Strategy for Monitoring and Evaluation of COVID19 vaccination
and key milestones

for discussion

version 0.1

08/12/2020

Assumptions: new IT system developed with reporting functionality

1. alignment of denominator data against data on immunisation registry (age groups, gender, region, occupation, risk group, workforce (HCW))
2. identify stakeholders for information dissemination and develop appropriate communication tools and processes
   a. which data elements are reported on by which group
   b. audience for reports and type of reports
      i. DoH, HSE, HPRA, media, general public
   c. identify spokespersons on reports
   d. establish schedule for reporting to different stakeholders
3. issue reports on number of vaccines administered to the population (by risk or targeted group) and uptake of vaccination by risk or targeted group
   a. demographics
   b. risk groups (occupation/social/age/clinical risk group)
   c. by vaccine, by dose
4. Assessing acceptance of vaccine by targeted population by
   a. proportion of those targeted that book for appointment
   b. proportion of those targeted that attend for 1st dose
   c. proportion of those who attend for 1st dose who attend for 2nd dose at appropriate time interval for each vaccine (vaccine specific)
   d. proportion of those who fail to attend for 2nd dose (as applicable to each vaccine)
   e. proportion of vaccine recipients who are vaccinated by completion status (completed, incomplete)- definitions for each vaccine as may differ
5. Establish procedures, processes and responsible individuals to monitor vaccination uptake and measure impact and vaccine effectiveness of programme on COVID19
   note: measuring impact will involve comparing incidence rates of different outcomes before vaccination programme with incidence rate after programme implemented, and monitoring trends- calculating incidence rate ratio against agreed outcomes; by target group as IRR may differ across groups;
6. Measuring impact
   a. difference in disease notification rate - data source CIDR
   b. difference in hospitalisation rate – data source CIDR
   c. difference in ICU admissions – data source CIDR and ICU surveillance (send to HPSC)
   d. difference in COVID19 cases identified in screened population – screening work - ? source data
   e. difference in COVID19 deaths
   f. difference in asymptomatic detection rates (when screening done)
   g. other possible impacts that can be measured at later stage include impact on health and wellbeing, societal impacts (education, work, mobility), economy – these would
be done at later stage and would be more research based and use modelling methods

note: positive impact of vaccination would be decline in the above incidence of outcomes. monitoring will be done as programme rolls out but accurate estimates can only be done when substantial numbers are vaccinated- two- three months after commencement of programme and onwards. best estimates will be possible after 4 – 6 months

7. Trends in incidence will be monitored on a daily basis, similar to current epi tracking and formal calculation of IRR will be done as programme rolled out more extensively.

8. Measuring vaccine effectiveness- assessment of disease vs infection
   a. measuring direct and indirect effect of the vaccination programme on the probability of developing disease once vaccinated by comparing the risk of developing the disease amongst vaccinated and unvaccinated
   b. studies will look at VE against confirmed diagnosis, or severity of disease (hospitalisation, ICU, death)
   c. studies to include sentinel GP primary care studies (IMOVE)
   d. planned Severe acute respiratory infections (SARI) admissions to hospital study where SARI patients are investigated for clinical diagnosis, vaccination status and outcome (ICU admission, ventilation, death) and comparison made between COVID19 lab confirmed patients and non- COVID19 confirmed cases (other pathogens)
   e. screening methodologies to assess vaccine effectiveness can be done once a large proportion of the population is vaccinated
   f. case control or cohort studies will be done in the vent of outbreaks occurring in the community of closed settings (these would require input of Department of Public Health staff in the areas)
   g. VE may also be used to look at carriage – at this stage the first vaccines are not believed to impact on carriage, but the Oxford vaccine may----

9. monitoring vaccine failures – from the beginning
   a. all COVID19 cases reported to CIDR will be investigated to obtain vaccination status data from the immunisation registry system- process to be agreed
   b. definitions of vaccine failures to be agreed at EU and international level for different vaccine
   c. reports to be run at weekly intervals looking at number of cases that occur among vaccine recipients and categorised by vaccine failure type
   d. primary vaccine failure – developing disease after completed vaccination schedule and appropriate time after vaccination (to be defined time limit). this may also vary by vaccine used
   e. secondary vaccine failure (indicative of waning immunity over time)- ie initial protection but develop disease at later stage (at this time expected duration of immunity is unknown)
   f. this will be done by both HPRA and HPSC

10. monitoring immunity in the population by research studies that involve serum samples being taken over a period of time, or seroepidemiological studies of the general population.