October 01, 2021

The Independent Scientific Advisory Group for Emergencies (SAGE)

The Independent SAGE

Call for more transparency around JCVI recommendations for childhood vaccination against COVID-19

www.independentSAGE.org
@independentSAGE
YouTube: IndependentSAGE

Submitted to The UK Government and the People of Great Britain & Northern Ireland by Sir David King, former Chief Scientific Adviser, UK Government, Chair of Independent SAGE

Call for more transparency around JCVI recommendations for childhood vaccination against COVID-19

The most recent statement of the Joint Committee on Vaccination and Immunisation (JCVI) on 3 September recommended that only 12-15 year olds with specific underlying health conditions receive the Covid-19 vaccine, despite their risk benefit analysis showing marginal benefit for all 12-15 year olds.

No minutes from JCVI meetings discussing Covid-19 are available since 16 February 2021. The three public statements in July, August and September on whether to rollout vaccination to all 12-17 year olds lack transparency. Unlike previous statements on vaccine priority groups, dose interval and the use of the AstraZeneca vaccine, the statements on childhood vaccination do not contain the detail needed to understand or assess their decision on the balance of the risk- benefit, and fall short of the requirements for openness set out in the committee's Code of Conduct (see Annex). In this short statement we highlight where transparency is needed and call on the JCVI to make the missing information publicly available.

JCVI statements on vaccination for Covid-19 in 12-17 year olds: lack of transparency

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) approved the use of the Pfizer/BioNTech vaccine for those aged 16 years and above in December 2020, and for 12-15 year-olds on 4 of June 2021.

The JCVI have released three statements to date on offering vaccines to 12-17 year olds. The first on 19t July 2021 recommended that COVID-19 vaccines should only be offered to those under 18 who were either living with immunosuppressed household members or had one of a specified set of pre-existing conditions. The second, on 4 August 2021, recommended one dose of vaccine for all 16 and 17 year olds but not 12-15 year olds. The third, on 3 September 2021, expanded the list of pre-existing conditions that made 12-15 year olds eligible for vaccination but did not recommend extending vaccination to all 12-15 year olds. This is despite the analysis they presented showing benefit from vaccination for healthy 12-15 year olds in terms of hospital admissions, ICU admissions and cases of Paediatric Inflammatory Multisystem Syndrome (PIMS) averted.

No explanation of their methods for determining risk-benefit has been provided, and the analysis provided across the three statements is lacking in several areas, as detailed below.

Information required for understanding risk/benefit tables from JCVI	Provided by JCVI?	Comments
Assumptions made about the risk of Covid		
Chance of needing hospital if Covid positive	Partly	This was an outcome considered by JCVI. In their July and August statements, JCVI quoted a rate of 100 to 400 hospitalisations per million for the second wave but no denominator was provided. We assume it is a population denominator since the confirmed case-hospitalisation rate in children is about 1 in 200. Using population denominators is not appropriate (since it includes millions of children who never had Covid). No risk estimates were provided disaggregated by healthy / underlying conditions and no risks were provided in the 3 September statement.
Chance of needing intensive care if Covid positive	Partly	This was an outcome considered by JCVI. Estimates for the risk of admission to intensive care (2 per million for healthy children vs 100 per million for children with underlying health conditions) were provided but with no explanation of the denominator. It is not clear if this risk of ICU admission includes PIMS or not.

Chance of developing Paediatric Inflammatory Multisystem Syndrome (PIMS) if Covid positive	Partly	This was an outcome considered by JCVI. In their July statement, JCVI provided a risk of 5 cases per 10,000 infections in children in the 2nd wave but not disaggregated by underlying health condition. No estimates were provided in the September statement and we do not know what risk they used for their analysis of healthy children. PIMS can affect otherwise healthy children and disproportionately affects children from ethnic minorities.
Chance of dying if Covid positive	Partly	This was not an outcome considered by JCVI in their September risk benefit analysis. A mortality rate of 2 per million was specified in the July & August statements but this used a whole population denominator (30 deaths in just over 12 million children). This is not appropriate (since it includes millions of children who never had Covid). No risk was provided in the 3 September statement.
Chance of developing Long Covid if Covid positive	Partly	This was not an outcome considered by JCVI in their September risk benefit analysis. In the August statement, JCVI quoted rates of 1%-10% for the incidence of Long Covid in children and said that vaccination is expected to provide some protection. However, Long Covid was not mentioned in the risk benefit analysis on 3 September.
Assumptions made about the risk of the vaccine		
Chance of developing myocarditis after vaccination with 1 or 2 doses	Yes	JCVI estimated the risk of myocarditis per million was 3 to 17 for the first dose and 12 to 34 for the second dose. However, they did not state which vaccines they were considering (e.g. Just Pfizer or both Pfizer and Moderna?).
Chance of hospitalisation due to vaccination	No	JCVI has an outcome table of hospitalisations averted, but it is not clear whether this is assuming that all cases of myocarditis are hospitalised or not.
Assumptions made about future exposure to Covid		
Future number of projected cases of Covid and over what time frame	No	The harms of a vaccination programme are the same for a given number of people vaccinated. Its benefits depend on how many people it then prevents from catching Covid. The lower the chance of catching Covid, the lower the benefits of vaccination. In assessing risk-benefit, it is crucial to specify how many future cases you are assuming (and ideally, you would look at risk-benefit over a range of future scenarios).
Method used to assess adverse outcomes prevented		
Method used to calculate risk benefit	No	No details were provided on how risk benefit was calculated.

This lack of information means that the JCVI statements on childhood vaccination for Covid-19 are not interpretable and cannot be scrutinised. This is in marked contrast to previous statements by JCVI on Covid-19 vaccination as detailed below. The statements fall short of the requirements for transparency in the Code of Conduct (see Annex) and we note that no minutes from JCVI meetings discussing Covid-19 are available since their meeting on 16 February 2021.

Previous JCVI statements on vaccination for Covid-19: transparent and evidence based

In December 2020, the JCVI published its recommendations on the order in which adults should be offered vaccination, which it updated in January 2021 by suggesting a change to the vaccination dose interval from 4 to 12 weeks. These recommendations were detailed and evidence based, setting out how epidemiological, surveillance and demographic data on cases, hospitalisations and deaths had been considered. Additionally, JCVI cited mathematical modelling work supporting an age-based priority list, initially published as a preprint, and gave a detailed description of the methods and assumptions used.

On 7 April 2021, the JCVI advised that adults under 30 should be offered the Pfizer vaccine instead of the AstraZeneca one due to emerging evidence of a very small risk of developing blood clots following the first dose of AstraZeneca. This advice was updated on 7 May 2021 to also preferentially offer Pfizer to adults aged 30 to 39. The JCVI explained that the advice was based on consideration of the (then) low levels of circulating Covid-19, lower risk of adverse outcomes from Covid-19 in young adults, higher risk of vaccine-associated blood clots at younger ages and the availability of sufficient Pfizer doses to maintain rapid vaccination levels. This advice has been regularly updated, most recently on 3 September 2021, with detailed data about numbers of adverse vaccine-related events and demographic patterns. Throughout, the JCVI were careful to emphasise the rare incidence of vaccine-related blood clots, the association of blood clots with Covid-19 disease itself, and the importance of considering community prevalence in determining the risk/benefit of AstraZeneca vaccine for different age groups.

What we are asking from JCVI

Since the September statement, the UK Chief Medical Officers were asked to further consider vaccination in adolescents, taking into account broader concerns such as disruption to education (although the JCVI explicitly considered disruption to education due to Covid in their July statement). On 13 September 2021, the CMOs recommended offering one dose of vaccine to all 12-15 year olds, which was accepted by the four home nations and vaccination is now beginning.

Surveys by the Office of National Statistics have consistently shown a willingness by the majority of parents to vaccinate secondary school children, with 54% of parents saying they would definitely accept a vaccine for their child and another 32% saying they were unsure but probably yes. Independent SAGE are concerned that the lack of detail in the JCVI risk-benefit analysis and the reporting surrounding it might encourage hesitancy in the 32% of unsure, but in principle willing, parents.

At least one major trial of the use of vaccine in children under the age of twelve has now been completed. It is expected that applications will be made shortly to a number of regulatory bodies concerned with safety of medicines. If and when a vaccine is approved for use in the UK it is important that there is no delay in a risk benefit analysis of its use and deployment across the UK if benefit is shown.

We are asking that JCVI as soon as possible:

1. **Release the information detailed in the table in the spirit of transparency and Open Science so that scientists and other interested parties can understand the rationale for previous statements**
2. **Make preparations now for their consideration of vaccination in children under the age of twelve following approval by the Commission on Human Medicines and the MHRA. This should include a clear statement of how their consideration would proceed.**

Annex - the JCVI Code of Conduct

The JCVI terms of reference and code of conduct: requirement for transparency

The JCVI advises on vaccine policy in England and Wales. Its terms of reference and code of conduct state that its role is to advise the UK health departments "*on immunisations for the prevention of infections and/or disease following due consideration of the evidence on the burden of disease, on vaccine safety and efficacy and on the impact and cost effectiveness of immunisation strategies*".

The responsibilities of the committee members include openness ("*Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands*" (p12)).

The JCVI process should involve a "*robust, transparent, and comprehensive appraisal of the available evidence*" (p19) that can include commissioned mathematical modelling studies (in recent years conducted primarily by Public Health England (p22)) on the impact of a potential immunisation programme. These studies should also be "*conducted to a sufficiently high standard to be publishable in the peer-reviewed scientific literature*" (p22). Mathematical modelling studies should include "*all relevant assumptions and the sources"* and *"a full description of the methodology and base-case and variant scenarios, in sufficient detail for full assessment*" (p23).

Finally, JCVI advice and recommendations should be published: "*JCVI advice and recommendations are published in the minutes of meetings. Where advice or recommendations relate to a new vaccination programme, or revisions to an existing vaccination programme, these are also published in a JCVI statement*" (p26). While JCVI is expected to release all papers, these can be withheld while going through the peer review process unless "*unless the investigators give specific permission for pre-publication Release*" (p27). During the Covid-19 pandemic, many important science papers have been routinely published as "pre-prints" (i.e. before peer review) to enable better decision making, including papers used for JCVI decision making, including papers used for JCVI Covid-19 decisions.

indie_SAGE