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Newsletter

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Dear Friends,

On behalf of the IMPF, it is our pleasure to present the Winter Session 2015 edition of the IMPF Newsletter. The Monsoon Session Issue focused on crucial health issues plaguing India such as substance abuse, multi drug resistant (MDR) TB, public health facilities, the importance of family planning, etc. The issue was widely circulated, prompting discussions and deliberations into looking for sustainable solutions to the above mentioned problems.

We dedicate this issue to Prof. Ranjit Roy Chaudhury, who recently passed away. Prof. Chaudhury was a renowned public health advocate and educationist, who contributed to the field of modern medical education, pharmacological science, research ethics, health policy, etc.

In this issue, we are highlighting some of the health challenges of osteoporosis, surrogacy, issues related to clinical trials, etc. The issue is also emphasizing the need of addressing the concerns that civil society and parliamentarians must collaboratively work and delve on to improve the health planning, policy and implementation.

IMPF is committed to bringing the issues to the notice of the policy makers and leaders and thereby to improve the health sector.

We express our sincere thanks to all the contributors who have made this newsletter significant and informative for parliamentarians across political parties. We appreciate the comments and suggestions received from our supporters, and look forward to working with you to carry forward our responsibilities.

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Prof. Ranjit Roy Chaudhury: A Tribute

Prof. Ranjit Roy Chaudhury was among a rare breed. He was a leader, a charismatic mentor, and firm believer in affordable healthcare for all Indians. He worked tirelessly towards passing legislation of free essential medicines to those who need it most. His philosophy and commitment to public service and health equity will continue to shape policy in the decades to come. His students and colleagues will carry on his legacy in the fields of public health, pharmacological sciences, research ethics and national health policy. Prof. Roy Chaudhury focused on reproduction pharmacology, clinical trials, indigenous medicinal plants, and the rational use of medicines.

We knew him best as the Chair of the Institutional Ethics Committee of the Public Health Foundation of India. He was always curious about some of the more “creative” interventions we decided to pursue, but he was not one to close his mind to unconventional methodological approaches that our researchers proposed to the committee. In fact, he decided it was time to plumb in deeper – to consider the way forward and enact guidelines for public health and translational research. Until the end, he was involved in strengthening and creating a more responsive set of ethical guidelines for health research.

A path breaker and a visionary, his list of accomplishments are long. He was the first Indian doctor to receive a Rhodes scholarship. After his stint at Oxford University, he came back to complete his DPhil in Pharmacology. He was also felicitated with an honorary degree of Doctor of Science from Chulalongkorn University, Thailand. He was a Professor of Pharmacology, Dean and retired as Acting Director of the Postgraduate Institute of Medical Education and Research, Chandigarh. During his tenure, he established the first D.M. Course in Clinical Pharmacology in the country. After retirement, he established the Delhi Society for Promotion of Rational Use of Drugs and was the Founder Director of the Delhi Medical Council. During the period, some of the earliest models of community engagement to promote rational drugs were tested and scaled up.

Prof. Chaudhury was a generous mentor and unafraid to make tough choices. He has been the Advisor to the Department of Health and Family Welfare, Govt. of National Capital Territory of Delhi and was nominated by the Ministry of Health and Family Welfare, Govt. of India as Chairman of the newly constituted Expert Committee for Reforms in Drug Regulation and Clinical Trials. Prof. Roy Chaudhury also served as the Advisor to the Union Minister for Health and Family Welfare, Govt. of India. He was Chairman, Task Force for Apollo Hospitals Educational and Research Foundation (AHERF), Indraprastha Apollo Hospitals where he worked to connect the work of the Apollo hospitals to research.

At the time of his passing away, he was serving many organisations including the Sasakawa Foundation, the Population Foundation of India to name just two. He was chairing no fewer than ten committees at the Ministry of Health and Family Welfare and many more at the institutions he served. In recognition for his landmark contributions, he was awarded the Padma Shri in 1998. He was recently honoured with a Lifetime Achievement Award – 2013 by FICCI and the first Lifetime Achievement Award in “Integrated Medicine” by the College of Medicine, London and the Soukya Foundation.

All his accomplishments aside, Prof. Roy Chaudhury was a true gentleman. We never saw him lose his patience or turn down anyone who needed his help. The day before he passed away, he had called for a special meeting of the Population Foundation of India board on a Saturday to take forward a collaborative project with *Public Health Foundation of India* (*PHFI*). At that age, most people would have been happy to be reading the newspaper and drinking their morning cup of tea, but not Professor Roy Choudhury.

His commitment to the country and public health was absolute. Without his landmark work we would not have the clinical trials framework and the awareness about the problem of antimicrobial resistance.

The best way we can honour this amazing Indian is to take his work forward, while remembering his gentle smile, good humour, graciousness, and depth of commitment that he brought to the millions of lives.

- Melina Magsumbol
- Prof. Ramanan Laxminarayan
Public Health Foundation of India, New Delhi

Osteoporosis – 'The Silent Disease'

Osteoporosis (OP), characterized by low bone mass with micro-architectural deterioration of bone tissue leading to enhanced bone fragility, is a major public threat worldwide. Osteoporosis is a silent disease, reflected only in a low bone density, till a fracture occurs. Though the exact prevalence is not known in India, one in four women older than 50 years is believed to suffer from osteoporosis. The attainment of peak bone mass in adolescent years and the rate of bone loss during postmenopausal years are some of the major factors contributing to weak bone health in older women. The accelerated bone loss in postmenopausal OP is a result of a decline in oestrogen concentrations.

The prevalence of osteoporosis increases with age, and according to World Health Organization (WHO), up to 70% of women over the age 80 years have osteoporosis. Though the Indian subcontinent is situated between 8.4° and 37.6°N latitude and majority of the population living here experience perennial sunlight, recent modernization of India resulting in working indoor, and reduced physical activity have resulted in limited sun exposure. The women from Indian subcontinent who have migrated to western countries are at increased risk of accelerated age-related bone loss when compared to their counterparts living in the same geographic region due to their darker skin, conservative dressing and their genetic pattern. This silently progressing metabolic bone disease is widely prevalent in India and osteoporotic fractures are a common cause of morbidity and mortality in adult Indian men and women. Expert groups peg the number of osteoporosis patients in India as going beyond 36 million by 2015. Osteoporosis has numerous medical implications and a huge economic impact.

In western countries, women suffering from osteoporosis far outnumber men, and this is largely thought to be due to the effects of the menopause. There are no epidemiological data on fracture prevalence, although most clinicians would agree that hip fractures are common. In India, the men-women ratio may be distorted because men are more likely to be brought for hospital care. The lower peak age as compared to the West may simply be linked to a shorter life span, as also to the inclusion of traumatic / non-fragility fractures in the analysis.

The pathogenesis of osteoporosis is complex. In childhood and adolescent period, bone formation exceeds resorption, resulting in continued skeletal growth and denser, longer and heavier bones. This process slows down in adulthood, and peak bone mass is attained at about 30 years of age. After this, resorption begins to exceed formation. Normal bone loss averages 0.7% per year. It gets accelerated at the time of menopause to 2-5% per year, which may continue for up to 10 years. Peak bone mass is primarily determined by genes but may be modified to a considerable extent by certain factors like physical activity, calcium, vitamin D nutrition, smoking, alcohol, concurrent illnesses, and medications (glucocorticoids, anti-epileptics). The level of peak bone mass achieved at puberty is a major determinant of bone mass in later life and hence an important factor in the ultimate development of osteoporosis.

TREATMENT

- Avoid load-bearing exercises.
- Calcium and vitamin D tests should be done routinely.
- Hormones are administered to improve bone strength.
- Certain drugs that harden the bones can also be administered.

Healthy lifestyle (diet, exercise and sunlight exposure) can have a major positive impact on the bone metabolism and bone health of Indians. The peak bone mass of the population can be increased significantly by appropriate and timely intervention in children. Pharmacological interventions are expensive and should therefore be targeted to only those at high risk of fractures.

- Dr. Kirit Premjibhai Solanki, MP
Professor of Surgery, GCS Medical College
Hospital & Research Centre, Ahmedabad

Clinical Trials: Secret Regime?

Clinical trials are done on human volunteers who participate from altruistic motivations in what could be a dangerous enterprise. Prior informed consent must be obtained after full disclosure of the risks involved. If during the trial, it shows up unacceptable risks, the trial must be stopped.

Imagine a trial involving 6 week old infants. Their parents trustingly allow their babies to be experimented on. If the trial shows serious, statistically significant increase in risk of a potentially fatal complication, it will be unethical to further test the drug without informing the volunteering parents of the risks that the trial has already shown.

The 'Indian rotavirus vaccine' was studied in a randomized controlled trial in 3 centres, one of which was Vellore where 1000 infants received the vaccine and 500 were controls. A dreaded complication of this vaccine is intussusception where the intestine telescopes into itself and there is risk of gangrene and death. The number of intussusceptions at Vellore was almost 20 times the corresponding figure at Delhi suggesting that children there are more susceptible.

The centre-wise segregated-data on how many babies among the vaccinated developed clinical evidence of intussusception has not been disclosed. The study doctors are saying that the sample size studied was small and so although the data shows statistically significant risk; it is not adequate to comment on the adverse effects. Biostatisticians say this is disingenuous. A previous vaccine Rotasheild was withdrawn from the market because of intussusceptions. The number of intussusceptions with the new vaccine is 5-10 times higher. A much smaller sample size can show up statistical significance because of this high incidence of intussusceptions with this new vaccine. The Declaration of Helsinki mandates that research must never take precedence over the rights and interests of individual research subjects. Only after the data is put out in the public domain can independent scientists and statisticians comment on it. *Nemo judex in causa sua* meaning no one should be a judge in his own cause. The researchers cannot select not to disclose safety data.

Without disclosing this data, there is a plan to do a study on 100,000 more children exposing them to this risk. The data has not even been shared with the Government's advisory body – the National Technical Advisory Group on Immunization (NTAGI) in spite of repeated requests.

It is interesting that the PMO has requested analysis of the segregated Vellore data, twice, and it has been denied. In response to the reference (PMO No. 4219998/2015 dated 22.06.15), the minutes of Subject Expert Committee (SEC) meeting of 30.06.2015 merely state that they did not find the concerns of non-disclosure of safety data from Vellore well authenticated. On being asked a second time the minutes of the SEC meeting of 29.07.2015 states: “Further review of data with respect to site at Vellore with regard to intussusceptions may (be) undertaken, if required, based on observations of Hon'ble High Court of Delhi”. Thus it appears that the SEC will take instructions only from the High Court and not the PMO in this matter. Under the Right to Information Act 2005 this data, acquired with GoI funding, must be supplied on request to any citizen of the country. It is this that has been denied to the PMO.

It may be noted that the patent of this so called 'Indian vaccine' (Patent: (G9P11) US 5773009 A) is held by the US Department of Health and Human Services and so they are to profit from its sales. One wonders if this explains the impunity with which this country's authority is disregarded.

- Dr. Jacob Puliyel, MD MRCP MPhil.
Head of Pediatrics, St Stephens Hospital, Delhi

Surrogacy in India

India was among the few countries in the world that allowed surrogacy – where a woman could be hired to carry the child of a couple through a process of in-vitro fertilization and embryo transfer. But recently, India's home ministry has ordered Indian embassies abroad not to grant visas to couples visiting the country for surrogacy, or “reproductive tourism” as the practice has come to be known. India had been the destination to fulfil their dreams of becoming parents, thanks to its well-trained doctors, well-appointed fertility clinics and vast numbers of poor women willing to serve as surrogates.

Though laws governing surrogacy have yet to be passed, the government outlined its position in an affidavit placed before the Supreme Court. It said, India “does not support commercial surrogacy and the scope of surrogacy is limited to Indian married infertile couples only, and not to foreigners.”

The ban intends to protect the women from exploitation. Though, some who have worked as surrogates say the ban actually hurts them as it prohibits them from earning money that would otherwise take 10 years of domestic help to achieve. Some women's rights activists say India's burgeoning surrogacy business should be regulated, not outlawed. Banning it, they say, will only drive it underground, making it impossible to check the exploitation of the women hired as surrogates.

Since India made commercial surrogacy legal in 2001, thousands of fertility clinics have mushroomed across the country, making it a $1 billion to $2.3 billion business annually. The clinics have attracted couples from Britain, the United States, Australia, South Africa and Japan as a surrogate pregnancy costs around $20,000 to $35,000 in India, compared to around $150,000 in the United States, where surrogacy is permitted in many but not all states.

Activists in India say while the industry has proliferated, a lack of safeguards has led to rampant exploitation of thousands of poor, illiterate women by touts, agents, unscrupulous doctors and the owners of fertility clinics. The need, therefore, is felt for a strong regulation of the industry which would benefit all the concerned parties – the commissioning parents, surrogate mothers, and the child born of such an arrangement.

For now the industry was following guidelines issued by the ICMR. Its rules state that a woman cannot be a surrogate unless she has a living child of her own, and she can only do it once. The draft of a new law, called the “Assisted Reproductive Technology Bill”, is ready but not been passed in the parliament yet. The legislation would bar the use of agents, require couples seeking surrogacy to pay all of the surrogate's expenses, and allow only women between the ages of 21 and 35 to act as surrogate mothers. It also says that women who have had more than five live births cannot serve as a surrogate.

The Assisted Reproductive Technology Bill (ART) has been through several incarnations over the past few years, but may be passed in the winter session of Parliament. The Bill would only allow surrogacy for Indian couples (defined as a married man and woman) or a foreigner married to an Indian citizen.

The Bombay High Court passed an interim order staying the directive of the Union government and the Indian Council for Medical Research that banned surrogacy for foreigners, in an attempt to protect those in the final stages of the process from the government's sudden decision. The court asked clinics to provide details of couples who are in the middle of the surrogacy procedure, but barred medical practitioners from taking up fresh cases.

- Shefalika Shekhawat
National Law University, Jodhpur

Health for all – Learning from the World

> “Of all the forms of inequality, injustice in healthcare is the most shocking and inhumane.”
>
> – *Dr. Martin Luther King, Jr.*

India today, is the world's third largest economy in terms of its GDP (PPP) and has the potential to grow even larger in a more equitable and inclusive setting. It possesses a sophisticated arsenal of interventions, technologies and knowledge required to provide healthcare to its people. Yet the gaps in health outcomes continue to widen. As the never-ending debate regarding the perfect healthcare model for the country rolls on, there emerges a need to learn from healthcare facilities around the world.

Britain, with a National Health Service (NHS) is the forbearer of socialized medicine in the developed world; this means that in addition to paying for health insurance of all citizens, the government also pays doctors and runs hospitals. British citizens pay taxes, which the NHS allocates to providers. When a citizen shows up for an appointment, all services that he or she receives are paid for, with the exception of prescription of drugs.

Brazil has made rapid progress towards universal coverage of health through its national health system, the Sistema Único de Saúde (SUS). An important innovation in the system has been the development, adaptation, and rapid scaling up of a community-based approach to providing primary healthcare. Perhaps the most important FHS (Family Health Strategy) component is the extensive and effective use of community health agents. Each agent is assigned households in a defined catchment area. Agents visit each household within their area at least once per month, and collect individual and household data. During each visit, they draw information from household members why they missed an appointment, check whether prescriptions have been filled and whether patients have been taking their medications regularly and identify potential warning signs of violence, neglect or drug abuse, among other problems. Community health agents also actively look for risk factors and symptoms of common chronic ailments, thus bridging the primary healthcare with public health efforts.

One new model known as “Shared Administration”, being adopted in several municipalities, represents a joint venture between the municipal government and healthcare professionals. Healthcare professionals including physicians, nurses, and other health professionals are to be organized into cooperatives or Basic Health Units (UBS) to take responsibility for the care of the population. UBSs are autonomous health management units that determine the providers they use, the personnel they hire, and the cost-control mechanisms they adopt.

In the U.S., healthcare facilities are largely owned and operated by separate private sector business houses which in a way has raised the cost of healthcare for the general masses. However, federal, state, county, and city governments also own certain facilities. Recent reforms in the healthcare model in the form of “Obamacare” make health services accessible through a universal insurance, more affordable and without discrimination on any ground and provide healthcare for all.

India as the world's largest democracy spends a meagre 1% of its GDP on health according to a World Bank report, which is far less than other countries. Despite rapid economic growth over the past two decades, union governments have failed to invest generously in health.

India, therefore, needs a comprehensive health policy with the contribution of joint efforts by the governments, community participation, private partners, NGOs, individual citizens with reforms at all levels of governance and the use of simple yet innovative information and technology in realising our objective of Universal Health, as enshrined in Article 47 of our Constitution.

- Dr. Anand Sharma
Public Health Analyst

News Box 1

NIKSHAY - A Web Based Solution for Monitoring of TB Patients

Tuberculosis (TB) is an infectious disease caused by a bacterium, Mycobacterium tuberculosis. TB is spread through the air by a person suffering from TB. A single patient can infect 10 or more people in a year.

SYMPTOMS

- Cough for two weeks or more, sometimes with blood-streaked sputum
- Fever, especially at night
- Weight loss
- Loss of appetite

TB is one of the leading causes of mortality in India. It kills more than 300,000 people in India every year.

The Human Immunodeficiency Virus (HIV) is the strongest risk factor for tuberculosis among adults. An HIV positive person is six times (50-60% lifetime risk) more likely of developing TB disease once infected with TB bacilli, as compared to an HIV negative person, who has a 10% lifetime risk.

To monitor Revised National Tuberculosis Programme (RNTCP) effectively, a web enabled and case based monitoring application called NIKSHAY has been developed by National Informatics Centre (NIC). This is used by health functionaries at various levels across the country in association with Central TB Division (CTD), Ministry of Health & Family Welfare. NIKSHAY covers various aspects of controlling TB using technological innovations. Apart from web based technology, SMS services have been used effectively for communication with patients and monitoring the programme on day to day basis.

Source: http://nikshay.gov.in/FAQs.htm

News Box 2

Anti-Microbial Resistance

Antibiotic / Antimicrobial resistance is the ability of microbes to resist the effects of drugs – that is, the germs are not killed, and their growth is not stopped. Although some people are at greater risk than others, no one can completely avoid the risk of antibiotic-resistant infections. Infections with resistant organisms are difficult to treat, requiring costly and sometimes toxic alternatives.

Bacteria will inevitably find ways of resisting the antibiotics developed by humans, which is why aggressive action is needed now to keep new resistance from developing and to prevent the resistance that already exists from spreading.

- Antibiotics are among the most commonly prescribed drugs used in human medicine and can be lifesaving drugs. However, up to 50% of the time antibiotics are not optimally prescribed, often done so when not needed, incorrect dosing or duration.
- The germs that contaminate food can become resistant because of the use of antibiotics in people and in food animals. For some germs, like the bacteria Salmonella and Campylobacter, it is primarily the use of antibiotics in food animals that increases resistance. Because of the link between antibiotic use in food-producing animals and the occurrence of antibiotic-resistant infections in humans, antibiotics that are medically important to treating infections in humans should be used in food-producing animals only under veterinary oversight and only to manage and treat infectious disease, not to promote growth.
- The other major factor in the growth of antibiotic resistance is spread of the resistant strains of bacteria from person to person, or from the non-human sources in the environment.

Source: http://www.cdc.gov/drugresistance/

News Box 3

Diabetes

- Diabetes is a lifestyle disorder that causes high blood sugar levels.
- In 2013 it was estimated that over 382 million people throughout the world had diabetes
- Type 1 Diabetes – the body does not produce insulin. Approximately 10% of all diabetes cases are type 1.
- Type 2 Diabetes – the body does not produce enough insulin for proper function. Approximately 90% of all cases of diabetes worldwide are of this type.
- Gestational Diabetes – this type affects females during pregnancy.
- The most common diabetes symptoms include frequent urination, intense thirst and hunger, weight gain, unusual weight loss, fatigue, cuts and bruises that do not heal, male sexual dysfunction, and numbness and tingling in hands and feet.
- If you have Type 1 and follow a healthy eating plan, do adequate exercise, and take insulin, you can lead a normal life
- Type 2 patients need to eat healthily, be physically active, and test their blood glucose. They may also need to take oral medication, and / or insulin to control blood glucose levels.
- As the risk of cardiovascular disease is much higher for a diabetic, it is crucial that blood pressure and cholesterol levels are monitored regularly.
- As smoking might have a serious effect on cardiovascular health, diabetics should stop smoking.
- Hypoglycemia – low blood glucose – can have a bad effect on the patient. Hyperglycemia – when blood glucose is too high – can also have a bad effect on the patient.

Source: http://www.medicalnewstoday.com/info/diabetes/

News Box 4

Assisted Suicide for Mental Illness Gaining Ground

Passive euthanasia is legal in India. On 7 March 2011 the Supreme Court of India legalised passive euthanasia by means of the withdrawal of life support to patients in a . The decision was made as part of the verdict in a case involving Aruna Shanbaug, who had been in a Persistent Vegetative State (PVS) until her death in 2015.

Requests for euthanasia on the grounds of suffering related to psychiatric illness in Belgium, has recently become a topic of controversial debate. Euthanasia (referred to as assisted suicide in the Netherlands and Luxembourg, where it is also legal in cases involving suffering due to medical and psychiatric illness) has been legal since 2002 in Belgium, and the law was extended in 2014 to include emancipated children with suffering due to terminal illness.

Through a required process, patients must show their illness to cause “unbearable or untreatable suffering”; however, the definition is acknowledged to be subjective. Among the euthanasia deaths of 2086 patients who died between 2010 and 2011, 58 (2.8%) were related to neuropsychiatric disorders. The rates reflect a steady increase from just 742 in 2004-2005, which included only 9 (1.2%) for neuropsychiatric disorders.

According to medical ethicist Kenneth W. Goodman, the suggestion of patients being deemed to have “no further prospect of improvement” runs the serious risk of drawing a conclusion too quickly, he said.

Source: http://www.medscape.com/viewarticle/848910

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