

Ethical and coordinative challenges setting up a national cohort study during the COVID-19 pandemic in Germany

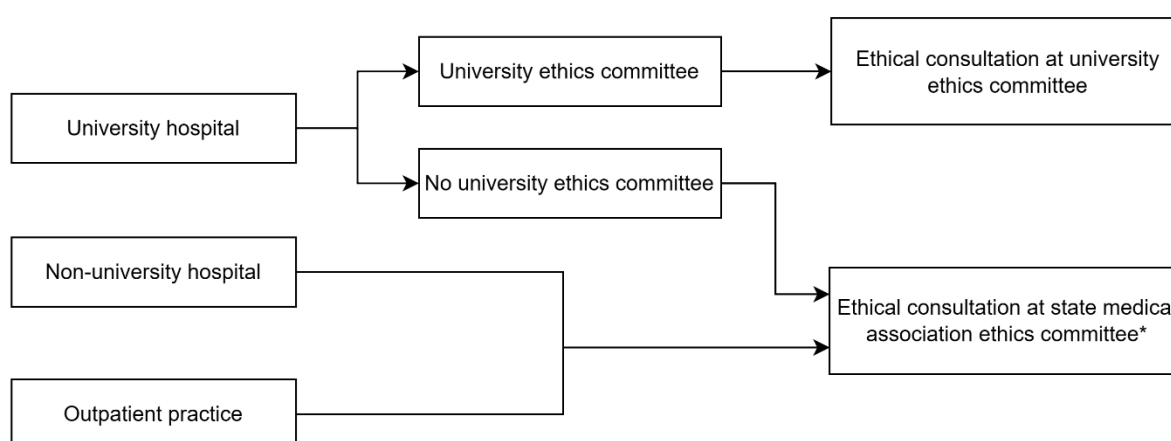
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Supplementary Information



*first ethical approval applying to all non-university sites in the responsible area of the state medical association

Scheme S1 Responsible ethics committee depending on the health care sector. The organigram shows which ethics committee provides ethical consultation for physicians depending on the type of study site.

Tab. S1 General overview of documents submitted to the responsible ethics committee for an ethics application for study sites of the Cross-Sectoral Platform (SUEP) and the High-Resolution Platform (HAP). SOP = Standard Operating Procedure; DZHK = German Center for Cardiovascular Research; NUM = Network University Medicine. *submission only at selected ethics committees

Documents to be submitted SUEP	Documents to be submitted HAP
• Confirmation of insurance • Cover letter ethics application • CV of applicant physician • Data set of the SUEP • Information on electronic recording of electronic consent • Informed consent forms • Insurance policy • Note to file: presumed will • Patient information • Primary ethics vote • Revocation form • Study protocol • SOP Data Transmission • SOP Manual • Table of submitted documents and significant changes • Terms of use of the NUM • Translation certificates • Translations of patient information and consent forms	• Concept paper of the NUM • Confirmation of insurance* • Cover letter ethics application • CV of applicant physician • Data flow diagram • Data protection concept of the DZHK • Ethics application • Informed consent forms • Insurance policy* • Network diagram of the NUM • Patient information • Primary ethics vote • Study protocol • Table: List of subprojects* • Vote of the State Commissioner for Data Protection and Freedom of Information on the Data Protection Concept of the Trust Agency (Mecklenburg-Western Pomerania) • Vote of the State Commissioner for Data Protection on the data protection concept of the DZHK (Lower Saxony)

Tab. S2 Correlation of hospitalization incidence in Germany and patient recruitment in NAPKON Cross-Sectoral Platform and High-Resolution Platform according to the COVID-19 waves defined by the Robert Koch-Institute (25). Wave consideration does not begin until calendar week (KW) 10/2021 because hospitalization incidences were not available until that week.

	Pearson correlation coefficient	95%-confidence interval	p-value
All waves (KW10/21-52/21)	0.77	0.61-0.87	< 0.001
Third wave (KW10/21-23/21)	0.88	0.65-0.96	< 0.001
Summer plateau (KW24/21-30/21)	0.74	-0.02-0.96	0.055
Fourth wave (KW31/21-51/21)	0.86	0.68-0.94	< 0.001

Tab. S3 Correlation of hospitalization incidence in Germany and patient recruitment in NAPKON Cross-Sectoral Platform and High-Resolution Platform according to the COVID-19 waves defined by the Robert Koch-Institute (25). Wave consideration begins at calendar week (KW) 45/2020, describing the first week in which NAPKON patients were recruited.

	Pearson correlation coefficient	95%-confidence interval	p-value
All waves (KW45/20-52/21)	0.31	0.06-0.52	0.017
Second wave (KW45/20-08/21)	-0.84	-0.94-0.60	< 0.001
Third wave (KW09/21-23/21)	0.88	0.67-0.96	< 0.001
Summer plateau (KW24/21-30/21)	0.63	-0.22-0.94	0.126
Fourth wave (KW31/21-51/21)	0.83	0.61-0.93	< 0.001

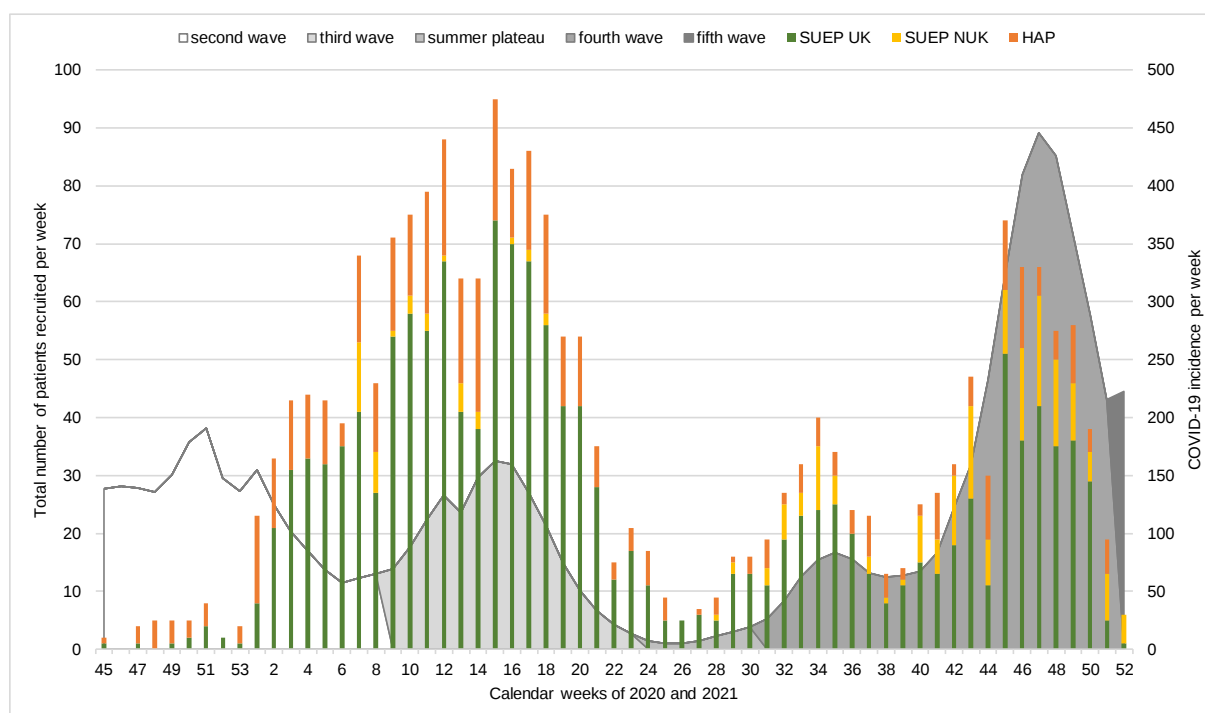


Fig. S1 Correlation of COVID-19 incidence in Germany and patient recruitment in the Cross-Sectoral Platform (SUEP, university (UK) and non-university (NUK) study sites) and High-Resolution Platform (HAP) study sites. Recruited patients per week are shown as stacked columns. The observation period is reported in calendar weeks, starting with the NAPKON recruitment launch in November 2020 and ending in the last calendar week of 2021. COVID-19 incidence represents the mean of infections per 100,000 inhabitants per calendar week in Germany (24). Waves are classified according to the specifications of the Robert Koch-Institute (25) and visualized in different shades.