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Cohort profile: A longitudinal regional cohort study to assess COVID-19 seroprevalence in blood donors – baseline characteristics of the SeMaCo study participants

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Abstract

Purpose: The SeMaCo study (funded by the Federal State of Saxony-Anhalt), a prospective, longitudinal cohort study with four survey phases spanning 3-4 months each over a period of 21 months, extends the spectrum of seroepidemiological studies in Germany. We present here a careful characterization of the sample from the initial survey phase to provide baseline data to assess the initial infection incidence, to determine the attitude towards COVID-19 vaccinations and to follow the vaccination success and vaccination acceptance over time.

Participants: A total 2.195 blood donors from the blood transfusion service of the University Hospital Magdeburg participated in the initial survey from 01/20/2021 to 04/30/2021).

Findings to date: 1909 (87.0%) of participants had no evidence of past infection or vaccination with SARS-CoV-2. Antibodies (IgG) against the SARS-COV-2 spike protein could be detected in 286 (13.0%). Among these, vaccination history revealed that 160 (59.5%) of the 269 IgG positive participants were vaccinated. From a total of 2,138 participants, information could be collected by the sociodemographic and contact questionnaires (51.7% male, mean age 43 years) and 2,082 individuals (9.2% vaccinated) by the vaccination questionnaire.

Future plans: The study primarily aims to measure the prevalence and long-term kinetics of IgG-antibodies against SARS-CoV-2. Including the baseline, the study foresees four survey periods of three to four months each. At each visit, we will assess the blood donors' attitude towards vaccination, the antibody response following vaccination and/or infection, as well as undesired vaccination effects. We aim to test the same participants during survey periods by repeated invitations for blood donation and study participation (follow-up). After the four survey phases, a longitudinal data set will be created that reflects the course of the antibody levels/frequencies as well as the infection and vaccination incidence.

Registration: The study is registered at the German Clinical Trials Register (DRKS): DRKS00023263.

Strengths and limitations of this study

- A strength of the study is the extensive information on sociodemographic characteristics, recorded occupational and personal contact frequencies, and detailed recording of vaccination status and attitude towards vaccination.
- The completeness of the data (serological findings as well as questionnaire data) is ensured by a permanent presence of study support on site.
- The study selectively enrolled blood donors. Therefore, the analyses may be valid for only a part of the healthy adult population, e.g. persons with a stronger health-conscious behaviour.
- Individuals having comorbidities associated with severity and progression of COVID-19 disease are not well represented in the study cohort.
- All data collected, with the exception of serological tests, refer to self-reported data from the participants. This includes positive SARS-CoV-2 PCR tests as well as vaccination data.

Introduction

The pandemic caused by the SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) has caused serious physical, psychological, and economic consequences for public health worldwide (1). The worldwide mortality rate is now 6.496.721million (as of 15th September 2022) (2).

Since the onset of the pandemic, many seroepidemiologic studies on SARS-CoV 2 have been conducted in Germany (3). Studies sampling blood donors are recognized as methodologically efficient as they are easily accessible and represent a significant part of the healthy, working-age population (4). The SeMaCo study (Serologische Untersuchungen bei Blutspendern des Großraums Magdeburg auf Antikörper gegen SARS-CoV-2) enrols blood donors from the city of Magdeburg (capital of the Federal State of Saxony-Anhalt (FSA)) and surrounding areas with appoximately 330,000 inhabitants. In Germany, 18 seroepidemiologic studies from the adult general population have collected data and blood samples through August 2021, plus five studies from blood donors, including the SeMaCo study (3).

SeMaCo repeatedly tests blood donors for antibodies to SARS-CoV-2 over a period of 21 months. This will reflect the prevalence and the increase of the pathogen in the population as well as the success of a vaccination campaign within our study population. Repeated testing of recurrent donors will also provide data on the long-term kinetics of the antibody response after infection and/or vaccination. Additionally, extensive sociodemographic characteristics are recorded, which will be the basis for subsequent analyses and exposures. Sociodemographic characteristics and personal and occupational daily face-to-face contact situations will be collected via a questionnaire. In the context of the donors' normal occupational and social activities will provide evidence for an interrelationship between the donors' contacts and the SARS-CoV-2 antibody detection rate may be observed. In addition, a further questionnaire asks the blood donors whether they are willing to be vaccinated, and if they were vaccinated, whether undesired vaccination effects have occurred. The evidence of specific antibodies to SARS-CoV-2 collected in the SeMaCo study will provide a better estimate of the true extent of the COVID-19 pandemic in FSA.

The aim of this cohort profile paperis to describe and characterise the SeMaCo baseline cohort and the study design. This cohort is formed by the study participants of the 1st survey period from 20 January 2021 to 30 April 2021. The cohort will be evaluated as follows:

- to analyse the distribution of sociodemographic data (for example, age, gender, schooling, employment status) of the recruited sample.
- to analyse the distribution of professional contact frequencies for the sample
- to analyse the distribution of private contact frequencies for the sample
- to analyse the proportion of (non-professional) caregivers within the sample.
- to investigate how many participants already had SARS-CoV-2 PCR testing performed at the time of the survey.
- to analyse how many participants already had positive PCR test results and/or a positive physician diagnosis for COVID-19 at the time of the survey.
- to assess the vaccination readiness and attitudes to vaccination in general.
- to analyse the serologic antibody findings against the SARS-CoV-2 spike protein in the context of a history of COVID-19 infection, and/or a history of a vaccination against SARS-CoV-2.

Cohort description

Cohort objectives and study design

The SeMaCo study is a prospective, longitudinal cohort study recruiting blood, plasma, and platelet donors from the Blood Donor Service of the University Hospital of Magdeburg over a 21-month period at 4 consecutive data collection periods (figure 1). The main objective the serological testing of SARS-

CoV-2 antibodies (using the LIAISON® SARS-CoV-2 TrimericS IgG assay, blood samples in the context of blood donation) in combination with the use of questionnaires.

Figure 1: Cohort enrolment

We aim to test the same participants during all four survey periods. New donors/participants will replace donors/participants who do not attend subsequent survey periods. The data presented here are from the baseline survey period.

The study participants had to complete two questionnaires for the baseline survey (figure 2). One was a contact questionnaire and the other a vaccination questionnaire. The contact questionnaire included the following characteristics: Sociodemographics, occupational and personal contact frequencies, non-occupational care activities, and questions about COVID-19 disease (including PCR testing). The vaccination questionnaire referred to vaccination status (including vaccines administered as well as vaccination date) and attitudes toward COVID-19 vaccines. Educational levels based on the Comparative Analyses of Social Mobility in Industrial Nations (CASMIN) classification are used as an indicator of social status. Three groups with low (1), medium (2), and high (3) educational levels were distinguished using the reported highest school and vocational educational attainment (5).

From the second sampling onwards, participants fill in a follow-up questionnaire that asks for possible changes in contact frequencies or changes in housing and living situation (follow-up contact questionnaire). Due to the frequent developments and changes in vaccines and number of vaccinations, the vaccination questionnaire (including attitudes toward vaccination) has to be answered again, regardless of the results from a previous sampling. In each study period, new participants are included in addition to replace dropouts.

To ensure compatibility, most of the contact questionnaire is based on the study protocol Corona-Monitoring (6) of the Robert Koch Institut (RKI). Additional used questions have been implemented with the approval of the Helmholz Center for Infection Research (7). The questions on marital status are based on the MethodCOV project (8), and the questions on vaccination attitudes were used with permission from the KUNO Child Health Study (9). Further questions were self-developed, e.g. on vaccination characteristics.

The assessment of the questionnaire data is conducted via the online tool LimeSurvey (version 3.23.1+200825) via tablets. In case a participant felt uncomfortable with this electronic solution, a pen & paper versions of the questionnaires were available. After completion of the survey phase, data were saved as a DAT file and syntax using the export function of LimeSurvey. The serological analysis and the transmission of the IgG antibody test results are performed by the Institute for Transfusion Medicine and Immunohematology. We assigned a five-digit participant pseudonym (ID-P) to each participant, which was used for data matching. All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS, version 26.0©).

Participants who did not indicate on the informed consent form that their blood samples should be analyzed for SARS-CoV-2 antibodies were excluded. Similarly, invalid blood samples were not considered for analyses within the study. After considering these criteria, 2195 participants with SARS-CoV-2 antibody findings were recruited as a baseline cohort. Some participants only participated in the serologic testing and did not complete questionnaires. Similarly, both questionnaires were not always completed. Therefore, there was a difference between contact/sociodemographic questionnaire and vaccination questionnaire. Figure 2 displays the classification of the sample based on the questionnaires used and the SARS-CoV-2 test result.

Figure 2: Sampling structure

The SeMaCo study is a cooperation between the Institute for Transfusion Medicine and Immunohematology with blood bank (ITIB), the Institute for Medical Microbiology and Hospital Hygiene (IMMB), and the Institute of Social Medicine and Health Systems Research (ISMHSR) of the University Medicine Magdeburg. The study is funded by the Ministry of Science, Energy, Climate Protection and Environment of FSA (funding codes I 122 and I 129). The entire methodological approach is described in detail in the study protocol that was recently published (10).

Patient and public involvement

None of the participants was involved in the design of the questionnaire or serological measurements. This includes on the design, recruitment and implementation of the study. Furthermore, all participants in the SeMaCo were informed of the use of the data for research in this study.

Findings to date

Cohort characteristics

In the SeMaCo study, we will correlate the frequency of SARS-CoV 2 infections with age, gender, and many other socio-demographic characteristics that could influence the exposure to SARS-CoV-2. Table 1 presents the sociodemographic information of 2.138 participants from the contact questionnaire.

Table 1: Sociodemographic information of first-time respondents from the survey period 20/01/21 to 30/04/21 (n = 2138)

	n	(%)
Gender	2,138	
Male	1105	(51.7)
Age	2,138	
18-34 years	708	(33.1)
35-49 years	532	(24.9)
50-64 years	723	(33.8)
65-74 years	171	(8.0)
75-84 years	4	(0.2)
Citizenship	2,138	(%)
German	2,113	(98.8)
German and other, exclusively Other	25	(1.2)
Education	2,138	
CASMIN low	42	(2.0)
CASMIN middle	1,298	(60.7)
CASMIN high	791	(37.0)

Still without a high school graduation (no CASMIN category)	7	(0.3)
Employment status	2,138	
Fulltime (including professional in-job training or self-employment)	1,341	(62.7)
Part-time (including vocational training, partial retirement or self-employment)	186	(8.7)
Temporarily reduced hours, Marginally or intermittently employed, Employed occasionally or irregularly	81	(3.8)
Retired, pensioner or in early retirement, Partial retirement	204	(9.5)
School pupil, student, trainee, advanced training program, Federal voluntary service or in voluntary social year, Retraining	274	(12.8)
Work as a homemaker, caregiver for children or dependent persons	6	(0.3)
Not employed, Permanently or temporarily unable to work, Registered unemployed or looking for work, Maternity leave, parental leave or other leave of absence	46	(2.2)
Marital status	2,138	
Married, living with spouse; registered civil partnership, cohabiting with partner (same-sex)	1,027	(48.0)
Married, living seperately from spouse; Registered civil partnership, living separately from partner (same-sex); Registered civil partnership annulled (same-sex)	36	(1.6)
Single, Divorced, Widowed	1,075	(50.3)

The description of the cohort also includes the private and occupational contact frequencies. These features aimed to follow changes in contact frequencies in the study population in the longitudinal course. We also asked the participants for changes in their contact frequencies for the time period since March 18, 2020, the start of the first lockdown in Germany. Table 2 provides an overview of the surveyed private contact frequencies of the sample (n = 2,138) of the initial survey. Table 3 shows the professional contact frequencies from the initial survey phase.

Table 2: Private contact frequencies of first-time respondents for the survey period 20/01/21 to 31/04/21 (n = 2,138)

	n	(%)
Contact with friends, relatives and neighbours at least once a week (before 18/03/2020)	2,138	
No regular direct contact with friends/relatives/neighbours	221	(10.3)
Regular direct contact with approximately 1 to 5 friends/relatives/neighbours per week	904	(42.3)

Regular direct contact with approximately 6 to 10 friends/relatives/neighbours per week	576	(26.9)
Regular direct contact with more than 10 friends/relatives/neighbours per week	437	(20.4)
Changes to contacts frequencies with friends, relatives and neighbours since 18/03/2020	2,138	
No change	442	(20.7)
Less frequent	1,687	(78.9)
More frequent	9	(0.4)
Number of people in the household	2,138	
Alone	487	(22.8)
2 to 4 people	1,536	(71.8)
5 to 8 people	115	(5.4)
Number of people in the household (without shared economic activity, e.g. shared flat)	136	
2 to 4 people	111	(81.6)
5 to 8 people	25	(18.4)
Private periods abroad since 18/03/2020	2,138	
Yes	508	(23.8)
No	1,630	(76.2)

Table 3: Occupational contact frequencies of first-time respondents from the survey period 20/01/21 to 30/04/21 according to the number of employees in the company or the number of students at a university (n = 2,138)

	n	(%)
Total number of students (for students in education)	17	
0 to 500	7	(41.2)
more than 500 (501 to 3,000)	10	(58.8)
Students in semester/academic year	299	
0 to 200	261	(87.3)
more than 200 (201 to 7,000)	38	(12.7)
Number of personnel in training organization	46	
0 to 500	37	(80.4)
more than 500 (501 to 8,000)	9	(19.6)
Number of students in vocational school	46	
0 to 500	31	(67.4)
more than 500 (501 to 5,000)	15	(32.6)

Employees on duty in workplace (main job)	1,608	
Less than 20	368	(22.9)
20 to 100	460	(28.6)
101 or more	780	(48.5)
Current professional contact with other people per week	1,875	
No contact	252	(13.4)
Infrequently, less than once a week	258	(13.8)
Once per week	134	(7.1)
Several times per week	1,231	(65.7)
Professional contact with other people, estimated number of personal contacts per week	1,623	
Less than 5	303	(18.7)
5 to 19	774	(47.7)
20 or more	546	(33.6)
Employees on duty in workplace (second job)	80	
Less than 20	55	(68.8)
20 to 100	11	(13.7)
101 or more	14	(17.5)
Current professional contact with other people (second job)	80	
No contact	26	(32.5)
Seldom, less than one per week	24	(30.0)
Once per week	11	(13.8)
Several times per week	19	(23.7)
Professional contact with other people, estimated number of personal contacts (second job)	54	
Less than 5	18	(33.3)
5 to 19	16	(29.7)
20 or more	20	(37.0)
Contact with work colleagues at least once a week (before 18/03/2020)	2,138	
No regular direct contact with work colleagues	186	(8.7)
Regular direct contact with around 1 to 10 work colleagues per week	901	(42.1)
Regular direct contact with more than 10 work colleagues per week	842	(39.4)
Does not apply (not employed prior to March 18)	209	(9.8)
Changes to contacts with work colleagues since 18/03/2020	2,138	

No change	933	(43.6)
Less frequent	1,163	(54.4)
More frequent	42	(2.0)

A special subgroup are nonprofessional caregivers. They carry an extra burden during the pandemic due to their responsibility towards another person that often has risk factors for severe disease, such as old age. This will allow for subgroup analysis and identify possible differences between caregiver and no caregiver. Table 4 illustrates the (non-professional) caregiving activities of first-time respondents (n = 2,138) collected from the socio- and contact questionnaire.

Table 4: Information on the (non-professional) care activities of the first-time respondents from the survey period from 20/01/21 to 31/04/21 (n = 2,138)

	n	(%)
Care provided by others (at least once per week)	2,138	
Caregiver	273	(12.8)
No caregiver	1,865	(82.2)
Site of care	273	
Nursing home	39	(14.3)
In own home	75	(27.5)
Received in the home of the person being cared for	168	(61.5)

Table 5 shows self-reported PCR tests performed and physician diagnoses of COVID-19.

Table 5: Possible Covid-19 infections based on information from PCR tests performed and physician diagnoses of initial respondents in the survey period 20/01/21 to 31/04/21 (n = 2,138)

	n	(%)
PCR test procedures	2,138	
Once	511	(23.9)
Multiple times	497	(23.2)
Never	1,130	(52.9)
Results of the PCR test	1,008	
Positive PCR test	93	(9.2)
Negative PCR test	913	(90.6)
Unknown	2	(0.2)

Physician based COVID-19 diagnosis	2,138	
Yes	69	(3.2)
No	2,069	(96.8)
Continuous symptoms until feeling healthy	84	
Symptoms subsided with the end of the coronavirus infection	61	(72.6)
Intermediatel partial retirementy free of symptoms and then symptoms recurred	23	(27.4)

To identify COVID-19 infection within the SeMaCo cohort, three variables are used:

- SARS-CoV-2 test results (in combination with vaccination data)
- Results of the PCR test
- Physician based COVID-19 diagnosis

Figure 3 shows the overlap between the positive PCR test, the COVID-19 physician diagnoses, and the poitive SARS-CoV-2 results without vaccination. Of the 93 participants with positive PCR test, 66 participants also reported receiving a COVID-19 diagnosis from a physician. The distribution of unvaccinated participants with antibody to SARS COV-2 after positive physician COVID-19 diagnosis and PCR testing is described in Table 6.

Figure 3: SARS-CoV-2 results

Table 6: SARS-CoV 2 findings (in BAU/ml) of the total sample (N = 2,195) during the initial survey period 20/01/21 to 30/04/21

	n	(%)
SARS-CoV-2 Results	2,195	
Negative results (< 33.8 BAU/ml)	1,909	(87.0)
Positive results (≥ 33.8 BAU/ml)	286	(13.0)
Positive results by vaccination status	269	
IgG^+ and vaccinated (including only initial vaccination)	160	(59.5)
IgG^+ and unvaccinated	109	(40.5)
Results split after initial vaccination	149	
IgG^- (< 33.8 BAU/ml)	32	(21.5)
IgG^+ (≥ 33.8 BAU/ml)	117	(78.5)
Results split after second vaccination	43	
IgG^- (< 33.8 BAU/ml)	0	(0.0)
IgG^+ (≥ 33.8 BAU/ml)	43	(100.0)
Results split according to positive PCR test results (only unvaccinated persons)	83	

IgG⁻ (< 33.8 BAU/ml)	8	(9.6)
IgG⁺ (≥ 33.8 BAU/ml)	75	(90.4)
Results split by positive physician diagnosis of COVID-19 (unvaccinated only)	64	
IgG⁻ (< 33.8 BAU/ml)	8	(12.5)
IgG⁺ (≥ 33.8 BAU/ml)	56	(87.5)

Attitudes towards vaccination and vaccination status were also assessed in the baseline survey. The differentiation of the cohort according to vaccination status is essential for the classification of the antibody findings (Table 6). The analysis of the influence of vaccination on the antibody detection rate is also important in the later course of the study. With regard to socio-epidemiological research, the survey of vaccination attitudes is a significant cohort characteristic. The information obtained from the vaccination questionnaire by respondents (n = 2,082) from the first survey period is shown in Table 7.

Table 7: Vaccination status and attitudes toward Covid-19 among baseline respondents from the survey period 20/01/21 to 30/04/21 (n = 2,082)

	n	(%)
Vaccination status (vaccination against COVID-19)	2,082	
Vaccinated	192	(9.2)
Unvaccinated	1,890	(90.8)
Number of doses	192	
One dose	149	(77.6)
Two doses	43	(22.4)
Vaccination attitude	2,082	
Endorse vaccination against COVID-19	1,599	(76.8)
Do not endorse vaccination against COVID-19	73	(3.6)
Undecided	408	(19.6)
Reasons for refusal to vaccinate (multiple answers)	73	
Fear of side effects	30	(41.1)
Vaccine not adequately tested	55	(75.3)
Vaccine still too new (wait and see)	31	(42.5)
Insufficient information about vaccination	15	(20.5)
Heard too many bad things about vaccinations	14	(17.8)
Other	9	(12.3)
General attitude towards mandatory vaccination	1,736	
Agree	529	(30.5)

Deny	822	(47.4)
Undecided	385	(22.2)
Refused vaccination (for self or child) previously, because judged not useful or dangerous	1,736	
Yes	162	(9.3)
No	1,541	(88.8)
Don't know	33	(1.9)
Postponed vaccination recommended by a physician for reasons other than health (e.g., flu-like infection).	1,736	
Yes	197	(11.3)
No	1,453	(83.7)
Don't know	86	(5.0)

Findings to date

The cohort profile presented here shows the methodological approach and a baseline cohort's establishment consisting of blood donors from Magdeburg and the surrounding area. This cohort will be examined for IgG antibodies against SARS-CoV-2 at a total of four survey phases. In addition to serological testing, participants will be asked to provide information on sociodemographics, contact frequencies, and vaccination status and acceptance (including reasons not to vaccinate), among other things. These data are the basis for the characteristics of the SeMaCo cohort described here.

In the SeMaCo cohort, there is a balanced gender distribution (51.7% vs. 48.3%). Based on serological investigations of blood donors from comparable studies (11) and the data reported to the RKI (12), very few gender differences with respect to Corona infections have been detected so far. 55.6% of SeBluCo study participants were male, a similar distribution as within the SeMaCo study. Information on a mean age and other characteristics of the sample are not yet included in the results of the SeBluCo study, as these are currently only interim analyses.

In addition to a rather equal gender distribution, the cohort has a medium to high level of education (CASMIN). This may have an impact on the vaccination attitude towards COVID-19, where more than 75% were in favour, as well as on the general attitude towards vaccination. Here, the March/April 2021 COVIMO surveys (13) of general vaccination readiness (72.6%) and mRNA-specific vaccines (74.5%) in the general population show similar vaccination attitudes to those of the SeMaCo study. The influence of educational level on attitudes toward vaccination has been described previously in various studies (14, 15) and reports (16, 17). The majority of the cohort described here are employed full-time (62.7%); only a small number of participants are employed short- and part-time (8.7%). The employment situation may also be related to vaccination acceptance, as shown by vaccination rate estimates conducted by the RKI (18). There, vaccination acceptance is higher for those who are employed than for those who work short or part-time ony or are looking for work. Likewise, the RKI data show a higher vaccination rate estimate for persons without compared to those with a migration background. In the cohort presented here, however, there are very few participants with a migration background (1.2%).

Despite the largely positive attitude towards COVID-19 vaccinations, the recorded vaccination rate is low. This is due to the limited vaccination coverage in Germany within the survey period (20/01/21 - 30/04/21). At the time of the survey, 2.7% of the German population had received full vaccination protection and 5.7% had received their first vaccination (as of 04/03/2021) (19), so there was a similar vaccination rate to the SeMaCo study cohort description (2.1% fully vaccinated, 7.2% first vaccination).

The course of the vaccination attitude within the cohort will also be part of future evaluations. In the SeBluCo study, a blood donor study run by the RKI, the proportion of vaccine-related antibodies rose to 63% at the end of April 2021 (11). Similarly, 59.5% of the IgG^+ SeMaCo participants were vaccinated at the same time point.

13% of blood donors in the SeMaCo study were seropositive during the survey period presented here. A similar seroprevalence was seen in blood donors (N = 1,000) in Northern Jordan between September 2020 and March 2021 (20). There, 14.5% of serum samples were IgG+, but with no indication of possible vaccination. In the SeMaCo study, 109 of the seropositive participants were unvaccinated and 160 participants reported at least one vaccination. In addition, the gender distribution of 96.7% male blood donors is far above the number of male donors (51.7%) in the SeMaCo study. The mean age of 28 years is also significantly lower than the mean age of 44 years in our study.

Taking into account vaccination data from participants, the prevalence of a "natural SARS-CoV 2 infection is reduced to 5.2% (IgG+ and unvaccinated), which differs from the SARS-CoV-2 prevalence in blood donors in other studies at the beginning of the pandemic. In April and May 2020, the SARS-CoV-2 rate in blood donor samples (N = 914) from Hamburg University Hospital was less than 1% (21). In a study among blood donors (N = 3,880) residing in South-western Germany, SARS-CoV-2 IgG-positive antibody detection was obtained in approximately 0.4% after the advent of the COVID-19 pandemic (22). In a study by Fischer et al. (2022), in which SARS-CoV-2 seroprevalence was also surveyed in blood donors in three federal German states (North Rhine-Westphalia, Lower Saxony, and Hesse; survey period Juli 2020 to June 2021), natural infection was detected in 206 (5.5% of the total sample) seropositive blood donors (23). In this study IgG antibodies were tested in 3,759 blood donors using the semiquantitative enzymatic immunosorbent assay (ELISA) from Euroimmun (Lübeck, Germany). A description of the sociodemographic characteristics of the sample could not be found within the study. In comparison to the SeMaCo study, Fischer and colleagues examined the positive samples using two additional tests from Abbott (Wiesbaden, Germany) and Euroimmun. Because these two tests increasingly target the viral spike and nucleocapsid, respectively, and vaccinated individuals do not produce antibodies to the nucleocapsid, this allowed them to distinguish between naturally infected and vaccinated individuals. The SeMaCo study also plans subsequent retesting for anti-nucleocapsid antibodies for the seropositive findings in all survey phases.

The SeMaCo cohort has higher levels of education (CASMIN), which may have an impact on seroprevalence over the course of the study, as socioeconomically disadvantaged individuals have a higher risk of infection as well as a higher risk of a more severe clinical course of COVID-19 (24). For example, the likelihood of SARS-CoV-2 infection (seropositive/PCR-positive or previously tested positive) among participants with low education (classified by CASMIN) was higher in the cohort of the Nationwide Corona Monitoring study (RKI-SOEP) than in the group with high education (OR 1.87) (25).

In their scoping review of challenges in studies of COVID-19 seroprevalence in blood donors, Saeed et al. (2021) reported considerable heterogeneity in methodological factors. Although the studies presented often stratified by age and sex, very few studies collected broad socioeconomic characteristics (26). The cohort characteristics presented here are diverse in set-up and are intended to grant the best possible comparability to other seroprevalence studies.

The SeMaCo study was able to give a first estimate of the actual SARS-CoV-2 infection number for the Magdeburg region (27). In addition, the broadly recorded sociodemographic characteristics and contact frequencies within the cohort can provide helpful information about vaccination attitudes and vaccination rates, which were also included. Likewise, the cohort profile will allow analyses of exposures of individuals with past infections. However, a generalization of the results should not take place, since the cohort consists exclusively of blood donors. Nevertheless, future analyses based on the presented cohort profile of the SeMaCo study can extend further social epidemiological research on COVID-19 to counteract health inequalities by providing new insights.

Strengths and limitations

Our study has several limitations. One important limitation is that the sample is restricted exclusively to blood donors from Magdeburg and the greater Magdeburg area, so the analyses therefore refer only to a part of the healthy adult population. Individuals with certain comorbidities known to influence the severity and progression of COVID-19 disease, such as diabetes mellitus (28, 29) or chronic heart disease (30), could therefore not be considered within the cohort presented here.

In addition, all data collected, with the exception of serological tests, refer to self-reported data from the participants. This also includes self-reports of positive PCR tests as well as vaccination data. This must be taken into account when interpreting the results presented here. Potential bias may also have arisen from unaccounted for personal characteristics that may affect that may affect antibody titer, such as body mass index (BMI) (31).

A major strength of the study is the extensive information on sociodemographic characteristics, recorded occupational and personal contact frequencies, and detailed recording of vaccination status and attitudes. An almost complete compilation of the serological findings through data collection by means of questionnaires could be ensured by a permanent presence of study support on site. This can provide important research contributions in later evaluations regarding possible exposures to infections or vaccination attitudes. Due to the longitudinal design and the four planned data collection periods, the cohort presented here can provide important information regarding the course of antibody frequency and vaccination attitudes. Another strength of the SeMaCo study is that participant samples will be tested with different SARS-CoV-2 antibody tests in the future to allow test comparisons.

Competing interests

No competing interests were disclosed.

Ethic

The study has been approved by the Otto-von-Guericke-University Magdeburg ethics committee (No. 163/20).

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Data availability statement

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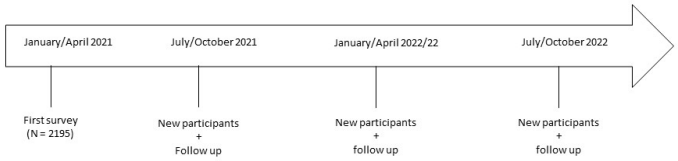

Cohort enrolment and follow-up schedule

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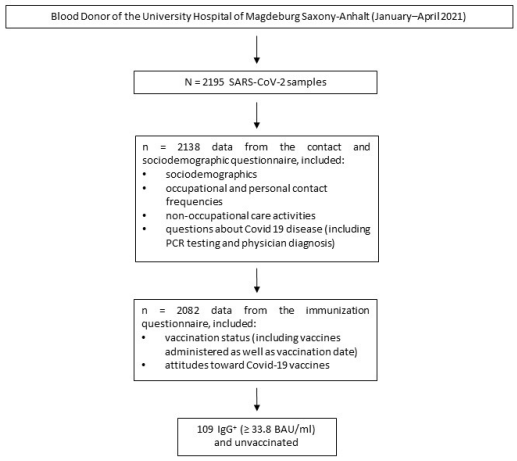

Sampling structure from the survey period 20/01/21 to 30/04/21

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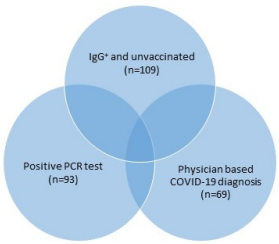

Illustration of the intersection between positive PCR test, the COVID-19 physician diagnoses, and the positive SARS-CoV-2 results (for unvaccinated participants).

338x190mm (96 x 96 DPI)

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Cohort profile: A longitudinal regional cohort study to assess COVID-19 seroprevalence in blood donors – baseline characteristics of the SeMaCo study participants

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Cohort profile: A longitudinal regional cohort study to assess COVID-19 seroprevalence in blood donors – baseline characteristics of the SeMaCo study participants

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Abstract

Purpose: The SeMaCo study, a prospective, longitudinal cohort study with four survey phases spanning 3-5 months each over a period of 22 months, extends the spectrum of seroepidemiological studies in Germany. We present here a careful characterization of the initial survey phase cohort to provide baseline data for the initial infection incidence and the questionnaire results, in particular to follow the attitude towards COVID-19 vaccinations, the vaccination success and the vaccination acceptance over time.

Participants: A total of 2,195 individual blood donors from the donor pool of the Blood Donation Service of the University Hospital Magdeburg were enrolled in the initial survey phase from 01/20/2021 to 04/30/2021. 2,138 gave sociodemographic/contact data (51.7% male, mean age 44 years) and 2,095 answered the vaccination questionnaire.

Findings to date: Out of 2,195 participants with antibody results 1,909 (87.0%) were antibody negative. The remaining 286 subjects (13.0%) were either antibody-positive and vaccinated (160/2,195; 7.3%) or antibody positive without vaccination information (17/2,195; 0.7%) or antibody-positive and unvaccinated (109/2,195; 5.0%). The latter result reflects the rate of true or highly probable SARS CoV-2 infections in our initial study cohort.

Future plans: The study primarily aims to measure the prevalence and long-term kinetics of IgG-antibodies against SARS-CoV-2. Including the baseline, the study foresees four survey periods of three to four months each. At each visit, we will assess the blood donors' attitude towards vaccination, the antibody response following vaccination and/or infection, as well as undesired vaccination effects. We aim to test the same participants during the survey periods by repeated invitations for blood donation to ensure a long-term (follow-up) in as many study participants as possible. After the four survey phases, a longitudinal data set will be created that reflects the course of the antibody levels/frequencies as well as the infection and vaccination incidence.

Registration: The study is registered at the German Clinical Trials Register (DRKS): DRKS00023263.

Strengths and limitations of this study

- A strength of the study is the extensive information on sociodemographic characteristics, recorded occupational and personal contact frequencies, and detailed recording of vaccination status and attitude towards vaccination.
- The completeness of the data (serological findings as well as questionnaire data) is ensured by a permanent presence of study staff support on site.
- The study selectively enrolled blood donors. Therefore, the analyses may be valid for only a part of the healthy adult population, e.g. persons with a stronger health-conscious behaviour.
- Individuals having comorbidities associated with severity and progression of COVID-19 disease are not well represented in the study cohort.
- All data collected, with the exception of serological tests, refer to self-reported data from the participants. This includes information of positive SARS-CoV-2 PCR tests as well as vaccination data.

Introduction

The pandemic caused by the SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) has caused serious physical, psychological, and economic consequences for public health worldwide [1]. The worldwide mortality rate is now 6.841.640million (as of 14th February 2023) [2].

Since the onset of the pandemic, many seroepidemiologic studies on SARS-CoV 2 have been conducted in Germany [3]. Studies sampling blood donors are recognized as methodologically efficient as they are easily accessible and represent a significant part of the healthy, working-age population [4]. The SeMaCo study (Serologische Untersuchungen bei Blutspendern des Großraums Magdeburg auf Antikörper gegen SARS-CoV-2) enrols blood donors from the city of Magdeburg (capital of the Federal State of Saxony-Anhalt (FSA)) and surrounding areas with appoximately 330,000 inhabitants. In Germany, 18 seroepidemiologic studies from the adult general population have collected data and blood samples through August 2021, plus five studies from blood donors, including the SeMaCo study [3].

SeMaCo repeatedly tests blood donors for antibodies to SARS-CoV-2 over a period of 22 months. This will represent the prevalence and the increase of the pathogen in the population as well as the success of a vaccination campaign within our study population. Repeated testing of recurrent donors will also provide data on the long-term kinetics of the antibody response after infection and/or vaccination. The evidence of specific antibodies to SARS-CoV-2 collected in the SeMaCo study will provide a better estimate of the true extent of the COVID-19 pandemic in FSA. Additionally, extensive sociodemographic characteristics are recorded, which will be the basis for subsequent analyses and exposures. Sociodemographic characteristics and personal and occupational daily face-to-face contact situations will be collected via a questionnaire. In the context the donors' normal occupational and social activities will provide evidence for an interrelationship between the donors' contacts and the SARS-CoV-2 antibody detection rate. In addition, a further questionnaire asks the blood donors for the occurrence of SARS CoV-2 infections, for their willingness to become vaccinated, and if they had been vaccinated, whether they observed undesired vaccination effects (the German SARS CoV-2 vaccination campaign started after vaccine approval on December 27, 2020).

The aim of this cohort profile paperis to describe and characterise the SeMaCo baseline cohort and the study design. This cohort is formed by the study participants of the 1st survey period from 20 January 2021 to 30 April 2021. The cohort will be evaluated as follows:

- to analyse the distribution of sociodemographic data (for example, age, gender, schooling, employment status) of the recruited sample.
- to analyse the distribution of professional contact frequencies for the sample
- to analyse the distribution of private contact frequencies for the sample
- to analyse the proportion of (non-professional) caregivers within the sample.
- to investigate how many participants already had SARS-CoV-2 PCR testing performed at the time of the survey.
- to analyse how many participants already had positive PCR test results and/or a positive physician diagnosis for COVID-19 at the time of the survey.
- to assess the vaccination readiness and attitudes to vaccination in general.
- to analyse the serologic antibody findings against the SARS-CoV-2 spike protein in the context of a history of COVID-19 infection, and/or a history of a vaccination against SARS-CoV-2.

Cohort description

Cohort objectives and study design

The SeMaCo study is a prospective, longitudinal cohort study recruiting blood, plasma, and platelet donors from the Blood Donor Service of the University Hospital of Magdeburg over a 22-month period at 4 consecutive data collection periods (figure 1). The main study objective is the measurement of IgG-titres against SARS-CoV-2 in the serum of blood donors using the LIAISON® SARS-CoV-2 Trimeric IgG assay (DiaSorin, 311510). This indirect chemiluminescent immunoassay detects specific IgG antibodies against the SARS-CoV-2 spike protein trimer with a specificity of 99,5 % and a sensitivity of 98,7 % (≥ 15 days after positive PCR). The serological tests are supplemented by two questionnaires.

Figure 1: Cohort enrolment

We aim to test the same participants during the survey periods by repeated invitations for blood donation to ensure a long-term follow-up in as many study participants as possible. The data presented here are from the baseline survey period.

The study participants had to complete two questionnaires for the baseline survey (figure 2). One was a contact questionnaire and the other a vaccination questionnaire. The contact questionnaire included the following characteristics: Sociodemographics, occupational and personal contact frequencies, non-occupational care activities, and questions about COVID-19 disease (including PCR testing). The vaccination questionnaire referred to vaccination status (including vaccines administered as well as vaccination date) and attitudes toward COVID-19 vaccines. Educational levels based on the Comparative Analyses of Social Mobility in Industrial Nations (CASMIN) classification are used as an indicator of social status. Three groups with low (1), medium (2), and high (3) educational levels were distinguished using the reported highest school and vocational educational attainment [5].

From the second sampling onwards, participants fill in a follow-up questionnaire that asks for possible changes in contact frequencies or changes in housing and living situation (follow-up contact questionnaire). Due to the frequent developments and changes in vaccines and number of vaccinations, the vaccination questionnaire (including attitudes toward vaccination) has to be filled in again, regardless of the results from a previous sampling. In each study period, new participants are included in addition to replace dropouts.

To ensure compatibility, most of the contact questionnaire is based on the study protocol Corona-Monitoring [6] of the Robert Koch Institute (RKI). Additional used questions have been implemented with the approval of the Helmholz Center for Infection Research [7]. The questions on marital status are based on the MethodCOV project [8], and the questions on vaccination attitudes were used with permission from the KUNO Child Health Study [9]. Further questions were self-developed, e.g. on vaccination characteristics.

The assessment of the questionnaire data is conducted via the online tool LimeSurvey (version 3.23.1+200825) via tablets. In case a participant felt uncomfortable with this electronic solution, a pen & paper versions of the questionnaires were available. After completion of the survey phase, data were saved as a DAT file and syntax using the export function of LimeSurvey. The serological analysis and the transmission of the IgG antibody test results are performed by the Institute for Medical Microbiology and Hospital Hygiene of the University Hospital of Magdeburg. We assigned a five-digit participant pseudonym (ID-P) to each participant, which was used for data matching. All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS, version 26.0©).

Participants who did not indicate on the informed consent form that their blood samples should be analysed for SARS-CoV-2 antibodies were excluded. Similarly, invalid blood samples were not considered for analyses within the study. After considering these criteria, 2195 participants with SARS-CoV-2 antibody findings were recruited as a baseline cohort. Some participants only participated in the serologic testing and did not complete one or both questionnaires. Therefore, there was a small difference between the numbers of subjects with antibody determinations (2,195) and completion of contact/sociodemographic questionnaire (2,138) and vaccination questionnaire (2,082). Figure 2 displays the classification of the sample based on the SARS-CoV-2 test results and on the completed questionnaires.

Figure 2: Sampling structure

The SeMaCo study is a cooperation between the Institute for Transfusion Medicine and Immunohematology with Blood Bank (ITIB), the Institute for Medical Microbiology and Hospital Hygiene (IMMB), and the Institute of Social Medicine and Health Systems Research (ISMHSR) of the University Medicine Magdeburg. The study is funded by the Ministry of Science, Energy, Climate Protection and Environment of FSA (funding codes I 122 and I 129). The entire methodological approach is described in detail in the study protocol that was recently published [10].

Patient and public involvement

None of the participants was involved in the design of the questionnaire or serological measurements. This includes the design, recruitment and implementation of the study. Furthermore, all participants in the SeMaCo were informed of the use of the data for research in this study.

Findings to date

Cohort characteristics

In the SeMaCo study, we will correlate the frequency of SARS-CoV 2 infections with age, gender, and many other socio-demographic characteristics that could influence the exposure to SARS-CoV-2. Table 1 presents the sociodemographic information of 2.138 participants from the contact questionnaire.

Table 1: Sociodemographic information of first-time respondents from the survey period 20/01/21 to 30/04/21 (n = 2138)

	n	(%)
Gender	2,138	
Male	1,105	(51.7)
Age	2,138	
18-34 years	708	(33.1)
35-49 years	532	(24.9)
50-64 years	723	(33.8)
65-74 years	171	(8.0)
75-84 years	4	(0.2)
Citizenship	2,138	(%)

German	2,113	(98.8)
German and other, exclusively Other	25	(1.2)
Education	2,138	
CASMIN low	42	(2.0)
CASMIN middle	1,298	(60.7)
CASMIN high	791	(37.0)
Still without a high school graduation (no CASMIN category)	7	(0.3)
Employment status	2,138	
Fulltime (including professional in-job training or self-employment)	1,341	(62.7)
Part-time (including vocational training, partial retirement or self-employment)	186	(8.7)
Temporarily reduced hours, Marginally or intermittently employed, Employed occasionally or irregularly	81	(3.8)
Retired, pensioner or in early retirement, Partial retirement	204	(9.5)
School pupil, student, trainee, advanced training program, Federal voluntary service or in voluntary social year, Retraining	274	(12.8)
Work as a homemaker, caregiver for children or dependent persons	6	(0.3)
Not employed, Permanently or temporarily unable to work, Registered unemployed or looking for work, Maternity leave, parental leave or other leave of absence	46	(2.2)
Marital status	2,138	
Married, living with spouse; registered civil partnership, cohabiting with partner (same-sex)	1,027	(48.0)
Married, living seperately from spouse; Registered civil partnership, living separately from partner (same-sex); Registered civil partnership annulled (same-sex)	36	(1.6)
Single, Divorced, Widowed	1,075	(50.3)

The description of the cohort also includes the private and occupational contact frequencies. These features aimed to follow changes in contact frequencies in the study population in the longitudinal course. We also asked the participants for changes in their contact frequencies for the time period since March 18, 2020, the start of the first lockdown in Germany. Table 2 provides an overview of the surveyed private contact frequencies of the sample (n = 2,138) of the initial survey. Table 3 shows the professional contact frequencies from the initial survey phase.

Table 2: Private contact frequencies of first-time respondents for the survey period 20/01/21 to 31/04/21 (n = 2,138)

	n	(%)
Contact with friends, relatives and neighbours at least once a week (before 18/03/2020)	2,138	
No regular direct contact with friends/relatives/neighbours	221	(10.3)
Regular direct contact with approximately 1 to 5 friends/relatives/neighbours per week	904	(42.3)
Regular direct contact with approximately 6 to 10 friends/relatives/neighbours per week	576	(26.9)
Regular direct contact with more than 10 friends/relatives/neighbours per week	437	(20.4)
Changes to contacts frequencies with friends, relatives and neighbours since 18/03/2020	2,138	
No change	442	(20.7)
Less frequent	1,687	(78.9)
More frequent	9	(0.4)
Number of people in the household	2,138	
Alone	487	(22.8)
2 to 4 people	1,536	(71.8)
5 to 8 people	115	(5.4)
Number of people in the household (without shared economic activity, e.g. shared flat)	136	
2 to 4 people	111	(81.6)
5 to 8 people	25	(18.4)
Private periods abroad since 18/03/2020	2,138	
Yes	508	(23.8)
No	1,630	(76.2)

Table 3: Occupational contact frequencies of first-time respondents from the survey period 20/01/21 to 30/04/21 according to the number of employees in the company or the number of students at a university (n = 2,138)

	n	(%)
Total number of students (for students in education)	17	
0 to 500	7	(41.2)
more than 500 (501 to 3,000)	10	(58.8)
Students in semester/academic year	299	
0 to 200	261	(87.3)
more than 200 (201 to 7,000)	38	(12.7)

Number of personnel in training organization	46	
0 to 500	37	(80.4)
more than 500 (501 to 8,000)	9	(19.6)
Number of students in vocational school	46	
0 to 500	31	(67.4)
more than 500 (501 to 5,000)	15	(32.6)
Employees on duty in workplace (main job)	1,608	
Less than 20	368	(22.9)
20 to 100	460	(28.6)
101 or more	780	(48.5)
Current professional contact with other people per week	1,875	
No contact	252	(13.4)
Infrequently, less than once a week	258	(13.8)
Once per week	134	(7.1)
Several times per week	1,231	(65.7)
Professional contact with other people, estimated number of personal contacts per week	1,623	
Less than 5	303	(18.7)
5 to 19	774	(47.7)
20 or more	546	(33.6)
Employees on duty in workplace (second job)	80	
Less than 20	55	(68.8)
20 to 100	11	(13.7)
101 or more	14	(17.5)
Current professional contact with other people (second job)	80	
No contact	26	(32.5)
Seldom, less than one per week	24	(30.0)
Once per week	11	(13.8)
Several times per week	19	(23.7)
Professional contact with other people, estimated number of personal contacts (second job)	54	
Less than 5	18	(33.3)
5 to 19	16	(29.7)
20 or more	20	(37.0)
Contact with work colleagues at least once a week (before 18/03/2020)	2,138	

No regular direct contact with work colleagues	186	(8.7)
Regular direct contact with around 1 to 10 work colleagues per week	901	(42.1)
Regular direct contact with more than 10 work colleagues per week	842	(39.4)
Does not apply (not employed prior to March 18)	209	(9.8)
Changes to contacts with work colleagues since 18/03/2020	2,138	
No change	933	(43.6)
Less frequent	1,163	(54.4)
More frequent	42	(2.0)
Professional trips abroad since 18/03/2020	2,138	
Yes	56	(2.6)
No	2,082	(97.4)

A special subgroup are nonprofessional caregivers. They carry an extra burden during the pandemic due to their responsibility towards another person that often has risk factors for severe disease, such as old age. This will allow for subgroup analysis and identify possible differences between caregiver and no caregiver. Table 4 illustrates the (non-professional) caregiving activities of first-time respondents (n = 2,138) collected from the socio- and contact questionnaire.

Table 4: Information on the (non-professional) care activities of the first-time respondents from the survey period from 20/01/21 to 31/04/21 (n = 2,138)

	n	(%)
Care provided by others (at least once per week)	2,138	
Caregiver	273	(12.8)
No caregiver	1,865	(82.2)
Site of care	273	
Nursing home	39	(14.3)
In own home	75	(27.5)
Received in the home of the person being cared for	168	(61.5)

Table 5 shows self-reported PCR tests performed and physician diagnoses of COVID-19.

Table 5: Possible Covid-19 infections based on information from PCR tests performed and physician diagnoses of initial respondents in the survey period 20/01/21 to 31/04/21 (n = 2,138)

	n	(%)
PCR test procedures	2,138	

Once	511	(23.9)
Multiple times	497	(23.2)
Never	1,130	(52.9)
Results of the PCR test	1,008	
Positive PCR test	93	(9.2)
Negative PCR test	913	(90.6)
Unknown	2	(0.2)
Physician based COVID-19 diagnosis	2,138	
Yes	69	(3.2)
No	2,069	(96.8)
Continuous symptoms until feeling healthy	84	
Symptoms subsided with the end of the coronavirus infection	61	(72.6)
Intermediately partial recovery free of symptoms and then symptoms recurred	23	(27.4)

To identify COVID-19 infection within the SeMaCo cohort, three variables are used:

- SARS-CoV-2 test results (in combination with vaccination data)
- Results of the PCR test
- Physician based COVID-19 diagnosis

Of the 93 participants with positive PCR test, 66 participants reported receiving a COVID-19 diagnosis from a physician. The distribution of unvaccinated participants with antibody to SARS COV-2 after positive physician COVID-19 diagnosis and PCR testing is described in Table 6.

Table 1: SARS-CoV 2 results (in BAU/ml) of the total sample (N = 2,195) and the participant with self-reported vaccination data (n=2,082) during the initial survey period 20/01/21 to 30/04/21

	n	(%)
SARS-CoV-2 Results	2,195	
Negative results (< 33.8 BAU/ml)	1,909	(87.0)
Positive results (≥ 33.8 BAU/ml)	286	(13.0)
Participant with vaccination data	2,082	
Positive results by vaccination status	269	(12.9)
IgG^+ and vaccinated (including only initial vaccination)	160	(59.5)
IgG^+ and unvaccinated	109	(40.5)
Results split after initial vaccination	149	
IgG^- (< 33.8 BAU/ml)	32	(21.5)
IgG^+ (≥ 33.8 BAU/ml)	117	(78.5)

Results split after second vaccination	43	
IgG$^-$ (< 33.8 BAU/ml)	0	(0.0)
IgG$^+$ (≥ 33.8 BAU/ml)	43	(100.0)
Results split according to positive PCR test results (only unvaccinated persons)	83	
IgG$^-$ (< 33.8 BAU/ml)	8	(9.6)
IgG$^+$ (≥ 33.8 BAU/ml)	75	(90.4)
Results split by positive physician diagnosis of COVID-19 (unvaccinated only)	64	
IgG$^-$ (< 33.8 BAU/ml)	8	(12.5)
IgG$^+$ (≥ 33.8 BAU/ml)	56	(87.5)

Attitudes towards vaccination and vaccination status were also assessed in the baseline survey. Of 286 positive SARS-CoV-2 results (≥ 33.8 BAU/ml), 269 had information from the vaccination questionnaire (17 persons without vaccination data). The differentiation of the cohort according to vaccination status is essential for the classification of the antibody findings (Table 6). The analysis of the influence of vaccination on the antibody detection rate is also important in the later course of the study. With regard to socio-epidemiological research, the survey of vaccination attitudes is a significant cohort characteristic. The information obtained from the vaccination questionnaire by respondents (n = 2,082) from the first survey period is shown in Table 7.

Table 7: Self-reported vaccination status and attitudes toward Covid-19 among baseline respondents from the survey period 20/01/21 to 30/04/21 (n = 2,082)

	n	(%)
Vaccination status (vaccination against COVID-19)	2,082	
Vaccinated	192	(9.2)
Unvaccinated	1,890	(90.8)
Number of doses	192	
One dose	149	(77.6)
Two doses	43	(22.4)
Vaccination attitude	2,082	
Endorse vaccination against COVID-19	1,599	(76.8)
Do not endorse vaccination against COVID-19	73	(3.6)
Undecided	408	(19.6)
Reasons for refusal to vaccinate (multiple answers)	73	
Fear of side effects	30	(41.1)
Vaccine not adequately tested	55	(75.3)

Vaccine still too new (wait and see)	31	(42.5)
Insufficient information about vaccination	15	(20.5)
Heard too many bad things about vaccinations	14	(17.8)
Other	9	(12.3)
General attitude towards mandatory vaccination	1,736	
Agree	529	(30.5)
Deny	822	(47.4)
Undecided	385	(22.2)
Refused vaccination (for self or child) previously, because judged not useful or dangerous	1,736	
Yes	162	(9.3)
No	1,541	(88.8)
Don't know	33	(1.9)
Postponed vaccination recommended by a physician for reasons other than health (e.g., flu-like infection).	1,736	
Yes	197	(11.3)
No	1,453	(83.7)
Don't know	86	(5.0)

Findings to date

The cohort profile presented here shows the methodological approach and a baseline cohort's establishment consisting of blood donors from Magdeburg and the surrounding area. This cohort will be examined for IgG antibodies against SARS-CoV-2 at four survey phases. In addition to serological testing, participants will be asked to provide information on sociodemographics, contact frequencies, and vaccination status and acceptance (including reasons not to vaccinate), among other things. These data are the basis for the characteristics of the SeMaCo cohort described here.

In the SeMaCo cohort, there is a balanced gender distribution (male 51.7% vs. female 48.3%) and similar to the gender distribution of the Magdeburg population from 2021 (male 49.4% vs. female 50.6%) [11]. The same can be observed for the average age between the SeMaCo study and the Magdeburg population (43.65 years vs. 45.27 years) [12]. Nevertheless, it has to be considered that the cohort presented here is a selective sample of blood donors. Although it has already been shown in other studies that sociodemographic characteristics of blood donors may be essentially comparable to the general population, with regard to myocardial infarction and asthma, the prevalence in blood donors is still lower than in the general population [13]. This is also reflected by the fact that health-related reasons and medication use is the most common reason against donating blood [14], which affects the blood donor population. This also relates to smoking behaviour, where blood donors have a healthier lifestyle [13].Based on serological investigations of blood donors from comparable studies [15] and the data reported to the RKI [16], very few gender differences with respect to Corona infections have been detected so far. 55.6% of SeBluCo study participants were male, a similar distribution as within the SeMaCo study. Information on a mean age and other characteristics of the sample are not yet included in the results of the SeBluCo study, as these are currently only interim analyses [15, 16].

In addition to a rather equal gender distribution, the cohort has a medium to high level of education (CASMIN). This may have an impact on the vaccination attitude towards COVID-19, where more than 75% were in favour, as well as on the general attitude towards vaccination. Here, the March/April 2021 COVIMO surveys [17] of general vaccination readiness (72.6%) and mRNA-specific vaccines (74.5%) in the general population show similar vaccination attitudes to those of the SeMaCo study. The influence of educational level on attitudes toward vaccination has been described previously in various studies [18, 19] and reports [20, 21]. For a certain infection prevention, but in particular for the mitigation of the clinical course of the COVID-19 disease, SARS CoV-2 vaccines have proven to be reliable. Therefore, socially equitable distribution as well as equitable access to COVID-19 vaccines should be a main policy goal. Bolcatto et al. (2021) describe vaccine nationalism as the main obstacle to equitable access to vaccines [22]. The majority of the cohort described here are employed full-time (62.7%); only a small number of participants are employed short- and part-time (8.7%). The employment situation may also be related to vaccination acceptance, as shown by vaccination rate estimates conducted by the RKI [23]. There, vaccination acceptance is higher for those who are employed than for those who work short or part-time ony or are looking for work. Likewise, the RKI data show a higher vaccination rate estimate for persons without compared to those with a migration background. In the cohort presented here, however, there are very few participants with a migration background (1.2%). Employees from the health sector and other "system-relevant industries and professions" had an increased risk of infection during the pandemic. The results of the SeMaCo study cannot be used to make conclusions about occupation-specific infection risk and vaccination attitudes towards COVID-19. In a survey of Italian nursing staff shortly before vaccine availability, vaccination readiness was 91.5%, with female gender and confidence in the effectiveness of the vaccine emerging as the most important predictors [24].

The vaccine shortage in Germany in the first quarter due to limited supplies delayed the vaccination coverage rate in the population [25]. Therefore, despite the largely positive attitude towards COVID-19 vaccinations, the recorded vaccination rate within the survey period (20/01/21 - 30/04/21) is low. At the time of the survey, 2.7% of the German population had received full vaccination protection and 5.7% had received their first vaccination (as of 04/03/2021) [26], so there was a similar vaccination rate to the SeMaCo study cohort description (2.1% fully vaccinated, 7.2% first vaccination). The course of the vaccination attitude within the cohort will also be part of future evaluations. In the SeBluCo study, a blood donor study run by the RKI, the proportion of vaccine-related antibodies rose to 63% at the end of April 2021 [15]. Similarly, 59.5% of the IgG^+ SeMaCo participants were vaccinated at the same time point.

13% of blood donors in the SeMaCo study were seropositive during the survey period presented here.. Of these, 109 participants were unvaccinated and 160 participants reported at least one vaccination.

Taking into account vaccination data from participants, the prevalence of a “natural SARS-CoV 2 infection is reduced to 5.2% (IgG+ and unvaccinated), which differs from the SARS-CoV-2 prevalence in blood donors in other studies at the beginning of the pandemic. In April and May 2020, the SARS-CoV-2 rate in blood donor samples (N = 914) from Hamburg University Hospital was less than 1% [27]. In a study among blood donors (N = 3,880) residing in South-western Germany, SARS-CoV-2 IgG-positive antibody detection was obtained in approximately 0.4% after the advent of the COVID-19 pandemic [28]. In a study by Fischer et al. (2022), in which SARS-CoV-2 seroprevalence was also surveyed in blood donors in three federal German states (North Rhine-Westphalia, Lower Saxony, and Hesse; survey period July 2020 to June 2021), natural infection was detected in 206 (5.5% of the total sample) seropositive blood donors [29]. In this study IgG antibodies were tested in 3,759 blood donors using the semiquantitative enzymatic immunosorbent assay (ELISA) from Euroimmun (Lübeck, Germany). A description of the sociodemographic characteristics of the sample could not be found within the study. In comparison to the SeMaCo study, Fischer and colleagues examined the positive samples using two additional tests from Abbott (Wiesbaden, Germany) and Euroimmun. Because these two tests increasingly target the viral spike and nucleocapsid, respectively, and vaccinated individuals do not produce antibodies to the nucleocapsid, this allowed them to distinguish between naturally

infected and vaccinated individuals. The SeMaCo study also plans subsequent retesting for anti-nucleocapsid antibodies for the seropositive findings in all survey phases.

The low seroprevalence of SARS-CoV-2 IgG antibodies among SeMaCo participants is due to the early phase of the pandemic. Similarly low seroprevalence were also found in other blood donor studies from Germany's neighbouring countries at the beginning of the pandemic [30, 31].

As the pandemic progresses, seroprevalence is expected to rise significantly due to an increase in vaccinations and infections. A seroepidemiological study among Austrian blood donors shows an increase in seroprevalence from 3.4% in June 2020 to 82.7% in September 2021, largely due to vaccination [32]. In Tyrolean blood donors with a similar age and sex distribution as in the SeMaCo study (43.65 years vs. 45.3 years, female 48.2% vs. female 41.9%), a significantly higher seroprevalence of SARS-CoV-2 antibodies was found in a later survey period than in the baseline study presented here, which were collected at an earlier point in the pandemic. Seropositivity there increased from 84.9% in October 2021 to 95.8% in April 2022, taking into account a very high vaccination coverage rate of 99.7% among seropositive participants [33].

The SeMaCo cohort has higher levels of education (CASMIN), which may have an impact on seroprevalence over the course of the study, as socioeconomically disadvantaged individuals have a higher risk of infection as well as a higher risk of a more severe clinical course of COVID-19 [34]. For example, the likelihood of SARS-CoV-2 infection (seropositive/PCR-positive or previously tested positive) among participants with low education (classified by CASMIN) was higher in the cohort of the Nationwide Corona Monitoring study (RKI-SOEP) than in the group with high education (OR 1.87) [35].

In their scoping review of challenges in studies of COVID-19 seroprevalence in blood donors, Saeed et al. (2021) reported considerable heterogeneity in methodological factors. Although the studies presented often stratified by age and sex, very few studies collected broad socioeconomic characteristics [36]. The cohort characteristics presented here are diverse in set-up and are intended to grant the best possible comparability to other seroprevalence studies.

The SeMaCo study was able to give a first estimate of the actual SARS-CoV-2 infection number for the Magdeburg region [37]. In addition, the broadly recorded sociodemographic characteristics and contact frequencies within the cohort can provide helpful information about vaccination attitudes and vaccination rates, which were also included. Likewise, the cohort profile will allow analyses of exposures of individuals with past infections. However, a generalisation of the results should not take place, since the cohort consists exclusively of blood donors. Nevertheless, future analyses based on the presented cohort profile of the SeMaCo study can extend further social epidemiological research on COVID-19 to counteract health inequalities by providing new insights.

Strengths and limitations

Our study has several limitations. One important limitation is that the sample is restricted exclusively to blood donors from Magdeburg and the greater Magdeburg area, so the analyses therefore refer only to a part of the healthy adult population. Individuals with certain comorbidities known to influence the severity and progression of COVID-19 disease, such as diabetes mellitus [38, 39] or chronic heart disease [40], were not represented in the cohort.

In addition, all data collected, with the exception of serological tests, refer to self-reported data from the participants. This also includes self-reports of positive PCR tests as well as vaccination data. Potential bias may also have arisen from unaccounted for personal characteristics that may affect antibody titer, such as body mass index (BMI) [41].

The serological tests were supplemented by two questionnaires. This resulted in different frequencies between the SARS-CoV-2 antibody samples (n = 2,195) and the information from the two questionnaires (contact questionnaire n = 2,138, vaccination questionnaire = 2,082) (Figure 2). Without linking the results of the serological tests with those of the questionnaires, no valid information about the cohort can be provided, as no conclusions can be drawn about possible infections or vaccinations.

However, as the number of participants with antibody tests but missing questionnaires is low (57 for contact, 113 subjects for the vaccination questionnaire), the informative value of our study will not be significantly impaired.

A major strength of the study is the extensive information on sociodemographic characteristics, recorded occupational and personal contact frequencies, and detailed recording of vaccination status and attitudes. An almost complete compilation of the serological findings through data collection by means of questionnaires could be ensured by a permanent presence of study support on site. This can provide important research contributions in later evaluations regarding possible exposures to infections or vaccination attitudes. Due to the longitudinal design and the four planned data collection periods, the cohort presented here can provide important information regarding the course of antibody frequency and vaccination attitudes. Another strength of the SeMaCo study is that participants' samples will be tested with different SARS-CoV-2 antibody tests in the future to allow comparisons between testing systems.

Contributorship Statement

RP: Data Curation, Formal Analysis, Investigation, Project Administration, Software, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; CS: Conceptualization, Methodology, Data Curation, Formal Analysis, Software, Writing – Review & Editing; PM: Data Curation, Investigation, Methodology, Software, Writing – Review & Editing; AJK: Conceptualization, Funding Acquisition, Methodology, Resources, Supervision, Writing – Review & Editing; HGH: Conceptualization, Funding Acquisition, Methodology, Resources, Supervision, Writing – Review & Editing; CA: Conceptualization, Funding Acquisition, Methodology, Resources, Supervision, Writing – Review & Editing; All authors approved the final version.

Competing interests

No competing interests were disclosed.

Ethic

The study has been approved by the Otto-von-Guericke-University Magdeburg ethics committee (No. 163/20).

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Data availability statement

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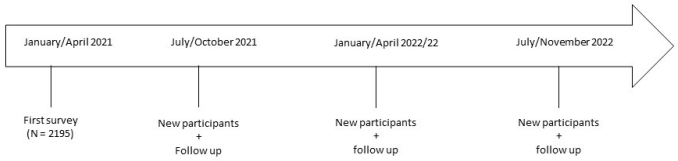

Figure 1: Cohort enrolment

338x190mm (96 x 96 DPI)

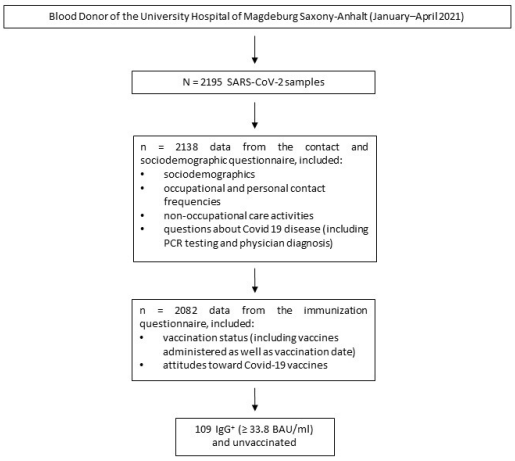

Figure 2: Sampling structure

338x190mm (96 x 96 DPI)