Access to and Barriers to Access for Essential Medicines in Nephrology and Related Non-Communicable Diseases: A Scoping Review Protocol

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Abstract

Objective: This scoping review aims to understand the extent of evidence regarding: 1) access to essential medicines, 2) barriers to access, and 3) interventions to improve access for chronic kidney disease (CKD) and related non-communicable diseases (NCDs).

Introduction: Access to essential medicines for treatment of NCDs is lacking in low- and low-middle income countries. In nephrology, access to essential medicines is especially important to reduce risk of CKD progression, as kidney replacement therapy is unavailable or cost-prohibitive in many regions of the world. As part of the International Society of Nephrology Emerging Leaders Program’s mandate to improve health promotion and access to prevention and management of kidney diseases globally, this scoping review serves as an initial step towards designing implementation studies to improve access to essential medicines.

Inclusion criteria: Articles of any study design involving populations with chronic kidney disease, cardiovascular disease, hypertension, and/or diabetes will be included. The core concept of essential medicines will encompass access to essential medicines, barriers to access, and interventions to improve access. All geographical regions and all World Bank Income categories will be considered.

Methods: Methods for this scoping review are based on the Joanna Briggs Manual for Evidence Synthesis. MEDLINE, EMBASE, Web of Science, CENTRAL will be searched. Included studies will be restricted to English language. Screening of title/abstract of each article and subsequent review of retrieved full-text articles will be performed by one reviewer, followed by a second reviewer checking the excluded lists for accuracy. A data extraction tool will be customized using Covidence software. Data will be summarized narratively, and in tabular and diagrammatic format.
Studies assessing barriers to access or interventions to improve access will be categorized by patient-level, provider-level, organization-level, community/regional-level, and national/health policy-level.

**Keywords:** essential medicines, nephrology, non-communicable diseases, access, barriers
Introduction

Access to safe, effective, quality and affordable essential medicines for all is one of the World Health Organization’s (WHO) Sustainable Development Goals for health (1). Essential medicines are defined by the WHO as ‘those that satisfy the priority healthcare needs of the population’ (2). The list of essential medicines for a particular country is chosen considering the local disease prevalence, efficacy, safety, and comparative cost effectiveness (2). Despite being considered a human right, access to essential medicines is lacking in almost 2 billion people globally, especially in low- and low-middle-income countries (LICs and LMICs) (3,4). The Lancet Commission on Essential Medicines Policies identified five key barriers to universal access to essential medicines: medicines affordability, sustainable financing, medicines quality, optimal medicines use, and research and development of needed medicines (5).

The global burden of non-communicable diseases (NCDs) is rising. NCDs are attributable to 71% of all deaths globally, with a majority of deaths occurring in LIC and LMIC (6). The economic impact of the five main NCDs (cardiovascular disease, chronic respiratory disease, cancer, diabetes and mental health) is estimated at US$47 trillion in cumulative output loss globally from 2011 to 2025 (7). Chronic kidney disease (CKD) is often a downstream consequence of other NCDs such as diabetes and cardiovascular disease, further exacerbating the economic burden to health care systems and societies (8,9). However, the proportion of international health aid dedicated to NCDs remains low at 2% (10). Kidney disease has received less attention among NCDs (11).

Treatment of advanced kidney failure with dialysis or transplantation is either unavailable or unaffordable for most people living in LICs and LMICs. (12, 13). Therefore, efforts to reduce risk of CKD progression, including identification of CKD and access to essential medications, are of
utmost importance. Adequate prevention and treatment of CKD and its complications are critically dependent on the continuous use of adequate and quality medicines (14).

Understanding the access to essential medicines and the barriers to access, especially in resource-poor regions, is mandatory for identification of potential interventions and to develop policy proposals to solve or mitigate this problem. Therefore, as part of the International Society of Nephrology (ISN) Emerging Leaders Program’s mandate to improve promotion and access to prevention, control, and management of kidney diseases globally, we will perform a scoping review to identify characteristics/factors related to essential medicines access for kidney disease and related NCDs (cardiovascular, hypertension, diabetes) across geographic regions and World Bank income categories. Specifically, the objectives of the scoping review are to assess the breadth of evidence regarding 1) access to essential medicines, 2) barriers to access, and 3) interventions to improve access, for the NCDs indicated above. This review serves as an initial step towards designing implementation studies to improve access to essential medicines.

Using a search in Prospero, we identified an existing systematic review protocol regarding access to NCD medicines in LIC and LMIC (15). However, this review aims to describe dimensions of access (including availability, affordability, price, accessibility, and acceptability) of essential medicines for all NCDs, while our review will focus on evaluating barriers to access globally for kidney disease and related NCDs.

This protocol follows the scoping review guidance from the Joanna Briggs Manual for Evidence Synthesis (16).

**Eligibility criteria:**

**Types of participants**
Populations with the following NCDs will be included: chronic kidney disease, cardiovascular disease, hypertension, diabetes. Articles assessing specific NCDs outside of these categories will be excluded, but articles covering NCDs broadly without identifying specific diseases will be acceptable. Study participants may include patients with NCDs, health care professionals, and other health care personnel.

**Concept**

The core concept examined by the scoping review is essential medicines for treatment of kidney diseases and NCDs related to kidney disease, as outlined in the ISN Global Kidney Health Atlas (14). Specifically, the factors of interest include access to essential medicines, barriers to access of essential medicines, and interventions to address barriers.

**Context**

All ISN geographical regions (Africa, Eastern and Central Europe, Latin America, Middle East, Newly Independent States and Russia, North America and the Caribbean, North and East Asia, Oceania and South East Asia, South Asia, Western Europe), and all World Bank Income categories (low, lower-middle, upper-middle, and high-income economies) will be considered.

**Types of evidence sources**

Articles of any study design, published in English, including qualitative studies, surveys, intervention studies, reviews, perspectives, and conference abstracts, that contain information about access to essential medicines, and/or barriers to access, and/or interventions to improve access for any of the relevant NCDs listed above will be included.

**Information sources/Search**
An initial limited search of MEDLINE will be performed to identify keywords and index terms in relevant articles, followed by a second systematic search using all identified keywords and index terms across all databases. The reference list of identified reports and review articles will be searched for additional sources to ensure completeness.

MEDLINE (1946-May 2021, see Appendix for search strategy), EMBASE (1974-May 2021), Web of Science (1976-May 2021), and Cochrane Central Register of Controlled Trials (CENTRAL) will be searched with the assistance of a medical librarian (SS).

**Source of evidence selection**

Titles and abstracts will be screened for inclusion by one reviewer (MMYW, VCS, GN, EKT), followed by two reviewers verifying the excluded list (MW, VK). Full texts will be retrieved for publications that meet criteria based on title and abstract screening. Each full text article will then be assessed for inclusion by one reviewer (MIAH, VCS, TC, UE, AF, RK, SK, VK, GN, EKT, EW, MMYW), and then two reviewers will verify the excluded list (MMYW, VK). Any discrepancies between reviewers in this process will be discussed and resolved by consensus.

Covidence software (Veritas Health Innovation, Melbourne, Australia) will be used to organize references, screen articles and extract data.

**Data Extraction**

Data extraction for each included article will be carried out by one reviewer (MIAH, VCS, RC, TC, UE, AF, RK, SK, VK, GN, NPK, EKT, EW, MMYW). A random sample of included studies will be cross-checked by a second reviewer (MMYW). The reviewers will independently extract data into a standardized extraction sheet. For each eligible article, the following information will be extracted: name of first author, year of publication, country, ISN region,
World Bank income category, study design and methods, aim of study, study setting, study population, NCDs addressed, article topic (general description of access to medicines, barriers to access, or interventions to address barriers to access), key findings, study limitations, and policy recommendations. Studies assessing barriers to access or interventions to improve access will be categorized by patient-level, provider-level, organization-level, community/regional-level, and national/health policy-level.

**Analysis of the evidence**

Evidence will be synthesized according to three main categories using narrative summary:

1. Description of access to essential medicines for any of the relevant NCDs will be summarized by ISN region and by World Bank income category

2. Barriers to access to essential medicines for any of the relevant NCDs will be summarized by patient-level, provider-level, organization-level, community/regional-level, and national/health policy-level barriers. A subgroup analysis by ISN region and by World Bank income category will be performed.

3. Interventions to improve access to any medicines for any of the relevant NCDs will be summarized by patient-level, provider-level, organization-level, community/regional-level, and national/health policy-level interventions. A subgroup analysis by ISN region and by World Bank income category will be performed.

**Presentation of the results**

Data extracted from the included articles will be presented in appropriate diagrammatic or tabular form. We will use a nested Venn diagram to summarize the barriers and interventions to
access of essential medicines by patient-level, provider-level, organization-level, community/regional-level, and national/health policy-level.

Other diagrams will include pie charts, bar graphs, and/or rose diagrams to summarize studies by ISN region and by World Bank income category.

**Risk of bias assessment**

Risk of bias of the included studies will not be assessed, given the heterogeneity of article types and the aim of the scoping review to characterize the available literature on the topic.

**Discussion**

This scoping review will consolidate the existing published literature regarding barriers to access to essential medicines in CKD and associated NCDs, levels at which these barriers are reported, and interventions to overcome these barriers. In particular, this will expand on the findings of the ISN Global Kidney Health Atlas, which, through a stakeholder survey process, identified access to essential medicines as an important barrier to sustainable kidney care (17).

The results will guide development of context-specific yet system-wide implementation strategies to increase access to essential medicines and reduce the burden of CKD. These strategies can then be tested in target regions/populations to assess their feasibility and impact. If found useful, these could favourably impact risk factor control and CKD progression.

**List of Abbreviations**

WHO: World Health Organization

CKD: chronic kidney disease

NCD: non-communicable disease
LIC: low-income country

LMIC: low-middle income country

ISN: International Society of Nephrology

CENTRAL: Cochrane Central Register of Controlled Trials

**Declarations**

Ethics approval and consent to participate: Not applicable

Consent for publication: Not applicable

Availability of data and materials: No applicable

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Authors' contributions: MMYW, VCS, GN, EKT designed the protocol with input from all other authors. SS designed the search strategy. MMYW, VCS, EKT, GN, VK were major contributors in writing the manuscript. VJ provided supervision for this project. All authors read and approved the final manuscript.

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Supplementary Files

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- Appendix.pdf