

Scoping Review of Reported Outcomes in Pre-Exposure Prophylaxis (PrEP) Research to Inform the Development of a Core Outcome Set

INPLASY202630101

doi: 10.37766/inplasy2026.3.0101

Received: 27 March 2026

Published: 27 March 2026

Corresponding author:

Roseline Dzekem Dine

dineroselinedzekem@gmail.com

Author Affiliation:

McMaster University.

Mbuagbaw, L; Dine, RD; Ayoub, N; Sivakumar, H; Fontaine, G; Golchi, S; Moodie, Z; Maleyeff, L; Parsons, M.

ADMINISTRATIVE INFORMATION**Support** - McMaster University.**Review Stage at time of this submission** - Formal screening of search results against eligibility criteria.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202630101**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 March 2026 and was last updated on 27 March 2026.**INTRODUCTION**

Review question / Objective To systematically identify and map all outcomes reported in studies on PrEP for HIV prevention to inform the development of a core outcome set.

Rationale Pre-exposure prophylaxis (PrEP) is a proven biomedical strategy for preventing HIV infection in high-risk populations. (1–3) As the body of PrEP research grows, outcome reporting across clinical trials and observational studies remains inconsistent, limiting the ability to compare and synthesize evidence. (4,5) Developing a core outcome set (COS) for PrEP studies would promote consistency, improve evidence synthesis, and ensure that outcomes relevant to all stakeholders, including patients, clinicians, and policymakers, are captured. A scoping review is the first step in COS development. This review will map all outcomes reported in the existing PrEP literature to inform the next phases of the COS development process.

Condition being studied The condition of interest is HIV infection, a major global public health concern for decades. This review focuses on HIV prevention through the use of PrEP, a biomedical intervention used by HIV-negative individuals to reduce the risk of acquiring HIV.(6,7) PrEP regimens include Tenofovir Disoproxil Fumarate/ Emtricitabine (TDF/FTC, Truvada), Tenofovir Disoproxil Fumarate/Lamivudine (TDF/3TC), Tenofovir Alafenamide/Emtricitabine (TAF/FTC, Descovy), Cabotegravir (Apretude), Lenacapavir (Yeztugo), and Dapivirine Vaginal Rings, all used to prevent HIV infection. These are administered via oral (TDF/FTC, TDF/3TC, TAF/FTC), intramuscular (cabotegravir, lenacapavir), and mucosal routes (dapivirine vaginal ring) depending on the formulation. (8) PrEP regimens differ in their antiretroviral components and target populations. For example, the Dapivirine Vaginal Ring is used only by women. (9) These differences make measuring outcomes complex. Therefore, there is a need to synthesize evidence and develop a core

outcome set to guide impact assessment and policy decisions.

METHODS

Search strategy Search terms included variations of 'PrEP', 'outcome', 'endpoint', 'measure', and will be refined with a librarian (see search strategy).

1. Search results

Ovid MEDLINE(R) ALL

1 PrEP.mp. 10972

2 pre-exposure prophylaxis.mp. or exp Pre-Exposure Prophylaxis/ 9329

3 HIV prevention pill.mp. 6

4 prevention pill.mp. 21

5 (Truvada or Descovy or Apretude or cabotegravir or emtricitabine or tenofovir or "TDF/FTC").mp. 12289

6 1 or 2 or 3 or 4 or 5 24159

7 exp HIV/ or HIV.mp. 431938

8 human immunodeficiency virus.mp. 114805

9 Acquired Immunodeficiency Syndrome.mp. or exp Acquired Immunodeficiency Syndrome/ 94751

10 AIDS.mp. 226844

11 exp HIV Infections/ or HIV infection*.mp. 349829

12 7 or 8 or 9 or 10 or 11 560023

13 exp Treatment Outcome/ 1369281

14 exp Patient Reported Outcome Measures/ 19891

15 HIV incidence.mp. or exp Incidence/ 328313

16 exp HIV Seropositivity/ 24408

17 Risk Reduction Behavior.mp. or exp Risk Reduction Behavior/ 15699

18 13 or 14 or 15 or 16 or 17 1718071

19 6 and 12 and 18 2786

20 limit 19 to english 2741

Embase

1 PrEP.mp. 26408

2 pre-exposure prophylaxis.mp. or exp pre-exposure prophylaxis/ 15689

3 HIV prevention pill.mp. 7

4 prevention pill.mp. 21

5 (Truvada or Descovy or Apretude or cabotegravir or emtricitabine or tenofovir or "TDF/FTC").mp. 45670

6 1 or 2 or 3 or 4 or 5 72827

7 HIV.mp. 517982

8 human immunodeficiency virus.mp. or exp Human immunodeficiency virus/ 559844

9 Acquired Immunodeficiency Syndrome.mp. or exp acquired immune deficiency syndrome/ 526263

10 AIDS.mp. 234857

11 exp Human immunodeficiency virus infection/ or HIV infection*.mp. 800951

12 7 or 8 or 9 or 10 or 11 1069657

13 HIV Seropositivity.mp. 1685

14 Risk Reduction Behavior.mp. or exp risk reduction/ 145977

15 HIV incidence.mp. 5279

16 13 or 14 or 15 152653

17 6 and 12 and 16 2319

18 limit 17 to english 2307

CINAHL

Query Limiters/Expanders Last Run Via Results

S18 S6 AND S12 AND S17 Limiters - English Language

Search modes - Proximity Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 629

S17 S13 OR S14 OR S15 OR S16 Search modes - Proximity Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 224,890

S16 (MM "Treatment Outcomes+") OR "Treatment Outcome" OR (MM "Outcomes (Health Care)+") OR (MM "Outcome Assessment") Search modes - Proximity Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 215,701

S15 "Risk Reduction Behavior" Search modes - Proximity Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 56

S14 (MM "HIV Seronegativity") OR (MM "HIV Seropositivity") OR "HIV Seropositivity" Search modes - Proximity Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 6,404

S13 "HIV incidence" OR (MM "Incidence") Search modes - Proximity Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 2,977

S12 S7 OR S8 OR S9 OR S10 OR S11 Search modes - Proximity Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 176,770

S11 (MM "HIV Infections+") OR "HIV infection*" Search modes - Proximity Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 99,789

S10 "AIDS" OR (MM "AIDS Patients") Search modes - Proximity Interface - EBSCOhost Research Databases

Search Screen - Advanced Search

Database - CINAHL 71,842

S9 (MM "Acquired Immunodeficiency Syndrome") OR "Acquired Immunodeficiency Syndrome" Search modes - Proximity Interface - EBSCOhost Research Databases
 Search Screen - Advanced Search
 Database - CINAHL 19,407

S8 (MM "Human Immunodeficiency Virus+") OR "human immunodeficiency virus" OR (MM "HIV Infections+") Search modes - Proximity Interface - EBSCOhost Research Databases
 Search Screen - Advanced Search
 Database - CINAHL 89,755

S7 "HIV" Search modes - Proximity Interface - EBSCOhost Research Databases
 Search Screen - Advanced Search
 Database - CINAHL 134,217

S6 S1 OR S2 OR S3 OR S4 OR S5 Search modes - Proximity Interface - EBSCOhost Research Databases
 Search Screen - Advanced Search
 Database - CINAHL 8,941

S5 TX (Truvada OR Descovy OR Apretude OR cabotegravir OR emtricitabine OR tenofovir OR "TDF/FTC") Search modes - Proximity Interface - EBSCOhost Research Databases
 Search Screen - Advanced Search
 Database - CINAHL 3,109

S4 "prevention pill" Search modes - Proximity Interface - EBSCOhost Research Databases
 Search Screen - Advanced Search
 Database - CINAHL 8

S3 "HIV prevention pill" Search modes - Proximity Interface - EBSCOhost Research Databases
 Search Screen - Advanced Search
 Database - CINAHL 3

S2 (MM "Pre-Exposure Prophylaxis") OR "pre-exposure prophylaxis" Search modes - Proximity Interface - EBSCOhost Research Databases
 Search Screen - Advanced Search
 Database - CINAHL 4,365

S1 "PrEP" Search modes - Proximity Interface - EBSCOhost Research Databases
 Search Screen - Advanced Search
 Database - CINAHL 4,824

Web of Science
 PrEP OR "pre-exposure prophylaxis" OR "HIV prevention pill" OR "prevention pill" OR Truvada OR Descovy OR Apretude OR cabotegravir OR emtricitabine OR tenofovir OR "TDF/FTC" (All Fields) and HIV OR "human immunodeficiency virus" OR "HIV infection*" OR AIDS OR "Acquired Immunodeficiency Syndrome" OR "HIV seropositivity" OR "HIV seronegativity" (All Fields) and "treatment outcome*" OR "health outcome*" OR "outcome assessment" OR "risk reduction behavior" OR "HIV incidence" OR "HIV seropositivity" OR "HIV seronegativity" (All Fields) 1,170

Cochrane Search
 (PrEP OR "pre-exposure prophylaxis" OR "HIV prevention pill" OR "prevention pill" OR Truvada OR Descovy OR Apretude OR cabotegravir OR emtricitabine OR tenofovir OR "TDF/FTC" (All Fields)) AND (HIV OR "human immunodeficiency virus" OR "HIV infection*" OR AIDS OR "Acquired Immunodeficiency Syndrome" OR "HIV seropositivity" OR "HIV seronegativity" (All Fields)) AND ("treatment outcome*" OR "health outcome*" OR "outcome assessment" OR "risk reduction behavior" OR "HIV incidence" OR "HIV seropositivity" OR "HIV seronegativity" (All Fields)) 931.

Participant or population Any population using or eligible for PrEP.

Intervention We included PrEP studies that studied any PrEP regimen. The regimen, whether allocated individually or within a cluster, delivered online or in-person by any provider, will be included.

Comparator

Any PrEP regimen versus no other intervention.
 Any PrEP regimen versus other types of intervention.
 Any PrEP regimen versus another PrEP regimen.

Study designs to be included This review will follow the Joanna Briggs Institute (JBI) methodology for scoping reviews and be reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol. (10).

Eligibility criteria

Inclusion Criteria:

- Population: Any population using or eligible for PrEP
- Concept: Outcomes related to PrEP for HIV prevention
- Context: Any setting
- Study Types: RCTs, cohort studies, case-control, cross-sectional,
- Timeframe: No date restrictions
- Language: English

Exclusion Criteria:

- Studies not related to PrEP
- Outcomes unrelated to PrEP (e.g., PEP, ART outcomes)
- Editorials, opinion pieces, protocols
- Non-English publications
- Reviews, qualitative studies, and modelling studies
- Article for which the full text cannot be retrieved.

Information sources A systematic search will be conducted on electronic databases such as MEDLINE, EMBASE, COCHRANE, CINAHL, GLOBAL MARKET INSIGHTS (GMI), and WEB OF SCIENCE.

Main outcome(s) We aim to capture the following outcomes: PrEP uptake/initiation, HIV incidence (effectiveness), adherence to PrEP, persistence on PrEP, drug resistance, breakthrough infections, safety, adverse events, behavioral changes (e.g., condom use, number of partners), social support, internalized stigma, psychological distress, self-efficacy, treatment satisfaction, and quality of life. We will also capture any additional outcomes related to how PrEP results are measured, to inform reporting in future studies.

Data management Collected data will be stored on a password-protected system and backed up in the cloud. Missing data will be identified and handled appropriately. Stored quantitative data will be converted in STATA version 18.0, and qualitative data in QDA Miner Lite, where further cleaning and analysis will be conducted. Any discrepancies will be resolved through consensus. Extracted data will be verified to ensure accuracy and relevance to PrEP.

Quality assessment / Risk of bias analysis Not applicable.

Strategy of data synthesis Outcomes will be grouped thematically using the Core Outcome Measures in Effectiveness Trials (COMET) taxonomy. (11) Frequencies of outcome occurrence will be calculated and grouped according to types, for instance, clinical, behavioural, patient-reported outcomes (PROs), implementation, and laboratory, based on the approach suggested by Levac et al.(12)

Subgroup analysis Not applicable.

Sensitivity analysis Not applicable.

Language restriction English.

Country(ies) involved 1. McMaster University, Department of Health Research Methods, Evidence and Impact, Hamilton, ON, Canada; 2. McGill University, Implementation Science Laboratory, Montreal, QC, Canada; and 3. University of Winnipeg, Winnipeg, Manitoba, Canada.

Keywords PrEP regimens; Scoping reviews; HIV prevention; Core Outcome Set.

Dissemination plans Results will be shared via peer-reviewed publication, conference presentations, plain-language summaries, preprint repositories, and integrated into a Delphi survey or other consensus process.

Contributions of each author

Author 1 - Lawrence Mbuagbaw - Conceptualization, acquisition of funding, and drafting of the study protocol.

Email: mbuagblc@mcmaster.ca

Author 2 - Roseline Dzekem Dine - Drafting of the study protocol and data screening.

Email: diner@mcmaster.ca

Author 3 - Nataly Ayoub - Data screening.

Email: ayoubn1@mcmaster.ca

Author 4 - Haranie Sivakumar - Data screening.

Email: sivakh3@mcmaster.ca

Author 5 - Guillaume Fontaine - Conceptualization and acquisition of funding.

Email: guil.fontaine@mcgill.ca

Author 6 - Shirin Golchi - Conceptualization and acquisition of funding.

Email: shirin.golchi@mcgill.ca

Author 7 - Zoe Moodie - Conceptualization and acquisition of funding.

Email: zoe@fredhutch.org

Author 8 - Lara Maleyeff - Conceptualization and acquisition of funding.

Email: lara.maleyeff@mcgill.ca

Author 9 - Marc Parsons - Conceptualization and acquisition of funding.

Email: marc.parsons@mail.mcgill.ca

References

1. Hefron R, McClelland RS, Balkus JE, Celum C, Cohen CR, Mugo N, et al. Efficacy of oral pre-exposure prophylaxis (PrEP) for HIV among women with abnormal vaginal microbiota: a post-hoc analysis of the randomised, placebo-controlled Partners PrEP Study. *Lancet HIV*. 2017 Oct;4(10):e449-56. doi:10.1016/S2352-3018(17)30110-8 PubMed PMID: 28732773; PubMed Central PMCID: PMC5649365.

2. Murchu EO, Marshall L, Teljeur C, Harrington P, Hayes C, Moran P, et al. Oral pre-exposure prophylaxis (PrEP) to prevent HIV: a systematic review and meta-analysis of clinical effectiveness, safety, adherence and risk compensation in all populations. *BMJ Open*. 2022 May 11;12(5):e048478. doi:10.1136/bmjopen-2020-048478 PubMed PMID: 35545381; PubMed Central PMCID: PMC9096492.

3. Sagaon-Teyssier L, Suzan-Monti M, Demoulin B, Capitant C, Lorente N, Préau M, et al. Uptake of PrEP and condom and sexual risk behavior among MSM during the ANRS IPERGAY trial. *AIDS Care*.

-
- 2016;28 Suppl 1(sup1):48–55. doi:10.1080/09540121.2016.1146653 PubMed PMID: 26883400; PubMed Central PMCID:PMC4828609.
4. Nunn AS, Brinkley-Rubinstein L, Oldenburg CE, Mayer KH, Mimiaga M, Patel R, et al. Defining the HIV pre-exposure prophylaxis care continuum. *AIDS Lond Engl*. 2017 Mar 13;31(5):731–4. doi:10.1097/QAD.0000000000001385 PubMed PMID: 28060019; PubMed Central PMCID:PMC5333727.
5. Marcus JL, Hurley LB, Hare CB, Nguyen DP, Phengrasamy T, Silverberg MJ, et al. Preexposure Prophylaxis for HIV Prevention in a Large Integrated Health Care System: Adherence, Renal Safety, and Discontinuation. *JAIDS J Acquir Immune Defic Syndr*. 2016 Dec 15;73(5):540. doi:10.1097/QAI.0000000000001129
6. World Health Organization (WHO). HIV/AIDS [Internet]. 2023. Available from: <https://www.who.int/news-room/fact-sheets/detail/hiv-aids>
7. Fauci AS, Folkers GK, Lane HC. Human Immunodeficiency Virus Disease: AIDS and Related Disorders [Internet]. In *Harrison's Principles of Internal Medicine*; [cited 2026 Mar 25]. Available from: <https://accessmedicine.mhmedical.com/content.aspx?sectionid=192025263&bookid=2129&Resultclick=2>
8. Rosas Cancio-Suárez M, Díaz-Álvarez J, Ron R, Martínez-Sanz J, Serrano-Villar S, Moreno S, et al. From Innovation to Implementation: The Evolution of HIV Pre-Exposure Prophylaxis and Future Implications. *Pathogens*. 2023 Jul 9;12(7):924. doi:10.3390/pathogens12070924 PubMed PMID: 37513771; PubMed Central PMCID:PMC10384104.
9. Dine RD, Muraca G, Sadeghirad B, Mbuagbaw L. Adherence to the Dapivirine Vaginal Ring Among Cisgender Women in Africa: Protocol for a Systematic Review and Meta-Analysis. *Health Sci Rep*. 2025 Jul;8(7):e71057. doi:10.1002/hsr2.71057 PubMed PMID: 40709072; PubMed Central PMCID:PMC12286888.
10. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*. 2018 Oct 2;169(7):467–73. doi:10.7326/M18-0850 PubMed PMID: 30178033.
11. Dodd S, Clarke M, Becker L, Mavergames C, Fish R, Williamson PR. A taxonomy has been developed for outcomes in medical research to help improve knowledge discovery. *J Clin Epidemiol*. 2018 Apr;96:84–92. doi:10.1016/j.jclinepi.2017.12.020 PubMed PMID: 29288712; PubMed Central PMCID:PMC5854263.
12. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. *Implement Sci IS*. 2010 Sep 20;5:69. doi:10.1186/1748-5908-5-69 PubMed PMID: 20854677; PubMed Central PMCID:PMC2954944.