10 Steps to establish a Clinical Quality Registry

1. **Articulate the purpose of the registry.**
   - Clear, concise, and agreed
   - You can have more than one purpose i.e.
     i. Monitor and report incidence
     ii. Monitor and report incidence and, detect and report variation in patient outcomes
     iii. Inform clinical practice and improve patient outcomes (clinical quality improvement).
2. **Determine if a registry is an appropriate means to achieve the purpose.**
   - Once the purpose has been determined, clearly articulated, and agreed, it is possible to determine if a registry is the appropriate mechanism to answer the question/deliver the required data and information or would other research methods such as a clinical trial or research project be more suited?
3. **Identify key stakeholders.**
   - It is critical to success to have engagement of key stakeholders from the early planning phases of a registry to ensure the registry meets their needs and they are committed to the project.
   - Stakeholders can include:
     i. Clinicians
     ii. Peak Body/Association
     iii. Relevant health services/jurisdictions
     iv. Industry
     v. Consumers/community
     vi. Government.
4. **Assess the feasibility and sustainability of a registry.**
   - This is a critical process before moving forward
   - The CQR Assessment tool may assist
   - A review of the cost drivers and potential funding required is also important.
5. **Build a registry team.**
   - The difference between a register and registry is the team and expertise built around it, this includes:
     i. Project management
     ii. Clinical oversight input
     iii. Stats and analytics
     iv. ICT
     v. Governance
     vi. Consumers/community members
   - The difference between a clinical registry and a clinical quality registry is that the CQR's purpose is clinical quality improvement through benchmarking, detecting variation and informing clinical practice to improve the quality and safety of health care.

Once a decision is made to proceed, the next considerations in planning are to:

6. Establish a governance and oversight plan.

- Recruit the expertise required into your governance group early in your process including an expert in registry development and operation, clinical expertise of the area of interest, stats and analytics, ethics, data management and ICT.

7. Define the scope and rigor needed and keep within these.

- Review your purpose and ensure your scope meets this to enable management of resources, workload and quality control and reliability.

8. Define the dataset, patient outcomes, and target population.

- Develop the minimum data set (MDS) needed to answer your research question
- Assess the burden of the collection and try to keep it to a minimum
- Be aware of the responsibility of collecting someone's data – if you collect it, you need to use it
- Do not collect data only because it would be interesting, and you might use it one day!
- Remember once you have your complete and accurate dataset you can always add projects that are time limited or for specific cohorts
- You can also add data fields at a later date, this should be limited, agreed by your governance group and be required to meet your purpose
- Seek additional expert advice (including stats and analytics advice) to ensure what you plan to collect is feasible and will answer your questions.

9. Develop a study plan or protocol.

- Document your planned protocol early this will assist with your ethics and governance applications and will help clarify processes such as consent before you begin.

10. Develop a project plan.

- Document your implementation process in a plan with timelines and resources allocated, this is critical to keeping on track and to enable your governance and advisory groups to assist if something is blocking progress or to guide you when new strategies might be required to move forward.
- A project plan means you are not doing it alone.

Next Steps

Maximise the value of the CQR you have created

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