



From questionnaires sent out, her province had identified 1 300 health care workers who potentially need dispensing licences but this number was being 'carefully scrutinised', she added.

Both Van Zeil and Putter refuted claims made by some private sector doctors that the national health department requirements for the licensing examination would disrupt State health care delivery. Distance learning and on-the-job learning were possible and the 300 hours could be fitted in over 2 - 6 months, the pair said.

Asked about private providers contracted to the State, Van Zeil said it was a 'somewhat grey area with some uncertainty'.

'It appears that those working from a

private facility will not only need a dispensing license but a permit as well,' she said.

The law would most affect State family planning clinics and non-governmental organisations working with provinces.

Thompson was awaiting legal opinion from the national health department around what was required for private practitioners, community-based organisations and private family planning clinics that rendered services on the province's behalf.

'If we can designate them as providers then it's 1 July next year, but if not then they have to comply immediately,' she said.

Asked how she saw private practitioners responding to the new

dispensing laws, Putter said much would depend on the outcome of the legal challenge to what dispensers saw as economically unsustainable new maximum dispensing fees.

'If the pricing regulations stand, then I think it may well not be so attractive to dispense anymore,' she said.

Putter said the new laws meant that the English maxim of 'the King can do no wrong', that the State had applied to itself in this area of health care, would be buried forever from 1 July 2005.

Thompson said the Western Cape was 'trying to model this for other provinces - national will try and help them to replicate what is being done here'.

Chris Bateman

## WINNING BACK MOTHER'S MAGICAL MILK

Within 6 years, HIV-positive South African mothers may be able to confidently and safely breastfeed their HIV-negative infants to natural weaning without transmitting the virus, thus significantly reducing the overall risks of infant mortality.

That is the goal of an ambitious and groundbreaking NIH-funded research project initiated by Professor Jerry Coovadia, Victor Diatz Professor of HIV/AIDS Research at the University of KwaZulu-Natal's Nelson Mandela Medical School.

Based on the likelihood of developing a single prophylactic injection to the infant every 2 - 3 weeks, the new methodology promises to boost the already impressive drop in HIV-positive infant prevalence brought about by the current expanding roll-out of antiretroviral PMTCT drugs.

Tackling HIV breastfeeding transmission head-on instead of becoming mired in the often emotive and contentious 'Third-World-formula-feeding' debate, Coovadia and his

associates at Harvard and in Austria are convinced they are on the most scientifically valid track.

'We all lived through the period when formula feeding was quite a disastrous practice and indeed, even now still is. Breastfeeding simply tops the list of interventions available for preventing some of those 11 million deaths of children under 5 globally each year,' said Coovadia.

***One of the most underrated social dangers of the AIDS pandemic in developing countries is that the risk currently inherent in breastfeeding may cause it to go 'out of fashion', even among HIV-negative mothers.***

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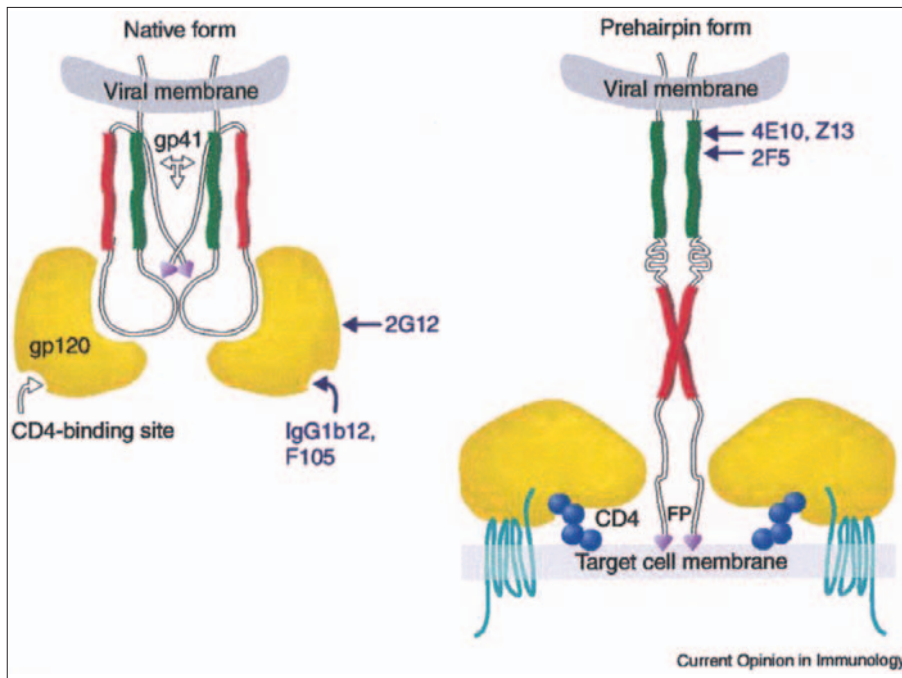


Professor Jerry Coovadia

among HIV-negative mothers. This would inevitably result in a dramatic increase in the two major infant killers, diarrhoea and pneumonia.

Coovadia cites research showing that breastfeeding can reduce all-cause mortality of children under 5 years old by 13% in high HIV-prevalence areas and by 15% in low HIV-prevalence areas.

'Breastfeeding is still the best option - almost all the modelling exercises I've seen come to the same conclusion,' he says.



Highly respected international colleagues of his had established the precise levels of infant mortality below which it was safe to formula feed and above which it was dangerous to formula feed. Infant mortality remained one of the best-known markers for socio-economic conditions.

Coovadia said his idea of using a prophylactic injection was born of reading the work of Professor Ruth Ruprecht at the Dana-Farber Cancer Institute of Harvard University more than 2 years ago.

Ruprecht created a model of neonatal Simian immune virus (SIV) transmission and used monoclonal antibodies to prevent transmission. Using an SIV coated with human envelope proteins, she created a surrogate response to the human virus – with remarkable success.

Coovadia immediately saw the potential for reducing mother-to-child breastfeeding transmission and, with Ruprecht's collaboration, began writing up a proposal for an NIH grant. The NIH was initially concerned about the likelihood of antibodies being produced but was eventually convinced that the idea had serious potential.

Together with his local colleague, Deseree Archary, a private Austrian company that manufactures human monoclonal antibodies, and experts in pharmacotherapeutics and other related fields, Coovadia's international team is about to embark on phase 1 of their trials.

'We have just over R1 million to find out the safety and tolerance levels and ascertain the dose in a sample of 30 - 40 HIV-negative infants born of HIV-positive mothers,' he revealed. Once this has been established, a much larger sample (many hundreds) of HIV-negative infants born of HIV-positive mothers will be injected (phase 3 trials).

'We'll have to plan very carefully – it's quite a dilemma because what would be our control group?' Coovadia said, adding that the best-proven treatment for a developing country would have to be used. He said a United States research group had wanted to use Ruprecht's work to treat HIV-infected babies but had not got their project off the ground.

'We're hoping that in the longer term it will have a role to play in HIV vaccines. It's a bit like a hepatitis B vaccine, where you give both an active vaccine and combine it with a passive antibody.'

Coovadia said 'huge advances' have been made in the prevention of HIV transmission from mother to child with figures down from highs of between 30% and 35% to just 1% or 2%.

'But the one thing we do not have a good answer to is breastfeeding. The big unanswered question is breastfeeding transmission. We know that if you avoid it altogether you come to a zero sum transmission, but formula feeding is not the answer in Third-World countries. We have to find an alternative, and at present there is not one.'

He explained that even if the current nevirapine prophylaxis trials for breastfeeding transmission proved successful, the 'hassle' of infants taking nevirapine daily, plus resistance and side-effects, made a far less frequent single injection a very attractive option.

Study paediatricians would be the first line of defense against any potential problems, followed by a local safety review, the NIH Statistics and Safety Division, and then the Data Safety Monitoring Committee. Safety trials had already been successfully concluded in adults, using a combination of three antibodies.

Coovadia's team expected to receive the final NIH go-ahead by the end of July, followed by the local ethics committee executive decision a fortnight later. The biggest delay could be the Medicines Control Council – that could take 3 months or longer, he said. Asked how long it would take for the injection to be finally proved effective and made available to the public, Coovadia replied, 'Five to six years, if all goes well'.

Two years ago there were an estimated 80 000 South African infants being infected annually with the HIV virus and modellers believe that a reasonable current annual estimate (given the PMTCT programme) is about half this.

Being able to eliminate breastfeeding transmission will help transform the paradigm even further.

**Chris Bateman**