affected are primigravid teenagers living far from hospital and relying on a traditional birth attendant who is unable to diagnose cephalopelvic disproportion.

When labour is prolonged and delivery delayed, herbal preparations with oxytocic and analgesic components are given orally by traditional birth attendants or inserted into the vagina, leading to uterine hypertonia, ruptured uterus, and fetal death.⁴ This is less frequent in multiparous women, where cephalopelvic disproportion is rare and labour proceeds quite quickly. Mortality was similar in booked and unbooked patients because many women attempted to deliver at home with traditional midwives, whose hazardous practices can lead to uterine rupture, sepsis, and shock.

The health education of rural people, the training and supervision of traditional birth attendants, and availability of transport may reduce the incidence of uterine rupture in remote areas. Particular attention to

regulation of training and practices of traditional birth attendants is required. Maternal prognosis may improve if women marry later and if family planning and antenatal and delivery care are available near women's homes and are affordable.

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Effect of inadvertent intradermal administration of high dose percutaneous BCG vaccine

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In the United Kingdom it is recommended that all children receive BCG vaccination to prevent development of tuberculosis.^{1,2} The standard route of administration is intradermal. In neonates a 10 times more potent percutaneous preparation is used, a small volume being injected to a depth of 2 mm with a modified Heaf gun. The two preparations have similar packaging and labelling and so may easily be confused.³ We report the outcome of inadvertent intradermal administration of the stronger percutaneous product and define the relation between the development of skin lesions and the dose of vaccine.

Subjects, methods, and results

Thirty two school children aged 11-14 received 0.1 ml of BCG vaccine intradermally at a routine school immunisation session. Nineteen received the preparation for percutaneous administration, which contains 50-250 million colony forming units per ml. Thirteen received the correct preparation, which contains 8-26 million colony forming units per ml (Evans Medical, Leatherhead, England). The error occurred because of the similar packaging and labelling of the two products. All parents and children were informed of the error and all agreed to a period of close observation. All observations were performed by the same observer (MMM). The study was not blind since a component of the consultation was to discuss any concerns with children and parents.

The area of induration increased progressively and was significantly greater in the group who had received the percutaneous vaccine intradermally (fig 1). Mean diameters were 0.96 cm (range 0.8-1.3, $P<0.02$ by Student's *t* test) at two weeks, 1.15 cm (0.9-1.5, $P<0.01$) at three weeks, and 1.23 cm (1.0-1.6, $P<0.01$) at six weeks; the mean diameter had decreased to 0.91 (0.6-2.2) cm by 15 weeks. By contrast, the mean diameter of the induration in those receiving the correct intradermal vaccine was 0.83 cm (0.7-0.9) at two weeks, 0.83 cm (0.6-1.1) at three weeks, and 0.77 cm (0.5-1.1) at six weeks.

The sequence of symptoms was itchiness, soreness, and discharge. These were similar in both groups, although discharge was more common at six weeks in the group given the percutaneous vaccine (nine out of

Fig 1—Mean (SE) diameters of skin lesions after intradermal BCG vaccine and percutaneous vaccine given intradermally

15 children v one out of 10 children). Ten of the 15 children given the percutaneous vaccine were examined at 28 weeks. They complained of no symptoms, and mature scars had formed (mean diameter 1.2 cm (range 0.8-2.0)).

Comment

This study emphasises the requirement for clear packaging and labelling of drugs. If subjects inadvertently receive the percutaneous BCG vaccine intradermally they may, however, be reassured that the lesion will resolve over a few months without treatment. Although the lesions were sometimes painful, the induration was larger, and discharge was more common after six weeks when the high dose preparation was given intradermally. The lesions had started to resolve at 15 weeks.

The results also suggest a clear dose-response relation in vivo between the size of the inflammatory response and the dose of vaccine. We do not know whether there is a relation between the size of the inflammatory response and the protective effect of BCG or the size of the scar.

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Conflict of interest: None.

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