner test the coxpox vaccine on animals before he tested it on James?*No.*Did James’s father give free, informed consent? ‘Informed consent’ means that the person is fully aware of the **purpose and** **risks** of the experiment before they agree to it. ‘Free’ means that they are not being forced to take part in the experiment in any way.*As the History Detective activity shows, we will never know for sure! But what about in the version of events in the JAMES short film? Do you think James’s father gives free, informed consent in the film?**Today, most participants in medical trials are “paid volunteers”. Or sometimes a doctor will ask an ill patient if they would agree to take part in a clinical trial for a new (and hopefully more effective) medicine.*Do you think that nowadays children should have to give their informed consent to take part in a medical trial and not just their parents? Was a small dose of cowpox given to James first?*No.*Did Dr Jenner make notes about the possible side-effects?*Yes, some notes were made. In the* ***Speckled Monster*** *and* ***History Detective*** *resource, children read extracts from Dr Jenner’s publication in which he describes how the cowpox made James a bit unwell. But this was only* ***one*** *description of the side-effects on* ***one*** *person.*Did Dr Jenner do trials involving thousands of people before the vaccine was made available to the general public?*No. Dr Jenner repeated the experiment on James and a number of other children and then Jenner and others quickly began vaccinating the general public. Whole towns and villages were offered the cowpox vaccination very soon after the experiment on James.**As the* ***Great Vaccine Debate*** *activity shows, Dr Jenner’s critics argued that this was too hasty and that more testing should have been done first. They even claimed they had proof that the vaccine didn’t work and that it was actually dangerous.**However, it is interesting to compare this to the 2014-15 Ebola outbreak in western Africa. New experimental vaccines were offered to people before**the usual full testing was complete, on the grounds that it was unethical not**to offer a potentially life-saving vaccine in the face of such a deadly disease. Of course, the people offered the new Ebola vaccines still had to give informed consent and understand that the vaccine was not yet fully tested.**You could argue that in Dr Jenner’s case it would have been equally unethical to withhold vaccination from the general public when smallpox was such a deadly disease and variolation – the only other prevention – was also dangerous and had hugely unpleasant side-effects.*Did Dr Jenner use **control groups** in his experiment?*No. The idea of control groups did not exist in 1796.* *This meant it was harder for Dr Jenner and the other supporters of vaccination to prove that vaccination worked.*Did Dr Jenner and his followers continue to monitor the vaccine after it was introduced to the general public?*Yes. As the* ***Great Vaccine Debate*** *activity shows, people paid very close attention to the impact and effect of the smallpox vaccine.**One thing people eventually noticed was that, contrary to what Jenner claimed, cowpox didn’t give lifelong immunity to smallpox****.*** *Because of this, towards the end of the 19th century the government started giving booster jabs**to people to refresh their immunity.* *Nowadays, data is continuously and rigorously collected and monitored on the effectiveness and side-effects of all vaccines being used by the public*.Would **you** take part in a clinical trial for a new vaccine? |  |
|  | **Enrichment activity**Imagine that smallpox still exists (oh no!), and that the cowpox vaccine has only just been discovered. The vaccine is currently being tested, and is about to enter **Phase Two** of the trial process. All the volunteers for the trial must give their **informed consent.** You have been asked to create a **leaflet** explaining the trial to people thinking about participating in Phase Two**.** You **must** include – * What the purpose of the trial is
* Any potential risks or side-effects of the cowpox vaccine (hint – look back at Dr Jenner’s description of what happened to James after he was given the cowpox vaccination)
* That volunteers must be in good general health
* How long they will the trial last, and where will they have to go to be monitored? (Hint – look back at Phase Two on your goose pox vaccine trial timetable)
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