Bedfordshire Hospitals NHS Foundation Trust

22/03/2022

Dear Requester,

FOI 1195

Thank you for your Freedom of Information request which was received within the Trust.
Please note, this is a cross-site response for Bedford site and Luton site.

You asked:

1. How many people have the Doctors, Nurses and other health care employees working for or on behalf of **Bedfordshire Hospitals NHS Foundation Trust**, either on or off site, administered Covid-19 injections to, to date?
   Please note that all vaccines delivered by the Trust's vaccination hub were recorded in the National Immunisation and Vaccination System (NIVS) point of care system. The Trust is only able to access information regarding vaccinations delivered by the hospital hub. We do not hold information on every vaccination delivered by trust employees working in other vaccination centres.

   Our records show that 40,734 doses were given over the period Jan-Dec 2021 across both BH and LDH sites.
2. Have they given these injections to any children, if so how many?
   No, no children were vaccinated by the Bedfordshire Hospital Vaccination Hub (as at 28/02/2022).

   As part of the **legally required process of Informed Consent**, before giving these injections:
   All vaccinations and information were delivered in accordance with the green book and patient leaflets provided with the drug and from Public Health England.

1. Were patients routinely informed of the individual risk that Covid-19 posed to them, for their particular age group?
   Yes
2. Were patients routinely informed that these vaccines are still part of an ongoing trial until 2023?
   Information leaflets indicated that the vaccines were initially authorised by the MHRA (medicines regulator) under Regulation 174 following a robust but expedited clinical trial process. This means that on risk-benefit there was sufficient evidence to deploy its use in the general population whilst keeping a very close eye on use and safety reporting to influence any necessary changes in practice. Information leaflets and advice to recipients were updated

through the various campaigns as the populations based data evolved and the authorisation changed from regulation 174 to authorised.

This is also covered under the Legal Aspects of vaccine administration issued by Public Health England.

3. Were patients routinely informed that these vaccines were authorised for emergency use only?
   Yes, see above.
4. Were patients routinely informed that these mRNA vaccines have never before been used on human beings?
   No, as this is not accurate. All COVID-19 vaccines made available by PHE for NHS use were authorised by the MHRA following a review of robust data from appropriately designed RCTs. Due to the rapid requirement for availability of vaccinations to protect the public from the virus, the MHRA provided temporary authorisation followed by full authorisation as the dataset matured. Please refer to https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19
   At the point the Trust began administering Pfizer vaccinations clinical trials had already been conducted on over 43,500 human participants.
5. Were patients routinely informed that the vaccine manufacturers currently all have immunity from liability for any adverse events and death?
   No
6. Were patients routinely informed there is no medium to long term safety data for these vaccines?
   Not explicitly by staff but this is inferred in the information provided above.
7. Were patients routinely informed there is no data on how these vaccines affect fertility or the reproductive system?
   The information provided changed over the campaigns as new data, both pharmacovigilance and RCT data became available.
8. Were patients routinely informed they can still catch and spread Covid-19 after vaccination?
   Yes
9. Were patients routinely informed of the constituent components / ingredients of the vaccines they received?
   Yes - This is covered in the patient information leaflet.
10. Were patients routinely made aware of the Yellow Card data for these vaccines, which shows a disturbingly high number of serious injuries and deaths compared to all other vaccines combined over the last 30 years?
    Patients were routinely made aware of the UK centralised process in place by the MHRA for recording and collecting data relating to medicines use and adverse events i.e. the yellow card system.
11. Exactly what other **Informed Consent**, if any, was given/obtained, relating to the risks and benefits of these vaccines?
    All recipients of the vaccine booked themselves into a slot to receive the vaccine. This highlights an individual's independent decision making process based on the data available in the public domain and their choice/decision to receive a COVID vaccine. Informed consent was also given at the point of care and recorded in the NIVS system.

Informed consent was given in accordance with information detailed within the Green Book and legal mechanisms for prescribing/administration of the vaccines i.e. Patient Specific Directions, Patient Group Directions, and the National Protocol, which the Trust was working under.

Please note that the Trust has a formal internal review and complaints process which is managed by the Information Governance Manager/Data Protection Officer. Should you have any concerns with our response, you can make a formal request for an internal review. Requests *for internal review* should be submitted within three months of the date of receipt of the response to your original letter, and should be addressed to: dataprotectionofficer@ldh.nhs.uk. This option is available to you for up to three calendar months from the date your response was issued.

If you are not satisfied with the Trust review under the Freedom of Information Act 2000 you may apply directly to the Information Commissioners Officer (ICO) for a review of your appeal decision. The ICO can be contacted at: ICO, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF www.ico.org.uk

Yours sincerely,

FOI Officer

Bedfordshire Hospitals NHS Foundation Trust