The new National TB Control Program of India (Known as DOTS) is like a new born baby; It has yet to pass the ultimate test...

# The Test of Time

### Dr. Raman Kakar

"Doctor out to fight TB" - The Statesman (Press Trust of India)

"... a pioneer in the field of TB" - The Tribune

" ... a crusader fighting TB" - Hindustan Times

" ... an awareness activist" - The Times of India

#### Will history repeat itself?

For eradication of tuberculosis, the govt. of India introduced in the late 1990s an entirely new program called DOTS. The program has been technically supported by the WHO and funded by the World Bank.

Why this sudden switch over to a new package? The answer is obvious: Total failure of the National TB Control Program (NTP) launched in 1962.

Were the causes behind this failure properly investigated before initiating a new mammoth program? Was the health care machinery of India, with all its obvious lacunae, properly evaluated before adopting this new recipe? Was the overall global scenario taken into account before designing its novel features? Is the technology radically different from the one practiced in the advanced countries? Has the program been tailor-made to suit the socio-economic & political conditions of India?

A lot of questions need to be answered before we can judge the program. It can either be a great success in our fight against TB or spell a great disaster for the millions of poor and helpless people who are at the mercy of a handful of policy makers.

Will history repeat itself?

#### Time will tell!

Contribution: Rupees 395.

To order a copy, please contact:

TB Free India,

Address: House No. 593, Sector 16, Faridabad.

E-mail: tbfreeindia@gmail.com

Telephone: 9891397528 (M), 0129-5076000.

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Ву

## Dr. Raman Kakar

Edited by: S.K.Dua

Pradeep sapra Ruchika kathuria

Lachhman Dass Arora

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e-mail: tbfreeindia@gmail.com

Address: 593, sector 16, Faridabad, Haryana. Pin code: 121002.

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Author:

Dr. Raman kakar

E-mail:

raman24march@yahoo.com

Tel:

+91-129-5076000

9891397528 (Mobile)

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#### An Obeisance



Dr. Suvinder Chadha

I dedicate this book to a person whose indefatigable spirit and zest for living a full and fragrant life, placing lamp posts at each mile stone of this eternal journey, has propelled and powered my instincts to compose this humble diction with a hope that it might in some way benefit the suffering millions. Dr. Suvinder Kumar Chadha, first an enigma as a rival cricket player and a care free bosom friend in medical college; then a delightful surprise as a picture of sacrifice in giving and forgiving; eventually an ideal as an embodiment of fortitude and forbearance, exuding innate compassion and human values, sharing joys but keeping his sorrows and sufferings to himself, serving the nectar of comfort and solace to all he came across but silently consuming 20 bitter pills each day to combat the excruciating agony of physical afflictions relating to kidney, heart, blood pressure, diabetes, infections and malignancy.

His immense drive to live life originated from his conviction: 'give to the world the best you have and that is how the best will come back to you sooner or later, for each thought, word and action vibrates a distant chord in the law of eternity'.

Though destiny ferried him far away to the other side of the globe (to Marion, Columbus, Ohio, USA where he went on to certify Board twice), yet the awesome distance could hardly deter him from influencing my thought process or giving impetus to my humble endeavor in tuberculosis. True to his inexorable vibrance, gamesmanship and compulsive winning spirit, while I wrote feverishly struggling to finish the pages of the book, he defeated me in this, our final game, the race against time - fading away into sublime sleep on 14<sup>th</sup> July 2004.

#### Introduction

Since, for the past 20 years, the author has been practising clinical medicine in Faridabad, a satellite town of Delhi, his entire network of human contacts happens to be in the vicinity.

The town, with a population of 22 lacs (2.2 million), houses several vibrant clubs formed exclusively by doctors, like Physician's Forum and IMA. Indian Medical Association, Faridabad chapter, is a large body of over 500 qualified doctors of all kinds - private, government and corporate. Having been an active life-member of some of these associations, the author enjoys a comradeship with numerous doctors. This gives him a unique and effortless access to their personal views & opinions on all sorts of medical issues.

Besides, with the establishment of several state of the art corporate hospitals in the city - like Escorts, Metro, Sun Flag and Sarvodaya - level of the ongoing educational activity of the medical fraternity has shot up, increasing the interaction amongst doctors exponentially.

And the author has made the most it. During the past about 3 years, whenever he has been invited to a meeting, lecture, conference or a social event - and which happens no less than once in a fortnight - he has made it a point to attend and that too with one mission in mind: to interview fellow physicians selectively and gather relevant information about the ongoing TB control program of India, i.e. DOTS. And what more rewarding moment to quiz a colleague than while he savours chilled beer!

TB being a chronic ailment, its hapless victims, desperately groping for relief, often show propensity to switch from one doctor to the other. Every now and then, therefore, a few TB patients who have taken treatment under DOTS but are dissatisfied cross over to the author's clinic for treatment (and vice versa). The author investigates case histories of such patients in great details as they are a rich source of authentic information about the program.

Furthermore, the author has, from time to time, visited several dispensaries and interacted with doctors, laboratory technicians, nurses, pharmacists, senior treatment supervisors, and multipurpose health workers - the real foot soldiers of DOTS.

Thanks to the vision of late Mr. Rajiv Gandhi (former Prime Minister of India) that ushered in the unprecedented and magnificent revolution in the fields of telecommunication and information technology, the author has been able to sustain (and financially afford) an exhaustive bilateral dialogue with some of these persons about the day to day practical aspects of operation of DOTS. Besides, he has been picking the brains of some of his batch-mates who are settled virtually in every nook and corner of Haryana and Delhi and

have their own extensive networks.

In short, the author has unreservedly harnessed the entire human resource at his disposal in gathering every bit of information about DOTS. It has formed the basis of this book which is primarily meant not to be just a theoretical discussion but an analysis and review of some practical value.

Obviously, author's first hand experiences are limited to the operation of DOTS in parts of Haryana & Delhi. He wonders if the observations can reasonably be extrapolated to the country as a whole. There may be redeeming spots as well as dark dungeons on the horizon of DOTS, spread as it is all over the country.

Besides, the author has felt compelled to include without a shred of documentary evidence some incidents or remarks narrated by insiders, because he believes that, govt claims notwithstanding, the gut feeling of the field workers is a reliable indicator of performance. And such knowledge can help our policy makers in improving the program.

However, it seems like a foregone conclusion that, if ever approached by anyone at a later date, most of the govt employees are likely to deny the statements. After all, who would wish to risk his career and invite government ire? Furthermore, the author owes not just deep gratitude but also a duty of confidentiality to such well meaning persons. In deference to their wishes and interests, therefore, their names have been withheld or written in code words or, in some instances, simply forgotten. After all, purpose behind this endeavour is not to play the blame game and waste more time dwelling in the past - a luxury we Indians can ill afford at such rudimentary stages of our development; the aim is to somehow improve the future of this program.

Besides, the author probably suffers from a peculiar cognitive disability. Unlike gifted academicians (who are habitually meticulous), he just can't seem to manage to keep track of the sources of his information (hence very few references in the book). Such discomfiture does not however deter the author to commit to the truth, as it is in humankind's best interests.

Therefore, before outrightly dismissing the unsubstantiated material for want of proof - gathering which will take forever, delaying this publication while time runs out in our fight against TB - please just pause to think: were some of the unconfirmed material not true, would an Indian continue to die of TB every single minute? Even after 58 years of independence?

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#### What is tuberculosis?

The scourge of tuberculosis has been around since times immemorial. Like a vampire, it has been stalking humans for thousands of years, selectively victimizing the weak, the poor and the malnourished - debilitating, tormenting & torturing them, and eventually consuming them.

The disease is caused by a germ that spreads through the air. When a full-blown TB patient coughs, he throws out germs into the air exposing others who might inhale the germs and get infected. And since we all breathe the same air, no one - yes no one - is immune to getting infected.

However, not all TB patients emit germs; only about 30% of them could be infectious - only those cases of lung TB who while coughing pass up germs in the sputum (phlegm). A useful thumb rule to work with TB patients is 'No cough means no infectiousness'.

Man-to-man transmission is through the air. Once inhaled, the germ attacks the respiratory tract causing disease primarily in the lungs. No wonder, TB mostly (80%) occurs in the lungs. And it is this form i.e. lung TB, which is capable of producing cough and germ-emission and is mainly responsible for the entire gamut of transmission - the chief concern for the health institutions involved with TB control worldwide.

However, TB can occur anywhere in the human body - from head to toe. Depending upon which organ is involved, it can present itself with any set of signs and symptoms. When it occurs in an organ other than the lung like bone, lymph node, brain, kidney or intestine etc., it is hardly infectious to others - since there is no cough and no emission of germs into the air.

Once inside the lungs, the germ can right away kick-start the typical chronic sickness, producing a long standing cough, low grade fever and progressive weight loss; the patient slowly wastes away and, if not properly treated, may eventually die. Or else, the germ may settle down as a seed for future trouble. It is known to have great resilience; it can remain dormant in the human body without causing illness for several years after which, all of a

sudden, it can reactivate causing sickness.

At any given point in time, 40% Indian adults remain infected with the bacillus (which means that they might harbor dormant germs). Fortunately, everyone infected doesn't develop disease. Only about 10% of them would actually end up falling sick. The rest (90%), probably the ones with robust immunity, though infected, never develop disease during their lifetime.

#### Tuberculosis kills one Indian every minute:

Tuberculosis kills one Indian every minute. India is home to the largest number of TB cases for a single country in the world. And if all of them were made to assemble at one place, we would get a city bigger than Delhi - there being about 14 million (1.4 crore) TB patients in India.

Transmission rates in India are alarmingly high. Every day, about 20000 healthy Indians are believed to get freshly infected with this germ, over 5000 develop the sickness and over 1000 die of it.

Every third TB patient in the entire world is an Indian. In other words, one third of the global burden of TB is borne by India.

Tuberculosis is a major hurdle in social and economic development of India. Each year 3 lac (0.3 million) children are forced to discontinue their schooling due to TB in the family. 1 lac (0.1 million) sick women get divorced due to social stigma.

TB primarily affects working adults. 75% of all cases are in their prime productive years i.e.15 to 50 years age group. Every year over 17 crore (170 million) work days are lost due to the sickness all over India; direct and indirect cost of the disease to the nation is estimated to be to the tune of a staggering Rupees 12000 crore (US \$ 3 billion) per year.

Globally, 90 lac (9 million) fresh cases develop every year and 30 lac (3 million) die of it.

However, 95% of cases and 98% of global TB deaths occur in the developing countries.

Ironically, nearly each TB death is avoidable.

2

#### Why DOTS?

# (Why in the first place did India need a 'new' TB control program at the dawn of 21st century?)

Today, 40 years after effective drugs and other tools for TB eradication were discovered and made available to man, there are more new cases than ever before and more people die of it than ever before. Even during the era when man had no medicine for TB, not so many people died of it.

The real culprit is premature discontinuation of medicines by patients':

**'Symptomatic relief = cure'** appears to be a belief deeply rooted in human psychology. It is common sense that when symptoms disappear; it obviously means that the sickness is gone and it indeed holds true in several ailments. Man has relied on this simple yet plausible thumb rule for several generations - and not without reason.

Alas, it does not hold true in TB!

#### TB treatment is long - painfully long!

Medicines for TB have got to be taken for a minimum of 6 months for complete cure. However, once effective treatment begins, symptoms subside rather quickly - bringing in a sense of relief and well-being. Believing that they have been cured, patients stop taking medicines. It is estimated that as many as 60% of TB patients in India (and 30% globally) discontinue their medication prematurely, failing to complete the stipulated course. This is a blunder. Though apparently feeling and looking healthy, such patients are not yet fully cured; they are likely to relapse in future.

#### Incomplete treatment is the norm in India rather than exception.

Even though effective tools for TB eradication have been available since 1950's, the disease continues unabated, thwarting man's efforts at its control. Why?

Premature discontinuation of medication by ignorant, misguided and gullible patients at such an enormous scale is the single largest challenge for man in his efforts at TB control.

Unbelievable but true:

Hard as it might seem to fathom, but it is true. What really remains at the heart of man's failure is nothing but that insignificant-looking formula, namely 'symptomatic relief = cure' that remains deeply ingrained in human mind, and which provokes default and premature cessation of treatment. And that is the fundamental reason why man had to conceive this elaborate new initiative, popularly known as DOTS (Directly Observed Treatment Shortcourse).

The new program has essentially been designed to check the very menace of compliance failure.

Obviously, just making provisions or prescription of TB medication does not guarantee cure; what needs to be ensured is that the patient indeed swallows them regularly for 6 to 8 months. And that is exactly what DOTS is designed to achieve.

#### What is DOTS?

What exactly is this new TB treatment program?

DOTS is the short form of 'Directly Observed Treatment Short course'. It is a novel package for TB control assembled by Karel Styblo of the IUATLD (International Union Against Tuberculosis and Lung Disease) and promoted worldwide by the WHO (World Health Organization).

DOTS is thus a brand name for a comprehensive strategy designed essentially to check default.

Complete address of a patient is recorded and verified at the very outset. His health worker can trace him at any time at will. It enables the worker to keep a strict watch over the patient all along so that he simply cannot quit treatment midway and disappear into the sea of humanity (as used to happen so often in the past). Thus it is ensured that each and every patient put on treatment completes his full course of medicines and gets fully cured.

Besides, no hospitalization is generally done; patient stays at home. But generally he is not allowed to carry home his medicines.

He is required to come to a clinic 3 times a week and swallow each dose of medicines right in front of a health worker; the therapy is thus entirely supervised (hence the name Directly Observed). But that's during the first 2 months, after which the element os supervision is relaxed a bit.

In the past - under the traditional unsupervised therapy - it used to take several weeks before default was detected and by which time it was too late to

do anything. And besides, what could the doctor do anyway; it was impossible to contact the patient in the absence of record of his home address.

But now, under DOTS, default is immediately manifested. Meticulous records are maintained so that no concealed irregularity can occur. If the patient fails to turn up for his dose on an appointed day, it is instantly evident.

Furthermore, default is designed to trigger 'immediate follow up action'. The health worker alerted by the 'miss' would at once go to the patient's home and administer the missed dose, thus saving the disruption of treatment. He would also preach the patient to desist from such irregularity in future.

A subtle but fundamental shift has thus taken place. Onus of cure rests not any more with the patient but with the health care system and which, empowered with personal information about the patient's whereabouts, retains the ultimate initiative.

Several more features have been added in this new initiative. Highly effective & modern medicines are used which cure faster - within 6 to 8 months (hence the name - Short course). And what's more, all investigations and drugs are provided free of cost. In fact, a menu of several specific elements required for good TB control have been included.

# The 5 fundamental principles of the WHO-recommended DOTS strategy are:

- Political will (that would ensure adequate funds and resources).
- High quality sputum smear microscopy (to ensure proper diagnosis).
- Drugs (SCC) given under direct observation (to ensure compliance).
- Adequate supply of high quality drugs.
- Systematic monitoring and accountability for every case registered.

Each one of these 5 elements is equally and absolutely essential if the program is to succeed. Weakness in one area - any one of the  $5\,$  - can spell doom for DOTS.

After all, a chain is only as strong as its weakest link.

3

# The big picture: Back drop to the genesis of this new program & the history of the global conspiracy of silence and inaction

#### History of tuberculosis:

TB is an ancient disease. It has haunted humankind since time immemorial. While scores of other diseases like small pox and plague too have consumed millions of lives, their reign has been short-lived. TB has perpetually gone on unabated, torturing and killing ceaselessly.

Astonishingly, the disease managed for thousands of years to remain elusive, staying well beyond the realms of science, remaining forever an enigma, a mystery. Not having the slightest clue to its etiology, man remained helpless, virtually groping in the dark, attempting to ward off an unknown and unseen enemy. No other ailment so overwhelmingly common and so unswervingly fatal has ever succeeded in evading relentless human research, thwarting scientific revelation for such a long stretch of time in the history of mankind!

One by one, several members of a family were observed to be afflicted and consumed. In all his wisdom therefore, man concluded that it was some kind of a hereditary phenomenon; some sort of a family 'curse'. Thriving on such ignorance, belief that 'TB runs in the family' survived for centuries.

It was in 1882 that Sir Robert Koch finally demystified the secret of this illness. He uncovered the causative agent, a germ, asserting confidently "in the future the fight against this terrible plague of mankind will deal no longer with an undetermined something, but with a tangible parasite<sup>1</sup>." Ironically, it was reported that the audience was so stunned by the import of his performance that they neglected to applaud.

Thus after baffling and devastating the world for thousands of years, the clever germ revealed itself to humans and got labeled as Mycobacterium Tuberculosis. The landmark revelation consigned the age-old legend - the 'family theory'- to the dustbin of history. It armed mankind with its first-ever

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<sup>&</sup>lt;sup>1</sup>Testing a Horrible Superstition

diagnostic tool namely,' **sputum smear test for TB**', which continues till date to be the gold standard test for the third world nations.

Wilhelm Conrad Roentgen invented the technique of radiological imaging (X-ray) in 1895. Thanks to invention of these 2 tools, diagnosis became possible with bone chilling certainty. However, there was nothing man could do about it - except to wait for death since there was no cure; the first medicine was to arrive after 50 years - in 1944.

#### Pre antibiotic era:

While epidemics of consumption have ebbed and flowed for thousands of years, there was a time not too long ago when the disease had been widely and equally rampant over most corners of the globe, and that notably includes the so-called developed nations of today. Just as in the third world, morbidity and mortality due to TB had been uniformly ferocious even in Europe and North America. By 1800, one of every 250 people in the Eastern United States was dying of the disease, which accounted for almost 25% of all deaths¹. In England and Wales too TB reportedly remained much the largest single cause of death till the middle of the nineteenth century.

# An inexplicable downward trend in the fury of the scourge in the West while it was still incurable:

However, after 1850s the scenario in the West began to improve somewhat; the intensity of the disease began to abate gradually. Deaths due to TB documented in Western Europe show a steady decline after middle of the 19th century, surprisingly, a century before any medicine for the disease was discovered. The first medicine for TB became available only around 1944. This inexplicable downward trend in the fury of the scourge, although incurable at that time, could plausibly be attributed to improvement of the health and immunity in general; the infant mortality rates were in decline; the average life span was slowly increasing.

Socio-economic development inevitably brought about a progressive improvement in the standards of living. Healthful nutrition helped fortify immunity levels of individuals protecting them from infections. Better education inculcated healthy habits, infusing new awareness about significance of hygiene and ventilation in disease prevention in general. Anti-

<sup>&</sup>lt;sup>1</sup>Testing a Horrible Superstition, chapter 2, page 29

spitting campaigns picked up momentum in certain parts of Europe. The rising trends of dispatching patients to sanatoria often located in remote villages or at hill resorts, far away from the mainstream society, led to effective isolation of infectious cases, thereby reducing transmission levels amongst general public.

#### Era of chemotherapy:

And then 1944 ushered in the era of chemotherapy; the first ever medicine became available! Thereafter, from 1944 through 1966, anti-TB drugs kept appearing on the horizon in rapid succession and with a blissful regularity:

1944: Streptomycin (S).

1952: Anti-tuberculosis activity of Isoniazid (H) discovered.

1954: Pyrazinamide (Z).

1962: Ethambutol (E).

1966: Rifampicin (R).

To this day we continue to fight TB primarily with the same 5 drugs; of these Rifampicin (R) and Isoniazid (H) remain our most effective weapons.

[Several other drugs too appeared on the horizon in the meanwhile but being less effective either went into oblivion gradually or remain the second choice e.g. Thiacetazone and PAS (para-amino salicylic acid, 1946)].

#### Effective drugs wipe out TB from the West:

More evolved and affluent nations of the West were, as ever, highly sensitive to the ongoing research. Ever eager to discard the old in favor of the new, weak in favor of the strong, they constantly updated their policies, irrespective of the cost involved. Habitually and religiously they switched over to the very best as soon as it was discovered and made available; the healthy trend had a salutary effect over the prevalence therein. Already on the decline, their graph of death rates nose-dived, so much so that by around 1970s TB had truly and dramatically started vanishing from Western Europe and Americas. A jubilant Western media trumpeted success stories of TB cures. An impression that the current interventions would more than succeed in eliminating the disease

gained ground. It seemed that at long last, man could afford to heave a sigh of relief. The fear psychosis prevailing all around began to dissipate. The world was deluded into believing that the war had finally been won. Scientists all over the developed world were euphoric.

#### A massive switch off:

The entire research work, ongoing primarily in the multi-million-dollar-laboratories situated in the West, was dropped. R&D on TB literally ground to a screeching halt. Momentum built over several decades was lost. The switch off was abrupt, prompt, unceremonious and complete. Once the inertia descended, it was there to stay.

The ecstatic international community, the think tank of our globe and which plays a key role in determining the overall direction of R&D,lost interest in TB despite soon realizing that the war was far from being over, since the third world was still visibly and incessantly burning with the blaze of TB. Clearly, there was hardly any reason to rejoice just yet. However, history suggests that the international community chose simply to turn a blind eye to the ongoing devastation in the poor nations, which were ignored and abandoned deliberately and left alone - bleeding and licking their wounds!

Silently, the germ was thus allowed to slide out of science's focus and recede into oblivion. Even otherwise, during those times of1970's, science was going through a transition. It was witnessing a paradigm shift in R&D from medicine's historical preoccupation with infectious illness to the prevention and treatment of life style diseases like heart disease and that of cancer.

The global fight against TB is lead by several organizations e.g.:

- The World Health Organization (WHO).
- The International Union Against Tuberculosis and Lung Diseases (IUATLD).
- The U.S. Centers for Disease Control and Prevention.
- The Royal Netherlands Tuberculosis Association (KNCV) etc.

Through whichever prism one might examine the infamous switch off, one can never condone it as a 'benign inadvertent slip.' After all, being the chief custodian of overall scientific data, some of these very organizations themselves remain entrusted with the responsibility of receiving, on a regular basis, regional scientific data emanating from every nook and corner of the

globe and interpreting it in terms of the disease status therein. By any stretch of imagination, there is no way these agencies could have been unaware of the brewing epidemic over half the globe causing millions of deaths!

And we are not talking here of days, months or years - but 3 long decades!

#### The insignificant, expendable people:

World history of tuberculosis is a classic example of how there exists one set of standards for the elite West while an entirely different one for the third world. The story of TB uncovers glaring hypocrisy rampant at the highest echelons of the world order. It underscores the sad reality that the poor masses of the third world are insignificant creatures; it is as if they simply don't exist. They are perpetually overlooked, just like insects. They just don't figure anywhere in the overall scheme of things. In life, they are hardly noticed; in death, never missed. The story reveals an abject insincerity lurking in the attitude of international organizations worshiped as the global saviors. Graced with the duty of disease-surveillance across the world they are revered as watchdogs for human health. They are entrusted with the sublime responsibility of alleviating human suffering all over the globe.

#### And not just over a portion of it!

While vociferously proclaiming to be the champion of the suffering humanity, these premier institutions first raise a systematic hue and cry. In the name of TB patients of the third world, they skillfully raise billions of dollars from the compassionate taxpayers of the world. Then they fail to exercise the required diligence in formulation of priorities; failing to exercise rigorous control over the disbursal of funds to ensure their optimal utilization, willfully capitulating to the machinations of the powerful lobbies having vested interests and to the pulls and pushes of the political forces, thus allowing the precious life-saving pooled resources to be recklessly frittered away in diverse ways. And the original intended noble purpose of reaching out to ameliorate the suffering of the TB patients is thus woefully defeated. The perpetual financial transgression, whereby some of them are reported to gobble up as much as 80% of the collections on their own welfare in the name of administrative costs, is no less than an ongoing 'legalized' plunder; overriding the masses in the name of public interest.

#### Human has acted virtually as a scavenger on its own race:

History of TB exposes an insatiable human greed; how man has cunningly exploited the suffering and death of fellow beings as a sadistic tool for furthering his personal agenda of amassing wealth, wielding power and

acquiring material comforts. Thus human has acted virtually as a scavenger on its own race. Working individually or in the garb of a government department or under the aegis of an international organization, man has virtually converted the entire affair of TB eradication into some kind of a lucrative industry; **the deeper the crisis the bigger the spoils**. The saga of this illness is a testimony to man's infinite proficiency in devising novel ways in relentlessly pursuing his selfish designs, while all along masquerading as a messiah, pretending to help. The shameful history of TB questions the very concept of national governance or the concept of organization. The international organizations too have failed, and failed miserably, in their fundamental duty, betraying the faith reposed in them and allowing the world to slide to the brink of an impending global disaster.

#### Proof?

#### Good question!

Despite effective tools for eradication of TB being available with man since about half a century, 1 billion people have meanwhile been allowed to succumb to it - most, if not all, in the third world. Worse, a respite is hardly in sight on the horizon. Ironically the scale or the magnitude of the problem is yet to be appreciated or understood in the right earnest by the powers that be, which hardly seem fully awakened from slumber or galvanized into action. They hardly exhibit due sense of urgency even today. While a single TB death in the West is the subject matter of a thorough enquiry, how come a billion deaths in the third world have failed to evoke a serious or comprehensive investigation for so many decades?

#### A whole new dimension was added to the disease spectrum in 1980s:

Losing momentum in R&D and shifting focus away from the ongoing devastation over half the globe was yet to unfold its inevitable consequences; the circle was yet to complete itself.

And strange are the ways of mother nature!

Somewhere around 1980's, our world changed; a whole new dimension was added to its disease spectrum. Out of the blue, a new virus emerged! It was soon recognized to be a deadly agent that knocked out a person's immunity, making him more vulnerable to opportunistic infections like TB. The world was to name it HIV/AIDS. Soon, co-infection with HIV was established to be the single most powerful factor known to increase the risk of developing TB in man. As the virus spread its tentacles, fresh cases of TB were seen sprouting up, and in significant numbers. Spread of the virus in the Western

communities brought in its wake a spurt of fresh cases of TB there.

#### A change in the Skies too:

While the virus worked tirelessly on the ground, yet another factor, this one in our skies, was busy transforming our world in unfathomable ways. Seeds for the change had been sown by Wright Brothers way back on Dec.13th 1903, when they successfully took off on their brief historic flight on a primitive flying machine and which paved the way for the invention of an airplane. Mass production of airplanes ushered in a revolution in the way man travels. Given man's natural penchant for exploring the distant unseen lands, the arrival of Jet age soon translated into an ever-increasing zest of air travel, enormous air traffic and the phenomenon of globalization.

#### Invasion of the developed world by tourists, immigrants and refugees:

Slowly but surely, there was a virtual invasion of the dreamlands of the West by tourists and immigrants from the rest of the globe. Also refugees of Asian, African and South American origins were pouring in too. Up to a third of such refugees are believed to harbor infection; they are potential carriers of TB germs, though in a dormant stage.

Furthermore, there was mass deployment of the Western soldiers to different troubled locations in the third world, inevitably exposing their pristine physical frames to tropical infections. Besides, there was an ever-increasing transportation of animals. All these resulted in thorough intermixing of human as well as animal populations.

Undetected by the customs or security agencies, the germ thus managed to sneak into every nook and corner of the West; seed now stood thoroughly sprinkled; it awaited germination! The stage was set for resurgence of TB in the West. Life had come a full circle.

Nearly half of the active TB cases in the United States occur in people born outside the country. Gradually the depressing realization dawned: the enemy had returned, and that too, with a vengeance. The West, believed to have long been 'cleansed', was once again back in the grip of infection. The developed world was sliding downhill - back to square one.

#### A turning point - The New York Epidemic:

In the early 1990s, the United States was hit with an unprecedented epidemic of (multi-drug-resistant) tuberculosis. The epicenter was New York city but cases rose nationally\*. In order to contain this, a mammoth effort as well as \$ 1 billion in excess health-care costs over a period of 2 or 3 years had to be mobilized.

#### A sudden change in the attitude of international community:

Now this onslaught of TB in New York, it seems, had a sobering effect on the international community. It was something it could no longer afford to ignore. It had suddenly turned into a different ball game altogether, forcing the WHO not only to take some drastic measures but also seen to be doing so. The organization finally broke its stoic silence on TB and in 1993 declared TB as a global emergency - an unprecedented declaration in 45 years - ever since WHO came into being in 1948.

Late Dr. S. P. Khanna, MD, - formerly Director New Delhi TB Center and a passionate crusader for the cause and who was in a position to place the Indian situation in the overall global context - aptly summed up the scenario to the author. The gist of what he said is this:

The international community has finally understood that West is in tangible danger. To protect themselves they have to contain the epidemic here, in the third world. Belatedly though, they have concluded that they have to act; not for others but for their own sake. They have acknowledged the writing on the wall that **no one is safe till everyone is safe**. It is not some new found upsurge of human compassion for the masses of the third world that has awakened the international organizations; it is the chilling realization that **TB** has to be curbed in the slums and shanties of the third world, if they wish to protect their side of the globe.

#### Nothing was attempted when so much could have been accomplished!

Coming as it was on the heels of the New York epidemic, timing of the WHO declaration seems a curious coincidence. It was akin to a sudden knee jerk reaction - too little too late. For over 2 long decades, right from 1970 through 1993, an unprecedented and irredeemable neglect of R&D in the field of TB had already been committed and indelibly entered in the medical history. Man may or may not see to it or confess this yet but it simply cannot be wished away. That quarter of a century might yet turn out to be the darkest era in the history of the disease; nothing was attempted when so much could have been accomplished! Directly or indirectly, this vacuum in the R&D represents the biggest failure of the WHO. It would always haunt man!

#### Were the lessons learnt?

One would have thought that having realized the folly, man would change

<sup>\*</sup> Preface page X11, Timebomb by Lee B. Reichman with Janice Hopkins Tanne, published by Tata Macgraw-Hill, 2002

course. He would sincerely attempt to atone for the historic sin of omission. He would reorganize priorities and re-channellize his energies towards the logical direction. In order to make up for the lost time he would redouble his efforts in finding a cure for TB in the right earnest.

But just like the fast changing world, man himself too was changing radically. His moral values were changing. He was progressively turning 'wiser', 'more focused', 'goal oriented', 'more practical' and 'go-getter,' all of which in simple terms meant nothing but more 'materialistic'. He was turning increasingly deaf and dumb to all humane considerations. Devoid of compassion and blinded by the newfound lust for wealth, he was lustily swaying on top of the powerful waves of market economy. The dazzling dollar was the pied piper that singularly determined what his priorities would be.

#### Even Science follows the market. Like a pet dog:

Not long ago, there was a time - yes, there was a time on the same mother earth - when following the invention of Polio vaccine Jonathan Salk had refused overtures to patent it, saying **it would be like patenting the sun**. Winds had since changed direction. Greed had polluted the air. Selfishness reigned supreme. Bereft of moral values, common sense or logic, man tamely surrendered to the economic forces, which predictably seduced the R&D yet again towards wayward directions.

The real focus: Despite an enormous market in terms of patients, only 5% of the 16 million people currently sick with TB can afford to pay for treatment - a lack of buying power that has dissuaded pharma - investors for decades. Of the total drug-sales on the globe, nearly 80% materializes in North America, Japan and Western Europe. Those regions are ogled by the pharmaceutical industry as ideal heavens where rich consumers reside, where prosperous governments lavish unlimited health covers upon their citizens, where affluent residents can afford fat insurance covers, and where no price is considered too high for human life or human health. The entire research effort remains unblinkingly focused on these tiny portions of earth. The imbalance is further exacerbated by peculiar financial behavior of funding agencies, health organizations and the profit-oriented drug industry. As a rule, fellowships, sponsorships, research grants and dream pay packages are forthcoming only if you chose to pursue the elitist agenda. Such selective supply of funds quarantees absolute concentration of the researchers in the rat race.

It is estimated that over \$56 billion a year is spent globally on health research. About 90% of this R&D effort is directed towards the diseases of the rich. Even Science follows the market. Like a pet dog! A study by Patrice

Trouiller, of Médecins Sans Frontières (MSF) revealed that out of 1223 new compounds launched in the market from 1975 to 1997, only 11 were for tropical diseases!

Sadly, a meager 10% of the health R&D is reportedly directed towards the afflictions of the poor who constitute a whopping 90% of the global population.

In simple words, when new drugs or vaccines are conceptualized or short-listed and the work for their development embarked upon, bulk of the world's population is left out of the picture. Not even considered! For the highly competitive drug-industry, loyal solely to its ruthless shareholders, profit comes first - not people.

This relentless pursuit of profit led to the rise of the so-called lifestyle drugs whose prime function is to restore those social faculties or attributes that tend to diminish with age: Regaine for treatment of baldness, Viagra for male impotence, Xenical for obesity and Prozac for depression\*. One didn't have to wait to fall sick to take these pills; even 'normal' people could be persuaded to purchase them. Such drugs and their subsequent innovative refinements proved blockbusters for the industry.

The 1980s ushered in the era of diagnostic imaging, CT and MRI scanning and ultrasound besides interventional radiology and angioplasty. Sophisticated endoscopies and technical achievements of Minimally Invasive Surgery brought in a subtle shift in the way medicine was practiced. The simple art of clinical medicine was marginalized by the seductive trend of income-generating 'procedure-based specialty medicine' and intensive care medicine. The New Genetics promised unprecedented opportunities for medicine; the spiral staircase of the DNA spiralling the hopes of humanity. Advances in epidemiology brought about a new insight into the preventability potential of social factors.

However, all recent breakthroughs were in one lucrative field or the other: weight loss, beautification, mood elevation, cloning, test tube babies and drug-coated angioplasty stents! Clearly, pharmaceutical industry would prefer to find a cure for a bald American rather than a dying African or Asian.

#### Brain drain:

A vast majority of the most gifted scientists of the poor nations that simmer with maladies like TB, Malaria and sleeping sickness etc., are ironically prevented from contributing their genius to these ailments because of the

<sup>\*</sup>The Rise & Fall of Modern Medicine by James Le Fanu published in 2000 by Abacus

phenomenon of brain drain; thanks to the irresistible magnetic dollar, they are systematically lured away to the West where they too end up joining the popular rat race - finding cures for the rich and mighty!

TB failed to muster in 8000 years what AIDS seems to be generating with in mere 20 years of its identification! Kofi Annan, the secretary general of the United Nations, has sent an SOS call for a war chest of \$ 7 to 10 billion annually to fight AIDS. George W. Bush, the President of the United States of America has pledged a \$ 15 billion-aid package for Africa to help fight AIDS.

All aid for AIDS, little for TB.

{Note: The material in the preceding 2 pages draws heavily from 2 articles published in "The Economist' August 14, 1999: First is "Balms for the poor". The second is "Helping the World's Poorest" by Jeffery Sachs (Director of the Center for International Development and Professor of International Trade at Harvard University)}

#### A glimpse of what is possible today:

#### SARS:

The recent outbreak of SARS around March 2003 is a testimony to the fact that our world has virtually shrunk in size. It has become compact and well connected. No wonder, from an unknown village of Guangdong district in China, the mysterious SARS virus could swiftly travel down to the plush homes and corridors in Toronto, Hong Kong, Europe or any other country or continent. The response of the international community to the calamity was swift. It moved in unison and with a stunning speed. Steps were instantly taken to awaken the world to its dangers, to arrest its spread, to devise modalities of diagnosing it, to find its cure and even to embark on research for evolving a vaccine for prevention. Response of the media too was mindboggling. Every channel of radio & television, every newspaper & magazine seemed to rise up to the challenge, disbursing valuable information to even the remotest regions of the earth about epidemic's evolving status, its etiology, symptomatology, cure and precautions. Something drastic, something dramatic seemed to be happening by the hour. Resources never seemed a constraint. With a lightening speed and within no time, WHO declared a state of emergency!

Similarly, the response of the international community to a couple of other outbreaks in the recent times like **bird flue** - that saw 20 human lives lost and tens of millions of chickens slaughtered - and **mad cow disease** was swift, precise and awesome.

Why?

Ostensibly because these episodes posed a tangible, palpable and direct threat to the citizens of the developed nations. A glance over the time line of the course run by these outbreaks is an eye opener. It depicts in no ambiguous terms as to 'what is possible today if the international community has the will to act.'

And that is a big 'if.'

"A diagnostic kit for SARS took four months," says Rowan Gillies, president of the Nobel Prize-winning organization Medicines Sans Frontiers. "We still don't have one for TB".

Thanks to its spectacular management, SARS outbreak could be contained within months, although not before it had extinguished about 800 precious human lives in different countries.

In comparison, in India alone, TB incessantly consumes 1440 lives each day; an Indian dies of it every minute; half a million each year. Where is the same compassion or firm response? What happens to the same international community when it comes to tackling TB? It figures nowhere on the international agenda! Talk about equality! Justice! Human rights! Globalization!

The lackadaisical attitude of international community to the third world affairs isn't just limited to the issues of disease-control, but seems all-pervasive.

Rwanda's government and survivor groups accuse the international community of not doing enough to prevent the genocide of 1994, in which about 800,000 Tutsis and moderate Hutus were brutally butchered by Hutu militias in ethnic violence within a span of 100 days. Canadian General Romeo Dallaire, Head of UN peacekeepers in 1994, said France, which led the small international peacekeeping force at the time of the genocide, the UK and the US in particular did not care enough to stop the killing.\*

In a candid interview with BBC telecast on June 26<sup>th</sup>, 2004, Mr. Bill Clinton, the ex-President of United States of America, expressed regret over not having been able to pre-empt the killings.

As the paragraph is being written in June 2004, the question that currently haunts the world today is how long shall the international community continue to look the other way, postponing proactive action in Sudan, where malnutrition, starvation deaths, homelessness and ethnic cleansing on an

<sup>1</sup> India Today May 31, 2004, page 62

enormous scale are reported to have been brewing for quite some time now?

In an elucidating editorial titled "G-8 turns blind eye to impending catastrophe in Sudan" the Times of India dated June 16<sup>th</sup> 2004 warned that "as many as 300,000 people are waiting to die over the next 3 months in Sudan.... An Arab militia called Junjaweed has unleashed terror in Darfur region...The UN has urged the world to cough up \$ 200 million, but it might be a case of too little, too late. One might as well ask, after such knowledge, what forgiveness? The Nazis killed six million or more out of hate. **Today's civilized democracies prefer to kill out of benumbing indifference**. The Dark Continent has exposed the quiet savagery of the rest of the world. How does one explain this callousness? At the G-8 meet, the US made a strong case for writing off Iraq's debt of \$120 billion. The proposal to waive Africa's \$ 300 billions was once again set aside."

In stark contrast, the Bosnian crisis was reported to have provoked the largest ever involvement of international organizations into a conflict management process; the EU, the OSCE, the UNO, NATO etc. Ostensibly, because this is not Africa or Asia we are talking about! It poses direct threat to Europe, my friend!

#### Global conspiracy of silence and inaction:

Global commitment to eradicating TB has perpetually been shamefully pathetic. Ironically, the devastation due to TB in Asia and Africa that we witness today is but the predictable outcome of the global conspiracy of silence and inaction. Some of the glaring consequences of this neglect are:

#### 1. No effective vaccine - The single most significant failure of man:

Although TB devastates millions of families, man has failed to work diligently towards evolving an effective vaccine for its prevention. This represents the single most significant failure of man in this fight. An effective vaccine could have single-handedly transformed the face of our world. We are doomed to continue to use BCG vaccine (attenuated bovine tuberculosis strain discovered in 1908 and introduced in 1923), the efficacy of which can be said to be debatable, controversial or suspect. Forget about finding a new one, man has failed to improve upon this 80-year old antique, despite having in possession millions of research molecules in the modern research libraries.

#### 2. No new tests:

No new diagnostic test for TB has been invented that could successfully and practically replace the 120-year-old sputum smear test, which continues to be

<sup>\*</sup> BBC News April 7, 2004, bbc.com

the heart and soul of the latest TB program (DOTS) in India.

#### 3. No new drugs:

Not a single effective TB drug has been invented in the past 38 years after the advent of Rifampicin in 1966. More ominously, none appears imminent; there hardly being a promising formulation currently at advanced stages of human trials and thus likely to emerge shortly from the R & D pipeline.

#### A distant ray of hope:

However, in Oct. 2000, Global Alliance for TB Drug Development, a new not-for-profit venture came into being that aims at picking up the thread from where it had been left off by the world in the 1970s and at accelerating the discovery and development of affordable, fast-curing-drugs to fight tuberculosis. PA-824, an anti-TB molecule has among others entered the rigmarole of pre-clinical and clinical trials. A beginning... that emanates a distant ray of hope!

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#### Why this book?

The question that haunts the author day and night - and to fathom and explore answer to which has inspired him to venture this book - is this:

While preparing the blue print of this new endeavor (DOTS), while hammering out the numerous modalities involved in this complex multidimensional program, and while chiseling and fine tuning its final shape, was the international community influenced by the thought that the finished product will eventually be practised somewhere in the third world alone? Because that's where the disease largely thrives and that's where all the high burden countries lie? Was the process of its conception, planning and production affected by that infamous lackadaisical attitude of the international community that has perpetually plagued its responses towards the third world problems? Could the attitude have overshadowed the entire exercise? And if so, was it in any way able to cause a degree of dilution in design-quality? And if so, to what extent? Did it result in significant degradation in its efficacy? Would the international community have presided over the hustling with precisely the same degree of diligence, deliberation and care and arrived at exactly the same conclusions, were it meant not for the people of India but for those of USA, UK, Australia, Germany, Japan or France?

It is possible that the author is by nature a paranoid personality, a hard-core skeptic haunted by history or an old-fashioned clinician who is unqualified to grasp the intricacies and complexities of the newer & evolving sciences of public health, epidemiology and statistics. May be, there is something the architects of DOTS know that he doesn't. But his ominous apprehensions have been reinforced by numerous other doctors, he has interviewed. And the world can't afford to wait to find out the truth as time runs out. Howsoever belated it might seem, it is worth it even now to launch an exhaustive nation-wide debate & resolve the issues, even if it throws up the same conclusions all over again, perfectly validating DOTS. But if some of the fears expressed in the forthcoming chapters were to turn out true, we might have evolved, instead of DOTS, a **recipe for disaster**.

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#### How did DOTS materialize?

Abject neglect of R & D and the resultant failure of man in inventing the muchneeded modalities for prevention, diagnosis and cure were the fundamental reasons why the very need for conceiving such a peculiar and elaborate program arose at all. Man desperately needed a new wonder drug, which could effectively cure TB overnight. Alas, that was not to be.

For the international community - faced with the disgrace of half a century of inaction and a string of lapses by way of omissions or commissions - the need of the hour therefore was as much to do something about TB as to be seen to be doing so.

In the absence of any research, however, some time towards 1990's, scientists it seems decided to pursue the next best option - to make the most of whatever the world did know. They settled down with grit and determination to rethink and reorganize. Painstakingly and meticulously - they went about perusing through all existing research material some of which had been gathering dust for decades. They diligently reviewed all the contemporary knowledge, piecing together bit by bit every piece of information, every theory, every hypothesis that they could dig out from TB literature.

Thus they ingeniously prepared a new cocktail from old ingredients.

Man then embarked on a journey called DOTS.

# Some of the key research developments that formed the scientific basis of DOTS are as follows:

 In 1950s and 1960s, studies at Tuberculosis Research Center in Chennai demonstrated the efficiency and safety of home treatment of TB patients without any additional risk of disease to close contacts<sup>1</sup>.
 The startling results prompted a radical departure from traditional

<sup>&</sup>lt;sup>1</sup> Tuberculosis Chemotherapy Center, Madras. A concurrent comparison of home and sanatorium treatment of pulmonary tuberculosis patients in South India. Bull World Health Organization 21: 51, 1959.

sanatorium treatment and opened up new prospects for nation-wide programs in the developing countries whereby patients could stay at home and be treated.

- The problems of poor compliance to treatment of patients were identified and necessity and feasibility of supervised administration of every dose of treatment to TB patients demonstrated¹.
- It was also proved that intermittent chemotherapy was as effective as daily regime<sup>2</sup>. These findings offered the advantage of fully supervisable medication.
- In 1960s studies at the National Tuberculosis Institute in Bangalore documented the efficacy and feasibility of case detection by sputum smear microscopy even at the peripheral health institutions<sup>3</sup>.
- 1972 saw the introduction of 'Short-course Regimes' enabling the conventional duration to be approximately halved without lowering the therapeutic effect.
- Styblo<sup>4</sup> combined the principles of DOTS into a powerful treatment system that ensured monitoring, supervision and accountability for every patient started on treatment and demonstrated that this system could provide effective TB treatment affordable for developing countries.

#### Obsession with foreign stuff seems like a DNA problem with Indians:

As one can see, a substantial amount of the research that formed the scientific basis for DOTS (the latest TB control weapon) originated in India way back in the late 1950s. In other words, the principles of modern TB control have returned home (to India) after traveling around the world for nearly 40 years. Once stamped by the foreigners and re-mixed into imported cocktail and labeled as DOTS - Indians have welcomed it with open arms and with ever increasing enthusiasm. It is a case of suddenly becoming more sincere to the crown than the queen herself. Obsession with anything foreign seems to be a

<sup>&</sup>lt;sup>1</sup> Fox. W. Self administration of medicaments. A review of published work and a study of problems. Bull Int Union Tuberc 31: 307, 1962

<sup>&</sup>lt;sup>2</sup> 64 Tuberculosis Chemotherapy Center, Madras. A concurrent comparison of intermittent (twice weekly) Isoniazid plus streptomycin and daily isoniazid plus PAS in domiciliary treatment of pulmonary tuberculosis. Bull World Health Organ 31: 247, 1964

<sup>&</sup>lt;sup>3</sup>65 Baily. G.V.J., Savic D., Gothi G.D., Naidu V.B. and Nair S.S. Potential yield of pulmonary tuberculosis cases by direct microscopy of sputum in a district of South India. Bull World Health Organ 37: 875, 1967.

<sup>&</sup>lt;sup>4</sup> Styblo. K. Epidemiology of tuberculosis. In: Infections Krankheiten und Ihre Erreger. Mykobakteria und Mykobakteriellen Krankheiten. Eds. G. Meissner et al. Vol 4. VEB Gustav Fischer Verlag Jena, 1984

DNA problem with us, the Indians.

Forty years after the discovery of its principles in India, DOTS is being applied on a mass scale in our country. As has been pointed out by several writers in the past, DOTS is thus a classic example of research findings not being applied where they are most needed and where they were discovered. The whole world seems to have benefitted from the research done in India; the whole world ... except India!

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# The Indian Scenario: Milestones of TB Control Movement

#### Before India got freedom (before 1947):

Some of the initial steps that the country took towards TB control were:

- First sanatoriumwas established in Tilaunia (1906) followed by others.
- Tuberculosis Chemotherapy Research Center in Madras (TRC Chennai) was established (1917).
- Birth of TB Association of India (1939).
- New Delhi TB Center, Delhi was established (1939).
- LRS Institute of TB established at Mehrauli, New Delhi.

#### Pre-DOTS era - After freedom till DOTS was ushered in (1947 to 1997):

- BCG vaccination was launched on a mass scale in 1948.
- Late Pandit Jawahar Lal Nehru, the first Prime Minister of India, took keen interest in TB eradication, probably because his wife Mrs. Kamla Nehru had died of it & his daughter (Mrs. Indira Gandhi who too went on to become the Prime Minister), had a brush with Pleurisy during her youth.
- Dr. P. V. Benjamin was appointed the first TB advisor to the government of free India.
- National Tuberculosis Institute in Bangalore was established (1959).
- Several clinicians and scientists kept working anonymously and in isolation in different parts of the nation.

However, after independence, the entire country underwent considerable all round progress. During this half-century everything in India appeared to have virtually undergone transformation - the cities, the buildings, the roads, the cars, the industry, the telecommunication systems, the railways, the dams, the computers, the internet, the print and the electronic media etc. If there was one thing that did not change, it was the fate of a poor citizen who suffered TB

and remained at the mercy of the govt for cure. Because up-gradation in TB-technology in govt sector was not commensurate with the ongoing development.

#### The first wake up call (1958):

A national sample survey conducted by Indian Council of Medical Research (ICMR) from 1955 to 1958 documented the (enormous) burden of tuberculosis and the urgent need for a tuberculosis control program\*.

#### NTP launched (1962):

Alarmed by its findings, a National TB Program (NTP) was launched in 1962 whereby national policy for dealing with the malady was formulated for the first time. An elaborate infrastructure was created. A network of 446 District TB Centers, 330 TB clinics and more than 47,000 hospital beds were established throughout the country.

But that is just as far as it went. Having created the infrastructure, it seems, the government lost its steam. A complete lull followed. TB, it seems, was virtually forgotten. Year after year - for 30 long years (from 1962 through 1992) - the policy remained the same - literally static and unchanged. No serious attempt was ever made towards revision, improvement or fine-tuning.

During the corresponding period, the prosperous nations of the West remained highly sensitive to the advent of chemotherapy (from 1944 to 1969). They incessantly made prompt and judicious decisions and formulated adjustments in their regimes. As a result they were able to reign in TB.

However, those advancements failed to evoke enthusiasm in India. Govt literally slumbered - failing to keep pace with the R&D or to take advantage thereof. The policy makers of India continued to cling to the ancient, outdated regimes, neglecting to imbibe better technologies and vistas offered by modern science. Union and state govts stubbornly continued the practice of administering primitive regime - the STH regime of medication (consisting of Streptomycin injection, Thiacetazone and Isonex) - which:

- Was comparatively less effective.
- Took much longer to heal a patient.
- Was sometimes more toxic.
- Included a controversial medicine namely Thiacetazone -, which continued to be widely used in India wheras it had been discredited and discarded by several developed nations way back in the early 1970s.

<sup>\*</sup>Tubeculosis in India A Sample Survey 1955-1958. Special Report Series No. 341, Indian council of Medical Research, New Delhi, p. 1, 1959

#### Reason? = It was dirt-cheap!

However, STH regime had one overwhelming merit, which, it appears, proved decisive in favor in its continued usage. And that clinching merit was - it was dirt-cheap! Whatever other arguments and studies may have been cited in defense of Thiacetazone (and there was no dearth of them systematically flung at the critics by the govt during the pre-DOTS era), it was nothing but the phobia of the 'cost involved in a change' that was behind all inaction. The think tank of our nation it seems remained paralyzed in the monetary calculations; convinced that our nation couldn't afford the costlier and modern regimes in vogue.

# The enormous 'Human cost' though hard to quantify, was never reckoned worth considering!

Thus govt of India lagged way behind in the field of TB management and for half a century, unknown to the innocent citizens, one of the cheapest regimes silently reigned supreme in the government sector through the length and breadth of the country - a glaring testimony to the gloomy fact that, despite its tall claims, the government of India accords shamefully low priority to the health of its ignorant & poor masses.

#### The consequences of 30 years of national paralysis are all pervasive:

With a cumulative load of about 14 million patients, India today is home to maximum number of TB patients for any single country in the world. She shoulders about a third of the global burden. An Indian continues to die of TB every single minute. Astonishingly, more Indians die annually from it today than ever before in the past, including that pre-antibiotic era when TB used to be incurable. 40% of Indian adults remain infected with the germ. Every day, more than 20,000 people become infected; over 5,000 develop the disease and about 1400 die of it. In India there are more cases in 4 days than in a full year over the entire United States of America!

#### Public and media blissfully unaware of the silent Tsunami:

Ironically, while such silent tsunami was ceaselessly at work, people of this great nation continued to remain blissfully unaware of the magnitude of the brewing epidemic and its morbid mismanagement. While people were dying by the minute, there was a stark lack of general awareness - **no reports, no discussions and no debates on the subject accrued**. Media remained equally unconcerned and sickly silent, there were no headlines ever. There was hardly any informative or educative material available in the public domain on the lackluster subject. As a result no pressure was generated

within the society for a change for the better. Though NTP was reviewed in 1976 and again in 1988 - yet the exercise had remained limited to paperwork.

It is a shame that while our own house had been on fire, we Indians sat unconcerned & motionless. It had to be outsiders to create a commotion and wake us up, assess the damages and to suggest a remedy - DOTS.

At long last, in 1992 the Government of India and World Health Organization belatedly woke up and got down to the business of conducting a **National TB Review** with assistance from the Swedish International Development Agency (SIDA) and involvement of national and international experts. The results of the joint review committee were shocking<sup>1</sup>:

- Less than 30% treatment completion.
- Inadequate budget and insufficient managerial capacity.
- Shortage of drugs.
- Undue emphasis on X-ray diagnosis.
- Poor quality sputum microscopy.
- Multiplicity of treatment regimes.
- Emphasis on case detection rather than cure.

#### RNTCP:

Based on the findings and recommendations of that committee, Government of India evolved a revised strategy known as Revised National TB Control Program (RNTCP), which incorporates the strategy popularly called DOTS. After pilot testing the strategy, it was widely applied on our nation around 1998.

#### An unknown lobby of angels:

While policy makers of India slumbered, informal lobbies of anonymous scientists had kept working relentlessly in different parts of the world. Among them were 2 premier institutions of India namely - Tuberculosis Chemotherapy Center, Madras (Chennai) and National Tuberculosis Institute, Bangalore - which brought out pioneering research that went on to

<sup>&</sup>lt;sup>1</sup> Ref: Arora V.K.and Sarin.R, Revised National Tuberculosis Program: Indian perspective, Ind. J. Chest Dis. & Allied Sci. January March 2000, p.21-26

help shape not only India's subsequent policies but also laid foundations for the current global TB control initiative called DOTS.

It appears that several anonymous angels - working independently, under various govt institutions or under the aegis of international organizations such as WHO - were deeply motivated by the excruciating pain they felt at the yawning disparity that existed between the developed and the underdeveloped societies and which seemed to be widening further with each passing year. They, it seems, entertained a compelling desire to end this eternal injustice that was being silently perpetrated on the innocent masses in the third world - and that too by none other than their own respective govts - whereby under official state policies, patients were systematically consigned to ancient, if not obsolete, chemotherapeutic formulations of the 1950s.

It appears that somewhere in the late eighties, ending their lonely strife in isolation, they began regrouping their positive energies; their missionary zeal proving the common bond. The resulting coalition - though an informal, unknown group - seems to have generated and unleashed an unstoppable dynamic force. Once Karel Styblo conceived, assembled and developed the ingenious concept DOTS - a revolutionary piece of mastermind - the coalition smelling merit in it grabbed the opportunity. The conception, whole-hearted adoption and energetic promotion worldwide of this promising strategy, thus represent the culmination of a long process of original and radical thinking by some brilliant human minds, hell bent on making a difference in this - the most neglected field in medicine. DOTS was clearly born out of the sheer strength of their collective desire to help humanity.

To the author - a third world clinician, grappling with TB at the grass roots level & helplessly watching his patients slowly waste & die every now & then, needlessly and avoidably, of sheer lack of proper medication - the news that under DOTS every patient would be treated with the best known drugs - was literally unbelievable. It guaranteed other benefits of contemporary research too. It looked all set to usher in sweeping changes in the way TB was being (mis) treated in the third world & to free the mother earth from the killer germ.

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# 3 Radical Changes from the Past & Other Merits of DOTS

# 3 radical changes from past - that make DOTS a revolutionary package:

# 1. Generational switch in chemotherapy:

The greatest single merit of DOTS over the erst-while system of TB treatment as practiced in the third world is the regime-switchover. Instead of being treated with primitive, cheap, less potent drugs, each and every patient would henceforth receive the latest, expensive, more powerful drugs that heal speedily; in fact the very best available on earth and believed by some scientists to be nearly 100% effective! The new initiative (DOTS) would - at long last - put a full stop to the (mal) practice of handing out inferior drugregimes of the past era to the ignorant patients without their knowledge or consent. It was literally a paradigm shift.

The generational switch in chemotherapy' built right into the design as its core constituent, the new package looked all set to benefit millions and millions of patients in a single sweeping move. It can hardly be over emphasized that the concept was brilliant, genius, futuristic and noble. Global history was about to be re-written; TB scenario in govt sector in India was about to undergo transformation.

# 2. Supervised therapy to ensure compliance:

Incomplete treatment is the norm in India rather than the exception. As many as 60% Indians discontinue medication midway. As detailed earlier on page 3, DOTS was essentially conceived and designed to obviate the very menace of non-compliance, which is the biggest problem in TB control.

Hospitalization is not done. Patient stays at home but is not allowed to carry away his medicines to his house. He is required to swallow them right there - in front of a health worker - in a nearby dispensary that he is supposed to visit - 3 times a week for the first 2 months and once a week subsequently.

# 3. 'Intermittent regime' instead of the traditional 'Daily Regime' - The most drastic change in the way TB is treated:

Ever since anti-TB drugs were discovered, a TB patient has been given medicines every day without fail; doctors would not brook even a day's interruption. But under this new system, amazingly the patient doesn't need to ingest medicines daily but on an alternate day basis - merely 3 doses per week. In other words, DOTS advocates an intermittent regime instead of the traditional daily one. This change in the frequency of dose-delivery represents yet another drastic deviation from the past practice.

# Apart from these 3 fundamental changes above, other merits are:

While ushering in transformation in chemotherapy, DOTS came as a Godsent dream opportunity for the government to bring about several changes, long overdue. It was time to remove shortcomings of the past; to incorporate the lessons learnt through decades of hindsight, to eliminate reasons of program-failure (page 27). It was time to radically overhaul National TB Control Program launched way back in 1962. It was time for atonement.

# 4. Correcting a Historical folly:

DOTS was aimed at eliminating a historical folly going on amongst medical fraternity for nearly a century - namely near absolute dependence on chest X-ray for clinching the diagnosis of TB of the lungs (page 27). DOTS was therefore made essentially a sputum-based program - a well-meaning thought based on noble intentions.

TB control effort was made more focused by first targeting the infectious cases - the very source of transmission. Awarding top most priority to curing them would hopefully bring down transmission, reducing future burden.

# 5. A magic box - full of medicines ear marked for each patient:

Perpetual shortage of drugs that had plagued the erstwhile program (page 27) was eliminated through a novel provision - one box - one patient. The moment a patient is registered, a box full of medicines for his entire 6 or 8-month course of treatment is earmarked and kept aside exclusively for him; he alone will get medicines out of it. No other patient will share his packet of drugs. The other patient would have one exclusively for himself. The unique arrangement ensures unfailing availability of full course of treatment. Hence, treatment will never fail for lack of medicines.

# 6. Shortage of manpower:

Shortage of manpower that perpetually plagued NTP (page 27) would be eliminated through provision of fresh recruitment wherever needed.

#### 7. Ushering in standardization:

Even though TB is the most common chronic infection prevailing in India, yet Indian doctors do not follow a uniform pattern of its treatment (page 27).

In a study conducted by Sheela Rangan and Mukund Uplekar, about 100 doctors were thoroughly interviewed in the state of Maharashtra. Unfortunately, about 80 different prescriptions for TB emerged. Every doctor was found to be treating this disease in his own novel way - as per his own whims and fancies! And not as per WHO guidelines!

DOTS - it was envisaged - would wipe out this glaring anomaly - namely 'non-uniformity' rampant in India. It would usher in standardization not just across the length and breadth of India but globally.

# 8. Economy of effort and economy of expenditure:

It was not as if the entire infrastructure for this new program had to be built from a scratch. DOTS was so designed that it could simply be superimposed on the already existing infrastructure of NTP; it would readily get integrated into the general government health care apparatus. Furthermore, its domiciliary concept obviated any need for extensive civil works (and hence funds) for erecting new sanatoria or hospitals.

# 9. A giant step in TB research:

Through exhaustive record keeping, extensive monitoring, and meticulous data collection, an enormous and credible data bank would be created which would be future-oriented and would go a long way in research.

# 10. Accountability:

Introducing - for the first time ever - a concept of accountability in work culture. The government sector in general is lacking in this field. Health care is no exception. The government doctors have been kept out of the ambit of consumer protection act.

# 11. Sowing the seeds for disease surveillance:

Laying the foundation stone of infrastructure for disease surveillance, which is practically non-existent in India. It would eventually be utilized for monitoring and tracking the trends of various other diseases in future.

#### 12. A massive monetary package:

This new program supported by a large international monetary package presented a chance to turn over a new leaf, to really help the poorest of the poor, to redeem its badly tarnished reputation (not always misplaced), and to clear the air of mistrust and skepticism prevailing among the public at large.

# 13. An engine of progress:

DOTS could well become a powerful engine of progress by setting high standards in the government health-care sector. Infrastructure created for the program would be a permanent asset to the nation. Regional organization and specialized training would provide preparation to confront current and future health problems. It would be an unprecedented baby step towards excellence - first in TB but eventually in general health care.

#### 14. Promising unfathomable connectivity in the govt health sector:

Although, thanks to the vision of and action taken by late Mr. Rajiv Gandhi, former Prime Minister, India has seen stupendous increase in internet-usage, and has emerged as a global super power in information technology, it has yet to realize the benefits of IT as a support tool for health care delivery. With its unprecedented communication network, DOTS is practically the first step towards harnessing the potential of IT sector. Computerization and unbelievable electronic connectivity would usher in a whole new culture that augurs well for the future health scenario of our nation.

8

# Omission of Chest X-ray From Diagnostic Algorithm: A Suicidal Renunciation

Ever since the invention of X-ray in 1895, doctors have had a natural tendency of diagnosing Pulmonary TB on the basis of chest X-ray. For over a century, they have carried on with the practice - that of near-absolute dependence on radiology for labeling cases of lung TB.

During recent decades mounting scientific evidence has emerged that has questioned the validity of such an approach. Several studies involving hundreds of skilled doctors, highly proficient in X-ray reading, and thousands of X-ray films have proved beyond doubt that this propensity is incorrect. To depend on chest X-ray, as the sole modality for diagnosing lung TB, is fraught with the risk of making over-diagnosis as well as under-diagnosis.

The news, to put it mildly, is heart-breaking for the Indian doctors. However, they seem to be gradually coming to terms with the new reality even though reluctantly and embarrassingly.

# No chest X-ray pattern is absolutely typical of Lung TB:

A TB lesion can cause any and every kind of shadow in chest X-ray. Therefore, no chest X-ray picture or pattern is absolutely typical of lung TB. No shadow, whatever its shape, size or location, can be diagnostic of TB.

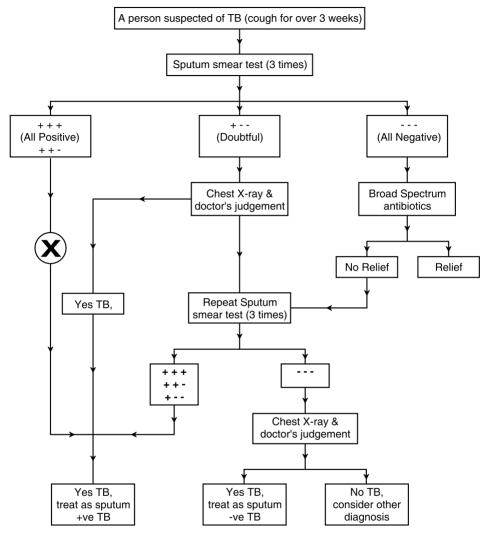
Furthermore, several other diseases of the lung like pneumonia, cancer, fungus etc. may mimic TB, producing similar shadows in chest X-ray, creating considerable confusion.

# There is only 1 definite proof of lung TB - a sputum positive report:

In order to establish the tubercular etiology of any abnormal shadow in chest X-ray, further examination is necessary, and only bacteriology can provide the final evidence. There is only one definite proof of lung TB and that is a sputum positive report. That is so because we are able to see with our own eyes the causative TB germ in a person's sputum with the help of a microscope.

It emerged that even a well-qualified and experienced doctor can misread a chest X-ray. He might label a shadow caused by some other

Diagnosis Algorithm: Standardized management plan for patients with tuberculosis.



#### Please note that:

- A patient, who is found to be unmistakably sputum positive, will not undergo a chest X-ray (marked ). Even after he has been placed on treatment, he will not be X-rayed for follow up during his long treatment.
  - Eventhough he may be highly infectious and in fact harboring a cavity.
  - Eventhough he might be a hard-to-cure (Cat II) case (since he tried anti-TB drugs in the past) and for whom it might be the last chance of a cure.
- Though a sputum negative patient is placed on Cat III treatment on the basis of some shadows in his chest X-ray, even he never undergoes any more X-rays and completes the course for 6 months - blindly.

ailment as being that of TB. Or he could mistake TB spots to be those of pneumonia, fungus, cancer or some other ailment.

He could simply miss a frank TB case, reading the chest X-ray as normal. In one study, 5% of sputum positive (infectious) cases were missed altogether, their chest X-rays were reported to be normal!

On the other hand, he could erroneously label a normal healthy person as suffering from TB.

While one doctor might report TB, another one examining the same film might claim no TB - with equal certainty!

# Doctors were thus found to widely disagree with one another.

Furthermore, a doctor was found to disagree with his own previous opinion as well. On Monday, he might dub an X-ray as pneumonia, but on Friday, when shown the same film, he might do an about turn and declare TB. Thus there exists a disturbing inconsistency not only in a doctor's own verdict, but also among the opinions of different specialists.

There can be over reading of X-rays or under reading of X-rays. In one study it was found that 32% was under reading and 2% of over-reading.

It is established that "purely radiological criteria cannot give confirmed diagnosis of lung TB". Realizing this fact, a proposed plan by scientists to produce an internationally accepted X-ray classification had to be dropped.

However, such confusion was found to be absent or minimal if - instead of X-ray - the diagnosis was arrived at on the basis of sputum microscopy, the other valuable modality of diagnosing lung TB. Very little inter-observer or intra-observer difference was seen in sputum microscopy.

"On the question: 'Is the smear positive for acid-fast bacilli Yes / No?' the frequency of agreement was 93%.1

In the light of this knowledge, and in a historic attempt to correct a century of folly, radiography was almost completely written off in DOTS (at least in several groups of patients)!

Besides, it was probably felt that radiography is neither cost effective nor expedient for the program.

But	
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To this day not a single study has even so much as remotely suggested

<sup>&</sup>lt;sup>1</sup> K. Toman, Tuberculosis case-finding and chemotherapy; Questions and Answers, page 12, World Health Organization, Geneva. Published by Jaypee Brothers, New Delhi, India

that in the diagnosis, follow up and management of lung TB:

- Chest Radiography is obsolete in TB and has no role whatsoever.
- Sputum smear microscopy alone is superior to when it is optimally combined with radiology.

# Divorce of radiology - Is it ethical? Is it not violative of human rights?

When it concerns precious human life, the best ought to be provided to mannothing but the very best. Not even 'second to best' ought to be acceptable. The issue of human life brooks no compromises!

Today is an era of globalization, human rights, equality and consumer awakening. Communication and awareness reign supreme. A patient expects the best of cures available on the globe. And he wants them now. He demands the benefit of a discovery at once. If an invention is clinched today, the modern man craves to get its benefits with effect from 'yesterday'.

By divorcing an invaluable tool of X-ray, we are weakening the crucial 'diagnostic element' of the mammoth program. This may have far reaching consequences. If our first step (the diagnosis) is on a weak footing, how can the rest of the journey (the cure) be successful? We risk not just diagnostic failure in a few isolated cases but total program failure. No doubt, we are indeed saving money (expenses to be incurred on radiology), but at what cost? A classic case of being penny wise, pound-foolish!

First, for several decades, man refuses to work diligently in the field of R&D on TB, forever the most neglected field of medicine (page 19). He fails to discover newer diagnostic tools and techniques. As a result, in the developing countries at least, he has no option but to continue to rely upon the same two time-tested but ancient tools for the diagnosis of TB of the lungs:

- First, sputum smear test, which is 122 years old.
- Second, chest X-ray, which happens to be 109 years old.

Every doctor practicing clinical medicine feels - albeit subconsciously - a subtle frustration at the peculiar handicap. While medical science is being inundated with newer tools to diagnose most other ailments, when it comes to diagnosing tuberculosis - the commonest of them all - he is miserably short of tools. He may feel the deficiency dimly - not ever having the need to express it in so many words, not even to himself - but nevertheless it can't be denied that deep down he definitely feels a woeful inadequacy - especially when faced with atypical cases of TB.

On top of this - and as if that was not enough - man goes on to turn the knife deeper. He drops one of the two tools at his disposal - namely radiography. While designing the diagnostic algorithm of the latest program DOTS (mind you constructed not in some past era but towards the dawn of the 21st century), he decides to shoot in his foot; he commits to a curious renunciation; and that too purportedly after 'enormous collective brainstorming'. The clock was thus turned back to pre 1895 era. A parallel of such a savage renunciation can hardly be found in the history of medicine.

The move is somewhat like:

- Piercing one of your eyes with a needle, declaring that one is enough.
- In the middle of a war, if the President of a state were to declare that 'since our overwhelming army seems large enough to win the war, let us economize by grounding the Air Force!'

# We are blindfolding ourselves:

To attempt to diagnose and treat TB of the lungs without the help of a series of chest X-ray pictures is like treating it blindly. It is as if we are blindfolding ourselves - intentionally, deliberately and over confidently.

# We slide to a position of great disadvantage:

We fail to perceive the extent of the lesion.

We fail to be warned if there is a cavity or a potential cavity.

We fail to efficiently monitor the patient's relative improvement at various stages of treatment.

After 2 months of medication, patient's symptoms usually have disappeared. The sputum of the patient has turned from positive to negative. For the next 4 months, we simply continue to administer the medication blindly because the only yardstick of success that we are left with is sputum negativity. In other words "continued absence of germs in his sputum" is our sole basis of the presumption that the patient is recovering. This is indirect evidence. On the other hand, if we could document through serial chest X-rays that the lesion is indeed shrinking progressively, we would be on a much better footing. But we have chosen to pull the ground from under our own feet by renunciation of X-ray.

The doctor is deprived of the only tool to verify (even if minimally) a

patient's claims about his past history. The doctor loses an opportunity, however faint, to reconfirm whether the patient's story seems true or false. Were he to stumble upon a shadow of an old lesion, which the patient has failed to report inadvertently or deliberately, it might help him to assign the correct category and which will eventually prove crucial in the outcome of sixmonth treatment.

# After 6 (or 8) months, the treatment is simply stopped. Blindly:

By not taking a chest X-ray at the end of this long and painful journey, we are deprived of a possible last minute warning that some suspicious looking residual disease still lurks behind. And we fail to obtain documentary evidence confirming that the patient has indeed been cured.

#### A medical crime:

Because no X-rays are taken, doctors fail to fulfill their duty of preserving invaluable data for future. Deliberately not obtaining and preserving, the visual record of a past event of such vital significance (that can even prove fatal) is a medical crime. The record could provide priceless insight into a patient's medical history for all times to come. It deserves to be preserved at all costs. If and when the patient returns in future with a chest ailment and the doctor takes a chest X-ray and needs to refer back to these 'baseline X-rays', he will find himself groping in a vacuum. Then he is bound to rue the omission.

Once treatment fails, we need to evaluate the patient for suspected MDR. Then along with other tests, an X-ray is taken. What will it be compared with? There is no previous record; no baseline picture to help this crucial evaluation.

DOTS is sputum-based program where everything depends upon the laboratory technician (LT). His verdict is final. The doctor only completes the formality. He only puts a final seal of approval over his verdict. An LT is supervised by Senior TB lab supervisor (STLS). If the LT and STLS jointly commit mistakes, no one can challenge the false diagnosis.

We deprive ourselves of the solitary possible chance to cross check, even if minimally and indirectly, the veracity of the patient's sputum positive reports. We miss a valuable opportunity to reconfirm the diagnosis, which is such an important event. We miss the only chance we had of nabbing erroneous false positive reports emanating from some substandard lab. A normal chest X-ray could raise valid suspicions which could kick start an investigation that might save us from over-diagnosis. If X-ray is included in DOTS, it will serve as the desperately needed (even if weakly effective) solitary tool in order to keep a semblance of check over the working of lab technicians and prevent them

from misleading the diagnosis.

# Manifestations of TB in an HIV positive person are different in that:

There is less cough.

Less chances of cavity formation.

Less chances of sputum positive report.

In such a backdrop, can the diagnostic algorithm (without provision of X-ray),be termed futuristic?

At the dawn of the 21st century, we are knowingly and under a well thought out policy depriving an innocent patient of his fundamental human right to something that was discovered way back in 1895; something that remains so vital to his diagnosis and management. How can we withdraw such a crucial and elementary facility in the name of economy, convenience or expediency of a program? DOTS is a compromise.

No doubt, DOTS is a giant step!

Backwards!

# From darkness to light:

Is there a TB specialist on earth who, in the sad event of falling sick with TB, would allow himself to be subjected to such blind diagnosis and follow up, forgoing the benefit of as fundamental a test as chest X-ray?

One doesn't have to be a genius to find the answer.

In order to get the answer from the horse's mouth, the author conceived an idea. He coined a simple question. Then he went around posing it to 10 eminent physicians; the criteria being that each one was:

- Highly qualified (MD Medicine or MD Chest & TB).
- In the age category of his wise 50's.
- Known to have tremendous track record including practical experience of over a decade in field conditions of our country.
- Enjoying an impeccable reputation in the city of Faridabad.

The question posed was this:

"God forbid doctor, if you ever came down with TB yourself, and your sputum sample came positive thrice, would you start treatment without first undergoing a chest X-ray - as is the standard practice under Indian DOTS?"

The author went ahead and completed the exercise.

The calculated and considered response of each one is given hereunder:

#### Dr. G.K.Khurana MBBS, MD Medicine:

"When you go on a long trip, you tend to pack up several things.... as back up. TB treatment is a pretty long journey. I would very much like to have an X-ray chest in my kitty before I embark on treatment. Supposing I land in some kind of complications or there is drug toxicity or my response is slow or there is treatment failure, then I would have this baseline X-ray to compare my current status with. No harm in packing an umbrella for that unexpected rainy day."

#### Dr. Pankaj Mohan, MD Medicine:

Strangely, even perpetually sputum negative cases who have been diagnosed on the basis of chest X-ray, do not get the benefit of repeat X-rays. Is it fair to monitor their progress on the basis of sputum tests?

No doubt, India can't realistically afford to emulate the US model.

But does India deserve to be clubbed with the poorest nations of Africa? Is India really that poor? Govt. clearly erred and let the nation down by underestimating its potential. India today falls somewhere in between the 2 extremes - The US & Africa. Accordingly, DOTS model ought to have been suitably upgraded - at the very least by addition of chest radiography.

# Dr. Anoop Chopra MBBS, MD Medicine:

"How can you be 100% sure that the laboratory technician has performed my sputum tests correctly? X-ray is a must - to reconfirm things. And why not? Is there a single city, town or village, which doesn't have easy access to this rudimentary facility? Chest X-ray is cheap and easily available almost every where in India. To include it in our diagnostic algorithm is very much within our grasp; sputum culture and sensitivity test is beyond our reach though."

#### Dr. K.K.Mishra MBBS, MD Medicine:

"X-ray is an absolute must. Sputum positive report is not the end of the world. X-ray gives a whole lot of other crucial information. What if the patient has an associated lung disease e.g. lung collapse, effusion, hylar lymphadenopathy, pneumoconiosis, fungus or even a cavity? Besides, X-ray happens to be a mandatory prognostic indicator. How much does an X-ray film cost? Just Rupees 25 (half a dollar) - even less, if purchased in bulk. This half-a-dollar is peanuts compared to the possible benefits; it ushers you from darkness to light. Is life of an Indian not even worth half a dollar?"

# Dr. Rakesh Gupta MBBS, MD Medicine:

"In a chest symptomatic, presence of shadows in chest X-ray gives impetus to the efforts to uncover the diagnosis; doctor surely moves with redoubled energy to confirm TB or else to rule it out; the shadows acting as the spark for action, ensuring early diagnosis. No stone should be left unturned when the suspected patient comes to the doctor for the first time because in TB 'first opportunity is the golden opportunity'. The patient must be effectively diagnosed and rationally treated and cured the first time over. It is just like if you missed the only direct bus to your distant village, you are in trouble; then you are forced to take the longer, indirect route, hopping onto whatever transport that comes your way. You end up spending more time, money and effort and yet you might not reach home before nightfall."

# Dr. M.C. Gupta MBBS, MD (Respiratory Diseases):

"Yes, X-ray is a must; to find out the extent of damage, any other co-existent ailment, and to assess the progress of the patient. No doubt sputum test will help detect sputum positive patients, which are about 25% of all cases. The diagnosis of the rest of 75% patients will get an impetus if X-ray is promptly done; the importance of early detection of each and every TB case cannot be overemphasized. After all, sputum negative of today may be sputum positive of tomorrow.

Why only X-ray, I would like to be tested in every possible way. Excuse me, this is TB, my friend - the future of my entire family would be on the line. No body knows what are the initial resistance levels prevailing in our city; no credible surveys have been conducted. So right from day one, I will take every single precaution; leaving nothing to chance."

#### Dr. Vinay Kumar Jindal MBBS, MD Medicine, FICA, FIACM:

"For confirmation of diagnosis of tuberculosis, no doubt positivity of sputum and histo-pathology are the key determinants, not radiology. But for follow up, I certainly need X-ray chest; especially at the end of 2 months, once sputum has turned negative, what is the progress indicator left with me? Or if the patient is unable to bring out any sputum, I certainly need to look at his X-ray pictures to ensure that he is responding."

#### Dr. R.L.Moga MBBS, MD Medicine

"I want my X-ray done. 100%. This is the only life I have and I want every possible test under the sun. For TB, a chest X-ray is the barest minimum investigation and it is the fundamental right of every Indian citizen to be entitled to such a facility. India is dreaming about becoming a superpower & is staking claim for a Security Council seat in the United Nations. Can we take pride in such feats, while our citizens continue to suffer and die of the very infectious diseases of the past era, which ironically are preventable as well as curable? How can the govt even consider denying such a simple, inexpensive facility? It is duty bound to ensure that the masses are not maltreated."

#### Dr. B.K.Parsad MD Medicine, MRCP (UK)

"I would be doomed if some joker messed up my sputum reports and came up with 'false positive' reporting. Given the sick state that our labs are in today, the possibility can never be ruled out. Hence, chest X-ray is not a luxury; it is an absolute minimal requirement & mandatory for pulmonary TB.

#### Dr. FANB. MD Chest & TB:

"How can I begin TB treatment without first doing a Chest X-ray? Professionally, nothing is more weird. Would you consent to undergoing a CABG (coronary artery bypass surgery of the heart) without obtaing your coronary angiography first?"

#### Dr. P. K. Babbar MBBS, MD Medicine:

"I can never start anti-TB drugs without a chest X-ray. Never ever! Excuse me, how many doctors trust DOTS. Why haven't the private practitioners joined the bandwagon yet? After all, it's been 5 years since it was imposed on the govt doctors per force from above. It is a 2nd class inferior package.

TB deserves to be accorded utmost respect because it is a life time disease; often running for generations in a family.

A cat II patient is treated with all 5 drugs simultaneously (practically the entire fire power that man has today), because it is the last opportunity for that patient. If this attempt fails, he is virtually doomed, may even die. For God's sake, if this one person doesn't merit a chest X-ray, no one on the earth does! To deal with such a situation with anything less than the very best is to play with human life. To hold back your punches when confronted with a deadly enemy is insanity. Not to utilize every tool at your disposal is a crime. I am afraid **DOTS may well go down in the history of mankind as the** 

#### costliest cost-cutting measure."

#### Dr. Romil Chhauda MBBS, MD Medicine:

"I have no words to answer such a preposterous question. I feel such strong resentment against the very concept. Is this 2004 or are we still in the stone age? India is dreaming of becoming a superpower in near future. Why no radiography man? Why on earth? It is sheer madness. It is malpractice. It is unethical. It is quackery. It is cheating. Not to do his chest X-ray, is like pushing your innocent patient and his children over into a well."

#### Basic thinking at the very top and the fundamental aim of the program:

The fundamental aim is to reduce transmission by converting our army of sputum positive cases into sputum negative ones.

Spurred by the passionate response of Faridabad doctors, the author framed some more novel questions and decided to elicit the response of leading academicians of Delhi. The top most name in his list happened to be a brilliant, well known, dedicated & soft-spoken man, Dr. V.K.Dhingra MD, & Deputy Director of a wonderful teaching institution, called New Delhi TB Center.

Dr. Dhingra's response at once deflated the euphoria of the author. After all, a woman already knows whatever a man discovers in the kitchen. With a knowing smile, Dr. Dhingra stated that there was nothing new about the author's idea; it was rather stale. During the past several years, similar soul-searching questions had been doing the rounds in teaching institutes of Delhi, Chennai and Bangalore and that he himself had quizzed several pioneers in the field who had virtually shaped the history of DOTS in India, having designed the Indian module. The names that he mentioned were awesome, literally who's who of TB. He told the author that the exercise had been performed informally; more like a game and no written records existed.

When requested to sum up the 'average response', this is more or less what Dr. Dhingra stated (it is not verbatim statement but what the author understood from what was said):

The immediate prime target is to somehow reduce the transmission levels by converting our army of sputum positive cases into sputum negative ones, thereby rendering the nation's environment less infectious for the citizenry. Decline in transmission today means reduced number of fresh cases erupting tomorrow,

hopefully lessening our future caseload. To achieve this fundamental aim across the entire length and breadth of the nation, DOTS has been purely designed for mass application and not for individual patients.

While a private doctor's endeavor is to cure each and every patient, the outlook of the govt is to reduce the overall long-term burden on our nation. Originally, DOTS was never designed to cure 100% people in the first place. Govt. would be more than happy to cure majority of them, especially the infectious ones who spread disease, because reducing the infection rates significantly would be in public interest & good for the future of our nation.

Admittedly, DOTS is not the best of the modalities when it comes to individualized treatment; it is one more practical option for the general population.

A deflated author failed to appreciate it then that Dr. Dhingra had virtually hit the nail on the head by perfectly summing up the thinking at the very top, saving the author weeks of hard work by obviating the need for him to pick the brains of other academicians at least in that context.

# On autopilot mode:

As DOTS is sputum-based program, a doctor quickly learns to postpone making any diagnosis on the initial visits of the patient; he simply hustles him into the sputum-testing pipeline. As time goes by, DOTS-habits become firmly ingrained in him. Gradually, he tends to function all too mechanically, without due application of mind. He puts his brain on autopilot mode, refusing to think.

#### Total lack of discretion:

Not only does he stubbornly refuse to send a deserving patient for an X-ray chest, he becomes so indifferent that he resents taking the trouble of peeping at an X-ray film, which the patient has got done privately and has carried along in the hope that it would help the doctor clinch the diagnosis.

"Even if I did find a lesion in his X-ray, I can't do anything differently. Why waste energy then?" asked a doctor defensively. Conveniently, he blames this procrastination on his total lack of discretion, as he is supposed to strictly follow program manual and not to try anything differently. Clearly, in certain situations at least, his DOTS training prohibit him from utilizing his expertise in favor of his patient even if he wished to.

#### No surrender please:

On the one hand, the program boasts of one essential feature - an efficient

retrieval mechanism, specifically designed to capture all irresponsible defaulters so that no patient is able to escape its net.

On the other hand, a patient who is glaringly X-ray positive and approaches DOTS voluntarily (or referred to by a private doctor) is not grabbed instantly. The 'trained' doctor may refuse to look at the X-ray, may miss the obvious diagnosis, may deliberately ignore the big lesion or may mechanically signal the patient on towards sputum testing rigamarole where he might get lost.

Such a patient was like a sitting duck - waiting to be picked up. But thanks to the negligent attitude promoted by the vagaries of DOTS, he is casually allowed to slip through the fingers! A golden opportunity is missed. He could have been cured with a great economy of effort. But thanks to the indifferent attitude towards X-ray generated by its diagnostic algorithm, he is casually let off the hook! A potential source of transmission is thus allowed to sneak back and disappear into the mammoth population of our nation!

What an irony! It is akin to George W. Bush the President of America declaring a new policy, 'we will energetically search and chase Osama Bin Laden all over the globe till we catch him, but will not accept his surrender.'

# Sputum simply dries up!

In several cases, as soon as effective treatment is initiated, sputum simply dries up! Despite genuine efforts, patient fails to cough up any sputum. Howsoever the doctor may insist, the patient meekly sings the familiar song, "sorry sir, I couldn't bring any sputum sample, because there is 'no' sputum!" A report stating 'sputum not obtainable' can by no means be said to imply sputum smear negativity.

In the absence of any parameter other than sputum test, for evaluating the recovery of such a patient, DOTS becomes a highly deficient program. Omission of the provision for X-ray in the program exposes an utter limitation in its design.

# Substantial population of ex-patients:

In a few years, we will obtain a substantial population of ex-patients emerging out of DOTS pipeline, whose "past X-ray records" simply do not exist. Whenever one of them comes down once again with symptoms like prolonged cough etc., the attending physician will be at a great disadvantage in assessing him for lung TB. The doctor would have to contend with a strange kind of vacuum whereby for comparison he has nothing to refer to. In the absence of that missing series of 'baseline X-rays' depicting the residual

scarring left behind by the previous episode, the doctor would be at an irritating loss. The scenario would be congenial to promotion of over diagnosis.

How can we under the law allow such a fateful event in a person's life go unrecorded? The patient has a right to have it duly recorded in every possible way (even radiologically), even if it will afford a minimal benefit for his future safety?

And if this issue is still controversial, or debatable, even then the benefit of doubt ought to be given to the patient till such time that the issue of obtaining and maintaining the record is fully and satisfactorily resolved.

#### The other extreme:

If to depend solely on chest X-ray for diagnosis of PTB was a blunder, to depend solely on sputum test, sacrificing howsoever-small advantage offered by chest X-ray, is a blunder of equal magnitude. It is like swinging from one to the other extreme position. Earlier, If the doctors were legitimately blamed to be treating not TB but shadows, now under DOTS what we are doing is treating sputum reports, not human beings!

But when the most powerful institutions like the WHO, World Bank and Govt. of India commit such an act in partenership with their brute might, what can anyone do? The shreaks of a few isolated doctors writhing in agony are voices in the wilderness.

Inability of the author to express explicitly or illustrate in numerical numbers the fate of unfortunate victims of diagnostic algorithm of DOTS or to base his ominous gut feeling on authentic verifiable scientific data or to convince the reader on this passionately felt issue, does not necessarily mean that he is wrong. Not being an academician or a genius in written or verbal acrobatics, the author can only express his pangs of anguish, overwhelmingly reaffirmed by scores of other field doctors he has quizzed during recent years.

# It's an era of precision:

Just like a calculator, modern man expects everything to be exactly programmed. Everything must be meticulously planned to the very last detail, and that too well in advance. Response to each and every possible eventuality must be predetermined, automatic and reproducible. In the computer age, there is no patience for vagueness, no room for clumsiness, no

respect for the unpredictable. There is flow chart handy to manage each and every situation; a sleek checklist waiting to be simply tick-marked. Every situation must be discernible either in white or in black; there is no tolerance for gray - a dirty word that no more exists in modern man's dictionary.

DOTS is an example of application of this modern scientific trend over a subject in medicine. A valiant effort has been made to make treatment of tuberculosis relatively arithmatical. In fact, the whole clinical aspect of TB has been 'simplified' to a considerable extent; redefined in a comprehensive, crisp manner; reduced into a capsule form.

A sputum report is either positive or negative; there is no third possibility. Therefore, it gels with man's penchant for precision. No wonder, DOTS has embraced sputum smear test as its baseline test.

The other test namely X-ray happens to be a different ball game; it threatens to usher in indecision and confusion; its introduction into the program would potentially shift the paradigm, from a simple 'black or white' to a 'gray' one. It would give credence to 'clumsy' and 'superfluous' variables like clinical sense, past experience, expertise, X-ray reading skills and second opinions - very facets of the 'ancient' clinical art, which modern man seeks to dispense with. After all 'hard data' must get precedence over 'abstract feelings.' Detached objective evaluation of a statistician is considered superior to subjective impressions of men in white coats.

Reading an X-ray requires special skills, training and experience. Inclusion of radiography would automatically make TB specialists indispensable. It would have shifted the program from the domain of non-experts (or the public health functionaries) to that of TB specialists-just what program bosses had by design sought to avoid right from the word go. First exclusion complemented the second; first radiography was chopped off and thereafter the person capable of juggling with it (namely the specialist) was kicked out too.

However, outwardly this deletion of X-ray was blamed on poverty. Is India really so poor today? Is it really as poor as some of the African nations? To uniformly club together hundreds of nations possessing vastly different levels of economic status, is unfair. X-ray facility is available practically in every nook and corner of India; Sputum culture though is another story.

One must confess that in recent years, several fields of medical science have witnessed virtual transformation and programming in the West, obviating to a variable degree the very need for extra-ordinary clinical skills. But one must never forget as to what scale of back up has made that change possible?

There, they have at their beck and call, an ever-growing multimillion-dollar laboratory system which is nearly foolproof and which performs all the good work, of checking and rechecking every single detail. They have ready access to every test given in the textbook. There is no dearth of resources. Furthermore, expert opinion of experienced specialists is readily and systematically available with the click of a mouse.

Is it prudent to emulate the programs of the West while instead of adding further, we run down further our already fragile and unreliable investigation support-line? Is it always possible to avoid gray areas in medicine? Especially when you don't possess the support of modern laboratories? Moreover, it is not mathematics; two plus two is not always four in medicine; it could be five, seven or even nine.

Radiology was sacrificed at the altar of 'passion for precision'.

Program expediency and sheer economical considerations rather than patient welfare seem to have been the overriding determinate in the unfortunate renunciation of X-ray and the TB specialist.

#### Recommendation No. 1

Failure of the govt for a decade to rectify this glaring deficiency of radiography in the current diagnostic algorithm by duly introducing mandatory chest X-ray into it, is a symptom of a deep seated malady in its attitude. Clearly, something is seriously amiss at the very top of the global think tank as well.

Depending solely on sputum test for diagnosis is unsafe. Keeping some margin of error is a way of life in India, and not without merit. Cross checking and reconfirming every piece of information - at least from 2 independent sources - is not extravagance, futile or unrewarding in an unreliable setting that prevails in India.

Each and every TB patient must undergo a Chest X-ray at the very outset before initiation of treatment.

Thereafter, all cases (except extra-pulmonary cases) should undergo repeat chest X-rays at the end of 2, 4 and 6 (or 8) months of treatment.

# Chest X-ray of all extra-pulmonary cases:

Along with sputum tests, an extra-pulmonary TB case must undergo a chest X-ray at the outset, before being initiated on Cat-III treatment.

Why?

Several extra-pulmonary cases are known to have a pulmonary element as well. If - at a later date during the course of his cat III regime - a lesion is detected in his lungs, it is bound to complicate matters - since he rightfully belongs to Cat I (and not to Cat III).

# For God's sake, India is not that poor today:

To demand or expect 'sputum culture and sensitivity tests' or 'second line anti-TB drugs' as a routine in India at present is unrealistic. But chest radiography is very much within reach of India, a country clearly far better off than some undeveloped nations with whom it shares its primitive module.

# Economically & logistically, chest radiography is feasible in India:

# X-ray plants:

Most govt hospitals already possess X-ray plant in running condition.

Some hospitals also possess MMR cameras, which ought to be repaired on a war footing and made operational.

New plants ought to be installed wherever needed. A 60 MA plant - good enough for the purposes of chest or limbs - costs much less than larger plants.

# X-ray Films:

Cost of a single X-ray film (when purchased in bulk by govt.) = Approximately Rs. 21.

Cost per patient (4 X-rays are recommended through an entire course) = Rs. 84.

Total cost on films alone that we would have incurred on 4 million patients initiated on DOTS thus far =  $4 \times 84 = Rs$ . 33.6 million = US \$8 million.

# How to generate resources for radiology?

It is Peanuts: For a package as large as that of DOTS (worth millions of dollars), this expenditure of US \$ 8 million on films is virtually peanuts, isn't it?

 Even purchasing additional X-ray plants is entirely feasible. All that is required is political will.

- 2-year moratorium on foreign travel: Approximately 25,000 patients could receive the benefit of a chest X-ray picture each well within the amount spent on a single foreign trip made by a minister's entourage (which by conservative estimates would cost no less than Rs. 5 lacs). Therefore, let us in national interest declare a 2-year moratorium on foreign jaunts on public money by anyone (except of course for urgent national and international matters, the permission for which ought to be granted by the cabinet, which will publicly explain the grounds for such a decision through national newspapers & media).
- Furthermore, ministers and officials ought to be barred from going to foreign countries on public funds for receiving any medical treatment (which is even otherwise often available locally) at least till such time that the masses begin to receive minimal health care.
- Dissolve the post of RNTCP consultant a white elephant on the global exchequer - and channelize the resources thus saved towards creating permanent infrastructure, X-ray plants and filling vacancies at the grass roots levels.
- Seal the gaping holes (as narrated to the author by a radiologist): Govt is reportedly able to purchase films at the rate of Rs. 21 per film (which in the open market would cost Rs. 25). Some corrupt employees reportedly manage to steal some of the films and sell them in the black market at Rs. 20. Simultaneously, they go to a scrap dealer and purchase an equal number of used films at Rs. 80 per kg. The junk is preserved for the records and shown as used or damaged films. While all along, public is told the usual lie: 'X-ray plant is out of order.'
- The author often wonders as to how on earth can an X-ray unit in a busy civil hospital (or a community health center) be allowed to remain out of action for more than a few hours at a stretch? Can there be a bigger criminal neglect than this? After all, it is like a lifeline for millions of local populace since their correct diagnosis (and hence cure) hinges precariously upon its uninterrupted output.
- Which one would you prefer: sure-shot cure or a free package that is less certain? Another option is to make the patients pay for their own X-

rays. For correct diagnosis and treatment, even the poorest of the poor in India can and will happily arrange a sum of Rs. 84 divided into 4 bimonthly instalments of Rs. 21 each.

Just because we are providing something free is no excuse to deliberately allow it to remain sub-standard.

9

# Another Dangerous Omission: Exclusion of TB Expert

# Attitude of the world towards a TB expert has undergone a sea change:

No doubt, TB control is no more purely a medical problem. It is more of a socio-economic issue craving higher priority and proper management. For over half a century now, man has indeed possessed the medical tools - diagnostic as well as curative - necessary for its eradication. Therefore, rather than being a medical matter, it is more an issue of correct application of the principles of public health management in resource-poor settings.

# TB control demands the involvement of a wide range of persons:

Furthermore, it is well understood now that 'rather than being the monopoly of a handful of specialists, TB control concerns and involves a wide range of persons' as has been aptly advocated by WHO think tank in lucid terms:

"...the control of tuberculosis has ceased to be a primarily technical problem, requiring rare and highly specialized skills for its solution....Yet the multitude of possible solutions will all have one feature in common: the participation of a rapidly growing number of non-specialized people, including physicians, nurses, technicians, various government agencies, international voluntary organizations, and interested groups of citizens."

#### An attempt to mobilize infinitely larger domain of doctors:

India is a vast country, virtually swarming with TB patients; their sheer number thwarting all efforts at TB control. Patients overwhelmingly outnumber experts and the enormity of the problem poses a logistical nightmare.

Through DOTS, a logical attempt is being made to rescue 'TB treatment' from being the fiefdom of a handful of specialists to an infinitely larger domain of qualified doctors who would be trained and mobilized to lend a helping hand in this colossal effort.

The attitude of the WHO towards TB-expert is aptly reflected in K.

<sup>&</sup>lt;sup>1</sup> K. Toman Tuberculosis case-finding and chemotherapy; Questions and answers, page XI, World Health Organization, Geneva. Published by Jaypee Brothers, New Delhi, India

Toman's brilliant book, which is a rare and commendable attempt to explain in lucid terms the concepts underlying DOTS:

"On such occasions, a rather skeptical attitude has sometimes been observed on part of a few persons - mostly specialists - towards the new approach. This small but influential group has a deep-rooted if bona-fide belief in the omnipotence of sophisticated technology. They distrust inexpensive and apparently less-than-perfect procedures that can be used by non-specialized personnel, even though these procedures have proven their worth both in controlled trials and in regular practice."

# Result: TB specialist dubbed the villain & left out deliberately:

While the entire world today increasingly espouses the concept of specialization in every field under the sun, DOTS shuns it. India has the dubious distinction of harboring not only largest number of TB patients for any single country in the world, but also TB experts - a bulk of them serving in the government sector. But curiously, their potential virtually remains untapped. Instead of posting them at key positions, right at the helm of DOTS affairs and entrusting them with running this TB program, they have been deliberately left high and dry. They rot at non-TB assignments, while patients and the program rot at the hands of non-experts. As to why the government has continuously failed for 7 long years to optimally exploit this rich human resource in its kitty, defies logic.

Astonishingly, under DOTS, just like a patient suffering from tuberculosis, a TB expert himself has been made untouchable. Dubbed a skeptic, he stands isolated, completely divorced from the program - just like the fly removed from a pot of milk. Probably his 'rigid' stance, 'unpliable' clinical habits, 'logical' convictions hard to unlearn, his 'inconvenient' queries and 'assertive' recommendations are often embarrassing to the program bosses. Unlearning age-old practices and convictions would take a long time. The impatient top bosses of RNTCP, themselves expert in social, preventive and public health fields, probably also feel threatened that their authority would be eroded. The buzzword echoing in the corridors of power seems to be that 'DOTS is better off without the TB specialist; keep the expert at an arm's length.' The think tank of the nation as well as WHO seem to have thoroughly convinced themselves that a specialist is the villain that would potentially wreck the program - a phobia which has resulted in a unique lack of professionalism in the

<sup>&</sup>lt;sup>1</sup> K. Toman Tuberculosis case-finding and chemotherapy; Questions and answers, page XII, World Health Organization, Geneva. Published by Jaypee Brothers, New Delhi, India

#### program.

It is not by accident but by deliberate design then that during the past several years, most of the top program bosses influencing Indian RNTCP have been anybody but TB experts. People from social and preventive medicine, public health or community medicine have mainly affected the transition from NTP to RNTCP in India e.g.:

- Dr. G. R. Khatri (ex Deputy Director General (TB), Central TB Division, Directorate General of Health Services, New Delhi), during whose tenure DOTS was ushered in across India and the Indian module was essentially finalized, is a specialist (not in TB but) in public health.
- Dr. L. S. Chauhan (currently Deputy Director General (TB), Central TB Division, Directorate General of Health Services, New Delhi) is not a TB specialist.
- Dr. Tom Frieden, (ex TB Chief of WHO for South East Asia Region) under whose tenure DOTS was ushered in across India, and the current module was essentially clinched, is reportedly a world-renowned specialist probably not in TB but - in public health or community medicine.
- **Dr. Reuben Granich**, MD, MPH, Medical Officer Tuberculosis (P), WHO, Regional Office for South East Asia, New Delhi.
- Dr. D.F.Wares MB ChB, MPH, Short-term Professional (TB), WHO, Regional Office for South - East Asia, New Delhi.
- Dr. Suvanand Sahu MBBS (gold medalist), MD PSM from All India Institute of Medical Sciences, currently the key person of the WHO overseeing RNTCP.
- RNTCP consultants: A vast majority of the 100 odd RNTCP consultants inducted so far into the top rung of the national network are not necessarily TB experts (with a few exceptions); most of them are possibly from social and preventive medicine / community medicine / public health or various other non TB streams.
- District TB Officers (DTOs): If we consider the state of Haryana to be an example, there are no selection criteria. Most District TB Officers the key persons that run the program are non-TB experts. In Haryana, only two DTOs happen to be experts Dr. Rohtas Yadav (MD Chest & TB) DTO Narnaul, and Dr. Devasheesh Parashar (Diploma in TB) DTO Gurgaon.
- However, the state of Delhi seems to be a pleasant exception to this rule

and the author's investigations found it to be faring much better.

- MO TUs: Similarly just anyone can be assigned to the post of Medical Officers TB Unit. Most of the MO Tus are thus non-TB doctors.
- The real foot soldiers: A vast majority of the army of doctors manning DOTS in the field at the grass roots level in various dispensaries, PHIs, CHCs are of course plain MBBS or non-TB experts.

Deliberate exclusion of both - radiolography as well as TB specialist - from the menu of a TB program seems very strange; isn't it like trying to cook an omelette without the eggs?

# Working for DOTS - not by choice or self-motivation - but by default:

As DOTS expands; the plain MBBS doctors serving the government suddenly find themselves saddled with additional TB work. But remember, they are into DOTS not by choice or self-motivation but 'by default' - simply because they happened to be serving the govt. at the right place at the right time. The single training of a few hours that they are indeed made to undergo cannot be deemed to be sufficient by any stretch of imagination.

On the one hand, Government of India is ignoring TB specialists who are already well trained, while on the other it is spending exorbitant sums on TB training of plain MBBS doctors, starting from a scratch.

If we leave aside postgraduates of general medicine, surgery and pediatrics, experts of various other streams like psychiatry, eye, ENT, anesthesia, skin, orthopaedics or gynecology hardly study any more TB during their post graduation. So they hardly add on to their undergraduate levels of knowledge of TB. Thus, for all practical purposes, it can be reasonably concluded that they know no better than plain MBBS doctors.

# Absolutely Non-technical operation - TB experts do not even remotely keep a watch over the clinicians at the grass roots level:

All said and done, DOTS is simply a non-technical operation because at the grass roots level not only are the patients being diagnosed and managed by non-TB-specialists, but also the entire clinical aspect of this mammoth operation is being conducted without a semblance of supervision by TB experts who, it appears, have been deliberately kept at bay. Even if some experts are there in the program, they are kept far away from patients, busy in

traveling, training, scanning spreadsheets, quarterly reports and computers.

Such large-scale non-technical clinical operation through doctors - who are not even remotely supervised or supported by experts - fosters wrong diagnosis, under- diagnosis or over-diagnosis especially in sputum negative and extra pulmonary cases. Several non-TB cases could find their way into DOTS registers. Non-experts may be dogged by several erroneous beliefs from the past teaching and the arrangement is fraught with grave danger to human lives and needs immediate addition of supervisory element.

"Whenever my relative is suspected of TB, I take him straight to our medical specialist' and not to my District TB Officer(DTO) or Medical Officer TB Control (MO TC), both of whom I fear are capable of labeling a non-TB case as TB and vice-versa," said a lab technician working for DOTS for 4 years. Coming from an insider, it is a serious indictment of the efficiency of the system. (Note: DTO and MO TC referred to herein were both plain MBBS).

# The visiting card:

In a gathering of doctors, after screening of 'Teen Batein', an award winning 40-minute Hindi documentary on TB produced by the author, a particularly well-dressed middle-aged doctor came up to the author and complemented, "you have included excellent TB X-rays in your film. How did you manage to procure so many of them?"

The author was mighty pleased that someone had at last noticed the prize X-ray collection that he had painstakingly procured. "Over the years, I have retained some X-rays of my ex-patients and late patients; a few films, I borrowed from other doctors for a while but never returned; and some were gifted clandestinely by a generous friend who worked as a radiographer in the local civil hospital."

"So your policy is: beg, borrow or steal?" he laughed good-heartedly.

"Exactly," confessed the author with a smile.

But then he did something strange; he affectionately grabbed the author by the arm and took him to a corner so that no one could overhear. Then he seemed to hesitate for a while. Coming closer and lowering his voice, he said, "if I came over to your place.... of course whenever you have the time.... could you possibly teach me how to read a chest X-ray? .... I didn't pay attention and missed out on X-ray lectures during my college days; anyhow that was 15 years ago."

The author was impressed by his honesty, humility and courage. With

genuine respect he replied, "sure, sir. I would be delighted to. In fact, I have done such sessions with other doctors in the past. Just give me your contact number and let us stay in touch."

"Great. Here's my visiting card." Saying so and handing his card, he politely ushered the author in the direction of the cocktail trolley. As the author carefully put the card in the pocket, the gentleman materialized once again; this time with a 'patiala peg' of Royal Challange for the author.

The author arrived home late that night. Whistling softly, as he emptied his pockets, he noticed the visiting card staring at him. He picked up his golden case, flicked it open, took out his reading spectacles, donned them and curiously looked at the visiting card.

Although it was a very hot summer night, and his senses had been comparatively dulled by alcohol, yet he felt a chill run down his spine as he slowly grasped the implications of what he held in his hand.

Written on the card was:

Dr. FRA (Name withheld).

MBBS.

District TB officer (RNTCP).

After all, tackling TB is not a simple task. It is not the same as tackling polio, malaria or leprosy. Diagnosing cases of TB and treating them for 6 long months is a highly complex process - infinitely more complicated than giving a few drops of polio vaccine to every child, or giving 4 tablets of Chloroquin to every case of fever!

Close supervision by TB experts is a must in this complex program.

(Note: The author has the highest regard for plain MBBS doctors & doesn't mean in any way to disrespect them or belittle their immense contribution; they are virtually the linchpin of health care in rural India. Besides, universities can merely give degrees and not brains or dedication.)

# Profile of an average doctor manning DOTS in India:

TB has always been one of the most neglected fields in medicine. After completing graduation, the author never wanted to take it up for life. But having failed to qualify for PG in general medicine, paediatrics, Eye or orthopaedics - the streams in vogue in mid-seventies - he was left to choose one of the two options: either remain a plain MBBS (a graduate) for the rest of the life, (which, the seniors warned, would be like a stigma in the world scurrying towards super specialization) or else grab whatever is being

offered in the name of post graduation, even if it was a one year unpaid, unpopular PG diploma in TB that nobody wanted. He took the latter option.

In medical colleges, TB is generally accorded a low priority because young doctors today are well aware that it is a disease of the poorest of the poor and medical practice in the subject is hardly lucrative. If you disagree, just take the trouble and dial her mobile number and broach the topic with the author's wife.

Besides, the moment you decide to pursue specialization in TB, it is virtually good-bye to the universal dream of migrating to USA, UK, Australia or New Zeland since the disease has evaporated from there. No wonder, while there is a virtual scramble for postgraduate courses in lucrative fields like radio diagnosis and cardiology today, there are hardly any takers for TB.

Even at the undergraduate levels, of the vast syllabi a budding doctor is supposed to gobble up during his medical studies, TB happens to be just one more passing subject, meriting just a few lectures - a drop in the ocean. Final professional of MBBS has 4 main subjects; surgery, medicine, gynaecobstetrics and eye-ENT. General medicine is itself a vast subject. What's more, it has further 4 sub-subjects attached to it like appendages: paediatrics, skin, psychiatry and chest & TB. Obviously, TB does not enjoy the status of a full-fledged subject meriting a separate exam.

Dr. Balvesh Khanna MBBS pointed out that, "most text books by authors from the West (where TB is no more a big issue) hardly do justice to it. Davidson's Principles and Practices of Medicine edited by John Macleod (14th edition) has devoted barely 10 of its total 843 pages to Pulmonary TB".

Given such a backdrop, would it not be reasonable to infer then that an average doctor who is a plain MBBS graduate cannot be deemed by any stretch of imagination to be a master of TB? And who constitute the enormous brigade of government doctors manning DOTS in India? Of course, majority are plain MBBS doctors who had studied TB but probably only half-heartedly and that too several years in the past. They might have since forgotten most of the material they had learnt then.

# No systematic pressure on doctors to keep knowledge up-to-date:

In developed nations, the general competitive environment is quite conducive to progressive learning. There, a doctor could be sued for anything, even for failing to give his patient the benefit of a research clinched yesterday. Fear of litigation keeps a doctor on his toes. Insurance companies too keep him on a tight leash, driving him to perform better and better.

In India, updating your knowledge is a matter of personal preference.

Some doctors are driven by competition, some by ambition. Others are obsessed with perfection or earning more money. Some slog for name and fame. But the system itself hardly exerts any systematic pressure on doctors to excel. There is no compulsion or incentive to read books & journals & keep abreast of the latest developments. The laxity is more rampant in the govt. sector, which has so far managed to remain outside the ambit of Consumer Protection Act. And besides, one ends up getting the same salary anyway.

# There is no pressure exerted on doctors by the innocent public:

Deeply religious and God-fearing, the Indian society continues to be dogged by popular beliefs such as exact number of breaths allotted to a living creature are predestined, date and time of death is 'written', the matter of life and death is in the hands of God alone. How can anyone in his right senses ever blame the saintly figure of a doctor for causing due to negligence as natural a thing as death?

Masses still stay besieged by the saga of consumption from the past era that death from TB is inevitable. Once a person comes down with TB, he must die, sooner or later. A poorly performing NTP over the past 4 decades has failed to stem the tide of TB deaths, thus perpetuating such convictions. Education is shamefully non-existent. So when the 'inevitable' does happen and the patient dies, no one questions it. It shocks no one. Rather it often brings in a sense of relief that the waiting is over and a liability gone.

Complacence among doctors is rampant. All that The Medical council of India (MCI), the licensing authority and the watchdog of medical profession, can boast of having accomplished since independence is to churn out some printed papers. Curiously, once a doctor registers with MCI, he hardly ever hears from it. The author has never heard from MCI ever since he registered with it some 28 years ago!

# Continued medical education (CME) of doctors in India:

Faridabad city situated on the outskirts of Delhi is home to about 500 qualified doctors. They have formed several vibrant organizations like Indian Medical Association, Physicians' Forum, Indian Association of Pediatricians and Gynecological society etc. There is a flurry of educative activity going on. Every fortnight there is some educative event or the other taking place. Super specialists of various streams are invited and through wonderful audio-visual lectures they update the local fraternity. Such sessions are highly educative and help propel the medical science vertically upwards - towards excellence.

But curiously, every other lecture seems to be focused directly or indirectly on cardiology (mainly angiography and angioplasty), currently the

hottest topic, probably because the offers of sponsorship galore. There is a virtual invasion of the city by the highly competitive public relation departments of neighboring institutes - Indraprastha Apollo Hospitals, Escort Medical Center, Metro Heart Institute, Escort Heart Institute, Batra hospitals, Max hospital and several other heart centers. These multi-star corporate hospitals along with some companies (producing medicines or devices related to heart) seem ever eager to sponsor these events that provide ample publicity and which are invariably followed by cocktails and dinner.

In return, they strictly dictate their own agenda of topics. Being profit oriented, their aim is to aggressively market their own specialists. They literally vie with one another for a chance to impress the jam-packed audience of city practitioners, hoping to rope in a few referrals. A single case referred for angioplasty in return means recovery of the entire sponsorship cost.

Who is interested in dry, non-productive subjects like TB, Malaria, filariasis, anaemia? Where to find someone willing to sponsor a session in such style? And how many doctors will show up if invited to a drab afternoon session over a cup of tea & biscuits? Despite significant amount of wonderful medical interaction, updates on TB, Malaria or other common man's ailments is negligible to nil. Is the scenario any different in other parts of the country?

**Dr. A.K.Kundu MD, FICA, President of IMA & Physician's Forum,** an excellent orator & organizer justified the aproach, saying, "cardiology today is pulsating with excitement. Something new is happening virtually everyday; a new drug, an investigation, a procedure, an equipment or a study. In TB, nothing has happened; the same 5 drugs and a few tests. Despite there being 14 million TB patients in India, all that's been invented in the past 3 decades is watch your patient's larynx while he swallows drugs! What's the point in holding lectures when there's nothing new to report to the medical fraternity?"

# 10

# TB God of a district: The District TB Officer (DTO)

Under the design of DOTS, a district TB officer is the epicenter of all action; everything revolves around him. He is the champion of all issues relating to TB control and its eradication. For the entire population of his district, he is like TB God. So as to enable him to discharge the onerous duties efficiently, he reportedly is accorded priority for all kinds of premium training programs.

District Faridabad is home to about 22 lacs population. It has an intricate network of DOTS, which broadly stands sub-divided into 4 TB Units (1 TU per 5 lac people), 19 microscopic centers (1 MC per 1 lac people) and hundreds of DOTS outlets littered all over the vast expanse of district. It is the District TB Officer(DTO) who is responsible for efficient and smooth functioning of this entire network. He is stationed at the centrally located TU housed in the premises of the local civil hospital. Across the length and breadth of the area under his jurisdiction, every doctor looks up to him for guidance in case he faces any problem - be it diagnostic, curative, administrative or logistical in nature.

#### **Duties of the DTO Faridabad:**

- Clinical work: personally manning an extremely busy TB Unit. He is considered to be trained to diagnose, categorize, treat and manage all sorts of eventualities that might occur in TB patients.
- He is expected to personally visit and supervise the other 3 TB Units, 19
  microscopic centers and scores of sub-centers which serve as DOTS
  outlets; he can barely cope up with it even if travels as many as 22 times in
  a month.
- To hold weekly meetings of LTs, STLSs, TB HVs, STSs, pharmacists, health workers and various other employees and sort out their difficulties or grievances, and motivate them towards target-achievement.
- To organize periodic meetings of the district TB society, of which he is the member secretary.

 To ensure timely and correct compilation of the quarterly reports of DOTS and to see to it that these are e-mailed to the state head quarters, DDG TB and the WHO, where these will be fed into the overall national data.

#### Catch-22:

On around 20.04.2003, when Dr. Mrs. Dhiman, the district malaria officer, was transferred away from the city, DTO Faridabad was assigned an additional charge of malaria department. What descended as a stopgap arrangement for a few days went on and on for several months as no one was sent as a replacement. One can imagine the enormous implications of such a precarious arrangement for thousands of patients suffering from either of the two diseases (malaria as well as TB), especially during the period from July to September 2003, the peak malaria and dengue season.

Furthermore, in his capacity as District Malaria Officer he was officially prevented from discharging DOTS work from time to time. He was sent away to National Institute of Communicable Diseases, 22 - Sham Nath Marg, Delhi for a week from 27.07.2003 to 02.08.2003, purportedly for receiving yet another non-DOTS training.

If the DTO works for malaria, it is at the cost of TB and vice versa; virtually a catch-22 situation; a mess created not by DTO himself but by the government.

Managing the immunization of the entire population of children in the district is the most important but onerous responsibility of the **District Immunization Officer** (DIO) has the onerous responsibility of . Pulse polio event is especially busy time for him as he has to do an awful lot - to oversee the arrangements of the administration for advertisement of the approaching day, to meticulously plan and oversee logistics of this mammoth exercise, to make a blue print of all the possible centers, to arrange transport, to manage finances for the taxis to be hired, to ensure smooth and timely vaccine distribution to each of the scores of mobile teams, to coordinate the effort with Rotary clubs and private nursing homes etc. For at least a month DIO has virtually no time for anything else - not even for his family.

In early May 2004, when Dr. Chakkar Pal, the District Immunization Officer Faridabad, proceeded on a long leave, guess who was saddled additionally with this high pressure work of managing the pulse polio week falling from May 22 to May 26, 2004?

Of cours, e our friend, the District TB Officer! For a month he was virtually out on a spin - for polio work, TB obviously forgotten.

DTO Faridabad is also in-charge of **Leprosy Control Program** of the district. He was sent away to Delhi for 2 days i.e. on or around Oct.13 to 14, 2003 in the name of an important meeting in connection with the subject of leprosy.

DTO Faridabad was assigned additional supervisory duties at **'Trade Festival 03'** from Oct. 3 to 12, 2003; the order virtually meant that he was supposed to dump DOTS work and drive down 10 km each day to the picturesque venue of Suraj kund, which was hosting a trade festival, yet another non-DOTS rendezvous lasting about 2 weeks.

From time to time, DTO is made in-charge of a Community Health Center (CHC) as well.

# A tourist guide:

Every time an RNTCP consultant or anyone from Central TB Division or WHO sets foot on his territory, it is customary for the local DTO to ferry him around like a tourist guide. It is a wasteful tradition; several experts moving together to inspect one microscopy center. Why? They could cover double the centers if each one went alone - sheer wastage of precious manpower.

#### The HQ factor:

He has to frequently (almost once a month) visit the state capital, Chandigarh / Panchkula on one pretext or the other - for some 'important' meeting, for submitting progress report of DOTS, or for some non-DOTS assignment. Besides hampering his important clinical work with patients, these frequent junkets on Shatabadi express or a taxi cost the exchequer a fortune.

A program officer cum Senior Medical Officer (SMO) shared this with the author recently: "Last time around, I woke up at 4 AM, began my journey at 5 AM from Faridabad, drove for 5 hours and was in the boss's office in Chandigarh (Panchkula) at 10.30 sharp. I was free at 10.35 to go back to Faridabad. My boss could spare only 5 minutes for the 'very important' meeting as 'he himself had been summoned by the big boss'. Like me, 7 other SMOs who had driven down and arrived from other districts of Haryana too left dejected, without doing anything at all. Sheer wastage of work force and resources! It is virtually dictatorship out there and no accountability."

By virtue of being a program officer, a DTO is the right hand man of the Chief Medical Officer(CMO) of the district and remains vaguely involved with every other government program; and there are about 18 of them that go on and on.

The Chief Medical Officer might, from time to time, pour in to his lap

multitude of duties; for example to conduct an enquiry pending against a private doctor or a chemist or some government employee of the district.

Being a senior member of the overall medical team of the district, he is often required to visit a **health camp** organized somewhere in the far flung rural area of the district.

Like other government doctors, he too confronts routine **post-mortem** work. As a follow up, he is duty bound to furnish evidence as an expert medical witness in the **court of law** on specified 'dates', whenever summoned.

He is often ordered to attend officially a **religious fair**, **cultural festival**, **trade fair**, **a social**, **political or a sports event**.

He also gets his share of routine duties relating to medical store, pharmacy or purchase committee.

Just like every other government doctor, he too is open to being assigned numerous other non-DOTS assignments like - flood duties, riot duties, disaster management, election duties, accompanying a demolition squad of the administration, police teams visiting a volatile flash point e.g. venue of employees' strike etc.

#### This is the 18th piece of baggage:

Every health employee - be it DTO, MO TU, any doctor in PHC, CHC, LT, STS, STLS, MPW, LHV or any other health worker - is vaguely sharing the burden of every single of the 18 national programs. It is a mess. The claim that each one is responsible for every program ultimately means that no one is responsible for any program.

Embarking indiscriminately on more and more programs has proved counter productive - leaving the meager healthcare system cluttered; DOTS is clearly failing to receive the top priority it deserves.

It is not uncommon for doctors in the periphery to look upon DOTS as yet another headache slapped thoughtlessly from above. There is a degree of pessimism in the air; most workers suspect that DOTS too will go on and on like a soap opera without making a difference - just as is the case with malaria, leprosy, blindness, family welfare and school health programs etc.

#### List of national programs:

- National Malaria Control Program (NMEP).
- National Leprosy Control Program.

- Reproductive Child Health (RCH) Program.
- Immunization Program.
- School Health Program.
- Blindness Control Program.
- Polio Eradication Program.
- Family Planning Program.
- Safe Motherhood and Child Health Program.
- MSS.
- Antenatal clinics.
- Post-partum Center.
- AIDS Control Program.
- Maternal and Child Health Services.
- Vande Matram Program (regarding antenatal care).
- Swasthya Apke Dwar (health at your doorstep) Program.
- PNDT (Pre-natal sex-detection test).
- Goitre Control Program.
- Revised National Tuberculosis Program (RNTCP).

#### VIP duty:

A DTO is not exempt from being drafted for VIP duty whereby a team of doctors is ordered at short notice (prior intimation might compromise security) to drop routine work, hop into an ambulance grabbing an assortment of emergency drugs, surgical drums, splints, blood units and an Oxygen cylinder (even if that's the only one 'full' in the civil hospital), and await a VIP, receive him, shadow him around - as long as he chooses to remain within the district (sometimes a day or two even) and then see him off.

Whenever the governor or the chief minister of any state (be it Haryana, Punjab, Himachal Pradesh etc.) travels down to nation's capital Delhi by GT road, he happens to pass through 5 districts of Haryana - Ambala, Kurukhetra, Karnal, Panipat and Sonipat. District administration of each of these 5 districts is supposed to provide him a medical umbrella right from point of entry to exit: **the 5 medical teams virtually playing a relay race.** 

"A physician, a surgeon (and sometimes an orthopedic surgeon and an anesthetist too), an LT, a pharmacist and the driver, packed tightly like sardines, in a small Maruti ambulance wait at entry point to begin the chase" lamented a doctor from Karnal. "Our old, poorly maintained and wobbly ambulance running full throttle at 80 Km an hour is no match to the Mercedes cruising at 120. We barely reach Gharounda (half way point) when the police picket signals to us that the wireless message has confirmed that the royal entourage has already crossed over in to Panipat jurisdiction. We return."

In India, where we barely have 1 qualified doctor per 2000 people, to disturb him from his busy routine work due to such hypothetical 'sarkari' reasons is no less than a crime against humanity. Continuation of such a wasteful protocol into 2005 is a shameful blot on our democracy.

Remember, in the rare event of an actual mishap, the VIP is likely to be hustled away in one of the cars in the accompanying fleet or a helicopter, straight to one of the prestigious hospitals in Delhi like Indra Prastha Apollo or All India Institute of Medical Sciences or PGI Chandigarh. Can you realistically expect a VIP to consign himself to a general civil hospital meant for the masses and which is no match to the state of the art corporate hospitals to which every VIP has ready access?

#### DTO is always on the move, he can hardly sit peacefully & see patients:

The list of DTOs duties is virtually never ending. No wonder the poor chap is perpetually running around breathlessly. He is always on the move, to Chandigarh, to Delhi or to a remote village of the district; imparting training or receiving training; conducting inspections or being inspected; court cases or all kinds of odd jobs unconcerned with DOTS. Bulk of his time and energy is consumed by non-DOTS work. And why not? First and foremost, he is a govt. doctor, then a Senior Medical Officer, then a program officer, then a trouble shooter for the state government, and last of all a DTO! Obviously, he can't be present at two places at the same time. A DTO virtually ends up spending less time in his doctor's chair at his TU than in the seat of his jeep. What he rarely gets to do is what he can do best - dsiagnosing and categorizing TB patients. As a result of this arrangement, patients of his own TU suffer for want of a senior trained doctor, casting a shadow right under the very source of light. Quite often the situation is so pathetic that in his unavoidable absence, the all-important job of examining patients, categorizing them and clinically monitoring their progress suffers. The patients are practically managed by just anyone - a lab technician, a pharmacist or even a health worker therein.

Or rarely, as happens at a few places including Faridabad, the clinical work is relegated to a junior doctor called MOTC (Medical Officer TB Control) recruited on an ad hoc basis for a year specifically to do the clinical work at TB Unit at a pay of Rs. 15,000/- per month.

A career-oriented doctor is hardly interested in such an ambiguous, insecure and temporary job. Only a young fresher or an unemployed doctor would come forward to accept it, and that too as a stopgap arrangement, till he finds a better placement or a seat in post graduation. MOTC receives special training. Ironically, by the time he or she begins to grasp the intricacies of TB treatment and DOTS program, the year is over and it is time to say good-bye, paving way for the next candidate, often a raw hand who needs to undergo the drill of training about the nitty-gritty of TB.

"In the wide spectrum of my duties, DOTS happens to be just that - a tiny dot" confessed an MO TU, saddled with a multitude of duties unconnected with DOTS. He gets his share of burden from other programs too. Often he is even supposed to take turns at night shifts just like any other doctor posted in the CHC.

He is junior to and at the mercy of the SMO in-charge of the respective CHC and the CMO, both of whom can push him around at will and make him do just anything and everything 'in public interest.' They can even at the drop of a hat strip him of the very charge of TB.

"Civil surgeon pushes me for family planning targets and for malaria work. In 2003, during dengue scare, I was made to physically sit in the 'fogging vehicle' and roam around the streets of the city of Faridabad every morning. Now as the parliamentary elections draw near, during the summer of 2004, we are bracing ourselves for the populist program called Swasthya Apke Dwar and a spate of rural health camps. I am really fed up; where is the time for DOTS?" he lamented.

#### No selection criteria for the post of District TB Officer:

During 2002 to 2005, in Faridabad, there was no dearth of TB experts (2 in ESI hospital NH3 & 1 in ESI hospital sector 8) or Medicine experts (at least 6 doctors having a degree of MD). Yet, a non-expert & a plain MBBS doctor remained appointed at the key post of District TB officer.

In his entire 3 year long painstaking investigation, the author was surprised to find - over & over again - how exceptionally honest, deeply religious, God-fearing, kind-hearted to patients & hard-working this gentleman (the DTO) is - just the kind you wish every govt servant to

#### be like - so as to realize the dream of 'Ram Rajya' (God's nation).

But alas, he is not an expert on TB and is just a puppet in the hands of an indifferent system and insensitive bosses, having little respect for DOTS.

#### A strange dichotomy:

When it comes to recruiting RNTCP consultants there are elaborate and crisp selection criteria & an exhaustive rigmarole. In 2004, hundreds of applications were invited and received from doctors through nationwide ads. These were then meticulously screened. Numerous candidates were invited for preliminary interviews. Some 160 odd candidates were short-listed, followed by the drill of final interviews to zero in on to the 'best' 50 to be finally selected.

On the other hand, when it comes to appointing DTOs, MO TUs, and all of those other doctors who are to perform the real day to day work with patients at the grass roots level, any Tom, Dick and Harry can effortlessly get in to the driving seat; there exist absolutely no prerequisites, preconditions or qualifications. Any doctor with the right political connections can get himself appointed as DTO or MO TU in a jiffy; even if his past record is screaming that he is corrupt, incompetent, inefficient, disinterested, rude to patients or known to concoct data. Will such a political appointee work? Will he listen to the chief medical officer or the State TB Officer?

#### Part time work:

A DTO, being the TB chief of the district, is the one responsible for protecting some 22 lacs people from the dreadful malady, and yet, thanks to the multitude of nonsensical duties he remains saddled with, through sheer lack of govt. commitment, the poor chap ends up working merely part time for TB.

#### **Dual charge:**

Dr. PRK, a DTO, said ,"I am SMO number 2 in my 100 bedded hospital. A variety of hospital issues - relating to patients, drugs, consumables, dutyrosters of staff, meetings, OPDs, indoor and numerous administrative problems - consume all my day. DTO is my additional charge since 2 years, ever since our district was included in DOTS. Instead of the 20 times that a DTO is expected, I barely get to visit my Microscopy Centers & DOTS centers twice in a month and that too whenever the WHO consultant comes visiting. Wherever it is dual charge - and that's exactly the case in all the newly covered districts of Haryana - DOTS gets a low priority and the bosses know this."

"And what about data? Those exhaustive performas the WHO claims to have recently 'further revised & improved' and which a DTO is supposed to fill in great details up on each visit?" asked the author.

He said, "Once the CMO is with me, filling up data is hardly any problem. You see, I am simply helpless."

How can the author believe in the tall claims of the govt and not this fellow, when he happens to be his batch-mate as well as a friend - ever since they shared those 5 years in the medical collage, Rohtak, some 30 years ago?

#### Who is in real terms presiding over this entire program?

On the one hand, WHO states that TB is a global emergency. On the other hand, it continues to silently preside over such an indifferent, half-hearted, callous and casual approach! Is the awesome task of TB eradication just a part time job? Is this the way to deal with human beings caught between life and death? Is it some kind of a sick joke?

#### Recommendation No. 2

### Create an 'Exclusive TB Constituency' within the general health care network:

Every employee working in TB from top to bottom - DTO, MO TU, LT, STLS, STS - shall perform TB related work exclusively and nothing else. Each one will be exempt from non-DOTS work, at least for the next 5 years to begin with. CMOs and other high officials can no longer depute them to non-DOTS errands as per their own whims and fancies, reducing them to mere stupneys.

#### Strengthen STDC:

It is imperative that the STDC (State Training and Demonstration Cell) is systematically strengthened so that it enjoys adequate powers within the states. Only then can the elements of management, supervision, monitoring and training - so crucial to program success - can be optimally sustained.

#### Strengthen the TB units, the pillars on which the program rests:

Failure of the govt for a decade to have passed simple orders correcting this major anomaly, questions its very commitment. Remember, political will is the first of 5 fundamental requirements for DOTS.

What should have originally been included, as preconditions, before

disbursal of grants to the states, ought to be corrected now - without any further delay. Orders must immediately be passed to the effect that:

- A DTO is hereby exempt from all duties and responsibilities that do not concern DOTS unless of course there is a national calamity.
- Similarly, MOTU too is exempt from needless non-DOTS workload.

**Minimum qualification** for the posts of DTO and MOTC (MOTU) ought to be fixed as follows:

- MD (Chest & TB),
- MD (Medicine),
- Diploma (Chest & TB).

Diagnosis and category of every patient registered with DOTS, ought to be cross checked and certified by a TB specialist, a Medicine specialist, a DTO or an MO TU:

DOTS has rendered the time tested clinical arts like history taking, inspection, palpation, percussion, auscultation and even X-ray reading virtually redundant. The **'no-touch-technique'** it promotes, not only fuels social stigma but also fosters wrong diagnosis, since the system lacks in-built checks and balances. There is virtually no back up of sophisticated tests, which, in case of a lapse, can sound warning bells and help timely correction.

It is a risky scenario whereby:

- A single doctor can & often does label the patient with TB, assign a category and start treatment - with absolutely no peer-review at all.
- Besides, a single test (namely sputum) is the hallmark of Indian DOTS.

#### 3 crucial milestones in a patient's journey under DOTS:

It is imperative that the design be modified to ensure that before treatment begins, more than one doctor, and that includes at least one TB expert (or an MD medicine), systematically screen every patient. Each patient must be made to pass through a **foolproof multi-tiered system of physicians** whereby **lapses done by one stand corrected by another.** And vice versa.

#### Ideally a TB specialist, an MD medicine, DTO or MO TU must:

- Reconfirm the diagnosis of each patient.
- Certify the category allotted to each patient.
- Certify that a patient has indeed improved sufficiently at the end of second month of treatment, so as to be safely shifted on to CP (continuation phase).
- Certify after 6 (or 8) months that the patient has been fully cured and that treatment may be stopped.

Furthermore, the state govt. must be made to give **an undertaking** that all TB specialists on its rolls (engaged in non-DOTS work) will be meaningfully roped in for key DOTS assignments, unless there are some serious contraindications in the past record of someone.

#### Once a DTO always a DTO (at least for the next 5 years):

A DTO must first be carefully selected, then trained and thereafter retained with the program. He ought to be transferred only as a DTO of another zone. Otherwise, our country stands to lose since it means sheer wastage of training resources and an injudicious transfer would only produce yet another 'jack of all trades, master of none.'

The same is true of the post of MOTU.

All transfers / postings of DTOs, MO TUs, and other doctors on the forefront of DOTS must not remain in the exclusive domain of the state machinery that, if we go by the past, is likely to operate casually or arbitrarily at the local level. Such decisions ought to be studiously examined by some central nodal agency constituted by Govt of India and WHO as well.

#### Not just doctors but other DOTS workers must work exclusively for TB:

In Delhi, a TB health visitor has been recruited on contract purely for TB work. In contrast, in Haryana, the corresponding person is entangled in 18 different programs; the former is certainly a more effective arrangement than the latter and must be emulated wherever possible.

Similarly, an LT, STLS, STS etc must be earmarked exclusively for TB work in every TU and microscopy center.

#### For God's sake leave govt doctors alone; let them perform clinical work:

We barely have 1 qualified doctor for 2000 Indians. The fundamental job of a doctor is to treat patients. Thoughtless orders displacing him from his chair and disrupting his clinical rythm are morally and ethically wrong.

A good doctor is the one who stays put on his seat and is available rather than a more qualified one who remains absent. In the purported name of an administrative chore, an enquiry, an inspection, training or a meeting, it is often the bosses themselves who uproot a doctor from his seat, disrupting clinical work during peak-patient-hours. Hence the ques get longer & longer.

A doctor in Faridabad complained helplessly sometime in April 2004, "the other day, all of a sudden an order came from the DC's office. Most of the doctors were supposed to rush immediately for training on 'how to operate the modern electronic voting machines.' While the corridors of the hospital were brimming with patients, doctors' chairs were empty. It was a chaotic sight."

Such non-clinical work, however important, ought to be done only after peak working hours, by which time most patients have been disposed off.

Abolish the ancient protocol of VIP duty for govt doctors, which is nothing but humiliation of the public & mockery of human rights.

### 11

#### Criminal mismanagement of the human resource

#### The transfer policy - a major headache for DOTS:

Around April 2000, RNTCP was initially launched in three districts of Haryana in its first phase. Thereafter, no more coverage took place for the next 3 years. In these 3 'covered' districts a significant proportion of doctors were reportedly imparted DOTS training. But, side-by-side, during 2000to 2003, several of the 'trained' doctors had been routinely albeit indiscriminately transferred away - to districts not yet 'covered' by DOTS. They were replaced with untrained ones from there.

A senior medical officer posted at the periphery lamented, "thanks to the reckless transfer policy, at any given time during these 3 years, the ratio of trained v/s untrained doctors remained as bad as 50:50. Similarly, bulk of LTs, pharmacists and other staff at the forefront of DOTS is often untrained. Transfers are silently posing enormous nuisance for DOTS; the concept of multipurpose workers can only be successful if once trained they are left undisturbed at a center to work with the program,"

#### A thriving industry:

The author suspects that there is virtually no transfer policy in states. Just as the word of the king was the policy in the medieval times, employees are shuttled arbitrarily as per the whims and fancies of the politicians today. Only that the kings these days are called ministers. While affecting a transfer, parameters like merit and performance of the candidate are never considered. The ritual of maintaining ACRs (annual confidential reports) is a sham. Even promotions go strictly by years the man has put in.

As far as the government of Haryana is concerned, it recognizes only 3 types of doctors: medical officers, senior medical officers and chief medical officers. It simply refuses to take any cognizance of their expertise or stream or specialization in the field of medicine. It is a classic example of how by the sheer efflux of years an ass is supposed to become a horse. As such, India's

politicians and bureaucrats are infested with too much power; they are at liberty to exercise it at times for benefits in cash or in kind, or for votes, or for sadistic pleasures; caste and kinship reign supreme, nepotism is the basis for distribution of patronage. If we had a firmand rational national policy in place, how could politicians oblige their lobbies.

#### Therefore it is a policy not to have a policy.

Since no doctor wants to be posted to a rural area, it is virtually a constant tug of war where might is right. Come March - April, the transfer activities hot up. This is often the 'season' for the clerical staff handling files at the HQ. Through their touts strategically placed in the periphery and in constant touch through telephone, they can generate a handsome remuneration for their manoevres. At least under some incompetent ministers and secretaries, transferbusiness virtually becomes a thriving industry.

Result?

Total chaos reigns in the health care system, of which DOTS is an integral part.

Every one the author talked to admits privately (of course off the record) that once trained, a DTO and an MO TU who is performing well ought not to be disturbed for 3 or even more years at a station. And he must move on to the post of a DTO or MO TU only.

But there are wheels within wheels. Under the constitution of India, 'health' is a state subject. WHO, Central govt. or DDG TB, who have conceived the program, have little control over the murky transfer business, which falls in the domain of local politicians and bureaucrats. That obtains a peculiar situation!

Can the ministry of Railways after modernizing its trains and tracks, afford to surrender one aspect of its operation to the ministry of surface transport-the management of its 'engine drivers'?

#### Several out of sight medical crimes ongoing in some govt hospitals:

"Scientific advances have brought about sweeping changes in most medical branches. However, the most dramatic transformation has probably come about in the field of anesthaesia. Newer drugs and gases have appeared on the horizon - nitrous oxide, volatile anesthetics like halothane, enflurane, drugs that could cause sedation, analgesia and anaesthesia, as well as muscle relaxants.

"Gone are the days when a stethoscope and blood pressure apparatus were all that we had for monitoring the patient sleeping naked on the cold operating table with his tummy cut open and blood pouring out and for whom it is virtually touch and go. A whole gamut of machines and cords have been invented now to monitor the functions of heart, brain, kidneys and lungs etc on a continuous basis, enhancing patient-safety".

"Anesthetists are further super-specializing now a days - for complex and difficult operations - like open-heart surgery, kidney transplant, cancer operations and pediatric surgeries etc. Today, to even think of a surgery- any surgery - being conducted without the watchful gaze of a skillful & qualified anesthetist is no less than a medical crime."

(Dr. Anita Sood, MD Anaesthesia, Nagpur, Maharashtra)

Alas, unknown to the public that is exactly what goes on in several govt. hospitals today - due to thoughtless reshuffling of anesthetists.

#### No anesthetist in ESI Hospital sector 8 Faridabad:

It is a busy 50-bedded referral hospital with 24-hour emergency services. The lone anesthetist, Dr. N. K. Bansal had to work efficiently and overtime to cope up with 2 general surgeons, 1 orthopedic surgeon, 2 gynecologists, who were entirely dependant upon him for all their surgeries. He was virtually the fulcrum of the operation theater pulsating with activity.

One fine day in Nov. 2000, he was given the marching orders. He was sent to a very small rural center, Bhoda Kalan (Distt. Gurgaon), where his anesthesia skills were sure to rust since there was no operation theatre worth its name. Worse, a suitable replacement was not immediately forthcoming in the ESI hospital. Cases wait-listed for surgery, some in queue for several months, suffered indefinite postponement or outright cancellation; a few life saving emergency surgeries were indeed carried out; the exasperated surgeon resorting to administering spinal anesthesia himself with a nurse promising to keep vigil over the vitals!

However, Dr. Mukheeja, though not having done DA or MD in anesthesia, good-naturedly came forward to help at least in some selective surgeries, which didn't need general anesthesia. Furthermore, for some 'VIP' surgeries, a qualified anesthetist would be specially called in from ESI hospital, NH 3 NIT, which is 5 kilometers away and is well endowed with 3 qualified anesthetists. As the paragraph is being written on June 1, 2004,

sheer ad hocism, which seemed to have descended over the operation theatre merely for a few days, lingers on.

It is roughly 4 years now!

In the meanwhile, the hospital saw several managers (Medical Superintendents) who came and went. No one had the courage to raise the issue with the higher authorities beyond certain 'limits of decency'. On 22<sup>nd</sup> Oct. 2004, the author found that there was no general surgeon, no orthopedic surgeon, and no radiologist. There were only 8 nurses to look after 50 inpatients and the ultrasound machine was perpetually out of order. What to talk of accountability, no insider can dare question even such blatant irregularities because whistle-blowers attract severe and sure punishment.

#### Through proper channel:

In India, voice of a govt employee is systematically and deliberately stifled through bureaucratic terror. A govt doctor is not permitted to write a suggestion or a complaint directly to the District Collector, Director General, Secretary, Commissioner, Health Minister, Chief Minister or the Prime Minister. He is required to write and proceed 'through proper channel' only (which means to his immediate boss or the civil surgeon) who would either snub him or at best sit over the report and that would be the end of the story. It is preposterous. The govt servants must immediately be liberated from such suffocating and strangulating tradition, which is the biggest barrier to improvement in our democracy.

It is just one of the numerous instances of how an innocuous looking transfer order passed at the HQ could unfold devastating implications in a farflung hospital, endangering lives.

#### The saga of mismanagement goes on and on:

The top govt officials are virtually making a mockery of the very concept of post graduation in allopathic medicine. It requires another book, much bigger than this one, to cover the details of such mismanagement. However, the author can not help but mention some of the glaring anomalies so apparent that even blind can observe:

- The 2 general surgeons, 1 orthopaedic surgeon and a gynecologist in the 50 bedded, overcrowded Mukand Lal general hospital Yamuna Nagar are resigned to conducting all operations without a qualified anesthetist.
- 100-bedded Civil Hospital Panipat similarly doesn't have an anesthetist

of its own; the one working in the neighboring 50-bedded ESI hospital would visit off and on.

While there is desperate shortage of anesthetists, thus endangering lives in various operation theaters of Haryana, several specialists in the field are made to fritter their expertise doing administrative or alien work, which can be assigned to anyone:

- Dr. Sushma Madan (anesthetist) works as the Director Health Services Haryana.
- Dr. Mrs. Veena Chugh (anesthetist) works as a civil surgeon.
- Dr. Ramesh Chand Mittal (anesthetist) is the District Training Officer, Kaithal.
- Dr. Hazari Lal (MD Anaesthesia) is the District TB Officer Kaithal.
- Dr. Navdeep Singal (MD Anaesthesia) is reportedly completely demoralized serving in the casualty and general OPD of government hospital Ballabgarh.
- Dr. Aparajita (DA) is the District School Health Officer, Ambala.

#### Scarcity of General Surgeons in government hospitals:

It is well known that there is excruciating scarcity of General Surgeons in govt hospitals. There are long, never-ending waiting lists in operation theatres and seriously ill people risk fatal complications on account of delays. As a result, poorest of the poor are forced to turn to private nursing homes for common emergencies like acute appendicitis, cholecystitis etc. As a result, they have to sell off their belongings - land, hutment or animal - to raise the money to clear the bills. As a result, they often end up in perpetual debt for years to come.

On the other hand, all that several accomplished surgeons of the government do with their golden fingers is: 'turning the pages of files and writing administrative reports':

Dr. Neel Kanth Sharma MS General Surgery is among the most dedicated, brilliant and experienced surgeons having virtually spent a lifetime inside operation theatres of Haryana. Wherever he has been posted (including Faridabad where the author personally kept a watch over his performance in fascination), his reputation has preceded him. Public has flocked him - and with good reason. He has to his credit plethora of life-saving surgeries. Alas, there are no 'lifetime achievement awards' for great people like him in the govt service. 'Enter OT just after sunrise and emerge around sunset' that's what his entire life has been like... till recently - when suddenly everything changed. A fax from the head quarters arrived. His hands with Midas touch were virtually handcuffed by the govt by way of 'promoting' him to the post of Chief Medical Officer, Ambala. Every hour, every day, every week, every month that he is kept away from his missionary surgical work, the nation is impoverished.

- Dr. Avinash Sharma (MS General Surgery) another accomplished surgeon too wastes her immense talents working as Principal Medical Officer, Ambala.
- Dr. Om Parkash Mittal (MS General Surgery) is Chief Medical Officer Karnal.
- Dr. Manohar Singh Dhanoa (MS General Surgery) works as Chief Medical Officer.
- Dr. Satvir Chaudhary (MS General Surgery) is the Chief Medical Officer Panchkula.
- Dr. S.L. Mehra (MS General Surgery) is enduring a non-surgical posting as District Medical Officer, Sonepat.

#### Complete Blindness at the top with regard to medical management:

With prevelance of blindness at 8.5% (as per National Program for Control of Blindness, NCPB presenting vision < 6/60 in the better eye), it is estimated that 3.8 million Indians become blind annually from cataract, its commonest cause. In order to reduce the backlog of cataract blindness and 'operable' cataract, it is necessary to operate each year as many eyes as develop cataract - at least 3000 operations per million population per year or perhaps even more. In such an overwhelming scenario, 'all hands on deck' is imperative. Is the following state of affairsthen in public interest?

- In the entire district of Narnaul there is not a single government eye specialist. The post is lying vacant since a long time and the work of District Blindness Society is suffering.
- Similarly there is no eye specialist in the busy Mukand Lal hospital Yamuna Nagar and several other referral hospitals.

#### On the other hand, eye surgeons are doing non-opthalmology work:

- Dr. Raj Kumar, an eye surgeon, who has been serving with a missionary zeal towards eradication of blindness from our country, having performed over 1000 cataract and 100 glaucoma surgeries, has been virtually barred from pursuing the noble work; he languishes as Malaria cum TB Officer, District Panipat.
- Dr. O.P.Hooda (MS Ophthalmology) works as senior medical officer CHC, Naharpur.
- Dr. Mrs. Neh Lata singh (MS Opthalmology) is the civil surgeon, Panipat.
- Dr. R.C.Chaudhary (DOMS) is the District Health Officer, Sirsa.
- Dr.O.P.Dabas (MS Ophthalmology) is the district Family Welfare Officer, Rewari.
- Dr. Ram Chander Singh (MS Ophthalmology) is rusting as District Malaria officer, Bhiwani.
- Dr. Narender kumar Dhawan an eye specialist is the civil surgeon, Kaithal.
- Dr. D.S.Dhankar (DOMS) is currently the Malaria cum TB officer, Riwari.
- Dr. Ram Niwas Yadav (Diploma Opthalmology) is made to waste his skills working as District School Health Officer, Gurgaon.
- Dr. M.D. Sharma (MS Opthalmology) is working like a general doctor as SMO CHC, Hatheen.
- Dr. R.K.Sharma (Diploma Opthalmology) is currently (as on Nov 6, 2004) wrestling with general work in the Casualty of Ballabgarh civil hospital.

#### latrogenic shortage of MD Medicine doctors:

There are no medicine specialists in several large referral hospitals of Haryana (e.g. Mukand Lal hospital Yamuna Nagar and civil hospital Narnaul) while several talented specialists do administrative or alien work:

- Dr. Ajesh Goel (MD Medicine) is posted in PHC Khizrabad.
- Dr. Narveer Singh (MD Medicine) is the civil surgeon Jind.
- Dr. N.K.Chaudhary (MD Medicine) is helplessly wasting his talents in

non-clinical duties as District Health Officer, Bhiwani.

#### Bone chilling defficiencies:

- There is no govt orthopedic surgeon in in the entire district of Narnaul.
- There is no orthopedic surgeon posted in civil (BK) Hospital, Faridabad.

#### On the other hand:

- Dr. Rajender Singh Dahiya (MS Orthopaedics) is the Chief Medical Officer, Bhiwani.
- Dr. Chakar Pal (Diploma Orthopaedics) is the District Immunization Officer, Faridabad.
- Dr. Shiva Nand (Diploma Orthopaedics) is handling general OPD at CHC, Mulana.
- Dr. Pawan Kumar (Diploma Orthopaedics) is the MO PHC Rasoolpur, District, Yamuna Nagar.

#### Radiologist:

While several radiologists remain misplaced in other streams, there are no radiologists in several referral hospitals in the government sector e.g.:

- The entire district of Narnaul.
- Mukand Lal general hospital Yamuna Nagar.
- ESI hospital sector 8 Faridabad: A patient requiring urgent ultrasound is reffered to NH3 ESI hospital (which is about 5 km away) where he is given 'date after date' (just as in an Indian court). In the end it might take up to 1 month for undergoing as simple a test as an ultrasound!

Besides, in the absence of radiologists, the ultrasound machines therein purchased with a lot of fanfare undergo dis-use atrophy. Can India afford the luxury of such criminal wastage of resources? Alas, there is no accountability.

#### Post mortem blues:

For most doctors post mortem work is an unwelcome headache. Faridabad civil hospital recieves abundance of it - about 40 to 45 postmortems conducted per month - thanks to the heavy traffic on national highway no. 2 that literally

bifurcates the city, and also accident-prone industrial activity. Unable to escape, several duty doctors uncomfortably grapple with the heavy load of post-mortem responsibilities (often delegating part of the dirty work to a class 4 employee). On the other hand:

- Dr. S. Sharma (MD Forensic medicine) and a master in the art of post mortem, is made to waste his rare talents and expertise managing skin OPD in the neighbouring ESI hospital NH 3, NIT Faridabad (June, 2004).
- Similarly Dr. Pankaj Vats (MD Forensic Medicine) has spent a lifetime being posted in every other department except where he belongs; currently he is the senior medical officer CHC, Nuh, Gurgaon.

#### **Child specialists:**

While there is desperate shortage of paediatricians in various hospitals, experts are rusting elsewhere:

- Dr. Jagmal Singh DCH is the District Malaria Officer, Kurukhetra.
- Dr. Prem Sagar Ahuja DCH is the District Immunization Officer, Ambala.

#### **Gynaecologists:**

There is no gynaecologist in civil hospital Faridabad since 2 years, while Dr. Vandana Aggarwal MD OBG is the deputy director AIDS control society.

#### **ENT** sugeons:

- Dr. Love Datta Chaudhary an ENT surgeon is the District Immunization Officer, Panipat.
- Dr. Anoop Singh another ENT surgeon is the District Health Officer, Hissar.
- Dr. Sham Kalra (DLO) an ENT surgeon is the Family Welfare Officer, Panipat.
- Dr. L.N.Garg an ENT specialist is the District Malaria Officer, Ambala.
- Dr. RPS Balwara MD Dermatology is District Medical Officer, Hisssar.

#### Note:

 Aforesaid gives the current status as on or around 27<sup>th</sup> Oct 2004 when the chapter was concluded. Several changes may occur by the time the

- book is published, if it ever is (since publishers view TB as an unpopular, non profitable subject and prefer famous authors).
- Sometimes the doctor himself is a willing party to such aberration, attracted to a station on account of his children's education, other personal difficulties or some vested interest like an established private practice running parallel.
- Otherwise, most of the affected specialists are a completely frustrated lot, having been sidetracked from their life's mission. Wife of an anesthetist, a government doctor herself, reportedly shared with her colleague, "He always wanted to be the best anaesthetist. He studied hard all his life for that during graduation and post graduation. But ever since he joined the government service, he has been assigned all kinds of jobs except in the field of anesthesia. It is sheer mental torture. He can't sleep at night, sits up and reads books. We feel trapped."
- So one can see how anomalies in postings can lead to night mares and even suicidal tendencies.

#### Grooming the wrong candidates:

- Dr. Prabha Khanna, ex-DTO Faridabad, was short listed, selected and sent on a coveted WHO fellowship for studying TB control apparatus of USA, Philippines and Japan. Soon after her return from the enlightening world tour, the govt itself threw a spanner in the works, ordering her to vacate the TB seat for a fresh incumbent, who would need to be trained from the scratch. A single order thus inflicted on the public exchequer a loss worth lacs of rupees. What a shame! Yet there is no accountability.
- Dr. Subodh Kumar Nawal (MD Chest & TB) is a well known TB specialist in the city of Hissar (Haryana). Way back in 1996, he was sent on a WHO fellowship to study the TB management at Chicago and San Frasisco. Besides, he is credited to have acquired a decade of experience as head of the local 45 bedded govt TB hospital. Typically, soon after the flood of DOTS inundated the city, he was swept away - to family welfare department. Don't we need brilliant and trained doctors in DOTS?
- As soon as Mr. Raj Kumar, Health Commissioner, Haryana & an enthusiastic proponent of DOTS returned in 2004 from foreign parleys concerning health issues, he was removed from Health department.
- Amazingly, there are no criteria or minimal qualifications for doctors

promoted to key administrative posts e.g. medical superintendents of civil hospitals, chief medical officers of districts or directors of health services. As a result, most of these managers have virtually no degrees or diplomas in hospital administration or in management. They have no clue how to manage. Seniority is the sole criterion though unofficially caste, connections and corruption determine who gets what.

#### An ongoing game of musical chairs:

Posting an eye specialist to TB is blatantly unfair both to the public and the doctor himself. It is anti-tuberculosis, anti-DOTS, anti-national and anti-humanity. However, such orders are passed as a matter of routine and with impunity. Due to total lack of transparency in India, public never gets to hear of the murky inside business.

The scenario is like a game of musical chairs that virtually goes on and on amongst the DTOs and other employees, which culminates not in rewards but in chaos and confusion, and untold suffering to patients. It hardly augurs well for the future of DOTS however well it might seem on a spreadsheet.

Even 7 years after its inception, DOTS in India still remains at the mercy of ruthless state politicians and indifferent bureaucrats who are blissfully unaware as to what DOTS is all about; or that how their 'routine management activities' could potentially ruin it or to what extent their political machinations could endanger the lives of the innocent citizens.

Mediocre performance by bureaucracy presided over by indifferent and ignorant political class is one of the major reasons why India lags behind.

On the one hand, the govt. as a matter of policy sponsors its doctors for doing post graduation (with pay) and ends up spending a fortune on the exercise. After they return with enriched expertise, due care is not taken to place them in their respective specialties, depriving not only them of the much-needed training but also the public of the fruit of their added knowledge. They are assigned a wrong slot.

Ironically, the government indulges in all such irregularities in the very name of the purpose that it defeats with impunity - namely public interest.

#### Recommendation No. 3

#### Time to search our souls:

While Indian doctors are known for their great contribution in health care in the gulf countries and even in the US, how come they seem to be failing at home in their duty of looking after their ailing compatriots? It is mainly because of the degenerate trend of sub-optimal utilization of the human resource by the home govts. It is time to pause and search our souls and explore thoroughly if such mismanagement (as is going on in Haryana) goes on elsewhere as well.

Is the health care scenario more or less similar in other states and union territories? The author suspects that the sick phenomenon is quite wide-spread or it might be all pervasive throughout India. (During the first week of Nov. 2004, the state of Uttaranchal had sponsored TB training of one Dr. Durga Pal (DTO of District Bageshwar) at LRS Mehrauli TB Institute, Delhi. He happens to be originally an eye surgeon!).

Gradation lists of doctors, complete with the details of their names, degrees, trainings and current postings should be regularly published in national newspapers for public and media scrutiny every year.

#### Create a separate cadre for specialists in Haryana:

Dr. FJ, a sincere & devoted doctor and an office bearer of the HCMS (Haryana Civil Medical Services) Association who is deeply disturbed over the issue of mismanagement & has invested years of research to the vexing problem, offered strong recommendion: "It is an era of super-specialization. Of the 2000 odd doctors employed with the govt of Haryana, about 300 have attained a post-graduate degree / diploma in some stream or the other. They deserve to be categorized & recognized - not just as MOs, SMOs or CMOs, as has been the perpetual practice, but as specialists. A separate specialists' cadre ought to be created. For my association, I had recently calculated the requirement of specialists for entire Haryana having 30 civil hospitals, 64 CHCs & 402 PHCs. We need about 804 experts. There is an urgent need to reorganize the entire human resource network accordingly."

He went on to reveal the silly & selfish reason for shelving off such wonderful proposals in this regard. The top brass at Directorate felt that

'recognizing the specialists' might add yet another dimension to the already highly contentious issue of annual transfer / posting; this would increase headaches to the top bosses themselves who will then have to rack their brains to accommodate doctors as per the wishes of their political masters.

#### **Political appointments:**

DGHS (Director General Health Services) is the top most post in Haryana that is at the helm of health affairs. Can we afford to allow such top posts to remain what they have been reduced to today - political appointments?

#### Selection criteria for the administrative posts:

The administrative posts (DGHS, Civil Surgeon, Medical Suprintendent, PMO or Director etc.) ought be awarded selectively to those doctors who have attained degrees or diplomas in Management or hospital administration.

#### Does such misdeployment go on in other departments as well?

Besides health care, what about other sectors operated by the govt e.g. education, judiciary, public sector, telecommunication, post and telegraph, railways, defence, power, public distribution, pollution control? Are these too being mismanaged through similar reckless and sick practices? Are these too failing to excel because of messing up of human resource from top to bottom?

### Let us redeploy the entire human resource on the basis of expertise and merit and make laws to protect such moves for all times to come:

Parliament must make new laws ensuring that a specialist can be posted only in his respective stream of expertise.

All abnormal postings (like employing an eye surgeon to TB) must be somehow declared illegal all across the nation - at the levels of the Central, State and Union Territory govt. How it ought to be achieved is the nuts and bolts of the issue that the author is unqualified to comment upon.

#### First and foremost, rein in the Superman:

The ultimate source of much of this mismanagement is an Indian bureaucrat who is treated like a superman. No doubt some of them are extremely intelligent, sincere, hard working & brilliant. However, each one of them is taken to be perfectly **capable of heading any department under the sun**; be it law and order, revenue, health, labor, environment, transport, industry, electricity, irrigation, finance, urban development, agriculture, human resource, education, defense - you name it. He is often made to actually hop from one to the next by their short sighted & selfish political masters.

IAS (Indian Administrative Service) to some stands for Indian Avtar Service while to others it is Indian Angel Service. Must we allow such practice of decision-making at the very top by generalists to carry on indefinitely - right into the 21<sup>st</sup> century, which is an era of super specialization? Must such top-level ambiguity and hence mediocrity be allowed to persist any longer?

Isn't it time to put full stop to the mismanagement by infusing a semblance of specialization and rationalization in the highest echelons of administration? Qualification, aptitude, temperament and preferences of young IAS, IPS, IRS officers ought to be thoroughly analyzed and identified at the very outset. Over the years, they should be groomed accordingly and retained in that particular stream so that we have more specialists (and not generalists) at the helm of our nation's affairs?

#### Inject competetion to cure the monopoly:

The top civil services, monopolized since Independence by the elite Indian Administrative, Foreign and Central Services, is in dire need of reform. All posts at the level of joint secretary and above ought to be thrown open to outsiders - exceptional experts with indisputable caliber & repute in their respective fields - allowing lateral entry. This one step will rejuvinate our degenerate policy making apparatus by infusing a healthy competition - the much needed oxygen that is known to have successfully taken the developed nations of the globe vertically upward.

### 12

# Intermittent regime has yet to pass the ultimate test - the test of time

#### A drastic change in DOTS - the way a TB patient takes his medicines:

Ever since anti-TB drugs were discovered over 50 years ago, a TB patient has always been asked to swallow his medicines every day. It was believed imperative that he took his doses daily - without fail. In fact doctors would take pains to ensure this and wouldn't brook even a day's gap.

But in DOTS, amazingly, the patient doesn't need to take medicines daily but on alternate days. He ingests merely 3 doses per week - something unthinkable in the past. In technical terms, DOTS advocates an intermittent regime instead of the traditional daily one. This change in the frequency of dose-delivery represents a drastic deviation from the past.

#### What is the scientific basis of intermittent regime?

Certain studies revealed that instead of giving anti-TB medicines daily, even if these were administered intermittently i.e. merely 3 times in a week:

- Cure rates remained the same as with daily regime.
- Conversion of the sputum (from positive to negative) occurred at the same rate as with daily regime.
- Total duration of treatment remained the same.
- Side effects too were claimed to be less.

#### Why was intermittent regime chosen?

It is obvious that in intermittent regime when patient takes 3 doses per week:

- Supervision becomes possible (whereas the daily regime is unsuitable for supervision since it is practically impossible for the patient to visit every single day and be observed). This is a remarkable operational advantage.
- Even more dramatic were the economic implications: Cost is nearly

halved (since less drugging is involved overall).

### Intermittent Regime, it seems, expressly became the darling of the powerful fund managers since it costs half as much:

From public health perspective, the most irresistible feature of intermittent regime was that when applied on a mass scale, cure would be achieved with great economy of resources (barely within half of what would be needed if the traditional daily regime was employed).

In simple terms:

- With the same resources, we could benefit twice as many humans.
- In less than half the estimated cost, we could rid the world of TB.

Thus the intermittent regime seemed far too appealing. Once the enormous monetary implications of intermittent regime were grasped by the public health managers - and the relevant studies supporting it were rediscovered, even though they had been done several years ago and lay dumped deep in the archives - it instantly generated enormous hope and vibrancy. The intermittent regime expressly became the darling of the powerful lobbies of public health specialists, donors, fund managers and the economists. WHO chose to back it full throttle with all its might.

However, subtle voice of some lobbies of clinicians advocating caution before jumping to sweeping conclusions were drowned in the brohaha generated; their immense discomfiture and consternation got squashed in the momentum generated by the possibility of a TB free world. Adoption and promotion by WHO meant there was no stopping now, no looking back.

#### Why did WHO choose govt. sector for implementing DOTS in India?

The author felt a sinking feeling deep down his chest when he first learnt of the decision of WHO to hand over absolute control of the new program, RNTCP-lock, stock and barrel - to the govt sector. But as time passed and as his bewildered mind began grasping the scale of implications of the WHO's decision, he understood the reason for such depression.

How could WHO arrive at this fateful decision? Wasn't WHO aware that Central TB Division was the very agency, which had presided over our nation's

TB control effort since the past 30 years (1962-1992)? And during which time nearly 15 million innocent patients had lost their lives? While patients were dying by the minute, the agency had done little. It seems that it simply watched with stoic detachment, failing to effectively stem the tide.

Far greater than its inaction, its failure lay in its silence. It made no efforts whatsoever towards awakening the nation to the grave dangers of this brewing epidemic; it failed miserably in its duty of sharing with countrymen, the gloomy but vital information that lay in its custody. It failed to create, sponsor or promote comprehensive and exhaustive publications on TB's alarming status in public domain or to do anything to initiate a nation-wide debate.

Rather than help launching an investigation, fixing accountability and punishing the guilty, the WHO ironically went right ahead and did just the opposite. It chose to reward the very agency.

Entrusting it with millions of dollars!

#### Big is beautiful:

The ostensible reason for this was that other than govt., there was no other single organized and credible health player - having presence in every village, slum or street of India - with which WHO could deal effectively. The RNTCP project was simply too big for anyone except the government of India, which alone had an intricate health network spread all over this vast nation.

#### And why must govt. of India try to re-invent the wheel?

"The number of countries implementing the DOTS strategy increased by 25 during 2002, bringing the total to 180 (out of 210)": WHO Report 2004, Global Tuberculosis Control.

Such positive declarations appearing from time to time happen to be such an awesome argument in favor of the program. A right thinking man would obviously presume that each one of those 180 countries would have done their homework before consenting to it. Why try to reinvent the wheel then? Why dissipate time and energy in the rigmarole of evaluating something, which already stands validated by so many nations? Better economize the effort and conserve your energies. India it seems chose conveniently to toe the line just like a sheep in the flock.

'That a protocol has been accepted by several other nations' is it reason

enough to blindly accept it? Besides, although named universally as DOTS, each country has adopted a different module, tailor-made for its own specific needs, causing significant amout of dissimilarity.

# The entire process of creation / finalization of Indian module it seems was held hostage to the whims and fancies of a handful of select powerful officials:

During mid 1990s, when the module of India was being chisseled out, history was in the making. This one decision would have profound & sweeping consequences for millions of people. Besides it was a radical departure from the past medical practices.

#### And yet, no nation-wide debate ensued on the subject:

Nothing seems more weird than the stark lack of debate in India before a landmark transition of such magnitude. While trivial issues hog the limelight in the print and the electronic media, tuberculosis fails to grab the headlines or receive the attention it deserves. Media has perpetually remained indifferent to the lackluster subject. Worse still, there hasn't been adequate interaction or consensus amongst the medical fraternity itself on some of the controversial features of DOTS. It is so ridiculous, so scandalous that the public remains unaware and unconcerned as to how the govt unilaterally formulates strategies to grapple with such a national calamity. One of the aims of writing this book is to simplify the technical subject of TB-control for the public, so that a thorough nationwide debate sparks off now, belatedly. Even if eventually we come to the same conclusions all over again.

#### Think tank of the nation never consulted:

- Nobody, it seems, bothered to consult the think tank of our nation the faculty in our medical collages.
- Besides, not a soul from the vast private sector, it seems, had an inkling as to what was about to happen.

#### So the question of a national consensus on DOTS simply doesn't arise:

It seems that only a handful of personnel - who happened to be holding the key posts - abrogated to themselves overwhelming powers, hijacking the entire decision making process. The exercise, it seems, was possibly held hostage by them - the top of whom were either non-medicos or from public (community) health stream (and not from TB as explained on page 54). They unilaterally clinched the issue - probably in intimate consultation with the WHO.

#### 'Something is better than nothing' phenomenon:

Every Indian knows that, with a few exceptions, in the name of free treatment, the government sector has always provided poor facilities to the poor people who have mostly accepted them gratefully. We Indians have an attitude that 'something is better than nothing' and are easily pacified. Contentment is a virtue we worship. We seem besieged with apologetic thinking - 'oh, this is more than enough for us' - probably a symptom of collective low self-esteem prevailing in our race as a result of years of slavery and occupation.

We don't dare to dream!

Even in the wildest of our dreams we can't imagine that top class treatment (at par with the West) could ever be provided to our masses. Wouldn't that be asking for 'too much'? Let us be 'realistic'. After all, DOTS is several notches above the previous National TB Program, practiced thus far in India. Let us be patient and take one step at a time. So we gratefully settle for something, which is no doubt much better than the previous practices and policies, but several notches below the international best or what is possible.

#### Is something better than nothing?

Ordinarily, 'something is better than nothing' is true.

But is it true in TB?

No, absolutely not.

#### In TB "nothing is better than something".

From public health point of view, for a country's future 'not having a TB program at all' is better than 'having a poorly performing one in place.' If we don't have a TB program, patients die. Transmission stops. Story ends.

On the other hand, if we have a bad program in place, it no doubt manages to snatch the patients from the jaws of death. But it stops short of fully curing them. Alive? Yes. But cured? No; they continue to live but are still sick and infectious. **They do survive but only as chronic germ factories** - a rich source of transmission - busily creating more sick people in the community.

#### For govt of India, financial inducement could have been the real reason:

It seems possible that the real reason behind the decision of govt. of India to accept DOTS (with intermittent regime being its core constituent) was not just the claims that the intermittent regime is as good as (or better than) the daily regime, but also the financial inducement. Every monetary package has some arm-twisting potential. It was probably a 'take it as such or leave it' kind of proposition by WHO. The inflow of millions of dollars was contingent upon acceptance by the government of the basic concepts of the package of which intermittent regime was an integral constituent.

#### We are a poor people!

No doubt intermittent regime costs much less. We Indians believe that we haven't the required monetary resources.

We believe that we are poor.

Yes there is no doubt that we are poor!

But it is not poverty of resources.

It is poverty of commitment and honesty.

It is poverty of management skills.

It is poverty of ideas.

It is poverty of dreams.

Had intermittent regime been so great, would USA and several other nations continue to prefer daily regime?

#### Peanuts in the overall perspective:

Since cost of drugs forms only a miniscule portion of the overall expense on this program, conversion to daily regime would have meant an additional expenditure, which would only be marginally higher than what is actually being spent; and which is well within the resources and is virtually peanuts compared to the scary prospect of program failure.

#### Benefit of doubt:

Efficacy of alternate day regime, even if reasonably supported by research, is yet to pass the ultimate test - the test of time.

Therefore, benefit of doubt ought to have been given to the patient. But the govt chose not to do so and typically throwing caution to the winds.

#### How did government of India consent to such a controversial module?

The million-dollar question arises as to how could the scientists of Govt. of India accept such a controversial module of the program in the first place?

#### Were the Pilot studies absolutely reliable?

To be fair to the government, it must be acknowledged that before embarking on a large-scale nation-wide implementation, pilot studies to confirm their feasibility were indeed carried out by the authorities.

Having done considerable homework and successfully concluded several rounds of negotiations, the ground had already been laid; pilot studies were the final bottleneck since the millions of dollars worth package would be awarded only if its feasibility in India was reaffirmed through successful pilot testing. Every thing hinged on their success. There is a general feeling among some insiders that once the bureaucratic set up of the govt had made up its mind on DOTS, there was no scope for failure, dissent or disagreement. That the pilot projects would be a success, seemed like a foregone conclusion. After all, how could these tiny projects be allowed to thwart awesome govt intentions? How could they cough up unfavorable cure rates and throw a spanner in the works? Furthermore, these pilot projects were also prestigious for WHO since the results would virtually have far reaching and sweeping repercussions over the future of its DOTS strategy as well as TB-control effort not only in India but globally.

#### Probably over-attention and pampering plagued these pilot studies:

It is suspected that the Central government machinery devoted to the pilot projects extraordinary levels of attention, virtually unsustainable once the program is applied far and wide over the country.

Even otherwise, it is well known that pilot studies generally have certain limitations - they often have strict inclusion and exclusion criteria so that their results are far superior to actual field conditions.

The words of the well-known physician, Dr. Cn Deivanayagam in an editorial in Journal of Indian Medical Association, echoed such discomfiture over the reliability of pilot projects of DOTS:

'In two pilot sites implementing DOTS, the health workers screened patients to determine their ability to conform to the DOT element of RNTCP. If considered untrustworthy, they were (excluded from DOTS and) provided standard short course therapy. Also patients in absolute poverty, socially

marginalized, itiinerant laborers and those who were poorly integrated into the city were excluded from RNTCP'.1

The author feels that he would be failing in his duty if he omitted to report some unconfirmed information that he heard from some reliable quarters:

#### At one pilot site, records were initially maintained with pencil!

• After the culmination of successful pilot studies at another site when it was observed that relapse seemed more common than expected, creating shadows of doubt, response of officials was typically to play it down and remain tight-lipped. But when pressed by some persistent junior insiders for explanation, the failures were cleverly albeit informally attributed not to program weakness (or to lack of efficacy of DOTS) but to doctor-error (namely faulty categorization of patients on account of lack of training and experience) during the pilot studies.

Was it fair then to expect that the actual field results could ever match those of the pilot studies?

A Kenyan study<sup>2</sup> confirmed that there was considerably more irregularity in a group of patients treated by routine tuberculosis services than in a group under a trial study.

### Validation of DOTS - virtual monopoly of govt of India over entire operational research:

Research climate in India is unhealthy. Since the entire operation of DOTS was through the government sector (private sector was left out), the papers that have been published and which further validate the program have all been compiled by the employees of the government or bear its concealed approval. Some insiders suspect that once it was decided to implement the intermittent regime, a lot of research was invested into it to validate it. What followed was "Manoeuvring and manipulating the research towards a predetermined direction."

<sup>&</sup>lt;sup>1</sup>Editorial, Tuberculosis in the twenty-first Century: The Indian response, by Dr. Cn Deivanayagam, page 139 JIMA, Volume 101, number 03, march 2003, ISSN 0019-5847.

<sup>&</sup>lt;sup>2</sup>K. Toman, Tuberculosis case-finding and chemotherapy; Questions and answers, page 118 ref 5, World Health Organization, Geneva. Published by Jaypee Brothers, New Delhi, India & East African/British Medical Research Council Investigation. Tubercle, 47:1 (1966).

By virtue of being a part and parcel of powerful lobbies of bureaucrats and politicians, some scientists holding authoritative posts in the govt sometimes act like godfathers to some select young researchers who willfully support the govt.'s 'official' point of view. These officials use their position to help arrange finances for research projects and exploit their contacts to get the work published in international journals. It goes without saying that their own names are (un) duly added to the list of researchers. Such mutually beneficial arrangement has deep connotations - it provides the govt officials with a degree of leverage to manoeuvre and manipulate the agenda of R&D & its outcome towards a predetermined direction.

After all, this entire program has so far remained within the realms of the govt. So the govt has had a head start in the research arena. To challenge the awesome & voluminous studies churned out by the govt, empty words based on doubts or suspicions or feelings are not enough. Even otherwise, gut feelings have no place in science today.

You have to produce another study. And that requires time, infrastructure and resources - accessible only to those working in one of the big TB institutions, most of which in turn remain under direct or indirect govt-control.

**No competition worth its name:** Hence, in the absence of any competition worth the name, it is virtually smooth sailing for the govt. Its word virtually goes unchallenged - at least till such time that some joker gobbles up enough courage, time and resources and manages to conclude a counter study & is able to find someone willing to publish it, swimming against the nation wide tide and braving heavy odds.

## Does a trial with a regime consisting of an injection mean green signal to a purely oral regime?

In order to validate the belief that "supervised intermittent regime is as effective as unsupervised daily regime" several studies have been quoted. In most of the pioneer studies, the regimes put on intermittent trial were those, which consisted of (along with oral drugs) an Injection SM. Obviously, a patient cannot prick himself; an injection has to be given by a health worker. In a regime where the specific act of administering an injection is involved, it automatically ensures an intimate and definite interaction between the patient and the health worker on a regular basis. In such a situations, obviously the elements of supervision as well as compliance are bound to turn out much superior than when purely oral regimes are put on trial, where the act of giving

the shot is not involved

Cat I and Cat III of DOTS are purely oral regimes. Therefore, quoting such studies in their support seems inappropriate and unfair.

Furthermore, most of the trials cited in favor of intermittent regime were conducted way back in the 60s and 70s. The world has since changed. The initial drug resistance patterns may have undergone a sea change from those good old times. In India, 2 of the drugs, INH and SM, have surely been misused for too long and resistance to them would have gone up. Besides, ever-rising MDR and HIV make TB control a different ball game today.

#### "Would you consent to taking intermittent regime yourself, doctor?"

When questioned, most of the doctors at the forefront of DOTS, were rendered speechless. Some of them confessed that they would not take a chance by submitting their own sons and daughters to it. They would opt for the time tested daily regime.

"If there is no paucity of funds, I would certainly prefer daily regime rather than the A/D regime," says Dr. Parkash Chugh, MD TB & US returned.

Scores of govt doctors have expressed, of course off the record, lack of conviction in the 3-times-a-week regime that they are being forced to practice.

#### An undercurrent of: Excuse me, I am not convinced!

The author or his friends have interviewed several govt. doctors who have been managing DOTS, ever since its inception in Delhi. Some of the interactions were so frank and hearty that a couple of them went as far as confessing to indulging in a 'bit of private practice' at home so as to generate some extra income, which may be a crime under the law in Delhi, but in the eyes of the author it is hardly something improper morally.

What did they give to patients who came to their house after office hours? Guess what?

**Daily regime!** (And not alternate day regime!) That much about the conviction of doctors themselves! Even after working for 5 years with DOTS.

#### Some personal encounters of doctors with TB during 2004 - 05:

- A senior doctor working in LRS TB institute reportedly chose to give daily regime to his sputum positive father.
- Another doctor from the same institute unfortunately fell sick himself and

reportedly decided to take daily regime.

Dr. K. A. B., DTCD, an MO TU in Haryana, said that to the mother of a friend, a medical representative of a pharma company, he had just given daily regime, 'to be on the safe side'. He went on to reveal, "to my close relations and personally known patients, I always give DOTS with an innovation - I ask them to supplement the missing 4 doses a week from the market & make it daily regime. They save half the expenditure."

#### Butterflies in my stomach:

A private practitioner said, "Whenever I pick up my pen with the intention of prescribing alternate-day regime, I get butterflies in my stomach."

#### Most patients resent A/D regime:

"How would you feel if you were not given food on one day and forced to gulp down double the amount the next day? That's exactly what DOTS does. Higher doses of INH and E can be too hard on anybody's system. Personally, I would prefer daily regime with its more humanly dosages," exclaimed a passionate lab technician from New Delhi who has been working sincerely with DOTS for several years.

"Most patients hate to swallow so many pills at once. Forget the human being, ingesting 3,550 mg of antibiotic is too much for a pig" he lamented.

Can something that's no good for those advocating and administering it, be given to the masses? We must pause to ponder: If DOTS were as good as claimed by the govt., would such skepticism continue 7 years down the line?

### 13

#### Is DOTS really supervised in India?

Of the 5 fundamental principles of the WHO recommended DOTS strategy (as detailed on page 5), the most crucial is: Short-course chemotherapy, given under direct observation; in other words - its DOT element.

The success or failure of an intermittent regime as provided under DOTS, hinges on one factor - 'strict supervision of each and every dose as far as possible'; in other words - its DOT element.

Patients treated without direct observation have a substantially higher risk of adverse outcome than those treated under direct observation, concluded a study from Kerala. "The 53 patients who were not directly observed were much more likely to have treatment failure or relapse, as compared to those who had received DOT (45% v/s 3% relative risk 16.6, 95% confidence intervals 6 46, p< 0.0001). Non-receivers of DOT accounted for 86% of treatment failure or relapses.<sup>1</sup>

When the success or failure of an intermittent regime hinges on one factor namely 'strict supervision of each and every dose', the million-dollar question that arises is:

#### Is DOTS really supervised in India?

When the design of Indian DOTS was finalized its most crucial component, namely supervision, was compromised to a large extent, nearly to the tune of half. Of the 78 intermittent doses recommended for curing a Cat.1 patient, as many as **36 were willingly set-aside from the purview of supervision**. Hence, not all of the 78 but merely 42 doses are supposed to be supervised. In other words, the program is supervised to an extent of 53.85% and unsupervised to the extent of 46.15%. Only the intensive phase is supposed to

<sup>&</sup>lt;sup>1</sup> Balasubramaniam V.N., Ommen K. and Samuel R. International J. Tub & lung Dis. Vol 4, No. 5, May 2000. P. 409 - 412

be fully supervised, the continuation phase is to be partially supervised. Is such a compromise compatible with cure and thus acceptable? The name DOTS is thus a misnomer.

# POTS (Partially Observed Treatment Short course) seems a more appropriate name for Indian module.

In simple terms, the program was significantly diluted at birth, half of its most crucial component having been sacrificed in its original design itself. That left no scope for any laxity in the next stage of the program, namely 'implementation'. The founders of DOTS thus ensured that we inherited a tight situation where there is absolutely no room for mistakes, no margin of error; that we had to walk on the sharp edge of a knife all the while.

### To be maximally effective, the DOTS program must be both confidential and convenient.<sup>1</sup>

It is well recognized that for 'intermittent chemotherapy' to be really successful the following features are essential:

- Each and every dose ought to be fully and truly supervised.
- The patient must be observed religiously, while he performs the act of swallowing his medicines.
- Appropriate arrangements ought to be made so as to administer the dose at the place of patient's choice e.g. his home, the clinic or a park.
- Patient ought to be provided his doses exactly at the hour of 'his' choice.
- The health center that supplies medicines ought to be located close to his residence so that it is within easy reach of the patient. It is important to provide DOT at a time and place that is convenient and acceptable to the patients.<sup>2</sup>

Tall claims of the government notwithstanding, practically, none of the above is strictly adhered to in India, because health services are scarce, under-staffed, under-equipped, cash-strapped, overworked and the area to be covered is vast.

Daily regime is the one that is time tested whereas intermittent regime has yet to pass the ultimate test: the test of time.

<sup>&</sup>lt;sup>1</sup> Balasubramaniam V.N., Ommen K. and Samuel R. International J. Tub & lung Dis. Vol 4, No. 5, May 2000. P. 409 - 412

<sup>&</sup>lt;sup>2</sup>Balasubramaniam V.N., Ommen K. and Samuel R. International J. Tub & lung Dis. Vol 4, No. 5, May 2000. P. 409 - 412

Furthermore, intermittent regime to be successful ought to be fully and truly supervised.

However, daily regime is unsuitable for supervision as it is practically impossible for a patient to come daily; he simply can't be expected to visit everyday to ingest his medication under direct observation.

The most important advantage cited in favor of intermittent regime over the time tested daily regime is that it becomes humanly possible to supervise an intermittent regime.

However, the operational research has amply demonstrated that the very element of "supervision" stands so much compromised in the field conditions in India that the very basis of selecting intermittent regime over daily regime is **rendered null and void**.

So why persist with intermittent regime? Why not implement daily regime (SAT).

#### Balasubramaniam report:

In a retrospective study including 200 consecutive newly detected, sputum positive patients registered under the project (DOTS) in Pathanamthitta district (Kerala) has shown that more than a quarter of patients (26.5%) did not actually receive it (in other words though recorded as having been directly observed, were in reality not supervised).

## Another study echoed the same sentiment:

"In nearly 40 visits of investigators to various sub-centers and primary health centers, the investigators had not seen even a single patient taking medicine in front of the health workers. Investigator himself had seen medicine boxes in the patients' houses." <sup>2</sup>

(Note: Is it not curious that in the last decade since DOTS descended on India, there have been very few studies done on the crucial aspect of 'levels of supervision' in the field conditions? Why has the government not undertaken such studies at different sites? Why hasn't it encouraged independent agencies to explore this vital aspect parallelly? However, the few that have

<sup>&</sup>lt;sup>1</sup> Balasubramaniam V.N., Ommen K. and Samuel R. International J. Tub & lung Dis. Vol 4, No. 5, May 2000. P. 409 - 412

<sup>&</sup>lt;sup>2</sup> Evaluation of DOTS under RNTCP in District Sonipat of Haryana. 2003. A study by Dr. Kuldeep Singh. Page 171

been done reveal a shocking state of affairs).

Our policy of going easy on supervision - during the continuation phase - may yet prove harmful in the long run:

"Irregularity in the continuation phase may nullify the benefits of an initial intensive phase. As long as high level of regularity cannot be ensured, even first rate regimes will produce inferior results."

Non-enforcement of strict supervision in intermittent regime can prove suicidal for our nation.

## The Dangerous 'Miss':

Munna Lal, a mason, had agreed to visit for his doses on Monday, Wednesday and Friday. Second month into the course, one Friday morning he duly swallowed his dose at 8 A.M and rushed to the site of construction where his contractor was waiting to hand him an urgent telegram. He had to leave immediately and go to his village for a couple of days. He couldn't return in time for his next dose, which fell due on Monday. As soon as he alighted from the bus on Tuesday, he headed straight to the DOTS center but was disappointed to find it closed on account of some holiday. Next day, Munna Lal got busy with shuttering work very early in the morning and it was only around 2 PM in the afternoon that he could get a breather to slip away to the subcenter and gulp down his dose.

- Thus an 'insignificant looking miss' had indeed occurred. It had caused a
  gap of over 5 days (5 x 24 = 120 + 6 = 126 hrs.).
- Is it acceptable?
- Is such a prolonged gap compatible with cure in the regime in DOTS?
- If yes, how many of them are permissible to a patient during his entire course of DOTS?

No one seems to have any answers to these crucial questions even though it is crystal clear to all insiders that such situations are everyday occurrence in the current environment. There have been no studies on the subject.

### Sunday truce:

It is the notorious 'Sunday off' factor, which is more likely to give birth to such

<sup>&</sup>lt;sup>1</sup> K. Toman Tuberculosis case-finding and chemotherapy; Questions and answers, page 118, World Health Organization, Geneva. Published by Jaypee Brothers, New Delhi, India

prolonged gaps in treatment. Why keep such a gap of 2 days, while other gaps are single day ones? Has the mycobacterium tuberculosis given an undertaking to the government of India that it will not multiply on a Sunday, since it is a national holiday? Is there a 'Sunday truce' with the germ? Isn't it sheer program expediency? Do we not give medicines on Sundays to patients of other diseases, say malaria or typhoid?

#### Recommendation No. 4

Make DOTS 5/7 (five doses per week), instead of the current 3/7:

The founders of DOTS are making us walk on the sharp edge of a knife. Even a minimal 'margin of error' has not been catered for under DOTS.

To be reasonably successful in India we have to keep sufficient margin for error. We must therefore attempt to implement the very best so that a reasonable margin of error is built into the program; so that even if it does get diluted to some extent on account of imperfect implementation (and going by the past record such an eventuality is highly probable), it still manages to cure majority of patients producing a positive impact in the end.

We have pumped millions of dollars into DOTS. **Going thus far and no further?** For God's sake provide some wriggle space at least. Smart thing would be to commit to the very best and aim at the highest targets.

Therefore, in order to create a small cushion for error and to neutralize the root cause of those prolonged risky gaps, we must dispense 2 extra doses - to be supplied in the form of 'take-away' on Saturday & Tuesday. The patient will ingest them himself, unsupervised at home on Sunday and Wednesday. In other words, please make it 5/7, five doses per week (instead of the current 3/7).

## Some anaecdotes regarding supervision element:

#### "Our DOTS is not DOTS":

An orthopaedic surgeon posted in a backward rural area of Mewat, met the author in a marriage party at Suraj Kund: "Our DOTS is not DOTS," he declared.

"What do you mean?" the author asked, all ears.

"I mean the program is not directly observed; it is not in real terms supervised."

"What makes you say that?" prompted the author.

"Last week I drove my RNTCP consultant to a patient's house. With a broad smile, she greeted the patient by his first name. The patient instantly looked relaxed and called out to his son to make tea for the team. Skillfully she discussed first his job and then his pet cow. Once he looked reasonably disarmed, he became chirpy. Then she came to the point. 'Are you getting your doses on time?' she asked him casually.

'Yes. No problems at all.'

Pointing to the nervous health worker she persisted, 'does he cause you any trouble in giving medicines?'

'No madam, not at all. They are all quite cooperative.'

It was our turn to relax.

She caringly pressed on with the subject, 'Tell me, because I can set things right.'

The patient thought for a moment and suddenly darted into the room. Feeling obliged to give some sort of a proof of our helpfulness, he came out and produced a couple of extra loaded strips saying, 'See, I have no problem getting medicines.' My heart sank. It was so embarrassing. That, despite my repeated lectures to all my workers 'n' number of times that for God's sake don't do such things, at least not in the vicinity of our dispensary since that's the area prone to inspections."

Afterwards, when she was gone, the worker was far from being repentant, saying 'it is not my fault; it's just bad luck. What can I do sir; the patient turned out such an idiot? I had worked really hard. Time and again I had rehearsed with him as to what to say in case of an inspection'."

Rather than observing the dose-ingestion, health worker wastes energy on tutoring his patients- how not to be caught and what to say during an inspection.

A Medical Officer TB Unit shared with the author that "the most glaring drawback of the program is its DOT component itself, which seems to be the weakest link. How can a non-resident health visitor, who visits a remote sub-center rarely and briefly, do justice with supervision?"

Pintoo a cook in a dhaba and a resident of village Ajrondha, sector 15 A, Faridabad, and a cat 2 case corroborated this lacuna saying, "The nurse visits

merely once a week, is **always in a hurry**. She is unpunctual. She would arrive any time between 9 and 11 AM, quickly distribute 2 or 3 strips each to every waiting person, lock up and disappear. It is my mother who goes, keeps waiting and collects medicines for me (as I can't be absent from my duties at the kitchen of the dhaba; I am busy preparing lunch from 8 AM onwards)."

#### Ek anar sou bimar:

"Family Planning Officer pulls me in one direction, 'your tubectomy cases are far short of targets'; School Health Officer bullies me, 'why haven't you visited girl's primary school yet'; while the Malaria Officer shouts at me to drop everything else and run for a door to door inspection of open drains and water logging in coolers. You tell me is it humanly possible for me to administer DOTS religiously? Furthermore, at least 6 or 7 working days are washed out in meetings, be these at PHC, CHC or at CMO office. I have kept 20 spare strips at a kiryana store (general merchant serving as DDC); patients know it - they can pick up their dose whenever I fail to show up," lamented a multipurpose health worker, pleading anonymity.

Dr. SSD, a dedicated SMO who remained deeply involved with the program and who has just retired from Haryana, didn't mince his words, "View it from whichever angle, one thing is absolutely clear: DOTS is anything but well-supervised. The name 'directly observed' is a misnomer in India."

## Cough up 500 and carry home your baggage:

A patient lamented that he could not arrange to pay up the health worker Rs. 500, which was the going rate in that area if you wished to carry home your box of entire six-month-medication. The culprit, a health worker vehemently denied it at first, but when confronted with the patient and fully reassured of confidentiality, revealed his 'valid' reasons, "The medicines belong to the patient. Why must I stand in between the two like a barrier? Receiving the full quota is a big relief to the patient who won't need to visit over and over again; it also saves me from day to day headache."

"Ek patta do, ek patta lo!" complained a patient. What he meant was: Shell out a 10 Rupees note on each visit, and carry home an extra strip & save a trip.

There is peculiar lack of understanding of the concepts of DOTS. A health worker who was reported to be rather generous in disbursing carry home strips to patients rather than make them swallow them there and then under his

watchful gaze, proffered his logic to the author, "Come on. Why would a patient come all the way to pick up his dose, if he didn't mean to eat it?"

Symptom-free? = Yes. Sputum-negative? = Yes.

Fully cured? = No, not yet. (Dr. F.S.D.G. Diploma TB, ex-DTO)

Having served as a DOTS trainer for a long time, an ex-DTO harbored several reservations, "Thanks to a multitude of lapses in supervision resulting in compliance irregularities that inevitably occur during the long course of treatment, the patient dubbed at the end as 'cured' is in reality not yet fully cured. He may look and feel well. He is symptom free and sputum negative, yet he is far short of being completely cured. It may just be a transient suppression with medicines. Hence the patient is prone to relapse. With time, relapses are now beginning to emerge. It is all under the wraps yet. But how long? Just wait till it happens and becomes public knowledge; all hell will break lose then".

## A recurring pattern:

Do isolated incidents like these really matter in a country of one billion? No, not at all.

Then why make so much fuss?

Because, they serve to aptly represent the prevailing climate. They feed right into a typical recurring pattern. They reinforce the widespread pessimism about inaptness of the government services that have been entrusted with implementation of DOTS. Furthermore, these episodes speak volumes about ineffectiveness of the modular training - in driving home the fundamental concepts behind DOTS.

## 14

## Technical controversies in design

First and foremost, the intermittent regime (thrice weekly) that forms the very foundation of Indian DOTS has yet to pass the ultimate test - the test of time (as detailed in chapter 12, page 87-97).

Furthermore, DOTS seems to undermine some of the cardinal principles, which have been laid down by the scientific community in the past:

## 1. "Never add single drug to a failing regime" remains a well-known 'Don't of TB':

Let us assume that there is a patient who is already resistant to several drugs. If we give him a regime that includes those drugs and one new drug, we encourage the germ to become resistant to the newly added drug. That is why we 'never add a single drug to a failing regime.' But that is precisely what is being practised under DOTS: when treatment of a category 1 patient fails, we give the patient category 2, which is nothing but addition of simply one more drug (namely SM) to what he had been taking.

## 2. Drug dosage - DOTS is a crude package:

To administer sub-clinical dosage of anti-TB drugs in a daily regime is a sin. It amounts to 'sheer quackery'. The patient may improve initially but would never fully recover.

Dr. D.A.C., a senior expert having tremendous experience of DOTS right from its inception in Delhi and having served in LRS Institute Mehrauli and Rajan Babu TB hospital and famous for his lucid discourses on the subject on the television channels, and who had remained intimately involved with the original study conducted in Delhi for ascertaining the average weight of an Indian patient in the run up to DOTS, provided the following insights:

Refined way of allopathic practice is to weigh each patient, calculate

one by one the dosage of each of the 3, 4 or 5 drugs to be given. Then administer them strictly as per his body weight.

One of the biggest flaws in DOTS is that the same ready-made kit containing a cocktail of drugs in fixed dosage is uniformly fed to each and every patient - irrespective of whether his weight is 35 or 50 or 59 kilograms.

## Body-build of a typical Indian patient:

Which patient is most likely to register with DOTS?

Of course, the one who is too poor to afford a private doctor and badly needs 'free treatment.' And who fell prey to TB in the first place on account of his poverty, undernourishment and low immunity. It seems reasonable to conclude that such an Indian patient would weigh, on an average, anywhere between 35 to 50 Kg.

No doubt this would form the single largest segment of patients in India. Keeping this 'ideal Indian patient' in mind, the dosages of DOTS were finalized - to cater to this average weight category (35 to 50 kg.). However, it is only an average range. The question to ponder is: can this fixed dose package be universally and sweepingly applied to each and every Indian?

As the program expands, becomes more popular and picks up momentum and as more and more individuals from better-fed affluent classes of society step onto its bandwagon, this 'average range of weight' appears less and less.

- Ataller patient is likely to weigh more.
- A patient from the upper strata of society is likely to weigh more.
- A diabetic patient is likely to weigh more.

"If you weigh 50 kg or more, please stay away from DOTS," cautioned Dr. D.A.C. He further pointed out some irritants in this context:

## Patients weighing from 50 to 59 kg:

A patient weighing 50 to 59 kg, does not receive extra dosages that he rightfully deserves; DOTS seems desperately deficient in curing him.

## Patient weighing over 60 kg:

A patient weighing over 60 kg, indeed gets an additional capsule of R 150

mg - over and above the usual fixed-dose combipack. The arrangement is quite miserly:

- Is 600 mg of R really sufficient for a patient weighing 70 kg?
- And what about other drugs? Doesn't he deserve 2 gm or even more of PZD (instead of the usual 1.5 gm)?
- This imbalance of dosages is one of the biggest lacunae of DOTS; all those who are over 50 kg and approach DOTS, are starkly vulnerable to treatment failure and MDR because for them it's an under-dose, an inadequate package! This imbalance gets further exacerbated:
  - In the case of intermittent regime (as provided under DOTS) where plasma concentrations are required to be sustained till fourth or even fifth day at times.
  - If patient also has a co-existing systemic disease e.g. Diabetes.
  - Co-infection with HIV.
  - In fussier forms of TB like gland TB.

# DOTS is good enough for a very poor, very thin, fresh sputum positive patient:

Another knowledgeable and experienced District TB Officer, Dr. N.R.Y., MD TB, believes that DOTS is good enough only for a very poor, very thin, fresh sputum positive patient. Such a patient generally responds well to cat 1 regime and indeed receives full quota of medicines and gets cured. For the rest, the program doesn't have much to offer; their prospects often remain as bleak as in the pre-DOTS era; rather risk of MDR is more now.

# Compounding the problem further, it has been generally observed that no one bothers to record the weight of the patients in the field:

"All the 3 Tus of district Sonepat, which were visited, had no provision for weight recording. Weighing machine was not there even in the room of MO-TC. Out of 202 patients, only 31 patients had one (single) entry of weight in their treatment card'.<sup>1</sup>

## 3. Cavity v/s minimal lesion: Is it fair to be so terribly uniform?

No doubt, abject non-uniformity of regimes practiced thus far by the Indian doctors has been condemned for what it is - an inexcusable crime.

While attempting to remedy that, DOTS seems to have gone overboardby swinging to the other extreme. It has become too terribly uniform, coming up with mere 3 categories to fit in all kinds of TB cases.

#### DOTS does not bother to make even the most basic distinctions:

Thanks to the renunciation of chest X-ray, it fails to differentiate between a new patient with 'extensive bilateral cavitary lung-destruction' (a bad case) and the one with 'minimal lesion' (a good case), treating them both uniformly (exposing the former to some risk of failure or relapse). Once their sputum samples are confirmed as positive, both are treated with a solitary formula namely cat 1.

A DTO staunchly defended the approach saying, "we are giving both of them a powerful 4 drug regime. What more do we have to offer anyway? It is more like over-treating the good case rather than undertreating the bad one. Therefore, both are likely to be cured; so where is the problem?"

The problem is that we are foregoing a golden opportunity to improve chances of success in the bad case. Once we become acutely aware of the extensiveness of the damage in a person (through a timely X-ray), we do have 3 more options up our sleeve that remain completely forgotten in the current program:

- Time tested and possibly more effective 'Daily' regime.
- Giving right away all the 5 drugs (cat 2 regime).
- Stretching the Continuation Phase (CP) a bit longer.

{As per reliable sources, in some Delhi centers it was felt that some patients displaying a massive initial bacillary load (**initially highly sputum positive +++**) tend to respond rather slowly - so much so that some of them refusing to convert in to sputum negative well into 4th or 5th month. So the need to give Continuation Phase (CP) for longer duration was acutely felt. Some of them reportedly had to be switched midstream to cat II. And a few of them eventually slid into Cat II failure!}

"Patients with cavitation on initial chest radiograph and positive cultures at completion of 2 months of therapy, should receive 7-month (31 week, either 217 doses [daily] or 62 doses [twice weekly]) continuation phase.<sup>1</sup>"

A senior and distinguished sikh doctor Dr. D.P.S. having devoted a

<sup>&</sup>lt;sup>1</sup> Evaluation of DOTS under RNTCP in District Sonipat of Haryana. Study by Dr. Kuldeep Singh. page 159

lifetime to the subject and currently on the brink of retirement from a large TB hospital feels that "the scenario is virtually akin to a 'langar' (mass meal) cooked in a gurudwara (holy shrine of Sikhs), where same dalroti (food) is served to one and all - eat it or leave it; nothing can be or will be specially prepared to cater to your tastes or needs!"

Yes, we are attempting to achieve uniformity - but at what cost? Several patients genuinely need individualized, tailor-made treatment.

#### Confusion in the air:

Besides, DOTS regimes are uniformly applied to every patient in every region, state, city, town or village of our vast nation, which seems to negate the basic principle of TB treatment that states that: Initial resistance patterns prevailing in the local community must be taken into account before choosing a drug regime for an area." Sputum culture and sensitivity test is neither feasible nor done as a routine in India. So one can never be sure as to what are the prevailing levels of initial resistance in different states. In such a confusing background (and till such time that the matter is not scientifically resolved), benefit of doubt ought to have been granted to the patient which typically has not been done.

## 4. What is the scientific basis of cat III regime?

Initial resistance patterns prevailing in the local community must be taken in to account while deciding the number of drugs to be given. Studies in different parts of India have all come up with variable & confusing results:

Resistance to SM ranges from 4.8% (Bangalore 1985-86) to 14.9% (Wardha 1982-89)\*.

Resistance to INH ranges from 3.2% (Military Hospital, Pune) to 23.4% (North Arcot)\*.

It is well established that in areas where Initial resistance to INH is significantly high, four drugs ought to be given.

In India, such is the case.

Therefore, as a routine, no TB patient should be treated with mere 3 drugs; everyone ought to be treated with a minimum of 4 drugs. Since only 3 drugs are given in cat III, DOTS is flouting the basic principle.

#### 5. Casual climate further fuels resistance:

<sup>&</sup>lt;sup>1</sup>Am | Respir Crit Care Med Vol 167. pp 605

<sup>\*</sup>Status of Drug Resistance in Tuberculosis after the introduction of Rifampicin in India by C.N.Paramasivan, page 155, Table 1, JIMA, Volume 101, number 03, March 2003, ISSN 0019-5847

In a developed country, it is virtually unthinkable that a patient can lay his hands on - much less get to swallow - even a single anti-TB pill without due confirmation of TB as the diagnosis.

In stark contrast, it is virtually free for all in India:

- Every quack, every pharmacist, every chemist can and does dispense anti-TB medicines just as effortlessly as he does those for common cold or viral fever.
- Qualified doctors sometimes embark on a therapeutic trial of anti-TB drugs on suspected cases without compelling indications.
- Self-medication too is rampant here.

## • Furthermore, there is a catch even in DOTS:

A sputum negative pulmonary or an extra-pulmonary case (having non serious illness) is assigned cat. 3 even if he:

- Has indeed taken anti-TB medicines but for less than 28 days.
- ► Has indeed defaulted- but the default is less than 2 months.

The intake of medicines in the former and default in the latter case, though brief, is completely ignored. The figures of 28 days and 2 months have been arrived at arbitrarily and without any scientific basis.

After all, even a brief exposure (or default) can generate significant resistance in the patient.

In such a casual climate, by the time a TB patient officially comes knocking at the doors of DOTS, he has, knowingly or unknowingly, had his share of exposure to anti-TB medication, which can pose a negative bearing on the outcome if he is put in the soft category, namely cat-3.

# 6. Few trials done with respect to extra-pulmonary TB (hence no scientific basis):

Very few randomized controlled clinical trials have been done in the arena of extra-pulmonary TB. Hence most of the DOTS guidelines with respect to such cases are arbitrary and without sound scientific basis.

Be it a bone specialist, skin specialist, general surgeon, gynaecologist, neurologist, gastroenterologist, Urologist or a cardiologist - who end up treating bulk of extra-Pulmonary TB cases - hardly feel comfortable prescribing the 3-drug Cat III regime in the first place. Intermittence is another irritant. A raging debate continues over drug combinations and their dosage.

Duration of treatment remains a major controversy; orthopedic surgeons vehemently disagree at the brevity of duration (6 months); they prefer to treat bone TB for over a year and often prefer to include injection SM initially. Some go a step further and suspect that in bone TB, cat III regime appears desperately inadequate; rather than curing, this brief exposure to RHZ only serves to foster MDR.

The oft-repeated argument in favor of DOTS is that: 'if a 6-month-course can successfully cure a pulmonary case that is brimming with millions of bacilli in lung cavities, why would it not be enough to cure an extra-pulmonary case that is known to be pauci-bacillary (having a small germ-load)?' The logic seems quite plausible... in theory that is. But should we allow our country of one billion to be consigned to a mammoth program that is based in part over theoretical considerations? Must we not give the benefit of doubt to the patient? Must we not, if at all, err on the higher (and safer) side?

#### 7. Chemoprophylaxis - hardly being done:

In practice, no preventive course is being given to the contacts of sputum positive case or even an MDR case.

Even the leading institutions, which are entrusted with the job of training doctors, seem to have little conviction in the guidelines they preach. Otherwise why would an institute like LRS Mehrauli ignore an important stipulation, namely "a child below 6, whose mother or father has sputum smear positive status ought to be given INH chemo-prophylaxis." In practice, only a few kids and that too below the age of 2 were reportedly found to actually get the preventive protocol (in a peer review in 2004).

#### 8. Side effects:

In case a patient comes down with drug-induced hepatitis, DOTS offers only 2 options to him: either discontinue or continue treatment. Another plausible option remains forgotten: if the patient is sputum positive and has a small baby (e.g. an infectious female patient who has just delivered a baby), then omit RZ, but continue to give SE or SHE.

#### 9. Childhood TB:

Diagnosing TB in a child is not a child's play. Not only plain MBBS doctors, child specialists and TB specialists too often find it hard to do justice.

Having somehow arrived at the diagnosis, it is then not easy to calculate dosage for a child. The business of crushing bitter tablets and giving its fractions or powders is crude, cumbersome and hardly a practical solution. How can you expect compliance from kids unless drugs are given in the form of palatable syrups, which are nowhere on the scene? Dispersible tablets are reportedly being contemplated though.

Guidelines for administration of DOTS to children are not at all clear. At places, intermittent regime is being doled out to kids too; how can a child's delicate stomach possibly tolerate double dose of INH?

## 10. Why just 24 injections of SM?:

Intensive phase in cat II lasts for 3 months. But curiously, one of the 5 drugs namely injection SM is stopped at 2-month point (after 24 shots). Whatever other arguments may be advanced to support it, it seems like yet another stingy cost cutting measure. SM ought to be continued for the third month as well because Cat II contains some of the toughest cases.

11. If a patient consumes tablets from the strips in divided doses, his treatment is likely to fail. It is imperative that the complete dose is ingested all at once and at the stipulated time, so as to achieve and maintain the desired serum-levels of the drugs. In the current Indian scenario where the element of supervision is so slack, can patients be expected to adhere strictly to the requirement?

## 12. DOTS fosters drug resistance:

Since sputum culture is not done, an MDR often gets registered as a Cat 2 case; the abortive attempt only further worsening his MDR status.

#### 13. DOTS is silent on some vital issues:

- What to do with our significantly large segment of critically sick that virtually face liquidation. An unknown number might already have been sacrificed.
- 'If, when and how' of giving steroids to cases of Pleural Effusion and Pericardial Effusion etc.
- DOTS is virtually silent about several procedures (or their indications) like FNAC, gland excision, drainage of cold abscess, rib resection, paracentasis for pericardial effusion, drainage of empyema through under-water-seal-drainage & Immobilization of bones and joints etc.
- Besides, how can a patients with immobilizing disability be expected to visit DOTS center over and over again and be supervised?
- Shouldn't a slow responder be treated for longer than 6-8 months?

#### Is DOTS evidence based?

"The only regimes that should be prescribed are those that have been tried out successfully in controlled clinical studies i.e. as regards not only the combination of drugs, but also their exact doses, rhythm and length of application. Any arbitrary alteration of such regimes as well as any improvisation must be strongly discouraged<sup>1</sup>."

DOTS, it seems, flouts all these commandments one by one. It appears to be ridden with all that is forbidden - arbitrary alterations, assumptions, modifications, improvisations and innovations.

## The concept of 2-phase chemotherapy:

"The concept of two-phase chemotherapy was arrived at on the basis of theoretical considerations, empirically and experimentally discovered facts, and technical and operational requirements for meeting patients' needs<sup>2</sup>."

It is the era of evidence-based medicine.

Question of a meta-analysis doesn't arise since DOTS hasn't been around long enough for that.

Mandatory Randomized Controlled Trials (RCTs) were, it seems, not conducted appropriately, extensively, patiently and exhaustively - to check out each and every of the numerous features of DOTS before consigning the entire country to its large-scale implementation. Rather than sound scientific foundation, the whims and fancies of a handful of top-notch and powerful scientists seem to have been the basis of its construction. It appears that several of the modalities were okayed just because those select few 'felt' OK about them (expert opinion). However:

- Drug combinations advocated by the program under its 3 categories are not exactly the same as those used in the original trials.
- Similarly the original trials, it seems, had different drug-dosageschedules.
- Some trials with their twice-weekly rhythm of drug delivery can't be said to necessarily validate thrice-weekly schedule of DOTS.

<sup>&</sup>lt;sup>1</sup>K. Toman Tuberculosis case-finding and chemotherapy; Questions and answers, page 177, World Health Organization, Geneva. Published by Jaypee Brothers, New Delhi, India)

<sup>&</sup>lt;sup>2</sup>K. Toman Tuberculosis case-finding and chemotherapy; Questions and answers, page 130, World Health Organization, Geneva. Published by Jaypee Brothers, New Delhi, India

- Trials conducted with a regime that includes a paranteral drug (injection SM) can't serve as a green signal for a purely oral regime.
- Actual trials had different total durations of application.

## Several concepts were not put through drill of Rigorous Trials e.g.:

- Making TB specialist (or sometimes a qualified doctor itself) practically leave the scene.
- Whether it is possible to train and optimally motivate a large work force with single training.

# Randomized controlled clinical trials ought to have been conducted to compare results in the following groups:

- A group of people put on the usual sputum based diagnostic algorithm of DOTS v/s another group where both sputum and chest radiography are optimally utilized.
- A group that gets 6 months treatment v/s another which gets a longer course.
- A group treated by 12th pass workers versus a group treated by TB specialists v/s a group treated by plain MBBS doctors trained through the module of DOTS.
- A group of patients having access to medicines at convenient timings (from 6 to 10 a.m. and 6 to 8 p.m.) versus a group treated at routine timings.
- Agroup of Cat II patients who receive 24 injections of SM during Intensive Phase (IP) versus another that receives 36.

#### Just a few drops in the ocean:

One may rightfully ask: In such a mammoth program shouldn't we concentrate on the big picture first? Should we dissipate our energies worrying about tiny segments of patients some of whom may not even be infectious to the society? After all, how many extra-pulmonary cases, overweight patients or children might get affected adversely? How many cases suffer side effects, anyways? How many kids who might fall sick for want of chemo-prophylaxis? The answer to each one possibly is - a few.

Therefore, most of these objections, even if valid, hardly concern the

majority segment but affect just small groups - just drops in the ocean. Shouldn't we ignore them? But then, what is ocean made up of? Drops!

And besides, try convincing an affected patient whose life is virtually on the line. Try asking his near and dear ones whether it is worthwhile trying to rectify the lacunae, if any!

## Value of a single individual:

In order to rescue one individual from a hostage crisis, US would within no time spend millions of dollars. Even govt. of India would readily spend tens of lacs for a cause that is in media focus and public watch or for the overseas treatment of a single individual - who is a VIP.

In India, the law of the land respects an individual and staunchly protects his rights. The law goes out of the way to ensure that no innocent person - accused of a crime - ever gets convicted. The policy is to let 100 accused persons who might have committed the crime go scot free than to convict even a single innocent person on the basis of inadequate evidence. Benefit of doubt is always given to the accused. Philosophy of DOTS is just the reverse. Interests of an individual have been sacrificed - clearly and knowingly - for reasons of sheer economy and operational expediency, ironically in the name of mass welfare.

Besides, unlike in the law, benefit of doubt wherever possible has not been given to the victim - the patient.

Biggest ever calculated gamble in the history of mankind:

Exhaustive and clinching 'randomized controlled clinical trials' using precisely the same regimes, drugs and dosages (as stipulated under DOTS) were not religiously concluded beforehand; the results of the pilot projects and the ongoing implementation itself serving largely as 'field trials' validating and justifying the program. The pilot projects, which flashed the ultimate green signal for momentous expansion, remain under a cloud. And it is an open secret that the data of implementation (field trials) may be highly unreliable. Thus at the dawn of the 21st century, the entire nation was deliberately converted into a massive laboratory and Indians into guinea pigs while a half cooked, half-baked program was enforced, making it the biggest ever calculated gamble in the history of mankind - putting at stake millions of lives!

## The fundamental question to ponder:

In the name of public interest, to what limit can a govt or a UN agency legitimately go in making compromises in the field of medicine? Do they possess a blank cheque? Do they enjoy complete immunity so much so that they can even trample on the central tenets of medicine? Can a group of elite professionals (whether working for a govt or the WHO) abrogate to themselves the right of not conforming to the time tested scientific standards and brazenly violate the basic doctrines of allopathic medicine?

And just because the govt is providing something free of cost to the public, does it make it legal if it knowingly & deliberately keeps the quality diluted?

The ultimate fear that haunts the author day and night is this:

The tremendous advantage forthcoming to the nation from the generational switch in chemotherapy under RNTCP might have been lost, partially or entirely, through some timid decisions, like:

- Divorcing chest radiography.
- Omission of the TB expert.
- Choice of 'thrice a week' regime.

## 15

## A Glimpse of How TB is Treated in U.S.A.

**Dr. Sushil Munjhal (DTCD, MD Chest & TB),** the author of this chapter, is currently serving as the Nodal officer HIV at Lala Ram Swaroop (LRS) Institute of TB & Respiratory Diseases, Mehrauli, New Delhi.

"Time-wise, while it's the dead of the night in India, it's bright daylight in USA. So is it in the context of TB," summed up Dr. Sushil Munjhal soon after his arrival from USA where he had gone on a 3-month fellowship at New York School of Medicine. Dr. Munjhal, a compassionate doctor, a sparkling expert and a selfless thinker, is always passionately concerned about the future direction of our nation's TB control movement. Several of his original and thought provoking inputs have quietly found their way in to the relevant chapters of this book - getting amalgamated with the rest of the material - without being rightfully attributed to him.

However, the thoughts that he has penned down immediately after his return from the US are as follows:

## Indian module is a crude version - a primitive replica!

Although TB program of New York can also be given the brand name DOT (just like the Indian one), it is on an entirely different paradigm. Just as although a Mercedes Benz and a bullock-cart can both be legitimately grouped together as a 'mode of transport', yet there is simply no comparison between the two.

While the diagnostic algorithm in Indian DOTS solely and precariously hinges upon sputum examination - direct smear (radiolography stands more or less excluded), the very basis of treatment in USA is essentially the state of the art sputum culture and drug sensitivity testing (each test would easily cost about Rs. 6000 in an Indian private lab). Every investigation that DOTS prohibits us from conducting on our citizens here is being performed in the US.

A doctor in India can't even imagine the plethora of tests routinely conducted there - sputum examination (direct smear), chest X-ray, sputum culture and drug sensitivity, and that too fast track; wherever indicated, even PCR, Eliza, Ultrasound, CT scan, MRI and DNA finger printing - virtually every thing given in the text books.

# The WHO guidelines (of DOTS) are not good enough for an American patient:

An American citizen is diagnosed and treated - not as per the WHO guidelines as stipulated under DOTS and which are only for the poor countries of the third world but - as per The Official Joint Statement of 'The American Thoracic Society', 'Center for Disease Control and Prevention' and 'Infectious Diseases Society of America' approved in Oct. 2002.¹ The recommendations are virtually eye-opener - far different than Indian DOTS. Chest radiography is an essential constituent of diagnosis which is based essentially upon the sophisticated sputum culture for AFB and sensitivity test. Treatment regimes are different. Daily regime (or 5 days per week) is the most preferred regime, at least during the Intensive phase. Besides, intermittent regime is not compulsory there; it is optional. A patient is offered various options (and that includes daily regime) and is free to choose any one that suits him.

#### Abundance of resources:

Even though the total number of cases reported annually is appx. 750 in New York, its TB department remains endowed with over 100 sleek Toyota cars exclusively for TB work.

The patient / health worker ratio is exceedingly favorable.

Facilities provided to a DOT worker are simply out of this world. He would religiously supervise each and every dose, as his routine is not cluttered with all sorts of odd jobs. In an entire working day he might merely cater to 4 patients. He picks up a Toyota (fitted with a car phone) and drives down personally to deliver the dose wherever the patient desires. He carries along plenty of incentives - hot dog coupons of Kentucky Fried Chicken / Mcdonalds and coins enabling one to commute on subway trains - for the patient who eagerly awaits the meeting.

<sup>&</sup>lt;sup>1</sup>Am j Respir Crit Care Med Vol 167. pp 603-662, 2003. DOI: 10.1164 / rccm. 167. 4. 603. Internet address: www.atsjournals.org

Besides, work culture there is superb. Work is literally worship. You could be fired, sued or jailed for minimal negligence. There is near absolute accountability of the health team for each case registered. The retrieval mechanism is virtually foolproof.

I heard an interesting incident about a defaulter who disappeared from New York and sneaked away probably to Las Vegas. The health worker is said to have doggedly investigated the patient's whereabouts - till he was traced. Then he officially flew over to California and confronted him. Exercising his powers, he presented him in a regular court of law. The patient was offered the services of an advocate to fight the case.

After hearing, the magistrate would award him one of the several options:

- The patient goes scot-free.
- Patient is let off with a warning in which case he will stay at home but under watchful care of a specific health facility till cured.
- He is kept in a hospital that would act like a temporary jail till fully cured.

The patient in question was told was awarded the second option - let off with a warning."

In India, there are more cases in 4 days than in the entire United States in a year.

## In comparison, it is a virtual stampede here in India:

An Indian worker saddled with a multitude of non-TB duties copes up with an entire battalion of patients. And he often doesn't even get a broken bicycle. As far as workers or patients are concerned, incentives are unheard of; when it comes to top managers themselves, it is a different ball game though. Besides, the work culture in the government sector is appalling. The performance of an employee is generally lacklustre and lethargic. Backed by unions, he is adept at playing games and skirting rules. In fact the degree of one's clout is measured from the extent to which one is able to flout the law and get away with it through political godfathers.

## 16

## **Quality of Sputum Smear Microscopy in India**

One of the 5 key components of DOTS (as detailed on page 5) is: High-quality sputum smear microscopy.

DOTS is totally a sputum smear based program. Every issue is clinched on the basis of sputum test:

- Who is suffering from TB?
- Which category does he belong to?
- Is he infectious to the society?
- Who ought to be accorded top priority for treatment?
- Is he responding to the treatment?
- Has he been cured?
- Has the treatment failed?
- Is he getting a relapse?
- How many patients have been cured?
- What is the cure rate in our country?
- What is the relapse rate infour country?
- Who could be an MDR?

All these crucial questions, in DOTS, are answered wholly or partially, directly or indirectly, through one thing - the sputum smear reports.

Sputum test is the heart and soul of Indian DOTS.

And who performs this test?

Of course the laboratory technician (LT)!

Naturally then Lab technician(LT) is the hero of DOTS.

Everything depends upon him; on his efficiency, discipline, motivation, dedication, honesty and hard work.

God forbid, if he happens to be inefficient, dishonest or reckless, it will be disastrous.

## Lab Technician (LT) is the hero:

Not only is Diagnosis completely in the hands of LT, evaluation of treatment response also stands wrested away from the domain of the doctor and remains contingent upon the reporting of the LT.

"Which patient will get treatment and which one won't are virtually dictated by the LT. By manipulating his reports, he could virtually do anything. He is in a position to favor a known patient by labeling him as sputum positive (falsely) so as to get him in to a favored category or deny treatment to a patient by refusing to report the positive status of his sputum" lamented a doctor.

There are insufficient checks and balances to restrain this hero. Senior TB lab Supervisor (STLS), who is supposed to supervise his performance, is often short of expertise to do the needful.

#### **Dubious Labs in India:**

According to its brochures, SRL Ranbaxy a recent private sector laboratory venture in India claims to be accredited by NABL (National Accreditation Board for testing and caliberation Laboratories - as per ISO IEC 17025) and by CAP (College of American Pathologists) and claims to be the only lab in India to comply with international standards like: CPA (Clinical Pathology Association), NCCLS (National Council for Caliberation Control in Lab System), ILAC (International Labs Accreditation Corp), APLAC (Asian Pacific Lab Accreditation Corp), AACC (American Association of Clinical Chemistry), GSCC (German Society of Clinical Chemistry), IATA (International Transport Association). One hears the amazing stories that soon blood samples would fly in to be tested here, as some European nations decide to out- source lab testing to India.

But this is one extreme. Such labs represent an exception and these are often far too expensive - way beyond the reach of a common Indian. Study of labs in India is truly like a roller coaster ride.

## Any joker can set up a clinical laboratory in India:

On the other extreme lies what is available to the common man. Any joker can set up a clinical laboratory in India. All he needs is just a few impressive machines, a swanky premises and a commercial license from municipal corporation, as if he were opening a general store or a garment shop.

Result?

Every city & town is littered with unqualified people running illegal labs.

No checks and balances are in place to evaluate the quality of services provided or the veracity of the reports churned out. It's virtually a free for all, a state of complete anarchy; no mandatory licensing, periodic calibration, standardization, random checking or rigorous screening.

The diagnosis, and hence human life, depends on lab reports, which seem to have no authenticity. Forget about eliminating it, there have been no credible surveys by the government of India till date to assess the magnitude of this growing menace.

## Ironically, labs of the Govt sector often have the worst track record:

Govt simply doesn't seem to care; the worst culprits ironically are the laboratories run by the govt itself within the premises of its civil hospitals, CHCs and PHCs. Government labs are infamous for cheap, worn-out equipment, poor maintenance, substandard reagents, obsolete technologies, crude methodology and, above all, an indifferent and unionist work culture, and illegible handwritten reports on any shred of waste paper.

There is virtually no competitive spirit or fear of accountability therein. Forget the elaborate sputum test, one finds it hard to trust even a simple Haemoglobin or blood sugar report originating from there.

One can not deny that there is an undercurrent of suspicion that our govtrun blood banks are busy in the business of spreading AIDS, Hepatitis B and all sorts of other infections.

One of the major reasons for such a sorry state of affairs is criminal mismanagement by the powerful lobby of unimaginative and shortsighted politicians and bureaucrats. Displaying complete insensitivity to what futuristic medicine is all about, there is rampant disregard of the rich human resource available.

#### Non-experts head most govt labs while real experts rot elsewhere:

• Dr. Sat Narain Sharma (MD Pathology), exceptionally honest, dutiful and

dedicated to his profession, remains bogged down with administrative duties in civil hospital, Narnaul.

- Dr. P.K. Jain (MD Pathology) is unable to pass on the benefits of his vast experience and talents to the public since he is tied down with work of an ordinary doctor at Pataudi.
- Dr. A.P.Bhatia (MD Pathology), a hard working doctor, is managing TB as MO TU cum SMO at CHC, Nilokheri.
- While district civil hospital, Bhiwani, goes without a Pathologist, Dr. Aditya Swaroop Gupta (MD Pathology) is rotting away in a small peripheral center nearby.
- Dr. Raj Bir Singh Pingalak (MD Pathology) hard working and brilliant in his field is similarly resigned to doing non-speciality work - as Medical Superintendent Mukand Lal general hospital, Yamuna Nagar.
- Dr. Mrs. Anju Gupta (MD Pathology) is grappling with gynaec obstretics work in civil hospital, Palwal.
- Dr. D.P.Lochan (MD Microbiology) is the Deputy Chief Medical officer (M) Ambala.
- Dr. K.D.Sharma (MD Microbiology) rusts in non-lab work as District Training Officer, Bhiwani.
- Dr. Lok Vir (MD Microbiology) is manning the busy casualty of B.K.Hospital Faridabad.

## No accountability:

In USA or UK, a single false positive report of a sputum sample could come back to haunt the technician; he could find himself embroiled in a million-dollar-suit or land in jail. Fear of accountability can be a great incentive to perform efficiently. In Indian labs, especially in the government sector, accountability or its fear is virtually unknown. Reporting is often casual, negligent or sometimes even through conjecture.

"The thing I hate most is to touch a sputum cup, open it and make a slide" a female lab technician is reported to have shared with her colleagues once.

The author shudders to remember a thumb rule advocated by an LT during the pre-DOTS era, "Just raise the sample and shake it softly against sunlight... here ... like this". Then he would stare at the sample and say, "If you can detect a reddish tinge, go right ahead and report it positive. Most of the

time you will be right."

## As if haemoptysis were synonymous with TB!

Dr. F.A.N. (MBBS, MD Chest &TB) told the author:

"In the pre-DOTS era, as a routine, I rarely received a sputum positive report from my government hospital lab. At times, I felt deeply frustrated so much so that finally I had to resort to setting up a microscope in the nurse's duty room in our TB ward to examine doubtful slides myself. Of course, with the advent of DOTS things have improved, and improved significantly. But even then, it would be gullible to pretend that things have all of a sudden become perfect; it will take several more years for that if it ever does happen."

A friend of the author who returned after completing his MD recently confided, "During my 3- year-residency in XYZ Hospital, Delhi, I recollect having come across hardly 5 or 6 sputum positive reports! Sputum positive reports are generally a rare commodity, at least outside DOTS network. In one highly probable TB patient, I got sputum done several times but it was always reported negative. Smelling that something was wrong with the lab, I went up to the technician and complained. He said 'no problem, sir. Let me do it all over again just for you sir.' And then it did come positive."

Dr. F.A.N. (MBBS, MD Chest &TB) shared this:

"In case of massive haemoptysis (bleeding in the cough), the key question always is if and when to give blood transfusion, which could be life saving. It can be precisely answered only by the lab, which evaluates patient's dipping Haemoglobin levels. Even a few hours delay can prove decisive; it can mean the difference between life and death. I was so fed up with the unreliable and wayward Haemoglobin reports emanating from the lab of our government hospital, that I had to purchase a haemoglobinometer and keep it handy in my personal locker in the ward, so as to confirm things, whenever in doubt."

## Is it wise to put all your eggs in one basket?

Dr F.S.C.K (MD medicine) has one basic question, "How can a program based exclusively on a solitary test (namely sputum test) be a roaring success unless the government labs are made 100% reliable? How can I undergo a change of heart overnight? I find it impossible to put complete faith in my lab technician whom I have known for years and who is very much like any other average govt. employee. He and the likes of him cannot be absolved of their share of blame for poor reporting all along the failed National TB Program.

The murky past record makes me extremely uncomfortable. Is it wise to

put all your eggs in one basket, knowing full well that the basket has numerous holes difficult to repair? It is the same work force. Only label has been changed; from NTP to RNTCP; does it automatically guarantee efficiency?" He then cautions, "everything hinges on one person, the LT, and who could be unreliable."

# It is the same work force; only the label has been changed - from NTP to RNTCP; does it automatically quarantee efficiency?

Dr. S. S.D, SMO recently retired as in-charge of a CHC in Haryana, said, "the typical sarkari - casual and laid back - attitude of lab technicians is dangerous. Some of them don't seem to realize the import of performing their duty with utmost care. Several of the lab technicians are neither well trained nor motivated. Quality of sputum slides on which the diagnosis is based and the program hinges is often disgustingly atrocious."

#### Contractual worker works harder than his permanent counterpart:

An MO TU lamented about one of the microscopy centers under him, "the lab technician is a permanent government employee; he is a union leader himself; he simply doesn't work. We have given up on him. His senior, the STLS, examines all sputum slides instead. Being on a yearly contract basis, STLS does listen to me.

An STLS is basically supposed to keep a check over the lab technician, to oversee his work, to recheck 100% positive slides and 10% of the negative ones. How can anyone check and improve himself; in the current instance doesn't it all become meaningless? The unionist culture is wrecking the program; some workers will never ever get to work".

#### Secret locker:

From a known positive sputum sample, an LT prepares 20 good slides and keeps them handy in a red box in his locker. Then he is ready to pick up one and assign a false sputum positive label to an originally negative case, in order to notch up his cure rates. (Similarly 20 known sputum negative slides are kept, ready in a green box).

Ulta pulta: (As reported to the author by Dr. F. S. D. G., an ex-DTO):

"Visibly stunned at the news that his sputum had been found to contain TB germs, an intelligent schoolteacher had protested to me in a weak voice, 'but sir, how is it possible? The technician had examined my slides in my presence and had reassured me verbally on the spot that those were free of germs.'

I immediately called my lab technician. Fortunately, he recognized the teacher and remembered the incident all right.

'Then how come his sputum is marked positive in his report as well as your register?' I demanded to know.

'Sorry sir, a bit of a confusion, somewhere,' answered the lab technician.

Origin of that 'a bit of a confusion' was finally traced to his clumsiness in labeling of samples. What clearly emerged was that he habitually did a sloppy job of sticking name tags on cups of sputum samples, putting it off and which had led to that ulta-pulta reporting.

Although the teacher was saved from being condemned to that toxic 6-month anti-TB-course, it remains a mystery as to what happened to the sputum positive guy. And how many more patients have suffered thus! I shudder to think that such carelessness is not uncommon (if not rampant) in the periphery."

A TB patient must absolutely deserve his treatment; it should never ever be initiated lightly. To condemn someone to 6-month needless course on the basis of false positive reports is a serious crime.

Anyone who finds it hard to believe that such irregularities can occur frequently in the field conditions of India has got to belong to another planet.

## Re-using slides:

Depending solely upon sputum test as the only proof of TB is particularly more risky in areas where due to paucity of funds there is a common practice of washing and re-using the slides as indeed happens in several labs in India outside of DOTS of course. If not washed properly, a portion of the previously stained sample may remain sticking on microscopic scratches of the slide; the red rods of dye detected therein could in reality belong to the previous sample,

giving a false positive result. Hence in the current scenario prevailing in India, the chances of false positive results are significant. And in the absence of any provision for minimal checks and balances by way of chest X-ray, such results have the potential of condemning healthy persons having no TB at all, to misplaced stigma and torture of toxic medication for a long time.

## The study by Dr. Kuldeep Singh<sup>1</sup> found that:

- Sputum examination guidelines were violated in nearly 90% of the present study.
- In 38.6% patients, only single sputum examination was performed before declaring these patients as tuberculosis patients.

**Comptroller Auditor General (CAG)** of India observed that in Jabalpur and Satna it was found that sputum was examined only once whereas 3 smear examinations were stipulated for a single case<sup>2</sup>.

#### A Confession:

The author must confess here that over the years, over-worked technicians in our Malaria department gained tremendous experience by scanning thousands of slides during successive malaria seasons, at times doing just that, day in and day out. As a result, some of them became highly skillful in identifying malarial parasite in the blood slide - way smarter than their counterparts in the private sector or the foreign countries.

Similarly, there is no denying that with the onset of DOTS, sputum testing has progressively improved quite a lot in the government microscopy centers.

### Especially where that is the only chore being performed by the LT.

Some of our lab technicians are fast becoming highly proficient - probably the best anywhere in the world - in tracking the TB bacillus in someone's sputum. The author feels increasingly comfortable in sending to civil hospital Faridabad more and more suspected cases that are too poor to afford Rs 180 [in a private lab the cost of 3 sputum tests = Rs. 180 (@ Rs. 60

<sup>&</sup>lt;sup>1</sup>Dr. Kuldeep Singh's Evaluation of DOTS under RNTCP in District Sonipat of Haryana. page 151

<sup>&</sup>lt;sup>2</sup>Comptroller Auditor General (CAG). National Disease Control Program review - National Tuberculosis Control Program, Chapter 1. New Delhi: CAG (India); 2002. Available from website: http://www.Cagindia.org/reports/civil/2002 book3 / chapter 1.htm

per test)]. The lab technician in the local civil (BK) hospital, Mrs. Bimla Rani, does sputum microscopy exclusively round the clock. She is doing genuine, dedicated and marvelous work. But the author fears that her's is just a sporadic effort and it can't be generalized.

Not just yet.

#### Recommendation No. 5

- Govt of India must initiate an exhaustive survey to comprehensively assess the extent of the menace of sub-standard laboratories in the country and then explore ways to curb it.
- A regulatory authority for monitoring and regulating all the clinical laboratories of India must immediately be created on the lines of Medical council for doctors and dental council for dentists.
- Peer review of sputum slides: Blind cross checking should be done through regular interchange of some sputum slides from one DTC to the other - x to y, y to z and vice versa. This must be made an ongoing exercise at all times.
- One Lab Technician exclusively for sputum testing work at each TB
   Unit and microscopy center: At each TU and microscopy center, one LT
   must concentrate exclusively on conducting sputum tests. Otherwise, the
   moment workload of other tests spills over, sputum test invariably is
   accorded the lowest priority & its quality is the first casualty.
- Open more microscopy centers: In Faridabad, it would help people if
  the dispensaries running in sector 27-B and Parbatia colony were
  designated as Microscopy centers; currently public has to travel far to get
  sputum tested.

## 17

## Quality of RNTCP Drugs - How reliable could it be?

One of the 5 key components of DOTS (as detailed on page 5) is: Adequate and uninterrupted supply of **high-quality drugs**.

### Rhetoric versus reality!

During late nineties, in the run up to the large-scale implementation of DOTS in India, several meetings, lectures and presentations were tactically organized by govt of India and WHO, with the specific aim of sensitizing India's medical fraternity. The idea was to generally familiarize doctors with this new national strategy, to win over their wholehearted support, answer queries, clear doubts, allay fears and to remove skepticism, if any. Invited or otherwise, the author too managed to sneak into some of them held in Delhi.

The top scientists from WHO and Central TB Division were seen to market DOTS in a fascinating manner in awe-inspiring auditoria. They surely had done their homework. Through brilliant presentations, extraordinary oratorial skills, wonderful audiovisual tools, large screen scientific projections, LCD connected to their lap top computers (something quite unusual during those yesteryears - at least in the field of TB), they quoted several studies selectively in order to convince the audiences. Churning out interesting and mind-boggling data, they skillfully rendered the audiences virtually spell bound and speechless.

The author was particularly impressed by one oft-repeated statement. He cannot quote it verbatim but could never forget the gist of it, which goes something like this: 'there is no need to harbor any doubts about the reliability of drug-quality under DOTS program since global tenders will be floated for the procurement of high quality drugs.' Coming from the highest authorities, the promise of an era of freedom from the omnipresent menace of substandard drugs was most reassuring.

#### But hindsight is a great tool.

Today - after several years, as the program unfolds - the gullible author has come to realize as to what it was all about: calculated moves, fascinating tactics, clever ploys employed by seasoned players. All the holy claims had been nothing more than rhetoric - like hollow election promises of seasoned politicians - once the election is over, the commitments evaporate into the thin air and things are back to 'normal'.

The author is shocked to find that all kinds of brands of drugs are being handed to TB patients. Every Tom Dick and Harry seems to be able to receive orders for manufacturing and supplying DOTS strips to the government.

In Jan. 2002, author's own compounder Rajender Kumar Bairwa unfortunately came down with sputum positive lung TB. He was deliberately sent into DOTS pipeline so as to obtain first hand experience. He kept receiving drugs produced by the following 2 firms:

- Micron Pharmaceuticals: 2117, A-2, Phase-III, GIDC, VAPI 396195.
   Batch No. H-136 R-136 X-73
- Pure Pharma Ltd. 41, 42 & 44, Industrial Estate, Polo Ground, Indore 452015. Batch No. Z-20022 E-20079 H-20034 R-20041, Manufactured Dec. 2002, Expiry July 2005, For RNTCP supply, CGS not for sale.

[In May 2004, Mrs. Anju Kathuria w/o Ramesh Chand Kathuria R/o Hindu Para, opp. Sanatan Dharam Mandir, Alwar too received from Govt. Hospital, Alwar drugs for cat 2 manufactured by **Pure Pharma Ltd.**, batch no: E 20038, H 200022, X 20006, DNOH 20019, Mfg. Oct. 2002, Exp. May 2005].

Some other firms that supplied drugs to RNTCP are:

#### VYSALI Pharmaceuticals Pvt. Ltd.:

Streptomycin Injection: 750 mg. Manufactured by: VYSALI Pharmaceuticals Pvt. Ltd., IX/639 EDATHALA, Cochin-683561. M.L.No.23/28/93, Batch No. 012402, Mfg. Feb. 2002, Exp. Jan. 2005, For RTCP supply, C.G.S, Not for sale.

{This Injection of Streptomycin was given to Mrs. Leena 27 years female, w/o Sh. Shiv Kumar, TB card no 2172/04, registered on 20-01-2004. Address: House No. 13, Street No. 8, Bhikam Colony, Near Sial Market, Ballabgarh - 121004. Telephone No.: 2301412 (R), 2311647 (R) and 9811640479 (M)}

## Nestor pharma:

Drugs manufactured by 'Nestor pharma,' Dabua Colony Faridabad were

reportedly supplied to several centers including Kheri Kalan PHC.

Not having dispatched any of these samples for quality testing owing to logistical limitations, the author cannot and does not in any way mean to claim here that any of the drugs mentioned above are / were substandard.

# But the observation hardly inspires confidence in DOTS, given the murky background prevailing in India:

- About 20% of all the medicines could be fake or sub-standard in India<sup>1</sup>.
- According to WHO, 35% of fake drugs in the whole world come from India<sup>2</sup>.
- The India Pharma Alliance (IPA) claims an annual damage of Rs. 4,000 crores to the pharmaceutical industry due to spurious drugs<sup>3</sup>.
- 1 in every 4 drugs sold in India is spurious<sup>4</sup>.
- CII (Confederation of Indian Industry) further estimates that spurious drugs account for 17% of the US\$ 4 billion pharmaceutical Industry in India and the web spreads from Kashmir to Kanyakumari. India has a whopping Rs. 4000 crore spurious drug market which is growing like a cancer. However, about Rs. 2500 crore worth of this shady business operates out of a single notorious spot in Delhi, called Bhagirath Palace.
- The Union Health Minister A. Ramadoss (himself) disclosed in the Rajya Sabha that 69% of injections used in govt hospitals were "unsafe", either because of improper sterilization or poor nursing skills (TNN, Times of India, New Delhi, Dec. 18, 2004).
- Deeply concerned that its anti-tuberculosis drugs were widely duplicated, Lupin Laboratories Ltd. reportedly considered printing its brand name on each and every capsule in a circular fashion, not easy to duplicate.
- Hoechst Marian Roussel Ltd. suspects that 15% of all its products available in the market were fake.

In India, bulk chemical used as raw material for making tablets is available cheap. Tablet-machinery, which happens to be compact, inexpensive, and handy, can easily operate from a small room, garage, slum, shanty or an underground basement. Availability of improved printing-technology further

<sup>&</sup>lt;sup>1</sup>The Week May 18, 2003

<sup>&</sup>lt;sup>2</sup>Patralekha Chatterjee in Lancet 2001, 357 No. 9270; 1776, 2<sup>nd</sup> June and The Week May 18, 2003

<sup>&</sup>lt;sup>3</sup>India Today Sept. 2, 2002

<sup>&</sup>lt;sup>4</sup>Cover story in the weekly newsmagazine 'Outlook', Sept. 22, 2003

helps in counterfeiting. Hot spots of fake drug manufacturers are breeding and buzzing in India like mosquitoes.

## As per official records of Mashelkar Committee\* report:

"In all, there are about 5877 drug-manufacturing units. Besides, there are 1806 blood banks, 199 medical devices units, 638 surgical dressing units, 272 disinfectant units, 318 repackaging units, 2228 cosmetic units and 278 other units in India. There are reported to be more than 3.5 lakh sales outlets in the country"\*.

For monitoring and regulating such a mammoth industry the government seems to possess a negligible arrangement of "...about 800-900 druginspectors for about 600 districts in the country."\*

Drug testing facilities are pitiably deficient:

Of the 31 states / union territories... "Only 17 states have drug testing facilities of which only 6 laboratories have facilities for complete testing of all categories of drugs"\*.

Of the thousands of batches of drugs and formulations churned out annually, samples of less than 1% get picked up and tested - in a handful of overworked labs that work at a snail's pace. Often by the time testing reveals that a particular batch was sub-standard, over a year has already elapsed and the public has already consumed bulk of the poison.

There is practically little government control over 150 odd private drug testing labs some of whom may well be only too eager to furnish the good-quality-certificate, thus legalizing the operation of drug companies who happen to be their valued customers and hence their paymasters.

Policing by a handful of inspectors of Drug Control Authority is practically non-existent. Manufacturing fake drugs is not a cognizable offence. It comes under the Drugs and Cosmetics Act, 1940 or the Copyright Act.

An accused in India can often afford to engage the best legal brains and comfortably procure bail. Litigation, being a painfully slow process, is rather exploited as delaying tactic by the rich and mighty. Typically, 20 years have silently passed by; the hapless victims of the greatest industrial disaster of the

<sup>\*</sup>Report of The Expert Committee -popularly known as Mashelkar Committee - on 'A Comprehensive Examination of Drug Regulatory Issues, including the problem of Spurious drugs', November, 2003, page 3,80.

world, the **Bhopal Gas Tragedy** that occurred on Dec 3, 1984, are still breathlessly screaming for justice!

30 million cases are reportedly pending in various Indian courts. The average time spent for a dispute to be resolved is about 20 years. Conviction rate in criminal courts of India is merely 6%. Even if convicted, the spurious drug dealer is usually let off lightly with a fine of Rs. 5000/-, or rarely a jail term for 2 or 3 years. Absence of stringent laws, protracted delays, mild convictions make it a low risk, high profit business.

To estimate the real scale of an under-cover activity like that of spurious drugs is no easy task. Forget about tackling it, government of India is yet to initiate a systematic study to gauge its extent.

(The preceding chapter draws heavily upon the articles published in The Week May 18, 2003 and India Today Sept. 2, 2002)

Piqued and alarmed at the scale and gravity of the racket, Union Health Minister of India Smt. Sushma Swaraj, a consciencious leader, was constrained to declare:

"Mass murder for the sake of profit should be treated only by one law, the death penalty". Thereafter, on Dec 18, 2003, Union Cabinet chaired by the then Prime Minister Sh. Atal Bihari Vajpayee reportedly went on to clear a draft bill for necessary amendments to the existing penal provisions under the Drugs and Cosmetics Act, 1940. The bill would go to the parliament for final approval before it becomes the law of the land.

#### Govt. drug supplies are the worst culprits:

On July 17, 2003 CII informed Mashelkar committee that:

Government (drug) supply: majority fail quality test<sup>2</sup>.

## Empty capsules of Rifampicin fed to Karnataka kids down with TB:

"Hundreds of Rifampicin capsules provided free of cost across the state could be just the plastic casings with no drug inside. Over 100 capsules of Rifampicin 150 from 15 sealed strips obtained by TOI (Times of India) during an investigation had no Rifampicin drug in them. The samples obtained are from batch no. 570024 of the public sector Karnataka Antibiotics and

<sup>&</sup>lt;sup>1</sup> Hindustan Times July 10, 2003, on page 11

<sup>&</sup>lt;sup>2</sup> Report of The Expert Committee -popularly known as Mashelkar Committee - on 'A Comprehensive Examination of Drug Regulatory Issues, including the problem of Spurious drugs', November, 2003, page 75

Pharmaceuticals Ltd. The suspect batch was manufactured in January 2004 and has an expiry date of August 2006. Since February 2004, the state has using its nearly Rs. 53-crore medicine purchase budget - procured over 38,000 strips of Rifampicin from this batch at a cost of nearly Rs. 3.8 lakh."

Procurement of drugs by government is a big political game, since enormous amount of money changes hands. Nearly every one involved in the process tends to extract his pound of flesh. One frequently hears all sorts of murky stories at local levels - civil hospitals, district and state levels. But nothing is more depressing and ominous than when bad news emanate from the highest echelons of the union government e.g.:

#### The infamous CGHS scam widely reported in the press:

"The CBI (Central Bureau of Investigation) officials have detected a criminal conspiracy hatched by the then CGHS additional director, Jawahar Lal, the scheme's chief controller of accounts, Jawahar Thakur, the then (Union) Health minister's private secretary, Gunjan Parasad, his additional private secretary, Sudershan Kumar and a retail chemist in Delhi, Rajesh Gupta. The size of the scam can be gauged from the fact that drugs worth Rs. 150 crore are purchased for CGHS every year."

On the basis of an informal interaction with senior doctors running the program, Dr. Vijay Sukhija MBBS running a busy private clinic in North Delhi had this to report:

Initially when DOTS was launched in Delhi, the medicines, it seems, were procured from just anywhere, even from small time local companies. Alarmed by the lack of response exhibited by their patients, doctors raised a hue and cry in various meetings. Their forceful protests bore fruit. Thereafter - since about 2 years - medicines produced only by better-known companies are being supplied from the Central Stores.

#### Patients return sick:

"In the previous program several patients discontinued treatment half way down the line. But those who did manage to complete the over-a-year long

<sup>&</sup>lt;sup>1</sup> Times of India, Times Eye, By Johnson TA/TNN dated Dec. 23, 2004, front page.

<sup>&</sup>lt;sup>2</sup> By Bhaskar Roy, Times News Network, Jan 21, 2004, Times of India Delhi edition page 11.

course, simply never came back. They were cured once and forever. But since DOTS has arrived, many patients who have duly completed Cat 1 / Cat 2 / or both, one after the other, surprisingly come back knocking on our doors-as sick as ever. Our heart sinks when we see this," said a nurse of Nehru Nagar hospital. "Intensive phase seems pretty effective; it does achieve its aim of sputum conversion. It is thereafter that things seem to go haywire. Probably the CP is too short; its duration of 4 months seems inadequate; it ought to be made longer - for 6 months at least. Or drug-quality is poor." she opined.

#### God knows what, but something is seriously wrong:

F.B., a lab technician working with DOTS for several years, seemed puzzled, "Earlier, prior to DOTS, patients used to get cured for ever. Even though the course was long and drugs cheap but they were reliable. All those patients who did complete the full course then are hale and hearty till date. Some of them would meet us even now and express gratitude. God knows what but something is seriously wrong now a days. Are the medicines not effective? Once the course is over, a patient may come back again with symptoms. Relapses seem pretty common. It is so frustrating."

#### An Uncomfortable feeling:

Dr. K.A.M.B, MBBS, DTCD and a hard working MOTU, had this to say:

"Even two and a half years into DOTS, I have an uncomfortable feeling deep down. You cure a patient with great effort and within 3 or 6 months you find him walking back to your center - with relapse. Now, there can be 3 possible reasons:

- Patient didn't take medicines properly.
- Medicines were sub-standard.
- Efficacy of DOTS itself is suspect.

The bosses blindly presume that the 1st reason (i.e. non-compliance) is the real culprit and rebuke the workers. They have a closed mind. They are hypnotized with the aura of the WHO. They silence us by vaguely citing some study or the other that we never get to actually see. Nobody is ready even to listen, much less consider or discuss the other 2 possibilities."

#### Why work hard?

FSB, a Senior Treatment Supervisor had this to say:

"Observing me quietly while I diligently sermoned a patient to be more regular, a doctor in charge of a PHC took me aside affably and asked, "Have you seen the sloppy packaging of the strips arriving from above? Don't you feel there is something fishy about their quality? That patient is not going to get cured anyway. Why work so hard man?"

#### For God's sake re-examine the data of Relapse:

Data notwithstanding, so many individuals working with DOTS for several years in different capacities and at different places have independently expressed this common apprehension that somehow relapse after DOTS seems too common, casting a serious doubt over the permanence of cure achieved with DOTS. There is an urgent need for re-examining the relapse data, this time by an independent agency outside the purview of govt or WHO.

#### No. Not me please!

On being asked, "Would you accept DOTS strips yourself?", most of the doctors said no. Rather than ingesting medicines from the free RNTCP supply, they wouldn't mind spending their own money to purchase top quality medicines from a reliable chemist.

#### Just one drop of urine:

Even if we presume for a moment that everything else works perfectly fine under DOTS, a sloppy control over drug quality can single handedly ruin everything. Whereas any other lacuna affects a few individual patients or some isolated pockets, the dreadful effects of this one factor would be all pervasive.

In the vicious atmosphere prevailing in India, a transparent and foolproof mechanism for stringent quality control is a precondition to success. Rigorous ongoing vigilance at all times is an absolute must. Relentless surveillance ensuring reliability of drug-quality is essential.

Drug mafia's are significant campaign-contributors in any election and always represent a powerful lobby. If we are complacent, the law of averages will

soon catch up with DOTS (if it hasn't already done so). This one-drop of urine is capable of contaminating our entire bowl of soup.

#### Outsourcing - will it work?

#### A consulting agency was hired in 2003 to monitor drug quality:

The highly sensitive work - that of of keeping an eye over the quality of drugs at all times - has been delegated to a company, probably by the name of PPR K Pharmaceuticals, Hyderabad.

Program officers reportedly would pick up drugs from the DOTS pipeline at random and get them tested regularly. Only time will tell whether the arrangement will pay dividends, but one thing is clear -The Central TB Division seems to have successfully distanced itself from the contentious drug quality issue. It has, to a considerable extent, washed its hands off this onerous and vital responsibility.

#### Recommendation No. 6

### The international organizations ought to donate ready-to-use high-quality anti-TB medicines to India - instead of hard cash!

Whenever a needy person approached the author's mother, she would always make a genuine effort to extend help. She would give him whatever it was that he actually needed: atta (flour), dal (pulses), kerosene oil, food, blanket, clothes of different but specific sizes - for himself, his wife or for his kids. But one thing she would never give - cash. "He might be tempted to misuse cash for buying bidi, cigarette, tobacco or alcohol." she would sermon.

No doubt the onus is on the donor to ensure that the donation is not misused and reaches the intended beneficiary. Therefore, rather than hard cash, WHO and The World Bank ought to arrange to supply ready-to-use high-quality drugs - produced in some country having high standards of quality control - for consumption in at least these 5 countries - India, Indonesia, Pakistan, Nigeria and Bangladesh - because these are indisputably bedeviled by 2 problems that complement each other; first, a high burden of tuberculosis and second, high levels of corruption.

Corruption Perceptions Index (CPI) 2002 released by Transparency

International, Berlin does the ranking of 102 countries from the 'least corrupt' to the 'most corrupt. Finland with a score of 9.7 out of 10 is the least corrupt country while Bangladesh with 1.2 is the most corrupt one. India with a score of 2.7 ranks a lowly 73rd among the 102 countries.\*

#### Changes in the law of the land:

- Drugs and Cosmetics act 1940 ought to be urgently reviewed and made more stringent.
- Dealing in spurious drugs should be made a non-bailable offence.
- Death penalty for the crime of dealing in spurious drugs
- Fast track courts for speedy trial of such cases for the society, certainty
  of punishment is more rewarding than its severity.

#### Encapsulate every possible govt. function with a definite time-frame:

Attach the paradigm of time to every possible govt action. Just as the current revolution in the fields of information technology & telecommunication (ushered in by the great vision of late Mr. Rajiv Gandhi & his trusted genius, Mr. Sam Pitroda) continues to transform virtually everything - something one could never have fathomed through the 1990s - expeditious investigation and speedy delivery of justice will likewise improve virtually everything in India even something seemingly as unconnected as quality of drugs. The interminable delays act like oxyzen for the corrupt & the evil.

Fix a legal time table for every move. An FIR must be filed by the police within 24 hours of a crime being committed, investigation concluded within 15 days, the case ought to be decided in the court of law within 90 days. Similarly, 48 hours for a file to be processed and moved on, 72 hours to acknowledge, reply or redress a complaint. Attach the paradigm of time factor to everything and it will transform the country.

<sup>\*</sup> Corruption in India, The Roadblock to National Prosperity, by N. Vittal. Published by Academic Foundation 2003

### 18

# How Reliable could be the Data churned out by DOTS?

One of the 5 fundamental essentials of DOTS (as detailed on page 5) is: Systematic monitoring and accountability for every patient diagnosed and initiated on treatment.

"TB India 2004 RNTCP status Report" published (for the fourth consecutive year) by Central TB Division, Directorate General of Health services, Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi (http://www.tbcindia.org) is a meticulously compiled document that can be said to be the 'ultimate' report on the status of Revised National TB Control Program in India. It highlights several achievements on page 4:

#### "Cure rate (expected 85%) ......86%"

Since DOTS is a govt run program, this report is the most authentic and prestigious national document on the subject, and it receives wide publicity. Its figures are profusely quoted in doctors' lectures, meetings, workshops and conferences as also in journals, magazines and newspapers, eventually reaching the citizenry.

24th of March is commemorated as the World TB Day. It is customary for the government of India to release some material in newspapers for public awareness on that day (at least). Some of the statements (based invariably on the above-mentioned document) released in the past read like this:

#### "Cure rates under RNTCP have been maintained at over 80%"

Dr. S. P. Aggarwal, DGHS. (The Hindu, 24th March 2002, page 13)

### "The quality of services have been maintained with a cure rate of over 80%"

Dr. C. P. Thakur, Health Minister (of India) (The Hindu, 24th March 2002, page 13).

(Note: The above 2 statements formed part of a full-page TB day message published under the aegis of Mr. K.R.Narayanan, the ex President

of India, and Sh. Atal Bihari Vajpayee, the ex Prime Minister of India).

#### "Cure rates under RNTCP have been maintained at over 84%"

Dr. S. P. Aggarwal, DGHS. (24th March 2003)

(Note: The above statement was part of the full-page TB day message published in several newspapers under the aegis of Mr. A.P.J. Abul Kalam, the President, and Sh. Atal Bihari Vajpayee, the Ex Prime Minister of India).

#### "The success rate has gone up from 30% to 84%"

TB day message from Mrs. Sheila Dixit, Chief Minister, and Dr. A.K.Walia, Health Minister, Delhi Govt., published in several newspapers on 24th March 2003.

#### Cure rate of the program = 86%- A camouflaged national figure:

Ever since late 1990s, when DOTS was being born in India, the government reports have been making such unmistakable and vivid claims to the effect that the cure rates of this wonderful new program are mind boggling - about 85%. The author has heard of this spectacular number over and over again in doctors' meetings, workshops, lectures, presentations and conferences so much so that the majestic figure of 85% had got deeply ingrained on his mind.

TB India 2004 - RNTCP status Report states on its page 4, achievements under RNTCP. 2003:

#### Cure rate (expected 85%) ......86%"

What was the impression the author gathered from this entire media blitzkrieg? Just what anyone who can read and comprehend simple English would. Just what scores of other doctors did. It is a fairly simple statement, isn't it? It clearly implies that cure rates of the program were 86%. Of the patients who were initiated on treatment under RNTCP, 86% have been cured. In other words of all the patients treated under the program, 86% were cured.

Simple, isn't it?

Right?

Wrong!

There is a catch in it.

What it actually means is this: "Of all the 'new sputum smear positive patients' treated under the program, 86% were cured. The figure therefore reflects the cure rate of merely a select subgroup of patients (sputum smear positive cases who had never taken any anti-TB medicines in the past). The cure rate obtained in this small - easy to treat - segment has been chosen arbitrarily, albeit quietly, to serve as the sole indicator of the program as a whole.

86% is not the cure rate of total number of patients - not at all.

What is disturbing is not that it has been so devised but that it is not duly clarified or emphasized in the public domain that such is the case; this vital aspect of information is conveniently withheld. Only a curious peeping Tom might stumble upon it and that too somewhere in the fine print.

The inferior results obtained in difficult-to-treat-category - cat II (that consists of hard core defaulters, relapse and failure cases) - are not included. In 2001 those were 69%¹. And if clubbed together, success rates of DOTS will automatically climb down significantly.

For several years the author had no inkling of his misconception. In mid-2003 when an academician patiently explained the true picture to him, the author could barely believe his ears. He felt as if he had literally been duped; taken for a ride all these years. And imagine by whom! One wonders how many govt. officials, media persons, doctors manning DOTS, funding partners, the health workers, the patients, their relatives or the citizens at large are privy to this camouflaged national figure!

#### Symbolic of dishonest attitude lurking at the very top:

The ignorant, gullible citizens are misled into believing that the program cures 86% of all cases, tantamounting to bluffing that smacks of employment of third degree marketing measures by seasoned managers.

This is one of the biggest lacunas of this program. Worse, it is symbolic of a dishonest attitude lurking at the very top-a disturbing and dangerous prospect for the future of any national program.

<sup>&</sup>lt;sup>1</sup>WHO Report 2004, Global Tuberculosis Control, Surveillance, Planning, Financing page 31.

#### Recommendation n No. 7

The govt of India and all the state govts must, with immediate effect, be ordered to desist from perpetrating such **bluff** any longer. Henceforth, it should be made absolutely clear in simple language that the cure rates of 86% are with respect to the 'new sputum smear positive cases' only and not that of the entire program per se.

#### Comparison with previous program is unfair:

"Treatment success rates tripled from 25% in the earlier program to 86% in RNTCP"

(TB India 2004 - RNTCP status Report states on its page 4).

#### ".... Tripling the success rates...."

A. Raja, Minister of state for Health (24th March, 2003).

#### "The success rate has gone up from 30% to 84%"

Message from Mrs. Sheila Dixit, Chief Minister and Dr. A.K.Walia, Health Minister, Delhi Govt., published in several newspapers on the World TB day, 24th March 2003.

Comparing the results of RNTCP with those of our previous National TB Program (NTP) is blatantly unfair. NTP was admittedly an abject failure. To gloat over the current increased success seems totally unjustified. **Since there has occurred a generational switch in chemotherapy,** there can be no comparison between the two programs. How can you reasonably compare a power-packed regime of EHRZ with a primitive one of STH?

Can you justifiably compare -

- A colored television with a black & white one?
- A mobile phone with a loud speaker?

For God's sake, it is unfair. Nothing on earth could be more misleading.

Under India's previous National TB Program (NTP) what was being doled out to the patients? Not only were they administered ancient STH regime but that too in an erratic manner. Of the 3 drugs given in its initial phase, 2 drugs, namely Isonex and Thiacetazone are dirt-cheap; only the third drug namely Streptomycin injection is somewhat costly.

So, when we confess that there was perpetual shortage of drugs under the previous program (as detailed on page 27), it implies that it was this injection SM, which was perpetually in short supply and from time to time missing from the stocks. The patient ended up receiving merely the familiar light-yellow-colored combination-pills of Isonex and Thiacetazone, each of which cost the exchequer merely 25 paisa, often laced with a handful of nonessential multicolored vitamin or Paracetamol tablets cleverly dispensed towards increasing the volume of free medication. They played no role in his disease per se, though they provided some symptomatic relief and psychological reassurance to the innocent patient.

Absence of the powerful drug Streptomycin, an integral part of the regime, resulted in the patient hardly getting any relief from his symptoms in the initial months. How long could you expect a sick person to continue a therapy without getting an iota of relief? The poor chap would be fed up and would eventually look elsewhere for cure. A significant number of patients who deserted those days belonged to this category.

In contrast, the regime of DOTS today is more power packed and there are no shortages and it is capable of bringing in quick relief from symptoms, obviating a fundamental reason of compliance failure. So there is simply no comparison.

Another sizable chunk of patients used to give up treatment because they simply got sick and tired of the long and protracted course of STH regime, which ran for over a year. With the duration of treatment nearly 'halved' under DOTS, another major irritant stands eliminated.

Furthermore, the current cure rate is only with respect to a select group of cases whereas there was no such categorization previously; so the 2 figures are virtually incomparable. Such preposterous comparison will only invite further complacency!

#### Compare with China if you must:

The cure rates of Indian DOTS ought to be compared with those achieved in the developed nations, which employ almost the same drugs, tools and technology and yet seem to be doing wonders; only they are utilizing their resources infinitely more efficiently, honestly and sensibly.

All right, if not with the US, UK or Australia which are far too advanced, the Indian results should be assessed in the light of cure rates obtained in China

(96%)\*, Vietnam (93%)\*, Cambodia (92%).1

#### A systematic misinformation campaign unleashed by the govt of India:

#### 1. Actual coverage - to get to the truth, divide the official figures by 2:

"The RNTCP now covers more than 778 million people in 431 districts in 27 states and union territories"\*

(TB India 2004, RNTCP status Report, Page11)

The claim, though factually correct, does not reflect the true picture in view of the fact that even in the so called 'covered' districts, half the patients continue to go to the private sector, which is least interested in joining DOTS and remains outside of it. To obtain the actual coverage you have to divide the official figures by 2.

### 2. "Considering the per capita expenditure of US \$ 5 cents, this is also a very cost effective program"\*

(Foreword, TB India 2004, RNTCP status Report)

For the reason explained above, due to relative non-inclusion of the private sector, DOTS is able to cater only to half the patients and hence half the projected population. Is the calculation morally correct then?

#### 3. Policy of concealment:

The true indicators of good performance of any program are its low failure rates. For realistic assessment, along with strengths, we must take into account all its deficiencies. The overall picture is woefully incomplete without putting weak areas into the perspective. "TB India 2004 RNTCP status Report" seems relatively tight-lipped with respect to problem areas e.g. relapse rates, failure rates, drop out rates, default rates, MDR rates, death rates and rates of occurrence of side effects.

These figures have not been duly highlighted. They can only be found, if at all, in passing in the fine print. Why this policy of concealment? These indicators deserve to be divulged and publicized with complete honesty and simplicity in the public domain.

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<sup>&</sup>lt;sup>1</sup>WHO Report 2004, Global Tuberculosis Control, Surveillance, Planning, Financing page 28.

**4.** The claims that under this program, **top most priority** is accorded to curing 'new sputum smear positive' patients does not seem to hold ground in view of the fact that even they are not granted the benefit of mandatory chest X-rays, a fundamental facility.

#### 5. ">3000 private practitioners involved in RNTCP"\*

(TB India 2004, RNTCP status Report page 4).

The statement becomes dubious in view of the fact that none of the 70 odd so-called 'private practitioners' involved in RNTCP in District Faridabad possesses an MBBS degree; they are all non-allopathic 'doctors', some having no degrees at all whatsoever and could be justifiably termed as illegal quacks in the realms of jurisprudence. What about other districts in the country?

Is it not a curious coincidence that the figure is expressed in absolute numbers and not as a percentage of qualified private doctors? Only a fraction of this figure of 3000 would be qualified doctors. Of the 5,50,000 odd qualified doctors in India, over 75% could be in the private sector. So if % age of qualified private doctors who have joined this program is calculated it would come out to be 0.0 something %; hence the seasoned statisticians on the payroll of the government have cleverly used the absolute expression.

### 6. Diversionary tactics like creating defunct committees for misleading the nation:

A Program Advisory Committee (PAC) was constituted by the govt. of India for RNTCP. A stroke of luck saw the author appointed as one of the 9 members on this committee. Its first meeting was held on Feb 27, 2004 at Nirman Bhavan, New Delhi. Two of the distinguished members - Directors of TRC Chennai and NTI Bangalore - naturally had to fly in. Nonseriousness of the government officials was apparent from day one. Some of the members including the author had not been communicated any agenda in advance. Guess what reportedly prevented the Joint Secretary (RT) from attending and chairing the meeting - a delayed flight, probably from Ahmedabad. Despite pleadings and protests by some members, no meeting of this committee has been convened since.

#### Why such secrecy?

Some of the members of the committee mentioned above (including the author) strongly feel that they are being deliberately kept in the dark regarding the entire spectrum of RNTCP activities going on at a feverish pace - ironically it is the very program they are supposed to advise on. It is as if the program is the monopoly of a few officials. Despite repeated personal requests, the author was curtly denied invitation (and hence meaningful exposure) to several educative events e.g.:

- 3 day event on the World TB Day (24<sup>th</sup> March, 2004) when delegates from most of the high burden countries had visited India.
- 3 day Program Review Meeting held around Oct. 17, 2004.

#### A disturbing yet recurring pattern in India's health data in the past:

Judge a man from his past record - and not from his assurances or promises for the future.

The track record of the government of India in implementing health programs has been quite dismal. However, the data it has projected has often painted a rosy picture. If one critically reviews the past data, it hardly inspires confidence.

It reveals a disturbing yet recurring pattern: that of govt's propensity to mislead through juggling with figures - at least till such time that the focus of the nation shifts away - to another hot issue or till the funds are still flowing in.

#### 1. Data of Population control program:

In mid 1970s, when political and administrative bosses set unrealistic targets and brought to bear intense pressure on government employees, the latter displayed a remarkable resilience, devising ingenious methods to cope up. To pep up achievement numbers, individuals who were unmarried, too old (70 years), had single child or no children were forcibly sterilized. Some surgeons reportedly with mutual consent resorted to skin vasectomy (whereby they would just 'slit and stitch' the superficial skin, quietly leaving the spermatic cord, vas deferens, and hence fertility intact), or skin tubectomy (fallopian tubes were deliberately left uncut). Some lady doctors would silently insert a copper T in to the womb of every female visiting OPD, without her prior knowledge or consent.

Did target-oriented approach and pressure tactics (which incidentally are the hallmarks of DOTS today) really work then? Number

Have we forgotten the spectacular claims of the govt during those years - the data projected by the unbelievable figures of sterilization?

The population explosion continues unabated.

#### 2. Data of HIV/AIDS:

While spectacular data regarding condom-distribution emanates from the government publications, at some of the peripheral centers, cartons and cartons loaded with condoms are reportedly set on fire by exasperated health workers fed up of the pressure from above. One shudders to think if data of DOTS receives even a fraction of such treatment!

#### 3. Data of Polio:

One of the main reasons why the goal of Polio eradication continues to elude us after numerous 'just this one last' pulse polio weeks (which never seem to end to considerable embarrassment of the workers who face the flak from public), is that false data was cooked up and fed from below and accepted blindly at the top.

It is not uncommon for the teams to claim having given drops to more children than are known to inhabit an area.

A District Immunization Officer had this story to tell:

I was pleasantly puzzled and asked the nurse, "how come you have achieved 110% coverage?"

She replied, "I gave drops to some kids who happened to be visiting from the neighboring colony, sir." That evening, back at the head quarter, I perused the reports filed by all the 'neighboring colonies' of the entire zone. They failed to reflect any such absence of kids from anywhere. Rather most of them had similarly exceeded their targets!

Mr. R. K. Malik a leading exporter and Assistant Director (Polio Plus) Rotary International (Distt. 3010), Faridabad who - for the past seven years - has been spearheading the rotary effort in close coordination with government sector sounded rather disillusioned with 'sarkari' attitude when he said, "the health employees seem more concerned about numbers to be dispatched to their superiors - rather than the real coverage. Besides, even children above 6 are deliberately included - to inflate numbers."

A WHO consultant (naturally privy to inside information) could barely suppress a smile while he told the author, "At last things seem to have got streamlined now. Reporting has become far too smooth. If pulse polio is on the 10<sup>th</sup>, suitable report is ready for dispatch by the evening...... of 9<sup>th</sup>."

#### 4. Malaria program:

Despite all the hype and hope created from time to time through projecting excellent figures, NMEP (National Malaria Eradication Program) has been going on forever like a soap opera without delivering results; the word 'eradication' scaled down to the word 'control' at one stage.

Once the focus of the nation shifts away from a topic, things slide back to 'normal'. Any doctor who has ever served in malaria department is privy to the open 'secret' as to 'how the mosquito was aided and abetted in gradually turning resistant to DDT' (once a lethal compound - highly effective in killing mosquito). He would tell you - off the record of course - that it is a man made disaster, caused by human greed that gave way to large-scale adulteration of this chemical.

'They' began mixing simple chalk powder with DDT. Prolonged exposure to such substandard diluted insecticide offered the resilient mosquito with a window of opportunity just what it craved for - to mutate and develop resistance so as to dodge it. ('They' stands for the omnipresent antinational elements and their touts, stalking corridors of power, waiting relentlessly for the slightest opportunity to rape any government proposal - be it for the benefit of the blind, lepers, pregnant mothers, children or TB patients).

#### 5. Poverty alleviation programs in India:

Political manipulation of statistics was resorted to in redefining poverty in India, changing the number of k-calories required per day per individual.

#### Soap opera:

The government of India has spent millions of dollars and decades of effort purportedly in the name of health programs - towards controlling or eradicating major ailments: TB, malaria, blindness and population explosion etc.; yet the goals remain as far away today as ever. The programs go on and on; so do the problems; just like the two parallel lines of a railway track. This is yet another opportunity to search our souls; are we really serious this time around or is DOTS yet another soap opera in the making?

#### Is data of DOTS reliable?

### How can one in his right mind even begin to suspect the reliability of DOTS data? May be the information or the interpretation is wrong:

The author often wonders how such an enormous data originating from a multitude of unconnected sources and prepared by such an enormous work force having diverse thinking, culture and temperament, and originating from entirely different directions and corners be even suspected to be uniformly unreliable! It simply seems unfathomable. There has got to be some misunderstanding - and a monumental one at that.

But then, prior to the invasion of Iraq, wasn't the entire world led into believing that stockpiles of weapons of mass destruction indeed lay hideden in Iraq and which could be deployed within 45 minutes?

#### Fear of 'job loss' stalks every worker every single minute:

Population explosion has made getting a job in India a Herculean task. Count yourself lucky if you can land one with the government during lifetime.

Besides, if the job is temporary, the worker is perpetually insecure. The question that haunts him is, "will I continue next year?" The sword of uncertainty always hangs on his head. After all, he has a family to support. It would be crazy to let go of the job lightly. He will do anything to retain it. Keeping his eyes closed, ears plugged and mouth shut is relatively a small price for being able to continue feeding his kids.

He wouldn't mind manipulating the figures "ever so slightly" or pulling up cure rates a few notches towards the targets. Especially when the doctor in charge willfully overlooks these artistic maneuvers. After all, it is a team effort; it won't hurt to fudge a little.

#### Climate is created right from the day one:

Although no one directly orders that figures be cooked yet a climate seems to be somehow created wherein everyone feels compelled to come up with the expected cure rates. The design of DOTS - implicit in which is a veiled threat of being singled out, black listed, charge sheeted and thown out of job - ensures this.

### Target-oriented approach fosters fudging of facts - right from ground zero up to the very top:

Thanks to the target-oriented approach, a considerable amount of pressure is

constantly brought to bear upon its workers. Pressure can be a wonderful tool to extract the best out of the workers. But undue pressure can also prove a double-edged weapon; it can also coax them into a defensive mode, provoking them to proffer false reports to save their skin. Howsoever hard working a worker might be, he is dubbed inefficient if his results are poor. And his ad hoc job is in grave danger. Insecure that he is, he is acutely conscious and extremely cautious of his quarterly reporting. Despite genuine efforts if the cure rates fall short of targets, he can't even dream of taking the risk of reporting them honestly as such. He feels constrained to manipulate his figures 'ever so slightly' and register false but expected percentages.

#### Data oriented (not human oriented) approach makes them DOTS-smart:

As a worker becomes DOTS-smart, he learns how to stay clear of trouble. He learns to devise innovative methods to protect his data, because it is crystal clear to him that for the sake of one's own future, figures are far more valuable than humans; paper work far more important than patient-care; fiction far more rewarding than reality.

#### 1. Manipulations begin even before a patient is registered:

The question upper most in a health worker's mind is 'how can I predict as to which patient will eventually default'. If he can somehow spot the future defaulter right now, it will save him a lot of trouble, because each defaulter poses a potential headache. He formulates his own thumb rules for predicting compliance behavior of patients and registers accordingly.

#### Preliminary screening:

As a result of such a mindset, some of the most deserving patients are turned away! Deliberately!

- Any patient who is visibly too sick to walk is right away black listed and excluded. Obviously, he is less likely to turn up regularly.
- Similarly, anyone who is too old is looked upon suspiciously as a potential defaulter.
- A TB patient who also has simultaneous diabetes mellitus (sugar problem) is likely to prove a difficult-to-cure case & might pose headaches. Why bother with him?
- A TB patient having an associated ailment like asthma, jaundice,

alcoholism, addiction, HIV or pregnancy too evokes disinterest.

#### Polite postponement:

"We never directly refuse any one. We can't legally. Politely just keep putting them off on one pretext or the other (e.g. repeat sputum tests), till they tire away to a private doctor. Postponement is a suitable tool to shoo away the undesirable elements," revealed a health worker. "Show your ration card" is another popular ploy to send an unwanted migrant labourer away.

#### Test dose of a few days:

A health worker said that a patient, initiated on treatment, is defensively watched. If he defaults and disappears, so be it. There is no need to chase him (even if he were sputum positive!), because there exists (as yet) no record. He was just a ghost; there is no tell tale sign that he ever came here. On the other hand, if he behaves well for the first 15 days, he has passed the entrance test; he has earned a seat. Now his name merits formal entry in DOTS registers."

#### 2. Manipulations in category allotment:

#### Sticking a false label:

All that is needed to enhance the cure rates is to falsely register a few symptomatic healthy persons in to cat 1. Just pick up any 2 sputum positive slides and preserve them in his name; that is it. Once a non-TB person is falsely labeled as TB and put on cat 1 treatment, no one can ever detect the mischief. In the absence of provision for X-ray, even God cannot prove that it is a false label because the sputum-negativity thereafter is attributable to excellent treatment response.

**Over diagnosis** is a useful tool sometimes used deliberately to improve figures. Besides, untrained doctors are consigning several non-TB cases to DOTS e.g. cases of bronchiectasis, haemoptysis, normal but symptomatic individuals with persistent old healed spots in the X-rays but persistently sputum negative. These cases are always a welcome asset, because at the end of the day, it is always a win-win situation; there will be no failure, no relapse, no MDR (because there is no TB in the first place) and all they can do is enhance cure rates.

#### Deliberate craftsmanship:

A study revealed that "18.3% patients were wrongly categorized as New smear positive cases of category-1. When patients were asked about details of their disease then they revealed that they had taken Anti-TB drugs earlier

also.... It is possible that these patients were deliberately put in to category-1, so that target of detection of New Smear Positive can be attained effortlessly. Otherwise it is unlikely that such hefty numbers of patients did not give the past history of treatment of tuberculosis properly"

#### **Upgrading category:**

Deliberately label a cat III patient as cat 1. While the patient receives the benefit of a stronger regime and is sure to get cured, the 'smart' move goes a long way in enhancing the cure rates effortlessly.

#### 3. Default goes unreported, cure rate hiked through fictitious entries:

Let us assume that 10 cases are initiated on Cat.-1 in a dispensary. And within 45 days, 2 of the patients default. Despite health worker's persuasive efforts they refuse to return.

What happens?

Only 8 out of 10 patients are continuing treatment. So the conversion rate and the cure rate can at best be 80%. And that too, if each of the 8 remaining cases does turn negative and thereafter complete his treatment.

After 2 months,, as per targets, conversion rate is expected to be 90%.

So what happens?

The team members make fictitious entries as if those 2 defaulters have converted to sputum negative; the conversion rate is thus hiked to 100%. Preserving negative slides in their names is hardly a problem.

Thereafter, the cards are constantly filled in till end - as if the 'defaulters' are continuing to pick up their medication regularly and both the defaulters are shown in the records as cured. On paper, the outcome looks great.

But in reality both are still sick and possibly transmitting disease. Their quota of medication is probably sold away by some smart Alec.

Howsoever hard the inspectors, RNTCP consultants and DTOs might work, they can't check each and every patient.

The doctor in charge conveniently looks the other way because it is his own performance that is being boosted.

A doctor in to DOTS since its inception confided, "I gladly ignore such manipulations. Otherwise, poor reports from my center put me in trouble."

<sup>&</sup>lt;sup>1</sup> Evaluation of DOTS under RNTCP in District Sonipat of Haryana. 2003. The study by Dr. Kuldeep Singh. Page 163

Another doctor confided, "pressure is the name of the game - from top to bottom. Shouting on subordinates and terrorizing them may or may not improve quality of services to the patients but it invariably improves one thing - the thing that really matters in DOTS - the quarterly reports. Basically it is a case of telling the masters just what they want to hear."

Coming back to the fate of those 2 defaulters, both will resurface at some neighboring dispensary where they might hide the episode of default for fear of rejection. Hence they risk being placed in Cat-I or 3 (although they clearly deserve Cat-II), and risk treatment failure.

### 4. In re-treatment cases, down playing the source of past treatment - was it a private doctor or DOTS itself?

If there is one area where there is absolutely no pressure over the workers it is while recording relapse cases. The column of relapse/ failure/ default is often left unfilled in cards.

When a patient 'cured' by DOTS returns with relapse, he is put on Cat-II. But one secret is not highlighted - that the source of his past treatment was DOTS itself (and not a private doctor as the silence insinuates) because that would reveal program weakness and spoil its image.

A Lab. Technician said, "several Cat-II patients in our center are the one's that we had 'cured' recently. Their return puts a big question mark over the efficacy of the DOTS. But nobody knows. Either I know or God knows!"

#### Recommendation No. 8:

- While recording Cat II cases, add a new column on TB cards and registers to be filled in: What was the source of previous treatment - DOTS / Non DOTS?
- 'How much relapse actually occurs with DOTS' is the single most important question that needs to be answered, and answered honestly.
   Transparency and honest reporting will only improve the program.
- Faulty data-collection technique and monopolized reporting:

One of the biggest drawbacks of the data collection technique lies in the way quarterly reports are compiled and filed. A single individual (namely the District TB Officer) does it all - after obtaining inputs from various sources at the grass roots levels. He has complete monopoly over the entire exercise. He remains solely accountable and responsible for filing reports for an entire district, which is too big for him.

The quarterly reports ought to be filed directly by the very doctors who are actually treating patients at the grass roots level e.g.: MO TUs, doctors of PHIs, doctors of CHCs, DTOs & STSs etc.

#### Data of DOTS found dead wrong!

A recent study by Dr. Kuldeep Singh\* revealed shocking reality:

- Home visits were conducted in 225 patients, out of these 23 patients were not found alive. However, in the record, they were shown as cured\*.
- Compliance rate in the study is 67.8%\*.
- Cure rate in the study, if we follow the guidelines of RNTCP were 50.5%\*.

#### Too good to be true:

Of the 431 districts in 27 states and union territories, guess which district tops the nation in terms of performance?

District Vaishali.

Quarter after quarter, District Vaishali has consistently exhibited superb cure rates, touching 94%, as reiterated in the government data:

- Treatment outcome for a year = 94%.\*\*
- "RNTCP Performance Report, Fourth Quarter-2003, page 5" = 94%.

Guess where is this super-district Vaishali situated?

It is located in one of the most backward states; known for its poverty, illiteracy, lawlessness, lack of development and for abject inefficiency of its state machinery.

Furthermore, come July-August the state is usually inundated with flood waters grinding work to a halt. But it seems the DOTS workers of Vaishali are simply unstoppable even during a crisis. They keep up the spectacular performance - like spider man!

#### Yes, it is the state of Bihar.

During the past about 3 years nearly 11000 patients have reportedly been placed on treatment there. Curiously, the spectacular figures have remained unwaveringly brilliant; these have refused to show any fluctuations over a long stretch of time, negating the commonly accepted operational observations like:

<sup>\*</sup> Evaluation of DOTS under RNTCP in District Sonipat of Haryana. 2003. page 138,175

<sup>\*\*</sup> TB India 2004, RNTCP Annual Summary-2003, page 55

- A reasonable variation in a district's performance is to be expected.
- During the 2nd and 3rd quarters, cure rates are generally lower.
- As the number of patients increases in a center and a district, cure rates tend to decrease.

Isn't it too good to be true? Several academicians find it hard to digest.

#### Just an error? Or symptom of deep-seated, wide-spread malady?

A letter issued to DTOs, CMOs and STOs all over India by Ministry of health, Govt. of India {D O No. 19015/10/98 TB (Pt - 11) Jan. 3, 2005}states:

"Overall sputum positivity rate of 14% is now nearly in acceptable range and only 60 (12%) districts have reported sputum positivity rate of more than 20% as compared to 126 (28%) districts in last quarter which is definitely an improvement in the right direction. However, 6 districts of - Darang, Goalpara, R K Mission, Wokha, Faizabad and Mirzapur - have reported **sputum positivity rate of more than 95%**, which can't happen and has to be a reporting error".

#### Some anecdotes with regard to data:

#### I am deeply skeptical:

Dr. D.A.C., an ex-boss of a chest clinic currently serving in the largest TB hospital of Delhi stated, "we had a good team. We worked really hard and yet could barely manage to achieve about 80% cure rates; I wonder how every Tom Dick and Harry seems to churn out better cure rates! I am skeptical!"

#### How many are actually cured is immaterial:

Pointing to a just-compiled quarterly report under the glass top of his table, a senior medical officer of a rural zone is reported to have confessed to a visiting medical representative, "I have to submit 85% cure rates or I'll be nailed by the commissioner; how many are actually cured is immaterial."

#### TB patients are mere dots on a spreadsheet:

"Program bosses have no concern for the patients. It seems individual patients hardly matter to them. They are mere dots on a spreadsheet; officials are only concerned with running the program and which is judged and

presented through figures only," lamented Dr. F.S.D.G. an ex-DTO.

#### Approach is data oriented, not society oriented:

A sincere, hard working STS complained, "policies it seems have been made in AC rooms; the ground reality is way different. The stress is not on the patient but on the reports; there is a plethora of reports to be filled in."

#### DOTS data is an eyewash:

"Spectacular data of DOTS is nothing but eyewash" says a retired pharmacist who continues to work as a DOT provider, "it is constantly made spicy and sexy by fictitious entries" he says.

When asked, "How do they do it?" he simply said, "with a ball point."

#### Damning internal reports galore:

The internal evaluation report on 'In-depth review of RNTCP' in Jind district, Haryana (Aug 24-26)<sup>1</sup> prepared by a dedicated team of officials from WHO and govt after conducting thorough and painstaking interviews of patients and health workers corroborated the widespread skepticism of data.

### Monitoring indices have been exhaustively designed to nab cheating, but time is at premium:

An RNTCP consultant reassured the author by explaining "the multitude of monitoring indices are so exhaustively designed that to a trained eye, the awesome data can be immensely revealing. If a DOTS center is indulging in spoil sport by fudging figures, an expert sitting right here in Delhi is able to smell it - just by juggling with figures on a computer screen."

But this can happen not before 4 or 5 quarters have elapsed; by which time the erring DTO, LT, HW have already been transferred or even promoted and damage to the patients irreparably done; the revelation is only of academic value.

#### Bleak future:

Several doctors have expressed fears that the cumulative effect of such manipulated data might snowball after 5 or 6 years when it will be so distant in time that the damage would have been done already and irrepairably.

### The last person in town to come to know about a woman's infidelities is her husband:

RNTCP consultants are reported to admit privately amongst themselves that a 'slight' degree (to the tunes of about 10%) of fudging of facts may be going on. How come in their publications, the govt of India and WHO fail to mention any such possibility? Aren't they aware?

But then, the last person in town to come to know about the infidelities committed by a woman is... her husband.

Poorly collected data when spuriously supported by statistical techniques and jargon can be dangerously misleading. The amount of statisticulation that is now going on in the name of 'DOTS is fast eliminating TB' is astounding. And when none other than a mammoth organization like the government of India chooses to be a silent spectator, it can simply play havoc.

Benjamin Disraeli famously said that there are 3 kinds of lies:

Lies, damn lies and statistics.

#### Who can dare to speak up?

Who can dare question the validity, efficacy of DOTS or genuineness of its data when the WHO, World Bank and Govt. of India are backing it with all their might? Such intimidating credentials would check any sane person from even beginning to think critically - even in one's dreams. And who can speak up? Who can dare question?

Utter one word against DOTS and all hell may break lose. You could become persona non grata. You could lose your case for a grant. Your imminent call for fellowship may never materialize. You could suddenly become untouchable amongst your own institution. You could be transferred

<sup>&</sup>lt;sup>1</sup> Dainik Bhaskar 28.8.2004, "TB ke khilaph jang ki khuli pol

away to the worst stations. You may lose your job. You could end up spending the rest of your life defending yourself in a quagmire of enquiries. If ever there is one moment when you could be certain that the govt. machinery will act efficiently, it is in crushing dissent through stern retribution. Freedom of speech, which is supposed to be the main currency in a democracy, seems to be in desperate short supply amongst DOTS employees, who perpetually keep their lips sealed out of fear.

The world is a dangerous place, not because of those who do evil, but because of those who look on and do nothing - Albert Einstein.

### 19

#### **Levels of Political Commitment in India**

Of the 5 cardinal requirements of DOTS (as detailed on page 5), the first and the foremost is political commitment.

The million-dollar question is: do we have it in India?

#### 1. The biggest stumbling block in India: 'Health' is a State subject:

That the subject of health is a 'State' subject remains enshrined in the constitution of India. What it means in simple terms is that the ultimate authority and responsibility of implementation of all health related activities rest with the state govt machinery. The Central Govt can merely make plans, frame guidelines, forward grants and make recommendations. Thereafter, it can only sit back and hope for compliance since it enjoys little leverage over state officialdom. It can't intervene directly; it can merely exercise a limited control (that too indirect) over the day-to-day working in the states.

- The entire gamut of transfers & postings (of DTO, MO TU, LT etc.) remains within the domain of the state machinery (as detailed on page 72-86). The central government that conceived the program can only watch the game being played from a distance like spectators sitting on the benches of the stadium.
- RNTCP yes, DOT no: The Central govt has little choice but to helplessly contend with irrational tantrums of the State govts. For example the state of Tamil Nadu initially said 'yes' to DOTS but 'no' to direct supervision. It refused to accept the program in toto stubbornly resenting its core element, namely DOT. Hence, for an unknown period of time, the DOTS strips were reportedly dispensed away to patients on a take-home basis without supervision.
- Soft preconditions for states: In their race to grab cheap appreciation and publicity in achieving various milestones (e.g. fastest expansion), officials of the Central govt, it seems, failed even to diligently draft an imaginative charter of effective preconditions - to

be fulfilled by states before they could receive their share of grant thereby missing a golden opportunity to exercise rigorous control.

2. Since states were never consulted - rather literally ignored - during the entire process of finalization of the DOTS module, there are serious hiccups in its acceptance and implementation. Just as with all other national programs, the entire exercise of planning of DOTS was done by the Central government unilaterally, without ever consulting the state officials or generating a consensus between the planners and executers, which has produced lack of coordination between them. That is why DOTS risks becoming lifeless - just like other national programs.

Furthermore, the same bureaucratic phenomenon prevails down the line within the states; there is no corrective feedback approach or flexibility built into the state machinery. All decisions are taken at the very top in airconditioned rooms with a typical 'we know what is best for you' approach.

"The key person out there at the grass roots level who is ultimately to follow instructions in letter and spirit feels completely isolated and left out. He has no say at all in the program. He has never been consulted; neither before preparing the module nor afterwards, during implementation. Not only is he never taken into confidence, his voice is ignored - rather systematically stifled. There is a complete barrier between the two tiers," lamented a medical officer in the periphery. "So our heart is not into DOTS, we work without conviction and the program becomes lifeless," he added.

### 3. Several years on, a peculiar lack of coordination within DOTS continues to prevail all over India:

India is in the midst of a peculiar confusion today. The various wings of medical profession seem to perceive DOTS differently; as if they are not on the same page of the book.

Serious reservations harbored by the private sector are well known. The govt has done little to mitigate them through sensitization and otherwise.

Various medical collages, which are to some extent autonomous bodies, too entertain views on DOTS, which are often poles apart.

Not just that, even streams under the govt control itself often seem to be at loggerheads. DMS (Directorate of Medical Superintendents), DPH (Directorate of Public Health) and DME (Directorate of Medical Education) entertain different opinions, perceptions and priorities. There is apparently

little consensus or harmony - call it lack of coordination, professional rivalry, interdepartmental animosity or clash of egos. Such hostilities among various agencies - like public health, medical managers, TB specialists, medical colleges and private sector - are surely wreaking havoc with each passing year. Ultimate loser is the patient who has no inkling of it all. Had the govt really done its homework and ensured that all of them worked in unison, complementing one another, it could have produced a snowball effect doing wonders in achieving targets speedily and effortlessly. Alas, serious govt commitment has been missing all through it seems.

#### 4. There is a strange contradiction in the program:

- A representative of WHO and Government of India (called an RNTCP consultant) oversees and monitors the program. He happens to be the only full-time worker in the entire program. All others down the line that he is supposed to supervise, monitor and control (e.g. a DTO, an MO TU, LT, pharmacist etc.) end up working part time for TB, since they have 18 other programs in their laps.
- While the consultant himself is just an insecure WHO employee (being on ad hoc basis for a year), those he is supposed to rein in are often well-entrenched permanent employees of the state government having strong unions.
- Furthermore, transfers-postings or promotions-demotions of subordinates are not in the control of the consultant. He has to make do with whatever compliance he receives from the state officials.
- An RNTCP consultant admitted that they were virtually helpless since they have no direct control over employees or decisions. It is a Herculean task to coax the permanent employees of the state to put their act together, through mere persuasion. The consultants have to tight rope between smiling and fuming. If they exert too much pressure, it might improve reports, through mere falsification of data.

#### 5. Quacks: India is unique. It differs from others in several ways:

Indian health care system is unique. Nowhere in the world would an uneducated TB patient be faced with the daunting task of searching for the 'doctor right' out of a maze of shady options constituted by innumerable quacks that are estimated to be 4 times as many as the qualified doctors.

An estimated 20,000 quacks thrive in Delhi.<sup>1</sup>

- According to Dr. P. Janardhan Rao (Secretary, Anti-quackery Cell, Indian Medical Association), there could be over 75,000 quacks in the state of Karnatka.<sup>2</sup>
- And 1,00,000 in West Bengal an estimate dubbed conservative by the National President of IMA, Dr. Sudipto Roy.<sup>2</sup>

These death merchants obtain fake degrees and forged certificates, which sometimes even claim them to be proficient in conducting surgeries. Under the very nose of the government, these back lane butchers and self-professed 'doctors' continue to prosper.

It seems the forefathers of DOTS failed to envisage that the program will run into stiff competition, not only from the qualified private sector but also from the illegal albeit flourishing unqualified sector, deeply entrenched in every village, town and city.

#### 50 years after independence, why do quacks continue to thrive?

- The commercialized private sector is too expensive and hence beyond the reach of a common man.
- The government sector has virtually failed to deliver. Several farflung PHIs don't even receive the courtesy of a weekly visit by the doctor posted therein; the patients have no option but to go to quacks. Abject failure of the government infrastructure to reach out to the poor keeps fueling their proliferation.
- There is no political will to clamp down on the quacks.

#### 6. What a funny situation prevails in India?

While purportedly for improving medical services, the government has proactively brought the qualified private sector under the ambit of consumer protection act, it has no will to clamp down on the illegal quacks swarming the nation like cockroaches simply because they happen to be significant opinion makers amongst the masses, constituting a potential vote bank. The politicians obviously do what is best for the votes rather than the voters.

#### 7. A faulty TB treatment system running parallel to DOTS:

Unabated free sale of anti-TB drugs through unregistered and unbridled

<sup>&</sup>lt;sup>1</sup> Times of India, June 23, 2004 page 2

<sup>&</sup>lt;sup>2</sup> Times of India, New Delhi, June 10, 2004, page 3, Times City

chemists often without doctors' prescriptions and also through quacks amounts to a faulty TB treatment system running parallel to DOTS, frustrating it as well as hiking the prevailing levels of initial resistance to TB drugs in India. It is like leaving a gaping hole unstitched in the pocket of your new expensive trousers. Isn't it a testimony to the lack of political commitment?

#### 8. Steroid misuse:

In a country where 40% of the adult population remains infected with TB germ at any given point in time, unregulated and large-scale misuse of steroids by the unqualified sector promotes development of disease (TB) in the public.

#### 9. Sub-standard Drugs:

Continuation of production of anti-TB medicines - whether for DOTS or for sale in open market - by small time unknown, unscrupulous companies smacks of that familiar morbid nexus among the key players - politicians, bureaucrats and pharmaceutical houses.

#### 11. Ignorance at the very top:

The first step towards inculcating commitment in someone is by making him thoroughly aware. Has there been any effort whatsoever to make politicians and bureaucrats aware? Has there been any effort at creating a suitable module to duly educate them? How can you possibly expect commitment from the rulers when they have not yet been suitably informed? Has there been any presentation ever in the parliament or in state assemblies on the subject that relentlessly consumes an Indian life every minute?

12. Decades of Criminal silence on the part of govt owned media e.g. Prasar Bharti, AIR & DD on the burning issue of TB is literally shocking. No worthwhile systematic effort whatsoever has been made to produce or telecast any episodes, serials, quiz, songs, documentaries, dramas, films, dance numbers etc. for awareness on a regular basis.

### 13. Thanks to political interference, nothing seems to happen systematically, automatically or on merit:

In India, nothing operates as per its original design. We Indians by nature have little respect for the design of anything. We invent modifications as per

convenience. We look for formulas or quick-fix solutions. We invent shortcuts; we have scant respect for the manuals, modules or rules; we believe rules are for fools. We have a penchant for inventing a crooked approach, a backdoor entry. We work not through merit but godfathers. We would keep on distorting the original design till it is beaten out of shape. No wonder, nothing seems to happen here systematically, automatically or on merit. The modules of DOTS are cosmetic documents - something for the records; there is no guarantee that the ground reality wouldn't be totally different.

Ironically, those enjoying political patronage flout the rules the maximum.

- Failure to fill up numerous vacant posts of doctors, ANMs, MPWs, LTs and other staff is a glaring evidence of lack of political commitment.
- To extend political patronage to 'habitually truant' doctors or employees must be declared a serious anti-national offence. It ought to be clamped down with an iron hand. Exemplary punishment ought to be meted out to both - the negligent as well as the protector.
- Continued political interference and nepotism reportedly in recruitment of contract workers of DOTS hardly inspires confidence.
- Failure to provide on a priority basis basic facilities like electricity or telephone to rural health centers.
- Failure to renovate some badly dilapidated buildings of rural dispensaries.
- The Minister's cronies: A voice claiming to be calling from the offices of the Minister of a state reportedly ordered a pharmacist to hand over the full 6 month quota of drugs to a certain patient, who was obviously well connected. The pharmacist reported the matter to the doctor. The dedicated and conscientious doctor stubbornly refused to comply saying, "the next time he calls, ask him to give it in writing." The doctor was telephonically threatened with a transfer. Several months later, at the time of writing this paragraph, the doctor was still there thankfully.

## 14. An example of sheer bankruptcy of political commitment at introspection or self-improvement:

In USA a public health official enjoys enormous amount of power over the citizenry. In India, he is considered to be at the lowest rung of bureaucracy, having little clout. No body cares to follow his recommendations - at least not

during the 'peace-time' (healthful seasons). The authority he wields is hardly commensurate with the charter of responsibilities. But sheer bankruptcy of political commitment is evident only in the event of a disease breaking out. Year after year, the country has witnessed amusing games being played by the politicians and bureaucrats. They perform spectacular theatrics of holding enquiries - and predictably nailing the softest target - some poor doctor - as a convenient scapegoat for the perpetual mess created by the entire government machinery.

No wonder then, in Dec. 2003, when Dengue broke out in Delhi affecting 2,853 persons and killing 34, it was a foregone conclusion that a doctor - and not the municipal commissioner or the health minister - would be implicated.

By any stretch of imagination, can a doctor be single handedly held responsible for the following lapses?

- The failure of Municipal Corporation Delhi to timely hire an estimated 1,136 field health workers required for a house-to-house surveillance.
- Non-utilization of 7 out of the 13 Crore Rupees 'plan fund' allocated for public health.
- Choked drains of Delhi.
- Stagnating water in domestic coolers.

Even if the doctor in question is eventually absolved of the charges, the poor chap is doomed to a life sentence of harassment.

How can the country improve unless we pledge to investigate in the right earnest to uncover the truth and cleanse our system?

#### 15. RCH Fiasco in District Faridabad:

Every time when treatment gets interrupted, it is the patient who invariably gets to be blamed and labeled as a defaulter - even if it occurs due to system failure!

#### Case of Mrs. Ganga\*

Ganga was put on Cat-3 w.e.f. 29.01.2004. She would pick up strips from a small dispensary operating in village Fateh Pur Chandeela, Faridabad from one Miss Shikha, (who reportedly worked under the overall supervision of one Miss Geeta based at civil hospital).

After duly receiving about 16 doses, she found the sub-center suddenly locked - and for good. She would go there daily in the hope that it might open. Finally, on 20.04.2004 a neighbor informed her that there was little hope of its reopening as the lady nurse had gone away - probably on a long maternity

leave - without alternative arrangements. He also told her that it had jeopardized not just her treatment, but also that of several other patients who too were visiting likewise and making enquiries.

So Ganga had approached the author for further treatment.

#### Case of Ram Charan\*\*

Diagnosed as PTB at Safdarjang hospital, Delhi and referred back to the local DOTS network of Faridabad. After several attempts, around March 22, 2004, he was duly registered with RNTCP and instructed to collect his strips from a dispensary in sector 30, located close to his residence. It seems he was put on cat.2 (he has lost his card recently). He duly received 8 injections and oral doses.

But thereafter a full stop; he kept visiting over and over again but every time he was deeply disappointed to find the dispensary shut down allegedly on account of 'orders from above.' 'Several other patients too are visiting like me ....in vain' he told the author whom he had approached for further treatment

#### Mysterious closure of DOTS centers:

Both these cases suggesting mysterious closure of DOTS centers were intriguing enough to kick-start a tiny investigation. This is what the author found out:

Several years ago, under the aegis of **Reproductive Child Health** (**RCH**) **scheme**, run through international funding, a large infrastructure was created in Faridabad - a nucleus of 2 hospitals and an outreach network of 32 small peripheral health centers. The hospitals [located in sector 30 and 3 (Ballabgarh)] recruited on a yearly contract basis several persons in its staff e.g. doctors (an epidemiologist, a gynaecologist, a paediatrician and an anesthetist), nurses, pharmacists, lady health visitors (2) and clerks etc.

Under its novel peripheral operations, to reach out to the masses, RCH project had recruited 32 female workers - technically called ANMs (auxiliary midwife nurses) or MPHWs (multi-purpose health workers) - to oversee a

<sup>\*</sup> W/o Dambar Bahadur R/o 341, B-block, sector 21-B, Faridabad. (Tel: Shanti (sister) 0129- 2416098, Vijay (son in law) - 9818066327)

<sup>\*\* (40</sup> years male, s/o Punia Ram (a laborer originally hailing from Gangapur city in the state of Rajasthan), currently residing at: house no. 15, sector 30, Shramik Vihar, Faridabad. Tel: pp Pandey general store 0129-2250948.) Diagnosed as PTB at Safdarjang hospital, Delhi. (Vide OPD No. 95436, unit 3 by Dr. B. Gupta/ Dr. Rita SR medicine on Dec. 11, 2003).

pocket of about 10,000 people each.

A nurse would operate from a tiny rented room (called a sub-center) located in the middle of a village, a colony or a slum and cater to medical needs of the people of that pocket - like organizing check-up of pregnant women through liaison with the doctors in the hospitals, extending logistical help during deliveries, arranging for the vaccination of kids, and generally assist the CMO in the implementation of the various programs at the grass roots level.

When DOTS appeared - with its policy of providing TB treatment right up to the doorstep of the patient - one more duty was added onto her multitude of duties - namely 'to act as DOTS provider for the TB patients of that paticular pocket.' Thus, of the 209 DOTS centers in the district of Faridabad, 32 were such RCH sub-centers, designated as DOTS outlets. On an average, onus of curing 10 to 15 TB cases was thrown into the lap of each of these 32 nurses.

On 31st of March 2004, all of a sudden, the state govt's honeymoon with its funding partners drew to an end tearing apart the dream arrangement. The stipulated five-year term of the first phase of the RCH project came to its end and the inflow of funds got terminated making RCH the baby of the state govt. But the finance department of Haryana reportedly was in no mood to sanction funds for the continuation of the project.

#### Salary of those 32 nurses was stopped.

As uncertainty prevailed, their fate hung in the balance. Completely demoralized, some nurses continued to work without pay on their own risk, hoping against hope that the state government would not ditch them nowafter 5 years of dedicated services. Others, unable to bear the fatigue of uncertainty and bankruptcy, headed for their home-towns; they closed down the sub-centers, handed over charge to their bosses and returned the stocks of drugs therein.

#### Back to the pavilion:

As a result, scores of red, green and blue 'magic' boxes of RNTCP brimming with variable numbers of strips belonging to and bearing specific names of individual TB patients began pouring back into the parent TB units; literally back to the pavilion!

Just like Ganga and Ram Charan, scores of other TB cases too were devastated by this system failure.

Total number of such TB patients in the city of Faridabad who might

have suffered treatment cessation by this fiasco could be=  $32 \times 10 = 320$ .

### Names of some of the affected RCH sub-centers and their respective nurses (the name of the nurse within the bracket) goes like this\*:

Neelam Bata Jhuggi East (Rukhsana) and West (Neelam Bajaj); Gandhi colony (Padma); Sanjay Gandhi Memorial Nagar (Bimla); Indra colony (Shikha Yadav); SGM nagar E block (Urmila Khanna); Sant Nagar (Monika Batra); Dabwa colony (Geeta Malhotra); Mehtru Dera (Krishna Kumari); Anang pur Dairy (Manju Bala); Ekta Nagar (Lalita Kumari); Dayal Nagar (Sudesh Chawla); Shastri colony (Laxmi Devi); Bhur colony (Sunita Devi); Baselva colony (Asha Rani); Ajrondha village (Anita Kumari).

#### Self-inflicted wounds:

What a tragedy! There is many a slip between the cup and the lip. The patients stand duly diagnosed and identified; they are more than willing to take treatment; the medicines are very much there but the strips are being taken away...far away from their reach. Criminal mismanagement at the highest political level - of a perfectly predictable contingency! And of what scale! The RCH imbroglio uncovers abject lack of commitment of the state government at the very top.

#### Did TB patients under RCH operation in other cities too suffer similarly?

This happens to be the story of just one city; a mere tip of an iceberg. It should form an interesting study to find out if similar mess was created in other districts of Haryana (especially Bhiwani) and in other states of India where the RCH scheme had been in operation?

#### In TB-treatment, an interruption of 2 months is like eternity:

While an interruption of 2 months may not mean much to a leprosy patient, it is like an eternity for a TB case, spelling doom for him and his family. Whatever happens next on the political chessboard at the head quarters, the lives of TB patients living in affected pockets and registered with RNTCP seem irredeemably doomed - already.

Even after 2 months, on May 31, 2004, the day of filing this report, the controversial issue of continuation or termination of the services of those 32 nurses was still unresolved and the hapless employees could be seen agitating passionately in front of the offices of the Chief Medical Officer and Deputy Commissioner.

#### Some of the pertinent questions that arise are:

- Did this prolonged malfunctioning of 15.3 % (32 out of 209) DOTS centers
  of the entire district of Faridabad get duly reflected in its quarterly reports?
  If not, isn't skepticism about the data justified to some extent?
- If govt of India, WHO and World Bank were indeed aware of the incident, has an exhaustive investigation been conducted, accountability fixed and action initiated against the erring high powered officials whose inaction might have harmed hundreds of TB patients?
- And if govt of India, WHO and World Bank didn't even hear of it, in the first place, what became of the lofty claims about the monitoring mechanism of the DOTS apparatus that happens to be one of the five cardinal requirements?
- Has a damage control exercise been undertaken; to review the affected cases and to do whatever is necessary to redeem the situation e.g. retreatment of the affected patients after duly upgrading their category?

#### Isn't it a complete eye wash?

However, internal evaluation report of 'In-depth review of RNTCP' Faridabad, Haryana (July 21-23, 2004) conducted jointly by WHO, govt of India, state and district officials fails to take cognizance of any such problem during one of the relevant quarters. It fails to mention any such lapse.

On the contrary, this report begins by these words:

"In general program is getting satisfactory support from political circles."

Isn't it a complete eye wash?

# 16. Be it the Union Govt., the State Govt., or the District Administration, pattern is the same alover India: Technocrats remain virtually powerless:

The 'Health' infrastructure - e.g. manpower, jeeps & ambulances etc. - is often usurped by the district administration effortlessly on one pretext or the other and the Chief Medical Officer and the Director General Health Services, both of whom are technocrats, have no option but to comply helplessly without uttering a word. Alas, vice versa is not true. There is abject non-ownership of 'Health related activities' by the district administration. As against about 76 jeeps requisitioned for pulse polio operation in May 2005,

only about 17 were made available.

### Alas, no thermometer invented yet to measure political commitment:

Alas, to measure political commitment there is no thermometer. DOTS looks great if you saw the papers; atrocious if you saw patients - familiar sights and sounds and smells of a typical government department. Is the program headed the NTP fate?

A chain is only as strong as its weakest link. Of its 5 components, political commitment is shamefully low; it might well prove to be the Achilles heel of Indian DOTS.

# 20

# The other half of the story: The Private Sector

# What role has the private sector played in TB control since 1947 when India attained independence?

The private sector cannot be absolved of its indifference, inaction and non-contribution to TB in the past. It has generally maintained a lukewarm interest in this, a non-revenue generating branch.

Commensurate with the current wave of steep rise in income of other professionals - advocates, chartered accountants, businessmen, IT professionals, MNC managers, marketing executives dealing in mobile phones and cars etc. - aspirations of doctors too have sky rocketed today. Having spent a fortune on education, every private doctor seems to be in a hurry - to strike oil and make it rich. He doesn't mind deviating 'a little bit' from ethics.

# You scratch my back - I'll scratch yours:

For mutual gains, specialists in the private sector sometimes forge close-knit circuits whereby innocent patients get systematically ping-ponged for 'second' opinions. Commissions from such referrals constitute a significant chunk of a doctor's monthly income.

This 'cut' system in turn fosters over-investigation; CT scan is sometimes ordered less for clinching the diagnosis, more for the return gift of Rs. 600. The multi-star corporate hospitals no doubt represent an engine of medical progress and are responsible for lifting the medical science vertically uptowards excellence. However, doctors employed therein are rumored to be under systematic pressure through performance allowance to over-investigate their patients so as to inflate the bills.

Jumping the knife to promptly perform caesarian section - without first exhausting all other options of natural delivery - not only hikes the income many folds, it also liberates the obstetrician from the prospect of sleepless

nights of uncertainty and stress - that an ethical 'wait and watch' approach entails.

They say the best surgeon is the one who knows when not to operate. Not any more. Rising tide of avoidable surgeries is a testimony to the current wave of commercialism taking precedence over professional values. Whether to shift a patient into or out of Intensive Care Unit (ICU) is decided less on merits of the individual case and more on sustaining high occupancy therein. Number of endoscopies, angiographies, lapcolies and other rewarding surgical procedures are the real indicators of prestige and income of a hospital today. In doctors clubs, hush-hush discussions center as much around disease as around 'figures.'

All kinds of shady but expensive vaccines have flooded the market. Doctors conveniently remain silent while drug companies perpetrate fear psychosis. The companies have lately struck a novel marketing strategy to 'protect' the kids of our nation. Their representatives no longer focus their energy on the colony doctor but rather on the local cable TV or the school principal, a single clarion call from whom mobilizes thousands of families, eager to shell out the 'discounted' prices for the sake of their children.

# Corporate hospitals & large nursing homes are beyond the reach of a common man:

Most of the private clinics charge exorbitant fees and are beyond the reach of a common man who faces the brunt of common ailments like TB. The first time ever the author noticed how a note-counting machine looked like was - not in a bank but - in a corporate hospital.

Consultation fee of a super specialist in Indraprastha Appollo Hospital, New Delhi is about Rs. 500. You have to deposit a fee of Rs. 1,000 before you enter the chamber of the world renowned dermatologist Dr. DRK; even if it might take his brilliant mind just 2 minutes to clinch the spot diagnosis. Average daily expense of staying admitted in a corporate hospital comes to about Rs. 5000 to 10000. Resuscitation measures and life support to the terminally ill may or may not save life but they sure leave the entire family in debt trap for years to come.

The author is a witness to numerous corporate hospitals mushrooming and blossoming in and around Delhi in the last couple of decades but he has never heard of a single one that is devoted exclusively to tuberculosis.

The standard practice with several clinics is to somehow get rid of a TB

patient. The moment he is confirmed to be an infectious case, he is treated like burning coal. He is handed a slip bearing the camouflaged 4 words "referred to TB hospital", which actually mean 'please go to hell.'

#### A GP - if he's home, he's open:

As far as a common man is concerned, a general practitioner (GP) continues to be the backbone of our country's health-care system. Though a bit old fashioned and meagerly equipped, he is more affordable, accessible and offers flexible opening hours.

His clinic is at your doorstep, his residence at a stone's throw. In case you fall sick, he is the first one to be contacted. Be it the dead of night, rainy day, sweaty afternoon or a lazy Sunday, the poor chap is available. A faint knock at the door and he is sure to materialize - frowning, yawning or grumbling.

You feel as if you have a right on your family physician. So what, if he is entertaining guests at home or is watching the nail biting slog-over-session of India-Pakistan cricket match? Don't you hesitate - go right ahead & knock.

If he's home, he's open.

If it is a genuine emergency, you may well barge into his bedroom and grab his attention.

No wonder, he happens to be such a popular specimen - a friend, a philosopher and a guide.

If suitably enrolled, qualified GPs could have been the richest source of referrals to DOTS network. If optimally involved, they could have effectively shared 50% of the burden of this massive excercise and which would have provided immense relief to the government sector.

### Stigma of TB amongst medical fraternity itself:

Stigma of the disease has not spared experts themselves. A specialist, shy of having the 'dirty' word TB appear against his name on his visiting card, prescription pad or sign board, prefers to be called instead a specialist in respiratory medicine, chest medicine, or pulmonology. Numerous brilliant TB doctors have divorced the subject and gradually moved away - on to critical care, intensive care or sleep disorders - streams of medicine that are considered more prestigious, glamorous, futuristic and of course lucrative.

The private sector of India is colossal. It comprises of '80% of all

qualified doctors, 75% of total dispensaries & 60% of India's hospitals'. It caters to at least 50% of all TB cases. Failure of govt to stitch up a merger with it is the most scandalous omission of DOTS program:

DOTS was launched through the govt sector alone. For several years private sector, which caters to about half the caseload, remained simply forgotten. Its non-inclusion from the very outset has predictably diluted the effectiveness of the program. It is akin to working with merely one arm instead of both. Timely involvement of the private sector would have meant optimal division of labor, effortless expansion, more intensive and meaningful coverage, and possibly far better results.

### Look busy do nothing:

First, the WHO handed over the entire operation - lock stock and barrel - to the govt sector. Then, compounding its blunders, it continued to rely entirely on the same govt agency for clinching the crucial task of involving private sector into it. Result? Several years on, the job is still desperately undone.

Arrogant unilateralist attitude relentlessly pursued by the office of the Central TB Division right through the entire exercise - from A to Z - exhibiting total and disdainful neglect of the private sector has jeopardized the prospects of an optimal merger. Failure to take into account the sensibilities and reservations of the private doctors has resulted in numerous insurmountable problems in their large scale involvement.

A private doctor is the master of his own clinic. Unlike his govt counterpart, he is not dependent for his earnings upon periodic reports of a senior official. He is not at the mercy of a senior boss. So he is likely to be more forthright, frank, independent and outspoken. Unless reasonably and scientifically convinced, he is less likely to toe the official line meekly. **He won't hesitate to call a spade a spade or to raise valid questions.** As more and more such 'doctors' get involved, the monopoly enjoyed thus far by the govt. officials is likely to be eroded. No wonder the agency has been dragging its feet; deliberately going slow in involving GPs. Although outwardly it seems to be going through the motions of doing a lot, but without making much headway, which - the author suspects - has been the real intention.

Look busy do nothing.

Non-inclusion of GPs remains the single most glaring lacuna of Indian program and might well prove its curse.

### Tacit approval of quacks by the WHO and Government of India:

It appears that having failed miserably in its efforts towards large-scale involvement of qualified private practitioners into the program, the govt seems resigned to stooping down to involving unqualified quacks instead.

#### District Faridabad:

Of the 70 odd 'doctors' that the govt claims to have inducted into the program in the entire district of Faridabad, no one possesses an MBBS degree or a legitimate license issued by the Medical Council of India.

Of these 70 doctors:

- 25 odd 'non-MBBS doctors' have been designated as DOT providers in the twin blocs of Hodal and Hatheen (having about 8 primary health centers).
- And in the urban area of Palwal, during the year 2002, a third of the entire case-load (185 out of a total of 560 patients) was reportedly managed by 9 private practitioners of non-allopathic medicine, out of whom:
  - 2 were Ayurvedic Medicine practitioners.
  - 1 was a Private Pharmacist.
  - 5 were 'doctors' without any qualification whatsoever (designated as DOT providers).

### **District Gurgaon:**

District Gurgaon has enrolled 55 doctors into DOTS, of whom:

- 3 happen to be bonafide Chest Physicians.
- 1 is MBBS.
- 7 are BIMS.
- 44 are 'Practitioners of Indigenous Medicine' (whatever the term means).

#### **District Sonepat:**

Of the 7 'doctors' inducted under TU Gannaur in district Sonepat, Haryana, no one has an MBBS degree or a license from Medical Council of India.

#### **District Karnal:**

Of the 8 or 9 'doctors' inducted in district Karnal, only one Dr. Sood possesses an MBBS degree. (The reason for his joining the program is probably personal; the local energetic MO TU reportedly happens to be his personal friend).

#### Questions to ponder are:

- Is the story similar all over India?
- Isn't it a tacit approval of quacks and quackery by the WHO and government of India? Is it not validation of something illegal?
- Wouldn't such a partnership with government serve as a status symbol for these quacks? Will it not go a long way in enhancing their credibility in public eye?

# When a private practitioner (who is MBBS) agrees to act as a mere DOT provider:

Is it fair to claim that he has been fully involved, once a qualified (MBBS) doctor agrees to act merely as a DOT provider? It is just a half-hearted stance - it seems more like agreeing to become a fence sitter while continuing to wait and watch. Doesn't he possess far more potential to contribute to RNTCP? Only when more intensely involved - e.g. his clinic serving as a microscopy center or referring all suspects into the program - should he be counted as fully involved.

# When a medical college agrees to open a DOTS center in its premises:

Isn't it blatantly unfair to claim that a medical college has been fully involved, once all it does is to merely allow a DOTS center to be opened in its premises?

#### A foe turned Ambassador:

A private practitioner can't be expected to remain neutral to DOTS, which is in direct competition with him. He is for it or against it; either way passionately so. Thanks to the abject non-sensitization (a grave omission of the govt), not only has he failed to emerge an ambassador of DOTS, he remains at times hostile to it and effectively mars its image in his 'territory'.

# How can you protest an invisible decision?

Private doctors have a plethora of serious apprehensions about the program. Deeply skeptical of the govt overtures, intentions and claims, a private doctor is afraid to burn his fingers by getting involved with something that may fail to deliver eventually in the long run as happened with other programs.

Furthermore, he isn't clear as to what is his status in case a patient on DOTS decided to haul him in the court of law (A govt doctor enjoys relative immunity from consumer protection act).

A valid question that is often raised, and legitimately so, is:

If the private sector had serious reservations about DOTS, why has it chosen to remain absolutely silent all these years? Why hasn't it protested?

But then, once you are completely left out, how can you protest invisible decisions?

#### Isn't there a message in it?

Is it not curious that WHO and govt of India have had to probably switch tactics midstream and (after so many years) resort to employing a new breed of doctors - RNTCP consultants under PPM (public- private-mix) - at exorbitant cost with the specific purpose of hopping from pillar to post pleading with the private doctors (and others e.g. NGOs, public sector etc.) to join the program? Even now, several years down the line, private doctors hardly seem eager to jump on to the bandwagon!

Why?

Just one class of Indian doctors seem to be operating DOTS in India: those who can't help it, who have no other choice, who simply can't refuse orders from above, in other words - those employed with the government.

Isn't there a message in it? Were DOTS as great as it appears from govt. claims, wouldn't an overwhelming response be forthcoming automatically? After all, it is after ages that something new for TB has emerged on the horizon.

No sooner a new model of car, TV or phone hits the markets, than it sparks a wave of enthusiasm among consumers; every one seems to want to own it. Restless queues begin building up at the booking counters.

But the story is different... if ... the model is dubious, controversial or defective! Or the manufacturing company lacks credibility!

# 21

# Financial Aspect: For Now, The Honeymoon Carries On

(Note: The financial figures and calculations quoted in this chapter could be rough, approximate, wide off the mark or even presumptive. Furthermore, time line of receipt or expenditure of funds (spread over several years) is unclear to the author. Obviously then, the first question that comes to the mind is that if only sketchy information was available, why include this topic and burden the readers at all? The author strongly felt that to obtain an overall perspective of DOTS, it is essential to taste the flavor of its financial aspect, even if incomplete. The idea is not to undertake an audit of DOTS accounts (which is beyond the capacity of the author or the scope of this book) but merely to draw attention to a less known angle and take a baby step towards obtaining a semblance of the big picture. However, there are several reasons for such inaccuracies, not least that as far as financial matters are concerned, government of India and WHO seem virtually to operate from within impregnable castles, shrouded in a veil of secrecy).

# A. Where does the money for DOTS come from and how much?

The World Bank credit of Rs. 604 crore (US \$142 million) was awarded to the Govt of India - for a 5-year period starting May 1997 initially to cover a population of 271 million, later extended to cover 740 million populations till September 2004.

In addition to the World Bank, DOTS expansion in India is being supported by DFID, DANIDA, USAID, GFATM, and GDF.

DFID is providing US \$26 million to cover the entire state of Andhra Pradesh.

DANIDA is providing US \$14 million under phase I, and an additional US \$6.7 million (pending approval) under phase II to cover 14 districts of Orissa.

USAID is providing a grant assistance of US \$ 6.58 million for covering the entire 21 million population of Haryana.

Further, the Global Fund for AIDS, TB and Malaria will be providing US\$

8.6 million to cover 56 million population in the 3 states of Jharkhand, Chhattisgarh, and Uttaranchal in the first round, and US\$ 29 million to cover 110 million population in Bihar and Uttar Pradesh in the second round. The Global Drug Facility is providing anti-TB drugs for Orissa, and also for an additional 200 million population as a commodity grant valued at US \$ 2 million per year. (Source: Joint Monitoring Mission, RNTCP India Sept 2003)

Apart from this foreign inflow, govt of India and the respective state govts too provide some resources for TB as per budgetary allocations.

Funding agency	Specific purpose	Indian Rs. (In crores)	US\$ (In millions)
World bank		604.00	142.00
DFID	Andhra Pradesh	110.59	26.00
DANIDA	Orissa (14 districts)	59.55	14.00
Global Fund for	Jharkhand, Chattisgarh	36.58	8.60
AIDS, TB, Malaria	Uttaranchal (56 million		
population)			
USAID	Haryana	27.99	6.58
Global Drug Facility	Drugs for 200 million population of Orissa @2 million US\$per year	42.54	10.00
Total received so far		881.25	207.18
& probably already spent.			

(It is a diagrammatic representation of the text that precedes the chart).

#### Note:

- Funding gap: To sustain DOTS implementation until March 2010, a total funding gap of around US\$ 260 million will reportedly have to be filled after the current loan agreement with the World Bank expires in September 2004.
- Continuation phase of the program is likely to demand much less money: A population of 820 million reportedly stands covered currently. By the first quarter of 2005, whole of India will probably have been covered by DOTS; the entire basic infrastructure that would ever be required will have been firmly put in place once and for all. Thereafter, DOTS would switch over to another mode - the continuation phase - that is likely to involve much less expenses.

B. Currently TB control is almost 100% Central govt. sponsored effort.

Annual Budget for TB for the entire country = 115 crores (Appx.).

Money spent on RNTCP (after its large-scale implementation i.e. six years from Jan. 1999 to end 2004) =  $115 \times 6 = 690$  crores.

Total funds received and spent (if one calculates as in A) = Rs. 881 crore.

Total expenditure as per budget (calculating as in B) = Rs. 690 crores.

It is unclear which of these 2 figures is closer to the actual expenditure.

Giving benefit of ignorance & confusion to the govt., let us take the lesser of the 2 amounts as actual expenditure to do some hypothetical calculations,:

Money spent on RNTCP in 6 years (Jan. 1999 to end 2004) = 690 crores.

# Cost of drugs per patient = Rs. 300 (US \$ 7):

For whose sake was this massive program conceived and devised in the first place? Who is the intended beneficiary?

ATB patient!

And what is the ultimate purpose behind putting together the entire paraphernalia of this elaborate program?

Of course, to cure TB patients!

How?

By giving them medicines.

And how much do medicines cost?

Rs. 300 per patient!

As hard as it is to fathom, it is true!

Cost of an entire 6-month-course of medicines used up in treating a Cat 1 patient = Rs. 300 (US \$7).

# Unbelievable feat of the government of India:

The concerned officials of the govt of India deserve profuse complements for having bargained sincere and hard with the drug companies to have successfully brought down the cost of medicines to the current unbelievable levels of Rs. 300 per patient (US \$ 7), which is about a third of what it would cost, if you purchased them from a retail chemist in the open market in India.

#### Note:

- When checked last (in Feb. 2005) the author learnt that current cost per patient (cat 1) was about Rs. 280. A round figure of 300 has been taken for simplification and to err on the higher side. However, the figure is subject to fluctuations just like the cost of any other commodity.
- No doubt Cat II regime is costlier (since the duration of treatment is longer and it involves an additional drug - namely injection SM). But then, Cat III regime that involves less drugging is slightly cheaper. So let us assumefor the sake of simplification - that the net effect gets neutralized and therefore let us take Rs. 300 as the average cost per patient.

#### Number of cases DOTS has cured till end 2004 = 39 lacs.

[Since its inception, the program has cured (rather initiated on treatment) over 30 lac patients<sup>1</sup>.

About 9 lac patients have already been placed under RNTCP treatment during current year (i.e. 2004)<sup>2</sup>.

Total number of cases put on treatment under RNTCP till the end of 2004 = 39 lac (3.9 million)].

Total amount spent (on drugs alone) on these 39 lac patients till 2004 = Rs.117 crores. (39 lacs x Rs. 300)

Total no. of TB cases estimated in India (old and new) = 1.4 crore (14 million).

Total cost (of drugs alone) needed to rid India of TB = Rs. 420 crores = US \$ 100 million (1.4 crores x Rs. 300).

Total money already spent by DOTS = Rs. 690 crores.

(It is about twice the amount required for providing medicines to each and every Indian patient).

#### In other words:

<sup>&</sup>lt;sup>1</sup>TB India 2004 RNTCP Status Report, published on 24<sup>th</sup> March, 2004.

<sup>&</sup>lt;sup>2</sup> RNTCP performance Report, India Third Quarter, 2004 page 1.

In grappling with less than a third of the nation's TB burden, DOTS has already usurped about twice the amount required (for drugs alone) to cure every patient of India and rid the entire country of tuberculosis.

How much share (in the form of drugs) does a patient receive? = 17%.

[Total amount that has reached the intended beneficiary i.e. the TB patients (in the form of drugs alone) during all these years till 2004 through DOTS = Rs. 117 crores.

Total money spent by DOTS so far = Rs.690 crores.

% age reaching the patients in the form of drugs =  $117/690 \times 100 = 17\%$ ].

Rajiv Gandhi, the late prime minister of India had famously remarked once that for every one Rupee invested for poverty alleviation program, the beneficiary gets only 15 paise. Perhaps out of the remaining 85 paise, 40 paise can be accounted for by way of overheads and the rest 45 paise are definitely lost in corruption.

Let us assume for a moment that the hypothetical discussion done above is absolutely wrong since it involves some presumptive figures and the complex time-line of expenditure is unclear (as detailed earlier on page 178). Let us consider the WHO Report 2004, Global Tuberculosis Control, Surveillance, Planning, Financing (page 37, table 17), which states that:

"In 2002, the actual total cost per patient treated in India was estimated to be 72 US \$\*".

A patient (who gets 7 US \$ worth of drugs) receives = 9.7 %.

[7/72 x 100]

#### Note:

- No doubt you can't give drugs to someone without first arriving at correct diagnosis. The infrastructure built for diagnosis too ought to be added up towards the patients' kitty. So it is unfair not to add in these calculations the cost involved in the diagnosis.
- But then what is equally true is that the mainstay of India's diagnostic algorithm is sputum test, the consumables involved in which cost virtually

peanuts; microscopes being just a one time purchase.

- Furthermore, it is argued (and not without reason) that the flexibility and several other novel features incorporated in to this model of community care are future oriented, justifying such intensive initial financial and training investments. Such a scale of regional organization and specialized training is in effect practical preparation to confront not just TB but also other current and future problems.
- But aren't we stretching this argument a bit too far? For example, what purpose will an RNTCP consultant - that the govt of India can never afford once the foreign funding stops - possibly serve the future India?

#### Is this fiscal prudence?

The intended beneficiary receives (in the form of drugs) 17%; The rest (83%) is gobbled up in construction of the delivery channels and dries up somewhere in the pipeline. Is this fiscal prudence? Isn't there something fundamentally wrong with the concept? How could an agency even conceive such a mammoth and costly program woven around the miserly provision whereby the real beneficiary gets to receive virtually peanuts?

The scenario might in fact be even more pathetic, if calculated properly with actual figures. The govt must do this exercise and place the results in public domain.

Situation seems even worse in some other countries where cost per patient is even higher - as per the WHO Report 2004, Global Tuberculosis Control, Surveillance, Planning, Financing (page 37, table 17).

#### What infrastructure has been built with DOTS funds?

#### 1. Binocular microscopes:

A major chunk of money has obviously gone into purchasing innumerable high quality binocular microscopes. TB is rampant in India. The microscopy centers set up under RNTCP are predictably inundated with sputum samples. No other work is being performed with these newly installed microscopes except sputum examination or sometimes blood tests for malaria. It is unlikely that these microscopes would ever be put to use for research work.

Therefore, advanced features often offered as accessories - video adapters for video-graphy, photo adapters for 35 mm or digital cameras along with magnification for micro-photography - for possible up gradation in future are nothing but unnecessary baggage, merely serving one purpose - that of

enhancing the original cost.

When you know from day 1 that you were going to purchase about 8000 machines, the scale of bargaining that becomes possible would be mind-boggling. Was it taken advantage of (just as was brilliantly done in the purchase of drugs)?

The information that ought to be made public is:

- How many microscopes have been purchased till date?
- What is the cost per machine?
- What is the total expense incurred under this head?
- How many companies have concluded the task?
- How many extra pieces the govt has purchased purportedly to replace damaged or worn out machines? How much has been spent under the head of replacement so far?

Note: Unless there is an accident or a hammer is used, life expectancy of a microscope is no less than a human being; more so when AMC (annual maintenance contracts) - rumored at about Rs. 2000 per machine per year (and actuals on spares being extra) - with authorized agent of the parent company are said to be duly in force.

About 80% of the total 1 billion population of the country has so far been covered. 'A microscopy center for every 1 lack population' means that about 8000 microscopes have so far been purchased by govt of India. Presuming that the cost per machine is Rs. 10000:

# Appx. total cost of 8000 microscopes = 8000 x 10000 = Rs. 8 crore = US \$ 2 million.

# **Dummy microscopy centers:**

For the states that are perpetually cash strapped, obtaining RNTCP grant from the Center obviously remains a top priority. But for this they are supposed to fulfill certain preconditions - at least for once - at the time of initial high-level inspection.

It can often become a numbers' game. The author did hear an unconfirmed report that in order to prove that the requisite number of microscopy centers have indeed been opened up in the state, at times dummy centers are created with ghost employees. Signboards are duly erected over a subcenter in a remote village and a microscope is temporarily installed therein.

In a country where question papers of elite exams are often leaked well in

advance, is it difficult to predict the exact date of WHO inspection? On the fateful day, a well-tutored lab technician with his drama troupe arrives and gets busy - posing as if they work there. As soon as the inspection team departs, they too pack up their stuff, and pick up the microscope and return - bag and baggage - to the parent PHC, their original place of work.

"To genuinely assess a center in a remote area, one must reach quietly and unannounced and talk (not just to the staff but also) to the villagers" said an experienced insider, adding defensively, "But sometimes to indulge in such disgraceful exercise may be a genuine compulsion for the employees; the law and order situation in some remote belts is not congenial to safe and honest working."

### Non-functional microscopy centers:

According to unconfirmed reports, some of the designated microscopy centers are completely or partially non-functional.

Despite RNTCP maturing into its fourth year in district Faridabad, 4 of the 22 designated microscopy centers - Faridabad old, Punaira Khurd, Hassan Pur and Mandkola - have perpetually no lab technician as found on July 29, 2004. In Hassan Pur the microscopy work is reportedly being done by a non-LT an ordinary health worker who is claimed to have been imparted 'training' to examine malaria and TB slides!\*

### 2. Civil works undertaken - negligible to nil:

Infrastructure for RNTCP did not have to be built from the scratch. The program has been integrated with the already existing health care network in the country. It has simply been superimposed on the already functioning PHCs, CHCs, civil hospitals, anganwaris, subcenters, ESI dispensaries, CGHS dispensaries and NTP clinics. The government infrastructure built over the last half a century has thus served as a suitable and sound foundation over which RNTCP has been implanted.

Since DOTS is based on domiciliary style of treatment, no new TB hospitals or sanatoria have had to be built, no new buildings have had to be erected; the already existing ones have been converted into microscopy centers and DOTS centers, with minimal, if any, modifications. Therefore the civil works required have been practically negligible to nil. Every district TB society was given a sum of approx. Rs. 20,000 for renovation of the existing

<sup>\*</sup> Bhaskar News, Dainik Bhaskar July 29, 2004

lab involving minor repairs of flooring or adding a washbasin or a slab etc. and remodeling it in to a standard microscopy center

Total expense in this head = **US\$ 4 million**.  $(20,000 \times 8,000 =$ **Rs.16 crore).** 

(As per a DTO the amount has recently been revised upwards from 20,000 to Rs. 28,000).

# 3. Cost of purchase of computers, printers, fax machines etc. = not known.

### 4. Salary for regular staff - doesn't impinge on the kitty of DOTS:

The pre-existing army of doctors already employed with the state governments and who have been managing the nationwide health network continues to remain at the forefront of DOTS. They have simply been assigned additional DOTS duties in their respective jurisdiction. Similarly, other employees (like health workers, nurses, ANMs, anganwari workers, multi-purpose workers, pharmacists and lab technicians) are the same old ones; only additional DOTS work has been assigned.

The army virtually remains the same; only new duties have been assigned and new training and ammunition has been supplied. The mammoth army continues to draw salary from the respective government sources just as before, without impinging on DOTS kitty.

# 5. Salary for contractual staff:

However, at some places, which were under-staffed or over-worked, additional workers have indeed been recruited on a contractual basis so as to cope up with the DOTS work. This group includes Medical officer TB control (Rs. 15000 per month), Lts (Rs. 5000 per month) and others. They are of course paid out of the DOTS funds under the head 'salary for contractual staff'.

# 6. Training:

DOTS being a highly labor-intensive program, human resource development is a top priority. Trainings galore here; training of the RNTCP consultants, top government officials, staff of the DDG TB, DTOs, MO TUs, army of doctors, LTs, STLSs, MPWs, health workers; TB training of HIV workers, HIV training of TB workers etc. etc. The 3 institutes that prepare master trainers for India are: LRS Delhi, NTI Bangalore and TRC Chennai. The real question is how many

field doctors in the periphery get to receive the rigorous 12-day-training in these institutes and thereafter how many of them are retained for long in RNTCP?

#### Profligacy at the top, parsimony at the bottom:

On Oct 28, 2001 a one-day national workshop was organized at India Habitat Center, New Delhi in order to hammer out modalities for involvement of private doctors into RNTCP program. About 100 delegates had been invited from all over the country. With a strange stroke of luck - possibly to represent private practitioners from the state of Haryana and thus to add on to some kind of quorum - the author too was invited by a telephone call, though at the very last minute.

The author was excited to get this dream opportunity to rub shoulders with literally the who's who of TB in India. He caught an EMU (electric local) train and reached the venue - well before time. He was overawed to be welcomed into an air-conditioned auditorium and presented with several complimentary gifts including 'Stop TB Use Dots' badge, some impressive printed material and an expensive looking sleek office bag. They were all there; top bureaucrats and doctors from Ministry of Health, Central TB Division and the WHO, South East Asia Region. The daylong discussions took place in real style. Delivering colorful audiovisual presentations, speaker after speaker declared what a historic moment that had been. The lecture session was followed by group discussions with the comments of every member meticulously recorded in one of the numerous laptops doing the rounds. All this was interspersed with frequent coffee breaks and a sumptuous five star lunch. Unaware of the agenda and thus completely unprepared (like so many others), the author speechlessly sat through, nodding and smiling. But he was spellbound; mighty pleased with his luck to be part of the 'historic moment'.

As if that were not enough, towards the concluding moments that evening, as the author hurriedly got out to leave so as not to miss his evening train back to Faridabad, he was abruptly halted by a waiting receptionist in the lobby. Quietly and unceremoniously, he was handed a crisp 500-Rupees-note obviously as compensation for expenses incurred. Though to and fro train journey from Faridabad would cost Rupees 7 + 7 = Rs. 14/-, he prefferred to hold his tongue in cheek and not utter a word. Like a cool cat, he pocketed the unexpected bounty.

But what happened next came as an anticlimax. Suddenly all his

excitement evaporated and he got the shock of his life at what he witnessed. His train forgotten, he simply could not make himself move and stood rooted to the ground. Without blinking an eyelid, he kept staring with complete disbelief - at the fascinating spectacle.

What had happened was that the next delegate had emerged from the conference hall and had stopped at the counter. The receptionist had taken out a wad of crisp 500 Rupees notes. He had put the bundle on the table. He flicked open the tape binding them. Then he put his finger on his tongue and began to count, busily and speedily... one... two... three.

Involuntarily, so did the author!

The man stopped counting finally at.... 34.

Then he acted strange - he handed them all to the waiting delegate who pocketed them expressionlessly and departed.

The dazed author was furiously calculating in his mind, "thirty four fiveza...... one seventy. Put two zero's at its tail. ....it is 17000".

Oh God! His heart sank.

It was Rupees 17000 all right.

What had that person done to deserve the booty?

The author watched with stunned silence as delegate after delegate coming out were reimbursed thousands and thousands of rupees. Within a span of 20 odd minutes, lacs of rupees had been disbursed away.

Everybody gone - the jamboree over - the depressed author habitually began his subtle but persistent enquiries. He was told that it was reimbursement of the airfare. After all, these 'men of wisdom' had been specially invited to take part in this important meeting from far and wide. They had flown in from Kerala, Mumbai, Kolkata and Bangalore etc.

This was author's first brush with the unfathomable profligacy that goes on at the top!

As a routine!

A White elephant - an RNTCP consultant is an annual liability of about Rs. 18 lacs (US \$ 40000) per head to the TB kitty:

For exhaustive monitoring, aggressive implementation and somewhat direct control over the program, WHO and Govt of India have recruited in a phased manner about 100 doctors - RNTCP consultants on exorbitant pay scales. The very need for creating such a post arose in the first place because WHO and Gol had virtually no direct control over or faith in the working of or the data proffered by thousands of doctors already running the program (as DTOs, STOs, MO Tus etc.) all of whom dance solely to the tune of their own pay masters - the respective state governments.

These special consultants were recruited, it seems, as **an afterthought** so that WHO and the union govt could receive reliable inputs from their own sources and exercise somewhat direct intervention in the program.

### Everything in style right from day one:

Final interviews for recruitment of a new batch of RNTCP consultants for northern region were conducted by a joint team of 3 officials from GOI and WHO at Boardroom, Business Center, Hotel Ambassador, Sujan Singh Park New Delhi from July 29 - 31, 2004. The venue remained booked for 3 days exclusively for the purpose [the tarrif ordinarily being Rs. 5000 per day (Rs. 1500 per day for secretarial help if asked for would be extra while a session of tea and cookies would be complimentary)]. Of the 70 odd candidates interviewed, the outstation ones were extended the courtesy of reimbursement of return second class AC 2 tier train fare.

Later, ditto exercise was reportedly replicated in Mumbai, Bangalore and Calcutta for recruitment in the respective regions.

How much did the exotic selection exercise cost = not known.

### Pay and perks of these consultants are just like top MNC managers:

- Apart from a handsome monthly pay package of about Rs. 40000 plus Rs. 10000 as local transport allowance, these consultants are entitled to an assortment of perks.
- A free mobile phone with Rs. 3000 per month worth of free talk time.
- A free laptop along with its AMC (annual maintainance contract).
- Those consultants who maintain headquarter (and most of them do) recieve recurring costs of maintaining an office e.g. pay for a secretary.
- A printer, a fax machine and recurring costs on every thing one can think of - round the clock internet connection, ink cartridges, stationary,

floppies, CDs, postage, reimbursement for updating Antivirus software from time to time etc.

- Most consultants would claim about Rs. 30,000 to 40,000 per month in the name of costs incurred on touring and overnight stays for various official reasons e.g. internal evaluations, meetings, inspections etc.
- Vehicle maintainance allowances and reimbursement for wear and tear.
- Lavish stay and travel facilities in the name of training or review.

# Total expense on 100 odd RNTCP consultants = Rs. 18 crore per year (recurring).

As per an RNTCP consultant, even by conservative estimates, all this would add up to an annual liability of no less than Rs. 18 lacs (US \$ 40,000) per consultant. Since there are about 100 of them in India currently, the total annual expense on them = 18\*100 = 18 crore = 4100000 US \$ - virtually unsustainable by Govt of India once the flow of international funding begins tapering off. So the concept can hardly be termed futuristic.

### Legalized plunder ongoing at the top:

# Meeting No. 1:

World Health Organization, Nirman Bhawan, New Delhi organized a training session for RNTCP consultants from May 14 to 31, 2003 in the premises of resort Hotel Hill View, Faridabad. The delegates and trainers had come in from far and wide. It is reported that for practical exposure, 4 teams of 6 doctors each and with a leader were made. The teams went around for 3 days deep in to the districts of Gurgaon, Rewari and Faridabad for survey. Each team finally brought out the findings in the form of a presentation.

# The hotel's bill for stay of delegates reportedly = Rupees 7,99,030,

(that included Rs. 42,400 on audio-visual equipment, Rs. 15,100 for taxi charges and 18,400 for extra pax lunch and dinners).

The author does not know how much was spent on **travel component**.

However, the RNTCP travel reimbursement policy reportedly goes something like this:

Upto 300 Km: Taxi.

Over 300 Km: Train AC first class.

Over 600 Km: Airfare.

From the aforesaid travel policy and some unconfirmed reports about several trainers and trainees having been flown in from South India, one doesn't have to be a Sherlock Holmes to reasonably infer that the travel component would be even bigger than **Rs. 7,99,030** that was spent on boarding and lodging.

Assuming that the amount spent on travel component was also Rs. 7,99,030.

Then the total cost of the meeting = Rs. 15,98,060.

No. of patients that can be cured with this money = 5,327 patients.

$$(=15,98,060/300=5327)$$

In other words, resources worth drugs enough for curing 5,327 patients were squandered by 100 elite doctors in doing some 'very important' talking.

In the entire year of 2004, total number of patients put on treatment in the entire district of Faridabad = 3600.

#### Meeting No. 2:

Exactly a year later, around May 13, 2004, about 300 delegates converged again on the same venue - this time purportedly for conducting Program Review. The elite gathering included the entire fleet of 77 odd RNTCP consultants from the entire length and breadth of our country, several State TB Officers and some program managers. Practically the entire hotel remained booked for unknown number of days.

Cost incurred = not known.

#### Meeting No. 3:

Recently, the conglomerate of wise scientists reportedly descended on the same venue yet again from Oct. 17 to 19, 2004 for program review.

Cost of their stay at the Hotel = probably Rs. 9,07,023\*.

Cost on travel component = Not known.

(Note: It is sheer providence that the author happened to learn about the 3 meetings since he lives in Faridabad where these meetings were held. He has no way of knowing what goes on elsewhere in the vast country. So probably this is just a tip of the iceberg).

#### TB today stands for 'Tourism Bonanza' for the 'Top Brass':

The spate of meetings, workshops, conferences and presentations

unleashed in the aftermath of DOTS invariably in exotic resorts and five star ambiences speak of a new genre of travel that may appropriately be dubbed as Tourism Bonanza (TB) for the Top Brass (TB). Calling a meeting means exorbitant travel expenses; and it seems meetings galore under the program. Some of the officials under the aegis of Ministry of Health (TB) as well as some RNTCP consultants today are seen criss-crossing the country, flying back and forth on one pretext or the other - preparing ground in yet-to-be-covered regions, interaction with health secretaries of various states, inspection, training, monitoring, internal evaluation reports, peer review, involvement of the private sector, involvement of NGOs, enrolling CEOs of public sector units, rectifying a snag, forming numerous task forces.

The extensive tour itineraries of the top brass will any day shame that of an American diplomat or an Arab sheikh. The high-flying culture of the international agencies seems to have been emulated religiously at the top.

Sometime in early June 2004, when the author tried to contact Ministry of health (TB), he learnt that senior officials were away to Geneva on a week long tour. Again on Oct. 14, 2004 when the author called up to seek 'permission' to attend the approaching Program Review Meeting to be held on Oct. 17, the officials were reportedly away traveling - this time probably to China. On 5<sup>th</sup> and 6<sup>th</sup> Nov a voice that answered the author's phone told the author that the officials were off to a foreign country - probably to France.

#### What hypocrisy!:

Strangely when it comes to financing facilities for the top officials, policy makers and their cronies themselves, it seems there is no dearth of resources available; lakhs and lakhs of rupees are squandered with impunity within a jiffy - purportedly for training, review or a meeting!

# Rhetoric of poverty is exploited selectively:

It is clearly a top-heavy program. Profligacy goes on unabated at the top, while there is dreadful parsimony at the bottom. The top bracket emulates sleek MNC culture while bankruptcy reigns supreme at the bottom rung. While perks and incentives galore at the top, there are virtually **no incentives for the real foot soldiers** - the health workers, lab technicians, pharmacists and doctors - that perform the actual dirty work at the grass roots levels. No one

Unconfirmed figure

seems even remotely inclined to begin to consider or talk about providing any incentives to these people at the bottom.

### Apart from Rs. 300 worth of drugs, no incentives for a patient.

Who was the intended beneficiary that gave birth to this program, and which in turn has provided plum jobs and perks to top officials, doctors, public health professionals and managers?

Ironically, when it comes to providing even minimal benefits to the TB patients themselves, rhetoric of poverty is cleverly hyped up. Sulking that we are a poor nation, they are systematically deprived of everything - even minimal fundamental investigations (like chest X-ray). Furthermore, raising the bogey of poverty we stoop down to accepting and applauding a much cheaper intermittent regime - instead of the 'time-tested' daily regime.

### Going thus far and no further?

In case the time tested Daily (instead of thrice weekly) regime had been chosen and implemented, and chest radiography too was added, it was well within the realms of possibility in this package of 690 crores. Provided of course that the squandering of resources at the very top was plugged.

WHO and Central TB Division seem to virtually operate from within impregnable castles; a cloud of secrecy engulfs their operations. With total lack of transparency prevailing in the money matters in RNTCP, and an outsider like the author having virtually no access whatsoever inside the corridors of power and much less to the details of accounting, one wonders if the few incidents mentioned above are only a tip of the proverbial iceberg.

# One day, each and every penny will have to be returned:

The program is being run not through charity or aid but strictly through loan. Each and every penny has got to be returned and that too along with some amount of interest, howsoever small. Even if it were being run through charity or aid, no one has the right to waste it. Even if RNTCP consultants are so far supported by the WHO, something seems seriously amiss.

# One fine day the honeymoon is going to be over:

Some time in future, flow of foreign funds is bound to come to an end. Once international funding stops, DOTS will become purely the baby of the Govt. of India. That will be the moment of reckoning. How will the govt really sustain this program! Will it go the RCH program way? (pp 167-169).

# How can a country, whose public spending on health is so shamefully low, sustain such a program on its own in the long run?

.In terms of public spending on health, India ranks 171<sup>st</sup> out of 175 countries for which data is available in Human Development Report, 2004. Public spending on health in India is a mere 0.9% of the GDP. There are only 4 countries - Nigeria, Indonesia, Sudan and Myanmar - that spend lesser amount. Of the current health care spending of 5.6% of the GDP, private spending accounts for as much as 4.7% (Govt. accounting for only 0.9% of the GDP).

#### Recommendation No. 9

- Let us thoroughly investigate and calculate exactly how much of the RNTCP kitty spent on the program thus far has been consumed on tickets of airlines, shatabdi's, Rajdhani's and taxi fares and fuel! Who are the concerned travel agents doing business with the department?
- Get a further break up giving complete itinerary of every top official in the last few years with his tangible contribution to the cause, if any.
- The author wonders whether such highflying, high profile meetings can't be significantly trimmed in number and luxury, if not dispensed with. Why not hold them in TB hospitals? Why can't these officials stay in government rest houses that lie unoccupied gathering dust all the time?
- Sub-optimal occupancy of all those aristocratic, sprawling rest houses and guesthouses owned (and maintained at exorbitant costs) by various government departments (a legacy of the Raj) on the one hand and unfathomable expenditure on officials' stay in hotels on the other, both deserve a thorough survey by the government of India.
- Besides, in the present era of advanced telecommunication, internet, web-conferencing, video-conferencing and virtual classrooms, some of the meetings can easily be effectively conducted through these channels accomplishing similar results, and with more speed, obviating the very need for frequent physical movement and the expense thereon.
- Introduce financial transparency: No information is made public as to how much is the funding, where it comes from and how it is spent. How much of the kitty goes into training, traveling, lodging, boarding and administrative costs? It is this lack of transparency that breeds corrupt practices, Secrecy shrouding the govt operations is oxygen for the corrupt lobby. Besides, every Indian has the right to such information.

- Whenever any Indian goes abroad on public funds (whether he works for state or central government), exhaustive details must be made public.
- It is time, the so called largest democracy of the world comes out with a law that each govt department must divulge complete details of its expenditure up to the very last penny in a comprehensible manner through web sites, newspapers and magazines on a quarterly basis.

# **22**

# DOTS has to contend with wide spread corruption

In India, there is no other infectious ailment, that is as rampant, as emaciating and as debilitating as tuberculosis, and which virtually wreacks havoc with an entire family!

But corruption seems far more infectious than tuberculosis and wrecks havoc with the entire nation.

Prevalence of TB in a society is an apt indicator of its poverty.

What is not appreciated yet is that it also is an indirect **index of inefficiency & corruption in governance**. India is a classic example. Here, the TB situation continues to be grim despite relative poverty alleviation in recent decades.

P. Chidambaram, the Finance Minister of India while presenting the Union Budget 2005-06 on Feb. 28, 2005 suggested that India is no more a poor country:

"India is not a poor country, yet a significant proportion of our people are poor. Poverty is not only income poverty. Other indicators of poverty are illiteracy, disease, infant mortality, malnutrition, absence of skills and unemployment. The whole purpose of a democratic government is to eliminate poverty...."

A survey¹ done by ORG-Marg for Transparency International India over a period of twelve months has revealed that the **health** and the power sectors are the most corrupt sectors...... "the largest amount of money is, however, tucked away in the **public health care system** by doctors and nurses, with active involvement of diagnostic centers, chemists and pharmaceutical companies. By charging patients extra for medicines that are supposed to be supplied free; by pushing them to purchase medicines from specific chemists and companies; by recommending un-required diagnostic tests at preferred pathology laboratories; and by simply seeking gratification for proper care; the

<sup>&</sup>lt;sup>1</sup> Corruption in India by N. Vital "The Road Block to National Prosperity

doctors and nurses in public sector hospitals were garnering a cool 28 per cent of all the bribe money transacted in India in a year."

Former Planning Commission secretary Mr. N. C. Saxena had observed that Rs. 60 out of Rs. 100 in wage-scheme is reserved for wages and the rest for asset creation. But in reality only 10-15 goes to poor workers. "The rest is illegal income for bureaucrats, contractors and politicians." Furthermore, "although the (rural housing) scheme is quite popular because of 100% subsidy of Rs. 20,000 per beneficiary... corruption is also rampant. Instances of corruption to the tune of Rs. 5,000 to 8,000 out of the approved amount of Rs. 20,000 have come to light."

Resources are being eaten up in the process of distribution, and thriving middlemen are a threat to all subsidy schemes floated for the masses.

Kirti Parikh, a member of the Planning Commission claims, "in my study on PDS, I found that the poor get only 20 paise out of every Re. 1 that is meant to go to them through ration items."

#### Benefits of DOTS accrue to almost everyone:

In the assembly lines of DOTS, as funds flow downward, anyone who is dishonest gets sufficient opportunity to extract his pound of flesh.

Some top scientists are rewarded by coveted foreign assignments and WHO fellowships.

Some receive lucrative grants for research projects. Others get name and fame.

Some perpetually entertain hopes of landing a lucrative and juicy job with an international organization - a passport to riches.

RNTCP consultants are as such highly paid.

DTOs - disbursing officers themselves - are entitled to extensive travel and purchase activity.

Attractive perks for senior doctors while receiving or imparting training.

DMs, CMOs and DTOs, the privileged members of the District TB Society, get bonus opportunities to recruit some of their own cronies or those of a local politician.

Free flow of funds ushers in a peculiar vibrance. For the corrupt, opportunities galore in DOTS. Bulk purchase of medicines, done at whatever

<sup>&</sup>lt;sup>1</sup> The Times of India, June 26<sup>th</sup> 2004, by Shivani Singh, TNN

levels, undoubtedly begets handsome commissions in India. No wonder, pharmacists in health departments are known to construct bigger houses than doctors. Purchase of binocular microscopes, computers, printers, fax machines, photocopiers, motor cycles, fuel, stationary, sputum cups, slides, dyes, bill boards, charts, pamphlets and other printed material for IEC activities present profiteering opportunity for those having vested interests.

For every one of them, directly or indirectly, it presents a win-win situation.

DOTS thus has the potential of benefitting everyone.

Everyone.

Except the patient!

### One wonders what must go on in HIV/AIDS:

If such be the state of affairs in tuberculosis, where it is still possible, at least to some extent, to verify some of the tangibles, determinants and variables - like number of dispensaries upgraded, microscopes set up, number of patients diagnosed and treated, number of them cured, relapsed or died etc. - one wonders what must go on in the popular business of HIV/AIDS where we are engaged in a spectacular fight against virtually an unseen, unknown enemy; where there is complete vacuum as far as tangibles are concerned. From top to bottom, it is virtually nothing but shadow boxing. Every thing seems to float in the thin air. There is nothing determinable - except passionate rhetoric, plethora of printed papers and a mind boggling, meticulously compiled and unchallengeable data shrouded in fascinating and abstract terminology.

Newsletters of various five star NGOs that work for HIV/AIDS are typically oozing with incomprehensible verbose language. Somewhat like the following: the organization is committed to dispelling myths and misconceptions around sex, sexuality, sexual health and sexually transmitted diseases through disseminating knowledge and impacting attitudes, beliefs and actions by skills-building sessions like ongoing face-to-face counseling, pre and post-test counseling, telephonic counseling, maintaining confidentiality, informed consent, Humnawaz & Humjoli meetings for transgendered people, peer education programs, outreaches held to access Hijras & Giriyas, highlighting gender based injustice and violence and various issues of adolescence - all adding up to just an awesome bubble of confusion that an ordinary person can hardly comprehend, much less dare question.

# 23

# Operational controversies in design

#### **DOTS Versus Starvation:**

First and foremost, the main beneficiaries of DOTS can be the poor masses who simply can't afford treatment from a private doctor. 26% of Indian citizens live below poverty line. They are destined to toil 7 days a week for bare survival; as laborers, masons, rickshaw-pullers, farm-hands, coolies or unskilled factory workers. Such people simply have no other option.

#### A daily wager in India has to dig the well everyday:

To earn that one-dollar, a poor man wakes up at 5.30 in the morning and gets busy right away; cleaning the jhuggi, taking a bath, purchasing ration on credit on a day-to-day basis, and cooking. Morning sure is a rush hour since he has to show up at the labor market before 8 a.m. so that a prospective employer may pick him up.

His mind is focused only on one mission - to somehow grab a suitable job for the day (and not on DOTS). His work (from 8 am to 5 pm) takes him to a different & unknown destination every day, nearby or far away.

How can he even consider visiting a DOTS center - more so when it is quite an unpleasant task - begging a dose of medicines from some rude, ill-humored health worker? And in the bargain forego his wages and starve his kids?

Starvation sure is a stiff competitor of Indian DOTS.

### A nation running late; everything behind schedule:

No govt. run hospital, no primary health center, no dispensary in India is open at 7 a.m. or at 7 p.m., which are the convenient hours for a poor worker. In winters hospitals and dispensaries are supposed to open at 9 a.m. but a true Indian is fully conversant with the 'Indian standard time.'

As per a wedding card if 'arrival of barat' is slated for 8.00 p.m., one instinctively 'knows' it means 10. If a minister's rally is announced for 10 a.m. and one spots a helicopter hovering in the sky around 12 noon, one knows that his highness has arrived. Police arrives at the scene of the crime late. Post is delivered late. Buses ply late. Planes fly late. Trains run late; no wonder almost every announcement at the railway station is laced with "inconvenience caused to the passengers is deeply regretted".

Justice, if you ever get it, is delayed. The country as a whole seems to be moving in unison - behind schedule.

Dispensaries are no exception. Work starts only around 10 a.m. When eternal delay is a part and parcel of our culture, why complain?

#### **Unmatched timetables:**

The timetables of the laborer and that of the govt. dispensary simply don't match; the wide disparity in between the two is a fundamental defect in the design of DOTS and if not rectified may prove a nail in its coffn.

#### The distance is a killer:

Obviously, implementing DOTS is a lot easier in situations where several patients live in a small area. Everyone is accounted for, traceable and accessible - for example, patients working in a factory having a DOTS center, patients living in a close-knit Railway colony, patients of a dam project living and working together, a prison camp or patients of a village having its own DOTS center.

India is a vast country with a huge landmass. Its enormous population of over 14 million TB cases is scattered allover. A TB patient is to be found virtually in every nook and corner of the nation. In contrast, government-health-centers are sparse, however large their numbers may sound in absolute terms. By any stretch of imagination it would be incorrect to claim that each and every patient is practically living next-door to some govt. dispensary or the other or that he is being provided treatment at his doorstep.

Several villages have no dispensary and the patients need to go to the neighboring village that may house one. The reality is that often a patient 'has to' walk quite a distance to collect his doses. Often, he may even need to use other means of transport like a rickshaw, a Tonga or a bus in which case he might end up spending anywhere between Rs. 20 to 40/- on each trip. Can a poor patient who earns less than a dollar (Rs. 46/-) a day, afford it every other day?

Even logistically speaking, is it humanly possible for a patient residing 5 kilometers away to come all the way 3 days a week? Doesn't he deserve some kind of relaxation from the cruel drill of to and fro visits?

One patient lamented:

"DOTS is suitable only for an unemployed person."

The author has read this famous quote of a patient somewhere:

"TB ruined my life - DOTS my livelihood."

#### A small village having no health center in it:

Patients living in a village, which has no center of its own, hardly display any enthusiasm for registering at a neighboring village, since it presents a logistical nightmare. Obviously the program is reaching a limited population that is lucky enough to have a sub-center in immediate vicinity in the village.

Did the founding fathers of DOTS consider whether such a program could possibly work successfully in a country like India where:

- Population is so overwhelming?
- No definite official address is assigned to millions of huts located amidst sprawling illegal slums; tracking down someone is like finding a needle in the haystack.
- Unemployment is rampant and most people (and hence patients) are short of time since they survive as daily wage earners.

# DOTS flickers initially like a tube-light before it shines:

It is an era of speed in health care. Great importance is attached to time factor. Every single minute of the patient is respected. Every conceivable effort is made so that he may heal quickly and go back to his routine with minimal interruption.

Today a gall bladder is removed through minimal invasive surgery (laproscopic cholecystectomy) as a day care procedure, obviating the very need for prolonged and cumbersome hospital stay.

Angiography and angioplasty are similarly performed in a jiffy and almost as out patient procedures.

Even in the event of a major surgery - like the heart by-pass surgery (CABG) - the patient expects to be discharged from the hospital within 5 days and go back to work within 10 days!

In stark contrast, even after due confirmation of diagnosis (how long that might take is another story), DOTS begins to work at a snail's pace. It may take from 8 to 15 days of initial delay before the patient actually gets to swallow his first dose.

The process of address verification itself may take between 2 to 5 days. Furthermore, it takes several days for his quota of 6 months medication to be dispatched to the dispensary that is situated near his house.

This is nothing but procedural delay.

### Operationally, DOTS is an Insensitive program:

- DOTS is unsuitable for several groups of people: Persons who are perpetually on the move e.g. truck drivers, engine drivers or migratory populations like gypsies, workers at brick kilns or stone quarries hailing from backward states and who frequently go back home.
- A genuine emergency back home: Sometimes there is a genuine emergency back home (like a wedding or a funeral) and the patient must go. If he is not provided some extra doses, treatment gets interrupted.
- A Student: It hardly suits a student who can't afford to remain absent from school? He risks losing an academic year.
- Difficult cases like alcoholics and drug addicts often get excluded.
- An Indian female, culturally more conservative, finds the arrangement too intrusive since confidentiality is hardly guaranteed. Besides, sometimes her male escort has no time for frequent visits.
- Adverse reactions: The program responds slowly in case there are adverse drug reactions.

### Policy of liquidation?:

**Ironically, the terminally ill became the first victims of this mammoth life-saving program.** It virtually amounts to persuing a 'policy of liquidation' in order to reduce the burden of transmission.

DOTS program encompasses the concept of home treatment. But it is curiously silent on the crucial question "what to do with the enormous segment

of seriously ill patients of our nation who need indoor treatment?" It is virtually mum on the vexing issue; failing to advocate a suitable provision of indoor beds for the critically sick and dying.

For a population of over 22 lacs (2.2 million) in Faridabad, there is virtually negligible indoor arrangement for admitting the seriously ill TB cases. Before the storm of DOTS swept the city, there used to be 2 places to go to:

- First, TB ward of District Civil Hospital also known as B K Hospital (B K stands for Badshah Khan).
- Second, 25-bedded TB ward of ESI hospital NH3, NIT Faridabad.

But somewhere in the month of Jan. 2003, the 40-bedded TB ward of the B K hospital, which was perpetually overflowing with critically or terminally ill TB patients, was suddenly and unceremoniously shut down, possibly as a fallout of DOTS.

Probably the administration was completely preoccupied and overwhelmed with expansion and implementation of this new highly labor-intensive program and there was a virtual shift in its priorities from hospital admission to domiciliary treatment. It simply put a big lock over its gates without ever bothering to give any explanation to the public.

As a result, the most vulnerable, the critically sick patients of the district who arrived there from far and wide with a great hope were simply turned away.

Having no other TB hospital to turn to, too poor to afford private nursing homes, too ignorant to go far away either to New Delhi or to Vrindavan in the neighboring state of Uttar Pradesh (which is a logistical nightmare anyway), they were simply left to die; how many of them would have lost their lives in the ensuing milieu will never be known because there is no credible agency which bothers to keep track of TB deaths in India.

#### The lucky few:

However, a sub-group of the seriously ill TB patients of the district was rather lucky. Since a family member happened to work in a factory, they were covered under the umbrella of ESI scheme (Employees State Insurance scheme). They were lucky enough to possess an ESI card, which entitled them to avail indoor facility of the ESI Hospital, NH3 NIT - a wonderful place. Two highly dedicated and experienced TB experts had been managing the ward remarkably efficiently through 2001-2003:

- First, Dr. Amar Nath Bhayana (MD Chest & TB), a brilliant clinician, a man
  of ethics, impeccable credibility and compassion, and famous in the entire
  district for his dedication and expertise in the field of tuberculosis.
- Second, Dr. Dhingra (PG Diploma in Chest & TB) possessing tremendous clinical experience, highly efficient and committed.

After 2-year-closure, the lock of TB ward of civil hospital, Faridabad was reopened. The ward was renovated & tastefully decorated. It raised hopes. But eventually it was re-allotted to another stream (children ward) in June July, 2004, bidding permanent good bye to TB. As if - believe it or not - TB had been eradicated from the district.

#### **Recommendation Number 10**

- Reopen the TB ward in civil hospital, Faridabad and at other places wherever these have been recently shut down, with a sunset clause - the decision will be reviewed after every couple of years.
- Create an organization to specifically keep meticulous account of TB deaths in every district.
- A 48 hour deadline: Address verification must be concluded within 48 hours. A patient must ingest his first dose within 48 hours of his diagnosis being confirmed.
- Till such time that the program is made 5/7 instead of the current 3/7 (as recommended on page 102), DOTS outlets should remain open from 7 am to 10 am and from 5 pm to 7 pm and also on Sunday morning.

# 24

# Could a couple of dancing lessons make you Michael Jackson?

#### Single training - the hallmark of DOTS in India:

That a single training is enough for a doctor to learn all about TB seems like an over-simplified and unrealistic idea. "Training imparted = Trained" is not necessarily true. At times, it may prove to turn out presumptuous, far-fetched, wishful and misleading. A single brief training might enable a doctor to grasp working steps of the module. It might refresh some of his knowledge and acquaint him with the procedures, practicalities and modalities of day-to-day operation. It cannot bring about a clear understanding of the fundamental concepts or the desired change of heart overnight. It cannot inculcate motivation, compassion and even diagnostic skills.

# A numb.ers game:

The question is what is the level of awareness, motivation, skill or passion generated at the end of the day.

Could a few dancing sessions make anyone a Michael Jackson?

Does it effectively ignite fire in the belly to fight TB?

Can the doctors really efficiently diagnose and categorize their patients?

No comprehensive survey has ever been done by an independent agency to gauge the efficacy of training. It is like a numbers game, something for the benefit of the records. Besides, several 'trained' doctors are moved away from the program to non-TB work.

Under the head 'expenditure on training' an enormous amount of hard earned money belonging to the taxpayers of the western countries, donated with compassion and ear-marked to help the TB patients, is thus silently flowing down the Indian drains.

# Prolonged Learning curve of doctors and other workers of DOTS:

Patients suffer during the 'learning curve' of the doctors of DOTS, which can often be a very prolonged period.

# 3 - day modular training of doctors - extremely boring:

After her training Dr. Mrs. Vijay Kakar a gynaecologist in ESI hospital, sector 8, Faridabad had this to say, "Not a single patient was present there to learn the practical aspects of diagnosis. Not an iota of training was given on clinical aspects; inspection, palpation, percussion or auscultation. The course leader did not carry a stethoscope. Not a single X-ray was presented; X-ray view box was nowhere in view. No audiovisual aids were utilized; every one was provided with a copy of the module and the trainer kept reading line by line-like a parrot. A few mock exercises conducted on how to suspect TB were no doubt informative. All said and done, it was typically an Indian style of teaching - dull, depressing, boring and uninspiring; the only interesting part during the 3-day affair being the daily allowance of Rs. 100 and the delicious complimentary lunch."

{Incidentally, when DTOs go for their training lasting 12 working days, apart from travel and stay etc., they and their trainers recieve Rs. 200 per day (though earlier a trainer used to get Rs. 600 per day)}.

She further added, "Since there was to be no test at the end, the attitude of some of the colleagues was casual and non-serious. There was no field training at all. Some of the vital topics that were never broached are:

- How to motivate a defaulter?
- What special care to undertake in dealing with a female?
- How to tackle an alcoholic or an addict?
- How not to accentuate stigma in one's daily dealings?
- How to maintain patient's confidentiality while paying a home visit?
- How to motivate health workers working under us?
- When to refer and where?
- Moreover, there was a stark lack of material to spark passion and motivation".

#### Break in continuity:

It is imperative that right after the training, a doctor goes on to practicing what he has just learnt. But doctors simply return to their respective non-TB work. An orthopaedician goes back to the fracture clinic and a gynecologist to antenatal work. They just refer suspected cases to TB department. It causes a break in continuity. After a long gap, if and when called upon to perform TB work independently, they can hardly do justice.

Dr. FSDG, working in a large hospital (having about 45 doctors on its

rolls), complained, "Doctors from various streams promptly refer all TB suspects to me, without even bothering to record history or ordering sputum tests. Every thing is put in my lap. I wonder if they still remember how to fill up a TB card - even though on paper most of them are **'RNTCP trained'**."

#### Am I a beggar?

Rajinder kumar Bairwa, a patient, says, "I had to go cycling 4 kilometers one way to get each dose. Often the worker was not on seat. Sometimes he would be busy with other work. Sometimes he would make me wait while he simply buried his head in Punjab Kesri, the newspaper. Once, while he was leisurely sipping tea, I pleaded with him to hurry up. He got mad. He rebuked me as if I was a beggar. It was as if how can a cup of tea be allowed to go cold? I never went back there." Thereafter, he took private treatment and was cured.

#### Recommendation No. 11

- Incorporate modern audiovisual tools of training: There is an army of people needing training - doctors, lab technicians, pharmacists, and health workers. Govt must prepare suitable audio-visual programs and bombard the country through radio and television, and create awareness and inculcate motivation. Some of these tools will also help the patients.
- Each govt sponsored training must conclude with an exam; anyone who fails will repeat the training - at his own expense - till he clears it.
- Interestingly, it was observed that some medical officers studiously duck their turn for TB training on one pretext or the other, for fear of getting branded with RNTCP and getting stranded with it forever.
- At times unmotivated, unsuitable doctors, for sheer monetary gains, get themselves designated as RNTCP trainers. Fix qualifications for this.
- Honing inter-personal skills mandatory constituent of TB training:
   Rude behavior, negligent attitude, indifference, callousness, insulting language and disrespectful tone promote non-compliance. Howsoever poor a person may be, loss of dignity is unacceptable to a self-respecting individual and could result in instant discontinuation. A well-behaved & polite health visitor is an asset for DOTS, as he enhances compliance.

#### Correct categorization - the heart and soul of DOTS

#### Diagnosing TB is a complex affair:

Symptoms of TB are quite ordinary - e.g. cough, phlegm and fever. Often nothing dramatic happens. Moreover, these symptoms are often too mild to alarm a person, to suspect a dangerous disease like TB or even to seek serious medical advice.

The real clues to TB in a person are persistence of these symptoms for a long time (say over a month) with loss of weight. 'Long sickness with weight loss' become even more significant if the person is already malnourished, or has had a close contact with an infective patient in the past. Moreover, all diabetics and HIV +ve persons being more prone to TB must remain extra vigilant if ever 'a long illness with weight loss' should start occurring in them.

#### Failure of suspicion means no investigations, no diagnosis and no cure.

Therefore, it is imperative for every doctor - at least in a high burden country like India - to maintain at all times a high index of suspicion of TB and to quiz his patient thoroughly.

History taking is even more vital in extra pulmonary TB where often it is the high index of suspicion lurking ceaselessly in the trained mind of a doctor, which proves the initial trigger that kick starts a thorough interrogation and investigation and which eventually clinches the diagnosis. Can a single training really inculcate such skills in a doctor?

The author feels that the brief modular training of DOTS faisl to drill in a doctor's mind 2 crucial things:

- The import of detailed history taking.
- The significance of maintaining a high index of suspicion at all times.

#### Assigning the category:

Once the patient has been duly diagnosed, the most crucial step is to place him in the appropriate category. To assign the exact category is the key to success and the fate of the patient rests on it. And this serious task must be executed by no one but a well-trained doctor himself and with the greatest care, diligence and deliberation.

#### The ultimate sin of a physician in DOTS:

Consigning someone who rightfully belongs to the difficult-to-treat category (Cat.2) into the softer categories (Cat.1and Cat.3) is the **ultimate sin** of a physician under DOTS because the patient might not be cured - the long and protracted exercise might simply end up in treatment failure. And inadvertently, the doctor might be guilty of fostering drug resistance and death.

#### The dwindling art of 'history taking':

The first chapter taught to a medical student in clinical medicine is the art of history taking. In tuberculosis, taking detailed history is an absolute first step towards arriving at the correct diagnosis and thereafter assigning the appropriate category. Extracting the right history is the key. It needs diligent interaction with the patient.

This is an era of speed. Time is at premium. The doctors are busy. The art of history taking seems to be relegated to the back seat; the medical fraternity seems to be slowly forgetting it.

A senior medical officer posted in a remote rural area has a multitude of duties and a big ego; he often regards it below his dignity to 'waste' time on as simple a thing as talking; and that too with a TB patient. He would prefer to delegate it to someone else - an inexperienced junior or a health worker.

#### Patients' own word decisive in finalizing his category:

Which patient is put in Category-I?

Apatient who has these 2 features:

- He is sputum positive (which of course is crystal clear from his sputum positive reports).
- He has never taken TB medicines in the past. And how do you find that out? Simple! You ask him. If he declares so, he is labeled cat. 1 case.

Notably, No chest X-ray is done.

Solely on the basis of what he tells, he is assigned the category.

In other words, a doctor is totally at the mercy of the patient.

What if he lied or kept quiet about a previous episode of TB?

The only chance, however slim, that a doctor possibly has of confirming the veracity of his statements is through 2 sources:

- First, through a clever and diligent cross examination, which is timeconsuming, cumbersome, rather unpopular and unlikely to take place in the overcrowded peripheral health centers.
- Second, by taking a chest X-ray, which might still be littered with some old healed scars the tell tale signs of that previous episode. Then, confronted with hard evidence, the patient can no longer sustain the lie and is likely to spill the beans. Well, that would be a gain of immense value, even if it accrues only infrequently and in a small fraction of cases. Such a disclosure would help the doctor put the patient in the right category, namely Cat.II, and this move could be life saving.

Therefore, in the current program, putting a patient in Cat II depends solely upon proper history-taking. This makes it a risky business.

#### A common mistake that proves lethal:

A sputum positive and X-ray positive patient took anti-TB medicines from a GP for 2 months. Then he ran out of money and joined DOTS. There, his sputum was found negative (since with GPs medicines he had converted to sputum negative by then).

Hence, he was found sputum negative but X-ray positive.

Nobody at the busy DOTS center bothered to take detailed history.

He too didn't volunteer information of his recent stint with TB medication.

Noticing his X-ray shadows not improving with the usual antibiotics, he was allotted cat 3 (although he clearly deserved cat 2.)

He didn't respond; rather turned sputum positive after 4 months. Then he was switched over to Cat 2, (which ought to have been assigned in the first place). But by then a lot of damage had already been done:

- He had lost faith in DOTS.
- He was fed up of the 'heat' (side effects) of the medicines.

- Avoidable financial and labor burden put on the health center & workers.
- The 2-month-course with the GP must have generated some resistance.
- Plus additional resistance would have been generated by this recent misplaced 4-month exposure to RHZ in Cat 3.
- Even otherwise, 2 drugs namely SM and INH having been misused far too long in the past in India display significant resistance levels in India.

As a result, his cat 2 regime too failed. He had probably turned MDR. Such sequence of events is commonly encountered / reported under DOTS.

Nowhere is the significance of 'history taking' as starkly demonstrated as when such a Cat 2 case is misplaced in Cat 3, which is not uncommon.

Large scale disregard of the art of history taking and the resultant wrong categorization by non-experts in DOTS is making India lose 2 of its most powerful weapons, namely Rifamycin (R) and Pyrazinamide (Z).

#### **Recommendation Number 12**

Training must be modified to drill in the utmost significance of:

- Maintaining a high index of suspicion of TB at all times in India.
- History taking: A doctor must be trained to invest 10 minutes exclusively in recording detailed history, as if he were a third year medical student.
   Otherwise the risk of the patient landing in the wrong category becomes quite tangible.

#### 'I Know, I Know' Syndrome

An undeclared, albeit fundamental, principle of allopathic medicine is that "no one but a qualified doctor holding a bonafide degree and a legitimate license will treat the sick". This forms the heart and soul of modern medical science. Sadly it is being disregarded under DOTS - openly, with impunity - and worse - with tacit blessings of the government of India and the WHO.

#### **Delayed diagnosis:**

(As narrated by an insider but could not be personally confirmed by the author for logistical reasons)

Mohd. Yunus, a resident of 9/183, Dakshinpuri, New Delhi was initially put on DOTS category 1 regime at the local DOTS center. He got no relief whatsoever even after completing this 6-month-course. He was subjected thereafter to 8 month long course under category 2. When that too failed to show any favorable results, he was eventually referred to the reputed TB hospital, LRS Institute, situated at a stone's throw from Kutub Minar, Mehrouli.

It was here that a chest X-ray, probably the first ever, was finally performed. It revealed lung-collapse. Bronchoscopy was instantly ordered and conducted and biopsy taken. It took one week for the histopathology report to be ready, which revealed that the real diagnosis was not TB but 'small cell carcinoma' (cancer).

Mohd. Yunus was saved the pain of the shocking news that his illness probably had nothing to do with TB for which he had been taking bitter medicines for so long; it had actually been cancer. While the report was under process, he died.

Dakshin Puri, among the first few proud centers to be brought under DOTS coverage in the country, remains today a central point of DOTS activity. Being conveniently located, it is visited by scores of national and international experts each year. Obviously, none of them ever got to examine Mohd. Yunus!

Why?

- One reason was obviously 'not doing an X-ray', which would have given a
  new impetus and shifted the very direction of investigation. The sight of
  lung-collapse would have set the alarm bells ringing, kick-starting lifesaving measures.
- Secondly, DOTS is virtually held hostage by sputum tests. The 'no touch technique' as promoted by DOTS - whereby a doctor (neither trained nor encouraged to do so) scarcely ever inspects, palpates or auscultates the patient's chest - is hardly congenial to correct diagnosis, especially in an atypical case.
- Thirdly, Mohd. Yunus was probably the victim of the complete barrier between a patient and a doctor, inherent in the design of DOTS; the doctor rarely gets to do a follow up, which remains delegated to a health worker who is often 12th class pass employee and who represents the sole point of contact between the patient and the health-care system. The health worker is ill equipped to appreciate a patient's genuine and urgent need to see an expert.
- Hence the delay in diagnosis and the fatal outcome!

#### Doctor-patient relationship is virtually non-existent in DOTS:

Once the diagnosis is clinched and the relevant category is assigned, the patient may never come back to the doctor again! 'Doctor-patient relationship' so vital to TB cure simply doesn't exist in the current module. Doctor has been assigned very little clinical role and that too in the initial phase. Once the treatment begins, all that he does pertains to paper work, data monitoring, staff-supervision and training. Unfortunately, the most crucial element, namely 'interaction with the patient', stands delegated to the health worker instead. Be it for logistical reasons, practicality, simplification, or expedience, the doctor has been stripped of fundamental duties, negating the basic tenets of allopathic medicine.

#### A class 12th pass person is fast becoming the real 'Doctor Sahib":

A health worker is the one who on behalf of the health-care-system interacts with the patient on a day-to-day basis. He is the custodian of the patient's quota of medicines, administers him the doses and ensures he gets sputum tests done on time. Naturally then, he is the one who is looked upon as the real 'doctor' by the uneducated, innocent patient. He is often called 'doctor sahib'.

A class 12th pass person has virtually been invited to step into the shoes of the doctor.

#### Bottom rung of the system:

A sub center represents the terminal end of the health-care-chain and is a small entity. A doctor doesn't sit there. A health worker runs it. The patients are fully and truly at the mercy of the health worker, who represents the bottom rung of the health personnel. With a solitary training of a few hours, can he realistically be expected to understand the nitty-gritty of DOTS, the crucial importance of his job, namely direct supervision of each and every dose and ensuring religious compliance by every patient? To most of them, sadly, it is one more routine program, just like malaria, leprosy and polio, slammed 'mindlessly' from above, adding to their headaches.

All said and done, despite all the hype created about DOTS, fate of at least quite a few patients ultimately rests solely in the hands of some untrained, unscrupulous workers who couldn't care less.

A health worker, absolutely ill equipped, is left to adjudge the crucial question as to 'when, if at all, does a patient need to see the doctor'. Such an arrangement is fraught with grave danger. There is every possibility that an associated disease, if present in a patient, may be missed.

This could lead to prolonged delays in:

- Spotting and managing the emerging drug-reactions,
- Recognizing treatment failure,
- Suspecting MDR,
- Recognizing some associated ailments e.g. Diabetes Mellitus or HIV.

It is well established in medicine that the fate of a patient hinges on **'who sees him first'**. As soon as he arrives with his complaints, if he is first seen, heard and evaluated by a trained doctor, closely supported by a specialist at hand, it could be life saving at times. And vice versa!

It is well understood now that rather than a handful of specialists, TB control concerns and involves a wide range of persons as has been advocated by WHO think tank:

"Yet the multitude of possible solutions will all have one feature in common: the participation of a rapidly growing number of non-specialized

people, including physicians, nurses, technicians, all government agencies, and international voluntary organizations, and interested groups of citizens." <sup>1</sup>

But isn't 'reducing DOTS to a program run by a mere **12**<sup>th</sup> **class** pass' stretching the argument too far?

#### Program sans doctors!

It appears that some health workers have begun to seriously believe that the program is so simple, it hardly requires doctors.

A health worker looked completely convinced when he exclaimed, "the subject of TB has been simplified; to diagnose, categorize or treat a TB patient is so simple and straightforward! It is no big deal! Anyone can do it! All you need is DOTS training. Is a doctor God?"

Another one had this to add, "why do we need doctors? Isn't the Polio program being run by us?"

"The entire knowledge stands condensed to a handful of formulae, which are so easy to remember and to apply," exclaimed a pharmacist brimming with (over) confidence.

#### **Recommendation Number 13**

This 'I know, I know' syndrome is ominous!

The most dangerous misconception that is spreading like wild fire amongst the DOTS employees is that 'to categorize a TB patient is so easy. Anyone can do it! Even I can do it'. It is extremely dangerous and ominous. If the preposterous trend is not checked urgently with an iron hand, it will spell doom for patients and the program.

<sup>&</sup>lt;sup>1</sup> K. Toman page Tuberculosis case-finding and chemotherapy; Questions and answers, page X1, World Health Organization, Geneva. Published by Jaypee Brothers, New Delhi, India

#### General Inefficiency of the government sector

DOTS is an extremely labor intensive program, the entire success edifice of which rests solely upon human element. Be it the doctor, the lab technician or health worker, the pivotal role has clearly been assigned to the most powerful-yet most vulnerable - asset of the nation - the human being.

Of the numerous centers investigated directly or indirectly by the author and his informal team during the past several years, at certain places, employees were found to be stunningly loyal, disciplined and dedicated; just like the personnel of the armed forces. They exhibited a rare aptitude for the project and performed cohesively like a well-oiled machine. The author was pleasantly surprised to find that for some, treatment-completion and patient-cure are a passion, a mission, and religion. For them nothing seems more exhilarating, meaningful and enjoyable than to ensure that each and every patient enrolled achieves complete cure.

#### 3 centers deserve special mention:

- NDMC (New Delhi Municipal Corporation) Polyclinic, 37, Shaheed Bhagat Singh Marg, New Delhi (near Cannaught Place) catering to about 3,50,000 people. It had mere 41 patients put on DOTS in 1998. The numbers have been swelling ever since, surpassing all targets; 660 patients on DOTS in 2003. Data notwithstanding, the work here is truly exemplary. Although it is always a team effort, one of the major reasons seems to be the energetic and ethical leader, Dr. Ravinder Verma (MD TB) who is not only a brilliant clinician, but also highly dedicated, hard working and caring.
- TU Gannaur in Sonepat district of Haryana serving a population of over 2,00,000 had a mere trickle of 171 TB cases in 2000 that progressively grew to 609 patients during 2003. It has realistically and convincingly overshot all targets. MO TU, Dr. Shailender Khamra, brimming with compassion for the rural poor, works day and night and happens to be an

honest, motivated and fearless leader.

 TB department of ESI hospital, NH3, NIT Faridabad headed by Dr. A.N.Bhayana.

The author salutes all those patriotic employees and others like them who are anonymously fighting this great war - silently, selflessly and ceaselessly.

However, with due apology to them, the question that we must explore is this - are **such sporadic efforts good enough for our massive country?** 

Don't they seem to represent an exception rather than the rule? It is inefficiency that seems to be the rule here. In general, work culture in the govt. sector is appalling. Duty is avoided like plague. **Time pass attitude** of govt employees is hardly congenial to DOTS success. Employees seem to have a knack of discovering innovative excuses to shirk work. 'Inventing ingenious methods of dodging work' that's the second best quality we Indians seem to possess; the first and foremost being 'producing children'!

#### A nation on a holiday:

Can a program like DOTS realistically work in India where the menace of procrastination seems much more rampant than tuberculosis itself. Who will religiously enforce supervision of doses when employees have more days off than they spend working?

Consider these potential holidays in the govt sector in a year:

- Sundays = 52
- Saturdays = 52
- Earned leaves = Appx. 30
- Medical Leaves = 15
- Casual Leaves = 10-15 officially. (But a friendly clerk could from time to time keep wiping out the office record of the CL's already availed, so that one could easily end up availing twice as many).
- Gazetted Holidays
- Restricted Holidays
- Birth anniversaries of great leaders.
- Death anniversaries of great leaders.
- Unexpected and last minute declaration of a holiday by a state chief minister as per his personal whims and fancies (sometimes after the employees have already reported on duty).

- Nation-wide laxities around festive seasons like Diwali, Dussera, Rakhi, Holi, and Durga pooja, Eid, Ramadan, Christmas and New Year etc.
- One-day cricket matches that virtually paralyze the nation.
- Election fever is hardly congenial to work.
- Government paralysis during change of guard after elections.
- Strike-call by the employees or a bandh call by a political party.
- A political rally.
- Traffic jams.
- Extremes of the weather e.g. torrential rains, fog, heat or cold wave etc.
- Furlows (One remains physically absent but is marked 'present' in office records by proxy). The practice is rampant in rural govt offices.

#### A delicate arrangement:

The author can never forget what a friend once shared with him, "we were three of us posted in that remote rural center. But we all lived in the city, about 6 or 7 kilometers away. Exhibiting superb mutual understanding, we took turns; only one of us would drive down to the village and manage its OPD single-handedly, while the other two enjoyed furlow. This delicate, rhythmic arrangement continued for 3 years, though with one absolute precaution: a sick-leave application from each one of us was always tucked in the bottom drawer, duly signed but left blank at the column of date - to be filled in and produced - just in case there was a surprise inspection by the civil surgeon."

#### A new year gift to 504 doctors:

It is an open secret that the levels of truancy in the rural belts around India are uniformly high. It is hardly surprising then that on Jan. 1, 2005, of the 11,000 odd doctors employed with the state of Madhya Pradesh, 504 were hand picked through a survey for award of a special new year gift each - 204 served with suspension orders and about 300 with show cause notices - for remaining absent from rural health centers<sup>1</sup>.

#### Water flows from above downwards:

When this is the state of affairs of doctors one can imagine what could be going on lower down. Other employees too seem to have honed the skills of truancy and might just show up once in a while. Besides, barring centers located on

<sup>19,10</sup> PM bulletins of NDTV, Aaj Tak, Sahara Samay, Jan 1,2005

highways, the ones deep in the rural interior are rarely inspected.

With everyone enjoying so many off days, who will provide thrice-a-week dose? Thanks to such national luxury, many a miss are bound to occur. The uneducated patient, unaware of the govt. calendar, comes over all the way, waits and then goes back, dejected and demoralized. The rhythm of treatment is interrupted.

A patient lamented, "I have no problem with his holidays, but he (health worker) should not forget to give me an extra strip in advance for the approaching holiday; why must I have an interruption?"

In such a backdrop and when each dose is crucial, it is a wonder how so many patients are actually being cured by DOTS in India.

A good example of a well performing labor intensive program is Indian Railways. With its workforce of over 15 lacs the trains in India amazingly cover round-trip-distance between earth and moon four times a day, every day. And yet, guess what is the main cause behind 60% of train accidents?\*

Human failure!\*

When this is so in a relatively good department, what will be the fate of millions of patients at the mercy of health department known for its inefficiency and corruption?

Starvation deaths in our country continue to occur not due to non-availability of food grains. The defect lies with our distribution system as the food grains lie rotting in FCI (Food Corporation of India) godowns and warehouses; another glaring example of inefficiency prevailing amongst our human resource.

<sup>\*</sup> Drawn heavily from - "White paper" April 2003, Safety on Indian Railways: By Govt. of India, Ministry of Railways (Railway Board)

# Anecdotes suggesting: Non-ownership of the program by employees. Quality of Recruitment. Credibility level of Inspections.

#### Some doctors view it as a Punishment posting:

A doctor working for DOTS said, "ordinarily in government job, you can get along doing as much or as little work as you want; some work hard, others don't. Not so in DOTS. Here one faces a lot more responsibility as well as accountability. One is forced to work hard and for long hours - to cope up with the targets. Besides, there is that ever-hovering personal risk of multi drug resistant infection in these poorly ventilated dingy govt rooms without even an exhaust fan; it makes it a punishment posting."

#### Private practice:

Dr. Gandhi, a WHO consultant for Polio at Madhya Pradesh felt that in several states - like MP and Bihar - where govt. doctors are legally allowed part-time private practice after office hours, their commitment to govt. run programs diminishes even further; top priority is their own practice.

#### DOTS - An unwelcome guest:

It has undoubtedly put extra strain on the already fragile health care system. Frequent visits by patients, inherent in supervised intermittent chemotherapy, means added workload. A patient on DOTS would visit about 42 times in 6 months (4 times as many as in the pre-DOTS era). Understaffed and underequipped, some primary health centers are beginning to burst at the seams. DOTS is often looked upon by workers as an unwelcome guest, causing inconvenience and botheration.

#### Passing the buck:

Patients are diagnosed at Tus and referred to sub-centers. There, one particular worker is assigned TB work; entire DOTS related work is his baby alone. Other staff therein - doctor, pharmacist, nurse etc. - have nothing to do

with TB cases. They act merely as a conveyer belt - feeling no responsibility towards the 'unwelcome' TB patients. So at the grass roots level the program is treated as if it were the sole property of a specific health worker.

#### Eloped with the key (narrated by Dr. F.A.N.):

Upon receiving several complaints from patients, an SMO carried out a surprise inspection at a dispensary. Sure enough, the erring health worker was found absent - he had gone somewhere. Worse, he had reportedly taken along the only key to the cupboard having DOTS medicines.

The MO expressed his helplessness, "what can I do? The civil surgeon has called him. All TB work is with him, you see."

"Other staff simply didn't seem to want to have to do anything with TB patients or DOTS," the SMO confided in the author.

#### **Expiry of ESI card:**

An SMO at civil hospital, Ballabgarh was reportedly infuriated at the plight of a patient whose treatment had been stopped at a subcenter simply because his ESI (Employees State Insurance) card had expired. "Once a patient is registered, he must be provided complete treatment - card or no card," he is reported to have shouted.

#### A poor source of referrals:

Most cases are diagnosed at TUs or Microscopic Centers. Only a small fraction of these cases are estimated to have been originally referred by health workers and paramedics - revealing abject disinterest in general. Shouldn't they be our richest source of referrals as they are the ones working at the grass roots level? They fail to make the desired contribution.

#### A lame excuse - Jurisdiction problem:

A block is a political and geographical entity having its own independent financial infrastructure and is not amenable to any re-demarcation. A patient is refused help simply because his residence falls in a different bloc. So what if he has to walk 5 kilometers for the other subcenter?

"Just as it is difficult in India to get a case registered in a police station, so it is sometimes with DOTS," lamented a TB patient who was being ping-ponged

from one center to the other on the pretext that his village was not in their jurisdiction. It is beyond the powers of local doctors to undo the mess; strong political commitment at the top is required.

#### "Am I not a citizen of India?"

Ram Naresh a skilled laborer working in a forging unit near Badarpur border possessed a valid ESI card from ESI dispensary, Usha, Faridabad in Haryana. He could not get registered under DOTS.

Reason: The health worker refused to verify his address, saying, "How can I go to another state for verification?"

Though his factory was in Haryana, the residence fell in Delhi, a few yards from Delhi-Haryana border.

"Am I not a citizen of India?" he asked. The question to ponder is does such procrastination go on at every border - be it between 2 blocs, 2 districts, or 2 states?

#### Please show me your ration card:

In India who would not come to possess as simple a document as a ration card?

Obviously, the poorest of the poor, homeless or an uneducated person - just the kind who deserves free help the most.

Ironically no ration card at times means no DOTS.

#### The cruel distance (as narrated by an LT):

"Noticing bacilli in his first sputum sample, I asked a patient to come back tomorrow with second sample. He told me it was already his 4<sup>th</sup> visit to our hospital. He and his wife had been shuttling from pillar to post, from one OPD room to the other. They lived in village Dhouj, 15 km away. Exhausted and spent up, they had no money - not even Rs.10 for bus fare! They had literally walked all the way that morning. Then they both started weeping."

"So what did you do?" the author asked the LT.

She said, "I bent over my microscope. Pretending to look into it, I wept too."

#### The earthen pitcher (as told by Dr. SSD, a just retired SMO):

"How is supervision of DOTS possible when clinics have no proper arrangement for water?" asked the doctor. "For several days, I kept observing

patiently. Nobody bothered to wash the earthen pitcher or fill fresh water in it. Despite my repeated orders, no one seemed willing to own the responsibility of keeping it neat & clean. As I watched silently, patients would put dirty hands and used glasses into it; it was such a miserable sight.

One day, I solved the problem. In a fit of anger, I picked up a large stone and broke the pitcher myself,"

Having an army background, the doctor simply couldn't tolerate such indiscipline.

#### Some anecdotes about appointment & recruitment:

#### Just-retired familiar faces:

As DOTS expanded at a breakneck speed, several just-retired government employees managed to come back through the back door as contractual staff, simply because the civil surgeons knew them by face. They had all along worked with the NTP. They didn't work then, they don't now.

There's more to the recruitment process. After the author swore that no names would ever be disclosed, a doctor substantiated the rumors that a health worker reportedly had to pay hefty bribes in order to somehow get in to the program. "The going rate for a health worker is Rs. 30,000 initially for appointment and thereafter Rs. 1000."

"Rs. 1000 for what?" Asked the author.

"Per yearly renewal."

#### Overseeing someone more qualified and better trained:

Some candidates who have been appointed as STLS hardly possess the qualification or training of performing sputum microscopy. They are supposed to oversee and crosscheck the working of Lts who are far more proficient at microscopy.

One of the STLS had the courage to confess, "I feel ashamed. I am not an expert in sputum microscopy. LT is obviously far more qualified and far more trained. How am I to monitor him?"

On the other hand, the LTs have strong resentment brewing against such appointees.

Some STS and STLS are reportedly completely incapable of discharging another crucial responsibility: motivating and inspiring the MPHWs and LHV

and ANMs

The episodes are symbolic of how the routine system of recruitment in India is interfering with efficiency of DOTS.

#### Powerlessness of STS, RNTCP consultants and DTOs:

An STS said, "when despite my repeated warnings, a health worker didn't desist from giving away the entire box of medicines to a patient, I had to lodge a written complaint. The doctor in charge of the respective PHC took no action. My genuine complaint went into the dustbin. I lost face; other workers too stopped to listen to me any more."

RNTCP consultant himself seems to have little power; he operates through persuation!

Forget about exempting me from Polio duty even if there is a pressing backlog of TB work, the poor DTO himself gets drafted sometimes.

CMO and some SMOs are the real bosses and for them DOTS is hardly 'something holy' from the moon.

#### Self-serving self-inspection hardly the best of tools to uncover truth:

Curiously, only insiders - those who directly or indirectly remain on the pay roll of govt of India or WHO - get to conduct all inspections and reviews. Outsiders - like professors of medical collages, private practitioners or free-lancers like the author - are never invited and offered opportunity to conduct inspections or reviews.

Is it fair?

#### Inspections by foreigners:

They say 'eyes don't see what the mind does not know'. People in the developed West are born and brought up in an environment where work culture is unpolluted & pristine; honesty of speech and action, and credibility in reporting are taken for granted. Everyone as a rule is considered truthful unless proved otherwise.

In India, it is just the reverse. We tend to assume that every one is a liar till proved otherwise; and not without reason. Credibility is hardly a virtue present here. Lying is a way of life here and proffering false reports is considered a minor sin.

So when powerful teams from the West visit India, they have no inkling of what goes on here under the surface. They are ferried on conducted tours and shown exactly what they need to be shown. Seasoned officials receive them with traditional pomp and show and virtually dupe them by manipulating the itinerary, orchestrating the tour plans, the route of the transport and thus the centers to be inspected. By design they are driven selectively to the best centers, which have been inspected over and over again - open the riverside windows; keep the slum-side tightly shut.

'Surprise checks' are often preceded by communication of elaborate tour schedules. Language is another barrier in elicitation of truth. Besides, the foreigners are perpetually short of time; you can't imagine anyone flying thousands of miles to New Delhi and not sparing at least a day or two to visit the Taj Mahal, the 8th wonder of the world.

Furthermore, inspection teams conducting home visits in the field remain at the mercy of the erring health workers themselves for geographical and logistical support. No wonder, villages with poor record never get to see the light of the day.

#### Empty strips are invaluable:

(Information provided by Dr. SSD, a just retired SMO from Haryana):

No sooner does the inspection team arrive and the names of the patients (and hence the villages) to be inspected are revealed, a doctor would sneak out and pass on the list.

All the health staff would get busy on the mobile phone - alerting colleagues and patients.

Someone would pick up the motorbike and rush to alert the rest personally.

For house to house inspections, a health worker always carries a few empty strips handy in his pockets.

Entering first, he discreetly slips an empty strip to the patient. At an opportune time during the interaction the tutored patient would take that empty strip from his pocket and declare 'I just swallowed it si'r.

WHO bosses can hardly conceal their smiles - from earlobe to earlobe.

"And supposing the worker didn't get that much of an opportunity?" prompted the author.

"In that case, he throws a strip on the floor, creating the 'just-gulped-scenario'."

#### A Lottery at the last minute: (As narrated by Dr. K. A. B):

"Dr. Deepak Yadwanshi, our new RNTCP consultant, is extraordinarily clever and diligent. He goes strictly by the rules. As always, his team for internal evaluation was too secretive - which patients will be home-visited would be decided strictly at the last minute by a genuine lottery - 8 out of 50 names" lamented a doctor.

"So how did you cope up?" prompted the author.

"It was tough. I had to mobilize the entire manpower - even 2 college going sons of the pharmacist. Everyone went out rushing - on scooters, bicycles or motorbikes - from village to village. Since we didn't know which ones, we had to alert not just 8 but all the 50 patients."

"What exactly was the message you sent to the patients?"

"Basically that they must insist that they have just eaten the dose - and that too right in front of the worker,.... which is in reality impractical, you see."

#### Recommendation No. 14

- Surprise element in an inspection is the key to uncovering the truth.
- inspection of every single patient by outsiders:
  - Ideally, an ongoing mechanism must be put in place whereby every single patient put on DOTS yes everyone be home-visited unannounced and interviewed by independent observers preferably in the absence of the local workers once within the intensive phase itself and once later towards the end of his treatment.
- Please end all secrecy: All internal evaluation reports and review reports conducted thus far by the WHO, the govt of India or RNTCP consultants ought to be published verbatim in the public domain so that the country can deduce as to which way the program is headed.

# Will DOTS Withstand The Onslaught Of Expansion?

#### **RNTCP Implementation Time-line<sup>1</sup>**

- 1992: National review of the National TB program (NTP). DOTS strategy adopted and RNTCP developed.
- 1993: RNTCP (DOTS) pilot tested in a population of 18 million.
- 1997: Soft loan of Rs. 604 crores (US\$ 142 million) obtained from the World bank to implement RNTCP in one third of the country and to prepare the rest of the country for adopting RNTCP at a later date.
- 2000: RNTCP expanded 15 fold (from 1997) to become the second largest program in the world.
- 2001: 450 million population covered under RNTCP.
- 2002: More than half of the country (530 million) covered.
- 2003: Around 75% (778 million) of the country covered.
- 2004: Population of 850 million planned to be covered.
- 2005: Entire country planned to be covered under RNTCP.

Although the pilot projects were initiated early, it was only around 1998-2000 that floodgates were virtually thrown open to its large-scale and speedy implementation in a phased manner. It is hoped that the entire nation will have been covered by DOTS by the first quarter of 2005.

#### As DOTS expands, cure rates drop:

Expansion seems to be somewhat inversely proportional to success.

DOTS has higher chances of success in a low prevalence nation. In a high burden country like India, where sheer number of patients pouring in could

<sup>&</sup>lt;sup>1</sup>TB India 2004, RNTCP Status Report, page 20, published by Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi 110011, http://www.tbcindia.org

simply overwhelm (inundating) the health services, chances of its success progressively diminish.

Why?

DOTS is a highly labor intensive program. Each case registered means added workload.

But more importantly, a single noncompliant patient, who plays hide and seek with the system, is capable of usurping team energy that would otherwise be sufficient to cure 10 responsible cases.

In other words:

# Energy spent on 1 defaulter = energy required to cure 10 good patients.

It is not so much the rise in number of good patients as that of defaulters that fatigues the workers and overstretches the already fragile health-care system.

As the program expands and number of cases grows in general, total number of defaulters visiting - rather who stop visiting - the DOTS outlets goes up proportionately making things messy.

# A habitual defaulter proves a real parasite on the retrieval mechanism, pulling down the cure rates.

Similarly, rising number of failure, relapse and resistant cases entering the program milieu becomes unmanageable, and which frustrates the teammorale as well as the program reputation.

Furthermore, as the program ropes in more and more burdensome, chronic and difficult-to-treat TB patients like addicts, alcoholics, diabetics and HIV positives, it is bound to have a sobering effect on results.

It is no secret that in India the health services as such are quite precarious. These factors will further strain the health services in general, which at places might even snap.

#### Taking pride in expansion:

Govt of India is vociferously claiming it to be one of the fastest growing programs in the world. Haryana has been praised profusely for speedy and exemplary expansion:

"Haryana - the fastest expansion in recent months: RNTCP was first launched in three districts of Haryana in April 2000. Another two districts were

launched in March 2003. The strong commitment of the state Govt. especially the Secretary Health and DGHS Haryana towards the TB program lead to the launching of remaining 12 districts by the 1<sup>st</sup> week of February, 2004 covering the entire population of 21 million within six months making it one of the fastest DOTS expansion in the country.<sup>1</sup>"

#### What is the ground reality in Haryana?

- In several districts of Haryana till date there exists no exclusive post of a DTO, so vital to smooth functioning of the program; TB work is slapped on anyone as an additional charge on an ad hoc basis.
- For all practical purposes, therefore, Panipat, Rewari, Yamuna Nagar and Kaithal can be said to be 'headless' districts.
- Dr. V.K.Sood, the lone program officer of district Jhajjar, officiates as the DTO as he officiates every other program.
- And guess who performs TB work in district Fatehabad? The civil surgeon cum skin specialist, Dr. R.C.Aggarwal himself.
- When such ambiguity bedevils the vital domain of DTOs themselves, one can imagine the state of affairs with regard to other staff down the line.

#### District Faridabad:

- 4 years into DOTS and still short by 8 lab technicians and 3 microscopy centers, the scene in district Faridabad is hardly a matter of pride.
- CHC 'Kherikalan' (Faridabad) oversees a jurisdiction of about 60 square kilometer, which houses 7 PHCs and 31 dispensaries. On world TB day 2004, it was found that merely 2 lab technicians were posted in the entire jurisdiction - 4 posts of LTs lay vacant. Would a patient consent to traveling 20 km simply to get his sputum examined?
- Furthermore, come July, and these rural centers would be inundated with high fever cases requiring blood test for malaria. How many blood slides can a lab technician humanly examine every day? 50? So there often occurs a backlog. Stacks of slides would have to be sent elsewhere for reporting. Or an SOS would be sent to the state capital demanding extra lab technicians, which is sure to fall on deaf ears. At times a non-LT is put on the job as reportedly at Hasanpur dispensary. During the peak malaria

<sup>&</sup>lt;sup>1</sup>TB India 2004, RNTCP status Report page 30 http://www.tbcindia.org.

- season TB work gets a low priority even if there is no shortage of LTs. One can imagine what goes on in desperately understaffed conditions.
- Furthermore, the infamous internal evaluation report on 'In-depth review of RNTCP'(Aug 24-26) of another district, namely Jind, highly damning and pessimistic, hardly offers a reason to rejoice.\* (Ref: Dainik Bhaskar 28.8.2004, "TB ke khilaph jang ki khuli pol")
- From 2000 through 2003, guess who managed TU Palwal in Faridabad district?: Dr. B.S. Sharma Diploma Pediatrics (a child specialist).
- The expertise of Dr. Sukh Dev Goyal (Diploma in TB) and an experienced and articulate DOTS trainer is clearly being underutilized in ESI hospital sector 8, Faridabad.

#### District Gurgaon - People are at the mercy of God:

- Arrival of DOTS in District Gurgaon in 2000 seems to have sparked off a
  game of Kho-Kho there. Four years have seen 4 to 5 DTOs come and
  depart; among them an orthopedic surgeon, an ENT surgeon, an exDTPO on the verge of retirement and so on. What a shameful waste of
  training resources! (Now finally, a keen DTO, Dr. Divyanshu Parashar,
  DTCD, having considerable experience as MOTU has been brought in).
- Ferozepur Jhirka and Punhana are two Community Health Centers in District Gurgaon having a population of about 5 lacs. It is a particularly backward area of Haryana. A well-trained doctor, Dr. J.P.Parsad, MBBS, posted in PHI Pinungwa (which is one of the 3 Tus of District Gurgaon) handled the entire TB work of this large zone till he was transferred away in June 2003. Dr. Pardeep came in his place but soon left reportedly accepting the offer of doing PG in Paediatrics. The next incumbent Dr. Dharmender too stayed briefly and managed to go away. Since then the post of MO TU lies vacant as no doctor seems keen on staying in the backward area. Not just that, most of the PHIs in the zone like Shingar, Tigaon, Pinangawa, Nagina, Marora and Bhima often operate without a doctor except that once in a while a doctor would be sent on temporary deputation. For diagnosis as well as categorization, all TB cases of this large populace of 5 lacs remain at the mercy of:
  - Dr. Lodha, SMO Punhana, who happens to be logistically inaccessible, being the only doctor available in the widespread zone!
  - STS therein.
  - Health workers.

(Let us hope and pray that inclusion of these 2 CHCs into the newly created district, Satyamev Puram in October 2004 ushers in some respite for its people).

#### Expansion of DOTS seems to be schedule-driven not safety-driven:

'Safety first' hardly seems to be a virtue of DOTS.

Speedy expansion is in reality leading to pitiable dilution of the program. To take pride in the breakneck speed of expansion rather than in its quality of services to patients seems funny.

The need of the hour is to pause, take stock, improve program-quality, plug its loopholes and attempt to cure every single patient picked up by DOTS centers already established. This is a very tedious, painstaking and diligent task. However, the stress of the Central TB Division seems to be on expanding to more and more areas instead. After all, it is the business of expansion that offers the scope for purchases and therefore seems to be more lucrative and hence popular amongst the top brass!

#### Will history repeat itself?

The efforts of the Govt. seem to be to expand horizontally at a breakneck speed. The hasty manner seems to ensure that more and more patients would be covered rather than cured. Aren't we committing the same fundamental mistake that plagued and discredited our previous national program, i.e. "Emphasis on diagnosing more and more patients rather than on ensuring that each and every case detected is fully cured"? Will history repeat itself?

### Anaecdotes depicting how social stigma hampers DOTS

In Indian culture, society is considered supreme; it exerts enormous social pressure upon its members. No one seems free from this. Loss of face in the community is something everyone dreads the most. Some Indians would rather die than bear a social stigma, which is a major barrier to DOTS in rural India. A sick villager is mortally afraid of anything that might reveal his disease status. He hates to be seen visiting a DOTS center, or visited by the staff, being observed while swallowing medicines or being forced to bring his own glass of water - all tell tale signs.

Ram Nath (name changed), a hard working health worker narrated this incident with a heavy heart:

"When I arrived at this patient's house to give him the missed dose, the family looked visibly stunned. Upon recognizing me, their neighbours, who had been merrily sipping tea, too suddenly fell silent and departed, leaving behind the remaining tea and sweets untouched. later, the patient said to me accusingly, 'the revelation amongst the village folk about the nature of my illness would completely ruin the prospects of my daughter's wedding."

Another sensitive and dedicated STS said, "what I hate most is to escort a jeep-load of alien inspectors into the narrow village lanes, chased by curious kids making noise; it reveals the status of my poor patients. Consultants and DTOs must desist from such public displays." DOTS is too obtrusive, too obvious; maintaining someone's confidentiality is hardly a priority.

'TB' is a dreadful label to be slapped more so in a society that has a penchant for stigmatizing anyone at the drop of a hat on any basis - caste, creed, color, sex, region, state, religion, nature of work, education, size of house, thickness of purse, mode of transport used or spoken language etc.

TB patients are accorded lowest priority at some dispensaries. Eventhough 10 a.m. is more convenient time for them, they are ordered to report only after 11 a.m., by which time most of the general patients have been disposed off and the staff is relatively free. They are assigned this separate

slot so that they do not mix up with other patients visiting the dispensary. Such stigmatization further compounds the problems of the patient, who is already desperately trying to cope up with the un-ending ordeal of to and fro visits.

#### Mortally afraid of catching infection:

A health worker told the author, "I am here on contract just for a year. The last thing that I would like to carry forward with me when I take up my next assignment is infection of TB."

#### Not a minute more than is absolutely essential:

"Some health workers are perpetually worried about catching infection. They habitually keep patients at bay. Would they ever want to interact with a patient a minute more than is absolutely essential? Would they ever be enthusiastic in educating him about the vital precautions? Can they ever be trusted to supervise the act of ingestion of medicines?" commented a senior medical officer. Then he added with laughter, "The chores of education or supervision are the first casualty and are generally dispensed with. Unless of course we provided him with a set of binoculars to operate from a 'safe' distance."

#### Most reluctant:

The author could not agree more with with the assessment of an SMO of North Delhi, who has worked with DOTS ever since its inception and has tremendous experience. He stated that 'most of the health workers are most reluctant to go and chase defaulters with any enthusiasm. All they do is a balancing act - between fear of catching disease and that of loss of job; the latter driving them to perform at least minimally'; by remote control as far as possible.

And the origin of social stigma is directly traceable to general lack of awareness.

# Know TB, No TB (If we know TB, there will be no TB)

Single most ominous failure of all national and international agencies engaged in TB control lies in their failure to recognize the significance of creating sufficient mass awareness about this ancient disease.

Each and every hurdle faced in TB control can directly or indirectly be traced back to its single root cause - namely lack of awareness at some level or the other:

- Premature cessation of treatment by patients on a large scale is a reflection of their ignorance of the cardinal rule that TB treatment must be taken for a minimum of 6 months for complete cure.
- Interminable delays in diagnosis arise from widespread ignorance of our public regarding symptomatology of this ailment.
- Origin of a plethora of myths and stigma that hamper our efforts at control is linked to ignorance.
- Our health care system is oblivious of the absolute and urgent necessity to educate patients, their family members and friends regarding simple yet vital precautions that an infectious patient must take to check transmission.
- Non-uniform treatment patterns prevalent amongst doctors betray their poor update about latest guidelines.
- Unbridled proliferation of quacks, malfunctioning of govt dispensaries and continued production of substandard drugs are all symptoms of lack of awareness amongst policy makers of India.
- Paucity of research on TB is a sign of lack of global vision amongst the highest echelons of the world bodies, funding agencies and pharmaceutical industry.

"...mass awareness campaigns about TB are not commensurate with the threat it poses" declared Sh. Atal Bihari Vajpai, the ex-Prime

Minister of India at Vigyan Bhavan while inaugurating the second meeting of 'Stop TB Partners Forum' on 24th March, 2004, the world TB day\* (Hindustan Times March 25, 2004).

#### For the government, image is supreme:

In general, for a top government official, image comes first; reputation of the department under him is supreme. Whatever might happen, the holy image must not get tarnished. An adverse report - irrespective of whether it is true or false - must be withheld, suppressed and stymied. Because it can create an inconvenient hue and cry which might disturb the apple cart. The first and foremost casualty of the resulting commotion is sure to be the job of the Boss himself. Therefore, self-defense makes it imperative that quick denials be issued and undesirable facts (even if true) are tactfully played down.

Smart thing is to maintain a status quo. Image must get precedence over everything else - even human life. Confessing to something like a brewing TB epidemic would be a matter of great embarrassment for the ruling party. And some politicians are generally more sincere to the party than to the nation. No wonder, for over half a century, term after term, facts seem to have been systematically concealed from the media and public with remarkable finesse; the true picture never allowed to emerge in the public domain.

#### Role of media:

To the author, perpetual silence of the media seems like the saddest part of the story. Media cannot be absolved of its indifferent role in this context. In the race for viewership, it craves for elements of drama, sensation, mystery and entertainment. It has forever stayed away from the depressing and lackluster subject of TB. Besides, unlike HIV/AIDS, it is hardly a matter of immediate concern for the developed western world.

Global media leaders like CNN and BBC - who to a great extent set the agenda of topics worldwide - must confess to this grave omission. Their obsession with terrorism, Afghanistan war, Iraq invasion and Israel-Palestine conflict has blacked out vital topics like tuberculosis, which quietly sniffs out infinitely more human lives than all of these issues put together.

We might have been closer to our goal of TB eradication today had the media accorded to TB even half as much air time as it had chosen to accord to the intimate extra-marital affairs of a single individual, the ex president of the United States of America, Mr. Bill Clinton.

#### The single most important message:

With regard to HIV/AIDS the single most important message to learn is that "you could catch HIV/AIDS if you practiced unsafe sex".

The corresponding one for TB is that "for complete cure, 6 to 8 months' course of drugs must be completed, even though the patient might feel much better much earlier."

While the globe is thankfully being bombarded with the former, the latter remains completely forgotten. The fact that this one-line-message - so critical to ridding us of this ancient scourge - has failed to seep into the third world psyche, speaks volumes about the effectiveness of Information, Education and Communication (IEC) activities on TB.

**Like some petty vendors** trying to sell some merchandise, government's shamefully meager IEC activities are focused on the narrow zone of solely marketing its DOTS program. Far sightedness lies in utilizing the same resources, air time and effort towards creating much-needed and ever-lasting general awareness about TB which would empower the public and the patients, ushering in several benefits one of which would be to decrease default rate and automatically lessen the burden on DOTS network and eventually propel the country towards complete freedom from TB.

**Swami Vivekanand** is reported to have said that feeding the hungry is noble; you have given him comfort... till he feels hungry again; providing medicine to the sick is even nobler, you help him tide over the bad patch ... till he falls sick again; but educating a person is supreme - since he can henceforth manage his food and treatment for the rest of his life.

Education is the key to development of our country. Awareness about TB will never harm our citizens while withholding information and truth - however bitter - surely will. To delay the production or spread of educative programs on TB (even if the delay is in the name of protecting patients from stigma) is antinational, anti-India. Can we allow lack of awareness to ruin our current initiative i.e. DOTS?

#### Who is next please?

Everyone on the road doesn't meet with an accident. However, law in Delhi requires everyone riding a two-wheeler to wear a helmet so as to prevent head injury - just in case. By the same logic our entire population of one billion needs to be taught a little bit about TB. It makes sense to familiarize oneself with as

common an ailment as this while still in sound health.

Who knows who is next?

Can a sailor afford to put off lessons in navigation till in the middle of a storm?

#### **Emulate Cola war:**

For such a pressing issue, govt ought to be working overtime and at a feverish pitch - just like Pepsi and Coke who have been running their mind boggling media campaigns - thanks to the cola war. Clearly profit making seems a better incentive than the prospect of saving lives.

#### How serious is the agency?

A mass media agency (Swami and co.) was hired to oversee the nationwide media campaign and to develop prototype IEC materials. For creating TB awareness, the company is claimed to have engaged and enrolled Rahul Dravid and Zaheer Khan, two leading cricketers.

#### A Solar eclipse missed:

Recently the duo was all over the TV screens, virtually hogging all the limelight on every channel of radio and TV.

They were literally the focus of billions of eyes in the Indian subcontinent as they played a special fixture at Lahore.

It was not a test match but a one-dayer.

It was not just any fixture but the historic final of the series.

It was not between any 2 teams but between 2 arch rivals - India and Pakistan.

But what made it as rare an event as solar eclipse was this - the day of this fixture happened to be the World TB Day, 24<sup>th</sup> of March 2004.

All that the duo had to do was to put one sticker on shirt or utter one sentence on TB and the message would reach billions in the entire subcontinent. But they did not do so.

Govt and its chosen media co. were caught napping - once in a lifetime opportunity was missed. This is just one more in the series of omissions that have perpetually gone on for donkey years. Shouldn't such an arrangement be reviewed seriously - whether it deserves to be continued or terminated?

# Collective failure of Central TB Division, CHEB (Central Health education Bureau) and Prasar Bharti - arms of govt of India itself:

When the govt has its own Prasar Bharti, why in the first place did the need to outsource the crucial job of creating awareness arise at all? Because of abject failure of CTBD, CHEB and Prasar Bharti.

There is a striking lack of awareness of the existence, availability and importance of RNTCP at every level.

#### **Recommendation Number 15**

Create a new post of **TB educator** who will obsessively & incessantly sing the TB song - with the patients, the public & the media and create awareness.

#### Let TB messages piggyback the ongoing HIV awareness campaign:

A remarkable awareness campaign worth millions of dollars on HIV/AIDS is currently going on in India. NGOs are feverishly vying with one another to be seen excelling in the effort, as it is seen as a passport to foreign grants.

Smart thing would be to hook TB awareness to it. Let TB messages piggyback HIV/AIDS. Then the coveted goals can be achieved effortlessly and speedily and that too without spending a penny or an iota of extra energy.

But such brilliant ideas have been stalled - ostensibly on the presumption that linking TB with HIV might further enhance stigma of TB - another glaring example of concentration of all power in just a handful of stubborn hands.

#### Is TB awareness synonymous with marketing of DOTS?

For the past 6 years, the govt has procrastinated, ostensibly thinking: 'How can we go all out with TB awareness campaign on national media channels since only a portion of the country is covered with DOTS? It might generate a nationwide demand for DOTS, even in areas yet to be covered and which would be chaotic'. As if TB awareness were synonymous with DOTS. The country has in the bargain lost more time and this might have harmed the prospects of DOTS. But what stopped the govt from acting and spreading simple messages (not about DOTS) about the disease per se, which would have acted like manure and prepared the ground for the imminent program?

There are several vital messages in TB, which have no controversy about them whatsoever. Why these too await action? Simple messages like:

- TB is curable.
- TB treatment is long. It must be completed at all cost.
- It is not a hereditary disease.
- TB as such is not fatal; premature discontinuation of treatment may be.
- What precautions an infectious patient must take to check transmission to his family and friends.
- Infection is not synonymous with developing sickness.
- TB does not catch easily provided the general immunity of the person is robust.
- With effective treatment, an infectious case quickly turns non-infectious.
- Several forms, like extra pulmonary, are often non-infectious to others.
- What are the common symptoms of TB?
- Being more prone, all diabetics need to be extra-vigilant.
- Sputum test is the crucial test for diagnosis.
- To take treatment from quacks is dangerous etc. etc.

DOTS is such an elaborate package and yet strikingly there is nothing in its kitty for the specific purpose of educating or motivating the patient. Doctors and health workers, virtually overworked, hardly have any time or intention to talk to a TB patient. Besides, there is no educative material - films, books, CD's, cassettes, stories, magazines, newspapers, dance numbers, quiz, poems etc. created by the govt for this purpose at all.

**The horses** of DOTS are not galloping in unison, at the same speed or in the same direction. Generating patient awareness would help steer at least the key dark horse (namely the patient) in the desired direction, easing strain on the rest of the horses (namely doctors, health workers, LTs etc.).

#### The film, 'Teen Batein' is oozing with all the right kind of messages:

Not only did the govt fail in its duty to produce any educative film itself on TB in half a century after independence, it also failed to grab the opportunity offered to it - and that too free of cost - to create awareness through 'Teen Batein' - a comprehensive, award-winning Hindi film on the subject produced by the author way back on the world TB day, 1999. The author kept pleading with Ministry of Health & that of Information & Broadcasting for a couple of years but all in vain. The author has never felt more frustrated in his entire life than at the stoic silence, abject apathy to the cause & the inaccessibility within these two ministries, who failed even to intimate if they had rejected the appeal.

The book, 'A Death Every Minute' too is woven around the same messages:

On world TB day, 2002, the author released a simple book - probably the first comprehensive book on TB in public domain for a common man - and pleaded with the govt. to take it up on a mass scale and pass it on free of cost to every patient and relative starving for information. It was translated in to Hindi, Tamil and several other languages. But - the author learnt unofficially - that the image-conscious govt was allergic to its very name and the bitter truth depicted therein. As expected, no reply was ever received.

Loss of 6 precious years towards creating awareness: Govt's undeclared rejection of the film& the book through stoic silence is a symptom of its complete lack of appreciation of the role that awareness can play in TB control. If taken up in the right ernest, these 2 effective tools of awareness would have generated sufficient awareness in the past 6 years, relieving our DOTS workers to some extent from the menace of default.

- 'Teen Batein' or a similar film be shown on prime time on all govt channels (like Door Darshan) regularly, maybe every week..
- With his first dose of DOTS, each patient must be handed a modified copy of 'A death every minute' in his own vernaculour language.
- Prepare numerous tools for educating politicians, IAS officials, doctors, public, media, patients, risk groups, college & school kids etc.
- Awareness material on TB ought to be provided to every MP, MLA of every state, & members of IAS training Institute, Mussourie.

**Note:** This page seems like self-promotion by the author. But it is not. During the last few years, despite having searched desperately, **the author has failed to find another suitable book or film on TB for the lay man.** 

# MDR Multi - Drug Resistant Tuberculosis

**Hippocrates (460-377 BC)** identified phthisis (one of the several historical references to TB) as the most widespread disease of the times,

- Noting that it was almost always fatal\*.
- He opined that attention to the patient was a waste of time and that they
  are a burden on the state\*.
- He went on to state (what no doctor could dare do today); he warned his
  colleagues against visiting patients in the late stages of the disease, since
  their inevitable deaths might damage the reputation of the attending
  physicians\*

Ironically, even after thousands of years, all these 3 observations mentioned above seem perfectly valid in today's India - should one agree to substitute the word 'Phthisis' with 'Multi-Drug-Resistant TB'.

#### Man is fighting literally with his back to the wall:

There are only 5 potent TB drugs known to man. Some of them are already losing their effect due to the phenomenon of drug resistance.

It takes up to 15 years and over US \$ 500 million for the complete research and development of a TB medicine. In contrast, it may take only a few months of its misuse by patients for the resilient TB germ to develop resistance to it, to devise mechanism to dodge its bactericidal effects, to mutate in to a more fussy strain.

That is exactly why, unlike in other diseases, TB is never treated with a single drug, but always with a combination of 2 to 5 medicines given simultaneously. The situation is fast getting out of hand as man is constrained today to employ in routine 3 or 4 or even 5 of them.

#### 4 drugs are being given together in Cat I.

<sup>\*</sup>Testing a Horrible Superstition, chapter 2, page 23

#### 3 drugs are being provided in Cat III.

#### All 5 drugs are being given in Cat II cases.

There is no reserve left for man to fall back upon, especially for patients that fail to respond. It won't be incorrect to state therefore that man is walking right on the edge; fighting literally with his back to the wall. As drug-misuse goes on and as the germ gets smarter, as it learns to resist more and more drugs, one after the other, man desperately runs out of medicines with which to cure TB.

Since, as things stand today, no new drug is expected to emerge soon from the R&D pipeline, some scientists fear we may be headed back to the pre-antibiotic era of our grand parents when TB was incurable.

#### Once a patient is initiated on DOTS, it is virtually 'now or never':

In the erstwhile program, patients invariably received STH regime. They were deprived of the modern medicines (like RZE), which paradoxically was a blessing in disguise in case the treatment (with STH) failed since the patient still had something to fall back upon. He had yet another reasonable second chance of being cured through employing the 'top weapons' of modern medicines (RZE, the best medicines known to man) to which he was yet unexposed.

But in the aftermath of DOTS, for the failed candidate there is nothing left to fall back upon since we begin with 'the best weapons' themselves. There is hardly any 'reasonable second chance'. Once a patient is initiated on DOTS, it is virtually a 'now or never' situation. If the attempt fails, the prolonged exposure to drugs is likely to generate in him a degree of resistance.

#### A failed attempt at DOTS is no joke.

It is a gloomy event and a bad omen for the patient and his family.

Pendulum of DOTS swings between 2 extremes: cure and MDR. There is very little middle ground. A patient on DOTS is like the one riding a tiger; there is no scope for failure. There are just 2 outcomes at the end of DOTS pipeline: heaven or hell, so much so that every unsuccessful candidate exiting DOTS pipeline ought to be viewed suspiciously as a potential MDR case.

DOTS has thus introduced casino effect - win more, lose more.

No doubt, DOTS will cure more patients but... it will also turn more in

### to MDR!

In fact, the moment India decided to switch over to DOTS, it virtually zoomed up the stakes involved in its TB control effort, virtually leaving no scope for failure. A failure due to any reason (poor implementation) will simply be catastrophic, much worse than a failed NTP.

Paradoxically, DOTS was launched with tremendous fan fare to stem the very tide of MDR that it might in fact be fuelling.

# Drugs for Resistant TB - more expensive, highly toxic yet less effective:

Resistant TB cases are very difficult to treat even in the best of Institutions endowed with unlimited resources and engaging the best of doctors. The second line drugs, which are used in such cases, are very expensive, highly toxic and quite ineffective and need to be administered for much longer period - often for about 2 years!

It is unthinkable that a common man in India can ever afford this kind of treatment. He is too poor to buy even the much cheaper medicines used in ordinary TB cases. Moreover, how can he be trusted to complete this longer course when he failed to successfully complete the much easier 6-month-course, which has led to this mess in the first place? His characteristics namely poverty and ignorance - are there to stay and can't be wished away.

### In India, die he must:

Dr. S.D. Parashar MBBS sums up his perception of the current Indian scenario by quoting his professor's words, which he strongly feels still hold true after several decades: "Once an MDR - always an MDR; it invariably has a grave prognosis in India. A sputum culture report confirming that a patient is indeed resistant to R & H is a scary document; the piece of paper is literally a death warrant. A common man in India simply can't afford the costly drugs. Die he must - the poor one dies of drug scarcity, the rich one of drug-toxicity."

### Away from my clinic please:

Dr. Rakesh Gupta MD Medicine has no qualms about stating what his approach is. "I never try to treat a suspected or confirmed MDR. It ought to be done only in an institution where free medicines and experienced physicians are available. A half hearted treatment only adds fuel to the fire; a more dangerous strain (resistant to yet another drug) may emerge out of such

effort."

He went on to confide further, "When I refer an MDR patient to L.R.S. Mehrauli TB institute in Delhi or some other famous hospital, deep down in my heart, I know it is just a formality. All I am doing is just washing my hands of the poor chap because hardly anyone referred has ever got better. A patient rarely gets free or subsidized medication anywhere. The referral is basically to ensure that he wastes and coughs and dies at some place - any place - away from my clinic. A doctor has a right to protect his reputation, doesn't he?"

### A Moral Dilemma:

'Whether to treat merely ordinary TB cases, leaving MDR cases alone to their fate (inevitable death), versus embarking on a far more expensive program of tackling both - ordinary as well as MDR cases' is a dilemma for any poor nation.

How can a country, which is not yet showing credible signs of being able to cure its ordinaryTB patients (where treatment costs just Rs. 300 and lasts for merely 6 to 8 months) even begin to talk about being ready to cure its MDR cases (where treatment costs Rs. 2 to 3 lacs and lasts for 18 to 24 months)? And that too where a patient has to travel hundreds of kilometers for getting a 'sputum for AFB culture and sensitivity test'?

On the one hand we delete radiology from DOTS in the name of economy, while on the other we brag about launching an elaborate and costly venture, DOTS-plus, for dealing with our MDR cases?

So when the govt of India stakes claims to DOTS plus program in front of the Green Light Committee, to some insiders it seems like the most ludicrous dichotomy on earth. In the current Indian scenario, all talk of DOTS plus seems like a sick joke.

One is forced to wonder if there is some truth in the rumors that there is some overt pressure being exerted by some lobbies of pharmaceutical industry having vested interest in promotion of their costly second line anti-TB drugs. Implementing DOTS plus would only distract our attention from the more urgent goal - enhancing the cure rates of simple DOTS.

### **Recommendation Number 16**

# DOTS Plus - please hold on for a few years:

In India, DOTS plus ought to be implemented only after we have succeeded in bringing our current DOTS program at par with the best in the world, achieving cure rates of 96% throughout the country as a routine.

# More efficient evaluation of suspected MDR cases:

Equip more govt labs with facilities for 'sputum for AFB culture and sensitivity' testing.

### Revive sanatorium movement - this time not for simple TB but - for MDR:

If we do not take some bold initiatives to check transmission of the dreaded MDR TB germs right now, we might in future be confronted with the unthinkable prospect of an epidemic of incurable variety of TB. We must revive our sanatoria - more to remove such dangerous patients away from general public and less to cure them. Every confirmed MDR case ought to be offered a deal - he gets lifelong free treatment, food and lodging if he chooses to move away permanently and live in a sanatorium till he is cured or perishes.

### Hoping against hope:

Hindus consider **Vrindavan** in the state of Uttar Pradesh as one of their holiest places. The city houses a large TB hospital.

Legend goes that once a patient arrives therein, chances of his recovery get brighter as 'Lord Krishna Himself protects him'. Hopeless cases - Hindus and Muslims alike - from far off towns, cities and states inundate the hospital with great hope.

### "Is mitti mein kuchh hai":

People seem to have an unflinching faith - "Is mitti mein kuchh hai" (there is something special in the soil here). And faith can move mountains. And who needs faith more than a desperate, incurable, dying TB patient?

# Rename Ayodhya as "Ram-Rahim Bhoomi":

Just like Vrindavan, Ayodhya is another holy town that enjoys dual

allegiance of both - Hindus and Muslims.

The author hereby appeals to the leaders of both Hindus and Muslims to forget and forgive the past and take initiative, and for mutual gains agree to declare Ayodhya - a perpetual bone of contention between the two - as Ram-Rahim Bhoomi, a model MDR city - first of its kind in the world. A large sanatorium ought to be erected right at the disputed holy site, having a common temple and a mosque in the middle, and where all confirmed cases of MDR TB in India, who are virtually face to face with death, should be welcome under His care and allowed to live there indefinitely - till they either recover or die.

This step will benefit the nation in several ways:

- It would defuse the ongoing eyeball-to-eyeball confrontation between the
  two communities Hindus and Muslims both uniformly mauled by the
  common enemy, the mycobacterium tuberculosis. It will go a long way in
  redeeming the fate of future generations of both the communities alike.
- Usher in lasting peace to the nation, diffusing a potential time bomb of hatred. In this era of competitive economy, our country can ill afford the luxury of dissipating nation's precious energy in nonproductive religious controversies.
- Physical removal of MDR cases from villages, towns and cities of India will mean their effective isolation within the MDR sanatorium of Ram Rahim Bhoomi, thereby protecting the remaining 1 billion countrymen from getting exposed and infected with virtually incurable strains.
- When most MDR cases get together at a place, it will make it logistically possible to effortlessly launch a pilot project of DOTS plus therein.
- What's more, all this can be achieved without any extra burden on the nation's exchequer as the generous offerings at the holy shrines of both the communities can be channelized towards sustaining the program and also rehabilitation of the fortunate survivors.
- It will mitigate terminal suffering of the dying by keeping their hopes alive till the very last, providing at least the solace of breathing their last in the holy air.

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# What must urgently be done: The Remaining Recommendations

Apart from the 16 recommendations mentioned already in the preceding chapters, some more are given hereunder. Of the total 40 recommendations given in this book, over 50% can be implemented without spending even 1 naya paisa while the rest will need some extra funds. However the amount of funds needed are very much within the reach of modern India; all that is required is political will.

### 17. Sorry!

To begin with it is our collective moral obligation to acknowledge that mistakes have been committed in the past - by way of omissions and commissions. As a result, grave injustice has accrued to millions of inconspicuous families in India and several other third world nations (page 8 - 19).

Although the hapless families themselves have since reconciled to their fate accepting the tragic death of a member as God's wish and remain, till date, blissfully unaware of the injustice done. They have not the slightest of inkling that their tragedy could have been averted.

Yet the world owes them atonement for permitting such avoidable yet untold suffering, mind you, not on account of the malady per se but due solely to its gross mismanagement by the powers that be. It is particularly tragic after 1960s, by which time TB had become curable and death from it virtually avoidable.

In order to wrap up that unfortunate chapter once and for all, we must first come to terms with ourselves by putting the past in the right perspective. Only after concluding this unfinished business can we morally and legitimately feel comfortable within ourselves and move on in right earnest with our efforts for charting a new future.

The least we can do is to say, "we are sorry". Implicit in this atonement is our solemn pledge to be more vigilant in future and never to allow such negligence or indifference to creep into our attitude ever again.

To help us never to forget our lapses and the consequent human cost we have had to pay and the lessons learnt thereof, we must commemorate 25th September as the 'World Regret Day' or 'sorry day' or 'afsos divas' or 'day of penance' as a token of respect and homage to those millions of unknown departed souls and their bereaved relatives and friends.

# 18. Four fundamental reasons why we must introduce changes in this new program pro-actively & with a sense of urgency?

# A. TB patients have no lobby; they are expendable:

By its very nature, TB is a chronic, debilitating disease. It works on its victim ever so quietly - like a slow poison. It usually runs its course uneventfully; there are no dramatic events that may attract attention. Rather social stigma that surrounds it pushes others away.

With medical facilities being so deficient in India, a patient would generally keep on deteriorating gradually till he becomes too sick to work. Then he would need physical as well as financial support from his family members.

He is completely at the mercy of his relatives and friends who themselves survive from hand to mouth - and who would soon begin to feel the financial pinch of supporting him. And then there is that stigma and the perpetual fear of contracting infection. Relatives are further frustrated by the patient's lack of response to the unscientific medication doled out by various quacks and local doctors. It is only a matter of time before they get completely fed up of the never-ending liability and lose their steam and eventually desert him.

Castigated thus by the near and dear ones, patients become quite lonely and isolated. Overwhelmed with the emaciating disease, social stigma, poverty and the non-performing health care system, they continue to wage their lonely battle for survival. During this phase they are completely preoccupied with the nuances of day-to-day survival - food, medicines, movement; simple chores like going to the toilet and taking a bath overwhelm them.

They are so engrossed in their strife that they can never think about conjuring up a lobby, an association, a union or a group; they remain isolated and unconnected with one another and hence powerless. Having no social security, no insurance cover, no money, no job and being up against heavy

odds, their plight is far worse than the formal under-priveledged classes of India who by virtue of having organized and effective lobbies, have the collective power to grab the political class by the throat and extract benefits.

The government spends millions and millions in the name of TB; yet when it comes to providing even minimal benefits to the patients themselves, rhetoric of poverty is hyped up. Pleading that we are a poor nation, they are systematically deprived of the barest minimal benefits. One of the reasons for this sorry state of affairs is that not even a single patient or his representative from our '14-million-strong-lobby of patients' is physically present during decision-making parleys - ever! How can one protest an invisible decision?

The govt can afford to ignore TB patients because the poor chaps have no unity, no common forum and hence no nuisance value. Never in the history of independent India have TB patients held a rally, jammed the traffic, disrupted trains, and stormed an assembly or gheraoed the parliament.

They have no voice and there is no one to lend his voice to their silent screams. They are virtually expendable.

So TB patients rot! They perish! Ever so quietly!

Therefore, the onus is on the educated class to be more sensitive & make the requisite changes.

# B. Under DOTS, cost of a single treatment failure is astronomical to the society:

When TB treatment fails, it is ominous - just as when a student of class X fails his final exams. The patient faces the dreadful prospect of another protracted course of toxic and costly drugs and further work-loss and bankruptcy. His family continues to suffer in every possible way. Disruption in children's education, loss of prestige, ongoing social stigma and devastation in relationships within and outside the family simply can't be measured in financial terms.

# And man has yet to invent a meter for measuring such abstract and incalculable losses.

How can you even begin to calculate the cost of human life? When therapy fails, a patient continues to be a potential source of transmission. Every single day that he continues to be sick (and infectious), chances of some of his contacts catching infection remain alive.

And when a contact does fall sick, his treatment and work-loss in turn adds up to the cumulative socio-economic burden. Such potential losses can't

be measured or visualized. Only someone who has personally gone through the traumatic journey can appreciate the horrendous consequences physical, social and mental - for a patient and his family.

The cost of a single treatment-failure is virtually astronomical! Besides, it sustains the chain of transmission in the mankind, pushing further away the coveted goal of eradication of TB.

### C. Issue of human life transcends financial considerations:

The risk of generation of Resistant TB is far greater in DOTS than in the previous program, NTP (where the failed candidate always had that reserve option of modern drugs to fall back upon).

Therefore DOTS must be modified without any reservations about financial factor. Whatever the additional cost incurred in bringing about a positive change, it is bound to prove cost effective in the long run. Benefit of doubt wherever it exists must be granted to the patient! When human life is on the line, every other factor ought to be set aside! To try and economize in such a situation is shortsightedness!

Timely debate, analysis & admission of lapses will help turn the tide. Stubborn denial will worsen the scenario and postpone solution. Stakes are high. It is time for humanity to make a choice - whether to conquer the epidemic or perish.

We cannot afford at this late stage to experiment or make feeble adjustments; something drastic needs to be done - and right now!

### D. RRNTCP?

- In 1962 we embarked on NTP.
- In 1998 we revised it to RNTCP.
- If we do not take appropriate corrective steps right now, our nation faces the comic prospect of a revision yet again in future; we would then have in our lap RRNTCP (Re-Revised National TB Control Program)!

# 19. Rename DOTS as Dost (directly observed short treatment) in India:

DOTS in India must be re-named as Dost (a Hindi word, which means 'friend').

## 20. More meaningful and extensive coverage:

# • Harnessing the private sector:

Sensitization of the private sector must be undertaken on a war footing as a first step towards their large-scale involvement.

# Rope in the corporate sector:

Delhi Development Authority (DDA) had allotted institutional land to 16 private hospitals (that includes Escorts Heart Institute, Indraprastha Apolo, Jaipur Golden and Rajiv Gandhi Cancer hospitals etc.) on concessional rates with (there being) a condition in the lease deed that 25% of indoor and 40% of outdoor patients will be treated free so that the poor too could avail of these facilities. But a special committee formed by Delhi High Court reaffirmed that the stipulation was being grossly violated. Thanks to the lack of govt. commitment in getting the poor their due, it still remains a distant dream\*. (Times News Network, Times city, page 3, 1.7.2004, TOI).

Such hospitals all over the country ought to be designated as TU's or microscopy centers under RNTCP with immediate effect.

- Bring **armed forces** in to the fold of the program.
- Rope in Indian Railways as well.
- Several public sector undertakings, which continue to remain alienated from it, ought to be brought into the fold.

# 21. Patient friendly measures:

### Convenient timings:

DOTS outlets must be open from 7 AM to 10 AM and 5 PM to 7 PM everyday - especially on Sundays and Holidays.

# 15 minute-disbursal mandatory:

Today, you order a pizza on phone and it is cooked as per your specifications and hand delivered to your residence - within 45 minutes. Guaranteed. Any delay, even of a minute, liberates you of the liability to pay; it becomes free.

The carton bearing the name of the patient is lying right there. To pick it up, take out a blister pack and push out the tablets and make the patient swallow them is just a 20 second job. But it takes 45 minutes to 2 hours. Is it fair to the patient especially when his embarrassment at being seen loitering in the premises of a TB center grows with every passing minute?

(And when, unlike in the case of a pizza, cooking if any is to be done later-

while filing quarterly reports).

Medicines should ideally be placed in a room, which is very close to the main gate, never deep inside a big building or on the first or second floor. The supervised disbursal must be achieved within 15 minutes of the patient stepping inside the gate.

### 22. Dot on time:

Courier services represent another recent revolution in India; delivery of letters and parcels has become prompt and dot on time.

# A single cyclist effortlessly manages to deliver 50 parcels a day.

Will it be better if, instead of 50 patients simultaneously wasting their precious time and energy in visiting the dispensary, a courier boy is engaged to **'hand-deliver & see-swallow'** doses to each and every patient (50 per day) in a colony - early in the morning or late at night right at patient's residence or place of work? It is worth exploring as a pilot project.

### 23. In case of side effects:

Sometimes the intolerance to drugs is genuine. The patient simply cannot tolerate so many drugs in a single dose. So he deserves to be switched from classical DOTS to daily DOTS. But the doctor hardly enjoys any such discretion under DOTS.

# 24. Strengthening the diagnostic element of DOTS:

### Diabetes mellitus:

India is tipped to become the diabetic capital of the world in future. Therefore, we must put in place mandatory screening of every TB patient initiated on treatment under DOTS by doing his blood sugar levels.

### HIV:

Similarly, mandatory HIV screening for every TB case.

# 25. A dose of DOT for every one from top to bottom:

It is not only the patients who need to be watched closely. In fact, the doctors manning DOTS, DTOs, consultants, administrators, politicians, officials of the Central TB Division, WHO & UN themselves seem to be in dire need of a massive dose of DOT. They urgently need to be observed, trained, managed, evaluated and disciplined with serious commitment and absolute transparency - so that this time around they indeed live up to the trust reposed in them by the entire world.

# 26. Make DC (District magistrate, deputy commissioner) the real watchdog:

Deputy Commissioner (or District Magistrate) is the chairperson of the district TB society. Rather than being just a figurehead, the unique situation ought to be meaningfully harnessed.

In the current Indian system of governance, a DC can be termed the uncrowned king of his district. The tremendous clout that he wields can stimulate the work force. The very mention of his name is enough to energize a lazy worker. It can act as an effective deterrent for the errant workers and patients, reigning in false or inflated reporting.

DTOs or the civil surgeons are comparatively ineffective and powerless before the strong workers' unions.

DC must be made accountable, especially for any false reporting. He must select at random 1 smear positive case every month and follow him up closely but independently. He can be the best watchdog for DOTS.

# 27. First precondition to success - fill up vacant posts & end shortages: There is no District TB Center created or a regular MO TB in Faridabad and all the 7 newly created districts of Haryana (out of the 19).

Hundreds of primary health centers across India that are reeling with shortages of doctors must at once be provided their required numbers.

The vision of our forefathers was to have a small health center in every village, every pocket and every colony. This unit - called a sub-center - would cater to about 5,000 people and would be manned (not by a doctor but) by 2 health workers: 1 ANM (female) and 1 multipurpose health worker (male).

Over the years, as population exploded, a sub-center began catering to 8 - 9000 people (instead of 5000) and the workload increased progressively. Worse, posts of these workers were never duly filled at places as planned.

# No. of Lab. Technicians, Multi purpose workers & staff nurses permanently recruited in Haryana since 1992 (13 years) = 0 (Zero).

Some have since retired & promoted, further escalating the shortage.

Insiders believe that currently:

Posts of MPWs = 50% filled (50% vacant).

Posts of ANMs = 90% filled (10% vacant).

As a result, most of the sub-centers are being run single-handedly by an ANM. Now if she happens to proceed on a long leave (e.g. maternity leave), DOTS goes down the drain.

# A non-resident DOT provider is ineffective; he must live in the same village:

A large village with a population of 5,000 indeed gets assigned a health worker exclusively who can certainly provide DOTS efferctively to the patients tliving in that village.

But when villages are small and scarcely populated, there is not enough work to justify employment of an exclusive worker. So one employee is placed in-charge of a cluster of 4 to 5 villages. **Now this is the tragedy of rural DOTS.** Can a human being realistically shuttle from village to village every other day supervising doses? It is virtually impossible. Rather than being a jumping jack, he must be a local resident of that village.

# Involve AWW (Angan Wari Workers) meaningfully:

We seem to have forgotten another plausible option. An AWW of ICDS (Integrated Child Development scheme) under the Social Welfare Department is virtually omnipresent in every small village of India. She is in charge of only 1000 people and is best suited. She is hardly overworked and remains more accessible to rural folk. She can accomplish DOTS comfortably and with great economy of effort. She may be given this additional responsibility in her respective village with an incentive of Rs 300 per month.

In villages having neither an AWW nor a MPW, a resident (a sarpanch, a teacher or a shop keeper) ought to be designated as DOT provider, paying him the usual Rs. 175 per 'treatment completed' plus some more perks.

## 28. Training:

There is an army of people who need to be trained. Along with the traditional training sessions, we must prepare suitable audio-visual programs.

There is a need of **Harnessing e-technology** for preparing interesting and educative tools for awareness and training. Numerous target oriented modules for a variety of audiences must be created on a war footing e.g. for doctors, health workers, lab technicians, pharmacists, consultants, administrators, politicians, patients and public at large. We must bombard the country with these modules through print media, radio and television to create

awareness.

# **Training of doctors:**

- Extensive radiology lessons showing hundreds of X-rays ought to be an integral part of training of doctors to hone their X-ray reading skills.
- Extensive field exposure and lessons in interpersonal skills are a must.
- Every training session must conclude with an exam. A failed candidate would repeat the drill of training - on his own expense.
- Overall, training must be made more rigorous and extensive. After all, while training to go into a jungle to catch a rabbit, isn't it prudent to learn how to shoot the gun - just in case there is an unexpected encounter with a tiger?

## Foreign training:

Painstaking advance planning ought to go into the selection of candidates who are sent on training abroad and fellowships. It is imperative that the candidate on his return stays on course and enriches the future of our nation. It must be made absolutely certain that:

- The candidate is not due for transfer to another stream.
- The candidate is not due for promotion and hence displacement away from the subject.
- The candidate is not about to retire.
- The candidate must be made to sign an undertaking that he will not leave service or the stream for the next 5 years at least.
- An undertaking must be obtained from the deputing officer to the same effect.
- An undertaking must be obtained from the state government to the same effect.

In case of a fiasco, all 3 ought to be held accountable and the national losses ought to be recovered from them.

# 29. Mandatory 'Rural Draft' for every government doctor:

75% of our populace inhabits rural India. However, carrier-oriented doctors hardly ever want a rural posting since there is no incentive.

Indian parliament must enact a law that "every govt. doctor must be

drafted for a 3-year mandatory rural innings - preferably the very first posting - because he is still young, energetic, more mobile and probably a bachelor (or even if married, still unencumbered by school-going kids, the most daunting barrier).

Furthermore, irresistible allowances (may be a rural allowance of Rs. 3000 per month) and perks (free house, assured seats for their wards in good schools in the nearest city and transport to ferry them to and fro) ought to be made available if the govt. is serious about uplifting rural health-care. Ironically, a doctor posted in a metropolis today ends up getting not only fatter paychecks but also superior professional exposure.

## 30. Replace age-old practice of maintaining ACR of a doctor with QTR:

Abolish age-old system of maintaining ACR (annual confidential reports) of a doctor. Replace it with QTR (quarterly transparent report), which ought to be exhaustively and cumulatively compiled - his performance being projected through point system. It should clearly reflect each and every detail like number of patients seen & cured, procedures done, operations performed, night / emergency duties done, contributions made during natural calamities, family planning output, behavior with patients and colleagues etc.

QTR will no more be a secret document; it ought to be widely published and recorded permanently in a data bank, and accessible to anyone on a web site - so that no one - yes, no one, not even politically connected - can mess around with it - ever. The corrupt and the incompetent today keep getting promotions and rewards as the file containing adverse ACRs disappears 'mysteriously' at the opportune moment. And one can't challenge it since no data exists in public domain. All future transfers / promotions ought to be strictly based on QTRs.

Not just doctors, it ought to be applied universally on every govt servant.

### 31. Vision 2010:

## Communication is at the heart of the problem:

There can only be 2 possible outcomes of treatment. One, the patient completes his full course and gets cured. Second, he defaults and remains ill and takes a step towards becoming MDR; former takes the patient to a positive future while the latter to a life in hell.

Each outcome will catapult the patient into a different destination,

unfolding extreme consequences - but of opposite nature - not only for the patient himself but also for his family, the society, the nation and the future of mankind.

Astonishingly, there is a very thin line between these two destinations, which are poles apart. Amazingly, the key factor, which determines which of the two outcomes a patient will beget, is communication between him and his health worker.

Whether he will duly complete the treatment or dump it, hinges solely on continuity or disruption in this bond of communication. Astonishingly, even a soft but timely nudge can work wonders in saving the patient from drifting towards the disastrous outcome. A single, friendly but timely, telephone call could do the trick and correct the course of an erring patient.

A stitch in time saves nine. Timing is the key.

Single most important factor that eventually decides the fate of the patient and hence that of our entire TB control effort can be said to boil down to just one thing - communication.

# Hello Reliance / Bharti / BSNL / Idea / Hutch / Tata etc.! Would you step forward and prove your mettle!

DOTS must be integrated with the unprecedented and magnificent revolution currently going on in India, namely telecommunication and information technology, thanks to the visionary steps taken long ago by Mr. Rajiv Gandhi and Mr. Sam Pitroda.

"Around 17.9 lack (1.79 million) new telephone subscribers were added in November 2004, resulting in a tele-density of 8.4%. The gross subscribers' base, consisting of fixed and mobile, has touched 9.03 crore (90 million), according to TRAI (Telephone Regulatory Authority of India)"\*.

We now possess a rapidly growing infrastructure of an intricate network of land lines, STD booths and mobile phones that reaches out practically to every nook and corner of our country. The scenario must be gainfully exploited for establishing contact with a patient the moment he tends to default.

Smart thing will be to jot down at the very outset, along with the other details of his address etc., some PP telephone number of each and every patient - be it a phone in the neighborhood, a local STD booth or a mobile phone of someone living near his residence or his place of work. Then one can contact him speedily with economy of effort. Besides, it will drastically reduce the workload on workers, especially Senior Treatment Supervisor.

Every DOTS center must be provided sufficient telephones lines. Whenever anyone applies for a license for STD booth, he should be asked first to furnish an undertaking in national interest that he will co-operate in tracing any patient in the respective locality, village, colony, street or neighborhood, if and when called upon to do so by the DOTS providers.

In the next phase, further steps can be contemplated gradually - to make that crucial phone call - not after the event has occurred but - beforehand. A reminder for the approaching day of appointment (just like an insurance premium reminder) can be sounded rather than after a default has occurred.

Eventually, in the future, as the revolution brings down the prices further, each patient should be provided a free mobile phone as an incentive or could be offered one on subsidized rates so as to stay perpetually in touch with his health worker so that question of default doesn't arise and there is 100% compliance.

Is it possible in a country like India?

Why not - when the govt of India can afford to spend over Rupees 31,00,000 per annum just to maintain the pay, perks and privileges of a single member of parliament (MP), and which notably includes three telephone connections and 1,70,000 free local calls per year (466 free calls per day)!

### 32. Generous incentives for the patients & the workers:

A doctor who has recently been transferred from a PHC to the much larger ESI hospital expressed surprise, "Compliance here is much better than the rural centers. Probably because the patient gets incentive; apart from his TB doses he readily gets whatever he needs - tonics, antibiotics, anti-diarrhoeals, anti-malarials, and anti-asthmatics for self as well as for family. There is no scope for any such advantage in the rural periphery where neither doctors nor medicines are available. Incentives can really do wonders."

# Free ration as incentive to patient:

Upon successful completion of doses of a month, each patient ought to be given a coupon for free rations - 5 kg of atta (or rice) and 5 kg of dal and some kerosene oil - from the local ration depot. Suitable integration with the govt's Public Distribution System in this regard should be made. (As suggested by Mr. Mahesh Bhatt, Lab Technician, New Delhi TB Center, Delhi).

<sup>\*</sup> Financial Express Dec 8, 2004, page 20.

### Yearly awards to encourage the best workers:

In coordination with local clubs (like Rotory, Lions etc.) public functions must be organized and prizes awarded to hard working TB workers - be it DTO, MO TU, LT, STLS, STS, MPW, TBHV, ANM or LHV etc. It should be a regular feature on every World TB day. Awards could be hard cash, making temporary workers permanent, or certificate of appreciation. Appraisal of candidates for this purpose ought to be done by outsiders (and not by govt. officials).

# Private DOT-provider gets nothing. Give him his due for God's sake:

Mr. FSTB, a particularly hard working and energetic STS managing 2 blocs in southern Haryana, was visibly upset when he shared this with the author, "Barring 2, all 27 odd DOT-providers engaged and trained by me are working fairly well. During the past 3 years, they would have successfully treated anywhere from 10 to 50 patients each. But they have received nothing in return - except, of course, my sincere gratitude and courtesy. None of them has ever received even a single naya paisa from the department, not even Rs. 175 per case cured that they are entitled to."

"Being an ad-hoc employee, how can I disturb the applecart by raising this sensitive issue of financial irregularity? Besides, the moment they become aware of their entitlement, they will disengage from the program in protest, posing major headaches for me. My job will be in jeopardy. So I simply keep my lips sealed."

Who has been pocketing their share of money? What is the modus operandi? Does such malpractice go on elsewhere too? Doesn't it paint a pessimistic picture of the efficacy of the (avowedly fantastic) monitoring apparatus put in place for RNTCP?

Role of STS is vital for the success of the program because he is the key connecting link between District TB Center and its entire fleet of DOT providers scattered all over.

Besides, the ritual of "address verification" is an absolute must so as to:

- Stay in touch with the patient at a later date.
- Prevent fake registrations.
- Avoid inclusion of chance visitors or outsiders in to the local register.

STS must therefore be given a special place and attention. Although he bears

the brunt of workload and social pressure yet enjoys no authority, no job security and no incentives.

### What is the logic of employing an STS being on an ad hoc basis?

What if one fine day he gets an offer better than Rs. 6000 p.m. and quits? The program suffers. The new incumbent will pose 2 major problems:

- Rigamarole of his training beginning from a scratch.
- His geographical orientation of the vast unknown zone housing a population of 5,00,000, which will take up to a year.

Emoluments of an STS must be enhanced to Rs. 8000.

He must be made permanent.

## He ought to be given entertainment allowance:

An STS has to do a lot of public dealing. He has to frequently interact with all kinds of DOT providers - e.g. private doctors, sarpanches or shopkeepers. So that he may entertain them at the very least with a simple cup of tea, he must be provided Rs. 300 per month.

Give an STLS Rs. 300 as traveling expense so he can be more mobile.

# 33. A 24-hour help-line for TB patients:

A 24-hour help-line for TB patients, centrally connected, and attached to control rooms and tape recorders just as in the police vans must be created. Any doctor working with DOTS or any patient anywhere in India can directly file his complaints and suggestions therein.

# 34. Amalgamation and Integration of all health related funds:

Every department receiving foreign funds seems to keep its cards close to its chest. There is complete lack of information sharing between various agencies attempting to accomplish the same or similar things in isolation, which results in sheer wastage of resources and energy. Everyone seems to be singing his own health song as per his own whims and fancies.

Funds arriving for various health purposes ought to be amalgamated and well coordinated in order to ensure optimal utilization. An overview must be taken. The plentiful funds flowing in several programs like Reproductive Child Health program, Mewat Development Board activities, HIV/AIDS and RNTCP etc. ought to be meaningfully integrated. Furthermore, various health camps, awareness campaigns, training sessions, community meetings must so devised that these include not just one but all subjects if possible. It would lead

to tremendous economy of material & human resources.

# 35. The bitter pill:

"Once a patient refuses to take medicines, I generally get to hear of it after about 15 days. I visit him a couple of times and do everything in my power to convince him and rope him back into the program. When all attempts to retrieve him fail, I finally use the unpleasant option. I threaten him that next time I will gather villagers and publicly embarrass him by revealing his infectious status and the risk it poses to them." said Dr. S.S.K a highly dedicated MOTU.

"In the last 4 years, I have had to resort to this bitter option only 3 times" he added thinking hard. Then he went on to exhibit his amazing memory skills and total involvement with DOTS - by recounting, one by one, the names of those 3 patients and the villages they had belonged to!

### Social embarrassment the ultimate tool to enforce compliance:

Dr. FSKS MD TB: "In Indian culture, social embarrassment is the ultimate deterrent. Therefore, a dramatic measure ought to be attempted publicly once in a while in an area. Nab the habitual defaulter, blacken his face, hang a sign board around his neck saying 'Beware of me - I am a time bomb' and take him around in the neighborhood."

## 36. Involve religious leaders into creating awareness:

Educate and enroll religious leaders and ask them to incorporate TB awareness in their religious discourses. One clarion call from the Shahi Imam, Shankaracharya or Head of Akal Takht can do wonders in education of the devotees and their families.

# 37. Critical Review of each module currently in operation around the world:

A competent independent agency (not on the payroll of WHO or UN) ought to critically evaluate the efficacy of various modules currently being implemented in about 150 countries in order to improve them wherever possible.

## 38. Human rights commission ought to critically examine each

provision of this package to evaluate if the module flouts the basic spirit of human rights.

# 39. CAG (Comptroller and Auditor General) must investigate this dubious fashion of purchasing done around 31st March each year:

Not only are the annual budgetary provisions for medicines and equipments shamefully meager in Haryana, those are not even utilized optimally, judiciously, diligently or in a phased manner through the year.

It is an open secret that the entire fund is mysteriously spent recklessly only on the last day of the financial year! Just when funds are about to lapse! Orders from Chandigarh / Panchkoola are faxed to every hospital literally at the eleventh hour and the purchasing is done in a tearing hurry, without doing any home work, exposing the entire exercise to massive corrupt practices and inflow of substandard, third rate equipment.

# 40. Health insurance cover for the masses (somewhat on the lines of ESI-Employees State Insurance):

In Faridabad city, a poor person could belong to either of the 2 categories:

**First**, a poor factory worker who is ESI covered. He is entitled to go to ESI hospitals and dispensaries for free out-patient & indoor treatment for self and family. ESI hospitals are better than general hospitals since they have more funds.

He thus is clearly much better off than the **second** variety - an equally poor person who is a free lancer - rickshaw puller, push-cart-vendor, mason, laborer, plumber or unskilled worker etc. - who has no insurance cover. During sickness he is virtually on his own; he goes to civil hospitals, which often is a painful and traumatic experience. In the name of free medication all that one gets there is paracetamol, APC, chloroquin, multivitamins, sulfadiazine, chlorpheniramine malleate etc. and that too possibly manufactured by local dubious companies.

This second variety of poor person could also go to a private doctor in which case he is exposed to the risk of being fleeced. How shall he raise the money for illness when he earns merely about Rs. 50 per day, which is not even enough to feed the family? He begs loans from others.

In a nut shell, chances are that, for want of proper treatment, even a minor ailment like diarrhoea, pneumonia, anaemia, malaria, an infected wound, delivery, abortion or acute appendicitis could prove fatal! Needlessly!

Therefore, first and foremost, the need of the hour is that we in India

initiate a health insurance scheme for the masses - somewhat on the lines of ESI model. Everyone - and that means every poor person of our country - must be covered. Those who can afford less may contribute negligible or less; those who earn more should contribute proportionately more.

Otherwise, how on earth can poor workers earning Rs. 50 a day ever be expected to save anything and keep it handy for such a rainy day? And since infections galore, rainy days are aplenty here.

# The most risky thing on this earth:

Unless and until this one thing -an effective cover of health insurance for everyone who is poor - is not duly accomplished in letter and in spirit, the most risky thing on earth will continue to be - being born in a poor family in India.

# Abbreviations

TB Tuberculosis.

NTP National TB program.

DOTS Directly Observed Therapy Short Course.

RNTCP Revised National Tuberculosis Control Program.

DDG TB Deputy director general tuberculosis.

CTBD Central TB Division.

WHO World Health Organization.

IUATLD International Union Against Tuberculosis and Lung Disease.

DTO District TB Officer.

MO TU Medical Officer TB Unit. LT Laboratory technician.

STS Senior treatment supervisor.

STLS Senior TB lab supervisor.

MPW Multi-purpose health worker.

MC Microscopy center.

TU TB unit.

MO Medical Officer.

SMO Senior Medical Officer.
CMO Chief Medical Officer.

MBBS Bachelor of Medicine, bachelor of Surgery.

MD Doctor of Medicine.

MS Master of Surgery.

DA Diploma in Anesthesia.

DTCD Diploma in tuberculosis & chest diseases.

PTB Pulmonary tuberculosis.

PHC (PHI) Primary Health Center (institution).

CHC Community Health Center.

OPD Out patient department.

Govt Government

### About the author

It takes courage to listen to one's conscience and devote the entire life towards attainment of one's ideal. Dr. Raman Kakar, MBBS, DTCD, a TB specialist from Faridabad (Haryana), has embarked upon such a course, setting himself a unique and singular goal: eradication of TB by creating mass awareness. With a missionary zeal he has steadily marched towards his vision of a TB free India.

# He has created unprecedented tools of mass awareness:

- Teen Batein (तीन बातें): an award winning Hindi
   Film on TB, dubbed subsequently in English.
- A Death Every Minute: a simple & comprehensive Book on TB for the common man in English.
   Recognizing its immense value for TB patients & the overwhelming public response, the book was promptly published in Tamil & in Hindi ( एक मौत प्रति मिनट ). This is being followed by Punjabi, Urdu, Nepali & Kannad versions.
- Besides, he has been tirelessly communicating to the masses through all means & media;
  - Through lectures, presentations and discourses at diverse forums: schools, colleges, villages, slums, clubs, NGOs, industrial units, religious congregations etc.
  - Through publishing stories & articles in the print media: newspapers, magazines & journals.
  - Through talks & interviews on various TV & radio channels like Star News, BBC World News, All India Radio, BBC Radio & several cable networks.

This pioneer work has been hailed by a cross-section of society. Indian Medical Association has honoured him with R.C.Oration & President's Appreciation awards in Haryana, and Community Service award at the national level. Govt. of India appointed him a member of the Program Advisory Committee of Revised National TB Control Program (DOTS).

The scourge of tuberculosis has been around since times immemorial. The disease is caused by a germ that spreads through the air. No one is immune to getting infected.

Not long ago, TB was the most dreaded disease as it was incurable. With the discovery of anti-TB medicines between 1944 & 1966, the rich nations were able to contain it during the 1970s. But there's been no respite for the poor people of the third world. 95% of the global cases & 98% of TB deaths occur in the developing nations - the tragic reason behind lack of research on TB or its cures.

TB kills one Indian every minute. One third of its global burden is borne by India. In 1962, the govt. formulated a national TB program, which turned out to be a total failure. More Indians die of TB today than ever before.

Recently, govt. of India has adopted DOTS, a new strategy. Every TB patient can now receive the best possible medicines free of cost & under close supervision.

However, this new program is hardly free from controversies. A chest X-ray has been omitted; the diagnosis rests primarily on 'spotting of germs'



in a person's sputum (phlegm). Instead of taking medicines daily, the patient now takes merely 3 doses per week. Besides, the TB expert has been practically removed from the scene.

Did sufficient care, research & consensus go into the making of this new package? Is it consistent with the basic doctrines of allopathy & with the principles of human rights?

It seems as if a handful of govt. officials have unilaterally gone ahead with such a colossal program worth millions of dollars, involving

landmark deviation from the past, without an exhaustive nation-wide debate or even a consensus amongst the Indian medical fraternity. In a democracy, such abject lack of communication between the state & the citizens, while deciding the fate of ailing millions, is ironic; more so when, thanks to the vision of late Mr. Rajiv Gandhi, the former Prime Minister of India, the country today stands empowered with an unprecedented revolution in the fields of communication & IT.