3. Vaccine coverage

Vaccine coverage is a key indicator of the performance of the immunisation delivery system. Moreover, data on vaccine coverage are used to estimate the level of susceptibility in the population and identify areas or populations at increased risk of outbreaks. Identification of undervaccinated groups can be used to adapt delivery of the programme. Vaccination data at an individual and population level are also used to support the analysis of vaccine effectiveness, impact and safety.

3.1 Existing models for vaccine coverage reporting

PHE is responsible for monitoring coverage of all vaccines in the national immunisation schedule. Aggregated data are reported by the vaccine providers or from Child Health Information Systems are reported and analysed by PHE and published on a regular basis. (3). Most vaccines are delivered via primary care and uptake data are extracted automatically from GP electronic health record systems onto the ImmForm platform. Delivery through other providers, such as NHS trusts for vaccination of healthcare workers, or school immunisation teams for vaccines delivered in school, is typically monitored through regular manual reporting by the provider.

3.2 National Immunisation Management System

The COVID-19 vaccination programme is being delivered through a range of models including hospital trusts, mass vaccination centres and primary care networks. NHS Digital have led the development of a new national vaccination register and call/recall system for COVID-19 and influenza vaccination - the National Immunisation Management System (NIMS). Demographic data, GP data and employee data (for NHS staff) will feed into the NIMS to identify vaccine eligible groups so that they can be invited for vaccination and individual vaccination data feeds into the NIMS from the vaccine providers. Data from the NIMS also feeds back into GP systems to update the individual's electronic health record with their vaccination history.

3.3 Proposed model for COVID-19 vaccine coverage monitoring

COVID-19 vaccine coverage will initially be monitored using both the existing approaches outlined in section 2.1 as well as data extracts taken directly from the NIMS. It is anticipated that vaccine coverage monitoring through the NIMS will ultimately replace the existing approaches once data flows are established and data validation has been completed for all vaccine eligible groups.

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4. Safety

Rapid detection and evaluation of possible adverse events associated with vaccination is vital for providing reassurance that the vaccine does not cause harm. Major safety concerns that are common and occur within a short period of vaccination are likely to be detected through the clinical trials. Rarer or more delayed adverse events require continuous post implementation monitoring. Safety surveillance will be undertaken in collaboration with the MHRA, further details on the MHRA proactive vigilance of COVID-19 vaccines are available here.

4.1 Signal detection

A signal of a potential adverse events may come from a range of sources such as the pre-licensure clinical trials, MHRA assessments of Yellow Cards reports, active follow up of cohorts vaccinated during the implementation of the national programme or from other countries or specialist health care professionals seeing increases in consultations for specific conditions.

PHE will work with the MHRA and the Health Protection Research Unit (LSHTM) using the Clinical Practice Research Datalink (CPRD) to identify any potential safety signals using sequential testing methods for a pre-specified set of events of interest. Another component of the signal detection will be identifying whether the number of reports has exceeded the expected number for that specific condition in the same population in the absence of vaccination, to evaluate any potential signals compared to a historic baseline. This work will be led by MHRA and PHE and will generate backgrounds rates using hospital admission data (Hospital Episode Statistics (HES) for a list of prespecified conditions of interest.

4.2 Rapid assessment

To assess any signal coming from these sources a more detailed investigation is needed before a full epidemiological study is performed. This investigation may include ecological studies using large routinely collected national datasets, such as HES, Secondary Uses Service (SUS) or the Emergency Care Dataset (ECDS), which may be undertaken assuming coverage of the vaccination is high in the population of interest. These analyses will be used to compare trends in disease rates before and after the introduction of the vaccination programme in defined vaccine targeted and comparator populations without requiring individual vaccination status. These studies cannot establish causation or quantify a risk but are seen as a rapid exploratory analysis with the view to inform the epidemiological hypothesis-testing stage of the assessment and to