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Medical technologies: Transformation or tyranny?

New medical technologies are selling us dreams of genetic engineering, stem cell treatments to eradicate all disease, perfect bodies, perfect babies and super vaccines. But who is asking whether these healthcare technologies are relevant to our needs? Do they help us lead more fulfilling lives or do they exacerbate existing inequities? What must we consider when making decisions related to these medical technologies, as individuals and as a society?

SANDHYA SRINIVASAN

PUT A SINGLE DROP of your blood on a specially treated strip of paper and in seconds you will know if you have malaria or just an ordinary fever. Wrap a bunch of wires around a person's skull and turn the switch on to find out exactly what s/he is thinking. Create a baby in a test tube – give it the body of an Olympic athlete and the intelligence of a Nobel laureate; you can even pay a woman to carry that baby for you. Men: find out if your child is really your own – send DNA samples to a lab and see if they match. Get tested to find out if you have a particular cancer – or if you are likely to develop that cancer in your old age. Change the shape of your nose. Correct your vision with laser surgery. Replace your knees, hip, heart, kidneys, lungs, liver… Do you think you're a woman trapped in the body of a man? Hormones, surgery and psychotherapy can change the way you look and how you feel about it as well. Mood stabilising drugs will calm you down when you're anxious and lift your spirits when you're depressed. Paralysed? Get injected with stem cells and start walking again. Genetic engineering, super vaccines, stem cell treatments will eradicate all diseases…

Some of these technologies have been around for decades. Others are relatively new, and yet others may remain in the realm of possibility, in our own lifetimes.

The newspapers would have us believe that medical science is galloping forward, providing access to technologies that were until recently unimaginable. That technology is opening a new, wonderful world, that people will live longer, healthier, happier lives in a society that has unlimited possibilities.

Indeed, medical technologies touch our lives at every stage and in so many ways. However, they cannot be accepted without reflection and debate.

Medical technologies: Some questions

The writers in this issue of *Agenda* discuss different aspects of medical technologies already out there in the 'market'. They ask questions such as: What are the factors shaping the development and diffusion of technologies? Are the current trends in healthcare technologies relevant to our needs? Do they help us lead more fulfilling lives or do they exacerbate existing inequities? Do they solve existing social problems or create new ones? What must we consider when making decisions related to these medical technologies, as individuals and as a society?

Knowledge, attitudes and choices

Information is not always power. Anoop Kumar Thekkuveettil, Mala Ramanathan and Harikrishnan S discuss the use, misuse and consequences of new pre-natal diagnostic technologies. Already, women may be encouraged to undergo tests to identify genetic conditions, on the assumption that they are morally obliged to choose a 'perfect baby'. Disability is to be 'overcome' by elimination of the disabled rather than by forcing changes in society to include the needs of those with disabilities. Soon, women who give birth to babies with disabilities will be viewed as irresponsible mothers. The growing use of such technologies is a matter of concern, note the authors, calling for greater discussion and regulation of pre-natal technologies.

Sameera Khan gives a first-person account of how a pregnant woman is advised to undergo these tests: her vulnerability may be ignored, she may receive scant information on the risks and benefits of these tests, and there is an underlying value judgement on disability. She concludes: "On the one hand, it must be acknowledged that… (pre-natal) tests involve some very private and complicated decisions by people. On the other hand, it is also important to note that many of these private decisions also carry profound social implications." In an interview carried alongside Khan's article, gynaecologist Duru Shah discusses the role of clinical judgement in providing medical care; in addition to this judgement, the medical professional must also respect the patient's concerns.

Sanjay A Pai's history of imaging technology, starting with the x-ray, through CT scans, MRIs and now teleradiology, also highlights the consequences of promoting tests without ensuring that they are useful, and without informing people of their limitations. Women are advised to undergo regular mammograms for early detection of breast cancer. They are unlikely to be told that the chances of getting a 'false positive' mammogram result are high – which can not only cause anxiety but also result in unnecessary further tests before

they are found not to have breast cancer. Certain imaging technologies also have risks. Finally, Pai notes that refinements in imaging technology have come at a hefty price, but without necessarily improving healthcare for people.

Social perceptions of the good life

Does technology always lead to an improved quality of life? Parents of hearing-impaired children may feel that cochlear implants will bring their children 'back into the world of sound'. But others believe that it is an attack on a cultural and linguistic minority. When a doctor offers a cochlear implant, s/he presupposes that deafness is a disability. Shabnam Minwalla speaks to parents, medical professionals, and advocates of the deaf community, to present the ethical controversy surrounding the implant.

Controlling women's bodies

One of the earliest battles in healthcare ethics concerned research in and promotion of contraceptives in the name of 'reproductive health'. Sarojini N B traces key events in the history of injectable contraceptives and contraceptive implants to illustrate the manner in which research in medical technologies has been shaped by the needs of the state to control women's reproductive lives.

The science behind contraception can also be used for reproduction. Assisted reproductive technologies are perhaps the most visible and recognised of medical technologies. The ART industry has exploited the social pressures on Indian women to have children. It claims to offer women new choices when in fact it increases the pressure on women to use these technologies, despite the high costs, poor success rates and risks to their health. It has now expanded beyond the local market to set up surrogacy factories targeted at the 'surrogacy tourist', exploiting poor women's desperation to get them to risk their health for money.

Chayanika Shah takes all these facts as given, and moves on; while calling for regulation of these technologies to reduce the risk of harm to women, she also proposes that ARTs can be liberating – they can be used to change social norms on what a family should be.

Selling dreams

ARTs are the source of stem cells and stem cell research has resulted in treatments for certain conditions, but more often it has used false advertising to sell miracle cures to desperate patients, writes Sandhya Srinivasan. Amit Sengupta describes the controversies surrounding stem cell research in the West where it has been criticised not only by conservatives opposing it on grounds of 'immorality' but also by those who point out that it has created an international trade in ova.

Cosmetic technologies present other concerns. Manjima Bhattacharjya interviews women in the glamour industry in India on their views on the 'ideal body', obtained through diet, exercise, beauty regimens, and cosmetics. She describes the model's regimen as "driven by a desire to transform, reform, or 'correct' one's body according to both the imagined and real needs of their industry". Medical technology provides the means for this transformation.

Compromising medical ethics

Doctors are supposed to care for patients, and the patients' interests should be foremost in their minds. But they have conducted medical procedures that are of no medical value – by collaborating in interrogation using medical techniques, and participating in executions. Amar Jesani documents the history of medical interrogation. 'Truth serums', 'lie-detection' tests and 'brain mapping' involve medical professionals in their professional capacity – but as agents of the state rather than advocates for a patient. Vijay Hiremath discusses doctors' involvement in the death penalty, to certify death. He also comments on a recommendation by the Law Commission that hanging be replaced by lethal injection: this would further involve medical professionals in the death penalty by making them actually perform the execution. Jesani argues forcefully that by participating in torture, doctors are "eroding the very core of the medical profession".

Pills and profits

In her 2004 book *The Truth About the Pharmaceutical Industry: How They Deceive Us and What to Do About It,* Marcia Angell meticulously documents the US industry's uncontrolled growth in its profit-seeking mission, and the support it has received from the government – funds to develop drugs that could then be patented by private companies, drug approval procedures that permit the patenting of 'me too' drugs, loopholes to extend a drug's exclusive marketing rights, and so on. Angell also points out that – despite patent protection – few innovative drugs have been developed in the last decade to replace drugs that are going off patent. For example, just seven of the 78 drugs approved by the US Food and Drugs Administration in 2002 were classified as improvements over older drugs.

But the pharmaceutical industry must generate profit. S Srinivasan illustrates how desperate drug companies faced with a drought of innovation have turned to finding new uses for drugs of little value. He discusses the phenomena of disease-mongering and ghostwriting to create markets for new medical conditions such as 'erectile dysfunction' and 'social phobia'.

A number of deadly diseases are preventable by vaccines and it is generally accepted that they are important public health technologies. The problem is that vaccines are given to healthy children to protect them from a disease that they do not have. And while not all vaccines are of equal value,

all of them carry some risks, however small. Prabir Chatterjee discusses controversies about vaccines – "which ones to use, how they should be promoted, how much the public should know, and their role in public health programmes".

The challenges of high technology

Intensive care technologies pose unique ethical challenges. The patient is often not in a position to participate in treatment decisions. ICU care is extraordinarily expensive and emotionally distressing for the family. In India, ICU care can bankrupt a middle class family. Two paediatric intensivists, Akash Bang from a community hospital and Arvind Kasaragod from a corporate set-up, describe the dilemmas of paediatric intensive care. Can decisions be made on medical need alone, and is it possible to ignore the financial burden on families?

Finally, which technologies do we choose? Biswaroop Chatterjee votes for the microscope rather than rapid tests which are currently being promoted in government programmes. The microscope is an inexpensive tool that can be used by a trained technician to provide an accurate diagnosis at a cost affordable to the community. It also makes most sense in a comprehensive healthcare system rather than a vertical, disease-focused programme. Kavery Nambisan makes a plea for the real innovation – appropriate and affordable technology – and reports on the achievements of rural surgery in India.

The economic drivers of scientific research

These articles drive home the message that technologies are not simply natural consequences of a scientific endeavour; nor are they necessarily products of the search for ways to improve people's lives. Serendipity has little to do with the application of science. The pursuit of scientific knowledge is always tempered by the money needed to do research, which in turn is determined by the interests of funders, who must answer to their shareholders, official or otherwise. Likewise, drugs for many conditions remain unavailable because the companies that control their patents see no market for them. The development and diffusion of technologies depend on their potential to exploit existing demands and create new ones, and to serve powerful interests.

Research agendas are not generally reflective of people's needs. For example, of the US$73 billion spent annually on health research across the world, less than 10% is directed at diseases that affect 90% of the world's population, according to the Global Forum for Health Research. This is so because the 10% constitute the real market for the products of this research.

The pharmaceutical industry is a good example of the fact that the subject of research is determined largely by those who fund it, as they want returns on their investments. According to a study by the Drugs for Neglected Diseases Working Group, convened by the international health organisation Medecins Sans Frontieres, of 1,393 new drugs brought to market between 1975 and 1999, just 16 were for tropical diseases. We don't have new drugs on hand for tuberculosis, which kills 370,000 Indians every year – one of the top 10 causes of death and the leading cause of death among adults in India. As for access to drugs, 87,000 of the 1.9 million new cases of TB in India every year are of multi-drug-resistant TB, for which treatment can be Rs 100,000 to Rs 350,000 per person – and more. This, in a country where the majority of people pay for healthcare out of their own pockets, without insurance, often even when they fall ill with diseases covered by government programmes.

Decisions regarding technologies are determined by the big actors including industry and governments, and the policies that support their interests. For example, which drugs should be available in the tuberculosis control programme and how should they be made available? These decisions are based not just on knowledge of a drug's safety and efficacy and the bacteria's resistance, but also on our understanding of how healthcare should be provided – as discrete programmes or as a comprehensive system with services for preventing illness as well as treating it. Or when a disease control programme is funded by a foreign loan – and is then required to buy a test kit manufactured by a particular company. Or contraceptive research that focuses on injectables and implants – methods that are controlled by providers rather than users.

Cost and access

Access to a technology is also shaped by socio-economic factors. The best treatment may not be available to those who need it most. For example, while tens of thousands of children in India suffer damaged heart valves due to untreated infections, a few hundred receive valve replacement surgery. A fraction of the 32 million diabetics in India can afford the drugs they need. One study found that Indians with diabetes in rural areas can spend up to 25% of their annual income on treatment —for the urban poor this rose to 34%. Poor women face additional barriers to healthcare.

This is the irony in a country where the most sophisticated medical care is available even as the right to basic care is not guaranteed. A government hospital in Mumbai is in the process of setting up a liver transplant surgery programme. On the other hand, user fees effectively deny the poor far simpler surgical procedures. But certain contraceptives are more easily available than medical treatment in government centres, as population control is considered a priority.

Further, when government policy does not assure everyone a standard of medical treatment, you get a two-tiered system of care: one for those with the money and another for those without. Chennai-based trauma surgeon George Thomas has commented that though the development of joint replacement has had an immense impact on the quality of life of people with damaged knees, in India, implants of

poor quality continue to be widely used. The cheaper Indian implant for knee replacement can cost Rs 50,000 – and even this will not meet quality standards. The standard, better quality ones (all imported from the US or Europe) cost Rs 65,000, and the more sophisticated ones can cost up to Rs 350,000, which restricts their use to the few patients who can afford to pay such prices. Thomas, who is also editor of the *Indian Journal of Medical Ethics*, notes that doctors are regularly forced to make such decisions – to give substandard treatment because it is all that the patient can afford. This happens because healthcare is based on profit rather than on what the patient needs.

The influence of privatisation of healthcare

Gastrointestinal surgeon Sanjay Nagral, one of the founding members of the Forum for Medical Ethics Society, has argued that the pressures of a privatised healthcare system drive the manner in which specific technologies are developed and disseminated. Writing in the *Indian Journal of Gastroenterology* in 2006*,* he comments on the larger context in which liver transplant surgery has been established in India. For those with extreme liver disease, the only option is a transplant, from a cadaver or from a live donor.

Extracting a part of the liver for 'living donor transplant' is major surgery which has, on occasion, led to the donor's death. Living donor transplant programmes in other parts of the world have been developed systematically, with trained, experienced personnel, the infrastructure and procedures to ensure that donors are properly informed, and not coerced. Such programmes publish their rates of success and complications. They have also developed alongside cadaver-based transplant programmes.

Cadaver programmes require a concerted effort to promote organ donation: a system of identifying brain-dead donors, counsellors, mechanisms to share organs across institutions, and so on.

Living donor transplant programmes in developing countries such as India have grown at the expense of cadaver-based programmes. They have been established without ensuring standards and public reporting. We don't know how many people have suffered complications or died in India following donation of a part of their liver – hospitals are not required to report these figures. But, according to Nagral, one in five donors suffers complications and many more liver donors have died than kidney donors. He points out that living donor programmes in India are mostly in the private sector "where the market is the prime determinant of how specialty medicine develops", and they must deliver results to get more patients. There is also a possibility that liver transplant tourism – based on a liver trade akin to the existing kidney trade – may be the next medical tourism promoted in India.

Food is the best technology

We must remember that the technologies with the greatest impact have been those that we might take for granted: adequate food and clean water. Indeed, the greatest improvements in life expectancy were not because of antibiotics and vaccines.

Public health researcher Mohan Rao at the Centre for Social Medicine and Community Health, Jawaharlal Nehru University in Delhi, refers to the English doctor Thomas McKeown who charted the decline in the death rate in England and Wales; McKeown found that it started in the 18th century *before* effective medical technology became available. He concluded that this drop in deaths from infectious diseases was mostly from improved nutrition because of greater availability of food. Similarly, TB was killing fewer people much before the bacteria was even identified in the 1860s, and definitely before anti-TB drugs were developed in the 1940s. McKeown also held that improved resistance because of improved nutrition was largely responsible for deaths even from waterborne diseases like cholera.

A matter of choice

Physicians and surgeons advise their patients on which tests they must have and, often, at which laboratory. They can guide them on how to avoid a heart attack: by changing their lifestyles, or popping a pill, or getting their stomachs stapled to prevent them from eating too much. Fertility specialists can choose to prescribe IVF for every woman who walks into their clinics, or they can start with other procedures and include advice on adoption or just not having children. Government policymakers take decisions on which vaccines to introduce into the national immunisation programme. Hospital administrators have a say in which drugs to buy, and whether to stock expensive brands or generic formulations. Drug company heads decide whether to sell antiretroviral treatments at lakhs of rupees a year or at a few thousand. Researchers are supposed to ensure that trial participants are properly informed and their consent is taken before they are given an experimental drug. Medical associations should reprimand their members for participating in medical interrogation – but they may decide to turn a blind eye to the practice.

People are involved in the development, promotion and use of medical technologies, and they do this because they benefit from their actions, whether as individuals or as a group. They have an ethical responsibility to oppose their misuse.

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Crafting perfect children

With technologies for pre-natal diagnosis becoming more accurate and less invasive, it is likely that there will be greater social pressure on women to produce 'perfect' babies, greater social endorsement of termination of pregnancies with foetal abnormalities, and even less societal tolerance of disabilities than at present. It is time both service providers and pregnant women began to discuss the ethical dilemmas raised by these diagnostic technologies

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AS TECHNOLOGY for pre-natal diagnosis improves, as it becomes more accurate and less invasive, it is possible that the attitude of medical professionals towards the choices that women make – particularly reproductive choices to either terminate or continue a pregnancy – will undergo subtle changes. The current practice seems to be to offer non-invasive pre-natal diagnosis for those women who have a family history of genetic diseases or are of high maternal age, and prepare them for a high-risk pregnancy. There is not much reason yet to think that this has become the norm for all pregnancies. Pre-natal testing is usually a multi-step process involving screening for chromosomal aberrations, biochemical tests and ultrasound. An alternative is to test for a specific gene mutation to learn the parents' carrier status of certain diseases, including cystic fibrosis, Duchenne muscular dystrophy, etc. Women with a positive diagnosis on this test will have to go through more invasive tests like amniocentesis or chorionic villus sampling (CVS), both of which carry higher risks for the foetus and also enhance the chances of maternal complications.

The discovery that there are detectable amounts of cell-free foetal DNA (ffDNA) and RNA (ffRNA) in maternal blood changes the science of pre-natal diagnosis dramatically. It is now possible to do an array of tests on the foetus' health and genetic makeup without using invasive approaches. ffDNA will allow a mutational analysis of genes, and ffRNA gives information on variations in gene expressions in comparison to the 'normal' foetus. The implications of changes in technology for reproductive choices must be discussed for the ethical dilemmas these technologies pose both for providers and for pregnant women.

Adrienne Asch, in her seminal article in the *American Journal of Public Health* ('Pre-natal Diagnosis and Selective Abortion: A Challenge to Practice and Policy', *AJPH*, November 1999), states: "Professionals should re-examine negative assumptions about the quality of life with pre-natally detectable impairments and should reform clinical practice and public policy to improve informed decision-making and genuine reproductive choice." Developing spaces for such a discussion is becoming increasingly difficult in a system where pre-natal diagnosis is seen as mandatory so that families do not have the burden of disability and of the healthcare expenses associated with it. As these modern diagnostic techniques become more and more accurate, the "social endorsement" to terminate pregnancy on detection of foetal disability may serve to diminish women's choices.

On the one hand, choices do increase because women have better information to weigh the positive and negative sides of their decisions. Alternatively, choices get restricted because societies and women themselves will find it difficult to forgive women who opted to have a baby with disabilities having prior information of the disability – as well as women who chose medical termination.

Technologies for pre-natal diagnosis are becoming more accurate and less invasive. For example, the nuchal ultrasound scan can predict Down's Syndrome in the first trimester, whereas the earlier ultrasound methods could detect disease only in the second trimester. Besides routine non-invasive techniques like blood tests and sonograms, and invasive amniocentesis and CVS, techniques such as pre-implantation genetic diagnosis (PGD) are recommended in many developed countries. PGD is done on embryos grown in-vitro and allows the detection of genetic disorders before implantation of the embryo. In 2007, The American College of Obstetricians and Gynaecologists recommended Down's Syndrome screening for all pregnant women regardless of their age (the risk of Down's Syndrome increases with age, especially above 35). Such recommendations indicate that there is great demand in society for healthy babies. At present, more than 350 genetic diseases can be detected using various techniques, and this number will increase with the advent of the human genome project and the use of single nucleotide polymorphism studies. As genetic counselling and pre-natal diagnosis become common in India, as evidenced by the increase in the number of centres offering screening and counselling services, it is possible that there will be pressure on women to produce 'perfect' babies – just as there was pressure to produce boy babies after the availability of technology to detect the sex of the foetus.

Historically, human society has looked for healthy individuals who contribute to the economy. From this perspective, people who are unable to work effectively are viewed as

wasted resources. Such a view of human capital can result in low tolerance for those less able to contribute. For example, an analysis on social reasons for the genocide of the Jews in Europe in the middle of the last century (A N Sofair and L C Kaldjian, 'Eugenic Sterilisation and a Qualified Nazi Analogy: The United States and Germany, 1930-1945', *Annals of Internal Medicine*, 2000) indicated that the prevailing laws created a view that certain people were not productive and therefore a burden to society. German laws before World War II allowed for the sterilisation of people viewed as unproductive. This law also allowed for the 'euthanasia' of certain groups considered disabled. Such perspectives continue to be reflected in the views of industrialised societies today on homeless people. Whenever people do not have a strong voice, society's dominance over them is visible. This has been true for women, gays and the current debate on children with disabilities.

To an extent, as Adrienne Asch has pointed out, public health experts also moulded this view on diseases and the need to eradicate them. This perspective continues to prevail when we deal with non-communicable diseases or the uncertainties that surround pre-natal diagnostics for foetal genetic disorders. Public health practice in general is largely informed by utilitarian principles of the greatest good for the greatest number, and therefore accepts disregard for individual rights, including those for reproductive autonomy for women.

It is essential to discuss issues related to reproductive rights as well as societies' outlook on what a person should be. Women often face pressures both from clinically driven choices dictated by medical professionals and socially driven choices dictated by families. In Indian society, tolerance for disability is low, not only because it affects a human being's functioning but also because of the high familial costs involved in the management of such disabilities since there is very little societal provisioning for this. In addition, while public policy on disability calls for making every public structure disability-friendly, this is not prioritised in fund allocations or new constructions. So, as a whole, physical spaces are unfriendly to differently-abled populations.

There can be both direct and indirect pressures on women, depending on their situation, to restrict their choices, whatever they might be. This can be in terms of urging MTP for those whose financial resources cannot go through the gamut of genetic testing for a confirmatory diagnosis after initiating pre-natal screening. It is possible to evaluate the foetus for the presence of structural heart disease very early, in the first trimester itself. If the foetus is found to have a major cardiac anomaly (for example, it has only two or three heart chambers instead of the normal four), the prognosis for the newborn is very poor. The child may require multiple major cardiac surgeries, which are costly and available in few metros in India. Even after such surgeries, the child will have disabilities. In such cases, MTPs are recommended by medical practitioners.

On the other hand, pre-natal screening tests can also facilitate making such a choice and enhancing choices for women who have the financial means to go through the battery of tests needed for a confirmatory diagnosis.

This only serves to highlight the inequities existing in society with regard to access to healthcare and diagnostic facilities. Alternatively, there could be counselling for testing, and appropriate mechanisms and sites of delivery where the pregnancy and the outcome can be managed effectively to reduce potential problems. For example, if a cardiac anomaly is detected, delivery can occur in a centre where cardiac care facilities are available. This could save the life of the infant. Pre-natal echocardiographic evaluation, also called foetal echocardiography, is a simple and safe tool to evaluate the foetal heart. It is not very expensive but it is not universally available and the expertise to conduct it is limited. This again, without societal provisioning, will not only serve to widen existing equity gaps but also result in labelling women who choose a less orthodox option as deviant in their reproductive choices.

There are two arguments that justify the relevance of genetic testing and pre-natal diagnosis in India. The first uses the argument that scientific developments need to be harnessed for the wellbeing of populations, and wellbeing means having populations that are less affected by genetic conditions that are disabling. The second is that declining fertility underscores the need for better reproductive choices for women. Since society calls for crafting children that are acceptable in the labour markets, there is a need for creating perfect or efficient babies who can take their place in the family and the labour market with enhanced values. In either of these cases, the tolerance for any form of disability is limited and will be linked to the ability to overcome it through either social or economic might. This could again serve to widen existing inequalities.

There is therefore a need to carefully evaluate emerging technologies for the ethical dilemmas that may emerge, or the potential to vitiate existing inequalities. There must be discussion and regulation of these technologies as their use increases across the country.

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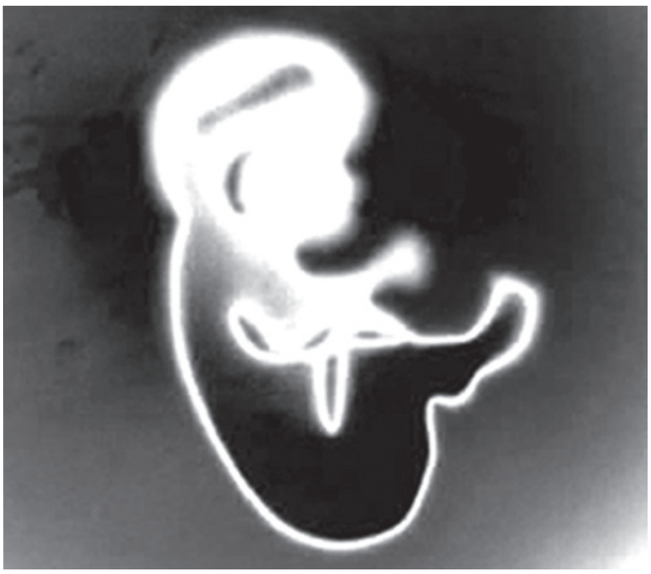
Dilemmas of a mother-to-be

We have medicalised pregnancy to such an extent and made it so technology-dependent and doctor-centred that the women who are pregnant and their families feel lost, alone, fearful and often uninformed of the choices that lie before them as they consent to a battery of tests such as triple markers, 3-D ultrasounds and amniocentesis

SAMEERA KHAN



THE MOMENT YOU FIRST LAY EYES on your baby is special. "Okay, mummy, now do you want to know if it's a boy or girl," asked the doctor as I was barely getting over the exhaustion and pain of labour. "No!" I shrieked. "Tell me if it's okay, if it's fine. Is it totally healthy? Is it all there?" Though I had longed for a daughter, at that point what mattered most was the wellbeing and health status of my baby, not its gender. Only once I had been assured that it had all the required toes, fingers and organs intact, and that everything was functioning the way it should, could I truly let myself relax.

I have been pregnant twice (at the ages of 34 and 38); both were fairly trouble-free. But on the journey from conception to birth, I have found myself lost, alone, sometimes fearful, and very often uninformed of the choices that lay before me. Later, when I talked to women who had been pregnant before and after me, and read some of the literature put out by mothers and researchers in online blogs and books, I realised that there are many questions and decisions (and indecisions) that plague pregnancy and childbirth; many are to do with the health status of the mother and the developing foetus. Unfortunately, most of them remain unanswered and unshared.

That is because we have medicalised pregnancy to such an extent, and made it so technology-dependent (though I think some of it is necessary) and doctor-centred that pregnant women and their families often feel (and are treated as being) incompetent and incapable of having a valuable opinion on the matter.

The first time I underwent the triple marker blood test, I wasn't told that it was a screening test; that it did not give a diagnosis but a 'risk assessment' of the chances that the foetus had an abnormality. The assessment was based on whether the test result was below or above a certain cut-off, along with other factors such as the mother's age, etc. When I received a normal screening result the first time, the obstetrician assured me that while I didn't necessarily need to do an amniocentesis, it was still advisable given my age and the fact that only an amniocentesis could positively tell whether the foetus had Down's Syndrome. The risks of bleeding and possible miscarriage from an invasive procedure like amniocentesis were barely discussed. My husband and I chose not to do the procedure.

The second time I underwent the triple marker I was again assured that my results fell within the normal range. This time, my obstetrician did not insist on an amniocentesis but instead helpfully weighed the risks I ran of having a baby with Down's (less, as shown by my triple marker results) against the risks I ran by doing an invasive procedure (more). The decision was left to me and my husband; again, we decided against amniocentesis.

At the same time we also sought other opinions, medical and others. Some medical opinions, including from the doctor who did my hour-long 3D ultrasonography, clearly implied that we were stupid not to do the amnio given that, "Ma'am, you are 38!" (this despite the fact that the detailed 3D scan revealed no foetal anomaly and was in any case being done at almost 23 weeks, about five weeks too late for an amniocentesis). Another worried friend felt pressured to tell me about a woman she knew who had received a normal screening result from the triple marker test and didn't undergo amniocentesis, but then gave birth to a child with Down's Syndrome.

My friend wanted me to know that I could not trust the

triple marker results. That is true, because the false negative result is high in triple marker screening. This means that the test identifies you as being low-risk for having a baby with Down's or Trisomy 18 or a neural tube defect, when in reality your baby could be affected by any one of these disorders. It can also give false positive results – ie the test incorrectly concludes that there is a relatively high risk that the foetus has an abnormality.

The point is that these tests are available in order to make further decisions regarding the pregnancy; they can be valuable when the pregnant woman and her spouse are properly informed of their purpose.

So where does this leave the parents-to-be? Confused, isolated and desperate for detailed, sensible information that could make the picture clearer. But in most pregnancy books or websites there seems to be a conspiracy of silence – pre-natal tests are discussed in a normal routine manner with very little complexity or detailing. It is only gradually that you stumble across snippets of information and put them together to realise that eventually the choices you face are stark and brutal – that consenting to undergo a pre-natal test means accepting the possibility (likely or remote) that your baby may be born with a disability of some kind. And you have to think about what this means.

At some point in the discussion and debate about false negative triple marker results and amniocentesis, I realised that besides seeking more information on these, what I really needed to do was to confront my attitudes towards abortion and disability.

By the time I had done the triple marker test at 18 weeks, I already felt emotionally attached to my foetus. Though I've always believed in a woman's right to abortion, at that stage I found it very difficult to accept the idea of aborting my foetus. One way of avoiding that eventuality, I thought, was to avoid the amniocentesis. At the same time, I was also worried that the amniocentesis itself could harm my 'normal' foetus. I tried focusing on the thought that, if I knew something was abnormal with my foetus, would I still feel the same way about it? Was I ready for a lifetime with a disabled child?

In that particular emotional state, I felt I was. I was lucky that my triple marker result was within the normal range so I could refuse an amniocentesis and avoid the possibility of an abortion. What if it hadn't been? What if my 3D ultrasonography had shown a problem? Would I still have taken a strong 'no amnio-no abortion' stance? I am not sure what I would have done.

Don't get me wrong: pre-natal tests and scans can be useful in many ways and can offer critical information that can improve the care of mother and baby and also help some parents make an informed choice about the future of the pregnancy. At the same time, one cannot forget that pre-natal tests give us information based on which we have to make hard choices. I often find that parents-to-be and their doctors do not look beyond the test – let us do this test now, this scan now, and then try this procedure – at the larger picture. I, on the other hand, found myself steeped in the big issues: What is 'disability'? When is a disability something to be taken in one's stride? Can we make space for a differently-abled person within our family and in our society? When does a disability become unacceptable or intolerable? Should only 'perfect' (the doctor will use the word 'healthy') babies have the right to be born? If my foetus were not perfect and suffered an abnormality of some kind, what would I feel about that? What was my attitude to differently-abled people? Could I only sympathise or respect them from afar, or could I actually care and love one as my own?

Some friends and family felt that I didn't need to think through all this and disturb myself. I could just do the tests and go with the flow (usually that meant 'medically terminate the pregnancy if it is found that the baby will be born with some kind of abnormality'). I realised that the only way I could make an informed choice was if I made myself aware of all the possibilities and their consequent challenges, and faced them head on however painful they may be, rather than shove them under the carpet.

Pre-natal tests and scans need to be seen as part of the big picture. On the one hand, it must be acknowledged that such tests involve some very private and complicated decisions by people. On the other hand, it is also important to note that many of these private decisions also carry profound social implications. Thus, it seems vital that such testing be accompanied by a larger public dialogue and debate about our attitudes to disability and disabled people, our view of the girl-child (given India's skewed male-female census ratio and the role of sex-determination tests in the termination of female foetuses) and finally about whether one can ask questions such as: do some babies merit more of a chance at life than others?

It is the public discussion of pre-natal sex determination that has ensured social (and legal) censure for the termination of female foetuses. Such a discussion has been by and large ignored on the subject of disability, and, in most cases, termination of foetuses with abnormalities has been accepted without reflection.

This is definitely not to suggest that women should not have the right to abortion. That choice should be available to all women. Abortion is a very personal decision and a woman may need to make that choice at a particular point in her life. She certainly needs no censure or judgemental gaze; instead she needs support and understanding.

The debate on pre-natal testing, however, needs to become more finely nuanced so that technology is used in a more thoughtful and ethical manner.

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Negotiating the maze of pre-birth technologies

Duru Shah, former president of the Federation of Obstetric and Gynaecological Societies of India and currently on the ethics committee of the International Federation of Gynaecology and Obstetrics, demystifies pre-natal tests, stresses the importance of counselling before these tests, and discusses the Niketa Mehta case in which a woman sought to abort a foetus with cardiac abnormalities after the legally-permissible 20 weeks

SAMEERA KHAN

What are the pre-natal diagnostic tests available, and what can we learn from them?

First, there are blood tests. For example, the dual marker and triple marker tests look at the level of certain hormones which are 'markers' associated with Down's Syndrome. There is also a test for thalassemia major.

Second, we use ultrasound extensively, four-five times in the pregnancy. Here we look for markers for certain abnormalities. In the case of Down's Syndrome, for example, certain physical characteristics suggest that the foetus has this condition. With an ultrasound at 18-19 weeks we can pick up lots of information on structural problems.

Finally there are invasive tests. These test the amniotic fluid, chorionic villus tissue or foetal blood. Sometimes we even do a skin biopsy of the baby. The other tests will give you a probable diagnosis – each one has its own proportion of false positives and false negatives. But when we test the tissue, we are actually looking at the genes, chromosomes, DNA, and this gives us a confirmatory result for certain genetic diseases.

How do you decide that your patient needs a particular pre-natal diagnostic test?

One is the age of the patient. But I do the triple marker blood test on all my patients. The risk of having a baby with Down's Syndrome is higher as the woman gets older, but that doesn't mean that a younger woman cannot have such a child. So I offer the test to all my patients who can afford it – it costs Rs 1,500.

Women aged 40 and above will certainly do it. The main reasons why someone would do a test includes a family history of a particular genetic disease (such as thalassemia or Duchenne's muscular dystrophy), or a consanguineous marriage, or if one of their siblings has been affected, or if they already have a child with a genetic problem. Also, certain genetic conditions are more commonly found in certain ethnic groups. So if you belong to an ethnic group in which a particular disorder is common, it is virtually mandatory.

There are also pre-implantation diagnostic tests that we do for women undergoing in-vitro fertilisation (IVF) who also have a history of multiple abnormal births. Here I would do an IVF, and once the embryos develop to the eight-cell stage, remove a single cell and do a biopsy to look for specific diseases. This is being done in patients of Duchenne's muscular dystrophy and cystic fibrosis. It also helps women whose blood is Rh-negative and whose partner is Rh-positive. If the baby is Rh-positive, it can be attacked by the mother's blood and die. You can do IVF and PGD and transfer only Rh-negative embryos.

Why do gynaecologists offer tests that do not provide a clear diagnosis but only a 'risk assessment'? Doesn't this just confuse the patient?

These are screening tests that help you identify high-risk patients with whom you do the invasive tests. But you have to put everything in perspective – you look at the ultrasound report, the dual marker report, the triple marker report, the foetal ultrasound which is done later, put this together with the patient's age, whether it is a consanguineous marriage, the family history, and so on – and accordingly counsel the patient on how much importance you will give to the screening report. If the assessed risk is high, you will definitely offer the invasive test. If the result is borderline, it is less clear. If it is a borderline reading and she is an older woman, *and* if the ultrasound also gave a borderline reading, I would 100% offer her an amniocentesis test. But if it is a 40-year-old woman for whom a screening test shows

Before you do the triple marker you have to talk to them and take them to the end of the line and make them see the implications of all the tests

low risk, I might tell her: "Don't worry, the ultrasound looks okay, this test looks okay, that looks fine, you don't need an invasive procedure."

You also have to keep in mind the risks attached to doing the invasive test. An invasive test has its own risks.

So the triple marker is to take a decision on whether to undergo an invasive test such as amniocentesis?

Yes, the triple marker is a screening method, not a confirmatory method.

What kind of counselling is done prior to an invasive test like amniocentesis?

We tell the couple why we are doing the amniocentesis, the indications for it, the risks, and explain the procedure in detail.

We also ask them to think about what they will do if the test is positive and there is no treatment for the condition (amniocentesis looks for chromosomal and genetic disorders, for which there is no therapy available). Would they want to continue the pregnancy or terminate it? This you have to discuss with the patient before the procedure. Otherwise, after you get a report and the patient says it is against my belief to do a termination, what is the sense in doing the invasive test? In fact then I'd rather not do the triple marker either. So before you do the triple marker you have to talk to them about all this – take them to the end of the line and make them see the implications of all the tests.

There are some patients who tell me that they don't want to do the triple marker because if it finds that the risk is high, and they don't want an amniocentesis, then they are stressed for the rest of the pregnancy. So they'd rather not know. Whatever the decision, I have counselled the patient beforehand, prepared her for all the possibilities. The patient has to make the final decision.

What if a pregnant woman is unable to make a decision?

If she needs a confirmatory test, I will make it clear to her that in case the test shows a child is affected *and* I am unable to offer any therapy, then this is what the condition will be and the patient will have to make up her mind about continuing or terminating the pregnancy. If the patient makes it clear in advance that she will under no circumstances abort the pregnancy, I have to think about what I am gaining in doing the test. If I can offer her some sort of therapy, then yes I would do the screening test.

What happened in the Niketa Mehta (2008) case? Why was she subjected to pre-natal tests after the 20th week when Indian law prohibits an MTP except to save the mother's life?

In the Niketa Mehta case, a foetal 2-D echo, a colour Doppler that picks up any problems within the heart, was used. We do it routinely in patients who are diabetic, have a history of congenital heart disease in the family, or who already have a child with the problem. Or if the ultrasound scan at 18-19 weeks showed some abnormalities. But it can be done only at 23-24 weeks because it is only then that you can see things properly in the heart.

Basically, after 20 weeks we use a lot of ultrasound and colour Doppler tests for certain heart, neurological and kidney problems. These tests are done to know in advance if the baby has a problem so that at birth we can get the baby out quickly, and get in a cardiac surgeon immediately. Parents who have conceived after a long time are very keen to continue. So it does depend on how keen the parents are about that particular child and on continuing the pregnancy.

But in the case of Niketa Mehta, the foetus had too many major heart abnormalities so the chances of the child having a normal, healthy life were very poor.

Currently, medical termination of pregnancy is legal only up to 20 weeks of gestation. You have been quoted as saying the Medical Termination of Pregnancy Act should not focus on the week of gestation but on the health of the foetus as the basis for termination. Could you elaborate on this?

I think the MTP Act should not restrict the termination of pregnancy by any particular week of gestation. They could legalise a cut-off at around 24 weeks. Most cardiac, neurological and kidney-related problems surface by then. But even after that cut-off, MTP could be offered on a case-to-case basis – if a situation arises that is going to give a poor quality of life to a child, who may have to live from birth with multiple surgeries, and who may never really recover from an abnormality. Every such case should be referred to a committee which would take into account the opinions of an obstetrician, paediatrician, paediatric surgeon, lawyer, maybe a layperson too, perhaps another parent.

Unfortunately in the Niketa Mehta case, the committee sat on the fence and did not make a proper suggestion. I suggest that there be an independent committee at the Centre, not controlled by any medical college or by anyone else, and local committees at the state and city levels with a similar structure. Of course, it's going to be a big task, but the time has come for us to deal with this.

I happen to be on the ethics committee of FIGO – International Federation of Gynaecology and Obstetrics – and we are discussing these very recommendations at the moment. The FIGO guidelines clearly mention that if a child is severely handicapped and this is going to affect the child's quality of life, then termination at any stage of pregnancy is recommended.

Regulate technology, not lives

Should social problems have social solutions or technological ones? Assisted reproductive technologies are reinforcing the importance of 'one's own' children. The normative, genetically-linked family is being strengthened in the process, when we should in fact be building a society that respects a diversity of relationships and families

CHAYANIKA SHAH

THE ASSISTED REPRODUCTIVE Technology (Regulation) Bill, 2008 (1), has been posted on the websites of the Indian Council of Medical Research (ICMR) and the Ministry of Health and Family Welfare for comments from the general public. It follows, and draws from, the functional and ethical guidelines for assisted reproductive technologies (ARTs) issued by ICMR in 2005. News reports suggest that the Bill is intended to protect couples seeking the technology against exploitation by unscrupulous medical professionals (2, 3) and unethical marketing practices of ART clinics. It also purports to regulate surrogacy and respond to social and ethical issues around parenting associated with ARTs.

However, close inspection of the Bill suggests that it is not designed to achieve such concerns. On the contrary, the intention seems to be to protect clinics from complaints in social disputes such as who the 'real parent' of the child is. It does not protect women from dangerous technologies. It dwells on the infrastructure for clinics but underplays the side-effects of the procedures. It specifies who may access the technologies, but is unclear about whether these technologies are actually treatments for infertility. It also tries to safeguard the rights of the 'commissioning couple' vis-à-vis the surrogate, while claiming to protect the rights of the surrogate.

In this commentary on the ART Bill, I will discuss the principles behind ARTs to understand what should be regulated to protect the bodies of women who use these techniques. I will also raise some questions about repeated use of technological solutions for social problems. Finally, I will propose that these technologies might actually be used to redefine certain norms in society.

But to begin with, who do the assisted reproductive technologies really assist?

Who do ARTs assist?

Assisted reproductive technologies are essentially what the name suggests – technologies to assist reproduction. They are not treatments for infertility. Even in those rare cases when they are assisting the infertile, they do not cure them of infertility or treat them for it. In fact, they make no such claims.

Who can ARTs assist in having children?

They can assist those women who have husbands or male partners with no sperm, or low sperm count, or sperm that are not motile enough, or sperm that for some reason the women's bodies repulse. They can assist women who do not have fertile eggs being produced in their bodies, or who cannot carry a full-term pregnancy. They assist single women who do not have male partners to provide sperm and therefore need ARTs though they are fertile. They assist women who may or may not have husbands and have proven fertility but who decide to nurture a child for someone else in their own bodies (providing either the nurture alone or also the ovum or egg) either in an altruistic manner or in a commercial transaction.

ARTs also assist men in a heterosexual relationship who have sperm-related problems. They assist single men who can use altruistic or commercial services from fertile women to beget children with their paternal lineage. They can also assist men who are in sexual relationships with other men to have their own genetic child from a woman without having sex with her.

ARTs can help people with many kinds of biological and social infertilities or inabilities to have their own genetically-related children. Since they do not treat the biological causes of infertility, they are actually a technological solution to the social problem of not having a child of 'one's own'.

It is true that not having a child that bears a genetic imprint of oneself is a social problem. It can make life for some people miserable and for many others very difficult. This is because genes are one of the ways in which families are made. Such families are assumed to be the essential material and emotional support for all people. They are also the only social security available to many people and therefore difficult to forego.

A social problem needs a social solution. We need to have social security for all. We need to make a society that is more tolerant of all kinds of love, relationships and families. We need a society that respects diversity and difference. We need to explore the ways in which material and emotional

support can be shared between a group of individuals irrespective of their ages and abilities.

ARTs, however, underline the importance of genetically linked families. In that sense, they provide individual solutions to a wider social problem. By feeding into normative notions of family and support, they necessarily weaken all struggles to redefine the problem itself.

What are ARTs?

To add to this, many of these technologies (that are flaunted as major achievements of science) are harmful, especially for the women whose bodies they invade. This fact is underplayed by the providers in the same way that the effect of harmful and invasive contraceptives is ignored. Once again, individual women are forced to make a choice between the physiological suffering of ARTs and the social recriminations of not having a child of 'one's own'. However, we need to understand the principles of these technologies to comprehend the price that is paid.

Broadly speaking, there are two kinds of technologies: one in which fertilisation of the egg happens in-vivo (inside the woman's body) and the other in which part or all of the process is done in-vitro (in the laboratory).

The first set of technologies involves manipulation of the man's sperm (from the woman's husband or partner, or from other men). These sperm are then introduced into the woman's uterus or vagina through a syringe (instead of the normal procedure of using a penis). Fertilisation occurs inside her body (in-vivo) in the usual manner and need not involve any alteration of her hormonal cycles. The manipulation of sperm happens outside the male body. This set of technologies does not interfere with the regular functioning of the body. It may not need much medical supervision. The technology is very rudimentary and can, in fact, be used by women and men themselves without the intervention of a medical professional.

These technologies are very different in character from in-vitro technologies. It might be technically correct to call both

India has become a centre for surrogate motherhood. Photo: AFP

ARTs, but they cannot be equated. Doing so undermines the graveness of in-vitro technologies.

In-vitro fertilisation (IVF) means the egg is fertilised outside the body. For this, the egg has to be retrieved from the woman's body and fertilised, and the fertilised embryo has to be implanted into a body that has been prepared to nurture a pregnancy. Extraction of an egg is not a simple process, unlike normal sperm extraction. It needs medication which can have serious side-effects and also minor surgery. Similarly, insertion of the embryo requires preparing a woman's body to receive it (usually with synthetic hormones). It also involves the use of procedures slightly more complex than those required for the insertion of sperm.

In IVF, the woman giving the egg and the woman receiving the embryo might not be the same. In rare cases, the egg could be made of parts contributed by two women. Therefore it can involve chemically controlling, intervening in and manipulating two or more women's bodies. It means constantly monitoring the women, controlling their bodies with the help of a medical team, and the use of technology, both chemical and surgical. This is where the power of science and technology is eulogised, and this is where maximum manipulation of technology happens.

As ARTs are practised today, there is no standardisation of drugs used, no proper documentation of procedures, insufficient information for patients about the side-effects of the drugs used, and no limit to the number of times a woman may be asked to go through the procedure. Doctors and clinics compete and boast of high success rates for less money. They do not disclose the fact that a 'successful cycle' need not lead to a baby being born. They do not disclose the actual costs involved in the process (4). They do not give exact information on the procedures and their possible side-effects.

Such malpractices are not addressed in the ART Bill. For the women whose bodies will be sites where these technologies and businesses operate, this is one of the biggest lacunae in the Bill. Checking infrastructure and record maintenance which the Bill provides for is no guarantee that the best medical procedure is followed.

Second, the Rules of the Bill that lay down details of the nature of procedures, selection of patients, and possible side-effects assume that ART is being used only by heterosexual infertile couples. So they specify indications for various techniques based on the nature of infertility (5). The side-effects are underplayed as 'ART procedures carry a small risk both to the mother and the offspring' (6). Evidently, the risk is 'small' in comparison to the pain and trauma of infertility. In any case, the use of fertile women's bodies for egg retrieval or for surrogacy does not figure in the discussion on risks.

The Bill has provided for many informed consent forms to be filled and records to be kept. But it does not require that adequate information be given to the people seeking ART or to the surrogate. For example, the consent form for couples asking for IVF and ICSI (intracytoplasmic sperm injection) has only the following information about the possible side-effects: "The drugs that are used to stimulate the ovaries to raise oocytes have temporary side-effects like nausea, headaches and abdominal bloating. Only in a small proportion of cases, a condition called ovarian hyperstimulation occurs where there is an exaggerated ovarian response. Such cases can be identified ahead of time but only to a limited extent. Further, at times the ovarian response is poor or absent in spite of using a high dose of drugs. Under these circumstances, the treatment cycle will be cancelled" (7).

Is this adequate or even indicative of the kind of problems that are possibly in store? And even this is not part of the informed consent form for the surrogate who might go through the same procedure.

Low temperature preservation

There is another aspect of ARTs – cryopreservation – which involves technology. Various types of germ cells are created and extracted from the human body using ARTs. Sperm are extracted (all of which may or may not be used), eggs are removed from women's bodies after super ovulation (sometimes as many as 14 or 15 per cycle), all of which may not be used for fertilisation, and embryos are generated after fertilisation (sometimes seven to eight per cycle), all of which may not be inserted for continuation of pregnancy. These are inevitable by-products of these technologies (8).

It is possible to preserve the by-products and use them later. They can be used for reproduction or in research laboratories. So arrangements have to be made and technology used to create the temperatures at which this preservation is possible. The germ cells are stored for future use in 'banks' which function much in the same way ordinary banks do where resources can be stored and saved by individuals to use when needed by them or by someone else. Sperm banks have existed for some time now where sperm are cryopreserved and from where individuals can get 'safe and matching' sperm.

The new Bill acknowledges that the low temperature facilities are for more than sperm. And so they have renamed these facilities – but instead of 'germ cell banks' they have been renamed 'semen banks'! The proposed 'semen banks' will preserve sperm, eggs and embryos and also be places for registering surrogates. One wonders if this nomenclature is a result of careless drafting or a patriarchal mindset which assumes that only the male's contribution results in life and not the 'inactive' egg inside an even more 'inactive' woman's body. I hope it is the former, but I am

almost certain that it is a combination of both and this makes the proposed Bill more suspect.

Further, there are no specifications about the nature of equipment, staff or facilities that the 'semen banks' ought to have. While they are treated in this lackadaisical manner, these banks are entrusted with advertising for and sourcing donors of oocytes and sperm and surrogates as well.

The worst, however, is reserved for the definition of surrogacy and how the Bill addresses this social reality.

Restricted surrogacy

The Bill defines surrogacy as an "arrangement in which a woman agrees to a pregnancy, achieved through assisted reproductive technology, in which neither of the gametes belongs to her or her husband, with the intention of carrying it to term and handing over the child to the person or persons for whom she is acting as a surrogate; and a 'surrogate mother' is a woman who agrees to have an embryo generated from the sperm of a man who is not her husband, and the oocyte of another woman implanted in her to carry the pregnancy to full term and deliver the child to its biological parent(s)".

By this definition, all surrogacy arrangements that involve the woman bearing a child using her own egg (oocyte) and the commissioning man's sperm are illegal. The definition underlines the fact that the surrogate mother is not the biological parent, thus emphasising that only those who contribute the genetic material can be considered biological parents. The fact that a human body nurtures the pregnancy has, according to this Bill, nothing to do with biology.

By this definition, fertile surrogate mothers will necessarily have to use technology meant for treatment of infertility. Surrogates will now be forced to use only the second set of technologies and not the first, even though they can get pregnant with methods like artificial insemination which are much safer for them. The need to conceal the identity of the gamete donor emphasises that the child's parentage is understood to be a product of the genes. It underlines the perspective that nurture in the biological body has no role to play. The surrogate is just a womb that has to be prepared to receive the embryo.

Registration of surrogates with a 'semen bank' further underlines the fact that the surrogate is seen as just another component of the technology – a womb. In true reductionist science paradigm, a child is made with the help of a sperm, an oocyte and a womb. Just as the 'semen bank' looks for donors of eggs, sperm or zygotes, it is also entitled to advertise for and register surrogates. This ignores the fact that while the donated egg or zygote gets separated from the woman's body, the womb continues to stay inside her and thus has to be looked at differently. For this one would need to treat women as human beings, not just child-bearing devices.

In fact, what is incomprehensible is why this Bill talks about surrogacy at all. The Bill is about regulation of assisted reproductive technologies which it defines as 'all techniques that attempt to obtain a pregnancy by handling or manipulating the sperm or the oocyte outside the human body, and transferring the gamete or the embryo into the uterus'.

Since the technology concerns a human body and a uterus, why should a clinic, a doctor, and a giver of such technology be concerned with which human body and which uterus? Does it matter if the uterus belongs to a woman who is married and is carrying her 'husband's' child or to one who is married but not carrying her 'husband's' child? Does the provider of the technology need to know what kind of legal contract she has made with the man whose sperm contributed to the embryo – that of marriage or that of surrogacy? Do the health concerns vary with the reasons for pregnancy? If not, why does the Bill put a limit on the number of times an embryo transfer can be done for a surrogate but not for other women?

A surrogacy contract, much like a marriage contract, is definitely needed to protect the woman's rights. The question is: does this need to be put under the ART Bill? Inclusion here simply underlines the notion that women are baby-producing machines, if not in their avatars as wives then definitely in their avatars as surrogate mothers. A Bill that is meant to safeguard the provider and the commissioning couple (because they are seeking to produce children through methods that are not normally used by 'non-normative' means) will not protect the rights of the surrogate. She is the most marginalised and vulnerable in this triad. Her rights need to be protected, but not under a Bill that regulates technology. We need to oppose the inclusion of surrogates' rights within this Bill and also oppose this definition of surrogacy.

When the commissioning parents do not provide the gametes, donors are kept secret, presumably so that the rights of the child are protected. With or without technology, there are many disputes around parentage of children. There have been a number of instances when the gamete donors, especially the legal husbands of mothers of the children, have not fulfilled their responsibility towards the children and/or questioned the child's paternity. These are issues that are social in nature. They will come up however much we try and deny the surrogate mother the right to be the mother in the first place, and define parentage only through the genes. A woman should not have to go through the range of in-vitro technologies just to ensure that she is not also the genetic parent for fear of future legal problems.

Debates within

Finally, if the rights of surrogates are not taken care of in this Bill, how are we going to ensure that these rights are protected? For that we must first acknowledge that surrogacy is another name for the reproductive labour that women have always done (9). Through these technologies, when the emphasis is once again on the germ cell and gamete theory of children and everyone is under a moral pressure to have 'a child of their own', the surrogate who asks for monetary compensation and voluntarily gives her child to someone else to nurture is probably the only subversive element in the story.

In a caste-ridden, hierarchical, patriarchal society like ours, adoption of children is a process that helps break many norms of caste and lineage. Even though the Bill mentions adoption, and doctors state that they offer adoption as an option right at the beginning, these technologies and the people providing them actually underplay adoption. The availability of these technologies itself pushes people to try and have their 'own child' rather than adopt. Considering the amount of money that providers make, and the credit that they get for 'providing children in people's lives', it is hard to imagine that they would even suggest adoption before having milked these opportunities.

Yet there is a minor but subversive potential in these technologies. They can be used by all those who are socially not allowed to have children of their own. They also allow for the possibility of multiple parents – the gamete donors, the pregnancy-nurturing mother, and the parents in whose guardianship the child grows up. Of these, the smallest role is actually that of the gamete donors. The surrogate/woman who carries the pregnancy is an important part of the child's life. And she, in her act of getting pregnant with the conscious decision of not nurturing the child beyond birth, redefines motherhood, lineage, and reproductive labour.

Of course this perspective raises new issues to resolve. Acknowledging surrogacy as legitimate labour and permitting a market in surrogacy could push women back into their role as reproducers, thus endangering the hard-won gains that women have made to be more than mere reproducers. There is also the argument that surrogacy will encourage exploitation of poor women as cheap labour, available to all and sundry, especially foreigners. Also, women's bodies will continue to be exploited through commercial control over their reproduction, as they are already exploited through control over their sexuality.

My response to such concerns is that the reproduction market and the consequent exploitation of women is a reality in all aspects of women's lives. It is a battle to be fought at a larger level. It cannot be fought over an individual's very limited 'choice' of using that market potential to her full ability through using whatever sells best – physical, reproductive, or sexual labour. By creating a hierarchy of legitimacy between these various kinds of labour, we allow a moral edge to our arguments that makes the surrogate even more vulnerable than she already is. Instead of talking of the rights and wrongs of surrogacy, we need to find out more about who these surrogates are and what they need to deal with the forces in this burgeoning industry where technocrats are called 'doctors', businesses are called 'clinics', and clients are called 'commissioning parents'.

Until the voices of these women are heard and concrete demands emerge from their experiences, let the Bill do just what its name indicates it should do – regulate technology, not human beings.

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References

1 Ministry of Health and Family Welfare, Government of India, Indian Council of Medical Research. The Assisted Reproductive Technology (Regulation) Bill and Rules – 2008 (Draft). New Delhi: MOH&FW, ICMR; 2008 (cited December 30, 2008). Available from: http://icmr.nic.in/art/Draft%20ART%20(Regulation)%20Bill%20&%20Rules%20-%202008-1.PDF

2 Unnikrishnan C H. 'Bill to Regulate IVF Clinics to be Tabled Soon'. LiveMint.com *The Wall Street Journal* September 24, 2008 (cited December 14, 2008). Available from: http://www.livemint.com/2008/09/24001126/Bill-to-regulate-IVF-clinics-t.html

3 Mukhopadhyay P. 'Surrogacy Law on the Anvil in India'. One World South Asia, October 18, 2008 (cited December 14, 2008). Available from: http://southasia.oneworld.net/todaysheadlines/surrogacy-law-on-the-anvil-in-india/?searchterm=ART Bill

4 For a very brief but fairly comprehensive list of side-effects of these interventions see *Cheap and Best: Analysis of Websites, Brochures and Advertisements on Assisted Reproductive Technologies in India.* New Delhi: Sama-Resource Group for Women and Health; 2008. p 36

5 There is an attempt in the Bill to define a couple as any two persons, and yet every time there is a couple being mentioned in the Bill, what is meant is always a heterosexual, married couple. Similarly, although technically single persons can use the technology, all along what is implied is that there is a married couple that is availing of the technology

6 Page 67, section 6.13 on complications

7 Form D, page 81 of the ART (Regulation) Bill, 2008. The only other information that is given is about how the technique may not succeed and that there is no guarantee that there shall be a pregnancy

8 This is similar to the ways in which multiple pregnancies are by-products of these technologies. Since every embryo inserted may not result in a pregnancy, many embryos are inserted at a time into a woman's body. There is, at present, no limit on the number of embryos that may be inserted into a woman's body. Very often, more than one embryo result in pregnancies and that is the secret behind the miracle of multiple pregnancies! Similarly, as each cycle of super ovulation is physically taxing, drugs are administered so that many eggs mature and can be extracted in one cycle

9 In any case, all women can be considered to be surrogates for their husband's children. How else do we explain the fact that the moment a child is born she gets the father's name and guardianship? The mother is not taken to be the natural guardian. Until very recently, children were also assumed to be as much a property of the father as the woman herself. Every mother is paid for this labour in society in kind and in status

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Women as wombs

The unethical use of technology to control reproduction has a long and contentious history. There can be no doubt that women need effective contraception. The question is: Are the contraceptives being tested and promoted both effective and safe? Shouldn't women be able to control their use? Shouldn't women have the right to choose, with complete awareness of the risks involved?

SAROJINI N B

JUST BECAUSE WE *can* do something, *should* we do it?

As medical technologies develop in ways that were unimaginable only a few decades ago, this is a question that has come to plague all of us since the second half of the 20th century. Advancements in the field of reproductive medicine, reproductive technologies in particular, have prompted this question. In a sense we 'can' do something because it has been made possible; research in medical technologies, whose direction and type have been shaped by the needs of the state and international bodies, has furthered intervention in the reproductive potential of women.

The contemporary construction of reproductive technology is not without a past. It is important to historicise the 'modern' new reproductive technologies (NRTs) and see them not as isolated scientific breakthroughs but as contained within this particular context. However, the unprecedented expansion of these technologies, further impacted by developments in the field of biotechnology, has resulted in an urgent need for interrogation into issues that lie at the interface of technology, health and society. It is in this context that a focused understanding about the health and social implications of NRTs for women becomes essential.

International agencies, family planning organisations and governments have justified invasive medical interventions – hormonal contraceptives, anti-fertility vaccines, chemical sterilisation, and tubectomies performed in unsafe conditions – in developing countries using arguments such as fertility rates are 'out of control' and a 'population explosion' is imminent. Scientists have collaborated in this enterprise, testing contraceptives on poor women without their consent, despite evidence of the side-effects and serious health consequences of this practice. When research towards the approval of such contraceptives has been opposed, regulatory authorities have permitted their introduction through the back door, often solely on the basis of their 'approval' elsewhere, even if the mandated India-based trials have not been conducted.

The unethical use of technology to control reproduction thus has a long and contentious past, primarily because of the dubious historical association of 'family planning' with 'population control'. Women's and health rights activists have raised questions about the safety of hormonal contraceptive technologies, the way in which clinical trials are conducted, collection of informed consent, and the family planning programme's inadequate efforts towards women's health in general. Furthermore, women's health activists have protested the inclusion of women in the healthcare system essentially as reproductive beings, to the exclusion of their other health needs.

This paper looks at the framework within which particular hormonal contraceptive methods are developed, the concerns they pose, and some associated interventions made by the women's movement. Drawing on the histories of the women's and health movements – starting in the 1970s – it sketches a broad picture of ethical concerns in contraceptive technologies such as injectables and implants.

Background

A qualitative leap in contraceptive research came in 1960 when the US Food and Drugs Administration (USFDA) approved the oral contraceptive pill containing hormones which interfered with the reproductive process in various ways, including by preventing ovulation and by making the uterine lining incapable of sustaining a pregnancy. The hormonal contraceptive freed women from both the fear of an unwanted pregnancy and, significantly, male consent or cooperation. The pill was thus promoted as liberating, especially in circumstances where women were unable to insist on the use of barrier methods. However, problems soon began to be reported – it was suspected, for instance, that the oral contraceptive raised women's risk of a stroke – and newer versions of the pill with lower doses of the hormones were developed which reportedly have lower risks.

Medical exploitation of poor women, particularly in the third world, has been and continues to be rampant. In her 1993 book *Women as Wombs,* Janice Raymond points out that women in developing countries have been the primary experimental population for multi-centre

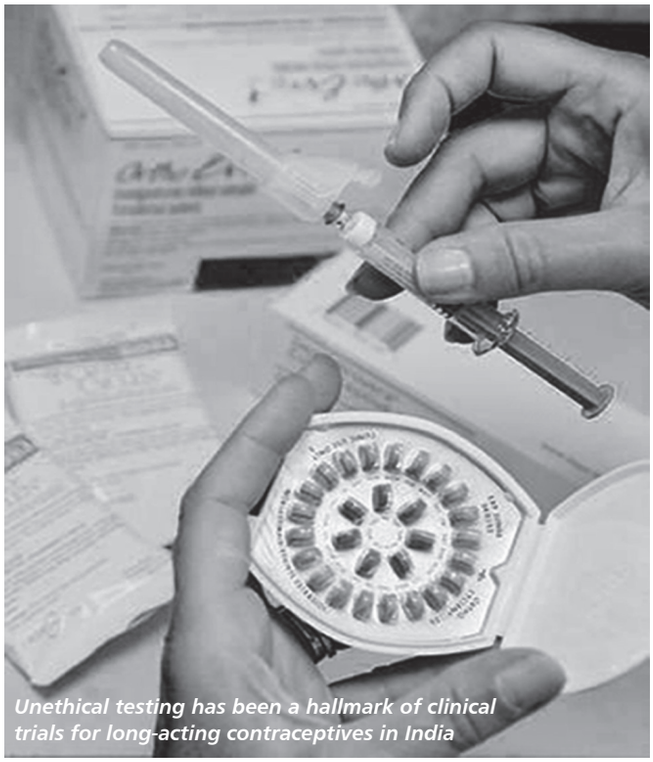
testing of contraceptive implants, injectables, and anti-pregnancy vaccines. Research has targeted the female reproductive system because it is easier to interfere with. The consequences of this deployment are a whole range of side-effects, from irregular and severe bleeding, loss of libido, weight gain and severe headaches, to serious risks that include osteoporosis, blood clots and strokes. Public health services in India do not provide women the kind of screening and related care that must accompany these methods of contraception. Such methods are 'effective' for population control, but may not always be what women themselves want, and there is enough evidence that these contraceptives have been tried on women in circumstances that preclude their informed consent.

Injectable contraceptives

Norethisterone Enanthate, or Net En, is a synthetic form of the hormone progesterone in an injectable form, and is manufactured by the German company Schering. The 200 mg injection must be administered every two months to prevent conception. Depo-Provera is the brand name of Depot Medroxyprogesterone Acetate (DMPA), which is manufactured by Upjohn Co and must be administered every three months. Both prevent pregnancy mainly by stopping ovulation through the injection of a high dose of a synthetic hormone like progestin into the body.

Before their introduction in India, injectables had a controversial run in other countries. Depo-Provera was denied approval by the USFDA when Upjohn made its first application in 1967, and later in subsequent applications. It was eventually approved by the USFDA in 1992. Clinical trials of Depo-Provera have been going on in India since the 1970s. However, in 1975, Depo-Provera trials were discontinued without providing any explanation. As part of a study on Depo by the WHO, in the late-1970s, about 1,700 women from 10 centres all over the world – including Mumbai and Chandigarh in India – were given either Depo or Net En once in three months. At the end of the first year in Chandigarh, 60% of women on Net En and 82% on Depo dropped out of the trial. The discontinuation rates because of amenorrhea – absence of menstrual bleeding – and bleeding irregularities were much higher in Chandigarh than in all the other centres, including Mumbai. However, when reporting the results, researchers conveniently excluded the Chandigarh data from the calculation of averages. This is described in *Contraceptives: Our Choices, Their Choices,* by the Forum for Women's Health.

Net En, on the other hand, was withdrawn from markets in the US in 1971 following animal toxicology tests which found that rats administered the contraceptive developed tumours, indicating that it could be hazardous to women. Approval was finally given to Schering by the Federal Health Office in Germany, in 1983, with the press and information section of the National Health Authority issuing a statement



Unethical testing has been a hallmark of clinical trials for long-acting contraceptives in India

that read: "Their (injectables) use can only be justified in rare cases; the products are clearly second rate," but with a qualifying label stating that the drug was what they described as being "second rate" (as quoted in a 1994 interview with the Drugs Controller, by Rukmini Anand and C Sathyamala).

However, in 1983-84, the Indian Council of Medical Research (ICMR) initiated what it described as a Phase IV trial in urban and rural centres to assess the acceptability of Net En towards its introduction into the National Family Welfare Programme. Paramedics were given the task of recruiting women for the trial from a rural health centre in Patancheru, a village close to Hyderabad in Andhra Pradesh, which was to be one of the sites of this study. While 2.1% of women in the trial got pregnant, 41.21% experienced menstrual abnormalities. On the basis of these trials, ICMR, in its recommendations, stated that Net En could be made available at urban health centres where a doctor is present, and where comprehensive medical care can be provided.

Members of Stree Shakti Sanghatana, a women's collective in Hyderabad, who visited Patancheru, found that the poorest of women had been recruited for the study, that too without being informed about the drug's side-effects and contraindications. They were routinely told: "Injectable *le lo, baccha nahin hoga."* ("Take this injection, you will not conceive.") When the Sanghatana provided information on side-effects and contraindications to the participating women, only five out of 50 remained in the trials. This was

not an isolated incident; in Jaipur, the Sawai Man Singh Medical College issued posters and pamphlets advertising the injectable incorrectly, touting it as a "miracle" solution to unwanted pregnancy. Saheli-Women's Resource Centre, Chingari, and other women's groups filed a writ petition in the Supreme Court against the Union of India, ICMR, Drugs Controller General of India (DCGI) and others, asking for a stay on the Net En trials. The story of this case is given in Saheli's *Enough is Enough – Injectable Contraceptive Net En: A Chronicle of Health Hazards Foretold* (1999).

There has been insufficient research and testing on contraceptives – specifically for dosage and long-term side-effects – for Indian women. By the early-1980s, ICMR concluded that Depo-Provera was unsuitable for introduction in India. Dr C L Jhaveri, a gynaecologist and former chairperson of the Indian Association of Fertility and Sterility, was refused a licence to import Depo, primarily because there was no policy on whether drugs that had not been approved in India, but which had approval elsewhere, should be made available here. Thereafter, Dr Jhaveri contested this decision by filing a case against the DCGI and the Union of India. A women's organisation (Women's Centre, Mumbai) and a health network (Medico Friend Circle), along with the Union of India, filed a case against Dr Jhaveri in 1985. They argued that use of the drug in India's family planning programme could be disastrous for women's health. Following this, Dr Jhaveri was prohibited by the court from importing the drug or using it on women. This is discussed in *The Issues at Stake: Theory and Practice in the Contemporary Women's Movement in India* by Nandita Shah and Nandita Gandhi, and by Padma Prakash in *Women's Health Movement in India: A Historical Perspective* (2005).

However, despite the disturbing findings of the clinical trials, the DCGI, on ICMR's recommendation, approved the marketing of Net En in 1986 and Depo-Provera in 1993. Net En was officially launched in India for 'social marketing' by German Remedies Ltd.

Current status of injectable contraceptives

Although injectables have so far been kept out of the family welfare programme, the possibility of their future inclusion remains. It is also well known that these drugs are being prescribed by both private practitioners and those in public hospitals. Both Depo-Provera and Net En are easily available over the counter, without a doctor's prescription. Moreover, persistent attempts are being made to introduce new injectables through clinical trials and camps set up by NGOs at public health set-ups.

In 2004, in a series of public hearings on the right to health, initiated jointly by the National Human Rights Commission (NHRC) and Jan Swasthya Abhiyan (JSA), testimonies of women's experiences with Depo-Provera were presented by Sama-Resource Group for Women and Health before officials from different states. The NHRC panel was surprised to find that a public health establishment was administering Depo-Provera and subsequently demanded an explanation from the concerned authorities.

In October 2004, a workshop 'Expand Choices of Contraception' towards the introduction of injectables was organised by Parivar Seva Sanstha, a national-level non-governmental organisation (NGO), in collaboration with the Government of India, UNFPA, Population Foundation of India, and the Packard Foundation. This was met with opposition from a number of organisations including the All-India Democratic Women's Association, Sama, Saheli and Delhi Science Forum, that collectively submitted a memorandum to the then health minister. The ministry, in a letter to Saheli (No N 14013/22/2000/TO, dated April 19, 2007) responded:

In this connection I am to inform you that injectable contraceptive which was accorded marketing permission is being used in the country on the prescription of a physician since early '90s. However Government of India is not contemplating to introduce the same in the National Family Welfare Programme till the study on the effects of injectable contraceptive on Indian women's health is completed by ICMR and the NIRRH, Mumbai, and the findings are favourable. Based on the results of these studies, the department will take a decision on the introduction of injectables under the National Family Welfare Programme.

On April 16, 2008, the Ministry of Health and Family Welfare called a meeting to discuss Phase IV trials to be conducted at 31 district and medical college hospitals through nine NGOs, prior to the introduction of Net En and Cyclofem (a monthly combination injectable) in the public health system. The participants were informed that ICMR had already completed Phase III trials of Net En and Cyclofem, on the basis of which "experts" had approved the initiation of Phase IV trials.

On April 29, a memorandum addressed to the Union Minister for Health and Family Welfare, Anbumani Ramadoss, challenged the basis of these trials as well as the introduction of injectables in the public health system. It demanded to know what new evidence of "safety and acceptability" for Net En had emerged, on the basis of which the ministry was planning to launch Phase IV trials of a contraceptive which had previously been rejected as unsafe for introduction in the public health set-up. The memorandum pointed out that the Technical Committee of the Drugs Technical Advisory Board had already opined that DMPA, the key constituent of Cyclofem, should not be allowed for mass use in the family planning programme, and demanded to know on what scientific basis this recommendation was being overridden. Over 50 organisations and individuals endorsed the memorandum.

Following pressure from women's groups, the summary reports of the Phase III trials of Net En and Cyclofem were displayed on the ministry's website for feedback and clarifications. The ICMR website stated that the Phase IV trials would not be launched without taking relevant concerns into consideration:

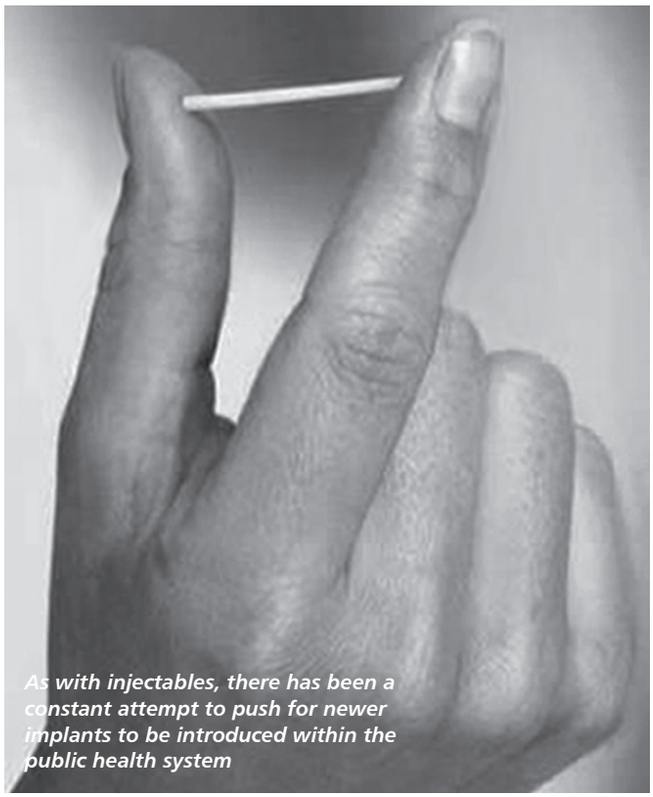
…The study has only recently been approved. After receipt of budget, the formative phase (six months) will be initiated which includes preparation of various guidelines (technical, operational, etc), procurement of drugs, setting up of various committees for review, monitoring, etc.

More recently, teaching hospitals and other tertiary-level hospitals have been known to offer their premises and infrastructure to researchers and NGOs that set up camps offering these injectables at discounted rates. For instance, at the Sardar Vallabhai Patel Hospital attached to the Lala Lajpat Rai Medical College in Meerut, an NGO, in collaboration with a post-graduate student at the college, set up a camp distributing information about Depo-Provera and also offering the injectable for use. The injectable was being given at a discounted rate of Rs 50 as opposed to Rs 180, the rate in the private market. Later it was confirmed that this was part of a two-year research being conducted by the student, and that Depo was not otherwise available on a routine basis at the hospital OPD. However, all women who approached the hospital for contraception were told about Depo as part of their "basket of choices", and were then directed to the table set up by the NGO outside the OPD, for further information.

Contraceptive implants

Norplant is a contraceptive implant initially developed at the US-based Population Council. It consists of six capsules, each the size and length of a matchstick, containing the steroid Levonorgestrel. The hormone is released slowly over five years, and prevents ovulation for that period. It was distributed in the US by Wyeth-Ayerst and is also licensed to the Finland-based Leiras Pharmaceuticals for low-cost provision to governments and family planning organisations in developing countries. Norplant received approval by the USFDA in 1990, but by 1994 at least 200 lawsuits had been filed in the US against its distributor Wyeth-Ayerst as women started reporting serious health problems. This raised doubts about the drug's long-term safety, and was of particular concern because the implant was promoted among poor women who have little access to healthcare for treating side-effects and are likely to suffer because of delays in detection and treatment of illnesses like ovarian cancer that have been linked to the implant.

In 1985, the World Health Organisation (WHO) declared Norplant to be an "effective and reversible method of fertility regulation particularly advantageous to women who wish an extended period of contraceptive protection" and "suitable for use in family planning programmes along with other methods of fertility regulation". However, the



As with injectables, there has been a constant attempt to push for newer implants to be introduced within the public health system

WHO simultaneously recommended training and supervision of medical personnel; more research on the implant's long-term side-effects and its use during lactation; post-marketing surveillance and acceptability studies. The WHO document emphasised the importance of screening women carefully "especially bearing in mind the side-effects" ('Facts About an Implantable Contraceptive', in *Bulletin of the World Health Organisation* 1985: 63(3): 485-94).

According to ICMR, at the end of five years of clinical trials almost 25% of Norplant users had requested its removal because of bleeding problems, and another 15% for medical problems including headache and weight gain. This was stated by R S Sharma, M Rajalakshmi and Jeyaraj A in 2001, in their article 'Current Status of Fertility Control Methods in India', in the *Journal of Bioscience* published by the Indian Academy of Sciences. Concerns associated with Norplant included difficulty in removal of the implant. To reduce the incidence of side-effects and the number of implants to be inserted, new implants have since been developed.

As is the case with injectables, there has been a constant attempt to push for newer implants to be introduced within the public health system. After the unethical trial of Net En in Patancheru became publicly known, research switched to hormonal vaginal rings, nasal sprays and a new Norplant. Norplant-2 trials were conducted on women in India during the 1980s. ICMR stated that due to financial constraints, it had not followed the 1,500 women who

were given Norplant-2. On December 6-7, 1990, ICMR had a closed-door meeting with "health advocates" to discuss the introduction of Norplant and other spacing methods in the National Family Planning Programme. In this meeting, ICMR reported that 1,466 women were given Norplant-2 between January 1986 and September 1991. Discontinuation after 36 months was 36-40%. ICMR stated that the method was safe and did not affect a return to fertility. Trials of Norplant-2 were discontinued when the council could not get supplies.

More recently, in August 2004, ICMR started a 17-centre, Phase III study evaluating Implanon, a single-rod contraceptive implant made by the Dutch manufacturer Organon, which provides contraceptive protection for three years. The study sought to assess its efficacy, side-effects, return to fertility following discontinuation, and acceptability in terms of the percentage of women who would continue using it. The study also sought to gather users' perspectives on the method and relative popularity of the method when offered in the "cafeteria" approach. As of February 2006, 2,550 women had been enrolled in this study. According to the ICMR report, 813 women completed one year of use, and 76 women completed more than 18 months of use (ICMR Annual Report on Reproductive Health [2005-2006]).

Clinical trials and informed consent – a revisit

It can be safely concluded that unethical testing has been a hallmark of clinical trials for long-acting contraceptives in India. From lack of informed consent to outright coercion, scientific investigation on contraceptives has fallen woefully short of meeting universally accepted ethical norms. Essential information should compulsorily be made public. This includes existing information on the safety aspects of the hormonal contraceptive, data on complications arising out of the procedure, known adverse effects, time for return to fertility, research design, and basis for approval.

Since the Patancheru experience, women's groups have monitored violations of informed consent procedures in the administration of contraceptives during clinical trials and research. A study conducted by the Forum for Women's Health on women who had been part of Norplant trials in Baroda revealed the unethical and unscientific way in which the trials were conducted. In an important work, *An Epidemiological Review of the Injectable Contraceptive Depo-Provera*, Dr C Sathyamala reviewed the scientific literature on Depo to establish that the risks with use of this injectable were unacceptable. Interviews by Sama in 2000 ('Unveiled Realities – A Study on Women's Experiences with Depo-Provera, an Injectable Contraceptive') found that women in Delhi were administered injectable contraceptives in a public hospital without their informed consent. Vital information regarding the safety and adverse effects of the contraceptive was withheld from the women, depriving them of their right to make an informed choice.

For safe administration of any invasive spacing method, women need to be screened and supervised by the medical team at regular intervals. These may need to be more frequent, and for a longer period, in the case of hormonal contraceptives: there are serious risks associated with their use, and a quantity of the drug may persist in the woman's body for some time after the method is abandoned. The return to fertility after the contraceptive is stopped is also a matter of concern. As these methods are provider-controlled, there is tremendous potential for abuse; this needs to be recognised and addressed. There is no such monitoring in India.

Those administered these contraceptives are poor women who visit government hospitals, where they are effectively treated as living laboratories. The testimonies of women who have participated in clinical trials reveal that informed consent is rarely, if ever, taken. Often, women who come to government centres for health services are recruited into trials and may not even know that they are in a trial, and that a drug is being tested on them whose full effects are not yet known.

Side-effects no "old rhetoric"

The side-effects of hormonal contraceptives include menstrual irregularities, cessation of menstrual bleeding, general weakness, migraine headaches, and severe abdominal cramps. In a country where a large percentage of women in the reproductive age suffer from anaemia, irregular and heavy bleeding can have catastrophic consequences. There are also unresolved concerns over the return to fertility and the health of babies born after cessation of use of the injectable or implant.

To give just one illustration, it is now widely accepted that injectable contraceptives like Depo-Provera can lead to reduction of bone density, resulting in an increased risk of osteoporosis. In the 'Important Safety Update on Depo-Provera' from Pfizer, Canada, Depo's manufacturer and current distributor states: "As a result of new clinical studies, one with adults and one with adolescents, we now have clinical data regarding the use of Depo-Provera and its associated effect on bone mineral density (BMD)." It adds: "Bone loss is greater with increasing duration and may not be completely reversible." The USFDA has mandated that Depo-Provera carry a 'black box' warning label, the agency's most severe warning, regarding bone loss. The FDA requires that the product label contain information to the effect that "loss of BMD (bone mineral density) in women of all ages, and the impact on peak bone mass in adolescence, should be considered, along with the decrease in the BMD that occurs during pregnancy and/or lactation, for women who used Depo long-term". Also recommended is the "addition of a statement based on post-marketing experience regarding rare cases of osteoporosis including osteoporotic fractures reported". The warning will also suggest that Depo use should be limited to two years unless other forms of birth control cannot be used. However, lax laws in India have not

mandated this disclosure, as a result of which women users remain unaware of the health risks associated with Depo.

Users have inadequate or no information regarding the health risks and side-effects of these contraceptives, a fact reiterated in the recent National Family Health Survey (NFHS-3). Only one-third of women contraceptive users said they were aware of side-effects, while only one-quarter knew what to do in case of side-effects. The survey has also raised questions about the overall safety of injectable contraceptives. NFHS-3 found that among all available spacing methods, the discontinuation rate was the highest for injectables (53%), followed by pills and male condoms.

Engagement of the women's movement – challenges ahead

Women's groups and health groups in India have long fought ethical violations occurring during research on and promotion of long-acting, hormonal contraceptives and other unsafe technologies. The list is endless and includes research on anti-fertility vaccines, illegal trials of quinacrine for chemical sterilisation, trials without informed consent, and coercion in the use of IUDs and sterilisation.

However, public debate on injectable contraceptives in India is still characterised by strident rhetoric that often serves to polarise discussions, including within the women's movement itself. Some welcome these technologies as products of scientific progress and argue that it is the context that makes them good or bad. There has been debate about whether there should be a blanket rejection of all hormonal contraceptives, or only of those that do not grant control to women as users. One group of health activists defends the use of injectable contraceptives and implants; they argue that such contraceptives are the only way poor and powerless women have control over their lives (neither husbands nor in-laws know if a woman is using an injectable). It is argued that injectable contraceptives have helped expand available choices for effective contraception, and, as such, a woman's decision to avail of any available contraception should be respected. It is also argued that no available contraceptive is 100% effective or completely free from side-effects, and, as such, the side-effects are more inconvenient than life-threatening. Further, perhaps the high risk of morbidity and mortality associated with unwanted pregnancies needs to be weighed against the side-effects of contraceptive methods, which are much less.

There can be no doubt that women need effective contraception. The question is: Are the contraceptives being tested and promoted both effective and safe? Shouldn't women be able to control their use? Shouldn't women have the right to choose, *with* complete awareness of the risks involved? Lakshmi Murthy argues in her article 'The Body as Victims' in *The Hindustan Times*, 2000, that the trumpeting of 'choice' should be viewed with caution when 'choice' is guided by a population control lobby backed by sophisticated marketing by pharmaceutical companies that stand to make huge profits.

Most of the emerging contraceptive technologies have multi-systemic effects and require more careful study in order to ensure their long-term safety vis-à-vis the health of both women users and their future progeny. Therefore, the dynamics of contraceptive use and the issue of informed choice merit close examination.

Radical feminist Renate Klein, in a 2008 article in *International Forum*, points out that the issue of concern is really about the context in which technologies are developed, and how they come to be used.

However, feminist critiques of the indiscriminate 'technologisation' of medical systems and practices have more often than not been interpreted as opposition to *all* technology. Feminists question the contexts and ab/uses to which technologies are put, because very often they involve adverse consequences for certain segments of the population, and for women in particular. Equally significant is the concern that life-saving healthcare technologies are still not available to most women in the world. *Our Bodies, Ourselves* (1994) emphasises: "We must judge the value of the reproductive technologies in the context of the social, political and economic setting…" Further, in her paper 'Feminists Against Women: The New Reproductive Technologies', Wendy McElroy puts forward the thought that the political effects of medical procedures on women as a class must be pitted against individual benefits, thus transcending the scale of medicine from one of mere science to that of an ideology.

In strategically marketing its products, the pharmaceutical industry has succeeded in appropriating feminist language of choice and empowerment, and deploying it against the interests of women. All women everywhere – irrespective of race, age, nationality, class, etc – are being projected as a homogenous whole that will benefit equally and substantially from all types of contraceptives. Vulnerable women are not raw material for research, available for sacrifice at the altar of larger systems of patriarchy, pharmaceutical companies, techno-medicine, etc. Mandated protocols of informed consent, counselling, and the provision of adequate health infrastructure and care cannot be overridden. Inadequate research into long- and short-term health risks must become unacceptable. These are matters not just of ethics, but also of human rights and social justice.

(The author would like to thank Vrinda Marwah and Anjali Shenoi for their inputs to this article)

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Challenges of a paediatric intensivist

A seven-year-old with a certain chance of recovery was removed from ventilator support and died because his parents could no longer afford it; a 13-year-old girl died without life support because her parents didn't want to spend any more on their daughter. Two paediatric intensivists discuss the tragic ways in which economics and gender bias decide who will benefit from medical technology in India

AKASH BANG
ARVIND KASARAGOD

INTENSIVE CARE consists of life support – ventilator, dialysis, intravenous medication, and nutrition – along with intensive monitoring. The equipment used includes mechanical ventilation, equipment for acute renal failure, intravenous lines, nasogastric tubes, suction pumps, drains, catheters, disposables – all provided by specialised staff. ICU expenses can be many times higher than treatment in a ward or room.

Two intensivists, one from a community hospital and the other from a corporate set-up, comment here on the dilemmas they face.

'Cost is the deciding factor': *Akash Bang*

Ethical challenges in intensive care arise out of three situations: because certain investigations or treatments are just not affordable; because a decision must be taken for or against a particular investigation or treatment, and the available scientific evidence in this regard is inadequate; and because developments in science have changed the definition of death. The first one – cost – is perhaps the biggest concern in India.

Challenges in monitoring

Intensive care involves two things: intensive treatment and intensive monitoring. The focus of intensive care worldwide is shifting towards more intensive treatment modalities and intensive mechanised or automatic monitoring. Automated monitoring is ideal because it gives you minute-by-minute variations in body functions and the opportunity to act with the least time lag. Compare this with manual monitoring with human factors like fatigue, ignorance, inaccuracy and disinterest playing a part. How frequently can you check a patient's blood pressure? Every 30 minutes? Every 15 minutes? Definitely not more than that. But we know that a steep drop in blood pressure that persists even for a few minutes could cause brain damage and start a vicious spiral of low blood pressure leading to more brain damage which in turn brings the pressure down further until it goes so low that there is multi-organ dysfunction and then failure. This can be prevented if there is minute-by-minute monitoring.

But the problem is the cost to the patient. We need specialised needles, lines and catheters for such monitoring. In most places, the patient's family must actually buy these needles. This leads to the first screening: those who can't buy the needle will back out at this point itself. Second, we need costly machines and paediatric intensive care units. Patients must cough up the money for all these. Third, intensive monitoring needs specialised nursing staff and doctors. Their salaries are also finally sucked out of the patients' bills!

This is true for all types of intensive monitoring: invasive blood pressure monitoring for a patient with shock or infection; central venous pressure monitoring for a patient with cardiac or renal failure or shock; intracranial pressure monitoring for a patient with raised intracranial pressure, and so on. All these types of monitoring are so interlinked that they are needed for almost all seriously ill children. And the cost of the needle or catheter to even start this monitoring is between Rs 2,000 and Rs 5,000.

There are many situations where paediatric intensive care units (PICUs) in community hospitals don't even start intensive monitoring. We know that one day of intensive monitoring could prove so costly that it could finance the cost of maybe five days of medical treatment for the patient. This poses an ethical challenge to us intensivists: we know that by not starting intensive monitoring, we are giving sub-optimal therapy, but we may still choose to do it as a trade-off.

Then there are PICUs where the child is not admitted until the parents come up with a deposit of Rs 15,000-20,000. The day the bill exceeds the paying capacity, the child is transferred to a less expensive hospital. They will probably justify this by saying: "Our motto is to provide the best possible care as long as it is affordable to the patient. Once the patient cannot afford it, we don't believe in providing sub-optimal therapy." Nobody is right or wrong here. Isn't life full of shades of grey?

Apart from cost, automated intensive monitoring has probably led to overdependence on these gadgets. The clinical acumen, intuition and judgement that the earlier generation of doctors possessed and practised are being underutilised due to machines. I have seen trainee doctors noting down the patient's heart rate from the monitor rather than by feeling the patient's pulse. When everything is on display on the monitors, who has the time, energy and drive to crosscheck these by doing it manually?

Challenges in treatment

There are many essential but expensive therapies involved in life support: renal replacement therapy for renal (kidney) failure; inotropes/vasoactive medication for severe shock; liver transplant for liver failure; the ventilator for respiratory failure, etc. The most common therapy and a typical example would be the ventilator, the cost of which could range from Rs 500 to Rs 3,500 a day. A child may need a ventilator for a few hours or for a number of weeks.

Once, during my PICU fellowship training in Bangalore, I was involved in the care of a child from a very poor family from Madanpalle district in south Andhra Pradesh. He was brought to our PICU with Guillain-Barre Syndrome. This is a disease where the muscles become progressively weak and respiration becomes difficult – all with a perfectly intact consciousness and comprehension. Recovery occurs after a period that could range from a few days to a few weeks. It is probably one of those rare instances where a complete recovery can be expected; you just have to tide over the period of muscle weakness.

Somehow this child didn't recover quickly. We continued ventilating him as we knew that sooner or later he was going to recover. The family was poor so we took it upon ourselves to generate some money for him. Through the departmental fund and by talking to IT professionals, we gathered around Rs 20,000. However, sometime during the fourth week of ventilation, the family decided they couldn't go on any longer. The child – a seven-year-old – understood that he was going to die. He was perfectly conscious; the only problem was his muscular weakness. He probably just needed a few more days on the ventilator. Due to the length of his stay, we had developed a fondness for him and used to play music for him on night duty. On the day he was being taken away by his relatives, he was a mute spectator to preparations for his own death. I can never forget his gestures signalling us not to take him off the ventilator. He left the PICU with tears in his eyes, obviously calling out for a chance to live. We counselled and requested the relatives repeatedly, but they had decided to take him home. One of the nurses had taken the relatives' number and called the family the very next day. The family thanked us for all that we had done but informed us that the child had died within two-three hours of his departure from the PICU.

It's a challenge to explain to relatives that intensive care may not yield the expected results. More often than not, they believe that if they are spending so much why shouldn't the child recover? Or, worse, they may say: "You tell us exactly what the chances are that this child survives. Depending on your answer, we will decide whether to spend the money. And if we do decide to spend, we will decide how much." How can anyone answer such a question? In children, it's even more difficult (than in adults) to predict the outcome. They have very delicate systems which can head either way – improvement or deterioration – at the slightest trigger, and at very short notice. Sometimes with no notice at all!

An intensivist goes through extreme stress on- as well as off-duty. Practising intensive care can be very rewarding, and at the same time very frustrating. It can infuse you with life, zeal, thrill and enthusiasm. And it can also suck the life out of you. You can become a humble facilitator, or an arrogant demigod.

Whichever way it works, one thing cannot be argued: it brings you closer to philosophy, spirituality and the creator, whether you call it Nature or God. It makes you realise the most naked truth of human life – that nothing is permanent. As they say, we must have courage to do what we can, humility to accept what we can't, and the wisdom to understand the difference.

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'She's a girl, just take the tube out': *Arvind Kasaragod*

Paediatricians are the most humane group of people in any field. They rarely do anything that is not in the best interest of the child. But there are situations where, for example, the child has a malignant tumour and has just a few months to live, but on a ventilator. The parents say absolutely not; if the child is going to die let it happen. I have heard of doctors removing the breathing tube and putting the child into a car, with the knowledge that the child will die soon after the life support has been removed. This can't be documented anywhere. Some of the cases which are recorded as "discharged against medical advice" will have been cases like this.

The other thing that I have seen is the huge gender bias. More often than not, if it is a girl the family doesn't want to spend money. If it is a boy, they say: "Do everything you can." This is true not just among the very poor; it happens even with the middle class. There was a 13-year-old girl with dengue shock syndrome. We got her late in the course of the disease, but we were able to resuscitate her. At the end of 24 hours we knew she was going to turn the corner. But by then the bill had touched Rs 80,000. We pleaded with the parents to give her 24 hours. The father said: "She's a girl; her body won't be good for marriage. If she had been strong she would have made it through by now. We don't have a problem with withdrawing care. Just take the tube out, she is probably meant to die anyway."

This is even more acute with neo-natal intensive care. Today, any baby above 26 weeks gestation, especially more than 750 gm, has a chance of survival. But at the counselling stage, if the parents are from a low socio-economic class, when we tell them what the medical chances are and what it is going to cost, they are quick to respond: "Transfer us to a public hospital. If the patient survives in spite of that, fine."

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X-rays: Too much of a good thing?

The invention of x-ray and ultrasound technologies has had one important negative consequence in India – sex-selection, with the sex ratio in places like Chandigarh down to 773:1,000. There is another: over-investigation and over-exposure to radiation. With the number of CT scans quadrupling since 1992, as many as 2% of cancers could now be attributable to radiation exposure

SANJAY A PAI

OF THE MANY TECHNOLOGIES that have had an impact on medicine, the development of radiology and imaging stands out as unique. There are many reasons for this: the discovery of x-rays was a serendipitous one; the exact dates on which the discovery was made are known; the application of a new field of medicine was immediately obvious to doctors and the public; and the application of this technology to medicine was done almost immediately after the discovery of x-rays. Besides, the new technology entered the minds and lives of the common man in more ways than one would have expected in the early years, while much later, additional developments in the field brought other changes in our lives. Changes that perhaps would not even have been dreamed about at the time of the development of the first x-rays.

Discovery of x-rays

Wilhelm Conrad Roentgen was director of the Physical Institute at the University of Wurzburg, in 1895. On November 8, 1895, Roentgen was working in his laboratory with a cathode ray tube when he noticed some fluorescent rays at a distance that was greater than expected for cathode rays. Roentgen was clever enough to realise immediately that he had stumbled across a new type of ray (a form of electromagnetic radiation) that was hitherto unknown to man. He spent the next six weeks in his laboratory working at a feverish pace to identify the ray. He found that the unknown rays, which he called "x-strahlen" penetrated many materials, but not lead. Importantly, he realised that the rays blackened photographic plates and produced shadows of bones.

On December 28, 1895, Roentgen submitted his paper 'On a New Kind of Ray – A Preliminary Communication' to the *Proceedings of the Physical-Medical Society*, of the University of Wurzburg. On January 1, 1896, he sent copies of the paper to colleagues and friends in different parts of Europe. One of these friends was Franz Exner in Vienna. Exner exhibited the paper and images to some of his friends at a party in his house a few days later. One of them was a physicist, Ernst Lecher, whose father, Z K Lecher, was editor of the newspaper *Vienna Presse*. On January 5, 1896, *Vienna Presse* carried on its front page an article describing the discovery and, more importantly, suggesting that this new wave might be useful in medical diagnosis. On January 6, 1896, the *London Standard* cabled the news around the world. The *New York Sun* and later the *London Standard* were quick to suggest the medical potential of the wondrous ray.

Roentgen received 1,000 letters within a week, and over 1,000 articles were written on x-rays in the first year itself.

It was not long before x-rays began to be used in medicine. The first medical x-ray was used to diagnose a Colles' fracture (a fracture of the radius, one of the bones that make up the forearm) on February 3, 1896, by Dr Gilman Frost, with the assistance of his brother Edwin, an astronomer.

How important is the discovery of x-rays? What do the experts feel? Andras Gedeon, in 'Science and Technology in Medicine', includes x-rays among the 99 most important technological advances that have contributed to medical science since 1528. Eugene and Alex Strauss place it as the 11th greatest advance in medicine out of the 100 most important concepts in medicine that they enumerate in their book *Medical Marvels*. They consider advanced imaging techniques such as CT, PET, ultrasound and MRI as the 49th greatest such advance. However, Meyer Friedman and Gerald Friedland, in their book *Medicine's 10 Greatest Discoveries* rate the discovery of x-rays as one of the top ten discoveries. The Nobel committee awarded the first Nobel Prize in physics – in 1901 – to Roentgen. Finally, not just experts but laypersons agree: in November 2009, nearly 50,000 people voted that x-rays were the greatest modern scientific discovery.

Those who have seen the 1980s movie *The Gods Must Be Crazy* will recall the amusing plot where a group of happy, content African tribals come across an empty bottle of Coca-Cola and find the bottle so useful in their daily activities that they cannot imagine life without the omnipotent empty Coke bottle! Certainly, all of us have experienced similar things with respect to newer technologies – in recent years we have often wondered how we were able to live life before the worldwide web, or digital photography, or cell

phones! A hundred years ago, it appears that it was x-rays that filled this breach.

Because x-rays were the hottest thing in the news, and everyone was aware of the almost miraculous powers of these wonderful rays, unscrupulous businessmen used the word x-rays indiscriminately and unscientifically to sell their goods. None of them had anything to do with x-rays of course! Thus, we had x-ray whiskey which was "scientific, substantial, beneficial", an x-ray coffee bean grinder, x-ray blades ("the finest blades known to science"), x-ray dry batteries, x-ray flashlight batteries, x-ray cream furniture polish, x-ray soap, x-ray golf balls and x-ray headache tablets! There was also some fear about the possibility of the new ray invading people's privacy – a London firm attempted to sell lead underwear!

The plain x-ray, of course, still remains a very useful diagnostic tool. Variations of the x-ray such as Barium meals and Barium follow-through (where a patient swallows a paste of Barium radio-opaque material which lines the lumen of the gastrointestinal tract and delineates it, thereby helping diagnose conditions such as tumours, ulcers, etc), fluoroscopy, etc, have also proved immensely useful over the years.

After World War II, use of the ultrasound machine made significant contributions to the practice of medicine. The ultrasound, developed during the war, works on the simple principle that sound waves bounce after hitting an object. This, of course, is the principle that bats use to fly.

Ultrasonography, in particular, has entirely changed obstetric practice. This is largely because it is safe and does not emit radiation, as do x-rays and CT scans, which may be unsafe. It is now routine to perform serial scans on pregnant women to evaluate the growth rate of the foetus, check for congenital anomalies, etc.

In India, however, this great advance has an important negative social consequence: sex-selection. It is not uncommon for Indian parents to desire boys rather than girl-children. In many parts of India therefore, particularly in the north, female babies are aborted. In Haryana, this has reached a stage where the state's female:male ratio is an alarming 861:1,000. In Chandigarh, the capital of Punjab, which has a literacy rate of 81% and among the highest per capita incomes, the sex ratio is 773:1,000. This skewed ratio has led to a drastic decrease in the number of marriageable girls in Punjab and Haryana – with another alarming consequence, that of bride trafficking. Guesstimates suggest that there are about 50,000 trafficked brides in Haryana, many of them from Orissa, West Bengal and Jharkhand. Because sex-selective abortion was particularly high among Sikhs, the Sikh clergy in 2001 issued an edict threatening social ostracisation of Sikhs who practised sex selection.

Today, it is illegal for a radiologist to disclose the sex of the foetus during an ante-natal scan of the mother. A law, the PNDT, or Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, has been introduced to counter the practice. In fact, radiologists are required by law to disclose that they have not revealed the sex of the baby to the parents on every scan that they perform. Disclosing the sex of the baby is punishable by law and can result in imprisonment of the radiologist. In the West, of course, where such a problem does not exist, one can learn the sex of the foetus in the second trimester, thus taking away the fun and anticipation of not knowing whether one is the parent of a boy or a girl some months down the line!

There are other problems with x-rays. While the marked overexposure to x-rays amongst radiologists and technicians that took place a century ago no longer exists, patients who undergo many x-rays still get overexposed to the rays. (One early victim, albeit on a small scale, was Thomas Alva Edison who experimented with x-rays and found that he developed sore eye!) A single CT scan or nuclear medicine study, for instance, can deliver an effective dose of 10-25 millisieverts (mSv). Compare this with an estimated annual background radiation dose of 3 mSv per year. A single chest CT may have a dose of 8 mSv – the equivalent of 400 chest x-rays.

Excessive radiation could lead to cancer. Thus, x-rays, while usually beneficial, can be a double-edged sword: too much exposure could potentially lead to cancer. A recent editorial (August 27, 2009) in the *New England Journal of Medicine* by Michael Lauer states that the number of CT scans has quadrupled since 1992, and that perhaps as many as 2% of cancers could now be attributable to radiation exposure during CT scanning. Also, the number of myocardial perfusion scans increased by 6% per year between 1993 and 2001. Myocardial perfusion scanning leads to more radiation exposure than any other procedure, yet there have been no studies that have shown any benefit of this investigation in improving health outcomes! Physicians remain complacent merely because it is difficult to accurately measure the risk associated with radiation, and because the cancer, if it develops, does so many years after exposure to radiation and cannot obviously be linked to imaging in the past.

Besides this obvious problem, there is another lesser known one (lesser known to the layperson at any rate). Imaging, like most other things in medicine – and in life – has its limitations. Screening for cancer and other illnesses is common nowadays, and health checks, with all their naysayers and proponents, are here to stay. Apart from the unnecessary radiation that, say, a 'routine chest x-ray' subjects a person to – with no medical indication – imaging sometimes throws up false positive results where non-diseases are identified as diseases. The best known examples of this are in screening mammography and in abdominal ultrasonography. In screening mammography, a study by Elmore and his colleagues, published in the

New England Journal of Medicine in 1998, showed some discouraging findings. They carried out a ten-year retrospective study of 2,400 women and found that 9,762 screening mammograms and 10,905 screening breast examinations were performed, with a median of four mammograms and five clinical breast examinations over the ten-year period. Of them, almost 24% of the women had at least one false positive mammogram – compared to just above 13% of women who had a false positive clinical examination! The false positive tests resulted in 870 out-patient appointments, 539 diagnostic mammograms, 186 ultrasound examinations, 188 biopsies, and one hospitalisation. They estimated that among women who do not have breast cancer, over 18% will undergo a biopsy after 10 mammograms, and 6% will do so after 10 breast examinations. Further, for every 100 dollars spent on screening, a further 33 dollars will then be spent to evaluate the false positive cases. It goes without saying, of course, that many of these women will undergo severe psychological stress because of the possibility of their having cancer.

Medicine has ceased to be merely a healing profession. For many, medicine is now a business, and the proliferation of private hospitals and imaging centres is clear evidence of this. For many, the bottom line is profits, and this can have adverse effects on the patient's health and rights. It is well documented that physicians who own imaging centres tend to over-investigate their patients. There may not be a conscious desire to do so; it could be a subconscious or reflex act, or part of a defensive culture. Or it may just reflect the fact that physicians are human. However, with every additional imaging done, the patient is exposed to unnecessary radiation (of course, this is true in any hospital not just in a private hospital).

At a time when patient safety is the buzzword in the West – and is a topic that's being addressed even in India – it is time to take appropriate steps. Hillman and Goldsmith, writing in the *New England Journal of Medicine* (2010) believe that the medical school curriculum would be a good place to start. They are correct. Medical students are rarely, if ever, educated about the risks of x-rays. Most teaching in radiology, in India at any rate and probably in the West too, revolves around identifying classic images and making diagnoses. What's lacking is a holistic approach to the science. Given that very few students will become radiologists (who will, hopefully, have at least some idea of the dangers inherent in x-rays), while many will embrace general practice (meaning an end to their formal education), this is the best time to introduce the idea that x-rays can be harmful.

It is also imperative that associations and government agencies show enterprise and try to reduce unnecessary radiation. There is evidence that diagnostic accuracy does not necessarily decrease when the radiation levels of a CT scan are reduced; this suggests that research needs to be done to establish appropriate cut-off levels of radiation. It is also the duty of medical and health professionals to educate the lay public about the hazards of unnecessary radiation.

The amazing advances in technology, particularly in the fields of communications and software, over the past two decades, have led to a new field: teleradiology. Teleradiology is the transmission of radiologic (x-ray or scan) images by electronic means to another geographical location where a radiologist can see the image and interpret it. The advantages of this are obvious: areas which do not have a specialist radiologist (smaller towns or villages) can enjoy the benefit of an expert opinion from a big centre, at very little cost. But there are those who argue that teleradiology, already a specialty where patients often do not come in contact with their radiologist-physician, is separated from its patients by an even greater, unfathomable chasm. Moreover, the field is relatively young and Indian medical laws are probably still unclear on medico-legal issues with respect to consent, error, malpractice, etc.

Finally, teleradiology leads to an unusual situation. We are experiencing the outsourcing of radiology and other images from American hospitals to radiologists in India. The time difference between the two countries – and the high cost of medicine in America – means that a radiologist in India can interpret an image and send back a report even before his American counterpart gets to the hospital in the morning to see the previous night's x-rays and images. And we have the West lamenting American jobs being lost to India ('Bangalored'). Can this be interpreted as unfair, even unethical? It is of course delightfully ironic that this is the reverse of what has been claimed over the years: that the brain drain, when talented young doctors and other professionals migrated to affluent countries, was unethical because it deprived developing nations of their very best minds!

The discovery of x-rays changed the face of medicine. X-rays and further advances in the field – ultrasonography, CT scans and MRIs, among others – have led to better precision in diagnostic radiology. Interventional radiology – where the radiologist sometimes plays a therapeutic role as well – is yet another development.

All of these advances have, however, not been without their associated problems. We are grappling simultaneously with changes in our approach to healthcare – but almost always at greater expense, sometimes complications, and occasionally with no evidence at all of better outcomes.

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The right to hear, or the right to be deaf?

Is the cochlear implant a medical miracle, giving the deaf the opportunity to listen and speak, albeit with some distortions? Or is it, as many hearing-impaired people themselves believe, the ultimate invasion of the ear, the ultimate denial of deafness, the ultimate refusal to let deaf children be deaf?

SHABNAM MINWALLA

IT'S A JOURNEY that four-year-old Apurva Patil can retrace in her sleep: first an early morning ride on a two-wheeler to the Nashik railway station; then a scramble to bag a seat on the Mumbai train; and finally a short bus ride to Mahalakshmi.

"For a whole year we did this trip twice a week, and even now we visit the Aured centre every fortnight for therapy," says Apurva's mother Bhagyashree Patil determinedly. She is convinced that these sweaty, bumpy journeys will eventually lead her little girl from the world of silence to one of sound and comprehension. And already, watching Apurva play in the Aured compound, it's difficult to believe that she was deaf for the first 30 months of her life.

"I realised something was wrong when Apurva was seven months old and didn't respond to the sound of Diwali crackers," recalls Bhagyashree, adding that the doctor suggested a cochlear implant. "We run a small grocery store in Nashik and I felt that we would never be able to raise Rs 800,000. But from the very next day I started visiting trusts, ministers, the chief minister, doctors…"

Fifteen months later, Apurva underwent surgery at Hinduja Hospital in Mumbai – an electronic device was implanted in her skull and a bundle of electrodes made to bypass her damaged cochlear and directly stimulate her auditory nerves. A few weeks later, the microphone and processor (the external part of the equipment) were switched on and for the first time Apurva could hear birds chirping, cars honking and her mother talking. Today, after two years of therapy, she can carry out a conversation with relative ease.

Apurva is one of about 4,200 recipients of cochlear implants in India. But, although many of these stories have equally happy endings, cochlear implants continue to generate controversy and uncertain reactions. Advocates of the implant say that it works much better than a conventional hearing aid because it doesn't merely amplify available sounds, it picks up frequencies that would otherwise escape the damaged cochlear. Critics however believe that the surgery thrusts the child into a twilight world, inhabited neither by the deaf nor the hearing, and full of distortion.

"When parents find that their child is deaf, they run from pillar to post praying for a miracle. What's this if not a miracle? A cochlear implant may not make the deaf un-deaf, but it is a huge opportunity to listen and speak," says Aziza Tyabji Hydari, director of Aured, an NGO that helps deaf children to acquire spoken language. Mukesh Jadly from Delhi, whose 12-year-old daughter received an implant five years ago, agrees: "My daughter goes to a mainstream school, talks on the phone and has an excellent vocabulary. Of course, there are some things she cannot do – watch TV, speak a second language. But while we cannot copy God, the cochlear implant is the best option available today."

Many, like Dr Dilip Deshmukh, disagree. "A cochlear implant does not completely restore hearing to the implanted ear, nor is the quality of sound completely natural," says the expert on Indian sign language and respected mentor of the deaf community in India. "While some children and adults benefit from an implant, others have benefited very little. Those who make the decision to implant children choose to risk the child's health. Children with implants are at a 30-fold increased risk of meningitis. An implant is the ultimate invasion of the ear, the ultimate denial of deafness, the ultimate refusal to let deaf children be deaf."

Indeed, much of the resistance to cochlear implants stems from the deaf community, which asserts that it is a cultural and linguistic minority – and that sign language, rather than a cochlear implant, is the natural and painless option. "Deaf children learn to be successful everyday without hearing," wrote Shelli Delost and Sarah Lashley of MacMurray College, in 2000, pointing out that the life-changing decision is usually made by hearing parents for children too young to have an opinion. "It is common for parents to be introduced to a number of audiologists and speech therapists when their child is first diagnosed with a hearing loss, but to never be taken to meet a deaf adult so that they may receive the other perspective. It may never be mentioned that deafness is considered to be a cultural identity for some people, and that implants are seen as unnecessary."

The deaf community believes that the medical approach to deafness – that it is a disability that needs to be fixed – damages the self-image of the deaf child. Moreover, a

cochlear implant sets the stage for other complications: a four- or five-year-old who has had no exposure to sound is suddenly expected to function in what must seem like the Tower of Babel. The auditory and speech training that follows an implant often becomes the focus of the child's routine and identity – so much so that success is only about mastery over hearing and speech.

"Whenever we attend conferences in the West, there are demonstrations by the deaf community outside the venue," says Dr Shankar Medikeri, a Bangalore-based ENT surgeon, pointing out that cochlear implants are nevertheless considered standard protocol. "After all, it is the parents who make the decision – and it is only natural that they would want their children to hear and talk like they do."

Indeed, the arguments of the deaf community would long have been swept aside were it not for the frighteningly unpredictable nature of cochlear implants, for, after spending anything between Rs 6 lakh and Rs 10 lakh, and devoting long hours to therapy, some recipients never manage to understand spoken language. At best, they can hear and recognise sounds like a car horn or a pressure cooker whistle. Which is why cochlear implants have taken almost three decades to gain acceptability.

"When I started working with cochlear implants, my friends treated me like an enemy," says Rajesh Patadia, senior audiologist at Hinduja and Aured, who painstakingly adjusts the equipment for the requirements of each child. "The surgery has been performed in India since about 1990, but the initial candidates were chosen badly and the results were poor."

Who then is the right candidate? People who have become deaf late in life are usually quick to decode signals sent by their implants because their brains retain a memory of sound and speech. So, though a late-deafened adult told a *New York Times* reporter that his implant "made everyone sound like R2D2 with laryngitis," it is an undeniable godsend.

When it comes to children who are congenitally deaf, however, early detection and intervention are necessary if they are to become adept at hearing and speaking. "Ideally, the implant should be done between the ages of one and two. But even if it is done before five years it makes a big difference," says Tyabji Hydari, pointing out that it is a matter of neuroplasticity. "Our neural connections are in place when we are born. But we learn to listen only when the brain is stimulated with sound. There are windows of time when different types of learning occur. The critical period for speech and language development is six months of pregnancy to two years – and if you lose the critical window you never really make up." Patadia adds: "It's like dough. If you use it quickly you can make something good; if you wait a little it gets cracked; and if you wait a lot it becomes as hard as a rock."

Even if the implant takes place early, children need up to three years of therapy before they can confidently navigate a world full of chatter and clatter. The abilities of the audiologists and trainers are critical at this stage.

Apurva, for example, underwent seven months of therapy in Nashik but only mastered a single word – Ma. So her mother made the long journey to Aured, where the audiologist began the tricky business of re-adjusting her equipment and the teacher began getting acquainted with the child. "Within a week she had picked up seven or eight words, and now she has become so smart she is ahead of all the normal children in her class at school," beams the proud mother.

Even when the results are unlikely to be so dramatic, however, Tyabji Hydari believes that cochlear implants are justified. "Why should we only be looking for 'good' results," she demands. "If a seven-year-old has an implant which enables him to attend a mainstream school, make more friends and become independent, isn't that worthwhile? He may not be able to take part in debates or elocutions, but so what? We believe in reduction of disability for every child." Dr Medikeri adds: "Sometimes children have a malformed cochlear or certain abnormalities caused by meningitis. In their case, a cochlear implant may be less effective. What is most important is that the parents must be told exactly what to expect."

Even when the surgeons are less than encouraging, however, parents tend to pin their hopes on the cochlear implant, forgetting that in some cases it may take months, even years, before the child can understand and respond to a simple question like: "How was school?" This can lead to a great sense of frustration and a dangerous delay in language development. Which is why experts like Dr Deshmukh insist that children with hearing loss should grow up bilingual – comfortable with both sign language and whatever oral language they can pick up.

While this may help in the initial period of adjustment, it's clear that individuals with successful implants depend more and more on the tiny computer behind their ear. "It makes them a part of the hearing world," explains Patadia. "They make our lives miserable when a wire breaks or some part of the equipment gives trouble. Because now that they know the importance of hearing, they cannot do without it."

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The Wild West of stem cell procedures

From street-side stem cell clinics promising people in wheelchairs that they will walk, to corporate cord blood banks that offer to store your baby's umbilical cord blood, an unethical and unregulated industry in stem cell procedures is feeding off the desperation of Indian patients. A comprehensive regulatory structure is urgently needed

SANDHYA SRINIVASAN

ON AUGUST 17, 2010, a Bangalore hospital announced what it suggested was a major medical breakthrough: it had used stem cells to successfully treat four children with thalassemia, a blood cell disorder for which the children would otherwise have painful blood transfusions for the rest of their lives. The hospital's director was quoted in the press as saying that newer indications for stem cell therapy are breast cancer, renal cell cancer, heart disease, spinal injury, Parkinson's disease and Alzheimer's disease. According to the hospital's website: "As stem cell transplants become more routine, they may be used to fight lung cancer, sickle cell anaemia, multiple sclerosis, lupus, AIDS and many genetic diseases."

These are incorrect and misleading statements that will give false hope to people with such conditions.

It is true that stem cell technology has proved effective in certain conditions. The special qualities of these immature cells, found in various parts of the body including the bone marrow, umbilical cord, foetus and embryo, are being researched for the treatment of a number of diseases. Stem cell therapy can be autologous, from the person's own body, or allogenic, donated by a person whose tissue type is matched as closely as possible to the recipient to prevent rejection of the transfusion.

But little of what gets publicised today comes from systematic research with proven safety, effectiveness and realistic levels of success. Much of what we are seeing is the unethical promotion of stem cells as miracle cures.

On the one hand, street-side stem cell clinics promise the wheelchair-confined that they will walk. On the other hand, corporate cord blood banks exploit the market for 'bio-insurance': store your baby's umbilical cord blood – for a fee – just in case s/he falls ill with some terrible disease that might be cured through the use of those cells. The picture is one of unethical and unscientific medical practice, false advertising, misrepresentation, and the exploitation of people's desperation, hopes and fears. The publicity generated by such hype helps business.

At the same time, the practice of established therapies, such as bone marrow transplantation, can have ethical implications that need urgent discussion.

Bone marrow donation by children

Going back to the Bangalore hospital, the children were cured after they received transfusions of stem cells extracted from bone marrow – one received the transfusion from his grandmother and the others from their siblings aged between 12 and 14 years.

The hospital managed to get the story covered widely; the haematologist is quoted as saying that their experiences with the four children "now prove the therapeutic potential of bone marrow-derived stem cells, from a matched donor".

Bone marrow transplant for certain blood conditions is one of the few established indications for using stem cells. So there's nothing medically new to report about doing bone marrow transfusions for children with thalassemia.

But there are other issues to comment on in this account. For one, the use of children as bone marrow donors is a practice with many ethical implications. The American Academy of Paediatrics' Committee on Bioethics was concerned enough to develop a policy statement on "children as haematopoietic stem cell donors".

According to the committee, the risks of bone marrow donation are small but they do exist: they are mostly to do with the anaesthesia used when extracting bone marrow, but there can also be "nerve, bone or tissue injury", infection, and transfusion reaction. A number of short-term and some long-term problems are described, including pain at the donation site and bleeding problems. There is also a very tiny risk of death – one per 10,000 donations. Parents who must make such decisions are conflicted between the desire to have their seriously ill child recover and the knowledge that they are subjecting their healthy child to pain, and some risks, however small. The committee advocates that a "donor advocate" and a child mental health professional or an ethics consultant should be involved in the process.

These are issues worth discussing when publicising bone marrow transplants among siblings. Are procedures in place to ensure that parents give their consent on behalf of their

child, after being apprised of these risks? Are small children asked for their assent before donating bone marrow to a sibling? Are clinical ethics committees consulted in such cases?

Incidentally, the World Marrow Donor Association's minimum age for unrelated bone marrow donation is 18, or the age of consent. There does not seem to be any minimum age for related donation. This is all the more reason to ensure that guidelines to protect donors are followed.

In India, a one-year-old child has 'donated' his bone marrow to a sibling.

Ethical issues in sibling cord blood transfusions

Also in the Bangalore hospital, a four-year-old boy with Fanconi's anaemia, another genetic disorder of the blood, is waiting for the birth of his sibling in order to receive a transfusion of the infant's umbilical cord blood, considered a particularly good source of stem cells. And in September last year, a cord blood stem cell bank in Chennai got good coverage for its announcement that it had conducted "India's first successful stem cell transplant using a sibling's cord blood cells".

The recipient in Chennai was an eight-year-old child with thalassemia. According to the article posted on the company's website, the parents were asked to "consider another pregnancy and go for umbilical cord blood stem cell banking". A pre-natal test "confirmed that the foetus was not affected with thalassemia," and when the baby was born its cord blood cells were transfused into the older sibling. But it turned out that the baby's cord blood cells were insufficient, and were supplemented with bone marrow cells extracted from the one-year-old baby. There was no mention of what it meant for a very small child to be subjected to this painful and possibly risky medical procedure.

Though the cord blood transfusion didn't work for the child in Chennai, assuming that cord blood transfusions will eventually become established in India, we should anticipate another concern: the possibility that our medical profession will promote the creation of 'saviour siblings' – babies whose cord blood and, if necessary, bone marrow, is used for stem cell therapy. In such circumstances, assisted reproductive technologists can bypass pre-natal testing altogether. Embryos produced for IVF can be tested to rule out certain disabilities as well as to identify those with a genetic match to the child that needs stem cells. This is the subject of a recent film, *My Sister's Keeper.* Pre-implantational genetic diagnosis to select against disability is legal in India and can easily be used to select a match for donation of organs.

Such saviour siblings are apparently already being created in India. The Indian assisted reproductive technology (ART) industry has shown that it is quick to pick up on and promote what the market demands. Look at our surrogacy camps.

Is the creation of a saviour sibling a good or a bad thing? Is there something wrong about creating a child expressly to save another? What is the ethical basis for organ donation by a minor? How does one conclude that a child wishes to donate to its sibling? Is a child able to consent to such donations? Is there a benefit to the family that outweighs the risk of such practices? We certainly need to discuss such issues. We have the technology, and are certain to use it – we should be anticipating such concerns and thinking of how to respond.

Bio-insurance: Exploiting the fears of pregnant women

A different set of ethical questions is posed by the practices of umbilical cord blood banks that collect the umbilical cord at the time of a baby's birth. The Bangalore and Chennai stories gave plenty of publicity to the two cord blood banks involved. These banks make money by aggressively marketing 'biological insurance' – store your baby's cord blood with us and if your child happens to fall ill with some terrible disease, the stored stem cells could be used to develop a treatment.

Pamphlets describing the services and tariffs of these banks are available in the waiting rooms of some gynaecologists' offices. Pay between Rs 60,000 and Rs 120,000 and store your baby's umbilical cord blood cells for 21 years. Check out the discounted packages to "accommodate stem cell banking in the common man's budget". Pay in easy monthly instalments. Some companies make big promises: if you store your baby's stem cells with them, "your child and family can (have) access to potential treatments for over 75 serious ailments such as leukaemia (blood cancer), thalassemia, brain injury, juvenile diabetes and many more".

Professional organisations in India should be commenting on the science and ethics of such practices. But the websites of the Indian Academy of Paediatrics and the Federation of Obstetrics and Gynaecology Societies of India have nothing on stem cells. However, the guidelines for stem cell research and therapy published by the Department of Biotechnology and the Indian Council of Medical Research require that those running cord blood banks inform parents that "at present the use of stored umbilical cord blood for self is practically nil".

The American Academy of Paediatrics (AAP) trashes the notion of cord blood as "biological insurance"; the chances are remote that a child will develop a health problem that can be treated with its own cord blood. The AAP mentions two situations in which cord blood might be stored: directed donation, when a sibling has a medical condition that can

be treated with cord blood transplantation, and in a public bank for use by anyone who might need it, as in a regular blood bank, for certain established uses.

But the private cord blood cell bank in Bangalore conveys the message, in not so subtle terms, that *only* private banking can assure you of the cord blood should your child need it in the future – implying that your *own* cord blood could actually be of use to you.

The AAP tells physicians to "be aware of the unsubstantiated claims of private cord blood banks made to future parents that promise to insure infants or family members against serious illnesses in the future by use of the stem cells contained in cord blood". It also notes that "families may be vulnerable to the emotional effects of marketing for cord blood banking at the time of birth of a child and may look to their physicians for advice".

Such warnings don't seem to matter to many doctors in India who seem to actually mediate between pregnant women and cord blood banks by stocking pamphlets for these banks. And companies have no qualms about running ante-natal workshops where expectant couples are educated on "the benefit of cord blood stem cell banking".

I must add that not all doctors support the promotional methods of cord blood cell banks. I was alerted to this practice when an obstetrician-gynaecologist called me to complain that a bank tried to distribute its leaflets in his waiting room. He was outraged that someone could exploit the fears of a pregnant woman at her most vulnerable.

The corporate sector in stem cell banking

Even if stem cell therapies are in the early stages of research, their potential has drawn the interest of speculators. By 2010, the umbilical cord blood banking business in India is apparently expected to reach anywhere between Rs 140 crore and Rs 2,700 crore – it depends on who's being quoted. Already, at least four big players have moved into the market.

The corporate health sector's interest in cord blood banks should make us sit up and think. Cord blood in India and China is apparently being viewed as a commodity, the need for which is anticipated in future stem cell research and therapy. Since cord blood is unlikely to be of personal use, the chances are that such banks will cater to people from other countries seeking stem cell procedures. When combined with our trained human power and infrastructure, stem cell tourism may be the new medical tourism. For example, a tripartite venture between an international organisation, a corporate hospital and a drug company has announced that it plans to "build an inventory of 25,000 ethnically diverse units here to help treat critically ill patients in India and abroad". It must be presumed that the "ethnically diverse units" in this and other banks will serve an international demand for stem cells, with the corporate hospital partner conducting the stem cell procedures.

In April 2010, an amendment in the Drugs and Cosmetics Act laid down standards for cord blood cell banks which are approved by the Drugs Controller General of India (DCGI). More detailed regulations are being discussed that spell out requirements for these banks, for storage and transportation of stem cells and for their release. While such standards are welcome, they may be motivated more by a need to meet international standards, towards India's medical tourism policy.

Menstrual blood banks are in the future. As the director of one of the larger cord blood banks told a business journal in March this year: "Menstrual blood banking has the potential to expand our revenue stream multi-fold considering that our total market would no longer be 2% of the population, which represents pregnant women, but almost every woman in the country."

The Wild West of stem cell 'therapies'

If corporate cord blood cell banks see big profits in stem cells as a commodity in themselves, dozens of clinics – and some big hospitals too – promise miracle stem cell cures for diseases where conventional medical treatments have failed, using procedures that are untested for safety and efficacy.

In June 2009, a corporate hospital conducted "brain stem cell transplant surgery" on a woman with brain damage. It reported that after the surgery the woman was conscious and able to communicate and move her limbs. The chief neurosurgeon, who is also vice-chairman of the hospital, is quoted as having said: "To our knowledge such attempts were made only in China. This is the first attempt in the country, and India is the second country in the world to use such therapy." Another hospital representative stated that they were looking at bringing out stem cells as a "product" by 2011.

We've heard from many such clinics in recent years, treating conditions where nothing else has worked. The website of one clinic takes care to state that all the procedures that it offers are "experimental therapy" and are approved by an ethics committee. But it does not carry any details on this committee. It claims to follow ICMR guidelines for stem cell research and therapy. These clinics also solicit email enquiries while asserting that they are not legally liable. None of these feats is published in credible medical journals.

One of the better known of this ilk is an in-vitro fertilisation (IVF) doctor who claims to have used embryonic stem cell procedures to cure more than 600 patients with conditions such as Alzheimer's, multiple sclerosis, renal failure, cerebral

palsy, and diabetes. Her patients include politicians and her first press conference was attended by the Union health secretary, the prime minister's wife, and a former chief minister. She has been written about in the media, but her work has not been subjected to scrutiny by her peers.

No one knows how much the placebo effect is responsible for some feeling better after such procedures – or how many have been harmed by them. The only way we'd know that is with systematic research that documents all aspects of the procedure, measures all reported benefits as well as side-effects, and is published. But such doctors deliberately refuse to submit their work to the rigorous demands of formal research.

This unregulated industry in stem cell procedures, described sometimes as 'research' and sometimes as 'therapy', thrives in the absence of any serious efforts at regulation. It feeds off the desperation of people with serious illnesses and for whom established treatments have failed, and who might feel that they have nothing to lose in trying an untested procedure.

But these procedures may also be unsafe, and the side-effects could be serious, even lethal. There are at least two documented instances of patients developing tumours after undergoing stem cell procedures. But such information can come only from systematic research.

And of course they cost large amounts of money; desperate patients are willing to pay for any hope of a cure.

Guidelines and a law

This spectrum of unethical practices is possible because the various guidelines and regulations governing the practice of stem cell research and therapy in India are neither comprehensive nor enforceable.

The DBT/ICMR's 2007 guidelines apply to all stem cell therapy and research. They state that all stem cell therapy other than bone marrow transplantation for certain accepted indications is considered experimental. They call for a national apex committee for stem cell research and therapy. All centres doing stem cell research should have an institutional committee registered with the national committee. Stem cell research may be conducted only after review by the scientific committee and an ethics review committee. Stem cell research towards a marketable product must also get approval from the Drugs Controller General of India. A committee should monitor the trial and conduct site visits when required.

But these are only guidelines. So clinics and hospitals across the country can advertise and offer stem cell 'cures' without fear.

All medical professionals are expected to abide by the Medical Council of India's Code of Medical Ethics. The Code of Medical Ethics requires that all research abide by ICMR guidelines for biomedical research. At present, almost all stem cell procedures are in the research stage, and embryonic stem cell therapy is not accepted as standard treatment anywhere in the world. So, for example, the IVF specialist who is actually conducting embryonic stem cell research – of unknown scientific value – is committing unethical medical practice in the guise of therapy.

The less said about the code and its enforcers, the better.

Centres conducting embryonic stem cell research are legally required to get clearance from the national apex committee. That national apex committee has been constituted, but a government order has not yet been issued for it to function, according to Dr Vasantha Muthuswamy, former senior deputy director general of ICMR who was responsible for developing the ICMR ethical guidelines for biomedical research. This allows the IVF specialist to conduct embryonic stem cell procedures, which are actually research, calling it therapy, without fear of punishment.

At present, only stem cell research towards developing a drug must be approved by the Drugs Controller General of India. In order to give its approval, the DCGI requires evidence that the research is scientifically valid, documents on the trial design and previous data on the safety and efficacy, and review by an ethics committee.

The DCGI approves cord blood banks as they deal in a product, just as blood banks do. But procedures using stem cells are not treated as drugs and are not covered by the Drugs and Cosmetics Act. So stem cells can be used without proof of safety or efficacy. Stem cells should be categorised as biological products, such as blood products and vaccines, according to Dr Muthuswamy. This would bring all research on stem cells under the purview of the law. This should happen under the National Drug Authority (NDA), an autonomous body which is meant to regulate drugs, devices and biological products. The NDA has been formed but is yet to become fully functional.

The 2007 guidelines are included in ICMR's draft law to regulate biomedical research. This Bill has been pending for some years.

A comprehensive and effective regulatory structure that takes into account questions of scientific and ethical practice is urgently needed to put a stop to the malpractices conducted in the name of stem cell therapy.

Note: Names of doctors, hospitals and companies have been deliberately left out – not because the writer feels they are unfairly accused, but to avoid giving them more free publicity

The great stem cell debate

Should research be encouraged just because something is possible, even if we are not clear about the consequences? Who sets the boundaries, and how does society conduct an informed debate on this subject? The promise of stem cell research is too valuable to be undermined because these ethical concerns are not posed and addressed adequately

AMIT SENGUPTA

STEM CELL RESEARCH has been in the public discourse for contradictory reasons. Advances in research hold out the promise of treatments for conditions that were hitherto seen as incurable. Stem cells, many believe, can become an almost inexhaustible source of spare organs. Already, research is advanced enough to project that stem cells will play a role in the treatment of ageing disorders such as Alzheimer's, Parkinsonism, cardiomyopathy, diabetes, etc.

On the flip side, stem cell research is faced with numerous ethical concerns. While the most prominent critics of stem cell research have been neo-conservative elements in the George Bush administration in the US (led by George Bush himself [1]), critics of stem cell research are not limited to conservatives who oppose stem cell research on grounds of 'immorality'. Interestingly, one of the first actions taken by Barack Obama after assuming the US presidency was to reverse the US government's opposition to embryonic stem cell research (2).

However, no matter which side of the debate one may be on, the genie is out of the bottle; stem cell research is clearly here to stay.

What is stem cell research?

In order to understand the contours of this debate, it is necessary to understand what stem cell research is all about. Stem cells are cells from the human body that have still not become specialised in their function, that is, they have not formed into cells in the muscle, or skin, or intestines, or any other part of the body performing a specific function. These cells are thus called 'pluripotent' – they have the potential to develop into any kind of cell with a certain specialised function.

Stem cells have two important characteristics that distinguish them from other types of cells. In addition to being unspecialised cells, they react to certain 'triggers' that induce them to become cells with special functions. Research is being conducted on two kinds of stem cells from animals and humans: embryonic stem cells and adult stem cells.

Stem cell research is not really new, but the major advance came in 1998 when methods to isolate stem cells from human embryos and grow the cells in the laboratory were discovered (3). These are called human embryonic stem cells. Human embryos are now routinely formed by the fertilisation of a human egg by a sperm under laboratory conditions – what we call in-vitro fertilisation, used as a means to treat infertility in couples. Normally, the number of embryos formed for a couple is much larger than required to induce pregnancy; these can be used as a source of embryonic stem cells.

Stem cells can be harvested from a three-to-five-day-old embryo, called a blastocyst. The opposition to stem cell research centres around the use of human embryos. In the US, 'anti-abortion' and 'pro-life' lobbies have been in the forefront of the campaign against stem cell research.

Stem cells are grown in the laboratory through a process known as 'cell culture'. In the case of embryonic stem cells (still the preferred source of stem cells), the cells are transferred from the blastocyst into a culture dish that contains nutrients known as 'culture medium'. The cells divide and spread over the surface of the dish. Over the course of several days, the cells divide and multiply in the culture dish. They are then transferred into fresh culture dishes – this process is called 'sub-culturing'. After six months, 30 of the original cells can yield millions of stem cells. Stem cells that have proliferated in cell culture for six or more months without differentiating, are pluripotent, and appear genetically normal are referred to as an 'embryonic stem cell line'. Once cell lines are established, batches of them can be frozen and shipped to other laboratories for further culture and experimentation.

Challenges for stem cell research

Stem cells are also found in the adult body, in different organs like the bone marrow, brain, etc. These cells remain non-specialised for years and start to become specialised in function to repair some damage or to replace old specialised cells that die out. These are called 'adult stem cells'.

These stem cells, later in life, give rise to the multiple specialised cell types that make up the heart, lung, skin, and other tissues. Scientists are now engaged in determining how stem cells remain unspecialised and are able to multiply for many years; also in identifying the signals and triggers that cause stem cells to become specialised cells. If this can be done, the cells can be artificially introduced into the body

to repair damaged organs like a damaged heart, or brain, or liver – the potential is virtually unlimited.

A key area of research is also to understand the signals in a mature organism that cause a stem cell population to proliferate and remain unspecialised until the cells are needed for repair of a specific tissue. Many related questions still remain to be answered. For example, are the internal and external signals for cell differentiation similar for all kinds of stem cells? Can specific sets of signals be identified that promote differentiation into specific cell types?

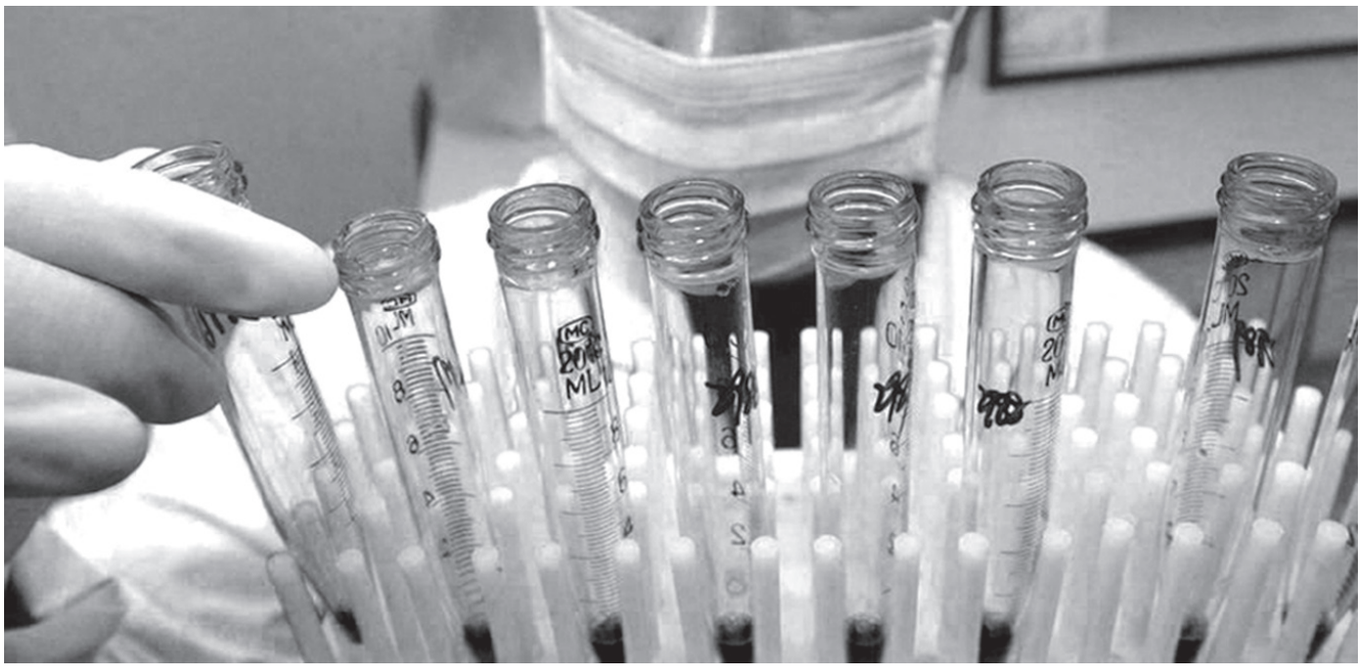
Adult stem cells

Attention is now also turning to the use of adult stem cells. Adult stem cells typically generate the cell types of the tissue in which they reside. A blood-forming adult stem cell in the bone marrow, for example, normally gives rise to the many types of blood cells such as red blood cells, white blood cells and platelets. Until recently, it had been thought that a blood-forming cell in the bone marrow – called a 'haematopoietic stem cell' – could not give rise to the cells of a very different tissue, such as nerve cells in the brain. We now know, however, that this is not true. For a long time, most scientists believed that new nerve cells could not be generated in the adult brain. It was not until the 1990s that scientists agreed that the adult brain does contain stem cells that are able to generate the brain's three major cell types.

Such new insights now suggest that certain adult stem cell types are pluripotent. This ability to differentiate into multiple cell types is called 'plasticity' or 'transdifferentiation'. Haematopoietic stem cells in the bone marrow may differentiate into three major types of brain cells (neurons, oligodendrocytes, and astrocytes); skeletal muscle cells; cardiac muscle cells; and liver cells. Similarly, bone marrow stromal cells may differentiate into cardiac (heart) muscle cells and skeletal muscle cells, and brain stem cells may differentiate into blood cells and skeletal muscle cells. Current research is aimed at determining the mechanisms that underlie adult stem cell plasticity. If such mechanisms can be identified and controlled, existing stem cells from a healthy tissue might be induced to repair a diseased tissue.

Comparative advantages of adult and embryonic stem cells

Human embryonic and adult stem cells each have advantages and disadvantages regarding potential use for cell-based regenerative therapies. Embryonic stem cells can become all cell types of the body because they are pluripotent. Adult stem cells are generally limited to differentiating into different cell types of their tissue of origin. However, as discussed earlier, we now know that some adult stem cells can exhibit plasticity. Another difference is that, while large numbers of embryonic stem cells can be grown in a culture medium, adult stem cells are rare in mature tissues, and methods for culturing them in large numbers are yet to be standardised. A potential advantage of using stem cells from an adult is that the patient's own cells could be expanded in culture and then reintroduced into the patient. Use of the patient's own adult stem cells would mean that the cells will not be rejected by the immune system. This represents a significant advantage, as immune rejection (where the body's immune mechanism fights and kills cells from a different organism) is a difficult problem one would encounter if embryonic stem cells are introduced into a person. The 'rejection' can only be circumvented with



immunosuppressive drugs which have other toxic side-effects.

Potential applications for stem cell research

There are many ways in which human stem cells can be used in basic research and in clinical research. Human stem cells could also be used to test new drugs. Today, human volunteers are used to test for safety and efficacy of new medicines. In the future, new medications could be tested on cells generated from cell cultures obtained from stem cells. Thus, for example, a medicine to treat a heart condition could be tested on cells artificially grown in a laboratory and made to differentiate into heart muscle cells. In order to do that, we would need to be able to precisely control the differentiation of stem cells into the specific cell types on which drugs will be tested.

Perhaps the most important potential application of human stem cells is the generation of cells and tissues that could be used for cell-based therapies. Today, donated organs and tissues (for example, in cases of heart, kidney, cornea or liver transplant) are often used to replace ailing or destroyed tissue, but the need for transplantable tissue and organs far outweighs the available supply. Stem cells, directed to differentiate into specific cell types, offer the possibility of a virtually unending source of replacement cells and tissue to treat diseases including Parkinson's and Alzheimer's, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, rheumatoid arthritis, blindness, kidney or liver failure, etc. It may, for example, become possible to generate healthy heart muscle cells in the laboratory and then transplant those cells into patients with chronic heart disease. Preliminary research in mice and other animals indicates that bone marrow stem cells, transplanted into a damaged heart, can generate heart muscle cells and successfully repopulate the heart tissue. Other recent studies in cell culture systems indicate that it may be possible to direct the differentiation of embryonic stem cells or adult bone marrow cells into heart muscle cells.

Ethics of stem cell research

Research on stem cells involves something very different from what many believe it to be – human cloning. No serious researcher on stem cell research is engaged in producing a whole human being from stem cells. Rather, the effort is to standardise the method of producing cells in the laboratory that are able to perform specialised functions.

However, as in many new areas of research, new ethical concerns need to be addressed. What singles out stem cell research for special attention is that it deals with human tissue. This raises ethical issues regarding ownership of the basic material on which the research is conducted. For example, at present, most researchers working to produce human embryonic stem cells use embryos that were created but not used during in-vitro fertilisation procedures (4). The use of unused embryos – the by-products of in-vitro fertilisation – being used for stem cell research is a grey area. Many countries discourage payment for egg donation if they are to be used for research (5). At the same time, a large number of 'unused embryos' are picked up by those engaged in stem cell research. What remain unresolved are ethical issues regarding the use of eggs 'donated' for an entirely different purpose.

While no mainstream research programme works on human cloning, it does not mean that human cloning is not possible. In fact, human cloning – if undertaken with resources and available expertise today – is likely to be much easier to crack than many other problems that stem cell researchers are grappling with. Scientists have produced clones of many mammalian species, and there is no particular reason why humans would prove more difficult to clone. There is, however, a fair level of consensus that human cloning is a boundary that should not be crossed. We know too little about cloned animals to predict their long-term futures and possible genetic instability. We know even less about the social consequences if humans were to be cloned.

In science, as we nudge at the frontiers of the hitherto unthinkable, we shall increasingly be faced with dilemmas. Should research be encouraged just because something is possible, even if we are not clear about the consequences? Who sets the boundaries for such research? How does society conduct an informed debate on such research? There are no definite answers to these questions. But what is clear is that they will need to be answered soon if we are not to see a face-off between science and the public it seeks to benefit. A better public understanding will definitely help. So will better levels of social consciousness among scientists. In the case of stem cell research, we need a debate that is neither coloured by the likes of the neo-cons in the US nor by 'big' science with big funding, big interest lobbies and big corporate backing. The promise of stem cell research is too valuable to be undermined because ethical concerns are not posed and addressed adequately.

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Endnotes

1 In 2006, President George W Bush vetoed the House Resolution 810 Stem Cell Research Enhancement Act, a Bill that would have reversed the Dickey Amendment which made it illegal for federal money to be used for research where stem cells are derived from the destruction of an embryo

2 'Obama Reverses Bush-Era Stem Cell Policy'. Associated Press. http://www.msnbc.msn.com/id/29586269

3 Thomson J A, Itskovitz-Eldor J, Shapiro S S, Waknitz M A, Swiergiel J J, Marshall V S, Jones J M (November 1998). 'Embryonic Stem Cell Lines Derived From Human Blastocysts'. *Science* (New York) 282 (5391): 1145-7. doi:10.1126/science.282.5391.1145. PMID 9804556

4 Our Bodies Ourselves, 'Egg Donation for IVF and Stem Cell Research: Time to Weigh the Risks to Women's Health', http://www.ourbodiesourselves.org/book/companion.asp?id=25&compID=97&page=2

5 For example, in the US, the 2005 guidelines of the National Academy of Sciences for human embryonic stem cell research discourage paying for eggs for research

Moment of truth: Medical ethics and human rights in narcoanalysis

The Supreme Court has declared illegal the use of medical technologies for investigation of individuals without their consent and several safeguards. Nevertheless, narcoanalysis, brain mapping and other medical technologies continue to be used. The participation of doctors in these practices erodes the very core of the medical profession

AMAR JESANI

I DID NOT KNOW Dr Ramanadham personally, though he was active at the same time I was in the trade union and human rights movements. His work inspired many of us, for the involvement of medical professionals in doing something progressive is quite rare in India. Amongst such rare doctors today is Dr Binayak Sen, who has used his professional skills only for the poor, and involved himself in human rights work (he was imprisoned on false charges by the Chhattisgarh government). Incidentally, both Dr Ramanadham and Dr Sen specialised as paediatricians.

The participation of some doctors in the violation of democratic rights or in conservative and anti-people activities is not new in India, as the Medico Friend Circle discovered in its investigation of the Gujarat carnage in 2002 (1). In 1995, the Indian Medical Association undertook a survey of medical persons to find out what they knew about torture (2). It found that almost 60% of doctors believed that torture was justified in certain circumstances, and saw no harm in it!

Historically, medical professionals have always been involved in designing techniques for torture as well as the death penalty all over the world. Most of the time, doctors participate for two reasons, or, should we say, two misconceptions. One, that when these things are inevitable, doctors should do something to make them humane. And two, the more efficient the method the quicker the result and hence less pain and suffering.

When I was working for human rights organisations, we used to take up campaigns when somebody died in police lock-up. There would be a small committee of journalists, lawyers and doctors like me, and we would conduct investigations and then come out with a report. Normally, our scrutiny was focused on the conduct of the police because they were the culprits in the killing. But I found that in all these cases, even if a doctor was not directly involved in carrying out the torture, often the tortured person would have been brought for treatment to medical personnel at a public hospital. Doctors would treat the person and then allow him to be taken back to police lock-up for more torture. The doctors restore the tortured person to health so that the person can be interrogated again in the same manner, and information or a confession extracted. The aim of torture is not to kill – often killing is regarded as failure – and so medical help may be needed to keep the tortured person alive. It is in this cycle of torture-treatment-torture that there is intentional or unintentional involvement of doctors.

The involvement of doctors in carrying out the death penalty is well documented. In India, even the judiciary forces doctors to participate in these executions. In 1995, the Supreme Court struck down a provision in the Punjab and Haryana Prison Manual relating to hanging (3). The prison manual said that a person who is hanged should be kept hanging for half-an-hour. The reason was very simple. Hanging emerged as a more efficient and humane method of judicial killing in the 19th century, in colonial times. In hanging, the knot and its placement are required to be such that the impact of hanging breaks a vertebra in the neck, which leads to severe injury to a crucial part of the brain, thus killing the person instantaneously. However, sometimes instantaneous death does not occur and the person has to be kept hanging so that death is caused by asphyxia. That's why the colonial administration had the half-hour rule.

The petitioners argued that such a practice was barbaric. The court agreed and passed an order that a doctor should be called upon to examine the person soon after s/he is hanged. As soon as the doctor certified the person dead, the body could be brought down.

Since 1994, therefore, a doctor has to examine the person who has been hanged every few minutes and, if s/he is found alive, is supposed to give instructions to keep her/him hanging!

Now, this makes the doctor barbaric. A person whose job is to heal, to give life, to resuscitate, is made to collude in the actual judicial killing by assisting the hangman. It is a travesty of the fundamental principles of the professional ethics of doctors.

Unfortunately, our medical associations have allowed this judgment to go unchallenged. (There was one exception, though. Immediately after the judgment in 1994, the Forum for Medical Ethics Society that publishes the *Indian Journal of Medical Ethics* wrote to the Supreme Court in protest, to get its views against the judgment heard; the court turned

down the request. Thereafter, it made a representation to Justice Ranganath Mishra, then chairperson of the National Human Rights Commission, but no change was effected in the judgment.)

The process by which the bulk of any profession turns against humanity does not happen overnight. Nazi physicians who used their medical skills to participate in atrocities did not become inhuman overnight. It took years to learn to become inhuman, by adjusting their ethics to the demands of the Nazis, before eventually participating in the inhuman acts of the state. That is the reason why such adjustment of ethics, the slippery slope, must be nipped at the very outset.

Examining the science of lie-detection and narcoanalysis

Are the techniques used for lie-detection and narcoanalysis scientific? Two aspects of any science are important. One is validity: is it a scientifically validated method? To what extent does it measure what it claims to measure? Another is reliability: is it really a reliable method? How consistently can it be reproduced across time, persons involved, and situations?

When I examine the science of a method, it does not mean that I give less importance to human rights and ethical content, or to use of that method. Both scientific and unscientific methods can be used to violate human rights. Because a method is scientific, its use does not automatically become ethical or humane. Good scientific methods and devices have often been used for very bad purposes. But an examination of science is necessary to engage with those medical scientists who are otherwise neutral but get swayed by the claim to scientific validity of such methods. Besides, an unscientific method deceives and does not serve even its basic purpose of finding out what it intends to find, and, in the process, punishes the innocent. A review of scientific literature on the use of lie-detection and narcoanalysis to establish crime shows there is not enough material to assure us that these are scientifically researched methods. (In biomedicine, for making a claim to science one uses the golden standard of the randomised controlled trial.) Moreover, not much of the inconclusive literature available on the subject is from scientific journals. Most research on the subject is sponsored or conducted by people in the security, intelligence, police and military agencies. So there is a major conflict of interest.

Lie-detection methods

Polygraph: Lie-detection is different from narcoanalysis. The former is not invasive, but the latter is, as it introduces drugs into the body system. In practice, there is a strong connection between the two; they complement each other. The polygraph is a lie-detection method in which it is assumed that when you are telling a lie, that is, when your mind is trying to deceive, it has a direct physiological impact, that is, your physiological responses change – the breathing pattern changes, pulse rate changes, the way one sweats changes, and so on. These physiological changes are used in the polygraph method to detect lies. They ask you questions, and electrodes attached to your body record changes in your pulse rate, breathing rate, blood pressure and other things. They compare changes or lack of changes when you lie and do not lie. The lying is found out by asking control questions (those for which answers are already known) and relevant questions (relevant to the crime's investigation).

Computer voice test recorder: A voice recorder is attached to a computer with certain specialised programmes and functions. Like physiological changes recorded in the polygraph, this device records changes in voice, which is supposed to have a different character when one is lying from when one is telling the truth. The sophisticated computer programme eventually pronounces whether the person was lying in response to the relevant questions. I looked up court judgments in the US on the use of this device, and came across cases where the computer had erred, leading to the incarceration of innocent people. In one, the person later received compensation from the manufacturer of the machine.

Brain mapping/brain fingerprinting: The new technique of brain mapping and brain fingerprinting is used not only for lie-detection, but also as the basis for undertaking narcoanalysis. It uses well-known diagnostic instruments, the electro-encephalogram (EEG) and functional magnetic resonance imaging (fMRI). Such machines are now used on a regular basis in forensic laboratories at Bangalore, Mumbai and Ahmedabad. These are also the places where narcoanalysis is carried out.

Brain mapping shifts attention from the physiological response of the body to electrical responses in the brain itself. This supposedly takes care of limitations in measuring physiological responses through the polygraph. Besides, the person is not made to say anything; he or she is only made to hear something and the rest is done by the machine to find out how the brain is responding. They say that knowledge of what you know about persons, places, events, etc, is stored in your mind. If asked, I may tell the truth or lie. Or I may prefer to stay silent, saying that to keep silent is my right. Once this method is employed, we no longer have the right to our silence. Technically, one may stay silent in the sense that one has said nothing. And yet the machine attached to my skull provides my interrogators the information. Let us see how this is done.

The person is connected to the EEG or fMRI, and not required to talk. The person is given auditory stimuli of name(s), place(s), event(s), etc. Now, there is something called the P-300 brainwave. According to theory, this brainwave is not under the person's volition or control. A fraction of a second after hearing the stimulus, and if the stimulus is recognised, this brainwave spikes. The electrical spark in a specific area of the brain is recorded in the fMRI or EEG machine. That way, according to them, they can get the contents of the brain

– not details of what the person knows, but whether s/he knows about certain specific things that they are interested in finding out. In short, they get this information without the person's active participation, without him/her ever verbally answering a question or having any control over what the brain's electrical activities have been.

Now, whether this interpretation of the P-300 brainwave is scientific or not, and whether it is based on evidence, I have no idea. But it is on this basis that they believe you know something, and then they have to persuade you to bring it out of your mind. And it has to be brought out in such a manner that you are unable to exercise any control over what you say. Because if you are allowed to use your mind to control what you say, then you may lie or filter out what you do not want them to know. Having seen the contents page of your mind, they believe they can follow it up with narcoanalysis to read the remaining pages.

Before I deal further with narcoanalysis, it may be useful to discuss what independent scientists have to say about lie-detection techniques. In the last few years, two major scientific or professional committees evaluated these techniques. Lie-detection methods are used to screen applicants for sensitive jobs. It was in this context that the US Department of Energy requested the National Research Council (NRC) for an evaluation of the technique. The NRC appointed an expert committee that brought out a report in 2003 (4). The second review was done by a Working Party of the British Psychological Society in 2004 (5). Both committees concluded that lie-detection techniques were not scientific, or were based on dubious science.

The assumption that there is always a mutual correspondence between psychological and physiological states is wrong. I also feel the assumption that P-300 brainwaves provide accurate information on whether the brain knows something is an extremely mechanical understanding, with doubtful scientific validity. Another important issue is the fear of being labelled a liar, which can create physiological responses that may actually lead to totally erroneous conclusions about the information obtained. Thus, in all these techniques, the possibility of what we call false positives and false negatives is very high.

False positives are when those who are telling the truth are wrongly judged to be liars. (Even if the judgement of the machine, or one derived by the investigator on the basis of data provided by a machine, needs corroboration, the person is doomed as a suspect.) False negatives, on the other hand, are those judgements where a person is actually lying, but the machine and investigators judge him or her to be telling the truth. False negatives can also be achieved by what is called counter-measure, by training oneself to misguide the interrogator or machine. There is a very interesting case described in one of these two reports (5). A person called Floyd 'Buzz' Fay was falsely convicted of murder in the USA. He was actually judged a criminal and murderer simply because he failed a lie-detection test. He was sentenced to life. After he had spent two-and-a-half years in prison, the police found the real murderer and Fay had to be released. But when he was in prison on such grave though false charges, he started training the prison inmates to beat the lie-detection test, and he did it very well. He provided training for a duration of 20 minutes to those who had told him that they had committed the crime for which they were supposed to go through a lie-detection test. He gave the training to 27 people; 23 beat the machine and got away scot-free!

Narcoanalysis

Now let us look at narcoanalysis, which is fast replacing lie-detection techniques as the preferred method of making a person tell the truth and nothing but the truth. I started with lie-detection and brain mapping because faith in narcoanalysis is part of the same mindset that believes there is a technology (or the possibility of one) to recognise truth from lie, or to get to the truth against a person's wishes. It is also one of the latest in a chain of attempted technological fixes, and has the best so-called 'scientific look' to it. Its importance lies in the capacity to seduce scientists into believing that it is scientific and free of the shortcomings of the lie-detection techniques mentioned earlier. And, of course, that it is something less than torture. That is why it is more important, and so much more dangerous.

From what I have learnt, narcoanalysis, as a procedure of using a drug to facilitate the extraction of relevant information from a person's mind, has a history of over 80 years. I do not know much about its early history. Currently, the drug used for narcoanalysis is called sodium pentothal. This is a trade name given by the company, Abbott Laboratories, which discovered it in 1935. Its real name is thiopental sodium, which is a thiobarbiturate, a part of the barbiturate group of drugs. Before this became the drug of choice, doctors undertaking narcoanalysis to treat patients used several other drugs like sodium amytal, scopolamine and nitrous oxide. Apart from drugs, hypnosis was also used in psychiatry. All these procedures were designed to help patients suffering from certain mental illnesses.

The use of drugs by security agencies happened alongside their medical use. For instance, the CIA had done covert experiments with LSD – causing the death of one unsuspecting participant – during the Cold War in order to use the drug's mind-altering properties to its advantage. During the Cold War period it was believed that the Soviet Union knew a method of brainwashing people. I remember from the 1970s that if a person became Marxist, we were told that s/he had been brainwashed. This term was used very commonly at that time; today it is hardly ever heard though a different kind of ideology is washing the minds of a large number of people! The death in this covert LSD experiment became a scandal, leading to Senate hearings

which also revealed that the CIA was experimenting with sodium pentothal. Some of the documents of the Senate hearings are available on the Internet (6).

Sodium pentothal: Sodium pentothal also has an interesting history. It was developed and tested as an anaesthetic agent. It is given intravenously and is a very fast-acting anaesthetic. It acts within 45 seconds of being introduced into the bloodstream. Almost 60% of it concentrates in the brain, and the person immediately starts losing consciousness. It can also be given for a relatively longer period of time. Surgery can commence immediately, and the person can be kept under anaesthesia for the duration of the surgery. After one stops giving it, it takes 15 minutes to three hours to wear off; so, recovery from anaesthesia is also relatively fast. It is therefore a very useful drug. After it was developed, they used it as an anaesthetic agent in an emergency situation during World War II, in the famous Pearl Harbour attack. When Pearl Harbour was bombed, injured persons were given sodium pentothal while being provided surgical care. Several died due to an overdose of this anaesthesia, information that was not made available to the public until the 1990s when freedom of information legislation helped get it out. The point I am trying to make is that this very useful drug can kill if it is not used judiciously. Its proper use requires the services of a doctor whose sole aim would be to care for the person, not just to extract information by any means.

Sodium pentothal is also famous for its use in other areas like euthanasia. Voluntary euthanasia is where the doctor helps a patient who is suffering from an irreversible, debilitating illness that would surely lead to a slow death, to die. One of the drugs injected in order to hasten death is sodium pentothal. The lethal injection that is used in the US to carry out the death penalty is also sodium pentothal.

Sodium pentothal in narcoanalysis: Let us understand the assumptions underlying the use of sodium pentothal, an anaesthetic drug, for its intended forensic use in narcoanalysis. There are four different stages of anaesthesia. The first is called induction. The second is a phase of excitement and the beginning of loss of consciousness, when the person is partly conscious, or semi-conscious, or is in a trance-like state. As one continues to give the anaesthetic substance, the person goes into the third stage of anaesthesia, the surgical plane, when a person loses sensation and is totally unconscious. Loss of consciousness in this stage is reversible. However, a higher dose than this leads to the last and fourth stage: coma or overdose, which is often irreversible due to depression of the brain stem and medullary regions, and can lead to death as happened at Pearl Harbour.

In narcoanalysis, the person remains in the second stage of anaesthesia. The hypothesis is that, with this dose and in this stage of anaesthesia, sodium pentothal not only produces an effect similar to hypnosis (a trance-like state), but, by its interaction with certain chemicals in the brain, it also makes the person speak the truth. The hypothesis governing the forensic use of narcoanalysis is that activity in the upper or cortical part of the brain is required in order to filter or alter a person's response to stimuli. Another assumption is that, compared to telling the truth, lying demands more complex processing in the brain in order to decide how to lie and what to say in a lie. And this complex processing takes place in the upper or cortical portion of the brain. The final assumption is that, if the aforementioned hypothesis is true, then experts need only have a mechanism or a drug that can stop or reduce the influence of the upper or cortical part of the brain whose role is critical in forming a lie. Once that is achieved, the brain's capacity to lie is altered or controlled by the investigator. And the hypnotic effect produced by the drug ensures that the person tells the truth and nothing but the truth when asked a question.

In sodium pentothal, have scientists found such a drug, and in narcoanalysis such a mechanism that can alter the brain in the manner required? They claim that it is so. In the October 2006 issue of the *Indian Journal of Medical Ethics*, I wrote an editorial (7) disputing the science of narcoanalysis and criticised its practitioners for violation of ethics and human rights. The topmost forensic practitioner of narcoanalysis in India responded (8) to the editorial. He stated that sodium pentothal has the ability to inhibit the working of a neurotransmitter inhibitor in the brain called GABA, or gamma amino butyric acid. The assumption is that this neurotransmitter inhibits the way the brain controls the response that a person gives, and by inhibiting this neurotransmitter at a certain depth of anaesthesia, sodium pentothal removes or reduces the inhibitory powers of the upper or cortical brain.

Is there any sound scientific proof for such a series of assumptions? The medical journals are silent on this. On the contrary, there is more evidence, both empirical and otherwise, to argue that foolproof assumptions of this nature are not possible.

As I said earlier, it is known that the second stage of anaesthesia produces excitement and the person is not fully unconscious but in a trance-like state. Psychiatrists who have used this drug have talked of patients being very lucid in narcoanalysis and have also talked about narcohypnosis. Under such assumptions, they used this drug for decades to help victims of trauma, whose minds had suppressed their memories of the trauma or were reluctant to describe their trauma as, by doing so, they were re-living their painful experience, all of which were causing them psychological problems.

After writing that editorial I interacted with a few psychiatrists to understand their viewpoints. I found some provided very good support, though many of them have still not written publicly on the issue. I also interacted with a psychiatrist from the armed forces who said that he

had used this drug for narcoanalysis to help his patients. He also told me that he discontinued its use, as well as narcoanalysis, because while patients gave information in the hypnotic trance induced in the process, they also gave lots of misleading information. His contention, thus, was that the method was not reliable. However, at the same time, I must add, he said that he had full faith in the security agencies and contended that, in any case, the security of the nation was more important than human rights!

Narcoanalysis and hypnotic suggestion: While I was giving a public lecture in Mumbai on narcoanalysis, a person from the audience said that forensic experts planted ideas in the mind of his relative accused of a crime while he was undergoing narcoanalysis. His question was whether it was possible to do so through suggestion during narcoanalysis. I am not a scientist, least of all an expert on this subject, to be able to give a definitive answer. However, it is known that the trance-like state of hypnosis was used in psychoanalysis and, as a person was considered more prone to suggestions in this state, it was also used in psychotherapy.

I have no scientific evidence, but commonsense says that if sodium pentothal produces a trance-like hypnotic state in the second stage of anaesthesia, making a person talk with less inhibition about giving or recollecting information, then perhaps the reverse could also be true. Therefore, scientists who are confidently using sodium pentothal to make a person speak the truth have an obligation to provide evidence that their assumptions and hypotheses do not work at all in reverse. Unless that is done, there will always be a suspicion that the truth found in narcoanalysis could also be manufactured truth, planted by the interrogators themselves.

Narcoanalysis and torture

Is narcoanalysis a type of pharmacological torture? The United Nations' definition of torture (9) has four components. The first is that torture produces physical/ mental suffering and is a degrading treatment. The second is that it is always intentionally inflicted. The third is that it is inflicted for certain purposes such as getting information, confessions, etc. And the fourth is that it is inflicted by an official actor or an actor acting on behalf of an official. Narcoanalysis satisfies all four components.

It is degrading because it deliberately uses a drug that attempts to alter the state of mind of a person against his/ her wishes. It produces mental suffering in an individual, more so if he or she discovers that some of his or her fantasy revealed in the procedure is used to make accusation of a real crime. In the present Indian condition it is even more so because the police or forensic laboratory has, on occasion, released video clips of the actual narcoanalysis of a person to the media, where it is played out on TV repeatedly when it is not even admissible as evidence in a court of law. Thus, it inflicts a high level of mental suffering and stigmatisation of the individual by society. The rest of the components of the definition are easily satisfied. Indeed, it is deliberately inflicted – so deliberately that it is systematically done in an operation theatre and not in a prison or police lock-up. It is also a method not only to extract information, but also to force a confession. And it is always done by the police through its forensic laboratory and personnel employed there, along with the doctors in a hospital who are specifically appointed by the police to carry out the procedure (10).

We have always thought of torture as gory, blood-soaked and barbaric. So we are often misled into believing that anything that does not look gory, spill blood or break bones is not barbaric and a form of torture. Torture remains torture even if it does not spill blood, break bones, and is done in a sterile, air-conditioned operation theatre. What is true of the procedure for the death penalty, which moved from bloody firing squads and the guillotine to the electric chair and sterile lethal injections, holds good for torture as well. Narcoanalysis produces torture as clearly as the lethal injection produces death.

Doctors, ethics and narcoanalysis

The last point I want to make is regarding the relationship of narcoanalysis to doctors and their medical ethics. As I said earlier, sodium pentothal is a very dangerous drug if not used judiciously. It needs to be tested in small doses to rule out the possibility of producing shock or an allergic anaphylactic reaction. The anaesthetist also needs to know how to identify any harmful effects that could jeopardise a person's life. The drug can suddenly lower blood pressure, cause cessation of respiration, apnoea, unexplained constriction of the larynx or a laryngeal spasm (needing emergency surgery). It can also cause delirium, nausea and headache. It is also used very commonly in surgeries simply because it is used very carefully by properly trained anaesthetists in the setting of an operation theatre in a hospital. That is why you will find that, although a forensic laboratory will claim that it did narcoanalysis, it was actually performed in an operation theatre of a hospital, mostly in a public hospital. The Godhra accused were narcoanalysed not in a laboratory but in the SSG Hospital in Baroda, a public hospital with a medical college (11).

That means narcoanalysis is a method that cannot be carried out without the assistance of doctors. Indeed, it is also not disputed that one or more doctors directly participate in it, and are continuously present during the interrogation; the work these doctors do is nothing short of assisting the interrogators. They not only assist, but are actually responsible for creating the conditions for the interrogation to proceed, continue and conclude as desired by the interrogators. Clearly, doctors are directly involved in this procedure of pharmacological torture. Besides, since there is a possibility of a series of life-threatening adverse outcomes, other doctors, including a surgeon, have

to be on call. And above all, there is also the association of the hospital and its head, who is normally a doctor, with the procedure. He/she not only allows the procedure, but also makes all critical facilities of the hospital – physical as well as human resources, which includes doctors and nurses – available to the interrogators to carry out this torture in the name of scientific medical procedure.

What does this mean to human rights and human rights defenders? All the exemplary work that was done by human rights activists, and all the human rights gains in relation to medicine that were achieved in the 1970s and 1980s are being thrown out of the window. These achievements and gains were: the doctor, himself or herself, will not participate in torture, will not remain present where torture is carried out, and not only that, if he or she comes to know about such torture as a doctor, he or she will immediately report it.

Health professionals must recognise that they are being forced or persuaded on various pretexts to violate their own professional ethics. Their participation is sending a message to society that the medical profession tolerates those members who are performing medical procedures in violation of the wishes of the individuals on whom they are carried out, thereby also violating the ethical principle of informed consent (12). This is an important issue even in terms of the history of the medical profession. For instance, during the 19 months of the Emergency in the 1970s, we all know about the forced vasectomies performed on men. But who performed those vasectomies? Doctors did. They willingly participated in the name of a top-priority national programme; they felt an urgency to sterilise people without consideration as to whether the people brought in by the police and other government officials were in any way coerced, forced, or, for any other reason, unwilling to undergo the operation.

This is a very important issue for associations of various health professions. The World Medical Association (WMA) issued the Tokyo Declaration against torture and on doctors' role in torture way back in 1975. In response to events that followed 9/11 in 2001, it revised this declaration recently to ensure that there was absolutely no ambiguity in the prohibition on doctors' participation in torture (13). The Indian Medical Association is a member of the WMA, is signatory to the declaration, and thus has a moral obligation to stop doctors from participating in torture and the death penalty.

To conclude, the participation of doctors in narcoanalysis and the death penalty, and the tolerance of medical associations of their unethical acts, are eroding the very core of the medical profession. It is in the best interest of healthcare professions, the human rights movement and society in general that doctors and nurses are immediately removed – completely and unequivocally – from participation in narcoanalysis, from police interrogations of all kinds, and also from their participation in the death penalty.

Note: Narcoanalysis, brain mapping and other interrogation techniques that depend on the involvement of the medical profession have been the target of a five-year-old campaign by those working in medical ethics. On May 5, 2010, the Supreme Court of India issued a path-breaking judgment declaring illegal, and a violation of human rights, the use of medical techniques for investigation of individuals without their consent, as well as other extensive safeguards. Amar Jesani has commented on this judgment in the July 2010 issue of the Indian Journal of Medical Ethics*. Press reports indicate that the tests are continuing, because the accused either consents or is unable to refuse consent.*

(This paper is an abridged version of the 22nd Dr Ramanadham Memorial Lecture delivered by the author at a meeting organised by the People's Union for Democratic Rights at the Indian Law Institute, New Delhi, on September 15, 2007. It was reprinted in the July 2008 issue of the Indian Journal of Medical Ethics *http://www.ijme.in/163co130.html. The meeting proceedings, including the full text of the speech, are available on www.pudr.org)*

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References

1 Medico Friend Circle. 'Carnage in Gujarat: A Public Health Crisis'. Pune: Medico Friend Circle; 2002

2 Indian Medical Association. 'Report on Knowledge, Attitude and Practice of Physicians in India Concerning Medical Aspects of Torture'. New Delhi: IMA; 1995. p 24

3 Parmanand Katara, Advocate vs Union of India and another. Writ petition No 827 of 1991, decided on January 19, 1995, in Supreme Court Cases (SSC), 1995; 3: 248-49

4 National Research Council. Committee to review the scientific evidence on the polygraph. Washington, DC: National Academies Press; 2003

5 BPS Working Party. A review of the current scientific status and fields of application of polygraphic deception detection. London: British Psychological Society; 2004

6 Joint hearing before the Select Committee on Intelligence and the Subcommittee on Health and Scientific Research of the Committee on Human Resources 4, US Senate, 95th Congress, August 3, 1977 (cited September 21, 2006). Available from: http://www.hiddenmysteries.com/freebok/mk/toc.html

7 Jesani Amar. 'Medical Professionals and Interrogation: Lies About Finding the Truth'. *Indian Journal of Medical Ethics,* October-December 2006; (4): 16-17

8 Mohan B M. 'Misconceptions About Narcoanalysis'. *Indian Journal of Medical Ethics,* January-March 2007; 4(1): 7-8

9 Article 1 of the UN Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment. 1984

10 Keller L. 'Is Truth Serum Torture?'. Thomas Jefferson School of Law, research paper series on public law and legal theory: 2004 (cited January 3, 2006). Available from: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=599143

11 Bhan R. 'A Shot at Justice? "Truth Drug" for Godhra Accused'. *The Indian Express,* June 23, 2002

12 Jagadeesh N. 'Narcoanalysis Leads to More Questions Than Answers'. *Indian Journal of Medical Ethics,* January-March 2007; 4 (1): 9

13 World Medical Association. Declaration of Tokyo. Guidelines for Physicians Concerning Torture and other Cruel, Inhuman or Degrading Treatment or Punishment in Relation to Detention and Imprisonment. Adopted by the 29th World Medical Assembly, Tokyo, Japan, October 1975, and editorially revised at the 170th Council Session, Divonne-les-Bains, France, May 2005 and the 173rd Council Session, Divonne-les-Bains, France, May 2006 (cited June 15, 2008). Available from: http://www.wma.net/e/policy/c18.htm

Doctors as executioners

It was a doctor who invented the guillotine, a dentist who helped design the electric chair, and an anaesthesiologist who conceived of the lethal injection. It is a doctor who climbs up a ladder to certify that a prisoner kept hanging for several minutes is actually dead, and a doctor who administers the lethal injection. It's time the medical fraternity took a stand against capital punishment since every method of execution is intrinsically cruel and violative of their professional ethics

VIJAY HIREMATH

IN THE LAST FEW YEARS, the use of medical technology and the involvement of medical professionals in criminal investigations has increased. Narcoanalysis, brain mapping and other medical tests for the purposes of interrogation have been challenged as unscientific and a violation of human rights; essentially, they have been viewed as forms of torture to extract confessions from the accused. The Supreme Court of India, in a recent judgment regarding the use of these tests, ruled that they could not be conducted without the consent of the accused.

Though the role of health professionals in these methods has been widely debated, the Supreme Court has not commented on this aspect (1).

Doctors are also involved in the execution of the death penalty, inasmuch as they certify that the convict being executed has, in fact, died. In 1993, the Law Commission circulated a 'Consultation Paper on Mode of Execution of Death Sentence and Incidental Matters'. There was a suggestion that lethal injection be used, which would further involve medical professionals in the death penalty by making them actually carry out the execution.

The death penalty in India

India continues to be one of the few countries in the world that has retained the death penalty, extending its application in recent years to include, for example, crimes under special laws such as the Organised Crime Control Acts enacted in various states, and the Unlawful Activities Prevention Act – all under the guise of fighting terrorism. The number of people sentenced to death has increased in the last few years. Although one is thankful that executions have not taken place at the same rate at which death sentences have been awarded (the last execution in India occurred in 2004 when Dhananjoy Chatterjee was convicted and sentenced for rape and murder), we cannot assume that executions will continue to be stayed.

It has been pointed out that most pending mercy petitions are for poor people. Ex-President of India A P J Abdul Kalam in 2005 questioned the criteria for awarding the death sentence and mentioned that most mercy petitions pending with him at that point of time involved extremely poor people. People convicted in political cases are also more likely to receive the death sentence than others convicted of similar crimes. The case of Afzal Guru, who has been convicted in the Parliament attack case and sentenced to death, comes up every so often. His mercy petition is pending before the President of India. His execution has become a political issue, with many right-wing parties demanding that he be hanged immediately. In the case of Swami Shradhanand, the Supreme Court commuted the death sentence in 2008 but also held that a convicted person should not be released on parole or be liable for premature release. This too is a dangerous trend as, eventually, the country could abolish the death penalty only to substitute it with life imprisonment without chance of parole or premature release.

In the recent case of Mulla vs State of UP (AIR2010SC942), the Supreme Court, while deciding on the death sentence for the accused, who were from Uttar Pradesh and were extremely poor, held that the courts should examine socio-economic factors while awarding sentences, especially the death sentence.

Methods of execution

Section 354 (5) of the Criminal Procedure Code states: "When any person is sentenced to death, the sentence shall direct that he be hanged by the neck till he is dead." The Air Force Act, the Army Act and the Navy Act prescribe shooting as one of the additional modes of execution of persons sentenced to death.

On July 6, 2009, the Supreme Court rejected a petition filed by Ashok Kumar Walia stating that hanging was a painful method of execution and asking that it be replaced by lethal injection. The apex court asked the petitioner who was arguing in person to create public opinion on the issue (2). The petition was dismissed at the initial stage; no detailed arguments were heard on behalf of the petitioner.

Law Commission reports

The 35th Law Commission report in 1967 recommended

Capital punishment is barbaric and a violation of basic human rights. Every method of execution is intrinsically cruel. Since doctors play a crucial role in all methods of execution, the line between medical practitioner and executioner becomes blurred. Internationally, there have been medical associations that have taken the stand that no medical practitioner will be asked to take part in bringing about the death of a convict. The principle behind this reasoning is that the medical profession is intended to save lives, not bring an end to them

that the mode of execution of the death sentence be replaced by a more 'humane' method of execution. The Law Commission of India, in 2003, in its 187th report recommended that Section 354 (5) of the Criminal Procedure Code be amended and alternative modes of execution be introduced. However, there has been no change in the method of execution in India.

The Law Commission report (3) contained responses to a questionnaire on the death penalty as well as on the method of execution. Eighty-nine per cent of people who participated in the survey said that Section 354 (5) should be amended. The survey also found that 73% of respondents wanted the mode of execution to be changed to lethal injection. An analysis of responses from judges who participated in the survey shows that 80% were of the opinion that Section 354 (5) of the Criminal Procedure Code should be amended.

The Law Commission report also showed that an overwhelming majority of people who participated in the survey believed that a person should have the automatic right to appeal to the Supreme Court once the high court has confirmed the death sentence. They also felt that a death sentence should be decided by a five-judge Bench of the Supreme Court.

In Deena vs Union of India (4), the Supreme Court held that execution of the death sentence should satisfy the following criteria:

- It should be as quick and as simple as possible.
- The act of execution should produce immediate unconsciousness passing quickly into death.
- It should be decent.
- It should not involve mutilation.

Death by hanging does not satisfy any of the criteria laid down by the apex court. Yet it continues to be the only mode of execution in the country, apart from death by shooting as under the Army, Navy and Military Acts.

In 1995, the Supreme Court of India struck down a provision in the Punjab and Haryana Prison Manual that stated that the body of the person executed should be kept hanging for half-an-hour. The apex court held that a dead body too should be treated with dignity (5). There have been several cases reported where hanging has not immediately resulted in a broken neck, and the convict is left to slowly strangle to death. This results in the convict's eyes popping almost out of his head, his tongue swelling up and protruding from his mouth. In cases where the neck is in fact broken, the rope often tears large portions of the convict's flesh and muscle from the side of the face where the knot is. In many cases, the convict ends up urinating and defecating on himself before he actually dies. The prisoner remains dangling from the end of the rope for 8 to 14 minutes before a doctor climbs up a small ladder, listens for a heartbeat with a stethoscope, and pronounces him dead. Given these facts, it is clear that hanging is neither quick and simple nor a decent method of execution as it involves mutilation of the body and, in some cases, prolonged suffering and torture before death.

Across the world, methods for executing people sentenced to death include hanging, shooting, the electric chair, lethal injection and, in some countries, stoning.

Although lethal injection is widely believed to be less painful, there have been cases in the United States where the person is still alive 20 minutes after the injection

has been administered (6).

The idea of using this method of execution was first put forward in a medico-legal journal in New York, USA, in 1888. In 1977, the issue was re-introduced by Dr Stanley Deutsch of Oklahoma Medical School. Lethal injection is the primary method of execution in the US. According to the description provided in the consultation paper of the Law Commission, this method of execution involves the prisoner being secured on a gurney with lined ankle and wrist restraints. A cardiac monitor and a stethoscope are attached to the prisoner, and two saline intravenous lines are started, one in each arm. The saline intravenous lines are turned off and sodium thiopental is injected, causing the inmate to fall into a deep sleep. The second chemical agent, pancuronium bromide, a muscle relaxant, follows. This causes the inmate to stop breathing due to paralysis of the diaphragm and lungs. Finally, potassium chloride is injected, stopping the heart.

Of all the methods available, lethal injection appears to be the quickest and least painful. However, the reality is that even this method could result in cruel and unusual suffering. Amnesty International has documented numerous "botched" executions involving lethal injection. The case of Scott Carpenter, who was executed in Oklahoma on May 18, 1997, serves as a prime example of this. Two minutes after the injection was administered, Carpenter started making noises; his stomach and chest had "palpitations" and his body suffered 26 violent convulsions in the process. He was officially declared dead 11 minutes after the injections were first administered.

In most of these methods of execution, medical professionals play an important role. Under no circumstances however are they to try to alleviate the pain or suffering of the person sentenced to death, if the person does not die immediately.

Medical professionals have also played a key role in discovering new methods of execution. In the 18th century, Dr Antoine Louis designed, and Dr Joseph-Ignac Guillotine advocated, the decapitating machine as a humane method of execution that became infamous as the guillotine. Dr Alfred Southwick, a dentist, helped design the electric chair that was considered "more humane" for many years. Medical expertise played a vital role in use of the gas chamber, even in hanging. Dr Stanley Deutsch, an anaesthesiologist, conceived of a lethal injection along the lines of intravenous induction of general anaesthesia. The first 'clinical trial' of the lethal injection was carried out in Texas in 1982, on a 40-year-old African-American man who was injected with anaesthetic agents as two doctors watched. He was dead within minutes (7).

Conclusion

With the recent terror attacks in Mumbai and bomb blasts in various cities all over the country there is little possibility of the death penalty being abolished in India in the near future. However, parliamentarians and the judiciary must realise that capital punishment is not a deterrent to crime; that criminal cases are not free from error and that innocent people may be sentenced to death; that the criminal justice system in India is completely stacked against the poor and that there is a greater possibility that, for a similar offence, a rich person will escape the noose while a poor person is hanged.

Capital punishment is barbaric and a violation of basic human rights. It is time the death sentence was abolished in India. There can be no argument for humane killing; every method of execution is intrinsically cruel.

Since doctors play a crucial role in all methods of execution, the line between medical practitioner and executioner becomes blurred. Internationally, there have been medical associations that have taken the stand that no medical practitioner will be asked to take part in bringing about the death of a convict. The British Medical Association held that it was opposed to any proposal to introduce a method of execution that would require the services of a medical practitioner. The American Medical Association has also taken the position that medical professionals participating in executions are going against the oath they take, and that such actions violate professional ethics.

The principle behind this reasoning is that the medical profession is intended to save lives, not bring an end to them. It seems appropriate that the Indian Medical Association and all other Indian organisations responsible for the practise of medicine in this country state their position on the issue. A statement by medical associations that Indian medical and health professionals will not participate in executions and the use of torture as a method of interrogation and investigation will greatly advance the move towards abolition of the death penalty and medically-based torture in India.

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References

1 Reference to the latest Supreme Court judgment

2 Times News Network. 'Execution by Hanging to Continue: SC', *The Times of India*, July 7, 2009. http://timesofindia.indiatimes.com/India/Execution-by-hanging-to-continue-SC/articleshow/4746794.cms

3 http://lawcommissionofindia.nic.in/reports/187th%20report.pdf

4 Deena vs Union of India (1983) 4 SCC 645

5 (1995) 3 Supreme Court Cases 248

6 Case of Scott Carpenter, executed in Oklahoma on May 18, 1997

7 Amar Jesani 'Medicalisation of "Legal" Killing: Doctors' Participation in the Death Penalty', October-December 2004. http://www.ijme.in/124ed104.html

Disease-mongering: Any which way to find a market

By branding impotence 'erectile dysfunction' and heartburn 'gastro-oesophageal reflux disease', pharma companies turn commonplace conditions into threatening diseases to market existing drugs or new drugs of doubtful or no utility. This article is an eye-opener on the extent to which drug companies obfuscate, bribe, offer kickbacks and make irrational, harmful, useless and even banned medicines

S SRINIVASAN

THE PHARMA INDUSTRY is a good example of how looking at all science and technology-based business endeavours purely as profit-making machines ends up swallowing itself, a harakiri of sorts that sets it on a collision course with the very people – the sick and the needy – that it needs to survive. This is happening at a time when the rate of innovation, discovery of really useful new molecules, is falling rapidly. So there is desperation aboard the pharma ship: about finding new uses and new markets for existing molecules, and overstating the usefulness of newly arranged molecules of doubtful or no utility.

Today the general public – literate and illiterate – is somewhat aware that corporate misdemeanours are a given and that consumers and end users need to be constantly on the lookout. Still, very few of us are aware of the extent to which drug companies obfuscate, bribe, offer kickbacks and make irrational, harmful, useless and even banned medicines. Or that they appoint doctors as key opinion leaders to give false certificates about the efficacy of their products. Or that they take cooperative doctors on exotic holidays and more, conduct unethical and unscientific clinical trials and selectively report the findings.

In this article, I illustrate how corporations ensure that drugs find their market. The tactics they use are astonishing for their brazenness as much as they are depressing for their venality – even if one thinks from previous experience that these are par for the course. Specifically, I discuss two phenomena: disease-mongering and ghostwriting.

Disease-mongering: "The corporate construction of disease"

One of the important ways drug companies make money is by telling people they are sick even when they are passing through one of life's many normal transitions. A collection of papers published in the April 2006 issue of *PLOS Medicine* discusses this practice of "disease-mongering", something that suits both the industry and the medical profession, as it helps in medicalising problems. In 2004, an editorial in the journal *Bulletin on Drug and Health Information (BODHI)* referred to a number of instances in the US of "branding" medical conditions, quoting from an article by Vince Parry, 'The Art of Branding a Condition' in the journal *Medical Marketing & Media*. Some examples from these articles:

When Warner Lambert invented a condition called 'halitosis' – which makes ordinary bad breath sound serious – sales of Listerine rose from US$100,000 to US$4 million in six years.

In the 1980s, Glaxo needed to expand its market for ranitidine (brand Zantac) and created a condition called 'gastro-oesophageal reflux disease (GERD)' a serious sounding name for heartburn, an age-old complaint. The company also set up the Glaxo Institute for Digestive Health, which in due course led to a PR exercise, Heartburn Across America. Annual sales of Zantac peaked at US$2 billion.

"Capturing impotence in an acronym"

During the 1990s, Pfizer had to create a market for sildenafil citrate (Viagra). It labelled the broader condition of impotence 'erectile dysfunction' (ED). Calling impotence ED probably caused less embarrassment to shy patients as they could now discuss a medical problem called ED with their doctors!

Manufacturers of fluoxetine (brand Prozac, a serotonin re-uptake inhibitor, SSRI) marketed it for 'premenstrual dysphoric disorder', a new name for a severe form of premenstrual syndrome, a routine hormonal transition. The marketing strategy was to frame the "disease prevalence to maximise the size of the medical problem". Pfizer even set up an organisation called Impotence Australia to host advertisements of SSRIs in the media – the logic presumably being that depression is caused, among other factors, by impotence. In the US, SSRI antidepressants have been widely promoted through what is called direct-to-consumer advertising. In a 2005 paper published in *PLOS Medicine*, Jeffrey Lacasse and Jonathan Leo observe: "The impact of the widespread promotion of the serotonin hypothesis should not be underestimated. Antidepressant advertisements are ubiquitous in American media, and there is emerging evidence that these advertisements have the potential to confound the doctor-patient relationship."

"A legendary example of this condition-branding strategy

was the development of Xanax (alprazolam) for panic disorder in the 1970s," writes Parry. "In DSM-II, panic disorder fell under the broad category of anxiety neurosis. Without a well-branded condition, patients experiencing panic attacks often went to cardiologists, thinking their problem was a heart condition, only to be labelled 'cardiac complainers' and hypochondriacs due to a lack of physical pathology. Dr David Sheehan, a pioneering thought leader in the field of panic, helped characterise the condition and push for a new way to diagnose and treat it. Upjohn, the makers of Xanax, helped fund this early research, as well as publications and speaking tours to cardiologists to help raise awareness of the heart-brain connection in the minds of panic disorder patients. Xanax was the only benzodiazepine to be studied that showed clear evidence of effectiveness. Through an unrestricted grant to the National Institute of Mental Health, a three-day thought leader conference resulted in a published consensus on the diagnostic criteria of panic disorder and how best to treat it."

Australian journalist/researcher Ray Moynihan has documented the media's promotion of drugs. In an article 'Selling Sickness: The Pharmaceutical Industry and Disease-Mongering', in *BMJ* in 2002, he and his co-authors note that, in Australia, baldness in men was medicalised by Merck to sell its hair-growth drug finasteride (Propecia); Merck funded a new International Hair Study Institute so that men could wise up to the bald truth by consulting their doctors. Hair loss, the public was told, could lead to panic and other emotional difficulties and even have an impact on job and wellbeing. Needless to say there were several articles around 1998-2002 in the media about the life-threatening process called hair loss!

Moynihan also notes that irritable bowel syndrome**,** a common functional disorder, found a drug in GSK's Lotronex (alosetron hydrochloride). GSK used a "medical education" firm In Vivo to shape medical and public opinion – with a plan that included setting up an "advisory board", consisting of pre-selected "key opinion leaders" in each Australian state. The campaign was stopped because the USFDA recommended withdrawal of the drug after reports of serious and sometimes fatal adverse reactions. FDA investigators discovered that use of Lotronex could result in ischaemic colitis, a potentially life-threatening condition which is caused by reduced blood flow to the colon. Additionally, the drug can cause severe constipation, which can result in a ruptured bowel. As of October 2000, there had been 91 reported cases of hospitalisation (many more likely went unreported) in which some patients required surgery and at least five died. As a result, GSK agreed to remove the drug from the market in November 2000. However, the USFDA, facing pressure from desperate patients, announced on June 7, 2002, approval of a supplemental new drug application that allows restricted marketing of Lotronex to treat only women with severe diarrhoea-predominant irritable bowel syndrome. And in 1997, Roche started promoting its antidepressant Aurorix (moclobemide) as a valuable treatment for "social phobia". Its PR company issued a press release saying more than 1 million Australians had a "soul-destroying condition" called social phobia. Soon Roche's promotion of Aurorix became case study material for positive action in marketing circles.

Disease-mongering in India

There are plenty of examples of disease-mongering in the Indian scenario.

Piracetam is promoted for vague conditions like "intellectual decay," "social maladjustment," "lack of alertness," "changes of mood," "deterioration in behaviour" and in "learning disabilities in children associated with the written word". The recommended duration of treatment for the last indication is "entire school year" in a dose of "3 g per day", or seven to eight capsules of 400 mg daily. If the drug is administered as recommended, parents must buy at least 2,700 capsules at a cost of Rs 12,775 per year. Claims of the drug's efficacy include the treatment of sickle cell anaemia, stroke and vertigo. In Britain, Piracetam is permitted for use in just a single indication, a rare disorder called cortical myoclonus, and only as an adjunctive therapy. Its use is contraindicated for adolescents under the age of 16. An editorial in the July 2005 issue of *MIMS India* points out that "the drug is contraindicated in hepatic and renal impairment, during pregnancy and lactation. It is to be used cautiously in (the) elderly. Its side-effects include: diarrhoea, weight gain, insomnia, nervousness, depression, hyperkinesis and rash. It can interact with warfarin and result in bleeding. Piracetam is not marketed in the United States".

The same *MIMS India* editorial notes that buclizine is promoted as an appetite stimulant. The drug is not commercially available in the US and is restricted worldwide for treatment of migraine in combination with analgesics. Internationally reported adverse effects include drowsiness, blurred vision, diarrhoea, difficulty in passing urine, dizziness, dryness of mouth, tachycardia, headache, nervousness, restlessness, hallucinations, skin rash and upset stomach. Bottles of buclizine in India do not contain either the package insert or the patient information leaflet.

E Merck found that the Government of India's price control on its Vitamin E medicine Evion, selling some Rs 35 crore, was getting uncomfortable: the National Pharmaceutical Pricing Authority (NPPA) had placed Vitamin E under the Drugs Price Control Order. The NPPA fixed price (inclusive of all taxes) was Rs 9.20 for Vitamin E 200 IU and Rs 14.82 for 400 IU, for a 10-capsule strip. In 2009, E Merck found a good way to get out of this jam: it added wheatgerm oil and some omega fatty acids and called it a dietary supplement, thereby escaping the price control order – dietary supplements are not drugs according to one interpretation of the law (not true, if you go by the definition of a 'drug'

in the Drugs and Cosmetics Act of India). The new dietary supplement is made under licence of the Prevention of Food Adulteration Act, reserved for food products like *achars* and *masala* powders and jams. The new price of the 'improved' product: Rs 60 for a 10-capsule strip. Other companies routinely do this by tweaking their ingredients to escape price control. Lost in the brouhaha is whether Vitamin E has any role as a drug or as a dietary supplement, especially at the dosages indicated, and whether it should have been licensed in the first place by the Drugs Controller General of India (DCGI).

Vaccines: Products in search of a market

Ever since hepatitis B vaccines started being made by Indian companies, starting with Shanta Biotech of Hyderabad, the classes of people who 'need' this vaccine have been expanding; the Ministry of Health and Family Welfare would have us believe that it is a bigger problem than AIDS. India now has a glut of hepatitis B vaccine manufacturers – all in search of a market – and some are on the verge of closing. They have succeeded in convincing policymakers that the vaccine must be given to all newborns by including it in the National Immunisation Programme. The business media have gleefully reported this as a "shot in the arm" for the ailing vaccine industry.

Among the other vaccines knocking on the door is the HPV (Human Papilloma Virus) vaccine advocated as a tool to fight cervical cancer, which is linked to HPV. In 2009, two "demonstration projects" of the HPV vaccine, collaborations between the government and PATH International, were launched in Gujarat and Andhra Pradesh. In April 2010, they were shut down following reports of unethical practices. The vaccine is known to be effective only against lesions caused by specific HPV types; its known protection against HPV is only for five to six years though it is promoted for lifelong immunity; protection against cervical cancer can only be known in 30-40 years, which is how long it takes for cervical cancer to develop; it is expensive – Rs 9,000 for three shots – with possible booster shots later. Does this make sense in a public health system that allocates Rs 12.50 per capita for government health insurance?

Merck went one step further, advocating mandatory vaccination. Women In Government (WIG), a recipient of Merck funding, has introduced Bills in 20 US states, in one case writing the legislation, in another case getting an executive order issued requiring vaccination for all girls entering the sixth grade, unless parents opt out. If Merck's Gardasil becomes routine, the $360 course will generate annual sales of $3.2 billion by 2010.

Charlotte Haug makes a very important point relevant to the introduction of all new drugs, vaccines included, in her 2009 article in the *Journal of the American Medical Association*, 'The Risks and Benefits of HPV Vaccination': "When do physicians know enough about the beneficial effects of a new medical intervention to start recommending or using it? When is the available information about harmful adverse effects sufficient to conclude that the risks outweigh the potential benefits? If in doubt, should physicians err on the side of caution or on the side of hope? These questions are at the core of all medical decision-making. It is a complicated process because medical knowledge is typically incomplete and ambiguous. It is especially complex to make decisions about whether to use drugs that may prevent disease in the future, particularly when these drugs are given to otherwise healthy individuals. Vaccines are examples of such drugs, and the Human Papilloma Virus (HPV) vaccine is a case in point… When weighing evidence about risks and benefits, it is also appropriate to ask who takes the risk, and who gets the benefit. Patients and the public logically expect that only medical and scientific evidence is put on the balance. If other matters weigh in, such as profit for a company or financial or professional gains for physicians or groups of physicians, the balance is easily skewed. The balance will also tilt if the adverse events are not calculated correctly."

Ghostwriting

No man but a blockhead ever wrote, except for money.
– Samuel Johnson, 1709-1784

Premarin and Wyeth

On August 5, 2009, the *New York Times* was one of several newspapers across the United States reporting that Wyeth Pharmaceuticals engaged a medical writing company to produce 26 articles from 1998 to 2005 pushing Premarin as Hormone Replacement Therapy (HRT) in women. The work was 'outsourced' to Design Write that employed writers to write them and forward them to top experts, mostly academics in obstetrics and gynaecology, who looked at them, okayed them with minor changes and submitted them to journals under their own names. That Wyeth was involved in funding the articles was not of course mentioned.

Ghostwritten articles are read by physicians who take them as independent proof that the company's drugs are safe and effective. The company's attorney acknowledged that the articles were part of a marketing effort, but said that they were also fair, balanced, and scientific. Wyeth, the world's No 12 pharmaceutical company by sales, is being bought this fall by No 1 drug maker Pfizer.

Rofecoxib and Merck

Merck did a lot to promote rofecoxib. It suppressed data on the drug's adverse effects, especially the increased risk of heart attacks and possible death. And it refused to withdraw the drug when it should have. Part of Merck's "marketing" efforts were supplanted by ghostwriting, according to Joseph Ross, a doctor at Mount Sinai School of Medicine,

New York, who, with his colleagues, scrutinised 250 documents relating to rofecoxib created between 1996 and 2004, released by Merck. Ross and his co-authors conclude, in a 2008 article in *JAMA*: "This case study review of industry documents demonstrates that clinical trial manuscripts related to rofecoxib were authored by sponsor employees but often attributed first authorship to academically affiliated investigators who did not always disclose industry financial support. Review manuscripts were often prepared by unacknowledged authors and subsequently attributed authorship to academically affiliated investigators who often did not disclose industry financial support."

Fake journals

Merck Sharpe & Dohme (Australia) (MSD[A]) went one step 'better': it published an entire fake journal called the *Australasian Journal of Bone and Joint Medicine,* paying an undisclosed sum to Elsevier to produce several volumes of a publication that had the look of a peer-reviewed medical journal but contained only reprinted or summarised articles, most of which presented data favourable to Merck products, with no disclosure of company sponsorship ('Merck Published Fake Journal'; posted by Bob Grant on http://www.the-scientist.com/blog/display/55671). "I've seen no shortage of creativity emanating from the marketing departments of drug companies," Peter Lurie, deputy director of the public health research group at the consumer advocacy non-profit Public Citizen, said after reviewing two issues of the publication. "But even for someone as jaded as me, this is a new wrinkle."

George Jelinek, an Australian physician and long-time member of the World Association of Medical Editors, commented that the "average reader" (presumably a doctor) could easily mistake the publication for a "genuine" peer-reviewed medical journal. "Only close inspection of the journals, along with knowledge of medical journals and publishing conventions, enabled me to determine that the journal was not, in fact, a peer-reviewed medical journal, but instead a marketing publication for MSD(A)."

He also stated that four of the 21 articles featured in the first issue he reviewed referred to Fosamax. In the second issue, nine of the 29 articles related to Vioxx, and another 12 to Fosamax. All of these articles presented positive conclusions regarding the MSD(A) drugs. "This is straightforward marketing," he said.

Ghostwriting in medicine is clearly unethical. Dr Richard Smith, former editor of the *BMJ* and former chief executive of the BMJ Publishing Group, admitted in a 2005 article in *PLOS Medicine*: "We are being hoodwinked by the drug companies. The articles come in with doctors' names on them and we often find some of them have little or no idea about what they have written," he wrote. "When we find out, we reject the paper, but it is very difficult. In a sense, we have brought it on ourselves by insisting that any involvement by a drug company should be made explicit. They have just found ways to get round this and go undercover."

"Articles in medical journals," says S Sismondo, also in *PLOS Medicine*, in 2007, "have real effects upon physician prescribing behaviour, which is why pharmaceutical companies invest so much in their publication. Journal articles are heavily used in detailing, to validate claims and rebut worries. Even independent of detailers, responsible physicians and medical researchers search the literature to gather evidence about the best treatments. Published scientific articles are the sources of medical information with the highest authority. Systematic reviews and meta-analyses almost all start with the published literature – so even fully independent reviews are influenced by ghostly activities. Therefore, the ghost management of journal articles is a step in the intervention into medical practice."

Ghostwriting befuddles the truth. Psychiatrist Daniel Carlat comments on his blog: "As with baseball players on steroids, when companies pour marketing money into ghostwriting campaigns, *they change the rules of the academic game. The playing field is no longer level; the drug company's version of the truth gains the upper hand*. Sometimes, their truth really is the truth, but sometimes it's a carefully crafted lie. Sorting it out is difficult even for physicians who specialise in the area being written about. It's essentially impossible for the average generalist physician, to say nothing of patients who did not have the advantage of attending medical school."

Concluding remarks

Disease-mongering and ghostwriting are two sides of the same coin. In an ideal world these things ought to be corporate crimes of the highest order. They involve perjury as much as playing with people's lives, giving false hope by selling dishonest cures. That companies do such things is probably to be expected. That doctors and medical professors should aid and abet is a crime against humanity – one that is likely to increase with medical college seats being retailed for Rs 1 crore and more in India. This is another horror against which even activists do not seem to be raising their voice.

(This article draws upon material from (The Revised) A Layperson's Guide to Medicines. *LOCOST, Vadodara, 2006; Ray Moynihan and Alan Cassels:* Selling Sickness: How the World's Pharmaceutical Companies Are Turning Us Into Patients. *New York: Nation Books, 2005; MIMS India various issues,* PLOS Medicine*, 2005)*

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A microscope at the grassroots

Jan Swasthya Sahyog's experiences in a small hospital with an active village outreach programme show that the cost, versatility, sensitivity and specificity of the microscope make it the most important investment for a small healthcare unit

BISWAROOP CHATTERJEE

ACCORDING to Monica Cheesbrough, an authority on medical laboratory practice in tropical countries, microscopy forms 70-90% of the diagnostic work at the community health centre level. A laboratory at this level can increase the accuracy of diagnosis and thereby curtail expenditure by reducing the need for 'shotgun' therapy. It can also assess response to therapy, screen for diseases, and investigate epidemics (1). Some of India's most important public health problems, such as tuberculosis (2) (estimated burden of 3.8 million patients shedding bacilli in their sputum in 2000), malaria (3) (reported burden of 1.7 million patients in 2003), and cancer of the uterine cervix (4) (estimated burden of 0.11 million new patients in 2004) can be diagnosed or screened with the help of a microscope.

From our experience in a small hospital with an active village outreach programme, we feel that a microscope is the most cost-effective investment that a small healthcare unit can make. We use the microscope every day to investigate the following symptoms that many of our patients complain of:

Cough with or without fever

Ziehl-Neelsen-stained sputum smears are used for acid-fast bacilli, for the presumptive diagnosis of tuberculosis. In the early years of our hospital, when we did not have an x-ray machine and had to depend entirely on microscopy to diagnose pulmonary tuberculosis, we resorted to concentrating sputum samples with a solution containing 1% sodium hydroxide and 3% ammonium sulphate (5). This increased our sputum-positivity rates by 89% in a series of 1,966 patients.

Gram-stained sputum smears are used for patients with productive cough and fever. Streptococcus pneumoniae, the most common cause of severe, community-acquired pneumonia worldwide, has a characteristic microscopic picture, with numerous pus cells and abundant encapsulated Gram-positive cocci in pairs (6).

Absolute eosinophil count is used for patients with tropical pulmonary eosinophilia and Löffler's Syndrome (7). Laboratories in northeastern India could also look for Paragonimus ova in sputum from patients complaining of cough and bloody sputum (7).

Diarrhoea

We use saline mounts of stool for pus cells, which indicate the need for antibiotics; saline and iodine mounts of stool for parasites and their ova and cysts (7); hanging drop preparation of stool for Vibrio cholerae (8); and Modified Kinyoun-stained stool smears for oöcysts of Cryptosporidium and Isospora (7).

There have been several instances at our centre when the detection of Isospora in patients with long-standing diarrhoea and severe weight loss has led to the diagnosis of HIV infection. These patients have subsequently been cured of their diarrhoea with a course of Co-trimoxazole worth Rs 25.

Fever without localised symptoms

We do peripheral blood smears for malaria parasites (7). Our village health workers use bus conductors to send blood smears to our health centre for same-day reporting – a system that has served more than 9,000 patients so far with

average slide positivity rates of around 20%.

We also do total and differential leukocyte counts in blood; microscopic examination of urine sediment for pus cells and bacteria; slit-skin smears for acid-fast bacilli. Multi-bacillary leprosy is common enough in our area for type II reactions to be a significant cause of 'fever of unknown origin'. Some of these patients lack discrete skin lesions and can be diagnosed only with the help of a microscope (9).

Laboratories in Bihar, West Bengal and Assam could also look for L-D bodies in splenic or bone marrow aspirates to diagnose kala-azar.

Joint pain and/or swelling (10)

We use total and differential cell count of synovial fluid and Gram-stained smear of synovial fluid for bacteria.

Dysuria (burning sensation while passing urine)

We use a wet mount of urinary sediment for pus cells and Trichomonas vaginalis (7) and Gram-stained urethral smear for pus cells containing Gram-negative diplococci, a finding that is highly specific for gonorrhoea in male patients (11).

Excessive vaginal discharge

We take a saline mount of vaginal fluid for Trichomonas vaginalis (7). And a Gram-stained smear of vaginal fluid to look for clue cells and bacterial morphological types for bacterial vaginosis (12); pus cells trapped in cervical mucus for endocervicitis (13); and yeast cells with pseudohyphae for Candida vaginitis.

More than half our patients are diagnosed with bacterial vaginosis and they go home with Rs 14 worth of metronidazole as the only treatment. If these women were to be given syndromic treatment for vaginal discharge, without a specific diagnosis, it would cost them Rs 50 for metronidazole, doxycycline, and fluconazole. In addition, they would be exposed to the risk of side-effects from medicines that many of them would not have needed.

Anaemia

Romanowsky-stained thin blood films for microcytic and hypochromic red cells as well as pencil-shaped, teardrop-shaped and target-shaped red cells in iron-deficiency anaemia; macrocytic red cells and hyper-segmented polymorphs in folic acid or Vitamin B12-deficiency anaemia; and extreme aniso-poikilocytosis in thalassaemia.

Sodium dithionite mounts for sickle-cell anaemia.

Infertility

Semen analysis. We always do this test before embarking on more invasive and expensive investigations on the woman.

Our laboratory is staffed completely by locally trained technologists who belong to the area, contradicting the misconception that it is difficult to train and retain dependable microscopists in the 'periphery'. Several of our technologists can perform all the tests mentioned here. They also function as trainers.

Microscopy vs disease-specific kits

Cost: A good Indian binocular microscope, inclusive of a voltage stabiliser, costs Rs 25,000 ($500) and provides the same resolution as competing brands abroad. Assuming a working life of just three years, under conditions of rough handling in high temperatures and humidity, the depreciation of the microscope will be Rs 28 per working day, or Re 0.56 per test, if 50 microscopic tests are done every day for 300 days a year. If one adds the cost of electricity, immersion oil, microscope slides, cover glasses, stains, lens tissue, and even the occasional replacement of microscope bulbs, the material cost comes to approximately Rs 9 per test. If one adds the salary of a technologist, at Rs 15,000 per month, ie, Rs 20 per test, the net cost of one microscopic test comes to Rs 29 (59 cents).

Few kit-based tests can be offered at these prices if one includes the salary of the technologist using the kit and the cost of transporting and storing kits under cold chain. Even though many modern kits are stable at environmental temperatures prevailing in temperate countries (up to 35°C), this 'room temperature' is exceeded in summer in many parts of India, especially in trucks and badly ventilated storage depots. Cooling in some form is therefore essential for the assured performance of these kits, and this should be factored in while comparing the costs of microscopy with disease-specific kits. A variable proportion of kits in stock often cross the expiry date and are wasted, leading to increased costs.

Versatility: Most diagnostic kits focus on just one parameter or analyte, such as malaria antigen, at a significant cost. A microscope does quite the opposite: it is a versatile instrument that helps diagnose dozens of illnesses. It can provide unexpected clues to the diagnosis, whereas disease-specific kits can only confirm what is suspected. For example, a technologist in our laboratory once diagnosed sickle-cell anaemia when he noticed sickle-shaped red blood cells in a sample of *urine* and then ran a haemoglobin electrophoresis on a blood sample to prove the diagnosis!

Specificity and sensitivity: If good-quality consumables are used and correct techniques followed, there is little doubt about what is seen under a well-maintained microscope by an experienced technologist; after all 'seeing is believing'. The specificity of microscopy for malaria diagnosis was found to be 100% when compared against PCR in a series of 124 febrile cases in Iran, in 2002 (14). This cannot be said about many disease-specific diagnostic kits whose performance depends on intrinsic design, standards of

manufacture, and conditions of storage. In a study done by us on 192 patients with fever, in 2008, we found that the top-selling malaria rapid diagnostic kit in our district had a sensitivity of 73% and specificity of 92%, when compared with microscopy of thick films.

The microscope as 'self-help' technology

A survey done in 2001 by the New Delhi Tuberculosis Centre found that 67% of chest symptomatic patients attending the out-patient clinic had already had a chest x-ray done, but not sputum microscopy. Most of the x-rays were advised by doctors in private practice and in government hospitals (15).

The Revised National Tuberculosis Control Programme (RNTCP) has provided a much needed boost to microscopy in rural areas. The programme, first launched in 1993, has set up microscopy centres (MCs) for every 100,000 population across the country (16). These microscopy centres have proved the feasibility of providing high-quality microscopy services in rural areas. However, the centres should be gradually integrated into the horizontal health system, not only to tap their immense diagnostic potential for other diseases but also to prevent 'work expanding so as to fill the time available for its completion', since only "2-3% of new adult out-patients in any general health facility will have a cough for three weeks or more" (17).

To quote E F Schumacher: "As Gandhi said, the poor of the world cannot be helped by mass production but by production by the masses… The system of *production by the masses* mobilises the priceless resources which are possessed by all human beings, their clever brains and skilful hands, *and supports them with first-class tools.*" A good microscope in the hands of a competent technologist is a perfect example of such a tool, a tool that can help us reach the Alma-Ata goal of "…essential healthcare based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination" (18).

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References

1 Cheesbrough M. 'District Laboratory Practice in Tropical Countries'. Part 1. Cambridge: Cambridge University Press; 1998

2 Tuberculosis Research Centre, Chennai. 'Burden of Tuberculosis in India for the Year 2000'. In: NCMH Background Papers – Burden of Disease in India. New Delhi, India. National Commission on Macroeconomics and Health, Ministry of Health and Family Welfare, Government of India. 2005. p 24-5

3 Dua A S. 'Programmes for the Control of Leprosy, Tuberculosis and Malaria'. In: NCMH Background Papers – Burden of Disease in India. New Delhi, India. National Commission on Macroeconomics and Health, Ministry of Health and Family Welfare, Government of India. 2005. p 9-23

4 Nair M K, Varghese C, Swaminathan R. 'Cancer: Current Scenario, Intervention Strategies and Projections for 2015'. In: NCMH Background Papers – Burden of Disease in India. New Delhi, India. National Commission on Macroeconomics and Health, Ministry of Health and Family Welfare, Government of India. 2005. p 219-25

5 Vasanthakumari R. 'Concentrated Sputum Smear Microscopy: A Simple Approach to Better Case Detection in Pulmonary Tuberculosis'. Indian J Tub 1988; 35:80-2

6 Donowitz G R, Mandell G L. 'Acute Pneumonia'. In: Mandell G L, Bennett J E, Dolin R, editors. *Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases*. 6th ed. Orlando: Churchill Livingstone; 2005. p 820-45

7 Sun T. *Parasitic Disorders: Pathology, Diagnosis and Management*. 2nd ed. Baltimore: Williams and Wilkins; 1999

8 Seas C, Gotuzzo E. 'Vibrio cholerae'. In: Mandell G L, Bennett J E, Dolin R, editors. *Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases*. 6th ed. Orlando: Churchill Livingstone; 2005. p 2536-44

9 Levis W R, Ernst J D. 'Mycobacterium leprae' (Leprosy, Hansen's Disease). In: Mandell G L, Bennett J E, Dolin R, editors. *Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases*. 6th ed. Orlando: Churchill Livingstone; 2005. p 2886-96

10 Cush J J, Lipsky P E. 'Approach to Articular and Musculoskeletal Disorders'. In: Fauci A S, Braunwald E, Isselbacher K J, Wilson J D, Martin J B, Kasper D L *et al* (eds). *Harrison's Principles of Internal Medicine*. 14th ed. New York: McGraw-Hill: 1928-35

11 Baron E J, Peterson L R, Finegold S M (eds). *Bailey and Scott's Diagnostic Microbiology*. 9th ed. St Louis: Mosby; 1994

12 Nugent R P, Krohn M A, Hillier S L. 'Reliability of Diagnosing Bacterial Vaginosis is Improved by a Standardised Method of Gram Stain Interpretation'. J Clin Microbiol 1991; 29:297-301

13 Holmes K K, Handsfield H H. 'Sexually Transmitted Diseases: Overview and Clinical Approach'. In: Fauci A S, Braunwald E, Isselbacher K J, Wilson J D, Martin J B, Kasper D L *et al* (eds). *Harrison's Principles of Internal Medicine*. 14th ed. New York: McGraw-Hill: 801-12

14 Haghdoost A-A, Mazhari S, Bahadini K. 'Comparing the Results of Light Microscopy with the Results of PCR Method in the Diagnosis of Plasmodium Vivax'. J Vect Borne Dis 43, June 2006, pp 53-57

15 Dhingra V K, Rajpal S, Aggarwal J K, Chopra K K. 'Dependence on Radiology for Diagnosing Pulmonary Tuberculosis: An Urban Situation'. Indian J Tub 2002; 49:153-6

16 Revised National Tuberculosis Control Programme. Central TB Division, Directorate General of Health Services. Technical and Operational Guidelines for Tuberculosis Control. New Delhi. Ministry of Health and Family Welfare, Government of India. 2005

17 Revised National Tuberculosis Control Programme. Central TB Division, Directorate General of Health Services. Managing the Revised National Tuberculosis Control Programme In Your Area – A Training Course. Modules 1-4. New Delhi: Ministry of Health and Family Welfare, Government of India; 2005

18 World Health Organisation (homepage on the Internet). Geneva: Declaration of Alma-Ata. International Conference on Primary Health Care, Alma-Ata, USSR, September 6-12, 1978 (cited June 12, 2009). Available from: http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf

Doubts about vaccines

Are strong-arm immunisation campaigns justified in the name of 'public good'? What is the ethical responsibility towards those who fall ill despite vaccination – or because of it? Why is there no notion of parental consent in India? In a shocking instance of unethical practice, the human papilloma virus vaccine for cervical cancer was administered to poor children in boarding schools without their parents' knowledge and consent

PRABIR CHATTERJEE

VACCINES ARE A PART of our daily lives today. In India, all children are meant to receive the BCG at birth and be immunised against diphtheria, pertussis, tetanus, measles and polio by the age of 1. The universal immunisation programme is promoted by governments and international agencies. Rules also exist to ensure that travellers are immunised against common vaccine-preventable diseases before they enter certain countries.

India's immunisation programme costs around Rs 900 crore; our total health budget is Rs 22,300 crore. Clearly, vaccines are widely accepted as playing a critical role in public health. Why then are there disagreements about vaccines – which ones to use, how they should be promoted, how much the public should know, and their role in public health programmes?

The technology and developments

Antibodies are the body's response to fighting infection. They are produced by the body when reacting to a virus, bacteria or toxin. Antibodies can be produced by natural exposure to the virus, or by vaccination. Newborn children receive a certain amount of protective antibodies from their mothers, and the first milk, or colostrum, provides the first immunisation. But these early 'acquired' antibodies soon wear off. We can prevent some diseases by 'challenging' the child with small amounts of the live virus in weakened or 'attenuated' form (such as for poliomyelitis), or the dead virus, or a part of it. We prevent others by giving a weak chemical that resembles the toxin (such as tetanus toxoid).

There have been major changes in vaccine technology in recent times, which make them safer, more effective, and easier to administer. For example, 'multivalent' vaccines, or combined vaccines for more than one disease, simplify the job of immunising hundreds of thousands of infants for five different diseases. And now, instead of getting the virus to grow on animal cells we use 'recombinant genetic engineering'. This involves cutting and splicing parts of different cells together. This is believed to be safer than vaccines from 'cell cultures' that may be contaminated by viruses from the original animal. New technologies in the preservation of vaccines will replace the mercury compound thiomersal currently used in many vaccines. While small quantities of thiomersal do not cause a problem, there is an additive effect with repeated vaccination (opponents of thiomersal happen to include many non-allopaths). Thiomersal has been phased out in vaccines in developed countries as new technologies are developed and used. But it continues to be used in government programmes in India. Indeed, one possible ethical issue in the development of vaccine technologies is that better technologies may also cost more, and may not be available to everyone.

Technological developments also introduce new technological challenges. For example, the conjugate pneumococcal vaccine uses an advanced technology, but its large-scale use may create new problems – a shift from the most common types of infection to less common serotypes – which will need new solutions.

Vaccine technology is used on healthy people to prevent an illness that *may* develop. But, like all other drugs, every vaccine can cause problems for a certain number of people, and some vaccines can be a problem for many people. When taking a drug for treatment, the person may weigh the *known* benefit of the drug against the possible harm. For a vaccine, the person must weigh the *possible* benefit of the vaccine against the possible harm. For the individual, what is the risk of acquiring the disease compared to the risks associated with the vaccine itself? Then, while the vaccine may harm a few people, it may benefit many more. At the public health level, one therefore has to consider how to balance the risk to a few people with the benefit to many.

How many people should be benefited in order for a vaccine to be acceptable? How many people can be harmed before a vaccine becomes unacceptable? Older, cheaper vaccine technologies may have higher risks, but may be used in public programmes because they are cheaper. What are the ethical implications of such a choice?

Then, there is the concept that if sufficient children are immunised against, say measles, the virus cannot circulate in the community. So individuals who refuse to get vaccinated, because of the risks – real or perceived – will benefit from the majority who accept the risk of vaccination.

Finally, many vaccines are given in early childhood and the recipients cannot make an informed decision on whether or not to accept the vaccine. So a proxy – the parent or guardian – decides for the child.

Such questions may provide us with a context in which to discuss various controversies about the way in which vaccines are made available and promoted in our society.

Eradication campaigns and their consequences

The first category of vaccine controversies concerns some vaccines that are accepted as useful by the World Health Organisation and the United Nations Children's Fund and used by governments throughout the world. While there is little controversy within medical circles about the importance of the diphtheria, polio tetanus (DPT) vaccine or the oral polio vaccine (OPV), questions are asked about the highly publicised campaigns to eradicate or 'eliminate' (reduce the number of cases to a certain level, as opposed to eradicating the disease from the face of this planet) various diseases using these vaccines on a massive scale. Campaigns such as the polio eradication programme have been questioned because they use a lot of manpower, time and money and may deflect attention from other important tasks. The campaign consists of 'pulses' in which all children below the age of 5 are administered the oral polio vaccine with the intention of flooding the environment with a weakened polio virus. The vaccine is thought to replace the wild polio virus circulating, in the hope that the wild virus will eventually be eradicated as it is believed that the virus cannot survive outside the human body for a long period. All government schools and health centres are taken over during the 'pulse', disrupting routine health and education programmes. These eradication and elimination programmes raise hopes extremely high but are not necessarily as successful as expected. The pulse polio campaign is more than a decade-and-a-half old (it started in December 1995 in India), but outbreaks of polio continue to occur in parts of the country. At the time of writing, a case has surfaced in Birbhum after a gap of six years, and there are four cases near Farakka in Murshidabad district of West Bengal. Stories are created to boost the image of the campaign, but little transparency is shown when there are setbacks.

Another important ethical concern about the polio eradication campaign stems from the fact that a minuscule number of children getting the oral polio vaccine will get vaccine-associated polio paralysis (VAPP). But, though every child taking OPV faces a small risk of VAPP, a much larger number have been protected from the disease up to now. There is an injectable polio vaccine, which is much safer. But it is more expensive and protects only the immunised child; it will not offer the possible public benefit of the OPV 'pulse' that passes through the child's digestive system and floods the environment with the weakened virus. So the oral polio vaccine is promoted as a public programme.

Should children who develop VAPP receive compensation for the injury they suffered by participating in a public programme? As far back as 2001, the Indian Expert Advisory Group spoke of doing something for all polio victims. However, no such policy has been implemented so far. It is estimated that over 100 children get VAPP in India every year.

In fact, such eradication campaigns build up pressure to get vaccinated. Pressure also builds during epidemics, and the publicity surrounding H1N1 is one example. However, non-epidemics can also be 'hyped'. Thus, there has been a debate as to whether H1N1 was ever as serious a threat as it was made out to be.

Informed consent and freedom of choice

The belief in 'public good' can be very strong. But strong-arm tactics in campaigns usually result in resistance from the public. The best example is in polio campaigns in Uttar Pradesh. Today, there are often six pulse polio rounds a year in Uttar Pradesh, and children may get 21 doses before they are five years old. If a parent objects on the 21st dose, the health department and administration try to penalise the family.

In some countries, parents must give consent for their children to be vaccinated. They are given vaccine information sheets that contain phone numbers to contact if the child falls ill after being vaccinated. Parents may refuse to let their child be vaccinated, though there are rare occasions when the government can appeal to the courts that not immunising a child would endanger a whole community.

There is no notion of parental consent in India. In a shocking instance of unethical practice, the human papilloma virus vaccine was administered to poor children in boarding schools without their parents' knowledge and consent. At least two of these girls died, though the link to the vaccine is not established.

Inappropriate promotion of useful vaccines

The hepatitis B vaccine is useful in a small section of society that is at risk of infection from the hepatitis B virus (HBV): those in the medical profession, patients who receive multiple injections, those with multiple sexual partners, and children of mothers with hepatitis B. However, companies have allied with social organisations to sell the vaccine at camps. The risk of hepatitis B has been highlighted, even exaggerated. And the vaccine is promoted for people who are *not* at risk: monogamous, healthy adults who do *not* work in medical care.

The incidence of HBV infection is not very high: only about 2% of Indians are chronic carriers at risk of further complications and can transmit the infection. In fact a study in the January 2010 issue of the *Indian Journal of Community Medicine* found that less than 1% of patients

at a Jaipur hospital were HBV-positive. Yet, there is pressure to include the vaccine in the universal immunisation programme. At one time, WHO said that large-scale immunisation programmes for hepatitis B made sense only when at least 4% of a country's population is hepatitis B-positive. Yet, universal hepatitis B vaccination for children has been introduced in some states in India, though the cost doubles the cost of the vaccine programme. Further, researchers Ashok Kale and Anant Phadke have calculated that a lower dose of hepatitis B vaccine, injected just under the skin, is as effective as the full dose that must be given in the muscle. The intra-dermal dose would reduce the cost of immunisation by 80% and be both effective and affordable as a public health programme. However, our government has taken the support of external funding organisations and opted for the larger, much more expensive dose.

Likewise, the haemophilus influenzae B (HiB) vaccine, meant for a particular type of influenza causing meningitis, is used in many western countries and is now being promoted in India though there is no reason to believe that rates of HiB meningitis are as high in India as they are in other countries. (In one Indian study, of 3,400 suspected cases, less than 60 had HiB.) The HiB vaccine is useful, but is it a priority in India yet? Still, in April 2009, the government declared that the HiB vaccine would be promoted for the prevention of pneumonia, with the support of the Global Alliance for Vaccines and Immunisation.

Haemophilus influenzae is not the only cause of pneumonia. Another common cause of pneumonia is pneumococcus and there are some 90 types of this bacterium – but only 23 types of pneumococcus have vaccines. Of these types, some are common in India and others are more common in other countries. At present, there is an effort to introduce a pneumococcal conjugate vaccine (a combination of vaccines against seven sero types of pneumococcus) into the country's immunisation programme. Community medicine expert Chandrakant Lahariya points out, in the May 2008 issue of *Indian Paediatrics*, that while childhood pneumonia is a serious problem in India, the actual burden of disease in India is not known. The point here is: should vaccines against a particular influenza, or against a few types of pneumonias, be given priority in our immunisation programme when we don't know how common these particular illnesses are in our country? Are efforts to introduce these vaccines based on epidemiology or commercial interests?

GAVI

In the July 2010 issue of the *Indian Journal of Medical Research*, paediatricians Zubair Lone and Jacob Puliyel refer to the "visible and invisible pressures brought to bear on governments to deploy expensive new vaccines".

The Global Alliance for Vaccines and Immunisation (GAVI) is a consortium of international agencies, set up in 2000, that provides some funds to governments of poorer countries to use newly developed vaccines. Vaccine manufacturers have argued that they must keep the prices of new vaccines high as few countries buy them for the first 20 years or so. GAVI therefore identifies potentially useful vaccines and subsidises their purchase by countries with large populations and low incomes. The argument is that this ensures that the price of the vaccine drops soon, and also motivates companies to research useful vaccines. GAVI was set up with a $750 million donation from the Bill and Melinda Gates Foundation. However, not too long after it was established, criticism emerged that it overemphasised high-tech vaccines, lacked sustainability and transparency, and relied too heavily on private funding.

That criticism is made even ten years later. GAVI is the principal organisation deciding what vaccines national immunisation programmes will use. It has pressed repeatedly for the expensive rotavirus, pneumococcal and HiB, and hepatitis B vaccines. Such vaccines are irrelevant when DPT has not reached many parts of the world, including India – just 47% to 65% of the 2.7 crore babies born every year in India get all their shots.

Further, there are still shortages of OPV and DPT. This can be because international donors focus on the pulse polio programme, and there is plenty of evidence of this. In another case, government vaccine units that make DPT at a low price were closed down on the argument that they didn't meet standards. GAVI then stepped in to fund a private company that would supply the pentavalent (DPT plus HiB plus hepatitis B) vaccine. It then turned out that the private company's low prices would remain only for a few years. Moreover, the private company was found to have links to friends of political party leaders and acquired vaccine seed cheap from the government laboratories that were closed down.

Unnecessary, low priority, or of questionable value

Though international agencies and our government do not promote or use the herpes zoster (chickenpox) vaccine, the government has allowed its sale. Advertisements in newspapers and on TV for the chickenpox vaccine create unnecessary hype. However, chickenpox does not have the effects of other vaccine-preventable diseases. And the vaccine does not prevent outbreaks, though it reduces the effects (it doesn't prevent infection, only reduces the severity for the patient).

Recent investigations on an HPV vaccine project in Andhra Pradesh led to the government halting all projects with this vaccine. The report and related discussions on the vaccine have highlighted a number of issues with ethical implications: is the HPV vaccine effective, safe and of public health value? Is it a priority for India? Is it being promoted for public health or other interests?

The HPV vaccine is meant to prevent cervical cancer due to HPV infection, which in turn is usually transmitted by sexual intercourse. A large number of cases of cervical cancer are due to HPV. But even in the West, few countries other than

the US and UK have started using the HPV vaccine widely. There are questions about its value. Will it give a false sense of complacency? Will people think that they are no longer at risk of HPV infection or uterine cancer and therefore neglect testing? Will they be careless about having unsafe sex? Will testing for cervical cancer decrease? Screening for cervical cancer is as important as the vaccine, and cannot be replaced by it. Further, 30% of all cervical cancers are not covered by the current HPV vaccines that work only against HPV types 16 and 18. The manufacturer is aware of the limitations of the vaccine but it is promoted aggressively, and this promotional campaign has now started in India.

Programme responses to adverse events

There are proven adverse effects as well as contraindications for all vaccines. The pentavalent vaccine against DPT, hepatitis B and HiB was introduced in Bhutan in July 2009 but was withdrawn from use in September 2009 after six children died following vaccination. A similar problem had arisen earlier in Sri Lanka. Also, there is a fear that the vaccine may increase the risk of asthma.

India has an adverse event reporting system and all reports of illness or death following administration of a drug or vaccine are to be investigated; not all such events are necessarily due to the medicine. The systematic collection of information about possibly-drug-linked events has helped uncover serious side-effects and harm such as the effect of thalidomide on foetuses. Collection of information also helps uncover any weaknesses in the vaccine delivery system. Finally, it helps reassure caregivers and the community when an event is found to be unrelated to the vaccine.

Standard procedures for AEFI reporting were prepared in 2005 and, starting 2006, a large number of cases were investigated for the first time. However, in certain cases it has been left to the media to bring these reports to light. It is sometimes difficult to persuade medical staff that it is to everybody's advantage to inform state or national authorities about these events. Transparency is not considered important.

The Japanese encephalitis vaccine

One example was in the immunisation campaign against Japanese encephalitis. JE is a mosquito-transmitted viral infection affecting the brain. After it caused a large number of deaths in Uttar Pradesh, in 2005, the Indian government acquired a vaccine from China. The SA-14-14-2 vaccine appears to be safe and effective and may soon be approved by WHO. The number of doses to be given is two, according to the manufacturer. However, experience in Nepal led to the Indian government using a single dose. When the government introduced it in mass campaigns in 2006, there was fear among the public and the press and some doctors opposed the campaign. A number of incidents of illness around the time of vaccination were attributed to the vaccine, and the media highlighted every mistake in the programme.

The government's response was not smart. For instance, when expired JE vaccines were supplied at a campaign centre, one official was quoted as saying that they couldn't check the batch numbers of *all* the vaccines. Of course, this is not correct; all health workers know that they have to check the expiry date on the label before giving medicines. This particular official was speaking under pressure from opponents of the vaccine, but such matter-of-fact replies to public doubts and fears are not uncommon.

Place that vaccines have as a technology in public health

Should governments promote the rotavirus vaccine instead of providing clean water? Clean water prevents rotavirus; it also prevents other diseases. Polio, cholera, typhoid are all faeces- or waterborne diseases and can be reduced if our water supplies improve. In the 1970s, a researcher called Thomas McKeown studied mortality due to various diseases in England and Wales over the previous century. Over 90% of reduction in TB, measles and other diseases occurred before vaccines or treatments for these diseases had been discovered.

Further, initiatives like clean water will reduce more than one disease. But the rotavirus vaccine can only prevent some types of rotavirus. It is probably as costly as providing clean water to the community. And there may be risks associated with the vaccine. An older version of the rotavirus vaccine was found to be associated with life-threatening intususception of the intestines (a potentially fatal situation in which part of the intestine slides into another section, leading to the bowels getting blocked completely) after it was introduced. The newer versions appear to be safer but are very costly.

Conclusion

These are not just armchair debates. In July 2010, the Delhi High Court was expected to hear a case challenging the government's plans to introduce the pentavalent vaccine into the universal immunisation programme. A pilot project will be conducted in Himachal Pradesh, Kerala, Tamil Nadu, Jammu and Kashmir and Karnataka. The vaccine will cost Rs 350 per dose, against the current Rs 15 for the DPT alone. The petitioners have argued that the vaccine's safety has not been established – it has been linked to deaths in Sri Lanka and Bhutan and has been removed from Bhutan's immunisation programme. Moreover, there is no evidence to justify including the hepatitis B and HiB vaccines in the universal immunisation programme.

It is time for all interested Indians to join the discussion on vaccines.

Prabir Chatterjee is a medical officer at Bochadanga gram panchayat in North Dinajpur district of West Bengal and a member of Medico Friend Circle. He has also worked in the field of immunisation in Jharkhand and Tamil Nadu

‘New and improved?’ Using technology to transform the body

Demand for cosmetic surgery is rising by 230% every year. Invasive and non-invasive surgical procedures are advertised on every street corner. Is this the ‘democratisation of beauty’, with the body becoming a site where it is possible for an individual to maximise life by becoming ‘new, improved’ versions of themselves, employing the latest in science and technology? Or is there a dangerous corollary to this preoccupation of science with the creation of the perfect face and body?

MANJIMA BHATTACHARJYA

IN THE COURSE OF my doctoral research on the life worlds of women working in the glamour industry in India (1), a section of my interviews focused on the women’s hard and gruelling inner world of work – that of building and maintaining the ‘ideal body’. Through various techniques such as dieting, consultations with a bevy of experts, exercise routines, the gym, beauty regimes and cosmetics, the model’s everyday life is ordered around the maintenance of a disciplined life driven by the desire to transform, reform, or ‘correct’ her body according to both the imagined and real needs of the industry. A fit and ‘ideal body’ is an inherent demand of their profession, they point out, drawing parallels with sportspersons, dancers and other performers.

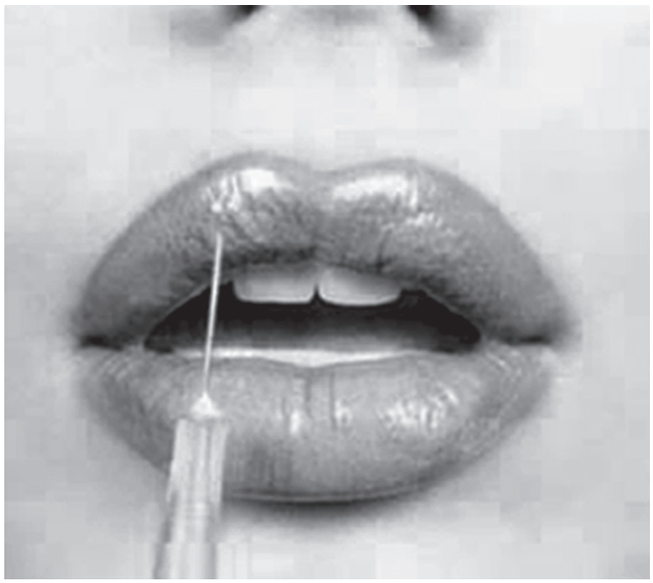
But an exercise regime or a dietary plan are still inadequate to fully exploit the potential of any body to be transformed. Many of the narratives reveal how medical technology today provides ample opportunities for this transformation.

Going under the knife: A first-person account

Mita, a Delhi-based ramp model from a middle class background, who had joined the India franchise of an international modelling agency, was advised to get a nose job done by her agency that felt she had tremendous potential, but for her nose. She was 19 years old at the time. Mita recalls taking the decision to go through with it:

My agent, who is like my godmother, only sat me down initially and said: “Look this is a problem. They saw it in the pictures. We feel you need to do this, but it’s completely up to you. No pressures.” So it was left to me. Initially I thought, “but what is wrong with me?”. I think what decided it for me was when I said to myself that there was no point in being in this industry if I didn’t do it. I was scared of course, worried in case something went wrong. I was getting work. But what’s the point in getting money and not getting recognition? So I decided to take the risk.

Mita and her agent consulted experts in the field and got a recommendation for a top cosmetic surgeon in Mumbai. They fixed an appointment and Mita herself was surprised at how smoothly and quickly the event took place, in a ‘barely-there’ encounter.



We went to Mumbai – me, my agent and my mom – met him one day and he explained the procedure to me. We didn’t have any telephonic conversations beforehand, nor did he show me any references or pictures. I was a bit surprised because I thought he would show me a computer image or something to show me an altered image – what it would look like. He refused to meet my agent, because she was not related to me. Only I and my mother met him. He said it’s a regular operation, lots of people undertake it… He told me that they would not change my face as such, but just straighten a bit of bone on the bridge of my nose that jutted out to the side, and bring in the nostrils a bit by reducing the cartilage. He didn’t even draw a diagram. He only explained it indicating it on my face. He asked me to come to Breach Candy Hospital the next day at 9 am for the surgery.

It was a one-hour operation. When I was lying on the stretcher before the operation, I was nervous. One male nurse came to me and told me, “don’t worry, local mein hoga na aapka *operation”. Basically they were going to numb my face, the area around my nose, and do the surgery, so I would be awake through the procedure! That psyched me out a bit!*

But once I was wheeled in, I found myself being a bit drowsy and actually going off to sleep. They put an IV drip into my wrist. That was the only thing that hurt actually.

The procedure itself involved only two slits under both my nostrils which were stitched up later, and the stitches removed. They inserted some equipment; they could see the inside on a monitor in front of them and drilled, chiselled away at the bone on the nose bridge and brought the cartilage at the sides in. After the operation I could breathe only through my mouth for a while, and that was tough. I was having painkillers. They inserted two gorges up my nostrils for a day or so; after that a metal cover was placed on my nose for protection. It took about a week for it to be better. I could eat more or less anything. I found it difficult to speak as it was all connected, and mostly because of the tight bandages on the nose. My eyes were all bloodshot and the area under my eyes became black and blue and yellow… Apparently that was normal; in any kind of surgery to the face, the trauma is taken by the area around the eyes. It took more than a month for this to go. The doctor had not told me about this, so for one month after I had to cover it up with makeup or something.

I only saw my face after I got home. Home, as in home in Mumbai where we were staying – with my distant cousins. We had to tell them, as we were to stay with them, because I think it was important for my mother that she be with people she knew, to have her own support. It was difficult for her, she was worried, crying a bit… but she was okay.

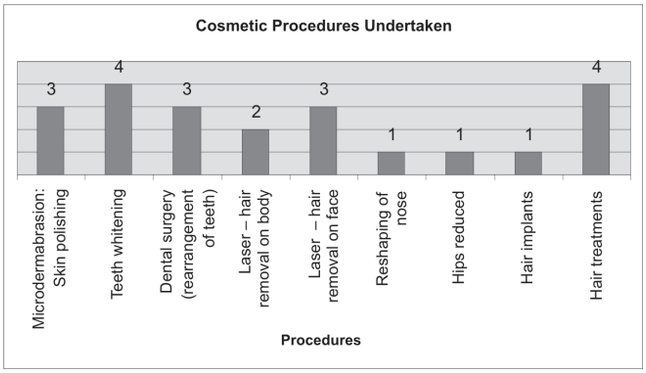
When I returned to Delhi, people could not really tell. It was only in my pictures that you could make out the difference. And it did make a difference. There were no restrictions; I could do anything really, as before. By and by people came to know. Lots of people do it but don't say… I don't know why.

Common procedures in the glamour world

While most of the women I interviewed acknowledged that cosmetic surgery was increasingly acceptable and common amongst those in the glamour industry, and a matter of 'personal choice', few were ready to disclose further details or share their experiences in detail, even if they admitted to having gone under the knife. "Everyone wants the world to think that they are naturally beautiful!" said one of the respondents by way of an explanation. Only some respondents admitted having undergone certain cosmetic procedures (see Figure 1).

These procedures – skin polishing, hair treatment, laser treatment, etc – are seen to be more normal (and less controversial or taboo) than others like breast implants. In many cases, respondents underwent multiple procedures. The same respondent who admitted to having undergone teeth whitening also said she had had dental surgery and laser treatment. Those who had undergone procedures

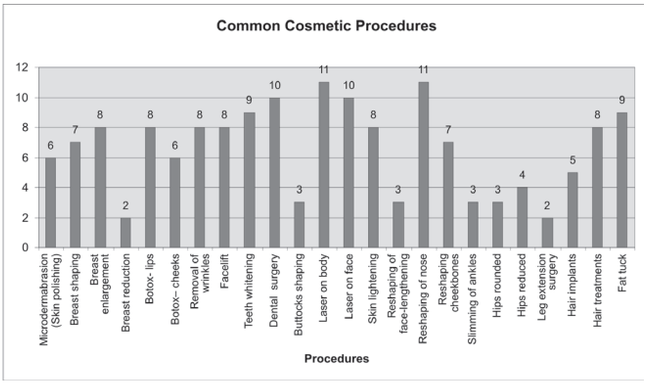
Figure 1



were mostly from the newer generation of models in the industry. While there is still some hesitation about turning to cosmetic surgery among the older generation of models (although there is certainly contemplation), the younger generation has tried out various procedures, from non-invasive procedures like laser hair removal to invasive ones like rhinoplasty (a nose job).

Respondents were more forthcoming about discussing procedures that were generally common in the industry (as opposed to those they had undertaken themselves). Figure 2 shows the perceptions of respondents as to which procedures are common in the fashion and beauty industry.

Figure 2



The most common procedures mentioned were hair removal on the face and body using laser technology, reshaping the nose, and dental surgery – almost a necessity in an industry where it is crucial to have 'the perfect smile'.

The director of an Indian franchise of an international modelling agency puts forward their stand on the use of cosmetic procedures:

Cosmetic surgery is common and I have nothing against it.

Because a little change in the shape of your nose can make an immense difference to your career. Because in photo-shoots, it's all about being seen at close proximity. It is common abroad for agencies to make specific requests to models to get that little nose job, if they feel it's going to impact that much. We do too. Sometimes in terms of teeth, sometimes in terms of the nose… And it's a safe surgery now you know, it's not complicated.

Teeth is very important… So we are constantly telling people to get cosmetic dental treatment. Laser hair removal is not so important – it's really their choice, whether they want to do it or go through the hassle of shaving everyday or whatever. But yes, teeth, nose, I've suggested ear tucks… because that can make a lot of difference. Sometimes maybe Botox, which is also sort of easy and safe. You can get it anywhere, normally for just Rs 2,000-3,000. Botox is very cheap. Dental will depend on what you need. A nose job will probably cost you between Rs 50,000 and Rs 70,000 – and that's if you go to the best in the industry.

All the respondents mentioned that while surgery was extremely common in the film industry, it was relatively less common amongst women in the modelling industry. However, the transition from modelling work to the film industry was assumed to require some amount of 'fixing', with popular legends being narrated of beauty queens winning titles like Miss Universe or Miss World and *then* undergoing nose jobs, Botox, bust enhancement surgery, etc, afterwards (even though they had just been judged the most beautiful woman in the world or universe) to enter the film industry.

'No one talks about the pain': Another account

Swati underwent painful dental surgery to correct her smile in order to facilitate her transition from being a model in print commercials, to television. Swati is from a middle class Jat family based in Delhi and was 24 years old at the time of the surgery. She had left her job as an airhostess two years before the surgery to pursue modelling, and had been getting regular work in mid-level assignments. Swati was a runner-up in the Gladrags pageant, which gave her a platform to get exposure to the industry abroad, and also model for a different league of brands as part of the Gladrags win. She went in for surgery *after* her win at the pageant. Here is her account:

I've got my smile corrected because I had a slight problem. Photographers always told me that I have a little line jutting out here… it was a flaw we had noticed in the pictures. So I went to Apollo, consulted a dental surgeon and got my smile corrected. What they do is that they grind your teeth – your original teeth – about halfway, and then they cap it. It's a very expensive treatment… in fact a lot of my savings went on it… but it's worth it. And it's a very common treatment; all the Miss Indias get it done.

The doctor has a lot of people coming in for this treatment. Not only models, people from everywhere – those who are about to get married, specially airhostesses, people in the service industry, and models. At least ten references she showed me, so she had a lot of people.

It was quite painful (laughs)*… She didn't tell me it was going to be so painful! So I wasn't really scared. When I went for my first sitting I realised that it wasn't easy. They had to give me local anaesthesia, two-three shots, and there was a lot of bleeding, a lot of pain. I really suffered for a month. I couldn't do any work. For three sittings she is just grinding your teeth! Meanwhile, she gives you temporary caps, which look horrible. I couldn't work while the caps were on. Neither could I go out and meet people. The whole thing was completed in about one-and-a-half months; each sitting was with a gap of ten days. But it was worth it. I was quite satisfied.*

I had second thoughts after the second sitting. But then it was halfway there, I couldn't go back on it. It was a bit too much, all this… bleeding and… it was horrible (shudders)*. And anything sweet just went and hit my gums so badly that the pain lasted for two days, three days. But I managed… I took a lot of painkillers! The temporary caps are just (a loose) fitting, so there's a gap between them and your gums… and those gums had already bled, right? So they were still raw. So if anything sweet hits your gum (in that state) there's a very, very bad pain… But I have to be careful. Now for the rest of my life I can't bite into anything hard with my teeth; like an apple. I have to slice everything and eat. The doctor just told me (about) the apple! But I realised four months back that I could not bite into corn on the cob, my favourite! So there are pros and cons.*

Chain reaction

It is too early to gauge whether Swati benefited from doing the surgery and giving up simple pleasures like eating corn on the cob. But Mita did indeed get much more work after the nose job. Her career grew from strength to strength; she became the agency's top model and even went on to win the Miss India title. In an interview (as the new Miss India) on television, in a chat show where the host enquired about using such new techniques, Mita made no mention of the nose job she had undertaken a year ago, but confessed to having undergone gum surgery to fix her smile. She explained that when she saw the videos of herself winning the crown, she realised she had a "nervous smile" which she felt was a flaw. So in the throes of the post-win analysis, she went through minor gum surgery which she hoped would steady her smile and increase her chances of winning at the international level. The host, in turn, applauded her honesty and herself confessed to having taken a few Botox shots to smoothen the lines on her forehead, and how she was feeling just fabulous about it. In the conversation that followed they were echoing the overall refrain that cosmetic

surgery is a matter of choice, it is a 'right' like any other, and (as a generation) we were lucky that we had the opportunity to avail of such advances in technology and were entitled to make the best of it.

Mita's second surgery also validated what many of the respondents had said: it doesn't end at one procedure. Those who overcome the mental inhibitions to surgical procedures get into a cycle and become "surgical junkies". First you do a dental job, then a nose job, then a facelift, then liposuction to reduce the hips, then one Botox injection… the cycle continues.

Mrinal, who has been a choreographer of fashion shows and events in the industry for about 25 years and has seen many young women 'change', even physically, as time went by, says:

Just before they go for, say a Mrs World or that sort of contest, many of them take shots of Botox to be able to get rid of the laugh lines or frown lines or the creases and all that… because it's such an easy way out for that one photo-shoot, or for that one spell of one or two days of looking picture-perfect. But I think what's alarming is what happens thereafter, because it's like a merry-go-round. You cannot step off it, you know. Which means that whatever the frequency is supposed to be (Botox I think needs to be re-administered every three months, six months, or every three weeks)… whatever the frequency of whatever you're getting done for that instant fix – do you ever get off that? Can you ever have the guts to get off that, having experienced the ease with which you can improve and enhance your appearance? But what do you do… it's all part and parcel of the package that comes with the 'look good' industry.

The democratisation of beauty

Swati's account, however, reveals that these procedures are not limited to people from the 'look good' industry, but are coveted by people in all walks of life. Recent studies point out that cosmetic surgery is becoming increasingly popular not only in the glamour industry but in general, and is popular amongst men as well as women, not necessarily from the elite. A study by Max Healthcare (2), at its three Delhi hospitals, analysed the profiles of 400 consecutive cosmetic procedures done in 2005 and found that, as compared to 2004, the demand for cosmetic surgery had gone up almost three times, by 280%. It also found that 30% of those undertaking surgery were men, and the greatest demand (77%) for the surgeries was from people in the age-group 18-40. Sixty-seven per cent of those who came for surgery were from the middle class; patients from rural areas or the suburbs increased from 5% in 2004 to 16% in 2005. This phenomenon is now being termed the 'democratisation of beauty' – anyone can avail of surgery to make themselves 'masters of nature' and open up wider life opportunities (3).

Is the use of medical technology to change the body a private matter or a public health issue? What about regulations, legalities or monitoring around this sort of intervention?

Newsweek's November 2003 cover story is revealing (4). It talks about the 'perfect face', global standards of beauty that are being created, and is solely focused on technological developments that help 'ordinary people' get a global makeover. Its legitimacy is propped up on the pillars of an unquestionable 'science', medicalisation of jargon and expertisation of the 'professionals' – today, there are experts on health, fitness, grooming, styling, nutrition, cosmetology, and so on.

The most striking is the relentless preoccupation of science with the creation of this perfect face and body for the female form. In fact, scientists claim to have hit upon the perfect ratio for the perfect face, called the 'golden ratio decagon complex'.

Besides this, mainstream media – fashion and glamour magazines, TV shows, lifestyle shows, 'makeovers', new forms of creating visual discourses like fashion photography – has a large role to play in creating a visual and textual discourse on glamour and beauty, and in normalising it. In fact, issues like cosmetic surgery are being portrayed as natural, easily accessible, and the extension of an ordinary routine of cosmetic care for the person, or the natural extension of a woman's toilette. The former editor of a woman's magazine that conducts the Miss India pageant, in response to my question on her views on cosmetic surgery, said:

If you can wear contact lenses, that's again a cosmetic change. It's also a need. But you are still interfering with nature. To a certain extent, (you do it) when you are conscious of a cosmetic need to hide something that would otherwise not make you look as glamorous. So if you can do that, if you can wear lipstick… These are all questions of degree.

It is therefore implied that cosmetic surgery is a natural extension of being 'feminine'… akin to 'wearing lipstick'. Actor Pooja Bedi feels that the ten-minute Botox treatment (a 'lunchtime procedure', says the media) is like a magic

wand. She says: "Botox is a natural purified protein that relaxes wrinkle-causing muscles creating a smooth, rejuvenated and more youthful appearance" (5). Vinita, another model based in Mumbai, also used 'human nature' to justify the impetus to "improve oneself". She says: "Human beings are like that; they never feel their body or face is good enough."

Emerging concerns

In the current discourse, the body has become a site where it is possible for an individual to maximise life by becoming "new, improved" versions of themselves, employing the latest in science and technology.

It is difficult to judge whether this is 'false consciousness'; much of it is indeed based on the assumption and experience of material gains. People appear to feel that certain physical attributes will widen economic, career and social opportunities and facilitate social mobility. It is not just for vanity but for practical reasons – marriage, a better job, a smoother climb up the corporate ladder (a newspaper report finds that men in the corporate world are undertaking surgery, as looking good has become increasingly important in the boardroom). Much has been written, for example, about the rush in China for cosmetic procedures – people wanting to widen their eyes, reshape their nose, even undertake painful leg extensions in an effort to be taller – in order to get employment in the new economy sectors for which many of these seeming superficialities are actually a prerequisite.

The implications of these trends are sombre. Being fat/short/dark is alluded to as a problem in the popular media, and solutions are simultaneously offered. Invasive and non-invasive surgical procedures are advertised in every neighbourhood, on street buntings, outside the local beauty parlour, in the leaflets that fall out of the daily newspaper, on the back of magazine covers lying on the table in the dentist's waiting room. New products – creams, lotions, hair-dye, serums, gels, vitamins – from competing brands promise to provide an 'ageing solution' and embalm you in a timeless vacuum. In a twisted real-life incident, newspapers reported a shocking case of a young girl in Delhi who killed herself because she felt she was too fat (6). The incident brought out various other reports by counsellors in schools who shared their concerns about the mental trauma that they were witnessing fat and less beautiful children going through (7).

Clearly, the preoccupation with body image is problematic. But at the same time, is it fair to pass judgement on something that people do legally, voluntarily, with some level of informed decision-making (although the absence of documentation of the actual experience of such interventions is achingly absent from the public domain, as Mita's and Swati's surprised reactions show) to enhance their own lives? Is the use of medical technology to change the body a private matter or a public health issue? What about regulations, legalities or monitoring around this sort of intervention?

These trends raise concerns we are only beginning to understand, as cosmetic surgery has so far not been really perceived as an 'Indian issue' or one that affects anyone other than a handful of wealthy socialites. Increasingly, evidence shows that this is not true.

Stories of those who have used medical technologies to transform their bodies are still few and far between; until we excavate their experiences and their reflections it is difficult to fully grasp the tensions around the issue.

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Endnotes

1 This article is based on my doctoral thesis titled 'Globalisation, Women and Work: A Study of Selected Centres of the Glamour Industry in India' from Jawaharlal Nehru University, New Delhi, for which I conducted in-depth interviews over two years (2004-2006) with 30 women between the ages of 19 and 45, working in ramp and fashion modelling, the beauty pageant industry, or aspiring to be TV actors, based in Delhi and Mumbai, as well as other key players in the glamour industry. I also undertook participant observation backstage through two Fashion Weeks (2004 and 2005). All names of respondents have been changed in this article to protect their identities

2 Report 'Cosmetic Surgery Goes Macho: Delhi Men Ready to Go Any Length for Looks' in *Hindustan Times*, New Delhi, December 28, 2005

3 It is pertinent here to note some statistics from China. A newspaper report claimed that the Chinese beauty industry is now estimated to be worth more than $24 billion a year. One hospital in Shanghai, the Shanghai Ninth People's Hospital, conducted over 30,000 cosmetic procedures in 2003, a jump of 40% over 2002 figures (*The Indian Express*, November 7, 2004). Dominant reasons for the procedures were for greater social mobility and wider opportunities in careers, jobs (to get an 'edge' over others in a competitive job market) and in social life

4 *Newsweek*, November 10, 2003, 'The Perfect Face (How a Global Standard of Beauty is Emerging and What People Are Doing to Get It)'; interestingly, the cover story 'The Global Makeover' came under the science and technology section of the magazine

5 Cover story 'The Power of Beauty', *The Week*, October 3, 2004

6 Report 'Lean and Mean: The Looks That Kill', *The Times of India*, April 13, 2003. Anjali Goyal shot herself in April 2003 in New Delhi believing that she was too fat; she was reportedly five feet tall and weighed 50 kg

7 This apparently prompted public schools such as Delhi Public School to tie up with weight-loss clinics like VLCC (Vandana Luthra Curls and Curves clinic) to draw up special diets for children that could be served in school canteens (*Times of India* report, op cit)

Making innovative technology work for you

Indian hospitals are frenetically importing every new technology, and building glossy mega-hospitals that only 15% of us can afford. But what we need is innovation that presents simpler and cheaper alternatives. This article by a rural surgeon points to the many innovations already in practice – from beating heart surgery to the use of mosquito nets for hernia surgeries, and fresh blood transfusions

KAVERY NAMBISAN

A "TOP INTERNATIONAL STORY" in *The Economist* recently praised the philosophy of the East that makes Indian doctors more innovative than their western colleagues. It mentioned the technique of "beating heart" surgery pioneered by Dr Vivek Jawali at Wockhardt Hospital, Bangalore, as an example. This procedure does away with the need for general anaesthesia or blood-thinners to prevent the clotting of blood in circulation. It is so safe and successful that medical tourists have begun to flock to the hospital.

The article also mentioned the advantages of innovation in the making of medical equipment. It quoted two examples from high-profile hospitals as typical of Indian doctors constantly striving to be "affordable" to ordinary people. Shivender Singh, head of Fortis Hospital in Delhi, has realised in the last few years that the frequent purchase of new, expensive diagnostic machines when the old ones are functional is unnecessary. "We opted out of the 'arms race' a few years ago," he says.

Dr Pratap Reddy, the 'Father of Apollo Hospitals', is suddenly tired of treating the affluent in cities. He wants to open small and medium-sized hospitals in smaller towns, benefiting these people like their city brethren.

God forbid. I don't mean to throw icy water on Dr Reddy's noble aspirations but I hope Dr Reddy will have a rethink. Until high-tech users like the Apollo Group choose to put need before greed and genuinely understand the dynamics and requirements of small towns and villages, such forays into the periphery are bad news.

Rajesh Vora

The article in *The Economist* talks about innovative technology in the field of laparoscopy, diabetic monitors and cardiac equipment. As always, the western media relates best to issues surrounding diseases they are familiar with. They are especially alert when their own people, in the form of medical tourists in India, have benefited.

Dr Jawali's beating heart technique is the only novel procedure cited in this half-page article. A very small percentage of Indian doctors are cost-conscious, with a view to helping the patient. Several others pretend: private hospitals which have made medicine a business have a charitable wing providing "free treatment" to 10% of patients. This is largely a publicity stunt, useful in the purchase of subsidised government land or to get exemption from import duty on sophisticated medical equipment.

We Indians are a strange people: we pride ourselves on our eastern heritage but follow the western precepts of progress. In medicine, we import technology, build mega-hospitals and have succeeded in catering to the rich. Cardiac centres and kidney hospitals, fertility centres, laparoscopy and lithotripsy clinics with a hospital administrator, marketing manager, public relations officer and an advertising panel are the trend even in our smaller towns. Who but the patient pays for the excess? Such hospitals invariably spend a fortune on equipment, electricity, salaries and gloss. A mere 15% of our population benefits from such frenetic advances, while millions die for want of money to avail of any of this expensive treatment.

There are exceptions of course. Recently I was in need of an angiogram as investigation for unexplained breathlessness. Since I live in Lonavala, which is without such amenities, I went to Nair Hospital in Mumbai. This congested government hospital has a fine cardiology department headed by Dr Chaurasia. It caters mostly to the poor and the average middle class. I had the angiogram done there

and although it did mean a total absence of any luxury, the procedure went well. The cost was 20% of what I would have paid privately. As a doctor I might have got a certain amount of extra attention, but I did not fail to observe the efficiency, the respect for stringent asepsis and obedience to medical protocol in dealing with every patient. There are others like Dr Chaurasia and his team but they are overshadowed by those who find themselves guiltlessly denying their much-needed services to ordinary people.

Affordability and easy access are the two essentials of healthcare. Ironically it has taken a major, global economic recession to bring home the point that health systems everywhere in the world must cut costs. Being conservative about the purchase of new equipment would fit into this objective. But by itself it cannot *reform* healthcare until the concept embraces every dimension of medical care. Innovation must take us outside the bubble in order to look for alternatives that are simpler and less expensive. Dr Jawali's technique of beating heart surgery, which simplifies all aspects of patient care before, during, and after surgery, is indeed an excellent example.

A simple and affordable device, which I recently read about in the *Journal of Rural Surgery,* is the use of discarded Uro bags (lined with stiff cardboard and reinforced with used plastic tubing) as an abdominal support after surgery. It costs nothing and is a boon to patients who need it temporarily.

Innovation does not begin with technology which, by the way, is not a monster we must kill off or maim. Progress is essential in every sphere of life. Even the humble rice vessel or the frying pan has evolved to suit our needs. True progress meets needs that are real. How far removed our modern society is from wisdom is obvious from the recent economic crisis. Every politician, businessman, banker and corporate honcho is waiting for "an upswing in consumerism". They want the innocent householder to go out on a spending spree. Have we reached that point of no return where we must keep spending in order to survive as a civilisation?

It is not yet time to lose hope.

Our government conceived of a socialised system of medicine that would reach everyone; it hasn't made it work. So, for now at least, we have to contend with a combination of government and private systems that are beneficial and affordable to every patient and also favourable to the doctors who practise it. This challenge of making two goods co-exist is something that seems to elude us. But there are doctors, working mainly in the periphery and away from any hype or attention, who have grasped the secret. They

Rajesh Vora

are creative and constantly evolving ways in which to cut needless spending.

In the early-1990s, Dr Brahma Reddy, working in a rural hospital in Andhra Pradesh, claimed that mosquito net material when properly sterilised can be used for mesh repair of hernias. The usual practice in India, as everywhere else, is to use imported prolene mesh which costs several thousand rupees for a single case. The mosquito net material, which is a co-polymer of prolene and polyethylene, is autoclavable and as good as the prolene mesh. Between 1996 and 1999, 359 hernias were operated on in four different centres in India using mosquito net. The infection rate was 4.7%, but there were no cases of mesh rejection.

Many surgeons like myself have been using the mosquito mesh with excellent results. It is available in sterilised packs and costs the patient no more than Rs 20 or 30. Its use has been written about in surgical journals in different parts of the world, but our own city counterparts are still hesitant to use it. There is always the suspicion that something so simple might not be very good. A difference of a few thousand rupees to the patient isn't significant in the context of their practice.

In the 1980s, when rural hospitals could not dream of cardiac monitoring, I worked with an anaesthetist who devised his own monitor, using a long-tubed stethoscope with a single earpiece. The diaphragm was taped to the patient's chest so he could move about the room during surgery and still monitor the heartbeat. He saved several lives using this technique.

Once when I was operating on a six-year-old with a ruptured bladder, the patient's heart stopped and his temperature soared to 107°F. It was the first case of malignant hyperthermia that we had seen, and there was no one to consult. So we did the best we could: chunks of ice were fetched from the refrigerator and the boy's abdomen washed repeatedly with litres of iced saline. He survived. I must add that this anaesthetist had no formal postgraduate degree in that field. A few years later, I saw a similar case in the UK when watching a plastic surgery procedure for ear deformity in a young nurse. She developed malignant hyperthermia, was rushed to the ICU and put on a ventilator. Several specialists supervised her treatment but she did not survive.

An important example of innovation that saves countless lives in rural areas is fresh blood transfusion. Official blood banks need expensive equipment, air-conditioned rooms, specially designed refrigerators and specially trained personnel. A basic set-up costs upward of Rs 10 lakh just to get started, and a continuous source of electricity. This is impossible in most rural hospitals. Doctors therefore use fresh blood from the donor to the patient. This is called Unstored Direct Fresh Blood Transfusion (UDBT). The donor's blood is checked for compatibility and safety, using WHO guidelines, before transfusion. It is safe, effective and saves much expense and trouble for the patient's relatives who would pay a lot more to get stored blood from an 'official' blood bank hundreds of kilometres away. With fresh blood, if the testing is done with care, chances of complications are negligible.

It is imperative that the authorities ensure that UDBT is carried out with scrupulous attention to safety. But to simply categorise it as illegal will deny life to thousands of patients. What is strange is that using UDBT under emergency conditions in the army is considered safe and legal if it is done "to save a precious life". Is the life of a soldier more precious than that of a villager?

Rural surgery is a vital sector in the healthcare of the nation. The Association of Rural Surgeons of India (ARSI) was started in 1992 by a small group of committed surgeons. The first conference of the Association was held in Sevagram, Wardha, where Mahatma Gandhi – that genius of commonsense – started the movement to make villages self-sufficient. Three years ago, a decision was taken to start a three-year course in rural surgery affiliated to the National Open University, in order to offer the benefit of all-round training, so essential in villages.

At the annual conference where surgeons present cases and exhibit innovative procedures and gadgets, there is much to learn. Every year, I come away carrying with me the benefits of another surgeon's experience. A doctor in Bihar performs a wide variety of surgery (gall bladders, appendectomies, hysterectomies, hernias, haemorrhoids, Caesareans) under local anaesthesia. Another does thyroidectomies in violence-ridden Jammu and Kashmir under local. A doctor couple in interior Tamil Nadu teach the technique of nursing and safe delivery to tribal girls…

Innovation is essential in all frontiers of medical treatment. A hospital that decides to look clearly at wasteful expenditure caused by too much lighting, needless use of heating and cooling systems like air-conditioners and geysers, wastage of water, and improper disposal of waste is far more progressive than another which does not consider it important.

The fascination with frenzied progress and escalating medical expenses has resulted in negligible benefits to common people. To change this mindset and think of cheaper alternatives is as essential in affluent nations as it is in India, Africa or China. Hopefully, the present need to economise will bring about this much-required revolution in medical care.

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