Austin Health

Comments for the Victorian Law Reform Commission (VLRC) in relation to Guardianship Law and meeting of May 17th, 2011 at VLRC offices. Provided by Professor Rinaldo Bellomo MBBS, MD, FRACP, FCICM, Pg Dip Echo in his personal capacity

Key points

1. Current law concerning research in emergency conditions is adequate
2. The details of procedural authorization are cumbersome. The impression is that this a bureaucratic step with little real meaning, supervision, assessment and validation. If the VLRC felt that such a step was necessary to make the public "safe", it should be made simpler and "more real". A possible approach would be to shift the reporting, assessment and follow-up of procedural authorization cases to the local HREC and have a two step approach: 1. Obtain authorization; 2. Provide a follow-up/closure document within a month.
3. The definition of minor research should be extended to include a) the measurement of non-genetic laboratory tests; b) the comparison of established and widely practiced standards of care; c) the observation and collection of already routinely available data
4. For minor research the HREC should be given the ability to judge whether a) consent is required (e.g. because the urine test to be done will be used by a drug company to develop a profitable technology); b) consent is not required but an "opt out" approach is required (with procedures to ensure that such an approach is appropriate as decided by the local HREC) (e.g. because we are comparing standard treatments that might given randomly anyway) and c) consent is not required (because the urine that would normally be discarded will be used Victorian investigators to develop a test that might benefit the community and does not have an obvious and immediate profit motive) . The key principle here is that the Law cannot imagine/foresee all possible permutations of research that might apply and should not try to legislate what the local HREC is in a much better position to judge. The NSW approach has created another bureaucratic machine associated with the assessment of what is minor. Why not suggest examples to guide local HREC's (see above) and acknowledge that, in many cases, the distinction is blurred and leave it to the HREC to make that decision?
5. Local HRECs provide a high level of protection to patients. It is dubious that legislation on top of that is helpful. It is likely that by creating unnecessary layers, it is more of a hindrance. It must be remembered that, in the last 10-15 years, the most egregious violations of patient safety in Australia (e.g. Bundaberg) have not come from research but rather from practice. Such practice

remains much less regulated, it is less rigorous in its self-regulation and non-scientific and statistically more likely to cause injury to Victorians than HREC approved research.

6. Research is always controversial. Things that are not controversial are not the subject of research.
7. Research cannot be stated to be in the patient's best interest. It can only be stated to be "believed not to be contrary to the patient's best interest". The only statements that can be made about research are not about what may or may not happen but rather about what the prior belief is by the investigator and whether such belief is endorsed as reasonable or justified by a local HREC.
8. Research cannot be stated to be in the community's best interest. It can only be stated to be "believed not to be contrary to the community's best interest". The only statements that can be made about research are not about what may or may not happen but rather about what the prior belief is by the investigator and whether such belief is endorsed as reasonable or justified by a local HREC.
9. The separation of medical treatment from medical research is difficult. Much treatment can then be retrospectively used to obtain data for research purposes. Much research provides a comparison of two treatments. Thus it provides both treatment and research. The relationship is fluid and incredibly variable. The law should not try to describe it.
10. The concept of substitute judgment appears more realistic than that of best interest.
11. Under conditions of major illness, the stress imposed upon the person responsible is already great because of the illness. Medical research shows that survivors of such illnesses retrospectively disagree with such substitute judgment 30% of the time (another 20% and this would be equivalent to the tossing of a coin). For potentially dangerous/novel/cutting edge/not yet established therapies (as determined by the local HREC) some kind of consent seems mandatory and the additional stress placed upon the person responsible seems justified. For other interventions which compare two standards of care or test normally discarded body fluids which are minor in risk and burden (as determined by the local HREC), an opt out system or weaver of consent system (see above) would not conceivably increase the risk to the patient or reduce protection but would a) alleviate the burden/risk upon the person responsible and b) decrease the burden associated with attempts to improve patient care by means of research.