

with COVID-19 (11%)<sup>1</sup> and a larger proportion (26%) of those with severe/fatal disease.<sup>2</sup> 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  $\geq 38^{\circ}\text{C}$  (20%).<sup>3</sup>

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.<sup>4</sup>

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.<sup>5</sup> 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](#))

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  $\geq 38^{\circ}\text{C}$ ) was more common than in adult studies (13% vs 4% in 16–55 years). Other recorded adverse events all resolved within a week.

## 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

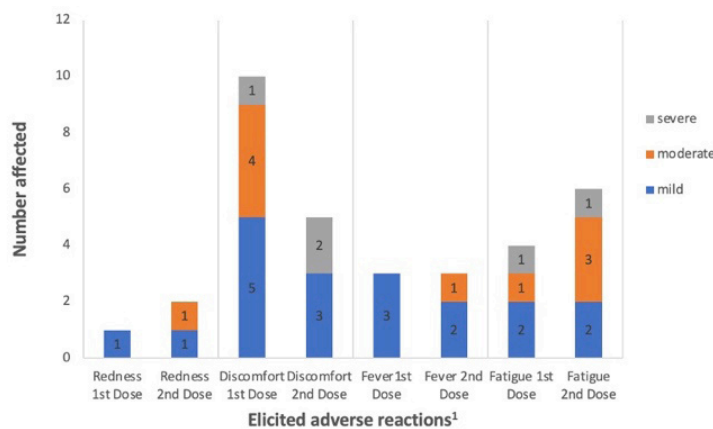
**Table 1** Characteristics of participants (n=27)

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%)	

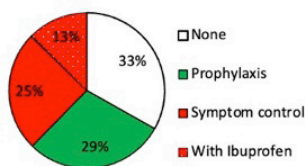
SMA, spinal muscular atrophy.

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

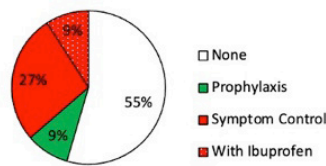
clinicians may have concerns regarding an increased risk of unexpected events. The parents choosing to take up this vaccination, at a time when it was off-licence with little



**Paracetamol use, 1<sup>st</sup> Dose**



**Paracetamol Use, 2<sup>nd</sup> Dose**



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

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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