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Study Report

Association between COVID-19 vaccines and paediatric safety outcomes in children and adolescents aged 5-19 years in the Nordic countries: Myocarditis, pericarditis and thromboembolic events

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Country (-ies) of study	Denmark, Sweden, Norway, and Finland
Author	Anders Hviid, Kristina Dvoncova

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1. ABSTRACT

Title: Association between COVID-19 vaccines and paediatric safety outcomes in children and adolescents aged 5-19 years in the Nordic countries: thromboembolic and thrombocytopenic outcomes, myocarditis and pericarditis

Keywords: COVID-19, vaccine safety, BNT162b2, mRNA-1273, adverse events, children, nationwide cohorts, Nordic countries.

Rationale and background: There is a clear need for a comprehensive mapping of the safety of COVID-19 vaccination in children and adolescents focusing on rare adverse events of special interest such as myocarditis, pericarditis and thromboembolic events including thromboembolism with thrombocytopenia.

Research question and objectives: The overall aim of this project was to take advantage of the Nordic setting (Denmark, Finland, Norway, and Sweden) and conduct nationwide cohort studies of current COVID-19 vaccine safety issues in children/adolescents.

Primary objectives – vaccine safety objectives:

1. To evaluate the association between COVID-19 vaccines and myocarditis and pericarditis in children and adolescents aged 5 to 19 years in the Nordic countries.

2. To evaluate the association between COVID-19 vaccines and thromboembolic outcomes including thromboembolism with thrombocytopenia in children and adolescents aged 5 to 19 years in the Nordic countries.

Secondary objectives – outcome after infection objectives:

3. To evaluate the association between COVID-19 infection and myocarditis and pericarditis in children and adolescents aged 5 to 19 years in the Nordic countries.

4. To evaluate the association between COVID-19 infection and thromboembolic outcomes including thromboembolism with thrombocytopenia in children and adolescents aged 5 to 19 years in the Nordic countries.

Study design: Nationwide register-based cohort studies in Denmark, Finland, Norway and Sweden during the study period 1 January 2021 to 31 October 2022. We took full advantage of the nationwide and longitudinal nature of the Nordic cohorts, and leveraged three complementary survival analysis approaches; 1) observed vs expected analyses providing standardised incidence rate ratios, 2) contemporary cohort analyses providing adjusted relative risks (rate ratios), and 3) self-controlled case series analyses nested in the cohorts providing relative risks.

Setting: Denmark, Finland, Norway, and Sweden during 1 January 2021 to 31 October 2022.

Population: The source cohorts consisted of all individuals 5 to 19 years of age during the study period of 1 January 2021 to 31 October 2022 in Denmark, Finland, Norway and Sweden. Having a positive RT-PCR test before the study start was an exclusion criterion, as well as a censoring criterion during follow-up in the primary analyses of vaccine safety. In the secondary analyses of risk after infection, vaccination was an exclusion criterion before study start and a censoring criterion during follow-up. Individuals with study outcomes in the 2018-2020 period were excluded.

Study size: The Nordic countries contributed with a total population of 5.1 million children/adolescents. Among the European countries that have implemented childhood/adolescent COVID-19 vaccination, the uptake in the Nordic countries was in the upper end of the range.

Variables and data sources: The outcomes of interest were myocarditis, pericarditis, and thromboembolic outcomes including thromboembolism with thrombocytopenia. Data sources were nationwide demography and health registers within each participating country. The outcomes of interest were identified in hospitalisation-registers based on ICD-10 codes. The study population of 5-19-year-olds in the participating countries almost exclusively received the Pfizer/BioNTech (BNT) mRNA-vaccine. BNT1 denotes the first dose, BNT1BNT2 denotes the second dose in a homologous primary course schedule and BNT1BNT2BNT3 denotes the booster dose in a homologous schedule.

Results: The total population under study was 5,098,625, 5-to-19-year-olds from Denmark (n=1,035,176), Finland (n=1,018,113), Norway (n=1,091,558) and Sweden (n=1,953,778). The combined cohort comprised 2,399,036 individuals vaccinated at least once (47%), primarily with homologous BNT schedules (88%). The total number of BNT doses administered was 4,147,856 doses. We observed that the BNT-vaccine was associated with myocarditis and pericarditis. The myocarditis association was present in the 28-day main risk period after both BNT1 (Relative Risk [RR] 2.75, 95% confidence interval [CI], 1.92-3.95), BNT1BNT2 (RR 2.81, 95% CI, 1.94-4.07), and BNT1BNT2BNT3 (RR 5.30, 95% CI, 2.24-12.53) in the contemporary cohort analyses. The pericarditis association was present in the 28-day main risk period after BNT1BNT2 (RR 2.58, 95% CI, 1.44-4.63) and BNT1BNT2BNT3 (RR 6.24, 95% CI, 0.81-47.85) in the contemporary cohort analyses.

Most of the thromboembolic outcomes were rarely observed after vaccination. Of particular note, we did not observe any cases of thromboembolism with thrombocytopenia after vaccination. We did not observe any association between vaccination and cerebral venous

sinus thrombosis, hepatic-portal-renal vein thrombosis, venous thromboembolism, ischemic stroke, and myocardial infarction.

BNT1 was associated with arterial thromboembolism in the 28-day main risk period (RR 2.59, 95% CI, 1.16-5.79), BNT1BNT2 was associated with deep vein thrombosis in the 28-day main risk period (RR 1.99, 95% CI, 1.05-3.78) and BNT1BNT2BNT3 was associated with pulmonary embolism in the 28-day main risk period (RR 18.71, 95% CI, 1.51-232.26) in the contemporary cohort analyses.

Discussion: Myocarditis, pericarditis, and thromboembolic events were rare after COVID-19 vaccination with BNT among 5-to-19-year-olds in the Nordic countries during 1 January 2021 to 31 October 2022. We confirmed an association between BNT1, BNT1BNT2 and BNT1BNT2BNT3, and myocarditis. The excess risks among 12-to-15-year-olds were 1.8 and 1.5 cases per 100,000 BNT1 and -BNT1BNT2 vaccinations, respectively. The excess risks among 16-to-19-year-olds were 1.5, 2.7 and 7.7 cases per 100,000 BNT1, -BNT1BNT2 and -BNT1BNT2BNT3 vaccinations, respectively. We provided evidence in support of an association between BNT1BNT2 and BNT1BNT2BNT3, and pericarditis. The excess risk among 12-to-15-year-olds was 0.6 cases per 100,000 BNT1BNT2 vaccinations. The excess risks among 16-to-19-year-olds were 1.1 and 3.3 cases per 100,000 BNT1BNT2 and -BNT1BNT2BNT3 vaccinations, respectively. We observed no cases of thromboembolism with thrombocytopenia after vaccination and no associations between vaccination and cerebral venous sinus thrombosis, hepatic-portal-renal vein thrombosis, ischemic stroke and myocardial infarction. We observed increased risks of deep vein thrombosis, pulmonary embolism and arterial thrombosis in the 28-day main risk period following vaccination. However, the events were rare, statistical precision low, and estimates not consistent across analysis methods and countries.

Conclusion: In conclusion, our results provide reassurance for the safety of BNT vaccination in children and adolescents. Serious adverse events, in the form of myocarditis, pericarditis and thromboembolic events, are rare in this population.

Marketing authorization holder: Not applicable.

Name and affiliations of principal investigator:

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2. LIST OF ABBREVIATIONS

AZD1222	Oxford-AstraZeneca adenovirus viral vector vaccine, Vaxzevria
BNT162b2	BioNTech-Pfizer mRNA vaccine, Comirnaty
mRNA-1273	Moderna mRNA vaccine, Spikevax
ICD-10	International classification of diseases revision 10
COVID-19	Coronavirus disease 2019
RT-PCR	Reverse transcription polymerase chain reaction
SCCS	Self-controlled case series analysis

3. INVESTIGATORS

All main responsible parties including the main author(s) of the protocol, the principal investigator, a coordinating investigator for each country/organisation in which the study was performed and other relevant study sites are presented in the table below.

Name	**Professional Title**	**Affiliation and address**
Jesper Kjær	Director of Department	Danish Medicines Agency, Data Analytics Centre, Axel Heides Gade 1, DK-2300 Copenhagen S, Denmark
Niels Henrik Meedom	Project manager and fundraiser	
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Petteri Hovi	Docent	Finnish Institute for Health and Welfare, Mannerheimintie 166, Helsinki, Finland, POBox 30, FI-00271
Øystein Karlstad	Senior researcher	Norwegian Institute of Public Health, Department of Chronic diseases, P.O.Box 222-Skøyen, NO-0213 Oslo, Norway
Rickard Ljung	Professor	Swedish Medical Products Agency, Division of Use and Information, SE3751 03 Uppsala, Sweden

The table below presents all named scientific personnel in the study group together with their respective role in the study.

Name	**Affiliation**	**Role in the study**	**Description of the function**
Anders Hviid	SSI (DK), KU (DK)	Principal investigator	Overall coordination and oversight of the study; responsible for the submission of deliverables. Local scientific coordination Denmark.
Kristyna Faksova	SSI (DK)	Junior epidemiologist	Literature review.
Kristina Dvoncova	SSI (DK)	Junior epidemiologist	Local project management, drafting study protocols.
Emilia Myrup Thiesson	SSI (DK)	Statistician	Conducts the Danish analyses and meta-analyses of country-specific results.
Jørgen Vinsløv Hansen	SSI (DK)	Statistician	Conducts the Danish analyses and statistical supervision.
Petteri Hovi	THL (FI)	Senior epidemiologist	Local scientific coordination Finland, review and approval of deliverables.
Hanna Nohynek	THL (FI)	Senior epidemiologist	Scientific supervision.
Tuomo Nieminen	THL (FI)	Statistician	Conducts the Finnish analyses.

Esa Ruokokoski	THL (FI)	Data manager	Finnish data management.
Øystein Karlstad	FHI (NO)	Senior epidemiologist	Local scientific coordination Norway, review and approval of deliverables.
Hanne Løvdal Gulseth	FHI (NO)	Senior epidemiologist	Scientific supervision.
German Tapia	FHI (NO)	Senior epidemiologist	Conducts the Norwegian analyses.
Inger Johanne Bakken	FHI (NO)	Statistician	Conducts the Norwegian analyses.
Rickard Ljung	SWE MPA (SE)	Senior epidemiologist	Local scientific coordination Sweden, review and approval of deliverables.
Nicklas Pihlström	SWE MPA (SE)	Statistician	Conducts the Swedish analyses.
Anders Sundström	SWE MPA (SE)	Statistician	Conducts the Swedish analyses.
Morten Andersen	KU (DK)	Senior epidemiologist	Scientific supervision.

4. OTHER RESPONSIBLE PARTIES

Not applicable.

5. MILESTONES

Milestones	**Planned dates**	**Actual date**	**Comments**
Start of data collection	3 August 2022	3 August 2022	
End of data collection	1 October 2022	1 October 2022	
Study Plan	5 September 2022	5 September 2022	
Study Protocol (posted on EU-PAS register).	3 October 2022	7 November 2022	Incorporating minor comments from reviewers.
Registration in the EU-PAS register	3 October 2022	7 November 2022	Incorporating minor comments from reviewers.

Study report (final report will be posted on EU-PAS register once approved by EMA and contributing parties).	3 January 2023	23 January 2023	
Study report revision		16 February 2023	Revised according to comments from EMA and co-authors
Manuscript(s) draft	2 February 2023	March 2023	

6. RATIONALE AND BACKGROUND

The initial phase 3 clinical trials demonstrating the efficacy and safety of the mRNA and adenovirus viral vector vaccines were conducted in adults only, as were the later trials of inactivated vaccines.[1–5] Although COVID-19 is milder in children than in adults, the infection also poses risks to children e.g. in the form of multi-systemic inflammatory syndrome in children (MIS-C). In addition, several societal effects should not be overlooked; children can be a reservoir and play an important role in the continued transmission of the infection in society while lock-down measures and quarantine regulations keeping children at home are likely to be detrimental to their general well-being. Following the adult clinical trials, clinical trials in children and adolescents of decreasing age have been conducted. This includes two phase 3 trials of the BNT162b2 (Pfizer-BioNTech) vaccine in 12-to-15-year-olds and in 5-to-11-year-olds, respectively, and a phase 3 trial of the mRNA-1273 (Moderna) vaccine in 12-to-17-year-olds.[6–8] While these trials have demonstrated satisfactory efficacy and safety, the number of participants has been modest (1517, 1131 and 2489 vaccinated in the BNT162b2 trial of 5 to 11-year-olds, the BNT162b2 trial of 12 to 15-year-olds and the mRNA trial of 12 to 17-year-olds, respectively) and the follow-up periods short. Thus, we have little clinical trial evidence with respect to rare adverse events or long-term adverse events following COVID-19 vaccination in children. Reassuringly, no major safety issues have appeared during the autumn/winter vaccinations of children/adolescents in 2021/22. However, there is a clear need for a comprehensive mapping of the safety of COVID-19 vaccination in children/adolescents focusing on rare adverse events of special interest such as myocarditis, pericarditis, thromboembolism and thrombocytopenia.

Myocarditis and pericarditis following COVID-19 vaccination

It is now well established that the risk of myocarditis and pericarditis is increased in the weeks following vaccination with the COVID-19 mRNA vaccines.[9–11] The association appears to be stronger for mRNA-1273 compared to BNT162b2, for the second dose compared to the first, for males compared to females and for younger adults compared to older adults.[11] The evidence on myocarditis following vaccination in children and adolescents is scarce. In both Israel and Hong Kong, increased risks have been reported in adolescents after vaccination with BNT162b2.[12,13] A US case series of fifteen patients 12-to-18-years of age described primarily myocarditis shortly after vaccination in boys and after the second dose[14], and a Danish case series described only one patient among 5-to-11-year-olds based on case ascertainment from all Danish paediatric departments.[15,16] In our previous Nordic study of myocarditis, we found an increased risk of myocarditis among 12-to-15-year-old boys after the first dose (rate ratio, 4.8) and after the second dose (rate ratio, 13.9) compared to unvaccinated.[11]

Thromboembolism and thrombocytopenia following COVID-19 vaccination

Both adenovirus viral vector vaccines, the AZD1222 (Oxford/AstraZeneca) vaccine and the Ad26.COV2.S (Johnson & Johnson) vaccine, have been linked to the risk of rare but serious thromboembolisms presenting with thrombocytopenia and bleeding (TTS, thromboembolism with thrombocytopenia syndrome).[16–20] The association appears to be strongest in females and younger adults. The evidence is less clear on a possible association with mRNA vaccines,[17,21] and there is a paucity of research on the association in children and adolescents.

7. RESEARCH QUESTIONS AND OBJECTIVES

The overall aim of this project was to take advantage of the Nordic setting (Denmark, Finland, Norway, and Sweden) and conduct nationwide cohort studies of current COVID-19 vaccine safety issues in children/adolescents.

Primary objectives – vaccine safety objectives:

a. To evaluate the association between COVID-19 vaccines and myocarditis/pericarditis in children/adolescents aged 5-to-19-years in the Nordic countries.
b. To evaluate the association between COVID-19 vaccines and thromboembolic and thrombocytopenic outcomes in children/adolescents aged 5-to-19-years in the Nordic countries.

Secondary objectives – outcome after infection objectives:

c. To evaluate the association between COVID-19 infection and myocarditis/pericarditis in children/adolescents aged 5-to-19 years in the Nordic countries.
d. To evaluate the association between COVID-19 infection and thromboembolic and thrombocytopenic outcomes in children/adolescents aged 5-to-19-years in the Nordic countries.

8. AMENDMENTS AND UPDATES

Number	Date	Section	Amendment or update	Reason
1.2	19-10-22	Page 5 Page 6 Page 7 Page 9 Page 10 Page 36 Page 37 Page 38-40	- Research question and objectives updated. - Summary of data analyses in abstract updated. - Milestones were modified according to the EU PASS template. - Research question and objectives updated. - Study design updated. - New section strength of the study - Description of statistical analyses updated. - Typos correction and redundant text removal.	Incorporating minor comments from the EMA assessment of study protocol version 1.1
1.3.	14-11-2022	Entire document Page 2 Page 7 Page 10-14 Page 15 Page 16	- Detailed spell check and typos correction. - Table of content was updated. - Milestones – dates format was updated. - The main risk period was updated. - Specified the end of the duration of the Omircon variant period for the purpose of this study. - ICD-10 codes (4-digits) were added for Ischemic	Incorporating minor comments from the EMA assessment of study protocol version 1.2

		Page 20 Page 38	stroke and Myocardial infarction. - Outcome variables table: The ICD-10 codes of thromboembolism and thrombocytopenia were updated. - A paragraph about statistical power was inserted.	
Study report	23-01-2023		- Excess risk and risk differences removed due to rarity of events in general. - Severity (hospitalisation) and variant specific analyses of infection risk removed due to rarity of events occurring after infection. - Only analyses of homologous BNT162b2 schedules included due to the restricted use of mRNA-1273 among children and adolescents in the Nordic countries combined with the rarity of events. - Minor ICD-10 code revisions: adding D65 and D68 codes in the TTS definition, re-defining the composite VTE outcome to include DVT, PE, CVST and Hepatic-portal-renal-vein thrombosis, and renaming "Splanchnic vein thrombosis" to	Draft of study report

			"Hepatic-portal-renal vein thrombosis". - ICD-10 code I819 added to "Hepatic-portal-renal-vein thrombosis". - ICD-10 code I80 (3-digit code only) removed from DVT - Study start changed from 27 December 2020 to 1 January 2021 - Follow-up in the analysis of infection as exposure was changed to 1 January 2021 to 31 October 2022; a sensitivity analysis was added with study end on 28 February 2022. - Comorbidity definitions standardized across countries. - Redundant "Outcome Variables" table deleted. - Codes for control outcomes added. - Denmark-only analysis added to evaluate robustness of results	
Study report	11-02-2023		- Excess risks according to age strata has been added (Table 8). - Removed the variants subsection since we do not use this info in analyses due to lack of power.	Revision of study report according to comments from EMA and co-authors

			- Expanded Discussion mentioning e.g. the modified SCCS method	

9. RESEARCH METHODS

9.1 Study setting and period

The study objectives were addressed through nationwide register data, which were used to construct country-specific cohorts of 5-to-19-year-olds with individual-level information on dates of vaccination and dates of adverse event outcomes together with relevant covariate information. The study period was from 1 January 2021 to 31 October 2022. For the associations between infection and study outcomes, the study period was the same. The Nordic countries provided a unique setting for the study of COVID-19 vaccine safety in childhood. Firstly, the ubiquitous nationwide demography and health registers, which included COVID-19 vaccination and surveillance registers, allowed for study cohorts with a combined size of 5.1 million children/adolescents aged 5-to-19-years. Secondly, the Nordic countries have had high vaccine uptake during the vaccination rollouts compared to many other European countries. Thirdly, the Nordic countries all have universal healthcare free of charge—reducing concerns about selection bias - and homogeneous data sources, which are easily combined. Fourthly, the Nordic countries have nationwide hospitalisation registers; most study outcomes are best ascertained in the specialised hospital setting in contrast to primary care databases.

9.2 Study design and subjects

We conducted nationwide register-based cohort studies in the four larger Nordic countries (Denmark, Finland, Norway, and Sweden). The cohort participants were followed from 1 January 2021 (the start of vaccination rollouts in Nordic countries were 27 December 2020) and classified in a time-varying manner according to vaccination (and infection) status. We evaluated the following outcomes of special interest a) myocarditis/pericarditis and b) thromboembolic and thrombocytopenic outcomes.

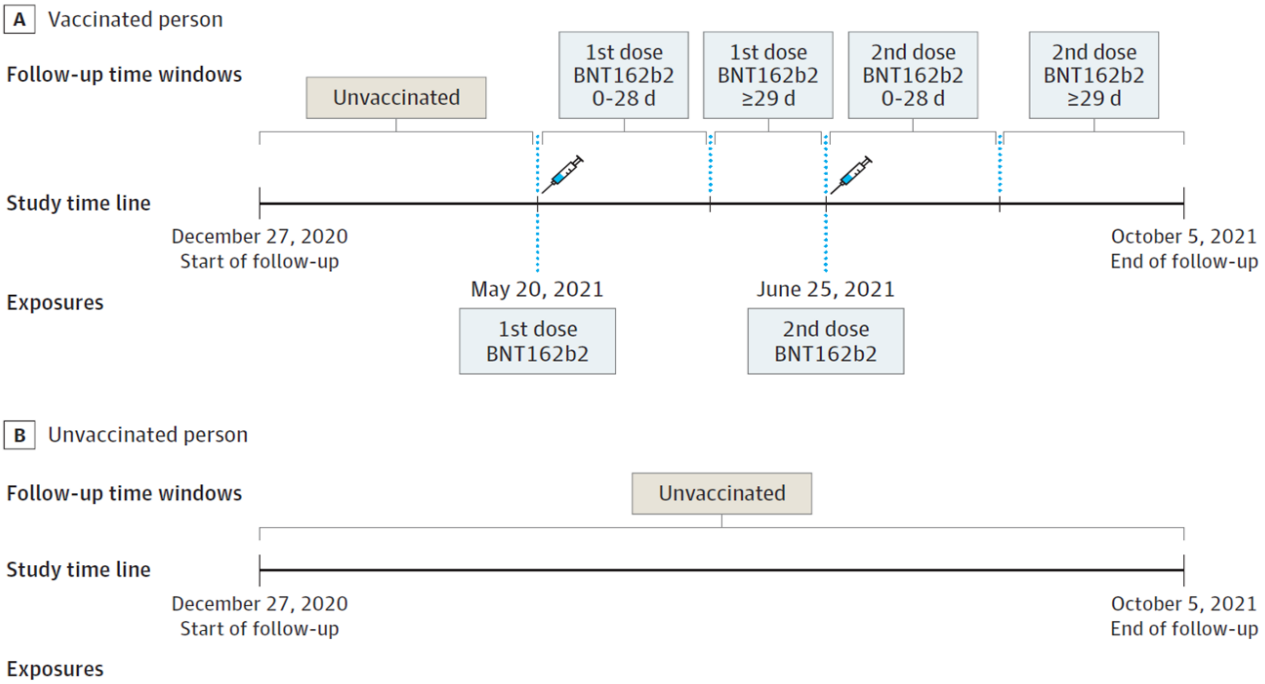
Main risk period of interest

We defined two follow-up periods of interest following vaccination. The acute period of interest lasted 28-days following vaccination. The acute period started on day 0 (the day of vaccination) and continued up to and including day 27. The post-acute period of interest started on day 28 following vaccination and lasted until another dose (where the person re-entered the acute period of interest following that dose), a censoring event or until the end of the study (31 October 2022).

We expected that outcomes such as myocarditis/pericarditis or thromboembolisms were more likely to occur in the acute risk period following vaccination. The primary comparison was between follow-up in the acute risk period of interest vs unvaccinated follow-up. Confirmed COVID-19 infection during follow-up was considered a censoring event.

In the figure below (Figure 1), we illustrate how the follow-up in our studies was classified according to vaccination status (note that the figure is from our previously published study on myocarditis in the Nordic countries where start of follow-up was 27 December 2020 in contrast to our current study where start of follow-up was 1 January 2021). Figure 1A: Example of an individual who was vaccinated with a first dose on 20 May, 2021, and followed up in both the acute and post-acute risk periods after the first dose, vaccinated with a second dose on 25 June, 2021, and followed up in both the acute and post-acute risk periods until the end of follow-up on 5 October, 2021. Figure 1B: Example of an individual who was not vaccinated

Figure 1. Schematic Illustrations of Follow-up Time Windows in the Cohort Study



during the study period and was followed up until the end of follow-up on 5 October, 2021. The end of follow-up in the current studies was 31 October 2022.

We analysed the follow-up periods and outcome counts using three complementary survival analysis approaches: 1) observed vs expected analyses providing standardised relative risks, 2) contemporary cohort analyses providing adjusted rate ratios, 3) self-controlled case series analyses nested in the contemporary cohorts providing relative risks. Each outcome was

analysed using all three methods and the results were interpreted in the context of each method´s strengths and limitations.

The following table illustrates the complementary nature of the selected methods together with their advantages and disadvantages:

	Reference follow-up	**Estimation**	**Main advantage**	**Main disadvantage**
Observed vs Expected	Unvaccinated time pre-pandemic	Indirect standardisation by age and sex	Can evaluate rare event associations, especially early in vaccination rollout.	No confounder control except age and sex. Compares separate calendar periods (historical comparator).
Contemporary cohort analysis	Unvaccinated time during the pandemic	Regression, including time-dependent and time-invariant confounder adjustment	Nationwide cohort with limited concern about selection and recall bias. Concurrent comparator. Adjustment.	Relies on the availability of confounder information.
Self-controlled case series	For those vaccinated: Follow-up time outside the risk periods	Regression, including time-dependent confounder adjustment	No time-invariant confounding by design.	The assumption that having the outcome has no significant influence on the future probability of exposure must be fulfilled.

9.3 Study population

The subjects of the study were all individuals 5-to-19-years-of-age during the study period 1 January 2021 to 31 October 2022. Age was defined as age on January 1 of 2021 and 2022. Thus, children classified as 4-year-olds on 1 January 2021, could contribute follow-up from 1 January 2022. The Nordic populations comprised 5.1 million individuals aged 5-to-19-years with COVID-19 vaccine uptake rates that were higher than many other countries in the European region. One of the key strengths of our approach was the use of nationwide data on whole populations reducing concern about selection bias e.g. by socioeconomic differences in who was enrolled in a specific health service provided.

9.4 Variables

Vaccination

The Nordic countries implemented national vaccination campaigns against COVID-19 on 27 December 2020, providing free vaccinations to all residents. Phased distribution plans were implemented prioritizing vaccination of individuals at the highest risk of COVID-19 complications and frontline personnel (nursing home residents, healthcare workers, and elderly). Denmark, Finland and Norway almost exclusively used mRNA vaccines after full or partial discontinuation of AZD1222 in March 2021 due to serious but rare events of thrombosis with thrombocytopenia. Sweden used AZD1222 for the majority of the population older than 64 years and mRNA vaccines in other age groups. Ad26.COV2.S has seen very limited use. The Nordic countries have vaccinated around 6 times more individuals with BNT162b2 than with mRNA-1273. In October 2021, Finland, Norway and Sweden recommended against the use of mRNA-1273 in younger individuals. Denmark made no official recommendation against mRNA-1273, since BNT162b2 was already exclusively used for the youngest age-groups.

COVID-19 vaccination in children/adolescents in the Nordic countries.

In Denmark, all 5-to-17-year-olds have been recommended two doses; 18-to-19-year-olds have been recommended three doses. Among 5-to-17-year-olds at high risk of severe COVID-19, a third dose has been recommended. Due to the rare occurrences of severely ill children and adolescents from the Omicron variant, the Danish competent authorities adopted changes in the vaccination guidelines. From 1 July 2022, it was not possible for children and adolescents under the age of 18 years to get the first dose of the vaccine, and from 1 September 2022, it was no longer possible for them to get the second dose of the vaccine. Children at high risk of severe COVID-19 was still offered vaccination based on an individual assessment by a doctor.

In Finland, 5-to-11-year-olds who are at high risk of severe COVID-19 or are in close contact with an immunocompromised person have been recommended two doses; it has been possible for all other 5-to-11-year-olds to also get two doses if so desired. Among 12-to-17-year-olds, two doses have been recommended and risk groups have been recommended three doses. The 18-to-19-year-olds have been recommended three doses. On 21 September 2021, THL recommended that BNT be used solely for males younger than 30-years-of-age.

In Norway, 5-to-11-year-olds at high risk of severe COVID-19 have been recommended two doses; it has been possible for all other 5-to-11-year-olds to also get two doses if so desired. Among 12-to-15-year-olds, one dose has been recommended with a second dose being

optional; risk groups have been recommended two doses. Among 16-to-17-year-olds, two doses with a 12-week interval have been recommended; risk groups have been recommended a shorter interval. The 18-to-19-year-olds have been recommended two doses with a third dose being optional; risk groups have been recommended three doses. Since October 6, 2021, Norway has recommended to only use the BNT162b2 vaccine for males or females under age 30.

In Sweden, 12-to-17-year-olds have been recommended two doses with a 4-to-7-week interval. Patients at high risk of severe COVID-19 in this age group have been recommended a third dose. Children 5-11-years-of-age with (severe) immune deficiency or immunosuppressive treatment have also been recommended vaccination. The 18-to-19-year-olds have also been recommended a third dose. Since October 6, 2021, Sweden has not recommended the use of mRNA-1273 for males or females under age 30. For that reason, vaccination schedules including this vaccine (mRNA-1273) are relatively uncommon in the targeted population. Since November 1, 2022, children under 18 years of age were no longer recommended COVID-19 vaccination due to the low risk of serious illness and death from COVID-19. Furthermore, the booster dose was not recommended for children 12-to-17-years-of-age. For high-risk group children, the recommendation to vaccinate remained.

In all of the Nordic countries, the 5-to-11-year-olds that have been vaccinated have received either 1/3 of an adult dose or a specific paediatric formulation with a lower dose.

The primary exposure of interest in our study was the BNT162b2 mRNA vaccine that has been used almost exclusively in children and adolescents. Since the use of mRNA-1273 was restricted in the youngest age groups due to the stronger association with myocarditis, we were not able to provide reliable estimates for mRNA-1273 across all countries due to the rarity of the outcomes. Some older adolescents may have received an adenoviral vector vaccine, but given the rarity of many of the study outcomes, we were not able to provide reliable information on these vaccines, and we censored individuals receiving an adenoviral vector vaccine. Vaccination was considered a time-varying exposure and individuals could contribute to follow-up both as unvaccinated and vaccinated. Among the vaccinated, we further stratified by the specific vaccination schedule. We used the nomenclature of BNTx for a BNT162b2 vaccine given as dose number x. We were able to evaluate the safety of the following homologous schedules: BNT1, BNT1BNT2, and BNT1BNT2BNT3. The 3-dose schedules were only relevant for adolescent 16-to-19-year olds and risk groups.

EXPOSURE VARIABLES - VACCINATION				
VARIABLE	**COUNTRY**	**DATA SOURCE AND DETAILS**	**VALUES/CODES**	**TIME-VARYING VARIABLE**
Vaccination schedule	Denmark	*The Danish Vaccination Register.* Defined according to the type/brand of COVID-19 vaccines administered and dates of vaccinations.	Categorical (multiple levels): BNT1, BNT1BNT2, BNT1BNT2BNT3	Yes
	Finland	*The National Vaccination Register.* Defined according to the type/brand of COVID-19 vaccines administered and dates of vaccinations.		
	Norway	*The Norwegian Immunisation Registry (SYSVAK).* Defined according to the type/brand of COVID-19 vaccines administered and dates of vaccinations.		
	Sweden	*The National Vaccination Register.* Defined according to the type/brand of COVID-19 vaccines administered and dates of vaccinations.		

Infection

The secondary exposure of interest was COVID-19 infection. To support risk/benefit evaluations, we provided comparable estimates of the associations between COVID-19 infection and the outcomes under study. In the secondary objectives on the risk of study outcomes following infection, we used a positive RT-PCR test as exposure. We included positive RT-PCR results from January 1, 2020, to October 31, 2022 (follow-up was from January 1, 2021 to October 31, 2022, similar to the primary analysis of vaccine safety). We considered infection as a time-varying variable. We defined two periods of interest following infection. The acute period of interest lasted 28-days following infection (the primary risk period of interest). It started on day 1 (the day after the positive RT-PCR test) and lasted up to and including day 28. The post-acute period of interest started on day 29 following infection and lasted until a

censoring event or until the end of the study. Vaccination and reinfections were considered censoring events.

EXPOSURE VARIABLES - INFECTION				
VARIABLE	**COUNTRY**	**DATA SOURCE AND DETAILS**	**VALUES/CODES**	**TIME-VARYING VARIABLE**
Documented SARS-CoV-2 infection	Denmark	The Danish Microbiology Database. Defined as the date of a registered positive PCR test for SARS-CoV-2.	Binary: yes/no	Yes
	Finland	National Infectious Diseases Register. Defined as the date of a registered positive PCR test.		
	Norway	Norwegian Surveillance System for Communicable Diseases (MSIS). Defined as the date of a registered positive PCR test or positive serology test for SARS-CoV-2.		
	Sweden	Register on surveillance of notifiable communicable diseases (SmiNet). Defined as the date of a registered positive PCR test for SARS-CoV-2.		

Study outcomes

We identified study outcomes using nationwide hospital registers: National Patient Registry (DK), National Care Register for Health Care (FI), the Norwegian Patient Registry (NO) and the Swedish National Inpatient Register (SE). Study outcomes such as myocarditis/pericarditis and thromboembolic events will primarily be diagnosed in specialist wards in hospitals, especially in children. We included the following study outcomes identified in the national hospitalisation registers based on ICD-10 codes.

Study outcome	**ICD-10 codes used to identify cases**	
	ICD-10 codes with only 3-digits (exact match) +	ICD-10 codes with 4-digits (starts with)
Myocarditis/pericarditis		
1: Myocarditis	I40	I400, I401, I408, I409, I411, I418, I514
2: Pericarditis	I30	I300, I301, I308, I309, I328
3: Myocarditis or pericarditis		A composite outcome: myocarditis (#1) or pericarditis (#2)
Thromboembolism and thrombocytopenia		
4: Thrombosis with thrombocytopenia syndrome		A venous thromboembolism (see study outcome #9) together with one of the following codes for thrombocytopenia at the same hospital visit: D693, D694, D695, D696
5: Deep vein thrombosis (DVT)		I801, I802, I803, I808, I809, I821, I822, I828, I829
6: Pulmonary embolism (PE)	I26	I260, I269
7: Cerebral venous sinus thrombosis (CVST)		I636, I676
8: Hepatic-portal-renal vein thrombosis (HPRVT)	I81	I820, I823, I819
9: Venous thromboembolism		A composite outcome: DVT (#5), PE (#6), CVST (#7), or HPRVT (#8)
10: Ischemic stroke	I63	I630, I631, I632, I633, I634, I635, I636, I638, I639
11: Myocardial infarction	I21	I210, I211, I213, I214, I219

12: Arterial thromboembolism	A composite outcome: ischemic stroke (#10). myocardial infarction (#11) or I74 (3-digit code), I740, I741, I742, I743, I744, I745, I748, I749

We excluded individuals with an outcome before study start, i.e. we included only new onset/incident events during follow-up in contrast to also including re-occurring events. The look-back period for exclusion before study start was 3-years, i.e. no events were allowed in the 2018-2020 period. The exclusions were analysis-specific, i.e. the occurrence of different study outcomes in the look-back period than the one under analysis were not exclusion criteria in that specific analysis.

Many of the diagnoses have been validated in the Nordic registers.[22–24] As an example, in Denmark, cardiovascular ICD-10 codes were concluded to have high validity, especially in younger adults, and to be well suited for research.[25] In a validation study of Swedish register data, we have estimated a positive predictive value of 96% (95% CI 93%-98%) for a myocarditis diagnosis code (ICD-10) (unpublished).

As control outcomes, we also included anaphylaxis (T782; positive control) and concussion (S060; negative control).

Covariates

We took the following potential confounders into account: age, sex, year- and calendar month of follow-up, country-specific region, maternal country of birth (Nordic, Western, non-Western), comorbidities and vaccination priority group. The vaccination priority group was used to identify children given priority vaccination due to being at higher risk of severe COVID-19 outcomes. We used the Nordic hospitalisation register data to define individuals' comorbidities relevant to the outcomes under study.

COVARIATES				
VARIABLE	**COUNTRY**	**DATA SOURCE AND DETAILS**	**VALUES/CODES (ICD-10 codes for comorbidities specified with 3-digits should include all codes starting with the 3-digits)**	**TIME-VARYING VARIABLE**
Age	Denmark	*The Civil Registration System.* Defined as age during follow-up.	Categorical (3 levels):	Yes (within a

	Finland	*The Finnish Population Information System.* Defined as age during follow-up.	5 to 11, 12 to 15, 16 to 19.	calendar year the age of a child is calculate as calendar year minus birth year). In descriptive table age is 2021 minus birthyear. Children born in 2017 (4 year olds in 2021) that only contribute risk time in 2022 are listed as 5-11 year olds.
	Norway	*Norwegian Population Register.* Defined as age during follow-up.		
	Sweden	*The Total Population Register.* Defined as age during follow-up.		
Sex	Denmark	*The Civil Registration System.* Defined as biological sex at birth.	Binary: male, female	No
	Finland	*The Finnish Population Information System.* Defined as biological sex at birth.		
	Norway	*Norwegian Population Register.* Defined as biological sex at birth.		
	Sweden	*The Total Population Register.* Defined as biological sex at birth.		
Calendar year and month	Denmark	Defined as calendar month during follow-up.	Categorical (multiple levels): Jan-Mar 2021, Apr-Jun 2021, Jul-Sep 2021, Oct-Dec 2021, Jan-Mar 2022, Apr-Jun 2022, Jul-Sep 2022, Oct 2022.	Yes
	Finland	Defined as calendar month during follow-up.		
	Norway	Defined as calendar year and month during follow-up.		

	Sweden	Defined as calendar month during follow-up.		
Country specific region	Denmark	*The Civil Registration System.* Defined by the place of residence - major administrative regions.	Categorical (5 levels): Capital, Zealand, Southern Denmark, Central Jutland, Northern Jutland	No
	Finland	*The Finnish Population Information System.* Defined by the place of residence - major administrative regions.	Hospital districts: Helsinki and Uusimaa, Tampere, Turku, Oulu, and Other	
	Norway	*Norwegian Population Register.* Defined by the place of residence - Health administrative regions (4 categories)	Regions (4 categories): Helse Nord, Helse Midt-Norge, Helse Vest, Helse Sør-Øst.	
	Sweden	*The Total Population Register.* Defined by the place of residence - major administrative regions.	Categories are based on city size and urban vs rural.	
Maternal country of birth	Denmark	*The Civil Registration System.* Defined as the place of birth of a child´s mother.	Categorical (3 levels): Nordic, Western, and non-Western	No
	Finland	*The Finnish Population Information System.* Defined as the place of birth of a child´s mother.	NA	
	Norway	*Norwegian Population Register.* Defined as the place of birth of a child´s mother.	Categorical (3 levels): Nordic, Western, and non-Western	
	Sweden	*The Total Population Register.* Defined as the place of birth of a child´s mother.	Categorical (3 levels): Nordic, Western, and non-Western	
Comorbidity 1: Asthma	Denmark	*The National Patient Register.* Defined as primary diagnoses regardless of the type of hospital contact registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: J45-46	Yes

	Finland	*Care register for Health Care.*Defined as primary or secondary diagnoses registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: J45-46	
	Norway	*Norwegian Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact in the hospital or from private-practising specialists and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: J45-46	
	Sweden	*National Patient Register.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: J45-46	
Comorbidity 2: Other chronic respiratory diseases	Denmark	*The National Patient Register.* Defined as primary diagnoses regardless of the type of hospital contact registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: E84, J41-44, J47, J84, P27	Yes
	Finland	*Care register for Health Care.* Defined as primary or secondary diagnoses registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: E84, J41-44, J47, J84, P27	
	Norway	*Norwegian Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact in the hospital or from private-practising specialists and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: E84, J41-44, J47, J84, P27	
	Sweden	*National Patient Register.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact and before the first COVID-19 vaccination. *Swedish Prescribed Drug Register.* Antidiabetic drugs use is defined as ≥2 filled prescriptions during 2020	Binary: yes/no ICD-10 codes: E84, J41-44, J47, J84, P27	
Comorbidity 3: Chronic cardiac disease	Denmark	*The National Patient Register.* Defined as primary diagnoses regardless of the type of hospital contact registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: I05-08, I20-28, I34-37, I42-49, I50-51	Yes

	Finland	*Care register for Health Care.* Defined as primary or secondary diagnoses registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: I05-08, I20-28, I34-37, I42-49, I50-51	
	Norway	*Norwegian Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact in the hospital or from private-practising specialists and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: I05-08, I20-28, I34-37, I42-49, I50-51	
	Sweden	*National Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: I05-08, I20-28, I34-37, I42-49, I50-51	
Comorbidity 4: Renal disease	Denmark	*The National Patient Register.* Defined as primary diagnoses regardless of the type of hospital contact registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: N03, N05, N07, N18, N19, N25-27	Yes
	Finland	*Care register for Health Care.* Defined as primary or secondary diagnoses registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: N03, N05, N07, N18, N19, N25-27	
	Norway	*Norwegian Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact in the hospital or from private-practising specialists and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: N03, N05, N07, N18, N19, N25-27	
	Sweden	*National Patient Register.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: N03, N05, N07, N18, N19, N25-27	
Comorbidity 5: Diabetes	Denmark	*The National Patient Register.* Defined as primary diagnoses regardless of the type of hospital contact registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: E10-14	Yes

	Finland	*Care register for Health Care.* Defined as primary or secondary diagnoses registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: E10-14	
	Norway	*Norwegian Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact in the hospital or from private-practising specialists and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: E10-14	
	Sweden	*National Patient Register.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: E10-14	
Comorbidity 6: Autoimmune disease, not including diabetes	Denmark	*The National Patient Register.* Defined as primary diagnoses regardless of the type of hospital contact registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: D510, D590, D591, D690, D693, D86, E035, E039, E050, E055, E059, E063, E065, E271, E272, E310 G04, G131, G35, G36, G61, G700 H20 I00-I02 K50, K51, K732, K743, K900 L10, L12, L130, L40, L63, L80 M05-06, M08, M30, M311, M313, M315-7, M32-34, M350-M353, M358-M359, M45, M60	Yes
	Finland	*Care register for Health Care.* Defined as primary or secondary diagnoses registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: D510, D590, D591, D690, D693, D86, E035, E039, E050, E055, E059, E063, E065, E271, E272, E310 G04, G131, G35, G36, G61, G700 H20 I00-I02 K50, K51, K732, K743, K900 L10, L12, L130, L40, L63, L80 M05-06, M08, M30, M311, M313, M315-7, M32-34, M350-	

			M353, M358-M359, M45, M60	
	Norway	*Norwegian Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact in the hospital or from private-practising specialists and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: D510, D590, D591, D690, D693, D86, E035, E039, E050, E055, E059, E063, E065, E271, E272, E310 G04, G131, G35, G36, G61, G700 H20 I00-I02 K50, K51, K732, K743, K900 L10, L12, L130, L40, L63, L80 M05-06, M08, M30, M311, M313, M315-7, M32-34, M350-M353, M358-M359, M45, M60	
	Sweden	*National Patient Register.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: D510, D590, D591, D690, D693, D86, E035, E039, E050, E055, E059, E063, E065, E271, E272, E310 G04, G131, G35, G36, G61, G700 H20 I00-I02 K50, K51, K732, K743, K900 L10, L12, L130, L40, L63, L80 M05-06, M08, M30, M311, M313, M315-7, M32-34, M350-M353, M358-M359, M45, M60	
Comorbidity 7: Epilepsy or convulsions	Denmark	*The National Patient Register.* Defined as primary diagnoses regardless of the type of hospital contact registered before the first COVID-19 vaccination.	Binary: yes / no ICD-10 codes: G40, R56	Yes
	Finland	*Care register for Health Care.* Defined as primary or secondary diagnoses registered before the first COVID-19 vaccination.	Binary: yes / no ICD-10 codes: G40, R56	

	Norway	*Norwegian Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact in the hospital or from private-practising specialists and before the first COVID-19 vaccination.	Binary: yes / no ICD-10 codes: G40, R56	
	Sweden	*National Patient Register.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact and before the first COVID-19 vaccination.	Binary: yes / no ICD-10 codes: G40, R56	
Comorbidity 8: Congenital malformations and chromosomal abnormalities	Denmark	*The National Patient Register.* Defined as primary diagnoses regardless of the type of hospital contact registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: Q00-07, Q20-28, Q30-34, Q60-64, Q90-99	Yes
	Finland	*Care register for Health Care.* Defined as primary or secondary diagnoses registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: Q00-07, Q20-28, Q30-34, Q60-64, Q90-99	
	Norway	*Norwegian Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact in the hospital or from private-practising specialists and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: Q00-07, Q20-28, Q30-34, Q60-64, Q90-99	
	Sweden	*National Patient Register.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: Q00-07, Q20-28, Q30-34, Q60-64, Q90-99	
Comorbidity 9: Malignancy or immunodeficiency	Denmark	*The National Patient Register.* Defined as primary diagnoses regardless of the type of hospital contact registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: C00-96, D70-72, D730, D81-84	Yes
	Finland	*Care register for Health Care.* Defined as primary or secondary diagnoses registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: C00-96, D70-72, D730, D81-84	
	Norway	*Norwegian Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact in the hospital or	Binary: yes/no ICD-10 codes:	

		from private-practising specialists and before the first COVID-19 vaccination.	C00-96, D70-72, D730, D81-84	
	Sweden	*National Patient Register and Cancer register.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: C00-96, D70-72, D730, D81-84	
Comorbidity 10: Psychiatric disorder	*Denmark*	*The National Patient Register. Defined as primary diagnoses regardless of the type of hospital contact registered before the first COVID-19 vaccination.*	Binary: yes/no ICD-10 codes: Any chapter F diagnosis	*Yes*
	Finland	*Care register for Health Care.* Defined as primary or secondary diagnoses registered before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: Any chapter F diagnosis	
	Norway	*Norwegian Patient Registry.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact in the hospital or from private-practising specialists and before the first COVID-19 vaccination.	Binary: yes/no Any chapter F diagnosis	
	Sweden	*National Patient Register.* Defined as any recorded ICD-10 diagnosis during inpatient or outpatient contact and before the first COVID-19 vaccination.	Binary: yes/no ICD-10 codes: Any chapter F diagnosis	
High-risk group	Denmark	A high-risk group variable was available (defined by comorbidities). In addition, we added nursing home status (everyone in a nursing home is considered high-risk, and there were a few children residing in nursing homes).	Binary: yes/no	Yes
	Finland	The high-risk group was taken as those in COVID-19 vaccination priority group 1, as described earlier.[26]	Binary: yes/no	
	Norway	A high-risk group variable was available (defined by comorbidities). In addition, we added nursing home status (everyone in a nursing home is considered high-risk, and there were a few children residing in nursing homes).	Binary: yes/no	

	Sweden	Vaccination before age-specific approval of use was considered vaccination of high-risk group children and adolescents. The dates were: 16+ – 21/12/2020, 12-15 yo – 28/05/2021, 5-11 yo – 25/11/2021.	Binary: yes/no	

9.5 Data Sources

We used the unique nationwide register data to construct country-specific cohorts with individual-level information on dates of vaccination and dates of outcomes together with relevant covariate information. All Nordic residents are assigned a unique national personal identifier at birth or immigration, enabling unambiguous linkage between registers within each country. The registers were updated daily and there was minimal lag time (except for the Swedish and Finnish patient registers, for which there was a lag of 2 to 4 weeks); we did not expect the lag time of information from these data sources to differentiate between vaccinated and unvaccinated groups. The Nordic countries have universal and tax-financed healthcare systems and reporting to national registers is mandatory, which provided near-complete follow-up of the study population over time.

In the following table, we present the key data sources (vaccinations, RT-PCR positive tests and hospital contacts) for our study. All data sources were nationwide registers. All study subcontractors had access to their country-specific data and could link data between registers for our study.

Country	**Details of the individual-level data sources**						
Denmark							
Title	**Info**	**Type**	**Setting**	**Study availability**	**Update**	**Lag**	**Ref**
The Danish vaccination register	The register holds information on all vaccinations given in Denmark including information on vaccination date, type, dose, and product batch number ever since November 15, 2015 (when reporting to the register became mandatory).	Register	Nationwide	2020 – today	Daily	No lag	[27]
The National patient registry	The register covers all hospital contacts/visits in Denmark with information on the duration of the contact/visit, department of admission and other hospital characteristics. Treating physician-assigned diagnoses have been registered according to ICD-10 codes since 1995.	Register	Nationwide	1995 - today	Daily	No lag	[22]
The Danish Microbiology Database	Information on positive results of RT-PCR tests for SARS-CoV-2 are obtained from The Danish Microbiology Database (MiBa) which holds information on all microbiology samples analysed at Danish departments of microbiology, including information on SARS-CoV-2 PCR test results, date of sampling, date of analysis, type of test and interpretation of the test (positive / negative). The SARS-CoV-2 PCR tests have been freely available to all individuals in Denmark regardless of symptom status throughout the COVID-19 pandemic.	Register	Nationwide	2020 – today	Daily	No lag	[28]

Country	Details of the individual-level data sources						
Finland							
Title	**Info**	**Type**	**Setting**	**Study availability**	**Update**	**Lag**	**Ref**
The National Vaccination Register	The register, which is based on the Register of Primary Health Care Visits, holds information on all COVID-19 vaccinations administered in Finland. Data include the date of vaccination, vaccine batch number and trade name.	Register	Nationwide	2020 - today	Daily	No lag	[29]
National Care Register for Health Care	The register comprises information on all in-hospital care (since 1969) and outpatient specialist care (since 1998) in Finland, including admission and discharge dates, whether hospitalization was planned or acute, codes for discharge diagnoses (according to ICD-10) and surgical procedures, whether discharged as deceased, to own private residence or other health care facilities, type of department and hospital. The register is held by the Finnish Institute for Health and Welfare.	Register	Nationwide	1967 - today	Daily	1-4 weeks	[30]
Finnish National Infectious Diseases Register	The register contains information on notifiable diseases which must be reported by the laboratories and the physician treating the patient, or performing an autopsy, in accordance with the Finnish Communicable Diseases Act. All laboratory-confirmed SARS-CoV-2 infections are recorded in the National Infectious Diseases Register The register is held by the Finnish Institute for Health and Welfare.	Register	Nationwide	2020 - today	Daily	0-1 weeks	[31]

Country	Details of the individual-level data sources						
Norway							
Title	**Info**	**Type**	**Setting**	**Study availability**	**Update**	**Lag**	**Ref**
The Norwegian immunisation register (SYSVAK)	The register holds information on administered vaccines in the Norwegian vaccination programs, including the date of administration and type of vaccine. For the COVID-19 vaccines, reporting to the register has been mandatory.	Register	Nationwide	2020 - today	Daily	No lag	[32]
The Norwegian Patient Registry	The register holds information on all contacts with specialist health-care services in Norway, including admission and discharge dates as well as diagnoses (recorded according to ICD-10) during	Register	Nationwide	2017 - today	Daily	No lag	[33]

(NPR)	hospitalization or outpatient contact.						
Norwegian Surveillance System for Communicable Diseases (MSIS)	The register holds information on selected infectious diseases for which reporting to the register is mandatory. This includes all COVID-19 tests and the date of testing and test results.	Register	Nationwide	2020 - today	Daily	No lag	[34]

Country	**Details of the individual-level data sources**						
Sweden							
Title	**Info**	**Type**	**Setting**	**Study availability**	**Update**	**Lag**	**Ref**
Swedish vaccination register	The register contains information on administered COVID-19 vaccines including data on the date of administration, the specific vaccine products, substance, formulation, batch number and dose number (for repeated doses) since 1 January 2021. The register is held by the Public Health Agency of Sweden.	Register	Nationwide	2020 - today	Daily	No lag	[35]
Swedish national inpatient register	The register comprises information on all in-hospital (since 1987) and out-patient (since 2001) specialist care in Sweden including data on admission and discharge dates, whether hospitalization was planned or acute, codes for discharge diagnoses and surgical procedures, whether discharged as deceased, to own private residence or other health care facilities, type of department, and hospital. For the current study period discharge diagnoses were recorded according to the Swedish clinical modification of the ICD-10 (i.e. ICD-10-SE). The register is held by the National Board of Health and Welfare.	Register	Nationwide	2017 - today	Monthly	2–4 week	[36]
Register On Surveillance Of Notifiable Communicable Diseases (Sminet)	The register contains information on notifiable diseases (for which reporting is mandatory) reported by either the analysis-performing laboratories, the treating physician or the autopsy-performing physician, in accordance with the Swedish Communicable Diseases Act. Data include the date of disease occurrence, date of testing, date of positive test and diagnoses. The register is held by the Public Health Agency of Sweden.	Register	Nationwide	2020 - today	Daily	No lag	[37]

9.6 Bias and limitations

Although the use of nationwide registers and complementary statistical approaches mitigates the concern for potential bias in our study, a number of limitations should be mentioned. Firstly, the outcome *thrombosis with thrombocytopenia syndrome* did not have a specific ICD-10 code in all the Nordic countries. Instead we relied on well-defined thromboembolic events alone or together with thrombocytopenia. Secondly, the national hospital registers do not have information on date of symptom onset, only date of diagnosis. However, for the outcomes in our study, we expect there to be very little lag between onset and diagnosis, especially in more severe cases. Thirdly, our ascertainment of SARS-CoV-2 infection was based on secondary use of national microbiology test results. Depending on the country and period, we did not have complete registration of all infected children and adolescents in the population, only those who tested positive. However, in the majority of the study period we expect the number of unrecognized infections in the Nordic setting to be low-to-moderate given the extensive testing regimes that were in place until the end of February 2022. Fourthly, due to the rarity of events and the preferential use of BNT162b2, we were only able to provide reliable safety information on the mRNA-1273 vaccine. Finally, the study outcomes were rare in children and adolescents and despite combining nationwide register-data from four countries, statistical precision was low for many estimates.

9.7 Study size (sample size and power)

Prior to study conduct, we expected the Nordic countries to contribute with a total population of 5.1 million children/adolescents. The following tables below shows the country-specific details on population size and expected COVID-19 vaccine uptake:

DENMARK (Status as of 22 November 2022)	**1 dose**	**2 doses**	**3 doses**	**4 doses**	**Unvaccinated**
5 to 11 yrs	169786 (39.3%)	138267 (32.0%)	76 (0.0%)	0 (0.0%)	262071 (60.7%)
12 to 15 yrs	206869 (75.5%)	198170 (72.3%)	694 (0.3%)	53 (0.0%)	67069 (24.5%)

16 to 19 yrs	245739 (88.2%)	242447 (87.0%)	66238 (23.8%)	771 (0.3%)	32997 (11.8%)
Total **5 to19 yrs**	622394 (63.2%)	578884 (58.8%)	67008 (6.8%)	824 (0.1)	362137 (36.8%)

FINLAND (Status as of 27 September 2022)	**1 dose**	**2 doses**	**3 doses**	**4 doses**	**Unvaccinated**
5 to 11 yrs	104,714 (24.9%)	57,193 (13.6%)	0 (0.0%)	0 (0.0%)	345,828 (82.2%)
12 to 17 yrs	283,595 (76.3%)	259,064 (69.7%)	14,495 (3.9%)	0 (0.0%)	88,090 (23.7%)
18 to 24 yrs	360,178 (84.9%)	339,814 (80.1%)	134,059 (31.6%)	1,696 (0.4%)	64,060 (15.1%)
Total **5 to 24 yrs**	748,487 (61.5%)	656,071 (53.9%)	148,554 (12.2%)	1,696 (0.14%)	497,978 (40.9%)

NORWAY (Status as of September 2022)	**1 dose**	**2 doses**	**3 doses**	**4 doses**	**Unvaccinated**
5 to 11 yrs	6,137 (1.3%)	1,054 (0.2%)	7 (0%)	0	452,024 (98.4%)

12 to 15 yrs	127,957 (45.2%)	19,694 (6.9%)	167 (0.1%)	6 (0%)	135,297 (47.8%)
16 to 19 yrs	59,682 (21.9%)	132,617 (48.7%)	32,447 (11.9%)	108 (0.04%)	47,401 (17.4%)
Total **5 to 19 yrs**	193,776 (19.1%)	153,365 (15.1%)	32,621 (3.2%)	114 (0.01%)	634,722 (62.6%)

SWEDEN (Status as of August 22)	**1 dose**	**2 doses**	**3 doses**	**4 doses**	**Unvaccinated**
12 to 15 yrs	24,920 (5.0%)	328,492 (66.5%)	1,092 (0.2%)	7 (0.0%)	139,209 (28.2%)
16 to 19 yrs	18,904 (4.1%)	25,2671 (54.3%)	114,084 (24.5%)	525 (0.1%)	79,401 (17.1%)
Total **12 to 19 yrs**	43,824 (4.6%)	581,163 (60.6%)	115,176 (12.0%)	532 (0.1%)	218,610 (22.8%)

Among the European countries that have implemented childhood/adolescent COVID-19 vaccination, the uptake rates in the Nordic countries are in the higher end. The median uptake in the European region among individuals 5 to 17 years of age was 23.3% (range from 2.1 to 44.7%) -https://www.ecdc.europa.eu/sites/default/files/documents/Overview-of-the-implementation-of-COVID-19-vaccination-strategies-and-deployment-plans-in-the-EU-EEA-April-2022.pdf .

9.8 Data management

Data management and statistical analyses were conducted using a Common Data Model (CDM), by which national register data were standardised to a common structure, format and terminology in order to allow the same statistical programming scripts to be used in each

country. The use of a CDM with common statistical programming scripts facilitated efficient use of resources and reproducibility of the statistical analyses.

The CDM contained detailed descriptions of how the different data sources for the study were to be organised and how the different variables in the data sources were defined (see annex 1). The analytical group in Denmark coded the statistical analyses using R-scripts (R version 4.2.2.). The R-scripts were made available on GitHub (also during the programming phase to facilitate input and comments). The analysts in each of the participating countries then ran the R-scripts and returned the output to Denmark. The country-specific results were combined in meta-analyses in Denmark. We were not able to combine the country-specific data directly due to data privacy regulations and it was not feasible to negotiate the approval of data sharing between 4 countries in due time.

9.9 Statistical methods

Observed vs expected analyses

In each Nordic country and for each outcome, we calculated historical incidence rates stratified by sex and age in the period from 2015 (Norway: from 2017) to 2019. Using the historical rates we calculated the expected number of cases in each sex and age strata of our study population by simple multiplication of the sex and age-stratified follow-up among those vaccinated (separately for the acute and post-acute periods following vaccination). For each outcome and during each post-vaccination period, the observed rate was compared to the historical rate, yielding age- and sex-standardised incidence rate ratios. Confidence intervals (95%) were calculated based on the Poisson distribution of the observed counts. Country-specific estimates were combined using meta-analyses; the combined standardised incidence ratio estimates were based on random effects models implemented using the *mixmeta* package in R (CRAN.R-project.org/package=mixmeta).

Contemporary cohort analysis

In each Nordic country, we estimated adjusted incidence rate ratios and excess risks by comparing post-vaccination (acute and post-acute) follow-up to unvaccinated follow-up. We used Poisson regression on the outcome counts with the logarithm of the follow-up time as the offset. We took potential confounders (described above) into account by direct adjustment (multivariable regression). Country-specific estimates were combined using meta-analyses; the combined incidence rate ratio estimates were based on random effects models implemented using the *mixmeta* package in R.

Self-controlled case series

The self-controlled case series (SCCS) were nested within the cohorts. The SCCS analyses compared periods of follow-up within cases only. Thus, all time-invariant confounders such as comorbidity and lifestyle factors were taken into account by design. In each Nordic country, we compared the post-vaccination periods (acute and post-acute after vaccination) to the unvaccinated periods to estimate incidence rate ratios using conditional Poisson regression with direct adjustment for calendar year and month. We used a 14-day pre-risk period before vaccination to take into account a potential healthy vaccinee effect. The pre-risk period of interest occurred before any dose. Being diagnosed with the outcome of interest was not a censoring criterion in the SCCS analyses, and follow-up was continued to allow for the possibility that an individual was later vaccinated. We combined country-specific results using the meta-analysis approach described above. The main assumption underlying this statistical method was that occurrence of the event under study (myocarditis/pericarditis or TTS) before exposure (vaccination) did not influence the future probability of exposure.

Sensitivity analyses

In addition to considering vaccine type, dose number, and sequence, we conducted sensitivity analyses where we stratified by age (5 to 11, 12 to 15, 16 to 19 years), sex (male or female), and different main risk periods of interest (7-days, 14-days and 90 days).

In addition, we present main results from Denmark to be able to evaluate the robustness of the results across countries.

9.10 Supplementary analyses and quality control

The use of three different statistical analysis approaches (observed vs expected analyses, contemporary cohort analyses, and self-controlled case series analyses) constituted our primary quality control. The strength and limitations of these approaches complement each other well. The three methods yielded broadly similar results, which supported the validity of the results. As mentioned previously, by utilising a CDM with common statistical analysis scripts, we ensured that analyses were performed in the same way in all participating countries enhancing the quality of the statistical analyses.

10. RESULTS

10.1 Participants and Descriptive data

The total population under study was 5,098,625 5-to-19-year-olds (2,481,634 girls [49%] and 2,616,991 boys [51%]) from Denmark (n=1,035,176), Finland (n=1,018,113), Norway (n=1,091,558) and Sweden (n=1,953,778); Table 1.

The combined cohort comprised 2,399,036 individuals vaccinated at least once. The total number of BNT doses administered was 4,147,856 doses. The vaccine uptake of at least one COVID-19 vaccine at the study end on 31 October 2022 was highest in Denmark (65.3% of all 5-to-19-year-olds), followed by Finland (52.5%), Norway (39.5%) and Sweden (38.8%). Two doses of BNT was the most common schedule used in Denmark (50.3% of all 5-to-19-year-olds), Finland (28.0%), and Sweden (26.7%), while one dose of BNT was the most common schedule in Norway (18.6%). Only 14.2% of all 5-to-11-year-olds were vaccinated at least once, while the majority of 12-to-15-year-olds (74.0%) and 16-to-19-year-olds (84.8%) were vaccinated at least once. In the older age groups with higher uptakes, 50.6% of 12-to-15-year-olds and 43.8% of 16-to-19-year-olds received two doses of BNT. Three doses of BNT were almost exclusively used in 16-to-19-year-olds (21.5%). Uptake was similar across sexes, while children with comorbidities (n=525,283 [10.3%]) had higher uptake than children without comorbidities; Table 1.

The number of infected children (children with a positive test) at the study end on 31 October 2022 was largest in Denmark (n=733504, 70.9%), followed by Sweden (n=451385 [23.1%]), Norway (n=438922 [40.2%]), and Finland (n=215695 [21.2%]); Table 1. The proportion of infection was similar in girls (36.7%) and boys (35.5%), but slightly higher in 12-to-15-year-olds (38.9%) and 16-to-19-year-olds (38.3%) than in 5-to-11-year-olds (33.5%). Children with 2 or more comorbidities had slightly lower infection rates (32.8%) than children with 1 comorbidity (35.8%) or no comorbidity (36.1%); Table 1.

10.2 Outcome data

The incidence rates (per 100,000 person-years of follow-up) of all the study outcomes in the combined Nordic cohorts during the study period 1 January 2021 to 31 October 2022 are presented in the Figure 1 stratified by age-group (5-to-11-year-olds, 12-to-15-year-olds and 16-to-19-year-olds). The corresponding rates are available in tabular format in Table 6.

10.3 Main results

Myocarditis

Vaccination was associated with an increased risk of myocarditis in the 28-day main risk period after both BNT1, BNT1BNT2 and BNT1BNT2BNT3 for all three analytical approaches; Table 2. There was no association with infection, but the number of cases was low and the confidence intervals were wide and compatible with both reduced and increased risks.

SCCS analysis

In the SCCS analysis, the association was strongest after BNT1BNT2BNT3 (RR 14.85, 95% CI, 4.58-48.14; 6 cases), but also present after BNT1 (RR 2.92, 95% CI, 1.90-4.50; 44 cases) and BNT1BNT2 (RR 3.79, 95% CI, 2.35-6.14; 45 cases); Table 2. These associations appeared to be strongest among boys and, for BNT1 and BNT1BNT2, among 12-to-15-year-olds; Table 3a. A shorter risk period after BNT1BNT2 and BNT1BNT2BNT3 vaccination was associated with comparatively larger increased risks, e.g. 37.18 (95% CI, 10.12-136.62) in the 7-day main risk period following BNT1BNT2BNT3 compared to 14.85 (95% CI, 4.58-48.14) in the 28-day period, although confidence intervals were overlapping.

Contemporary cohort analysis

In the contemporary cohort analysis, the association was strongest after BNT1BNT2BNT3 (RR 5.30, 95% CI, 2.24-12.53; 6 cases), but also present after BNT1 (RR 2.75, 95% CI, 1.92-3.95; 44 cases) and BNT1BNT2 (RR 2.81, 95% CI, 1.94-4.07; 45 cases); Table 2. These associations appeared to be strongest among boys and, for BNT1 and BNT1BNT2, among 12-to-15-year-olds; Table 3b. A shorter risk period after BNT1BNT2 and BNT1BNT2BNT3 vaccination was associated with comparatively larger increased risks, e.g. 12.84 (95% CI, 4.59-35.96) in the 7-day main risk period following BNT1BNT2BNT3 compared to 5.30 (95% CI, 2.24-12.53) in the 28-day period, although confidence intervals were overlapping.

Observed vs Expected analysis

In the Observed vs Expected analysis, the myocarditis association persisted, but the strength of the BNT1BNT2BNT3 association was attenuated; Table 2. The association was also more similar between BNT1 (RR, 3.24, 95% CI, 1.91-5.51), BNT1BNT2 (RR, 3.51, 95% CI, 2.57-4.79) and BNT1BNT2BNT3 (RR, 3.60, 95% CI, 1.43-9.08), than was the case for the other analytical approaches. The rates among the unvaccinated in the study period were slightly lower than the historical rates (RR, 0.75, 95% CI, 0.49-1.15). The increased risk after vaccination was largest in boys, 5-to-11-year-olds and in the 7-day main risk period; Table 3c.

Pericarditis

Vaccination was associated with an increased risk of pericarditis in the 28-day main risk period after BNT1BNT2 for all three analytical approaches and after BNT1BNT2BNT3 for the SCCS and Observed vs Expected analyses (the 95% confidence interval for the contemporary cohort estimate was also broadly compatible with an increased risk although statistical significance at the 0.05-level was not reached); Table 2. There was no association with infection. However, cases were rare and confidence intervals wide.

SCCS analysis

In the SCCS analysis, the association was strongest after BNT1BNT2BNT3 (RR 10.87, 95% CI, 2.03-58.18; <5 cases), but also present after BNT1BNT2 (RR 3.78, 95% CI, 1.89-7.56; 18 cases); Table 2. These associations appeared to be present among both boys and girls, and were strongest among 16-to-19-year-olds and in the 7- and 14-day main risk periods; Table 3a.

Contemporary cohort analysis

In the contemporary cohort analysis, the association was strongest after BNT1BNT2 (RR 2.58, 95% CI, 1.44-4.63; 18 cases); Table 2. The associations appeared to be strongest among girls, 16-to-19-year-olds and in the 7- and 14-day main risk periods; Table 3b.

Observed vs Expected analysis

In the Observed vs Expected analysis, the pericarditis association persisted, but the strength of the association was attenuated; Table 2. The rates among the unvaccinated in the study period were slightly lower than the historical rates (RR, 0.78, 95% CI, 0.63-0.97). The increased risk after vaccination was largest in girls, 12-to-15-year-olds and in the 7-day main risk period; Table 3c. There was an association between infection and pericarditis in the 12-to-15-year-olds.

Myocarditis or pericarditis

The association between vaccination and the combined outcome of myocarditis and pericarditis exhibited a similar pattern as the myocarditis association, primarily a result of the fact that myocarditis is more common than pericarditis in the 12-to-15-year-olds (myocarditis rate, 5.7 per 100,000 person-years; pericarditis rate, 2.2 per 100,000 person-years; Figure 1, Table 6) and 16-to-19-year-olds (myocarditis rate, 24.4 per 100,000 person-years; pericarditis rate, 11.0 per 100,000 person-years; Figure 1, Table 6) age groups. Vaccination was associated with increased risk in the 28-day main risk period after both BNT1, BNT1BNT2 and BNT1BNT2BNT3 for all three analytical approaches; Table 2. There was no association with

infection, but the number of cases was low and the confidence intervals were wide and compatible with both reduced and increased risks.

SCCS analysis

In the SCCS analysis, the association was strongest after BNT1BNT2BNT3 (RR 9.71, 95% CI, 4.06-23.21; 10 cases), but also present after BNT1 (RR 2.53, 95% CI, 1.73-3.71; 50 cases) and BNT1BNT2 (RR 3.87, 95% CI, 2.57-5.83; 59 cases); Table 2. These associations appeared to be stronger among boys and, for BNT1 and BNT2, among 12-to-15-year-olds; Table 3a. A shorter risk period after BNT1BNT2 and BNT1BNT2BNT3 vaccination was associated with comparatively larger increased risks, e.g. 34.35 (95% CI, 12.69-92.98) in the 7-day main risk period following BNT1BNT2BNT3 compared to 9.71 (95% CI, 4.06-23.21) in the 28-day period, although confidence intervals were overlapping.

Contemporary cohort analysis

In the contemporary cohort analysis, the association was strongest after BNT1BNT2BNT3 (RR 4.49, 95% CI, 1.61-12.54; 10 cases), but also present after BNT1 (RR 2.29, 95% CI, 1.65-3.18; 50 cases) and BNT1BNT2 (RR 2.83, 95% CI, 2.00-4.01; 59 cases); Table 2. These associations appeared to be similar among boys and girls, but with wider confidence intervals for girls, and, for BNT1 and BNT2, among 12-to-15-year-olds; Table 3b. A shorter risk period after BNT1BNT2 and BNT1BNT2BNT3 vaccination was associated with comparatively larger increased risks, e.g. 19.34 (95% CI, 8.71-42.93) in the 7-day main risk period following BNT1BNT2BNT3 compared to 4.49 (95% CI, 1.61-12.54) in the 28-day period, although confidence intervals were overlapping.

Observed vs Expected analysis

In the Observed vs Expected analysis, the association persisted, but the strength of the BNT1BNT2BNT3 association was attenuated compared to the two other analytical approaches; Table 2. The association was also more similar between BNT1 (RR, 2.36, 95% CI, 1.76-3.16), BNT1BNT2 (RR, 3.07, 95% CI, 2.30-4.10) and BNT1BNT2BNT3 (RR, 3.31, 95% CI, 1.60-6.84), than was the case for the other analytical approaches. The rate among the unvaccinated in the study period was slightly lower than the historical rates (RR, 0.71, 95% CI, 0.56-0.90). The increased risk after vaccination was largest in boys after BNT1 and BNT1BNT2, but was larger among girls after BNT1BNT2BNT3. The increased risk was largest in 5-to-11-year-olds after BNT1 and in 12-to-15-year-olds after BNT1BNT2, and in the 7-day main risk period; Table 3c.

Thrombosis with thrombocytopenia syndrome

Thrombosis with thrombocytopenia syndrome was very rare in this study. We observed no cases in the 28-day main risk period after BNT1, BNT1BNT2, or BNT1BNT2BNT3; Table 2. The

rate among the unvaccinated in the study period was lower than the historical rates (RR, 0.48, 95% CI, 0.06-1.75) but confidence intervals were wide. The rates among 5-to-11-year-olds (0.2 per 100,000 person-years) and 12-to-15-year-olds (0.4 per 100,000 person-years) were very low; Figure 1, Table 6. We observed no cases in 16-to-19-year-olds.

Deep Vein Thrombosis

In the contemporary cohort analysis, but not in the SCCS- and the Observed vs Expected analyses, BNT1BNT2 was associated with Deep Vein Thrombosis (DVT) in the 28-day main risk period (RR, 1.99, 95% CI, 1.05-3.78; 15 cases); Table 2. The BNT1BNT2 association was only present in the 12-to-15-year-olds (RR, 4.47, 95% CI, 1.15-17.32), and was consistent across different main risk periods; Table 3b. In the shorter main risk periods we also observed an association between BNT1BNT2BNT3 and DVT; Table 3b.

In the Observed vs Expected analyses, BNT1BNT2 was also associated with DVT in 12-to-15-year-olds (RR, 3.21, 95% CI, 0.98-10.54); Table 3c. The rate in the unvaccinated was significantly lower than the historical rate (RR, 0.59, 95% CI, 0.51-0.70); Table 2.

In the contemporary cohort analysis, infection was also associated with DVT (RR, 2.96, 95% CI, 1.19-7.39; 5 cases).

Pulmonary Embolism

Pulmonary Embolism (PE) was rare in the combined Nordic cohort, especially among the younger age-groups. The PE rates were 0.2, 1.1 and 6.2 per 100,000 person-years among 5-to-11-year-olds, 12-to-15-year-olds and 16-to-19-year-olds, respectively; Figure 1, Table 6.

In the contemporary cohort analysis, we observed an association between BNT1BNT2BNT3 and PE in the 28-day main risk period (RR, 18.71, 95% CI, 1.51-232.26; <5 cases); Table 2. However, only Norway was able to contribute to this analysis, RRs could not be estimated in the three other countries due to a lack of events. This effect was most pronounced among girls, 16-to-19-year-olds and in the 7- and 14-day main risk periods; Table 3b. The rate among the unvaccinated was slightly lower than the historical rate (RR 0.68, 95% CI, 0.53-0.88); Table 2.

Infection was associated with PE in the 28-day main risk period in the SCCS- and contemporary cohort analyses (RRs 7.71, 95% CI, 1.12-53.04 and 5.99, 95% CI, 1.20-29.95, respectively) and the association in the Observed vs Expected analysis was also broadly compatible with an increased risk (RR, 6.17, 95% CI, 0.75-50.57); Table 2.

Cerebral Venous Sinus Thrombosis

Cerebral Venous Sinus Thrombosis (CVST) was rare in the combined Nordic cohort, especially among the younger age-groups. The CVST rates were 0.6, 0.7 and 1.8 per 100,000 person-years among 5-to-11-year-olds, 12-to-15-year-olds and 16-to-19-year-olds, respectively; Figure 1, Table 6.

We observed no associations between BNT1, BNT1BNT2, or BNT1BNT2BNT3 and CVST in the 28-day main risk period in any of the three analytical approaches; Table 2.

In the contemporary cohort analysis, we did observe an association between infection and CVST in the 28-day main risk period (RR, 15.57, 95% CI, 1.14-212.02; <5 cases); Table 2.

Hepatic-portal-renal vein thrombosis

Hepatic-portal-renal vein thrombosis (HPRVT) was very rare in the combined Nordic cohort among all age-groups. The HPRVT rates were 0.2, 0.5 and 0.7 per 100,000 person-years among 5-to-11-year-olds, 12-to-15-year-olds and 16-to-19-year-olds, respectively; Figure 1, Table 6.

There were almost no cases after vaccination and we observed no associations between BNT1, BNT1BNT2, or BNT1BNT2BNT3 and HPRVT in the 28-day main risk period in any of the three analytical approaches; Table 2. The rate in the unvaccinated was much lower than the historical rate (RR, 0.23, 95% CI, 0.13-0.42); Table 2.

Venous thromboembolism

Venous thromboembolism (VTE), the combined outcome of DVT, PE, CVST and HPRVT, was not significantly associated with BNT1, BNT1BNT2 or BNT1BNT2BNT3 in the 28-day main risk period in any of the analytical approaches; Table 2. However, in the contemporary cohort analysis, the estimates and the confidence intervals for the associations after BNT1BNT2 (RR, 1.68, 95% CI, 0.92-3.08) and BNT1BNT2BNT3 (RR, 2.89, 95% CI, 0.86-9.71) were compatible with both no risks and somewhat increased risks.

In both the SCCS- and contemporary cohort analyses, infection increased the risk of VTE in the 28-day main risk period; Table 2.

Ischemic Stroke

Ischemic stroke was rare in the combined Nordic cohort among all age-groups. The stroke rates were 1.1, 1.6 and 3.3 per 100,000 person-years among 5-to-11-year-olds, 12-to-15-year-olds and 16-to-19-year-olds, respectively; Figure 1, Table 6.

We observed no significant associations between BNT1, BNT1BNT2, or BNT1BNT2BNT3 and stroke in the 28-day main risk period; Table 2. However, in the contemporary cohort analysis,

the estimates and the confidence intervals for the association after BNT1 (RR, 2.29, 95% CI, 0.91-5.74) were compatible with both no risks and increased risks. The rate in the unvaccinated was much lower than the historical rate (RR, 0.27, 95% CI, 0.17-0.43); Table 2.

Myocardial Infarction

Myocardial infarction was very rare in the combined Nordic cohort among all age-groups. The rates were 0.2, 0.2 and 0.5 per 100,000 person-years among 5-to-11-year-olds, 12-to-15-year-olds and 16-to-19-year-olds, respectively; Figure 1, Table 6.

There were no events after BNT1, BNT1BNT2 or BNT1BNT2BNT3; Table 2. The rate in the unvaccinated was broadly similar to the historical rate (RR, 0.79, 95% CI, 0.30-2.06)

Arterial thromboembolism

Arterial thromboembolism was rare in the combined Nordic cohort among all age-groups. The rates were 1.3, 2.0 and 4.2 per 100,000 person-years among 5-to-11-year-olds, 12-to-15-year-olds and 16-to-19-year-olds, respectively; Figure 1, Table 6.

In the contemporary cohort analysis, we did observe an association between BNT1BNT2 and arterial thromboembolism in the 28-day main risk period (RR, 2.59, 95% CI, 1.16-5.79; 8 cases); Table 2. This association was strongest in boys and 12-to-15-year-olds; Table 3b. In further stratified contemporary cohort analyses, associations were also present after BNT1 for girls, for 5-to-11-year-olds and in the 7-day main risk period; Table 3b. The rate in the unvaccinated was broadly similar to the historical rate (RR, 0.30, 95% CI, 0.18-0.51); Table 2.

Anaphylaxis

We did not observe any increased risks of anaphylaxis after vaccination with any of the three analytical approaches; Table 2. Also, there were no increased risks using a 7-day main risk period in any analysis; Table 3a-3c. The rate in the unvaccinated was broadly similar to the historical rate (RR, 0.75, 95% CI, 0.62-0.90).

Concussion

Concussion was common in the combined Nordic cohort among all age-groups. The rates were 320.9, 322.8 and 327.0 per 100,000 person-years among 5-to-11-year-olds, 12-to-15-year-olds and 16-to-19-year-olds, respectively; Figure 1, Table 6.

Vaccination with BNT1 and BNT1BNT2 was associated with small but significant increased risks of concussion in the 28-day main risk period; Table 2. There were no associations with infection and the rate in the unvaccinated was broadly similar to the historical rate (RR, 0.74, 95% CI, 0.54-1.02).

10.4 Other analyses

Denmark-only results

In Denmark, the myocarditis results were similar to the combined results, with the exception that the BNT1BNT2BNT3 association was not estimable; Table 7. For pericarditis, there was only support in the SCCS and Observed vs Expected analyses of the 28-day main risk period after BNT1BNT2; Table 7.

The DVT, PE and arterial thromboembolism associations that were observed in the combined Nordic analyses, for some vaccine schedules and some analytical approaches, were not present in any of the Denmark-only analyses; Table 7. DVT and arterial thromboembolisms were very rare after vaccination, and no PE cases were observed after BNT1, BNT1BNT2 or BNT1BNT2BNT3 in Denmark.

Supplementary results

In Table 4, we present cases and person-years of follow-up of all study outcomes and exposure categories in Table 2; for the Observed vs Expected analyses we present the observed number of cases and the expected number of cases.

In Table 5, we present the number of individuals excluded before study start due to having a registration of a study outcome in the wash-out period.

In Table 8, we present the excess risks of the study outcomes according to age group based on the incidence rate ratios from the contemporary cohort analyses.

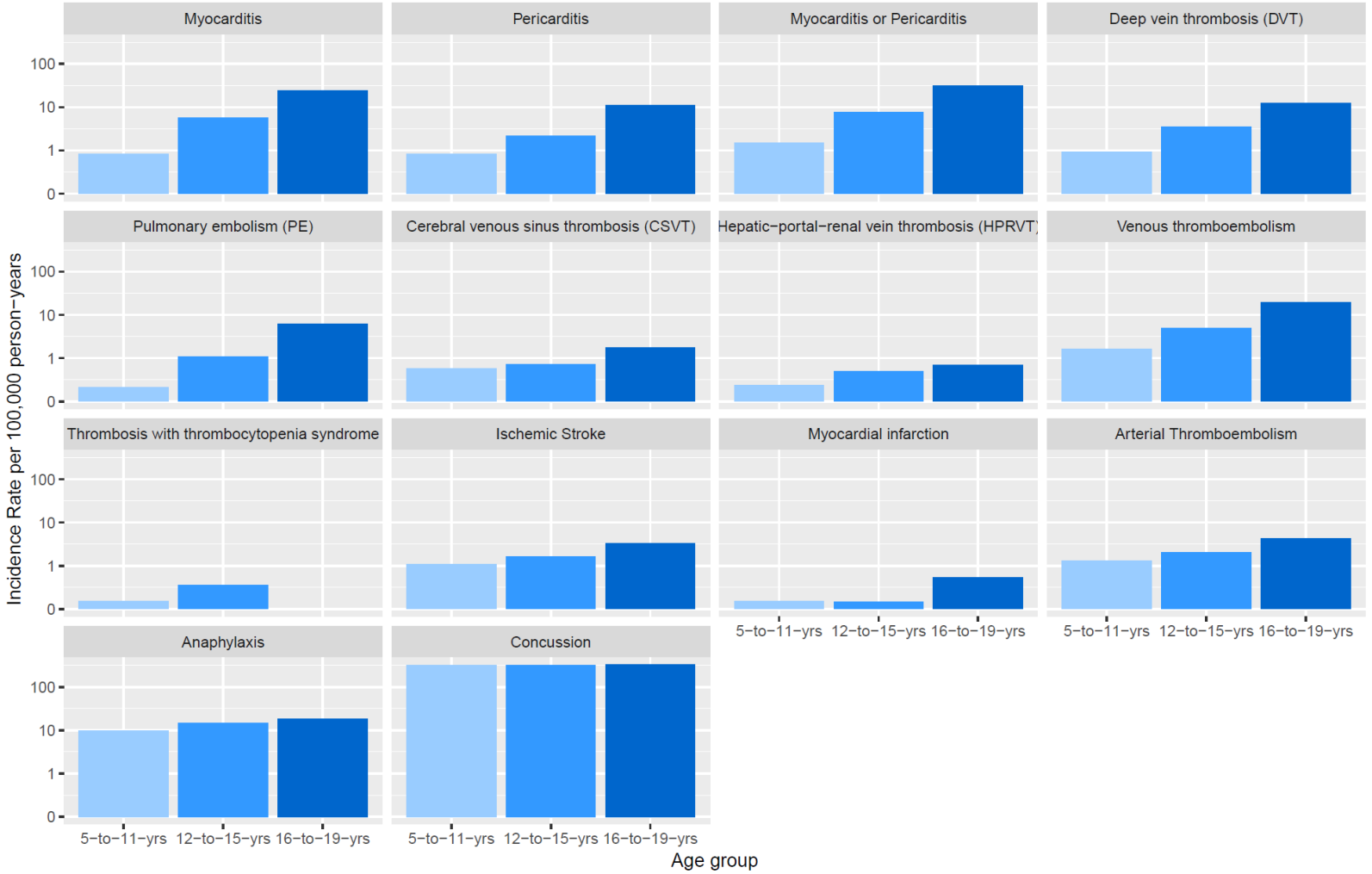
10.5 Adverse events/adverse reactions

Not applicable

10.6 Figure and Tables

10.6.1 Figure 1

Incidence rates of study outcomes among 5-to-19-year-olds during the study period 1 January 2021 to 31 October in Denmark, Finland, Norway and Sweden.



10.6.2 Table 1

Table 1: Vaccination and infection status at study end among 5-to-19-year-olds in Denmark, Finland, Norway and Sweden

Characteristics	Unvaccinated N (%[1])	BNT1 N (%[1])	BNT1BNT2 N (%[1])	BNT1BNT2BNT3 N (%[1])	Other vaccination N (%[1])	Infected N (%[1])	Non-infected N (%[1])	Total N
Denmark	359464 (34.7%)	43886 (4.2%)	520669 (50.3%)	106458 (10.3%)	4699 (0.5%)	733504 (70.9%)	301672 (29.1%)	1035176
Finland	483470 (47.5%)	76148 (7.5%)	285516 (28.0%)	45957 (4.5%)	127022 (12.5%)	215695 (21.2%)	802418 (78.8%)	1018113
Norway	660640 (60.5%)	203216 (18.6%)	143251 (13.1%)	34911 (3.2%)	49540 (4.5%)	438922 (40.2%)	652636 (59.8%)	1091558
Sweden	1196015 (61.2%)	43334 (2.2%)	522196 (26.7%)	92010 (4.7%)	100223 (5.1%)	451385 (23.1%)	1502393 (76.9%)	1953778
Girls	1297776 (52.3%)	173875 (7.0%)	713926 (28.8%)	150255 (6.1%)	145802 (5.9%)	911014 (36.7%)	1570620 (63.3%)	2481634
Boys	1401813 (53.6%)	192709 (7.4%)	757706 (29.0%)	129081 (4.9%)	135682 (5.2%)	928492 (35.5%)	1688499 (64.5%)	2616991
Age 5 -11	2166714 (85.8%)	102927 (4.1%)	253950 (10.1%)	388 (0.0%)	279 (0.0%)	845050 (33.5%)	1679208 (66.5%)	2524258
Age 12 -15	340187 (26.0%)	211796 (16.2%)	663527 (50.6%)	7549 (0.6%)	87205 (6.7%)	510283 (38.9%)	799981 (61.1%)	1310264
Age 16 -19	192688 (15.2%)	51861 (4.1%)	554155 (43.8%)	271399 (21.5%)	194000 (15.3%)	484173 (38.3%)	779930 (61.7%)	1264103
No comorbidities	2516307 (55.0%)	320521 (7.0%)	1271045 (27.8%)	229770 (5.0%)	235699 (5.2%)	1653158 (36.1%)	2920184 (63.9%)	4573342
1 comorbidity	162643 (35.1%)	40225 (8.7%)	177810 (38.4%)	42230 (9.1%)	40515 (8.7%)	166033 (35.8%)	297390 (64.2%)	463423
2+ comorbidity	20639 (33.4%)	5838 (9.4%)	22777 (36.8%)	7336 (11.9%)	5270 (8.5%)	20315 (32.8%)	41545 (67.2%)	61860
Total	2699589 (52.9%)	366584 (7.2%)	1471632 (28.9%)	279336 (5.5%)	281484 (5.5%)	1839506 (36.1%)	3259119 (63.9%)	5098625

[1] Row percentages.

10.6.3 Table 2

Table 2: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		SCCS		Contemporary cohort		Observed vs Expected		
	Exposure	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Countries included in meta-analyses[1]**
Myocarditis								
	Unvaccinated	178	1 (ref)	181	1 (ref)	181	0.75 (0.49-1.15)	DK, FI, SE, NO
	BNT1	44	2.92 (1.90-4.50)	44	2.75 (1.92-3.95)	44	3.24 (1.91-5.51)	DK, FI, SE, NO
	BNT1BNT2	45	3.79 (2.35-6.14)	45	2.81 (1.94-4.07)	45	3.51 (2.57-4.79)	DK, FI, SE, NO
	BNT1BNT2BNT3	6	14.85 (4.58-48.14)	6	5.30 (2.24-12.53)	6	3.60 (1.43-9.08)	FI, SE
	Non-infected	178	1 (ref)	182	1 (ref)	182	0.75 (0.49-1.15)	DK, FI, SE, NO
	SARS-CoV-2 infection	<5	1.56 (0.17-14.42)	<5	1.66 (0.22-12.51)	<5	1.53 (0.04-8.50)	FI
Pericarditis								
	Unvaccinated	112	1 (ref)	114	1 (ref)	114	0.78 (0.63-0.97)	DK, FI, SE, NO
	BNT1	7	1.26 (0.51-3.09)	7	0.98 (0.43-2.22)	7	1.09 (0.45-2.61)	DK, FI, SE
	BNT1BNT2	18	3.78 (1.89-7.56)	18	2.58 (1.44-4.63)	18	2.35 (1.40-3.94)	DK, FI, SE, NO
	BNT1BNT2BNT3	<5	10.87 (2.03-58.18)	<5	6.24 (0.81-47.85)	<5	4.14 (1.18-14.52)	DK, SE, NO
	Non-infected	113	1 (ref)	114	1 (ref)	114	0.78 (0.63-0.97)	DK, FI, SE, NO
	SARS-CoV-2 infection	<5	2.74 (0.18-42.78)	<5	4.39 (0.85-22.77)	<5	3.49 (0.53-23.02)	DK, FI[1]
Myocarditis or Pericarditis								
	Unvaccinated	261	1 (ref)	265	1 (ref)	265	0.71 (0.56-0.90)	DK, FI, SE, NO

Table 2: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		SCCS		Contemporary cohort		Observed vs Expected		
	Exposure	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Countries included in meta-analyses[1]**
	BNT1	50	2.53 (1.73-3.71)	50	2.29 (1.65-3.18)	50	2.36 (1.76-3.16)	DK, FI, SE, NO
	BNT1BNT2	59	3.87 (2.57-5.83)	59	2.83 (2.00-4.01)	59	3.07 (2.30-4.10)	DK, FI, SE, NO
	BNT1BNT2BNT3	10	9.71 (4.06-23.21)	10	4.49 (1.61-12.54)	10	3.31 (1.60-6.84)	DK, FI, SE, NO
	Non-infected	262	1 (ref)	266	1 (ref)	266	0.71 (0.56-0.90)	DK, FI, SE, NO
	SARS-CoV-2 infection	<5	1.50 (0.29-7.68)	<5	1.18 (0.28-5.04)	<5	1.41 (0.21-9.29)	DK, FI
Thrombosis with thrombocytopenia syndrome								
	Unvaccinated	<5	1 (ref)	<5	1 (ref)	<5	0.48 (0.06-1.75)	NO
	BNT1	0	NA	0	NA	0	NA	NA
	BNT1BNT2	0	NA	0	NA	0	NA	NA
	BNT1BNT2BNT3	0	NA	0	NA	0	NA	NA
	Non-infected	<5	1 (ref)	<5	1 (ref)	<5	0.48 (0.06-1.75)	NO
	SARS-CoV-2 infection	0	NA	0	NA	0	NA	NA
Deep Vein Thrombosis (DVT)								
	Unvaccinated	158	1 (ref)	160	1 (ref)	160	0.59 (0.51-0.70)	DK, FI, SE, NO
	BNT1	14	1.27 (0.63-2.58)	14	1.40 (0.78-2.51)	14	0.98 (0.54-1.78)	DK, FI, SE, NO
	BNT1BNT2	15	1.56 (0.81-3.02)	15	1.99 (1.05-3.78)	15	1.12 (0.63-2.00)	DK, FI, SE, NO
	BNT1BNT2BNT3	<5	2.07 (0.28-15.24)	<5	2.38 (0.53-10.76)	<5	1.22 (0.18-8.05)	DK, SE
	Non-infected	158	1 (ref)	160	1 (ref)	160	0.59 (0.50-0.69)	DK, FI, SE, NO

Table 2: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		SCCS		Contemporary cohort		Observed vs Expected		
	Exposure	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Countries included in meta-analyses[1]**
	SARS-CoV-2 infection	5	2.73 (0.89-8.34)	5	2.96 (1.19-7.39)	5	1.45 (0.47-4.51)	DK, FI, SE, NO
Pulmonary Embolism (PE)								
	Unvaccinated	64	1 (ref)	64	1 (ref)	64	0.68 (0.53-0.88)	DK, FI, SE, NO
	BNT1	<5	2.78 (0.75-10.36)	<5	2.58 (0.80-8.33)	<5	1.65 (0.45-4.23)	SE
	BNT1BNT2	<5	1.15 (0.34-3.89)	<5	1.36 (0.45-4.11)	<5	0.87 (0.25-3.05)	FI, SE, NO
	BNT1BNT2BNT3	<5	4.32 (0.20-95.01)	<5	18.71 (1.51-232.26)	<5	3.99 (0.10-22.20)	NO
	Non-infected	63	1 (ref)	64	1 (ref)	64	0.68 (0.52-0.88)	DK, FI, SE, NO
	SARS-CoV-2 infection	<5	7.71 (1.12-53.04)	<5	5.99 (1.20-29.95)	<5	6.17 (0.75-50.57)	FI, SE
Cerebral venous sinus thrombosis (CVST)								
	Unvaccinated	34	1 (ref)	34	1 (ref)	34	0.79 (0.55-1.14)	DK, FI, SE, NO
	BNT1	<5	2.26 (0.18-28.61)	<5	3.47 (0.31-39.31)	<5	2.54 (0.06-14.16)	NO
	BNT1BNT2	0	NA	0	NA	0	NA	NA
	BNT1BNT2BNT3	0	NA	0	NA	0	NA	NA
	Non-infected	33	1 (ref)	34	1 (ref)	34	0.79 (0.55-1.13)	DK, FI, SE, NO
	SARS-CoV-2 infection	<5	NA	<5	15.57 (1.14-212.02)	<5	8.49 (0.21-47.31)	DK
Hepatic-portal-renal vein thrombosis (HPRVT)								
	Unvaccinated	13	1 (ref)	14	1 (ref)	14	0.23 (0.13-0.42)	DK, FI, SE, NO
	BNT1	0	NA	0	NA	0	NA	NA

Table 2: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		SCCS		Contemporary cohort		Observed vs Expected		
	Exposure	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Countries included in meta-analyses[1]**
	BNT1BNT2	<5	1.06 (0.05-22.32)	<5	2.12 (0.18-24.55)	<5	1.58 (0.04-8.82)	SE
	BNT1BNT2BNT3	0	NA	0	NA	0	NA	NA
	Non-infected	14	1 (ref)	14	1 (ref)	14	0.23 (0.13-0.42)	DK, FI, SE, NO
	SARS-CoV-2 infection	0	NA	0	NA	0	NA	NA
Venous thromboembolism								
	Unvaccinated	245	1 (ref)	248	1 (ref)	248	0.55 (0.48-0.62)	DK, FI, SE, NO
	BNT1	18	0.99 (0.45-2.17)	18	1.13 (0.58-2.21)	18	0.76 (0.40-1.45)	DK, FI, SE, NO
	BNT1BNT2	20	1.45 (0.84-2.52)	20	1.68 (0.92-3.08)	20	0.97 (0.59-1.57)	DK, FI, SE, NO
	BNT1BNT2BNT3	<5	1.26 (0.33-4.75)	<5	2.89 (0.86-9.71)	<5	0.99 (0.21-4.62)	DK, SE, NO
	Non-infected	245	1 (ref)	248	1 (ref)	248	0.55 (0.48-0.62)	DK, FI, SE, NO
	SARS-CoV-2 infection	9	2.89 (1.24-6.74)	9	3.41 (1.71-6.79)	9	1.76 (0.81-3.83)	DK, FI, SE, NO
Ischemic Stroke								
	Unvaccinated	68	1 (ref)	68	1 (ref)	68	0.27 (0.17-0.43)	DK, FI, SE, NO
	BNT1	6	1.54 (0.56-4.27)	6	2.29 (0.91-5.74)	6	0.98 (0.37-2.60)	FI, SE, NO
	BNT1BNT2	<5	3.32 (0.27-41.63)	<5	4.41 (0.51-38.39)	<5	0.88 (0.21-3.64)	DK, SE
	BNT1BNT2BNT3	0	NA	0	NA	0	NA	NA
	Non-infected	69	1 (ref)	69	1 (ref)	69	0.28 (0.18-0.42)	DK, FI, SE, NO
	SARS-CoV-2 infection	<5	2.84 (0.20-39.86)	<5	3.98 (0.45-34.83)	<5	1.20 (0.03-6.69)	NO

Table 2: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		SCCS		Contemporary cohort		Observed vs Expected		
	Exposure	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Countries included in meta-analyses[1]**
Myocardial Infarction								
	Unvaccinated	5	1 (ref)	6	1 (ref)	6	0.79 (0.30-2.06)	DK, FI, NO
	BNT1	0	NA	0	NA	0	NA	NA
	BNT1BNT2	0	NA	0	NA	0	NA	NA
	BNT1BNT2BNT3	0	NA	0	NA	0	NA	NA
	Non-infected	6	1 (ref)	6	1 (ref)	6	0.78 (0.30-2.06)	DK, FI, NO
	SARS-CoV-2 infection	0	NA	0	NA	0	NA	NA
Arterial Thromboembolism								
	Unvaccinated	82	1 (ref)	83	1 (ref)	83	0.30 (0.18-0.51)	DK, FI, SE, NO
	BNT1	8	2.00 (0.82-4.85)	8	2.59 (1.16-5.79)	8	1.09 (0.48-2.45)	FI, SE, NO
	BNT1BNT2	<5	1.71 (0.41-7.06)	<5	2.25 (0.61-8.26)	<5	0.68 (0.16-2.83)	DK, SE
	BNT1BNT2BNT3	0	NA	0	NA	0	NA	NA
	Non-infected	84	1 (ref)	84	1 (ref)	84	0.30 (0.18-0.50)	DK, FI, SE, NO
	SARS-CoV-2 infection	<5	2.65 (0.23-30.97)	<5	3.85 (0.46-32.31)	<5	1.11 (0.03-6.17)	NO
Anaphylaxis								
	Unvaccinated	494	1 (ref)	503	1 (ref)	503	0.75 (0.62-0.90)	DK, FI, SE, NO
	BNT1	23	0.96 (0.51-1.81)	23	1.10 (0.55-2.20)	23	1.15 (0.60-2.21)	DK, FI, SE, NO
	BNT1BNT2	20	1.13 (0.61-2.11)	20	1.27 (0.73-2.21)	20	1.15 (0.71-1.87)	DK, FI, SE, NO
	BNT1BNT2BNT3	<5	0.79 (0.10-6.41)	<5	1.30 (0.18-9.47)	<5	1.26 (0.03-7.04)	SE
	Non-infected	506	1 (ref)	509	1 (ref)	509	0.76 (0.63-0.92)	DK, FI, SE, NO

Table 2: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		SCCS		Contemporary cohort		Observed vs Expected		
	Exposure	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Number of cases**	**Estimate (95% CI)**	**Countries included in meta-analyses[1]**
	SARS-CoV-2 infection	6	0.83 (0.35-1.99)	6	1.05 (0.46-2.38)	6	0.69 (0.25-1.87)	DK, FI, SE, NO
Concussion								
	Unvaccinated	12059	1 (ref)	12343	1 (ref)	12343	0.74 (0.54-1.02)	DK, FI, SE, NO
	BNT1	531	1.17 (1.06-1.29)	531	1.16 (1.00-1.35)	531	0.97 (0.74-1.26)	DK, FI, SE, NO
	BNT1BNT2	384	1.13 (1.01-1.27)	384	1.14 (0.96-1.36)	384	0.92 (0.74-1.13)	DK, FI, SE, NO
	BNT1BNT2BNT3	32	1.15 (0.76-1.76)	32	1.11 (0.68-1.81)	32	0.79 (0.45-1.39)	DK, FI, SE, NO
	Non-infected	12337	1 (ref)	12359	1 (ref)	12359	0.74 (0.54-1.02)	DK, FI, SE, NO
	SARS-CoV-2 infection	181	0.81 (0.67-0.99)	181	0.95 (0.77-1.18)	181	0.71 (0.42-1.20)	DK, FI, SE, NO

[1] Indicates that this specific country is not included across all analysis methods.

10.6.4 Table 3a

Table 3a: Sensitivity analyses for the SCCS method in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
Myocarditis								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	3.38 (2.14-5.34)	1.84 (0.25-13.63)	NA	7.13 (2.87-17.73)	1.99 (1.15-3.45)	2.58 (1.00-6.64)	2.47 (1.37-4.46)	2.37 (1.62-3.46)
BNT1BNT2	4.18 (2.49-7.00)	2.05 (0.19-21.98)	NA	14.66 (4.54-47.32)	3.13 (1.76-5.57)	12.73 (7.73-20.96)	7.52 (4.63-12.19)	1.02 (0.56-1.87)
BNT1BNT2BNT3	18.72 (5.58-62.78)	NA	NA	NA	15.78 (4.56-54.64)	37.18 (10.12-136.62)	18.49 (5.02-68.11)	4.10 (0.72-23.39)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	14.15 (0.52-385.83)	NA	2.45 (0.07-83.56)	NA	NA	2.95 (0.32-27.08)	2.41 (1.10-5.30)
Pericarditis								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	1.45 (0.54-3.89)	1.51 (0.10-21.94)	3.42 (0.07-177.84)	3.18 (0.38-26.81)	1.12 (0.34-3.69)	1.82 (0.42-7.93)	1.36 (0.39-4.73)	2.23 (1.30-3.83)
BNT1BNT2	4.07 (1.84-8.99)	12.95 (1.03-162.59)	NA	4.03 (0.41-39.37)	3.72 (1.55-8.91)	8.88 (4.08-19.33)	5.72 (2.75-11.86)	1.69 (0.70-4.09)
BNT1BNT2BNT3	13.88 (2.07-93.24)	61.81 (0.26-14507.43)	NA	NA	9.62 (1.24-74.40)	58.97 (10.86-320.21)	32.93 (5.61-193.38)	5.63 (1.63-19.40)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	5.39 (0.27-108.89)	NA	NA	NA	NA	NA	NA	0.71 (0.21-2.41)
Myocarditis or Pericarditis								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	2.84 (1.89-4.26)	0.86 (0.22-3.35)	2.38 (0.29-19.64)	5.33 (2.44-11.62)	1.64 (1.00-2.70)	2.40 (1.21-4.75)	2.22 (1.35-3.66)	2.45 (1.77-3.38)

Table 3a: Sensitivity analyses for the SCCS method in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
BNT1BNT2	4.14 (2.65-6.49)	2.44 (0.19-31.17)	NA	7.70 (2.02-29.45)	3.13 (1.90-5.16)	11.49 (7.50-17.59)	6.87 (4.55-10.38)	1.24 (0.75-2.04)
BNT1BNT2BNT3	15.54 (5.68-42.51)	5.96 (0.07-542.94)	NA	NA	9.94 (3.93-25.14)	34.35 (12.69-92.98)	17.30 (6.38-46.91)	4.49 (1.30-15.50)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	2.32 (0.18-30.59)	19.10 (0.79-463.00)	NA	8.20 (0.63-106.76)	NA	NA	3.05 (0.34-27.51)	1.83 (0.98-3.42)
Thrombosis with thrombocytopenia syndrome								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	NA	NA	NA	NA	NA	NA	NA	NA
BNT1BNT2	NA	NA	NA	NA	NA	NA	NA	NA
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	NA
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	NA	NA	NA	NA	NA	NA	NA
Deep Vein Thrombosis (DVT)								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	1.34 (0.48-3.76)	1.44 (0.58-3.60)	NA	NA	1.85 (0.83-4.10)	1.08 (0.26-4.58)	1.01 (0.43-2.40)	1.29 (0.76-2.17)
BNT1BNT2	1.33 (0.50-3.54)	1.80 (0.70-4.61)	NA	2.52 (0.46-13.92)	1.77 (0.75-4.20)	2.53 (0.74-8.72)	2.28 (0.99-5.29)	1.53 (0.80-2.92)
BNT1BNT2BNT3	NA	5.48 (0.20-152.94)	NA	NA	3.23 (0.50-20.86)	6.59 (0.91-48.01)	3.73 (0.63-22.07)	1.24 (0.40-3.84)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	2.67 (0.57-12.55)	NA	NA	3.78 (0.91-15.77)	7.43 (0.69-79.75)	4.80 (1.38-16.70)	2.05 (0.81-5.14)
Pulmonary Embolism (PE)								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)

Table 3a: Sensitivity analyses for the SCCS method in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
BNT1	2.48 (0.19-32.31)	2.97 (0.62-14.34)	NA	NA	2.12 (0.49-9.19)	2.73 (0.32-23.30)	1.38 (0.16-11.79)	1.13 (0.47-2.72)
BNT1BNT2	1.88 (0.26-13.64)	1.38 (0.22-8.63)	NA	NA	0.97 (0.27-3.47)	5.08 (0.41-62.88)	2.67 (0.22-33.16)	1.56 (0.57-4.29)
BNT1BNT2BNT3	NA	7.67 (0.24-243.86)	NA	NA	1.22 (0.03-45.20)	8.00 (0.40-160.70)	4.76 (0.23-97.13)	1.88 (0.08-43.71)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	10.49 (1.34-82.35)	NA	NA	4.86 (0.29-82.58)	NA	23.42 (0.90-606.31)	3.30 (0.64-17.13)
Cerebral venous sinus thrombosis (CVST)								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	NA	3.12 (0.14-69.59)	NA	NA	2.19 (0.05-89.31)	NA	NA	1.06 (0.30-3.68)
BNT1BNT2	NA	NA	NA	NA	NA	NA	NA	1.80 (0.29-11.22)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	NA
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	NA	NA	NA	NA	NA	NA	NA
Hepatic-portal-renal vein thrombosis (HPRVT)								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	NA	NA	NA	NA	NA	NA	NA	0.38 (0.02-5.96)
BNT1BNT2	2.31 (0.06-88.99)	NA	NA	NA	NA	NA	1.88 (0.10-34.59)	NA
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	NA
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	NA	NA	NA	NA	NA	NA	NA

Table 3a: Sensitivity analyses for the SCCS method in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
Venous thromboembolism								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	1.28 (0.53-3.10)	1.26 (0.57-2.80)	NA	0.89 (0.09-8.50)	1.22 (0.58-2.55)	1.14 (0.35-3.72)	0.79 (0.36-1.74)	1.20 (0.66-2.18)
BNT1BNT2	1.67 (0.74-3.74)	1.28 (0.59-2.76)	NA	4.45 (1.10-17.94)	1.39 (0.69-2.79)	1.52 (0.54-4.31)	1.88 (0.92-3.84)	1.56 (0.94-2.59)
BNT1BNT2BNT3	NA	3.02 (0.53-17.22)	NA	NA	1.69 (0.39-7.30)	4.17 (1.13-15.36)	2.27 (0.61-8.41)	0.84 (0.32-2.19)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	4.28 (0.55-33.41)	4.31 (1.49-12.45)	NA	NA	4.78 (1.67-13.72)	4.12 (0.47-36.11)	4.13 (1.39-12.24)	1.63 (0.80-3.35)
Ischemic Stroke								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	3.14 (0.17-59.06)	2.30 (0.59-8.90)	NA	NA	0.60 (0.15-2.49)	5.75 (1.43-23.16)	2.83 (0.70-11.49)	1.18 (0.52-2.68)
BNT1BNT2	2.01 (0.28-14.63)	NA	NA	29.10 (0.82-1028.89)	0.27 (0.03-2.80)	NA	NA	0.72 (0.20-2.67)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	0.77 (0.04-16.95)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	5.73 (0.27-120.40)	NA	NA	NA	NA	NA	1.64 (0.20-13.31)
Myocardial Infarction								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	NA	NA	NA	NA	NA	NA	NA	NA
BNT1BNT2	NA	NA	NA	NA	NA	NA	NA	NA
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	NA
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)

Table 3a: Sensitivity analyses for the SCCS method in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
SARS-CoV-2 infection	NA	NA	NA	NA	NA	NA	NA	NA
Arterial Thromboembolism								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	1.39 (0.21-9.33)	3.08 (1.02-9.28)	NA	4.91 (0.34-71.34)	0.98 (0.28-3.45)	4.53 (1.45-14.11)	2.26 (0.72-7.07)	1.29 (0.62-2.68)
BNT1BNT2	4.49 (0.82-24.57)	NA	NA	5.10 (0.34-75.65)	0.33 (0.03-3.34)	NA	NA	0.96 (0.30-3.05)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	2.57 (0.14-45.96)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	5.89 (0.44-78.77)	NA	NA	NA	NA	NA	1.46 (0.20-10.95)
Anaphylaxis								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	1.02 (0.48-2.20)	1.05 (0.57-1.93)	1.10 (0.13-9.38)	0.99 (0.41-2.39)	1.22 (0.41-3.61)	1.51 (0.76-3.01)	1.17 (0.66-2.08)	1.03 (0.76-1.41)
BNT1BNT2	1.46 (0.68-3.16)	1.17 (0.58-2.34)	1.51 (0.17-13.24)	1.26 (0.23-6.99)	1.35 (0.68-2.70)	1.40 (0.30-6.61)	1.50 (0.63-3.55)	0.86 (0.52-1.42)
BNT1BNT2BNT3	2.52 (0.26-24.12)	NA	NA	NA	0.78 (0.09-6.67)	NA	NA	0.79 (0.21-2.97)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	0.86 (0.20-3.80)	1.18 (0.37-3.79)	0.65 (0.08-5.21)	2.28 (0.65-8.01)	0.50 (0.06-3.97)	NA	1.52 (0.52-4.42)	0.98 (0.59-1.64)
Concussion								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	1.24 (1.09-1.41)	1.09 (0.95-1.26)	0.94 (0.66-1.35)	1.08 (0.92-1.27)	0.98 (0.76-1.26)	1.10 (0.92-1.32)	1.13 (0.99-1.29)	1.15 (1.07-1.24)
BNT1BNT2	1.11 (0.95-1.30)	1.16 (0.94-1.44)	0.95 (0.62-1.45)	1.16 (0.91-1.48)	0.94 (0.70-1.28)	1.06 (0.86-1.31)	1.08 (0.92-1.25)	1.20 (0.99-1.46)
BNT1BNT2BNT3	1.68 (1.00-2.83)	0.89 (0.50-1.59)	NA	1.75 (0.40-7.58)	0.97 (0.50-1.88)	0.87 (0.41-1.83)	1.22 (0.75-2.00)	0.96 (0.67-1.37)

Table 3a: Sensitivity analyses for the SCCS method in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	0.84 (0.68-1.03)	0.81 (0.62-1.07)	0.73 (0.54-0.99)	1.04 (0.69-1.58)	0.79 (0.53-1.17)	0.47 (0.26-0.83)	0.48 (0.31-0.73)	0.94 (0.85-1.04)

10.6.5 Table 3b

Table 3b: Sensitivity analyses for the contemporary cohort analyses in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
Myocarditis								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	3.12 (2.14-4.54)	2.99 (0.44-20.28)	10.18 (0.63-163.98)	5.26 (2.64-10.45)	1.96 (1.22-3.15)	2.40 (1.15-5.00)	2.56 (1.53-4.31)	2.21 (1.67-2.91)
BNT1BNT2	3.05 (2.00-4.64)	2.00 (0.63-6.36)	NA	4.36 (1.95-9.77)	2.52 (1.44-4.42)	9.19 (6.20-13.62)	5.44 (3.75-7.90)	0.85 (0.51-1.43)
BNT1BNT2BNT3	7.10 (2.97-17.00)	NA	NA	NA	4.92 (2.05-11.84)	12.84 (4.59-35.96)	6.54 (2.33-18.32)	2.44 (0.76-7.83)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	4.13 (0.48-35.39)	NA	8.39 (0.81-86.82)	NA	NA	3.35 (0.45-25.17)	3.02 (1.57-5.81)
Pericarditis								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	0.97 (0.40-2.37)	2.73 (0.30-25.12)	16.57 (0.86-319.49)	2.40 (0.43-13.55)	0.73 (0.24-2.16)	1.22 (0.29-5.07)	0.95 (0.29-3.09)	1.79 (1.07-3.00)
BNT1BNT2	2.85 (1.23-6.59)	12.24 (1.97-75.94)	NA	6.36 (1.45-27.80)	2.32 (1.18-4.56)	6.15 (2.94-12.86)	4.17 (2.24-7.76)	1.17 (0.55-2.50)
BNT1BNT2BNT3	14.43 (3.10-67.27)	43.27 (2.95-634.72)	NA	NA	7.18 (0.56-91.69)	53.44 (14.56-196.15)	29.47 (7.77-111.74)	3.61 (0.94-13.86)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	1.93 (0.22-16.91)	14.31 (1.46-140.21)	NA	7.98 (1.03-61.67)	NA	NA	NA	1.38 (0.59-3.22)
Myocarditis or Pericarditis								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	2.54 (1.80-3.58)	1.17 (0.34-4.06)	3.51 (0.70-17.77)	4.47 (2.38-8.39)	1.53 (0.99-2.37)	2.10 (1.10-4.02)	2.14 (1.33-3.43)	2.18 (1.68-2.83)

Table 3b: Sensitivity analyses for the contemporary cohort analyses in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
BNT1BNT2	3.09 (1.88-5.06)	2.98 (0.82-10.90)	NA	4.92 (2.44-9.92)	2.47 (1.45-4.21)	8.46 (5.95-12.02)	5.17 (3.71-7.20)	0.95 (0.63-1.45)
BNT1BNT2BNT3	8.45 (3.95-18.07)	9.82 (1.28-75.06)	NA	NA	4.30 (1.25-14.78)	19.34 (8.71-42.93)	9.91 (4.46-22.03)	2.26 (0.63-8.10)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	0.90 (0.11-7.47)	3.60 (0.44-29.41)	NA	4.33 (0.81-23.22)	NA	NA	3.05 (0.41-22.74)	2.35 (1.55-3.58)
Thrombosis with thrombocytopenia syndrome								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	NA	NA	NA	NA	NA	NA	NA	NA
BNT1BNT2	NA	NA	NA	NA	NA	NA	NA	NA
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	NA
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	NA	NA	NA	NA	NA	NA	NA
Deep Vein Thrombosis (DVT)								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	2.08 (0.89-4.85)	1.25 (0.53-2.93)	NA	NA	1.58 (0.85-2.94)	1.03 (0.25-4.26)	1.10 (0.47-2.54)	1.46 (0.88-2.42)
BNT1BNT2	2.52 (0.95-6.71)	1.47 (0.65-3.31)	NA	4.47 (1.15-17.32)	1.71 (0.67-4.35)	2.27 (0.70-7.39)	2.90 (1.34-6.31)	2.12 (0.99-4.57)
BNT1BNT2BNT3	NA	3.26 (0.65-16.27)	NA	NA	2.44 (0.50-11.88)	8.33 (1.88-36.84)	4.45 (1.00-19.84)	2.50 (0.98-6.36)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	2.50 (0.34-18.52)	5.40 (1.90-15.35)	NA	73.05 (4.00-1335.77)	4.94 (1.78-13.75)	22.97 (2.84-185.49)	6.42 (2.32-17.71)	2.19 (1.17-4.09)
Pulmonary Embolism (PE)								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)

Table 3b: Sensitivity analyses for the contemporary cohort analyses in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
BNT1	1.78 (0.19-16.54)	3.04 (0.75-12.27)	NA	1.74 (0.15-19.97)	2.18 (0.56-8.45)	2.58 (0.33-20.26)	1.28 (0.16-10.07)	1.48 (0.77-2.87)
BNT1BNT2	2.14 (0.42-10.91)	1.50 (0.30-7.55)	NA	NA	1.23 (0.40-3.79)	8.61 (0.85-87.52)	4.46 (0.44-45.59)	2.15 (0.92-5.02)
BNT1BNT2BNT3	NA	34.45 (2.28-520.58)	NA	NA	10.46 (0.82-133.07)	48.75 (4.20-566.45)	27.56 (2.33-326.55)	6.41 (0.49-83.36)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	10.03 (1.63-61.80)	NA	NA	6.41 (1.24-33.13)	NA	4.82 (0.65-35.53)	2.41 (0.99-5.83)
Cerebral venous sinus thrombosis (CVST)								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	NA	5.85 (0.32-106.88)	NA	NA	7.92 (0.31-205.25)	NA	NA	1.40 (0.48-4.07)
BNT1BNT2	NA	NA	NA	NA	NA	NA	NA	1.33 (0.19-9.44)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	46.97 (2.26-974.84)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	57.08 (2.41-1352.67)	NA	NA	NA	NA	NA	NA	4.63 (0.37-57.27)
Hepatic-portal-renal vein thrombosis (HPRVT)								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	NA	NA	NA	NA	NA	NA	NA	1.34 (0.18-10.01)
BNT1BNT2	3.25 (0.21-51.53)	NA	NA	3.77 (0.23-61.11)	NA	NA	4.75 (0.42-54.29)	11.79 (0.47-293.88)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	NA
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)

Table 3b: Sensitivity analyses for the contemporary cohort analyses in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
SARS-CoV-2 infection	NA	NA	NA	NA	NA	NA	NA	NA
Venous thromboembolism								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	1.54 (0.68-3.51)	1.22 (0.63-2.37)	NA	0.86 (0.10-7.37)	1.38 (0.80-2.39)	1.13 (0.35-3.59)	0.86 (0.40-1.86)	1.38 (0.72-2.66)
BNT1BNT2	2.33 (1.13-4.81)	1.22 (0.61-2.47)	NA	5.36 (1.65-17.41)	1.57 (0.67-3.67)	1.67 (0.61-4.58)	2.21 (1.03-4.76)	1.89 (1.07-3.32)
BNT1BNT2BNT3	NA	4.64 (1.27-16.93)	NA	NA	3.80 (1.05-13.76)	9.58 (2.88-31.82)	5.19 (1.55-17.31)	1.78 (0.78-4.08)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	3.19 (0.72-14.08)	5.21 (2.20-12.37)	NA	23.91 (2.01-284.77)	6.19 (2.54-15.05)	8.10 (1.07-61.27)	4.41 (1.80-10.82)	1.91 (1.16-3.15)
Ischemic Stroke								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	2.79 (0.54-14.43)	3.62 (1.05-12.52)	62.04 (3.90-986.52)	12.08 (1.04-139.95)	1.26 (0.34-4.66)	9.48 (2.59-34.66)	4.57 (1.25-16.74)	1.92 (0.86-4.31)
BNT1BNT2	11.38 (0.47-275.99)	NA	NA	13.06 (0.85-201.42)	0.91 (0.11-7.55)	NA	NA	1.49 (0.38-5.85)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	3.52 (0.31-39.39)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	5.95 (0.55-64.96)	NA	NA	18.04 (2.10-155.02)	NA	NA	1.00 (0.23-4.36)
Myocardial Infarction								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	NA	NA	NA	NA	NA	NA	NA	NA
BNT1BNT2	NA	NA	NA	NA	NA	NA	NA	76.37 (0.35-16873.79)

Table 3b: Sensitivity analyses for the contemporary cohort analyses in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	NA
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	NA	NA	NA	NA	NA	NA	NA
Arterial Thromboembolism								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	2.21 (0.47-10.51)	4.25 (1.54-11.71)	67.48 (4.39-1036.97)	5.39 (0.95-30.57)	1.54 (0.49-4.89)	5.68 (1.94-16.67)	2.83 (0.96-8.32)	1.80 (0.96-3.35)
BNT1BNT2	5.34 (1.25-22.82)	NA	NA	5.62 (0.49-64.23)	0.96 (0.12-7.82)	NA	NA	1.24 (0.44-3.51)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	3.79 (0.37-38.31)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	NA	6.83 (0.68-68.14)	NA	NA	13.71 (1.68-111.90)	NA	NA	0.97 (0.23-4.18)
Anaphylaxis								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	1.25 (0.49-3.18)	1.20 (0.67-2.13)	0.89 (0.12-6.77)	1.44 (0.40-5.20)	1.35 (0.49-3.70)	1.72 (0.87-3.38)	1.34 (0.71-2.53)	1.19 (0.91-1.55)
BNT1BNT2	1.61 (0.67-3.87)	1.30 (0.68-2.48)	1.50 (0.20-11.07)	1.56 (0.24-10.05)	1.52 (0.83-2.76)	1.52 (0.31-7.37)	1.60 (0.70-3.67)	0.98 (0.63-1.53)
BNT1BNT2BNT3	3.05 (0.41-22.89)	NA	NA	NA	1.25 (0.17-9.34)	NA	NA	0.94 (0.29-3.03)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	1.11 (0.27-4.53)	1.54 (0.55-4.31)	0.91 (0.12-6.95)	2.92 (1.03-8.30)	0.71 (0.10-5.10)	NA	2.02 (0.74-5.51)	1.32 (0.88-1.98)
Concussion								
Unvaccinated	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
BNT1	1.22 (1.06-1.40)	1.12 (0.98-1.29)	0.98 (0.73-1.32)	1.17 (1.01-1.35)	0.94 (0.65-1.37)	1.08 (0.84-1.40)	1.15 (1.02-1.31)	1.16 (1.04-1.30)

Table 3b: Sensitivity analyses for the contemporary cohort analyses in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
BNT1BNT2	1.09 (0.94-1.27)	1.18 (0.88-1.58)	0.90 (0.60-1.35)	1.23 (1.03-1.47)	0.89 (0.57-1.38)	1.06 (0.81-1.38)	1.07 (0.84-1.36)	1.20 (1.02-1.42)
BNT1BNT2BNT3	1.46 (0.79-2.70)	0.89 (0.44-1.81)	NA	2.30 (0.57-9.28)	0.97 (0.64-1.48)	0.87 (0.41-1.83)	1.18 (0.73-1.91)	0.96 (0.73-1.27)
Non-infected	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)	1 (ref)
SARS-CoV-2 infection	1.03 (0.85-1.26)	0.90 (0.67-1.22)	0.90 (0.65-1.24)	1.13 (0.82-1.55)	0.97 (0.66-1.43)	0.53 (0.28-1.00)	0.56 (0.37-0.86)	1.12 (1.00-1.25)

10.6.6 Table 3c

Table 3c: Sensitivity analyses for the Observed vs. Expected method in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
Myocarditis								
Unvaccinated	0.75 (0.46-1.21)	0.68 (0.40-1.18)	0.92 (0.51-1.64)	0.85 (0.36-2.05)	0.72 (0.50-1.04)	0.75 (0.49-1.15)	0.75 (0.49-1.15)	0.75 (0.49-1.15)
BNT1	3.68 (2.05-6.61)	2.38 (0.32-17.53)	101.34 (2.57-564.61)	8.46 (5.07-14.11)	2.24 (1.25-4.01)	3.09 (0.96-9.91)	2.87 (1.59-5.19)	2.79 (1.98-3.93)
BNT1BNT2	3.84 (2.77-5.32)	2.17 (0.66-7.14)	NA	6.89 (3.53-13.45)	3.07 (1.92-4.92)	12.36 (7.12-21.43)	7.37 (4.61-11.77)	1.08 (0.66-1.77)
BNT1BNT2BNT3	4.36 (1.73-10.99)	NA	NA	NA	3.63 (1.44-9.16)	9.02 (2.75-29.62)	4.55 (1.39-14.93)	1.99 (0.94-4.18)
Non-infected	0.75 (0.46-1.21)	0.68 (0.39-1.18)	0.92 (0.51-1.64)	0.85 (0.36-2.04)	0.72 (0.50-1.05)	0.75 (0.49-1.15)	0.75 (0.49-1.15)	0.75 (0.49-1.15)
SARS-CoV-2 infection	NA	8.33 (0.21-46.43)	NA	8.71 (0.22-48.54)	NA	NA	3.07 (0.08-17.10)	2.61 (1.15-5.89)
Pericarditis								
Unvaccinated	0.80 (0.56-1.13)	0.87 (0.58-1.29)	1.06 (0.53-2.14)	0.86 (0.56-1.32)	0.79 (0.63-1.00)	0.78 (0.63-0.97)	0.78 (0.63-0.97)	0.78 (0.63-0.97)
BNT1	1.40 (0.56-3.54)	3.53 (0.09-19.66)	13.04 (0.33-72.67)	2.13 (0.32-14.09)	0.96 (0.30-3.13)	1.33 (0.20-8.78)	1.12 (0.27-4.64)	1.69 (1.24-2.30)
BNT1BNT2	2.85 (1.64-4.95)	3.96 (0.48-14.31)	NA	5.69 (1.01-32.12)	2.31 (1.30-4.10)	6.26 (3.16-12.38)	4.04 (2.29-7.16)	1.29 (0.70-2.37)
BNT1BNT2BNT3	3.74 (0.57-24.72)	10.68 (1.62-70.53)	NA	NA	4.15 (1.18-14.54)	21.76 (5.25-90.23)	11.08 (2.67-45.96)	2.39 (1.06-5.38)
Non-infected	0.80 (0.56-1.13)	0.86 (0.58-1.29)	1.06 (0.52-2.14)	0.86 (0.56-1.32)	0.79 (0.62-1.00)	0.78 (0.63-0.97)	0.78 (0.63-0.97)	0.78 (0.63-0.97)
SARS-CoV-2 infection	2.86 (0.07-15.93)	15.39 (0.39-85.74)	NA	16.78 (2.54-110.84)	NA	NA	NA	1.36 (0.55-3.36)
Myocarditis or Pericarditis								
Unvaccinated	0.72 (0.48-1.08)	0.67 (0.47-0.96)	0.90 (0.57-1.43)	0.77 (0.59-1.02)	0.68 (0.54-0.85)	0.71 (0.56-0.90)	0.71 (0.56-0.90)	0.71 (0.56-0.90)
BNT1	2.76 (1.86-4.08)	1.00 (0.21-4.68)	9.09 (1.38-60.03)	5.92 (3.65-9.59)	1.62 (1.03-2.54)	2.38 (1.17-4.84)	2.18 (1.37-3.45)	2.24 (1.91-2.63)

Table 3c: Sensitivity analyses for the Observed vs. Expected method in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
BNT1BNT2	3.42 (2.41-4.86)	2.42 (0.96-6.11)	NA	5.42 (3.00-9.81)	2.73 (1.72-4.32)	9.46 (6.93-12.90)	5.84 (4.42-7.72)	1.10 (0.78-1.54)
BNT1BNT2BNT3	4.00 (1.79-8.94)	7.98 (1.21-52.73)	NA	NA	3.33 (1.61-6.89)	10.89 (4.51-26.27)	5.51 (2.28-13.30)	2.20 (1.30-3.74)
Non-infected	0.72 (0.48-1.07)	0.67 (0.47-0.96)	0.90 (0.57-1.43)	0.77 (0.59-1.02)	0.68 (0.54-0.85)	0.71 (0.56-0.90)	0.71 (0.56-0.90)	0.71 (0.56-0.90)
SARS-CoV-2 infection	2.17 (0.05-12.08)	5.51 (0.14-30.69)	NA	8.14 (1.23-53.76)	NA	NA	2.52 (0.06-14.02)	1.98 (1.12-3.49)
Thrombosis with thrombocytopenia syndrome								
Unvaccinated	4.89 (0.59-17.66)	NA	0.37 (0.01-2.04)	1.78 (0.05-9.92)	NA	0.48 (0.06-1.75)	0.48 (0.06-1.75)	0.48 (0.06-1.75)
BNT1	NA	NA	NA	NA	NA	NA	NA	NA
BNT1BNT2	NA	NA	NA	NA	NA	NA	NA	NA
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	NA
Non-infected	4.87 (0.59-17.58)	NA	0.37 (0.01-2.04)	1.78 (0.04-9.90)	NA	0.48 (0.06-1.75)	0.48 (0.06-1.75)	0.48 (0.06-1.75)
SARS-CoV-2 infection	NA	NA	NA	NA	NA	NA	NA	NA
Deep Vein Thrombosis (DVT)								
Unvaccinated	0.61 (0.48-0.78)	0.59 (0.47-0.74)	0.64 (0.12-3.32)	0.66 (0.41-1.08)	0.63 (0.52-0.77)	0.59 (0.51-0.70)	0.59 (0.51-0.70)	0.59 (0.51-0.70)
BNT1	1.70 (0.71-4.04)	0.81 (0.33-2.02)	NA	NA	1.25 (0.69-2.27)	0.80 (0.12-5.26)	0.75 (0.27-2.05)	0.92 (0.66-1.29)
BNT1BNT2	1.62 (0.60-4.37)	0.95 (0.41-2.20)	NA	3.21 (0.98-10.54)	1.09 (0.55-2.17)	1.55 (0.37-6.42)	1.66 (0.74-3.74)	1.08 (0.70-1.66)
BNT1BNT2BNT3	NA	1.87 (0.28-12.35)	NA	NA	1.22 (0.19-8.07)	4.26 (0.65-28.16)	2.27 (0.34-15.00)	0.98 (0.36-2.67)
Non-infected	0.61 (0.48-0.78)	0.59 (0.47-0.73)	0.64 (0.12-3.31)	0.66 (0.40-1.08)	0.63 (0.52-0.77)	0.59 (0.50-0.69)	0.59 (0.50-0.69)	0.59 (0.50-0.69)
SARS-CoV-2 infection	1.39 (0.04-7.77)	2.43 (0.64-9.22)	NA	6.76 (0.17-37.67)	2.31 (0.66-8.11)	9.05 (0.23-50.43)	2.85 (0.81-9.98)	1.21 (0.63-2.32)
Pulmonary Embolism (PE)								

Table 3c: Sensitivity analyses for the Observed vs. Expected method in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
Unvaccinated	0.89 (0.57-1.39)	0.60 (0.44-0.84)	1.78 (0.05-9.94)	0.83 (0.37-1.87)	0.67 (0.50-0.89)	0.68 (0.53-0.88)	0.68 (0.53-0.88)	0.68 (0.53-0.88)
BNT1	1.51 (0.04-8.41)	1.70 (0.35-4.98)	NA	3.31 (0.08-18.45)	1.42 (0.29-4.14)	1.64 (0.04-9.16)	0.83 (0.02-4.62)	0.98 (0.59-1.64)
BNT1BNT2	2.29 (0.35-15.14)	0.88 (0.13-5.84)	NA	NA	0.94 (0.27-3.31)	3.94 (0.10-21.94)	1.97 (0.05-11.00)	1.21 (0.65-2.26)
BNT1BNT2BNT3	NA	5.22 (0.13-29.07)	NA	NA	3.99 (0.10-22.21)	14.90 (0.38-83.01)	7.64 (0.19-42.54)	1.35 (0.03-7.50)
Non-infected	0.89 (0.57-1.39)	0.60 (0.43-0.83)	1.78 (0.05-9.93)	0.83 (0.37-1.87)	0.67 (0.50-0.89)	0.68 (0.52-0.88)	0.68 (0.52-0.88)	0.68 (0.52-0.88)
SARS-CoV-2 infection	NA	8.72 (1.07-71.36)	NA	NA	7.08 (0.88-56.73)	NA	3.25 (0.08-18.14)	1.79 (0.65-4.88)
Cerebral venous sinus thrombosis (CVST)								
Unvaccinated	0.90 (0.53-1.54)	0.75 (0.44-1.28)	1.20 (0.47-3.06)	0.98 (0.49-1.93)	1.05 (0.60-1.83)	0.79 (0.55-1.14)	0.79 (0.55-1.14)	0.79 (0.55-1.14)
BNT1	NA	5.21 (0.13-29.04)	NA	NA	3.28 (0.08-18.29)	NA	NA	1.27 (0.49-3.34)
BNT1BNT2	NA	NA	NA	NA	NA	NA	NA	1.66 (0.40-6.90)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	10.08 (0.26-56.15)
Non-infected	0.90 (0.53-1.53)	0.75 (0.44-1.27)	1.20 (0.47-3.06)	0.97 (0.49-1.93)	1.04 (0.60-1.82)	0.79 (0.55-1.13)	0.79 (0.55-1.13)	0.79 (0.55-1.13)
SARS-CoV-2 infection	19.32 (0.49-107.64)	NA	NA	NA	20.12 (0.51-112.12)	NA	NA	2.54 (0.06-14.18)
Hepatic-portal-renal vein thrombosis (HPRVT)								
Unvaccinated	0.29 (0.12-0.73)	0.25 (0.10-0.63)	0.13 (0.03-0.53)	0.54 (0.16-1.82)	0.43 (0.15-1.21)	0.23 (0.13-0.42)	0.23 (0.13-0.42)	0.23 (0.13-0.42)
BNT1	NA	NA	NA	NA	NA	NA	NA	0.92 (0.11-3.31)
BNT1BNT2	3.09 (0.08-17.24)	NA	NA	4.77 (0.12-26.56)	NA	NA	3.12 (0.08-17.36)	1.31 (0.03-7.32)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	NA
Non-infected	0.29 (0.12-0.73)	0.25 (0.10-0.63)	0.13 (0.03-0.53)	0.54 (0.16-1.82)	0.43 (0.15-1.21)	0.23 (0.13-0.42)	0.23 (0.13-0.42)	0.23 (0.13-0.42)

Table 3c: Sensitivity analyses for the Observed vs. Expected method in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
SARS-CoV-2 infection	NA	NA	NA	NA	NA	NA	NA	NA
Venous thromboembolism								
Unvaccinated	0.57 (0.47-0.69)	0.54 (0.45-0.64)	0.45 (0.16-1.25)	0.62 (0.47-0.83)	0.63 (0.54-0.74)	0.55 (0.48-0.62)	0.55 (0.48-0.62)	0.55 (0.48-0.62)
BNT1	1.18 (0.50-2.82)	0.80 (0.40-1.60)	NA	0.51 (0.01-2.83)	0.95 (0.52-1.72)	0.82 (0.20-3.39)	0.58 (0.23-1.44)	0.81 (0.52-1.25)
BNT1BNT2	1.45 (0.70-3.01)	0.72 (0.35-1.50)	NA	2.33 (0.83-6.54)	0.89 (0.50-1.59)	1.00 (0.29-3.51)	1.27 (0.62-2.58)	0.98 (0.70-1.38)
BNT1BNT2BNT3	NA	1.42 (0.30-6.64)	NA	NA	0.99 (0.21-4.63)	3.54 (0.76-16.54)	1.86 (0.40-8.70)	0.71 (0.28-1.76)
Non-infected	0.57 (0.47-0.69)	0.54 (0.45-0.64)	0.45 (0.16-1.25)	0.62 (0.46-0.83)	0.63 (0.54-0.73)	0.55 (0.48-0.62)	0.55 (0.48-0.62)	0.55 (0.48-0.62)
SARS-CoV-2 infection	1.23 (0.19-8.14)	2.68 (0.87-8.29)	NA	3.51 (0.09-19.56)	3.41 (1.36-8.58)	4.86 (0.12-27.07)	2.21 (0.75-6.50)	0.97 (0.58-1.63)
Ischemic Stroke								
Unvaccinated	0.25 (0.14-0.45)	0.33 (0.23-0.47)	0.19 (0.11-0.33)	0.34 (0.20-0.57)	0.71 (0.48-1.07)	0.27 (0.17-0.43)	0.27 (0.17-0.43)	0.27 (0.17-0.43)
BNT1	0.78 (0.12-5.13)	1.68 (0.48-5.91)	62.91 (1.59-350.49)	2.70 (0.33-9.75)	1.58 (0.38-6.56)	4.07 (0.98-16.86)	2.04 (0.49-8.48)	0.64 (0.36-1.14)
BNT1BNT2	1.94 (0.47-8.05)	NA	NA	1.49 (0.23-9.87)	0.90 (0.02-4.99)	NA	NA	0.43 (0.11-1.64)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	4.10 (0.10-22.83)
Non-infected	0.25 (0.14-0.45)	0.33 (0.23-0.48)	0.19 (0.11-0.33)	0.33 (0.20-0.54)	0.71 (0.48-1.06)	0.28 (0.18-0.42)	0.28 (0.18-0.42)	0.28 (0.18-0.42)
SARS-CoV-2 infection	NA	3.47 (0.09-19.35)	NA	NA	9.18 (0.23-51.14)	NA	NA	0.31 (0.05-2.08)
Myocardial Infarction								
Unvaccinated	0.71 (0.24-2.11)	5.15 (0.13-28.72)	NA	NA	1.35 (0.45-3.99)	0.79 (0.30-2.06)	0.79 (0.30-2.06)	0.79 (0.30-2.06)
BNT1	NA	NA	NA	NA	NA	NA	NA	NA
BNT1BNT2	NA	NA	NA	NA	NA	NA	NA	4.18 (0.11-23.27)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	NA

Table 3c: Sensitivity analyses for the Observed vs. Expected method in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
Non-infected	0.71 (0.24-2.10)	5.13 (0.13-28.59)	NA	NA	1.34 (0.45-3.97)	0.78 (0.30-2.06)	0.78 (0.30-2.06)	0.78 (0.30-2.06)
SARS-CoV-2 infection	NA	NA	NA	NA	NA	NA	NA	NA
Arterial Thromboembolism								
Unvaccinated	0.26 (0.14-0.49)	0.37 (0.24-0.57)	0.24 (0.10-0.54)	0.35 (0.19-0.63)	0.62 (0.43-0.90)	0.30 (0.18-0.51)	0.30 (0.18-0.51)	0.30 (0.18-0.51)
BNT1	0.64 (0.10-4.21)	1.81 (0.69-4.74)	60.08 (1.52-334.76)	1.78 (0.43-7.37)	1.60 (0.49-5.21)	2.68 (0.76-9.39)	1.35 (0.38-4.73)	0.64 (0.38-1.07)
BNT1BNT2	1.41 (0.34-5.85)	NA	NA	1.21 (0.18-7.97)	0.64 (0.02-3.55)	NA	NA	0.51 (0.16-1.57)
BNT1BNT2BNT3	NA	NA	NA	NA	NA	NA	NA	2.41 (0.06-13.43)
Non-infected	0.26 (0.14-0.49)	0.37 (0.25-0.56)	0.24 (0.10-0.54)	0.33 (0.18-0.60)	0.62 (0.43-0.89)	0.30 (0.18-0.50)	0.30 (0.18-0.50)	0.30 (0.18-0.50)
SARS-CoV-2 infection	NA	3.32 (0.08-18.48)	NA	NA	6.72 (0.17-37.45)	NA	NA	0.28 (0.04-1.83)
Anaphylaxis								
Unvaccinated	0.66 (0.54-0.80)	0.88 (0.70-1.12)	0.82 (0.57-1.18)	0.88 (0.75-1.02)	0.80 (0.58-1.10)	0.75 (0.62-0.90)	0.75 (0.62-0.90)	0.75 (0.62-0.90)
BNT1	1.25 (0.56-2.80)	1.31 (0.72-2.38)	1.09 (0.03-6.10)	1.09 (0.49-2.45)	1.38 (0.58-3.31)	2.09 (0.95-4.58)	1.48 (0.71-3.11)	1.15 (0.92-1.44)
BNT1BNT2	1.42 (0.68-2.95)	1.21 (0.61-2.41)	1.99 (0.05-11.10)	1.30 (0.35-4.91)	1.33 (0.74-2.41)	1.53 (0.40-5.88)	1.33 (0.65-2.70)	0.87 (0.52-1.45)
BNT1BNT2BNT3	3.27 (0.08-18.22)	NA	NA	NA	1.28 (0.03-7.11)	NA	NA	0.94 (0.23-3.89)
Non-infected	0.66 (0.54-0.80)	0.90 (0.71-1.15)	0.82 (0.57-1.17)	0.89 (0.76-1.03)	0.83 (0.61-1.12)	0.76 (0.63-0.92)	0.76 (0.63-0.92)	0.76 (0.63-0.92)
SARS-CoV-2 infection	0.74 (0.11-4.90)	1.25 (0.36-4.38)	0.53 (0.01-2.94)	2.24 (0.64-7.87)	0.70 (0.02-3.89)	NA	1.29 (0.37-4.54)	0.90 (0.59-1.35)
Concussion								
Unvaccinated	0.72 (0.51-1.02)	0.77 (0.57-1.03)	0.85 (0.68-1.07)	0.85 (0.65-1.12)	0.78 (0.67-0.90)	0.74 (0.54-1.02)	0.74 (0.54-1.02)	0.74 (0.54-1.02)
BNT1	0.99 (0.78-1.27)	0.95 (0.72-1.25)	0.89 (0.44-1.77)	1.02 (0.82-1.27)	0.95 (0.69-1.31)	0.91 (0.61-1.35)	0.96 (0.74-1.24)	0.94 (0.76-1.15)
BNT1BNT2	0.87 (0.74-1.03)	0.96 (0.70-1.31)	0.80 (0.51-1.27)	1.01 (0.86-1.19)	0.86 (0.62-1.18)	0.85 (0.58-1.25)	0.87 (0.63-1.19)	0.93 (0.86-1.01)

Table 3c: Sensitivity analyses for the Observed vs. Expected method in 5-to-19-year olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

Exposure	Boys	Girls	Age 5 to 11	Age 12 to 15	Age 16 to 19	7-days main risk period	14-days main risk period	90-days main risk period
BNT1BNT2BNT3	1.04 (0.49-2.22)	0.72 (0.39-1.36)	NA	2.02 (0.24-7.29)	0.77 (0.44-1.35)	0.62 (0.25-1.55)	0.85 (0.50-1.44)	0.67 (0.53-0.85)
Non-infected	0.72 (0.51-1.02)	0.77 (0.57-1.03)	0.85 (0.68-1.07)	0.85 (0.65-1.12)	0.78 (0.67-0.90)	0.74 (0.54-1.02)	0.74 (0.54-1.02)	0.74 (0.54-1.02)
SARS-CoV-2 infection	0.73 (0.43-1.25)	0.71 (0.42-1.18)	0.79 (0.49-1.27)	1.01 (0.63-1.62)	0.78 (0.48-1.27)	0.35 (0.13-0.98)	0.42 (0.22-0.82)	0.84 (0.55-1.28)

10.6.7 Table 4

Table 4: Case counts and person-years of follow-up in the SCCS, Poisson and Observed vs Expected analyses.

		SCCS		Poisson		Observed vs Expected	
	Exposure	**Number of cases**	**Person-years of follow-up**	**Number of cases**	**Person-years of follow-up**	**Number of cases**	**Number Expected**
Myocarditis							
	Unvaccinated	178	523.77	181	5322955.53	181	271.23
	BNT1	44	36.40	44	147886.50	44	14.91
	BNT1BNT2	45	29.25	45	113164.12	45	13.31
	BNT1BNT2BNT3	6	1.92	6	5043.71	6	1.74
	Non-infected	178	547.55	182	5329421.04	182	271.94
	SARS-CoV-2 infection	<5	1.74	<5	8696.79	<5	0.66
Pericarditis							
	Unvaccinated	112	279.06	114	5323112.16	114	148.05
	BNT1	7	13.94	7	117321.08	7	6.91
	BNT1BNT2	18	15.32	18	113174.18	18	7.79
	BNT1BNT2BNT3	<5	2.19	<5	8027.77	<5	1.43
	Non-infected	113	291.52	114	5329578.04	114	148.45
	SARS-CoV-2 infection	<5	1.19	<5	30536.48	<5	0.65
Myocarditis or Pericarditis							
	Unvaccinated	261	732.86	265	5322774.30	265	394.47
	BNT1	50	52.00	50	147874.36	50	22.30
	BNT1BNT2	59	41.17	59	113152.86	59	19.74
	BNT1BNT2BNT3	10	4.77	10	10334.25	10	3.54
	Non-infected	262	766.15	266	5329239.28	266	395.52

Table 4: Case counts and person-years of follow-up in the SCCS, Poisson and Observed vs Expected analyses.

		SCCS		Poisson		Observed vs Expected	
	Exposure	**Number of cases**	**Person-years of follow-up**	**Number of cases**	**Person-years of follow-up**	**Number of cases**	**Number Expected**
	SARS-CoV-2 infection	<5	3.47	<5	30534.48	<5	1.43
Thrombosis with thrombocytopenia syndrome							
	Unvaccinated	<5	2.95	<5	1099206.09	<5	4.13
	BNT1	0	0.23	0	30578.48	0	0.12
	BNT1BNT2	0	0.15	0	13612.52	0	0.06
	BNT1BNT2BNT3	0	0.08	0	1605.30	0	0.00
	Non-infected	<5	3.07	<5	1100394.53	<5	4.14
	SARS-CoV-2 infection	0	0.08	0	21240.23	0	0.08
Deep Vein Thrombosis (DVT)							
	Unvaccinated	158	313.62	160	5322886.24	160	272.30
	BNT1	14	23.52	14	147881.49	14	16.39
	BNT1BNT2	15	19.86	15	113161.13	15	14.30
	BNT1BNT2BNT3	<5	1.79	<5	6420.85	<5	1.69
	Non-infected	158	327.79	160	5329351.48	160	273.03
	SARS-CoV-2 infection	5	4.70	5	76280.34	5	3.52
Pulmonary Embolism (PE)							
	Unvaccinated	64	140.50	64	5323207.58	64	95.50
	BNT1	<5	3.96	<5	42128.48	<5	2.42
	BNT1BNT2	<5	7.34	<5	76179.35	<5	4.62
	BNT1BNT2BNT3	<5	0.71	<5	1604.36	<5	0.25

Table 4: Case counts and person-years of follow-up in the SCCS, Poisson and Observed vs Expected analyses.

		SCCS		Poisson		Observed vs Expected	
	Exposure	**Number of cases**	**Person-years of follow-up**	**Number of cases**	**Person-years of follow-up**	**Number of cases**	**Number Expected**
	Non-infected	63	147.68	64	5329673.60	64	95.82
	SARS-CoV-2 infection	<5	1.09	<5	33208.49	<5	0.77
Cerebral venous sinus thrombosis (CVST)							
	Unvaccinated	34	55.62	34	5323252.07	34	44.64
	BNT1	<5	0.69	<5	30578.59	<5	0.39
	BNT1BNT2	0	2.36	0	113185.11	0	1.81
	BNT1BNT2BNT3	0	0.31	0	10339.87	0	0.32
	Non-infected	33	57.40	34	5329718.44	34	44.74
	SARS-CoV-2 infection	<5	0.89	<5	21839.03	<5	0.12
Hepatic-portal-renal vein thrombosis (HPRVT)							
	Unvaccinated	13	22.70	14	5323243.93	14	68.06
	BNT1	0	1.84	0	147907.05	0	2.22
	BNT1BNT2	<5	0.53	<5	37835.67	<5	0.63
	BNT1BNT2BNT3	0	0.30	0	10340.18	0	0.14
	Non-infected	14	23.84	14	5329710.26	14	68.16
	SARS-CoV-2 infection	0	0.31	0	76288.06	0	1.00
Venous thromboembolism							
	Unvaccinated	245	493.40	248	5322662.37	248	452.37
	BNT1	18	36.06	18	147866.96	18	26.01
	BNT1BNT2	20	30.18	20	113148.02	20	22.52

Table 4: Case counts and person-years of follow-up in the SCCS, Poisson and Observed vs Expected analyses.

		SCCS		Poisson		Observed vs Expected	
	Exposure	**Number of cases**	**Person-years of follow-up**	**Number of cases**	**Person-years of follow-up**	**Number of cases**	**Number Expected**
	BNT1BNT2BNT3	<5	3.88	<5	8021.72	<5	3.23
	Non-infected	245	515.50	248	5329126.85	248	453.53
	SARS-CoV-2 infection	9	7.28	9	76276.51	9	5.97
Ischemic Stroke							
	Unvaccinated	68	108.73	68	5322930.70	68	257.64
	BNT1	6	5.27	6	103406.47	6	6.34
	BNT1BNT2	<5	2.64	<5	74829.39	<5	3.43
	BNT1BNT2BNT3	0	0.72	0	10339.21	0	0.56
	Non-infected	69	112.70	69	5329396.60	69	257.99
	SARS-CoV-2 infection	<5	0.46	<5	21238.03	<5	0.83
Myocardial Infarction							
	Unvaccinated	5	8.43	6	5323315.43	6	9.29
	BNT1	0	0.64	0	147909.94	0	0.52
	BNT1BNT2	0	0.29	0	113187.71	0	0.40
	BNT1BNT2BNT3	0	0.00	0	10340.91	0	0.09
	Non-infected	6	8.16	6	3015631.32	6	9.31
	SARS-CoV-2 infection	0	0.08	0	51777.71	0	0.09
Arterial Thromboembolism							
	Unvaccinated	82	136.82	83	5322863.74	83	291.88
	BNT1	8	6.88	8	103403.75	8	7.68

Table 4: Case counts and person-years of follow-up in the SCCS, Poisson and Observed vs Expected analyses.

		SCCS		Poisson		Observed vs Expected	
	Exposure	**Number of cases**	**Person-years of follow-up**	**Number of cases**	**Person-years of follow-up**	**Number of cases**	**Number Expected**
	BNT1BNT2	<5	3.54	<5	74826.83	<5	4.42
	BNT1BNT2BNT3	0	0.88	0	10338.54	0	0.85
	Non-infected	84	141.88	84	5329329.48	84	292.31
	SARS-CoV-2 infection	<5	0.69	<5	21237.57	<5	0.90
Anaphylaxis							
	Unvaccinated	494	910.87	503	5321403.87	503	683.18
	BNT1	23	40.65	23	147831.90	23	22.62
	BNT1BNT2	20	32.04	20	113124.03	20	18.18
	BNT1BNT2BNT3	<5	2.07	<5	2732.08	<5	0.79
	Non-infected	506	935.04	509	5327866.96	509	684.19
	SARS-CoV-2 infection	6	14.90	6	76259.21	6	9.37
Concussion							
	Unvaccinated	12059	22257.31	12343	5273891.63	12343	16135.70
	BNT1	531	898.56	531	146070.70	531	540.03
	BNT1BNT2	384	668.18	384	111753.37	384	418.29
	BNT1BNT2BNT3	32	58.54	32	10204.21	32	41.97
	Non-infected	12337	22788.42	12359	5280277.63	12359	16159.48
	SARS-CoV-2 infection	181	414.14	181	75348.99	181	239.04

10.6.8 Table 5

Table 5: Overview of the cases excluded in wash out period.

Outcome	Denmark	Finland	Sweden	Norway
Myocarditis	31	126	198	38
Pericarditis	50	35	100	55
Myocarditis or Pericarditis	69	157	283	84
Thromboembolism and Thrombocytopenia syndrome	0	<5	0	8
Deep Vein Thrombosis (DVT)	111	98	208	88
Pulmonary Embolism (PE)	25	24	79	28
Cerebral venous sinus thrombosis (CVST)	15	21	22	12
Hepatic-portal-renal vein thrombosis (HPRVT)	16	24	15	27
Venous thromboembolism	161	155	287	139
Ischemic Stroke	61	136	103	96
Myocardial Infarction	5	6	<5	<5
Arterial Thromboembolism	81	148	132	111
Anaphylaxis	99	553	651	394
Concussion	7821	14081	9643	11538

10.6.9 Table 6

Table 6: Incidence rates (per 100,000 person-years of follow-up) of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

	Age 5-11			Age 12-15			Age 16-19		
Event	**Number of cases**	**Person-years of follow-up**	**Incidence rate**	**Number of cases**	**Person-years of follow-up**	**Incidence rate**	**Number of cases**	**Person-years of follow-up**	**Incidence rate**
Myocarditis	16	1920643.6	0.83	102	1782684.0	5.72	399	1634411.0	24.41
Pericarditis	16	1920632.5	0.83	39	1782756.5	2.19	179	1634752.1	10.95
Myocarditis or Pericarditis	29	1920605.0	1.51	138	1782621.2	7.74	522	1634167.9	31.94
Thrombosis with thrombocytopenia syndrome	<5	NA	0.15	<5	NA	0.36	0	0.0	NA
Deep vein thrombosis (DVT)	18	1920582.9	0.94	62	1782669.6	3.48	205	1634509.8	12.54
Pulmonary Embolism (PE)	<5	NA	0.22	19	1782800.3	1.07	102	1634838.9	6.24
Cerebral venous sinus thrombosis (CVST)	8	1392902.2	0.57	13	1782794.2	0.73	29	1635002.5	1.77
Hepatic-portal-renal vein thrombosis (HPRVT)	<5	NA	0.24	9	1782778.4	0.51	9	1314557.8	0.68
Venous thromboembolism	31	1920510.8	1.61	89	1782591.6	5.00	321	1634256.4	19.64
Ischemic Stroke	21	1920458.6	1.09	29	1782659.8	1.63	54	1634857.0	3.30
Myocardial Infarction	<5	NA	0.15	<5	NA	0.15	<5	NA	0.53
Arterial Thromboembolism	25	1920432.0	1.30	36	1782636.6	2.02	69	1634799.5	4.22
Anaphylaxis	188	1919762.9	9.79	258	1781951.0	14.48	299	1633990.4	18.30
Concussion	6072	1892381.6	320.87	5689	1762351.1	322.81	5278	1614158.8	326.98

10.6.10 Table 7

Table 7: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark in the 1 January 2021 to 31 October 2022 study period

		SCCS		Poisson		Observed vs Expected	
	Exposure	**Number of cases**	**Estimate (CI)**	**Number of cases**	**Estimate (CI)**	**Number of cases**	**Estimate (CI)**
Myocarditis							
	Unvaccinated	18	1 (ref)	18	1 (ref)	18	1.52 (0.90-2.40)
	BNT1	9	4.79 (1.59-14.45)	9	3.39 (1.42-8.11)	9	7.06 (3.23-13.40)
	BNT1BNT2	6	4.49 (1.16-17.44)	6	2.13 (0.72-6.30)	6	4.91 (1.80-10.69)
	BNT1BNT2BNT3	0	NA	0	NA	0	0.00 (0.00-11.53)
	Non-infected	17	1 (ref)	18	1 (ref)	18	1.51 (0.90-2.39)
	SARS-CoV-2 infection	0	NA	0	NA	0	0.00 (0.00-17.44)
Pericarditis							
	Unvaccinated	21	1 (ref)	22	1 (ref)	22	0.81 (0.51-1.23)
	BNT1	<5	1.66 (0.48-5.80)	<5	1.08 (0.35-3.29)	<5	1.36 (0.37-3.49)
	BNT1BNT2	7	4.27 (1.15-15.87)	7	1.92 (0.66-5.60)	7	2.49 (1.00-5.14)
	BNT1BNT2BNT3	<5	3.18 (0.24-42.32)	<5	0.90 (0.10-7.89)	<5	1.33 (0.03-7.43)
	Non-infected	22	1 (ref)	22	1 (ref)	22	0.81 (0.51-1.22)
	SARS-CoV-2 infection	<5	2.74 (0.18-42.78)	<5	1.90 (0.22-16.35)	<5	2.06 (0.05-11.48)
Myocarditis or pericarditis							
	Unvaccinated	34	1 (ref)	35	1 (ref)	35	1.00 (0.69-1.39)
	BNT1	13	2.92 (1.29-6.64)	13	2.29 (1.16-4.52)	13	3.45 (1.84-5.89)
	BNT1BNT2	12	3.72 (1.41-9.83)	12	2.01 (0.92-4.42)	12	3.33 (1.72-5.81)
	BNT1BNT2BNT3	<5	2.16 (0.20-23.06)	<5	0.63 (0.08-5.11)	<5	1.05 (0.03-5.85)

Table 7: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark in the 1 January 2021 to 31 October 2022 study period

		SCCS		Poisson		Observed vs Expected	
	Exposure	**Number of cases**	**Estimate (CI)**	**Number of cases**	**Estimate (CI)**	**Number of cases**	**Estimate (CI)**
	Non-infected	34	1 (ref)	35	1 (ref)	35	0.99 (0.69-1.38)
	SARS-CoV-2 infection	<5	1.38 (0.12-15.57)	<5	0.90 (0.11-7.31)	<5	1.58 (0.04-8.81)
Thrombosis with thrombocytopenia syndrome							
	Unvaccinated	0	1 (ref)	0	1 (ref)	0	NA
	BNT1	0	NA	0	NA	0	NA
	BNT1BNT2	0	NA	0	NA	0	NA
	BNT1BNT2BNT3	0	NA	0	NA	0	NA
	Non-infected	0	1 (ref)	0	1 (ref)	0	NA
	SARS-CoV-2 infection	0	NA	0	NA	0	NA
Deep Vein Thrombosis (DVT)							
	Unvaccinated	29	1 (ref)	29	1 (ref)	29	0.61 (0.41-0.88)
	BNT1	<5	0.50 (0.11-2.31)	<5	0.63 (0.14-2.75)	<5	0.42 (0.05-1.52)
	BNT1BNT2	<5	0.81 (0.18-3.63)	<5	1.15 (0.29-4.57)	<5	0.67 (0.14-1.96)
	BNT1BNT2BNT3	<5	0.68 (0.05-9.22)	<5	1.53 (0.16-14.24)	<5	0.97 (0.02-5.39)
	Non-infected	29	1 (ref)	29	1 (ref)	29	0.61 (0.41-0.87)
	SARS-CoV-2 infection	<5	1.76 (0.16-19.08)	<5	3.21 (0.42-24.40)	<5	1.07 (0.03-5.98)
Pulmonary Embolism (PE)							
	Unvaccinated	7	1 (ref)	7	1 (ref)	7	0.48 (0.19-0.99)
	BNT1	0	NA	0	NA	0	0.00 (0.00-2.20)
	BNT1BNT2	0	NA	0	NA	0	0.00 (0.00-2.28)

Table 7: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark in the 1 January 2021 to 31 October 2022 study period

		SCCS		Poisson		Observed vs Expected	
	Exposure	**Number of cases**	**Estimate (CI)**	**Number of cases**	**Estimate (CI)**	**Number of cases**	**Estimate (CI)**
	BNT1BNT2BNT3	0	NA	0	NA	0	0.00 (0.00-9.36)
	Non-infected	7	1 (ref)	7	1 (ref)	7	0.48 (0.19-0.99)
	SARS-CoV-2 infection	0	NA	0	NA	0	0.00 (0.00-14.71)
Cerebral venous sinus thrombosis (CVST)							
	Unvaccinated	<5	1 (ref)	<5	1 (ref)	<5	0.37 (0.04-1.33)
	BNT1	0	NA	0	NA	0	0.00 (0.00-7.66)
	BNT1BNT2	0	NA	0	NA	0	0.00 (0.00-8.29)
	BNT1BNT2BNT3	0	NA	0	NA	0	0.00 (0.00-32.02)
	Non-infected	<5	1 (ref)	<5	1 (ref)	<5	0.37 (0.04-1.33)
	SARS-CoV-2 infection	<5	NA	<5	15.57 (1.14-212.02)	<5	8.49 (0.21-47.31)
Hepatic-portal-renal vein thrombosis (HPRVT)							
	Unvaccinated	<5	1 (ref)	<5	1 (ref)	<5	0.46 (0.12-1.17)
	BNT1	0	NA	0	NA	0	0.00 (0.00-7.83)
	BNT1BNT2	0	NA	0	NA	0	0.00 (0.00-9.50)
	BNT1BNT2BNT3	0	NA	0	NA	0	0.00 (0.00-157.86)
	Non-infected	<5	1 (ref)	<5	1 (ref)	<5	0.45 (0.12-1.16)
	SARS-CoV-2 infection	0	NA	0	NA	0	0.00 (0.00-14.98)
Venous thromboembolism							
	Unvaccinated	39	1 (ref)	39	1 (ref)	39	0.54 (0.38-0.74)
	BNT1	<5	0.36 (0.08-1.64)	<5	0.50 (0.12-2.14)	<5	0.29 (0.03-1.04)
	BNT1BNT2	<5	0.59 (0.14-2.45)	<5	0.93 (0.25-3.51)	<5	0.46 (0.09-1.35)

Table 7: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark in the 1 January 2021 to 31 October 2022 study period

		SCCS		Poisson		Observed vs Expected	
	Exposure	**Number of cases**	**Estimate (CI)**	**Number of cases**	**Estimate (CI)**	**Number of cases**	**Estimate (CI)**
	BNT1BNT2BNT3	<5	0.48 (0.04-5.58)	<5	1.52 (0.17-13.33)	<5	0.68 (0.02-3.80)
	Non-infected	39	1 (ref)	39	1 (ref)	39	0.54 (0.38-0.73)
	SARS-CoV-2 infection	<5	3.05 (0.50-18.77)	<5	4.59 (1.07-19.66)	<5	1.35 (0.16-4.89)
Ischemic Stroke							
	Unvaccinated	6	1 (ref)	6	1 (ref)	6	0.24 (0.09-0.51)
	BNT1	0	NA	0	NA	0	0.00 (0.00-2.63)
	BNT1BNT2	<5	19.84 (0.64-618.87)	<5	21.53 (0.94-492.73)	<5	0.86 (0.02-4.77)
	BNT1BNT2BNT3	0	NA	0	NA	0	0.00 (0.00-20.19)
	Non-infected	6	1 (ref)	6	1 (ref)	6	0.24 (0.09-0.51)
	SARS-CoV-2 infection	0	NA	0	NA	0	0.00 (0.00-5.40)
Myocardial Infarction							
	Unvaccinated	<5	1 (ref)	<5	1 (ref)	<5	0.97 (0.02-5.40)
	BNT1	0	NA	0	NA	0	0.00 (0.00-34.14)
	BNT1BNT2	0	NA	0	NA	0	0.00 (0.00-35.95)
	BNT1BNT2BNT3	0	NA	0	NA	0	0.00 (0.00-194.61)
	Non-infected	<5	1 (ref)	<5	1 (ref)	<5	0.96 (0.02-5.37)
	SARS-CoV-2 infection	0	NA	0	NA	0	0.00 (0.00-204.88)
Arterial Thromboembolism							
	Unvaccinated	10	1 (ref)	10	1 (ref)	10	0.33 (0.16-0.60)
	BNT1	0	NA	0	NA	0	0.00 (0.00-2.02)

Table 7: Relative risks of myocarditis, pericarditis and thromboembolic events in 5-to-19-year-olds in Denmark in the 1 January 2021 to 31 October 2022 study period

		SCCS		Poisson		Observed vs Expected	
	Exposure	**Number of cases**	**Estimate (CI)**	**Number of cases**	**Estimate (CI)**	**Number of cases**	**Estimate (CI)**
	BNT1BNT2	<5	4.08 (0.28-59.37)	<5	3.54 (0.31-40.92)	<5	0.64 (0.02-3.58)
	BNT1BNT2BNT3	0	NA	0	NA	0	0.00 (0.00-14.02)
	Non-infected	10	1 (ref)	10	1 (ref)	10	0.33 (0.16-0.60)
	SARS-CoV-2 infection	0	NA	0	NA	0	0.00 (0.00-4.63)
Anaphylaxis							
	Unvaccinated	25	1 (ref)	25	1 (ref)	25	0.71 (0.46-1.04)
	BNT1	<5	2.48 (0.69-8.90)	<5	2.73 (0.85-8.75)	<5	1.64 (0.45-4.21)
	BNT1BNT2	<5	1.55 (0.28-8.43)	<5	1.59 (0.33-7.69)	<5	0.94 (0.11-3.40)
	BNT1BNT2BNT3	0	NA	0	NA	0	0.00 (0.00-17.09)
	Non-infected	25	1 (ref)	25	1 (ref)	25	0.70 (0.46-1.04)
	SARS-CoV-2 infection	<5	2.54 (0.22-28.92)	<5	2.12 (0.26-17.32)	<5	1.14 (0.03-6.36)
Concussion							
	Unvaccinated	1445	1 (ref)	1503	1 (ref)	1503	0.66 (0.63-0.69)
	BNT1	87	0.99 (0.78-1.26)	87	0.90 (0.72-1.12)	87	0.64 (0.52-0.79)
	BNT1BNT2	75	1.07 (0.82-1.39)	75	0.93 (0.72-1.19)	75	0.66 (0.52-0.82)
	BNT1BNT2BNT3	6	1.00 (0.43-2.33)	6	0.76 (0.34-1.72)	6	0.43 (0.16-0.94)
	Non-infected	1503	1 (ref)	1507	1 (ref)	1507	0.66 (0.63-0.69)
	SARS-CoV-2 infection	35	0.79 (0.55-1.15)	35	0.89 (0.63-1.26)	35	0.58 (0.40-0.81)

10.6.11 Table 8

Table 8: Excess risks of myocarditis, pericarditis and thromboembolic events in 5-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		Age 5-11 yrs			Age 12-15 yrs			Age 16-19 yrs		
	Exposure	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**
Myocarditis										
	Unvaccinated	14	1 (ref)	NA	34	1 (ref)	NA	133	1 (ref)	NA
	BNT1	<19	10.18 (0.63-163.98)	0.57 (-0.37-0.63)	<19	5.26 (2.64-10.45)	1.75 (1.34-1.95)	25	1.96 (1.22-3.15)	1.46 (0.54-2.03)
	BNT1BNT2	0	NA	NA	11	4.36 (1.95-9.77)	1.52 (0.96-1.77)	34	2.52 (1.44-4.42)	2.66 (1.34-3.42)
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	6	4.92 (2.05-11.84)	7.70 (4.94-8.84)
	Non-infected	14	1 (ref)	NA	34	1 (ref)	NA	134	1 (ref)	NA
	SARS-CoV-2 infection	0	NA	NA	<5	8.39 (0.81-86.82)	3.55 (-0.93-3.98)	0	NA	NA
Pericarditis										
	Unvaccinated	14	1 (ref)	NA	25	1 (ref)	NA	75	1 (ref)	NA
	BNT1	<7	16.57 (0.86-319.49)	1.04 (-0.18-1.11)	<7	2.40 (0.43-13.55)	0.23 (-0.53-0.37)	<7	0.73 (0.24-2.16)	-0.32 (-2.66-0.46)
	BNT1BNT2	0	NA	NA	<18	6.36 (1.45-27.80)	0.55 (0.20-0.63)	<18	2.32 (1.18-4.56)	1.11 (0.30-1.52)
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	<5	7.18 (0.56-91.69)	3.32 (-3.01-3.82)
	Non-infected	14	1 (ref)	NA	25	1 (ref)	NA	75	1 (ref)	NA
	SARS-CoV-2 infection	0	NA	NA	<5	7.98 (1.03-61.67)	2.22 (0.08-2.50)	0	NA	NA
Myocarditis or pericarditis										
	Unvaccinated	25	1 (ref)	NA	56	1 (ref)	NA	184	1 (ref)	NA

Table 8: Excess risks of myocarditis, pericarditis and thromboembolic events in 5-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		Age 5-11 yrs			Age 12-15 yrs			Age 16-19 yrs		
	Exposure	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**
	BNT1	<22	3.51 (0.70-17.77)	0.58 (-0.35-0.76)	<22	4.47 (2.38-8.39)	1.86 (1.39-2.11)	28	1.53 (0.99-2.37)	1.16 (-0.02-1.93)
	BNT1BNT2	0	NA	NA	14	4.92 (2.44-9.92)	1.94 (1.44-2.19)	45	2.47 (1.45-4.21)	3.48 (1.81-4.46)
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	10	4.30 (1.25-14.78)	5.88 (1.55-7.14)
	Non-infected	25	1 (ref)	NA	56	1 (ref)	NA	185	1 (ref)	NA
	SARS-CoV-2 infection	0	NA	NA	<5	4.33 (0.81-23.22)	1.95 (-0.60-2.43)	0	NA	NA
Thrombosis with thrombocytopenia syndrome										
	Unvaccinated	<5	1 (ref)	NA	<5	1 (ref)	NA	NA	1 (ref)	NA
	BNT1	0	NA	NA	0	NA	NA	NA	NA	NA
	BNT1BNT2	0	NA	NA	0	NA	NA	NA	NA	NA
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	NA	NA	NA
	Non-infected	<5	1 (ref)	NA	<5	1 (ref)	NA	NA	1 (ref)	NA
	SARS-CoV-2 infection	0	NA	NA	0	NA	NA	NA	NA	NA
Deep Vein Thrombosis (DVT)										
	Unvaccinated	16	1 (ref)	NA	37	1 (ref)	NA	107	1 (ref)	NA
	BNT1	0	NA	NA	0	NA	NA	14	1.58 (0.85-2.94)	0.62 (-0.29-1.10)
	BNT1BNT2	0	NA	NA	<15	4.47 (1.15-17.32)	0.84 (0.14-1.02)	<15	1.71 (0.67-4.35)	0.59 (-0.70-1.10)
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	<5	2.44 (0.50-11.88)	1.43 (-2.39-2.21)
	Non-infected	16	1 (ref)	NA	37	1 (ref)	NA	107	1 (ref)	NA

Table 8: Excess risks of myocarditis, pericarditis and thromboembolic events in 5-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		Age 5-11 yrs			Age 12-15 yrs			Age 16-19 yrs		
	Exposure	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**
	SARS-CoV-2 infection	0	NA	NA	<5	73.05 (4.00-1335.77)	1.46 (1.11-1.48)	<5	4.94 (1.78-13.75)	2.92 (1.60-3.39)
Pulmonary Embolism (PE)										
	Unvaccinated	<11	1 (ref)	NA	<11	1 (ref)	NA	53	1 (ref)	NA
	BNT1	0	NA	NA	<5	1.74 (0.15-19.97)	0.14 (-1.85-0.31)	<5	2.18 (0.56-8.45)	0.66 (-0.96-1.08)
	BNT1BNT2	0	NA	NA	0	NA	NA	<5	1.23 (0.40-3.79)	0.14 (-1.07-0.53)
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	<5	10.46 (0.82-133.07)	4.36 (-1.05-4.78)
	Non-infected	<11	1 (ref)	NA	<11	1 (ref)	NA	53	1 (ref)	NA
	SARS-CoV-2 infection	0	NA	NA	0	NA	NA	<5	6.41 (1.24-33.13)	3.21 (0.74-3.69)
Cerebral venous sinus thrombosis (CVST)										
	Unvaccinated	8	1 (ref)	NA	11	1 (ref)	NA	15	1 (ref)	NA
	BNT1	0	NA	NA	0	NA	NA	<5	7.92 (0.31-205.25)	0.43 (-1.13-0.49)
	BNT1BNT2	0	NA	NA	0	NA	NA	0	NA	NA
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	0	NA	NA
	Non-infected	8	1 (ref)	NA	11	1 (ref)	NA	15	1 (ref)	NA
	SARS-CoV-2 infection	0	NA	NA	0	NA	NA	<5	NA	NA
Hepatic-portal-renal vein thrombosis (HPRVT)										
	Unvaccinated	<8	1 (ref)	NA	6	1 (ref)	NA	<8	1 (ref)	NA
	BNT1	0	NA	NA	0	NA	NA	0	NA	NA

Table 8: Excess risks of myocarditis, pericarditis and thromboembolic events in 5-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		Age 5-11 yrs			Age 12-15 yrs			Age 16-19 yrs		
	Exposure	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**
	BNT1BNT2	0	NA	NA	<5	3.77 (0.23-61.11)	0.29 (-1.30-0.39)	0	NA	NA
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	0	NA	NA
	Non-infected	<8	1 (ref)	NA	6	1 (ref)	NA	<8	1 (ref)	NA
	SARS-CoV-2 infection	0	NA	NA	0	NA	NA	0	NA	NA
Venous thromboembolism										
	Unvaccinated	29	1 (ref)	NA	52	1 (ref)	NA	167	1 (ref)	NA
	BNT1	0	NA	NA	<18	0.86 (0.10-7.37)	-0.06 (-2.98-0.28)	<18	1.38 (0.80-2.39)	0.56 (-0.52-1.18)
	BNT1BNT2	0	NA	NA	5	5.36 (1.65-17.41)	1.10 (0.54-1.28)	15	1.57 (0.67-3.67)	0.71 (-0.95-1.42)
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	<5	3.80 (1.05-13.76)	2.14 (0.13-2.69)
	Non-infected	29	1 (ref)	NA	52	1 (ref)	NA	167	1 (ref)	NA
	SARS-CoV-2 infection	0	NA	NA	<9	23.91 (2.01-284.77)	1.42 (0.74-1.47)	<9	6.19 (2.54-15.05)	6.14 (4.44-6.83)
Ischemic Stroke										
	Unvaccinated	19	1 (ref)	NA	17	1 (ref)	NA	32	1 (ref)	NA
	BNT1	<6	62.04 (3.90-986.52)	17.31 (13.09-17.58)	<6	12.08 (1.04-139.95)	1.34 (0.06-1.45)	<6	1.26 (0.34-4.66)	0.14 (-1.29-0.53)
	BNT1BNT2	0	NA	NA	<5	13.06 (0.85-201.42)	0.42 (-0.08-0.45)	<5	0.91 (0.11-7.55)	-0.04 (-3.38-0.36)
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	0	NA	NA
	Non-infected	19	1 (ref)	NA	18	1 (ref)	NA	32	1 (ref)	NA

Table 8: Excess risks of myocarditis, pericarditis and thromboembolic events in 5-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		Age 5-11 yrs			Age 12-15 yrs			Age 16-19 yrs		
	Exposure	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**
	SARS-CoV-2 infection	0	NA	NA	0	NA	NA	<5	18.04 (2.10-155.02)	3.48 (1.93-3.66)
Myocardial Infarction										
	Unvaccinated	<6	1 (ref)	NA	0	1 (ref)	NA	<6	1 (ref)	NA
	BNT1	0	NA	NA	0	NA	NA	0	NA	NA
	BNT1BNT2	0	NA	NA	0	NA	NA	0	NA	NA
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	0	NA	NA
	Non-infected	<6	1 (ref)	NA	NA	1 (ref)	NA	<6	1 (ref)	NA
	SARS-CoV-2 infection	0	NA	NA	NA	NA	NA	0	NA	NA
Arterial Thromboembolism										
	Unvaccinated	23	1 (ref)	NA	19	1 (ref)	NA	41	1 (ref)	NA
	BNT1	<8	67.48 (4.39-1036.97)	17.34 (13.59-17.58)	<8	5.39 (0.95-30.57)	0.55 (-0.04-0.66)	<8	1.54 (0.49-4.89)	0.32 (-0.94-0.71)
	BNT1BNT2	0	NA	NA	<5	5.62 (0.49-64.23)	0.37 (-0.47-0.44)	<5	0.96 (0.12-7.82)	-0.02 (-3.16-0.37)
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	0	NA	NA
	Non-infected	23	1 (ref)	NA	20	1 (ref)	NA	41	1 (ref)	NA
	SARS-CoV-2 infection	0	NA	NA	0	NA	NA	<5	13.71 (1.68-111.90)	3.41 (1.49-3.65)
Anaphylaxis										
	Unvaccinated	175	1 (ref)	NA	172	1 (ref)	NA	156	1 (ref)	NA
	BNT1	<9	0.89 (0.12-6.77)	-0.14 (-8.47-0.95)	<9	1.44 (0.40-5.20)	0.35 (-1.71-0.93)	14	1.35 (0.49-3.70)	0.43 (-1.72-1.22)

Table 8: Excess risks of myocarditis, pericarditis and thromboembolic events in 5-19-year-olds in Denmark, Finland, Norway and Sweden in the 1 January 2021 to 31 October 2022 study period

		Age 5-11 yrs			Age 12-15 yrs			Age 16-19 yrs		
	Exposure	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**	**Number of cases**	**Relative risk (95% CI)**	**Excess risk per 100,000 vaccinations**
	BNT1BNT2	<6	1.50 (0.20-11.07)	0.67 (-7.93-1.83)	<6	1.56 (0.24-10.05)	0.32 (-2.82-0.81)	14	1.52 (0.83-2.76)	0.62 (-0.36-1.16)
	BNT1BNT2BNT3	0	NA	NA	0	NA	NA	<5	1.25 (0.17-9.34)	0.58 (-14.07-2.54)
	Non-infected	175	1 (ref)	NA	174	1 (ref)	NA	160	1 (ref)	NA
	SARS-CoV-2 infection	<6	0.91 (0.12-6.95)	-0.05 (-4.03-0.47)	<6	2.92 (1.03-8.30)	1.55 (0.07-2.07)	<6	0.71 (0.10-5.10)	-0.66 (-14.62-1.29)
Concussion										
	Unvaccinated	5749	1 (ref)	NA	3897	1 (ref)	NA	2697	1 (ref)	NA
	BNT1	54	0.98 (0.73-1.32)	-0.37 (-7.83-5.20)	224	1.17 (1.01-1.35)	3.86 (0.20-7.03)	253	0.94 (0.65-1.37)	-1.89 (-16.64-8.25)
	BNT1BNT2	25	0.90 (0.60-1.35)	-2.19 (-13.04-5.05)	153	1.23 (1.03-1.47)	5.05 (0.84-8.58)	206	0.89 (0.57-1.38)	-3.33 (-20.14-7.50)
	BNT1BNT2BNT3	0	NA	NA	<32	2.30 (0.57-9.28)	37.44 (-49.50-59.02)	<32	0.97 (0.64-1.48)	-0.67 (-13.12-7.52)
	Non-infected	5752	1 (ref)	NA	3902	1 (ref)	NA	2705	1 (ref)	NA
	SARS-CoV-2 infection	92	0.90 (0.65-1.24)	-2.28 (-10.90-3.97)	59	1.13 (0.82-1.55)	2.80 (-5.60-8.90)	30	0.97 (0.66-1.43)	-0.72 (-11.67-6.70)

11. DISCUSSION

11.1 Key results

Vaccination

In this large multi-country cohort study of COVID-19 vaccination in 5-to-19-year-olds and myocarditis, pericarditis and thromboembolic events, we observed that the BNT-vaccine was associated with myocarditis and pericarditis. The myocarditis association was present in the 28-day main risk period after both BNT1 (RR 2.75, 95% CI, 1.92-3.95), BNT1BNT2 (RR 2.81, 95% CI, 1.94-4.07), and BNT1BNT2BNT3 (RR 5.30, 95% CI, 2.24-12.53); Table 2(contemporary cohort analyses). The association was robust across analytical approaches, and was strongest in boys, in 12-to-15-year-olds (for the BNT1 and BNT1BNT2 associations) and in the 7-day main risk period; Table 3b.

The pericarditis association was present in the 28-day main risk period after BNT1BNT2 (RR 2.58, 95% CI, 1.44-4.63) and BNT1BNT2BNT3 (RR 6.24, 95% CI, 0.81-47.85); Table 2(contemporary cohort analyses). While the BNT1BNT2BNT3 association did not reach statistical significance in the contemporary cohort analysis, the confidence interval was broadly compatible with an increased risk, and both alternative analytical approaches showed strong associations between BNT1BNT2BNT3 and pericarditis. The pericarditis association was strongest in girls, in 12-to-15-year olds and in the 7-day main risk period; Table 3b. However, in the Denmark-only results, the pericarditis association was only present after BNT1BNT2 in the SCCS- and Observed vs Expected analysis; Table 7.

Most of the thromboembolic outcomes were rarely observed after vaccination. Of particular note, we did not observe any cases of thromboembolism with thrombocytopenia after vaccination; Table 2. We did not observe any associations between vaccination and cerebral venous sinus thrombosis, hepatic-portal-renal vein thrombosis, venous thromboembolism, ischemic stroke, and myocardial infarction.

BNT1BNT2 was associated with deep vein thrombosis in the 28-day main risk period (RR 1.99, 95% CI, 1.05-3.78); Table 2, contemporary cohort analysis. However, this association was not replicated in either the SCCS analysis, the Observed vs Expected analysis or any analyses on Danish data only; Table 7.

BNT1BNT2BNT3 was associated with pulmonary embolism in the 28-day main risk period (RR 18.71, 95% CI, 1.51-232.26; Table 2, contemporary cohort analysis), but this was not consistent across analytical methods and was based on very few events from Norway only. In Denmark, no cases of pulmonary embolism were observed after BNT1, BNT1BNT2 or BNT1BNT2BNT3; Table 7.

BNT1 was associated with arterial thromboembolism in the 28-day main risk period (RR 2.59, 95% CI, 1.16-5.79); Table 2, contemporary cohort analysis. The SCCS analysis result was largely compatible with this (RR 2.00, 95% CI, 0.82-4.85), but in the Danish cohort there were no cases after BNT1; Table 7.

SARS-CoV-2 Infection

Both myocarditis and pericarditis were rare after infection. We did not observe any association between infection and myocarditis in the 28-day main risk period; Table 2. There was some support for an increased risk of pericarditis, but not consistently across analytical approaches and confidence intervals were wide; Table 2.

Thromboembolic events were rare after SARS-CoV-2 infection. We observed associations between infection and deep vein thrombosis, pulmonary embolism and cerebral venous sinus thrombosis, but not consistently across analytical methods; Table 2. There was little support for an association with ischemic stroke, myocardial infarction and arterial thromboembolism; Table 2.

11.2 Limitations

Despite the multi-country nature of our study with a combined cohort size of 5.1 million 5-to-19-year-olds, the study outcomes are still rare and especially so in the main risk periods following vaccination. In many situations where we do not observe an association, the confidence intervals are still quite wide and compatible with a wide range of effects from protective effects to increased risks. Consequently, in many cases, even though we do not observe an association, we are not able to provide strong evidence against an association.

We do not take multiple testing into account in our presentation of statistical precision. We evaluate the association between 3 exposure categories (in the evaluation of vaccination, BNT1, BNT1BNT2 and BNT1BNT2BNT3) and 12 study outcomes using 3 different analytical approaches. Assuming independence between these 108 analyses, we would expect 5 false-positive associations by chance alone. The issue of multiple testing is further compounded in the sex-, age-, and main-risk period stratified subgroup analyses; 8 stratified analyses for each of the 108 main analyses (864 analyses). Thus, subgroup analyses should be considered primarily descriptive. This is particularly warranted where we do not observe an association in the main analysis.

Our meta-analysis approach has the limitation that when pooling the adjusted RR estimates, we do not utilise estimates from a country if there are no study outcomes in either the main-risk or unvaccinated periods. As the main-risk periods are shorter than the unvaccinated periods, this exclusion is more likely to be due to no events in the main risk period, which can

lead to underrepresentation of the follow-up time during the main risk period in the meta-analysis. This may, in turn, lead to an overestimation of the relative risks of the study outcomes.

The validity of the hospital-register data and the diagnoses used is considered high. Evaluations of the validity of cardiovascular diagnoses coded using ICD-10 indicates high positive predictive value, especially in <60-year-olds.[25]. However, the validity of cardiovascular diagnoses in the 5-to-19-year-old population has not been evaluated separately, and we cannot directly infer high validity from evaluations in a middle-aged population.

Our results are susceptible to surveillance bias. The majority of follow-up among vaccinated in our cohort occurs after the thromboses with thrombocytopenia- and myocarditis signals were made public in the first half of 2021. Thus, we cannot exclude that surveillance bias, whereby clinicians are more likely to 1) assign the specific study outcome diagnoses, 2) diagnose subclinical outcomes, or 3) diagnose earlier, in the more immediate periods after vaccination, influences our results. We did include positive controls (anaphylaxis) and negative controls (concussion). We did not find any associations with anaphylaxis in the 28-day main risk period. This may be due to vaccination not increasing the risk of anaphylaxis in this population or the risk being attenuated by the duration of the main risk period. We observed a slight increase in the risk of concussion. This may well reflect small residual differences in health-care seeking behaviour between vaccinated and unvaccinated children.

Using positive tests to assess infections will underestimate the number of infections, and infected follow-up will be misclassified as un-infected which will attenuate any increased risks. This attenuation is most likely limited, since cumulative follow-up from misclassified 28-day main risk periods is modest compared to all follow-up in the un-infected group. However, we will overestimate the absolute risks of the study outcomes following infection since the denominator of all positive tests will be smaller than all infections. The impact of this bias is country-specific and greatest in Finland (21.2% of all cohort participants tested positive by study end; Table 1) and Sweden (23.1%), moderate in Norway (40.2%) and small in Denmark (70.9%).

A strength of our study is the use of three different complementary analytical approaches. However, each approach has limitations that warrants mentioning. The SCCS analysis relies on the assumption that experiencing a study outcome is not related to future vaccination propensity. We do utilise a 14-day pre-risk period, but cannot discount that experiencing a study outcome affects vaccination propensity beyond 14-days. In the most likely scenario where vaccination propensity decreases after an outcome, the resulting bias will be in the direction of an increased risk in the main risk period. An alternative to using the SCCS method

with a pre-risk period, is to use the modified SCCS method for event-dependent exposures.[38] The modified method allows for events which contraindicates exposure or prevents further observation such as death. However, this comes at a cost. The modified method is less statistically efficient which is an important issue when studying rare events. In our setting, the SCCS method does not stand alone and is complemented by the contemporary cohort analysis and the Observed vs Expected analysis. The results observed across the different methods were broadly compatible, which supports the internal validity of our results, also from the standard SCCS method.

The contemporary cohort analysis assumes that all potential confounding is taken into account by the inclusion of covariates in the regression model. A main source of potential confounding is confounding-by-indication whereby children and adolescents at high risk of severe COVID-19 due to underlying health conditions are offered vaccination before or with more doses than the general 5-to-19-year old population. These underlying health conditions might also be risk factors for the study outcomes. We do include adjustment for comorbidities, but cannot exclude residual confounding. In Denmark, where uptake was higher, and vaccinations were recommended by authorities to all 5-to-19-year olds and confounding-by-indication is thus less likely to have a measurable impact, we observe more null findings compared to the combined Nordic results.

The Observed vs Expected analysis takes only sex and age into account. The main assumption is that there have been no significant changes in reimbursement-, diagnoses- and recording-practices between the study period and the pre-pandemic historical comparison period. Many of the comparisons between periods of unvaccinated follow-up in the study period and the historical period, suggested lower rates in the study period. This could indicate that the relative risks in the Observed vs Expected analyses were underestimated.

11.3 Interpretation

The dose-specific results should be interpreted in the context of age. The 5-to-11-year-olds only contributed to BNT1 and BNT1BNT2 evaluations. This was also the case for 12-to-15-year-olds. Vaccine uptake was also low in the 5-to-11-year-olds compared to the older age groups.

Reassuringly, the study outcomes were rare to very rare after vaccination. In a study cohort of 5.1 million 5-to-19-year-olds with 2.4 million vaccinated (Table 1), we observed <5 or no events after vaccination for many of the thromboembolic outcomes and, notably, we observed no cases of thromboses with thrombocytopenia. A few associations were observed between vaccination and deep vein thrombosis, pulmonary embolism and arterial thromboembolism,

but these results were not consistent across analysis methods, were not observed in the Danish cohort, had low statistical precision and the majority of potential biases would be in the direction of an effect. Thus, we believe it is unlikely that these associations represent causal associations. The majority of current evidence in adults also points towards thromboembolic events being primarily adverse events following the viral vector vaccines.[17]. Further studies evaluating COVID-19 vaccination in 5-to-19-year-olds and thromboembolic events outside the Nordic region are warranted.

We observed robust associations between BNT1, BNT1BNT2 and BNT1BNT2BNT3 and myocarditis consistent with previous studies in both the Nordic countries and in other countries.[39] Subgroup analysis suggested that this was primarily an association in 12-to-19-year-old boys. In our study cohort, we observed 95 cases of myocarditis in the 28-day main risk period after vaccination. The excess risks among 12-to-15-year-olds were 1.8 and 1.5 cases per 100,000 BNT1 and -BNT1BNT2 vaccinations, respectively. The excess risks among 16-to-19-year-olds were 1.5, 2.7 and 7.7 cases per 100,000 BNT1, -BNT1BNT2 and -BNT1BNT2BNT3 vaccinations, respectively.

We observed associations between BNT1BNT2 and BNT1BNT2BNT3 and pericarditis. This association did not appear to be confined to boys alone. Pericarditis was rarer than myocarditis in our study. We observed up to 29 cases (exact count cannot be reported due to exposure category with <5) of pericarditis in the 28-day main risk period after vaccination. The excess risk among 12-to-15-year-olds was 0.6 cases per 100,000 BNT1BNT2 vaccinations. The excess risks among 16-to-19-year-olds were 1.1 and 3.3 cases per 100,000 BNT1BNT2 and -BNT1BNT2BNT3 vaccinations, respectively. The majority of previous studies on children and adolescents have focused on myocarditis or myopericarditis and few have reported on pericarditis alone.[39]

11.4 Generalisability

Our study is based on the general 5-to-19-year-old populations in 4 countries and, thus, our results have a high degree of generalisability to other general 5-to-19-year old populations by design. However, our results, only inform on the safety of BNT1, BNT1BNT2 and BNT1BNT2BNT3, and not on other vaccines that have been used in this population (in comparable countries, this would primarily be mRNA-1273 in the 16-to-19-year-olds). It should also be mentioned that BNT1BNT2BNT3 was almost exclusively used in 16-to-19-year olds, and we cannot inform on the risks of BNT1BNT2BNT3 in the younger age groups. It is also noteworthy that vaccine uptake was low in 5-to-11-year-olds and our results on BNT1 and BNT1BNT2, thus, primarily informs on vaccine safety in 12-to-19-year-olds.

We confirm the association between the BNT vaccine and myocarditis, provide evidence in support of an association between the BNT vaccine and pericarditis, and add significantly to the evidence on associations between the BNT vaccine in children and adolescents with respect to thromboembolic events.

12. OTHER INFORMATION

None.

13. CONCLUSION

Myocarditis, pericarditis, and thromboembolic events were rare after COVID-19 vaccination with BNT among 5-to-19-year-olds in the Nordic countries during 1 January 2021 to 31 October 2022. We confirmed an association between BNT1, BNT1BNT2 and BNT1BNT2BNT3, and myocarditis. The excess risks among 12-to-15-year-olds were 1.8 and 1.5 cases per 100,000 BNT1 and -BNT1BNT2 vaccinations, respectively. The excess risks among 16-to-19-year-olds were 1.5, 2.7 and 7.7 cases per 100,000 BNT1, -BNT1BNT2 and -BNT1BNT2BNT3 vaccinations, respectively. We provided evidence in support of an association between BNT1BNT2 and BNT1BNT2BNT3, and pericarditis. The excess risk among 12-to-15-year-olds was 0.6 cases per 100,000 BNT1BNT2 vaccinations. The excess risks among 16-to-19-year-olds were 1.1 and 3.3 cases per 100,000 BNT1BNT2 and -BNT1BNT2BNT3 vaccinations, respectively. We observed no cases of thromboembolism with thrombocytopenia and no associations with cerebral venous sinus thrombosis, hepatic-portal-renal vein thrombosis, ischemic stroke and myocardial infarction. We observed possible increased risks of deep vein thrombosis, pulmonary embolism and arterial thrombosis in the 28-day main risk period following vaccination. However, the events were rare, statistical precision low, and estimates not consistent across analysis methods and countries. The results from three different analytical approaches complement each other and support the internal validity of our study.

In conclusion, our results provide reassurance for the safety of the BNT vaccine in children and adolescents. Serious adverse events, in the form of myocarditis, pericarditis and thromboembolic events, are rare in this population.

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APPENDICES

Annex 1: Script of Common Data Model used for data management

Common Data Model for EMA/2020/46 TDA L5.04-ROC09

revised 01-11-2022

Study characteristics:

Study start: JAN 1, 2021.

Study end: OCT 31, 2022.

Historical rates period: JAN 1, 2015 – DEC 31, 2019. (or according to country-specific availability)

Study pop: Individuals born 2002 to 2017 (5 to 19 year olds in 2021-2022)

Description of input data:

Population: (pop_dat)

Variable names:

id (integer)

birth_year (XXXX integer)

sex (”M”,”F”, one-character)

censor_date ("YYYYMMDD", eight-character string)

censor_ind (character “M”, “E”, “D”,”S”)

high_risk (binary 0/1, 1: prioritised for vaccination due to high-risk associated with COVID-19, 0: otherwise)

ethnim: maternal country of birth (2-string character: “NO”, “WE”, “NW”,”UN”)

region: region of residence at baseline (country-specific definition, character variable “1”, “2”, …)

Description:

- Data set containing all individuals born 2002-2017 that were alive and living in the country on 2021-01-01.
- censor_date is the first date after 2021-01-01 where the individual either emigrated(E), died(D), goes missing(M) from registries, or the study end(S) (last possible day of follow-up OCT 31, 2022).
- censor_ind, see censor_date
- ethnim is the maternal country of birth, and is either Nordic(NO), Western(WE), Non-Western(NW) or unknown(UN); Nordic = Denmark, Finland, Norway or Sweden, Western = Europe, US, Australia and NZ; Non-Western = All other countries. (or country-specific definition)
- One observation per individual
- If a “high_risk” variable is not available, a possibility is to construct one from comorbidity data according to best country-specific definition or leave as missing.
- region, defined according to country-specific definition

Outcomes: (diagnosis_dat)

Variable names:

id (integer)

birth_year (XXXX integer)

sex (”M”,”F” one-character)

diag (character containing ICD10 codes eg. “I13” or “I514A”)

admission_date ("YYYYMMDD" eight-character string)

discharge_date ("YYYYMMDD" eight-character string)

diag_type – (character “A”, “B” indicating primary/secondary diagnosis)

pat_type – (character “I”, “O” indicating in- or outpatient according to length-of-stay definition – see below - or country-specific definition e.g. where there is no length-of-stay information available)

visit_id – (integer)

Description:

- Data set containing all primary and secondary diagnoses given to individuals born 1996-2017 for all individuals who have been living in the country at any time in the period 2015-01-01 to 2022-10-31.
- Here diagnosis given to individuals 1-6 years older than those in the population dataset need to be included for calculation of historical rates. The historical rates will be calculated, assuming the same age and sex distribution as of the population dataset.
- pat_type-variable is defined to be inpatient(I) if hospital stay is >= 5 hours and outpatient(O) if stay is less than 5 hours. If there is no length-of-stay information available, a country-specific definition can be used, e.g. based on already existing patient type variables.
- One observation per diagnosis, potentially several for each individual.
- admission_date and discharge_date should be based on “hospital visits” data, where consecutive admissions/recordings (e.g. occuring when changing department within the hospital at the same visit) are combined into one hospital visit. All diagnoses assigned during a hospital visit will be linked to the first admission date of the admissions/recordings comprising the constructed hospital visit. In this scenario, the diag_type follows the diagnosis. That is, multiple A-diagnoses are possible for a constructed hospital visit.
- visit_id is an integer which, together with the patient identifier, identifies the hospital visit. For each individual, the first hospital visit is given visit_id = 1, the second hospital visit is given visit_id = 2 and so forth. Note that the admission_date and the discharge_date should remain unchanged within each hospital visit.

Vaccinations: (vaccines_dat)

Variable names:

id (integer)

vaccine_type (3-character string “AZD”, “BNT”, “MOD”, “BO1”,”BO5”,”MO1”,”MO5”,“OTH” or “UNK”)

vaccine_date ("YYYYMMDD" eight-character string)

Description:

- Data set containing all vaccinations given to individuals in the population dataset.
- One observation per dose, potentially several for each individual
- The vaccines are:
  - AZD: Astra-Zeneca
  - BNT: Pfizer/Comirnaty
  - MOD: Moderna
  - BO1: Pfizer omicron variant BA1
  - BO5: Pfizer omicron variant BA5
  - MO1: Moderna omicron variant BA1
  - MO5: Moderna omicron variant BA5
  - OTH: Other, including JJ, NovaVax and others that might get licensed
  - UNK: Unknown vaccinetype

Infections: (infections_dat)

Variable names:

id (integer)

test_date ("YYYYMMDD" eight-character string)

test_type (3-character string, “PCR”, “ANT”, “UNK”)

Description:

- Data set containing information on all positive SARS-CoV2-tests for individuals in the population dataset.
- One observation per positive test, potentially several for each individual
- test_type, PCR test or antigen test, if known.