VILNIUS UNIVERSITY FACULTY OF MEDICINE

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MASTER'S THESIS

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

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VAISTŲ NAUDOJIMO TYRIMŲ DUOMENŲ BAZĖS BRANDOS VERTINIMAS (DURDAM): TARPTAUTINIS PAKEISTAS DELPHI KONSENSUSO TYRIMAS

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LIST OF ABBREVIATIONS

AFR - African Region

AMR - Region of the Americas

ATC - Anatomical Therapeutic Chemical

DDD – Defined Daily Dose

DUR - Drug Utilization Research

DURDAM - Drug Utilization Research Databases Appraisal of Maturity

DURG – Drug Utilization Research Group

DU – Drug Utilization

EMR - Eastern Mediterranean Region

EUR - European Region

NMD - The Norwegian Medicinal Depot

OTC - Over-the-counter

PDD – Prescribed Daily Dose

SEAR - South-East Asian Region

U.S. – United States

VRBREK - Vilnius Regional Biomedical Research Ethics Committee

WHO – World Health Organization

WPR - Western Pacific Region

SUMMARY

Data used in drug utilization research (DUR) is routinely collected from sales data, reimbursement databases, disease registries, or electronic health records, with databases varying in characteristics, content, and accessibility between countries. The aim of this study is to determine whether the maturity of drug utilization (DU) databases used in DUR could be appraised and, if so, to build a maturity appraisal tool. This Master thesis is a part of the DURDAM project (1). In the master thesis it was aimed to explore the components of DU databases for their ability to assess maturity and to gain consensus on the key attributes needed to develop a national maturity appraisal tool. Five research objectives were created to fulfil the overall aim: to identify and recruit international experts in DUR, to collate information on DU data available worldwide, to identify key attributes and characteristics of DU databases that explain the completeness and comprehensiveness of DU data, to draft statements to assess the maturity of DU databases and to build consensus among international experts on the key attributes of DU data for a national DU database maturity appraisal tool. In this project database maturity was defined 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 participants 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 next phase, the usability, acceptability and validity of the developed DU Databases Appraisal Tool will be tested. Results included the identification and purposeful sampling of 60 potential participants to ensure global representation, with 22 participants successfully recruited. These participants included clinical academics, healthcare professionals, and policymakers, achieving gender balance and a broad age range. Information on each participant's country's health system was captured, along with data on drug use and its availability for DU analysis. Ten statements relating to DU database maturity were formulated, addressing comprehensiveness, completeness, and accessibility. Consensus was achieved on

the primary endpoint with over 75% agreement on the proposed statements, with 13 participants providing feedback and 11 (85%) expressing support for all statements. Conclusions indicated that a modified Delphi consensus process was successfully conducted to select a core set of characteristics for DU databases. A consensus was established among a group of international experts regarding mature database attributes, leading to the development of a framework for the DUR maturity appraisal tool. Following steps include accessibility testing and validation of the DU Databases Appraisal Tool.

SANTRAUKA

Duomenys, naudojami vaistų vartojimo tyrimuose (*VVT, angl. DUR*), yra reguliariai renkami iš pardavimų duomenų, kompensacijų duomenų bazių, ligų registrų ar elektroninių sveikatos įrašų, o duomenų rinkiniai skiriasi savo savybėmis, turiniu ir prieinamumu tarp šalių. Šio tyrimo tikslas yra nustatyti, ar galima įvertinti vaistų vartojimo vaistų vartojimo (VV, *angl. DU*) duomenų rinkinių, naudojamų VVT, brandumą ir, jei taip, sukurti brandumo vertinimo įrankį. Šis magistro darbas yra DURDAM (1) projekto dalis. Šio magistro darbo tikslas buvo ištirti VV duomenų bazių komponentus, jų gebėjimą vertinti brandumą ir pasiekti sutarimą dėl pagrindinių atributų, reikalingų nacionaliniam brandumo vertinimo įrankiui sukurti. Tyrimo tikslui įgyvendinti buvo iškelti penki tyrimo uždaviniai: identifikuoti ir atrinkti tarptautinius VVT ekspertus; surinkti informaciją apie VV duomenis, prieinamus visame pasaulyje; nustatyti pagrindinius atributus ir VV duomenų bazių savybes, kurie paaiškina VV (duomenų pilnumą (*angl. completeness*) ir išsamumą (*angl. comprehensiveness*); parengti teiginius, skirtus VV duomenų rinkinių brandumui vertinti ir pasiekti sutarimą tarp tarptautinių ekspertų dėl pagrindinių VV duomenų atributų nacionaliniam VV duomenų rinkinių brandumo vertinimo įrankiui. Šis dviejų fazių projektas apibrėžė duomenų rinkinio brandą kaip išsamumą (*angl. comprehensiveness*), pilnumą (*angl. completeness*) ir prieinamumą (*angl. accesibility*) VVT tyrimams. Pirmoji projekto fazė buvo sudaryta iš trijų Modifikuoto Delphi konsensuso proceso etapų tam, kad būtų sukurtas brandumo įvertinimo įrankis. Atrankos metu buvo tikslas atrinkti 20-30 dalyvių, turinčių bent penkerių metų VVT patirtį ir mokančių anglų kalbą. Pirmojo etapo „Qualtrics" klausimyne, kuris buvo sudarytas iš atvirų ir pusiau atvirų klausimų, buvo suformuluotas teiginių apie brandumo dimensijas sąrašas. Antrajame etape svarbos įtraukimui (nuo „visiškai nesutinku" iki „visiškai sutinku") reikšmingumas buvo įvertintas 7 balų Likerto skalėje. Pasirinkti susiję su brandumu teiginių/grupių/teiginių rinkiniai buvo naudojami konsensusui pasiekti trečiajame etape. E-Delphi, platforma, kurią sukūrė Suomijos ateities tyrimų institucijos, įskaitant Turku Universiteto Ateities Tyrimų Centrą ir Ateities Tyrimų Draugiją, buvo naudojama modifikuotam Delphi procesui. Rezultatai apėmė 60 potencialių dalyvių identifikavimą ir tikslingą atranką siekiant užtikrinti globalų atstovavimą, su pradiniu tikslu – 10 asmenų kiekvienam Pasaulio sveikatos organizacijos (PSO, *angl. WHO*) regionui, tokiu būdu didinant tarptautinį vertinimo įrankio naudingumą. Iš jų sėkmingai buvo įtraukti 22 dalyviai. Dalyvių įvairovė apėmė klinikinių akademikų, sveikatos priežiūros specialistų ir politikos formuotojų mišinį. Tarp dalyvių buvo pasiekta lyčių pusiausvyra, taip

pat buvo pasiektas platus amžiaus diapazonas, rodantis projekto dalyvių gilią patirtį šioje sferoje. Pirmajame etape buvo surinkta informacija apie kiekvieno dalyvio šalies sveikatos sistemą, taip pat duomenys apie vaistų vartojimą ir jų prieinamumą VV analizei. Taip pat buvo suformuluoti dešimt teiginių, susijusių su VV duomenų rinkinių brandumu, apimančių išsamumą, pilnumą ir prieinamumą. Pagrindiniame vertinimo taške buvo pasiektas sutarimas, daugiau kaip 75% sutarus dėl siūlomų teiginių, 13 dalyvių pateikė atsiliepimus, iš kurių 11 (85%) išreiškė palaikymą visiems teiginiams. Išvados parodė, jog sėkmingai buvo atliktas modifikuotas Delphi konsensuso procesas, siekiant išrinkti pagrindinių vaistų vartojimo duomenų bazių savybių rinkinį. Tarptautinių ekspertų grupėje buvo pasiektas konsensusas dėl duomenų bazių brandumo atributų ir to dėka buvo sukurtas VVT brandumo įvertinimo įrankio pirminis variantas. Sekantys projekto žingsniai apims prieinamumo (*angl. accessibility*) testavimą ir VVT naudojamų duomenų bazių brandos įvertinimo įrankio validavimą.

1. INTRODUCTION

Drug Utilization Research (DUR) is a multifaceted field of study that plays a pivotal role in shaping healthcare policies, optimizing patient care, and advancing pharmacovigilance (1). DUR encompasses a wide range of methods designed to comprehensively analyse the prescribing, dispensing, and consumption of medications within healthcare systems. It facilitates a deeper understanding of medication utilization patterns, including aspects such as the determinants of drug use, drug safety, and the quality of drug therapy (2). Through the systematic examination of real-world data, DUR contributes invaluable insights to healthcare decision-makers, clinicians, and researchers (3). Therefore, DUR serves as a crucial bridge between the disciplines of pharmacoepidemiology and health services research, with the overarching aim of promoting the safe, effective, and evidence-based use of pharmaceuticals in diverse populations (4).

In March 2020 at the EuroDURG conference in Szeged, Hungary a review of DU database maturity across the world was commissioned by the executive committee. Previously members of the executive committee had been involved in reviewing the availability of DU databases across Europe and at the time a review of DU databases in South America was nearly finished. Because of the COVID-19 pandemic work was postponed until 2021 where a series of meetings of interested EuroDURG executive members met several times. From these meetings it was clear that there was limited shared understanding of the healthcare systems across the world, the databases available for DUR and that there were no clear definitions of DUR databases or how their "maturity" might be assessed.

It was agreed to address the lack of a clear definition of DUR database maturity by conducting a study to achieve the following:

- recruit a wide range of subject matter experts to identify the domains and items that are most important in assessing the maturity of a DUR database.
- for each domain/item they will also define what is low or high maturity and these can be combined for an overall maturity score.
- the subject experts can help with the development and testing of a self-assessment tool.

In this study our main goal is to create statements that can be used in a national DU databases maturity appraisal tool, the first item in the list above. Regarding what kind of

implications the tool could have on the broader community it is essential to consider its potential to become a significant instrument in the assessments of various databases. In an era where data-driven decision-making is increasingly vital, such a tool can provide a structured framework for assessing the quality, completeness, and reliability of healthcare databases, enabling healthcare providers, researchers, and policymakers to make more informed choices (5). By ensuring the maturity of healthcare databases, it becomes possible to enhance the accuracy and effectiveness of predictive models, treatment recommendations, and public health interventions. Furthermore, the healthcare sector generates vast amounts of sensitive patient data, and a maturity appraisal tool can contribute to the preservation of data privacy and security, addressing ethical concerns while advancing the responsible use of healthcare information. Such an approach aligns with the growing emphasis on data-driven healthcare innovation and fosters the trust and transparency essential for the responsible development of healthcare technologies (5, 6).

In addition to this, the significance of this study can be traced back to the first attempt on conducting DU research. The pioneers of this field Arthur Engel in Sweden and Pieter Siderius in Holland shed light on the critical importance of comparing DU patterns among different countries and regions. Their influential study, which revealed striking disparities in antibiotic sales across six European nations between 1966 and 1967, led to the formation of the WHO European Drug Utilization Research Group (DURG) (7). By continuing our predecessors work of cross-country DUR comparison our study's main goal is to gain consensus on statements to be included in a national DU databases maturity appraisal tool by which researchers who undertake DUR could assess their countries' DU database maturity and if possible, identify key areas of improvement and contribute to collaborative national comparisons.

Aim: To explore the components of DU databases for their ability of assessing maturity and to gain the consensus on the key attributes of the development of a national maturity appraisal tool.

Research objectives:
1. To identify and recruit international experts in DUR.
2. To collate information on DU data available in countries across the world.

3. To identify key attributes and characteristics of DU databases that explain the completeness and comprehensiveness of DU data.

4. To draft statements that could be used to assess the maturity of DU databases.

5. To build consensus among a group of international experts on the key attributes of DU data that could be used in a national DU database maturity appraisal tool.

In the project, during the last two rounds I independently managed participant communications by sending out the invitation and reminder emails to each of the participants. In addition to this, I was responsible for calculating the results and formatting the figures and tables. Throughout the recruitment process, together with the rest of the DURDAM team we researched and identified appropriate candidates for the study as well. Furthermore, I contributed to data analysis and provided insights to improve the overall study.

2. LITERATURE REVIEW

2.1. Drug Utilization Research (DUR)

2.1.1. Historical Development

According to the World Health Organization the first examples of DUR occur in the 1960s, specifically when the WHO Regional Office of Europe published a ground-breaking study on Drug Consumption from 1966-1967 (8). This work by Arthur Engel from Sweden and Pieter Siderius from Holland, revealing significant disparities in antibiotic sales among six European nations from 1966 to 1967 sparking an interest in the 1969 WHO symposium to establish an international DU studies classification system (7). Consequently, the WHO European Drug Utilization Research Group (DURG) was established and in the coming years The Norwegian Medicinal Depot (NMD) pioneered the development of a classification system known as the Anatomical Therapeutic Chemical (ATC) (9). Additionally, Norwegian researchers developed a technical unit of measurement known as the Defined Daily Dose (DDD) for its application in DU studies (10). In 1981, inspired by their counterparts in the North, the WHO Regional Office for Europe opted to endorse the ATC/DDD system for conducting DU studies across Europe. In the following year a WHO Collaborating Centre for Drug Statistics Methodology was established with a mission to advance the development of the ATC/DDD methodology. Finally, 1996 was the year when the WHO recommended the implementation of the system to be used internationally (11) (Figure 1).
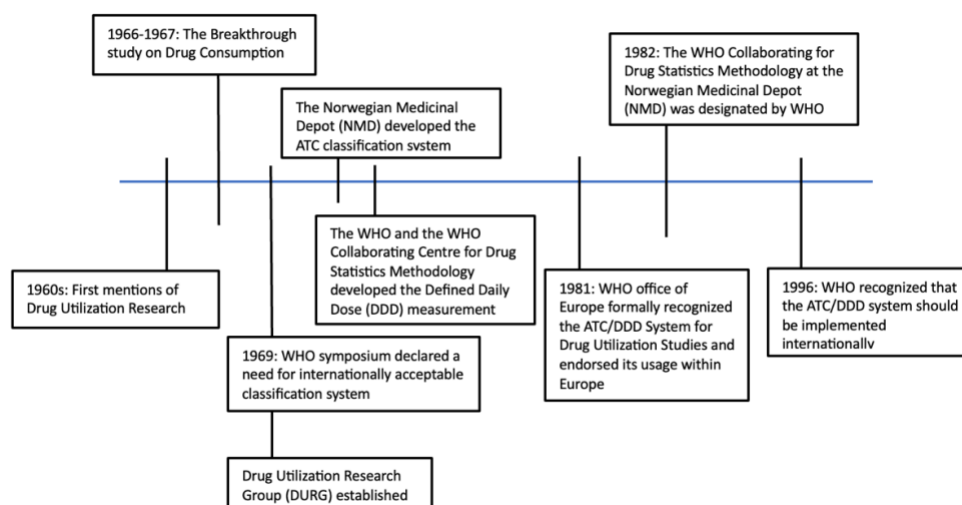

Figure 1. Development of DUR throughout the years.

2.1.2. Key Milestones in DUR Evolution

The second half of the 20th century certainly was the period of time when the development of the DUR concept gained momentum and underwent an advancement in its methodologies, institutional frameworks, and international collaboration.

Unambiguously one of the cornerstones in the field of pharmacology and DU studies was the invention of the ATC classification system. Developed by the NMD in collaboration with the WHO, the ATC system provides a standardized and internationally recognized framework for classifying pharmaceutical substances. Organized into hierarchical levels based on the anatomical, therapeutic, and chemical characteristics of drugs, the ATC system allows for systematic and comprehensive categorization: each drug is assigned a unique code, facilitating uniformity in the description of medications across diverse healthcare settings (12) (Table 1). The ATC system has proven invaluable in conducting DUR, enabling comparisons of drug usage patterns within and across different regions and countries.

Table 1. ATC classification systems levels.

Level	Level abbreviation	ATC Code	Level Identification	Example
1st Level	ATC1	A	Anatomical Main Group	Alimentary track and metabolism
Definition	Classifies drugs based on the main anatomical or physiological system on which they act or their therapeutic effects			
2nd Level	ATC2	A10	Therapeutic Subgroup	Drugs used in diabetes
Definition	Further categorizes drugs based on their therapeutic use within the anatomical main group.			
3rd Level	ATC3	A10B	Pharmacological Subgroup	Blood glucose lowering drugs, excl. insulin
Definition	Offers a more detailed classification of drugs within the therapeutic subgroup.			
4th Level	ATC4	A10BA	Chemical Subgroup	Biguanides
Definition	Identifies the chemical structure of the drug, particularly relevant for drugs with similar therapeutic uses			
5th Level	ATC5	A10B A02	Chemical Substances	Metformin
Definition	Provides the most detailed level of classification, specifying individual chemical substances or specific drug formulations			

However, it has to be realized that the use of classification system alone cannot suffice to enable carrying out comprehensive DU studies; an equally important aspect is the appropriate measurement unit. It is against this background that Defined Daily Dose (DDD) was devised as an additional use tool in complementing the ATC classification system by WHO Collaborating Centre for Drug Statistics Methodology in Norway. This means that the addition of the DDD unit of measurement to the ATC system significantly strengthened its effectiveness by providing a standardized metric for the assessment and comparison of drug use tendencies (13). The DDD works in tandem with the ATC classification system. While ATC indicates the characteristics of the drug, DDD shows the average daily maintenance dosage for an adult patient, expressed in its different units, for example, milligrams or grams that might change depending on the route of administration (14). Developed to address challenges associated with dosage forms, the DDD also provides practical monitoring in cases where usages fluctuate over time, especially with changes in formulation composition or alteration in pack sizes, which are common in health care facilities (15). Also, it is necessary to clarify the DDD from the prescribed daily dose (PDD), which helps refer to the average amount of the drug in a day prescribed and calculated on representative cross-sectional sample prescription (16). The PDD which can be distinguished through analyses of prescriptions, medical or pharmacy records will give the average daily amount of a drug that is actually prescribed while the DDD serves as a technical unit, constituting a fixed measurement standard, which may not always align with the recommended or PDD (16). It is also to be noted that since ATC/DDD classification corresponds to the dosage form of a drug, it has to lead to the possibility of multiple ATC codes and respective DDDs for a single medication. For example, products presented as both tablets and injections have different ATC codes, hence the DDDs could be different. Moreover, while most substances have assigned ATC codes, some have not been assigned DDDs. These include systemic agents such as topical products, antineoplastic agents, vaccines, sera, anaesthetics, allergen extracts, and contrast media. Most ophthalmologicals (S01) and otologicals (S02) usually do not have assigned DDDs, with some antiglaucoma drugs being an exception. Given that changes in the ATC and DDD classifications are likely to occur, attention is drawn to exactly which version of the ATC index an author uses in his or her research on drug consumption. This is most important during data analysis over time or for international comparisons (14).

An example of such analysis is the study "Trend of Antihypertensive Medicine Use in the Baltic States between 2008 and 2018." This study exemplifies the use of the ATC and DDD systems in a cross-national context, analysing trends in antihypertensive medication use across

the three Baltic countries (17). The researchers used nationally representative wholesale data and the ATC/DDD methodology to explore and compare usage trends, demonstrating significant differences and changes over the 11-year study period. The results from this study revealed distinct patterns and trends in the utilization of antihypertensive medications across Estonia, Latvia, and Lithuania. In 2018, Estonia and Lithuania showed higher usage rates at 372 and 379.5 Defined Daily Doses per Thousand Inhabitants per Day (DDD/TID), respectively, compared to Latvia's 267 DDD/TID. This indicates varying levels of medication access or differing healthcare policies that might influence prescription behaviours. Furthermore, the study highlighted a consistent annual increase in antihypertensive medication use across the three countries, with Estonia experiencing the highest annual increase at 10.88 DDD/TID, suggesting an improving focus on managing hypertension. The study also revealed another limitation within the ATC/DDD classification system, specifically with the classification of combination drugs. It was noted that since each combination product is counted as a single daily dose, if a treatment regime shifts from using two separate medications to one combination drug, the DU statistics might show a decrease. However, in reality, the actual use (or true use) of medications remains unchanged - patients are still receiving the same amount of active ingredients, just combined in one drug instead of two. Furthermore, the article also suggested that as the use of combination drugs increased, the true use of medicines may actually increase more than what the utilization data indicates. This discrepancy arises because the data might underreport usage due to the way combination drugs are counted in the system. In summary, this study not only highlighted the power of standardized tools in facilitating meaningful comparisons across various health systems and populations but also pointed out the limitations of the ATC/DDD system in handling combination drugs. These limitations can lead to misleading interpretations of DU data, underestimating the actual amount of drug consumption when patients switch from single ingredient drugs to combination products.

Another illustrative example of such a study that showcases the importance of using the ATC/DDD system for international comparisons and temporal data analysis is the research titled "Community level antibiotic utilization in India and its comparison vis-à-vis European countries: evidence from pharmaceutical sales data". This study, published in *PLoS One* in 2018 by Farooqui et al., leverages pharmaceutical sales data to analyse antibiotic usage patterns in India compared to several European countries using the ATC/DDD system. The study demonstrates how these standardized tools are vital for comparing DU across different healthcare systems and for tracking changes in drug usage patterns over time. The results of this comprehensive study by Farooqui et al. reveal intriguing insights into the trends and

patterns of antibiotic consumption. The study documented that, on average, the antibiotic consumption in India increased from 13.1 Defined Daily Doses per 1000 inhabitants per day (DID) to 16.0 DID between 2008 and 2012, indicating a rise in the usage of these medications. This was contrasted against the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) countries, where the average antibiotic use was 21.54 DID, suggesting that while India's antibiotic use was growing, it still remained lower than many European counterparts This kind of analysis helps policymakers and healthcare professionals understand differences in medication practices and can guide efforts to optimize drug use globally. It provides a robust methodology for ensuring that comparisons are based on standardized criteria, making it easier to interpret trends and variations accurately. (18)

All in all, the combined use of the ATC/DDD system enables the standardization of drug categories and provides a consistent metric for assessing DU. The usage of this standardized unit has played a pivotal role in promoting consistency, clarity, and international collaboration in the analysis of pharmaceutical data, contributing significantly to advancements in the understanding and management of DU worldwide. By streamlining the analysis of variations in medication utilization across diverse regions and demographic groups, researchers, healthcare practitioners, and policymakers can discern and address disparities in drug usage more effectively.

2.2. Delphi process

2.2.1. Origins and development

The Delphi method, first developed in the late 1940s by researchers at RAND Corporation, is a systematic approach widely recognized for leveraging collective intelligence and expert opinions. It involves a structured process aimed at fostering consensus and predicting outcomes on complex and uncertain subjects (19, 20). The definition of this concept truly allies with the naming of the techniques as well. The Delphi method derives its name from the Greek town of Delphi, which housed a temple with a renowned oracle, Pythia, through whom Apollo, son of Zeus and god of light, the sun, and prophecy, spoke to predict the future. When Pythia saw visions of the future, she would be in a hectic state of mind, turning side to side and speaking incoherently while conveying what she had seen. In comparison to the ancient tale of prediction, the Delphi method used in the present time is a much more refined and controlled technique compared to its so-called predecessor (21).

Originating at the Rand Corporation, the method's first deployment, known as "Project Delphi," was a ground-breaking endeavour aimed at predicting critical events in defence and military realms. During the 1950s, the United States Air Force sought actionable intelligence regarding Soviet perceptions of strategic U.S. industrial targets and the necessary firepower to disrupt munitions production (22, 23). Traditional research approaches of the era would have necessitated complex computational tools and subjective estimations beyond the technological capabilities of the time. In response, the research team, led by luminaries such as Dalkey and Helmer, pioneered an innovative methodology: leveraging the collective wisdom of experts through iterative rounds of anonymous surveys and feedback. By harnessing the diverse expertise of participants and distilling their insights into consensus-driven forecasts, the Delphi method provided a novel pathway to uncovering actionable intelligence in an era defined by uncertainty and geopolitical tension (23). This landmark application not only laid the foundation for subsequent advancements in Delphi methodology but also underscored its enduring relevance as a powerful tool for informed decision-making in complex, dynamic environments.

2.2.2. Delphi Method

The premise of the Delphi method remains consistent over time. At its core, the technique aims to achieve consensus on a particular topic by leveraging a group of experts specializing in that specific field of work. Initially, experts are selected based on their relevant knowledge and experience. The process begins with the formulation of a set of open-ended questions or statements related to the topic, which are then presented to the participants through anonymous surveys or questionnaires (24). Following the receipt of responses, a facilitator or moderator consolidates and anonymizes the feedback. The aggregated responses are then redistributed to the participants in subsequent rounds, along with any relevant summaries or analyses. Participants are encouraged to review and adjust their responses in light of the collective feedback received, fostering a process of convergence toward a consensus opinion or prediction. Through its iterative nature, the Delphi method allows for the refinement of responses across multiple rounds, aiding in mitigating biases and revealing novel insights. This systematic approach enables the Delphi method to harness the collective expertise of experts and offer valuable insights for decision-making across various domains, including technology forecasting, policy formulation, and strategic planning (25).

2.2.3. Advantages and Disadvantages of the Delphi Method

A significant advantage of the Delphi method lies in its capacity to harness a broad spectrum of expertise from geographically dispersed experts, thereby fostering a comprehensive understanding of intricate issues and potential future scenarios. This method's ability to engage a broad spectrum of expertise from geographically dispersed individuals is one of its significant advantages, enabling a comprehensive analysis of intricate issues in a cost-effective manner (26). As noted by Helmer and Rescher (as cited in Helmer, 1960) the anonymity afforded by the Delphi process cultivates a favourable environment to unfiltered and honest responses which are free from any kind of psychological factors' influences namely the "bandwagon effect" - where individuals align with the majority opinion for the sake of conformity rather than conviction (27). Such minimizing of the influence of dominant personalities enhances the openness of the participants, allowing them to express their own honest opinions and to re-evaluate their views in subsequent rounds, ultimately leading to more accurate and valid results (28).

However, the method is not devoid of challenges. The prolonged duration associated with multiple rounds of data collection and analysis can hinder the swift resolution of a specific problem, thus rendering it less suitable for time-sensitive decision-making contexts (29). Another issue is the lack of a universally accepted definition of consensus (where agreement levels may vary between 50% to 70%) that may complicate the determination of when a consensus has actually been achieved (30). Additionally, the method suffers from high attrition rates with increasing rounds, which can affect the reliability of the outcomes (31). A study highlighted in *PloS One* in 2018 discussed the retention rates throughout several recent international e-Delphi surveys, which varied significantly, with retention rates of 19.5% to 87.1% (32). This variability in retention underscores the challenges of small group sizes and high attrition rates, which can compromise the reliability of the outcomes in Delphi studies. Another significant challenge is the selection and definition of experts (33). Without clear guidelines on panel size and sampling techniques, the Delphi method can struggle with ensuring a representative and balanced panel. Moreover, the quest for consensus among experts may encounter hurdles, particularly in instances where divergent viewpoints persist, potentially introducing biases into the final conclusions (34).

Despite these limitations, the Delphi method remains a valuable tool for research and decision-making, particularly in scenarios where direct consensus is difficult to achieve. Its structured approach to collecting and refining expert opinion makes it a unique and powerful

tool in the arsenal of research methodologies. To maximize its effectiveness, careful planning, clear definition of consensus, and active management of participant engagement are crucial. These strategies can help mitigate some of the method's inherent drawbacks, ensuring that it continues to provide valuable insights across various disciplines.

2.3 Maturity assessment frameworks in Healthcare research

When talking about any kind of development in the healthcare field, it is critical to recognize that it's a matter of high importance due to its direct impact on human lives. In order to tackle such occurring issues, it's pivotal to appreciate maturity assessment frameworks as tools which can aid in determining the readiness and effectiveness of healthcare systems by utilizing and intergrading new technological advancements and novice methodologies (35). These frameworks offer a structured methodological approach in evaluating the progress and capabilities of healthcare organizations across various domains, such as technological adoption, data management, and overall research proficiency (36, 37). The essence of these frameworks lies in their ability of identifying developmental gaps, facilitating strategic enhancements, and helping in reaching the defined benchmark advancements over time, ensuring that the healthcare institutions could meet the changing demands and accordingly improve patient care outcomes (38).

According to the Oxford English Dictionary the definition of "maturity" is expressed as "The state of being complete, perfect, or ready; fullness of development." (39). And while the concept in 1979 by Phili B. Crosby was first introduced to be used for business or organizational type of processes to evaluate, it later on gained the momentum of being implemented in other fields as it was found to be useful in their enhancement as well (35, 40). The methodology of the maturity model used nowadays does not deviate much from its initial groundwork: a series of specific maturity stages which represent an anticipation or desire in the progress of evolution of the subjects of focus (35, 41). The lowest level signifies the minimal capabilities, while the highest indicates a complete state of maturity. During the progress of the process the maturity model acts as a benchmark for evaluating an organization's current stage of development as it uses the specific criteria and characteristics that have to be met in order to advance to higher levels of maturity. Assessment is made taking into account the criterions and a maturity level can then be determined (41).

Building on the established importance of maturity assessment frameworks in healthcare, it is worthy going through the findings and implementations of such specific

methodologies in contemporary research. For instance, the Public Health Information Technology Maturity Index (PHIT Maturity Index), as explored by Crowley et al. (2016), provides a structured methodology for evaluating IT development within public health sectors. In this study the researchers had a goal of developing a PHIT Maturity Index which could aid in the betterment of the healthcare field. Their aim was achieved consisting of the PHIT Maturity index, a questionnaire and a scoring system which they had created. This index benchmarks the current IT capabilities against expected outcomes, offering actionable insights for technological upgrades necessary for enhanced public health management. This index could assess areas like data management and system interoperability across defined maturity levels, from initial to optimized. By using the tool organizations had the ability to benchmark against best practices and identify IT gaps, guiding strategic enhancements in their sector. The maturity index was a vital contributor to the improvement of IT governance, enhancement of public health management and facilitation of faster response-rates in health emergencies, further bolstering better disease surveillance and patient data management across public health organizations (42).

Another valuable study to examine is that by Shaygan and Daim (2023), which explores the use of a Technology Management Maturity Assessment Model specifically tailored for healthcare research centres. This model contrasts with the PHIT Maturity Index by focusing more on the technological management aspects of healthcare rather than just public health IT systems. Shaygan and Daim's study aimed to create a framework that could systematically evaluate and enhance the technological capabilities of healthcare research institutions. Their model assesses several critical dimensions, including technological infrastructure, innovation management, and knowledge transfer capabilities, mapping them across various maturity stages from nascent to advanced. The results of the model's implementation highlighted significant improvements in research output and operational efficiency within participating centres. The model enabled these centres to pinpoint areas where technology management practices were lacking, prioritise technological investments, and facilitate the incorporation of cutting-edge technologies into their daily operations. The Technology Management Maturity Assessment Model demonstrated its effectiveness by helping institutions not only in the comprehension of their current technology management status but also by providing a clear roadmap for achieving higher levels of technological integration and sophistication. This approach proved particularly beneficial for enhancing data analytics capabilities and supporting more robust research methodologies, ultimately leading to improved healthcare outcomes (43).

Together, these two studies by Crowley et al. (2016) and Shaygan and Daim (2023) show how maturity assessment frameworks can be used in a variety of ways and can have a substantial impact in healthcare (42, 43). Namely, each of the frameworks presents unique guidance and instruments for bettering technology adoption and utilization in various parts of the healthcare industry. Since both public health and research-oriented healthcare institutions possess unique characteristics and requirements, such a differentiated approach to maturity assessment proves to be particularly vital for both domains.

2.4 Previous studies using Delphi to gain consensus in healthcare and/or data maturity

The Delphi method, renowned for its systematic approach to achieving consensus among experts, has been extensively utilized in healthcare research to solidify consensus on complex issues like healthcare service quality, clinical guidelines, and more recently, data maturity frameworks. This methodological approach serves as a critical tool in healthcare settings where collective expert opinions are crucial for guiding decisions and policy standards. One significant study leveraging the Delphi technique is by Maaß et al. (2024), which aimed at evaluating digital public health system maturity across nations (44). Through a multidisciplinary Delphi study, they sought to reach consensus on quality indicators that effectively measure the maturity of digital public health systems. This study not only outlined a methodological framework but also highlighted the versatility of the Delphi method in addressing the uncertainties inherent in measuring system-wide digital health initiatives across varied international contexts. Similarly, another study by Krasuska et al. (2020) focused on assessing digital excellence in hospitals within high-performing healthcare systems through an international eDelphi exercise (45). This study effectively used the Delphi method to forge a consensus among experts on defining digital maturity, which was crucial for developing actionable insights that guide technological advancements in hospital settings. Furthermore, the research by Zhang and Duan (2024) employed the Delphi method to develop and validate a maturity model for the medical humanities, illustrating its applicability beyond typical clinical and public health applications (46). This study underscores the method's utility in achieving a nuanced understanding of less quantifiable domains of healthcare, ensuring that educational and ethical dimensions are also advancing in alignment with clinical practices. Each of these studies reflects the Delphi method's robustness in facilitating structured communication among diverse expert groups to develop, refine, and validate frameworks and standards in healthcare. These frameworks are crucial as they help healthcare organizations

assess their current capabilities and set realistic benchmarks for technological and operational enhancements. By enabling a rigorous consensus-building process, the Delphi method ensures that the derived standards are comprehensive, reflective of expert insights, and adaptable to the dynamic nature of healthcare challenges. This approach not only fosters alignment with broad strategic healthcare goals but also ensures that the advancements in healthcare technology and data management are universally relevant and grounded in expert consensus.

In conclusion, the Delphi method's application across these studies demonstrates its effectiveness in harmonizing expert opinions to create impactful, evidence-based frameworks in healthcare. These studies collectively highlight the method's pivotal role in guiding the continuous evolution of healthcare practices, particularly in the realms of technology adoption and data maturity, ensuring that healthcare systems remain responsive to emerging challenges and opportunities.

3. METHODS

This project defined DU database maturity as comprehensiveness, completeness, and accessibility for DUR studies. The first phase of the project consisted of three rounds of a Modified Delphi consensus process to develop a maturity assessment tool, targeting 20 to 30 expert participants with at least five years of DUR experience and English proficiency. In Round 1, a list of statements on maturity dimensions was developed using open or semi-open questions in a Qualtrics questionnaire. In Round 2, the relevance of these dimensions was ranked on a 7-point Likert scale. In Round 3, consensus was reached on selected statements. The E-Delphi platform was used for the process.

3.1. Study design

This is a master's thesis project that encompassed a mixed-method approach, integrating both simple quantitative and qualitative analyses. The project's procedural flow is depicted in Figure 2 for clarity and reference.
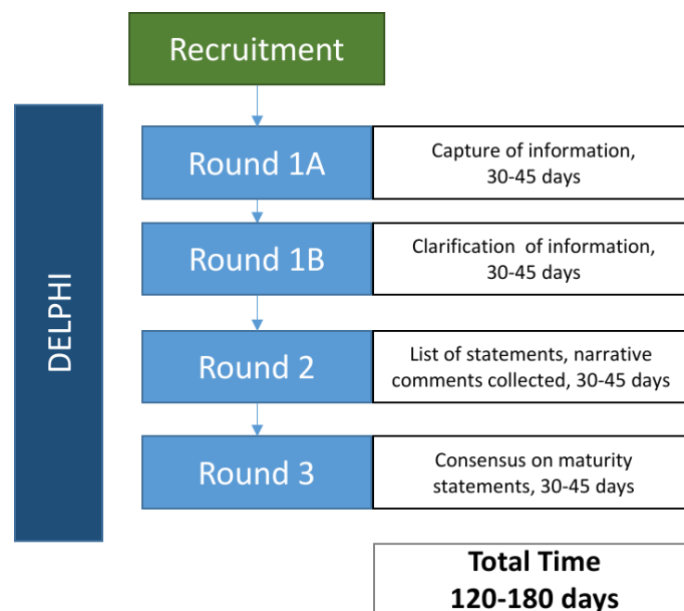

Figure 2. Workflow of the Project.

3.2 Study process and data collection

Objective 1: *To identify and recruit international experts in DUR.* (**Recruitment and Background information**)

Participants for the project were selected through a purposeful sampling method using recently published DUR, existing national academic research groups and international research networks. The assembled panel was designed to include diverse representatives from key stakeholder categories, such as clinical academics, healthcare professionals, public servants, and policy makers (25, 47). Ten individuals from each WHO region currently active in DUR, totalling 60 participants were selected. The inclusion criteria mandated at least 5 years of experience in drug use databases or DUR (48) and proficiency in using the English language, ensuring effective communication and collaboration within the project. The primary data collection instrument was a questionnaire built in Qualtrics featuring a blend of closed and open-ended questions. Individuals indicating an interest in participating in the project were surveyed to determine the primary focus of their DUR, the number of years of involvement in DUR and their gender. Details of the questionnaire can be found in appendix A.

Objective 2: *To collate information on DU data available in countries across the world.* (**Round 1A**)

As in the previous round the primary data collection instrument was a questionnaire built in Qualtrics featuring a blend of closed and open-ended questions. The survey was designed to collect information on the type of healthcare system (or systems) each participant conducted their DUR. Details of the questionnaire can be found in appendix B.

Objective 3: *To identify key attributes and characteristics of DU databases that explain the completeness and comprehensiveness of DU data.* (**Round 1B**)

In Round 1B the goal was to distinguish the main characteristics and features of the DU databases in order to gain a better understanding on the concepts of completeness and comprehensiveness in DUR. The online questionnaire was created using an online platform eDelphi, and the respondents were reached via email with the link to the questionnaire for each respective round.

Objective 4: *To draft statements that could be used to assess the maturity of DU databases.* ***(Round 2)***

From the findings of the previous rounds, round 2 evolved by integrating feedback from 1A and 1B with a concise list of 10 statements for participants review. This phase differentiated between comprehensiveness, assessed through the first three statements, and completeness, covered in statements 4 to 10. A 7-point Likert scale point system was used for evaluation in Round 2, with a minimum score of 1 "Strongly Disagree" and a maximum of 7 "Strongly Agree".

Objective 5: *To build consensus among a group of international experts on the key attributes of DU data that could be used in a national DU database maturity appraisal tool.* ***(Round 3)***

Progressing to the latest phase of the project Round 3 which was built on the responses from Round 2, the participants were asked to provide their agreement on a set of 10 statements and a preliminary framework of the DU databases maturity tool. Mirroring the structure of its predecessor, in Round 3, the dimensions concerning comprehensiveness were articulated through several statements (Statements 1 to 3), whereas dimensions pertaining to completeness were each represented by a single statement (Statements 4 to 10). A final review round was also conducted to enhance the chances of attaining a more mature consensus within the participants. In Round 3 – consensus minor adjustments were incorporated to the statements based on the collective insights. The experts had a chance once more to look through their previous answers that they submitted for Round 3 and to review the new modifications that were made. They had the option to alter any of their answers or add any comments if they so desired and, in addition to this, participants were provided with a graphical overview of all the other respondents' feedback for an additional perspective. It is also important to highlight the high level of engagement in this round; every respondent who participated in Round 3 came back for the final review. This demonstrated the experts' collective dedication to achieving consensus, a core principle of the Delphi method. In Round 3, the 7-point Likert scale was used for evaluation, just as in Round 2, with a minimum score of 1 "Strongly Disagree" and a maximum of 7 "Strongly Agree".

During the Delphi process the implementation of the definitions were the key factors in creating the statements for each round. In Rounds 2 and 3, the focus was on dimensions of

comprehensiveness and completeness, with the former represented by the initial three statements and the latter by statements four through ten. As it was mentioned before, participants rated the relevance of each dimension using a 7-point Likert scale, which included options ranging from 1 ("Strongly disagree") to 7 ("Strongly agree"). They were encouraged to express their level of agreement with each statement and to provide further comments and suggestions, all of which were carefully considered in the subsequent phase (49) Accessibility will be relevant during the next phase of the project which will revolve around the development and testing of DU maturity appraisal tool and is not yet completed.

3.3 Method of analysis

In this study, the tables and figures were created using Excel in the Microsoft 365 suite, with some sourced from the eDelphi platform. During the analysis, the results were categorized into three segments: "Not Mature" for selections of 1-3, "Mature" for 5-7, and "Neutral" for 4. This categorization made it evident which statements achieved a consensus of ≥75% and, as a result, identified which statements required modification for future iterations. From the collective consensus it was feasible to develop the framework of the DU databases maturity tool that could be implemented in the next phase of the project.

3.4 Ethical considerations

In this study, as no data directly related to patients or the public were collected, it has been assessed that formal ethical approval was not a required. This decision was supported by the use of the Medical Research Council's self-assessment tool and confirmed by the Vilnius Regional Biomedical Research Ethics Committee (VRBREK), which stated that student works such as this do not fall under the purview requiring permissions (50, 51). Beyond the scope of ethical approval, we have taken additional steps to ensure the integrity of our research practices. All data were handled in accordance with principles of confidentiality and data protection. Participants were fully informed about the purpose of the research, the nature of their contribution, and the potential use of findings. We obtained their informed consent with the understanding that they could withdraw at any time without any disadvantage. In recognition of the participants' contribution and in accordance with their preferences, we will list their names as corresponding authors. This decision to attribute authorship is in line with the ethical standards of research transparency and is intended to reaffirm their involvement. Consequently,

their participation will not remain anonymous, which has been clearly communicated and consented to by all participants involved. Furthermore, all research activities were conducted in a manner that respects the dignity and rights of the participants, upholding the principles of beneficence and non-maleficence. Any potential conflicts of interest have been identified and appropriately managed to maintain the impartiality of the research.

4. RESULTS AND OUTCOMES

To better present the results and the outcomes of Delphi process this Master thesis results are presented reflecting research objectives.

4.1 Objective 1: To identify and recruit international experts in DUR.

The recruitment process was central to the success of the study, requiring participants to have a minimum of 5 years or more of experience in DU databases or DUR and proficiency in the English language (48). Our recruitment aimed for broad international representation, targeting 10 individuals from each WHO region. With 60 invitation emails dispatched, we were encouraged by the enthusiastic response of 22 participants who committed to contributing to the project's objectives.

Prior to the start of the Delphi process, it was important to undertake a preliminary phase dedicated to understanding the backgrounds of the participants. To this end, recruited participants were surveyed of the 22 individuals who consented to contribute, 15 furnished comprehensive details regarding their age, gender, expertise, and the region they represent. Sixty, 60% identified as female, and the mean age of participants was 54 years, ranging from 36 to 70, suggesting a balanced representation of gender, and a wealth of experience (Table 2).

Table 2. Demographics of participants (based on all 15 actively contributing members)

Demographic	Percentage/Value
Gender: Female	60%
Gender: Male	40%
Age Range (years)	36 to 70
Mean Age (years)	54

To further enhance the representativeness and depth of insights, the project's participants were recruited from various key stakeholder categories, including clinical academics, healthcare professionals, public servants, and policy makers. This ensured a broad range of experiences and viewpoints from different health care systems (Figure 4). Among the 15 respondents, 14 primarily selected academia or universities, and one chose "Other". This

reflects a strong inclination towards theoretical knowledge and research capabilities within the group. Additionally, there were three respondents who paired "Academy/ University" option with another workplace: one with "Healthcare facility", another with "Government", and the third with "Other". The minimal representation from healthcare facilities, government, and other sectors indicates a lesser, yet significant, practical implementation perspective (Figure 3).
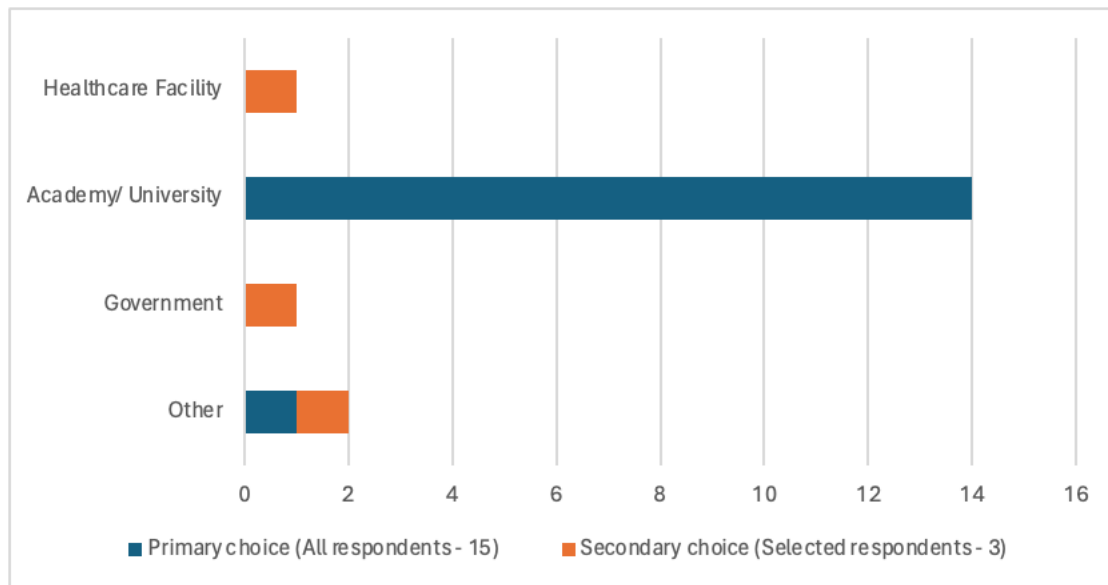

Figure 3. Main workplace of the participants

Five years of experience in DU databases or DUR was a requirement for inclusion in the study (23). Thirteen possessed a minimum of fifteen years of experience in at least one pertinent category. It is important to note that the participants had a choice of choosing multiple options in each of the categories (Figure 4). In the "15 and more years" section most of the respondents chose the "Clinical academic" domain (9), followed by 5 who chose "Healthcare professional" (3 of the respondents chose also "Clinical academic"), 1 selection of "Public servant" and 1 choice for the "Policymaker" category, in total there were 13 responses (2 respondents did not have such years of experience – one had 10-14 years of experience as a clinical academic, while the other had 5-9 years of experience in the same category). Notably, the clinical academic sphere is the most represented signifying a strong foundation in research and theoretical underpinnings among the participants. The second most represented group would be "Healthcare professional", this group bring in-depth, hands-on perspectives that are vital to understanding the practical implications and applications of research findings in real-world settings. The smallest presence was among the "Policy maker" and the "Public Servant"

options, and while small in numbers their role is significant. These individuals bring insights into the legislative and organizational frameworks that govern drug use and research, offering a valuable dimension to the participant's collective understanding (Figure 4).
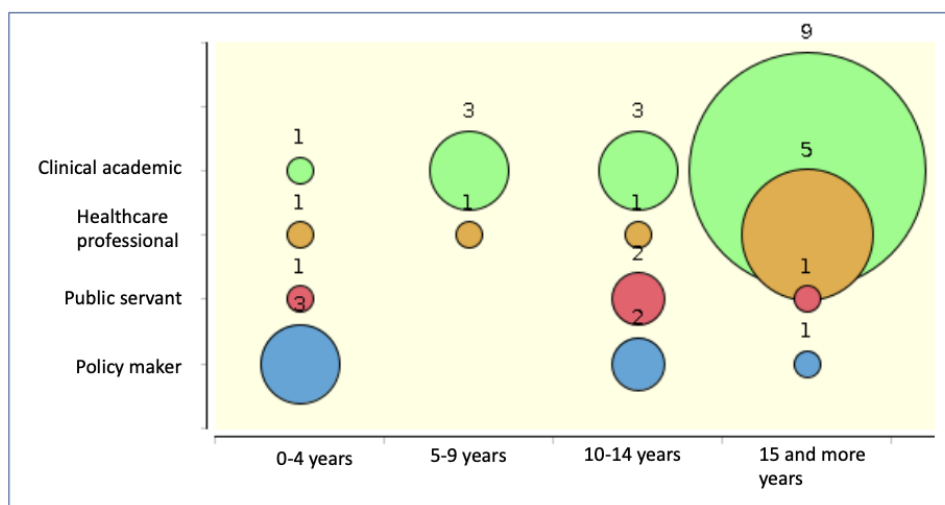

Figure 4. Participants experience in drug utilisation databases or research in drug utilization in years

Among the actively contributing members, 3 participants hailed from the African Region (AFR), 4 from the Region of the Americas (AMR), 1 from the South-East Asian Region (SEAR), 5 from the European Region (EUR), and 2 from the Western Pacific Region (WPR). The participants did not include representatives from the Eastern Mediterranean Region (EMR), despite repeated efforts to identify and approach suitable candidates - this is a limitation of this study. Nevertheless, the recruitment process ensured a breadth of global perspectives (Table 3).

Table 3. Participant Distribution Across WHO Regions (Based on 15 Actively Contributing Members)

WHO Region	Number of Participants
African Region (AFR)	3
Region of the Americas (AMR)	4
South-East Asian Region (SEAR)	1
European Region (EUR)	5
Eastern Mediterranean Region (EMR)	0
Western Pacific Region (WPR)	2

Phase 1 of the Delphi was designed to achieve a consensus on whether maturity of DU databases used in DUR could be appraised. This phase consisted of three distinct rounds, focusing on iterative feedback and refinement of ideas. The objective was to set a foundation for the second phase, which will involve the piloting of the DU maturity assessment tool developed from the Delphi process insights (Figure 5).
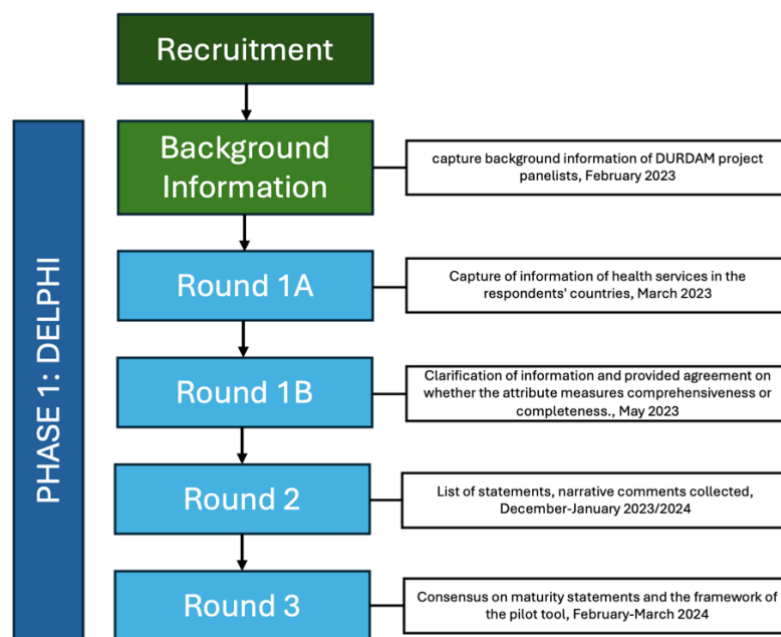

Figure 5. Flow-chart of the project

The preliminary phase of the project involved sixteen participants, providing a comprehensive base from which the project could progress. As the project transitioned through Rounds 1A and 1B, the number of participants declined to fourteen and then to twelve. In Round 2, there was an increase in the number of participants, with fifteen contributing. The Delphi concluded with Round 3, with thirteen participants, maintaining a robust level of involvement throughout the process of determining consensus (Table 4).

Table 4. Number of participants in the various stages of the project

Phase 1 Stages	Number of Participants
Background Information	15
Round 1A	14
Round 1B	12
Round 2	15
Round 3	13

4.2 Objective 2: To collate information on DU data available in countries across the world. **(Round 1A)**

In Round 1A, we embarked on an extensive inquiry to collect precise information about the health systems of our participants and the characteristics of the DU data they compiled. Advancing to Round 1B, we once again leveraged the critical expertise of our participants to identify key features of DU databases that signal their level of maturity. Round 1A of the Delphi process played a pivotal role in painting a comprehensive picture of the global health system landscape as it pertains to DU databases. A total of 14 responses were collected, offering insights into the participants' country-specific health systems, the nature and availability of drug use data, and how this information feeds into DU analysis. The findings revealed that while the overarching control of national health services was a common theme, the presence of regional control and various insurance plans added layers of complexity. Particularly notable was the diversity in funding models, coding systems for diseases and medicines, and the methodologies for recording medicine use—factors that are integral to the assessment of DU database maturity.

4.3 Objective 3: To identify key attributes and characteristics of DU databases that explain the completeness and comprehensiveness of DU data. **(Round 1B)**

As the project advanced into Round 1B, the focus shifted to a deeper exploration of two pivotal concepts in evaluating DU databases for maturity: comprehensiveness and completeness. This phase sought to precisely define and measure these attributes, recognizing

that a mature database must not only have a broad range of necessary variables, indicative of comprehensiveness, but also a detailed depth of data entries, demonstrating completeness. These dimensions together provide a robust framework for understanding and improving the quality and utility of DU databases in supporting substantive DUR. Comprehensiveness is perceived as the extent to which the variables of DU databases cover the necessary aspects, analogous to the width of a data table where the variables act as columns. A comprehensive database would include a wide range of pertinent variables, offering a broad perspective on the subject. Conversely, a database with limitations in scope or missing key variables would fall short on this attribute. Completeness, on the other hand, refers to the depth of the data—akin to the length of a data table where each row represents a unique measurement. It emphasizes the granularity of data, with a complete database offering detailed, individual records as opposed to aggregated or partial data. Together, these attributes were critical for the in-depth assessment of DU databases, enabling a rigorous evaluation of their capability to support robust DUR studies.

These two rounds were pivotal in enhancing our comprehension of health systems worldwide and the scope of DU databases accessible to us. This step was crucial for formulating statements to evaluate the maturity of DUR databases effectively. During Round 1A, we initiated a comprehensive investigation to gather detailed information regarding the health systems of participants and the nature of DU data being collected. Progressing to Round 1B, we sought the invaluable expertise of participants once more to pinpoint the essential attributes of DU databases that are indicative of their maturity. The insights accrued from both Rounds 1A and 1B were instrumental in crafting the criteria for evaluating the maturity of DU databases. For a more in-depth exploration of the project's initial phases and its overarching methodology, one could refer to the detailed documentation available at the Open Science Framework (OSF) titled "Drug Utilization Research Databases Appraisal of Maturity (DURDAM): Protocol for an International Modified Consensus Study," accessible via https://osf.io/cvwz9/. This document provides a framework for achieving international expert consensus on evaluating DU databases, highlighting a significant step towards establishing a standardized set of maturity assessment criteria (1). Round 1A and Round 1B were instrumental in deepening our understanding of global health systems and expanding our knowledge of the available DU databases. Those rounds were important for the upcoming rounds for constructing statements on how to effectively assess the maturity of DUR databases.

4.4 Objective 4: To draft statements that could be used to assess the maturity of DU databases. **(Round 2)**

This round was developed from feedback obtained in rounds 1A and 1B, incorporating a list of 10 statements and groups of statements presented to the participants. In this round, dimensions that related to comprehensiveness had several statements (first three statements) while dimensions related to completeness had one statement (covered in statements 4 through to 10). Each dimension was ranked by relevance on a 7-point Likert scale (This spectrum ranged from: 1 - "Strongly disagree," 2 - "Disagree," 3 - "Somewhat disagree," 4 - "Either agree or disagree," 5 - "Somewhat agree," 6 - "Agree," and up to 7 - "Strongly agree"), and it was asked of the participants to indicate how much they agreed with each statement, in addition to this their additional comments/suggestions were highly welcomed and were addressed in the next step (50).

The first three statements on types of treatment, location or source of data and treatment funding were made of a group of 7 statements that the participants had to express their agreement on based on the 7-point Likert scale. Alongside the rating process, participants were invited to enrich the quantitative data with their qualitative insights, offering narrative comments and suggestions that could potentially introduce new dimensions to the maturity model. As the evaluation progressed, scores were collated to identify median values and quartiles. Only the statements that achieved a consensus in the fourth quartile—indicating agreement from 75% or more of the responses—were selected for inclusion without alterations in the next round. This methodical approach ensured that the assessment process was both inclusive and dynamic, effectively capturing the participant's collective perspective and paving the way for the maturity model's evolution based on a balanced mix of quantitative and qualitative feedback.

While analysing the results we decided to split the results into three groups of "Not Mature" (for those who chose 1-3), "Mature" (5-7) and "Neutral" (4). By doing so it was clear on which statements the consensus ≥75% was met and accordingly it was clear which statements had to be altered moving forward. In statements on types of treatments the highest maturity score was achieved in the third and first statements with 73% respectively. Upon examining the results, a noteworthy observation was made: Statement that solely mentioned prescription medicines, such as Statement 7, received the same level of maturity rating (67% "Not Mature") as Statement 4, which included a variety of treatment types such as over-the-counter (OTC) medicines, non-medicines/devices, food supplements, herbals, and traditional

medicines. This indicates that even though Statement 4 covered a broader range of treatment types, the inclusion of prescription medicines alone in Statement 7 was enough to achieve a similar level of maturity consensus among the participants. None of the statements achieved a consensus ≥75%, however it was clear which were clearly more favourable and reflected the maturity judgment more (Figure 6).
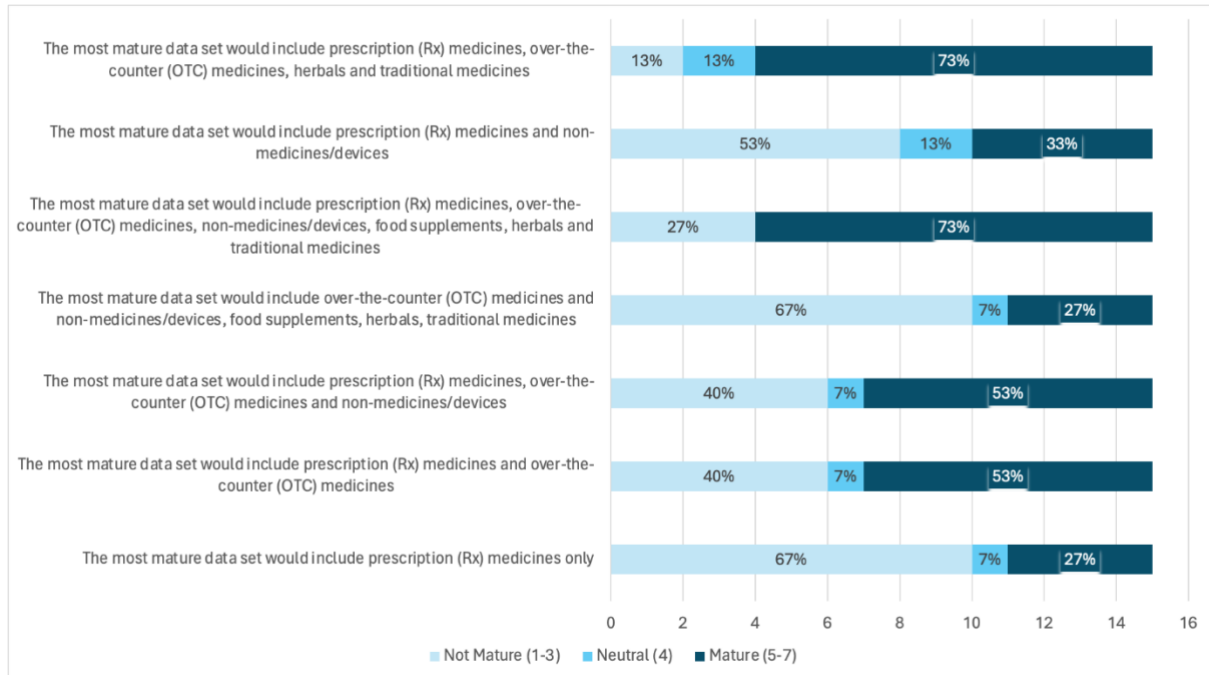

Figure 6. Statements on types of treatments

The second group of statements had quite a similar display of results. However, unlike the first, one of the statements in the second statement group attained ≥75% consensus. The fifth statement got an overwhelming 86% maturity rating. On the other hand, this section of statements had a couple of statements which got a high rating in the "Not Mature" rating scale: Both statements 3 and 7 got 71% respectively (Figure 7).
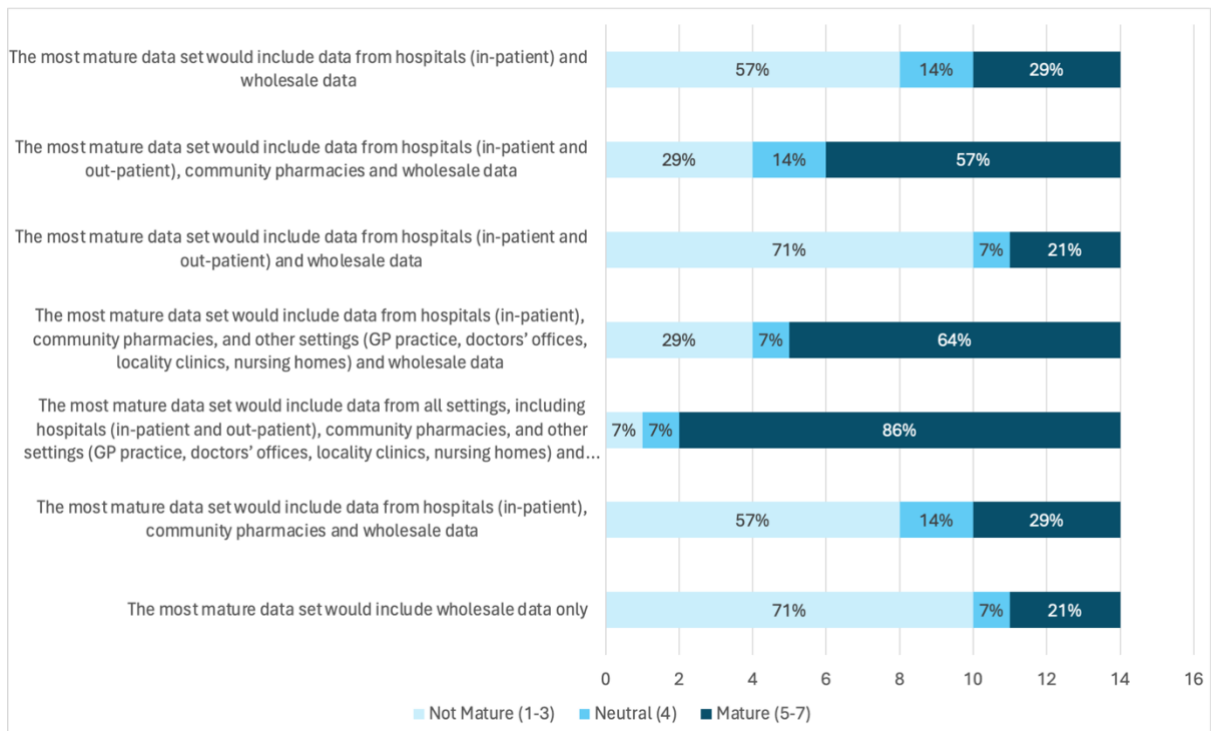
Figure 7. Statements on location or source data

In the examination of participant responses regarding funding for treatment, a distinct consensus emerged, particularly notable in the appraisal of the second statement. The participants showed near unanimity in their assessment on this statement, with an impressive 92% in agreement, indicating a recognition of its maturity. Only one participant member strongly disagreed with this statement. The third statement also garnered significant support, with 69% agreement, indicating a broad, though not unanimous, consensus. However, other statements did not achieve such high levels of agreement, underscoring the participant's view that revisions are necessary before proceeding. Notably, 69% of participants found both the fourth and seventh statements to lack maturity. Based on these results, it was clear that the participants ranked the statements in terms of maturity as follows: 2>3>6>5>1>7>4 (Figure 8).
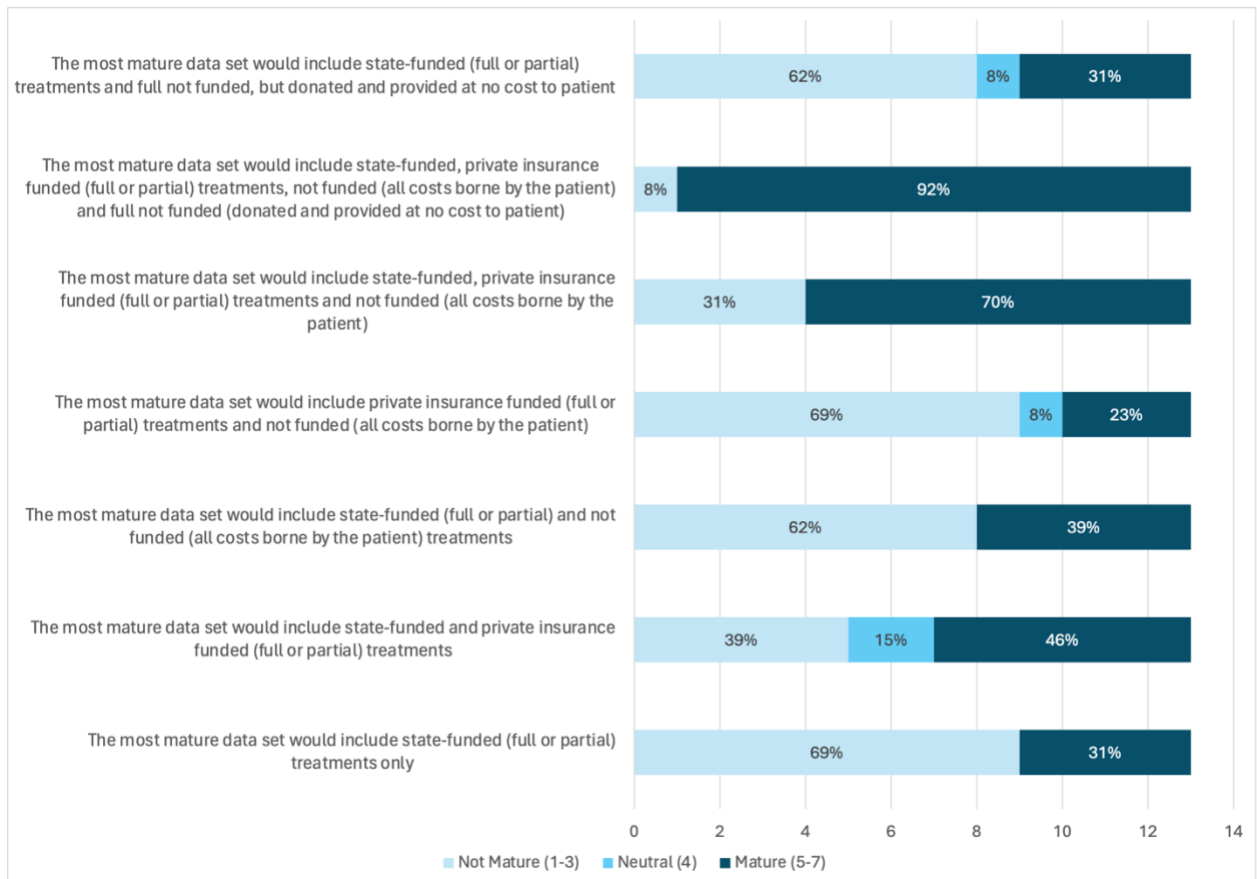
Figure 8. Statements on treatment funding

Through Statements 4 to 10 the participants had a singular statement on which they had to express their agreement on the 7-likert scale. In this section of the questionnaire, on which they had to express their agreement on various dimension concerning the concept of completeness, all statements garnered ≥75% consensus, with Statements 6, 8, and 10 achieving 100% agreement. In contrast, Statements 4, 5, 7, and 9 reached a consensus of 92%. Notably, despite the high level of agreement, there was one "Strongly Disagree" for both Statements 4 and 5, signalling room for further examination and refinement. The variety of opinions offered by the participants is invaluable, highlighting the need for nuanced adjustments as the project advances (Figure 9).
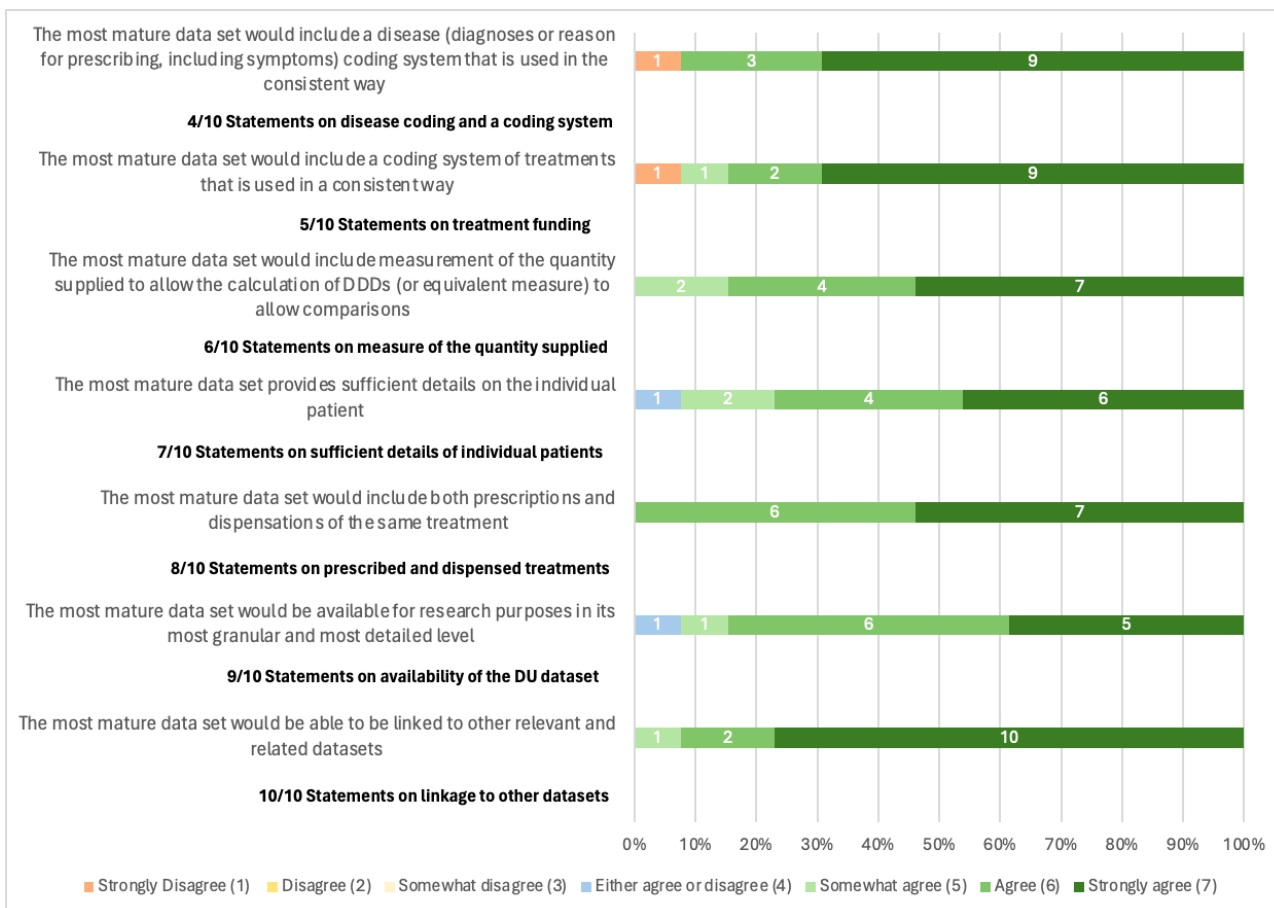
Figure 9. Statements that represent dimensions on completeness (Statements 4 through 10)

4.5 Objective 5: To build consensus among a group of international experts on the key attributes of DU data that could be used in a national DU database maturity appraisal tool. (**Round 3 and Round 3 - consensus**)

The third Delphi Round represented the culmination of the project. This phase fine-tuned the statements regarding comprehensiveness and completeness, achieving a higher level of refinement both in formulation and context, marking this as the project's high point. Additionally, participants were given a preliminary view of the DU database maturity appraisal tool. They were asked to express their agreement with the proposed framework on a 7-point Likert scale, anticipating its implementation in the project's second phase.

The round served as a two-part segment of the project, having the initial "DURDAM Round 3" and a review round called "DURDAM Round 3 - consensus". The methodology for both sub-rounds mirrored that of the previous, utilizing insights from Round 2 to sequence the attributes of each category within the statement groups. The participants were presented with

revised statements highlighting the relevance of the assessment scale. Each dimension was required of the participants to be ranked for relevance on a 7-point Likert scale. Inclusion in the subsequent project phase required meeting or surpassing a 75% consensus threshold. As with the previous round, the constructs of maturity remained central to the tool's development. Comprehensiveness-related dimensions were represented by several statements, whereas completeness was represented by a singular statement. Participants were requested to rank the statements and provide their level of agreement, along with qualitative feedback.

As in the prior round, the first three statements which represented comprehensiveness were made of a group of 7 statements that the participants had to express their agreement on based on the 7-point Likert scale. The sections were devised based on the results garnered in round 2 and each of the elements in each of the sections of statements were composed in such way that those statements that expressed the highest level of maturity were on the right and vice versa (Figure 10).

Statements with increasing level of maturity (Please select one statement from each row)						
prescription (Rx) medicines only	over-the-counter (OTC) medicines and non-medicines/devices, food supplements, herbals, traditional medicines	include prescription (Rx) medicines and non-medicines/devices	prescription (Rx) medicines and over-the-counter (OTC) medicines	prescription (Rx) medicines, over-the-counter (OTC) medicines and non-medicines/devices	include prescription (Rx) medicines, over-the-counter (OTC) medicines, herbals and traditional medicines	prescription (Rx) medicines, over-the-counter (OTC) medicines, non-medicines/devices, food supplements, herbals and traditional medicines
wholesale data only	hospitals (in-patient and out-patient) and wholesale data	hospitals (in-patient), and wholesale data	hospitals (in-patient), community pharmacies and wholesale data	hospitals (in-patient), community pharmacies and wholesale data	hospitals (in-patient), community pharmacies and other settings (GP practice, doctors' offices, locality clinics, nursing homes)	hospitals (in-patient and out-patient), community pharmacies and other settings (GP practice, doctors' offices, locality clinics, nursing homes)
private insurance funded (full or partial) treatments and not funded (all costs borne by the patient)	state-funded (full or partial) treatments only	state-funded (full or partial) treatments and full not funded, but donated and provided at no cost to patient	state-funded and not funded (all costs borne by the patient)	state-funded and private insurance funded (full or partial) treatments	state-funded, private insurance funded (full or partial) treatments and not funded (all costs borne by the patient)	private insurance funded (full or partial) treatments, not funded (all costs borne by the patient) and full not funded (donated and provided at no cost to patient)

Figure 10. Statements that represent dimensions on comprehensiveness (Statements 1 through 3) (First Version)

The consistency of the ranking system was maintained in this round as well. While assessing the results the split up of three categories was opted to retain and they were as such: "Not Mature" (for those who chose 1-3), "Mature" (5-7) and "Neutral" (4). In contrast to the last round a consensus of ≥75% was procured in all of the statements which reflected the scope

of comprehensiveness: the section of "Statements on types of treatment" gained a 85% consensus (11 respondents), section of "Location or source of data" attained a 92% consensus (12 respondents) and the last section which was called "Treatment funding" gathered a 77% consensus rating (10 respondents). From this group of statements only the last group of statements was on the verge of non-inclusion as it had a "Not Mature" rate of 15% and a "Neutral" rate of 8% (Figure 11). These results showcased that some minor adjustments had to be made on the statements in order to proceed with the upcoming phase of the project. Furthermore, the experts were briefed that when using the initial assessment tool, respondents would select one of the following options to assess their DU database characteristics. It was essential for them to keep this in mind to accurately evaluate whether the statements were appropriate for incorporating into the tool.
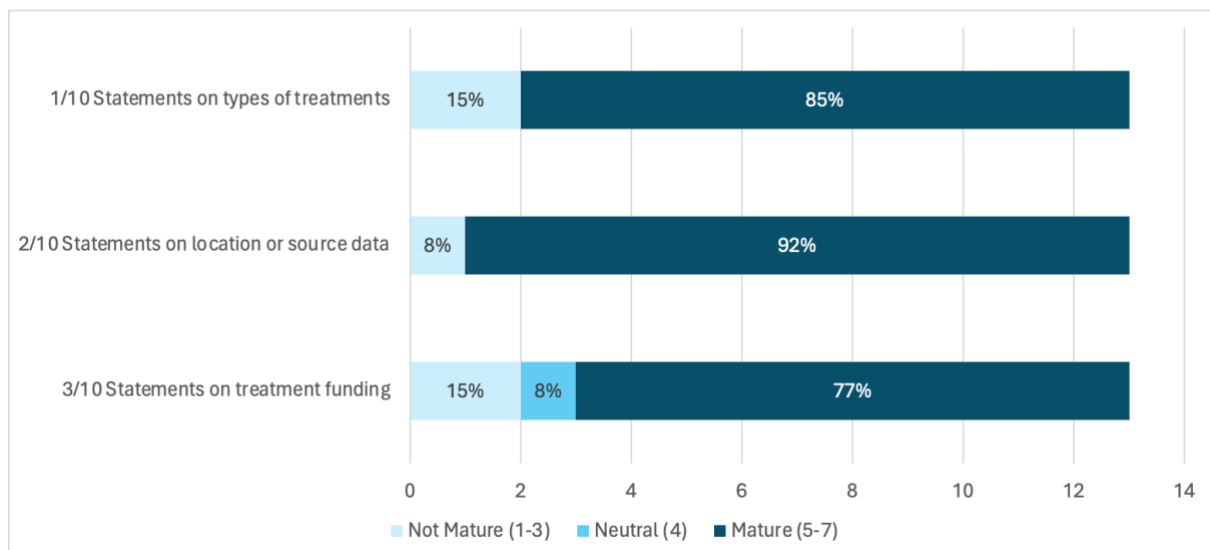

Figure 11. Statements that represent dimensions on comprehensiveness (Statements 1 through 3)

For statements on completeness, which ranged from the 4th to the 10th as in Round 2, they were singular statements. Like in the previous section of the round, the participants needed to keep in mind that when completing the assessment tool, the respondent would select "Yes" or "No" to assess their DU database characteristics. Based on this, they had to convey their assessment on the 7-point Likert scale. In this set of statements, a complete unanimous 100% consensus was met on the 4th, 6th, and 7th statements, indicating a robust agreement among the participants that no further alterations were needed for these statements, which represent the characteristics of completeness. Very closely following, we can observe that the 10th

statement gained a 92% maturity rate from the participants, with an 8% "Neutral" rate. The 5th and 8th statements both acquired a 92% consensus and an 8% "Not Mature" evaluation. These results are particularly intriguing as they suggest that while there is significant consensus on most statements, certain areas notably lack full agreement, pointing to potential ambiguities in how these statements are perceived or the underlying criteria assessed. Finally, the 9th statement displayed room for improvement in its formulation, as it attained a consensus in the fourth quartile (77%) and had a small percentage margin, with a 23% "Not Mature" rate, which underscored our concern. Comments from participants further illustrated the issues with this statement. One participant remarked, "This statement also does not make sense. Does it imply both granular AND detailed? I do not agree." Another commented, "This is a very vague statement which seems difficult to score in a valid way." These critiques suggest that the statement may be ambiguously worded or conceptually unclear, leading to difficulties in achieving a reliable assessment. Such feedback underscores the need for revaluating the statement's clarity and precision to ensure it effectively captures the intended dimensions without confusion. The differential rates of maturity across the statements warrant a focused discussion on the criteria for evaluating database characteristics and the implications for future iterations of the assessment tool. The participant's rankings, illustrated as 4/6/7 > 10 > 5/8 > 9, not only reflect the relative strength and weaknesses of each statement but also guide subsequent modifications to ensure more precise and universally understandable evaluations (Figure 12).
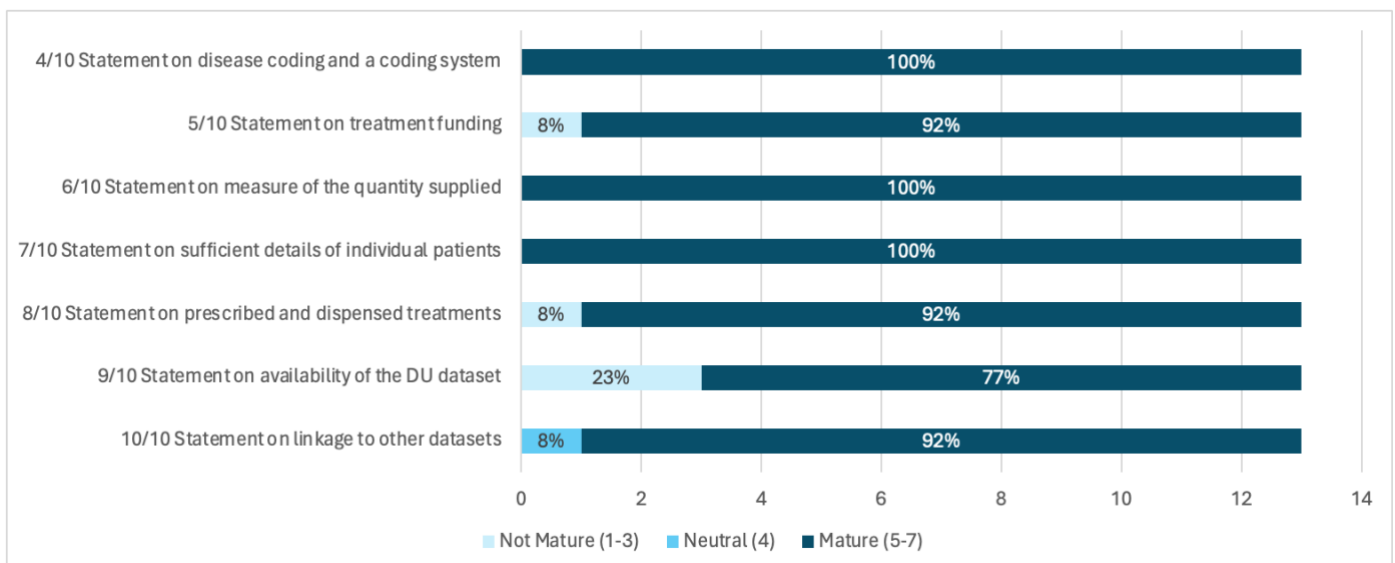

Figure 12. Statements that represent dimensions on completeness (Statements 4 through 10)

The round's high point was the unveiling of the DU database maturity tool's preliminary framework (Figure 13). Participants were asked to evaluate the framework on a 7-point Likert scale, focusing on whether they agreed with its projected appearance in the second phase of the project. It was noted that for the participants, this iteration was not final but provided insight into the structure and functionality of the tool. Furthermore, it was remarked that a scoring system would be integrated in subsequent stages of the project to facilitate the assessment of the DU database maturity. The majority of the respondents endorsed the tool's proposed design - 85% agreed with this proposition, and a consensus of ≥75% was achieved. Nonetheless, a few experts expressed dissatisfaction with the suggested template for the DUR database maturity appraisal tool, with equal shares of 8% in the "Not Mature" and "Neutral" categories. Although not indicative of a major shift, this feedback pointed that there was room for improvement in the concept and visual representation of the DUR maturity appraisal tool.

Figure 13. Proposed framework of the DU database maturity tool (First Version)

A final part of the Delphi process, Round 3 - Consensus (Appendix C), was implemented to confirm whether refinements to the appraisal tool (incorporating minor adjustments to enhance comprehensiveness and completeness based on the collective insights of the participants) improved consensus that these statements. It was encouraged of the participants to review the modifications and revise their previous input if desired. The major focal point of this round was that the participants were also presented with an anonymous graphical summary of other participant responses for added insight.

During Round 3, some experts expressed concerns about the complex arrangement of the data related to comprehensiveness - specifically the statements on types of treatment, location or source of data, and treatment funding. Feedback highlighted difficulties in efficiently reading and analysing the information. For example, one suggestion was: "This statement needs to be laid out better if included - perhaps each category on a separate line so it can be compared across easily." Taking this into account, we reorganized the attributes to facilitate clearer differentiation among each specific categories by presenting each category on a separate line. This was done to help participants more easily compare the attributes more effectively. In addition to this, the three statements on comprehensiveness reduced from groups of 7 attributes to a groups of 5. The total amount of characteristics in the most mature group section was 5, by increasing the number attributes in each group increasing order of maturity a clearer pattern emerged, facilitating easier analysis for the participants. This change not only made the data more navigable but also highlighted the progression in maturity more distinctly (Figure 14).

Statements with increasing level of maturity (Please select one statement from each row)				
prescription (Rx) medicines	prescription (Rx) medicines over-the-counter (OTC) medicines	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices herbals and traditional medicines	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices herbals and traditional medicines food supplements
wholesale data	wholesale data hospitals (in-patient)	wholesale data hospitals (in-patient) hospitals (out-patient)	wholesale data hospitals (in-patient) hospitals (out-patient) community pharmacies	wholesale data hospitals (in-patient) hospitals (out-patient) community pharmacies other settings (GP practice, doctors' offices, locality clinics, nursing homes)
Private insurance - fully funded	Private insurance - fully funded Private insurance - partially funded	Private insurance - fully funded Private insurance - partially funded State or government funded - both fully or partially funded	Private insurance - fully funded Private insurance - partially funded State or government funded - both fully or partially funded) Full costs borne by the patient	Private insurance - fully funded Private insurance - partially funded State or government funded - both fully or partially funded Full costs borne by the patient Donated or provided at no cost to patient via industry, health charity or NGOs

Figure 14. Statements that represent dimensions on comprehensiveness (Statements 1 through 3) (Second Version)

As previously mentioned, during this round the participants had the opportunity to review their answers and revise them if they so wished. Like in Round 3, a consensus of ≥75% was maintained. Only one statement had a change in results, the first statement, on types of treatment, saw an increase in the assessment of maturity from 85% (11 respondents) to 92% (12 respondents). This suggests the changes that were made further improved the development of the tool. The other two statements maintained a stable 92% and 77% consensus respectively the same response rate. It was pleasing to see the same number of participants responding in each round and a consistency on their assessment of maturity. Additionally, we must keep in mind that during this final iteration of the Delphi process, the option for participants to view an anonymous graphical summary bar chart of all other respondents' answers was introduced. The unveiled option to view others' answers could have influenced the participants in three distinct ways: First, it might have led to an acknowledgment of a lack of strong group support, potentially causing doubts about their own responses. Conversely, when the feedback indicated a high level of agreement, it could have reinforced confidence in their own decisions and motivated a drive toward a unified decision, allowing the project to progress seamlessly

without unnecessary obstacles. Thirdly, for a respondent whose views differ significantly from the majority, revealing the group's answers could either reinforce their unique stance by highlighting a clear perspective or prompt them to reconsider their position if they feel isolated or incorrect in their approach (52). It's worth noting the high level of engagement in this round with all respondents who participated in Round 3 providing responses for this final review. This underscores the experts' shared commitment to reaching a consensus, which is a fundamental aspect of the Delphi method (Figure 15).

Figure 15. Statements that represent dimensions on comprehensiveness (Statements 1 through 3) (Comparison of Round 3 and Round 3 – consensus results)

Regarding the statements covering the concept of completeness, Round 3 – response from participants led to changes in two of the singular statements. The 8th statement, on prescribed and dispensed treatments, achieved a unanimous consensus of 100%, an improvement from the previously gained 92%, increasing the number of statements with complete agreement from three to four. These include the 4th statement on disease coding and coding systems, the 6th statement on the measure of the quantity supplied, the 7th statement on sufficient details of individual patients, and the 8th statement on prescribed and dispensed treatments. The second statement that saw a change in consensus was the 9th statement on the availability of the DU database, increased from 77% to 85%. Furthermore, similar to the statements on comprehensiveness, these representing dimensions of completeness did not have

any worsening in maturity ratings. With these changes in some of the statement results, a new pattern in the participant's ranking emerged: 4/6/7/8 >10 > 5 > 9. (Figure 16)
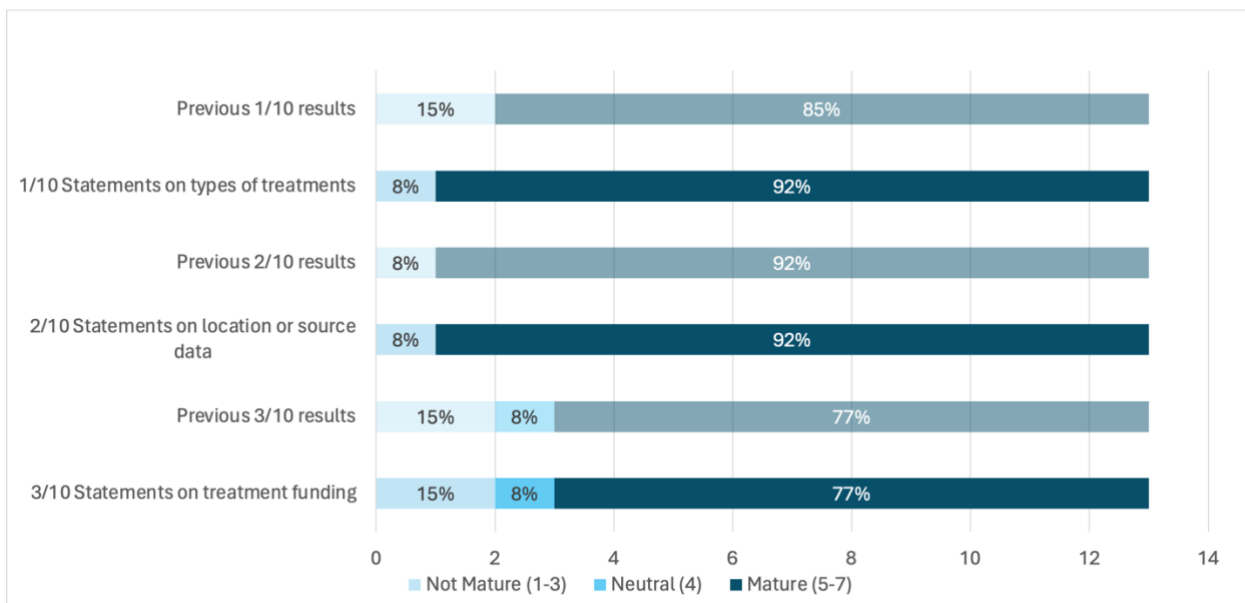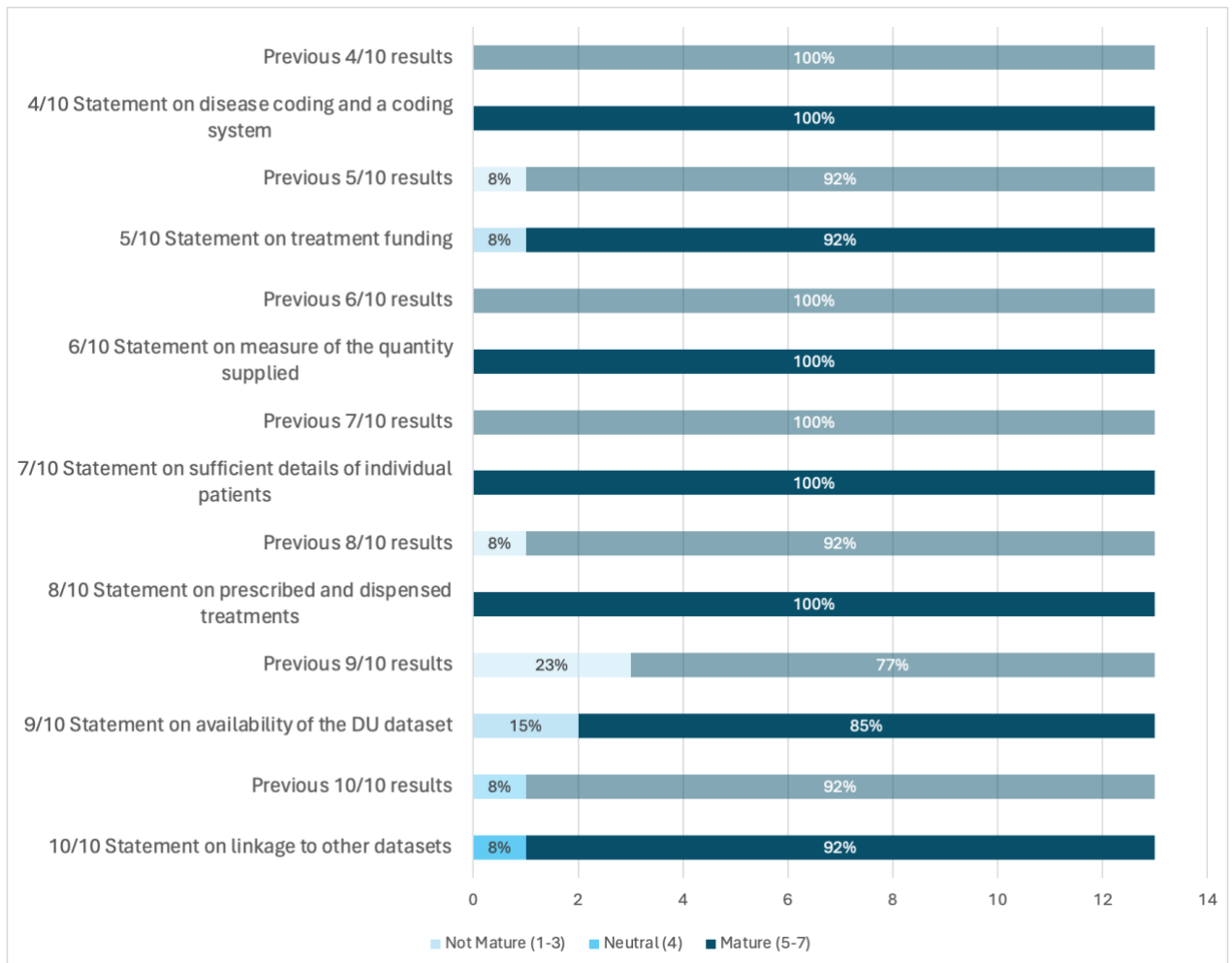

Figure 16. Statements that represent dimensions on completeness (Statements 4 through 10) (Comparison of Round 3 and Round 3 – consensus results)

The culmination of the entire Delphi process was the reveal of the final revised preliminary framework for the DU database maturity tool (Figure 17).

Statements with increasing level of maturity (Please select one statement from each row)				
prescription (Rx) medicines	prescription (Rx) medicines over-the-counter (OTC) medicines	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices herbals and traditional medicines	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices herbals and traditional medicines food supplements
wholesale data	wholesale data hospitals (in-patient)	wholesale data hospitals (in-patient) hospitals (out-patient)	wholesale data hospitals (in-patient) hospitals (out-patient) community pharmacies	wholesale data hospitals (in-patient) hospitals (out-patient) community pharmacies other settings (GP practice, doctors' offices, locality clinics, nursing homes)
Private insurance - fully funded	Private insurance - fully funded Private insurance - partially funded	Private insurance - fully funded Private insurance - partially funded State or government funded - both fully or partially funded	Private insurance - fully funded Private insurance - partially funded State or government funded - both fully or partially funded) Full costs borne by the patient	Private insurance - fully funded Private insurance - partially funded State or government funded - both fully or partially funded Full costs borne by the patient Donated or provided at no cost to patient via industry, health charity or NGOs

Statements which help to determine the maturity level of the data set (Please select Yes/No for each corresponding statement)	
Data set has a disease (diagnoses or reason for prescribing, including symptoms) coding system that is used in a consistent way	
No	Yes
Data set has a coding system of treatments that is used in a consistent way	
No	Yes
Data set has measurement of the quantity supplied to allow the calculation of DDDs (or equivalent measure) to allow comparisons	
No	Yes
Data set has sufficient details on the individual patient	
No	Yes
Data set has both prescriptions and dispensations of the same treatment	
No	Yes
Data set is available for research purposes in its most granular and most detailed level	
No	Yes
Data set can be linked to other relevant and related datasets	
No	Yes

Figure 17. Proposed framework of the DU database maturity tool (Second Version)

Following Round 3, we reviewed comments from the participants and made minor adjustments to the proposed framework. The participants were encouraged to review their responses and, if desired, to update their earlier assessments on the same 7-point Likert scale. Additionally, they were offered an anonymous graphical overview of participant feedback. Consequently, after participants gave their final response, a consensus of 85% was maintained

(Figure 18). A few respondents did not completely agree with the proposed structure of the tool, with 8% rating it as "Not Mature" and another 8% as "Neutral," and a consensus of ≥75% was achieved, allowing the project to progress to the next phase. In total, 3 statements saw a positive change in results: from the comprehensiveness category, the first statement on types of treatment; and from the completeness category, the eighth statement on prescribed and dispensed treatments and the ninth statement on the availability of the DU database. These changes in each category indicated that while the overall evaluation of the updated framework remained the same, the adjustments at some level were acknowledged. The experts expressed their positions on the adjustments either by updating their results to a more mature level or by maintaining their previous position. Positive comments such as "It is much better." indicated the changes were appreciated by the participants.
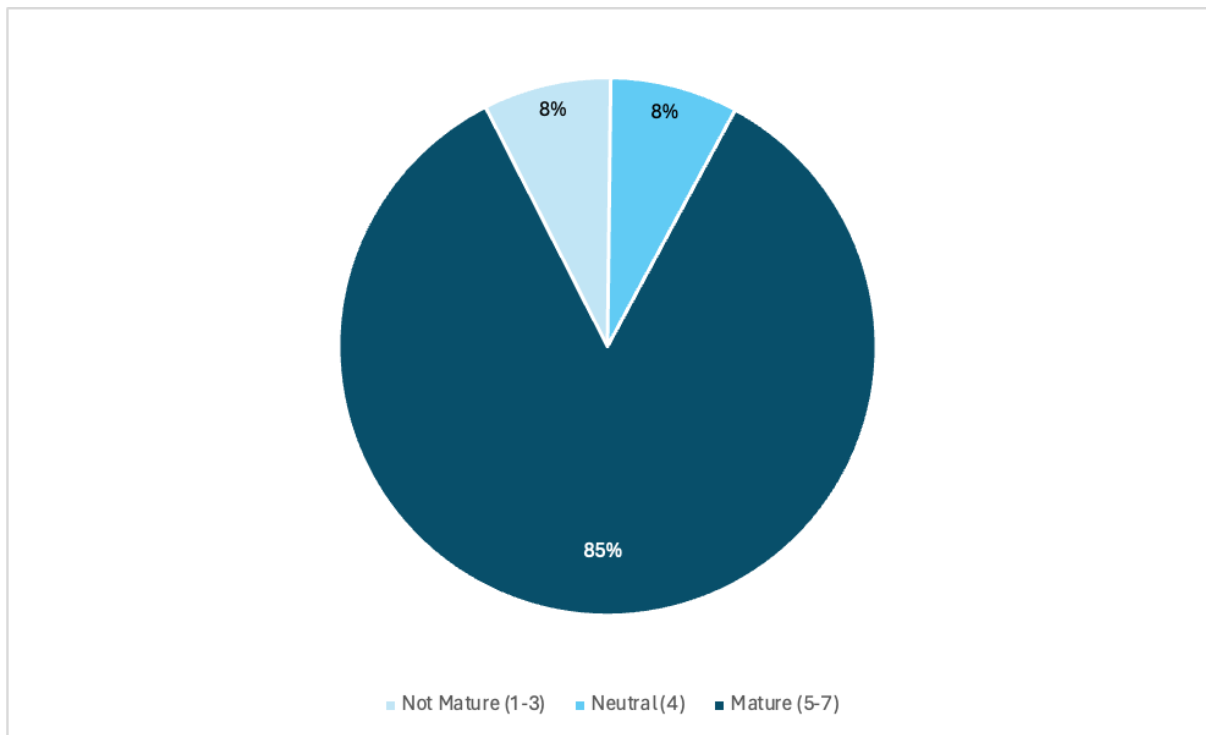
Figure 18. Overall agreement on the Proposed framework of the DU database maturity tool

4.6 Study Limitations

By using the eDelphi platform closed and open questions could be given to a panel of experts in the healthcare field for the purpose or arriving at a group consensus on the determination whether maturity of DU databases used in DUR could be appraised and, if so, to build a maturity appraisal tool. The questionnaire was designed for individual completion, thereby ensuring each participant's anonymity and enhancing time efficiency. Participants had the flexibility to respond at their convenience, without being constrained by a specific timeframe. This approach proved particularly advantageous for an international study, as it allowed respondents from various time zones to participate in the Delphi process at a time best suited to them.

This study, while comprehensive, has several limitations that have to be recognized in order to appreciate the findings accurately. The diversity of the expert participants, although broad, consisted of individuals which had extensive experience in DUR, this had the potential of overlooking fresh perspectives from emerging researchers and professional from related healthcare fields who could've offered novel insights into this maturity appraisal of DU databases project. This kind of limitation can be witnessed by the age range of the participant, which was relatively senior, spanning from 36 to 70 years, with a mean age of 54. As can be observed, the demographic profile of the participants appears to be weighted towards more experienced, possibly more traditional perspectives, and this may impact the variety of innovative or divergent opinions included in the study. This type of limitation aligns well with the concerns raised by Cloutier et al. (2020), who emphasized the importance of integrating diverse disciplinary insights in consensus studies to enhance the utility and innovation potential of research tools (53). Such kind of integration is vital not only for capturing a broad range of expert opinions but also for ensuring a comprehensive approach that can more effectively reflect the evolving dynamics and diverse needs of modern healthcare settings. Moreover, the study's reliance on the Delphi method, which is known for its robust consensus-building capability, also presents several constraints, particularly when diverse and complex expert opinions are vital for a balanced outcome. One significant limitation is the risk of groupthink, a phenomenon where the desire for group cohesion leads to decisions that prioritize harmony over critical evaluation, potentially stifling innovation and suppressing dissenting opinions (54). This can lead to decisions that might not fully explore all alternatives, as participants might modify their views to align with the perceived group consensus, reducing the diversity of viewpoints. Another issue is the dilution of minority opinions, where unique insights that do

not align with the majority view are gradually filtered out across the Delphi rounds. This movement towards a majority opinion can cause the loss of valuable perspectives, particularly those that challenge the status quo or introduce novel ideas (55). To diminish the effect of these issues its vital to ensure the anonymity of the responses, even-handed management that could encourage the airing of diverse ideas and a structured debate where participants could have the chance to critique the prevailing consensus (56). These are crucial strategies in up handling the Delphi process, which aid in preventing the method from unintentionally sidelining innovative or critical insights of the experts for a more comprehensive and effective decision-making process. Another limitation is the geographical representation of the participants. While efforts were made to include a globally diverse group, certain regions were underrepresented, which could influence the generalizability of the tool and its applicability across different healthcare systems with varied levels of technology adoption and infrastructure. Although the participants included contributions from regions such as the AFR, the AMR, the SEAR, the EUR, and the WPR, the absence of representatives from the EMR reflects a gap that may limit the tool's broader relevance and effectiveness. This regional imbalance can potentially skew insights and outcomes towards the characteristics and needs of more heavily represented areas, a challenge noted in studies by Jongen and Scholte (2022), who critique the structural biases that can affect the outcomes of international research collaborations (57). Such disparities highlight the ongoing challenge of integrating a truly comprehensive global perspective into research, underscoring the importance of striving for greater inclusivity in future projects. Additionally, the study's phase-based design necessitated a prolonged duration for consensus development and validation of the tool, which may not align with the rapid pace required for decision-making in healthcare settings where DU data is critical for immediate policy and healthcare decisions. This critique aligns with the analysis by Ahmad and Wasim (2023), who argue that faster, more agile research methodologies are increasingly needed in healthcare research to keep pace with policy and practice demands (58). In addition to the lengthy period required for undertaking the Delphi process, another inherent limitation arises: variations in participant engagement. Throughout the study, participant engagement varied significantly across different phases, initially involving fifteen experts but decreasing to twelve in intermediate rounds before slightly increasing again in the final stages. This fluctuation, noted in research by Avella (2016), highlights the challenges of maintaining consistent involvement and may affect the depth of consensus in long-term Delphi studies (59). Finally, the evolving nature of DUR and the continuous advancements in data technology require ongoing updates to the database maturity appraisal tool developed in this study, suggesting that the tool may need frequent

revisions to stay relevant and effective. This need for ongoing revision is supported by the systematic review by Fleurence and Shuren (2019), who highlight the dynamic nature of healthcare technologies and the continuous evaluation of evolving behavioural intervention technologies as essential for maintaining clinical and operational efficiency (60).

These limitations highlight the need for cautious interpretation of the study results and suggest areas for improvement in future research to enhance the robustness and applicability of the findings. Future research should focus on testing the usability and applicability of the maturity appraisal tool to ensure its validity in a global usage context.

5. CONCLUSIONS

1. Recruitment of International Experts: The study successfully identified and recruited a diverse panel of international experts specializing in Drug Utilization Research (DUR). This recruitment targeted experts with a minimum of five years of experience in DUR and proficiency in English, aiming for broad international representation. The final panel comprised of 15 actively contributing participants from various WHO regions, ensuring a diverse mix of clinical academics, healthcare professionals, and policymakers.

2. Data Collation on Drug Utilization: The project effectively gathered comprehensive information on drug utilization (DU) data from various countries. Insights were collected on each participant's country's health system, specifically focusing on how drugs are used and their availability for DU analysis. During the initial rounds of the Delphi process, participants provided detailed information about the characteristics of their national healthcare systems, including funding models, coding systems for diseases and medicines, and the methodologies for recording medicine use.

3. Identification of Key Attributes: The Delphi process was instrumental in identifying the key attributes and characteristics that define the completeness and comprehensiveness of DU data. The panel experts developed and refined a set of characteristics that included comprehensiveness, completeness, and accessibility, all essential for assessing the maturity of DU databases.

4. Drafting of Maturity Assessment Statements: Based on the identified attributes, the study successfully drafted statements that could be used to assess the maturity of DU databases. These statements were initially formulated to encompass the key attributes of comprehensiveness, completeness, and accessibility. Throughout the Delphi process, these statements underwent multiple rounds of feedback, involving rigorous discussion and refinement to ensure they accurately captured the necessary dimensions of data maturity. Each statement was crafted to prompt clear responses from the participants, reflecting their consensus or disagreements on specific aspects of data maturity. This iterative refinement was crucial not only for enhancing the accuracy of the statements

but also for ensuring they were understandable and applicable across different healthcare settings. The precision in drafting and refining these statements will be fundamental to developing a robust appraisal tool, designed to provide actionable insights into the strengths and areas for improvement within DU databases globally.

5. <u>Consensus Building on Key Attributes:</u> The final objective of building consensus among the group of international experts on the key attributes of DU data was successfully met, with an impressive 85% of participants expressing their support for the proposed framework of the tool.

In conclusion, the study effectively met its objectives, laying a solid foundation for the ongoing development and implementation of a national DU database maturity appraisal tool. The successful recruitment of a knowledgeable participants, comprehensive data collation, meticulous identification and drafting of key database characteristics and strong consensus among experts all contribute to the project's aim to improve the assessment of DU databases and ultimately improve DUR. Future efforts should focus on the national DU database maturity assessment tool usability testing and validating its effectiveness. These steps are crucial for confirming that the tool meets the needs of end-users and can reliably support the assessment of database maturity in diverse environments.

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APPENDIX A

Background information Questionnaire

The background of the expert group is presented in Table 2.

Country

Age

Gender

Professional background:

- Natural sciences

- Technological Sciences

- Medical and health sciences

- Agricultural Sciences

- Social Sciences

- Humanities

- Art

Workplace

- Health care facility (primary care, hospital, nursing home etc.)

- Academy

- Government

- Other

Matrix: Which group you define yourself versus Experience within drug use databases or research in drug utilization, in years.

	0-4 years	5-9 years	10-14 years	15 and more
clinical academics				
healthcare professionals				
public servants				
policy makers				

Please define your expertise field

DURDAM

This is a semi-structured questionnaire for the 1A round of DURDAM study. At this step we aim to capture information on the participant's country's health system, as well as the nature of collected drug use data and its availability for drug utilization analysis.

Data will be used only for the research purposes of the project. Personal information will be confidential and no unauthorized person will have access to the data provided.

Please let us know which country you are completing the survey for:

_____

Q1 **Do you have one drug use administration system for the country or separated administration systems by regions with the country?** Please explain

Q2 **Where are licensed medicines delivered in your country?** (Please check by X all relevant cells)

	In hospital (in-patient) (1)	In hospital (out-patient) (2)	In nursing home (3)	In community pharmacy (4)	In other community setting including GP practice, doctor's office, locality clinic (5)	Other (6)
Prescription (Rx) medicines (1)						
Over the counter (OTC) medicines (2)						
Other (3)						

Q3 **Please explain**

Q4 **Where are other pharmaceutical goods delivered in your country?** (Please check by X all relevant cells)

	In hospital (in-patient) (1)	In hospital (out-patient) (2)	In nursing home (3)	In community pharmacy (4)	In other community setting including GP practice, doctor's office, locality clinic (5)	Other (6)
Herbals (1)						
Traditional medicine (2)						
Food supplements (3)						
Non-medicines/devices (4)						
Other (5)						

Q5 **Please explain**

Q6 **How licensed medicines and pharmaceutical goods are funded in your country?**
(Please check by X all relevant cells)

	Full state funded (1)	Partial state funded (2)	Full or partial private insurance funded (3)	Full not funded (all costs borne by patient) (4)	Full not funded, but donated and provided at no cost to patient (5)	Other (6)
Prescription (Rx) medicines (1)						
Over the counter (OTC) medicines (2)						
Herbals (3)						
Traditional medicine (4)						
Food supplements (5)						
Non-medicines/devices (6)						
Other (7)						

Q7 **Please explain**

For medicines administered/supplied in hospital (in-patient)

Q8 **What classification systems are used for diagnoses?** (add some examples)

Q9 **Are diagnoses collected together with the drug use data?**

Q10 **What classification systems are used for medicines administered/supplied in hospital (in-patient)?**

Q11 **What measurement units are used for medicines administered/supplied in hospital (in-patient)?**

Q12 **How drug use data is collected in hospital (in-patient)?** (e.g. record/individual or aggregated data)

For medicines administered/supplied in hospital (out-patient)

Q13 **What classification systems are used for diagnoses?** (add some examples)

Q14 **Are diagnoses collected together with the drug use data?**

Q15 **What classification systems are used for medicines administered/supplied in hospital (out-patient)?**

Q16 **What measurement units are used for medicines administered/supplied in hospital (out-patient)?**

Q17 **How drug use data is collected in hospital (out-patient)? (e.g. record/individual or aggregated data)**

For medicines administered/supplied in nursing home

Q18 **What classification systems are used for diagnoses?** (add some examples)

Q19 **Are diagnoses collected together with the drug use data?**

Q20 **What classification systems are used for medicines administered/supplied in nursing home?**

Q21 **What measurement units are used for medicines administered/supplied in nursing home?**

Q22 **How drug use data is collected in nursing home?** (e.g. record/individual or aggregated data)

For medicines administered/supplied in community pharmacy

Q23 **What classification systems are used for diagnoses?** (add some examples)

Q24 **Are diagnoses collected together with the drug use data?**

Q25 **What classification systems are used for medicines administered/supplied in community pharmacy?**

Q26 **What measurement units are used for medicines administered/supplied in community pharmacy?**

Q27 **How drug use data is collected in community pharmacy?** (e.g. record/individual or aggregated data)

For medicines administered/supplied in other community setting including GP practice, doctor's office, locality clinic

Q28 **What classification systems are used for diagnoses?** (add some examples)

Q29 **Are diagnoses collected together with the drug use data?**

Q30 **What classification systems are used for medicines administered/supplied in other community setting including GP practice, doctor's office, locality clinic?**

Q31 **What measurement units are used for medicines administered/supplied in other community setting including GP practice, doctor's office, locality clinic?**

Q32 **How drug use data is collected in other community setting including GP practice, doctor's office, locality clinic? (e.g. record/individual or aggregated data)**

Q33 **If there is any other setting that the medicines could be supplied/delivered to the patients, please explain.** We are specifically interested in classification system used for diagnoses, classification system used for medicines, measurement units of drug use and how data is collected (individual or aggregated data)

Q34 **Which drug use data would be available for research in your country?**

Q36 **Could the drug use data be linked to any other data sets?** Please explain

Q39 This questionnaire is anonymous. Yet, having in mind that some information might be needed to be clarified, please provide your email address if you agree to be contacted for clarification.

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(1/10) Statements on types of treatment

The following is a series of statements that will be part of the DU databases maturity appraisal tool that assesses types of treatment in increasing levels of maturity. When completing the assessment tool the respondent will select one of the following to assess their DU database characteristics.

The previous version:

1	2	3	4	5	6	7
prescription (Rx) medicines only	over-the-counter (OTC) medicines and non-medicines/devices, food supplements, herbals, traditional medicines	include prescription (Rx) medicines and non-medicines/devices	prescription (Rx) medicines and over-the-counter (OTC) medicines	prescription (Rx) medicines, over-the-counter (OTC) medicines and non-medicines/devices	include prescription (Rx) medicines, over-the-counter (OTC) medicines, herbals and traditional medicines	prescription (Rx) medicines, over-the-counter (OTC) medicines, non-medicines/devices, food supplements, herbals and traditional medicines

The updated version:

(Following the feedback from the panellists', we revised the statements and accordingly adjusted the table)

1	2	3	4	5
prescription (Rx) medicines	prescription (Rx) medicines over-the-counter (OTC) medicines	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices herbals and traditional medicines	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices herbals and traditional medicines food supplements

Please express your consensus to the updated version. Below, you will find a graph displaying your initial response, the panel's feedback, and the collective consensus. Your last response will be saved when you navigate to the next or previous question.

HOW MUCH DO YOU AGREE THAT THE STATEMENTS IN THE SEQUENCE PRESENTED SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

Strongly disagree   Disagree   Somewhat disagree   Either agree or disagree   Somewhat agree   Agree   Strongly agree
○   ○   ○   ○   ○   ○   ○

ANSWERS

HOW MUCH DO YOU AGREE THAT THE STATEMENTS IN THE SEQUENCE PRESENTED SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

ELABORATE ON THIS TOPIC (ADD A COMMENT)

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(2/10) Statements on location or source of data

The following is a series of statements that will be part of the DU databases maturity appraisal tool that assesses location or source of data in increasing levels of maturity. When completing the assessment tool the respondent will select one of the following to assess their DU database characteristics.

The previous version:

1	2	3	4	5	6	7
wholesale data only	hospitals (in-patient and out-patient) and wholesale data	hospitals (in-patient), and wholesale data	hospitals (in-patient), community pharmacies and wholesale data	hospitals (in-patient and out-patient), community pharmacies and wholesale data	hospitals (in-patient), community pharmacies and other settings (GP practice, doctors' offices, locality clinics, nursing homes)	hospitals (in-patient and out-patient), community pharmacies and other settings (GP practice, doctors' offices, locality clinics, nursing homes)

The updated version:

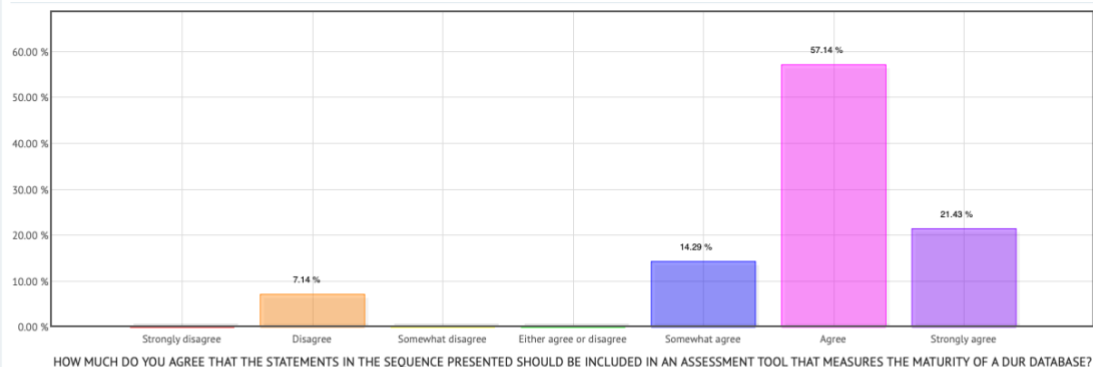(Following the feedback from the panellists, we revised the statements and accordingly adjusted the table)

1	2	3	4	5
wholesale data	wholesale data hospitals (in-patient)	wholesale data hospitals (in-patient) hospitals (out-patient)	wholesale data hospitals (in-patient) hospitals (out-patient) community pharmacies	wholesale data hospitals (in-patient) hospitals (out-patient) community pharmacies other settings (GP practice, doctors' offices, locality clinics, nursing homes)

Please express your consensus to the updated version. Below, you will find a graph displaying your initial response, the panel's feedback, and the collective consensus. Your last response will be saved when you navigate to the next or previous question.

HOW MUCH DO YOU AGREE THAT THE STATEMENTS IN THE SEQUENCE PRESENTED SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

Strongly disagree ○   Disagree ○   Somewhat disagree ○   Either agree or disagree ○   Somewhat agree ○   Agree ○   Strongly agree ○

ANSWERS

HOW MUCH DO YOU AGREE THAT THE STATEMENTS IN THE SEQUENCE PRESENTED SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

ELABORATE ON THIS TOPIC (ADD A COMMENT)

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(3/10) Statements on treatment funding

The following is a series of statements that will be part of the DU databases maturity appraisal tool that assesses treatment funding in increasing levels of maturity. When completing the assessment tool the respondent will select one of the following to assess their DU database characteristics.

The previous version:

1	2	3	4	5	6	7
private insurance funded (full or partial) treatments and not funded (all costs borne by the patient)	state-funded (full or partial) treatments only	state-funded (full or partial) treatments and full not funded, but donated and provided at no cost to patient	state-funded and not funded (all costs borne by the patient)	state-funded and private insurance funded (full or partial) treatments	state-funded, private insurance funded (full or partial) treatments and not funded (all costs borne by the patient)	private insurance funded (full or partial) treatments, not funded (all costs borne by the patient) and full not funded (donated and provided at no cost to patient)

The updated version:

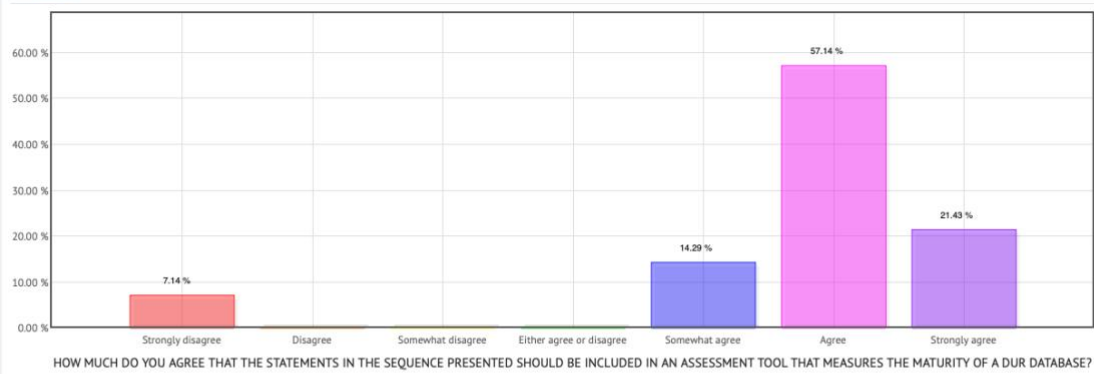(Following the feedback from the panellists', we revised the statements and accordingly adjusted the table)

1	2	3	4	5
Private insurance - fully funded	Private insurance - fully funded

Private insurance - partially funded | Private insurance - fully funded

Private insurance - partially funded

State or government funded - both fully or partially funded | Private insurance - fully funded

Private insurance - partially funded

State or government funded - both fully or partially funded)

Full costs borne by the patient | Private insurance - fully funded

Private insurance - partially funded

State or government funded - both fully or partially funded

Full costs borne by the patient

Donated or provided at no cost to patient via industry, health charity or NGOs |

Please express your consensus to the updated version. Below, you will find a graph displaying your initial response, the panel's feedback, and the collective consensus. Your last response will be saved when you navigate to the next or previous question.

HOW MUCH DO YOU AGREE THAT THE STATEMENTS IN THE SEQUENCE PRESENTED SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

Strongly disagree   Disagree   Somewhat disagree   Either agree or disagree   Somewhat agree   Agree   Strongly agree

ANSWERS

HOW MUCH DO YOU AGREE THAT THE STATEMENTS IN THE SEQUENCE PRESENTED SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

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(4/10) Statement on disease coding and a coding system

The following is a statement that will be part of the DU databases maturity appraisal tool. When completing the assessment tool the respondent will select "Yes" or "No" to assess their DU database characteristics.

Please review the statement once again and, if you so choose, revise your previous input. Below, you will find a graph displaying your initial response, the panel's feedback, and the collective consensus. Your last response will be saved when you navigate to the next or previous question.

Data set has a disease (diagnoses or reason for prescribing, including symptoms) coding system that is used in a consistent way	
No	Yes

HOW MUCH DO YOU AGREE THAT THE STATEMENT ABOVE SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

Strongly disagree   Disagree   Somewhat disagree   Either agree or disagree   Somewhat agree   Agree   Strongly agree

ANSWERS

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(5/10) Statements on medicines coding system

The following is a statement that will be part of the DU databases maturity appraisal tool. When completing the assessment tool the respondent will select "Yes" or "No" to assess their DU database characteristics.

Please review the statement once again and, if you so choose, revise your previous input. Below, you will find a graph displaying your initial response, the panel's feedback, and the collective consensus. Your last response will be saved when you navigate to the next or previous question.

Data set has a coding system of treatments that is used in a consistent way	
No	Yes

HOW MUCH DO YOU AGREE THAT THE STATEMENT ABOVE SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

Strongly disagree   Disagree   Somewhat disagree   Either agree or disagree   Somewhat agree   Agree   Strongly agree

ANSWERS

ELABORATE ON THIS TOPIC (ADD A COMMENT)

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(6/10) Statements on measure of the quantity supplied

The following is a statement that will be part of the DU databases maturity appraisal tool. When completing the assessment tool the respondent will select "Yes" or "No" to assess their DU database characteristics.
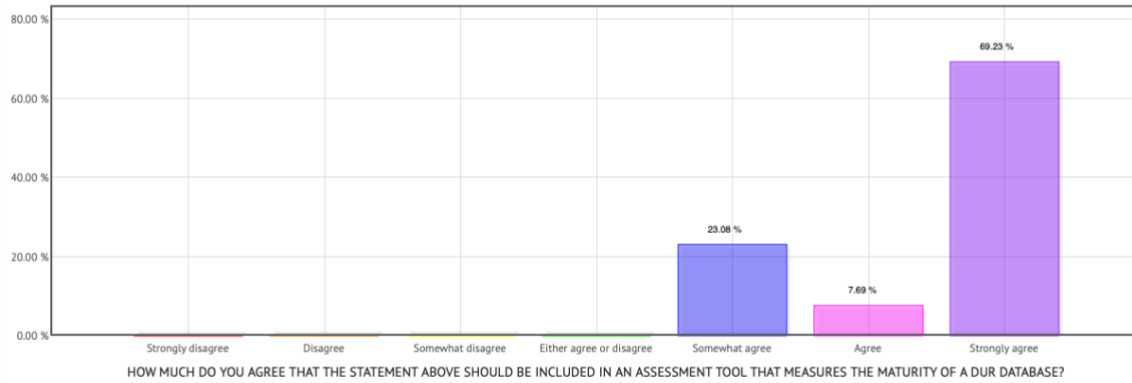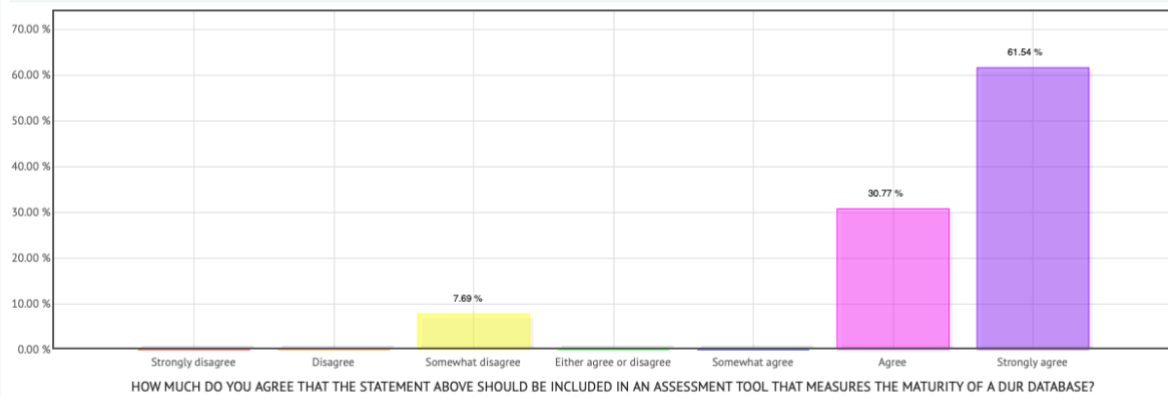
Please review the statement once again and, if you so choose, revise your previous input. Below, you will find a graph displaying your initial response, the panel's feedback, and the collective consensus. Your last response will be saved when you navigate to the next or previous question.

Data set has measurement of the quantity supplied to allow the calculation of DDDs (or equivalent measure) to allow comparisons	
No	Yes

HOW MUCH DO YOU AGREE THAT THE STATEMENT ABOVE SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

Strongly disagree   Disagree   Somewhat disagree   Either agree or disagree   Somewhat agree   Agree   Strongly agree
○   ○   ○   ○   ○   ○   ○

ANSWERS

ELABORATE ON THIS TOPIC (ADD A COMMENT)

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(7/10) Statements on sufficient details of individual patients

The following is a statement that will be part of the DU databases maturity appraisal tool. When completing the assessment tool the respondent will select "Yes" or "No" to assess their DU database characteristics.

Please review the statement once again and, if you so choose, revise your previous input. Below, you will find a graph displaying your initial response, the panel's feedback, and the collective consensus. Your last response will be saved when you navigate to the next or previous question.

Data set has sufficient details on the individual patient	
No	Yes

HOW MUCH DO YOU AGREE THAT THE STATEMENT ABOVE SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

Strongly disagree   Disagree   Somewhat disagree   Either agree or disagree   Somewhat agree   Agree   Strongly agree
○   ○   ○   ○   ○   ○   ○

ANSWERS

HOW MUCH DO YOU AGREE THAT THE STATEMENT ABOVE SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

ELABORATE ON THIS TOPIC (ADD A COMMENT)

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(8/10) Statements on prescribed and dispensed treatments

The following is a statement that will be part of the DU databases maturity appraisal tool. When completing the assessment tool the respondent will select "Yes" or "No" to assess their DU database characteristics.
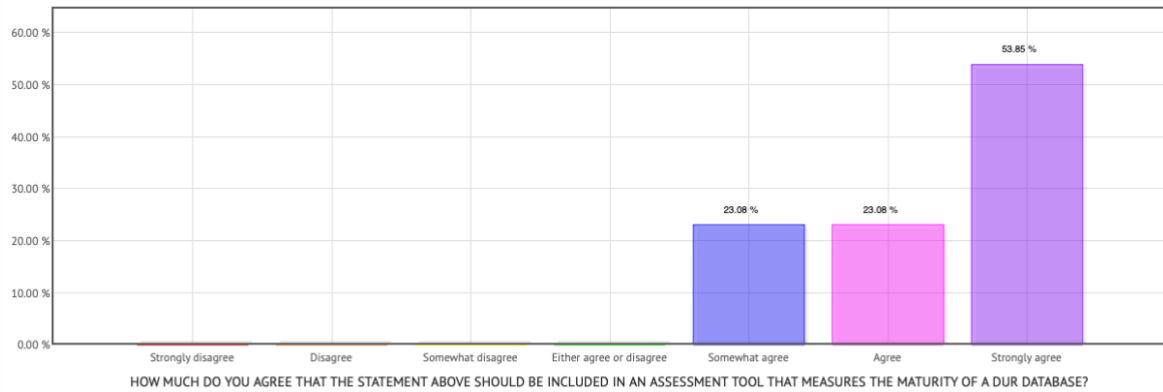
Please review the statement once again and, if you so choose, revise your previous input. Below, you will find a graph displaying your initial response, the panel's feedback, and the collective consensus. Your last response will be saved when you navigate to the next or previous question.

Data set has both prescriptions and dispensations of the same treatment	
No	Yes

HOW MUCH DO YOU AGREE THAT THE STATEMENT ABOVE SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

Strongly disagree   Disagree   Somewhat disagree   Either agree or disagree   Somewhat agree   Agree   Strongly agree

ANSWERS

ELABORATE ON THIS TOPIC (ADD A COMMENT)

SAVE

You have not answered the question

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(9/10) Statements on availability of the DU dataset

The following is a statement that will be part of the DU databases maturity appraisal tool. When completing the assessment tool the respondent will select "Yes" or "No" to assess their DU database characteristics.
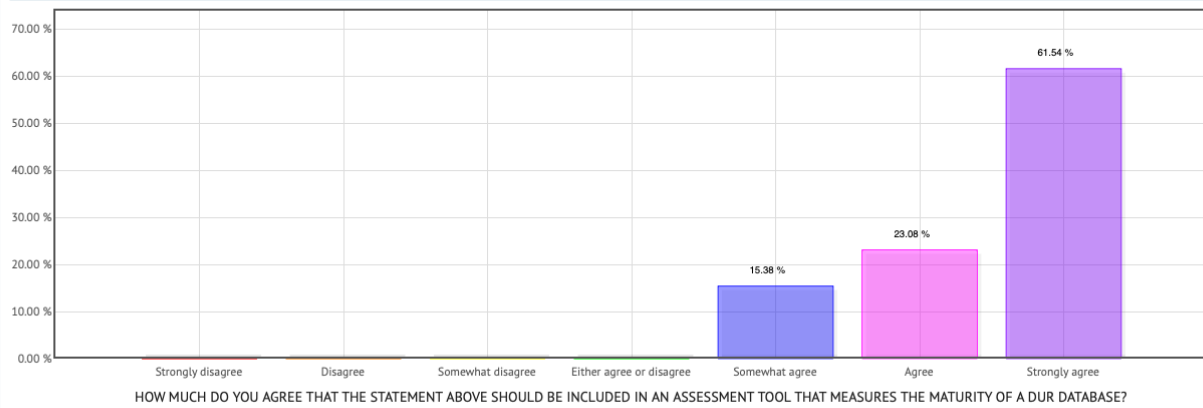
Please review the statement once again and, if you so choose, revise your previous input. Below, you will find a graph displaying your initial response, the panel's feedback, and the collective consensus. Your last response will be saved when you navigate to the next or previous question.

Data set is available for research purposes in its most granular and most detailed level	
No	Yes

HOW MUCH DO YOU AGREE THAT THE STATEMENT ABOVE SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

Strongly disagree   Disagree   Somewhat disagree   Either agree or disagree   Somewhat agree   Agree   Strongly agree

ANSWERS

HOW MUCH DO YOU AGREE THAT THE STATEMENT ABOVE SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

ELABORATE ON THIS TOPIC (ADD A COMMENT)

SAVE

You have not answered the question

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(10/10) Statements on linkage to other datasets

The following is a statement that will be part of the DU databases maturity appraisal tool. When completing the assessment tool the respondent will select "Yes" or "No" to assess their DU database characteristics.
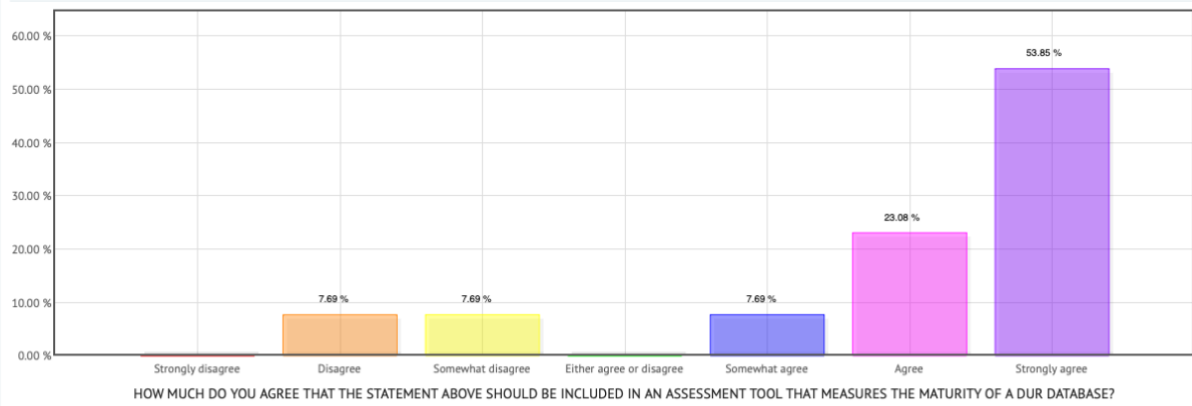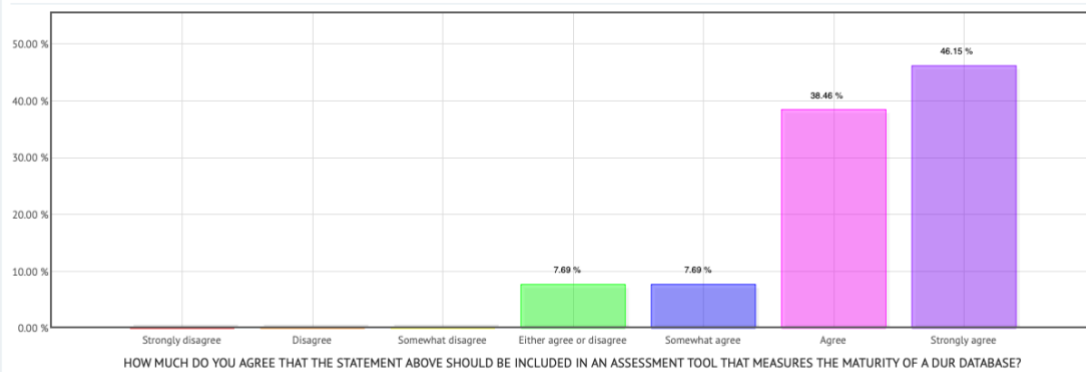
Please review the statement once again and, if you so choose, revise your previous input. Below, you will find a graph displaying your initial response, the panel's feedback, and the collective consensus. Your last response will be saved when you navigate to the next or previous question.

Data set can be linked to other relevant and related datasets	
No	Yes

HOW MUCH DO YOU AGREE THAT THE STATEMENT ABOVE SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

Strongly disagree   Disagree   Somewhat disagree   Either agree or disagree   Somewhat agree   Agree   Strongly agree
○   ○   ○   ○   ○   ○   ○

ANSWERS

HOW MUCH DO YOU AGREE THAT THE STATEMENT ABOVE SHOULD BE INCLUDED IN AN ASSESSMENT TOOL THAT MEASURES THE MATURITY OF A DUR DATABASE?

ELABORATE ON THIS TOPIC (ADD A COMMENT)

SAVE

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DURDAM round 3 - consensus

Proposed framework of the DU database maturity tool

Following Round 2 of the DURDAM DELPHI process we reviewed and refined statements related to dimensions of drug utilization dataset maturity. We are now delighted to share with you the preliminary framework of the DU database maturity tool. While this is not the final iteration, it offers insight into its structure and functionality. In subsequent stages of the project, we will integrate a scoring system to facilitate the assessment of DU database maturity. After Round 3 we analysed your comments and have made minor adjustments to the proposed preliminary framework of the DU database maturity tool. We encourage you to examine these changes and, should you wish, update your earlier contributions. Furthermore, an anonymous graphical overview of participant feedback is now accessible for your examination.
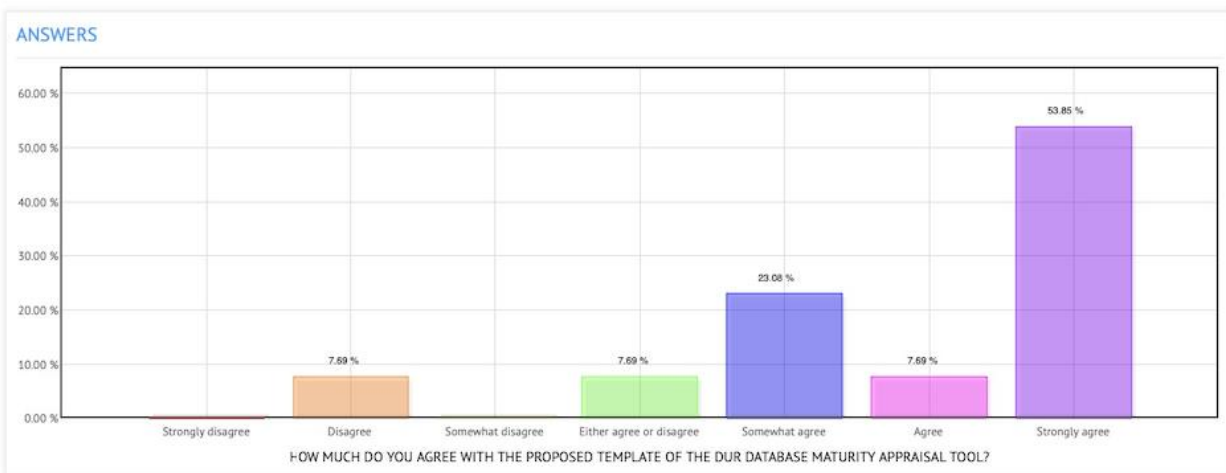
The previous version:

Statements with increasing level of maturity (Please select one statement from each row)						
prescription (Rx) medicines only	over-the-counter (OTC) medicines and non-medicines/devices, food supplements, herbals, traditional medicines	include prescription (Rx) medicines and non-medicines/devices	prescription (Rx) medicines and over-the-counter (OTC) medicines	prescription (Rx) medicines, over-the-counter (OTC) medicines and non-medicines/devices	include prescription (Rx) medicines, over-the-counter (OTC) medicines, herbals and traditional medicines	prescription (Rx) medicines, over-the-counter (OTC) medicines, non-medicines/devices, food supplements, herbals and traditional medicines
wholesale data only	hospitals (in-patient and out-patient) and wholesale data	hospitals (in-patient), and wholesale data	hospitals (in-patient), community pharmacies and wholesale data	hospitals (in-patient), community pharmacies and wholesale data	hospitals (in-patient), community pharmacies and other settings (GP practice, doctors' offices, locality clinics, nursing homes)	hospitals (in-patient and out-patient), community pharmacies and other settings (GP practice, doctors' offices, locality clinics, nursing homes)
private insurance funded (full or partial) treatments and not funded (all costs borne by the patient)	state-funded (full or partial) treatments only	state-funded (full or partial) treatments and full not funded, but donated and provided at no cost to patient	state-funded and not funded (all costs borne by the patient)	state-funded and private insurance funded (full or partial) treatments	state-funded, private insurance funded (full or partial) treatments and not funded (all costs borne by the patient)	private insurance funded (full or partial) treatments, not funded (all costs borne by the patient) and full not funded (donated and provided at no cost to patient)

Statements which help to determine the maturity level of the data set (Please select Yes/No for each corresponding statement)	
Data set has a disease (diagnoses or reason for prescribing, including symptoms) coding system that is used in a consistent way	
No	Yes
Data set has a coding system of treatments that is used in a consistent way	
No	Yes
Data set has measurement of the quantity supplied to allow the calculation of DDDs (or equivalent measure) to allow comparisons	
No	Yes
Data set has sufficient details on the individual patient	
No	Yes
Data set has both prescriptions and dispensations of the same treatment	
No	Yes
Data set is available for research purposes in its most granular and most detailed level	
No	Yes
Data set can be linked to other relevant and related datasets	
No	Yes

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The updated version:

(Following the feedback from the panellists, we revised the statements and accordingly the proposed template of the DUR database maturity appraisal tool)

Statements with increasing level of maturity (Please select one statement from each row)				
prescription (Rx) medicines	prescription (Rx) medicines over-the-counter (OTC) medicines	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices herbals and traditional medicines	prescription (Rx) medicines over-the-counter (OTC) medicines non-medicines/devices herbals and traditional medicines food supplements
wholesale data	wholesale data hospitals (in-patient)	wholesale data hospitals (in-patient) hospitals (out-patient)	wholesale data hospitals (in-patient) hospitals (out-patient) community pharmacies	wholesale data hospitals (in-patient) hospitals (out-patient) community pharmacies other settings (GP practice, doctors' offices, locality clinics, nursing homes)
Private insurance - fully funded	Private insurance - fully funded Private insurance - partially funded	Private insurance - fully funded Private insurance - partially funded State or government funded - both fully or partially funded	Private insurance - fully funded Private insurance - partially funded State or government funded - both fully or partially funded) Full costs borne by the patient	Private insurance - fully funded Private insurance - partially funded State or government funded - both fully or partially funded Full costs borne by the patient Donated or provided at no cost to patient via industry, health charity or NGOs

Statements which help to determine the maturity level of the data set (Please select Yes/No for each corresponding statement)	
Data set has a disease (diagnoses or reason for prescribing, including symptoms) coding system that is used in a consistent way	
No	Yes
Data set has a coding system of treatments that is used in a consistent way	
No	Yes
Data set has measurement of the quantity supplied to allow the calculation of DDDs (or equivalent measure) to allow comparisons	
No	Yes
Data set has sufficient details on the individual patient	
No	Yes
Data set has both prescriptions and dispensations of the same treatment	
No	Yes
Data set is available for research purposes in its most granular and most detailed level	
No	Yes
Data set can be linked to other relevant and related datasets	
No	Yes

HOW MUCH DO YOU AGREE WITH THE PROPOSED TEMPLATE OF THE DUR DATABASE MATURITY APPRAISAL TOOL?

Strongly disagree   Disagree   Somewhat disagree   Either agree or disagree   Somewhat agree   Agree   Strongly agree

ANSWERS

HOW MUCH DO YOU AGREE WITH THE PROPOSED TEMPLATE OF THE DUR DATABASE MATURITY APPRAISAL TOOL?

ELABORATE ON THIS TOPIC (ADD A COMMENT)

SAVE

You have not answered the question

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