# Analysis of clinical enquiries received by five COVID-19 vaccination centres in the UK

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#### ABSTRACT

The aim of this study was to explore the nature of clinical enquiries received by UK vaccination centres during the early stages in the roll-out of the COVID-19 vaccination programme. Four centres were situated in acute hospitals and one centre was in a designated public site. Data were collected for eight consecutive weeks between January and February 2021. The hospital centres administered a total of 28 995 doses of the Pfizer BioNTech vaccine, receiving 806 enquiries (1 enquiry per 36 vaccinations, 2.7%). The public centre administered 29 167 doses of AstraZeneca vaccine, receiving 439 enguiries (1 enguiry per 66 vaccinations, 1.5%). Combined enquiry rate was 2.1%. The most common enquiries were related to allergies (44%), compatibility with other medicine (22%) and immunosuppression (16%). These were the topics of clinical guidance that were subject to regular change. Public health programmes implementing novel therapies should ensure the provision of sufficient enguiry answering capacity.

#### **INTRODUCTION**

Following the implementation of the Public Health England SARS-CoV-2 (COVID-19) vaccination programme on 8 December 2020,<sup>1</sup> COVID-19 vaccinations have been administered to the UK national population, starting from January 2021.

A considerable volume of clinical enquiries regarding the vaccines were anticipated due to the novel nature of the programme. Medicine information services are well placed to support such clinical programmes by providing an enquiry answering service.<sup>2</sup>

The implementation of this vaccination programme presented a unique opportunity to explore the nature of clinical and medicationrelated enquiries received during the initial delivery of this new large-scale public health programme.

This study analyses the clinical enquiries received at five vaccination centres in London, UK, in regard to volume and type of enquiry. To date, there are no similar published data in the literature.

At the time of this study, only people over 65 years, clinically vulnerable and key workers (designated priority group 1) were eligible to receive the vaccine, in line with the UK government's priority grouping.<sup>3</sup>

## **METHODS**

#### Setting

This study was based on the findings from five vaccination centres run by an acute hospital Trust. Four hospital-based centres, all on different sites, provided the BNT162b2 mRNA COVID-19 Vaccine (Pfizer BioNTech) predominantly to staff working for the Trust and patients within the hospital. One public vaccination centre primarily operated for the benefit of the public, administering ChAdOx1 nCoV-19 vaccine (AstraZeneca vaccine). All services commenced operations in January 2021.

Within the hospital vaccination centres, staff administering the vaccine consisted of registered healthcare professionals (HCPs), most were clearly identifiable as HCPs as they wore uniform. The Pfizer vaccine required a mandatory 15 min observation period after administration.

Within the public vaccination centre, nonregistered trained professionals and volunteers administered the vaccine. The nature of the Astra-Zeneca vaccine allowed for rapid, large-scale administration of the vaccine with minimal waiting time for recipients.

Each vaccination centre used the following primary resources to answer enquiries:

- Immunisation Against Infectious Disease: Chapter 14(a) COVID-19-SARS-CoV-2 (Green Book).<sup>4</sup>
- ► Internal Trust Guidance: COVID-19 Vaccine Pre-Assessment Questionnaire.<sup>56</sup>
- Internal Trust Guidance: Easy to use guide to support further clinical evaluation of patients prior to administration of COVID-19 vaccine.<sup>7</sup>

Training sessions to support the use of primary sources were provided to staff within the public vaccination centres.

Secondary resources also directly available to vaccination centre staff, hospital staff and members of the public were the Trust Allergy Team, the Trust Medicines Information COVID-19 Vaccination Enquiry Answering Service and the Specialist Pharmacy Service website.

#### **Data collection**

Data were collected from all five vaccination centres (for eight consecutive weeks) between January 2021 and February 2021.

A senior member of pharmacy staff, present at each vaccination centre during opening hours, recorded all the clinical enquiries received within their centre, and entered them on a spreadsheet (Microsoft Excel 2010). The total number of vaccines administered was recorded at each centre.

Following consultation with vaccine recipients, enquiries were raised by the vaccinator to the senior member pharmacy staff when necessary.

Inclusion criteria: all clinical enquiries regarding the first dose of a COVID-19 vaccine.

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	Hospital vaccination centres (n=806)		Public vaccination centre (n=439)		
Category	Frequency (%)	Enquiries per 1000 people vaccinated (n)	Frequency (%)	Enquiries per 1000 people vaccinated (n)	Enquiry examples: to assess suitability to receive COVID-19 vaccine
Allergies	351 (44)	12.1	201 (46)	6.9	'I had a previous anaphylactic reaction to penicillin.' 'I have a peanut allergy and carry an Epipen.'
Immunosuppression	152 (19)	5.2	42 (10)	1.4	'I am taking prednisolone.' 'I am a HIV (Human Immunodeficiency Virus) positive patient.'
Compatibility with other medicines*	148 (18)	5.1	120 (27)	4.1	'I am taking Warfarin, my INR is currently 1.9.' 'I have received the flu vaccine last week.'
Comorbidities	52 (7)	1.8	31 (7)	1.1	'I am a diabetic patient and I take insulin.' 'I have been diagnosed with Down Syndrome and Epilepsy.'
Breast feeding	36 (4)	1.2	5 (1)	0.2	'I am currently breastfeeding.'
Acute illness (including COVID-19 infection)	21 (3)	0.7	26 (5)	0.9	'I have just completed an antibiotic course for a Urinary Tract Infection I feel well in myself.' 'I was tested positive for the COVID-19 virus 27 days ago, I currently feel fine and have no further symptoms.'
Conception	20 (2)	0.7	5 (1)	0.2	'I am actively trying to conceive.' 'I am planning to get pregnant next year.'
Pregnancy	18 (2)	0.6	2 (1)	0.1	'I am currently 16 weeks pregnant.' 'I have missed my last menstrual cycle but do not think I am pregnant.
Other	8 (1)	0.3	7 (2)	0.2	'Can I have alcohol after the vaccine?' 'Can you get the COVID-19 virus from receiving the vaccine?'
Total number of vaccinations	28995		29167		

\*Compatibility with other medicines: anticoagulants (31%); other vaccines (11%); antiplatelets (10%); biologics (9%); antimicrobials (5%); other (34%).

Exclusion criteria: logistical enquiries, clinical enquiries not relating to COVID-19 vaccine, postvaccination clinical enquiries and second dose enquiries.

#### Data analysis

Categorisation of enquiries was conducted by the researchers in accordance with categories within the Green Book.<sup>4</sup>

Data were analysed descriptively using Microsoft Excel 2010.

#### RESULTS

The hospital vaccination centres administered 28995 vaccinations and received a total of 806 enquiries, giving a mean of 1 enquiry per 36 vaccinations (2.7% enquiry frequency).

The public vaccination centre administered 29167 vaccinations, receiving 439 enquiries, that is, 1 enquiry per 66 vaccinations (1.5% frequency).

Overall, there was 1 enquiry per 47 vaccinations (overall frequency of 2.1%).

Table 1 details the volume and types of enquires received.

For all vaccination centres, vaccine appropriateness in patients with allergies, immunosuppression and taking other medicines were the most common enquiries.

#### DISCUSSION

Allergies, immunosuppression and compatibility with other medicines were identified as the most common types of enquiries received in both settings. This could indicate that potential vaccine recipients with these clinical factors could be more likely to approach the COVID-19 vaccine cautiously.

In December 2020, during the early roll-out of the UK COVID-19 vaccination programme, there were two reports of anaphylaxis following administration of the Pfizer BioNTech vaccine. This subsequently prompted a review of the guidance issued by the Medicines and Healthcare products Regulatory Agency.<sup>8</sup> The repeated updates to guidance governing the

management of individuals with allergies receiving the vaccines could have contributed to the large number of allergy enquiries.<sup>9</sup>

The medicines that prompted the majority of the compatibility enquiries were anticoagulants, other vaccines, antiplatelets, biologics and antimicrobials. Anticoagulants were the largest single group. The national protocol for both vaccines stated caution should be taken when administering the vaccine in individuals taking anticoagulation.<sup>10 11</sup> The vagueness of this guidance may have prompted the enquiries. For immunosuppression as well as anticoagulant use, there was additional patient counselling required which may also have prompted questions from vaccination centre staff.<sup>10 11</sup>

Immunosuppression (inclusive of those taking immunosuppressive drugs) is classed as a drug interaction within the national protocols requiring additional patient counselling.<sup>10 11</sup>

Regarding use with other vaccines, there was no evidence available on the coadministration of the COVID-19 vaccine with other vaccinations. However, the guidance recommending a 7-day gap was clear.<sup>4 9</sup> The lack of clear evidence behind this guidance could be a reason for the number of enquiries.

Individuals who were pregnant fell within the exclusion criteria for both vaccines.<sup>10</sup> <sup>11</sup> Therefore, enquiries regarding pregnancy were less likely to arise. Planned conception and breast feeding were also originally the reasons to not receive either vaccine.<sup>12</sup> However, guidance on these changed in January 2021 which could have led to confusion and some hesitation on the part of patients.<sup>10 11</sup>

The hospital vaccination centres received double the number of enquiries per administered dose compared with the public centre. Some of the differences may be attributed to the different populations served, the differing requirements for the vaccines and the fact that the hospital centres were staffed only by HCPs.

There are some limitations to this analysis. As only people over 65 years, clinically vulnerable and/or key workers received the vaccine during the data collection period, the queries would not be representative of the whole population. As the study was conducted in the early stages of the vaccination programme, changes in guidance after February 2021 are not reflected in the results. Further work could be conducted to analyse the enquiries from February 2021 onwards, including postvaccination and second dose enquiries.

## CONCLUSION

To the best of our knowledge, this study is the only published analysis of enquiries received during the implementation of the COVID-19 vaccination programme in the UK. As it includes enquiries from the members of the public and HCPs, this is considered a comprehensive analysis.

Common enquiries identified were reflective of the areas of government guidance that were subject to regular change. It is reasonable to assume that when new clinical programmes are being introduced, early enquiries are likely to comprise topics that are subject to change due to lack of evidence, reflective of changes in legislation and guidance, postmarketing surveillance and social media. We recommend new programmes or clinical interventions, especially large-scale public health programmes, take this into account and ensure provision of sufficient enquiry answering capacity.

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