Establishing the Dynamic Dashboard – Methodology for developing the categorisation fields

Introduction

The Global Antimicrobial Resistance (AMR) Research and Development (R&D) Hub was launched in May 2018, following a call from G20 Leaders, to address challenges and improve coordination and collaboration in global AMR R&D using a One Health approach. The Global AMR R&D Hub will support global priority setting and evidence-based decision-making on allocation of resources for AMR R&D through the identification of gaps, overlaps and potential for cross-sectoral collaboration and leveraging in AMR R&D. It is a global partnership currently consisting of 16 countries, the European Commission and two philanthropic foundations and four organisations participating as observers (membership list).

One of the key activities for the Global AMR R&D Hub is the development of a close to real-time Dynamic Dashboard that will become the global knowledge centre on current initiatives and funding in AMR R&D across the One Health continuum and the evidence base for guiding more efficient use of international resources. The Dynamic Dashboard will present basic and applied research projects and/or investments from publicly and privately funded R&D throughout the research and innovation value chain on treatment, preventive measures, diagnostic products, surveillance, policy and interventions (such as stewardship) across all One Health sectors. Project and/or investment information will be collected in a staged approach, beginning with R&D[1] relevant to human antibiotic resistant bacterial infections. The Dynamic Dashboard, containing this first stage of information, will be launched in quarter one (Q1) 2020[2]. This paper outlines the methodology used to establish the Dynamic Dashboard and the first phase of data[3] collection and categorisation. Following the launch, later in 2020 the dashboard will be expanded to collect project information from all One Health sectors (to include animal, plant and environmental health) encompassing R&D relevant to drug resistance in bacteria, fungi, viruses and parasites and at that time this methodology will be updated to reflect this.

Development of the roadmap and key questions

In early 2018, the Global AMR R&D Hub developed a provisional Work Plan for 2018 to 2021, of which the development of the Dynamic Dashboard is a key component. Feedback on the provisional Work Plan was sought through public consultation. The feedback received, specifically for the Dynamic Dashboard, indicated broad support for presenting AMR R&D information:

- At a high level on current initiatives and funding flows
- Across the complete chain of R&D
- On new antimicrobials, diagnostics and preventives
- On push and pull incentives, and
- For all One Health sectors.

In finalising the Work Plan, the Global AMR R&D Hub's Board of Members agreed that the Dynamic Dashboard should be developed in phases, with the first phase, to be launched in Q1 2020, focused on R&D

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[1] All research and/or development will be captured by the Dynamic Dashboard and is not limited to the traditional definition for R&D for product development. This will enable collection of important research looking to expand our understanding of AMR or investigating how surveillance, stewardship, access, social changes and/or policy implementation can be enhanced.

[2] Due to delays in development of the platform the Dynamic Dashboard will be launched in Q1 2020 rather than December 2019 as stated in the original Dynamic Dashboard Roadmap and Global AMR R&D Hub's Workplan.

[3] The term data refers to the information on the project and/or investment and not project results or outcomes.
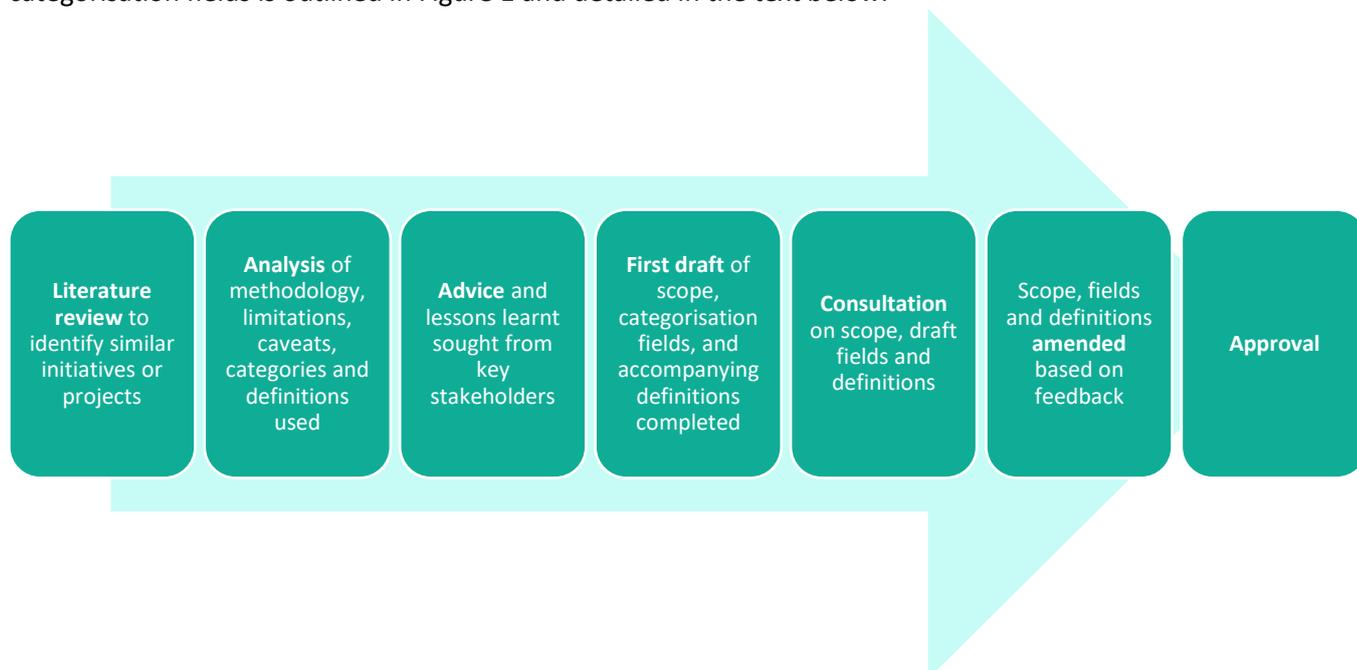
for human bacterial infections. The Dynamic Dashboard would then expand later in 2020 and detail on the phases and the timings are provided below in the 'Expansion phases' section.

To ensure the feedback received on the Work Plan was incorporated and to provide clarity around the vision and objectives of the Dynamic Dashboard a roadmap was developed and formally approved by the Board of Members in March 2019. The aim of the Dynamic Dashboard roadmap was to:
- Provide a clear and concise outline of the key elements and milestones
- Provide a clear definition on what type of activities are in scope (see below)
- Ensure that a One Health approach was taken from the beginning of the project, and
- To identify the key questions of policy- and decision makers that it had to be designed to answer.

Development of data categorisation fields

To present AMR R&D information at a high level that is informative to decision and policy makers it was necessary to develop categories (categorisation fields) that would answer the identified key questions (listed in the roadmap). Every AMR R&D project identified would then be categorised using these standardised fields that would be applicable to all One Health sectors, where appropriate. To enable the information collected by the Dynamic Dashboard to be analysed over time, it was vital that the categorisation fields developed were robust and consistent. The process for developing the data categorisation fields is outlined in Figure 1 and detailed in the text below.

| Literature review to identify similar initiatives or projects | Analysis of methodology, limitations, caveats, categories and definitions used | Advice and lessons learnt sought from key stakeholders | First draft of scope, categorisation fields, and accompanying definitions completed | Consultation on scope, draft fields and definitions | Scope, fields and definitions amended based on feedback | Approval |

**Figure 1 – Process for developing the data categorisation fields**

To identify other relevant published work that could be used to inform the development of the categorisation fields for the Dynamic Dashboard a literature review, using PubMed, was conducted in January and February 2019. In addition, the grey literature (including reports, conference and workshop proceedings) was searched through Google scholar and similar initiatives identified through relevant websites. After reviewing over 300 results from the searches, 25 different initiatives and journal articles (not all referenced are mutually exclusive) [1-33] were analysed in depth for methodology, limitations, caveats, categories and definitions to develop the first set of categorisation fields for consultation, initially with the Board of Members. Relevant initiatives were consulted to gain an understanding of what data is available, how that data is collected, what lessons were learned, and to gather opinions on the feasibility of the categorisation fields proposed. The categorisation fields will be structured as categories which may be supported by subcategories if required, an example of this structure is provided in Figure 2.

Extensive consultation on the draft categories and definitions was then conducted. Members of the Global AMR R&D Hub's Stakeholder Group representing organisations from non-governmental organisation/civil

society, industry, international funding initiatives and academia, provided input on the categories, definitions and scope of the Dynamic Dashboard. In addition, experts from the animal, plant and environment health sectors were also consulted. The feedback was consolidated and applied to the categories and definition of the dashboard.

Work is underway to develop subcategory fields, with key stakeholders, that answer specific key questions in the animal, plant and environmental health sectors which will be included under the relevant 'sector' field. These subcategories will not change any of the categories which were developed to be applicable to all One Health sectors. Once these subcategory fields are finalised an update to this methodology will be published.

The final categories for the first phase of the Dynamic Dashboard as agreed to by the Board of Members are provided at Attachment A. Where there may be some ambiguity with the categories, definitions have been developed and will be published on the Dynamic Dashboard website. As R&D projects are categorised, subcategories may be incorporated and definitions further refined as the need arises.
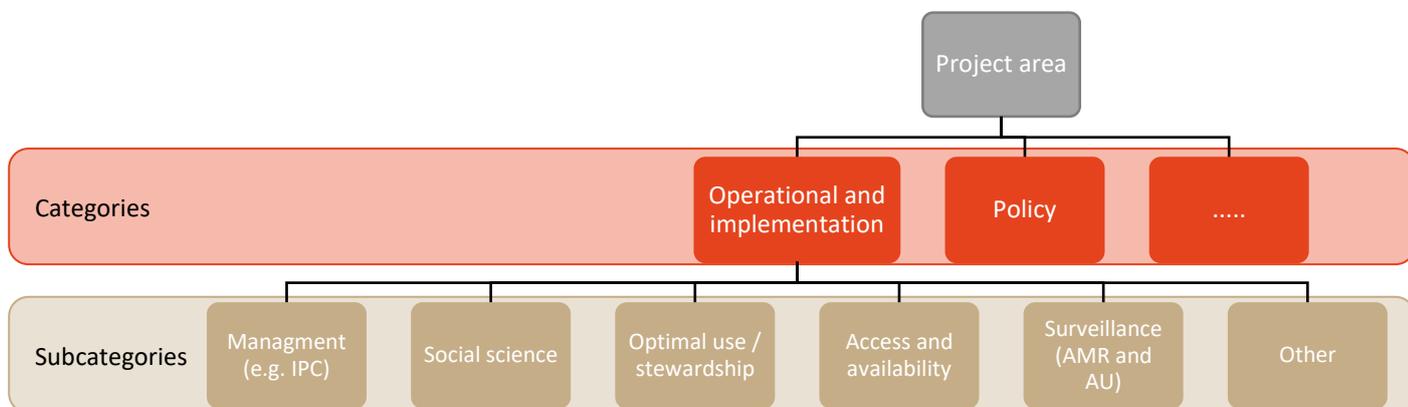
Figure 2 – Example of the structure of categories and subcategories

Inclusion criteria

To ensure projects and investments are collected in a systematic, transparent and comparable way, the scope of the Dynamic Dashboard was defined.

R&D and AMR scope

For an R&D project and/or investment[4] to be included in the Dynamic Dashboard, it must have a clear research and/or development component and satisfy the disease, geographical, types of R&D, funding and incentives scope defined in Table 1. In addition, the R&D must be related to AMR which was defined as any project or investment that:

- Addresses or investigates drug resistant bacteria, viruses, fungi and parasites (protozoa and helminths only) including improving understanding of transmission and environmental risk

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[4] Project/investment is defined as:
- a project funded by a granting body/agency and identified as such by the body/agency. This is the case for a large number of data entries used for the Dynamic Dashboard.
- a coherent set of activities financed by in-house resources of an institution and reported as such by the institution. This is the case for institutionally funded research.
- activities carried out by a company or not-for profit entity and defined as a programme, initiative, or measure by the entity. This is typically the case for activities linked to the development of a new intervention. An example could be the formal pre-clinical development of a compound to enter clinical trials (i.e. submit the first investigational new drug application in the US or the first clinical trials authorization in the EU).

- Investigates how to improve the access to all products globally
- Looks at how to improve processes, strategies and/or develop products for better stewardship and appropriate use of all antimicrobials (including monitoring antimicrobial use)
- Aims to develop any new antimicrobial, and
- Investigates ways to reduce antimicrobial use, such as alternatives to growth promotants and vaccines for diseases that drive inappropriate antimicrobial use, and reduces contamination of the environment with antimicrobial substances or drug resistant agents or organisms.

Table 1 – Overall Scope of the Dynamic Dashboard

Scope	
Disease scope	All bacteria, viruses, fungi, protozoa parasites, and helminths[5] affecting or colonising humans, animals and plants and their associated environments are in scope but research must be related to AMR.
Geographical scope	Global
R&D in scope	Basic and applied research is in scope. The activities could include but are not limited to: • All types of product-oriented and product-based R&D, including basic research, discovery, development (including field trials), and post registration studies for therapeutics, preventives, and diagnostics • Research of new or existing medical interventions[6] • Research into quality and counterfeit or sub-standard products • Research that improves understanding of the pathogen, virulence, transmission, impact of external factors and roles and interaction of different One Health sectors • Operational/implementation research such as exploring improvements to surveillance, access to products, digital products, infection prevention and control and disease management programs • Social science research to understand human behaviours relating to AMR • Research to inform policy or regulation development or revision • Relevant research training (such as support for PhDs & post-docs) and network establishment
Funding and incentives	• All types of public and private funding including project grants, programme grants, institutional funding, consortia grants, fellowships (following the defined R&D scope above), seed funding, centre funding, prizes and awards (only when associated with money) and pilot projects that have a clear research component • All push incentives for R&D • All pull incentives for R&D that target removal of the following barriers to R&D and uptake: technical, financial and lego-regulatory • Programme / initiative evaluation reviews • Case studies • Access programmes

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[5] Parasites in scope are protozoa and helminths. Ectoparasites are considered out of scope.
[6] In the context of AMR and for the purpose of the Dynamic Dashboard medical interventions are defined as interventions involved in the prevention, diagnosis and treatment of an AMR-related disease (or a condition) and include but are not limited to therapeutics, diagnostics, preventives, promotants, etc.

Timeframes

In the first phase, AMR R&D projects and investments that were active or committed on or after 1 January 2017 will be included. The timeframe may be expanded in later phases to include earlier time points so the Dynamic Dashboard can become a repository of historical AMR R&D project and investments. Investments will be presented as both US dollars and Euros.

Exclusion criteria

Information will not be collected for projects or investments on:

- The use of viral vectors to investigate non communicable diseases
- R&D on virally caused cancers, reactivated viral infections in immunocompromised individuals such cytomegalovirus or progressive multifocal leukoencephalopathy
- Grants solely for symposia or meetings or travel
- Funding for buildings / capital investments
- Training and professorships where there is not a strong focus on AMR R&D, or
- Research into insect vector control

Initial data collection

R&D project information is currently being collected from a large number of public and charitable funding sources using a variety of mechanisms. This includes collecting information from other studies that have already presented mapped and categorised AMR R&D information, downloading data directly from funder websites or downloadable databases and manually filtering relevant studies using standard key word search terms, searching open access databases, and contacting funders directly and requesting details. Variables being collected included study title, abstract, funder, funding awarded to the study, start and end date, lead institution, project identification number and currency. Categorisation of the R&D projects will be conducted by the Global AMR R&D Hub in a systematic and standardised way. Where possible, project level information will be provided through the search function on the platform to aid the ongoing utility of Dynamic Dashboard.

Methodology to guide the data management, cleaning and quality assurance; software/platform specifications; and dashboard presentation and utility is being developed and will be published with the launch of the dashboard. This will be accompanied with an outline of the data limitations and caveats.

Expansion phases

The expansion of the Dynamic Dashboard to cover animal, plant and environmental health AMR R&D and all relevant bacteria, viruses, fungi, and parasites will occur in phases. The scope of the phases and anticipated timings are outlined in Figure 3 noting that data collection will be ongoing for all phases once published.
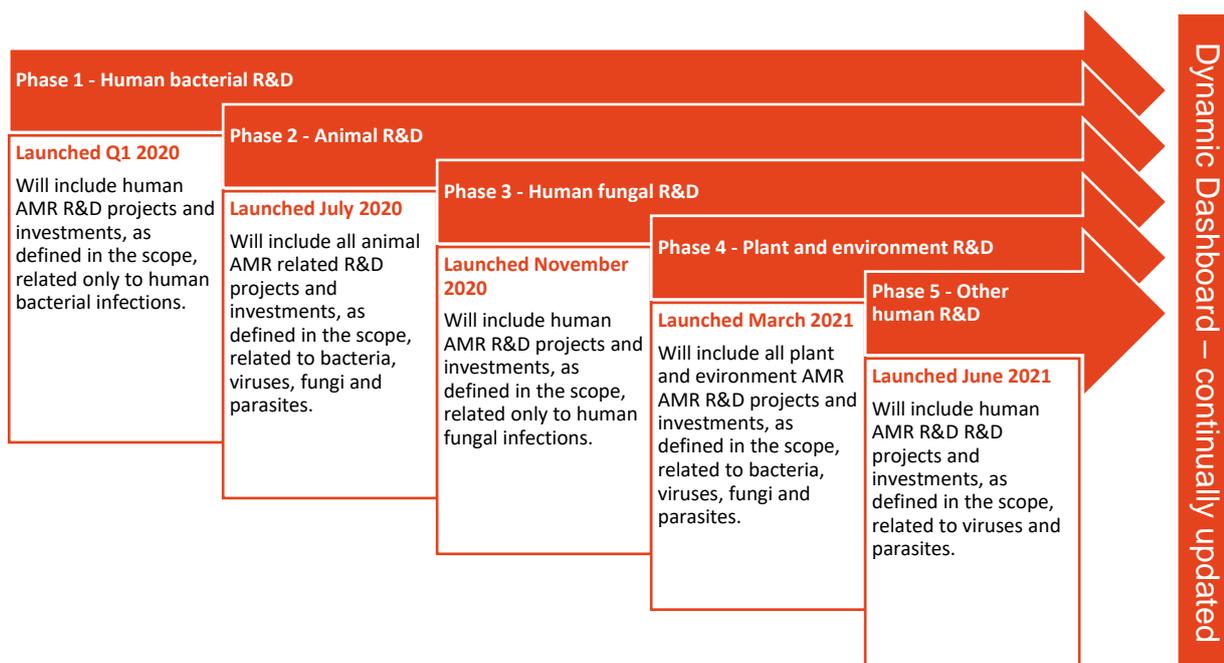
Phase 1 - Human bacterial R&D

Launched Q1 2020

Will include human AMR R&D projects and investments, as defined in the scope, related only to human bacterial infections.

Phase 2 - Animal R&D

Launched July 2020

Will include all animal AMR related R&D projects and investments, as defined in the scope, related to bacteria, viruses, fungi and parasites.

Phase 3 - Human fungal R&D

Launched November 2020

Will include human AMR R&D projects and investments, as defined in the scope, related only to human fungal infections.

Phase 4 - Plant and environment R&D

Launched March 2021

Will include all plant and evironment AMR AMR R&D projects and investments, as defined in the scope, related to bacteria, viruses, fungi and parasites.

Phase 5 - Other human R&D

Launched June 2021

Will include human AMR R&D R&D projects and investments, as defined in the scope, related to viruses and parasites.

Dynamic Dashboard – continually updated

Figure 3 - Expansion phases of the Dynamic Dashboard

Next steps

In addition to capturing R&D projects and funding across the One Health continuum, research outputs (products) and interventions into the workings of the market (incentives) will also be captured and presented.

Private investments into R&D

Investment from private entities (pharmaceutical companies, SMEs, biotech) of the different product development stages will be included based on currently accepted estimates. The Secretariat is currently exploring the best way to represent this information.

Health technology pipelines

Information on the different health technology pipelines will be collected and presented in a staged approach. Work is underway on how to present this information in a way useful for the target audience. It is envisioned that, initially, existing publicly available sources will be used to capture current development products in the therapeutic pipeline. This could be expanded to present a broader pipeline, for example adaptive R&D or pre-clinical pipeline, if needed. The Secretariat will work towards capturing development products in the pipeline for human diagnostics and vaccines. If feasible and desired, this would be further expanded later in 2020 to provide information on products for animal and plant use.

Incentives

Collating existing policy and financial interventions that have impacted the way in which R&D in the field of AMR is conducted, will be imperative for the Hub to realise its objectives and provide evidence to inform where further intervention in the market is warranted. Again, this will occur in a staged approach. An initial qualitative capture of the diversity of interventions – into both medicine and diagnostic markets - will be prioritised with the Hub initially highlighting specific, notable, examples and providing links to further information sources. This will subsequently be expanded to comprehensively capture significant lego-regulatory changes in countries around the world, include outcome/impact studies (where available). As feasible in the future, the Secretariat aims to investigate ways of fostering best practice sharing and learning between implementing countries/regions.

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Dynamic Dashboard Categorisation Fields

Categories for the funder and beneficiary

How the funder will be categorised:	How the beneficiary will be categorised:
• Public – government • Public – other • Private – for profit • Private – not for profit • Other, or • Not specified. Where possible information on the funder location will also be captured. If there is a funding intermediary (receives funding from other sources and then funds projects with this) additional information will be collected.	• Public research institution/facility • Private research institution/facility • Large industry MME • SME • Biotech • Other, or • Not specified. Where possible information on the beneficiary's location will also be captured.

Information on the funding

• How much – total and by year • When (start and end date) • If it is a push or pull incentive

How the project will be categorised

By sector:	By project area:
• Human • Animal • Plant • Environment • Cross-sector • Other, and/or • Not specified.	• Basic research • Therapeutics • Preventives and alternatives to growth promotants • Detection, screening and diagnostics • Operational and implementation • Policy • Capacity building and infrastructure • Other, and/or • Not specified.
By infectious agent: • Bacteria • Fungus • Parasite • Virus • Other • None/not applicable, and/or • Not specified. Where possible the specific bacteria, virus, fungus, or parasite name will also be captured.	**If the project is product based, then by research and development stage:** • Research/Discovery/Preclinical • Development/Trials • First registration • Implementation and post registration, and/or • Not specified. If relevant, if the product is on the development pipeline.