Acknowledgement of Country

Fearlessly Embrace the Research Adventure

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I have no conflict of interest to declare

Agenda

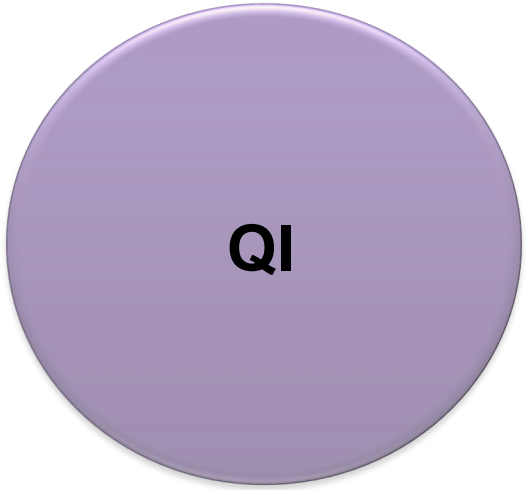
- Mentimeter intro
- QI and research
- Ethics vs Governance
  - Scenarios
- Good Clinical Practice
  - Quiz
- Existing data
  - Discussion
- Questions

ACTIVITY 1

ICEBREAKER


What’s the difference
between QI and Research?

Intention

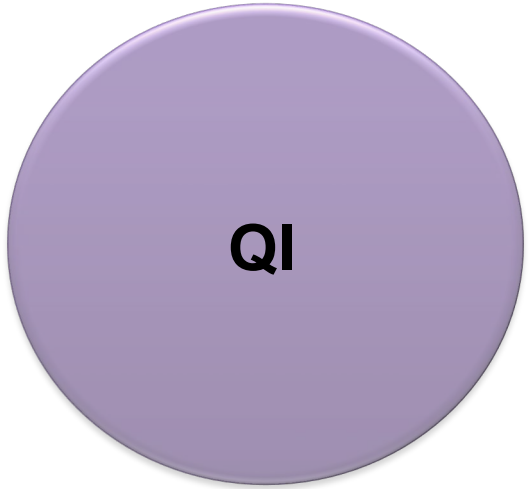


vs

Enhance processes and systems within organisations to achieve better results

Generate new knowledge, theories, or insights

Methodology

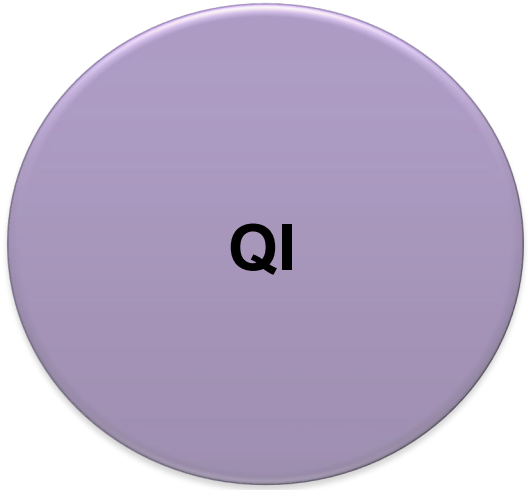


vs

Utilises systematic approaches like Plan-Do-Study-Act cycles

Follows rigorous scientific methodology

Goals

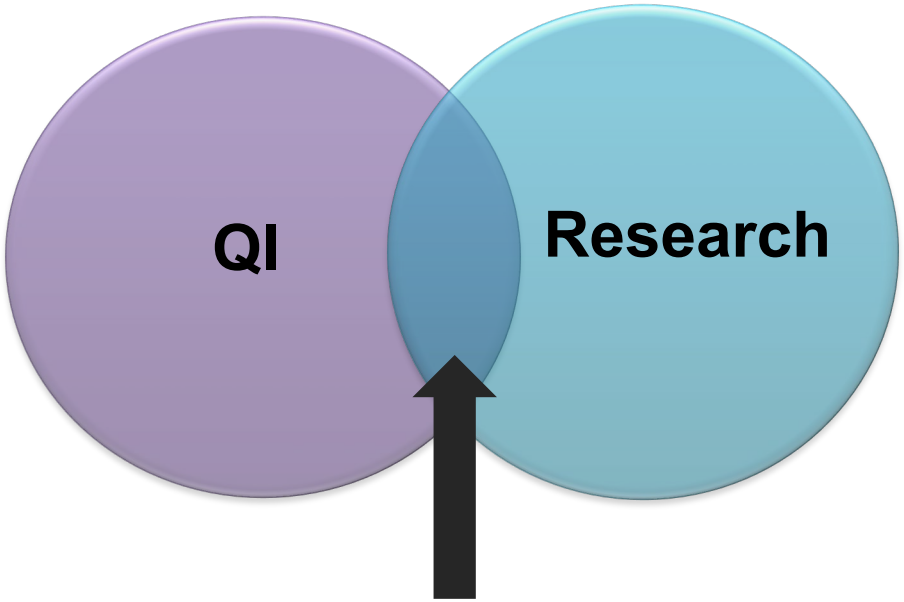


vs

Makes incremental improvements continuously

Contributes to the generalisable body of knowledge

Similarities



Data collection and analyses

Participant consent, privacy and confidentiality

May promote further work and/or publications


How do I know if my project needs ethics approval??

Ethics

Respect

Participant has the right to make their own decisions based on their beliefs and values.

Beneficence

Actions guided by compassion and for the good of the participant.

Non-maleficence

Do no harm

Research merit and integrity

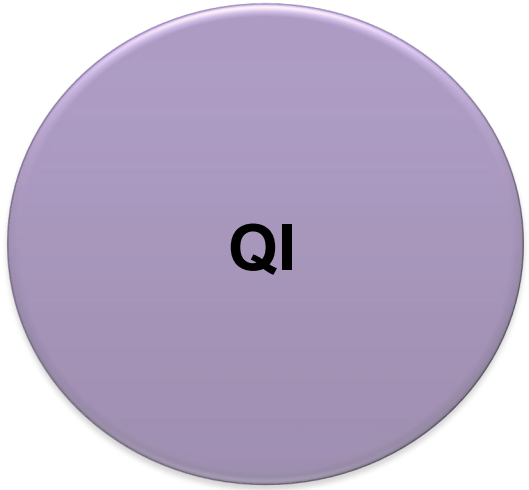
The research adheres to recognized standards of integrity and conducted in a manner that ensures quality and transparency.

Justice

Ensure that all participants are treated fairly.

Everyone you collect data from or about is a participant

Ethics



vs

Is consent required?

Privacy and confidentiality

Other implications?

All of it!

But different levels

Appendix A

THE CHECKLIST

Use of this Checklist is optional in NSW public hospitals. It is designed to assist in identifying when a proposed QI activity entails ethical 'risks'. For more detailed information related to each statement, please see *Considerations for reviewing QI activities*. This Checklist may be modified for use with local HRECs.

Section 1: ISSUES THAT MAY REQUIRE CONSENT	**TRUE/FALSE**
1. The project involves direct contact with patients, consumers, or members of the public.	☐
2. The project poses additional risks or burdens to the patient beyond their routine care.	☐
3. The data to be collected is of a sensitive nature or application.	☐
4. The purpose of the activity is not 'directly related' to the patient's disease, illness or its management.	☐
5. The data will be used or available in such a way that may identify individuals.	☐

*If the response to any of the above statements is "**true**", you should contact your nominated HREC delegate (or designated institutional body) to discuss. **Informed consent** is usually required. If approval is required, you will need to provide a project outline, including a description of how you intend to gain consent, as well a participant information statement.*

Section 2: PRIVACY and CONFIDENTIALITY	**TRUE/FALSE**
6. There is no process for de-identification of data.	☐
7. Access to personal information will extend beyond those who are members of the clinical care team, or to others who normally do not have access to the patient's record, or to other data sets.	☐
8. The project involves rare conditions or a small community.	☐
9. Data will be selected or identified by: • Aboriginal or Torres Strait Islander status; or • Ethnic, religious or minority group.	☐
10. Data will be collected beyond that which is normally collected in routine care.	☐

*If the response to any of the above statements is "**true**", you will need to provide more information and you **may need full Ethics Committee approval**. Please provide a brief explanation and a description of the consent process with your application, and contact your nominated HREC or QI delegate to discuss.*

Section 3: OTHER IMPLICATIONS	**TRUE/FALSE**
11. The project uses 'new' interventions, protocols or equipment.	☐
12. The project will involve allocation of patients to groups to enable comparisons.	☐
13. The project will involve genetic tests/testing.	☐
14. The project may potentially infringe the rights, privacy or professional reputation of carers, health professionals or institutions.	☐
15. The project involves use of placebo.	☐

*If the response to any of the above statements is "**true**", you will need to provide more information and it **is highly likely you will need full Ethics Committee approval** for your project. Contact your HREC representative.*

16. The project is likely to generate data that may lead to publication.	☐

If responses to all of the above statements in the checklist are 'false', then no ethical risks have been identified with this project and no ethics review is required.

ISSUES THAT MAY REQUIRE CONSENT

1. The project involves direct contact with patients, consumers, or members of the public.
2. The project poses additional risks or burdens to the patient beyond their routine care.
3. The data to be collected is of a sensitive nature or application.
4. The purpose of the activity is not ‘directly related’ to the patient’s disease, illness or its management.
5. The data will be used or available in such a way that may identify individuals.

If yes to ANY, ethics review is needed

PRIVACY AND CONFIDENTIALITY

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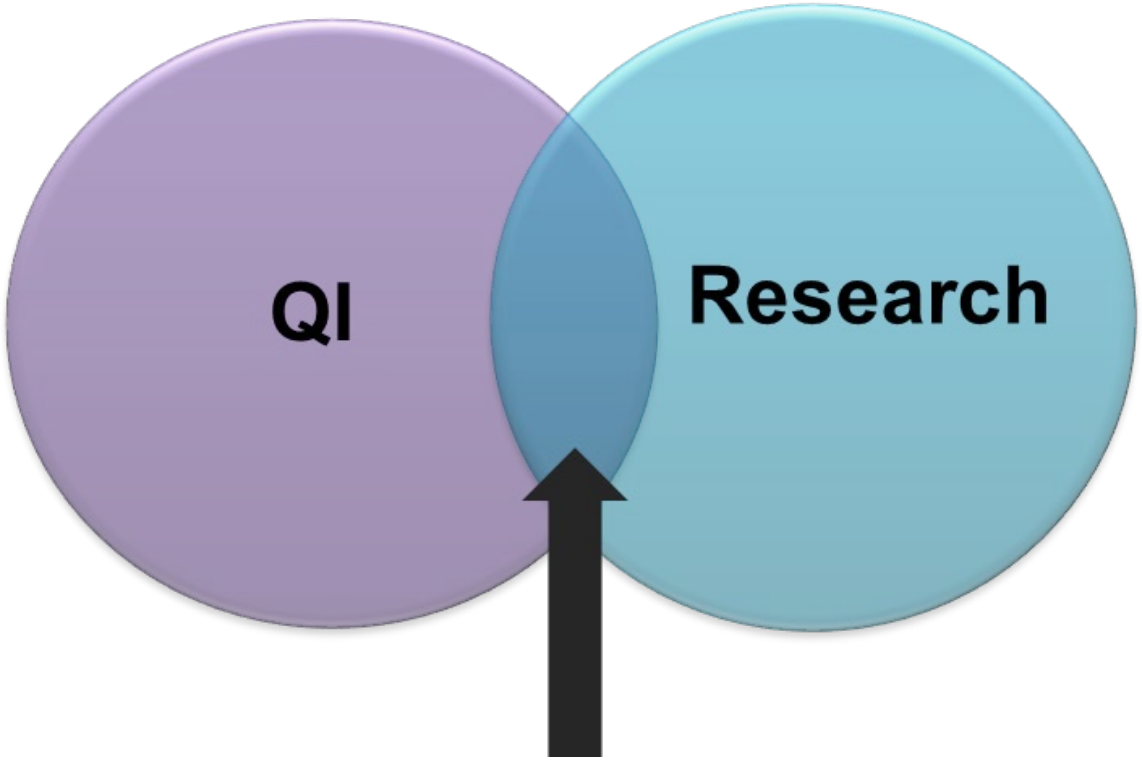
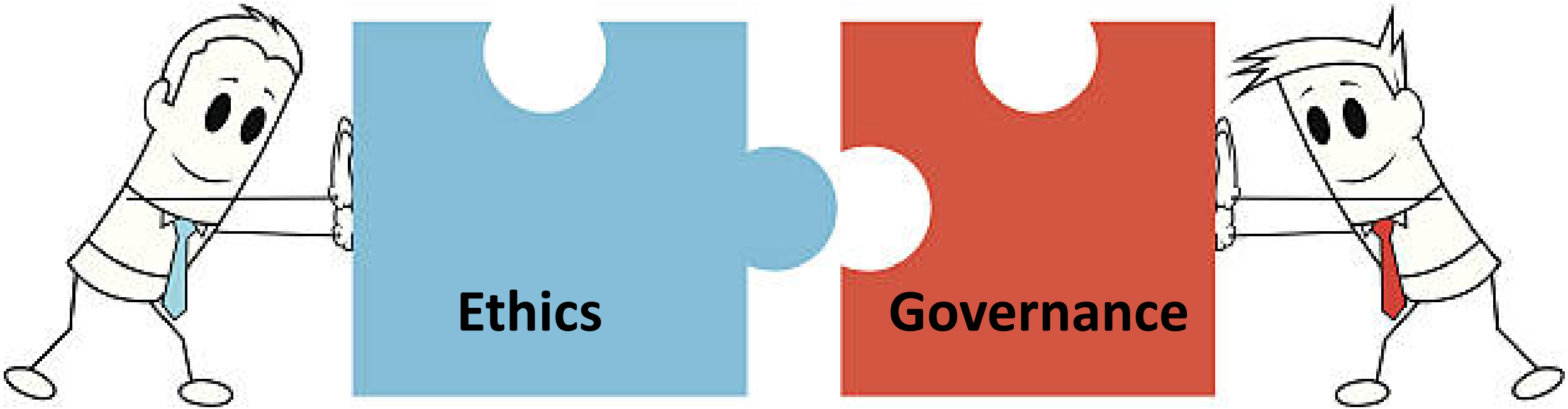


Ethics needed

ACTIVITY 2

SCENARIOS


What’s the difference between
Ethics and Governance?


Ethics
Governance

Ethics and governance processes


Yep... we need to
talk about GCP

Where do research regulations originate?

Declaration of Helsinki 1964 was the first document to set research principles

It is a set of 13 Ethical Principles for Medical Research involving Human Subjects

All staff involved in the care of research participants must be able to demonstrate knowledge and awareness of GCP

It is the duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject

The 13 Principles of Good Clinical Practice

ETHICS: Research involving humans should be conducted in accordance GCP

RISK vs BENEFIT: A study should only be initiated and continued only if the benefits justify the risks

PARTICIPANTS: The rights, safety, and well-being of the participants are the most important factor

The 13 Principles of Good Clinical Practice

STUDY DRUG: All available information on the study drug should be adequate to support the proposed study

GOOD QUALITY: Clinical trials should be scientifically sound, and described in a clear, detailed protocol

COMPLIANCE: A study should be conducted in compliance with **the HREC approved protocol**

MEDICAL DECISIONS: Medical care and medical decisions are the responsibility of a qualified physician

The 13 Principles of Good Clinical Practice

RESEARCH STAFF: Each individual involved in conducting research should be qualified by education, training, and experience to perform their respective task(s)

INFORMED CONSENT: Freely given informed consent should be obtained from every subject prior to clinical trial participation.

DATA: All research data should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification

The 13 Principles of Good Clinical Practice

CONFIDENTIALITY: The confidentiality of records that could identify subjects should be protected

INVESTIGATIONAL PRODUCT: Should be manufactured, handled, and stored in accordance with good manufacturing practice (GMP).

QUALITY ASSURANCE: Systems with procedures that assure the quality of every aspect of the study should be implemented

ACTIVITY 3

GCP

Free online GCP Training

New South Wales

DACRIN Sophie Mepham™

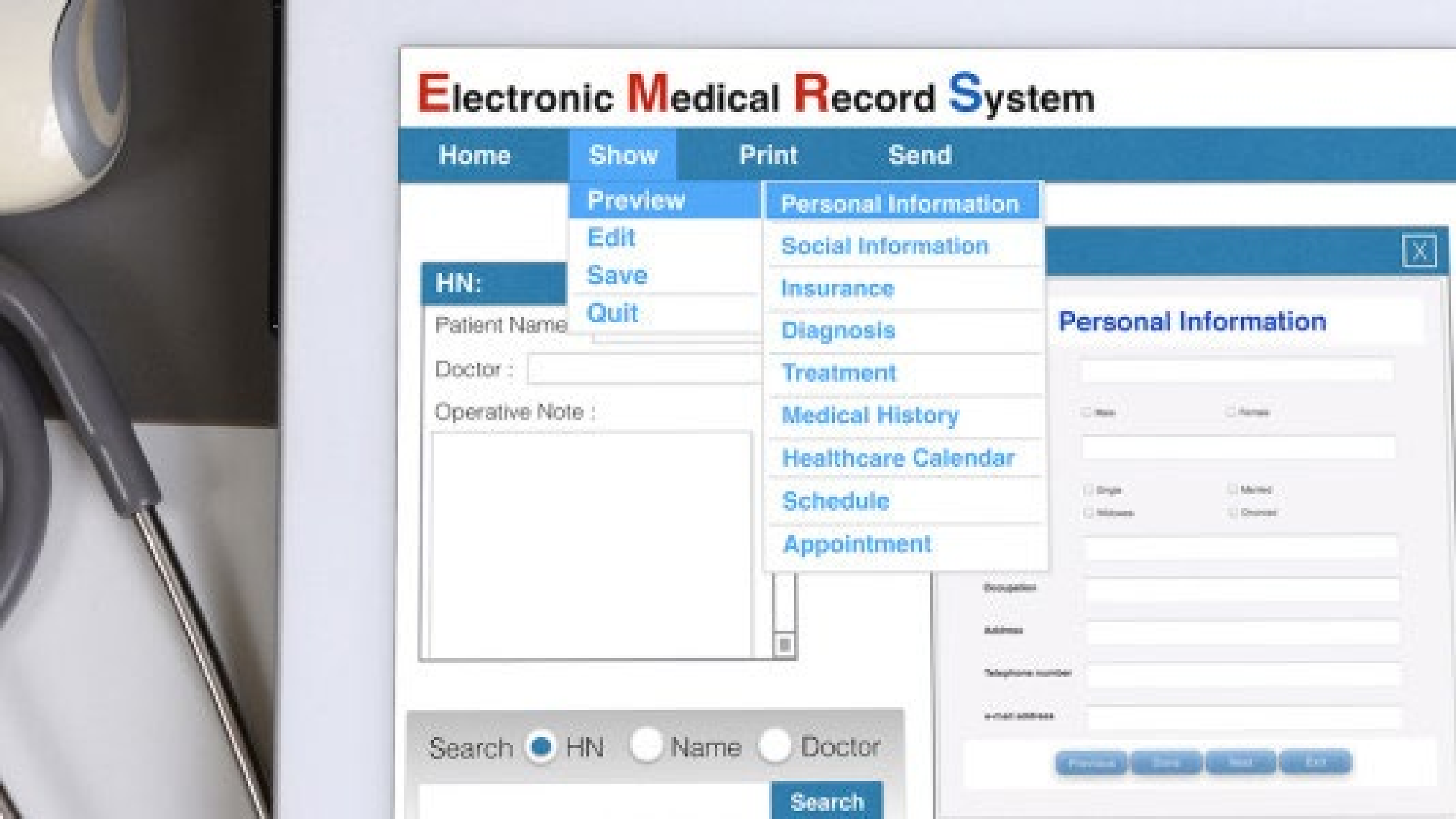
- Introductory – 4 hrs = 4CPD points
- Refresher – 2 hrs = 2 CPD points

Other states

A-CTEC

- Introductory – 2.5hrs


Where do I start?


Electronic Medical Record System
Home
Show
Print
Send
Preview
Edit
Save
Quit
Personal Information
Social Information
Insurance
Diagnosis
Treatment
Medical History
Healthcare Calendar
Schedule
Appointment
HN:
Patient Name
Doctor :
Operative Note :
Personal Information
Search
HN
Name
Doctor
Search

ACTIVITY 4

LEVERAGING EXISTING DATA

Leveraging existing data

- Real-Time Monitoring

- Utilise EMR data for continuous patient progress feedback

- Identify Process Inefficiencies

- Analyse existing data to identify bottlenecks in service delivery.

- Patient Cohort Analysis

- Examine existing data to tailor interventions for specific patient groups

- Patient Engagement and Education

- Track outcomes using existing data to enhance patient engagement strategies


I’ve got this… now let’s do some research

Transitioning to research

- Integrate Research into QI
- Collaboration with Experienced Researchers
- Seek Mentorship
- Additional Training

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www.health.nsw.gov.au/aod/dacrin