

## CORRESPONDENCE

### **Noble intentions can be dangerous**

A long time ago, I had a T shirt, on the front of which was written: "I took the least travelled path and look where the hell I am!" Dr Binayak Sen's case is no different. Dr Sen, who languished in jail for nearly two years (for a crime which is yet to be established), has taught me some things both about being an Indian and being a doctor. First, in India you cannot be an atheist because if the mighty state machinery wants to keep you behind bars and destroy your peace and well being: only God can save you. So you do need to believe in the almighty! Second, if you are a doctor, be very careful if you intend to practise in the under-served areas of the country. Many young doctors have such noble ideas but they should learn from Dr Sen's experience. Many of us think of going to a downtrodden rural area to serve the ill and the poor. Dr Binayak Sen had the courage to do this, and look where he ended up.

I would like to congratulate the Chhattisgarh government for accomplishing what not many a despot can even think of doing, and that is to demoralise a whole generation of Indians like me through the methodical use of executive and judicial powers. It is even more frightening that the ruling BJP intends to use the so-called "Chhattisgarh model" across the country if it is voted to power in the current elections. I earnestly hope that their dream (and my nightmare) remains unfulfilled so that we do not see many more Binayak Sens languishing behind bars.

**Shah Alam Khan**, Department of Orthopaedics, All India Institute of Medical Sciences, Ansari Nagar, New Delhi 110029 INDIA e-mail: shahalamkhan@rediffmail.com

### **Advocating the benefits of male circumcision: are doctors well informed?**

Madhivanan and Krupp rightly point out the health benefits of male circumcision, and this continues to get substantiated through newer reported studies (1-3). The authors conclude that given the reluctance of the government and health authorities to take up male circumcision as a public health prevention strategy, the onus should be on physicians to explain to their patients the usefulness and risks/benefits of the procedure according to current medical knowledge so that patients can make informed choices.

While I agree with this formulation, there are a couple of relevant concerns. One is the fact that this would probably be useful for middle class and upper class patients who have the resources to undergo the procedure in the absence of provision in the public sector (which most poor patients approach for surgical procedures). Though it is true that male circumcision does not cost a lot to perform, it could still be a significant cost for those who are economically disadvantaged.

The second issue is a question about the knowledge of recent evidence about benefits of male circumcision among physicians in India. It is doubtful if most Indian physicians know about it. Medical textbooks are often many years out of date on current medical progress. There is no established system in India for sharing medical updates. Continuing medical education courses and conferences do not reach a large number of physicians and in any case these are often dominated and supported by pharmaceutical promotions – and the pharmaceutical industry (other than perhaps medical device companies) has nothing to gain by promoting the procedure. Medical associations are a possibility, but these have limited memberships.

Information of significance to patients keeps emerging on a regular basis. For example, recent published research has shown that advanced paternal age is associated with neuro-developmental disorders, dyslexia and reduced intelligence in offspring; that extra vitamin E ingestion has no benefit, and could even be harmful; that consistent use of statins is associated with a lower risk for all-cause mortality among patients with and without coronary heart disease (4-6). Most physicians remain unaware of these kinds of recent advances.

We need to devise better systems of regularly updating the medical knowledge of physicians in India to ensure that they can provide patients with information of importance to them, like the utility of male circumcision, thus acting in their patients' best interests.

**Anant Bhan**, Independent Researcher, Bioethics and Public Health, Flat 405, Building A-11, Planet Millennium, Aundh Camp, Pune 411027, INDIA e-mail: anantbhan@gmail.com

### **References**

1. Madhivanan P, Krupp K. Doesn't the public have the right to know that male circumcision protects against HIV? Indian J Med Ethics. 2009 Jan-Mar; 6 (1): 5-6.
2. Tobian AA, Serwadda D, Quinn TC et al. Male circumcision for the prevention of HSV-2 and HPV infections and syphilis. N Engl J Med. 2009 Mar 26;360(13):1298-309.
3. Golden MR, Wasserheit JN. Prevention of viral sexually transmitted infections—foreskin at the forefront. N Engl J Med. 2009 Mar 26;360 (13):1349-51.
4. Saha S, Barnett AG, Foldi C et al. Advanced paternal age is associated with impaired neurocognitive outcomes during infancy and childhood. PLoS Med. 2009 Mar 10;6(3):e40.
5. Brody JE. Extra vitamin e: no benefit, maybe harm New York Times. 2009 Mar 26 [cited 2009 Apr 6]. Available from <http://www.nytimes.com/2009/03/24/health/24brod.html>
6. Shalev V, Chodick G, Silber H. Continuation of statin treatment and all-cause mortality: a population-based cohort study. Arch Intern Med. 2009 Feb 9; 169(3):260-8.

### **Counsellors are human**

I just read the review of our film *68 Pages* (1) and would like to thank you for considering the film to be reviewed in the esteemed journal and your positive comments on the film. I

would like to respond to a couple of questions raised by the reviewer.

1. Nowhere does *68 Pages* claim that the epidemic of HIV is not affecting the common man. Every communication around HIV in the country is targeted at general populations. As this film originated within marginalised communities we felt that a film could be done that would bring marginalised communities on centre stage. In fact, your referring to them as stereotypical groups is at best ridiculing them and denying them space.
2. We have a panel of experts under whose guidance the film was developed and we were informed that it would not be considered against ethical practice that in extreme situations the counsellor can touch the person being counselled; the touch can be from shoulder to elbow of the counselee to comfort him or her.
3. Kiran is not Mansi's "counselee" but his friend and they work together in the same organisation. Kiran takes a HIV test every three months. When his report tests positive Mansi is faced with the dilemma of having to differentiate between the personal and professional. Therein lies her failure as a person and a professional. She faces the consequence of her human failure as Kiran disappears without a trace. I think it was clearly expressed in the film that she could not handle the situation. The question is asked: are counsellors not human beings? Can they not fail?
4. The film is seen from the 68 pages of a counsellor's personal diary (to which she refers as her "worry tree" and the place where she vents all her concerns) so that audiences get to learn of her personal views on her professional conduct and the people with whom she interacts in the course of her work. There are some people whom she cannot leave behind in the counselling room and they come home with her and become part of her diary. Nowhere has the film indicated that she is getting personal with Umrao, Nishit or Paayal, or that she tells them how she feels about them. The scene with all four characters coming together to say their goodbyes when Mansi leaves for the USA was a bit of creative licence that we took in order to close the film on a positive note.

Counsellors are human beings. If they are not sensitive human beings, they cannot be good counsellors. This is my experience in my work in the Humsafar Trust that has connected with more than 60,000 gay men and transgenders in the last decade. Even today I have not become immune to the suffering around me. The day I become immune to all the suffering is the day I will stop working with human beings.

**Vivek Anand**, Chief Executive, The Humsafar Trust Centre for Excellence 3rd Floor, Transit Building, Old Vakola BMC Market, Nehru Road, Santacruz (East), Mumbai 400055 INDIA email: [avivekr@gmail.com](mailto:avivekr@gmail.com)

#### Reference

1. Chandrasekhar A. Where do you draw the line? *Indian J Med Ethics*. 2009 Apr-Jun; 7(2): 113.

#### "Show me the medicines"

I was doing my internship those days. Fresh from medical school, I was extremely enthusiastic and keen to apply the textbook knowledge to real-life situations. There were so many things to learn. I enjoyed working with a particular consultant who was always up to date with his specialty. He appeared to be very kind and was in every way, a role model. I very much liked his way of explaining prescriptions to his patients. In addition, he would always ask patients or relatives to get back to him and show him the medicines they purchased and then take the opportunity to reinforce the dosages and other details before concluding the consultation. He would get very upset if the patients did not show him the medicines. I would also copy this style in his absence, putting that extra bit of effort in a very busy hospital out-patient department. The stethoscope, the caring hand, the admonition if the medicines were not shown to me, and the opportunity to pretend to be wise, knowledgeable and in command a perfect setting for a new intern.

One day, I learnt that this consultant had a lucrative deal with the chemist next to the hospital. Because patients were asked to show the medicines they purchased, they would obviously buy from the nearby chemist shop rather than from shops nearer to their homes or elsewhere in order to avoid travelling all the distance again. I felt cheated like never before. The patients, I guess, would never know.

**Abhijit M Bal**, Consultant, Department of Medical Microbiology, Crosshouse Hospital, NHS Ayrshire and Arran, Scotland, UK email: [abhijit.bal@nhs.net](mailto:abhijit.bal@nhs.net)

#### Antibacterial products: myth or reality?

The media plays a pivotal role in creating public awareness about every aspect of life, including healthcare. This has revolutionised the lifestyles of even those who are not literate. The other side of the story is, however, not so bright. Advertising campaigns of personal hygiene products like soap is one example. The promotion of antibacterial products as being a guard against diseases like diarrhoea is actually misleading.

The escalating load of diseases has created concerns in the general population about preventive measures. Manufacturers have been thrusting antibacterial agents into soaps and other personal hygiene products for several decades but their use has markedly increased in the last eight to ten years (1).

The main purpose of this article is to highlight certain realities in this regard. The involvement of doctors in the publicity campaigns of these products is another area of concern. Most physicians do not know that they are being used to sell the products. But if they do know and they are deliberately associating themselves with the campaign for financial benefits, it is highly unethical and cannot be justified in any way.

The antibacterial agents in these products, particularly soaps, include chemical substances like chloroxylenol, hexachlorophene, triclocarbon and, most commonly, triclosan.

Triclosan is a non-agricultural pesticide used in soaps, toothpastes and lotions. It is derived from chlorophenols which are suspected carcinogens (2). Side effects of triclosan include skin irritation and increasing susceptibility to allergies (3). Chlorophenols are chemically related to dioxin, which is a chemical compound that is formed through combustion and chlorine bleaching (4). It is carcinogenic, deteriorates immune systems, leads to reproductive malfunction and damages aquatic environment (3).

Triclocarbon agents used in these products has been found to be bacteriostatic and are only effective against some gram positive bacteria but has no effect on gram negative bacteria, viruses and parasites that cause infectious diarrhoea (5,6).

Third world countries are being considered a productive market for the promotion of antibacterial products because a majority of the population is illiterate, and the electronic media is accessible to all and has great influence on common people. In addition to these factors, the burden of diseases like respiratory tract infections and diarrhoea is high due to unhygienic living and environmental pollution (7).

Cosmetic and pharmaceutical companies are taking advantage of this situation. They are manipulating the public psyche and are putting forth false claims of providing protective shields against the above-mentioned diseases. The objective of such companies is to capture all age groups. To achieve this purpose the advertisements are smartly targeting the impressionable young by using macho figures as well as comic characters to sell the products for diverse product appeal.

Plain soap, without antibacterial agents, is a simple and effective way of removing dirt and bacteria. On the molecular level, it binds with water on one side and grease and dirt on the other side, thereby rinsing away unsafe elements and providing adequate hygiene (8). The antibacterial soap gives no additional benefit. Various studies conducted all over the world have proven this fact (9, 10).

Attention should instead be focused on educating people about proper hand-washing practices rather than diverting their attention to fancy, expensive soaps that are labelled "antibacterial". Good hand-washing technique involves scrubbing hands with warm running water and any soap for about 15-20 seconds (11).

The UN General Assembly pronounced 2008 to be the International Year of Sanitation in order to deal with this global crisis which is a noticeable initiative to educate the masses. As an extension to this agenda, October 15 was declared as World Hand-washing Day which was supported by the Global Public-Private Partnership for Hand-washing with Soap (12).

The inclusion of companies manufacturing antibacterial soaps in this partnership means that the message "proper hand-washing" will be interpreted as "proper hand-washing with antibacterial soaps". Although the intention was good, the idea got hijacked by these companies and a distorted message was conveyed to the public. Instead of motivating people towards

proper hygienic techniques, this campaign turned out to be a publicity stunt for antibacterial products.

The media, medical associations and doctors should focus on educating the masses rather than supporting the false claims regarding antibacterial soaps. Existing public health programmes should integrate proper hand-washing education in order to reduce the prevalence of life-threatening diseases. This approach would be more sensible and useful to society in terms of appropriately utilising public health resources.

**Nausheen Saeed**, Assistant Professor, Dermatology, Ziauddin University, Karachi PAKISTAN email: minhalzay@yahoo.com

#### References

1. Ngo Ky. Antibacterial soap: unnecessary and harmful. Environmental Products for Important Causes [Internet]. 2005 Oct [cited 2008 Sep 22]. Available from: <http://www.products4causes.com/pdf/Triclosan.pdf>
2. Aviva G. Triclosan the ubiquitous antibacterial agent. Arts and Opinion [Internet] 2007 [cited 2008 Sep 23];6(6) Available from: [http://www.artsandopinion.com/2007\\_v6\\_n6/glaser-triclosan.htm](http://www.artsandopinion.com/2007_v6_n6/glaser-triclosan.htm)
3. Triclosan. [Internet] 2005 [cited 2008 Sep 17]. Available from: <http://www.grinningplanet.com/2005/10-04/triclosan-article.htm>
4. Polychlorinated dibenzodioxins [Internet] 2008 [cited 2008 Sep 23]. Available from: <http://en.wikipedia.org/wiki/Dioxin>
5. Heinze JE, Yackovich F. Washing with contaminated bar soap is unlikely to transfer bacteria. Epidemiol Infect. 1988 Aug; 101(1):135-42.
6. Walsh SE, Maillard JY, Russell AD, Catrenich CE, Charbonneau DL, Bartolo RG. Activity and mechanisms of action of selected biocidal agents on gram-positive and gram-negative bacteria. J Appl Microbiol. 2003; 94(2):240-7.
7. Ramzan A, Moorani K N, Shahid A. Assessment of nutritional status in children attending basic health unit of ShidiGoth. Pak J Med Res. 2008 ; 47:40-3.
8. Shapely D. FDA calls bluff on antibacterial soap [Internet] 2007 [cited 2008 Sep 22]. Available from: <http://www.thedailygreen.com>
9. Faoagali J, Fong J, George N, Mahoney P, O'Rourke V. Comparison of the immediate, residual, and cumulative antibacterial effects of Novaderm R, Novascrub R, Betadine Surgical Scrub, Hibiclenz, and liquid soap. Amer J Infect Control. 1995 Dec;23(6):337-43.
10. Koecher K, Krenke D. A comparative study of the immediate effects of a triclosan antibacterial, chlorxylenol antibacterial and lotion soap [Internet]. 2000 [cited 2008 Sep 22]. [murphylibrary.uwlax.edu/digital/jur/2000/koecher-krenke.pdf](http://murphylibrary.uwlax.edu/digital/jur/2000/koecher-krenke.pdf)
11. Mayo Clinic Staff. Hand washing: an easy way to prevent infection. [Internet] 2007. [cited 2008 Sep]. Available from: <http://www.mayoclinic.com/health/hand-washing/HQ00407>
12. Global handwashing day, October 15. [Internet] 2008 [cited 2008 Oct 1]. Available from: <http://www.globalhandwashingday.org>

#### Registering IECs and IRBs in India

To conduct animal experiments in India, the protocol has to be approved by a registered Institutional Animal Ethics Committee (IAEC). The activities of IAECs are monitored by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), New Delhi, which registers and gives approval for IAECs in the country.

To conduct clinical trials and studies on humans, the protocol and the informed consent forms are approved by IECs/IRBs (Independent Ethics Committees/Institutional Review Boards), but these committees do not have to register themselves with any central agency. Nor is there any agency to oversee or monitor the activities of these committees. Institutes are asked to form ethics committees as per Schedule Y of the Drugs and Cosmetics Rule, and it is assumed that all is well thereafter.

The scenario outside India is different. As per ANVISA (the Brazilian regulatory authority) guidelines, the IEC/IRB should be registered under the local government (1). In the USA, the IEC/IRB can function after getting itself registered by the Office for Human Research Protections (OHRP) under the United States Department of Health and Human Service (2). European countries such as France and Germany also have separate councils for registering IRBs/IECs.

In India, many pharmaceutical companies, research institutes, contract research organisations and medical colleges are involved in clinical trials and bioequivalence and bioavailability studies and they form their own IEC/IRB as per E6 Guidelines (Guideline for Good Clinical Practice) or Schedule Y to approve their study protocols (3). But there is no mechanism to check whether the members of the committees are qualified and experienced enough to run the committees in the best interests of subjects and patients volunteering to take part in clinical studies.

Further, one often hears complaints about inefficiency and bias of the committees which adversely affects the researchers. In the current scenario, there is no way one can get IRB-related grievances redressed. There seem to be no regulations on the formation and functioning of Independent Ethics Committees (4). Registration and monitoring by a central agency, along the lines of the CPCSEA for IAEC, will solve some of the problems associated with the current functioning of human research ethics committees. The total number of committees, details of the members, and the activities, will be readily available if a database of all the ethics committees in the country is created. Such a database is a must for administrative reasons and it would make things easy for the registering authority to monitor, educate and direct them when new developments occur. The registering authority will also be able to take corrective action in case of complaints or grievances against a committee or any of its members.

**Parasuraman S, Raveendran R**, Department of Pharmacology, Jawaharlal Institute of Post Graduate Medical Education and Research, Puducherry 605 006 INDIA email: parasuphd@gmail.com

#### References

1. Manual for good bioavailability and bioequivalence practices. 1st edition. Agência Nacional de Vigilância Sanitária, Brasília (DF); 2002. 17p.
2. US-HHS: Office for Human Research Protections / Registration of an Institutional Review Board or Independent Ethics Committee [Internet]. US Department of Health & Human Services, Washington, DC. 20201; [cited 2008 Sep. 24]. Available from: <http://www.hhs.gov/>
3. Guidance for Industry E6 Good Clinical Practice, Consolidated Guidance by U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), ICH. 1996 Apr.
4. Indian Council of Medical Research. Ethical guidelines for biomedical research on human participants. New Delhi: ICMR; 2006.

#### Corrections

In the article: "A new approach for teaching nursing ethics in Iran" (Nasrabadi AN, J Soodabeh, Parsa-Yekta Z, Bahrani N, Noghani F, Vydelingum V. *Indian J Med Ethics* 2009 Apr-Jun; 7(2): 85-89) the affiliation of the corresponding author, Soodabeh Joolaei, is the Iran University of Medical Sciences.

In the article by S Chhattopadhyay, "Teaching ethics in an unethical setting" (*Indian J Med Ethics*. 2009 Apr-Jun; 7(2): 93-6). the author's affiliation details were incorrect. They should have been given as follows: Professor of Physiology and Member, Institutional Ethics Committee, Kalinga Institute of Medical Sciences, Bhubaneswar 751 024 Orissa INDIA email: linkdrsc@yahoo.com

In the article by Geetha Desai and Prabha Chandra, "Ethical issues in treating pregnant women with severe mental illness" (*Indian J Med Ethics*. 2009 Apr-Jun; 7(2): 75-7), the statement that the paper was presented at the Second National Bioethics Conference in November 2007 should be corrected; the Second NBC was held in December 2007.

### Workshops on biostatistics and research ethics

SGPGI will be organising workshops on biostatistics and research ethics between July and September 2009 at Lucknow. Travel support may be available.

Those interested in further details may please contact Dr Rakesh Aggarwal at the Department of Gastroenterology, SGPGI, Lucknow at [sgpgi.course@gmail.com](mailto:sgpgi.course@gmail.com)