



International Newsletter

July 2005

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Condom testing training for Nigerian Team

A team of five Nigerians recently completed an intensive eight-day program of condom testing training at Enersol Consulting Engineers' laboratory in Annandale, Sydney.

The emphasis of the training course was on Condom Inflation Testing, Enersol Inflation Software and the Enersol Classic Inflation Tester.

The students also worked with the Enersol manual and automatic dimensions testers, dry and wet package integrity testers and visual and electronic freedom from holes testers.

The students were sponsored by Population Services International and represented the Society for Family Health Nigeria, AIDS/STI Control Programme of the Federal Ministry of Health Nigeria and NAFDAC, also part of the Federal Ministry of Health Nigeria.

The students were Solomon Segun Ojajuni, Joseph Olugbenga Olutayo, Matilda A.O John, Michael Afolabi Adeyemo, and Cordelia Ebele Nwabunike.

Their tutors were all members of Enersol's staff. John Gerofi - Managing Director, Gergaynia Shelley - General Manager, Grace Iskander - Laboratory Manager, Hung Truong - Laboratory Supervisor, Qing Tan - Engineer and Lisa



Students from Nigeria with members of the Enersol staff outside the entrance to the Enersol Laboratory in Annandale, Sydney.

(L-R) Hung, Michael, Grace, Cordelia, Solomon, Joseph, Lisa, Qing and Matilda Henretty - Administration and Information Technology.

Apart from intense practical condom inflation testing, Enersol software training and maintenance of the inflation machine, the students also covered; the ISO 4074 condom standard and the WHO specification, ISO 2859-1 sampling standard, practical random sampling, condom manufacturing, Windows XP and PC basics, good laboratory practice including report writing, package integrity testing, and calibration of inflation testing equipment.

At the end of the course the students were presented with a trainee manual and certificate of completion.

Dr Gerofi said that while the course had been designed to cover the specific requirements of the sponsor and the participants, Enersol would be happy to run future courses on any topic associated with Enersol's business.

• *For more information about similar courses please contact Enersol*

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International Congress on AIDS in Asia and the Pacific

‘More effort could save six million’

THE vast majority of countries in Asia and the Pacific were doing too little on AIDS and the numbers affected could rise by 12 million in five years without stronger political commitment and a focus on reaching groups most at risk, according to Dr Peter Piot, Executive Director of UNAIDS.

He told the International Congress on AIDS in Asia and the Pacific in Kobe, Japan, that large-scale HIV-prevention efforts linked to treatment could save six million Asians from infection 2010.

Dr Piot said that at the end of 2003 HIV prevention programmes were reaching “just one of every five sex workers, one of every 20 injecting drug users and one of every 50 men who have sex with men.”

A UNAIDS report released before the start of the conference said that while funding to fight AIDS in the region could rise to about \$1.6 billion by 2007, it would fall far short of the estimated \$5 billion that would be needed.

The report said the situation was complicated by cultural and political differences and the need to promote the use of condoms and education and empower women, who make up more than half the new HIV infections worldwide.

It also called on world leaders to make tackling AIDS in Asia and the Pacific a global priority as with AIDS in Africa.

An estimated 8.2 million people in Asia and the Pacific—including 5.1 million in India—are living with HIV; 1.2 million were infected last year. Just 15 per cent of those needing antiretroviral drugs receive them, though the number had risen three-fold in the past 12 months.

Dr Piot said that epidemics, often driven by drug use and paid sex, were growing fastest in Indonesia, Nepal, Vietnam and China. While Cambodia had joined Thailand in reducing HIV

prevalence, the region’s highest adult prevalence, 1.7 per cent, was in Papua New Guinea.

Dr Piot said that low-prevalence countries had an opportunity to avoid higher infection rates but should not be complacent. Each country needed to implement a strategy based on its own social and political realities and an understanding of how the disease is spreading there.

He cited China’s recent intensification of AIDS prevention and Malaysia’s new harm reduction policy as examples of the political will needed throughout the region.

Researchers, organizations involved in fighting AIDS and advocates for people living with HIV shared their experiences and many breakout sessions.

The United Nations Population Fund (UNFPA), organized a forum on scaling up HIV prevention for young people, featuring peer educators from China and

Kyrgyzstan and programme managers from India, Mongolia and Nepal.

In another session, Dr. Wasim Zaman, Director of UNFPA’s Country Technical Services Team (CST) for South and West Asia presented examples showing the importance of involving young people in designing programmes aimed at youth.

The International Planned Parenthood Federation and UNFPA hosted a discussion among service providers and policy makers on the integration of HIV interventions, including voluntary testing and counselling, in reproductive health programmes.

At the closing session, Dr. J.V.R. Prasado Rao, Director of UNAIDS Regional Support Team for Asia and the Pacific, reiterated the importance of reaching vulnerable populations—sex workers, injecting drug users, young people and migrant workers.

Letter to the Editor

Condom testing and the prevailing wisdom

IN OUR last issue Enersol’s Managing Director, Dr John Gerofi, discussed the history and the pros and cons of pre- and post-shipment condom testing.

He wrote that the prevailing wisdom now “is for globalization, harmonisation, certification and mutual recognition and concluded that it was an “unfortunate fact that for the present, some form of independent batch-by-batch testing remains necessary to maintain quality.”

The following letter in response to that article has been received from Ms Gugu N. Mahlangu, Acting Director, Laboratory Services for the Medicines Control Authority of Zimbabwe. Ms Mahlangu writes:

Dear John Gerofi,

I read your article on pre and post shipment testing of condoms in the May issue of the Enersol Newsletter. My impression was that you were suggesting that there were too many laboratories doing post-shipment testing, that this was contrary to globalisation, harmonisation, etc?

For those of us in Sub-Saharan Africa, whose populations have been ravaged by HIV/AIDS, post-shipment testing is the only sure way of ensuring condoms of reasonable quality. There is need to protect our populations against potentially unscrupulous dealers.

We have been requested to permit the shipping out of failed condoms.

For what purpose, one wonders? It is difficult to see the application of only pre-shipment testing as long as condoms remain the main defense against the transmission of HIV.

Regards

Gugu N Mahlangu (address supplied)

- Letters to the Enersol International Newsletter are welcome. Please keep your contributions as short as possible and email, fax or mail them to the address below.

‘ Culture wars’ create a condom impasse

THE American Senate’s inability to confirm President Bush’s nominee Lester Crawford as Commissioner of the Food and Drug Administration is being widely quoted in the U.S. as an example of kind of impasse the culture wars there can create.

Mr Crawford’s appointment is being blocked in the Senate by Democrat Senators Hillary Clinton and Patty Hill until the FDA approves the sale without prescription of the emergency contraceptive known as Plan B.

It has also been blocked indefinitely by Republican Senator Tom Coburn, who wants the FDA to require that all condoms are sold with a "medically accurate" label stating that they are not guaranteed to prevent all sexually transmitted diseases.

Even if the FDA does approve the sale of Plan B, there are indications that a number of other Republican Senators may then place a hold on Mr Crawford’s nomination pending the drug’s withdrawal.

The *Washington Post*, in a story headlined **Catch 22**, said the FDA had in practice become a symbol either of everything that’s wrong with big, slow, overprotective government or, alternatively, the insidious influence of corporate lobbyists on regulators.

Now, it added, it had found itself at the centre of the national debate about abortion and birth control as well.

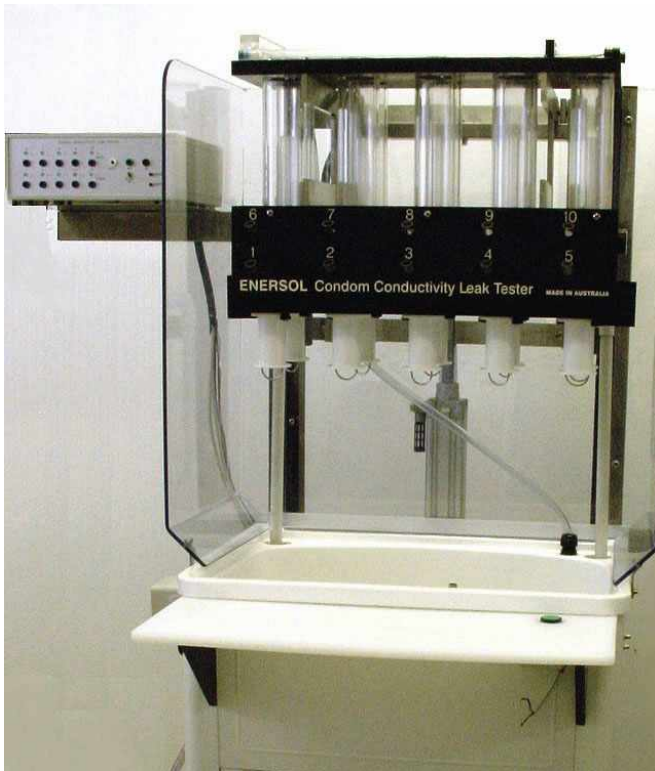
The Post said that it would like the agency to base its decisions as much as possible on science and not politics.

But, it added, making the confirmation of the FDA Commissioner into a contentious partisan issue is not the way to make that happen.

Currently the FDA requires condom boxes and packets to state: "If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.

AIDS expert

OLIVE Shisana has been appointed Chief Executive of the South African Human Sciences Research Council – the first black and the first woman to hold the post. Ms Shisana has built an inclusive HIV/Aids programme at the council over the past four years. A social scientist, she returned from exile in the US in 1991 to take a series of jobs that would help transform South Africa’s health system before becoming director-general of health. She also worked as director of community health at the World Health Organisation.



Another leaks tester from Enersol

The publication of ISO 4074:2002 increased interest in the use of conductivity testing for holes in condoms. As a result, Enersol developed the ultra-fast conductivity tester described in our May 2005 newsletter. Now, Enersol has up-graded its older 10-head conductivity leaks tester design to make it easier and more convenient to use.

The new model uses an air cylinder to move the test heads up and down. The operator loads the condoms and presses a button. The machine fills the condoms, lowers the test heads into the water, waits the required 10 seconds, measures and displays the result, and then raises the test heads. The operator can perform the tests sitting down. This new machine is highly regarded by Enersol’s own operators.

Pope on ‘ contraception mentality’

POPE Benedict XVI has told the bishops of five of the African nations most affected by HIV/AIDS that the church should continue teaching chastity and abstinence as the most effective way to fight the “cruel epidemic” and that the use of condoms contributed to a breakdown in sexual morality. He said in a Vatican address to the bishops of five of the African nations most affected by the pandemic - South Africa, Botswana, Swaziland, Namibia and Lesotho - that it was of great concern “that the fabric of African life, its very source of hope and stability, is threatened by divorce, abortion, prostitution, human trafficking and a contraception mentality.”

His remarks attracted criticism from experts who insist that the use of condoms is a well-proven method of avoiding infection and the spread of the HIV virus. Sub-Saharan Africa accounts for more than 60 per cent of the 40 million people in the world currently infected with AIDS. The UN estimates that without new initiatives and greater access to drugs, more than 80 million Africans may die from Aids by 2025 and HIV infections could reach 10 per cent of the continent’s population.

Low-allergy condoms and gloves

TWO breakthroughs in the search for methods of producing low allergy or allergen-free latex for condoms and gloves have been recently announced.

In London Regent Medical Ltd said that it had developed a powder-free surgical glove offering a reduced risk of latex allergy problems.

In Australia chemists working with the Malaysian rubber industry said they had developed a process for making low-allergen condoms and surgical gloves.

The Australian chemists said the low-allergen modified latex was just as strong, and provides as good a barrier, as unmodified latex. They published their results in the latest issue of the *Australian Journal of Chemistry*.

Between 10 and 20 per cent of health workers who rely on surgical gloves develop sensitivities to the natural rubber they are made from. Synthetic substitutes are generally not as strong and can tear more easily.

Synthetic polymer

Rather than mimic naturally occurring latex, the chemists at the University of Sydney's Key Centre for Polymer Colloids have been trying to remove the allergy-causing proteins and to encourage a strong

latex film to form. In their paper they say the new process involves grafting a synthetic polymer onto the molecules of rubber to displace the allergy-causing proteins. The presence of the polymer, known as polydimethylaminoethyl methacrylate or poly(DMAEMA) for short, and the absence of the proteins, also allows the latex to form a film.

An *ABC Science Online* report said that the whole process takes place at room temperature in less than an hour, and naturally occurring latex made into films by the dipping method had an allergen content of more than 200 units per millilitre, compared to less than 1 unit per millilitre with the modified latex.

Values comparable

The *Science Online* report said that when the researchers tested the properties of the modified latex, they found its barrier properties, tensile strength and how far it stretched before breaking were comparable to unmodified natural latex.

The chemists say in their *Australian Journal of Chemistry* abstract that the free radical polymerization of dimethylaminoethyl methacrylate (DMAEMA) on the surface of particles in natural rubber latex (NRL) used an iron(II)/tetraethylenepentamine (TEPA) redox couple initiation system, which results in significant grafting of poly(DMAEMA) to the surface of the particles.

Because poly(DMAEMA) functions as an electrosteric stabilizer, this leads to increased colloidal stability, which suggests that the proteins which normally provide the colloidal stability in NRL can be displaced.

This opens the way to preparing barrier products of low allergenicity, because the allergic response from NRL products arises from the proteins.

Dipped and cast films were prepared from the modified NRL and were shown to be of low allergenicity using the IgE-ELISA inhibition assay. Vulcanized films prepared from the modified latex were also found to be of low allergenicity.

In London, Regent Medical Ltd said that its Eclipse powder-free glove, which uses de-proteinised natural rubber latex, can be marketed at a price lower than most non-latex gloves.

It said the new glove is 20 per cent thinner than the standard Biogel glove and 30 per cent softer than the Biogel SuperSensitive glove.

Significant step

Regent described the Eclipse powder-free glove as a significant step forward in surgical glove technology and said it would change the way people think about the issues surrounding latex gloves. De-proteinised natural rubber latex (DPNRL) is natural rubber latex which has had the protein removed in a patented enzyme-based process.

Latex gloves have been the subject of court actions in the U.S. In the UK health trusts have been advised by the Health and Safety Executive to reduce their purchases and use of latex gloves.

Critics say American AIDS policy is a failure

MORE than a million Americans are living with HIV/AIDS according to the U.S. National Centres for Disease Control in a report critics said reflected both a victory and a failure in combating the disease. U.S. Government health officials had pledged to "break the back" of the AIDS epidemic by 2005 by cutting in half the estimated 40,000 new HIV infections that have occurred every year since the 1990s. It is the first time that the one million mark has been passed in the U.S. since the height of the AIDS epidemic in the 1980s.

Health officials said the prevention failure in part has come from AIDS victims living longer because of better treatment and an abandonment of safe sex practices by gay and bisexual men who account for almost half of HIV cases. The majority of the others infected are high-risk heterosexuals and injection drug users. More than a quarter of the people infected with HIV do not know they carry the virus, while recent outbreaks of HIV and other sexually transmitted diseases in major cities suggest that new infections may be as high as 60,000 cases a year.

Advocacy groups argued that the U.S. Government provided insufficient funds for public awareness campaigns and other programs. One critic said: "The U.S. has had a clear failure in HIV prevention, . . . experts have focused too much on whether it's better to promote abstinence or condom use to stop the spread of the virus."