The COVID-19 vaccine, informed consent and the recruitment of volunteers

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By Jennifer O'Neill.

Last week, in an announcement which offered hope in a time of growing despondence, Pfizer declared that their COVID-19 vaccine had *"outperformed expectations in the crucial phase 3 clinical trials, proving 90% effective in stopping people falling ill."* If approved, Pfizer's jab will be the first in a new era of vaccines. Instead of using a traditional approach, such as an attenuated, or weakened, viral vector, Pfizer's vaccine uses viral mRNA as "molecular instructions for human cells to make the coronavirus spike protein". This will potentially stimulate development of anti-SARS-CoV-2 antibodies. Tentative trial data appears promising. Of the 44,000 participants, only 94 developed COVID-19 symptoms. Given that the FDA have set the bar for licencing at 50%, it seems likely that the vaccine could be made available soon. Likewise, the UK equivalent body – the Medicines and Healthcare Products Regulatory Authority (MHRA) – are similarly poised to offer an emergency licence if satisfied that its safe and effective.

As the media rush to hail the new vaccine – bolstered by the subsequent news Moderna have a 95% effective vaccine in trials – it is important to ensure that information communicated to the public be truthful, transparent and accurate. This is best communicated by experienced professionals. Questions remain as to whether the vaccine is effective across all populations. Of particular concern is the elderly population known to elicit weaker immunological responses to vaccines. It is also yet to be seen whether the vaccine will completely block transmission or instead simply reduce symptoms in vaccinated individuals – vital in terms of easing social distancing measures. There is also a lack of longevity in terms of the data. Before the pandemic, it would take 10-15 years to develop a vaccine from inception to licencing, yet the COVID-19 vaccines data was collected over two months. Nevertheless, the UK Government forges ahead with plans to roll out the vaccine. The military are being enlisted to distribute vaccine vials on dry ice – in their "biggest task since the war" – and St John's Ambulance Volunteers are recruiting volunteers to administer the jab. Yet we must pause to consider how to ensure adequate levels of vaccine acceptance. Arguably, this is best achieved through shared decision-making and informed consent, which can be a vehicle to addressing vaccine hesitancy.

Mandatory vaccination was proposed as a solution to childhood vaccine hesitancy in 2019 by Health Secretary Matt Hancock. At that time, the House of Lords and the Royal College of Paediatrics and Child Health (RCPCH) opposed the move, arguing that it would backfire, creating determined vaccine refusers. Vaccine mandates may be undermined by high levels of exemption as they fail to address underlying fears. Studies suggest that comparable results may be achieved by strongly recommending vaccines instead. The RCPCH prompted healthcare practitioners to ensure "that every contact [with a patient]...be a vaccine opportunity" and so highlighted the crucial role informed consent holds in ensuring the success of vaccination strategies. This is particularly pertinent given the global conspiracy theories which surround COVID and in light of limited vaccine development time – two issues which are likely to contribute to vaccine hesitancy.

The process of shared decision-making is crucial to ensuring legally valid informed consent is obtained. It enables experienced practitioners to engage in a dialogue with patients to address treatment fears, answer questions and provides an opportunity to challenge misinformation. It must be recognised that the general public have questions surrounding the COVID-19 vaccine, and it should not be left to the media to answer them. The use of volunteers raises serious concerns as to whether this key part of a vaccination strategy has been considered. It is particularly important in light of the Cumberlege Report (First Do No Harm) which exposed a lack of trust in healthcare due to the "*..widespread lack of informed consent and a reluctance ...by those charged with patient care.. to listen and...act...*"[1].

An open dialogue as part of informed consent can be used to prompt consideration as to how autonomy is interpreted. Rather than the individualistic interpretations which stimulate talk of infringed individual liberties and anti-mask opposition, autonomy sits more comfortably as a relational value. The COVID-19 pandemic has demonstrated to great effect that when it comes to disease, we do not live in isolation. Our understanding of autonomy should therefore incorporate *some* social responsibility. Whilst ultimately upholding the patient's right to decide whether to incur individual risk, information disclosed to patients should be given from both individual and societal perspective. In this way, patients can be *fully* informed. The benefits of vaccination should therefore address both benefit to the individual *and* society, such as the potential for individual and herd immunity. It should also be disclosed that such immunity may not be long-lasting or equally effective across all age-ranges. Risk should be disclosed in terms of both *known* risks, including common side effects, and potentially *unknown* risk. The risk from *not* vaccinating should also be explained – both to the individual who may be at greater risk of contracting COVID-19 – and to society through increased transmission.

Such risk may include both primary infection and subsequent "Long-COVID". This will affect both the individual and society as a whole through increased strain on the NHS. Whilst there will still be vaccine refusal, such an approach will engage those who are, as yet, undecided by tackling misinformation and promoting solidarity.

Ultimately, by upholding autonomy, trust in the profession can also be rebuilt, which is vital given the likelihood of future epidemics and pandemics. This approach will require additional consultation time, but this should be seen, in the long-term, as an investment. Given the complexities of the issues raised, the suitability of an "expanded workforce ... [administering] these vaccines to the public", is thrown into doubt. It is particularly concerning that "people who are not healthcare providers ...[could] administer the vaccine" given that only last year MPs outlined the need for "*..better training of health professionals on what vaccines are, what they do, how they work and what is in them so that those professionals are ably equipped to answer [patient's] questions".* Whilst the current pandemic may necessitate a quick-fix approach, the long-term objectives of improving vaccine confidence and overall trust in medical science must not be lost.

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[1] https://www.bmj.com/content/370/bmj.m3099

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