

Manuscript

Delphi hackathon – a new approach to develop Core Outcome Sets for blood cancers

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Abstract

Background

The Delphi technique is a well-known and accepted method to reach consensus. However, major challenges in Delphi studies include recruiting suitable participants and avoiding a loss of participants between survey rounds. To mitigate these challenges, we present the Delphi hackathon as a new method to conduct Delphi studies. We have used this new approach to develop Core Outcome Sets for hematologic malignancies within the scope of the HARMONY Plus project - as part of the HARMONY Alliance.

The HARMONY Alliance is a public-private European Network established in 2017, which currently includes 53 partners and 140 associated members from 19 countries. Amongst many other goals of the HARMONY Alliance, Work Package 2 focuses on defining outcomes that are relevant to each hematological malignancy.

Methods

In the style of a classic hackathon, known from software development, we organized two virtual meetings where all participants simultaneously filled out the online Delphi surveys, followed by a third virtual meeting to reach final consensus.

The recruitment was done by advertising and providing information via the HARMONY communication team and patient umbrella organizations.

Discussion

Big challenges shown in previous Delphi surveys such as recruitment of the various stakeholders and their continued participation in the various Delphi rounds could be addressed by the new Delphi hackathon approach.

Keywords

Delphi process, Core outcome Set, hackathon, HARMONY, HARMONY Plus

Introduction

The Delphi technique is a method to reach consensus based on the results of multiple rounds of surveys sent to a panel of experts (1). The Delphi method requires at least two rounds of a survey to reach consensus and a sustainable result between different stakeholder groups. In the first round, the participants are asked for their personal opinions. In the following round, this opinion is to be reconsidered based on the other participants' responses in the first round. For this purpose, the summarized results of all other participants are made available prior to the second round. The ultimate result is meant to constitute a consensus of the group's opinion.

Amongst other topics, the Delphi technique is used to develop Core Outcome Sets (COS) for diseases, i.e., the minimum set of outcomes that should be collected and reported in future clinical trials according to patients, clinicians, and other stakeholder groups. Developing COS for hematologic malignancies (HMs) is one of the objectives of the HARMONY Alliance. The HARMONY (Healthcare Alliance for Resourceful Medicine Offensive against Neoplasms in Haematology) Alliance is a public-private European Network established in 2017, which currently includes 53 partners, inter alia 6 cancer patient umbrella organisations, and 32 associated members from 22 countries. One of HARMONY's goal is to use Big Data to improve understanding and treatment of hematological malignancies. In order to achieve this aim, HARMONY is structured into eight work packages of which Work Package 2 (WP 2) is focused on defining outcomes that are relevant to each hematological malignancy.

Within the framework of the HARMONY project, surveys using the Delphi method have been conducted in recent years with the aim to define COS for various malignant hematologic diseases (Figure 1) (2).

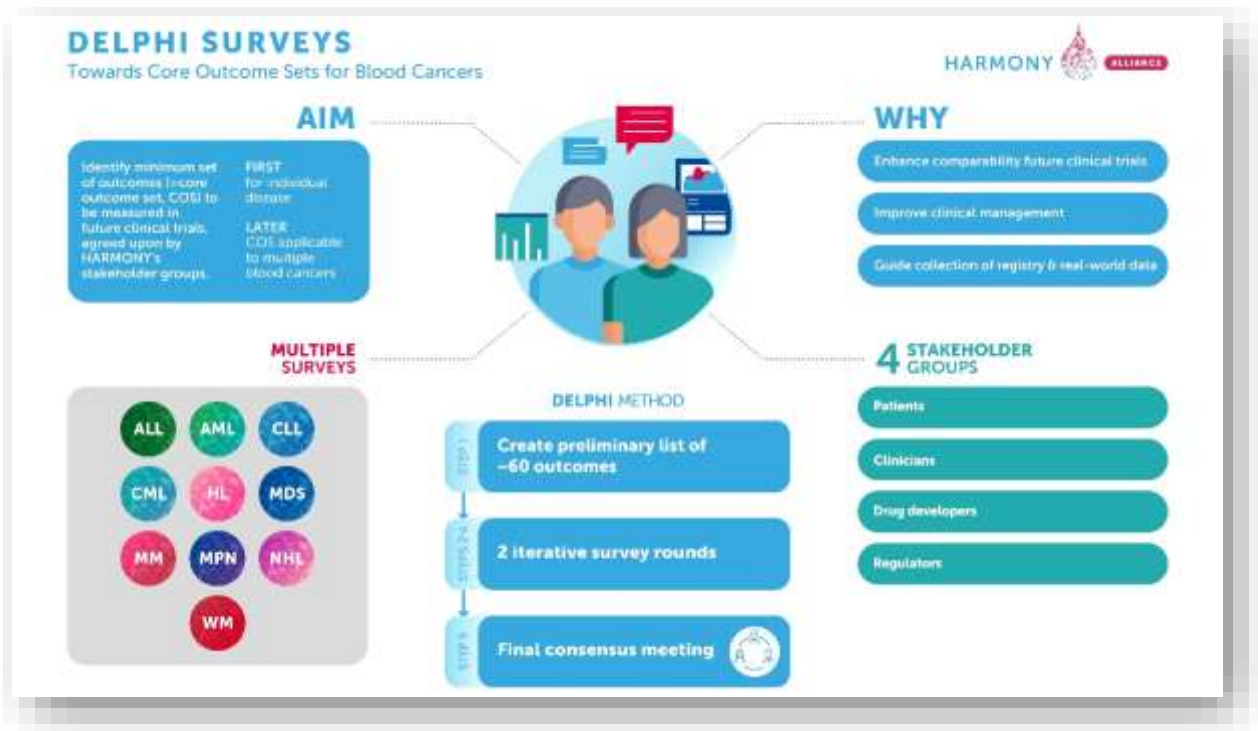


Figure 1: Infographic of the HARMONY Alliance Delphi Survey method

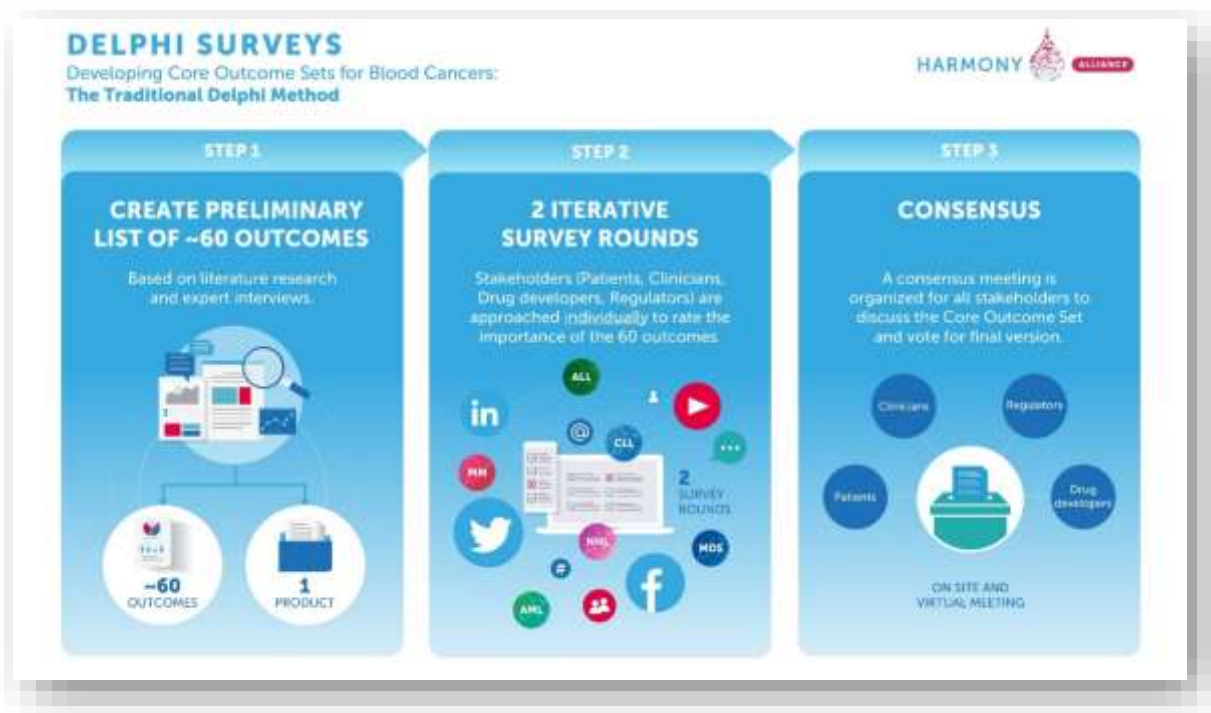


Figure 2: Infographic of the HARMONY Alliance Delphi Survey - traditional method

Similar to other traditional Delphi studies (3), the HARMONY Delphi studies were run as electronic surveys that were open for a certain amount of time and were brought to the attention of potential participants through email or social media (Figure 2). Many groups have described that the recruitment and adherence of participants between the individual Delphi rounds pose a great challenge (4). This was also confirmed by the experience from the Delphi surveys conducted by the HARMONY Alliance. In addition, the HARMONY Alliance had the challenge of achieving consensus among four stakeholder groups, i.e.:

- patients;
- clinicians;
- drug developers;
- regulators.

These four stakeholder groups had different information needs and levels of scientific literacy.

Aims

Our experiences with traditional Delphi surveys revealed several challenges:

- very busy schedules of the participants;
- challenges in reaching suitable participants, partly due to the rare nature of some of the hematologic diseases concerned;
- different information needs and demands on the survey;
- limited participation of the same people in the second Delphi round.

Therefore, we have reconsidered and revised the way of conducting the surveys and developed a new approach: the Delphi hackathon.

Methods

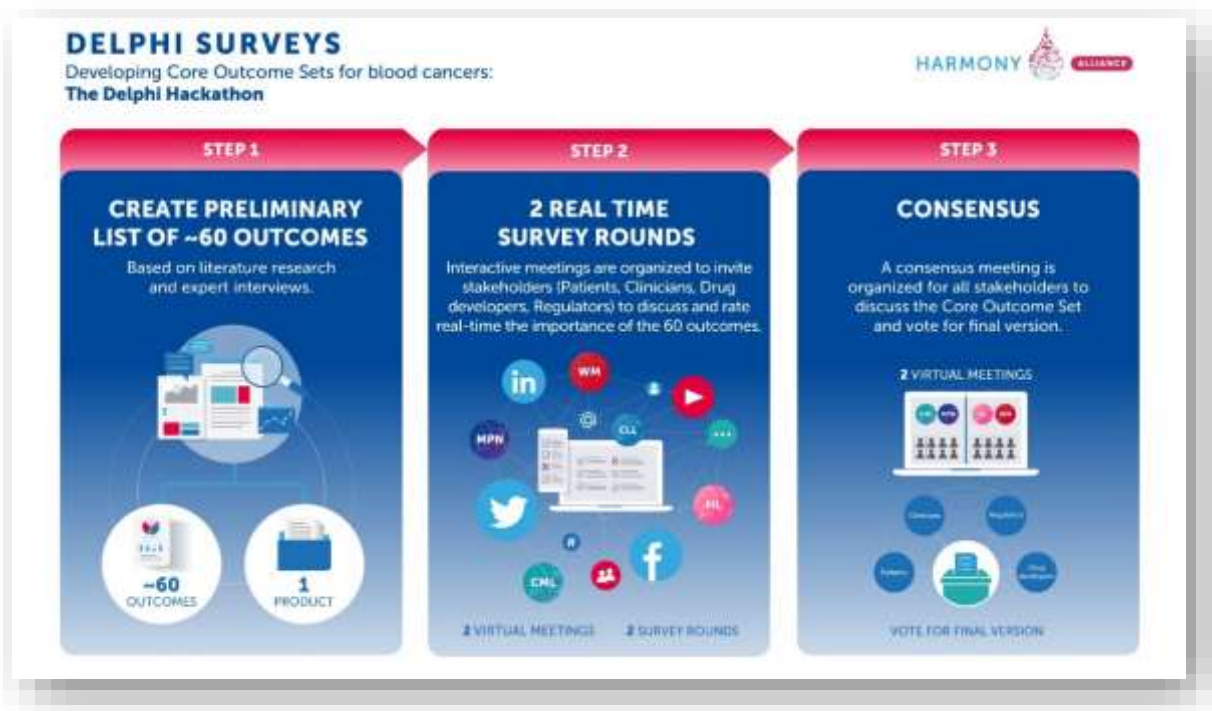
The COS development will follow recommendations of the Core Outcome Measures in Effectiveness Trials (COMET) initiative from the international Core Outcome Set Standards for Development (COS-STAD) (1, 5).

A prospective study protocol was published on HARMONY webpage (2). The protocol has been written following the Core Outcome Set-Standardised Protocol (COS-STAP) recommendations (6) in cooperation between Work Package 2 and 6.

The Delphi hackathon approach

In the style of a classic hackathon, known from software development, we organized two virtual meetings where all participants simultaneously filled out the online Delphi surveys, followed by a third virtual meeting to reach final consensus (Figure 3). The first two meetings were scheduled at an interval of two weeks, lasted 90 minutes each, and covered four different hematologic diseases: Chronic Myeloid Leukemia (CML), Myeloproliferative Neoplasms (MPN), Hodgkin's Lymphoma (HL), and Waldenström Macroglobulinaemia (WM). Recruitment mainly took place within the HARMONY community, targeting HARMONY's four main stakeholder groups - clinicians, patients, European Federation of Pharmaceutical Industries and Associations (EFPIA) members, and regulators. The recruitment was done by advertising and providing information via the HARMONY communication team and patient umbrella organizations. A protocol with detailed information on the study design and the planned analysis was developed and published before the hackathons took place (2). Some participants completed surveys for all four diseases, but the majority (especially the patients) only completed the survey corresponding to their own expertise.

Figure 3: Infographic of the HARMONY Alliance Delphi Survey – hackathon method



The first meeting started with a brief plenary introduction to the methodology and the purpose of the survey presented by the study leaders, followed by a hands-on introduction with screenshots of the Delphi tool explaining how to carry out the self-registration and the survey in practice. After the plenary introduction, break-out rooms were made available for all participants in addition to the main plenum room. The questions of the participants could easily be answered by the study leaders in these break-out rooms. In addition to content-related questions, technical and organizational issues could also be discussed here. The Delphi surveys consisted of a list of approximately 60 outcomes for HMs, e.g., overall survival, progression free survival, cost of treatment, pain, and fatigue. The participants were asked to score the importance of each outcome on the list. After completion of the first round, the participants could leave the first meeting.

In **the second meeting**, participants could reconsider their ratings of the outcome measures in view of the results of the other participants. All participants of the first round received several email reminders of the date of the second meeting. As in the first meeting, a short introduction was given at the beginning of the second meeting, emphasizing the goal of the Delphi survey to reach consensus. Summarized results of the other participants were made available per stakeholder group. Again, participants could ask questions via chat at any time. At this second meeting, break-out rooms were not offered anymore, because all technical and organizational questions could be addressed already during the first meeting.

A final consensus meeting was planned after completion of all analyses of the results after the second round. There was an eight-week interval between the second hackathon and the final consensus meeting. This meeting also took place virtually to give everyone the opportunity to participate. The goal of this meeting was to confirm all the outcomes that had been ranked high in the COS, and to discuss those that had not met any of the pre-determined consensus criteria. The summary of the results was shared with all participants prior to the consensus meeting for transparency and to allow for better preparation and discussion.

Study design

Recruitment of participants mainly takes place from members of the HARMONY Work Packages, but also participants outside the HARMONY Alliance are invited to take part in the Delphi survey within their stakeholders' group.

Ethics approval and consent to participate

HARMONY Alliance is structured into eight work packages of which Work Package 8 (WP 8) is responsible for ethical aspects of the project. Further information can be found here: <https://www.harmony-alliance.eu/en/work-packages/work-package-8-legal-ethics-and-governance> In consultation with the WP 8 the development and conducting of the Delphi survey was performed and an ethics approval is not required.

Recruitment of participants is made within HARMONY Alliance. Especially patients' recruitment is made by patient umbrella organisations, partners in HARMONY.

Before registration, all study participants receive information about the study and informed consent is obtained from all participants during the registration procedure.

Study management group

As recommended by the COMET initiative a study management group has been assembled to oversee the project (1). The group comprises a study coordinator, a haematologist with leading roles in treatment and clinical trials, drug developer with experience in past and current trials, patient advocates and methodological experts with experiences of systematic reviews and Delphi studies. The role of the study management group is to support the development of the study protocol and to review the list of outcomes and the associated lay versions and descriptions.

Consensus criteria

To reduce potential bias in interpretation of the results a clear consensus definition is important. We will use three categories of consensus that were already used in previous works (1, 3).

1. Consensus in = 70% or more over all respondents scored the outcome as critically important and 15% or fewer over all respondents scored the outcome as limited important
2. Consensus out = 70% or more over all respondents scored the outcome as limited important and 15% or fewer over all respondents scored the outcome as critical important
3. No Consensus

Outcomes that do not achieve consensus through several Delphi rounds will be discussed in a final face-to-face consensus meeting to finally ratify the core outcome sets. Representatives from all participating stakeholder groups will be part of this meeting.

Analysis

Analysis of the Delphi study will use descriptive statistics. The results for each Delphi round, for each outcome and for each stakeholder group will be presented in frequency tables. The analysis of the Delphi survey will be performed using the R statistical software version 3.5.2.

As an exploratory analysis we additionally identify outcomes considered as important for patients. The median Likert score for the patient group at the end of each round will be calculated and those outcomes achieving a median of greater or equal to 7 will be considered as important for patients and will be included in the COS. In this way patient-important outcomes can be separately discussed in the final consensus meeting.

Discussion

Strengths and limitations

One of the strengths of the hackathon approach is that blocking dates in calendars helps people to dedicate their time and attention to the survey. Emails asking to answer a survey are easily overlooked in the flood of work emails. The dates for both rounds were announced in advance. In addition, personalized email reminders were sent out several times between the Delphi rounds. This was meant to avoid a loss of participants between rounds. Of course, the fixed date can also be a disadvantage because some participants who are interested in the survey may not be available on the fixed dates. These votes and opinions would then be missed. To tackle this, the survey was made available on the internet for an additional ten days, together with explanatory information and recordings of the virtual meetings.

Another strength is being able to respond to questions, tailored to the information needs of individual participants. Experiences from the previous HARMONY surveys showed that the information needs varied greatly between the groups, and the hurdle to pose a question via email often was too high. Therefore, the possibility to immediately ask questions during the meeting – either in person or via the meeting chat was very convenient. In addition, the introductory words motivated participants to complete the survey, preventing them from dropping out.

Initially, there were concerns that the nature of the meeting might influence the outcome of the survey, because a major advantage of using the Delphi method is that all participants can cast their votes anonymously. However, by completing the survey in private and not via a split screen etc. anonymity could be maintained. We will publish the results of the Delphi hackathons (i.e., the Core Outcome Sets) in a separate paper following a final expert panel meeting.

Trial status

At the time of manuscript submission to the Delphi hackathon was open is completed.

Additional file 1

COS STAP checklist

Declarations

Acknowledgment

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An additional cash grant has been obtained from Bayer AG for conducting the Delphi survey development.

The manuscript was written and reviewed from different EFPIA members and members of the HARMONY Alliance, who were also involved in study design.

Availability of data and material

Not applicable

Authors’ contribution

All authors read and approved the final manuscript.

Consent for publication

Not applicable

Competing interests

All authors are members of the HARMONY consortium, otherwise there are no conflicts of interest with regard to the Delphi study protocol. MB and RSR are employed by AbbVie and Bayer, respectively.

Authors’ contribution

All authors made substantive contributions to the design of the study. KL, MB, RSR and TB elaborated the study protocol in detail; the co-authors critically reviewed it. KL drafted the manuscript, and all co-authors reviewed the manuscript and approved it to be published.

Abbreviations

- CML – chronic myeloid leukemia
- COS – core outcome set
- COMET – Core Outcomes Measures in Effectiveness Trials
- EFPIA – European Federation of Pharmaceutical Industries and Associations
- HARMONY – Healthcare Alliance for Resourceful Medicine Offensive against Neoplasms in Hematology
- HL – Hodgkin lymphoma
- HMs – hematological malignancies
- MPN – myeloproliferative neoplasms
- WM – Waldenstroem’s Macroglobulinemia
- WP - Workpackage

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