VACCELERATE – European Corona Vaccine Trial Accelerator Platform

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Lead author	REGIONH
Co-authors (Work Package/sub-task participants)	CLEO, EUC, KUH, SERMAS, UHC, UP

This deliverable report was approved by all Work Package participants involved in its development and preparation.

Table of Content

List of Figures

List of Tables

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Legal Disclaimer

Disclosure Statement

Abbreviations

CDC	Center for Disease Control
CEPI	Coalition for Epidemic Preparedness Innovations
CHIP	Center of Excellence for Health, Immunity and Infections
CLEO	Kentro Klinikis Epidimiologias Kai Ekvasis Nosimaton, Greece
CPME	Standing Committee of European Doctors
EC	European Commission
ECDC	European Center for Disease Control
ECRIN	Ecrin European Clinical Research Infrastructure Network, France
EMA	European Medicines Agency
EUC	European University Cyprus
EUVAP	European Vaccine Trial Accelerator Platform
KUH	Karolinska University Hospital
MIS-C	Multisystem inflammatory syndrome in children
NITAG	National Immunization Technical Advisory Group
PQ	Priority question
RegionH	Capital Region, Denmark
SERMAS	Servicio Madrileno De Salud
SWG	Stakeholder Working Group
UHC	University Hospital Cologne
UP	Université de Paris
VOCs	Variants of Concern
WHO	World Health Organisation
WP	Work Package
REDCap	Research Electronic Data Capture
RCTs	Randomized Controlled Trials
ICTRP	International Clinical Trials Registry Platform

1 Executive summary

Identifying and filling public health knowledge gaps in COVID-19 vaccine development has been deemed one of the key network objectives and included as one of the work streams within VACCELERATE. Within the scope of Work Package (WP) 7 – Public Health Needs under the auspices of VACCELERATE and RegionH, in collaboration with several partners (SERMAS, CLEO, KUH, EUC, UHC, UP) leads the work of task 7.2 focusing on the identification of unanswered questions for stakeholders. Specifically, task 7.2 aims to identify and prioritise emerging and unanswered public health and clinical research questions in relation to vaccine safety, efficacy and vaccination schemes. The goal of this task is to assess the gaps and prioritise topics where clinical trials are most urgently needed.

The work of task 7.2 is based on close collaboration with other work streams within VACCELERATE including general public outreach, among others. It is also anchored in a broad European and international dialogue concerning new COVID-19 vaccine clinical trials aiming to inform both on-going and future studies through a living document with priority questions that reflects knowledge gaps and emerging priorities from the public health perspective. As such, the main task objective is to *develop and maintain a living document of unanswered priority questions for future COVID-19 vaccine trials from the public health perspective.*

The work of the task includes the following concrete actions:

- Engage with partners from VACCELERATE and synergistic initiatives, including vaccine development stakeholders, through regular meetings in the Stakeholder Working Group (SWG)[1].
- Collect input from a broad stakeholder group regarding knowledge gaps and unanswered questions through an open-ended survey; repeat the survey with regular intervals (every 6 months), potentially to more targeted respondent groups, depending on the evolvement of the pandemic.
- Analyse, categorise, and synthesise survey responses to develop an initial list of unanswered questions; cross-check with the 7.1. database for ongoing relevant studies addressing these questions.
- Present the prefinal list of priority questions in the SWG for discussion; final list is subsequently made publicly available via the VACCELERATE website (https://vaccelerate.eu/).
- Ensure the continuous relevance by revising and updating the list of priority questions regularly (based on discussions with VACCELERATE partners and regular searches on emerging/changing priorities through the official websites and news channels of leading public health agencies (CEPI, ECDC, EMA, WHO Europe, ECRIN, CDC and other key organisations).
- Ensure synergies with WP4 and WP10 by using the developed structures to reach the general public and underrepresented groups in the repeated stakeholder surveys.
- Assess and re-evaluate the regularity of updates needed as the pandemic progresses.
- Follow up the existing and changing landscape of ongoing vaccine clinical trials through COVID-NMA initiative.

The current report outlines the work done between the October 2021 and January 2022 which focused on the revision of the initial list of priority questions identified in *D7.4 First report on unanswered COVID-19 vaccines and vaccination priority questions for future trials* finalised in September 2021.

[1] The SWG is composed of members of the VACCELERATE Coordination Board (WP leads), VACCELERATE Coordination Office (University Hospital Cologne), VACCELERATE Consortium (National Coordinators and partners) and the TCB & Vaccines Working Group (incl. reps from EC, CEPI, ECDC, EMA, WHO Europe, ECRIN and other organisations)

2 Deliverable content

With the objective to prioritise among the identified emerging and unanswered public health and clinical research questions in relation to vaccine safety, efficacy and vaccination schemes, a VACCELARATE consortium survey was circulated in November 2021. The survey has attempted to rank the list of questions compiled in September 2021 and identify the top 3 most important unanswered questions for potential upcoming COVID-19 vaccines clinical trials which need to be addressed. There was also an option to add new questions to the list.

The received responses were analysed in order to identify the priority topics where clinical trials are most urgently needed. The method, analytical process and results are described below.

The report also includes a list of possible new emerging questions identified from ongoing public discussion on the official websites, presentations, meetings, and press briefings of leading public health agencies (CEPI, ECDC, EMA and WHO).

2.1 Methods

- Survey

The survey aimed to rank according to priority the 17 questions identified in the initial stakeholder survey in August 2021, according to priority. The survey was circulated among the members of VACCELERATE consortium with the purpose of short listing the top 3 most important unanswered questions that could potentially be addressed in future clinical trials.
The survey has also included an open-ended format question allowing stakeholders to submit new topics they considered to be a priority. All previously identified priority questions were evaluated against each other outside of their initial thematic categories and overlapping questions have combined to prioritise with ease (e.g. PQ 1&6, PQ 11&13)
The survey is available in Appendix 1. The survey has been developed in and administered via the Research Electronic Data Capture (REDCap) platform and was circulated as an email with a link to all members of the VACCELERATE consortium (National Coordinators, Work Package leads and participants).

- Input from EMA and ECDC representatives

On the 13th of January 2022, a meeting was set-up between VACCELERATE and the representatives of EMA and ECDC to coordinate work from VACCELERATE with expectations of EMA and ECDC on identification of public health questions. The meeting provided an opportunity to seek input on several aspects of work carried out in WP7, specifically:

  - Current methodology for identification of public health questions by VACCELERATE
  - Current process of identification of relevant research/knowledge gaps by EMA/ECDC
  - Identification of key stakeholders for prioritisation of emerging questions (e.g. NITAG)
  - Recipients of the results generated in task 7.2
    Within the ECDC the specific recipient would be NITAG group
  - Format of the work (broad area of knowledge or specific questions)
    A combination of both would be preferred
  - Ensuring response in timely manner and best methods

Foresighting into the future through modeling, prediction, and dialogue with pharma. Agreed on establishing communication with NITAG to receive feedback on best technique to identify those questions.

- Added value of VACCELERATE
  NITAG already is in charge of identifying knowledge gaps, so foresighting would provide a real added value.

- Collaboration with task 7.1 on potential incorporation of priority topics into the COVID-NMA initiative

Analysis of the responses from the survey has been supported through discussions during regular meetings of WP7 partners and sub-task meetings of task 7.1 due to natural synergies between the two tasks. The discussion has enabled us to address the best way of using the COVID-19 NMA (covid-nma.com) tool/ website to explore and identify registered clinical trials that potentially can answer some of the questions and knowledge gaps.

- Regular searches on emerging/changing priorities

In parallel with the survey, CHIP/RegionH has been regularly monitoring ongoing public discussion on the official websites, presentations, meetings and press briefings of leading public health agencies (CEPI, ECDC, EMA and WHO) to identify potential new emerging questions.

2.2 Results – Survey

- Survey respondent profile

A total of 42 responses have been received. Similarly, to the initial survey, the distribution by professional background included clinicians in over half of the respondents followed by researchers, with limited input from policy advisers (n=2) and area experts (n=3) as shown in Figure 1 below.

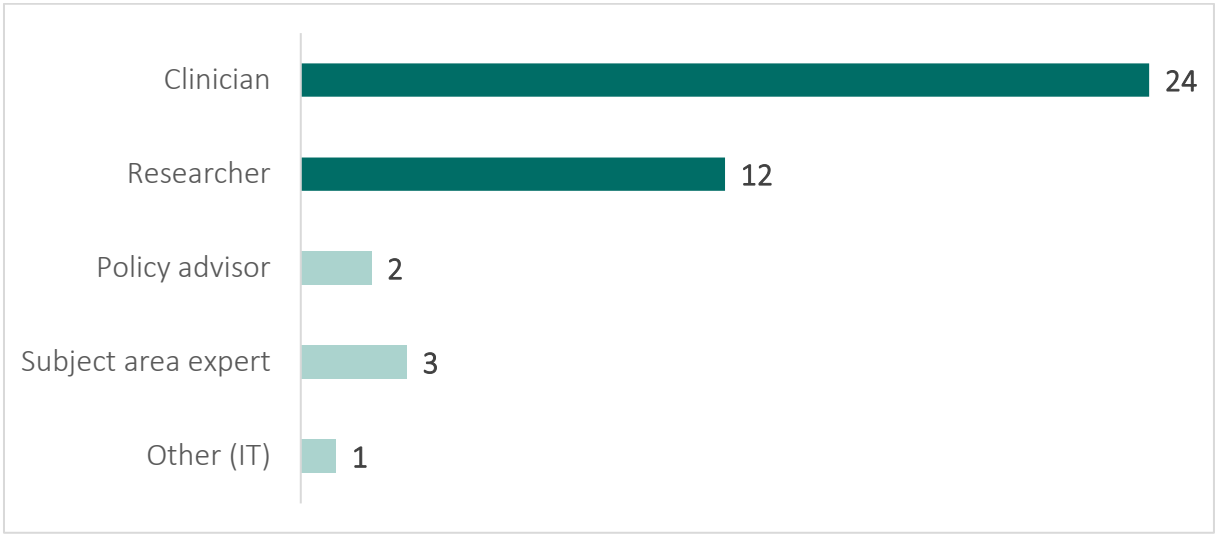

Figure 1: Professional background of the survey responders (n=42)

There were significant differences in the priority questions identified by the clinicians and researchers respectively.

- Top priority questions identified by clinicians (n=24)

The Figure 2 below specifies the responses collected in the respondent group clinicians.

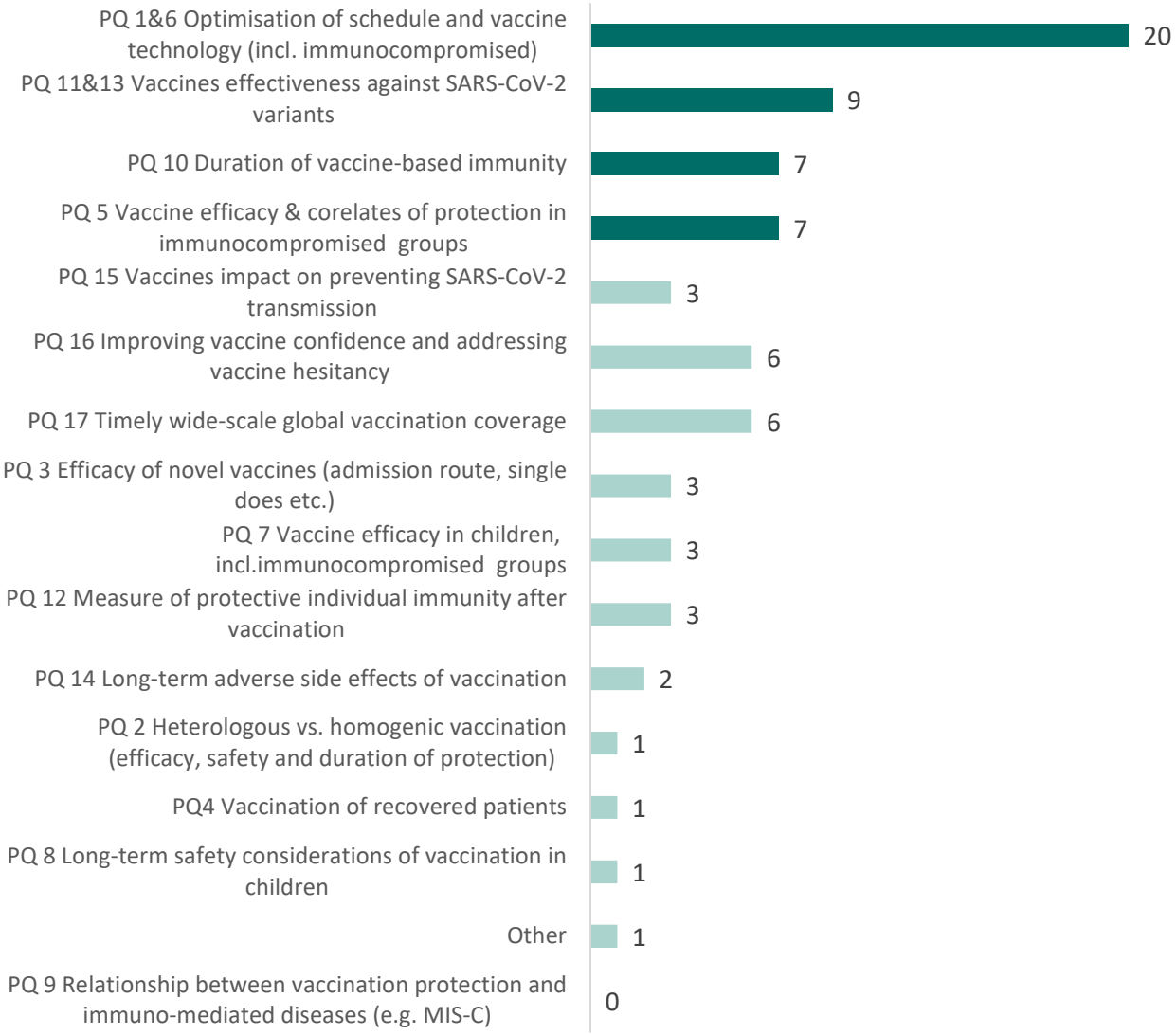

Figure 2: Responses by background of the survey responders (Clinicians)

The top 4 questions identified by clinicians among the initial list of priority questions are listed below, and in addition 1 new question was proposed.

Table 1: Top public health priority questions identified by Clinicians

Votes	Public health priority questions for future COVID-19 vaccine trials (by Clinicians)
20	1. - 6. How can immunisation schedule (booster timing and number) and technologies (vaccine dose and type) be optimised to ensure maximum protection (incl. immunocompromised groups)?
9	11.-13. Are currently available vaccines effective against SARS-CoV-2 variants in the short- and long-term and is there a need to develop new vaccine to protect against the VOCs?
7	10. How long does immunity (humoral-cellular) last after vaccination with current vaccines?
7	5. What is the vaccine efficacy and are there other immunological correlates of protection than antibodies in various immunocompromised groups?
1	*New! - Studies into vaccines for nasal administration and their effect on limiting transmission through effects in the nasal mucosa*

- Top priority questions identified by researchers (n=12)

The Figure 3 below specifies the responses collected in the researchers group.

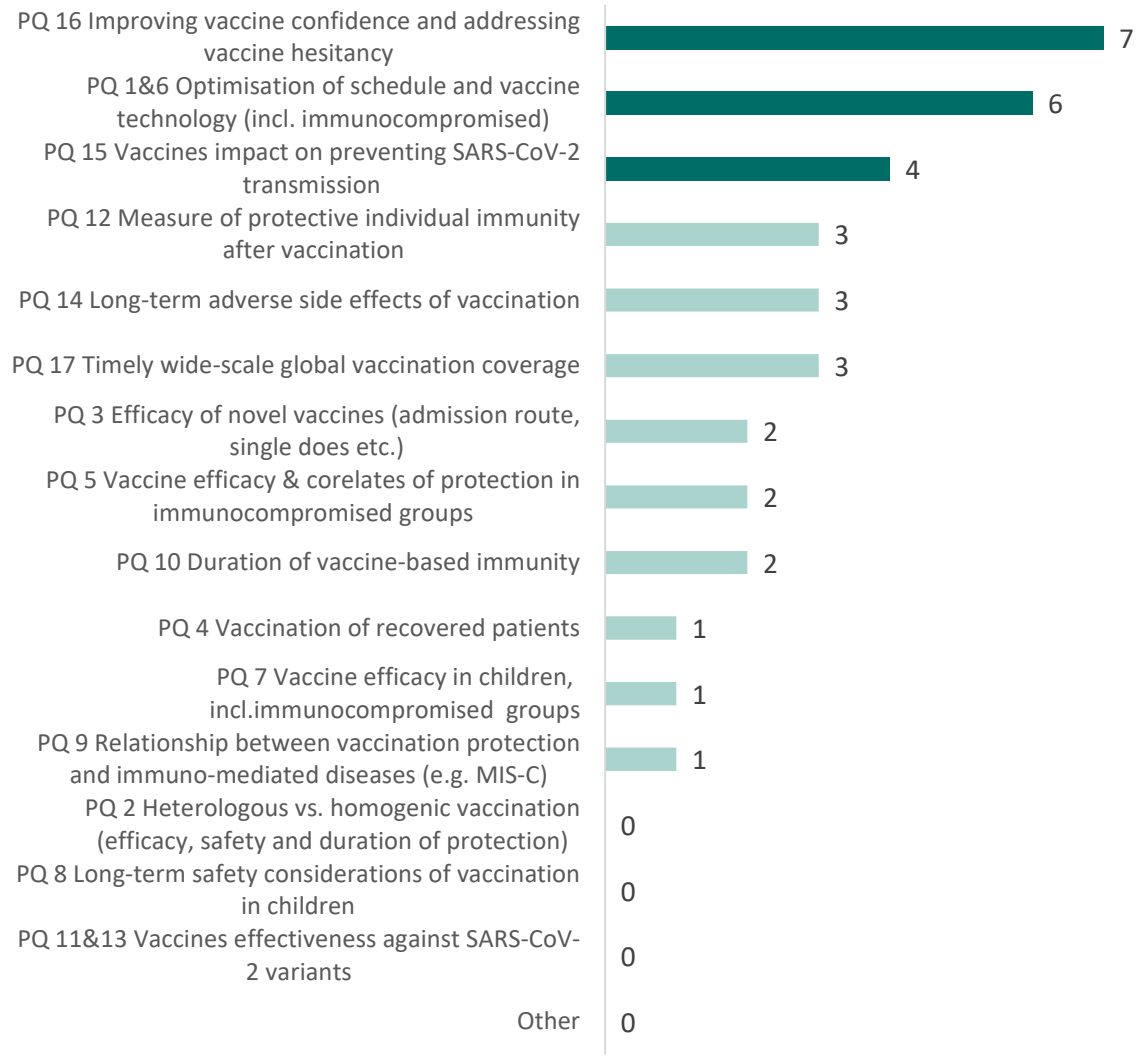

Figure 3: Responses by background of the survey responders (Researchers)

Overall, from the initial list of priority questions, responses provided by researchers identified 3 top priority questions from the initial list.

Table 2: Top public health priority questions identified by Researchers

Votes	Public health priority questions for future COVID-19 vaccine trials (Researchers)
7	16. How can awareness of and confidence in vaccine programmes be improved to address vaccine hesitancy and misinformation with focus on specific population groups?
6	1. - 6. How can immunisation schedule (booster timing and number) and technologies (vaccine dose and type) be optimised to ensure maximum protection (incl. immunocompromised groups)?
4	15. Are current vaccines and vaccine strategies effective in preventing SARS-CoV-2 transmission?

- Top priority questions identified by other professionals (n=6)

The responses received from other professional groups were too few for carrying out any comparison and suggest that policy advisors and subject area experts could be one of the priority groups for the next evaluation of the emerging priority questions for future COVID-19 vaccine trials.

- Final list of priority questions and overlap with the trials registered in COVID-NMA tool

After combing responses from all survey participants, we have rearranged the identified priority questions according the number of votes that they received. The Figure 4 below specifies the responses collected from all survey participants.

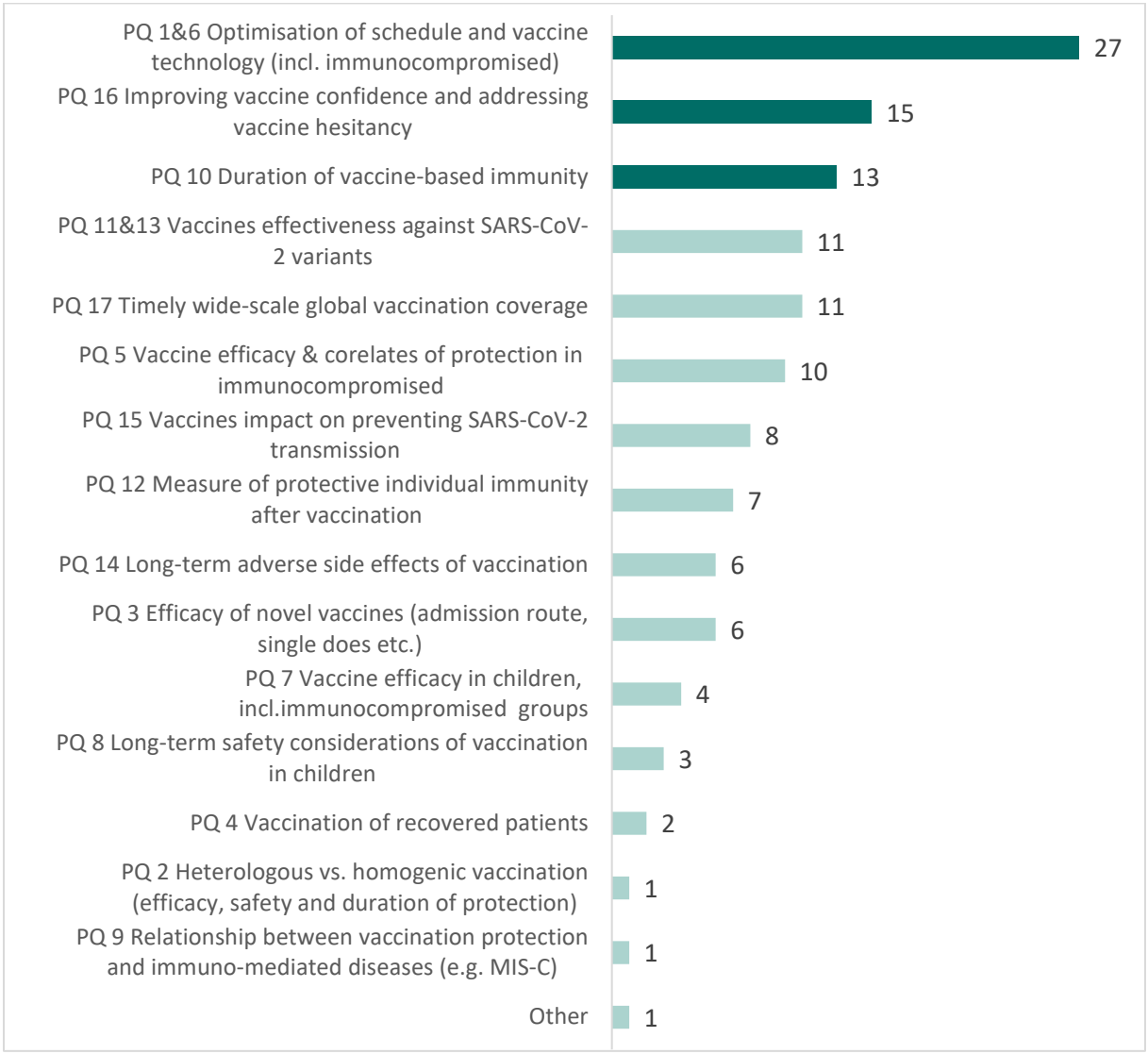

Figure 4: Public Health priority questions (by number of responses).

The responses from clinicians and researchers only overlapped in identifying 1 priority question:

Table 3: Top Public health priority questions identified by Researchers & Clinicians

Votes	Public health priority question for future COVID-19 vaccine trials (Researchers & Clinicians)

26	1 - 6. How can immunisation schedule (booster timing and number) and technologies (vaccine dose and type) be optimised to ensure maximum protection (incl. immunocompromised groups)?

2.3 Results - Collaboration with task 7.1 on potential incorporation of priority topics into the COVID-NMA initiative

The up-to-date living mapping of planned, active, completed and published registered trials assessing COVID-19 vaccines is conducted in the task 7.1. The COVID-NMA mapping is developed with the purpose of helping stakeholders plan future trials.
All randomized controlled trials (RCTs) and non-randomized studies registered in the WHO International Clinical Trials Registry Platform (ICTRP), clinicaltrials.gov and the European clinical trials register (https://www.clinicaltrialsregister.eu/) are searched weekly.

The data are made available on a platform through interactive data visualisation (https://covid-nma.com/vaccines/mapping/). Studies can be filtered by several variables such as the country in which they are taking place, study design, type of participants and type of vaccine, among others. The data are updated weekly on the platform. As of 25th of January 2022, 727 trials published on the COVID NMA website (https://covid-nma.com/).

Based on the 17 identified question searches were conducted in the database to estimate a potential number of clinical trials investigating the priority questions. The results of this search are provided in the table below in the column: "IDENTIFIED CLINICAL TRIALS Initial search on 14th January 2022"

The search results are marked in following colours:

Colour	Explanation
Grey	**Question cannot be answered by clinical trials** A number of priorities identified fall under the policy and public health umbrella. These issues are covered within VACCELERATE and will be shared with the relevant Work Packages.
Green	Information is easily found on the interactive data visualization (https://covid-nma.com/vaccines/mapping/) with use of **data filter**.
Yellow	Information is partially available, specific filter not available, only free text search option. Potentially more trials are not identified.
Red	Information not found, a specific data filter not available and free text search did not identify any potential trials.

The results of the search have been shared with UP who is in charge of the living data document of all registered COVID-19 vaccine trials. After the meeting, the UP team proposed improved search strategies provided in the table below in the column: "Suggestions/comments from UP Improved search strategies".

Table 4 List of identified public health priority questions for future COVID-19 vaccine trials and COVID-NMA mapping search results

VOTES	PUBLIC HEALTH PRIORITY QUESTIONS FOR FUTURE COVID-19 VACCINE TRIALS	IDENTIFIED CLINICAL TRIALS Initial search on 14th January 2022[2]	Suggestions/comments from UP Improved search strategies
27	**1. - 6. How can immunisation schedule (booster timing and number) and technologies (vaccine dose and type) be optimised to ensure maximum protection (incl. immunocompromised groups)?**	**Filter**: 'Booster' – 77 trials identified (incl. high risk patients[3]– 8) Vaccine schedule – 119 (incl. high risk patients – 5)	New filter added recently on immunosuppression status. You can combine booster and immunosuppression status filters.
15	**16. How can awareness of and confidence in vaccine programmes be improved to address vaccine hesitancy and misinformation with focus on specific population groups?**	Not applicable (policy question)	-
13	**10. How long does immunity (humoral-cellular) last after vaccination with current vaccines?**	Filter not available **Free text search**: *"Cellular immunity" – 9* *"Humoral immunity" – 5*	Free text search is the best option. It looks to the following trials characteristics: countries, trial registration number, first author, study aim, primary outcome, funding, treatment name and type.
11	11.-13. Are currently available vaccines effective against SARS-CoV-2 variants in the short- and long-term and is there a need to develop new vaccine to protect against the VOCs?	**Filter**: 'VOC' (alpha, beta, gamma, delta) – 22 'VOC' (omicron) - 0	-
11	17. How can wide-scale global vaccination coverage be ensured within reasonable timelines, especially in resource-limited settings?	Not applicable (policy question)	-
10	5. What is the vaccine efficacy and are there other immunological correlates of protection than antibodies in various immunocompromised groups?	Filter not available (search not successful)	Search option: Free text search for 'immunological correlates' and synonyms combined with immunosuppression status filter. **No results found**.

[2] Search conducted using COVID-NMA mapping website https://covid-nma.com/vaccines/mapping (accessed on 14th of January 2022).
[3] "High risk patients" filter in the COVID-NMA mapping refers to trials that recruit only elderly or people of any age who are at increased risk of severe illness from COVID-19.

8	15. Are current vaccines and vaccine strategies effective in preventing SARS-CoV-2 transmission?	Filter not available (search not successful)	Search option: Free text search for 'transmission' and synonyms. **Currently 2 irrelevant trials are found** but a surveillance on this type of search could be relevant.
7	12. What is the best measure of protective immunity after vaccination at the individual level and when after vaccination should it be taken?	Filter not available (search not successful)	Search option: Free text search for 'protective' and synonyms. **8 trials to screen.**
6	14. What are the long-term adverse side effects of vaccination in terms of vaccine-related or vaccine-induced diseases (autoimmune, oncologic, fertility etc.)?	Filter not available (search not successful)	-
6	3. Can novel vaccines achieve non-inferiority efficacy and safety by non-parenteral route and possibly with only one dose?	Filter not available (search not successful)	-
4	7. What is the efficacy and the specific immune response to the vaccine in children, including immunocompromised pediatric population?	**Filter**: 'Under 18 y.o.' – 74 (incl. high risk patients – 7)	New filter added recently on immunosuppression status. You can combine 'under 18 y.o.' and 'immunosuppression status' filters.
3	8. What are the long-term safety considerations of vaccination in children?	Filter not available (search not successful)	Search option: Free text search for 'long-term safety' and synonyms combined with 'Under 18 y. o. filter'. **No results found**.
2	4. What should the vaccination strategy be for recovered patients?	**Filter**: 'Recovered patients' – 5	-
1	2. What is the comparative advantage of heterologous vs. homogenic vaccination in terms of efficacy, safety, and duration of protection?	**Filter**: 'Heterologous' - 95	-
1	9. What is the relationship in terms of protection between vaccination and immuno-mediated diseases such as MIS-C?	Filter not available (search not successful)	Search option: Free text search 'MIS' and synonyms combined with 'under 18 y.o.' filter. **2 trials found.**

1	Other - Studies into vaccines for nasal administration and their effect on limiting transmission through effects in the nasal mucosa	Filter not available (search not successful)	Search option: Free text search 'intranasal' or synonyms. **2 trials found.** This search will miss a lot of relevant trial as the route information is collected manually in our database and not presented in the mapping.

2.4 Potential new emerging questions identified from ongoing public discussion

The regular monitoring of the ongoing public discussion on the official websites, presentations, meetings, and press briefings of leading public health agencies (CEPI, ECDC, EMA, WHO and participation in NITAG meeting) has pointed out that questions identified during the initial analysis still remain relevant. In addition to this, several new unanswered questions have been identified and would require further input from relevant stakeholders to identify if they should be added to list of unanswered questions for future COVID-19 trials. Following are the potential new emerging questions.

- Studies into vaccines for nasal administration and their effect on limiting transmission through effects in the nasal mucosa
- Developing vaccines which are protective against a broad range of coronaviruses (e.g. pan-sarbecovirus vaccine)
- Vaccination and Menstrual disorders (no pattern identified, transient nature)
- Vaccination in the pregnant women (especially 1st trimester) and feeding mothers (no concerns, just data limitations)
- Adapting COVID-19 vaccine platforms for other infections in the future
- Precision medicine approach to vaccination
- How can immunisation schedule (booster timing and number) be optimised for the paediatric population to ensure maximum protection?
- Integration of new type of vaccine (e.g. Nuvaxovid) in EU vaccination programs

2.5 Discussion

Identification of unanswered questions in relation to the vaccine and vaccination is first and foremost motivated by the need to ensure large, long-term scale immunity for the entire population. This means finding answers to the questions not addressed in the initial clinical trials, notably questions related to vaccine efficacy and safety in groups initially underrepresented in the trials such as those with compromised immunity, children, among others.

While opinions on the priorities may diverge, ongoing monitoring of the emerging knowledge gaps could help promote public health perspective in future COVID-19 vaccine trials that are relevant for large-scale protection at the population level.

Although preliminary knowledge gaps have been anticipated, the specific questions resulting from the stakeholder survey shed further light on the public health needs of vaccine development. The ongoing discussion with relevant EU stakeholders has also confirmed the relevance of the identified answered questions and a need for an overview of the emerging evidence that could fill these knowledge gaps.

The identified priority questions could feed into the ongoing update of the COVID MNA tool/website in the form of specific search filters and visualization, allowing different stakeholders the opportunity to identify the topics where clinical trials are needed.

The search of the COVID-19 vaccine trial mapping tool has demonstrated that the top priority question of vaccination schedule and booster doses has returned the highest number of clinical trials (77 trials looking into booster doses of vaccines – 77 trials identified (incl. high risk – 8) and 119 trials on vaccine schedule – 119 (incl. high risk – 5). The number of trials in general is relatively high, but only 8 of those are involving participants from high-risk groups, meaning that any future trials in this field should potentially focus on the underrepresented groups.

For the third top priority question on the duration of vaccine induced immunity only 14 potential clinical trials were identified. As there is a certain delay between initiation and registration of the clinical trial, further monitoring will help to assess if new trials can answer this question.

The search also helped to identify a significant number of vaccine trials looking into heterologous vaccination (n=95) and underaged population (n=74), whereas trials looking into vaccination of recovered patients (n=5) and vaccine efficacy against VOCs ('VOC'– n=22 for alpha, beta, gamma, delta, and n=0 for omicron).

The low number of trials for VOCs is mainly caused by their recent emergence and is likely to increase in the upcoming months. On the other hand, low number of trials in recovered patients and high-risk groups, can indicate a need for new clinical trials, as those groups are rarely included in the industry initiated clinical trials.

In order to further assess these questions, following topics can be added to the upcoming analyses of the existing clinical trials.

- Industry-initiated vs investigator-initiated clinical trials

Although the number of clinical trials on COVID-19 vaccines is vast, we have observed that majority of the unanswered questions could not be answered by the industry-initiated trials and would be better targeted by the investigator-initiated trials.

- Underrepresented groups in clinical trials

Overall, the participants of the COVID-19 trials have overwhelmingly represented healthy populations, while a number of population groups have been majorly underrepresented, specifically:

  - Pregnant and breastfeeding women
  - Immunocompromised patients
  - Patients with comorbidities
  - Migrant communities

- Prediction of future priority questions

Currently, the discussion around vaccine research is focused on the future, more foresight would be very important for the stakeholders, such as NITAG.

2.6 Next steps

The initial list of knowledge gaps developed within VACCELERATE in August 2021 have been re-evaluated by the clinicians and researchers involved in the consortium. The responses received from other professional groups were too few for carrying out any comparison and suggest that policy advisors and subject area experts could be one of the priority groups for the next evaluation of the emerging priority questions for future COVID-19 vaccine trials.

Reports, media briefings and meetings organised by reputable public health agencies and relevant scientific expert organisations have been monitored and a potential list of new questions was generated.

The report will be updated every 6 months throughout the duration of the project and the following steps will be the focus of the next phase of the process:

- Conduct a review of the ongoing studies included in the task 7.1. database to assess their linkage to and relevance for providing answers to the identified questions (including discussion of feasibility of introduction of the following search filters:
    - Industry-initiated vs investigator-initiated clinical trials
    - Underrepresented groups in clinical trials (pregnant participants, migrants etc).
- Ensure the continuous relevance by revising and updating the list of priority questions regularly based on discussions with VACCELERATE partners and regular searches on emerging/changing priorities through the official websites and news channels of leading public health agencies (CEPI, ECDC, EMA, WHO Europe, ECRIN, CDC and other key organisations).
- Discuss possibility of engaging with NITAG and other relevant stakeholders on the possibility of predicting future priority questions.
- Assess and re-evaluate the regularity of updates needed as the pandemic progresses.

It is suggested to provide space in the consortium for discussion of how the list of the identified priority questions is utilized in the process of identifying additional clinical trials to be conducted within VACCELERATE.

3 Deviations from the Description of the Action (DoA) and/or original deliverable

There are no deviations from the Description of the Action

4 Appendices

Appendix 1: Survey to identify public health priority questions for future COVID-19 vaccine trials

Survey to identify public health priority questions for future COVID-19 vaccine trials - November 2021

Within VACCELERATE a survey was circulated before the summer break to identify public health knowledge gaps in relation to COVID-19 vaccines and identify where clinical vaccine trials are most urgently needed.

Replies were received from 89 key stakeholders, analyzed and grouped into 17 priority questions. Now we need your help to rank the list and identify the top 3 most important unanswered questions for potential upcoming COVID-19 vaccines clinical trials to address. There is also one open field where you may add additional questions/topics currently not on the list.

Please submit your response by November 29, 2021. If you have any questions about the survey, please e-mail vaccelerate.rigshospitalet@regionh.dk.

We thank you in advance for your participation.

Respondent details (please fill in your affiliation details below)

Type of institutional affiliation (check one that applies best):

- ◯ University or research Institute/centre
- ◯ National public health institute
- ◯ Government ministry or agency
- ◯ Expert group or clinical society
- ◯ International organisation or network (expert or policy)
- ◯ Pharmaceutical company/vaccine developer
- ◯ Patient group representative
- ◯ Other (please specify)

If 'other' type of institutional affiliation, please specify: _____

Professional background (check one that reflects best the capacity in which you are responding to this survey):

- ◯ Clinician
- ◯ Researcher
- ◯ Policy advisor
- ◯ Subject area expert (national or international level)
- ◯ Other (please specify)

If 'other' professional background, please specify: _____

Country (please indicate the country where you are currently working):

- ◯ Albania
- ◯ Andorra
- ◯ Armenia
- ◯ Austria
- ◯ Azerbaijan
- ◯ Belarus
- ◯ Belgium
- ◯ Bosnia and Herzegovina
- ◯ Bulgaria
- ◯ Croatia
- ◯ Cyprus
- ◯ Czechia
- ◯ Denmark
- ◯ Estonia
- ◯ Finland
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- ◯ Italy
- ◯ Kazakhstan
- ◯ Kyrgyzstan
- ◯ Latvia
- ◯ Liechtenstein
- ◯ Lithuania
- ◯ Luxembourg
- ◯ Malta
- ◯ Moldova
- ◯ Monaco
- ◯ Montenegro
- ◯ Netherlands
- ◯ North Macedonia
- ◯ Norway
- ◯ Poland
- ◯ Portugal
- ◯ Romania
- ◯ Russia
- ◯ Serbia
- ◯ Kosovo
- ◯ Slovakia
- ◯ Slovenia
- ◯ Spain
- ◯ Sweden
- ◯ Switzerland
- ◯ Tajikistan
- ◯ Turkey
- ◯ Turkmenistan
- ◯ Ukraine
- ◯ United Kingdom
- ◯ Uzbekistan
- ◯ Other (please specify)

If 'other' country, please specify:

_____

Email address
Your email address will be stored exclusively for the purpose of contacting you in case clarification regarding your survey response is needed. It will not be shared with any other entity or used for any other purpose than stated here.

_____
(By providing my email address, I agree to be contacted in case of validation questions related to my survey responses.)

Top three questions/topics for future COVID-19 vaccine studies

Please select up to 3 questions/topics from the public health perspective* that you believe should be prioritised at the European level or in your country in future COVID-19 vaccine trials/studies.

*** i.e. issues that contribute to maximum societal benefit in terms of health protection and immunity.**

	Priority question 1	Priority question 2	Priority question 3
1. How can immunisation schedule (booster timing and number) and technologies (vaccine dose and type) be optimised to ensure maximum protection (incl. immunocompromised groups)?	○	○	○
2. What is the comparative advantage of heterologous vs. homogenic vaccination in terms of efficacy, safety and duration of protection?	○	○	○
3. Can novel vaccines achieve non-inferiority efficacy and safety by non-parenteral route and possibly with only one dose?	○	○	○
4. What should the vaccination strategy be for recovered patients?	○	○	○
5. What is the vaccine efficacy and are there other immunological correlates of protection than antibodies in various immunocompromised groups?	○	○	○
6. How can immunisation schedule (booster timing and number) and technologies (vaccine dose and type) be optimised for the immunocompromised group to ensure maximum protection?	○	○	○

7. What is the efficacy and the specific immune response to the vaccine in children, including immunocompromised pediatric population?	○	○	○
8. What are the long-term safety considerations of vaccination in children?	○	○	○
9. What is the relationship in terms of protection between vaccination and immuno-mediated diseases such as MIS-C?	○	○	○
10. How long does immunity (humoral-cellular) last after vaccination with current vaccines?	○	○	○
11. Are currently available vaccines effective against SARS-CoV-2 variants in the short- and long-term and is there a need to develop new vaccine to protect against the VOCs?	○	○	○
12. What is the best measure of protective immunity after vaccination at the individual level and when after vaccination should it be taken?	○	○	○
13. Are currently available vaccines effective against SARS-CoV-2 variants in the short- and long-term and is there a need to develop new vaccine to protect against the VOCs?	○	○	○
14. What are the long-term adverse side effects of vaccination in terms of vaccine-related or vaccine-induced diseases (autoimmune, oncologic, fertility etc.)?	○	○	○

15. Are current vaccines and vaccine strategies effective in preventing SARS-CoV-2 transmission?	○	○	○
16. How can awareness of and confidence in vaccine programmes be improved to address vaccine hesitancy and misinformation with focus on specific population groups?	○	○	○
17. How can wide-scale global vaccination coverage be ensured within reasonable timelines, especially in resource-limited settings?	○	○	○
18. If you want to indicate additional unanswered priority question/topic, select this option	○	○	○

Write here additional unanswered priority question/topic:

_____
(word limit 40)

General comments

Please include any other comments you would like to provide:

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