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# A DISCUSSION ON RESEARCH ETHICS APPROVAL AND LOW-RISK RESEARCH ON END OF LIFE CARE

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# AKA “SLIPPING THROUGH THE HDEC CRACKS”

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# summary

- Role of clinical research
- Overview of research ethics committee changes with Te Whatu Ora
- End of life research
- Publication considerations
- Future goals – ironing out the regional inequalities

# Clinical research

- Promotes the public good
- Quality improvement initiative, vs service development
- Enhance understanding of the patient experience, may differ from main world research centres
- Consideration of Maori and Pacific Island patients/research participants, following research guidelines.
- Comply with the NEAC standards for research, which includes Maori and Pacific Island participants

# Clinical research Ethics approval

- NEAC – submit to HDEC.
- institutional approval
- Online Ethics application form.
- Study protocol
- Peer review
- Maori and Pacific Island participant risk assessment
- Consent
- Storage of data and data privacy legislation.

# Clinical research – NZ resources

- In NZ clinical research is poorly funded/resourced.
- Australia – government funding for end of life care
- United States – research funding from philanthropists, big pharma for R&D.
  
- Completion of training - Overseas fellowship to add to experience in NZ
  
- Advance trainees have more encouragement to write a project or case study to a publishable standards as part of training. More frequently published in recent times.

# Research on end of life care

- Previously thought to be “unethical” to do
- Studies show that early referrals to palliative care improve the quality of life for patients
  - Early Palliative care for patients with metastatic non-small cell lung cancer. JS Temel et al. NEJM 2010. 363;8; 733-742.
- Vulnerable population, often lack capacity for medical decision making
- Obtaining informed consent an issue
- RCTs are done in areas such as:
  - pain management
  - Other symptoms such as delirium, shortness of breath, Artificial hydration

# Low risk studies

- Non-interventional
- Often retrospective
- Review of patient outcomes for the purposes of QI or audit
- Sometimes published – may be a field where there is a paucity of information on clinical practice
- Public interests - Informed consent may not be required if the benefits outweigh risks
  
- Requires HDEC review

# Finding the cracks in HDEC review

- Clinical studies that are non-university require institutional review
- TWO goal is to have a National Research Office. Status is approved but not yet operational

# Finding the cracks in HDEC review

- Te Whato Ora/Health New Zealand has disestablished some of the research offices.
- Historically they were of variable quality around the motu.
- Variable experiences for researchers across committees nationwide
  
- Waikato refer to Research personnel at North Shore Hospital

# Finding the cracks in HDEC review

- Maori and Pacific Island patients often described as vulnerable due to high incidence of some cancers in some groups eg lung cancer, pancreatic cancer.
- Access to Maori and Pacific Island reviewer for ethics committee applications has become sparse.
- Currently there isn't a publicly employed Pacific Island reviewer available for HDEC referrals, has to be organised independently
- Some of the Maori reviewers are no longer employed for this role

# Hospice-based clinical studies

- There may or not be an institutional research ethics committee to review a research proposal
- For non-university research studies

# Low-risk research activity

- Eligible for expedited review
- PCARN members report variation in access to HDEC appraisal.
- Low-risk clinical research often returned by HDEC without official confirmation of review

# Dissemination of research results

- Doesn't meet the criteria for publication
- New Zealand Medical Journal used to accept some articles on original research without HDEC confirmation of review, but has now modified its research ethics criteria.
- Often researchers are looking to publish in journals that are relevant to their subspecialty
- Often looking to publish in journals that have the highest impact factor
- NZ researchers can be limited due to HDEC

# Future goals

- Getting to where the National Research Office is fully functional
- Equitable access and support for researchers
- Consistent appraisal of low risk studies
- Transparent framework for assessment of studies, compliant with journal publication requirements.

# Thank you

- Are there any questions?