Available at: http://www.health.gov.au/tga/docs/pdf/devregdr.pdf (accessed Jun 2003). ❑

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COMMENT: The letter by Collignon, Dreimanis and Beckingham about reuse of single-use medical devices (SUDs) in Australian hospitals again brings in to stark contrast the issue of safety and quality of medical devices and the pressing need to provide affordable services to the Australian public. Seven years ago, Collignon and colleagues showed an unacceptably high reuse of SUDs in Australia, especially in public healthcare institutions.[1] Since then, the National Health and Medical Research Council (NHMRC) has produced an expert panel report on these devices[2] and the Therapeutic Goods Administration has promulgated detailed device regulations.[3] There has been continued debate in both the scientific literature and lay press, and the United States Food and Drug Administration has had extensive comments published on this matter.[4,5]

Given the intensity of this debate, it is surprising that so few hospitals completed the questionnaire. It is also surprising that, despite the overall reduction in the reuse of SUDs, there has been no apparent reduction in their pencils.

They make a strong case for mandated reporting of resterilisation protocols for all single-use items. Informed consent must be a prerequisite. Tracking systems could well provide beneficial information on the safety and efficacy of procedures for particular devices. Furthermore, clinical audit would provide an early warning mechanism should resterilisation prove inadequate. These are among the main recommendations of the Report of the NHMRC Panel.[2]

Extensive regulations and controls have been applied to the use of biological products such as dura mater, heterograft and cardiac valves, among others. There is, however, reluctance to apply similar stringent controls to devices which may be contaminated by more pervasive but less obvious biological hazards.

There are only three options:

- cease this practice wherever a viable alternative is available until there is incontrovertible proof of the safety of reuse;
- mandate detailed protocols which include audit and surveillance mechanisms coupled with appropriate informed consent whenever SUDs are reused;[2] and
- develop a research and evidence base for improvements in design and material technology so that the "cost efficien-

An evaluation of a SAFE-style trachoma control program in central Australia

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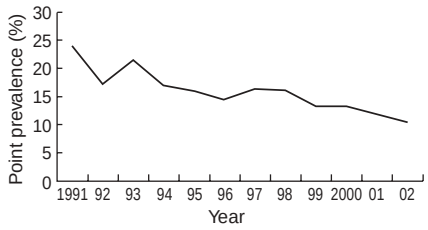
TO THE EDITOR: In their study of a SAFE-style trachoma control program (which included *Antibiotic* treatment, *Facial* cleanliness, and *Environmental* improvement, but not *Surgery*) in a remote Australian community, Ewald et al suggest that no systematic SAFE trachoma control program exists in Australia.[1]

In the Kimberley region of Western Australia, the Kimberley Public Health Unit (KPHU) has coordinated a trachoma control program since 1989. The World Health Organization SAFE strategy has been implemented since 1996, as described in the Kimberley regional trachoma control guidelines and a peer-reviewed publication.[2,3]

The trachoma control program in the Kimberley has been delivered by a variety of environmental health, health promotion, community and clinical health professionals employed by State and local governments, and by community-controlled and other non-government organisations. We believe a coordinated

Trachoma in Kimberley children



Point prevalence of follicular trachoma among children in the Kimberley region aged 5–15 years at annual trachoma screening, 1991–2002

regional approach is mandatory, because of the numerous organisations involved in program delivery.

The trachoma control program in the Kimberley continues to achieve good results. The prevalences of follicular trachoma during annual screening of school-aged children in the Kimberley have been published annually in the *KPHU Bulletin*.[4] Since 1996, in accordance with the WHO SAFE strategy, communities with trachoma prevalences of less than 5% were not screened in subsequent years and did not contribute to regional prevalence data. Thus, the observed decrease in trachoma prevalence between 1996 and 2001 is likely to be greater than that shown in the Box.

We believe the Kimberley region is well placed to achieve the WHO aim of eradicating blinding trachoma by 2020.[5] However, it is a concern that other regions of Australia with endemic trachoma infection may not conduct disease control activities in a coordinated manner because of lack of leadership in trachoma control or insufficient resources, or both. The community described by Ewald et al borders the Kimberley region and has strong cultural links with several Kimberley groups. The achievements in trachoma control in the Kimberley cannot be sustained in the long term without a nationally coordinated approach. We believe that it falls within the statutory responsibilities of State and Territory departments of health to ensure that environmental and clinical health services are coordinated to achieve trachoma control in Australia.

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TO THE EDITOR: The important article by Ewald et al shows that offering azithromycin treatment to 70% of a remote community may be inadequate to control hyperendemic trachoma, even when combined with a health promotion campaign.[1] Yet, significant short-term gains in similar locations have been achieved with as little as 20% of the population receiving azithromycin, where administration to children with trachoma and their household contacts was directly observed by health staff.[2]

In that study,[2] we reported a 6-month follicle resolution rate in schoolchildren of 72%, followed, however, by a return of trachoma prevalence towards baseline levels over 12 months. The critical factors for short-term success with azithromycin appear to be appropriate selection of cases and contacts, plus, where possible, directly observed therapy to minimise reinfection from untreated cases. Sustainability of initial reduction in trachoma prevalence is problematic, and issues of how extensively and how often to screen and/or treat need to be determined in the Australian context. Similar sustainability considerations have arisen in community scabies programs.[3]

Ewald et al are correct to identify population mobility as a major issue, with trachoma likely to be reintroduced by untreated children entering a community where a treatment program has occurred. Hence the need for a coordinated regional approach. However, a regional approach to trachoma control does not necessarily mean a uniform approach, and it is vital to tailor programs to suit the capacity of communities and their degree of commitment to labour-intensive treatment and health promotion.

Our study suggested that directly observed twice-yearly azithromycin therapy, with a health promotional component, is likely to be preferable to an annual program.[2] Mathematical modelling supports this more frequent dosing and, unlike in Africa, the cost of azithromycin should not be a constraining factor in Australia.[4]

Regardless of the strategy selected, if, after treatment, the prevalence remains hyperendemic (> 20%), then the outcomes from concurrent health promotion are compromised. Appropriately targeted and directly observed azithromycin therapy can help create conditions favourable for health promotion campaigns, which in turn prolong those gains by reducing trachoma transmission.[5] Major issues for trachoma control in Australia are (i) who to screen and treat (with directly observed azithromycin therapy); (ii) how often to screen and treat; (iii) how to plan trachoma programs as regional initiatives; and (iv) who will fund, coordinate and implement trachoma programs.

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IN REPLY: These letters reinforce a number of important points about control of trachoma (and other endemic infections) in Australia. The questions of whom and how often to treat need refining through Australian experience. Long-term control needs multifaceted, intersectoral collaboration to alter environmental and behavioural conditions

against disease transmission. Strategies should be sustained, regional (large as practicable); acknowledging, and guided by, Aboriginal kinship networks; and recommend observed drug treatment (which was negotiated for the final treatment in our study). A non-uniform approach could include more frequent treatment in hyperendemic communities, probably leading to less net use of antibiotic treatment.

Reports from the Kimberley Population Health Unit show a very mixed picture, with wide year-to-year fluctuations in prevalence in many communities. While hyperendemic communities remain in a region, the prevalence of trachoma may increase unnoticed in communities no longer screened because their prevalence has dropped below 5%. If not looked for, it is unlikely to be noticed. Further analysis, such as the graph provided by Johnson and Mak, is to be applauded in the context of a thorough analysis. When this happens, it will greatly strengthen the case for active trachoma control in other regions.

For trachoma prevention, and for many other reasons, we believe environmental health interventions are critical. These remain difficult to evaluate given the high mobility of people in Aboriginal communities. Reliable, long-term, regional environmental health and mobility data are needed as part of this broad issue. ❑

Gestational diabetes in Victoria in 1996: incidence, risk factors and outcomes

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TO THE EDITOR: Stone and colleagues must be complimented for their study of gestational diabetes mellitus (GDM) published recently in the Journal.[1] Although the study was comprehensive, in that it linked two pertinent records for 99.3% of the women delivering in Victoria in 1996, their analysis was necessarily limited to the parameters recorded in those two data sets.

Stone et al do not refer to relevant recent work from Toronto, Ontario,[2] and Sunshine, Victoria,[3] which has already determined the maternal risk factors for GDM: increasing age, racial origin, family history of diabetes mellitus, and pre-pregnancy body mass index. Data on the latter two of these four factors were specifically noted as not available to Stone's group, but could have been mentioned as *established* risk factors to consider in patient management.

The findings of Stone et al regarding age are similar to those previously reported. However, the relative risk for GDM in the Sunshine cohort increased from 25 years of age (odds ratio, 1.9; 95% CI, 1.3–2.7).[3] Recasting the all-Victorian data[1] with "< 25 years" as the reference datum would most likely produce a similarly significant result to that found in the Sunshine study.

Again, the Victorian data on racial origin are but the Sunshine data writ large. Stone and colleagues had to choose a reference datum for this parameter, but have not avoided a problem that bedevils all such work in the "New World": there is as yet no definitive Australian reference datum available for racial origin. For example, the designation "Australian" may be used, but parents who are themselves second or third generation Australian-born may have, say, pure Maltese ancestry, giving them a high risk of GDM and thus distorting the reference datum. I have argued this case in more detail elsewhere,[4] and took measures to circumvent the problem in the Sunshine study.[3]

Among their findings, Stone et al confirm that there is a significantly increased incidence of macrosomia in GDM-affected infants. I agree. Their work is unquestionably the definitive statement of Victoria's GDM-related macrosomia status (as at 1996), but it lacks one vital ingredient: it defines macrosomia, but does not cite the source of the data used as the study's benchmark. To enable comparisons with their work in future years, could we please have that benchmark referenced so that others may use it too?

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IN REPLY: We thank Davey for his comments, which provide us with the opportunity to highlight the benefits and limitations of reports using population-based data. The value of population-based data is that the reported incidence, risk factors and outcomes reflect current practice in the whole of Victoria and are not subject to bias introduced by local referral patterns or clinical practice. Our study[1] shows that, in addition to established risk factors for gestational diabetes mellitus (GDM), the reported incidence varies according to hospital size and geographic location, demonstrating the type of bias that can occur. In addition, the large number of subjects in our study (over 60 000) enables more accurate analysis of subgroups.

A limitation, already highlighted in our discussion, is that we are restricted to the parameters available within the data sources used. Davey and Hamblin's article[2] demonstrates the difficulty of obtaining individual patient data on body mass index, racial grouping, and family history of diabetes. Even working at the hospital level, they had to extrapolate from population-level data to derive an estimate of these risk factors among the control subjects.[2] Given that their study population is a subgroup of ours,[1] it is no surprise that the two studies showed similar results.

An important implication for providers of health services is that, with increases in the age at which mothers give birth and in the number of births to