EDITORIAL Health, Risk and Society

Accepted for publication 02/11/2020

Hopes, Hesitancy and the Risky Business of Vaccine Development

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Abstract:

Recent policy conversations about vaccination programmes primarily target the problem of vaccine hesitancy and the lack of public participation at the level required for community immunity, or herd immunity. In this editorial we will first explore the nature of public vaccine hesitancy, review what is known and demonstrate the significance of understanding vaccine hesitancy in the COVID-19 context. We argue that sociological research indicates that to sufficiently grasp vaccine hesitancy in the twenty-first century it is necessary to consider several aspects: the nature of medical decision-making, trust, risk and social responsibility, and the role of information technology and various forms of media. There are also questions about what influences the (successful) development and provision of a vaccine – issues that have been brought sharply into focus by the COVID-19 pandemic. As such, in the second half of the editorial we move to consider the supply side of vaccination. We examine what shapes this configuration and consider the role of key players such as those who manufacture the vaccines and, in turn, those who regulate development, again with a focus on the COVID-19 pandemic.

Keywords:

Vaccine hesitancy; vaccine development; trust; risk; COVID-19

Word Count (excluding references): 5970

Introduction:

As of the autumn of 2020, there are more than 100 COVID-19 vaccines in the preclinical or clinical trial phases of development (Mullard, 2020, Whittaker, 2020) with the hope that one may be available for use before the end of 2020 or in early 2021. However, should vaccine development of one or more candidates prove successful, social dimensions will necessarily play a highly significant role in controlling the COVID-19 pandemic. On the one hand, there are clearly significant manufacturing, distribution, delivery and administrative issues for governments to resolve in vaccinating millions of people, even within a single country (Bingham, 2020). Importantly, social and cultural beliefs and values will also be significant. Preliminary data suggest, for example, that in the US context, one-fifth of Americans, and more than half of people who already held beliefs of a sceptical nature toward vaccine safety, may be unwilling to receive a COVID 19 vaccination. This level of non-adherence rate may be high enough to pose a threat to collective immunity (Trujillo and Motta, 2020). The current COVID-19 context suggests then that sociological analysis of vaccination has perhaps never been more significant. In this editorial we reflect on what a sociology of vaccination reveals about these issues and on what questions remain unanswered, particularly relating to the COVID-19 pandemic.

Vaccination has been available in the UK for over two hundred years beginning with smallpox vaccination in 1796. Since then a number of other vaccines have been developed for deadly and debilitating diseases such as typhoid in 1896, MMR in 1988 and HPV in 2009. Vaccination is seen as one of biomedicine's greatest achievements. However, the social history of medicine shows us that the development and provision of vaccination and its uptake have consistently been controversial and met with resistance (Brunton, 2008, Porter and Porter, 1988). Indeed, Dube and colleagues (2015) (see also Durbach, 2004) show how in response to

state attempts to control smallpox, compulsory vaccination acts passed into law in the mid 1800s in the UK were viewed as a government assault on working class communities and resisted by individuals on the grounds that it was a violation of personal liberty. The 1950s and 1960s might be characterised as a 'golden age' for vaccination and though there was still some level of opposition, vaccination was widely accepted with major decreases in outbreaks of preventable disease and death. However, vaccination (partially) became a victim of its own success and this did not last. Hand in hand with a diminishing sense of danger and significantly improved rates of various sorts of preventable disease and death, the 1970s saw controversy over pertussis vaccination (resulting in major outbreaks of the disease). Later, the 1990s infamously were marked by controversy over MMR vaccination and a purported connection to autism. Immunisation rates diminished from before the controversy to below 80 per cent, in less than 10 years, resulting in measles outbreaks and deaths). Many of the arguments initially made by the anti-vaccination activists of the 1800s remain concerns for those displaying hesitancy or outright resistance today. These include that vaccines cause disease or are ineffective, that vaccines contain substances that are dangerous, that harm and safety risk is hidden by medical and government authorities, that the state or medical authority institutions are not to be trusted, that natural immunity is superior than that created by vaccination and that naturalistic approaches to health are superior (Dube et al., 2015)[1].

Recent policy conversations about vaccination programmes primarily target the 'problem' of vaccine hesitancy and the lack of public participation at the level required for community immunity, or herd immunity. In the early part of this editorial we will engage with

[1] It is important to note that, linked to this final point, the increasing popularity of complementary and alternative therapies have been seen to be one of the reasons why vaccine use has declined (Lok and Stijntje, 2019).

the nature of public vaccine hesitancy, review what is known and demonstrate the significance of understanding vaccine hesitancy in the COVID-19 context. Beyond the persistence of critical attitudes to vaccination, we argue that sociological research indicates that to sufficiently grasp and intervene into vaccine hesitancy in the twenty-first century it is necessary to consider in depth several additional dimensions. These include the nature of decision-making, trust, risk and social responsibility, and the role of information technology and various forms of media.

There are also unanswered questions about what influences the successful development and provision of a vaccine. These questions have been brought sharply into focus by the COVID-19 pandemic (Calnan, 2020). The discussion later in the editorial therefore considers the supply side of vaccination, examining what shapes it and considers the role of key players who develop, provide, organise, regulate and support the programmes - with a particular focus on manufacturers and the regulatory state.

Public Vaccine Hesitancy

Yaqub and colleagues (2014) define vaccine hesitancy as the harbouring of doubts about the benefits of vaccines and the questioning of their safety and necessity. Larson and colleagues (2015) argue that vaccine hesitancy is a kind of decision-making process that relies on particular approaches to risk and trust/confidence in health authorities. Interestingly, these authors show that there is significant disagreement about the extent to which vaccine hesitancy is shaped by socio-economic status. They suggest that it occurs, for example, across both those with low socio-economic status but also amongst university educated middle class people – although potentially in different forms, in terms of how trust attitudes and approaches towards risk manifest themselves. Vaccine hesitancy can very easily become vaccine refusal but these are arguably two distinct phenomena in that those who do choose vaccination can still hold hesitant views about benefit, safety and/or necessity. In this sense, vaccine hesitancy should be

seen as occurring on a spectrum that can include full or partial engagement with vaccination or vaccination refusal (Bedford et al., 2018, p.6557). Understanding hesitancy and the factors that underpin it is important because focusing only on refusal through uptake rates leads to underestimating the challenge of maintaining vaccination coverage in the future – particularly because hesitancy is a widespread phenomenon reported across a wide range of empirical work (see review by Yaqub et al., 2014). Equally, hesitancy towards a COVID-19 vaccination is likely to reflect many of the same factors that shape hesitancy to other vaccines in specific cases or at a general level. The focus on refusal rather than hesitancy is also predicated on assumptions about lay knowledge and decision-making which are inadequately appreciative of the range of sources drawn on in the process of (re)configuring attitudes and the importance of legitimacy and trust (at both interpersonal and institutional levels) and how this might vary over time and between types of vaccine. The picture is a more complex and nuanced one than that suggested by traditional medical assumption that a lack of access to information/the facts of vaccination (at least alone) drives refusal (Hobson-West, 2003, Yaqub, et al., 2014).

Decision-making about whether or not an individual or their child should be vaccinated is a rich, nuanced and contextual phenomenon (Reich, 2020) reflecting a number of factors. This includes interactions with family and friends – with Brunson (2013) and Attwell and colleagues (2018) showing that social networks shape and reinforce beliefs and subsequent vaccination behaviour. Other factors might include childbirth experience, past experience of vaccines or health services more generally, and necessarily also takes into account the presence of concerns about their own or their child's broader health (Danchin et al., 2018, Hobson-West, 2003, p.276, Hobson-West, 2007, Poltorak et al., 2005). The process, as such, is one that is distributed across a number of knowledges, experiences and interactions (Rapley, 2008) rather than as something simply reflecting a lack of access to the science of vaccination (Hobson-West, 2003, Yaqub,et al., 2014). Reich (2018, pp.67-75) meanwhile argues that hesitant

parents, reflecting broader structural drivers to act as informed consumers, engage in 'research' or information gathering that can be central to the vaccination decision. A 'good' parent in this context is someone who 'does the research' and makes an individualised, informed decision. For those hesitant or resistant towards vaccination, vaccination adherence is constructed as the 'easy', 'unthinking' decision rather than the result of a careful weighted decision about the benefits and risks (Hobson-West, 2005, pp.151-157).

A number of studies indicate the centrality of (dis)trust in the institutions and individual actors responsible for vaccination (Attwell et al., 2017, Peretti-Watel et al., 2019). Trust is therefore seen to be a key concept in understanding vaccine uptake although its investigation in much of the empirical research on vaccination is limited and lacks a clear conceptual basis (Larson et al., 2018). From their review of the vaccines attitudes literature Yaqub and colleagues (2014) show that the most commonly cited reason for general population support for vaccination is professional advice. The importance of trust in medical professionals in terms of provision of healthcare at various levels is, of course, well demonstrated by medical sociologists (Calnan and Rowe, 2008) and will undoubtedly be important in the provision of any successful COVID-19 vaccination. However, not all groups trust equally – for example, in the US context, black Americans, based on experiences of being failed by the medical system describe higher levels of mistrust than white Americans (Dew and Donovan, 2020). More generally, research shows that distrust in governments, the manufacturers of vaccines (and their desire to profit), as well as medical professionals and healthcare institutions are central in parental rejection of vaccination for their children (Attwell et al., 2017).

However, as noted above and as Yaqub and colleagues (2014) indicate, though lessened or at least more critical in its composition, trust in professionals remains. In this way, professionals themselves may also be implicated in vaccine hesitancy or refusal. Medical professionals do not necessarily uncritically or unequivocally believe in and advocate for what

can be described as the culturally dominant vaccination narrative themselves (which describes how vaccination eradicated and controlled deadly diseases) (Heller, 2008). Indeed, Manca (2018) shows how professionals in Canada, despite also embracing their role in promoting vaccination, do hold certain anxieties especially around new vaccinations relating, for example, to the potentially problematic commercial influence of the pharmaceutical industry. This indicates that whilst trust in medical professionals is important in terms of patient and public attitudes towards and action associated with vaccination, professionals themselves are embedded in a lattice of (dis)trust that involves various actors including fellow professionals, health organisations and institutions and commercial forces. Professionals are largely trusted by patients, acting as mediators between patients and faceless systems, but trust *by* professionals in these various actors is significant in the configuration of professional understandings, attitudes and ultimately influences practice (Douglass and Calnan, 2016, see also Brown and Calnan, 2016 and particularly Brown and Calnan, 2012). Healthcare professionals do not always have significant knowledge of or awareness about vaccines and national guidelines (Yaqub et al., 2014, p8) but where they do, there sometimes are concerns about the longer-term efficacy and safety of newer vaccines such as the HPV vaccine (Gottvall et al., 2011). Where concerns and/or distrust, for example, in the commercial interests and influences of the pharmaceutical industry exists amongst medical professionals about vaccination and this is paired with public and patient trust in them this could shape vaccine hesitancy or refusal by the public, although this requires empirical exploration.

Achieving herd immunity requires that 85-95 per cent of a community is vaccinated (though percentage estimates vary and relate to specific diseases) (Reich, 2020, p.108). Achieving herd immunity is desirable for governments because it protects public health and economic systems. Importantly, it also protects those in the community most vulnerable to infection (such as the immune compromised, those yet to be vaccinated or those for whom

immunisation is ineffective or has waned). Vaccination can, as such, be conceptualised as a social responsibility and vaccine hesitancy/rejection as possessing the potential to endanger other people (Attwell, et al., 2019). Considering the loss of life and economic damage caused by the COVID-19 pandemic, social responsibility attached to vaccination is likely to be significantly emphasised by governments. However, those who resist or reject vaccines personalise or individualise risk, emphasising how the risk of disease reflects an individual's own mix of genetic, environmental, social and lifestyle risk factors (Hobson-West, 2007; Poltorak et al., 2005). Indeed, Prior (2003) suggests that older adults refusing flu vaccination do so because they believe individually that they are not themselves at risk. The rationalisations for this include that they have a healthy constitution and that they lead healthy lifestyles, that they are in some way 'immune' due to previous illness, or because they adopt avoidance strategies (Evans et al., 2007).

In terms of the large-scale epidemiological presentation/understanding of risk and the social responsibility attached to vaccination, this view is presented as irrational. As Hobson-West (2003) argues, however, a personalised understanding of risk in an increasingly individualised, atomised neoliberal society can actually be seen as completely rational – and, indeed, potentially reflective of the fact that individual responsibility and choice are emphasised in other areas of medicine and public health (Hansen and Easthope, 2007). If society is truly "made up of individuals behaving as risk-minimising-autonomous-rational-consumers, then it makes sense to 'free ride'. In other words, if we believe that others will continue to vaccinate it is rational for the individual to refuse the jab and avoid the personal risk, whilst still enjoying the collective benefits of herd immunity" (Hobson-West, 2003, p.277).

In research on those who have refused vaccines for their children, Attwell and colleagues (2019) show that those refusing vaccination downplay the significance of the size

of the number of people refusing vaccination (thus not impacting community immunity) and deploy various rhetorical strategies to undermine or reconfigure narratives of social responsibility. This includes criticising vaccinating parents for not possessing the confidence in vaccination to realise that the unvaccinated do not pose risks to their children. Vaccines are a preventative public health strategy that label everyone at risk of disease rather than as 'healthy' or 'ill' (Armstrong, 1995) but may nevertheless primarily be understood as a tool for individual benefit (Reich, 2020). Overall, this scholarship suggests a powerful disconnect between the population-level logic underpinning vaccination and a general public concerned with choice and the empowerment of the individual operating within a market economy (Blume, 2006, p.639, Hobson-West, 2003, Hobson-West, 2007, Reich, 2018, p.68-69).

The most commonly cited reason for hesitancy towards vaccination is safety concern (Yaqub et al., 2014, p.3). For example, in some high-income countries such as France there is a relatively high rejection of vaccination because of concerns about safety (Wellcome Trust, 2019). There may be more reflexivity, or higher levels of mistrust shown towards the interests and influences of the pharmaceutical industry within the public spheres of certain countries over other countries, something which requires further research – although countries of the world appear currently united in their current hope and faith in the pharmaceutical industry to lead the way out of the COVID-19 pandemic (Bingham, 2020. Evans and colleagues (2007), in a study concerned with the lay beliefs of older adults show that the reasons for refusing or defaulting on influenza vaccination included worries about side effects, concern that it would make them ill or that vaccination did not work (claiming, for example, that in a year that they had had the vaccine their influenza was worse). Considering the haste and political and economic pressures associated with the search for COVID-19 vaccination, concern about safety is already emerging (Whittaker, 2020). As discussed above, attitudes towards

vaccination and associated vaccination decision-making is comprised of, influenced by and distributed across a number of factors and influences (Rapley, 2008).

That safety concerns are so central in vaccine hesitancy is perhaps hardly surprising considering the volume of news coverage of vaccine controversies. It is only possible to speculate at this stage on the role that traditional and new media will play in the configuration of attitudes towards any successful COVID-19 vaccination. However, Speers and Lewis (2004), in research concerned with both the nature of news coverage and public opinion about the MMR vaccination, conclude that that journalists served to misinform the public by not exposing the case against the link between autism and the MMR vaccination as rigorously as the case for it. Suppli and colleagues (2018) meanwhile highlight, with respect to Denmark, an association between negative coverage of the side effects of the human papillomavirus (HPV) vaccine and decline in vaccination uptake. The uptake had previously been 90 per cent but fell to 54 per cent in girls born only a few years later following the emergence of controversy in 2014. Whilst the (potential) downstream influences of negative news coverage on public vaccine hesitancy are illuminated by these studies, interestingly, Jang and colleagues (2019), again in the context of the controversial link between MMR and autism, highlight how information that is generated and circulated on social media can flow 'bottom up' and influence mainstream media agendas.

The internet certainly offers a diverse range of voice greater availability of access to information about vaccination but also the chance for those with anti-vaccination proclivities to spread their message (Dube et al., 2015) (and, as above, even potentially shape mainstream media discourse). In this sense, vaccine hesitancy and resistance might also be linked to the more general development of a populist post-truth society (Kakutani, 2018). Scientific facts have become the object of chronic debate and contestation and social media has been important in this, offering an opportunity to spread potentially false interpretations or information and to

gain and unite a significant audience (Arede et al. 2019). There is certainly evidence that vaccine hesitant parents utilise online information more so than those parents who have had their children vaccinated (Kata, 2012). Smith and Graham (2019), through analysis of the Facebook pages of anti-vaccination groups, reveal a community bound together by moral outrage over the 'harmful' practice of vaccination. Users feel suspicious of and lack trust in mainstream vaccination knowledge and practice as well as in medical and government authorities. The algorithmic and wider architecture of Facebook (and other social media), particularly through the means of 'sharing', may result in the views of the anti-vaccination community having influence beyond those who choose to engage directly and actively with anti-vaccination content. Interestingly Smith and Graham also argue that social media engagement with this type of content is dominated by women, possibly reflecting the continued influence of traditional values associated with motherhood and child rearing responsibilities.

Vaccine Development and Manufacture: A Risky Business?

In the second half of this editorial we consider the role played by commercial and state actors in the development of vaccines. As such, we explore the influences and interests shaping the development and manufacture of vaccines. We also consider the differences in the development and availability of vaccines globally. Vaccine manufacture tends to form part of the work of biotech and pharmaceutical companies which are usually based in the commercial sector – the profit motive is, as such, highly significant in influencing decisions to develop and manufacture. The global vaccine industry is made up of three segments: (1) the large multinational R&D-based vaccine manufacturers who have about 80 per cent of the value of the global vaccine market but only 20 per cent of the manufacturing volume; (2) Developing Country Vaccine Manufacturers (DCVMs); and (3) small, high income country biotechs and niche manufacturers. The last two groups have the other 20 per cent of the value and deliver

80 per cent of volume primarily manufacturing large volumes of established vaccines at low cost (Towse and Firth, 2020). There is some debate about how far the vaccine market is an attractive proposition for pharmaceutical companies. For a period of time vaccines were a neglected corner of the pharmaceutical sector, with limited profit compared to other drugs although there is the suggestion that it has become more profitable in recent (pre-COVID-19) years with the vaccine market believed to be worth $61 billion because of the global rise in the threat of infectious disease (Guzman, 2016).

Evidence (see Mullard, 2020) suggests that only 6 per cent of vaccines that begin development successfully come to fruition in the market. A new vaccine takes on average ten years to develop. These timelines and rates of success obviously pose a risk for those investing in vaccination research and development. However, the COVID-19 pandemic clearly characterises a special set of circumstances because of its global threat in both high and low to middle income countries, to public health and social and economic life. Hence, Towse and Firth (2020) show that governments across the world have been willing to provide financial support for vaccine development. In the UK the government has committed financial support to organisations like the Centre for Epidemic Preparedness, and it is also supporting national vaccine development by providing direct R&D funding for two vaccine candidates, at the University of Oxford (in partnership with AstraZeneca), and at Imperial College London. It has agreed to invest at risk in a manufacturing facility that can be used by AstraZeneca to manufacture the University of Oxford vaccine (Towse and Firth, 2020) although overall the vaccine manufacturing capacity in the UK is limited (Bingham, 2020). AstraZeneca has been willing to forego profits from the vaccine at least during the period of this pandemic (Bingham,

2020) – although they certainly will profit eventually and there should be significant reputational gains (Garrison, 2020) if this vaccine development is successful[2].

The UK government have also invested in the Vaccine Manufacturing and Innovation Centre (VMIC) which is a not for profit research company within the national scientific infrastructure and whose stated aim is to provide strategic vaccine development and manufacturing capability. The apparent willingness here to share the risks of investment with the commercial sector and, in some instances, with trialling and manufacturing being carried out at the same time, might explain why the time it has been predicted to produce an effective and safe vaccine for COVID-19 has been relatively short (varying between 6 and 18 months). However, this conceivably might also be part of a rhetorical approach aimed at maintaining hope and enhancing public morale in a time of uncertainty (Calnan et al., 2020) although there have been some more recent attempts to temper public expectations (Bingham, 2020).

The highly competitive, global race to produce an effective vaccine for COVID-19 sheds light on other possible influences on vaccine manufacture. There is the question of how far drug companies can be trusted to develop vaccines in the public interest and if they can be trusted to supply to all in need globally (Garrison, 2020). Concerns have long been expressed about transparency and a willingness to make public their trial results and share data and results in a coordinated effort. Also, the expectation is that the vaccine will be universally accessible - but this will likely depend on geography, type of healthcare system, as well as commercial interests (pricing and profitability) influencing to whom, where and how quickly the vaccine is distributed (Mullard, 2020). It may also depend on nationalistic pressures where governments negotiate contracts to prioritise the supply of vaccines to their own population (Godlee, 2020).

[2] The phase 3 trialling of this vaccine was paused and then restarted in the early autumn of 2020 following reports of side effect in a patient in the UK arm of the research. A volunteer also died in the Brazil arm of the study, prompting a review of the trial but it was established that the individual had not been given the vaccine (BBC News, 2020).

The recent epidemic of another infectious disease, Ebola, in some African countries casts light on a different influence on or approach to vaccine development. The international response to Ebola has been characterised as the most recent manifestation of the securitisation of global health, and as one consistent with a longer history of securitising infectious diseases already seen in the cases of HIV/AIDS, SARS and pandemic flu (Roemer -Mahler and Elbe, 2016). These authors argue that by portraying or framing this epidemic as a security problem exemplified by the sending of the military to this region this facilitated the adoption of pharmaceuticalised solutions. This argument suggests that securitisation creates a distinct political space for the development, approval and administration of new pharmaceutical interventions (Roemer-Mahler and Elbe, 2016). Certainly, this ultimately accelerated the development and manufacture of a vaccine for Ebola. However, as Mullard (2020) shows it took over 40 years to produce a vaccine for Ebola. This timescale might reflect the political and economic context where it originated – in lower- and middle-income countries and where the disease did not have a significant enough high-income country burden (Towse and Firth, 2020).

Towse and Firth (2020) distinguish between pull and push factors although the balance in high income countries may be different to those for lower and middle-income countries. Push incentives reduce the costs to organisations of Research and Development (R&D) and of building manufacturing capacity, and pull incentives seek to compensate for the possibility of the market alone not providing enough of an incentive to "pull" through R&D and manufacturing capacity investment. For example, the UK government are currently providing push incentives for the speedy development of a vaccine for COVID-19 and Gavi, the Vaccine Alliance provided pull incentives for an Ebola vaccine where there was also concern about securitisation. Towse and Firth (2020, p.7) state that the "pull mechanism used by Gavi in 2016 ensured that there was a stockpile of vaccine candidates ready for a subsequent outbreak in

2019. At the start of this outbreak, stockpiled doses were licensed for compassionate use, and trials were jointly funded by multiple donors. At the end of 2019, a Gavi pull fund of $173m (to run from 2019-2025) was established to fund a stockpile of 500,000 doses, to be made available free-of-charge to the low- and middle-income countries affected." Similar pull incentives may be necessary in the context of a COVID-19 vaccination in certain parts of the world, although the risk nature of COVID-19 necessarily interests actors in high income countries more than is the case for some other diseases.

Uncertainties and Regulatory Governance

In this final section we now turn to consider in detail how governments regulate the development and dissemination of vaccines. We also build on the previous section to consider how the interests of state and industry might cohere. In the UK, regulatory governance involves reviewing evidence from three phases or levels of conventional clinical trials which are carried out to assess efficacy and safety within a typical timeframe of six years. The trials could involve deliberately infecting persons for reasons of urgency, but these are not favoured for ethical reasons and where natural infection is high such as with COVID-19 (Michaelis and Wass, 2020). In the UK, an expert review of all trial data is then carried out by the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (until January 2021). The regulators check that the trials show that the product meets the necessary efficacy and safety levels. They also aim to ensure that, for most people, the benefits far outweigh the risks. After the expert review, the regulator can grant a licence for the vaccine which confirms the medical condition the medicine should be used for and the recommended dosage. Post market surveillance monitoring in the UK is undertaken by the MHRA through the Yellow Card Scheme. Reports of suspected side effects are sent to the MHRA by drug

companies (who are obliged to pass on any reports of suspected side effects that are defined as serious), health professionals, and, since 2005, patients themselves.

There are two types of vaccines, preventative and therapeutic, which both require regulatory approval as concerned with safety and efficacy (see above) and (in the UK at least) are also likely to require regulatory approval in relation to cost-effectiveness. The cost effectiveness of a vaccine is believed to be influenced by several factors, including vaccine efficacy and durability, severity of disease burden, vaccine price, and costs of delivery programmes (Kim, 2011). However, recent literature has highlighted how cost-effectiveness analysis can neglect the broader economic impact of vaccines and that socio-ethical contributions such as effects on health equity, sustaining the public good of herd immunity, and social integration of minority groups (Luyton and Beutels, 2016).

The UK immunisation programmes to infants, adults and senior citizens are *preventative* vaccines that are administered to otherwise healthy individuals often at a very young age. In addition, an increasing number of *therapeutic* vaccines are being developed, which induce anti-viral immunity to alter the course of disease after infection or disease occurs (Brassel et al., 2020). In the UK, market access for both vaccine types are separated. The cost-effectiveness of the assessment of therapeutic vaccines is in the remit of the National Institute for Health and Care Excellence (NICE), which generally applies the same criteria as for other health-related interventions. However, no therapeutic vaccine has been appraised by NICE up until now (Brassel et al., 2020). The Joint Committee on Vaccination and Immunisation (JCVI) is an independent committee which advises Ministers of Health in the UK on preventative vaccine policy. The JCVI approach aims to be consistent with NICE's technological appraisal process and has a threshold for cost-effectiveness of £20,000 per quality adjusted life year (QALY). This said, the especially high economic and social costs of the COVID-19 pandemic might mean that a successful vaccine is assessed by different criteria.

The trustworthiness of regulatory apparatus has been critically examined particularly in respect to whether regulatory agencies are sufficiently independent enough to ensure vaccines are safe and effective. The work of Abraham (2008, see also Abraham, 1995, 2009, 2010) finds that neoliberal corporate bias underpins pharmaceutical regulation. Abraham suggests that over time pharmaceutical companies have established privileged influence on regulatory procedures. As pharmaceutical companies are often positioned as the 'customers' of regulatory agencies, who rely on business from pharmaceutical companies for their existence, there has been a gradual diminishing of what counts as proof of efficacy and safety as well as the length of time taken to review drugs. Long wait times and high regulatory burden have been argued by the pharmaceutical industry to stop patients getting the drugs they need and as making the costs of R&D too high to be profitable. Considering the vast economic and social pressures of the COVID-19 pandemic arguments for even less rigorous regulatory review and even more rapid review times for COVID-19 vaccines can conceivably be particularly powerfully made. Whilst the pharmaceutical industry and regulatory state work are from this perspective in partnership, importantly, neoliberal corporate bias within pharmaceutical regulation does not mean that the regulatory state does not have its own set of interests that it will assert in the face of high cost or political gain. In the context of COVID-19, a vaccine seems to have been positioned as the way to restore normal global economic functioning, whilst there is certainly significant national and international political capital to be won in the development of a successful vaccine (Garrison, 2020).

Russia purports to have developed a vaccine for COVID-19 which has shown 'sustainable immunity' against the virus based on phase 1 and 2 trials (Burke, 2020) and which may be used before the end of 2020 but these findings have been contested by the World Health Organisation in terms of how rigorous the evaluation has been and whether it is legitimate not to wait for evidence from phase three trials (Burke, 2020, Mahase, 2020). Similar concern has

been lodged about the language of haste adopted by the US government in the run up to the 2020 presidential election[3]. In the UK, the MHRA has started rolling reviews of the data granted to them in real time, with the aim of speeding up review of efficacy and safety data (Ring, 2020), whilst there has been a government consultative proposal which has become law (DHSC, 2020) to bypass the licensing process dependent on the advice of the JCVI if a vaccine for COVID-19 becomes available which is safe and effective (whilst also ensuring that a wide range of healthcare workers are legally allowed to administer the vaccine). However, it has been argued that there is the risk that, in this global race against time, efficacy and safety will not be given sufficient attention and that the emphasis will be for vaccines that reduce severity of illness rather than protect against infection and provide only short lived immunity, which, in both ways, might be beneficial for industry profit, and/or political and economic interests but not for global public health (Godlee, 2020).

Conclusion

In this editorial we have discussed what shapes hesitancy towards vaccination amongst the public as well as considering the roles and interests of manufacturers and governments in vaccine development. We have shown in this editorial how the sociological literature concerned with vaccine hesitancy indicates that it is reflective of the nature of decision-making, trust, understandings of risk and social responsibility, whilst also being influenced by information technology and various forms of media. Critical social science research into vaccine development is much less extensive though some important work does exist (see, for example, Blume and Zanders, 2006; Hardon and Blume, 2005). Yet, as the Covid-19 pandemic has amplified, there are issues in the supply chain which need to come under the microscope

[3] Although the Food and Drug Administration (FDA) in the US has expressed the need to ensure safety in the wake of the pausing of the Oxford/Astra Zeneca trial (Boseley, 2020).

of social science research – particularly what influences the decisions about when, how and which populations get access to vaccination programmes and how strong and effective the apparatus of regulatory governance is.

There is a need also to develop a conceptual framework which shows the interconnectivity between the supply side of vaccine development and take up. Research has explored vaccine trust relations between parents and professionals (Brownlee and Howson, 2005) and these authors have also tried to extend the understanding of the shape and nature of trust relations to wider influences including some discussion of the role of the media in relation to vaccination programmes (Brownlee and Howson, 2006). Brown and Calnan's (2012) analysis of trust relations in relation to the pharmaceutical industry offers a broader framework illuminating a 'chain' of different bases of trust, which together produce knowledge and assumptions upon which patient and public trust is grounded. The same approach can be applied to public perceptions of vaccination as well as the interrelationships between the provider, the public health system, the safety regulator and the manufacturer in the construction of knowledge around vaccines - and thus can act as a starting point for the analysis of risk, trust and hope in this area.

Acknowledgments:

With thanks to Dr. Richard Bates for recommendations relating to the social history of medicine and vaccination. Also, to Luke Shoveller for ever provocative discussion. Thanks finally to the editor Dr Patrick Brown for a number of highly useful comments.

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