Acknowledgement of Country

Left : ”Dharawal”
Represents his ancestry
the generations past
and to come
Artist : Colin Isaacs

Obtaining Informed Consent in Intensive Care

Prepared by Jennene Miller
Liverpool ICU Research Clinical Nurse Consultant
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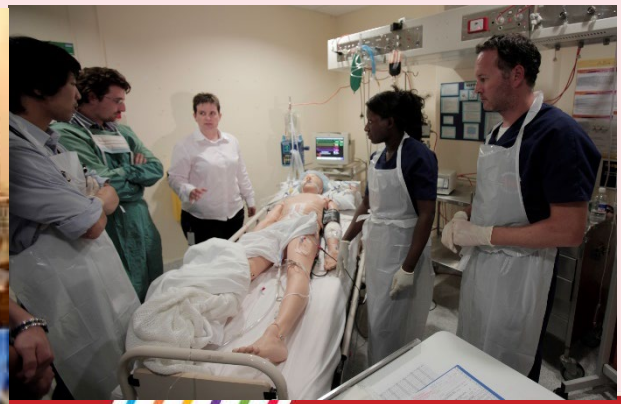
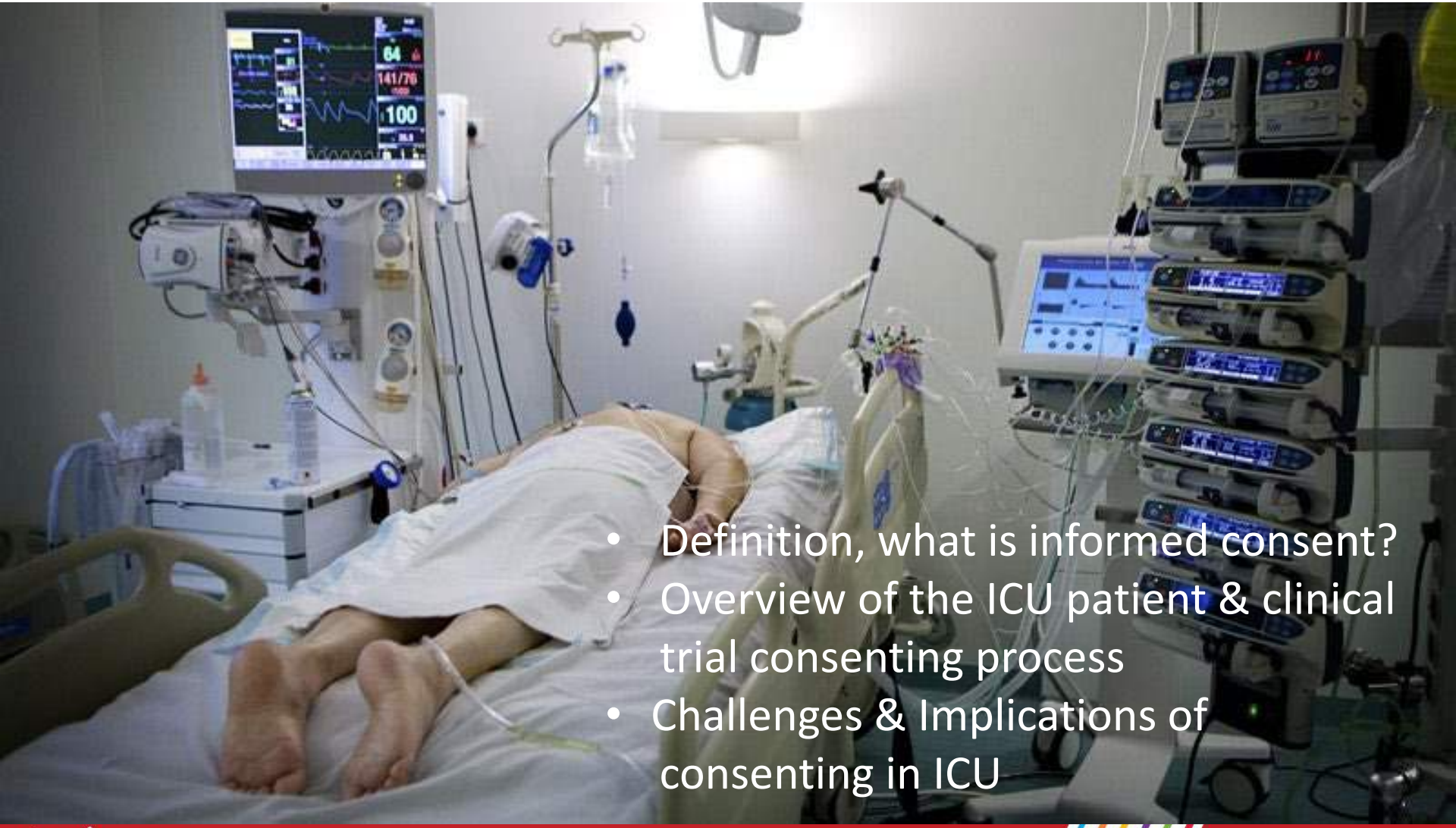


Introduction



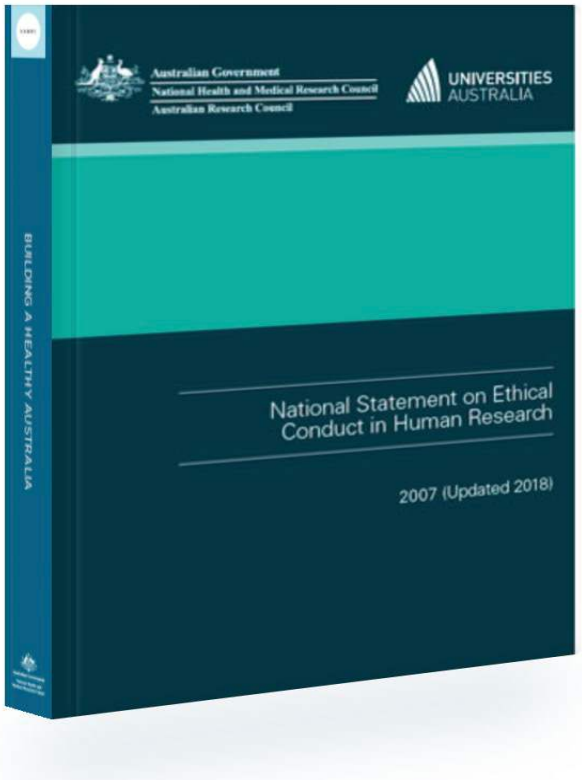
- Definition, what is informed consent?
- Overview of the ICU patient & clinical trial consenting process
- Challenges & Implications of consenting in ICU

NHMRC Definition

NHMRC National Statement

General requirements for informed consent:

- Voluntary Choice
- Sufficient Information
- Understanding of risks and benefits



- Informed consent is one of the most important aspects of research ethics and the focus is on ensuring the rights of the patient. The most important ethical principle is to protect the AUTOMONY of our patients, maintain their rights, safety and well-being whilst participating in research.

NHMRC Process to Follow for Consent

- Consent should be gained from patients wherever practicable
- Consent may be waived in emergency research (pending NCAT & HREC approval)
  - Due to urgent interventions/treatments
- Substitute consent
  - If patients are unable to consent
  - Ideally pre-randomisation but may be post-randomisation
  - Unconscious patients only if research is:
    - Minimally invasive; OR
    - Therapeutic + beneficial

- Overall, consent should avoid:
  - Stress/emotional factors
  - Dependence of patients/families on treating clinicians

Consent in critical care research

Main 4 types used in ICU for Randomised Control Trials:

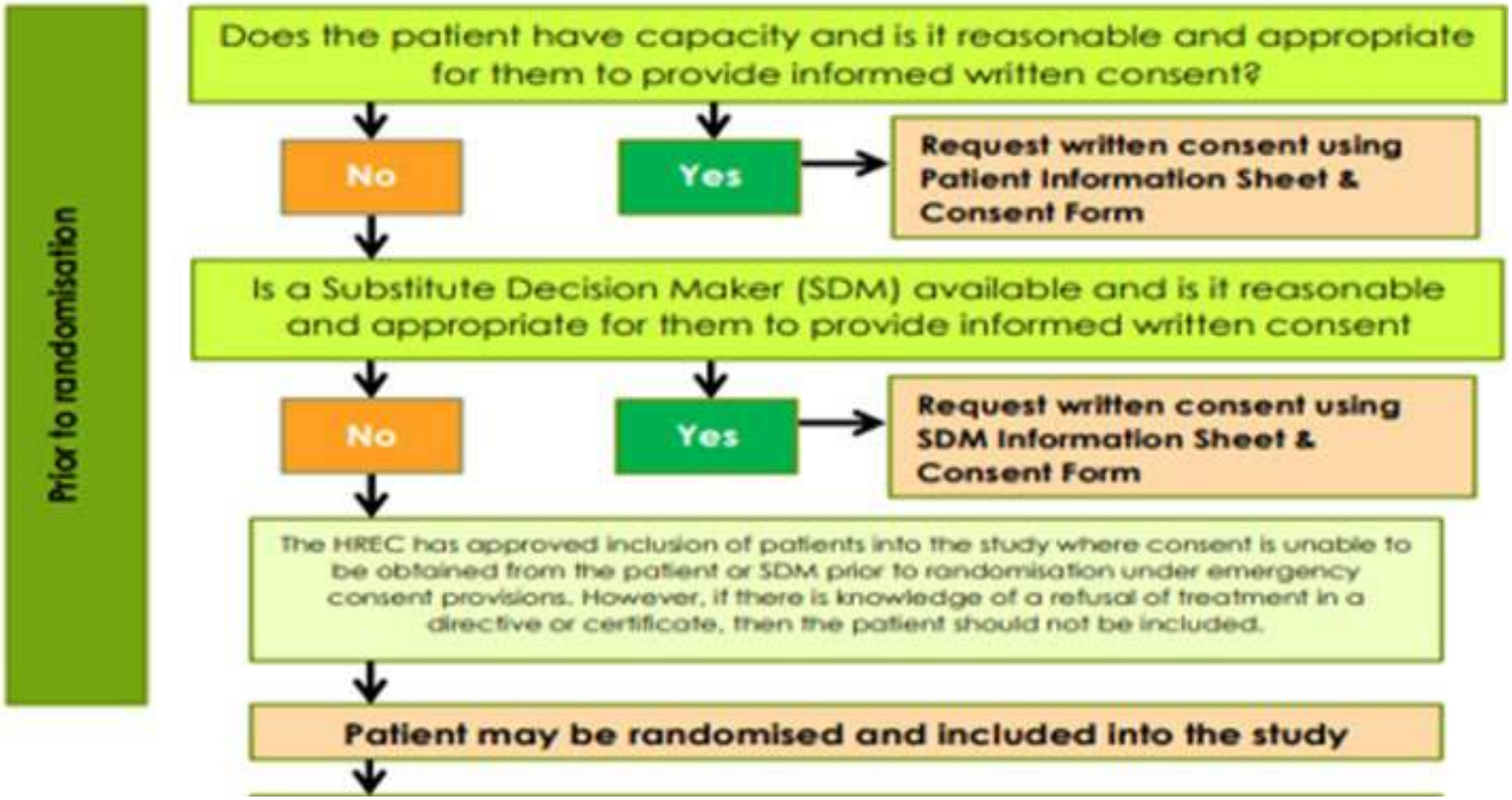
1. Prior consent from patient
2. Prior surrogate consent (Person Responsible, Proxy)

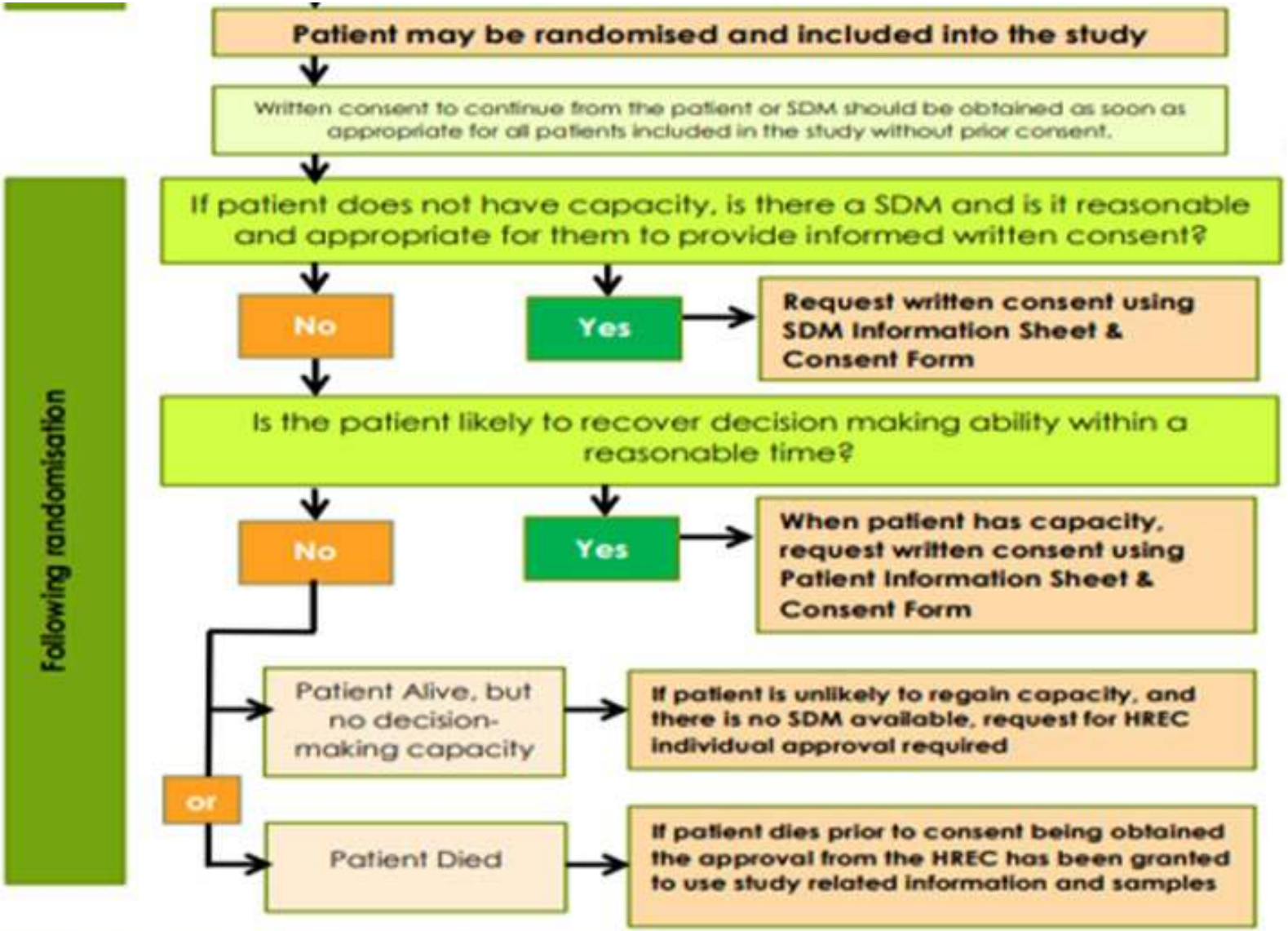
Emergency or standard comparative treatments with waived consent require:

3. Consent to continue from patient
4. Consent to continue from surrogate (Person Responsible)

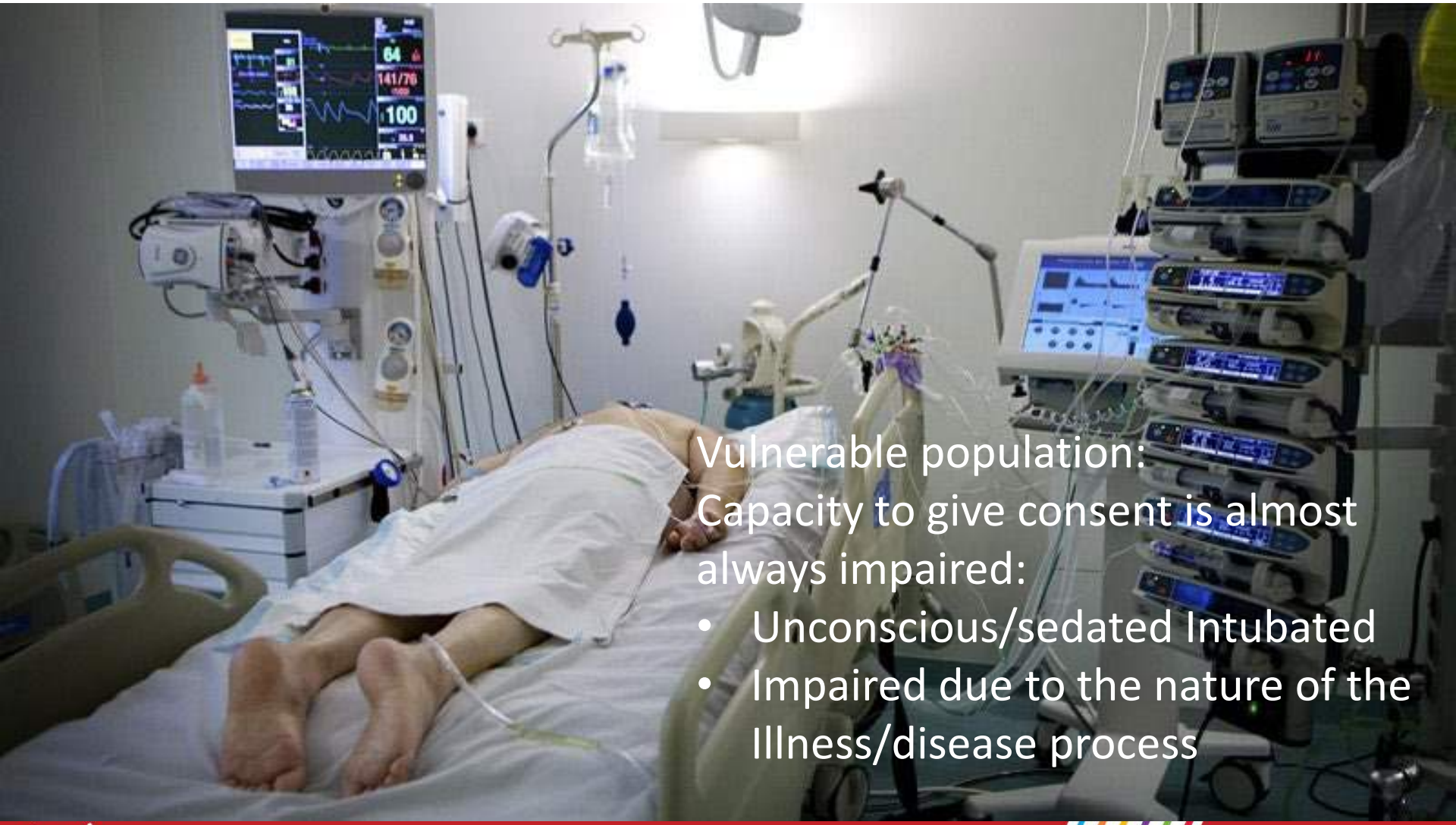
HREC COVID RESPONSE- Verbal & e-Consents HREC approved

FluDReSS Consent Flow Chart





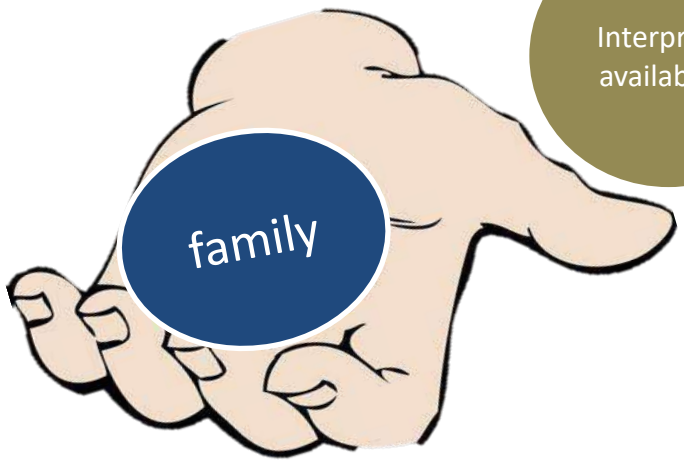
Intensive Care patient



Vulnerable population:
Capacity to give consent is almost always impaired:

- Unconscious/sedated Intubated
- Impaired due to the nature of the Illness/disease process

Challenges



Availability NOK
Timing
Pain
Consent approach
ICU Patient intubated sedated and unconcious
ICU interventions
Noisy, busy environment
Complex admission, co morbidities
Availability of research staff
fear

Distrust of medical institution
no social support
Family dysfunction
Stress, anxiety trauma
Religious beliefs
No surrogate decision maker
Low Literacy
Low health literacy
Errors in translation
Language barrier
Interpreter availability

Demographic & Logistic challenges

- Liverpool one of the busiest ICU in NSW

-admissions have high mortality and morbidity rates

- Large population catchment area for the SWSLHD

-patients may be separated from rural or overseas family

- 50% overseas, non-English speaking background
- low medical literacy
- Large cultural diversity in population
- Availability of interpreters is limited

Communication challenges

- Busy & noisy environment
- Open ICU-not private
- Difficult schedules finding convenient times and place
- Free of interruptions
- Relatives are;

  -Stressed, anxious, overwhelmed

  & sleep deprived
- Patients-confused, fear, pain all of the above
- Require multiple conversations
- Team collaboration
- Time considerations & constraints

Education Challenges

- Use of interpreters doesn't guarantee accuracy of medical translation and understanding
- Medical mistrust & false information
- Complex study designs and interventions

  -involve long discussions which are technically difficult
- Require language specific brochures, information & consents
- Limited coverage and availability of ICU Research staff & medical Staff to provide information, ongoing education and conduct consenting discussions 24/7.

Social Challenges

- large families

  - difficult identifying appropriate decision makers

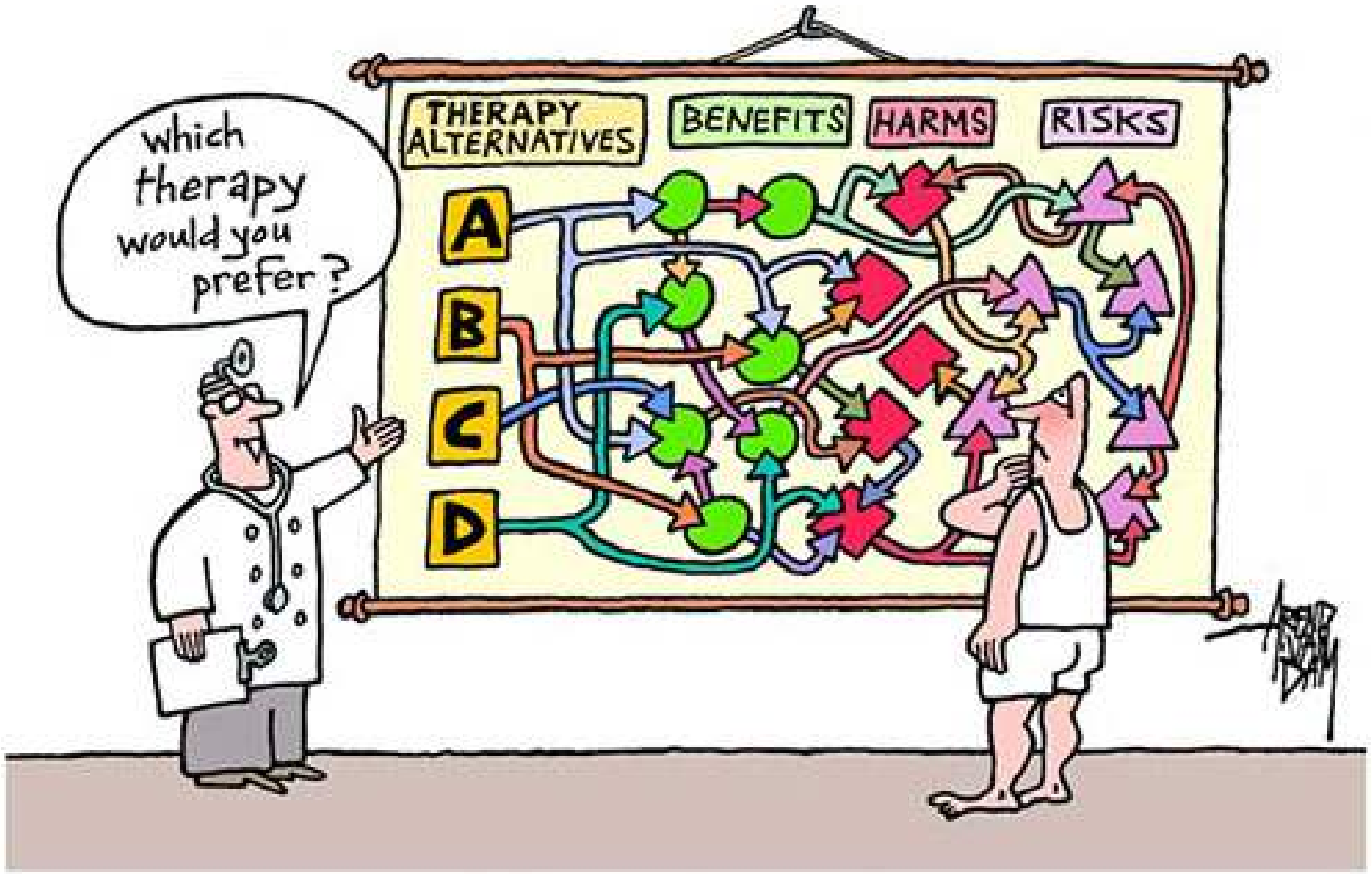
  -difficult getting family consensus

- Family dysfunction and estrangement is common
- Minimal social support
- Drug abuse, social and mental health problems in make it difficult to identify a reliable NOK

Implications for ICU Research

- Consent in ICU is complex and sensitive
  - Adhering the ethical principles to obtain informed consents is challenging
- Favourable ICU consenting models
  - Provision of opt-out, waivers and consent to continue, eConsents and verbal consenting models are well established in ICU and work in ICU setting
- Ongoing areas of collaboration
  - Working with local HRECs to refine protocols to create simple PICFs that support patients and families to increase recruitment numbers
  - Nationally HREC's role to harmonise and interpret the National Statement & Guardianship Acts that regulate our consent process and are critical to ongoing emergency and ICU research in Australia.

Questions?



informed consent