Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Since the first case of COVID-19 was identified in the USA in January, 2020, over 46 million people in the country have tested positive for SARS-CoV-2 infection. Several COVID-19 vaccines have received emergency use authorisations from the US Food and Drug Administration, with the Pfizer–BioNTech vaccine receiving full approval on Aug 23, 2021. When paired with masking, physical distancing, and ventilation, COVID-19 vaccines are the best intervention to sustainably control the pandemic. However, surveys have consistently found that a sizeable minority of US residents do not plan to get a COVID-19 vaccine. The most severe consequence of an inadequate uptake of COVID-19 vaccines has been sustained community transmission (including of the delta [B.1.617.2] variant, a surge of which began in July, 2021). Exacerbating the direct impact of the virus, a low uptake of COVID-19 vaccines will prolong the social and economic repercussions of the pandemic on families and communities, especially low-income and minority ethnic groups, into 2022, or even longer. The scale and challenges of the COVID-19 vaccination campaign are unprecedented. Therefore, through a series of recommendations, we present a coordinated, evidence-based, education, communication, and behavioural intervention strategy that is likely to improve the success of COVID-19 vaccine programmes across the USA.

Introduction

The Lancet Commission on Vaccine Refusal, Acceptance, and Demand in the USA formed to address the persistent and important threat to public health in the USA posed by suboptimal uptake of some vaccines. The focus of this first report by the Commission is the ongoing COVID-19 pandemic. Vaccine acceptance and uptake are essential to control the spread of COVID-19. Thus, the Commission has produced this report on current COVID-19 vaccine uptake in the USA, the consequences of low vaccination rates, and recommendations for the improvement of COVID-19 vaccine confidence and uptake.

Since the first case of COVID-19 was identified in the USA, in January, 2020, over 46 million people in the country have tested positive for SARS-CoV-2 and more than 735 000 people have died.1 Several COVID-19 vaccines have received emergency use authorisations (table 1) from the US Food and Drug Administration (FDA),2 but COVID-19 vaccine coverage in the USA remains insufficient to control the pandemic.3

Since January, 2021, 20% of adults in the USA have consistently reported that they will either get vaccinated only if required for work, or not get vaccinated at all.4 One of the most pressing factors contributing to this reluctance has been the unprecedented political polarisation that has affected virtually all aspects of the US pandemic response, as a partisan divide emerged during the previous administration.5–8 Research in political science, communications, and public health have shown that the politicisation of COVID-19 and the public health response to it has been highly detrimental to the success of the US response to the pandemic.9

In a survey from March, 2021, 49% of men affiliated with the Republican Party reported they would choose not to be vaccinated, as opposed to only 6% of men affiliated with the Democratic Party.10 Such findings reflect the fact that political leaders from both parties have allowed the pursuit of partisan goals to guide their actions and rhetoric.11–13 However, the rhetoric differs greatly and, therefore, the reasons for the current increase in COVID-19 cases and under-vaccination are not equally distributed. This increase also reflects rising anti-vaccine sentiments accelerated through the health freedom movement.14 The increase in misinformation is fuelled both by long-standing anti-vaccine movements and by foreign interference, with all of these groups capitalising on the algorithms of social media.15

The anti-vaccine movement in the USA is undermining public health. When COVID-19 was declared a pandemic, in 2020, many anti-vaccine groups were already organised and ready to campaign against masks, contact tracing, physical distancing, and other measures essential to pandemic control.16,17 Subsequently, the anti-vaccine movement in the USA has expanded its ongoing

| Initial FDA authorisation date | Vaccine type | Number of doses for full immunisation | Age for which use was approved |
|------------------------------|--------------|--------------------------------------|--------------------------------|
| Pfizer–BioNTech** Dec 11, 2020 | mRNA | Two | 12 years and older |
| Moderna Dec 18, 2020 | mRNA | Two | 18 years and older |
| Janssen (Johnson & Johnson) Feb 27, 2021 | Viral vector (adenovirus type 26) | One | 18 years and older |

FDA–US Food and Drug Administration. **The Pfizer–BioNTech vaccine received full FDA approval on Aug 23, 2021.

Table 1: COVID-19 vaccines FDA-approved for emergency use in the USA as of June 14, 2021
activities against both science and scientists. Ultimately, the major sources of anti-COVID-19 vaccine aggression emerging in the USA were led by political elements from the far right, together with anti-vaccine non-governmental organisations, including those identified as the so-called disinformation dozen by the Center for Countering Digital Hate. Such activities were further amplified by state actors, including Russia, seeking to destabilise the USA. Thus, overcoming the politicisation surrounding COVID-19, public health measures, and medical countermeasures has become a complex undertaking that, in some cases, will require interventions from outside of the health sector. Such comprehensive actions will be necessary to counter widespread hesitancy about COVID-19 vaccines and to prevent broader repercussions of low vaccination and risk behaviours.

Beyond the political divides, evidence amassing over the course of the pandemic has shown that COVID-19 disproportionately affects minority ethnic groups. In particular, the Centers for Disease Control and Prevention (CDC) have found vast disparities in the rates of COVID-19 cases, hospitalisations, and deaths for African Americans, Native Americans and Alaskan Natives, and Latinx groups, compared with their white counterparts. Inequities and disparities in the social determinants of health, including ongoing structural racism, access to adequate health care, socioeconomic status, physical environment, educational opportunity, and employment status, further exacerbate exposure to SARS-CoV-2 and the severity of COVID-19 disease.

These disparities are compounded by inequalities in vaccination. Tracking by the Kaiser Family Foundation has found consistently lower rates of vaccination among African American and Latinx people than among white US residents, which also contributes to the sustained transmission of COVID-19. These low rates are driven both by hesitancy and by access problems. Work to ensure equitable access to vaccines must also be coupled with efforts to address hesitancy. After sustained efforts at the community level to engage African Americans and Latinx people, some evidence shows that hesitancy in these communities is declining. In a March 2021 national poll, 25% of African American respondents and 37% of Latinx respondents reported choosing not to be vaccinated, compared with 28% of white respondents.

Potential consequences of insufficient COVID-19 vaccine confidence

The most severe consequence of failing to ensure adequate uptake of COVID-19 vaccines will be sustained community transmission. Exacerbating the direct impact of the virus, low uptake of COVID-19 vaccines will prolong the social and economic repercussions of the pandemic on families and communities. Currently, the lowest rates of COVID-19 vaccine coverage are found in conservative areas of the southern USA, including Louisiana, Mississippi, Alabama, and in the Mountain states of Idaho and Wyoming. These states have approximately 50% of the level of single-dose and two-dose vaccination coverage of that in the New England states of New York, New Jersey, California, and New Mexico. An important concern is the potential resurgence of COVID-19 in states with low vaccination coverage, similar to the peak of COVID-19 from July to September, 2020, in southern USA. Another concern is whether ongoing transmission might promote the emergence of variants, which could affect the ability of the USA to slow or halt COVID-19 virus transmission.

Strategies to promote COVID-19 vaccine acceptance

The scale and challenges of the COVID-19 vaccination campaign are unprecedented. A coordinated, evidence-based education, communication, and behavioural intervention strategy is essential to the success of this programme. Implementation should apply insights from research on vaccine education and communication while also recognising the extraordinary obstacles associated with developing and rolling out vaccines for the current public health emergency. Likewise, the plan should recognise potential implications of COVID-19 vaccines and vaccination on attitudes regarding routine vaccination.

Behavioural interventions

Public trust is a fundamental element of vaccination interventions and policies that achieve high coverage. We herein present evidence-based provider and healthcare system interventions to promote vaccination, and unique considerations in their applicability to COVID-19 vaccination (table 2). We organise our discussion according to a key factor for uptake: individual intention to receive the vaccine.

The most effective way to increase COVID-19 vaccine uptake is to make vaccination straightforward, so that it acts on existing intentions to vaccinate. One such approach is to keep vaccinations on people’s minds. Vaccination reminders do so by alerting a patient that a vaccine is available or due. Reminders are generally effective at increasing vaccination of children and adolescents, but their effectiveness for adults is unclear.

How the reminder is written is also an important consideration. For example, reminders sent twice to people already scheduled for an appointment and stating that a dose is “reserved for you” were most effective at increasing seasonal influenza vaccine uptake and should be considered for COVID-19 vaccine, especially for the second dose or for booster doses. Because few providers use existing reminder systems, centralising implementation of reminders within a health-care system or health department might be more effective. Nevertheless, the use of such alerts is more challenging for underserved populations who do not have regular sources of care, internet access, smartphones, or are otherwise disconnected from mass

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providers, which might correspond to high-risk populations (eg, the homeless).

Onsite vaccination

| Target population or setting | Settings where efficacy is unknown | Special challenges to COVID-19 vaccination |
|------------------------------|-----------------------------------|------------------------------------------|
| Centralised reminder         | Adolescent and adult vaccination  | Challenges with interoperability between COVID-19 vaccine registries and electronic health records might limit implementation of the reminder; reminders that use contact information in immunisation registries will have minimal penetration into adult populations because not all states input adult immunisations into online registries. |
| Default appointments          | Childhood and adolescent vaccination | Would not reach those who do not already have established providers, which might correspond to high-risk populations (eg, the homeless). |
| Standing orders               | Childhood and adolescent vaccination | Anticipated increased scepticism or questions regarding COVID-19 vaccines compared with other vaccines might make standing orders less effective. |
| Presumptive provider communication | Adult vaccination or when there is not yet a trusted relationship with the provider | Questions or scepticism around vaccine release and informed consent for COVID-19 vaccination might make this approach less useful. |
| Onsite vaccination            | Adolescent vaccination            | Both the Pfizer-BioNTech and Moderna vaccines require two doses for full immunisation. |
| Incentives and mandates       | Applicable to most vaccines       | Might encounter political barriers and fuel disinformation efforts from anti-vaccine and other counter-activism movements. |

Interventions are shown ordered to match a clinical encounter. “Childhood vaccines generally refer to vaccines administered to very young children (often from birth to children entering kindergarten [aged 5–6 years]); however, currently, there are no COVID-19 vaccines authorised or approved for use in children younger than 12 years.”

Table 2: Proposed interventions to increase vaccine uptake

Providers have several options when addressing the heterogeneous group of people who are disinclined to receive a COVID-19 vaccine. Patient counselling using reflective listening techniques or motivational interviewing might assuage vaccine hesitancy, but training providers on these communication techniques can be time-consuming, making scale-up challenging. For patients who refuse COVID-19 vaccination, recommending it at subsequent visits is a strategy supported by evidence based on parents who refuse human papillomavirus vaccination for adolescents. Whether this strategy works with adult patients is yet to be determined.

Other interventions, besides trying to persuade people, can effectively shape vaccination behaviour. Patient incentives can increase vaccine uptake; for example, financial incentives that eliminated out-of-pocket costs for the influenza vaccine appear to be effective. However, incentives might widen disparities if their use mirrors existing variation across health systems and public health jurisdictions.

Mandates—with or without non-medical opt-outs—are effective for vaccination across all age groups and health-care workers. To be ethical and practical, mandates are most appropriate after several criteria are met, including good access, an established safety record, and widespread support. The form, legality, and effect of mandates are complex, and a full discussion of these aspects is outside of the scope of this paper.

In general, the case for COVID-19 vaccine mandates is strongest for health-care workers, adults living in
congregate settings (such as universities), employment settings, and for activities where physical distancing is not possible (such as indoor concerts or crowded workplaces). Mandates for teachers and other adults in schools might increase vaccine uptake and reduce the transmission to children. Given the consequences of keeping children from school, mandates for school-aged children (aged 5–18 years) should be considered only after extensive experience with the vaccine and education for parents. Allowing individuals with proof of vaccination and communities with low rates of transmission to return to otherwise restricted social activities can also be an incentive for vaccination. Additionally, based on the 1905 landmark case, Jacobson versus Massachusetts, which resulted in the US Supreme Court upholding the rights of states to pass and enforce compulsory vaccination laws, the government has the right to enforce reasonable COVID-19 vaccine mandates for the protection of public health and safety of its citizens. With considerations of the aforementioned criteria and given the recent FDA approval of the Pfizer–BioNTech COVID-19 vaccine, appropriate COVID-19 vaccine mandates are an important and necessary element to controlling the pandemic.

Addressing sociodemographic inequities

Considering the devastating burden of COVID-19 on minority ethnic and socially vulnerable communities, guaranteeing equitable access to COVID-19 vaccines means ensuring even application of the approaches previously described, as well as of approaches used for other health promotion foci, such as pharmacist-administered vaccinations and outreach to community sites (eg, hair salons and churches). Identifying effective strategies to improve COVID-19 vaccination in marginalised communities could mitigate the disproportionate burden of COVID-19. More specifically, public health officials must engage with community leaders and local organisations to support accurate vaccine messaging that is culturally attuned to their respective communities. COVID-19 interventions and response efforts that address inequities and disparities need to be prioritised.

Promoting public health communication

Social media is an important channel to disseminate science-grounded messages about COVID-19 vaccination. Analytics tools and other methodologies enable researchers to assess the spread and reach of memes and narratives targeting distinct communities on social platforms. Videoclips from broadcast media and article weblinks from news sites provide additional visibility into mass-media messages that communities are sharing on social channels. Data on sharing behaviours, content, and reach can provide an understanding of what emerging narratives are gaining in popularity within specific communities or on distinct platforms. These data provide an opportunity to tailor a response or debunk misinformation for the communities that have already seen it, and enables those in charge of communication in a particular area or setting to establish whether a more widespread so-called prebunking is useful to ensure that the broader public receives accurate information on the misinformation topic before it gains traction.

An effective education and communication strategy should articulate the roles and responsibilities of the many entities that will contribute to COVID-19 vaccination efforts—beginning with federal, state, and local public health agencies, and extending to physicians, nurses, other health-care providers, and their respective professional organisations, among other contributors. Federal leadership through the CDC will be instrumental to the successful development and implementation of a coordinated national approach. Similarly, companion regional-based, state-based, and community-based efforts will be essential to tailor activities to the many audiences they are intended to reach, particularly health-care providers and the public. A vital role of the CDC and companion efforts is to provide people with opportunities to have their questions about the vaccines answered.

All vaccine education and communication efforts must include specific attention to minority ethnic groups and other populations who bear disproportionate burdens of COVID-19. Because of ongoing and historical mistreatment, distrust in government medical and public health programmes is pervasive among these groups. Tailoring pro-vaccine messages and engaging with local leaders across white, Christian, and conservative communities who also have low levels of vaccine uptake is likewise important. Without sustained, tailored efforts to reach and engage all US communities, COVID-19 vaccination programmes might not reach those who stand to benefit the most from these vaccines, potentially exacerbating disparities in morbidity and mortality. Developing approaches to engage and respond to those views with evidence and empathy is imperative. By partnering with local organisations, religious leaders, and other trusted community voices, health officials will be able to better understand and address specific questions and concerns about COVID-19 vaccines among such populations.

Another element that must be addressed are the programmes of so-called weaponised health communication against COVID-19 vaccines. As mentioned before, the sources of this weaponised health communication include dedicated anti-vaccine groups that promote COVID-19 conspiracies through social media and e-commerce platforms and systematic attempts to destabilise the USA in this space from some foreign governments, including Russia. Countering such activities requires a multifaceted response, possibly including the de-platforming of the more egregious anti-COVID-19 vaccine disinformation and strengthening diplomatic channels with Russia. Since January, 2021, some US conservative news outlets, including cable news networks, have also pursued a path of weaponised
health communication. Countering these activities by amplifying accurate and timely vaccine information is essential, but there are concerns that this action by itself will not be sufficient. Therefore, looking at levers outside the traditional health sector that previously have been successful in countering aggressive disinformation is urgently necessary.

Overall, a national campaign for COVID-19 vaccine education and communication must be dynamic, agile, and supported by adequate financial resources to help local and regional groups to improve vaccine uptake in their communities. Just as important as the development of these materials is their dissemination; the messaging means must be selected for maximum effect. Public health leaders and contributors must use evidence to re-evaluate the campaign formally and continuously, nimbly responding to shifting circumstances and knowledge, and revising approaches accordingly. Public education and communication efforts outlined here provide the opportunity for COVID-19 vaccinations to gain widespread public confidence and maximise the effectiveness of implementation in shifting the trajectory of this ongoing public health crisis.

Summary of major findings
The political environment has profoundly affected COVID-19 vaccine development, distribution, and ultimately uptake. This challenge requires continued direct and substantive communication to groups and prominent individuals connected to people who are indicating they will not be vaccinated, such as conservative groups. This area is one that many vaccine experts and scientists could find uncomfortable, but it might become essential for success. The USA now has a sharp geopolitical vaccine uptake divide, as states in the south and the Mountain region lag substantially behind the northeast or West Coast. These areas are at high risk of ongoing COVID-19 transmission. Compounding the vaccine geopolitical divide is systematic weaponised health communication from both dedicated anti-vaccine groups with tens of millions of social media followers, and state actors such as the Russian Government.

Another aspect of constructive public health policies is the recognition of the importance of human behaviour in shifting the course of the COVID-19 pandemic in the USA. However, established approaches offer guidance on how to examine the specifics of health behaviours around vaccination, and COVID-19 vaccines specifically. Applying state-of-the-art behavioural science to vaccination presents opportunities to address issues surrounding vaccine uptake.

Recommendations
To address the gaps outlined in this report, the Commission presents some recommendations to national, state, and local governments, as well as to other public and private entities.

First, pre-marketing and post-marketing vaccine surveillance needs to be communicated clearly and continually to the public, press, community organisations and leaders (especially for populations experiencing social and economic disadvantage), and health-care providers who will be engaging with distrustful or hesitant patients. Communication must adapt to reflect emerging situations, such as extent of community spread, safety events, level and durability of protective immunity, availability of new vaccines, requirements for boosting, and need for targeted campaigns based on the best evidence from behavioural science. Messaging and framing are also key: experts who communicate on local and national platforms should have relevant expertise in infectious diseases, epidemiology, vaccinology, immunology, social and behavioural science, and public health.

Second, science communication and knowledge translation outreach and partnership efforts should engage with local and national press and journalistic organisations to educate journalists, news editors and production staff, and social media staff to communicate accurate and non-sensational vaccine messaging; and offer technical advising (eg, regarding topics, issue framing, and graphics or visualisation) to news outlets and social media platforms to produce news content and public service announcements. This content should be designed to effectively educate and reassure broad, diverse audiences regarding key vaccine-related topics. Ideally, these media engagement efforts to build public trust on vaccines should be formulated and implemented as soon as possible.

Third, the most effective way to increase COVID-19 vaccine uptake is to make it straightforward to act on existing intentions to vaccinate. We recommend behavioural interventions with evidence of improving vaccine uptake for other immunisations, including reminders, strong clinician recommendations, and onsite clinics.

Fourth, once provided with the clear evidence that minority ethnic groups are disproportionately affected by the COVID-19 pandemic, community leaders should engage with local organisations to increase access to COVID-19 vaccines by implementing additional community-based vaccination sites with health-care staff who are culturally competent (ie, who integrate knowledge about individuals and groups of people into practices that are used in appropriate cultural settings to increase the quality of care). Additionally, this engagement could support accurate vaccine messaging that is culturally based and catered to such communities and other populations experiencing social disadvantage. Special focus, interventions, and response efforts to ensure equitable access and uptake should be a priority.

Fifth, outreach to politically conservative groups around the urgency of vaccinating all US residents, which includes engaging conservative leaders willing to serve as COVID-19 vaccine champions, should be promoted.
Finally, interagency government task forces need to be established to examine options for countering coordinated disinformation from both national anti-vaccine activist groups and state actors. Beyond the Health and Human Services agencies, such as the CDC, all government agencies must recognise the impact of anti-vaccine activities on homeland security, commerce, and justice, and consider representation from these branches of the federal government. Efforts must also include the Department of State to address the weaponised health communication around COVID-19 vaccines.

Conclusions
COVID-19 vaccines present the most plausible intervention to sustainably control the pandemic. However, surveys suggest that a substantial number of individuals might not seek the vaccine. Furthermore, because of vaccine hesitancy and refusal linked to politics, the USA is at high risk of having regions with considerably low vaccine coverage, such as the southern and Mountain states, where sustained COVID-19 transmission is underway, and which might also promote the ongoing emergence of variants of concern. Fuelling vaccine refusal are programmes of anti-vaccine disinformation. Therefore, a national communication and behavioural intervention campaign is essential to ensure a high enough COVID-19 vaccination coverage to effectively control the COVID-19 pandemic and thus allow a return to normal social and economic activity in the USA. Interagency government efforts must be simultaneously implemented to examine options to further defuse anti-vaccine disinformation.

Contributors
All authors contributed to the drafting and revising of the manuscript.

Declaration of interests
The Lancet Commission on Vaccine Refusal, Acceptance, and Demand in the USA is co-hosted by the Yale Institute for Global Health (New Haven, CT) and the Baylor College of Medicine (Houston, TX). PJH is a developer of a COVID-19 vaccine construct that was licensed by the Baylor College of Medicine to Biological E, a commercial vaccine manufacturer, for scale-up, production, testing, and licensing. NTB is a member of a Data Safety Monitoring Board for Pfizer and Merck, and personal fees from Biotechnology Innovation Organization, outside the submitted work. YAM is a member of a Data Safety Monitoring Board for Pfizer and a site principal investigator for a Pfizer vaccine trial unrelated to the submitted work. MMM reports personal fees from the US National Institutes of Health outside the submitted work. DRR also reports serving in an unpaid volunteer capacity on Moderna’s ethics allocation committee. DAS reports grants from the US National Institutes of Health and Pfizer, GlaxoSmithKline, Sanofi Pasteur, and Merck; and personal fees from Biotechnology Innovation Organization, outside the submitted work. DAS reports grants from the US National Institutes of Health outside the submitted work. DRR also reports serving in an unpaid volunteer capacity on Moderna’s ethics allocation committee. DAS reports grants from the US National Institutes of Health and Pfizer, GlaxoSmithKline, Sanofi Pasteur, and Merck; and personal fees from Biotechnology Innovation Organization, outside the submitted work.

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