The time to recommend antenatal HIV screening for all pregnant women has arrived
A small number of Australian babies continue to acquire HIV infection unnecessarily

The World Health Organization estimates that each year worldwide about 700 000 children are infected with HIV. Most of these infections occur through mother-to-child transmission in resource-poor settings, predominantly in Africa and Asia. Mother-to-child transmission rates of 30% continue to occur, despite the fact that this form of transmission is almost entirely preventable with antiretroviral therapy and formula feeding. The barriers to implementation of prevention strategies include restricted access to antenatal testing, cost and limited availability of antiretroviral therapy, poor workforce resources, and political obstacles, such as those occurring in South Africa.

The outlook for babies born to HIV-positive mothers in high-income settings has improved dramatically. Most pregnant women with HIV infection in Western Europe or North America can expect an infection risk for their infant of less than 2%. Fewer than 2% of infected women are unaware of their status only after giving birth. Overall, almost half of Australian women were aware of their HIV-positive status. None of the mother’s status is known. From 1998 to 2002, 103 pregnant women with HIV infection in women and, when it does occur, to identify it before or during pregnancy. Unfortunately, national policies on antenatal screening are flawed. The Australian National Council on AIDS and Related Diseases recommends that “[p]regnant women found to be at higher risk of HIV should be encouraged to undergo HIV antibody screening”, but does not explain the term “higher”. HIV antibody testing is now recommended for all pregnant women in the Northern Territory, New South Wales and Queensland, but the national guidelines continue to be followed in South Australia, Western Australia and Victoria. However, the facts show that existing practice fails to identify a number of preventable cases of mother-to-child transmission.

The policy of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists is that HIV testing of pregnant women is the standard of care. Between 1995 and 1999, surveys indicated that rates of antenatal testing in Australia increased from 20% to 33%, and a recent survey suggests that the rate continues to increase slowly.

Routine testing has been opposed on several grounds. There are quite reasonable concerns that routine testing might result in a degree of coercion and the conduct of testing without proper pre- and post-test counselling. Clearly, any recommendation to offer testing to all pregnant women would need to be accompanied by systematic strengthening of counselling and consent procedures. However, the strongest argument against routine antenatal testing has been that, given the low prevalence of diagnosed HIV infection in pregnant women, it is unlikely to be cost-effective. Our recent report challenges this position.

We evaluated the cost-effectiveness of universal antenatal testing. We assumed that society would pay $39 000 per life-year gained, about twice the national average per-capita income. This value has been shown to result in efficient resource allocation. This is less than the cost per life-year gained for other screening programs currently under way in Australia, and is the valuation of a life-year gained implicitly by the Australian Pharmaceutical Benefits Advisory Committee. The costs of universal testing — about $1.8 million — are offset by economic benefits for a prevalence of undiagnosed HIV of 0.0044%, or 1 in 23 000. The true prevalence is unknown, but available data suggest it is of this order. The major costs taken into account in our model were the training and time required for counselling about testing, and the pathology costs. The major benefit is that a young life might be extended by 60 or 70 healthy years.

Many women in Australia with HIV infection were born overseas and are less likely to have comprehensive health insurance than those born here. Their access to antenatal care is thus limited. It is possible that women with undiagnosed HIV infection are currently over-represented among those missing the testing currently being done. If there were to be a uniform national approach to HIV testing, then education of the public, providers and clinic populations could be expected to improve the consent process.

In the United States and Europe, anonymous HIV serological surveys among women giving birth in the 1980s gave way to recommendations for routine testing. Such surveillance of women giving birth has been seen as politically difficult in Australia. Given that concerns about cost-effectiveness have largely been resolved, the time has now come for public health and political courage to make it national policy that HIV testing be recommended for all women receiving antenatal care.

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The recent controversy about cancer registries and patient privacy in the United Kingdom highlights the need for more debate about the governance of medical registries. For 40 years, identified data from UK patients with cancer have been transmitted to cancer registries without the patients’ express knowledge or consent. Although many benefits have flowed from analysis of these data, societal conventions have now changed, and questions are being asked in the UK and other countries, including Australia, about the privacy issues involved in the governance of medical registries in particular and medical research in general.

Medical registries were traditionally established by public health authorities to monitor trends in the incidence of conditions such as infectious diseases and cancer. However, registries have become increasingly important in monitoring outcomes after the implementation of disease-prevention and treatment programs. They are now vital to quality-improvement programs that assess the safety of new drugs and procedures, identify best clinical practice and compare healthcare systems. For example, the Australian Orthopaedic Association National Joint Replacement Register currently monitors the use and survivorship of artificial hip- and knee-replacement prostheses, while the Victorian State Trauma Registry (VSTR) was established largely to monitor the effects of changes to the state trauma system.

For registries to be effective, they must include all eligible participants so as to avoid biases that would affect the applicability and generalisability of results, and they must collect patient-specific data so as to adjust outcomes for risk and management factors. Further, in the absence of a unique national identification number, registries require name-based identification if participants are to be contacted for follow-up, or if registry data are to be validated against those held in other databases.

The need for identified data raises consent and privacy issues. Registries must be established and governed in compliance with both federal and state legislation on privacy. Current requirements of this legislation have necessitated the development of consent procedures that maintain the effectiveness of medical registries, while informing patients and protecting their personal medical information. However, obtaining patient consent before participation in broad-based registries is often impractical and results in poor enrolment rates. A more practical approach is to inform participants of their registration but to allow them to opt out of the registry. This approach resulted in the loss of fewer than 0.5% of eligible participants from the VSTR (unpublished data). This both complies with privacy legislation and achieves enrolment levels sufficient to maintain the scientific integrity of registries.

Privacy legislation also sets down the circumstances under which privacy principles may be waived. For example, a human research ethics committee (HREC) may determine that the public benefit in allowing access to identified data substantially outweighs individuals’ right to privacy. However, as broad-based registries collect identified data from many sources, they are currently required to seek approval from many individual HRECs. This process is both time-consuming and expensive. Further, many local HRECs have insufficient resources or expertise to evaluate the scientific merit of epidemiological research or to interpret privacy legislation, and consequently may reject legitimate research proposals.

Registries could be established by legislation that overrides privacy provisions, but this approach lacks flexibility. A more workable system is required for establishing and governing medical registries that both safeguards individual privacy and allows the registries to continue to provide the foundations for quality-improvement programs and epidemiological research.

No general guidelines for establishing and governing registries have been published, either in Australia or overseas. However, the National Health and Medical Research Council (NHMRC) has produced guidelines for genetic registers, which complement the National Privacy Principles with respect to the collection, use and disclosure of sensitive information, data quality and security.