

Youth health research ethics: time for a mature-minor clause?

Lena A Sancı, Susan M Sawyer, Penny J Weller, Lyndal M Bond and George C Patton

HEALTH PRIORITIES IN YOUNG PEOPLE have changed in recent decades, with a recognition that psychosocial disorders such as depression, substance misuse and self-harm account for a greater burden of disease than physical illness.¹ The youth research agenda has broadened, with a stronger focus on prevention and early intervention and an expansion of settings to include primary care and community environments.

Societal views of young people's rights have also changed. The civil, political, economic, social and cultural rights of children and youth are embodied in the United Nations Convention on the Rights of the Child (UNCRC).² A purely protective framework in international law has given way to one that acknowledges the right of young people, in accordance with their age and maturity, to make their own decisions on matters affecting their lives.²

Changes in both the attitudes to youth and youth health priorities have markedly altered approaches to consent for clinical treatment.³ The implications for research are now emerging.⁴ In the United States, the National Commission for the Protection of Human Subjects of Research recognises situations in which the requirement for parental consent for adolescents under 18 years to participate in minimal-risk research can be waived.^{4,5} In the United Kingdom, young people aged 16 and older are considered capable of giving informed consent, and those under 16 may consent to take part in minimal-risk research if participation is in their best interests and they are "mature minors" (see below) and refuse parental involvement.⁶

The rationale for these changes goes beyond a changing societal view of young people. There is evidence that adolescents' involvement in research has been hampered by absolute requirements for parental consent.⁴ For example, the requirement for active parental consent for school-based surveys has been shown to lower response rates by 40%–67% and cause under-representation of at-risk groups.⁷

ABSTRACT

- Research into adolescent health issues is hampered by absolute requirements for parental consent.
- Society's recognition of adolescents' autonomy and decision-making capacity has been embodied in the legal recognition of the mature minor's right to make decisions on matters affecting his or her life. Psychological research indicates that young people from 14 years have decision-making capacity.
- US and UK research ethics guidelines acknowledge the mature-minor principle, but Australian guidelines are out of step with international practice.
- An absolute requirement for parental consent in Australian research ethics guidelines is potentially unethical if it denies mature adolescents' autonomy and is a barrier to participation, study validity and improved health outcomes through research findings.
- There are grounds for considering a mature-minor clause in the National Health and Medical Research Council research ethics guidelines, particularly in the context of youth participation in minimal-risk research.

MJA 2004; 180: 336–338

Australian research ethics guidelines are out of step with practice in other Western countries: the National Health and Medical Research Council (NHMRC) *National statement on ethical conduct in research involving humans*⁸ requires consent from both young people and their parents to involve adolescents under 18 years of age in any type of research. We believe there is an urgent need to reconsider the NHMRC guidelines for young people's participation in research, particularly minimal-risk research involving mature minors, if we are to effectively use research to improve young people's health status.

Clinical application of the mature-minor principle

The historical notion of children as property items, owned by their parents and lacking the right to consent to medical treatment, has changed.⁴ Children are now recognised as autonomous beings with discrete rights and interests. In the United Kingdom, the 1986 case *Re Gillick*⁹ established that children who satisfy the test of competency (ie, are deemed by their doctors to be "mature minors") can validly consent to their own medical treatment without parental consent. The mature-minor principle was confirmed in Australian common law in 1992, with the High Court of Australia stating that "parental power to consent to medical treatment on behalf of a child diminishes gradually as the child's capacities and maturity

Centre for Adolescent Health, Royal Children's Hospital, Parkville, VIC.

Lena A Sancı, MB BS, PhD, FRACGP, Postdoctoral Fellow (NHMRC) (also at Program Evaluation Unit, University of Melbourne, and Murdoch Children's Research Institute); **Susan M Sawyer**, MB BS, MD, FRACP, Acting Director; Associate Professor, Department of Paediatrics, University of Melbourne; and Respiratory Paediatrician, Royal Children's Hospital; **Penny J Weller**, BA/LLB, MA, PhD, Project Officer; **Lyndal M Bond**, BA(Hons), MA, PhD, Public Health Research Fellow (VicHealth, Department of Human Services) (also at Department of Paediatrics, University of Melbourne); **George C Patton**, MB BS, MD, FRANZCP, VicHealth Professor of Adolescent Health Research; Professor of Adolescent Health, University of Melbourne; and Associate Director Adolescent Health, Murdoch Children's Research Institute.

Reprints will not be available from the authors. Correspondence: Dr Lena A Sancı, Department of General Practice, University of Melbourne, 200 Berkeley Street, Carlton, VIC 3053. sancil@cryptic.rch.unimelb.edu.au

grow. A minor is capable of giving informed consent when he/she achieves a sufficient understanding and intelligence to enable him/her to understand fully what is proposed.¹⁰ Hence, the concept of a mature minor is dependent on the child's level of maturity, with no lower age limit defined.

A requirement for confidentiality is a corollary of the mature-minor doctrine.⁴ Indeed, a major barrier deterring young people from accessing healthcare for sensitive issues, such as sexual health, is the fear that parents will be informed.¹¹ It is usually in consulting about these sensitive issues that adolescents refuse to inform parents, leaving clinicians needing to assess mature-minor status before prescribing treatment that is in the adolescent's best interests.

However, the gravity and nature of the treatment are also taken into account when assessing a minor's capacity to fully understand all aspects of the situation and to objectively weigh up treatment options.¹² For example, mature minors are commonly prescribed oral contraceptives confidentially. However, a mature minor would not be deemed sufficiently mature to consent to a life-altering procedure, such as gender reassignment or sterilisation, for which even parental consent is insufficient.^{10,12} A parent's or guardian's consent is necessary if the minor is unable to make voluntary and informed decisions, judged by various indicators of maturity.^{13,14} For example, clinicians would need to involve a parent or guardian in the care of a 12–14-year-old girl with chlamydial infection if she were habitually meeting older boys and not able to fully comprehend the risks of this behaviour or the need to protect herself.

Implications for research

While few would deny that young people have a right to treatment, the right to participation in research, covered by the UNCRC, is not often appreciated.² Furthermore, the right of adolescents, as a group, to benefit from research findings can only be upheld if they are given access to participation. On the other hand, there is a need to balance the right of young people to participate in research with their right to privacy and protection from risks and exploitation.¹⁵

Consistent with earlier attitudes to children, human ethics committees and bodies producing research guidelines have taken a prominent role in protecting young people. However, research on child development and cognitive decision-making suggests that such caution is unwarranted. Usually from the age of 14 years, and clearly from 15 years, adolescents have the cognitive capacity for making informed decisions.^{4,14,16} Cognitive maturation also needs to be balanced with the insights that life experiences contribute to personal-risk assessment.

In our efforts to protect adolescents, could an absolute requirement for parental consent for a child's participation in research be unethical? A particular danger of being overly protective is that young people may become "research orphans", with little progress made in attending to their health issues.¹⁶ Denying young people the right to participate in minimal-risk research because they refuse (or are unable) to obtain parental consent denies them their autonomy and the potential benefits of research, and compro-

mises the research's validity.^{17,18} This is particularly applicable for high-risk young people such as homeless youth, intravenous drug users, or school truants.

What are the risks of research?

The risks of involving young people in research vary, ranging from potentially major side effects from novel therapeutic interventions to minimal risk for participation in descriptive studies or health surveys. Minimal-risk research may be described as research in which the risk of harm is "not greater than ordinarily encountered in daily life during performance of routine physical or psychological examinations or tests".¹⁹ While some people may be concerned that surveys of health-risk behaviours that include questions about sexual intercourse or self-harm might encourage these behaviours, there is no evidence to support this view.²⁰

Important ethical issues that arise in relation to minimal-risk research with young people (eg, financial compensation, privacy, the implications of uncovering people at risk of harm or illegal activity) are similar for adults, but with the added complexity of the potential need to involve parents or guardians. Ethics committees need to ensure that these issues are identified in the research plan and mitigated against.

On the other hand, there are potential benefits to young people from participating in research. Health surveys may provide them with a greater understanding of their own behaviours, which may assist them in seeking help.⁴ The process of obtaining informed consent may lead to increased self-respect and decision-making capacity in young people,²¹ who also value the opportunity to be altruistic.²²

Moving forward

To bring Australia into line with US and UK policy, NHMRC research guidelines should, at the very least, adopt the mature-minor principle to allow adolescents to participate in minimal-risk research.

Based on studies of adolescents' decision-making capacity,^{14,16} there are grounds for ethics committees to consider allowing young people aged over 14 years to participate in minimal-risk research without parental consent and without a formal mature-minor assessment.⁴

In research involving more than minimal risk, it is essential to protect young participants. Ethics committees have a central role in deciding the level of protection required and the necessary level of involvement of adolescents and their parents in providing consent to participate. The mature-minor assessment offers one level of protection.⁴ Independent clinicians or other suitably trained professionals could perform the assessment as part of the consent protocol.¹⁶

There are challenges in implementing this approach. Researchers would need a thorough understanding of requirements for adolescents' informed consent. Ethics committees would need to be fully informed about adolescents' developmental capacities with respect to the mature-minor concept, as well as having a sound understanding of the changing nature of health risks faced by young people in contemporary Australia.

We believe it is time for research ethics to become consistent with clinical practice and the law in tackling modern challenges to young people's health. The pending 5-year review of our NHMRC research ethics guidelines presents an opportunity for the Australian research community to debate the issues and to consider a mature-minor clause. It is essential that consumers and community members, including young people and parents, are engaged in this debate in order to align research practice with community values and attitudes.^{4,5,11,15,20,23}

Competing interests

None identified.

References

1. Moon L, Meyer P, Grau J. Australia's young people: their health and well-being 1999. Canberra: Australian Institute of Health and Welfare, 1999. (Catalogue No. PHE 19.)
2. Office of the High Commissioner for Human Rights. Convention on the rights of the child. 1990. Available at: 193.194.138.190/html/menu3/b/k2crc.htm (accessed Feb 2004).
3. Sawyer SM, Bowes G. Adolescence on the health agenda. *Lancet* 1999; 354 Suppl 2: S1131-S1134.
4. Santelli JS, Smith Rogers A, Rosenfeld WD, et al. Guidelines for adolescent health research: a position paper of the Society for Adolescent Medicine. *J Adolesc Health* 2003; 33: 396-409.
5. Smith Rogers A, D'Angelo L, Futterman D. Guidelines for adolescent participation in research: current realities and possible resolutions. *IRB: A Review of Human Subjects Research* 1994; 16(4): 1-6.
6. NHS Central Office for Research Ethics Committees. Multi-centre research ethics committees guidance notes, 2000. Research on children (Manual II.7 & V27.1). Available at: www.mrc.ac.uk (accessed Sep 2003).
7. Esbensen F-A, Deschenes EP, West J, et al. Active parental consent in school-based research: an examination of ethical and methodological issues. *Eval Rev* 1996; 20: 737-753.
8. National Health and Medical Research Council. National statement on ethical conduct in research involving humans. Canberra: NHMRC, 1999. Available at: www.health.gov.au/nhmrc/publications/humans//contents.htm (accessed Feb 2004).
9. *Gillick v West Norfolk and Wisbech Area Health Authority* (1986) AC 112.
10. *Secretary, Department of Health and Community Services v JWB and SMB* (Marion's case) (1992) 175 CLR 218, FC 92/010.
11. Levine RJ. Adolescents as research subjects without permission of their parents or guardians: ethical considerations. *J Adolesc Health* 1995; 17: 287-297.
12. *Welfare of a child A between: mother applicant and the public advocate respondent* (1993) FLC 92-402, 16 Fam LR 715 children.
13. Medical Practitioners Board of Victoria. Minors' right to consent to medical treatment. *Medical Practitioners Board of Victoria Bulletin* 2002; 2: 14-15.
14. Kuther TL. Medical decision-making and minors: issues of consent and assent. *Adolescence* 2003; 38: 343-357.
15. Wyn J, Lumley J, Daly J. Women's health: methods and ethics. In: Daly J, editor. Ethical intersections: health research, methods and researcher responsibility. Sydney: Allen and Unwin, 1996: 166-179.
16. Arnold LE, Stoff DM, Cook E Jr, et al. Ethical issues in biological psychiatric research with children and adolescents. *J Am Acad Child Adolesc Psychiatry* 1995; 34: 929-939.
17. Brooks-Gunn J, Rotheram-Borus MJ. Rights to privacy in research: adolescents versus parents. *Ethics Behav* 1994; 4: 109-121.
18. Rew L, Taylor-Seehafer M, Thomas N. Without parental consent: conducting research with homeless adolescents. *J Soc Pediatr Nurs* 2000; 5: 131-138.
19. Weber LR, Miracle A, Skehan T. Interviewing early adolescents: some methodological considerations. *Human Organization* 1994; 53: 42-47.
20. Santelli J. Human subjects protection and parental permission in adolescent health research. *J Adolesc Health* 1997; 21: 384-387.
21. Weithorn LA, Scherer DG. Children's involvement in research participation decisions: psychological considerations. In: Grodin MA, Glanz LH, editors. Children as research subjects: science, ethics, and law. New York: Oxford University Press, 1994.
22. Stanford PD, Monte DA, Briggs FM, et al. Recruitment and retention of adolescent participants in HIV research: findings from the REACH (Reaching for Excellence in Adolescent Care and Health) project. *J Adolesc Health* 2003; 32: 192-203.
23. Fisher CB, Wallace SA. Through the community looking glass: reevaluating the ethical and policy implications of research on adolescent risk and psychopathology. *Ethics Behav* 2000; 10: 99-118.

(Received 5 Sep 2003, accepted 24 Dec 2003)



Youth health research ethics: time for a mature-minor clause? LA Sancı, SM Sawyer, PJ Weller, LM Bond, GC Patton. Medical Journal of Australia 180 (7), 336, 2004. 95. Confidential health care for adolescents: reconciling clinical evidence with family values. LA Sancı, SM Sawyer, DM Haller, GC Patton, MSL Kang. Medical Journal of Australia 183 (8), 410-414, 2005. (2005) Practical evidence in favour of mature-minor consent in primary care research. Med J Aust. 183(8):439. 21. Sancı, LA, et al. (2004) Youth health research ethics: Time for a mature-minor clause? Med J Aust. 180(7):336-8. 22. Toner, K, Schwartz, R. (2003) Why a teenager over age 14 should be able to consent, rather than merely assent, to participation as a human subject of research. The American Journal of Bioethics. 3(4):38-40. 23. Iltis, AS.