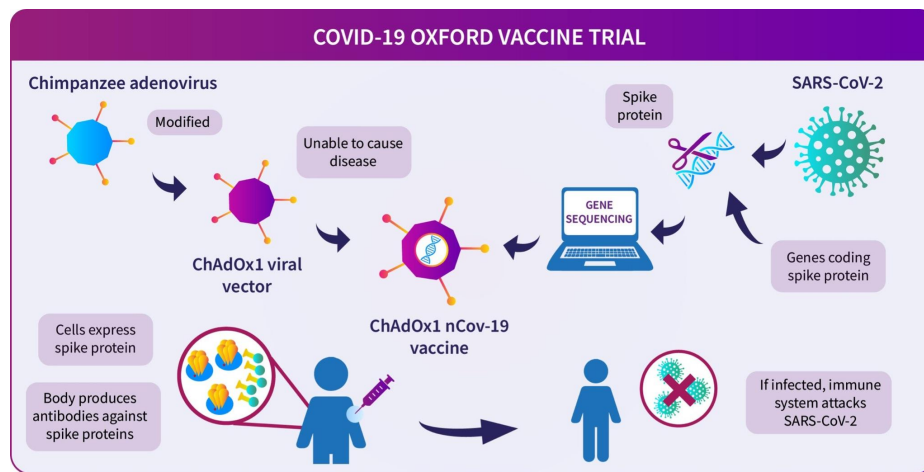


The research involved in vaccine development as a response to COVID-19

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(The Oxford University, 2020)

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Introduction

During the COVID-19 pandemic scientists around the world have collaborated to create a vaccination in an attempt to reduce the spread and create an immune response within the human body (WHO, 2020). In this report I will be investigating the research involved in vaccine development as response to the COVID-19 pandemic. I will specifically be investigating the AstraZeneca vaccination, vaccinations can take decades to develop, the AstraZeneca vaccination was developed and trailed within a 12 month period (Oxford Vaccine Group, 2021) I will be conducting in depth research into how the vaccine was developed including the research methods that were used and the critical thinking scientists used to trail the vaccine, I will be making recommendations on the practice of the research methods, including the timescale and how additional testing could've been considered. The ethical concerns, including the moral issue of testing the vaccine on animals, the use of human fetal cell lines and the exclusion of children, pregnant women and certain religious people in the initial vaccination roll out. I will be making recommendations regarding the education of vaccination testing and how it can be tailored. I will also be researching the government's roll-out priority selection, I will be making recommendations regarding their policy and how I would change the priority list to tailor it to the most vulnerable people. I will also be using my own knowledge and skills to critically think when making my recommendations for improvements. Throughout this report I will be using nursing competencies to guide me, such as evidence-based practice and utilizing informatics (NMC, 2020) while conducting my research to allow me to view the full scenario when analysing information regarding the Oxford AstraZeneca vaccination.

Topic

COVID-19 is a virus that causes respiratory tract infection. It can affect your upper respiratory tract, sinuses, nose, and throat or lower respiratory tract, windpipe and lungs (NHS,2020). During the COVID-19 pandemic there have been 141,412,405 cases worldwide, 3,026,390 of these cases resulting in death (Worldometer, 2021) The COVID-19 pandemic first surfaced in Wuhan China, December 2019, The University of Oxford (2020) had their first human trial phase as quickly as the 23rd of April 2020. One research method that was used in the AstraZeneca vaccination was human experiment trails, the vaccination was developed within four months of the first case in Wuhan and set out for human testing, the time frame before beginning on human testing appears to be rapid in comparison to other vaccinations, for example on average there is approximately 2-4 years of laboratory testing taken place before human/animal testing (International Federation of Pharmaceutical Manufacturers & Associations, 2019) the UK Government released a statement that the vaccine was safe for use after multiple trial phases and reviews (GOV.UK, 2021). Regardless of the UK Government's claims that the vaccine was safe, there were several European countries that suspended the use of the vaccine due to cases of blood clotting that had been identified in people after receiving a dose of the vaccine (The Guardian, 2021). Another concern that was raised with the AstraZeneca vaccination was the use of animals to test the vaccination, this caused some ethical issues among the population, especially the vegan and vegetarian groups as this is considered as animal cruelty, it also excludes these members of society to get the vaccination without going against their moral beliefs (CrueltyFreeEurope.org, 2020). Pregnant women and children are also yet to be eligible for a vaccine, although pregnant women and children who contact COVID-19 are at more risk of hospitalisation (BMJ, 2020) The COVID-19 AstraZeneca vaccination is also tested using Human Foetal Cell-Lines, for many religions where abortion is not permitted this can feel morally incorrect and impact the decision (Law and Religion UK, 20 20). The UK Government roll-out process has also been a topic for debate, there can be multiple ways to debate and discuss the issue, but the opinion that was a consistent trend among the public is that the clinically vulnerable should have been top priority in the vaccination process (The Herland, 2020)

Research methods

The AstraZeneca vaccine was developed using the ChAdOx1 vaccine technology (The Oxford University, 2020), this vaccine technology has previously been used to create immunisation against the flu, Zika and Middle East Respiratory Syndrome (MERS), another type of coronavirus that surfaced in 2012 (WHO, 2019). The information previously gathered in understanding Coronaviruses allowed them to identify the most suitable vaccination was developed using evidence technology more efficiently (The Lancet, 2020). An early stage in the development of the vaccination included HEK-293 cell lines testing, HEK-293 stands for Human Embryonic Kidney, the cell line originated from the kidney of an aborted baby in 1973 (Life, 2020) The testing of the vaccination on HEK-293 cell lines concluded clinical laboratory results in the AZD1222 group, were within normal clinical range and did not raise any safety concerns (European, Medicines Agency, 2021) Another research methods used in identifying the effectiveness of the vaccine was the use of animal testing (Haseltine. W, 2020) During the AstraZeneca vaccination trials, six monkeys were injected with the vaccination and later were exposed to COVID-19, three monkeys were not vaccinated and only exposed to COVID-19. All nine monkeys tested positive for COVID-19, $\frac{2}{3}$ of the monkeys suffered rapid breathing (Cold Spring Harbour Laboratory, 2020). The monkeys that received a dose of the vaccination used in the experiment were protected from more severe side effects such as, pneumonia which was a positive for the vaccine (Independent, 2020) although further research concluded the outcome that the monkeys noses that received a dose of the AstraZeneca vaccination harboured as much virus as did those of unvaccinated monkeys, despite the “uncertainties” the clinical trials to test the vaccination on humans proceeded (Callaway. E, 2020) The animal trials concluded that the vaccination could offer “partial protection” (Independent, 2020) and caused debate among many news providers and scientists on the accuracy of the animal testing period. The last research method that I will be discussing is the human testing stage of the AstraZeneca vaccination, Phase I/II trial consisted of 1,077 healthy adult participants, aged between 18-55 years old, the assessment took place by providing a single dose of the AstraZeneca vaccination to all participants. The participants who received one dose of the vaccine displayed results of increased antibodies of 95%. (The Lancet, 2020) The phase II part of the study involves expanding the age range of people the vaccine is assessed in. This part of the study will enroll up to 12,330 adults and children, with the aim to assess immune responses in different age categories (The Oxford University, 2020). Phase III of the vaccine testing was expanded internationally to Brazil, South Africa and Kenya. The USA also assessed the vaccine with a trial related to India (The Oxford University, 2020). The findings of trial phase III indicated that the vaccine is ‘safe and effective at preventing symptomatic COVID-19, it also protects against severe disease and hospitalisation’ (AstraZeneca, 2020)

Ethical Concerns

During the AstraZeneca vaccination roll-out there were ethical issues raised regarding the process of the vaccine trial methods and the exclusions of some population groups of having access to the vaccination. The first issue that I will discuss is the use of animals in the testing of the vaccination, a large part of the worldwide society has vegan, vegetarian and many animal cruelty protesters. Animal rights groups gathered to protest the university’s “flippant” attitude towards animals (Cambridge Times. 2020) The vegan society (2020) states that many vegans and vegetarians find compromising their beliefs to be “stressful and upsetting” when making decisions whether to revive the vaccination due to the animal testing involved in developing the vaccine. CrueltyFreeEurope (2020) claims that the monkeys used in the AstraZeneca vaccine experiment were monitored for 7 days for signs of infection before being killed and dissected.. Another ethically issue that was raised with the AstraZeneca vaccine was the use of human foetal cell lines, Catholic leaders in the United States and Canada have shown concern that the vaccine uses cells delivered from an aborted human fetuses cells in 1973 (Brookshire. B, 2020) The Catholic Church opposes all forms of abortion procedures therefore the problem of whether to revive a coronavirus vaccine has divided some members of the clergy (BBC, 2020) the majority of religious leaders have expressed that reviving the vaccination will not be seen as “Sinful” (Law and Religion UK, 2020) The exclusion of pregnant women and children is also an ethical issue that has been up for debate. There has been a willful lack of progress with developing the vaccine for

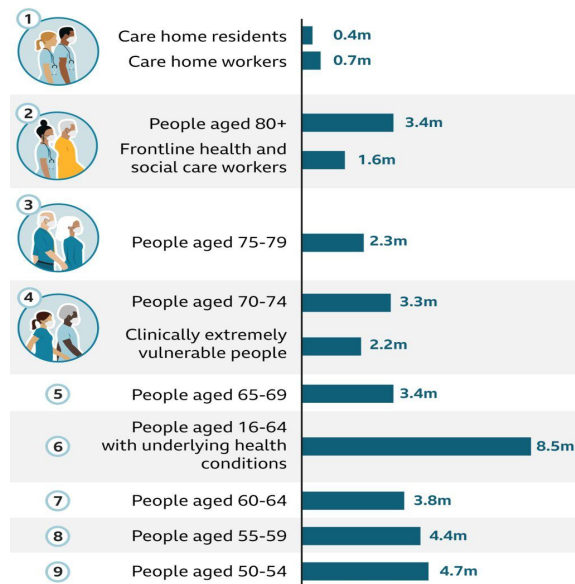
pregnant women and children (Kampmann. B, 2021) Respiratory diseases have always been commonly described as dangerous to pregnant women, when the COVID-19 pandemic surfaced it left pregnant women in the category of those who are vulnerable if they contract the virus, Worldwide research has concluded that pregnant women who contract COVID-19 are at risk of hospitalisation, research data also evidences that if a pregnant woman contracts COVID-19 it is a possibility that the placenta can be damaged which could cause harm to her unborn baby (Subbaraman. N, 2021) The British Medical Journal (2021) also supports the risk to pregnant women who contract COVID-19 and suggests that pregnant women are also more likely to experience preterm birth and their risk the admission of their child to a neonatal unit. Ethical issues regarding the exclusion of children can also be seen as an issue, 3.54 million of COVID-19 cases are children, with 12% of children who test positive for COVID-19 are hospitalised. The risk of human experiment could also be seen as a cause for ethical concern, due to the fast pace that the vaccine was developed and rolled-out, recently there has been discussions on the safety of the vaccine, Denmark have stopped the roll-out completely, under 30s are now being offered an alternative vaccination in the UK and German authorities have suspended the use of the AstraZeneca vaccine for under 60s (BBC News, 2021). The risk of blood clotting has been referred to as “extremely rare” due to the small number of cases, although it is still causing deaths. AstraZeneca (2021) suggests that there was no evidence of blood clotting found during their human trials.

The UK Government's rollout programme

After the vaccination was approved for use in the UK on December 30th 2020 (BBC, 2020), the UK Government released a strategy of who would be eligible for the vaccination in a roll-out programme, the below photograph was released by the UK Government as its ‘Vaccine Rollout Plan’

The first phases of vaccination aim to reach millions of people

Estimated number of people in each priority group



Government estimates more than 25 million in priority groups

(some people will fall into more than one category shown)

Source: ONS population mid-2019 estimates, BBC research

BBC

(BBC News, 2020)

The vaccine rollout plan was positive in multiple ways but also caused debate of groups who were excluded or not seen as much of a priority of others (Independent, 2020) The vaccination programme focused on Vaccinating Health and Social care workers prior to vaccinating at risk members of society. The average age for NHS workers is 43 years of age with a significant amount of staff being between the age of 18-30 years old (NHS Employers, 2020) this generally categorised NHS staff as a low risk group of becoming unwell with the virus. The majority of NHS workers confirmed that they had contracted the virus during the pandemic prior to the vaccine, suggesting that many had developed antibodies against the virus (The British Medical Journal, 2020). The key question of the rollout process was should've the highest risk individuals have received their vaccine first prior to those who received the vaccine based on where they were employed. Health and social care staff being top priority for receiving the vaccine was also a cause for debate among essential workers such as police officers, school teachers and shop workers, due to the schools reopening being announced by the government many workers in the education profession felt excluded as they would be coming into contact with unvaccinated pupils on a daily basis, the same opinion was presented by police officers, due to the police's role in enforcing of COVID-19 laws and rules, the police force was left vulnerable when dealing with individuals who were likely to be carrying the virus due to breaching of lockdown rules, shop workers also felt excluded due to being essential workers coming into contact with the public every day and not seen as a priority (Chroniclelive, 2020).

Health Data and Patient Safety during the rollout phase

After the vaccination was approved for use in the UK on December 30th 2020 (BBC, 2020), the UK Government released a strategy which indicated who would be eligible for the vaccination in a roll-out programme. The table below was released by the UK Government as its 'Vaccine Rollout Plan'

The vaccine rollout plan was positive in multiple ways but also caused debate regarding the groups who were excluded or not seen as much of a priority of others (Independent, 2020) The vaccination programme focused on Vaccinating Health and Social care workers prior to vaccinating at risk members of society. The average age for NHS workers is 43 years of age with a significant amount of staff being between the age of 18-30 years old (NHS Employers, 2020). This generally categorised NHS staff as a group with low risk of becoming unwell with the virus and the majority of NHS workers confirmed that they had contracted the virus during the pandemic prior to the vaccine, suggesting that many had developed antibodies against the virus (The British Medical Journal, 2020). The key question of the rollout process was should the highest risk individuals have received their vaccine first prior to those who received the vaccine based on where they were employed. Health and social care staff being top priority for receiving the vaccine was also a cause for debate among essential workers such as school teachers, police officers, and shop workers - (due to the schools reopening being announced by the government - How about changing this bit to , - _ when schools reopened many workers in the education profession felt they had been excluded despite the fact that they would be coming into contact with unvaccinated pupils on a daily basis; the same opinion was presented by police officers who, due to their role in enforcing COVID-19 laws and rules, were left vulnerable when dealing with individuals who were likely to be carrying the virus due to breaching of lockdown rules; shop workers also felt excluded due to being essential workers coming into contact with the public every day and not seen as a priority (Chroniclelive, 2020).

Conclusions

Research

As COVID was spreading so rapidly it was necessary to carry out research extremely quickly and it is a tribute to those involved in the research that, despite some problems regarding testing and trials, a vaccination was developed in such a short period of time. Clinical trials showed a very high rate of efficacy for COVID drugs despite the fact

that clinical trials are often susceptible to some level of failure. It may be said that results were better than expected. There is the ongoing question as to whether in the long term the speed of scientific review of data will stand up to scrutiny and whether at a later date this may compromise safety (Nature November 2020, The COVID vaccine challenges that lie ahead). In order to retain confidence in the vaccine it is important that companies who produce drugs and people who regulate them continue to publish data and engage in open and meaningful discussion.

Ethical concerns

There were several ethical concerns relating to COVID vaccinations and in the way the pandemic was handled which have been described in the body of this assignment but one over-riding ethical issue relates not to the effect on population groups but to the way in which decisions were made with little public scrutiny or consultation. There was very little constructive criticism made of decisions taken and it will be important as COVID subsides that there emerges an ethical obligation to involve the public in decisions relating to the provision of health services. Health services will change as a result of COVID and it seems likely that there will have to be new ways of thinking about how health services will be organised especially if there are to be further pandemics – of COVID or any other disease. The government, health service providers and their client groups will need to consider ethical implications such as which values and interests should take precedence and how competing interests should be managed. (e.g. there has been an increase in cancer cases during the current pandemic). It is my opinion that ethical considerations should be carefully considered in any future developments in the health service and that this should apply to the wider field of health care rather than to discrete situations such as vaccinations for COVID.

Health data and patient safety during roll-out phase of COVID vaccination

To produce and roll out the vaccine in under a year may be considered a major breakthrough. There was, perhaps, inevitably considering the speed at which the whole process was undertaken, debate as to whether some groups were wrongly excluded from the early vaccination programmes e.g. the police, school teachers, shop workers and whether some people who received early vaccinations should not have been given priority e.g. younger health care workers. It may be argued that vaccination programmes were meant to help a range of people not just the people who had been given vaccinations. There has also been discussion about the safety of the vaccines used with particular focus placed on how vaccines affect different groups of people e.g. ethnic groups, different age groups. Much has been written and discussed about the disparity in uptake of vaccinations in different groups, particularly early hesitancy in the UK among black, Bangladeshi and Pakistani populations compared to people from a white ethnic background. In any future vaccination programmes (and any future pandemic or epidemic) it will be important to be aware of and address reasons for any hesitancy shown e.g. worries about side effects and worries that relate specifically to ethnic beliefs/traditions. However, it should be remembered that uncertainty about vaccinations is a legitimate point of view.

In conclusion it is felt that much has been learned from the way in which the COVID pandemic has been handled. Research into the vaccine has been rapid and generally effective; ethical issues involving COVID bring into focus future ethical considerations as the health service evolves to meet its new and challenging role; patient safety centres on ensuring that all groups of people receive appropriate care regardless of ethnicity, socio- economic status, religion etc.

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