Orygen
The National Centre of Excellence in Youth Mental Health

Submission

# Draft National Clinical Quality Registry Strategy Consultation

20 June 2019

Orygen, The National Centre of Excellence in Youth Mental Health (Orygen) welcomes the opportunity to provide a submission to the Federal Department of Health on the Draft National Clinical Quality Registry Strategy. Clinical Quality Registries (CQRs) have the potential to improve patient care and support the delivery of health-related outcomes. While Orygen supports this initiative it is aware of the ambitious scale of the Strategy.

## About Orygen

Orygen is the world's leading research and knowledge translation organisation focusing on mental ill-health in young people. At Orygen, our leadership and staff work to deliver cutting-edge research, policy development, innovative clinical services, and evidence-based training and education to ensure that there is continuous improvement in the treatments and care provided to young people experiencing mental ill-health.

## Introduction

This submission considers the four strategic objectives of the Draft National Clinical Quality Registry Strategy, addressing the issues identified in the draft Strategy document and the outlined actions to address them. Orygen's submission considers the approach to and importance of monitoring the quality of health care, with a particular emphasis on youth mental health.

The integrity of CQRs is patient/client involvement in data collection and analysis. Successful implementation will be enabled by a comprehensive approach to data and resourcing for implementation and operation. Key factors to be considered in finalising the strategic document are:

Data

- should be underpinned by a minimum dataset
- retrieval and data linkage through automated processes is an aspirational concept
- is accurate, reliable, secure and de-identified
- is re-identifiable through a strictly controlled mechanism to enable data linkage through a registry-external system

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An initiative of The Colonial Foundation, The University of Melbourne and Melbourne Health

- an opt-in/out decision needs to be determined for data linkage.

Operation

- patients/clients involvement
- interactive data entry and reporting
- a compliance framework
- sufficient, skilled human resourcing to enable operationalisation
- time resourcing for data entry and utilisation.

## National CQRs are based on clinician/patient partnerships

### Issues

Orygen endorses the concept of interactive CQRs, but would caution that the interactive CQR be underpinned by a minimum dataset that is augmented by, but nonetheless largely independent of, ongoing interactive engagement (risk mitigation).

Consumer advocacy is an integral part of all Orygen operations across all functions. Orygen agrees that patients/clients are truly empowered when they are able to have a say in both their care, outcomes and experiences. Orygen recognises that young people are not only interested, but eager to be involved in their own health care. Young people are present on Orygen's major research and operational committees and are essential to the organisation's overall corporate and educational strategies.

By providing patients with an individual log-in to access their CQR data, they will be able to become more involved in the decision-making process, in partnership with their treating clinical team (clinicians, psychiatrists, psychologists and Case Managers). It may also be beneficial to allow nominated parties outside the direct clinical team (e.g. parent, carer, GP) to enter appropriate data (contingent on appropriate consents, security, etc.) as this capability would be of benefit to several cohorts, including young people.

Interactive data entry, reporting at consultations and following their health journey in collaboration with information from registries with provide enhanced care and patient centricity.

Interactive systems may also provide the following opportunities to enhance engagement if young people and clinicians are:

- engaged in the design of the CQR interface, it will be more "user-friendly"
- able to access and analyse the data they have inputted (e.g. run reports) they are more motivated to contribute good quality data.

Motivation for clinicians in especially relevant for systems with parallel data entry in the CQR and electronic medical records (EMR), and the CQR provides functionality that the EMR does not.

### Actions

Effective partnership, outcomes, data entry and longitudinal data collection and reporting will be critical to the success of Strategic Objective 1.

Young people experiencing mental ill-health could benefit from knowing where they stand compared with other in terms of their recovery journey. Similarly, carers, parents, and/or guardians might welcome increased transparency in care plans by being able to visually interpret (through a dashboard) progress and recovery and seeing how this compares to other patients in similar

situations. Clinical care-givers in other clinical services would also benefit from this process, as many of Orygen's patient cohorts present at multiple services across the period of their mental ill-health. It will be critical for clinicians to engage in this process of transparency, which needs to be supported operationally, through audited accreditation and standards development. To enable clinicians to engage with CQRs and unlock the potential benefit, the Department of Health needs to consider how clinician time resourcing will be provided (i.e. Medicare). This will require a rethink of governance arrangements to effectively support this Action Plan.

Key Performance Indicators against a Framework Standard need to be realistic and supported through the provision of resources. It is easy to overestimate how realistic it is to expect data entry by busy clinicians. As result, resources must be provided to help with ensuring data is entered and data entry is monitored. In addition, such an initiative will need to take into account the different operational considerations of primary versus tertiary health services and the funding source for clinical and operational resources. The provision of resourcing of operational personnel will enable clinicians to focus on nurturing partnerships with patients.

Reporting of Patient Reported Outcomes/Experience Measures (PROMs and PREMs) is in principle, supported by Orygen.

On a "nuts and bolts level" it must also be acknowledged that automatic data retrieval from existing EMR for direct import/linkage to a CQR is an aspirational rather than standard concept. This means that:

a) CQRs should be designed so that, where feasible, automatic data linkage/input is possible

b) In the currently majority of cases where this is not feasible, resources should be provided to either facilitate automatic data linkage/input or assist with data entry into the CQR, and corresponding quality assurance activities.

## National CQRs are Quality Assured, Efficient and Effective

### Issues

Accurate, reliable and secure data is absolutely paramount to the success of National CQRs. Data entry will need efficient validated systems compliant with industry sector electronic systems (FDA CFR 21 Part 11 – US based regulatory compliance, which is the current global standard for e-systems in this sector). Furthermore, privacy aligned with the European General Data Protection Directive will be required. **Confidence in security of databases is a much broader issue than compliance with legislation.** Orygen suggests that data security would begin with extensive, meaningful and early involvement of consumers in design and consultation processes. Key lessons learned should be taken and used from the My Health Record development and implementation. The success of CQRs requires consumer and organisational confidence to opt-in to a database, and to allow for functionalities, such as: the ability to filter for EU/CH citizens, right to be informed, right to object, right to access, right to rectification, right to data portability, right to restrict processing, rights in relation to data profiling, right to be forgotten, which can all be expected to be requested by patients.

Critical to any National Database will be de-identified data where any potential re-identifiability through data linkage (i.e. collaboration with other CQRs) is strictly controlled. National CQR identifiers will be required, not just where the only form of identification possible is that between the clinician and the patient. When designing a CQR, it would ideally have functionality that embeds certain identifying information in the registry, but is systematically 'invisible' to any user or caretaker of the registry for the purposes of data linkage. The benefit of data linkage may arguably outweigh the risk associated with housing 'invisible' identifiers, especially if the CQR security systems maintain

privacy and this is clearly outlined in all consent material, including both opt-out and opt-in options. There are strategies developed and delivered through the research endeavour that can be put in place and are currently successfully operationalised through the Framework Standard to effectively manage this issue and not cause delay. There is precedent for such identifying information to be kept in CQRs using 'opt-out' approaches to consent, but CQRs may need support in choosing appropriate security systems and also in arguing the case with approving bodies.

**Issue 1**

Orygen agrees there are challenges, but they are not insurmountable. They require human resources with registry expertise and industry sector know-how. The CQR initiative would gain much value from industry operational professionals, rather than clinicians, whose expertise can be drawn upon to support successful implementation.

**Issue 2**

The development of a National Standard would assist with a requirement to show evidence of collaboration with other CQRs, as part of operational set-up and commissioning. There are many sources of data to measure the impact of registries, for example via: consumer advocacy, systems and processes at health services, approved knowledge transfer, government relations, training and education of clinicians and patient groups, longitudinal reporting and research collaborations.

There is significant value in the transfer of registry data from the youth mental health system to the adult system, which is currently distinctly separate. By augmenting this process, the continuum of care can be enhanced to ensure that patient groups are supported as they are discharged into adult care.

Currently the Australian Clinical Trials Alliance (ACTA) is a strong advocate for Clinical Trial Networks (CTN) and CQRs, and is already an invaluable resource to fledgling and established CQRs. Orygen is grateful for the assistance of ACTA and supports ACTA's ongoing involvement in the national and international arena.

Orygen suggests the Department consider the establishment of a Network and/or Registry-specific journal, which would be a great resource to showcase impact and implementation of network and registry activities. There are a myriad of researchers and clinicians of national and international renown who are involved in Australian CTNs and CQRs; the scientific credentials of contributors and editorial team of such a journal would be considerable. Furthermore, ACTA is well positioned to develop and implement this initiative, with the necessary resourcing support from the Government.

**Issue 3**

Human Research Ethics Committees (HRECs) are now becoming increasingly aware of the utility for clinical care of both research (in terms of translation) and ongoing treatment plans. However, a national approach to CQRs would require the HREC sector to allow for mutual recognition of CQRs, both ethically and across governance structures. The Government should mandate this in line with the principles and intent of the National Health and Medical Research Council (NHMRC) National Statement. There is no reason why CQRs cannot be similarly approached to help streamline ethics approval. A mandated national approach to operationalise CQRs in individual States and Territories, similar to Directives in the EU with Member States, could be used.

In addition, consideration should be given to the development of an operationally optimised HREC for CQRs nationally. This would help to remove the requirement for individual, institutionally-based ethics approval. Governance of this process could be approached through the development of national legislation and the National Standard for accreditation.

The current environment is not conducive to opt-in approaches, which is reflected in the switch to an opt-out approach for the My Health Record digital health records system. There is mistrust of sensitive health information being held in large databases, which are potentially vulnerable to being hacked. It is proposed that a unique identifier is attributed to each patient, with no potential for re-identification at the CQR level. An 'invisible identifier' could be developed via a registry/external system with identifying information that could be used to facilitate data linkages. Ideally, this registry/external system with identifying information would be a stand-alone national resource that can be used by multiple registries. This would be an efficient and streamlined way to improve the security of registry data and improve trust in systems, enabling consent and ethics/governance approvals.

## Actions

**Action 1**

Orygen agrees that the development, through extensive expert consultation, of a compliance framework with a National Standard is justified.

Orygen agrees accreditation, re-accreditation (e.g. 3 to 5 year cycles) and *ad hoc* For Cause audits would assure confidence for CQR systems, integration and linkages. There needs to be formal recognition by an independent body of CQR operational competence against the standard.

The implementation of this standard should include the provision of resources for Vendor assurance and audits to ensure compliance. Demonstrating the CQR is audited for compliance would also assist in ongoing consumer engagement by emphasising that their health information is protected.

**Action 2**

Orygen agrees a communication and collaboration plan is fundamental in the development of the CQR. In addition to this, Orygen suggests there is:

- an Annual CQR summit to foster collaboration, operational continuous improvement and knowledge transfer, including with the attendance of international speakers and delegates to foster global collaboration
- assistance with streamlining and implementing CQR impact across the sector and with clinicians and consumers
- linkages to the clinical research sector with virtual or direct operational links to CTNs within Australia.

A Network and/or Registry-specific journal would be a helpful resource to showcase impact and implementation of network and registry activities. This would be particularly useful as a 'one stop shop' resource to publish all results, updates and initiatives of the CTN and/or Registry community (individually and as a sector). Communications should highlight both the clinical quality and research value of registries and networks.

The work should also be informed by ACTA's (http://www.clinicaltrialsalliance.org.au/) involvement with investigator-initiated research and Clinical Registry liaisons across the sector. ACTA is a national peak body supporting and representing both the networks and registries of clinician researchers that conduct investigator-initiated or "public-good" clinical trials within the Australian health system.

Orygen acknowledges and respects the work done by the Adelaide Registry Consortium and Monash University Registry Science and Research, but believes it is important to continue to seek new and innovative systems and solutions. For example, to further build on the experience and advice of such groups and pursue aspirational and innovative solutions on both a national and international level.

**Action 3**

Orygen agrees systems, such as the New Zealand ethics approval system, as well as committees, such as Medsafe SCOTT Committee (http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott ) should be consulted with to garner operational learnings for the success of the CQR Strategy. Key learnings from the My Health Record implementation should also be considered to avoid the risk or repeating any development and implementation errors.

Streamlined processes should be mandatory, user-friendly and rational. In order for the CQR to be streamlined operationally, a suite of Standard Operating Procedures and written agreements that are compliant with the current regulatory environment should be introduced. Consultation with Medicines Australia is also recommended for their experience with reaching consensus on legal agreements.

As outlined above, provision of a for-purpose HREC specialising in registry establishment, maintenance and use (for clinical quality and research) would be invaluable. This HREC may also streamline the submission and approvals of research projects seeking to utilise the resources within the CQR and other registries. Similarly, data initiatives might include a suite of templates covering data sharing, data storage and privacy aspects to assist in establishment and governance activities, as well as collaboration activities. Additionally, generic and specialist consumer resources may be developed and shared to assist engaging/informing registry users.

## The potential value of national CQR data is maximised

### Issues

The utility of data for the CQR minimum data will need to be evaluated and focused. In vulnerable patient groups, such as those with mental illness, every data point collected should be justified through knowledge of what the data is, what it means, why it is collected and how will it be used for a broader purpose beyond clinical care.

Data linkage is paramount to its broader utility. As noted in Section 10 of the draft Strategy, there are many forms of CQRs. Mental health has known datasets that would require integration and interoperability at a more granular level. The Strategy will need to differentiate its approach to interoperability across national, State and Territory and individual operational datasets, such as headspace Application Platform Interface. CQRs should be encouraged to leverage existing resources available in minimum data sets (e.g. METeOR MDS, Medicare data, PBS data, Client Management Interface/Operational Data Store and jurisdictional equivalents), as well as public hospital EMR where possible.

Standardisation across all CQRs will take time and investment. While it will not be feasible to apply retrospectively to existing CQRs, this aspirational goal should be borne in mind when designing new CQRs (e.g. a part of Framework guidance would be to consider existing systems during establishment phase).

**Issue 1**

Orygen believes secondary use of CQR data, including research is incredibly useful for a variety of impact routes, such as policy development, stakeholder liaison and informing treatment groups across cohorts.

Orygen agrees research is integral to utility of CQR data and that this can assist with elucidation of Quality Assurance and Low and Negligible Risk projects. In addition, standard research projects would benefit from CQR data being utilised to embed a more holistic approach to research findings and to better inform clinical practice. CQR data linkage is crucial to providing longitudinal and holistic

information, particularly in disease areas such as mental health, which are often chronic and long-term conditions with complex comorbidities.

Clinician involvement in practice is suitable for individual registries through the appropriate governance procedures, such as appropriately constituted steering committees with approved Terms of Reference and agreed legal and publication protections. Consideration must be given to how a governance leadership group will be compiled and which representative will be on committees.

With respect to privacy, data breaches and compliance where applicable to the General Data Protection Regulation (GDPR) Directive, any CQR system would need to assure compliance with regulatory obligations, which is especially critical for young people experiencing mental ill-health.

Again, Orygen suggests creating a "national resource", registry/external system that can securely and independently house identifying information and registry-specific identifiers. This could then be linked to other registries to facilitate data sharing.

**Issue 2**

Orygen agrees that CQR systems and health information systems should be as interoperable and interactive as possible. However, the actual data in the minimum dataset needs to be carefully considered to alleviate the vulnerabilities associated with mental ill-health and its impact.

Integration of one system into another is going to be dependent on data dictionaries and the nature/method of recording information. A particular registry may require more detailed, specific information that other health services on some matters, and vice versa.

Clinical coding of services in one system may make information from that system virtually useless for another, etc. so it is important that this mandated integration is treated with caution. An ideal medium may be that a CQR and health information system share a defined minimum dataset and that each may apply to access other, more specific data elements held within either the CQR of health information system.

A strong and robust consumer consultation approach via the treating clinical team member will be critical to this system being implemented in the mental health sector. Extensive consultation with the various therapeutic areas will also be required as part of the Strategy.

## Actions

**Action 1**

Orygen acknowledges key stakeholders include private practitioners, primary and tertiary clinical service providers, young people, their carers and family. The importance of maximising the utility of CQR data must be effectively communicated to this varied stakeholder group will be essential to the successful implementation of the CQR Strategy. Consumer engagement will be paramount in this process, as health service consumer input will enable the successful long-term implementation of the Strategy. Sound communication with young people about why data is collected and how it will be utilised underpins the success of data collection in the mental health sector.

Legislation, development of a standard and mandatory accreditation, possibly linked to funding models, as well as good operational starting points compliant with privacy, confidentiality and compliance with GDPR for EU data subjects are necessary.

A key element of data use and re-use is the data dictionaries. In-depth analysis and consideration must be involved in choosing and developing one (or several) harmonised data dictionaries. This process could perhaps involve the development of one (or several) data cleaning scripts/methods to facilitate incorporation of a particular dataset into another dataset using a harmonised data

dictionary. This process would require significant stakeholder consultation on which data sets/data dictionaries are most important at a jurisdictional, national and international level.

A review of these systems needs to be instigated with a gap analysis performed to ensure any failings in the CQR system are noted, risks identified and mitigated as part of the 10-year plan.

**Action 2**

The majority of young people are active on different forms of social media. To a large extent, the majority of Orygen's successes in data gathering has been for those projects where a smartphone, tablet or personal computer has be used for reporting of patient outcomes, experiences of care and informing plans, as well as ensuring medication or psychotherapies are taken or logged into respectively.

Any CQR platform will require interoperability with Apple and Android devices and platforms, to ensure uptake in the youth mental health space.

Orygen notes that this undertaking must be iterative and continually evolving. It will need to be responsive to changing technology and consumer priorities and will require ongoing resourcing.

## Sustainable Funding for National, Prioritised CQRs

### Issues

Following an extensive period of consultation in the youth mental health sector, Orygen has found that the success of CQR projects relies not only on funding, but on the successful onboarding of human resources with the skill sets required to operationalise a registry. Sufficient resourcing is required to ensure an adequate supporting workforce is available. Workforce positions and skills include:

- Executive Officer
- Biostatistician/Research personnel
- Bioinformatician/database maintenance personnel/Information Technology
- Quality Assurance and Quality Control experts with expertise in software validation
- Experts in Regulatory Affairs and Clinical Operations.

Maintenance activities come under the banner of infrastructure. A sustainable model would involve a combination of service provision to the broader stakeholder group (e.g. pharmaceutical, biotechnology sector and academic costs of research through NHMRC or National Institutes of Health (NIH) in the United States Category 1 funding) as well as in-kind.

Furthermore, clinician (or other professional) entry into a CQR would be required to be costed into routine consultations (e.g. with a Medicare item code for CQR time). This would further incentivise the clinicians to enter the data, so that consultation times are adequately adjusted.

Orygen agrees and supports the strategic prioritisation of mental health as a critical clinical domain with a great disease burden, and would welcome the opportunity to be involved further in due course.

A strategy must still be put in place for non-government funding support through service provision to supplement existing funds for reinvestment into the CQR. Researchers should be encouraged to include CQR data in research protocols, for example CQR data may provide evidence around outcomes for a "treatment as usual" cohort. Researcher access to CQR data could be remunerated on a not-for-profit basis so that the remuneration goes back into developing, maintaining and/or

administration of the CQR. Given the potential depth and nuanced nature of CQR data, this would be an attractive resource for researchers (commercial and non-commercial). CQRs should be given appropriate guidance on how to realise this funding potential.

One important funding consideration is the investment in infrastructure and harmonisation, which is crucial to producing a national environment conducive to CQRs that maximises data use and re-use. This funding should, for example centre around key items such as:

- National support and advocacy bodies such as ACTA
- Shared platforms either supporting/hosting or enabling registries (e.g. the data linkage facilitation system, centralised systems etc.)
- Shared resources for example data dictionaries or data cleaning scripts, harmonised documentation and templates, Agreements etc.
- Registry "body of knowledge" material to support stakeholders, registry science resources etc.

### Actions

The Strategy should include a Medicare and/or private health insurance CQR item code to ensure data entry by clinicians and the treating team as per the minimum dataset each time a patient is seen, or as required. This code should be independent of the type of visit (on site, remote, telehealth etc.) and the type of clinical service (primary, tertiary, private), however, an audit trail of the consultation should be maintained and built into the operational systems of the CQR. This would be able to be validated and is auditable based on reports generated from the Department of Health and individual CQRs.

Provision of funding linked to maturity of the CQR is, in principle a good idea, however, funding must be clearly linked to CQR requirements. The current NHMRC funding model does not work; once funds are awarded, unlike the National Health (England) Service or NIH models, there is no accountability for how funds are spent. The National CQR Strategy needs to incorporate accountability for expenditure with proof of deliverables or metrics achieved, in order to gain funding per individual items. This will ensure funds are expended for the benefit of the CQR and the patients it serves.

The efficient implementation of CQRs in youth mental health services has the potential for improved service experience and outcomes for young people experiencing mental ill-health.

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