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MNZH MAKE NEW ZEALAND HEALTHY

Guarantee Scientific Integrity In Informed Consent. In Brief.

THE PROBLEM: The Medical Council of New Zealand's guidance on informed consent (July 2021) establishes a clear professional obligation on clinicians: patients must understand the risks, benefits, and alternatives of treatment before agreeing to it. Yet in practice, the health system's capacity to achieve genuine informed consent is constrained by deficiencies in evidence quality, transparency, and timely updating of therapeutic data used in routine care.

For consent to be valid, patients must be able to approximately judge:

- The likelihood that a treatment will meaningfully improve symptoms or prevent deterioration.
- The likelihood that treatment may result in a severe, disabling, or life-threatening event.

At present, much of the information relied upon by clinicians, including formularies and manufacturer data sheets, lacks transparent citation of underlying studies, clear presentation of absolute risk, or linkage to full trial data and to regulatory submissions. Claims of efficacy are frequently presented without accessible reference to study design, duration, population characteristics, or limitations. Long-term outcome data are often absent or outdated.

Lack of Clear Data to Judge Risk and Benefit. Clinicians and patients are seldom provided with:

- Absolute risk reductions (e.g., per 100 treated).
- Numbers needed to treat (NNT) to prevent severe symptoms, hospitalisation or death.
- Numbers needed to harm (NNH) for serious adverse outcomes.
- Subgroup-specific data by age and sex and baseline metabolic status.

The Nutrition Blind Spot. The consent framework overwhelmingly centres on pharmacological or device-based interventions, neglecting the nutritional and metabolic dimensions of illness. For chronic inflammatory, metabolic, and mood disorders, nutritional insufficiency or dysfunction may materially affect symptoms and progression. Failure to discuss and document these dimensions narrows the patient's perception of available alternatives, undermining the ethical validity of consent.

Case Study: Antidepressants. The prescribing of antidepressants illustrates systemic weaknesses with current approaches. Publicly available safety and efficacy summaries consistently lack transparent linkage to trial datasets or regulatory submissions. Long-term outcomes, withdrawal risks, and youth-specific data remain insufficiently presented. Clinicians are not briefed on the supporting trial evidence for low-risk micronutrient supplementation across a large range of psychiatric conditions. The issues (discussed in the larger MNZH policy paper) is not unique to psychiatry issue, instead it is indicative of broader informational gaps across medicines and devices.

Severity Thresholds and Ethical Clarity. Regulatory frameworks distinguish between:

- Grade 1–2 harms: mild, reversible, self-limiting.
- Grade 3–5 harms: severe, disabling, life-threatening, or fatal.

Informed consent must clearly differentiate between these harm categories. Prescribing thresholds must correlate with harm severity. Agents associated with Grade 3–5 risks demand heightened ethical scrutiny and explicit patient understanding of both the probability and magnitude of harm.

***Higher Ethical Standard for Vulnerable Populations*.** When medicines are prescribed to young people whose neurological and endocrine systems are still developing; or during pregnancy, where maternal and foetal physiology are intertwined, the evidentiary threshold for informed consent must be higher. In practice, routine systems often lack age- and pregnancy-specific outcome transparency sufficient to meet this standard.

The central issue is not whether clinicians intend to inform patients; it is whether the system provides clinicians with the tools required to do so and whether the data is accessible to patients.

THE SOLUTION: A credible informed consent framework must convey both therapeutic benefit and potential for serious harm in absolute, comprehensible, and population-relevant terms. To meet a reasonable public-interest standard, consent materials must include:

- ✓ *Age- and sex-specific data on drug efficacy: symptom relief, prevention of escalation, hospitalisation, or mortality.*
- ✓ *Age- and sex-specific harm data: incidence, severity, withdrawal effects, and hospitalisations.*
- ✓ *Transparent comparison of pharmacologic vs. nutritional or lifestyle alternatives.*
- ✓ *Absolute risk framing: expressed per 100 treated, including NNT and NNH.*
- ✓ *Clarification of nutrient-based interventions, distinguishing mild tolerability effects from rare yet severe toxicities.*

1. **Foundational Health Assessment Prior to Pharmacotherapy** including nutrition screening.
2. **Integrate Nutrition as First-Line Strategy Where Appropriate.** Including for people diagnosed with brain-related conditions, where evidence supports benefit and risk is low.
3. **Mandatory Disclosure of Absolute Benefit and Harm Data** Require clinicians to provide age- and sex-stratified NNT/NNH tables.
4. **Transparent Formularies and Data Sheets including** Original trial citations (with DOIs, study durations etc). Develop safety summaries independent of manufacturer packaging materials.
5. **Trial Decoding Tools.** Published tables (including absolute event counts/study-level metadata)
6. **Public-Interest Evidence Synthesis.** Leverage modern analytic tools to extract absolute risk and adverse event frequencies; identify subgroup effects, methodological limitations, etc.
7. **Implement a statutory Five-Year Evidence Reappraisal Cycle** for all medicines listed on the Pharmaceutical Schedule.
8. **Independent, Publicly Accessible Safety Summaries.** Develop New Zealand-specific, publicly accessible safety summaries independent of manufacturer packaging materials.

This framework would align public drug information with contemporary standards of evidence synthesis, improve risk communication, and reduce the informational burden placed on patients and clinicians, while ensuring methodological rigor and transparency.