# Request for Proposals (RFP) for Common Metrics in Mental Health

## 1. RfP Background & Objectives

Mental health problems are predicted to be the biggest burden of disease by 2030. The largest contributors to this burden are the broad spectrum of conditions encompassed by anxiety, depression, and psychosis (including OCD, PTSD, schizophrenia, bipolar disorder, and post-partum psychosis). Although many interventions for anxiety, depression, and psychosis have been shown to be at least partially effective, their mechanisms of action are poorly understood.

Mental health research studies are conducted across a vast range of cultures, populations, and academic disciplines. Consequently, mental health research data is extremely fragmented. In addition, mental health measurement is also fragmented – there are currently more than 280 different tools for measuring depression alone, with each adopting a different methodology. This fragmentation prevents researchers from comparing results between studies, and ultimately holds back the development of new treatments and interventions for people living with mental ill-health. We also do not know enough about how to make the current measurement tools most acceptable to people with lived experience of depression, anxiety, and psychosis.

Given the current, fragmented landscape of mental health data, there is a critical need to take pragmatic action to make mental health research easier to interpret, compare, and communicate. Common measures are tools that a broad community agrees to use, in order to ensure that they are measuring the same thing. By agreeing on common measures, we can communicate, compare, and combine results from a wide range of studies to make new discoveries. They are not intended as the sole measures to be used, but rather as a common set that all use.

In October 2020, the International Alliance of Mental Health Research Funders<sup>1</sup> established a community of mental health research funders, academic publishers and data measurement experts committed to adopting common measures in mental health science. The Common Measures in Mental Health Science Governance Board (CMB), is led by Wellcome and the US National Institute of Mental Health<sup>2</sup>. The long term aim is to identify and adopt robust measures that can be applied in many mental health research settings – inspired by successful common measures in other fields (e.g, the haemoglobin A1c test to monitor diabetes, or the 'five-year-survival' measure in oncology).

The initial focus has been on self-report and demographic indicators for youth anxiety and depression.<sup>3</sup> Through consultation with measurement experts working in a diverse range of research and cultural contexts, the CMB has identified an initial set of measures relating to depression and anxiety. The initial agreement includes the following measures, which Wellcome has mandated their awardees to use (see Appendix 2 for a blog post from Miranda Wolpert, Director of Mental Health at Wellcome, with more detailed information about these measures):

<sup>1</sup> https://iamhrf.org/projects/driving-adoption-common-measures

<sup>2</sup> CMB-and-CMA-July-2020-pdf.pdf (wellcome.org)

<sup>3</sup> More information can be found at: https://nda.nih.gov/contribute/nimh-common-data-elements.html

- Measures of depression and anxiety: PHQ-9 (adults), GAD-7 (adults), RCADS-25 (children and adolescents). PHQ-2, GAD-2 and RCADS-10 may also be appropriate in exceptional circumstances
- Impairment: WHODAS 2.0 (adults)

It is important to stress that the Wellcome is not advocating for these measures to be used exclusively and recognizes that they are part of a holistic package in a research setting. The goal is not to identify perfect measures, but instead to identify low-burden, low-cost and high-information standalone instruments, that can produce meaningful information in the widest possible contexts.

## 2. RfP Specification

Wellcome now invites proposals from exceptional suppliers to design and deliver a programme of work producing a series of technical outputs that can be used by researchers, funders and publications to practically align research around core metrics in depression, anxiety and psychosis.

This supplier will be required to combine psychometric expertise with an efficient and practical approach.

We do not mandate any combination of scientific expertise, but suppliers must demonstrate how their approach would:

- 1. meaningfully involve people with lived experience of anxiety, depression, and/or psychosis (as appropriate) as part of their team and/or at multiple stages of their research project to inform the design, governance and delivery of the project.
- 2. Operate across multiple geographical locations and actively foreground LMIC research communities, and people with lived experience
- 3. Balance the expertise required to produce the technical deliverables with the experience of enabling equitable engagement with diverse groups.

Wellcome welcomes views as to how the supplier would link in with the Common Metrics Board and the experts on the Common Metrics Advisory Group<sup>4</sup>.

Below is a list of deliverables that must be developed with as much rapidity as possible, consistent with a rigorous approach, but certainly no longer than three years. However, we do not rule out the potential to fund further work.

## Depression & Anxiety Metrics (PHQ-9, GAD-7, RCADS-25) Deliverables

## 1.1: Depression & Anxiety Metrics Paper

Summarising the properties, strengths and limitations for PHQ-9, GAD-7, and RCADS-25<sup>5</sup> drawing on existing literature. Specific attention must be paid to:

- a) the cut offs and changes in the metrics scores that reflect clinically significant change, not just statistical significance.
- b) the efficacy of different measures in different cultural contexts.

<sup>&</sup>lt;sup>4</sup> <u>CMB-and-CMA-July-2020-pdf.pdf (wellcome.org)</u>

<sup>&</sup>lt;sup>5</sup> https://iamhrf.org/projects/driving-adoption-common-measures

- c) item level functioning (i.e. at the level of the individual questions of these measures). This may include consideration of when it is appropriate to use shortened version(s) of the metrics.
- d) A section for reflections from people with lived experience of anxiety and depression on how these measures can best be used and improved as relevant.

**1.2: Depression and Anxiety Metrics in Practice: Secondary Analysis and Publication** Conducting secondary analysis of existing studies or cohorts to examine what PHQ-9, GAD-7 and RCADS-25 measure, and how and if they can be used to measure real clinical change. Specific attention must be paid to:

a) the cut offs and changes in the metrics scores that reflect clinically significant change, not just statistical significance.

b) the efficacy of different measures in different cultural contexts.

c) item level functioning (i.e. at the level of the individual questions of these

measures). This may include the use of shortened version(s) of the metrics.

Ideally the team would have pre-existing access to relevant data, for example using a largescale cohort such as MCS or ALSPAC, and/or cohorts in LMIC. Findings must be published in an academic journal.

## 1.3: Anxiety and Depression Metrics Toolkit

The development of a practice-based toolkit providing a concise rationale for PHQ-9, GAD-7, and RCADS-25. This toolkit should be co-created with people with lived experience of anxiety and/or depression.

Based on deliverables 1.1 and 1.2 in addition to any consultation and decision making process the supplier has employed, we are commissioning a toolkit to aid best use of the selected measures. As ease of use and lack of burdensomeness is key to adoption, the toolkit must include simple guidance on how to use the measurement instruments for depression and anxiety selected:

- a) what cutoffs to use and approach to measuring clinical change should be used.
- b) what adaptations should be allowed to balance cultural applicability with comparability across different contexts, this should include a consideration of how strictly to enforce specific wording or modes of presentation.
- c) what and how different items can be used separately, if the order of items makes a difference and, if so, how this should be allowed for (including consideration of shortened version(s) of the metrics.

This guidance must be developed with the following user groups in mind:

- researchers designing protocols for clinical and epidemiological trials.
- funders looking to ensure they are supporting awardees to effectively use the selected metrics for all research related to depression and anxiety.
- journals reporting on research using the common metrics.

## Impairment Metric (WHODAS 2.0) Deliverables

## 2.1: Impairment Metric Paper

Summarising the properties, strengths, and limitations for WHODAS 2.0<sup>6</sup> drawing on existing literature. As this metric was developed by WHO, publications that substantially cover the points below may already be in the public domain, in which case we would expect a brief summary rather than duplication of previous work.

<sup>&</sup>lt;sup>6</sup> https://iamhrf.org/projects/driving-adoption-common-measures

Specific attention must be paid to:

- a) the cut offs and changes in the metrics scores that reflect clinically significant change, not just statistical significance.
- b) the efficacy of different measures in different cultural contexts.
- c) item level functioning (i.e. at the level of the individual questions of these measures)
- d) A section for reflections from people with lived experience on this measure and how it can best be used and improved as relevant.

## 2.2: Impairment Metric in Practice: Secondary Analysis and Publication

Conducting secondary analysis of existing studies or cohorts to examine what WHODAS 2.0 measures, and how and if it can be used to measure real clinical change. Specific attention must be paid to:

a) the cut offs and changes in the metrics scores that reflect clinically significant change, not just statistical significance.

b) the efficacy of the measure in different cultural contexts

c) item level functioning (i.e. at the level of the individual questions)

Ideally the team would have pre-existing access to relevant data, for example use a largescale cohort such as MCS or ALSPAC, and/or cohorts in LMIC. Findings must be published in an academic journal.

## 2.3: Impairment Metric Toolkit

The development of a practice-based toolkit providing a concise rationale for using WHODAS 2.0 to measure impairment in mental health studies. This toolkit should be co-created with people with lived experience of anxiety and/or depression.

Based on deliverables 2.1 and 2.2 in addition to any consultation and decision making process the supplier has employed, we are commissioning a toolkit to aid best use of WHODAS. As ease of use and lack of burdensomeness is key to adoption, the toolkit must include simple guidance on how to use the measurement instrument for impairment:

- a) what cutoffs to use and approach to measuring clinical change should be used.
- b) what adaptations should be allowed to balance cultural applicability with comparability across different contexts; this should include a consideration of how strictly to enforce specific wording or modes of presentation.
- c) what and how different items can be used separately, if the order of items makes a difference and, if so, how this should be allowed for.

This guidance must be developed with the following user groups in mind:

- researchers designing protocols for clinical and epidemiological trials.
- funders looking to ensure they are supporting awardees to effectively use the selected metrics for all research related to mental health.
- journals reporting on research using the common metrics.

## **Psychosis Metrics Deliverables**

#### 3.1: Psychosis Metrics Recommendation

A recommendation of up to three core measures to use in research into psychosis (for example, schizophrenia and bipolar disorder). These measures should be relevant to individuals both within and outside clinical settings. The recommendations will require the consideration of factors such as cost, as they must be sustainable in LMICs; burden, as they must be suitable for use rapidly at scale; acceptability to those with lived experience of psychosis; and relevance to majority of research studies, as we are looking for a core set with

broad applicability. These metrics will be reviewed and approved by Wellcome using the evaluation criteria listed below (appendix 1).

## 3.2: Psychosis Metrics Paper

Summarising the properties, strengths and weaknesses for the selected psychosis metrics drawing on existing literature. Specific attention must be paid to:

- a) the cut offs and changes in the metrics scores that reflect clinically significant change, not just statistical significance.
- b) the efficacy of different measures in different cultural contexts
- c) item level functioning (i.e. at the level of the individual questions of these measures).
- d) A section for reflections from people with lived experience of psychosis on these measures.

## 3.3: Psychosis Metrics in Practice: Secondary Analysis and Publication

Conducting secondary analysis of existing studies or cohort to examine what the metrics selected in deliverable 2.1 measure, and how and if they can be used to measure real clinical change. Specific attention must be paid to:

- a) the cut offs and changes in the metrics scores that reflect clinically significant change, not just statistical significance.
- b) the efficacy of different measures in different cultural contexts.
- c) item level functioning (i.e. at the level of the individual questions of these measures).

Ideally the team would have pre-existing access to relevant data or use a large-scale cohort such as MCS or ALSPAC, and/or cohorts in LMIC. Findings must be published in an academic journal.

## 3.4: Psychosis Metrics Toolkit

The development of a practice-based toolkit providing a concise rationale for common metrics in psychosis. This toolkit should be co-created with people with lived experience of psychosis.

Based on deliverables 3.2 and 3.3 in addition to any consultation and decision making process the supplier has employed, we are commissioning a toolkit to aid best use of the selected measures (ref. deliverable 3.1). As ease of use and lack of burdensomeness is key to adoption, the toolkit must include simple guidance on how to use the measurement instruments for depression and anxiety selected:

- a) what cutoffs to use and approach to measuring clinical change should be used.
- b) what adaptations should be allowed to balance cultural applicability with comparability across different contexts, this should include a consideration of how strictly to enforce specific wording or modes of presentation.
- c) what and how different items can be used separately, if the order of items makes a difference and, if so, how this should be allowed for.

This guidance must be developed with the following user groups in mind:

- a) researchers designing protocols for clinical and epidemiological trials.
- b) funders looking to ensure they are supporting awardees to effectively use the selected metrics for all research related to depression and anxiety.
- c) journals reporting on research using the common metrics.

## **Implementation Plan**

## 4.1: Toolkit Implementation Plan

This plan must take into account existing harmonisation initiatives and the specific needs of key stakeholder groups, including those with lived experience. It must set out a clear strategy by which the use of common measures and the assets developed in this programme of work are contextualised, their advantages made clear, and pragmatic guidance set out for widespread uptake and use in a rapid and sustainable manner.

We have not specified a timeline, and we believe that timeliness is extremely important in pursuing the common metrics agenda, but also want to ensure rigour. We encourage suppliers to advise us how quickly they can produce these deliverables. We will not fund a project longer than 3 years in the first instance. It is our expectation that workstreams will run in parallel, and we expect community engagement and key stakeholder input to occur throughout the project.

## 3. Response Format

We are carrying out this procurement in two stages; an expressions of interest stage followed by an invitation for full proposals.

**Expressions of interest stage:** We invite potential suppliers to respond to this call with responses to the following questions:

- 1. Outline how you will produce the deliverables detailed in the RfP specification (no more than 500 words)
- 2. Outline how you will engage with key experts and stakeholders across the field (including funders, research institutions, researchers from multiple disciplines, lived experience experts) in order to ensure that guidance and tools are adopted (100 words).
- 3. Outline how you will involve people with lived experience at multiple stages of the design and delivery of this project (e.g. during project design, literature scanning and data collection, analysis, toolkit design) (150 words).
- 4. Evidence of track record in this area including any failures that can be learnt from in this project (200 words).
- 5. Evidence of track record in working with research communities in global contexts (100 words).
- 6. Describe how you would work with Wellcome including how you would ensure Wellcome learnt from your work on this project and what expertise you would want from Wellcome (100 words).
- 7. A Gannt chart or similar showing a high-level timeline for the proposed work.
- 8. Provide a non-binding overall cost estimate (single figure).
- Suppliers should also add in any questions they want us to address (max 100 words) but to note we will only answer questions from suppliers invited to submit a full proposal.

From these answers we will invite a small number of suppliers to submit a full proposal. We will use the assessment criteria below to make this selection.

Assessment Criteria for EOI	Weighting
Strength of answers to Q1- 3 in response to	50%
requirements set out in this RFP	
Strength of answers to Q 4-5 in response to	25%
requirements set out in this RFP	

Strength of answers to Q 6-8 in response to	25%
requirements set out in this RFP	

**Invitation for proposals stage:** The exact form required for the full proposal will be shared with the selected suppliers. Below is what we anticipate may be included but we reserve the right to amend or adapt as relevant having reviewed expressions of interest.

For those suppliers invited to make a full proposal your response is likely to need to include the following:

- How you would address the requirements as set out in section 2? (200 words on each deliverable e.g. 1.1, 1.2 etc).
- Your methodology, i.e. how would you go about identifying the metrics for psychosis, developing the toolkits for all measures and engaging with the required stakeholders? (400 words).
- How will you involve people with lived experience at multiple stages of this project (e.g. during project design, literature scanning and data collection, analysis, toolkit design) (300 words).
- How you would ensure you reach the milestones set out in your proposed timeline? (400 words).
- What resources you will use and cost breakdown? (400 words).
- Any major risks and how you will address these (table, no more than 400 words).
- A worked example of the process for a researcher to find and use the common metrics in their research (400 words).
- A similar project you have undertaken in the past including any feedback from end users or other stakeholders in that project (400 words).
- How you intend to work with Wellcome in a collaborative way? (400 words).

Assessment Criteria	Weighting
How well the proposal meets specification	40%
of requirements	
Track record and expertise	25%
Strength of proposed plans for including	20%
people with lived experience	
Value for money	15%

## 4. RFP Timetable

#	Activity	Responsibility	Date
1	RFP Issue to Suppliers	WT	24th March 2022
2	Submission of expression of	Supplier	5 <sup>th</sup> May 5pm BST 2022
	interest to RFP (Email with expression		
	of interest –		
	structured as specified above)		
3	Submission of Supplier Q&A to	Supplier	5 <sup>th</sup> May 5pm BST 2022
	Wellcome Contact		
	(by email, in same email as		
	expression of interest- to note only		

	those suppliers invited to full proposal will have their questions answered)		
4	Advice to suppliers as to whether they have been invited to submit a full proposal and return Q&A to Suppliers (collated response to all shortlisted suppliers at the same time)	WT	26th May 2022
5	Submission of RFP Response	Supplier	24 <sup>th</sup> June 5pm BST 2022
6	RFP Evaluation Period	WT	27th June – 1 <sup>st</sup> July 2022
7	Supplier Presentations	WT & Supplier	4 <sup>th</sup> -8 <sup>th</sup> July 2022
8	Notification of Contract Award	WT	July 2022
9	Contract Negotiation	WT & Supplier	July-August2022
10	Intended Contract Start Date	WT & Supplier	September 2022
11	Contract End Date	WT & Supplier	September 2025

## 5. Eligibility & supplier relationship

We encourage applications from anywhere in the world, provided the Supplier can accept work that is contracted from the UK. We are keen to encourage diverse geographical coverage across both the global north and global south.

Suppliers can come from any sector (e.g. universities, NGOs/charities, commercial companies) or discipline, but at least one member of the team must have a proven track record of conducting high-quality measurement research. We encourage applications from mental health science researchers and researchers from wider fields with specialist expertise in measurement and metrics, including, for example, psychometricians, statisticians, economists, sociologists, psychiatrists, and psychologists.

Applications can be made by individuals (either self-employed or contracting via a current employer) or teams. We are open to collaborative applications where team members provide complementary expertise, but require a lead supplier with whom to contract directly. We encourage teams to consider recruiting co-researchers with lived experience to their team.

Suppliers must also have sufficient English to communicate with Wellcome and the wider networks of successful Suppliers using English. Please also note that all requested deliverables must be submitted in English.

We want to establish a learning partnership with the Supplier, working in an iterative way, learning together throughout the 3-year programme what works and does not work. Wellcome will maintain an active relationship with the Supplier, assigning a dedicated member of staff with expertise in the field of mental health to support the work as needed.

## 6. Response Format

The following headers support the timetable by providing further detail of the key steps.

#### **Expression of Interest**

Suppliers are asked to address questions in their expression of interest detailed in section 2 above.

#### Supplier Q&A

Prior to the submission of your RFP response, Suppliers are provided the opportunity to submit any questions they have about the exercise. All questions from shortlisted Suppliers will be collated and shared with all suppliers so please do not include any confidential information. All questions are to be submitted to the Wellcome Contact by e-mail in accordance with the RFP timetable. Please note we cannot enter into any individual correspondence with potential Suppliers during this period and questions from Suppliers not shortlisted will not be answered.

#### **RFP Proposal**

Invited suppliers are required to submit full proposals which respond to the sections detailed in Section 3 above.

#### Information Governance

Suppliers are asked to complete the <u>TPSRA2</u> assessment before the RFP submission deadline for Wellcome to assess how you handle data.

#### Contract Feedback

This section allows Suppliers to provide specific feedback to the contractual agreement which may be used should their proposal be successful. Contract feedback is to be incorporated into your proposal as an annex and in the following format:

Clause #	Issue	Proposed Solution/Comment

Only Suppliers who are registered companies will be considered. Suppliers submitting proposals should review <u>this document</u>.

#### **RFP Questions**

As noted above, all questions should be made at the expression of interest stage. Note we will only answer questions from Suppliers invited to submit a full proposal.

#### 7. About Wellcome

Wellcome exists to improve health by helping great ideas to thrive. We support researchers, we take on big health challenges, we campaign for better science, and we help everyone get involved with science and health research. We are a politically and financially independent foundation. Find out more about Wellcome and our work: wellcome.org.

#### 8. Non-Disclosure and Confidentiality

Prospective Suppliers should be aware that inappropriate publicity could have a serious effect upon Wellcome's business. The information contained within this document or subsequently made available to prospective Suppliers is deemed confidential and must not be disclosed without the prior written consent of Wellcome unless required by law.

## 9. Prospective Suppliers Personnel - IR35 and Off Payroll Working Rules

Before the RFP response deadline, Prospective Suppliers must make the Wellcome Contact aware if they are intending to submit a proposal where the services will be provided by any individuals who are engaged by the Prospective Supplier via an intermediary i.e.

- Where the Prospective Supplier is an individual contracting through their own personal services company; or
- The Prospective Supplier is providing individuals engaged through intermediaries, for the purposes of the IR35 off-payroll working rules.

#### **10. Independent Proposal**

By submission of a proposal, prospective Suppliers warrant that the prices in the proposal have been arrived at independently, without consultation, communication, agreement or understanding for the purpose of restricting competition, as to any matter relating to such prices, with any other potential supplier or with any competitor.

#### 11. Funding

For the avoidance of doubt, the output of this RFP exercise will be funded as a Contract and not as a Grant.

#### 12. Costs Incurred by Prospective Suppliers

It should be noted that this document relates to a Request for Proposal only and not a firm commitment from Wellcome to enter into a contractual agreement. In addition, Wellcome will not be held responsible for any costs associated with the production of a response to this Request for Proposal.

#### 13. Sustainability

Wellcome is committed to procuring sustainable, ethical and responsibly sourced materials, goods and services. This means Wellcome seeks to purchase goods and services that minimise negative and enhance positive impacts on the environment and society locally, regionally and globally. To ensure Wellcome's business is conducted ethically and sustainably, we expect our Suppliers, and their supply chains, to adhere to these principles in a responsible manner.

#### 14. Accessibility

Wellcome is committed to ensuring that our RFP exercises are accessible to everyone. If you have a disability or a chronic health condition, we can offer adjustments to the response format e.g. submitting your response in an alternate format. For support during the RFP exercise, contact the Wellcome Contact.

If, within the proposed outputs of this RFP exercise, specific adjustments are required by you or your team which incur additional cost then outline them clearly within your commercial response. Wellcome is committed to evaluating all proposals fairly and will ensure any proposed adjustment costs sit outside the commercial evaluation.

## 15. Diversity & Inclusion

Embracing diversity and inclusion is fundamental to delivering our mission to improve health, and we are committed to cultivating a fair and healthy environment for the people who work here and those we work with. As we learn more about barriers that disadvantage certain groups from progressing in our workplace, we will remove them.

Wellcome takes diversity and inclusion seriously, and we want to partner with Suppliers who share our commitment. We may ask you questions related to D&I as part of our RFP processes.

## 16. Working During Covid-19

Given the current working situation and impact of the current lockdown and possibility of future lockdowns we require all Suppliers to think hard about how they will work with Wellcome during this time. Suppliers must cost and build in contingency for potential delays due to Covid-19 and ensure that they are set up to work remotely with Wellcome on this contract. Further questions relating to Covid-19 should be addressed to Wellcome as part of the RFP questions.

## 17. Governance

Successful Suppliers will report to Suzi Gage, Research Lead for Metrics at Wellcome Mental Health on a day-to-day basis.

Successful Suppliers will be required to meet virtually (via conference calls) as part of our initiative to develop an international mental health science community, in order to share progress and learning. All meetings will be conducted in English.

Wellcome will need to own the intellectual property created in this commission and may wish to make the final outputs public itself (in whole or in part), either on its website or other media, and in doing so may apply a Creative Commons (CC-BY) licence to the outputs.

Subject to Wellcome using the deliverables for its own purposes first, we are keen that the final outputs reach as wide an audience as possible. For more details on intellectual property, Suppliers submitting proposals as a registered company should see the <u>contract</u> terms under section 9; Individuals submitting proposals as a sole trader should see <u>contract</u> terms under section 8).

Provided the final outputs are of publishable standard, Wellcome will encourage and work with Suppliers to publish the final outputs in suitable peer reviewed academic journals. Any such publication should be in line with Wellcome's <u>statement</u> on Open Access.

## **18. Wellcome Contact Details**

The single point of contact within this RFP exercise for all communications is as indicated below; Name: Olivia Donovan Role: Procurement Officer Email: RFP@wellcome.org For discussion 19th Oct

## **APPENDIX 1:**

## **Potential Evaluation Criteria**

Criteria	Achieved	Not Achieved
The deliverables have been developed with sufficient rigour and consultation as to ensure they will be adopted by the wider community.	The supplier is able to demonstrate that is sufficient stakeholder support for this approach, meaning the Wellcome can be confident they will be accepted by the wider field.	The supplier is unable to demonstrate that is sufficient stakeholder support for this approach, meaning the Wellcome can be confident they will be accepted by the wider field.
The deliverables foreground the perspectives of people with lived experience of depression, anxiety and psychosis from a diverse range of social and cultural backgrounds and geographic regions.	The supplier is able to evidence how the development of the programme and deliverables is done in collaboration with people with lived experience of depression, anxiety, and psychosis from a diverse range of social and cultural backgrounds and geographic regions. This collaboration must not be tokenistic, but should strive to actively establish meaningful connections and collaboration between psychometric experts and those with lived experience.	There is not sufficient evidence to show how people with lived experience of depression, anxiety and psychosis have been embedded in the programme in a sufficiently substantive way which has influenced the design and delivery of the programme.
The deliverables have been developed in such a way as to ensure they will be effective across both high- income and low-income contexts.	The supplier is able to evidence that the outputs have been developed in such a way as to foreground the context, needs and perspectives of research communities from LMICs, resulting in recommendations and toolkits that are applicable across both high-income and low-income contexts.	Outputs have not been developed in such a way as to ensure they are of equal applicability for researchers in high-income and low- income contexts.
The deliverables are suitable for use by researchers, funders and journals in supporting how	The toolkits are shown to be suitable for use by funders, researchers and journals in	The toolkits are not usable by all three of the stated user groups.

to implement the selected	their various different	
measures in their work.	capacities.	

#### Appendix 2: Blog post about the common metrics from Miranda Wolpert (06/07/2020)

Funders agree first common metrics for mental health science (linkedin.com)

I am not expecting this to be un-contentious, but it is much needed.

#### The problem

Without some common metrics there is no way for mental health scientists to know if they are investigating the same or different things.

Currently researchers across and within different groups (e.g. psychiatry, psychology, neuroscience, social science) measure mental health and mental health outcomes using very different measures. This makes it very difficult to compare across studies and hinders progress in determining how mental health interventions help or harm, in what contexts and why.

We urgently need a common set of measures to promote shared understanding in mental health science. But agreeing what those measures should be is no easy task.

Having spent much of my working life considering how to measure outcomes for children and young people with mental health problems, I can confidently say there are no perfect measures and that wider issues of transparency and appropriate use of measurement remain key challenges of mental health science.

An overview of some of the challenges is provided in the excellent 2019 paper by Jessica Flake and Eiko Fried "<u>Measurement Schmeasurement</u>". For example there at least 280 scales for measuring depression alone.

It is perhaps because these challenges seem insurmountable that we have "urgently" needed a common set of agreed measures across mental health science for some decades now!

#### Steps towards agreement amongst funders

Wellcome is part of an <u>International Alliance of Mental Health Funders</u>. The group recognised the need to find ways forward in terms of agreeing some common metrics and in 2019 convened a group to review key demographic variables.

Even agreeing demographic metrics - such as how to measure age or gender or ethnicity - is surprisingly hard to do. The group has spent the last year agreeing a proposed set of variables that is currently out to consultation across funders. The consultation closes in October 2020.

Alongside this initiative, and in the light of the known difficulties of agreeing core measures, two large funders of mental health science, <u>National Institute of Mental Health</u> (<u>NIMH</u>) and <u>Wellcome</u>, collaborated to explore the potential to agree a small number of core

metrics relevant to young people with anxiety and depression (since this is Wellcome's current <u>Mental Health Strategy</u> focus). This was intended as a starting point for wider take up, refinement and metric consensus.

Starting from the working assumption that there is no perfect or even "best" measure, we sought measures that were likely to be widely acceptable, relatively non burdensome and free to use, as well as shown to have acceptable measurement properties across a range of settings. We drew on best evidence from large scale international consultations such as those undertaken by the <u>International Consortium for Health Outcomes Measurement</u>.

On this basis, we agreed a small number of metrics to be highly recommended with immediate effect and to be mandated in the future. The agreed way forward can be found <u>here</u>.

#### **Recommended Self-Report Measures for Youth Anxiety and Depression**

Wellcome is recommending use of one or more of the following self-report measures be included in any study that considers youth anxiety or depression:

- 1. Patient Health Questionnaire (PHQ) (adult depression)
- 2. General Anxiety Disorder questionnaire (GAD) (adult anxiety)
- 3. Revised Child Anxiety and Depression Scale (RCADS) (child anxiety and depression)
- 4. World Health Organisation Disability Assessment Schedule (WHODAS) (adult impact on functioning)

NB. No suitable functioning child measure was found which is why none is on the list.

The table below shows what this means in terms of the questions asked a version of each measure (PHQ9, GAD7, RCADS25 and WHODAS12). Please see the references below for more details of the measures themselves, including shorter and longer versions.

Over last 2 weeks:		In general :	Difficulties due to MH problems over the last 30 days :
Not at all, Several days, More than half the days, Nearly every day		Feel this way "Never sometimes often or always"	None Mild Moderate Severe Extreme or cannot do
DEPRESSION (PHQ9)  1. Little interest or pleasure in doing things 2. Feeling down, depressed or hopeless 3. Trouble falling/staying asleep, sleeping too much 4. Feeling tired or having little energy 5. Poor appetite or overeating 6. Feeling tired or having little energy 7. Trouble concentrating on that you are a failure or have let yourself or your family down 7. Trouble concentrating on things, such as reading the newspaper or watching television 8. Moving or speaking so slowly that other people could have noticed. Or the opposite: being so fidgety or restless that you have been moving around a lot more than usual. 9. Thoughts that you would be better off dead or hurting yourself in some way	ANXIETY (GAD7)  1. Feeling nervous, anxious or on edge 2. Not being able to stop or control worrying 3. Worrying too much about different things 4. Trouble relaxing 5. Being so restless that it is hard to sit still 6. Becoming easily annoyed or irritable 7. Feeling afraid as if something awful might happen If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	CHILD ANXIETY & DEPRESSION (RCADS 25)  1. I feel sad or empty 2. I worry when I think I have done poorly at something 3. I would feel afraid of being on my own at home 4. Nothing is much fun anymore 5. I worry that something awful will happen to someone in my family 6. I am afraid of being in a crowded places (like shopping centres, the movies, buses, busy playgrounds) 7. I worry what other people think of me 8. I have trouble sleeping 9. I feel scared if I have to sleep on my own 10. I have problems with my appetite 11. I suddenly become dizzylfaint when there is no reason for th 12. I have to do some things over and over again (like washing my hands, cleaning or putting things in a certain order) 13. I have no energy for thinks 14. I suddenly start to tremble or shake when there is no reason for this 15. I cannot think clearly 16. I feel worthless 17. I have to think of special numbers or thoughts to stop bad things happening 18. I think about death 19. I feel ifike 1 don't want to move 20. I wory that I will sometimes get a scared feeling when there is nothing to be afraid of 21. I am tired a lot 22. I feel afraid that I will make a fool of myself in front of people 23. I have to do some things in just the right way to stop bad things from happening 24. I certestiess 25. I worry that something bad will happen to me	<ul> <li>IMPACT ON FUNCTIONING (WHODAS:2-12 item)</li> <li>1 Standing for long periods such as 30 minutes?</li> <li>2 Taking care of your household responsibilities?</li> <li>3 Learning a new task, for example, learning how to get to a new place?</li> <li>4. Problem joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?</li> <li>5. Emotionally affected by your health problems?</li> <li>6. Concentrating on doing something for ten minutes?</li> <li>7. Walking a long distance such as a kilometre [or equivalent]?</li> <li>8. Washing your whole body?</li> <li>9 Getting dressed?</li> <li>10 Dealing with people you do not know?</li> <li>11 Maintaining a friendship?</li> <li>12 Your day-to-day work?</li> </ul> Overall, in the past 30 days, <ul> <li>how many days were these difficulties present?</li> <li>for how many days did you cut back or reduce your usual activities or work</li> <li>not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?</li></ul>

We anticipate that some researchers may be concerned their preferred measure or question is not listed and unsure what this means for their current research projects. We want to stress:

1. We are not requiring researchers to use **only** these measures. We encourage researchers to use whatever additional measures and metrics they see as relevant.

2. The recommendation is for new research only. There is no need to amend existing research funded by Wellcome.

3. Longer or shorter versions of each measure may be considered.

4. Not all measures will need to be used in all studies. For example, **either** the child **or** the adult measure should be used.

5. The final decision as to exactly which of set of questions is relevant for a given proposal can be agreed at the point of funding.

6. Information must be captured at the level of the individual question response to allow comparison between studies at this level of detail.

7. This list will be reviewed and amended over time with input from both measurement experts and those with lived experience of mental health problems (see next steps below).

#### Next steps

Wellcome and NIMH will become the founding members of a Common Measures Board with input and support from the International Alliance of Mental Health Research Funders. The Common Measures Board will meet for the first time in October 2020. It will consider both the metrics above and others.

Funders who are members of the International Alliance <u>and</u> commit to requiring their research community to use at least some of the measures are invited to apply to join <u>the</u> <u>Board</u>.

The Common Measures Board will appoint an advisory group of experts, including those with lived experience of mental health problems, who will review and advise on current measures and suggest new measures and metrics going forward. This may include cross-cultural considerations and development of new measures.

The first substantive refresh of the initial core metrics is proposed for October 2022.

#### References

- <u>Patient Health Questionnaire (PHQ)</u> (can be used 12years +)
- <u>General Anxiety Disorder (GAD) questionnaire</u> (can be used 12 years +)
- <u>Revised Children's Anxiety and Depression Scale (RCADS)</u> (suitable for 8-18 years)
- WHO Disability Assessment Schedule (WHODAS) (suitable for 18 years +)