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A lesson from MMR: is choice of vaccine the missing link in promoting vaccine confidence through informed consent?

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ABSTRACT

A recent study suggests that vaccine hesitancy amongst key demographics – including females, younger individuals, and certain ethnic groups – could undermine the pursuit of herd immunity against COVID-19 in the United Kingdom. At the same time, the UK Joint Committee on Vaccination and Immunization (JVCI) indicated that it will not facilitate the choice between available COVID-19 vaccines. This paper reflects upon lessons from the introduction of the UK's combined Measles, Mumps and Rubella (MMR) vaccine strategy of the 1980s when Member of Parliament Miss Julie Kirkbride argued that had parents been allowed to choose between vaccine variants, then the crisis of low herd immunity – and subsequent outbreaks – could have been avoided. This paper explores this argument, as applied to the COVID-19 vaccination strategy, by considering how three key elements of informed consent – disclosure of risk, benefit, and reasonable alternatives – may be employed to tackle vaccine hesitancy and build vaccine confidence.

KEYWORDS

Informed consent; vaccination; treatment choice; vaccine confidence; vaccine hesitancy

The novel and highly transmissible SARS-CoV-2 virus responsible for Coronavirus Disease 2019 (COVID-19) has infected over 261 million people globally and claimed more than 5.2 million lives (John Hopkins University & Medicine. Coronavirus Resource Center, 2021). Symptoms range from mild disease to severe acute respiratory distress. The virus is also associated with "long-COVID" – a chronic, multi-systemic, vascular dysfunction linked to a range of conditions including chronic fatigue, dyspnea, insomnia, palpitations, impaired male fertility and mental health conditions (Huang et al., 2021). The United Kingdom (U.K.) government was first to announce that it had granted temporary approval for a vaccine against SARS-CoV-2 in late 2020. Whilst vaccine uptake has been high amongst the *general* UK population, a large-scale study by Robertson and colleagues in 2021 indicates that vaccine hesitancy – " . . . *[the] reluctance or refusal to vaccinate*" (World Health Organisation, 2019) – remains prevalent amongst certain demographics (Mahase, 2020). Such hesitancy can threaten to undermine the high levels of community vaccine coverage required to reduce viral transmission, protect the vulnerable, and minimize the risk of outbreaks.

In the late 1990s, vaccine hesitancy peaked when the UK replaced individual vaccines with a combined, triple "Measles, Mumps and Rubella" (MMR) vaccine (World Health Organisation, 2019). At the time, Member of Parliament (MP) Miss Julie Kirkbride asserted that had parents been afforded a *choice* between the combined tripe vaccine or equivalent *single* vaccines and then the "*[subsequent] crisis in herd immunity*" could have been averted (U.K. House of Commons, HC Deb, 2002). This paper looks at lessons from MMR vaccine controversy and questions whether vaccine choice could help improve COVID-19 vaccine confidence. In doing so, it addresses the principles of informed consent, which may support this proposition, namely, that as a "*prophylactic*" form medical treatment, patients should be informed of risks, benefits, *and* reasonable alternatives (Public Health

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(Control of Disease) (Act, 1984)) s.45E(2); (Montgomery v Lanarkshire Health Board Health Board, 2015, p. 81). It will be argued that by fully implementing the requirements of informed consent vaccine confidence may be improved; discussions pertaining to the benefits and risks of vaccination can be used to tackle misinformation, whilst choice of vaccine could address concerns for specific vaccine side effects or safety (Montgomery v Lanarkshire Health Board Health Board, 2015).

Vaccine hesitancy

The combined triple measles mumps and rubella (MMR) vaccine

In the late 1980s, six *single* vaccines were replaced by the combined MMR vaccine on the UK childhood vaccination schedule. The aim – that a single, combined, vaccine would result in fewer missed appointments and higher uptake – appeared to have been attained by 1997 when 92% uptake was attained with MMR, just short of the 93% threshold of herd immunity (UK. Department of Health, 2014; Middleton, 2003; United Kingdom Government (UK Gov), 2013). However, in 1998, The Lancet published a paper that erroneously linked the combined MMR vaccine to the development Crohn's Disease and Autism (Wakefield et al., 1998(retracted). The now-retracted article resulted in an increase in vaccine hesitancy, the effects of which were still evident as recently as 2019 when there was a decline across all routine childhood vaccination rates ("NHS Digital," 2019). The Lancet Article sparked a debate about choice between the combined MMR and single vaccines. A qualitative analysis of parental MMR decision-making found that parents lacked open and unbiased information about the existence of alternatives to the combined MMR, including that the single vaccines remained available privately (Brown et al., 2012). Due to the disconnect between public and private healthcare in the UK, there is a lack of data to directly link combined MMR refusal to single vaccines uptake. However, Casiday et al. (2006) suggest that up to 82.7% of MMR-refusing parents *believed* separate vaccines were safer and two-thirds of those sought single vaccines privately. A separate study by Wrang and Gornall, (2004) suggests that 21% of combined MMR-refusers had opted for private single doses. These findings suggest that whilst a single-dose vaccine schedule may carry additional burdens (multiple appointments and increased costs), *choice* of vaccine may have improved confidence and have avoided outright refusal. Sonawane and colleagues suggest that addressing vaccine hesitancy in these "*on-the-fence*" or undecided groups should be a public health priority (Sonawane et al., 2021). This was also the recommendation of Dr Eileen Rubery, chair of the UK committee, which introduced the combined MMR vaccine. Rubery suggested that the psychology of offering people choice – even at their own expense – could be instrumental in tackling vaccine refusal by allowing them to "*. . . reflect more calmly on the options and understand the benefits of the triple vaccine*" (Mayor, 2002). This, she argued, could *"end the stalemate of refusal"* amongst determined vaccine refusers and should be considered as a strategy by the Department of Health (2014); Mayor, 2002).

COVID-19 Vaccines. In 2020, during the COVID-19 pandemic, Figuerido and colleagues cautioned that global distrust of vaccine safety and efficacy would result in even more widespread hesitancy (2020). Indeed, when the UK government announced that it would use rapidly developed COVID-19 vaccines as part of the *"largest vaccination programme in British history*," fears were immediately voiced over their safety, given " *. . . the average time of making a vaccine from scratch* [is usually] *over 10 years . . .* " (UK Gov, JVCI, 19 Oct United Kingdom Government, Joint Committee on the National Security Strategy, 2020; UK Gov, Dpt. Health & Social Care, 11 Jan 21). Rapid approval of treatments can impede confidence as was the case in 2010 when many Americans rejected the rapidly approved H1N1 vaccine (Schoch-Spana et al., 2020).

Concerns over the COVID-19 vaccine were further compounded with the introduction of new vaccine technology. Vaccines work by exploiting the immune system's ability to differentiate between "*self*" and *"non-self"* surface proteins found on cells or pathogens. Some traditional vaccines do this by delivering non-virulent pathogenic surface proteins into the body which will then prompt development of specific "immune memory" against the pathogen – this allows the body to mount a quicker,

stronger immune response should it encounter the actual pathogen (Chaplin, 2010). Three COVID-19 vaccines were initially granted temporary, accelerated authorization for use in the UK's vaccination program: those from AstraZeneca, Pfizer and Moderna (Regulation 174(a) Human Medicines Regulation, 2012; Medicines and Healthcare Products Regulatory Agency (MHRA, 2021a, 2021b, 2021c)). Whilst the AstraZeneca vaccine re-deployed this existing, previously licensed technology against the novel virus, the vaccines from Pfizer and Moderna introduced a new, previously *unlicenced*, form of "messenger RNA" (mRNA) vaccine technology. The mRNA vaccines manipulate the body's own cells to make harmless viral protein replicas to elicit a similar immune response (see, Table 1; Medicines and Healthcare Products Regulatory Agency (MHRA, 2021c; Falconbridge & Sandle, 2020)). However, some feared that this amounted to manipulation of DNA (Centres for Disease Control (CDC), 2021 November 3rd). The rapid and "temporary" authorization of these new COVID-19 vaccines – particularly those employing novel mRNA technology in lieu of long-term safety data – have raised the question of whether they amount to an *experimental* form of medical treatment (Anand & Stahel, 2021). The Medicines and Healthcare Regulatory Authority refute this claim, maintaining that they " . . . *[do] not consider these vaccines to be experimental[. . . as . . .] [t]he main efficacy and safety results for the Phase I, II and III trials have been submitted . . . [and deemed] sufficient"* however, concerns persist (Medicines and Healthcare Products Regulatory Agency, 2021). The MHRA's counterpart in the United States – the Food and Drugs Administration (FDA), 2021 – has similarly granted "emergency use authorisation" (EUA) for the vaccines which *"makes a product available to the public based on the best available evidence*" (Food and Drugs Agency (F.D.A; U.S.), 2020). Whilst "temporary authorisation" and "EUA" status do not equate to experimental status, the public's mere *perception* that they do may have profound implications, particularly for minority groups. Sims and Lacks (2021) explain that the legacy of the Tuskegee experiments – when the U.S. government sponsored experiments conducted on Tuskegee men – continues to fuel justifiable vaccine hesitancy amongst Black Americans to this day (Sims & Lacks, 2021).

Such hesitancy is noted amongst ethnic minorities in both the US and the UK. Black and minority communities are not only disproportionately affected by COVID-19 viral infection but also have the lowest levels of trust in the COVID-19 vaccines (Laurencin, 2021; Robertson et al., 2021). According to the large-scale study by Robertson and colleagues, vaccine hesitancy is as high as 71.8% amongst Black demographics in the UK. Younger demographics are also up to six times more likely to be hesitant that those aged 75 or over which may be linked to fears of infertility or miscarriage (Moodley et al., 2021; Robertson et al., 2021). Perhaps fueled by a " . . . *spike in conspiracy content . . .* " on social media platforms that shows the *"[t]he dominant coronavirus vaccine narratives . . . [now focus upon] . . . discussion of political motives . . . and . . . impact [upon] personal liberties*" and associated misinformation, rather than the protective benefits of vaccination (De Graaf et al., 2020; Sesa et al., 2021). Although there remains a "*general willingness*" to be vaccinated in the UK, it is estimated that vaccination rates must reach between 67% and 80% of the population for herd immunity to be

Table 1. Summary of vaccine types and method of development in relation to the initial vaccines which were granted temporary authorization in the United Kingdom as of January 2021.

Vaccine	Summary of Method of Development
Pfizer/BioNTech (Medicines and Healthcare Products Regulatory Agency (MHRA, 2021a),	New generation of 'messenger RNA' (mRNA) vaccines work by delivering a set of instructions – *mRNA* – directly to host cells. directing them to the produce SARS-CoV-2 surface proteins which will illicit an immune response.
Oxford/AstraZeneca (Medicines and Healthcare Products Regulatory Agency (MHRA, 2021b) and	The Oxford/AstraZeneca' COVID-19 vaccine – *ChAdOx1-S* – is developed using a traditional method by re-deploying existing research toward the COVID-19 effort. It therefore uses genetically modified chimpanzee adenovirus to express SARS-CoV-2 surface proteins which will trigger immunity (Medicines and Healthcare Products Regulatory Agency (MHRA, 2021a).
Moderna (Medicines and Healthcare Products Regulatory Agency (MHRA, 2021c)	New generation of 'messenger RNA' (mRNA) vaccines work by delivering a set of instructions – *mRNA* – directly to host cells.

attained (Randolph & Barriero, 2020). This could lead to waves of COVID-19 reemergence and waves of further re-infection. Such a problem is only likely to get worse given the increasing likelihood of annual – or bi-annual – vaccination boosters (Torjesen, 2021a). Robertson and colleagues urge that strategies be developed to boost herd immunity amongst identified demographics (2021). (Parmet, 2005) asserts that vaccine choice – a central covenant of informed consent – can be a useful public health tool in promoting vaccine trust and confidence.

Informed consent to vaccination as a public health tool

Reinterpreting autonomy

As prophylactic treatment, vaccines are subject to the same informed consent requirements of any other medical treatment (s.45E(2; Public Health (Control of Disease) Act, 1984); Royal College of Surgeons of England, 2018). Informed consent is integral in upholding patient autonomy, etymological root of which derives from the Greek word "*autonomous*" meaning "self-law" or "self-governance" giving the impression of a purely individualistic principle. However, when interpreted as a *relational* concept, autonomy may be of public health utility. Indeed, whilst some liberals are literal in interpreting autonomy as that which is free from all external influence (Stanford Encyclopedia, n.d), even liberal philosophers such as Kant concede a relational dimension to the principle. According to Kant, an autonomous decision must be rational in accordance with the Categorical Imperative which holds that one must only act "*. . . according to that maxim by which you can at the same time will that it should become a universal law*" (Kant, 1785). Similarly, Mill – in his famed publication "On Liberty"- concedes that whilst individuals should be free to pursue their own interests, they may rely upon others to warn them of risk (Mill, 1998)]. Mill employs the "poison warning label" analogy and that of the dangerous bridge as examples of why it is reasonable to challenge an individual's seemingly irrational decision-making (Mill, 1998). Communitarians give greater recognition still to the relational aspects of autonomy; an approach that was evident in some US cities, such as New York, where greater emphasis was placed upon the collective benefit of vaccination (NYC.gov, 2020). This was also evident in the UK with its long history of healthcare solidarity where the vaccination campaign focused on slogans like "save the NHS" and "protect the elderly" (NHS Rotherham, Doncaster and South Humber, n.d.). However, individualistic interpretations of autonomy have become increasingly politicized, during the pandemic. This was particularly evident in parts of the US where partisanship played a key role in determining attitudes toward public health measures with autonomy centered upon implications for the individual, perceived coercision, restrictions on freedoms and implications for the individual alone (Ye, 2021). In contrast, by introducing a relational caveat, Kant's *relational* approach to Liberalism requires one's own actions to be applicable to all so that individuals be held to the same standards as others in society during decision-making. It is in this way that autonomy can have public health utility – whilst maintaining the individual's right to come to their own decision it incorporates wider considerations such as societal risk and community benefit (O'Neill, 2020).

Public health utility of informed consent

According to (Parmet, 2005) "*. . . [by] respecting choices, however broad or limited they may be, informed consent provides individuals and communities with the respect and knowledge necessary for their acceptance and support of public health procedures*" (Parmet, 2005 at 107). Pamet emphasizes that informed consent is a particularly important tool in circumstances whereby "emergency approval" underpins vaccine use in a public health emergency – as is the case with the COVID-19 vaccines. The WHO also recognizes the value of informed consent as a public health tool by asserting that practitioners "*. . . remain the most trusted advisor[s] and influencer[s] of vaccination decisions and [therefore] they must be supported to provide trusted credible information on vaccines*" (World Health

Organisation, 2019). Similarly, in 2019 UK Ministers lent their support to enhancing standards of informed consent to improve vaccine confidence by calling 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 questions"* (U.K. House of Commons. HC Deb, 2019). The *"information-seeking behaviours and [. . . trust in . . .] health-care workers"* which derive from informed consent are, according to Figueiredo and colleagues associated with improved vaccine confidence and uptake and so should be promoted (Figueiredo et al., 2020).

The requirements of valid informed consent were determined in (Montgomery v Lanarkshire Health Board Health Board, 2015) when Lord Reed clarified that doctors are under a duty to " . . . *take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments . . . "* (87). This creates a legal duty to *"involve patients in decisions relating to their treatment"* which, in the case of vaccination requires disclosure of

- The benefits of vaccination
- The material risks of vaccination
- *Reasonable* treatment alternatives or vaccine choices (Montgomery v Lanarkshire Health Board Health Board, 2015 at 80).

"Relational" benefits of vaccination

General information pertaining to the benefits material risks and reasonable treatment alternatives are outlined by the MHRA and set out in Table 2 (MHRA(a)(b)(c)). In applying a relational approach to autonomy, practitioners should disclose both individual and collective benefits of vaccination. For the individual, vaccine efficacy in reducing severe infection and hospitalization stands at around 62–98% (see, Table 2). The Oxford/AstraZeneca vaccine has been associated with the lowest efficacy of the three vaccines across some demographics, which has led some European countries to favor the other vaccine types – this may have a similar influence upon individuals who may seek more coverage (European Medicines Agency (2021); Kington, 2021). Disclosure of benefit would also extend to providing information about the link between immunization and the attainment of herd immunity whilst recent pre-publication findings from Israel also suggest that the Pfizer vaccine reduces transmission of COVID-19 by up to 90%, which confers a societal benefit in protecting the vulnerable (Lubell, 2021).

If it is accepted that relational autonomy may be of public health benefit – by acknowledging that individuals depend upon healthcare practitioners for *"support and assistance"* – then this relational aspect of consent can potentially be enhanced to promote utility (2006). Whilst the law does not require decision-making to be rational, it does require that patients have fully understood the information provided. MacLean, however, argues that by questioning the *rationality* of decision-making, healthcare practitioners can ensure understanding and so better protect autonomous decision making which is founded upon concepts of capacity and competence (MacLean, 2006). It is to this end that MacLean proposes a model of mutual persuasion. Mutual persuasion involves information disclosure from both the patient (e.g., medical history or symptomology) and the practitioner (e.g., treatment information) that is not just purely informative, but instead involves active dialog that can challenge misconceptions – thus ensuring understanding – and provide a platform for patient and practitioner to persuade the other of their stance and ensure that the decision-making is both relational and informed (MacLean, 2006). Such persuasion is not to be confused with coercion – which would invalidate consent – as with persuasion the ultimate decision lies with the patient. Instead, it seeks to *enhance* understanding and so support and enhance informed consent.

Table 2. Risks and benefits of COVID-19 vaccines as contraindications, side effects and efficacy (Medicines Regulatory and Healthcare Authority, 2020a, 2020b, 2020c).

Type of COVID-19 Vaccine	Contraindications	Side Effects	Efficacy
Oxford AstraZeneca (Medicines and Healthcare Products Regulatory Agency (MHRA; b), 2021)	• Not suitable for those with hypersensitivity or concurrent illness. • Animal studies are incomplete on potential risk in pregnancy, with official advice to only administer the vaccine in pregnancy if potential benefits outweigh the risk – as is the case with the Moderna vaccine	Common associated side effects such as: • pain at injection site, • headache, • fatigue • myalgia, • chills, • arthralgia • nausea Uncommon side effects (≥ 1/1,000–10,000) • Lymphadenopathy • Anaphylaxis, hypersensitivity • Decreased appetite • Dizziness, somnolence, Guillain-Barré syndrome • Thrombosis with thrombocytopenia syndrome • Vomiting, diarrhea • Abdominal pain, • Hyperhidrosis, pruritus, rash, urticaria • Pain in extremity • Neuroinflammatory disorders	62–90% efficacy
Pfizer (Medicines and Healthcare Products Regulatory Agency (MHRA; a), 2021)	Contraindications exist for those with a history of anaphylaxis and data on risk to fertility or in pregnancy is currently limited to animal models	Common associated side effects such as: pain at the injection site, • fatigue, • headache, • myalgia, • chills, • arthralgia • pyrexia. Uncommon side effects (≥ 1/1,000–10,000) • Lymphadenopathy • Myocarditis, pericarditis • Hypersensitivity reactions • Decreased appetite • Insomnia • Lethargy, acute peripheral facial paralysis	95% efficacy

(*Continued*)

Table 2. (Continued).

Type of COVID-19 Vaccine	Contraindications	Side Effects	Efficacy
Moderna (Medicines and Healthcare Products Regulatory Agency (MHRA; c), 2021)	Animal studies are incomplete on potential risk in pregnancy, with official advice to only administer the vaccine in pregnancy if potential benefits outweigh the risk – as is the case with the Moderna vaccine	Common associated side effects such as: pain at the injection site, • fatigue, • headache, • myalgia, • chills, • arthralgia • pyrexia. Uncommon side effects (≥ 1/1,000–10,000) • Anaphylaxis, hypersensitivity • Dizziness • Acute peripheral facial paralysis, hypoaesthesia • Myocarditis, pericarditis • Injection site pruritus • Facial swelling	98% efficacy

"Relational" risks of vaccination

Whilst the benefits of treatment are more easily ascertainable, risk is determined according to a test of materiality. A material risk is that which "*. . . in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to this risk" (*Montgomery v Lanarkshire Health Board Health Board, 2015 *at 87)*. The proviso that material risk may also pertain to that which the practitioner should "reasonably be aware of" necessitates *dialogue* rather than mere monologue of information disclosure alone – and therefore further supports a relational interpretation of the benefits and risks of treatment. Disclosure of risk would likely involve common side effects, with a test of materiality used to determine whether a reasonable person would consider any rarer side effects to be relevant to the decision-making process. A discussion with the patient will also be needed to determine what additional risks the "*particular patient*" is likely to attach significance to (Montgomery v Lanarkshire Health Board Health Board, 2015, p. 81). This may involve disclosure of rarer side effects such as those identified during ongoing adverse drug reaction (ADR) monitoring (Torjesen, 2021b). For patients who have, for example, had cosmetic dermal fillers it may be deemed material that the Moderna vaccine has been associated with an immunological reaction to fillers that resulted in peripheral facial paralysis (Munavalli et al., 2021). Long-term data for all of the vaccines are as yet unknown. Discussion pertaining to risk should also include the risk deriving from a *failure* to treat, which could include susceptibility to COVID-19 infection and its associated risks of long-term complications and mortality that has occurred across a range of age demographics (Huang et al., 2021; John Hopkins University & Medicine. Coronavirus Resource Center, 2021).

COVID-19 vaccine alternatives

The third item for disclosure according to *Montgomery* is that of reasonable treatment alternatives, however at law, ambiguity remains over the legal interpretation and application of "*viable treatment alternatives*" (Montgomery v Lanarkshire Health Board Health Board, 2015 at 87). The term was first used nearly a decade before *Montgomery* in *Birch v University College*

London Hospitals NHS Foundation Trust (Birch v & University College London Hospital NHS FT, 2008) whereby the court confirmed a duty to discuss "*any reasonable alternative or variant treatments*" (Montgomery v Lanarkshire Health Board Health Board, 2015; v & University College London Hospital NHS FT, 2008). However, this only applied when the alternative options were associated with reduced risk compared to the proposed treatment (v & University College London Hospital NHS FT, 2008). *Montgomery* confirmed such a duty to inform of "*possible alternative or variant treatments*" with Lady Hale asserting that medical treatments cannot be considered in isolation as "*[m]ost decisions about medical care are not simple yes/no answers . . . [t]here are choices to be made, arguments for and against each of the options to be considered . . .* " (Montgomery v Lanarkshire Health Board Health Board, 2015 at 109). However, colleagues (Cave & Milo, 2020) caution that ambiguity continues to surround requirement to disclose reasonable treatment alternatives.

The leading authority on treatment *selection* is the case of (Bolam v Friern Hospital Management Committee (1957)) 1 WLR 582 which applies a test professional judgment to questions of treatment suitability. The test considers the suitability of treatment according to the opine of a body of medical opinion which would, therefore, excluding patients from such matters (Bolam v Friern Hospital Management Committee, 1957, p. 587). Scholars such as (Poole, 2019) have cautioned against using the *Bolam* test in relation to questions of treatment choice, arguing that it undermines *Montgomery's* intent to facilitate greater patient-centric care (Bolam v Friern Hospital Management Committee, 1957; Montgomery v Lanarkshire Health Board Health Board, 2015; Poole, 2019). Indeed, Montgomery – which was a landmark departure from the *Bolam* standard on matters of informed consent – centered upon the negligent non-disclosure of treatment alternatives during labor (Bolam v Friern Hospital Management Committee, 1957; Montgomery v Lanarkshire Health Board Health Board, 2015). (Cave & Milo, 2020) therefore argue that selection of treatment alternatives should be determined according to *Montgomery's* reasonable patient test that promotes greater patient-centricity and therefore choice (Cave & Milo, 2020; Montgomery v Lanarkshire Health Board Health Board, 2015). Nonetheless, the recent case (Bayley v George Elliot Hospital NHS Trust (2017)) applied a "*Bolam gloss"* to the issue of "reasonable alternatives" by suggesting that alternatives must be within the knowledge of a reasonably competent clinician, must be accepted practice and must be *appropriate*, not just *possible* (Bayley v George Elliot Hospital NHS Trust, 2017 at 99(5); Bolam v Friern Hospital Management Committee, 1957). On these grounds, patients would be informed of appropriate vaccine choices so that they might accept a vaccine which they have more confidence in. Facilitating choice would be particularly beneficial amongst minority demographics who have justifiable vaccine hesitancy due to historical government sponsored experimentations such as that which was seen at Tuskegee. It may also promote confidence amongst younger demographics who may have lingering fears about fertility, providing an opportunity for determined vaccine refusers to be presented with a "more trusted" option. For these "*on-the-fence"* groups, it is arguable that the ability to select a *preferred* vaccine type is favorable over outright refusal (Williamson & Glaab, 2018). For determined refusers, the option of another vaccine type could, present a golden opportunity to address persistent hesitancy.

Despite the strong legal case in favor of facilitating vaccine choice – and given that the UK Government have explicitly recognized that informed consent to vaccination is required – it is perhaps surprising that the JCVI recently indicated that choice of vaccine would likely not be available due to " . . . *operational and programmatic reasons . . . [only] one vaccine [type] may be offered . . .* " (Joint Committee on Vaccination and Immunisation, 2020). Whilst it is understandable that there be such logistical difficulties during a public health crisis and that, to some extents, individual rights of autonomy be limited, it is important to recognize that failure to fully uphold informed consent may undermine " . . . *efforts to build confidence in vaccination programmes in the longer term"* and moves to restrict choice could generate a "*counterproductive resistance*" (Williamson & Glaab, 2018). Therefore, as far as is possible, public policy should aim to facilitate patient choice of vaccine and improve access.

Empirical data

There is a widespread lack of empirical data specifically addressing whether vaccine choice could influence confidence and uptake. A 2021 joint study by the University of Bristol and Kings College London's into "Vaccine Confidence, Concerns and Behaviours" suggest that over 50% of the UK population *do* have a preferred choice of vaccine between Pfizer (28%), AstraZeneca (18%), Moderna (6%), and Johnson & Johnson (5%; Allington et al., 2021a, p. 5). However, in the US – where vaccine choice *is* currently facilitated – only 65.4% of the population had completed the initial vaccine protocol by March 2022, compared to 72.3% of the UK population where there is no such choice (Our World in Data, 2022). Whilst this could suggest that choice inadvertently *impedes* vaccine uptake, it is pertinent to note that, in the US, political views can strongly influence vaccine uptake as according to Albercht (2022) Trump supporters are far less likely to be accepting of vaccination. In the UK, where the political scene is different and there's greater emphasis on healthcare solidarity, the most common reason for vaccine hesitancy stems from concern over vaccine side effects (60%; Sethi et al., 2021). Therefore, direct comparisons between the US and UK political and healthcare landscapes cannot easily be drawn. However, there are similarities. Vaccine hesitancy is high amongst ethnic minorities in both the US and UK, and data suggest that the US model facilitating choice *could* promote increased uptake amongst these hesitant demographics. According to an analysis across 42 US States by Ndugga et al., (2022), 62% of White, 52% of Black, 64% Hispanic and 84% of the Asian population had received at least a single COVID-19 vaccine dose. This, compared to a UK Office of National Statistics (ONS) study from December 2021, which showed 49.9% of Black African, 66.6% of Black Caribbean and 39.7% of Mixed Ethnicity groups in the 18–29 year age bracket had *not* received a single COVID-19 vaccine (Office for National Statistics, 2022). There is no direct data comparing rates across all age groups in the UK at present; however, these preliminary data suggest that uptake may be lower amongst ethnic groups than in the US where choice is facilitated. A study by Allington et al. (2021b)) into UK "Vaccine Confidence, Concerns and Behaviours" found that those who did *not* respond to a vaccine invitation were more likely to have vaccine safety concerns (54%) than those who planned to attend their vaccine appointment (30%). Their data indicate that concerns may relate to specific vaccines and note that there has been a marked decline in confidence in the AstraZeneca vaccine option since it was linked to blot clots with only 15% now preferring this option (Allington et al., 2021a). Given that the majority of the UK population have vaccine preferences which may be influenced by safety or side-effect concerns, it may be argued that facilitating choice could have a positive impact on vaccine confidence. Nevertheless, it is evident that there is a growing need for specific empirical studies into the impact that choice has on vaccine confidence to fill this evidential gap.

Facilitating choice and improving access

Strategies to improve informed consent and facilitate choice will require more engagement and better infrastructure. However, there are likely to be concerns raised over time and resource pressures. The British Society for Immunology addressed such concerns in launching its "vaccine engagement starts at home" campaign aimed at "*. . . address[ing] common questions and concerns . . .* " through webinars and social media (British Society for Immunology, 2021). Its aim – to address misinformation – could help lay the foundations of informed consent by ensuring patients have early access to information. Burgess et al. (2021) also encourage policymakers to recognize that community engagement can "*accelerate dialogue*" and represent a cost-effective way of promoting vaccine uptake. Whilst appointments should include adequate time for informed consent discussions to take place, implementing a process of early supported decision-making can, therefore, help ensure efficient use of time and resources (O'Neill, 2020).

There may be further concern as to the logistics of facilitating vaccine *choice* in the UK, however an improved booking and stock management system could improve the already fragmented UK vaccine booking system. During the pandemic, NHS England utilized an online appointment-booking system

via an app, whilst NHS Scotland relied upon a letter or call-based invitation system (Maishman, 2021). In Scotland, this meant that appointments may be been pre-arranged at "hard to reach" destination – although NHS Scotland state that efforts are made to avoid this (NHS Inform, 2021). Other countries in Europe – such as the Republic of Cyprus – successfully introduced vaccination portals to facilitate both improved vaccine access and choice. Patients registered with the public "General Health System" (GHS or ΓΕΣΥ) could also directly contact a designated call center to seek advice and information on the available vaccine types to assist decision-making. Patients could then choose their vaccine appointment according to suitable venue, time, and choice of vaccine (Government of Cyprus, Ministry of Interior, 2020). Notably, choice of appointment time and location can also help mitigate against missed appointments by allowing patients to schedule vaccination around work or childcare commitments. Text message alerts were also as a reminder prior to the appointment. Cypriot common law is largely based upon the English common law system and so the relevant common law principles apply (Montgomery v Lanarkshire Health Board Health Board, 2015, p. 81). Since the Cypriot model requires choice of vaccine be made *before* the appointment, pre-appointment engagement is all the more crucial. The choice of vaccine has proved highly popular, and the system has been adapted to accommodate growing demand for choice (Chrysostomou, 2021; Rosenbaum, 2021). The software used allows the Ministry of Health to monitor vaccine availability and stock so as to ensure vaccine replenishment so as to "*meet the needs of the population*." In the first month of operation, Cyprus was one of the leading EU countries for vaccination (Our World in Data, 2021). Notably, when Denmark suspended use of the AstraZeneca vaccine on clotting fears, the Cypriot portal recorded a marked increase in requests for Pfizer vaccines; a trend that confirms that facilitation of choice may avert outright vaccine refusal when trust in one vaccine is undermined. Arguably the facilitation of such choice avoided the cancellation of appointments on grounds of safety fears. By contrast, the UK vaccine strategy provides patients with whatever vaccine is available on the day which could create anxiety and reduced confidence which could fuel hesitancy and subsequently lead to appointment cancellations. Recent reports suggest that vaccines are going to waste under parts of the UK system due to missed appointments with 60,000 Scottish patients missing their COVID-19 vaccination appointments in March 2021 due to delayed postal deliveries (Tapper, 2021; PA Media, 2021). The benefit of an *online* booking system is that it can adapt to demand – when uptake drops amongst one cohort, the next can be given access to book their appointments and maintain vaccine distribution. Whilst the Cyprus model is based on a much smaller population, it has already been upgraded and adapted to handle higher levels of use and aimed to facilitate 15,000 appointments per day by 2021 (University of Nicosia, 2021). If a similar system could be adapted for the UK, it could complement the existing UK vaccination program, support the process of informed consent and promote increased vaccine uptake.

Conclusion

Greater patient engagement must be a priority for public health policymakers if an ongoing COVID-19 vaccination program is to maintain or improve rates of uptake. Studies suggest that vaccine hesitancy remains prevalent in key UK and US demographics and particularly amongst ethnic minorities. Whilst the US has a choice-based vaccine strategy, it has seen lower levels of overall vaccine uptake. However, this figure is likely to be influenced by the US' unique political landscape. Amongst ethnic groups, rates of vaccine uptake actually appear higher in the US than in the UK which could indicate that choice improves vaccine confidence. In the UK, studies also indicate that most of the UK population have a vaccine preference and that their perception of vaccine safety may influence attendance at appointments. Informed consent is often considered an opposing construct to the collectivism of public health strategies, however, as a relational construct it provides opportunity to address misinformation and to facilitate vaccine choice where appropriate. The combined MMR controversy suggests that vaccine safety fears are often long-lived and that where choice is facilitated, there is the potential for increased uptake and mitigation of outbreaks. Now is the time to fully embrace informed consent to vaccination as a part of the public health vaccination strategy. The policy

and infrastructure model available in other countries provides a template for facilitating vaccine choice in the UK. This could, in turn, promote greater efficiency, reduce vaccine waste, and maximize the roll out so that herd immunity be attained more readily.

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