IMPORTANCE OF "OPT_OUT CONSENT" IN IMPROVING THE SAFETY AND QUALITY OF HEALTHCARE

1. Clinical quality registries (CQRs) are being established in increasing numbers internationally to provide a powerful approach to improving the safety and quality of healthcare. Australia is amongst the leaders in these developments.

2 The role of clinical quality registries is to benchmark 'clinical quality indicators' amongst different providers. These indicators are selected by clinicians and epidemiologists (with assistance of consumers) as measures which best reflect the highest quality of clinical care. Their power to induce change comes from their ability to change clinician behaviour.

3 Clinical quality indicators include measures of process (ie what is done to a person) and outcome (how effective the treatment is at returning the patient to normality) . Outcomes are measured by contacting patients by SMS, email, phone call or letter after time has elapsed for recovery. Measurement of outcomes is a key distinguishing feature of CQRs.

4 When benchmarked the data provided by CQRs provides a powerful stimulus for improvement, no one wants to be amongst the lowest achievers. They may also provide a unique opportunity to learn from units with excellent results, and provide an early warning when performance slips. As a result the data is valuable to clinicians, administrators and policy-makers.

5 To effect change the benchmarking data provided by registries must be trusted and believed by clinicians. Achieving this requires some fundamental properties. In particular the units being benchmarked must report all cases rather than their best. This is often referred to as the 'no-cherry picking rule'

6 The NHMRC has recognised this very fundamental requirement by approving the use of opt-out consent for participants whose data is included in registries. According to the NHMRC National Statement on Ethical Conduct of Clinical Research "An opt-out approach to participant recruitment to research may be appropriate even when it is feasible to contact some or all of the participants, but where the project is of such scale and significance that using explicit consent is neither practical nor feasible"

7 Ethics committees deciding whether to approve 'opt-out' consent must consider a range of 'tests' including

public interest outweighs privacy risk
low-risk to participants
requires near-complete participation rate.
plain language information provided
'decline to participate' facilitated

data security ensured
governance/ responsibilities delineated
not prohibited by State, Federal, or international law

8 the existing constraints typically lead to involvement of 95% plus of eligible participants, thus largely negating the suspicion that any particular unit or clinician is selecting only the best patient outcomes for participation. It also allows those with strong safety obligations to decline participation, but in practice less that 5% choose to do this.

9 **IN SUMMARY, the present arrangements for opt-out consent allow the functioning on what is undoubtedly the most effective approach to improving safety and quality in the healthcare system. However, opt-out consent is fundamentally necessary in order for the data to be clinically credible and have the power to change behaviour amongst clinicians.**

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