Questions and Answers from: Introducing ICHOM: A Value-based Healthcare Model on Monday 10 June 2024

1. **How often is that update of the sets done?**

All Sets go through an automatic standardization process on the ICHOM Digital Term Bank each year. We aim to update the content of individual sets every 3 years to ensure that they are clinically up to date and in line with current care practices and patient needs.

2. **How do you prioritize which Sets are the next to work on?**

We take different factors into account, such as disease burden, global epidemiology, including prevalence in LMICs, new therapeutic options and research in the field, opportunity for impact on policy-making around the disease, and other factors alike. We also rely on funding which means we will only be able to pursue a project if we have secured sufficient funding for it.

3. **How is the Delphi consensus process organized?**

ICHOM uses a 3-round modified Delphi process to achieve consensus within the Working Group on the outcomes for inclusion in our Sets.

First round: The first survey includes a list of all outcomes identified through registry and literature searches, as well as patient focus groups. Working Group members rate the importance of each outcome in a minimum Set using a 1 to 9 Likert scale, where 1 indicates “not essential” and 9 indicates “essential to have”. For outcomes to be included or excluded, 70% consensus is needed within the Working group.

Second round: Outcomes that are not decisively included or excluded enter a second round of voting using the same 1 to 9 Likert scale.

Third round: Any outcomes that remain inconclusive enter a third and final vote, where Working Group members vote either “yes” or “no” on each outcome and 80% consensus for decisions is needed.

4. **Are there plans to widen the core Set to incorporate protected characteristics, e.g. disability, race and sexual orientation?**

When the Sets are developed, sociodemographic variables, such as race, ethnicity, and others alike, are always considered and included as the Working Group sees fit. As our Sets are updated, these metrics are reviewed and if there is consensus among the Steering Committees to include additional sociodemographic measures to capture these characteristics, then those changes are made accordingly.

5. **What about if there is no medical condition? If individuals are healthy and they want to keep it avoiding getting to the medical condition stage?**

We have developed four Life-Course Sets which overview general health for different age groups: Adult Oral Health, Overall Pediatric Health, Overall Adult Health, and Older Person Set. These address prevention and general wellbeing during different stages of life.

6. **How do ICHOM sets interface with or influence trial endpoints recommended for medicine licensing by health authorities such as FDA, EMA or MHRA?**

By aligning trail endpoints with the patient-centered outcomes, organizations can produce robust and novel evidence that is more relevant and compelling to health authorities. This will help ensure that benefits and risk of new medicines are thoroughly evaluated, ultimately supporting better patient outcomes and facilitating the regulatory approval process.

7. **How do you see the relevancy of achieving clinical documentation integrity and accurate healthcare outcomes measurement?**

ICHOM recognizes the importance of the timely collection of patient information and medical record completeness to delivering high-quality care. The development process for our Sets involves extensive consideration of clinical feasibility as well as thorough vetting of the psychometric properties of outcome measures included.

8. **How do you make sure in the Delphi study that you get a good representation of the patients? In my experience the more health literate patients are the ones to actively participate in studies, but they often do not give a "real-world" view.**

We always include patient representatives/advocates in our Working Groups, aiming to have at least 25% of our WG be composed of patient representatives. We also hold patient focus group meetings ahead of the survey process and group calls including clinicians to ensure patients have the space and time to express their point of view.

9. **Please reiterate what you mean by a Set.**

A "set" typically refers to a standardized selection of outcomes, outcome measures and other metrics which may impact outcomes for a given disease or condition. These are collections of metrics and indicators used to evaluate the results of medical treatments and interventions. The goal of such Sets is to provide a consistent, comprehensive, and patient-centered way to measure health outcomes across different healthcare providers and settings. The key characteristics of a set would be: (i) standardization, to ensure all healthcare providers measure outcomes in the same way, enabling comparisons and benchmarking; (ii) comprehensive, meaning it includes a range of outcomes that cover all aspects of patient health and wellbeing, not just clinical indicators; (iii) patient-centered, focusing on outcomes that matter to patients, including QoL, functional status and long-term health; (iv) clinically relevant, including outcomes that are imp for clinicians and are aligned with best clinical practice and CPG oriented; & (v) global applicability, as each set is designed to be used internationally, accommodating regional differences and patient populations.

10. **What are your recommendations on implementing ICHOM sets in a high multidisciplinary field with many quality instruments (guidelines, registries, decision aids, etc)?**

Engage stakeholders early and continuously, including clinicians, nurses, allied health professionals, administrators, and patients.

Conduct a gap analysis to identify overlaps and gaps between existing instruments and the ICHOM set, then develop a clear integration plan.

Integrate the ICHOM set into EHR systems for streamlined data collection, and ensure interoperability with existing registries and decision trees/tools.

comprehensive training and ongoing education to all stakeholders,

Establish continuous feedback mechanisms and define key performance metrics to monitor effectiveness.

11. **Why do you use FHIR and not OHDSI data mapping?**

FHIR is designed specifically for interoperability between healthcare systems, and makes it easier to integrate across systems; it also offers a flexible framework and is best suited for clinical use. FHIR is generally preferred for clinical applications requiring real-time data exchange and interoperability, while OHDSI is better suited for research and retrospective data analysis.

12. **How do the Sets apply to LMICs?**

All ICHOM Set materials are freely available and can be accessed by all interested parties. In the development of the ICHOM Sets we ensure that the measures used are globally representative and applicable, and include risk adjustment factors to capture social determinants of health. Furthermore, we are in the process of developing our "Primary subsets'' which will exist as summarised/simplified versions of the full ICHOM set for a particular disease area. The subset will be used as a "starting point" or "building block" for the most essential measures to capture for a specific Set. This may be particularly useful for low-resource or low-income settings that are interested in collecting the ICHOM measures but do not have the capacity to implement the full Set. Further support can also be accessed through one of our Partners and via the ICHOM team so please do not hesitate to contact us.

13. **Would ICHOM be able to map the sets to different coding systems? For example, not all countries are using SNOMED?**

ICHOM can provide this service at a cost. If you would like to have more information on this or request a service related to coding our Sets, please contact our team.

14. **Has there been interest from the international community in developing a standard or recommendation on use of common PROs across clinical conditions (i.e., use of generic PROM tools across clinical conditions)?**

ICHOM does not endorse or promote one PROM over another, as we believe the needs of patients living a condition is unique and cannot be generalized to other diseases. However, within Sets, we always cover the following when measuring patient-centered outcomes: quality of life, symptom burden, and functional status; therefore, there are some common PROMs between different Sets across different clinical areas. Further, we aim to harmonize outcomes and other metrics across Sets which will facilitate data collection.

15. **Where can we find results and benchmarks for the measures if we would like to compare our own set results with other providers or countries?**

ICHOM does not receive, have access to or own any data from providers using our Sets. There are a number of benchmarking initiatives globally who use our Sets, which are external to ICHOM. If you would like more information on this, please contact our team.

16. **How does sponsorship/funding work? Do you partner with pharma to do so?**

Sponsorship for the development of a new Set, the update of one or various sets, or a Learning Collaborative can come from any healthcare institution who wishes to fund our project. In the past, our projects have been funded by pharmaceutical companies, academic institutions, healthcare providers (such as individual hospitals or hospital groups), medical device companies, and health tech companies. Sponsors receive routine reports of progress but do not have decision-making power, to avoid conflict of interest. If you are interested in sponsorship, whether for a specific

condition/disease or would like to know what projects we are currently working on, please get in touch with us at info@ichom.org.

17. **For the project team, do patients also be involved there, or are they only participating in the working group?**

In the past, we have never had a patient representative form part of the Project Team, beyond the Working Group. However, the Chair or Research Fellow role is open to anyone, including patient representatives, who hold the research qualifications necessary to carry out the work necessary to be part of the Project Team.

18. **Is there a way to find out which programs are implementing specific ICHOM sets, such as "anxiety, depression" and "autism"?**

We are currently in the process of fully launching the Implementation Directory, a tool which will allow us to identify healthcare institutions implementing any Set created by ICHOM globally. In July 2024, an Implementation Map will be visible on our ICHOM Website, showcasing all implementers worldwide, through which you will be able to search implementers according to Sets. If you are currently implementing one of our Sets, please fill out this survey to be featured in our Implementation Map once it goes live on our website.

19. **Have you got data in these case studies about the benefit for quality of life of patients as experienced by themselves?**

ICHOM is currently working on the development and publication of case studies which will include insights on patient experience. Please keep an eye out in our Newsletter and website for this.

20. **The idea of reducing a standard set to a minimum for implementation can be quite beneficial in various contexts, has this been considered?**

In 2023, we launched the Primary Subset, which represents a reduced version of an original Set. This will allow healthcare providers looking to implement Sets to begin implementation through a smaller version of the Set and eventually scale up to the whole Set. The Primary Subset represents the most essential parts of the Set and is defined through a meticulous process with a Steering Committee of experts who go through a Delphi voting process to define this reduced version of the Set. Currently, we have completed the Primary Subset for Breast Cancer and work to define the Primary Subset for other Sets is underway.

21. **Does ICHOM provide help with local implementation? How?**

ICHOM does not have the staff capacity to provide help with local implementation. However, ICHOM partners with external companies and organizations who are dedicated to working with clients on implementation of the ICHOM Sets. Similarly, you may set up a call with our team to discuss your vision and we can provide some general insight into our Sets and help guide you. For more information, please contact our team.

22. **Are the measures only medical but also social in relation to the personal vision of patients on the outcome in terms of their standards, such as quality of life?**

Patient-centered outcomes and respective PROMs selected to be included in ICHOM Sets will always cover the following: quality of life, symptom burden, and functional status.

23. **Do you have a suggested electronic system that helps to manage PROMs?**

ICHOM works with a number of companies focusing on digital solutions as part of our ICHOM Partnership programme. For more information on this, please contact our team.

24. **Over here 25 % of patients have limited literacy in terms of language and also IT. How do you deal with that when implementing Sets?**

Throughout the years, ICHOM has learned a lot from providers who have implemented our Sets in different settings. Our team would be happy to speak with you to explore different ways in which you could overcome these barriers, please contact our team if you'd like to discuss your setting and potential implementation.

25. **I have seen that the sets online are now on sale and are quite expensive for some of us in LMICs. Is there any plan to make them more affordable.**

Our Sets are available for free; the IT-ready format of the Sets are available for a cost. We do take into consideration lower-income settings, for more information please contact our team.

26. **How do you deal with data quality to ensure real success on healthcare outcomes measurement?**

Quality improvement and measures of success are individual to each provider. ICHOM does not carry out quality improvement checks or reviews for providers using our Sets.

27. **Is there an LMIC learning collaborative and how can one join?**

We currently do not have an LMIC Learning Collaborative but we are always open to exploring new projects. If you'd like to propose an idea to our team and explore a collaboration with us, please contact our team.

28. **I'd like to implement your sets in my hospital, but I don't know how?**

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29. **Do you have any scholarship for the conference?**

We have introduced a Patient Scholarship in 2024 which allows us to provide support to patients who meet set criteria. Please contact events@ichom.org for more information.

30. **You've mentioned sponsorship for the development of new sets? How does this work?**

Sponsorship for the development of a new Set, the update of one or various sets, or a Learning Collaborative can come from any healthcare institution who wishes to fund our project. In the past, our projects have been funded by pharmaceutical companies, academic institutions, healthcare providers (such as individual hospitals or hospital groups), medical device companies, and health tech companies. Sponsors receive routine reports of progress but do not have decision-making power, to avoid conflict of interest. If you are interested in sponsorship, whether for a specific condition/disease or would like to know what projects we are currently working on, please get in touch with us at info@ichom.org.

31. **I've found that the reference and the data dictionary Excel file for some Sets are not the same when I look online. Which version should I go by?**

We are continuously updating our Sets so keep them clinically relevant, as well as in line with patients' needs. While we always update to the newest versions of all Set materials (Reference Guide, Data Dictionary, Flyer), we are aware that older versions of our Sets are available online through other sources who might feature our content. You can check between the documents to see which version is included in the title, e.g. V4.0 vs V5.0, to know which is the most recent version. If you are not sure which version is most recent, please refer to our web page which features all of our Sets, where you'll find the most version of the Set.