The Global Health Network

How to plan and deliver quality assured data in a clinical research study

In collaboration with: REDe (Research Capacity Network), ZIKAction, ZIKAlliance, ZikaPLAN, Horizon 2020

THE GLOBAL HEALTH NETWORK

Enabling research by sharing knowledge

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A training webinar using the ZIKAlliance Pregnant Women Cohort Study as a working example

Background

Study Co-ordinators and Principal Investigators from ZIKAlliance sites in Brazil, Colombia, Mexico, Venezuela attended this webinar designed to talk about data quality of the 'set of values' being collected in the pregnancy cohort studies (using 'case report forms'), ensuring that the data is 'fit' for its intended use in assessing ZIKA infection in pregnant women.

Why do we need to assure data quality?

- Studies need to collect accurate data and follow the protocol so that the safety and right of the participants are protected.

- Also, many 1000s of future patients' care may be guided by the answer produced – and so it needs to be correct!

- Therefore, EVERYONE involved needs to understand why their role is key to generating this answer and what errors could occur that matter.

- A fundamental step is thinking about what mistakes could matter and what can be done to spot this and avoid them happening.

- Mistakes that matter are ones where the participant may be put in danger, or the data that would change an outcome is inaccurate, or one where the rights of the participant may be affected.

- Here we are going to look at the ZIKAlliance pregnancy cohort study and think about what mistakes could happen and how they can be avoided.

How do you spot the mistakes that would matter?

This study aims to establish the risk of Zika virus causing congenital abnormalities to a developing foetus and the components of these abnormalities.

Therefore, mistakes that matter would be inaccuracies in any data where the measurements taken answer these questions, or anything that risks the rights and safety of the mothers and their babies.

How can we spot when errors could occur and set up processes to mitigate?

The study walk through

This works really well!

Get everyone involved around a table 'walk through' what happens at every visit

● Who is doing what, where and how? ... It's great to explain the whole study to everyone

Patient screening and enrolment - first visit

● consent / history / samples

Follow up visits

● What if they don't attend? Window of flexibility? What data and what samples? Birth / or end of pregnancy? What new challenges?

Talk through the settings, operational reality and process.
This turns your protocol into Standard Operating Procedures (SOPs) as you spot where problems may arise

So you have your SOPs - now you need a Quality Management Plan!

Your Quality Management Plan (QM Plan) considers where mistakes might happen – makes sure they are spotted and sets a process for avoiding them

For this study ….

What is being recorded and measured to answer the questions?
- Patient information (history and medical details through their pregnancy)
- Blood, urine and possibly ultrasounds (mother)
- Placenta, cord, blood and urine (baby) with PM samples if possible (?)

Other add-on studies might have been approved locally and require stool, vaginal swabs and a later protocol will follow the babies.

Your quality management needs to consider what mistakes could happen…

Writing your QM Plan: So what steps present risk? What could happen?

Taking consent
- High level of refusers (or everyone says yes!)
- Is the information given and is this working? Do they understand what is being asked (right the way through?) and do they know they can say no at any time?

Recording history and later recording details in follow up
- What if they don't come back?
- What is written into their notes and how and when is this transcribed?

Sample taking
- What is different from routine care and do the patients understand? Are there risks?
- Sample labelling, tracking, transport, analysis, sample storing
- Reporting results into notes, database and informing their doctor and the patient?

WHAT ELSE - CAN YOU THINK OF ANYTHING?
The study walk through will tell you!

Your quality management needs to consider what mistakes could happen…

Writing your QM Plan: How can you spot and then mitigate these risks?

Taking consent
- Who is taking this? Are they trained? How will you check? How could you tell something is up?
- Community engagement before the study works really well! (visit MESH www.mesh.tghn.org for resources)
- Ongoing 'consent' is really important – how can you implement this and check it is happening and working?
- Consistency?

Recording history, medical information and follow up visits
- How are you contacting them? Can you find them? What is the window?
- How is information being captured? What is going into notes or ledgers (appointments?) - this is source data
- What is being transcribed and by who – and when? How is it being checked?

Sample taking
- Do the mothers understand what is being taken for routine care and what is for research?
- What are the processes to assure labelling, tracking and storage is robust? How will you check?
- What quality management is in place in the lab and what can you check? Training, SOPs, calibration, validation, temperature logs, etc. How often and who is checking?
- How are results recorded? What is source data? How is it transcribed and how can you check?

Writing your QM Plan: GENERAL TOP TIPS!

- Who are your teams? Training is key and should be described in your plan. Write a 'role and responsibilities' log and add checking this within your QM Plan – who is supposed to be doing what and are they?

- Regular study team meetings – these are ideal for going over every aspect of QM and reviewing where mistakes are happening and identifying where and how they can be mitigated.

- QM checking (monitoring) – this does not have to be external but could be - or could be a mixture? Describe who and how often.

- What to check. Talk through this at the study walk through. Usually good to check everything at the start and then can be reduced if no problems occur. Keep thinking 'what mistakes matter' and that will guide you

  - 100% consent (How? Notes – talk to patients?)
  - Sample tracking – 50%, 20% think what is practical and will show up any glitches?
  - Information on the database to CRF to patient notes or other source data?
  - Recording history and medical information & follow up visits
  - Sample taking

What will you write in your Quality Management Plan?

- Recruitment *- How many consent forms will you check and what else might you do?*

- Loss to follow up – *How will you find out what happened and what % would be a problem?*

- Consent withdrawn at birth or end of pregnancy – *How will you check this?*

- Samples lost or damaged – *What forms will you check? How often and how many?*

- Highly varied data (information and results such as scans) – *Data management and data analysis plan are key here. What data will be entered into the database? What is the agreed format? Units, etc.*

- Staff capacity and variation leading to varied quality and adherence to protocol and SOPs – **Will you check training records? Talk to staff? What can you plan for here?**

- Communication between sponsors and sites – great distances – **Will your Quality Manager (or monitor?) check meeting minutes - or simply capture that they will happen?**

- Communication between study staff, hospital staff and laboratory teams – **This can be such a cause of problems? How can you plan for mitigating organisational or political issue?**

Who is going to be responsible for assuring quality?

- An in-house team member nominated as Quality Manager – that's fine!

- An external monitor (I'd still suggest an in-house QM person too!)

- Would reciprocal monitoring work?

- Are visits needed? Can database level checks work too? *

- What frequency?

*…. Some of this needs to go the Data Management Plan

What are the advantages of reciprocal monitoring?

- ✓ It is easy to set up and low cost
- ✓ It gives a new element to research staff careers and roles
- ✓ Best practice is shared and standards are raised (this is probably the best bit!)
- ✓ It can be implemented with a hospital, research centre or within a multi-centre regional study between the sites
- ✓ It brings sustainable and continuous process improvement

How to implement reciprocal monitoring?

- **Decide who** is going to join your scheme

- **Find** your monitors

- **Train them** as monitors

- **Set up** your scheme: each study taking part needs a

    (i) Monitoring plan, (ii) Schedule and (iii) Monitor

- ***REDe is here to help!!*** *REDe@theglobalhealthnetwork.org*

To summarise

- Assuring data quality is an essential element of conducting good research

- It does not need to be daunting, time consuming or expensive

- Focussing on the errors that matter is appropriate and works

- Training your staff as monitors is good for their career development and will raise your research standards

The REDe Quality Management Toolkit

Aims to provide the following:

1. An overview on quality management

2. A guide to assessing risk and identifying possible errors that matter

3. A guide for writing a QM Plan for their study

4. A tool set of templates, SOPs and forms to implement QM Plan

5. An introduction to reciprocal and in-house monitoring

You can find the toolkit at:
https://rede.tghn.org/resources/quality-monitoring/

e-Learning Modular Courses

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INTRODUCTION TO DATA MANAGEMENT FOR CLINICAL RESEARCH STUDIES

- We will be adding more courses and materials

- Visit the Training Centre at:
  https//globalhealthtrainingcentre.tghn.org

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