Initial experience of the safety and tolerability of the BNT162b2 (Pfizer-Bio-N-Tech) vaccine in extremely vulnerable children aged 12–15 years

Healthy children generally have a mild illness with SARS-COV-2; however, some comorbidities may predispose to severe COVID-19 disease. Neurological conditions were the predominant comorbidity of hospitalised children in the UK with COVID-19 (11%)[1] and a larger proportion (26%) of those with severe/fatal disease.[2] Children perceived to be at highest risk of COVID-19 were shielded, reducing risks of infection and therefore underrepresented in the data.

Vaccination safety data for BNT162b2 (Pfizer-Bio-N-Tech) is now available from healthy adolescents age 12 to 15 years. Similar to adult studies, common side effects were mild-moderate pain at injection site (86%), fatigue (66%), headache (65%), and fever ≥38°C (20%).[3]

Although the side effects from adult studies were mild, they were inversely related to age, that is, younger participants (<55 years) had more side effects.[4]

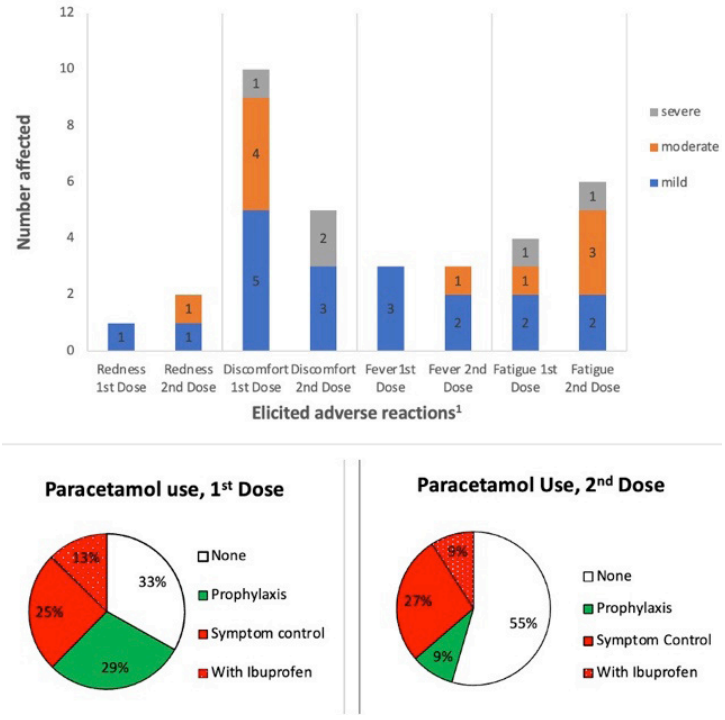

Figure 1 Solicited local and systemic reactogenicity profile (n=26 for first (1st) dose, n=22 for second (2nd) dose).

The Joint Committee on Vaccination and Immunisation (JCVI) advised that children aged 12 and over with severe neurodisabilities who tend to get recurrent respiratory infections who may spend time in residential care be offered vaccination.[5] Children identified by clinicians as meeting these 'Green Book' criteria were offered the vaccination with informed medical consent following discussion with the child's clinician.

Given the unknown side effects of vaccination in this complex group, we asked parents to record side effects to inform the risk–benefit for subsequent COVID-19 vaccinations for each child. This was recorded in a diary followed up with a telephone call.

The characteristics of the participants are summarised in table 1.

The adverse reactions were all mild/moderate except for one child with severe fatigue and severe discomfort combined with increased agitation until day 7 . One family reported a change in seizure type becoming clusters, which resolved by day 7. There were eight events in six children after the first dose which resolved in <72 hours: mild rash, headache, diarrhoea, presumed sore throat, neck pain, difficulty sleeping, low blood sugars. After the second dose, eight additional events occurred among five children: diarrhoea, vomiting, armpit swelling, and blisters around the mouth (which were not thought to be related to vaccination). (figure 1)

Table 1 Characteristics of participants (n=27)

Age at vaccination (years)		**Vaccine setting**	
12	5	Community	24
13	6	Inpatient	3
14	8		
15	8		
Ethnicity		**Gender**	
White	21	Male	16
Asian	3	Female	11
Black British/black dual ethnicity	3		
Underlying diagnoses			
Congenital neuromuscular condition including muscular dystrophy/SMA			4 (15%)
Cerebral palsy (non-ambulant)			8 (30%)
Metabolic/genetic conditions with associated neurodisability			12 (44%)
Neurological bleed/infarct/tumour			3 (11%)
Comorbidities			
Epilepsy			13 (48%)
Supported ventilation			7 (26%)
Oxygen dependence (day/night, or both)			9 (33%)
Tracheostomy			3 (11%)
Cardiac impairment			10 (37%)
Scoliosis			11 (41%)
Gastrostomy/jejunostomy fed			15 (55%)
Immunodeficiency			3 (11%)
Medication			
Anti-epileptics			13 (48%)
Anti-spasticity/dystonia medication			11 (41%)
Anti-reflux medication			13 (48%)
Prophylactic antibiotics			9 (33%)
Immunoglobulin replacement			1 (3%)

SMA, spinal muscular atrophy.

Parental reporting of local reactogenicity was less common than previously published data where the person reporting was themselves vaccinated, which makes the data difficult to compare. Paracetamol use with the first dose was high and fever (temperature ≥38°C) was more common than in adult studies (13% vs 4% in 16–55 years). Other recorded adverse events all resolved within a week.

Numbers were small but these data are especially important as they are representative of the children who are most likely to benefit from vaccination, and parents and clinicians may have concerns regarding an increased risk of unexpected events. The parents choosing to take up this vaccination, at a time when it was off-licence with little available safety data, did so because they (and their clinicians) believed their children to be at high risk from COVID-19. Indeed, many had been shielding and felt that vaccination would make a significant difference to their lives.

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Competing interests AF is a member of the JCVI and is chair of WHO's European Technical Advisory Group of Experts on Immunization committee. He leads another project investigating transmission of respiratory bacteria in families jointly funded by Pfizer and the Gates Foundation and is an investigator in trials of COVID-19 vaccines including ChAdOx1 nCOV-19, Janssen, and Valneva vaccines. The other authors have no relevant conflicts of interest to declare.

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