Original Article

Realtime Supervision and Quality Assessment of Statewide Community Based Sero-Surveillance for Anti-SARS-CoV-2 IgG Antibodies

Running title: Realtime Supervision for Sero-Surveillance of COVID 19

Arun K Aggarwal, Anuradha Nadda, Usha Gupta, Vivek Sagar, Anubhuti Sharma, Divya Monga

Department of Community Medicine and School of Public Health, PGIMER, Chandigarh, India

Corresponding author: Dr. Arun K Aggarwal

Email id: **aggak63@gmail.com**

Abstract

Introduction: By the year 2020, there was need to know the number of cases of COVID-19, either through modelling studies or through sero-prevalence of anti-SARS-CoV-2 IgG antibodies. Haryana govt. decided to undertake statewide community based sero-surveillance in all the districts. Quality sero-surveillance requires robust quality control mechanism. In this study, we present a model of supportive supervision for quality control of sero-prevalence survey for anti-SARS-CoV-2 IgG antibodies that was used for Haryana sero-surveillance-first round. *Methodology:* Teams from Haryana, under the guidance of investigators conducted Seroprevalence survey for anti-SARS-CoV-2 IgG antibodies in all 22 districts of Haryana from 17th to 19th August 2020. Team of investigators from independent tertiary care institute conducted realtime supervision using online mobile app 'Survey Man' with GPS feature. Each survey team visited conveniently selected surveillance sites. Each site was graded based on the sum of the scores obtained by team during supervision for quality assessment. *Results*- Team visited 13 clusters in 8 districts, and observed 28 survey teams in the community and 4 district laboratories. Most of the clusters (92%), and all laboratories were graded satisfactory (score 8 or above). There was intra and inter district variation in the randomization technique in selecting the study sample. The teams in some clusters were having trouble in interpreting the grid table that was used to select individuals in the families for surveillance. *Conclusion:* App-based, real-time monitoring, along with GPS was successfully used for monitoring the quality of community based sero-surveillance as well as for the large population based studies.

Keywords: Supervision, Quality Assessment, SARS-CoV-2, Sero-Surveillance, Antibodies

Introduction

In sero-surveillance survey done in Haryana, smartphone and a survey app was used in addition to traditional paper-based format to report data for the sero-surveillance of COVID-19 in all 22 districts [1]. We used the GPS app to report observations from our on-site supervisory visits, done for quality assurance, on a real-time basis. Here we present a model of supportive supervision for quality control of seroprevalence survey that may be of use to plan quality assurance for other such surveys at the state and the national level.

Methodology

Seroprevalence survey for anti-SARS-CoV-2 IgG antibodies in all 22 districts of Haryana was planned from 17 August to 19 August 2020. All the districts were to complete the survey within three days. Using digital mode, survey tools were finalized in consultation with Haryana state team. In order to maintain the quality of sero-surveillance, we planned to monitor and supervise the entire surveillance cycle. The complete cycle of sero-surveillance consisted of:

A). Orientation training of state surveillance team

B). Supervisory Plan and Sampling for Quality Assurance

C). Visit to sites and testing laboratories

D). Real time monitoring

E). Review Meetings with state core team

A). Orientation training of state surveillance team

Before the start of the sero-surveillance, an online training was imparted. All the nodal officers, surveyors, lab technicians and supervisors participated in the meeting. The discussions primarily focused on the following: 1) Overall objectives of survey 2) How to select the GPS cluster point within selected cluster 3) How to select first house 4) How to approach the family and take consent 5) How to fill the form using digital mode 6) How to prepare blood sample collection kit including vacutainers, bar codes, swabs, tourniquets, and biomedical waste management materials. 7) How to draw blood sample, label, transport and store.

It was expected that basic training had already been given by the concerned districts and state. However refresher training was done to bring everyone on the same page. Trainings to all 22 district officials was imparted in short time window of 3-5 days.

B). Supervisory Plan and Sampling for Quality Assurance

Supervision for Quality assurance was also planned during the survey days. For quality assurance, supervisory plan was designed. Total 8 districts were selected as per convenience sampling, with distance from Chandigarh, as the factor; so that team can reach the site early in the morning and come back to Chandigarh by late evening. Two faculty members, 3 PhD scholars and one senior laboratory technician led the field mission, backed up by the Principal Investigator who coordinated the entire mission.

Tools for Supervision

Online mobile app: The tool for the supervision was developed using an online app ‘SurveyMan’. GPS feature was added to the app to locate the position of the surveyors as well as supervisors. It also captured the phone numbers of the survey participants, surveyors and supervisors. The experience (both strengths and limitations) of using the Survey Man app have been published elsewhere [1]. The app additionally allowed for offline data collection. To ensure the quality of survey, both field visits and laboratory visits were included in the survey schedule. The

online survey app had two sections - one for the community cluster visit (10 indicators), and the other for laboratory visits (10 indicators). Each indicator on these forms carried a score of '1'.

C). Visit to sites and testing laboratories

All supervisors from district survey teams, of the main sero-survey, had micro plan of the concerned districts. Quality Assurance Team of PGIMER Chandigarh contacted these supervisors and randomly selected the 2 clusters from each district. A tour plan was made by each team keeping in view the distance and location of clusters and 1-2 houses were visited in each selected village.

For community cluster visit, the survey questionnaire had 10 indicators. These were:

Correct name of the district-cluster- house number,

Availability of complete team in the field (Medical officer, Auxiliary Nurse Midwife /Lady Health Visitor, Lab-technician,

Use of mobile app for data entry,

Aseptic precautions taken by lab technician,

Proper disposal of biomedical waste as per the bio medical waste management guidelines,

Proper labeling of the blood sample (initial three alphabets of name of the district-cluster number-house number),

Proper storage of sample,

Informed consent from the participant,

Photograph of team, and

Quality Assurance Team's's rating of the survey being conducted by team (on a scale of five).

For Laboratory Visit: One team visited the laboratories of the selected districts. The team checked if dedicated space was allotted for processing of samples, availability of ELISA kits, ELISA readers, and dedicated team of lab technicians to process samples, and adequate space for sample storage. Supportive supervision was done to ensure that the lab personnel had understood the methodology of processing the sample.

Indicators for laboratory visits were –

Proper condition of the sample,

Proper labeling of the sample at the time of receipt in laboratory,

Proper record maintenance,

Proper storage of sample,

Training of the staff,

Number of samples received by the lab (in conformance to guidelines),

Number of sample processed by the laboratory (in conformance to guidelines),

Photograph of team,

Quality Assurance Team's for the laboratory (on a scale of five),

Quality Assurance Team's rating for the lab-technician (on a scale of five). For laboratory supervision, specialists were detailed for the survey.

A rating of '5' was given a score of '1'. For the quality assessment of each survey team and laboratory, a grade was calculated based on the sum of the scores attained during supervision. Further an action plan was made based on the grade attained (Table 1).

Data submitted by the team was monitored in real time by the Principal Investigator who then communicated with the state team and gave feedback for the corrective actions.

D) Real time monitoring

The Principal Investigator from PGIMER, Chandigarh monitored in real time the

survey dynamics, the movement of the sample collection teams and supervising teams, through this online survey app.

PI could see all the summary of responses from the survey 'Forms' and randomly cross-checked any survey form. The feature helped in monitoring the quality of the forms in terms of completeness as PI can contact the surveyor (since the contact number of the surveyor(s) was visible), leading to real time monitoring & mentoring of the surveyors in the entire state on random basis.

For maintenance of the quality of blood sample collection, picture of sample with cluster ID was clicked and loaded in the survey app to avoid any discrepancy later on. This feature was supported by tool itself that allowed recording and uploading of various kinds of multimedia such as audios, videos and photos. Since, all surveyors were directly connected with PI leading to immediate action on any mistakes. Thus, real time supervision alerted the dedicated team ready for hand holding to solve almost all the problems by providing round-the-clock support.

To obtain feedback, maintain quality, and protocol adherence of the survey, telephonic calls were made randomly to the families and sample collecting teams. The problems faced by sample collection teams and supervising teams were addressed telephonically, and videos were also sent for clarifications. Any discrepancy in collection of the samples and lab results, as noticed during real-time monitoring, was conveyed telephonically and corrected immediately.

E) Review Meetings with state core team

Feedback was given to the state and district officials to take necessary steps and maintain the quality. In addition to this, following supervisory protocols were followed inhouse for quality assurance:

Medical officer of survey team was assigned the responsibility to check the survey form for completeness and accuracy after filling each form.

Senior medical officer's of the clusters were involved for supervision. Each supervisor was supposed to visit two clusters. Each cluster was divided into four quadrants for survey teams. The supervisors had to visit 10% of the houses; that is 1-2 houses per quadrant in the rural area, and 3-4 houses per quadrant in the urban area.

Designated medical colleges under state rapid response teams were also directed to supervise the clusters. One supervisor from each team was allotted one to three districts. At the selected clusters, supervisors had to visit 1-2 houses per cluster in rural area, and 3-4 houses per cluster in urban area.

Details of this inhouse level of quality assurance was not within the scope of this paper.

Results

We visited 13 clusters in 8 districts, and observed 28 teams in the community and 4 district laboratories. Most of the clusters (92%), and all laboratories were graded satisfactory (score 8 or above).

Most survey teams conducted the survey within the ambitious time span of 3 days. Practically entire state teams were in the field despite torrential rains throughout the state. Teams did follow the survey methodology with little deviations at some places explained later. As per the guidelines, survey teams had divided each cluster into quadrants and samples were collected from each quadrant. There was a doctor in each team. Internal supervisory teams of the districts and state were also in the field. Most of the android phone users were able to use the survey app. Medical officers took the informed consent to a large extent as per the trainings given to them. Household IDs were written correctly to a large extent on the survey forms as well on the blood sample vials.

Blood samples were collected, labelled and dispatched to the laboratories on the same day. For blood sample collection, at most clusters a good protocol for asepsis was followed. At many places biomedical waste management guidelines were also followed. (Table 2)

Three of the 4 testing laboratories were fully operational and prepared for the incoming samples.

Some gaps in the conduct of the survey also came to our notice. There was intra and inter district variation in the randomization technique to select the study sample. One cluster team carried out randomization by sampling every third house, while in another cluster consecutive door-to-door visits were done to complete the sampling. In some clusters, sampling was done by calling the families at a common convenient place due to many operational difficulties including heavy rains. The selection of subject from each household was to be done on the basis of a specified grid table. The teams in some clusters were having trouble in interpreting the grid table. Survey app did not have the option to use the grid table for sampling. In certain cases, the MOs were proactively guiding the team to correctly read the grid table, in the others we directed the teams in this regard. Due to operational difficulties with the online app and due to network issues, some MOs were finding it difficult to upload the form on the portal.

There were some instances of spilling of blood sample, and non-wearing of gloves by LTs. In one cluster the LT was moving around with an open used syringe. In certain clusters only yellow-biomedical waste management bags were available. In two clusters hub-cutter was not there. These teams were found practicing re-capping of the needles. At one cluster, team was struggling to draw the blood sample and was reluctant to follow standard operating procedures as they seemed to be untrained. The lab-technician from our team then demonstrated blood sample collection on-site. One of the testing laboratories, was not equipped with the requisite ELISA kits.

Discussion

The present study demonstrates importance of real-time supervision and quality assurance in a massive and rapid survey of national importance. The serosurvey was planned for all 22 districts to be completed in 3 days-time. It was not possible to depute independent teams for quality assurance in all 22 districts. Therefore, multipronged approach was followed by having mixed model of supervision with both internal and external agencies. It helped to build the inhouse capacity and also gave credibility to the survey findings.

A mixed type of supervision along with real-time monitoring, and use of geo-coding to locate the house were the main features of the study. Our study showed that quality of sero-surveillance was satisfactory in most of the clusters (92%) and in the laboratories. This study also showed that quality assurance helps to take last minute corrective actions and build the capacity if required. Those who are found performing well also get a moral boost when they are observed and appreciated.

Though the quality of sero-surveillance was found more than satisfactory, authors also noted certain gaps. At some places untrained staff was deployed. This survey was done during active Covid-19 pandemic when everyday some health staff was getting infected or getting quarantined. Thus, some trained staff due to infection had to take emergency leave and had to be replaced by the untrained staff at some places, as the mass survey was time bound and had to be completed within short period of 3 days. Others have also reported the link between the training of staff and survey quality [2, 3]. Districts had ensured deployment of trained staff

along with the untrained and supervisors were also vigilant, still the impact on quality is inevitable. Even trained staff can commit errors as was found in this survey where some trained staff was found doing error in sample collection. Independent quality assurance helped to take cognizance of this and note that magnitude of these errors was miniscule and even these errors were addressed during quality assurance visits.

Some gaps in deviation from the protocol were also circumstantial. In some communities, during the rains, it was difficult to move from house to house. Thus, field teams tried to find a sheltered place to sit in the sampled area and called the household members one by one to the place. They maintained privacy. The families needed to move just to the neighborhood. Thus, these types of novel adjustments did not influence the sanctity of the sampling method. Rather, the quality assurance visits brought to the light the passion of the field team, who were not deterred by the heavy incessant rains, and who also tackled the community resistance. Some families were reluctant to allow any health team member to enter their house due to the covid fear. Realtime monitoring helped us to track this and the approvals of such deviations were granted in real time. These gaps cannot be considered as absolute gaps but are the ground zero adjustments in the given context.

Most of health care providers were using universal precautions but disposal of bio-medical waste was found inadequate/ inappropriate in the present study as well. This necessitates a training programme for waste management in future [2]. We observed a lack of trained laboratory technicians and ELISA kits. These findings were similar to those observed by Panda B during supportive supervision of immunization session Odisha, India [4]. Authors suggest that supportive supervision along with handling the systemic issue, such as testing kits, trained health staff and timely indenting can improve the quality of COVID-19 sero-survey.

There were operational difficulties in the use of surveyman app, but with the involvement of app managers, most of the difficulties were resolved. Yet, the app could not provide access to each district supervisor and state supervisor to locate the survey teams and have independent control of the survey teams. Only Principal Investigator had this access. Due to rapid launch of the survey, supervisors, except the PGIMER team, were not well trained to use the app and thus they followed traditional method of supervision to a large extent. The app didn't work for 'ios' users. Quality assurance helped to bring such gaps to the notice of Principal Investigator who resolved most of the gaps in realtime by personal interaction with the surveyors and app manager.

Similar to the present study, Biemba G et al in their study done in two districts of Zambia observed that mobile app can be effectively used for the supervision of community health workers and delivering quality services [5]. A study was conducted by Henery JV et al. using Whatsapp group chats and photos of 1830 posts and 41 participants for six months. The authors demonstrated that use of mobile app can be an effective channel of communication for supervision and support at community level [6]. The added advantage of using global positioning system (GPS) to locate house for real-time monitoring and for taking action was used in present study similar to Noor AM et al. in Kenya and Sisay G et al. in Nigeria for finding distance travelled by patients for getting services from government health services [7, 8].

Thus, one of the greatest advantage real time monitoring over traditional supervision was visibility of the status of each survey team with immediate action

on any issue, if found. Also, incomplete or incorrect survey/forms were detected in time before the survey lost its desired qualities. Results have shown that the use of such a system can provide a solution that tracks the teams and assesses the data quality in real time, and can provide immediate solutions to the teams which is especially important for the large population based studies.

Conclusion

App-based, real-time monitoring, along with GPS was successfully used for monitoring the quality of community based sero-surveillance for anti-SARS-CoV-2 IgG antibodies. Countries can use our findings to measure and improve the quality of sero-surveillance as well as for the large population based studies.

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Table 1: Grading Matrix for COVID-19 Sero-surveillance

Total Score	Grade	Action Plan
10	Ideal	Appreciate the team
9	Good	Suggest site in-charge for attention to become the best
8	Satisfactory	Suggest local support of senior staff
≤7	Unsatisfactory	Request trained personnel for team and support from state. Revisit site.

Table 2: Sero-Survey Quality Parametres recorded in the Mobile App

Parameter	**Yes**	**%**	**Total**
Whether full team of Doctor, ANM/LHV and LT available in the field?	28	100	28
Whether Form was filled in the mobile phone app given to them?	27	96.4	28
Whether LT was withdrawing blood with aseptic precautions?	25	89.3	28
Whether LT was disposing Biomedical Waste as per the guidelines?	26	92.9	28
Were Blood samples properly labelled?	27	96.4	28
Whether blood samples properly stored?	26	92.9	28
How satisfied were you for the House Survey being conducted by team?	28	100	28

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