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This protocol is based on the JBI evidence synthesis guidelines for scoping reviews: https://jbi-global-wiki.refined.site/space/MANUAL/4687810/11.2+Development+of+a+scoping+review+protocol

Study protocol:"COVID-19 and Real-World Evidence: A Scoping Review on Factors That Affected Real-World Data Quality and Collection during the Pandemic and Methods to Address these Issues"

Administrative details for the data analysis	
Short title of topic	COVID-19 and Real-World Evidence: A Scoping Review
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Background	
Short title of topic	COVID-19 and the impact on Real-World Evidence: A Scoping Review
Background	The COVID19 pandemic has been linked to a unique situation with several periods of lock down, at least in some EU countries, and some changes in the way patients got access to the healthcare system. This is particularly true for the years 2020 and 2021. In pharmacoepidemiology, we often use real world data to generate real world evidence, data which have been collected in data sources under routine clinical care. Any change in this routine setting has an impact on the way data are collected and reported and then possibly used for non-interventional studies to support regulatory decision making. Nowadays, data from this period (2020-2021) available in these data sources may represent a different pattern of reporting collection than the years before and the years after the pandemic period. How to handle data collected during the pandemic is a real question as well as understanding of the potential issues linked to the data collection that occurred during the pandemic situation in many European countries and its impacts in the current use of such data for regulatory purposes.
Aim	To identify factors that affected the collection and quality of real-world data during the COVID-19 pandemic, assess how these factors impacted real-world evidence studies, and propose methods to address these issues.

1. Research question and objectives

Objective 1: to conduct a systematic literature review to evaluate the impact of the COVID-19 pandemic on the collection and quality of real-world data.

Research question: How did the COVID-19 pandemic impact the collection and quality of real-world data?

Objective 2: to conduct a systematic literature review to assess how real-world evidence studies may be affected when using real-world data collected during the COVID-19 pandemic.

Research question: How the utilization of real-world data collected during the COVID-19 pandemic impacts the validity of real-world evidence studies?

Objective 3: To conduct a systematic literature review to identify methods that have been employed for addressing issues in real-world evidence studies when utilizing real-world data collected during the COVID-19 pandemic.

Research question: What methods were employed to address the identified issues in real-world evidence when real-world data collected during the COVID-19 pandemic were used?

2. Research methods

2.1. Study design

We'll conduct a scoping review to map the current literature and create a framework for understanding how the collection (e.g., more tele-health consultations) and quality (e.g., increased risk of confounding and misclassification) of real-world data are affected during the COVID-19 pandemic, as well as the methods used to address these challenges. A systematic literature review of both peer-reviewed articles and grey literature texts will be performed to address the objectives of this study, in line with the broad scope of our aim.

2.2. Data sources

PubMed, Embase, purposefully selected websites of organizations and regulatory bodies.

2.3. Eligibility criteria

Time Frame: Peer-reviewed research and grey literature sources published from 2020 to the present.

Geographic Scope: Sources from all geographical areas will be considered.

Language: Only documents written in English will be considered.

Study Design: Peer-reviewed research (original articles and reviews) and grey literature reviews (scientific reports, guidelines, white papers).

Context: COVID-19 pandemic

Concept: The impact of the COVID-19 pandemic on real-world data and real-world evidence and methods used to address the potential issues.

2.4. Search strategy

The same search strategy will be used to address all 3 objectives and research questions. Since the third objective is a more specific aspect within the scope of objectives 1 and 2, it will be integrated into the search strategy designed for objectives 1 and 2. The preliminary search string has been peer-reviewed by an EMA librarian. The translation from PubMed to Embase was done by the automatic translator provided by Embase and then checked for validity by M.P..

Key words	COVID-19 OR COVID-19 pandemic OR SARS-CoV-2	**AND**	Impact* OR Effect OR Effects OR Implication* OR Influence OR Change* OR Alteration* OR Consequence* OR Aftermath*	**AND**	Real world data OR Real world evidence OR Routinely Collected Health Data OR Routinely collected data OR Electronic Health Records OR Medical Records OR Patient record* OR Health administrative data OR Registry data	Quality OR Validity OR Reliability OR Credibility OR Consistency OR Collection
PubMed Mesh Terms	"COVID-19"[Mesh] OR "SARS-CoV-2"[Mesh]				"Routinely Collected Health Data"[Mesh] OR "Medical Records"[Mesh] OR "Medical Records Systems, Computerized"[Mesh] OR "Electronic Health Records"[Mesh]	

PubMed search string

("COVID-19"[Mesh] OR "SARS-CoV-2"[Mesh] OR ''COVID-19''[tiab] OR ''COVID-19 pandemic''[tiab] OR "SARS-CoV-2"[tiab] OR "severe acute respiratory syndrome 2"[tiab]) **AND** (Impact*[tiab] OR Effect[tiab] OR Effects[tiab] OR Implication*[tiab] OR Influence[tiab] OR Change*[tiab] OR Alteration*[tiab] OR Consequence*[tiab] OR Aftermath*[tiab]) **AND** (("Routinely Collected Health Data"[Mesh] OR "Medical Records"[Mesh] OR "Medical Records Systems, Computerized"[Mesh] OR "Electronic Health Records"[Mesh] OR "Real world data"[tiab] OR "Real world evidence"[tiab] OR "Routinely Collected Health Data"[tiab] OR "Routinely collected data"[tiab] OR "Electronic Health Record*"[tiab] OR "Medical Record*"[tiab] OR "patient record*"[tiab] OR "Health Administrative Data"[tiab] OR "Registry data"[tiab]) **AND** ("collection"[tiab] OR "quality"[tiab] OR "validity"[tiab] OR "consistency"[tiab] OR "reliability"[tiab] OR "credibility"[tiab]))

Embase search string

('coronavirus disease 2019'/exp OR 'Severe acute respiratory syndrome coronavirus 2'/exp OR 'covid-19':ti,ab,kw OR 'covid-19 pandemic':ti,ab,kw OR 'sars-cov-2':ti,ab,kw OR 'severe acute respiratory syndrome 2':ti,ab,kw) **AND** ('impact*':ti,ab,kw OR 'effect':ti,ab,kw OR 'effects':ti,ab,kw OR 'implication*':ti,ab,kw OR 'influence':ti,ab,kw OR 'change*':ti,ab,kw OR 'alteration*':ti,ab,kw OR 'consequence*':ti,ab,kw OR 'aftermath*':ti,ab,kw) **AND** (('routinely collected health data'/exp OR 'medical record'/exp OR 'electronic medical record system'/exp OR 'electronic health record'/exp OR 'real world data':ti,ab,kw OR 'real world evidence':ti,ab,kw OR 'routinely collected health data':ti,ab,kw OR 'routinely collected data':ti,ab,kw OR 'electronic health record*':ti,ab,kw OR 'medical record*':ti,ab,kw OR 'patient record*':ti,ab,kw OR 'health administrative data':ti,ab,kw OR 'registry data':ti,ab,kw) **AND** ('collection':ti,ab,kw OR 'quality':ti,ab,kw OR 'validity':ti,ab,kw OR 'consistency':ti,ab,kw OR 'reliability':ti,ab,kw OR 'credibility':ti,ab,kw)) AND [english]/lim AND ([article]/lim OR [article in press]/lim OR [review]/lim OR [preprint]/lim)

2.5. Source of evidence selection

Title/abstract screening

The title abstract screening will be conducted by two independent researchers (Q.C. and M.P.) and the disagreement will be resolved by a consensus between the researchers.

Full text screening

The full text screening will be conducted by two independent researchers (Q.C. and M.P.) and the disagreement will be resolved by a consensus between the researchers.

2.6. Data extraction

The data extraction will be conducted by two independent researchers (Q.C. and M.P.) and the disagreement will be resolved by a consensus between the researchers.

2.7. Analysis of evidence

The analysis of evidence will be conducted by a researcher (M.P.) and a second researcher (Q.C.) will check the quality of the analysis.

2.8. Presentation of the results

A narrative synthesis of the results will be performed. We also plan to create a framework to guide future research on how real-world data collected during COVID-19 pandemic should be used in real-world evidence analyses.

3. Plans for disseminating and communicating study results

We plan to disseminate our results as a peer reviewed publication.