Covid neutralising antibodies in care home staff: a case study using rapid point-of-care diagnostic testing.

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Outline

The Covid-19 pandemic placed a huge amount of pressure on frontline staff looking after vulnerable patients (Daly, 2020) and care homes were at the forefront of this due to SARS-CoV-2 infection and Covid disease being particularly severe for individuals >65 years old (Schultze et al, 2022). Therefore, ensuring that staff who work in these homes remain protected and supported against Covid and the pressures this can bring from a wellbeing and staffing resource perspective are of paramount importance. Cornerstone Healthcare (CH) and PremaLabs Diagnostics UK Ltd (PLD) were both aligned on the importance of these goals and therefore commenced this project initiative to learn more about Covid immunity of staff in these care homes.

On April 17th and 18th 2023, we performed 137 rapid SARS-CoV-2 neutralising antibody (NAb) tests at two CH sites (South Africa Lodge [SAL] and Kitnocks House [KH]) using the PLD NAb diagnostic dry fluorescence immunoassay and the LS-2100 and LS-1100 fluorescence analyser devices. After exclusion of 5 visitors that volunteered for testing, there were 132 staff tested with these data used for further analyses. Some general conclusions of the findings are as follows:

1. A high level of immunity to Covid was found in the staff cohort overall – because all staff had reported receiving at least two Covid immunisations within the previous two years, with most staff also reporting one booster immunisation and one prior infection with SARS-CoV-2. This demonstrates longevity and effectiveness of the Covid vaccines.

2. Immunity across both CH sites was broadly similar although a greater number of staff at SAL were found to have insufficient immunity.

3. Males tended to have lower levels of immunity than females and the 50-59 age group showed the greatest immunity levels of the cohort.

4. We identified that 7.6% of staff assessed had insufficient levels of immunity and these staff would be considered those requiring further support to reduce the risk of Covid transmission to vulnerable residents. Extrapolating this proportion to total numbers of U.K. care home staff (696,340) means that almost 53,000 staff could be at risk.

5. A staff survey of experience after testing had concluded revealed that the majority found the process simple and quick, would highly recommend it to others, and that their results were better than expected. None of the respondents had negative comments and half found the process painless.

This study of Covid antibodies has therefore given us a better understanding of immunity to SARS-CoV-2 and the potential impact of Covid, to ensure worker safety plus that of the residents they support. The feeling among participants was overall incredibly positive with the majority recommending further testing for staff and residents in the future.

Methods

The test required an exceedingly small amount (20µl) of capillary blood taken from a fingerpick with the results provided in 15 minutes and quantitated by time-resolved fluorescence immunoassay. The data obtained are expressed as binding antibody units per millilitre (BAU/ml), the analytical device having a linear measuring range between 40 and 3000 BAU/ml. Prior studies with samples obtained before Covid (pre-2019) determined a positive/negative cut-off value of 47 BAU/ml, with values up to 100 BAU/ml considered borderline, whilst NAb values >1000 BAU/ml are considered to represent effective protective immunity to Covid (McLean et al, 2022).

Results

From the total of 132 staff tested (KH 43 staff, SAL 89 staff), the average BAU/ml was 1872.4, the average age was 40.4 years, and 71.6% were female. The male average BAU/ml of 1859.9 was lower than the cohort average, whereas at 1872.4 BAU/ml, the female average was consistent with the overall cohort average. At the lower end of NAb levels <1000 BAU/ml, there were 10 individuals (7.6% of total) and 50% of these were female which is below average for sex of the total cohort. The average age of these 10 staff was 40.2 years and 80% worked at SAL. At the higher end of measurement of >3000 BAU/ml (the limit of detection for the assay), there were 12 individuals (9.1% of total) of which 83% were female, which is above average for sex of the overall cohort. The average age of these 12 staff was 41.8 years and 66% worked at SAL.

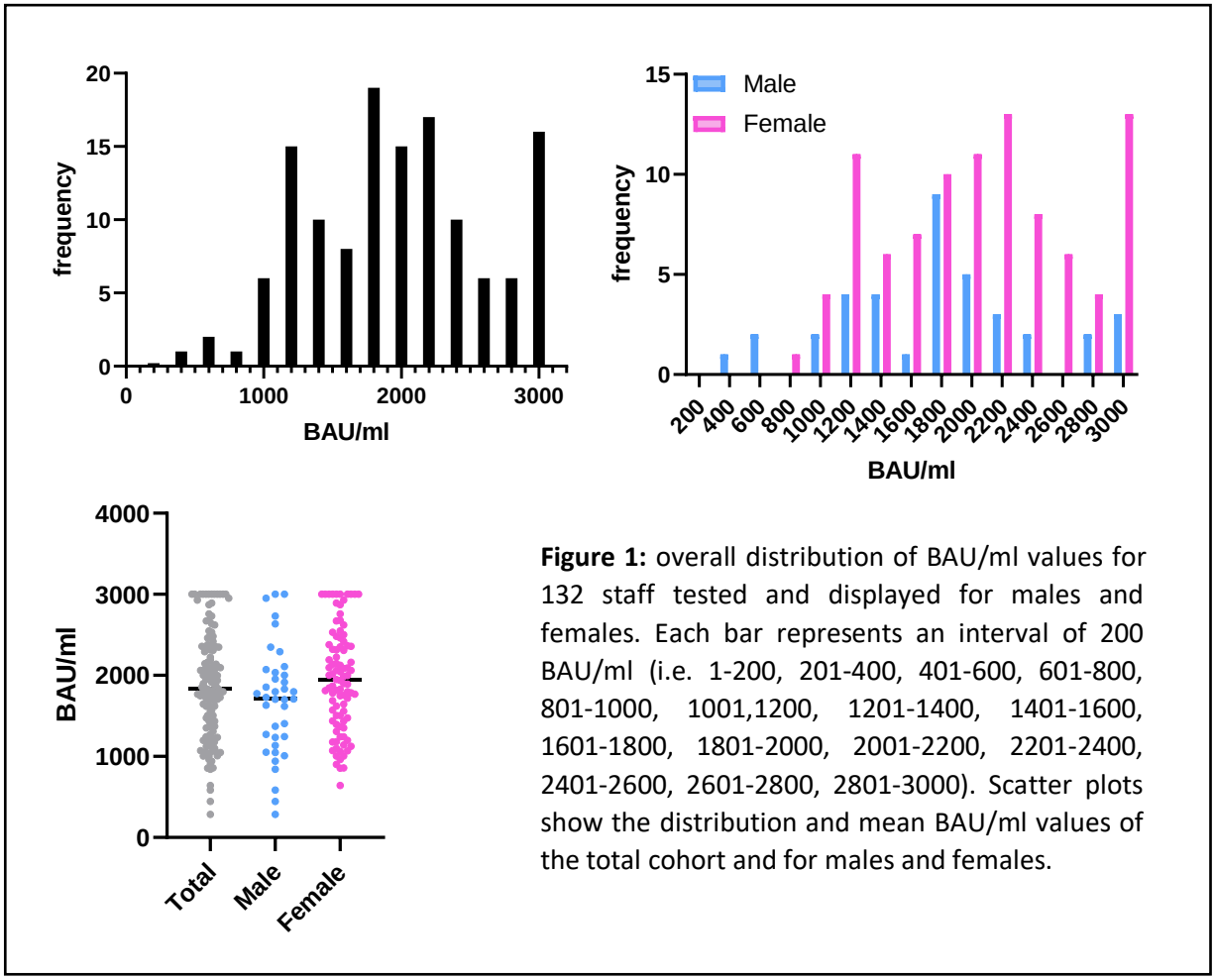

Figure 1: overall distribution of BAU/ml values for 132 staff tested and displayed for males and females. Each bar represents an interval of 200 BAU/ml (i.e. 1-200, 201-400, 401-600, 601-800, 801-1000, 1001,1200, 1201-1400, 1401-1600, 1601-1800, 1801-2000, 2001-2200, 2201-2400, 2401-2600, 2601-2800, 2801-3000). Scatter plots show the distribution and mean BAU/ml values of the total cohort and for males and females.

South Africa Lodge vs Kitnocks House: A greater proportion of the staff tested work at South Africa Lodge (SAL, n=89) compared with Kitnocks House (KH, n=43). However, the average BAU/ml was higher at KH (2011.19 BAU/ml) than at SAL (1872.86 BAU/ml). The average BAU/ml of SAL is remarkably close to the overall cohort average of 1872.4 BAU/ml due to the larger numbers of staff tested there. Despite KH staff displaying a higher level of Covid immunity, there was a lower proportion of females tested at KH (65.1% female versus 71.9% female at SAL). These findings are surprising, as females tended to have greater levels of immunity in the overall cohort. The average age was only slightly younger at KH (39.7 years) over SAL (40.6 years). When analysing the individuals with BAU/ml values <1000, termed insufficient in Figure 2, 8 of the 10 were tested at SAL which is the likely source of this bias. The overall proportions of staff immunity levels at each Cornerstone site tested is shown in Figure 2 below and demonstrates broadly similar proportions of good and very high levels of Covid immunity at each site.

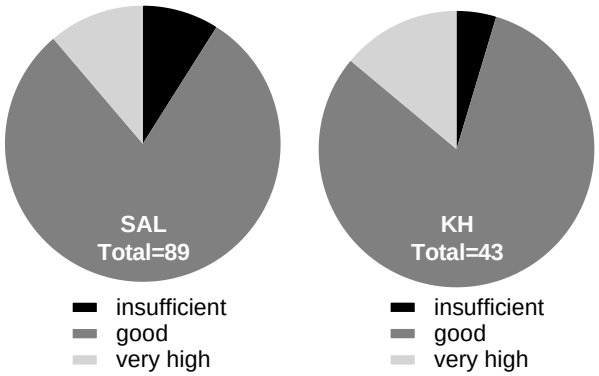

Figure 2: representation of immunity levels at SAL and KH as pie charts. Total numbers vary between sites as shown. The proportion of staff at each site with Covid immunity classed as very high (light grey), good) dark grey) and insufficient (black) is seen as slices of the total pie.

Table 1: average BAU/ml for staff age ranges.

(n=number of staff; SD=standard deviation; SEM=standard error of the mean)

Age Range	Average BAU/ml	n, SD, SEM
20-29	1834.8	32, 648, 114.6
30-39	1872.3	36, 655.6, 109.3
40-49	1860.4	32, 665.9, 117.2
50-59	**1880.6**	21, 658, 143.6
>60	1835.7	13, 662.6, 183.8

Data for age ranges in the overall cohort demonstrate just minor differences in average BAU/ml are associated with age. The only group with an increase of average BAU/ml above what is seen in the entire cohort was the 50-59 years age group (Table 1, bold type). However, the differences observed are not statistically significant due to the large variation in BAU/ml values, reflected as the relatively high SD and SEM numbers.

Prior Covid vaccination history. 31% (n=41) reported 2 vaccine doses, 48.5% (n=64) reported 3 doses, and 20.5% (n=27) reported 4 doses. Vaccine manufacturer covered the main ones used in the UK (Astra Zeneca, Pfizer and Moderna) as well as a smaller number of Covishield (India) recipients.

Prior SARS-CoV-2 infections history: 22% (n=29) reported having never been infected, 44% (n=58) reported 1 infection, 28% (n=37) reported 2 infections, and a small number 6% (n=8) reported 3 infections.

Vaccine Doses	Average BAU/ml	Infections *(and vaccinated)*	Average BAU/ml
2	1849.3	0	1862.3
3	1871.9	1	**1877.2**
4	**1875.0**	2	1863.75
		3	**2056.3**

Table 2: Average BAU/ml levels grouped by vaccine doses and infections reported. Bold type shows the BAU/ml score is above the average obtained for the entire cohort.

The level of vaccination and infection reported explains the high BAU/ml levels and Covid immunity observed in the cohort. In fact, all staff must have at least 2 vaccines to be employed at Cornerstone. Those groups with average BAU/ml levels above the overall group average reported having been infected with SARS-CoV-2 either one or three times previously and/or receiving 4 vaccine doses (Table 2). It was not possible to distinguish the relative roles of vaccination and infection based on the data collected, as all participants reported vaccination and the majority reported at least one infection. Additionally, many study participants struggled to remember exact dates of most recent vaccination or infection, therefore assigning length of time since last immune challenge to BAU/ml value was unreliable. This is reflected in the group with insufficient immunity (<1000 BAU/ml) with 50% reporting only two immunisations and many being unable to provide exact dates – none of this group reported receiving two booster vaccines and 50% had never been infected with SARS-CoV-2.

Conclusions

Overall immunity to Covid within the 132 staff assessed was found to be high due to 100% vaccine uptake (all volunteers reporting at least 2 Covid vaccinations) and significant exposure to natural infection with SARS-CoV-2 (78% reporting one or more prior infections). Females tended to have better levels of immunity than males although a higher proportion of staff are female. However, it was difficult to directly associate Covid immunity levels of staff to age, vaccine doses received, or infections reported due to the wide variety of results obtained within each group. Nevertheless, more vaccine doses (including boosters), more infections, as well as those in age group 50-59 tended to associate with higher immunity. Most importantly via testing, we identified ten individuals (7.6% of total) that had low levels of protection and a greater proportion of these were male than was found in the entire cohort. Of interest, eight of these Cornerstone staff with insufficient Covid immunity we identified were located at SAL and were predominantly male. Thus, for Cornerstone, a greater focus on this demographic should identify those more likely to transmit SARS-CoV-2 to vulnerable care home residents. The 10 individuals with insufficient immunity are advised to receive a Covid booster at the earliest and to undergo another NAb test 2-3 weeks afterwards to determine improved BAU/ml values. It would also be advisable for these staff to use PPE (facemasks and gloves) and dispose of these appropriately and more frequently when in contact with vulnerable residents. In conjunction, regular NAb testing of these staff and those with BAU/ml levels close to 1000 alongside the care home residents themselves would offer increased Covid security. The question remains, can this 7.6% of staff identified be extrapolated to a national number that is representative of all care home staff in England? If so, this would mean that a specific number of staff can be identified by a NAb screening programme who need greater protection against Covid to allow continued support of the vulnerable residents in these settings. There are almost 700,000 care home staff in the UK, with the overwhelming majority in England. Through our analyses, it could mean that almost 53,000 staff currently have insufficient immunity, with over 45,000 of them working in England, approximately 2,200 in Wales, 4,000 in Scotland and 1,400 in Northern Ireland.

In this study, we have demonstrated that mass testing of care home staff for Covid NAb is rapid, providing quantifiable data that can identify those at need of further vaccine boosters or use of PPE

to protect residents from exposure to SARS-CoV-2. Participant feedback during the testing was exceptionally good, with none reporting excessive pain or delays in the procedure. Only three volunteers required an additional fingerpick to obtain the necessary volume of capillary blood. Participants were extremely happy to receive their results after 15 minutes, rather than waiting several days for a laboratory-style analysis to be done. In fact, it became a competition among the staff as to who was highest after learning their immunity levels - with the highest level of BAU score being >3000 BAU/ml, at the limit of detection for the assay and representing superior Covid immunity.

Summary: we have confirmed the utility of the PLD NAb test and devices in a care home setting for mass testing of levels of immunity to Covid. This shows that we can apply the PLD tests to large groups rapidly using capillary blood sampling and provide results in minutes, helping to identify those requiring further advice or intervention. Application of this system to care home residents and to other tests in the PLD portfolio outside of Covid, such as inflammation monitoring, cardiac disease, and hormone status is therefore possible. A staff survey found that over half would be willing to have more tests performed and that 40% thought it would also be beneficial for residents. Overall, most staff reported that the test was quick, simple, painless and 90% stated their results were better than or as expected.

We conclude that the study was a success, in terms of staff satisfaction, quality of data obtained, and the ability to identify at-risk individuals easily and quickly. Therefore, we propose that expanded rapid point of care testing will find utility within the care home system in the UK.

References

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