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.

meningococcal disease in the PiC study were re-assessed before the patient became severely ill and did not lead to admission to intensive care units or mortality, although these observations are based on a low number of participants. Providing feedback to doctors on missed cases is essential for their continuous education.

Guidelines could be updated with improved diagnostics for early detection of serious illness and invasive meningococcal disease to improve their specificity without compromising sensitivity. However, the low number of cases of invasive meningococcal disease identified in the PiC study[1] highlights the difficulty of identifying predictors of the disease in future studies. These low numbers of cases could hinder the identification of new biomarkers. Furthermore, patients and doctors value false-positive classifications (resulting in overtreatment) differently to false-negative classifications (resulting in missed cases of invasive meningococcal disease). The relative weight of harms versus benefits might differ from patient to patient and from doctor to doctor.[8]

It is certain that less conservative clinical practice guidelines require parents to be more empowered to recognise serious infections in, or unexpected deterioration of, their child and to know how to act on this knowledge. Therefore, at the same time as clinical practice guidelines are revised and potential new biomarkers are implemented, we will need to develop appropriate tools to inform parents about serious illnesses and how to seek help.[9,10] Yet, the art of evidence-based medicine is the individual trade-off between the risk of missing invasive disease and the benefits of a more efficient clinical practice guideline. This approach cannot exist without adequate contingency measures (ie, the so-called safety net), which should be tailored to each individual case and its setting, and to the possibility of a rapidly deteriorating disease course.

We declare no competing interests.

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In favour of a bespoke COVID-19 vaccines compensation scheme

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The licensing of three vaccines in the UK and preliminary data from further vaccine candidates give reason to hope for substantial reductions of COVID-19 incidence in 2021. Uptake will depend on securing sufficient vaccine supplies, creating a robust and equitable distribution scheme, and fostering public trust in the safety of the vaccines with adequate legal safeguards to prevent and compensate for inadvertent harm.

Surveys and sociological research indicate a worrying increase in vaccine hesitancy in some countries over the past decade.[1] It is, therefore, vital to invest sufficient resources in creating conditions that maximise uptake and minimise opportunities for hesitancy. The time to do so is now. The novel technologies on which leading COVID-19 vaccine candidates are based and misinformation campaigns are already contributing to public uncertainty. Now that roll-outs have started,

existing concerns will probably be exacerbated by reports of adverse effects—regardless of whether confirmed to be connected to vaccines or not—such as the (contributory) role of the Pfizer-BioNTech vaccine for allergic reactions or the (non-contributory) role in deaths among Norwegian care home residents. In 1976, fears of an imminent pandemic triggered the rapid US roll-out of a new vaccine against swine flu (H1N1). Low H1N1 mortality and adverse effect reports led to an abrupt halt of the vaccination programme and reputational damage for public health authorities.[2] Rumours and conspiracy theories will also occur, as in 2019, when rumours about the new Ebola vaccine being unsafe led to hesitancy.[3] The Serum Institute of India (Pune, India) is already facing the prospect of litigation based on a volunteer alleging neurological illness after receiving the Oxford-AstraZeneca vaccine.

Following the roll-out of well tested vaccines, an important tool for maintaining public trust is to guarantee that victims are rapidly and adequately compensated. The importance of compensation is illustrated by the 1955 Cutter incident, during which inadequate specifications and production shortcomings resulted in the vaccination of around 200 000 US children with a virulent live polio strain, leading to 200 cases of paralysis and ten deaths. The Cutter incident laid bare the need for adequate compensation for those injured by the vaccine, many of whom had to resort to litigation to obtain compensation. This resulted in financially crippling lawsuits for manufacturers and significant emotional burdens for many families.[4] The passage of the UK's own Vaccine Damage Act 1979 was linked to overcoming ultimately unfounded public concerns about the new diphtheria, pertussis, and tetanus combination vaccine and the idea that "individuals who are vaccinated for the good of society, should be compensated for taking that risk when things went wrong".[5]

Guaranteeing that recipients of COVID-19 vaccines are automatically eligible for compensation that covers not only health-care costs but also loss of livelihoods will help to maintain public vaccine acceptance.[6]

Compensation can in principle be gained by bringing proceedings before the UK courts. There are, however, major obstacles to overcome in such proceedings, and consequently the success rate of actions involving medicines and medical devices in the UK has not been high, with claims failing on defect and causation grounds. The no-fault scheme created by the Vaccine Damage Act 1979 allows for a lump-sum payment in favour of people who have been severely disabled as a result of vaccination against specified diseases. COVID-19 vaccination has been added to this scheme. There is, however, an upper limit of £120 000 on awards, and so amounts are lower than damages awarded by courts—thus incentivising litigation. Another issue is whether the claimants are able to show a link of cause and effect between the injury and the vaccine, and more than 65% of claims do not succeed because of failure to overcome this hurdle of causation.[7]

We believe that a bespoke COVID-19 vaccine compensation regime should be created. This would avoid public and private resources being expended on complex and expensive litigation.[8] Such a compensation scheme should be based on a no-fault model, with a simple, swift, and accessible procedure, providing a fair and equitable remedy. Compensation should be based on need, and the sums available should be sufficiently high that victims are not tempted to litigate to top-up the award. There should be no arbitrary cap on damages. Proving causation could be facilitated by an expert-led process allowing for identification of situations in which vaccination is linked to a particular adverse effect. The scheme could be funded by a mixture of public and private funds.

Being proactive in establishing such a fund will improve the chances of any immunisation programme being effective while reducing overall costs to society. It would also mirror the proposal made by the COVAX vaccine facility, co-led by WHO and Gavi, the Vaccine Alliance, in favour of a public–private co-financed, no-fault scheme to compensate those in low-income countries who suffer any side-effects from COVID-19 vaccines.[9] New variants of severe acute respiratory syndrome coronavirus 2 with potential reduced susceptibility to existing vaccines and the strong likelihood that COVID-19 will become a regularly recurring endemic disease means that we need to ensure maximum public support of this first and all subsequent vaccine roll-outs.

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Bell's palsy and SARS-CoV-2 vaccines

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In light of the ongoing pandemic, development of vaccines to protect against SARS-CoV-2 infection and COVID-19 disease is an important public health priority. As of February 2021, two SARS-CoV-2 vaccines have received emergency use authorisation by the US Food and Drug Administration (FDA), both of which use mRNA technology. While the safety data are reassuring, phase 3 studies of both vaccines demonstrate an imbalance of cases of Bell's palsy in the vaccine groups compared with the placebo groups. This Comment has three purposes: to briefly review the literature on the association of Bell's palsy with vaccination, and vaccination for respiratory viruses such as influenza in particular, to consider biological mechanisms that might explain observed associations, and to reconsider statistical and epidemiological evidence from the reported safety data of the SARS-CoV-2 vaccine trials.

Associations between influenza vaccines and Bell's palsy have been studied extensively (table). Elevated incidence of Bell's palsy among recipients of an inactivated intranasal influenza vaccine was reported in a study conducted in 2000–01.[1] Since this vaccine contained the *Escherichia coli* heat-labile toxin as a mucosal adjuvant, which undergoes retrograde neuronal uptake, it was suspected that heat-labile toxin could affect the seventh cranial nerve through

	Vaccine type	Study design and population	Study period	Summary of the results
Inactivated intranasal influenza vaccine[1]	Virosomal subunit vaccine	A matched case-control study and case-series among patients with Bell's palsy (≥18 years of age)	2000–01	During the 91-day exposure period, compared with controls, recipients of the vaccine had an adjusted odds ratio for Bell's palsy of 84·0 (95% CI, 20·1–351·9)
Parenteral inactivated seasonal influenza vaccine[2]	Protein-based split vaccine	Review of adverse events reported to VAERS	1991–2001	Proportional reporting ratio of Bell's palsy after influenza vaccine: 3·78 (95% CI not provided)
Monovalent pandemic H1N1 influenza vaccine[3]	Split virion adjuvanted with AS03	Retrospective cohort study among 1 024 019 individuals vaccinated with pandemic influenza vaccine	2009–10	Increased incidence of Bell's palsy compared with unvaccinated people, with a hazard ratio of 1·25 (95% CI, 1·06–1·48)
Monovalent pandemic H1N1 influenza vaccine[4]	Two protein-based vaccines: adjuvanted with MF59, or without adjuvant	Review of adverse events reported to NADRRS, Taiwan	2009–10	Increased risk for Bell's palsy 0–42 days post-vaccination; estimated-to-expected ratio of 1·48 (95% CI, 1·11–1·98)
Quadrivalent meningococcal conjugate vaccine[5]	Protein vaccine conjugated to a carrier protein	Self-controlled case-series analysis among 48 899 individuals immunized with meningococcal vaccine (11–21 years of age)	2011–13	Increased relative incidence for Bell's palsy in participants receiving concomitant vaccines (5·0, 95% CI, 1·4–17·8)

VAERS=US Food and Drug Administration's Vaccines and Related Biologic Products Advisory Committee. NADRRS=National Adverse Drug Reaction Reporting System.

Table: **Summary of studies reporting an association between vaccination and Bell's palsy**