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## DRUG UTILIZATION RESEARCH DATABASES APPRAISAL OF MATURITY (DURDAM): AN INTERNATIONAL MODIFIED DELPHI CONSENSUS STUDY

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**Background.** Data used in drug utilization research (DUR) is routinely collected from sales data, reimbursement databases, disease registries, or electronic health records. The datasets, their characteristics, content, and accessibility vary between countries. The aim of this study was to determine whether the maturity of drug utilization (DU) datasets used in DUR could be appraised and, if so, to build a maturity appraisal tool.

**Aim.** To explore the components of DU databases for their ability to assess maturity and to determine the effectiveness and applicability of the national DU databases maturity appraisal tool for conducting comprehensive assessments of drug utilization databases.

### **Research Objectives.**

1. To undertake a modified Delphi consensus process, selecting a core set of drug utilization databases characteristics.
2. To build consensus among a group of international experts on mature dataset attributes in order to build a DUR maturity appraisal tool.
3. To evaluate the usability of the tool.

**Materials and Methods.** This two–phase project defined dataset maturity as comprehensiveness, completeness, and accessibility for DUR studies. Initially, three rounds of a Modified Delphi consensus process were utilized to develop a maturity assessment tool. Recruitment targeted 20 to 30 panel members with at least five years of DUR experience and English proficiency. A list of statements on the maturity dimensions was developed following open or semi-open questions in a Qualtrics questionnaire in Round 1. The relevance of listed dimensions of the maturity scales was ranked by a 7–point Likert scale on importance for inclusion (from “strongly disagree” to “strongly agree”) in Round 2. Selected maturity–related statements/groups/statements were used to reach consensus in Round 3. E–Delphi, a platform developed by Finnish future research institutions including the University of Turku Futures Research Centre and Society for Futures Research, was used for the modified Delphi process. In the second phase, the usability of the developed DU Databases Appraisal Tool was tested using a questionnaire.

**Results.** A total of 60 potential participants, experts in their fields, were identified and purposefully sampled to ensure global representation, with an initial target of 10 per WHO region, enhancing the international utility of the maturity appraisal tool. Out of these, 22 panelists were successfully recruited. The diversity of the participants included a mix of clinical academics, healthcare professionals, and policymakers. Gender balance was achieved among participants, who also displayed a broad age range, indicating a depth of experience.

*In Round 1*, information on each participant's country's health system was captured, along with data on drug use and its availability for drug utilization analysis. Ten statements were formulated, with four addressing comprehensiveness, four covering completeness, and two concerning accessibility.

*In Round 2*, opinions from panel members were solicited on selected statements. The statements assessing comprehensiveness involved multiple items, while those addressing completeness and accessibility comprised single statements.

*Round 3* achieved consensus in two semi-rounds on the primary endpoint, with over 75% agreement. Thirteen panelists provided consensus for the Drug Utilization (DU) Databases Appraisal Tool, with 84.62% of the panel members expressing their support.

Twenty experts, not involved in Phase 1, assessed the usability of the DU Databases Appraisal Tool. Usability test results are still being analyzed.

**Conclusions.** A modified Delphi consensus process was successfully conducted to select a core set of characteristics for drug utilization databases. A consensus was established among a group of international experts regarding mature dataset attributes, leading to the development of a framework for the Drug Utilization Review (DUR) maturity appraisal tool. Following steps include accessibility testing and validation of the DU Databases Appraisal Tool.

**Keywords.** Drug Utilization Research; Expert Consensus; Delphi method; Drug Utilization Research Databases; Maturity Appraisal Tool.