Development and Verification of Robust Comprehensive Code Lists to Ensure Consistency Across Global Real-World Evidence Studies

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Objective:

Demonstrate a framework using multiple sources and clinical input to enable effective global RWE programs, with both comprehensive and consistent value sets

Conclusion:

This demonstrates creation of comprehensive value sets

- → ensure consistency for global RWE studies
- appropriate comparison of scientific evidence across studies

Why is this important?

- · Code lists (value sets) provide a basis for computable operational definitions (CODefs) used in cohort selection, case ascertainment, cohort characterization, and outcomes assessment for real-world evidence (RWE) research.
- · Significant inconsistencies arise because:
 - · different coding systems are used across geographic regions
 - · no single reference source exists that contains a comprehensive list of codes/medications for a given clinical concept

1. ClinicalConcept

Identify the clinical concepts needed for the RWE study

2. Reference Sources

Review multiple global/regional reference sources

3. Initial ValueSet

Aggregate codes / meds across the sources for a comprehensive value set

4. Medical Review

Conduct medical review to confirm the value set

7 Drug Classes: 104 Distinct Meds

5. Map to Code Systems

Map to relevant code systems and link together

6. Organize by Indication

Organize linked value sets into relevant indication or therapeutic libraries

Antidepressant Therapies

43 References Sources

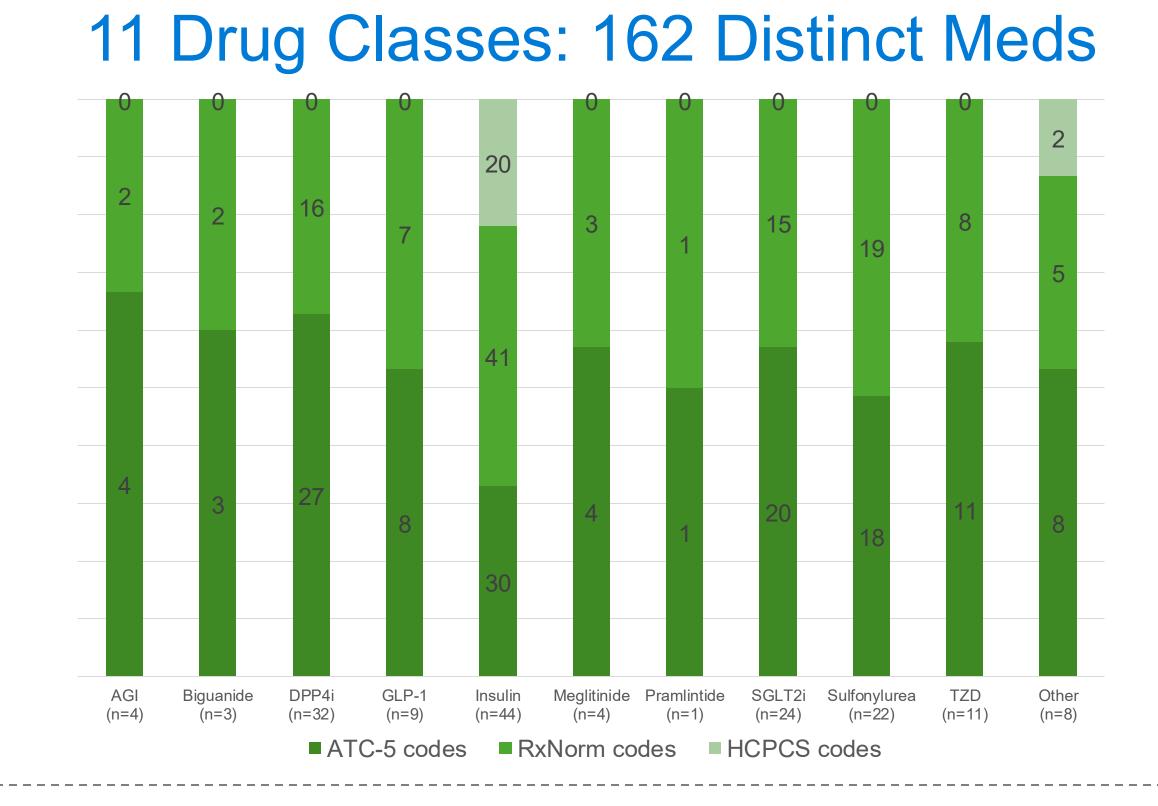
- Health institutes: WHO, APA
- Medical terminologies: WHO ATC, RxNorm, CPT HCPCS
- Published literature and value sets (e.g., NIH NLM VSAC)
- Reputable sites: Drugs.com, Wikipedia, OHDSI

26 distinct new value sets In the Depression Library

Antidiabetic Therapies

38 References Sources

- Health institutes: WHO, NHS, NIDDK, ADA, Diabetes UK
- Medical terminologies: WHO ATC, RxNorm, CPT HCPCS
- Published literature and value sets (e.g., NIH NLM VSAC)
- Reputable sites: Drugs.com, Wikipedia, OHDSI, CC, MC



35 distinct new value sets
In the Diabetes Mellitus
Library

Atherosclerotic

Cardiovascular

Diagnoses

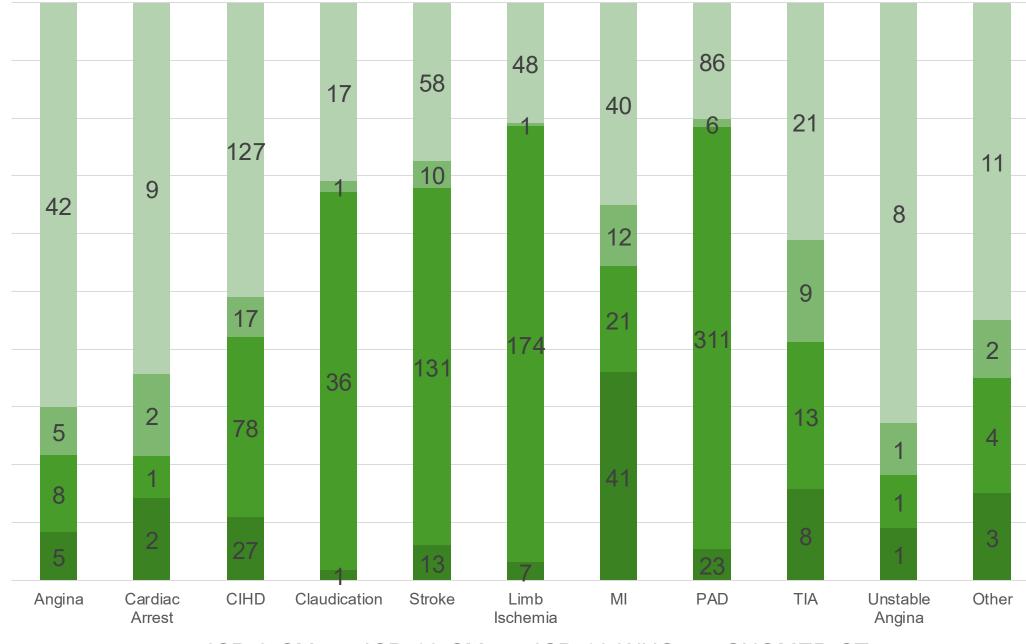
Disease (ASCVD)

13 References Sources

- Health institutes: NHS NICE, AHA, NHLBI, NRC, ICER
- Medical terminologies: ICD-9-CM, ICD-10-CM, ICD-10-WHO, SNOMED CT
- Published literature and value sets (e.g., NIH NLM VSAC)

* WHO: World Health Organization, APA: American Psychiatric Association, NIH: National Institutes of Health, NLM: National Library of Medicine, VSAC: Value Set Authority Center, OHDSI: Observational Health Data Sciences and Informatics, ADA: American Diabetes Association, CC: Cleveland Clinic, MC: Mayo Clinic, NHS: National Health System, NICE: National Institute for Health and Care Excellence (UK), NIDDK: NIH National Institute of Diabetes and Digestive and Kidney Diseases, AHA: American Heart

11 Distinct Medical Conditions



56 distinct new value sets
In the Cardiovascular
Library

Association, NHLBI: National Heart, Lung, and Blood Institute, NRC: National Research Council (US), ICER: Institute for Clinical and Economic Review