

USING THE LAW FOR PUBLIC HEALTH



Human Rights Law Network

Human Rights Law Network Vision

- To protect fundamental human rights, increase access to basic resources for the marginalised communities, and eliminate discrimination.
- To create a justice delivery system that is accessible, accountable, transparent, efficient and affordable, and works for the underprivileged. Raise the level of pro bono legal expertise for the poor to make the work uniformly competent as well as compassionate.
- Professionally train a new generation of public interest lawyers and paralegals who are comfortable in the world of law as well as in social movements, and who learn from social movements to refine legal concepts and strategies.

USING THE LAW FOR PUBLIC HEALTH

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CONTENTS

<i>Thanks</i>	<i>vi</i>
<i>Introduction</i>	<i>vii</i>
The Law and Public Health the Foundations	1
<i>Justice J.S. Verma</i>	
Report of the High Level Expert Group on Universal Health Coverage	6
<i>Dr K Srinath Reddy</i>	
NRHM: How far are we from Universal Health Coverage?	10
<i>Dr K. S. Jacob</i>	
From Insurance to Entitlement Cards.....	15
<i>Javid Chowdhury I.A.S.</i>	
The Reluctant Hospitals in the Capital Region.....	18
<i>Ashok Agarwal, Social Jurist</i>	
Irrational Drugs, Irrational Spending	21
<i>Dr. Sakthivel Selvaraj</i>	
Affordable Medicine, the Chittoragarh Model	26
<i>Dr. Samit Sharma I.A.S</i>	
Arogyasri, the AP Model.....	30
<i>Dr. Veena Shatrugna and Dr Rajan Shukla</i> 30	
Trends in Out Of Pocket Payments in Six States of India	33
<i>Dr. Narendra Gupta</i>	
Using Law to Access Essential Drugs	41
<i>S. Srinivasan</i>	
Withdrawal of Potentially Irrational Drugs.....	44
<i>Dr Mira Shiva</i>	
Vaccine Policy and Revival of PSUs	48
<i>Dr Madhavi Yenappu</i>	
Occupying Medicine: Vaccines We Should not Pay For	53
<i>Dr. Jacob M. Puliyl</i>	
The Indore Drug Trials	56
<i>Dr. Anand Rai</i>	

Trials and more Trials.....	58
<i>Sandhya Srinivasan</i>	
Maternal Deaths: What One Judgement can Do	60
<i>Anubha Rastogi</i>	
Maternal Deaths in Jodhpur	63
<i>Dr. Narendra Gupta and Shashi Tyagi</i>	
Right to Mental Health	72
<i>Dr. Amita Dhanda</i>	
Story of the Patna PIL.....	76
<i>Dr. Shakeel Ahmed</i>	
Japanese Encephalitis: The Cry from Gorakhpur.....	78
<i>Dr. R.N. Singh</i>	
A Random Harvest	81
I. Dalit Dimension of Public Health	
<i>Mark West</i>	
II. Accountability Tools	
<i>Sanjay Paul</i>	
III. Revolving Doors	
<i>Radha Holla Bhar</i>	
IV. Absence of healthcare in Bawani	
<i>Ms. Madhuri Krishnaswamy</i>	
V. The View from Kashmir	
<i>Dr Zubair Saleem</i>	
VI. Crib Deaths in West Bengal	
<i>Dr. Sidharth Gupta</i>	
VII. Guidelines? What Are they? The Assam Experience.	
<i>Dr. Sunil Kaul</i>	
VIII. Some Memorable Cases	
<i>Deepika Jain</i>	
IX. Primary Health Care in Karnataka	
<i>Eddie Premdas</i>	
Where Do We Go from Here	86

Presentations

Report of the High level expert group on Universal Health Coverage.....	90
<i>Shrinath Reddy</i>	
Public Health System: An overview	104
<i>K S Jacob</i>	
Universal Access to medicines.....	113
<i>Sakthivel Selvaraj</i>	

Using Law for Public Health.....	122
<i>Samita Sharma</i>	
Aarogyasree-II the AP Experience	142
<i>Rajan Shukla and Veema Shatrugna</i>	
Out of Pocket Expenditure in Health Care.....	151
<i>Narendra Gupta</i>	
Drug Pricing Case of AIDAN et al, Pharma Pricing Policy 2011.....	173
<i>S Srinivasan</i>	
Using law for Public health.....	184
<i>Mira Shiva MD</i>	
Vaccine PSU's & Rational Vaccine Policy: PIL in Supreme Court, SP Shukla & Ors Vs. Union of India	201
<i>Y Madhavi and N Raghuram</i>	
Occupy Medicine Useing the Law	212
<i>Jacob M PuliyeI</i>	
Drug Trial Regulation and Control– A challenge for Civil Society	228
<i>Dr. Anand Rai</i>	
The Clinical Trial Scenario in India: Issue and Concern.....	239
<i>Sandhya Srinivasan</i>	
Social Accountability of Maternal Health	246
<i>Sanjay Kumar Paul</i>	
In the name of One who created all that exists.....	252
<i>Dr Zubair Salim</i>	
Qualified versus Quacks Ducking the Real Issues?	260
<i>Satya Sivaraman and Dr Siddhartha Gupta</i>	
Crib Death in Government Hospitals in West Bengal: Who's Sin?.....	269
<i>Dr Siddhartha Gupta</i>	
Leading Judgments on Public Health in India.....	277
<i>Dr. Dipika Jain</i>	
Davan gere District Anaji PHC Photo (2010).....	283
<i>Eddie Premdas (Adv) RTH karnataka</i>	
ABBREVIATIONS.....	296
Participants list	300

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6. Colin Gonsalves
7. Mr. Satya Sivaram
8. White Ribbon Alliance of India
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5. Jennifer Kline
6. Kesang
7. Aditya
8. Kabir Ghosh

The proceedings were recorded by Imran Ali

INTRODUCTION

This was actually the 5th national meeting on using the law in public health. The first was here in 2008 then we went to Bombay and then we went to Goa twice and now we are back here. If you look at the work we have done in last two and half years even generally around the country we have done about seven or eight interventions a year and gotten good results from the high courts. Most importantly for the first time the Delhi High Court ordered a maternal death audit to be done officially. That is the first of its kind as far as the legal system is concerned.

We've had several cases of Dalit women that went in to hospitals and were refused services at hospitals. The case resulted in punishment of government officials, compensation for the victims and their families and a series of cases in the high courts across the country as well. We have here amazing information on what can be done, This is only a small amount of health activists and you can see the very solid work already done.

I think the legal community has lagged behind in realizing the importance of this work. I remember when I started in 2007 2008 it took me a long time to realize how this research integrates with constitutional law. Now it is time for the health rights activists to realize the legal potential this research has.

Can we bring practical benefits to the people with whom we work? The basic strategy of law must have this as the guiding light. You feel like crying when you hear about MP malaria child deaths. We sat down with Dr. Singh and two of

our friends will go to Gorakhpur, in a week we will have a PIL on Japanese Encephalitis.

Our friend from West Bengal tells us about the awful situation in the hospitals and that posts are sanctioned but people are not there. But remember the Right to Education Act, when someone went to the Supreme Court and the Supreme Court directed the appointment of thousands of teachers and the Supreme Court is now monitoring this. There are many PILs that are possible from the information presented at this conference. And we had the discussion about private practice and if doctors are to be stopped from private practice perhaps a case can happen. On the clinical trials information from Indore that Dr. Anand presented, we will soon go to court.

On whether we should have a law on right to health I think we are to go carefully I think we have burnt our fingers many times before on law making. Government is very quick to take a good suggestion and make a horrible law that will do the opposite of what you want. Sometimes a High Court order is as good as a Supreme Court Order.

We also heard about the Karnataka malnutrition deaths and that is something we have to look at very carefully to see if we go to the court on that. The State Human Rights Commission has issued a good order and this can also be taken to the court to be implemented.

Although we haven't spoken very much on legal strategies please keep in touch with all your ideas on litigation. We will send a dedicated

team to your area and they can do a dedicated fact finding and file petitions.

Public health laws are laws that have important consequences for the health of defined populations.

Public health laws derive from

- the Constitution of India;
- statutes, and
- other legislative enactments;
- agency rules and regulations;
- judicial rulings and case law; and
- policies of public bodies.

Government agencies that apply public health laws include agencies officially designated as “public health agencies,” as well as health-care, environmental protection, education, and law enforcement agencies, among others.

Law is foundational to public health practice. Laws establish and delineate the missions of public health agencies, authorize and delimit public health functions, and appropriate essential funds.

The concept of public health law has evolved into overlapping paradigms. One paradigm frames public health practice in relation to multiple sources of law (e.g., statutes and regu-

lations) and to fields of law (e.g., constitutional and environmental law). The other, a more scholarly view, focuses on the legal powers and duties of government to ensure public health and limitations on government powers to constrain the protected liberties of individuals.

This report addresses the following concerns and questions.

1. Has the National Rural Health Mission come anywhere near achieving its goals after its launch in 2005?
2. What is the story of the eleventh five year plan when it comes to public health?
3. The approach paper of the twelfth five year plan clearly points at privatization of public health. What is really in store for the people of India? What do our past experiences say?
4. What is our score card addressing critical public health indicators MMR and IMR?
5. What has been the experience of civil society of court interventions on public health?

Short or long all presentations are both thought and action provoking. If you need more details on any of the presentations or presenters do let HRLN know.

Colin Gonsalves



Justice J.S. Verma

THE LAW AND PUBLIC HEALTH THE FOUNDATIONS

HIGHLIGHTS

- There is a pressing need to improve public health conditions and to increase the level of nutrition.
- The State is well-enough acquainted with the concept of social justice.
- Article 39 calls for adequate means of livelihood, from which comes the right to food and the right to freedom from hunger.
- The WHO clearly defines health as a state of physical, social and mental well-being and not merely a state of being free of diseases.
- Amartya Sen defines non-freedom as lack of healthcare, increasing malnutrition and illiteracy. We have all three of them.
- Article 14 and 47 lay emphasis upon raising the level of nutrition and implementing a better public health system. All of this ultimately leads to Article 21.
- The Directive Principles of State Policies enshrined in Article 48(a) call for steps towards ensuring a clean environment.

Justice Jagdish Sharan Verma has served as Chief Justice Of Madhya Pradesh High Court, Rajasthan High Court and as the Chief Justice Of India.

What I have observed is that the Public Health conditions were very different when I was growing up than what it is today.

Let me begin by sharing with you one impression which gave to me a bird's eye view of how much change has taken place in the wrong direction.

My elder brother was a doctor and he ended up as head of the Railway medical services.

I often questioned him on why he decided to be a doctor as there was no background of medicine in our family?

This is what his answer was. He said that when he was growing up our father was posted in a very small place called Satna between Jabalpur and Allahabad and there existed a small railway dispensary with Dr. Mathur as the sub assistant surgeon.

He told me that he used to watch him, come down to the dispensary everyday in the morning and would make his way back to his residence only late in the evening.

He used to attend to all the patients who come to the clinic and then would go around the entire railway colony visiting all his old patients and anyone who needed medical attention and could not come to the clinic. Then only return to his home.

He would make sure that the families received appropriate medical care and made this sure through his home visits. Similarly there was a Dr. Shorey in the city who followed a similar routine.

This is what inspired my brother to become a doctor.

This example clearly reflects how a single person, truly professional in his attitude, can really make a difference even at the lowest level.

What I want to say is that the work this doctor was doing was not only rendering service to humanity but also motivating many and I am sure the number of persons that can be motivated has increased as the competition has increased.

This spirit of service had inspired my brother who went on to become the first Director General Railway Health Services, a post that was created for him in the service, as he was considered to be a pioneer of the Railway medical service.

Now we have constitutional obligations imposed on the state, Art 47 Directive Principle of State policy clearly mandates the State to raise the level of nutrition and improve the public health. There is much more. In the directive principles of state policy we have the concept of social justice engrained in it, particularly in Article 38 and 39.

“Denial of empowerment to sections of society is a denial of basic human rights”.

– Justice J.S. Verma

In Article 39 in its very first clause (a) mandates the State to provide for adequate means of livelihood for everyone, from which comes right to food which actually means the right to be free from hunger because it is not a matter of charity but the State's obligation to ensure that everyone has the means to earn a livelihood so he/she can live with dignity.

Now apart from many other provisions of the right is under Article 21 of the constitution calls for Right to life, legally justifiable and enforceable right fundamental right has been interpreted to mean right to life with dignity which obviously includes the performance of all these

mandatory functions and constitutional obligations which are mandated in the Constitution.

Now this is something which since 1950 at least is an obligation and therefore that's something which must be ensured for everybody and not merely those who are well off.

Incidentally the Supreme Court has also said that the constitutional guarantees must be so interpreted as to incorporate therein the international norms for the purpose of filling in gaps or increasing the scope of the content of the constitutional guarantees.

So the right to life with dignity apart from reading Article 47 and 39 etc into it we must read into it the international norms.

Further we must read into it is WHO's definition which clearly defines health as the state of complete physical, social, mental being and not merely the absence of disease or infirmity. So the state obligation to improve public health has to be so understood.

The Art 25 of the Universal Declaration of Human Rights (UDHR) which reads like this, "The first part states that everyone has the right to a standard of living for the health and well-being of himself and of his family including food, clothing, housing and medical care and necessary social services and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

Motherhood and childhood are entitled to special care and assistance." So all this must be read into Article 47 which further then has been read into Article 21 to become a justiciable human right and the enforcement of human rights is a constitutional obligation and Article 32 itself is a fundamental right which mandates the Supreme Court in its original jurisdiction to enforce the fundamental rights of every individual.

So when the need is to enforce the fundamental rights of a large section of people then we must appreciate the magnitude of that responsibility which is enforced through Article 32 on the Supreme Court and through Article 226, its corresponding provision, on the High Courts.

But for the Supreme Court there is a further provision in Article 142 which says that the SC can make any order for the end of justice in any particular cause.

This shows the extent of obligation on the State and all the State orders including the judiciary to ensure the improvement of public health.

Now if that is the extent of obligation than even one person being denied the standard of medical care that he needs is a serious matter to be considered.

"Any step taken by the State to improve public health is indeed an action to enforce the general public's fundamental right under Article 21."

—Justice J. S Verma

Now the Supreme Court has also said that there is a duty on the State to preserve life and it went to the extent of saying that even private medical practitioners were bound by this duty and not only those in government practice.

Good news and bad news

Now a few days back I was really upset when I read a news item that the Supreme Court had granted permission of export of some things which were considered dangerous for Indians.

We talk of a global race where all of us are supposed to belong to one family then how can

“Not only must the violation of human rights be taken care of, prevention of such violation is equally if not more important”.

– Justice J.S, Verma

you say that I will not take this poison but it is available and you can have it.

However, there is also some good news like I read in the paper yesterday that during our PM's visit to Russia a MoU come up to share information on the adverse effects of drugs.

There both types of things happening and then there was the news of a proposal to amend the Drugs and Cosmetics Rules 1945 so that in case of any death or grievous injury caused during any drug clinical trial then there would be a rebuttable permission that it was during the drug trial so that the burden of proof is to be shifted.

The Unfreedoms

Amartya Sen says that there are three unfreedoms lack of healthcare, malnutrition and illiteracy. We have all three. In short I want to say that consciousness is there to use law for public health and while there are men like Colin who are in court everyday to fight for this cause but there is a very higher and stronger constitutional obligation on the state. To ensure this we go to the basic Article 14 and 47 which is principal, fundamental and governance to raise the level of nutrition and public health. That is not the only solitary provision this has ultimately been read into Article 21 because the right to life with dignity is not there unless you are healthy in the sense WHO has defined it. The court has even gone further to expand the scope of Article 21 by reading even Art. 48(a) Directive Principles of a State Policy that is to ensure clean environment because clean environment is a human right equally as

well as a fundamental duty of every citizen under Article 51 A (g) to ensure the preservation and improvement of the quality of the environment.

Motherhood and Childhood

The Art 25 of the Universal Declaration of Human Rights (UDHR) which reads like this, “The first part states that everyone has the right to a standard of living for the health and well-being of himself and of his family including food, clothing, housing and medical care and necessary social services and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

Motherhood and childhood are entitled to special care and assistance.” so all this must be read into Article 47 which further then has been read into Article 21 to become a justice-able human right and the enforcement of human rights is a constitutional obligation and Article 32 itself is a fundamental right which mandates the Supreme Court in its original jurisdiction to enforce the fundamental rights of every individual.

So when the need is to enforce the fundamental rights of a large section of people then we must appreciate the magnitude of that responsibility which is enforced through Article 32 on the Supreme Court and through Article 226, its corresponding provision, on the High Courts.

Are we moving in the wrong Direction?

To state the obvious today we have a corporate culture even in the field of medicine. Five star facilities are available today but what is needed is a minimum standard of healthcare available to everyone and all said and done the government hospitals even then are not ensuring that.

What we need to do is to ensure that they are better equipped so that the tendency to be drawn into the corporate business culture can be checked.

After all medicine is a profession but is fast becoming a business.

The doctors seem to be moving in a wrong direction.

Increasing corporatization and privatization is resulting in healthcare becoming more and more inaccessible.

But there exists enough scopes of enforcing it through the medium of law. Today media and judiciary are the ones taking up every cause so why not this.





Dr K Srinath Reddy

REPORT OF THE HIGH LEVEL EXPERT GROUP ON UNIVERSAL HEALTH COVERAGE

HIGHLIGHTS

- When we compare Infant Mortality Rates, we are far behind Sri Lanka, China, Brazil and Thailand. India stands witness to an increasing number of deaths every year.
- Limited health funding is one of the primary reasons for the deteriorating state of the public health sector in India.
- India has one of the highest out of pocket expenditures and people are being constantly pushed into poverty.
- India also has the highest number of underweight children.
- The Government certainly has to increase public expenditure on health i.e., 1.4 per cent of GDP to at least 2.5 per cent by the end of the 12th plan and at least 3 per cent of GDP by 2022.
- We have an abundant number of health insurance schemes but most of them are seriously flawed. Tertiary care has gone up in these schemes but primary and secondary care is in a state of great neglect. Insurance companies have fragmented the system further.
- The drug regulatory system needs to be strengthened and the rational use of drugs needs to be promoted.
- The Department of Pharmaceuticals needs to be transferred to the Ministry of Health.
- We also need to stress on the importance of community participation and citizen engagement.

Dr. K. Srinath Reddy is the Chairman of the Public Health Foundation of India and of the High Level Expert Group on Universal Health Coverage.

I am going to present before you the report of the high level expert group on Universal health care. On 9th December, 2011 it was presented to the Health Minister and now I am sharing it here at a public forum.

All of you must have observed the excitement around China and India being compared solely on economic fronts. I think it is equally pertinent to also compare the health situations existing in both the countries. When we compare the Infant mortality rate, we are far behind Sri Lanka, China, Brazil and Thailand, with increasing number of deaths occurring every year.

**KEY HEALTH INDICATORS:
INDIA COMPARED WITH OTHER COUNTRIES**

Indicator	India	China	Brazil	Sri Lanka	Thailand
IMR/1000 live-births	50	17	17	13	12
Under-5 mortality/1000 live- births	66	19	21	16	13
Fully immunised (%)	66	95	99	99	98
Birth by skilled attendants	47	96	98	97	99

Source: World Health Organization (2011) IMR – Infant Mortality Rate

The limited equity of health funding is one of the primary reasons for the deteriorating state of the public health sector in India. The country's public health spending is comparatively low in relation to the other countries mentioned. The fraction of the country's spending is invested on public health. India has one of the highest out of pocket expenditures and people are being constantly pushed into poverty.

**LOW PRIORITY TO PUBLIC SPENDING ON HEALTH –
INDIA AND COMPARATOR COUNTRIES 2009**

	Total public spending as % GDP (fiscal capacity)	Public spending on health as % of total public spending	Public spending on health as % of GDP
India	33.6	4.1	1.4
Sri Lanka	24.5	7.3	1.8
China	22.3	10.3	2.3
Thailand	23.3	14.0	3.3

Source: WHO database (2009)

India's health scenario is such that currently it has the highest number of underweight children. There is a huge disparity in Infant Mortality Rate across states.

Let us reflect on the question of why exactly health reform is needed? 28% of the rural residents and 20% of urban have no funds for health care.

The current health schemes in the country do not cover everything. There is a huge urban rural disparity in health services. The operational definition of Universal Health Care is based on the guiding principle of Universality.

WHY IS HEALTH SYSTEM REFORM NEEDED?

- 18% of all episodes in rural areas and 10% in urban areas received no health care at all
- 12% of people living in rural areas and 1% in urban areas had no access to a health facility
- 28% of rural residents and 20% of urban residents had no funds for health care
- Over 40% of hospitalised persons have to borrow money of sell assets to pay for their care
- Over 35% of hospitalised persons fall below the poverty line because of hospital expenses
- Over 2.2% of the population may be impoverished because of hospital expenses
- The majority of the citizens who did not access the health system were from the lowest income quintiles

NSSO (2006)

Good news and bad news

But the programmes meant for the poor are anti poor in their design. Until and unless, the society does not have a stake, this system of UHC might collapse. The core element has to be universal, not merely in definition but also in its implementation.

HEALTH SERVICES : URBAN RURAL DISPARITY

- 80% of Doctors
- 75% of Dispensaries
- 60% of Hospitals

Are Located In Urban Areas

• Qualified Physicians:

11.3/10,000 - Urban Areas
1.9/10,000 – Rural areas

Universal Health Care

Now I want to brief you about the vision of our expert groups. We have attempted at tailoring it according to the state needs, and primary and secondary care being our key elements. The tertiary care is not really tenable as defining tertiary needs becomes a bit problematic but we are aware that certain elements of it have to be included. The government certainly has to increase the public expenditure on health, i.e. 1.4% of GDP to at least 2.5% by the end of the 12th plan, and at least 3% of GDP by 2022. We have also debated the question of how additional expenditures can also be raised and also the issue of subsidies.

Our Definition of UHC

Operational Definition

“Ensure equitable access for all Indian citizens resident in any part of the country, regardless of income level, social status, gender, caste or religion, to health services (promotive, preventive, curative, and rehabilitative) that are affordable, appropriate and of assured quality.”

Definition

- *“Ensuring equitable access for all Indian citizens resident in any part of the country, regardless of income level, social status, gender, caste or religion, to affordable, accountable and appropriate, assured quality health services (promotive, preventive, curative and rehabilitative) as well as public health services addressing wider determinants of health delivered to individuals and populations, with the government being the guarantor and enabler, although not necessarily the only provider, of health and related services.”*

National Health Package

Harmful products such as tobacco should be taxed to decrease consumption. In such cases, health should not be the hostage to such kind of revenues. There is a need to accept flexible norms keeping in mind the substantial difference between different states. Decentralisation in terms of decision making needs to take place

Our Vision

- **Universal Health Entitlement** for every citizen - to a **National Health Package (NHP)** of essential primary, secondary & tertiary health care services that will be funded by the government.

Package to be defined periodically by an Expert Group; can have state specific variations

Are we moving in the wrong Direction

We have abundant number of health insurance schemes floating in the country with most of them being flawed. Tertiary care has gone up in these schemes and the primary and secondary care is in state of great neglect.

The idea of the insurance company is to exercise the gate keeper function and they further fragment the system.

These independent agents are causing the fragmentation of the system. We need to follow examples of the public health system in Tamil Nadu.

We also recommended that the government should prioritize the strengthening of the public services.

The infrastructure in districts hospitals should be substantially strengthened. The fragmenting of the system into primary, secondary and tertiary creates a network of producers. We need to improve access to medicine, vaccines and technology.

The drug regulatory system needs to be strengthened and rational use of drugs needs to be promoted. The Department of pharmaceuticals needs to be transferred to the Ministry of health.

Health Financing & Financial Protection

- Government (Central government and states combined) **should increase public expenditures on health** from the current level of 1.4% of GDP to at least 2.5% by the end of the 12th plan, and to at least 3% of GDP by 2022.
- Ensure availability of **free essential medicines** by increasing public spending on drug procurement;
- **General taxation as principal source of health care financing** – complemented by additional mandatory deductions from salaried individuals & tax payers, either as a proportion of taxable income or as a proportion of salary

Doubling of Frontline Workers

Urgent steps towards the doubling of ASHA's from one per 1000 population to two per 1000 population in rural and urban areas is need of the hour. The roles and responsibilities of the ASHA workers need to be defined clearly.

There prevails a lot of confusion and non clarity around their duties. Are they at the tip of the health care system or merely community workers meant to mobilize?

There is a need for more medical colleges, better nursing schools and better human resource practices.

We also need to stress on the importance of community participation and citizen engagement.

We also need to learn some lessons and follow Brazil, Thailand, China, Mexico, as they have almost achieved the universal health coverage.

I would like to end with a quote by Toni Morrison. "If you do not create the future, the present extends itself"

Human Resources for Health

- **Ensure adequate numbers of trained health care providers and technical health care workers at different levels – giving primacy to the provision of primary health care.**
 - **Doubling ASHAs from one per 1000 population to two per 1000 population in rural and tribal areas;**
 - **Introduction of mid-level health workers such as Bachelor of Rural Health Care (BRHC) Practitioners for recruitment & placement at rural Sub-Centres and Nurse Practitioners in urban Sub-Centres**

“If we don't create the future, the present extends itself”

- Toni Morrison (Song of Solomon)



Dr K. S. Jacob

NRHM: HOW FAR ARE WE FROM UNIVERSAL HEALTH COVERAGE?

HIGHLIGHTS

1. Out-of-pocket expenditure for health is a major cause of indebtedness and it actually represents a major crisis in health care.
2. NRHM has refocused on health and it is prioritizes on rural India. There has been major financial, infrastructure, and personnel inputs. By many standards the NRHM is a success. NRHM has made an impact in rural India.
3. The question is do we have a delivery mechanism to implement Universal Health Coverage.
4. We urgently need regulation of medical practice. These societies and regulatory authorities should set up standard medical and diagnostic guideline for the delivery of health care
5. There should be professional development and re-certification for all medical professionals so that people are up to date with knowledge which is continually coming in.
6. So, we have to bring in this concept of audits. We have to look for corrective action when policies, processes, procedures and practice those meet the norms of our quality.
7. There is a systematic lack of outcome and output data. It is only inputs that are evident to the system.
8. I have seen volumes of data very superficially analyzed, actually even this data can be analyzed. I believe that they are not analyzed because it actually shows that health and caste are related; health and poverty are related things which we do not want to show to the public.
9. Data which is collected is not employed to correct the system; not employed to target specific vulnerable groups which they should be doing
10. The state government is supposed to produce 15% of the NRHM budget. This rarely happens, most of the time it is the only central funds which have been used.

Professor K.S. Jacob is on the faculty of the Christian Medical College, Vellore, Tamil Nadu

An overview of the Public Health System: My background is from academia. I am a recent convert to public health. My field experience consists of the Common Review Mission on the NRHM to different parts of the country to see the state of the public health System there. I am also a member of some of these national committees related to NRHM and State review committees of health in the planning commission.

All of us will agree that the public health system in India is inadequate - they have been neglected. This results in a lot of out-of-pocket expenditure that out-of-pocket expenditure for health is a major cause of indebtedness and it actually represents a major crisis in health care.

The National Rural Health Mission has actually done a lot for public health system in India. It has refocused on health and it prioritizes on rural India. There have been major financial, infrastructure, and personnel inputs. It has attempted to integrate resources with the state and integrate different vertical programmes. It has attempted to decentralize health care and management. It has built flexibility in the system. It has a huge component of community participation and ownership. So, by many standards the NRHM is a success. So, what I am going to tell you after this should not take away from the fact that the NRHM has made an impact in rural India.

Now Professor Srinath Reddy's High Level Expert Group has recommended universal health coverage and many of us here and many people believe that this is an excellent idea. An idea which the country should take forward and I believe it may be accepted by the government. I also believe it would be adopted in the 12th plan which the Prime Minister has said will be a Health Plan. Therefore, I believe that the ideals which have been listed in this document by this committee will get increased funding.

The Ten Universal Health Coverage Questions

So, now the question is how the country will implement this idea of Universal Health Coverage. There is political, administrative and financial will to increase health financing for India and the Indian people. So, the question is do we have a delivery mechanism to implement Universal Health Coverage?

There are many unresolved issues I shall very briefly highlight them.

1. How will we have standards and who will regulate standards for this health care delivery?
2. Will there be an audit and accountability of set services? Will we look at process data of input or outcome assessment of quality of care?

12th plan, the Prime Minister said will be a Health Plan.

3. How will we use such data?
4. Will the NRHM continue to function in this project mode or will there be integration?
5. Will the new platform compete with the old?
6. What happens to insurance and outsourcing?
7. How will we procure supplies?
8. What are the new inputs and old ethos of the State Health System?
9. How can we improve community participation?
10. How will we bring in social determinants of health and governance?

Audit, Certification, Norms and Standards

I shall just briefly dwell on these. Now the Medical Council of India as we all know is a regulatory authority but it has never engaged the medical practice or reviewed the medical practice.

It has only engaged in setting up of new medical colleges. We urgently need regulation of medical practice. I believe that in addition professional medical societies have not been looking at the standards of the practice. They have been looking at only the interests of their profession. These societies and regulatory authorities should set up standard medical and

So we have gone to the hospital where 24x7 doctors available in the building but the delivery is conducted by the sweeper or somebody who is not actually trained but the fact that we see that they actually do a reasonable job means that they are ones who actually conducting these deliveries.

diagnostic guidelines for the delivery of health care and these should be mandatory. Many countries have standard guidelines which are followed in their smallest of hospitals. There is no reason why India should not adopt this policy.

There should be professional development and re-certification for all medical professionals so that people are up to date with knowledge which is continually coming in. This issue of ethical standards will enforce an ethical standard on the medical fraternity. I believe this is an important question the regulatory authorities who should not turn a blind eye to gross

medical negligence and exploitation and this should also come in from a legal point of view.

I have been to many NRHM missions. The NRHM is an ideal, it has lots of good points. It tells you how normal delivery should be conducted; how should new born babies be taken care of.

But every time you go, even if the equipment is available, if the buildings are there, and the personnel are there, we find that there is really no system which delivers this output. So we have gone to the hospital where 24/7 doctors are available in the building but the delivery is conducted by the sweeper or somebody who is not actually trained but the fact that we see that they actually do a reasonable job means that they are ones who actually conducting these deliveries.

So when we say 24x7 who is to audit this 24x7 delivery and hospitals? So, these occasional national common review missions point out glaring deficits in the functioning of the system but unless the hospital, the institution, the district, or the state administration takes it upon themselves to audit hospital functioning we will have poor health care delivery in public health facilities. So, we have to bring in this concept of audits. We have to look for corrective action so policies, processes, procedures and practices meet acceptable standards. These assessments have to be constant and internal rather than occasional and external.

There is in the medical profession a paternalistic attitude and this huge power differential between doctors and patients. *The patients actually don't know what they are entitled to. There is also a cultural silence within the medical fraternity* that in the hospital if gross negligence is going on or exploitation is going on all the other doctors keep very silent, they may even be complicit or collude in propagating such practice.

If we look at the NRHM, I have been to many meetings, to many of these steering committees we get huge documents on the inputs into the NRHM amount buildings, machines, or personnel broken down by state and by district but we never get output how many babies are born alive; how long did the mothers stay in the hospital; did she have PPH i.e. Post Partum Hemorrhages. So, there is a systematic lack of outcome and output data. It's only inputs that are evident to the system.

The Janani Suraksha Yojna which has really mobilized women across the country to deliver their children at hospitals but has not really bothered that the baby was born normally; was the baby alive; will they go home safe. Right now lots of data is actually collected but it's not correlated with the National Sample Survey data.

Employ Data Target the Vulnerable.

So, massive data is collected. They are stored and superficially analyzed. I have seen volumes of data very superficially analyzed actually even this data can be analyzed. I believe that they are not analyzed because it actually shows that health and caste are related; health and poverty are related things which we don't want the public to know.

So, this data which is collected is not employed to correct the system; not employed to target specific vulnerable groups which they should be doing. There is a huge issue that the data generated by the National Rural Health Mission and many of the government programme are not used at the point of delivery. So, if some data is generated and not used at the sub-center or at the district level but it is sent to Delhi then much of this data may not be accurate.

I do not want to say that there is lots of instances of fabrication but much of this data is

not accurate because they are not being used at the point of delivery and sent to Delhi. So, if they send there how do they know that this is correct or not. This is a huge issue lots of incorrect data has been coming in which I think the ministry also is aware so it's not that they are not aware.

Will the States Take Charge.

NRHM is a project of central government. There is no integration between the already existing state government system and central government NRHM scheme. The state government is supposed to produce 15% of the NRHM budget. This rarely happens most of the time it is the only central funds which have been used.

Do they really have money to put in the 15%; will they have money to take over the NRHM when this project ends. What is happening in

**Health and caste are related;
health and poverty are related.
We don't want actually show
this to public.**

the state is that the NRHM is treated as a project. There is a parallel state health service. The NRHM initiative is supposed to be integrated but has not been actually integrated. So, what happens is *NRHM is a set of buildings, equipment, doctors but not a fully functioning health system at the state and district level.*

So, we have direct competition between the NRHM platforms and state Platforms. The VHND (Village Health and Nutrition Day) compete with the ICDS nutrition scheme; the Anganwadis compete with the ANMs; the mobile clinics with the sub-centers. So, many for example underprivileged have mobile clinics scheme which is very popular with the people that the sub-centers are being run down because of this competition.

Then, we have the issue of procurement of supplies. Tamil Nadu government has set up this Medical Supplies Corporation and I believe that 12 states have followed suit for central-

ized sourcing; for reduction in cost and controlling quality. There is a huge resistance in many states today both from the doctors side and from the middle man side.





Javid Chowdhury
I.A.S.

FROM INSURANCE TO ENTITLEMENT CARDS

HIGHLIGHTS

1. There are not enough resources in the public health system. So little is given that it is a miracle we have a public health system at all. At Rs. 200 per capita per year, what miracle do we expect?
2. Insurance is projected as a panacea. Traditional insurance schemes most often lead to inferior health outcomes and high health care cost inflation.
3. The problem is the insurance sector is catering to a population that is very limited and with a limited level of services.
4. We have to be careful of taking money from the primary health care to finance insurance schemes.
5. All health insurance cards should, be replaced by National Health Entitlement Cards.
6. The technical and other capacities developed by the Ministry of Labour for the RSBY should be leveraged as the core of UHC operations – and transferred to the Ministry of Health and Family Welfare.
7. A high level of capacity has been developed within the Ministry of Labour for the management of the RSBY. This capacity should be utilized for the roll out of the UHC system even if the functions performed by the insurance companies will now be performed by the Ministries and Departments of Health.
8. The proposed UHC system, in addition to all insurance benefits focuses on reduction of the disease burden facing communities along with early disease detection and prevention.
9. It places emphasis on an extensive and high quality primary care network which in turn is likely to reduce the need for secondary and tertiary facilities
10. There has to be a Public Health Act. There have been very interesting legal interventions around health. Many PILs have helped generate visibility in areas that had no visibility.

Mr Javid Chowdhury I.A.S is the former Secretary of the Union Ministry of Health and Family Welfare

While focusing attention on Health Insurance Schemes Mr. Javid Choudhury emphasized the recommendation High Level Expert Group on Universal Health Care .The recommendation is as follows.

Recommendation 5.1.11: All government funded insurance schemes should be integrated with the UHC system. All health insurance cards should, in due course, be replaced by National Health Entitlement Cards. The technical and other capacities developed by the Ministry of Labour for the RSBY should be leveraged as the core of UHC operations – and transferred to the Ministry of Health and Family Welfare.

Smoothly transforming the RSBY into a universal system of health entitlements and building on its existing capacity and architecture, to over time, issue citizens with a National Health Entitlement Card with a minimum amount of disruption, would in our view be the best way forward. A high level of capacity has been developed within the Ministry of Labour for the management of the RSBY. This capacity should be utilized for the roll out of the UHC system even if the functions performed by the insurance companies will now be performed by the Ministries and Departments of Health.

The proposed UHC system is a modified version of the traditional health insurance model with a few critical differences in terms of provider network and design which, in our view, are essential for realizing better health care access and cost outcomes. It has all the characteristics of traditional health insurance in terms of risk pooling and financial protection. In addition, the proposed UHC system focuses on reduction of the disease burden facing communities along with early disease detection and prevention.

The emphasis is on investing in primary care networks and holding providers responsible for wellness outcomes at the population level. It places emphasis on an extensive and high quality primary care network which in turn is likely to reduce the need for secondary and tertiary facilities. Moreover, effective triaging and management of patients can ensure quick treatment times. Traditional insurance schemes, including those being funded by the government (such as RSBY and the Rajiv Aarogyasri Healthcare Insurance Scheme) are entirely focused on hospital networks rather than primary care services.

The advantages of such a network design for consumers are a large supply of hospitals in the network and short waiting times for hospital admissions. However, since there is virtually no focus on primary level curative, preventive, and promotive services and on long-term wellness outcomes, these traditional insurance schemes most often lead to inferior health outcomes and high health care cost inflation.

Many PILS have helped generate visibility in areas that had no visibility.

Mr.Javid Choudhry further went on to elaborate his point as follows:-

The health insurance coverage is about 300 million which is not bad but the government scheme only covers secondary care and there are state sponsored schemes like Aarogyasri which only cover secondary and tertiary care.

The per capita cost is still very high.

He emphasized the importance of an extensive and high quality primary care network .Once that is in place it will reduce considerably the need for secondary and tertiary facilities.

We should have a package of health care optimally priced where you start with primary care, outpatient care and not secondary and tertiary care.

Primary care and outpatient care schemes now are only provided to certain government service employees.

The problem is the insurance sector is catering to a population that is very limited and with a limited level of services.

I must mention that the High Level Expert Group has recommended that outpatient care should entirely be covered by the state, and no way for private sector to be a part.

For outpatient care 80 % doctors are in urban and peri-urban areas.

The forces against the HLEG report are piling up.

So the committee recommended that part be contracted through state and part through private. A lot of the good health centers in this country are in the private sector for good or bad. But the private care should not be through insurance companies because then there is no incentive to reduce cost and we know what happens when the insurance companies get a hold of the country, see America.

It is necessary to use the private sector fully but not with insurance.

The span of insurance companies should increase but we have to be careful of taking mon-

ey from the primary health centres to finance insurance schemes.

You must have a package of universal health coverage covering primary health care and secondary contracted through the private sector in part.

There have been very interesting legal interventions around health. Many PILs have helped generate visibility in areas that had no visibility.

The World Bank objected to the high level expert group recommendations and World Bank funds most disease control programs in our country.

It is essential to marshal our forces in strength and pursue a PIL because our constitution has so many rights but not a right to health.

There has to be this public health act which at the moment is at some stage. But more importantly we should recognize the novelty of PIL and what a proactive bench of the Supreme Court has done with them. The Supreme Court has used the PILs to force government to take these decisions and apply their mind to it.

There are not enough resources in the public health system, so little is given that it is a miracle we have a public health system at all.

At Rs. 200 per capita per year, what miracle do we expect?

We are seeing this situation so if a PIL can be done requesting a continuing mandamus so the government provides the resources, infrastructure, human resources etc. needed by the different sectors some changes can happen.



Ashok Agarwal,
Social Jurist

THE RELUCTANT HOSPITALS IN THE CAPITAL REGION

HIGHLIGHTS

1. The condition of government MCD hospitals is such that there is no provision for X ray films. Patients are forced to access private hospital facilities.
2. Last year we organized a meeting in a basti and resolved a case where a patient was referred to a private hospital. On being admitted to the private hospital, he wasn't given any medicines for eight months.
3. There was another case where a person from UP approached AIIMS for his treatment. He was refused on the grounds of not having a BPL card.
4. There was another investigation we carried on along with young law graduates. We decided to visit G.B Pant hospital and started registering complaints of patients standing at the medical counter. Most of them complained about lack of medicines and high prices.
5. According to the hospital (Apollo) authorities, free treatment did not include consumables and medicines. As a result of this, we filed a PIL on May 1998 and the Court ordered that these wards be put in place at the earliest possible. The High Court Judgment of 2007 further ensured the provision of all medical expenditure under free treatment.
6. The Justice Quereshi Committee was specifically formed to enquire into this matter. As a result of the findings of this Committee, it was found that at least 70 per cent of the hospitals should be giving out free treatment.
7. In 2007, the High Court passed another judgment stating that 10-25 per cent OPD treatment should be granted free to patients by hospitals set up on government land. The Supreme Court rejected petitions filed by hospital authorities.
8. There are around 42 hospitals in the NCR giving out free treatment to its patients.
9. People, who have an income below Rs.6,422/- are entitled to free treatment and they do not need an income proof.
10. Hospitals are required to give out a declaration form to patients. It is not mandatory to present a BPL card.

Mr. Ashok Agarwal, Senior Advocate Supreme Court of India

Why cannot health be a fundamental right? Also instead of referring to it as just health, why don't we make it public health?

The condition of government MCD hospitals is such that there is no provision for X ray films. Patients are forced to access private hospital facilities.

There was the case of a clerk who was suffering from tuberculosis. He received no medication for almost three months. When we inquired into the matter, we discovered that most of the MDR patients were not receiving essential drugs.

It was only after we carried out further the investigations and filed a Public Interest Litigation that the medicines were restored.

We also dealt with another case of bleeding and filed a PIL again. The Medical Superintendent was present at the court hearing. The Judge made some enquiries into the general working conditions of the hospital and said that a number of people had complained about the fact that dogs had been spotted sleeping on patient beds.

The Medical Superintendent said he thought nothing about such a commonplace matter.

Last year we organized a meeting in a basti and resolved a case where a patient was referred to a private hospital. On being admitted to the private hospital, he wasn't given any medicines for eight months.

There was another case where a person from UP approached AIIMS for his treatment. He was refused on the grounds of not having a BPL card. The doctors at AIIMS demanded an amount of Rs.80,000/- which was eventually brought down to Rs. 20,000/-. When we discovered this case, we filed a Public Interest Litigation. As a result of this, the High Court issued an order and stated that a BPL card was not

required for accessing public health facilities. Court intervention helped the patient receive treatment free of cost at G.B Pant hospital.

There was another investigation we carried out along with young law graduates. We decided to visit G.B Pant hospital and started registering complaints of patients standing at the medical counter. Most of them complained about lack of medicines and high prices.

The same exercise was again conducted in LNJP Hospital and the same problems were registered there as well.

At Apollo hospital, which is basically a joint venture between the Delhi Government and the Apollo Group, the provision of free treatment hasn't been functional for a long time. The Delhi Government has granted 15 acres of land to the Apollo Group and the government fetches around Rs. 1 crore as monthly rent. When the hospital was initially set up in 1996, it agreed to the provision of free IPD and OPD treatments. It also promised to set up a poor ward which did not come into operation for a long time.

The promise of free bed provisions remain a false promise. There were disputes over what exactly free treatment would include. According to the hospital authorities, free treatment did not include consumable and medicines. As a result of this, we filed a PIL on May 1998 and the Court ordered that these wards be put in place as early as possible. The High Court Judgment of 2007 further ensured the provision of all medical expenditure under free treatment.

It became mandatory for hospitals, which had been allotted land by the Delhi government, to offer free treatment to needy patients. The Justice Quereshi Committee was specifically formed to enquire into this matter. As a result of the findings of this Committee, it was found that at least 70 per cent of the hospitals should be giving out free treatment. Certain recom-

mendations were made but no strict guidelines were laid out.

In 2007, the High Court passed another judgment stating that 10-25 per cent OPD treatment should be granted free to patients by hospitals set up on government land. The Supreme Court rejected petitions filed by hospital authorities and issued an order on 1 September 2011 stating that 10% to 25% OPD treatment should be given free of cost. This particular Court order

did bring in gradual improvements in the Public Health System. There were around 42 hospitals giving out free treatment to its patients.

Now, the most important question is that of eligibility criteria for free treatment? People, who have an income below Rs.6,422/- are basically entitled to free treatment and they do not need an income proof. Hospitals are required to give out a declaration form to patients. It is not mandatory to present a BPL card.





Dr. Sakthivel Selvaraj

IRRATIONAL DRUGS, IRRATIONAL SPENDING

HIGHLIGHTS

1. We have a system where financing mechanisms are unfair.
2. We have an unreliable and inefficient procurement system.
3. 70-80 percent out of pocket spending is on drugs.
4. India produces 92000 brands and no other country manufactures these many brands.
5. Households spend about one-third of the household expenditure on healthcare on the hospitalisation while the rest two-third is actually spent on the outpatient here.
6. It is very apparent from the national samples of the data we find that almost 13 % of India's population actually incurs what we call catastrophic spending. Households spend in about 10% of their total income on healthcare.
7. Except few southern states like Tamil Nadu, Kerala and to some extent Karnataka which spends about 14-15% of their total health expenditure on drugs and the most of the states spend about 4-5% and in many states they spend even less than 3%.
8. Procurement and distribution in this country has been pathetically bad.
9. There is huge variation between states but also in districts, for instance in Bihar, if you look at the district variation in drug spending, again a huge variation between districts. Districts like Buxar to about 780, so that's about drug expenditure per illness episode.
10. We did a survey in Tamil Nadu and Bihar and it was evident that in Tamil Nadu the availability of baskets of essential medicines is 89-90% as against about 33% in Bihar.

Dr. Sakthivel Selvaraj, Health Economist

What I intend to do here is to essentially identify the major barriers to access to medicines and provide you with the major recommendations that we have come up with the high level expert group on universal health care coverage.

As you all know, most developed countries some 40-50 years ago, while several middle developed countries or low income countries in the past 10 years, have embarked on the path of universal access to health care, which includes Mexico, Brazil, Thailand and Ghana.

The interesting thing about Ghana, a country in southern Africa, is that they have a system of universal access to medicine i.e. free or cashless medicine to everyone in Ghana, the country which doesn't have a production capacity and which imports most of its drugs from India has such a scheme of free medicine accessibility.

And Ghana is very important for the simple reason that it is a low income country and lower than our Indian economy. India which boasts itself as being the pharmacy of the developing global south supplies essential generic material with good quality and affordability not only to low income countries but also to most high income countries like U.S. and European countries.

So the question with us is- do we have enough resources and capacity to achieve universal access to medicine? As far as India is concerned there are 6 major issues/impediments to access to medicines-

1. And one of the foremost important issues is about the unfair health financing mechanism. And what does it mean? It basically means that if you have three principle viz, prepayment, cross-subsidisation and risk pooling then it is called fair health financing mechanism which we don't have. We have situations in which households end up paying a lot of money and a major share of their income on healthcare especially on drugs. This is what is happening in our country, so we have a system where financing mechanisms are unfair.
2. Another major problem in our country is that we have an unreliable and inefficient procurement sale system.
3. And of course the drug pricing is an important issue and given the fact that 70-80 percent out of pocket spending is on drugs.
4. In addition to these, in India, there is another issue of irrational use of drugs and not only use but irrational manufacturing, prescription and dispensing to the country which produces 92000 brands and no other country manufactures these many brands.
5. Another major issue is patent issue; India has followed a very people friendly patent policy from about 1972 to 2005. We have moved away from process to product patent policy, which has great implications for access to medicine .

Let me first address the first question that why did I call the financing mechanism in the country as unfair? It is unfair because India spends around 4.2 percent of its GDP on healthcare and most developing countries spend around 5% of GDP on healthcare.

Now is this low or high, I'll say it is almost similar to most of the developing countries. So what is the problem? The real problem is

the public private match. When we look at the distribution of 4.2% of the GDP who is spending more on the public sector i.e. government, which is supposed to spend a lot, spends only one-fifth of this 4.2% and the rest almost 70% is from the households.

So households, you and me, spend a lot of money on healthcare. And if you look at out of pocket spending it is going up phenomenally in the last 20 years or so and we all know why it has gone up. It has gone up because the government has been under spending while the growth of the private sector has been tremendous. And that is the reason why the household expenditure has gone up in the last 20- 30 years.

But if you look at the composition of the household spending, what is it on, what is a large amount being spent on? It is very clear and apparent that a large part of this household spending actually goes on outpatient expenditure while on the other hand the mix is basically about two third and one-third. Households spend about one-third of the household expenditure on healthcare and on hospitalisation while the rest, two-third, is actually spent on the outpatient here.

If observed, the share of the out of pocket expenditure by different categories, for instance, drugs itself assumes 69% of the total household spending i.e. almost 70 % of the households spending on healthcare goes on for buying drugs. This is the major issue.

Somebody talked in the morning about people going into debt due to out of pocket spending. It is very apparent from the national samples of the data we find that almost 13 % of India's population actually incurs what we call catastrophic spending and what is this catastrophic spending?

It can be defined as household spending in about 10% of their total income on healthcare.

And this 13% of catastrophic expenditure is very high even among the developing countries. I just wanted to bring to your attention one of some of the policy intervening in on this country for the last 4 years i.e. since 2007.

There are two major policy interventions seen; (1) the NRHM in 2005 and (2) starting from 2007 we have seen a plethora of publicly funded health insurance schemes. Karnataka again has a very interesting thing; there are three health insurance schemes that is also public funded health insurance.

Now, what does this health scheme do? It only focuses on hospitalization coverage either secondary or tertiary care hospitalisation cov-

In India households end up paying a lot of money and major share of their income on the healthcare especially on drugs.

erage. It is evident from this national sample survey that the households actually end up in spending a lot of money on outpatient care and not the hospitalisation coverage. But our policy makers instead of focusing on the outpatient expenditure are focusing on the hospitalisation coverage. The evidence is there but they have taken their own route to address some other issues. As I have said that the Indian government, central and state put together spends around 20% of their income on health care.

If you look at government expenditure on drugs it is very interesting. On an average the government spends around 12-13% of their total spending on healthcare on drugs but I must qualify the fact that except few southern states like Tamil Nadu, Kerala and to some extent Karnataka which spends about 14-15% of their total health expenditure on drugs and the most

of the states spend about 4-5% and in many states they spend even less than 3%.

Many state governments spend less on drugs and that is precisely why you see hardly any medicine in the public health facilities. So shortage and stock outs are norms in this country. Why so? This is the reason, that we spend hardly any money on buying drugs. Procurement and distribution in this country has been pathetically bad.

Not only there is huge variation between states but also in districts, for instance in Bihar, if you look at the district variation in drug spending, again a huge variation between districts. Districts like Buxar standing about 7 on an average

India is one of the major culprits in terms of producing irrational medicine. Irrationality rules prescription, dispensing and use of these drugs

to about 780, so that's about drug expenditure per illness episode.

But if you look at drug expenditure per capita, it is about as low as Re.1 to Rs.84. if you look at Bihar on an average it spends about Rs.8 on drugs, per capita whereas if you see in Tamil Nadu and Kerala on an average the per capita spending is about Rs.40 to Rs.50 and now it is even more. Given the fact that government are spending very low and as we know it has implications on the availability of medicines.

If you look at state-wise availability of free or partly free medicines available at government facilities, given the fact that most of the drugs are dispensed at outpatient care level, it is apparent that the top state, in terms of the outpatient expenditure drugs available freely, is Tamil Nadu followed by other states and, of course, state like Bihar are almost in the lower

end of spectrum. And same thing goes with the free medicines available if it is in the hospitalisation or inpatient coverage. Now we see a comparative scenario of the availability of drugs, the essential drugs which are 20 to 30 in number which are supposed to be available in public health facilities especially in PHCs and CHCs. Most of the PHCs are supposed to have 25-30 essential medicines that are supposed to be dispensed free. We did a survey in Tamil Nadu and Bihar and it was evident that in Tamil Nadu the availability of baskets of essential medicines is 89-90% as against about 33% in Bihar.

In case of stock outs of drugs Bihar again performs badly as against Tamil Nadu. And the reason behind this is not only that Bihar spends a lot also that there is a issue of procurement in the social system. Because if your procurement and distribution system is inefficient and unreliable then you might still have shortages and stock outs of drugs even if you spend a large amount.

The third major issue in India is that it is one of the major culprits in terms of producing irrational medicine; along with manufacturing is prescription, dispensing and use of these drugs. Of the top 40-50 drugs in this country 10% are highly irrational, like cough mixtures or useless liver drugs or antacids. And with this comes the problem of safety and even costing.

Irrational use of medicine is a big issue which we need to tackle. Next we look into the irrational prescription in public health facilities. It is observed that percentage of encounters with syrup prescribed is less than 3% in Tamil Nadu whereas it is about 26% in Bihar. Why is this happening? Even it happens in public health facilities. If you would have a proper procurement and distribution system it would not have been like Bihar rather it would have been something like Karnataka.

What do we do? Does the country have enough resources, do we have the capacity to provide free medicines to everyone? We certainly do have the resources and capacity, but the policies we have are wrong. We are a country that produces and supplies generic essential medicine to 193 countries around the world there is no question of capacity.

As per the High Level Expert Group (HLEG) recommendations India needs to scale up its public health spending from 1.2% to 2.5% at least at the end of this 5-year plan and 3% at end of 13th five year plan. Out of this we believe that government needs to spend .5 % more of GDP on healthcare i.e. about Rs.30, 000. It is very apparent that if government spends more on drugs, the out of pocket spending will come down gradually over the next five to ten years quite substantially. Putting money is not enough; we also need to strengthen the procurement and distribution system in each state. Centralized procurement and decentralized distribution should be adopted. Another major thing is AYUSH medicines; we need to have Indian system of medicine in public health facilities.

Drug and vaccine security is extremely important given the fact that now our top five Indian drug companies are being acquired by multi-

national pharmaceutical companies. We need to revise the public sector capacity and revive PSUs which can help us with drug security in the backdrop of acquisition and benchmark cost based pricing. In the last 10-15 years India has become a major import dependent country. I think we are in a bad situation in terms of API dependency. We can also revisit the FDI.

Currently the government spends only 0.1% of GDP on drugs but it need to spend at least 0.5% of GDP on drugs in healthcare. It will reduce the out of pocket expenditure substantially. And

India produces and supplies generic essential medicine to 193 countries around the world.

the nation as a whole can save about 0.5% of GDP by spending more on drug procurement. It will also reduce a lot of irrational drug use.

Some of the things can be done immediately like public procurement and public distribution could be done in one year. And after 2-5 years public procurement and private distribution can be done.





Dr. Samit Sharma
I.A.S

AFFORDABLE MEDICINE, THE CHITTORGARH MODEL

HIGHLIGHTS

1. The Indian pharmaceutical industry makes high profits from ignorant and hapless consumers.
2. Doctors as prescribers willingly abet this by prescribing certain brands of medicine instead of giving the option of cheaper non-branded drugs.
3. The poor suffer the most because they neither have the purchasing power to obtain the drugs nor are they aware of their choices.
4. To improve the healthcare system in Chittorgarh, the district administration conceptualised a simple yet effective initiative to introduce low cost drugs to the people.
5. The programme builds upon available resources to make the system work in favour of the citizens.
6. The following three steps summarise the process of implementation:
 - a) asking doctors to prescribe generic drugs
 - b) procuring good quality drugs for government co-ops and
 - c) spreading awareness among patients and their families.
7. The result of these efforts has been the establishment of district wide low cost shops to make medicines more affordable.
8. Patients are now aware of the low-cost medicines that are available in the market, which has also encouraged private pharmacists to stock generic medicines.
9. Government doctors are required to follow new orders of prescribing non-branded medicine and are closely monitored by the government.
10. The positive response to the programme has encouraged the state government to introduce similar initiatives across the state.

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The cost of medicines represents a significant portion of household healthcare expenses, particularly for the marginalised populations. In India, at least three-fourths of the total out-of-pocket expenditure is spent on buying essential drugs and medicines. The problem of affordable medicines is exacerbated by worrying pharmaceutical market trends that includes the presence of oligopoly elements, artificial monopolies and aggressive marketing to induce demand. The Eleventh Five Year Plan acknowledges this concern and makes access to good quality medicines a priority area for policymakers. The objective is to make medicines available at reasonable prices in all public healthcare facilities.

At present, the functioning of the pharmaceutical industry is such that the patients are at the losing end even though they are the paying consumers. To increase visibility and gain market share, drug manufacturers employ medical representatives to lobby with doctors to prescribe their branded medicines instead of salt (chemical) names. In such cases, the pharmacist, under the Provision for Drugs & Cosmetics Act, is legally bound to give the patient the prescribed medicine, thus increasing the sales for the company. Medical representatives also offer monetary/non-monetary benefits to doctors for selling their medicines, which further encourages the doctors to prescribe branded medicines. This nexus between doctors and manufacturers has proved disadvantageous for patients.

Every medicine has a salt name that indicates the chemical composition and a brand name to reflect the manufacturer. If a doctor prescribes the salt name, then the pharmacist can offer the patient a choice between the branded and generic medicine. The price of branded medicines is higher because in addition to manufacturing expenses, there are subsequent costs related to patenting, clinical trials, and market-

ing. The same drugs are also produced under various brands and are sold at higher prices depending on the perception of people.

For instance, Paracetamol, a generic name for medicine is known in the market as Crocin, Calpol, Metacin, and Pyrin. The cost of production for one tablet is only 15 paisa but it is sold at 80 to 90 paisa in the retail market. Another problem is availability, as generic medicines are manufactured when the branded medicine patents are about to or have already expired. Increasing availability of generic medicines would mean access to affordable medicines by the masses.

The Rajasthan Scenario

The health sector scenario in Rajasthan is similar to rest of the country. In Rajasthan, an alarming average of 89.4 percent of household health expenditure is on procuring drugs. At least 30 to 40 percent of the state's population is unable to afford drugs due to high costs. Also, the doctors, due to benefits received from pharmaceutical industry, are habituated to prescribe the drugs by brand names. This has led to irrational prescribing and dispensing of medicines among the poor segments of the population. In addition, access to medicine is a serious concern in the state. The residents in rural areas

In Rajasthan, an alarming average of 89.4 percent of household health expenditure is on drugs. .. At least

30 to 40 percent of people are unable to afford these drugs.

need to travel long distances to visit a health facility or to buy essential drugs. The drugs are distributed through primary healthcare centres, private pharmacists and government stores, including cooperative (co-op) and low cost drug stores. The cooperatives are autonomous organisations, with control over their own activities and budgets. The objective of co-ops is to buy and sell products required by government employees and government organizations including pharmaceutical and medical products.

Pharmaceuticals generate the largest revenue compared to other products sold at co-ops such as textiles, stationary, or computers.

The Initiative its Objectives

In 2007, the Chittorgarh district administration, concerned about the suffering of poor patients, started a campaign to make medicines more accessible to the people. The problems of the existing delivery system were identified at three levels:

- I. Doctors prescribing the medicines by brand name, thus preventing competition and creating a monopolistic marketplace
- II. Pharmacists charging maximum retail price for medicines from patients even if they can provide them at discounted rates
- III. Consumers' limited knowledge about price of medicines

The project was envisioned with the following objectives:

- To make medicines affordable to the poor
- To reduce out of pocket expenses by making medicines available, as low-cost generic medicines, through Low Cost Drug Shops
- To increase the accessibility of drugs, especially in the remote rural areas

- To decrease expenditure of the state exchequer, by bringing down
 - The government employees' health care reimbursement bill
 - The pensioners' medical fund expenses
- To promote rational use of drugs, minimising prescription of unnecessary drugs and by adopting Essential Drugs List and Standard Treatment Guidelines

Working Design

Implementing this initiative required synergised efforts at all three levels of problem identification:

- I. Encouraging Medical Practitioners to prescribe medicines under generic/salt names
- II. Making good quality, low cost drugs available for sale at Government Co-Ops
- III. Generating awareness among people to buy non-branded medicines

The district administration pursued a consultative process with medical practitioners and chemist associations to present their goal of improving the healthcare system. A documentary was presented by the administration to educate the audience on grievances of poor patients. This helped in reminding doctors of their Hippocratic Oath to practice their profession ethically. Although the administration legally mandated the government doctors to prescribe the low-cost medicines, private doctors also agreed to follow the suggestion voluntarily.

Involving Doctors

Between 2002 and 2006, the state government of Rajasthan had issued various circulars/orders directing government doctors to use salt names in prescription instead of spe-

cific brands. This was conventional professional practice as the Code for Medical

Practitioners in India requests doctors to prescribe medicines according to the salt name. It is only due to the recent incentives from Medical Representatives that doctors have been prioritizing brand names. Otherwise, even in Indian medical schools, doctors are taught to prescribe medicines by their generic names.

When the law was first enforced by the district administration, doctors were reluctant to use salt names for a couple of reasons. First, they would stop receiving promotional benefits from the pharmaceutical companies if they stopped prescribing branded medicines

Second, if they gave prescriptions with salt names, then the pharmacy would have the option of selling the brand of their choice, which would not necessarily be the best choice for the patient. Therefore, to ensure that patients have access to good quality medicines, the administration established low-cost drug stores and made low cost drugs available at government co-ops.

Procuring for Co-ops

As part of the transformation process, a list of pharmaceutical companies was identified by a committee of doctors to ensure that only good quality generic drugs are procured. The committee, in consultation with district doctors, made a list of generic medicines required for common diseases and then identified the manufacturers. The criteria followed by the doctors to select the manufacturers included company's annual turnover, profitability and certificate of Good Manufacturing Practice from World Health Organisation.

A tender was then issued by the cooperative store to source generic medicines, surgical

and IV fluids from pre-selected companies. The government co-ops bought the medicines from the lowest bidder.

Prior to the tender process, co-ops would merely source the medicines as dictated to them by doctors, which were mostly branded and expensive.

The drugs procured by the co-ops are now sold at much below the Maximum Retail Price. A discounted rate is offered after adding 20 percent profit margin to the buying cost. The profits are used to pay for expenses such as the pharmacists' salaries, and co-op maintenance.

The usual perception of generic drugs is that they are of inferior quality and hence, bought only if the patient cannot afford branded drugs.

There were two challenges first, availability of generic medicines and second, consumers' negative perception of generic drugs.

As such, a challenge arose in persuading people to opt for generic medicines. The government engaged in local electronic and print media to promote the use of generic medicines. The basic aim of the campaign was to educate people about the similarity between the quality of generic and branded medicines and to encourage them to buy non-branded medicines. Signs such as "Buy generic drugs: They cost less" or "Ask your doctor for generic medicines" were posted in villages

Government Co-ops posted comparative price lists at the entrance of their stores to further inform people.



Dr. Veena Shatrugna

AROGYASRI, THE AP MODEL



Dr Rajan Shukla

HIGHLIGHTS

1. The Aarogyasri is a government health insurance scheme that is in force in the state of Andhra Pradesh (AP).
2. In July 2008 Aarogyasri-II was set up. This scheme caters for emergency and life-saving operations that require specialist doctors and equipment that are not available in government hospitals.
3. The insurance companies run a risk free business due to Aarogyasri HI.
4. Another point to note is that the people themselves are to decide what hospital they wish to go to. However, in reality this is not the case. A group of people called Arogya Mithras Kendra decide what hospital is the best for the people who live below the poverty line.
5. A key action that is needed is a committee set up by law to monitor this Aarogyasri process. The committee should ensure that all players are transparent and that the procedures being followed by the insurance companies and the hospitals are actually correct and efficient.

Dr. Veena Shatrugna, Ex-Deputy Director, National Institute of Nutrition and Member of the Anveshi Executive Committee.

Dr. Rajan Shukla, Faculty Member, IIPH Hyderabad

The Aarogyasri is a government health insurance scheme that is in force in the state of Andhra Pradesh (AP). The scheme caters for people who live below the poverty line which in the case of AP is approximately 80% of the population. The scheme aims to treat people who are extremely sick and are in a life threatening situation. Some of the more common ailments that the scheme caters for are cancer, kidney failure, heart problems and neurosurgical diseases.

This scheme was initiated by a Dr. Y.S. Rajasekhhar Reddy who was the Chief Minister of AP. He noticed that farmers were committing suicide due to expensive health care and that poor people were borrowing 63.1% of their health expenditure. The private sector stated that they were able to help and had the facilities but only if the government was willing to pay. The government agreed, however after some time they noted that they had spent 168 crore on 55,000 people. This showed some level of inefficiency so in order to tackle this Aarogyasri was set up.

Aarogyasri-I was put in place in April 2007; however, it only covered a surgical procedure. Therefore, if someone had appendicitis they would want to be covered until they are completely cured not that they are covered for one mere procedure. Most sicknesses require a number of procedures before the patient is cured. As such, Aarogyasri-I was not famously looked upon.

In July 2008, Aarogyasri-II was set up. This scheme caters for emergency and life-saving operations that require specialist doctors and equipment that are not available in government hospitals, because it is assumed that these ailments are well provided for in government hospitals. In reality though these ailments are not well provided for in government hospitals so the people incur out of pocket expenditure to go to private doctors and in AP

this out of pocket expenditure is catastrophic for households who live below the poverty line.

This then implies that Aarogyasri-II will only accept people who are extremely sick and are about to die. Only when a sick person reaches this stage will specialised help and insurance be available to him/her. This is not an ideal way to improve the health system as many of these sicknesses can be cured if they are diagnosed at the early stages. Therefore, it would be better if more money was invested in primary health care as opposed to tertiary. This will then allow people to be diagnosed before the disease gets any worse and ultimately save the government a lot of money as they will not have to pay copious amounts to private specialist doctors.

This scheme sounds and looks good on paper however it excludes common ailments such as malaria and dengue fever

Another negative aspect of Aarogyasri-II is that a lot of unnecessary procedures are taking place, for example, a person may have five CT scans when only one is needed. The private doctors then charge for each CT scan or each procedure that they perform. This means that the insurance company and ultimately the government are paying more money than is needed.

It is worth noting at this juncture that the insurance companies run a risk free business due to Aarogyasri HI. This is so because they deduct 20% for administrative costs as soon as the premium is paid. If the claim is more than 150% of the premium paid (after deducting 20% administrative costs) then the government pays the excess. Then, if there is an unspent amount that has to be returned to the government, the insurance company keeps 10% of it. Thus, there is no risk passed on to the insurance company

which means that they have no incentive to monitor efficiency, wastages, inflation and supply side moral hazard.

An additional negative aspect is that the protocol that is followed is too systematic, that is, procedures must be done in a certain order regardless if they are needed or not. An example would be where a doctor needs to operate on an acute appendix; he/she would perform a lap appendectomy. However, if the appendix is chronic and the person is in excruciating pain then an open surgery would be the right path to take. Unfortunately though, due to the rigid protocol in force under Aarogyasri-II the doctor would have to perform a lap appendectomy first and if this cannot be done then an open surgery may be conducted. This is almost a bureaucratic approach to health. It would be much better if doctors exact protocol in a way that is more efficient.

Another point to note is that the people themselves are to decide what hospital they wish to go to. However, in reality this is not the case. A group of people called ArogyaMitran Kendra

decide what hospital is the best for the people who live below the poverty line. These people are the first point of contact for the poorer population. These people are paid by the insurance companies to persuade people to go to the private hospitals, instead of the government hospitals, so the insurance company can make more money.

Other issues that are of concern are the fact that a patient has to go to the town to avail these services because there is no doctor near the villages and that the government has chosen to spend more money on tertiary care at the expense of primary care.

A key action that is needed is a committee set up by law to monitor this Aarogyasri process. The committee should ensure that all players are transparent and that the procedures being followed by the insurance companies and the hospitals are actually correct and efficient. This committee would also prepare reports that would be available for the public so that they can analyze how the money is being spent.

Scope for improvement

- Map BPL health care needs.
- The scheme does not appropriately respond to cover catastrophic health care needs of BPL population.
- Still barriers to access, specially for Marginalized groups.
- Authorizations & Payments designed by technology intensive procedure rather than health conditions.
 - facilitates use by hospitals rather than patients.
 - Promotes technology intensive health care set-up, not necessarily the best health care service or easily accessible health care service.
 - Lacks strategic purchasing

Strengthen Public health delivery in Primary and Secondary care.



Dr. Narendra Gupta

TRENDS IN OUT OF POCKET PAYMENTS IN SIX STATES OF INDIA

HIGHLIGHTS

1. About 23% persons do not access care in India only because of their inability to afford it and about 40% slide below the poverty line after single hospitalisation.
2. A functioning public health delivery system is one of the pre-requisites of a developed economy. Most of the countries which are at the top of the Human Development Index (HDI) provide quality healthcare at affordable cost to its citizens.
3. Nearly 80 percent of outpatient and 60 percent of hospital care is through private providers. (NSS 60th Round)
4. The cost of private healthcare especially for outpatient care is striking: it is nearly 22 times of public health facilities in the rural areas and over 40 times in the urban areas.
5. The personal and family expenditure in seeking health care is rising incredibly.
6. The government of India spends least on its public health system, therefore ranking it as 42nd among the highest average in the out of pocket expenditure.
7. The Tamil Nadu public health system presents us with an exemplary example and a model to be followed. Studies have revealed that Kerala also ranks high in out of pocket services.
8. Most of the expenditure is made out of the savings of the people, and large part of the amount is borrowed. Reduction of OoPE is a secondary aim of the NRHM.
9. But despite several health schemes being in place, there hasn't been any considerable reduction in the rate out pocket expenses on health.

Dr. Narendra Gupta, Jan Swasthya Abhiyan Rajasthan

1) Description of the Interventions

In most low income developing countries, expenditure relating to health care is overwhelmingly borne through out of pocket expenditure. The consequence of this is that a significant number of sick persons indulge into self medication and seek consultation only when the ailments begin to turn into catastrophic forms.

Studies conducted by the National Council of Applied Economics Research, National Institute of Public Finance and Policy and National Samples Survey Organisation (60th round) reveal that about 23% persons do not access care in India only because of their inability to afford it and about 40% slide below the poverty line after single hospitalisation.

These are very shocking findings and impinge on the health status of the country which is striving hard to reduce the high infant and maternal mortality. The proposed study is essentially to assess the nature of out of pocket payments of households in health care and examine its relationship with NRHM interventions

2) Study Questions

NRHM is a nationwide intervention rolled out simultaneously across all states in India from 2005 onwards. In 2010, NRHM has completed five years of its operation. This gives us the opportunity to address the basic evaluation question:

- Has there been a reduction or increase in the out-of-pocket expenditure for households on health care?
- Has there been a reduction or increase in the share of out-of-pocket expenditure on health care in the total consumption expenditure of the household?
- Are there differences in the pattern of OoP payments across different

(a) social and

(b) economic categories

- How is implementation of NRHM related to the pattern of out-of-pocket expenditure on health care?

3) Perspective

Across the world, national governments and donors alike are focusing on greater public investment in health and health services.

Broadly, these take two forms: first where disease specific publicly funded health service delivery systems are being set up according to the epidemiological profile of the country and the region (example of HIV/AIDS and Tuberculosis in Southern Africa); second, a directing public investment into existing government health systems which have long suffered from underfunding and lack of adequate, quality health-care workers.

The neglect of public investment in healthcare has had a severe impact on developing countries which is reflected in their indicators of morbidity, infant, child and maternal mortality, and the increase in out-of-pocket expenditure to buy care from private providers which are often of questionable quality.

The National Rural Health Mission in India is an interesting case of a partnership between the Federal government and the States which try to do both the general and disease specific interventions under one umbrella. With an annual budget of nearly US\$ 3billion per year, it is one of the largest such programs in the world.

Therefore it is important to evaluate whether its primary objective of bringing down the out of pocket expenditure on healthcare by households, especially the poor has been achieved in its first five years of operation.

In addition, the evaluation would also throw light on whether the NRHM has been able to

make a greater impact of reducing the share of out-of-pocket expenditure for poor and marginalized groups who are more vulnerable to health shocks. This evaluation is also part of a wider process of generation and dissemination of data on the health service delivery in India, which is severely lacking at present.

4) Justification

Public spending on health in India in proportion to gross domestic product of any country has been one of the lowest and has been the significant barrier in affordability to quality health care. Both the national and state governments in India have introduced number of schemes and programmes for improving the access and one such very major initiative is National Rural Health Mission which claims to have made an architectural correction in the public health system as it is governed and operationalised. However, even after five years of its implementation, it is not clear as to how much this has impacted the out of pocket payment, one of the most significant reasons for lack of accessibility to health care and cause for continuing high infant mortality rate and maternal mortality ratio. Findings of the study would provide valuable information to understand the effect of NRHM on household expenditure in health care.

5) Study objectives

The major objectives of the study are:

- To assess the change in out-of-pocket (OoP) expenditure of households for health care between 2004-10 .
- To examine the change in OoP expenditure in various social and economic groups
- To examine the pattern of OoP expenditure in relation to various parameters of NRHM implementation.

A functioning public health delivery system is one of the pre-requisites of a developed economy. Most of the countries which are at the top of the Human Development Index (HDI) provide quality healthcare at affordable cost to its citizens. In most of the Nordic countries which regularly top the HDI list, healthcare is at the centre of the social security system. Recent debates in the United States and the United Kingdom also point to the important role that publicly funded, equitable healthcare provision plays in ensuring socially desirable outcomes as far as the quality of life is concerned.

Whole generations of productive human resources can be obliterated when health systems cannot cope with the demands placed upon it.

In low income developing countries on the other hand, public healthcare systems have been in decline for the past several decades. This is reflected in two basic sets of indicators: (i) life expectancy, mortality and morbidity rates and incidence of communicable diseases; and (ii) demand for private healthcare providers and high level of health expenditure financed through the household or individual's own resources.

The causal impact of these sets of outcomes on the other is still an open empirical question. However, it is now an accepted fact that neither would show improvement unless public expenditure on healthcare is increased concurrently with an increase in access and quality of health service delivery.

Improvement in public health systems is a huge challenge facing any country, big or small. It assumes added significance in countries such as

India which is at the beginning of a demographic transition with more young people below 25 years of age than persons in old age. It is often said that this would lead to a 'demographic dividend' for these countries in the medium term with more productive labour being available for employment. At the same time, there is an apprehension that it would be frittered away and maybe even get worse if there is persistent malnutrition, morbidity and unaffordability of healthcare.

The experience of sub-Saharan Africa with HIV/AIDS has shown that whole generations of productive human resources can be obliterated when health systems cannot cope with the demands placed upon it. This is often due to the neglect on the part of the government to give priority to improving the healthcare system and providing adequate budgetary allocation which a functioning health system needs.

Improving the public health system needs interventions on both demand and supply sides. Without a wholistic approach to reforming the system, there is high possibility that the significant investment would not show results. For example, a large-scale public information campaign on tuberculosis may generate demand for testing and treatment of the disease at an early stage, but without adequate public health centres, trained staff and a dependable supply of medicines, the patients will still have to pay to get treatment from private providers.

Conversely, building state-of-the-art public health facilities on the supply side without an improvement in quality and increase in health awareness will again be wasteful of government and/or donor money. There will be perceptible difference in indicators only when the two sides – demand and supply – are both improved simultaneously.

It is in this context that it is important to evaluate the role of a health system improvement

and reform programs such as NRHM. Evaluating a nationwide program on this scale is an arduous task. It is nonetheless extremely important because in the absence of an evaluation framework, it is difficult to make any judgement on its efficacy and impact at the micro level.

Health system improvement has several components – infrastructure, staff appointment and training, health administration, medicines and equipment, and measures to ensure equity in healthcare services. These interventions are designed primary to improve a) access, and b) quality of healthcare. The evaluation criteria would need to focus on the impact of these two specific aspects of NRHM.

In recent years, a large body of evaluation literature has developed around 'randomized evaluations' which is supposed to be the gold standard today. Unfortunately, a randomized

India has one of the highest proportions of privately funded expenditure on healthcare in the world.

evaluation strategy is unsuitable for our purposes since NRHM was rolled out nationwide at the same time. In fact, a critique of randomization is also emerging within states that traditional program evaluation at the scale of NRHM for example is being neglected in favour of small, boutique interventions which may not be scalable. At the same time, significant advances have been made in utilizing methods such as natural experiments which is more suited to our evaluation strategy.

The method we followed falls in the second category described above. Our objective was to evaluate the outcome in terms of a reduction in out-of-pocket expenditure for households who need curative medical care.

As mentioned earlier, India has one of the highest proportions of privately funded expenditure on healthcare in the world. The latest available nationwide data for healthcare from National Sample Survey (60th Round) shows clearly that nearly 80 percent of outpatient and 60 percent of hospital care is through private providers.

The cost of private healthcare especially for outpatient care is striking: it is nearly 22 times of public health facilities in the rural areas and over 40 times in the urban areas. The difference in the cost of hospitalization is lower: private

WHO estimates that a significant burden of out-of-pocket expenditure can be traced to medicines which have to be privately bought even when the patient accesses the public healthcare system.

inpatient care is twice as expensive compared to public health facilities in the rural areas and nearly four times in the urban areas.

The average inpatient cost in public health system is nearly the same in both rural and urban areas. So the difference in the cost burden is primarily due to the lack of access to public healthcare – which points to the fact that greater utilization of public healthcare would reduce out-of-pocket expenditure significantly.

As a corollary, if the incidence of benefit of public healthcare is skewed towards the poor, investment in public healthcare system through NRHM will also be equity enhancing.

WHO estimates that a significant burden of out-of-pocket expenditure can be traced to medicines which have to be privately bought even when the patient accesses the public

healthcare system. One of the major reforms proposed at the inception of NRHM was to make medicines available at all the points in the referral chain – starting from the village sub-centres, to primary health centres (PHCs), community health centres (CHCs), and district as well as state hospitals.

Availability of medicines also serves as a proxy for quality of care available from the public health facilities. We propose to use availability of medicines as an instrument to answer our question – whether NRHM has been able to reduce out-of-pocket expenditure through improvement in quality?

The empirical strategy follows the recent literature using natural experiments to determine the effectiveness of large-scale programs. Our strategy would be to use the National Sample Survey 60th Round in 2004-05 as the baseline to determine the level and nature of out-of-pocket expenditure. NSS have both all-India and state level out-of-pocket expenditure by household, gender and socio-economic status, disease-wise incidence and use of facilities (both public and private).

After generating the baseline, we selected the states as per the NRHM classification of the most backward states as far as health status is concerned. Within states, three worst districts were chosen as per the District-Level Health Status (DLHS) survey of 2005-06.

The field survey was carried out using the same methodology as NSS to generate representative list of households at the district level. The survey tool will be adapted from NSS 60th round to focus on our evaluation questions – access to health facilities and availability of medicines for out-patient care, and compare them to the baseline out-of-pocket expenditure of 2004-05 obtained from NSS 60th Round survey.

Data was collected from households and public and private healthcare facilities. The survey

instrument collected out-patients records from January to June of 2004 and 2010, classified by place of residence as well as disease and socio-economic profile. A catchment area method was adopted to carry out the household survey for each health facility. Simple difference-in-difference approach was then used to evaluate reduction in out-of-pocket expenditure with increase in healthcare access collected through the facilities survey.

There were several issues that need to be addressed before any reduction (or otherwise) of out-of-pocket expenditure can be causally attributed to NRHM. First, under the Constitution, state governments are responsible for administration of the public health system within their jurisdiction. Therefore, budgetary expenditure by states compliment the resources being invested through NRHM to improve the public health system.

Through the analysis of the Central and state budgets for health, we were able to establish that improvement in infrastructure, human resources and quality has been through the financial allocation through NRHM.

Second, out-of-pocket expenditure is almost surely to increase in absolute terms, but our strategy needed to look at its share in total health expenditure and total household expenditure. A reduction in the proportion of out-of-pocket expenditure for both health and total expenditure would be a significant break from the past, and can be attributable to NRHM if our first issue is addressed.

Third, our evaluation was restricted only to the rural area since that is the NRHM mandate. We therefore collected data on utilization and access upto the CHC level, and not for district hospitals which are in urban or semi-urban areas.

In order to complete a wholistic evaluation strategy, a qualitative survey was adminis-

tered to selected stakeholders, including out-patients, other family members, village health volunteers, community leaders, members of the community-based committees in charge of monitoring the health centres, and to the healthcare staff themselves.

This provided a way to listen to the views on the health system, to enquire about improvements over the last five years and also disseminated advocacy messages. It is hoped that with the grant, a continuous process of evaluation of the healthcare system will be put in place which was done every year with the participation of local volunteers and the village community. This ensured sustainability to this initial evaluation of NRHM.

The study was carried out through a collaborative and participatory mechanism amongst the civil society organisations in each of the selected states. A nodal organisation which has experience and capacity to carry out the work relating to such studies especially of data collection and data entry was identified for this purpose.

6. Scale of Study

The study was carried out in six states of India. The decision of number of states was based on convenience and availability of required funds. While selection of some of the states was based on the continuing work in these states through civil society organisations, others have been chosen based on their geographical locations. The states where study was done are as follows:

- Assam
- Bihar
- Jharkhand
- Rajasthan
- Tamilnadu
- Uttaranchal

In each of these states, number of districts was selected (between two and five depending

upon the number of districts in the state) on the basis of regional diversity.

- For states with upto 20 districts: 2 districts to be selected.
- For states with 21 to 30 districts: 3 districts to be selected
- For states with 31 to 40 districts: 4 districts to be selected
- For states with 41 and above districts: 5 districts to be selected

7. Sampling strategy

In the chosen states, districts have been selected through '**probability proportional to size sampling technique (PPS)**'. PPS is a widely used standard sampling technique and is the appropriate technique to use when the sampling units are of different sizes. On the basis of PPS technique, this study will be done in following districts:

S. No.	State	District	Population (2001)
1.	Assam	Kamrup	2,515,030
2.		Sonitpur	1,677,874
3.		Cachar	1,442,141
4.	Bihar	Madhubani	3,570,651
5.		Gopalganj	2,149,343
6.		Banka	1,608,778
7.		Aurangabad	2,004,960
8.	Jharkhand	Sahibganj	927,584
9.		Purbi Singhbhum	1,978,671
10.	Rajasthan	Bharatpur	2,098,323
11.		Nagaur	2,773,894
12.		Tonk	1,211,343
13.		Baran	1,022,568
14.	Tamilnadu	Vellore	3,482,970
15.		Coimbatore	4,224,107
16.		Virudhunagar	1,751,548
17.	Uttaranchal	Tehri Garhwal	604,608
18.		Nainital	762,912

Thus, this study was conducted in the above mentioned 18 districts of 6 states of India.

The sample size was 200 households per district. The sample was obtained by selecting 10 villages per district and 20 households per village. It would be ensured that out of the 20 households surveyed at least 7 in-patient cases are covered from each village.

The villages were randomly selected using the village directory of the 2001 Census and the sampling of them will be done by PPS technique.

So the sample design can be summarised as below:

Out of Pocket Expenditure (OoPE) in Health Care

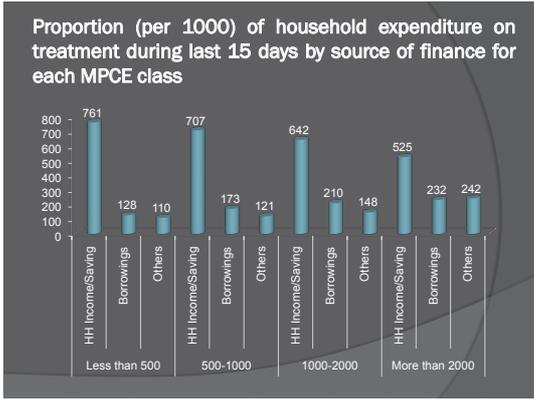
- OoPE are non-reimbursable fees which a patient or family is responsible for paying directly to health practitioners or suppliers, without intervention of a third party. It often occurs, when publicly funded facilities are unable to provide the required health services and supplies for free or through insurance.
- India was ranked as having the 42nd highest average OoPE, with 74.4% of private expenditure being paid as out of pocket. (WHS 2011)
- OoPE accounts for an average increase in poverty by as much as 3.6 and 2.9 percent for rural and urban India respectively (Gupta 2009)

- Number of States: 6
- Number of Districts: 18
- Number of Villages: 180
- Number of Households: 3600

Operational Details

The study was a joint effort of Prayas, National Institute of Health & Family Welfare and Ox-fam. Other stake holders such as Public Health Foundation of India and Institute of Economic Growth were consulted if they would like to be part of it. An advisory committee was constituted to oversee the study. The ethics committee of NIHFV was requested to provide approval for the study.

On the basis of studies conducted by PRAYAS across five states in India, (Assam, Jharkhand, Rajasthan, Tamil Nadu, Uttar Pradesh) and the



out of pocket expenditure situation has been evaluated on the basis of data gathered. The personal expenditure in seeking health care is rising incredibly.

To understand the out pocket expenditure situation, we first need define it clearly. It is basically characterised as a non reimbursable fee paid directly to the health practitioner. The government of India spends the least on its public health system, therefore ranking it as

42nd among the highest average in the out of pocket expenditure.

The Tamil Nadu public health system presents us with an exemplary example and a model to be followed. The government of Tamil Nadu has been providing free medicines since 1999 but despite that we are still high on the OoPE. Studies have revealed that Kerala also ranks high in out of pocket services.

Looking at the scenario around public health and increasing out of pocket expenditure, how do we then look at these several health programmes? Most of the expenditure is made out of the savings of the people, and large part of the amount is borrowed. Reduction of OoPE is a secondary aim of the NRHM. But despite several health schemes being in place, there hasn't been any considerable reduction in the rate.





S. Srinivasan

USING LAW TO ACCESS ESSENTIAL DRUGS

HIGHLIGHTS

1. Mostly useless drugs came under price control in the pharmacy policy of 2002 and this is not in the interest of people.
2. In 2011 the Government has told the court that it is coming up with a new policy.
3. All essential drugs should be under price control.
4. All irrational medicines should be removed.
5. Only rational drugs should be marketed in India.
6. Free medicines for all through public sector should become the policy
7. The Government needs to look eastward and see what Thailand has done.
8. Under the Pricing Policy 2011 of the Government of India, 348 drugs will be under price control. But if you go into the details there are problems.
9. The most popular medicines are the costlier ones because that is what doctors prescribe. You can not leave everything to the market as far as medicine is concerned.
10. This is not a price control policy but a free for all price policy.

Mr. S.Srinivasan, LOCOST Baroda

The pharmacy policy of 2002, was trying to control medicine based on the amount of share the company had in the market. Mostly useless drugs came under price control and this is not in the interest of people. Between 2003-2011 there were several rounds, rejoinders, the government appointed so many committees. Finally we approached the court in April 2011, the court asked how are we going to move forward and the Government said, we are coming up with a new policy. The court gave the government two more months but even this policy has some problems. In October, Government came with a new policy.

These have been our prayers 1. All essential drugs should be under price control. 2. All irrational medicines should be removed. 3. Only rational drugs should be made and marketed in India. 4. Free medicines be available for all in public sector. I think the Government is coming around to the last prayer and this looks like it is going to be a reality.

The Government needs to use Compulsory License on essential drugs under patent. Thailand has done this, they have the courage to take on American companies. But we don't have the courage. Under the Pricing Policy 2011 of the Government of India, 348 drugs will be under price control.

The draft National Pharmaceuticals Pricing Policy (NPPP-2011) declares that all 348 essential medicines (as per the new National List of Essential Medicines, NLEM 2011) will be under price regulation. The shift in focus from market share to whether medicines are essential is to be welcomed. However, the policy still leaves scope for non-essential and irrational medicines to be made. It also has made calculating ceiling prices of the many medicines not in NLEM a tedious, if not impossible, exercise.

In addition to the NLEM 2011, top selling 300 medicines of the IMS could have been covered. The draft policy delinks the ceiling prices of formulations from the price of bulk medicines. Indeed, the arguments given in the draft policy for removing price control of bulk medicines do not make sense. The government should have kept the option of price control on bulk medicines in the event of cartelisation or abnormal increases in price of bulk medicines.

The latter may result in the scarcity of a particular essential medicine formulation unless it is already overpriced relative to the cost of the bulk medicine used. Worse, this may result in the bulk medicine or the formulation not being made within the country.

Secondly, using the WPI (Wholesale Price Index) to revise prices is not a good idea. It adds

For paracetamol then the ceiling price will be Rs. 20 even though the cost is Rs.2.

an inflationary element to the ceiling price automatically every year. The WPI (100 for base year 2004-05) for 2010-11 is 143.3. Most medicine prices have not really increased 43 per cent during the period. It would have made sense to have the ceiling price of a medicine formulation tied directly to the related bulk medicine price increase during the year.

Problems.

The price control will be based on weighted price of the top three brands, so what happens is not what happens with the other industries like car industries where the most popular car is a cheap car but the most popular medicines are the higher priced one. The costlier medicines are bought by more people because the

doctor prescribes them. This is what economists called market key failure. You can not leave everything to the market as far as medicine is concerned. Also the government will take the weighted average so the ceiling price will be very costly. For pareceteomal then the ceiling price will be Rs. 20 even though the cost is Rs.2 . So this is not a price control policy but a price free for all policy. So we have given all these critiques and the next hearing is in Jan. 2012. There are other exemptions given in the draft policy- any medication that is selling at less than Rs. 3 is out of price control and it gives leeway to drugs that cost much less to produce.

A better pricing policy is one that brings down the price of all overpriced drugs. That has some linkage to the actual cost of production. They said this is just a draft policy and they have taken all recommendations and then they will finalize it and it will go to a council of ministers headed by Sharad Pawar.

So, what is a better pricing policy? That will be one that brings down the prices of overpriced medicines; that has some linkage to the actual cost of production, and therefore to the cost of the raw material; and does not legitimise over-

pricing of medicines. Nominally reducing the price of the top-selling brand is tokenism.

A good starting point would be to take as reference price the prices of well-run public procurement systems and take a multiple, say 4 to 6, of the reference price as the ceiling price. The present WAP procedure will make the ceiling price 20 to 70 times the public procurement price — which is a little rich.

Table 1: A Comparison of Medicine Prices

Generic Name of Drug (1)	Unit (2)	Chittorgarh Tender Rate (3)	MRP Printed on pack/strip (4)	TNMSC Prices (5)	(Column 4/ Column 5) (6)
Albendazole Tab 400 mg	10 tablets	11.00	250.00	4.55	54.94
Alprazolam Tab IP 0.5 mg	10 tablets	1.40	14.00	0.51	27.45
Amlodipine Tab 2.5 mg	10 tablets	2.30	23.00	0.41	56.01
Atorvastatin Tab 10 mg	10 tablets	9.90	65.00	2.10	30.95
Cetirizine 10 mg	10 tablets	1.20	35.00	0.49	71.42
Diazepam Tab 5 mg	10 tablets	1.40	18.00	0.55	32.72

The draft policy gives the impression of a policy cobbled to satisfy perfunctorily the Supreme Court Orders of March 2003 and October 2011, one that will leave major players mostly unaffected. Here is a policy with some bark and a little bite.





Dr Mira Shiva

WITHDRAWAL OF POTENTIALLY IRRATIONAL DRUGS

HIGHLIGHTS

1. When we talk about hazardous drugs we are talking about drugs that kill and maim when used.
2. Sometimes when you prescribe a drug the side effect is on the person but sometimes it is on the next generation.
3. Drug induced suffering has medical, pharmaceutical and legal dimensions.
4. I want to specially highlight this book, *Banned and Bannable Drugs* by Dr. Wishvas Rane.
5. The issue of counterfeit drugs is about trademark not bad drugs and good drugs.
6. A PIL in 1983 asked for banning of import manufacture and sale of drugs recommended for banning and cancel licenses.
7. The court ordered public hearings, and this was the first time they had done this but the one in Chennai no health groups were notified and only drug companies were there.

Dr. Mira Shiva, Coordinator All India Drug Action Network

just want to flashback on the earlier presentation on Thalidomide and historically how, this drug was supposed to be very scientific and not hazardous of all. Thalidomide was given for morning sickness and no animal testing done.

By 1965, 450 cases of SMON were reported from Japan. In five years, the number is reported to have risen to 11000. Dr. Ole Hanson who started a court battle in the Tokyo High Court to ban the drug cautioned that the drug would cause blindness. In 1973, reports started pouring in from England, Australia, and Switzerland about nervous disorders caused by the drug, but the company insisted that it was virus-caused. Finally, in 1976 the company conceded in the Tokyo High Court that SMON was caused by its drug and apologized in these words: "In view of the fact that medical products manufactured and sold by us have been responsible for the occurrence of this tragedy in Japan, we extend our apologies, frankly and without reservation, to the plaintiffs and their families."

ones to know which country has taken what action on. The drug induced suffering has the medical, pharmaceutical and legal aspects that require people to put their heads together and to take on big pharmaceutical companies. You have to take legal measures, you have to know law, there are three strands and they have to work together.

- **The Power to Harm Mind, Medicine & Murder on trial John Cornwell 1996**
- **Banned & Bannable Drugs Dr Wishvas Rane, MS. VHAI AIDAN 1982 onwards 5 Editions 2003**

I want to specially highlight this book, Banned and Bannable Drugs by Dr. Wishvas Rane. Because when they are doing the banning they do it in the name of generic drugs and this book

**KICADIS
KYOTO INTERNATIONAL
CONFERENCE ON DRUG
INDUCED SUFFERING 1979**

**UN CONSOLIDATED LIST OF
DRUGS & CHEMICALS BANNED &
SEVERELY RESTRICTED
UN**

**HAI
HEALTH ACTION
INTERNATIONAL 1981**

**Drug Induced Sufferings, Medical,
Pharmaceutical & Legal aspects 1980
Problem Drugs IOCU, HAI Bad
Medicine Dr Milton Silverman Worst
Pills, Best Pills Public Citizen**

In 1979 there was an international conference on drug induced suffering. The UN consolidated a list of drugs and chemicals that are banned and severely restricted. This document still continues to be one of the very important

has a list of brands of drugs that are banned and why and what are the alternatives.

This thalidomide and diethylstilbestrol was given to make normal babies more normal and there were enough women taking and

when they grew up the daughters and sons developed reproductive disorders and infertility. Moral of story is that sometimes when you prescribe a drug the side effect is on the person but sometimes it is on the next generation. This issue of counterfeit drugs is about trademark not bad drugs and good drugs.

The **Dalkon Shield** was a contraceptive intra-uterine device (IUD) developed by the Dalkon Corporation and marketed by the A.H. Robins Company. The Dalkon Shield was found to cause severe injury to a disproportionately large percentage of its users, which eventually led to numerous lawsuits in which juries awarded millions of dollars in compensatory and punitive damages. By 1986 – 192,000 claims filed mainly in US

2300 \$ million total compensation amount to pay for claim applicants through TRUST set up for the purpose

EP Case FDC HIGH DOSE EP DRUGS

On 8th March 1982 International Women’s Day EP campaign launched.

As a result ICMR was recommended. It was the classic case of a widespread misuse of a drug. Many countries have high dose of EP. It was a highly successful and innovative campaign. By June 1982 there was ban order from DCGI. Drug companies went to court and obtained a stay order saying that health was a state subject and centre had no business to ban it and it was a violation of Industrial Regulation Act.

Activists responded with studies of Dr. Isabel Gal’s warning about association of HPT with High dose EP with congenital malformation. Views and data of experts from Health Action Internationals Network. On 15th June 1988 High dose EP banned. On 30th June 1988 Ban Order – Gazette notification no. 700 E Public came to know through newspaper reports.

Contents

Dr. Vincent Panikkulangara an advocate from Cochin filed a PIL in 1983 and asked for banning of import manufacture and sale of drugs recommended for banning and cancelation of licenses. In 1986 The court ordered public hearings, and this was the first time they had done this but the one in Chennai no health groups were notified and only drug companies were there. They did not want any action to be taken because by the time the hearing was taking place in Delhi we had a lot of information .

The IV contamination case in Delhi, the testing showed that it was safe. But it was Glycerol adulterated with industrial diethylene glycol resulting in deaths and kidney failure. I.V. fluid Contamination deaths in Safdarjang hospital Delhi. 35,000 bottles Glycerol with fungus grossly visible.

Justice Lentin said that, these cases describe and illustrate ugly facets of the human mind and human nature, projecting errors of judgment misuse of ministerial power and authority and apathy toward human life, and corruptions.

There were deaths in JJ hospital Mumbai, Dr. N H Antia of FRCH sent a communication to Justice Bhagwati about JJ Hospital deaths on post card. This was treated as PIL.

The Lentin Commission said these pages describe and illustrate ugly facets of the human mind and human nature, projecting errors of judgment misuse of ministerial power and authority, on apathy toward human life, and corruptions. Unsafe use of medicine and irrational use of drugs is a public health issue but when

we are talking about hazardous drugs we are talking about drugs that are dangerous when they are used.

We need to know what hazardous drugs are, what is unsafe medicine and what is unsafe use of medicine. Examples include: Eg. rapid administration of calcium, overdose insulin, IV fluids, HIV contaminated blood products, ANTI D for Rh negative mothers with Rh +ve babies(testing, batch numbers) .

Partnership for Safe Medicine deals with counterfeit drugs. It has a heavy dose of industry sponsorship and involvement. This is not be confused with movements against hazardous and banned and bannable drugs. International Medicinal Product anti Counterfeit Taskforce (IMPACT), uses WHO logo, but basically is an initiative of IFPMA and PhRMA. The 1st India meeting was IFPMA initiated and used the Jan Aushadhi logo. Consumer groups and health associations and the chemicals ministry were involved. Obviously there was high level corporate interest in decision making.

A 14 Point Programme for Health Activists

1. Challenge Hazardous Drugs, Producers, Promoters and Protectors’.
2. Challenge Potentially Hazardous Policies, Corporate Friendly measures that threaten Public Health eg TRIPS plus Agendas being pushed through Indo EU FTAs,
3. Ask whether counterfeit agendas threaten affordable generic equivalents, What is IMPACT and ACTA are upto.
4. Rejecting Potentially Hazardous Drugs, Using essential /rational drugs only Rationally
5. Reject and boycott products of Corporations indulging in potentially hazardous moves eg Novartis using every move to get section 3’ d’removed avoiding use of their products Calcium Sandoz, Volvuran .
6. Demand a Rational Drug Policy,
7. Promote Rational Drug Use,
8. Monitor Adverse Drug Reaction
9. Master Post Marketing Surveillance
10. Campaging for Banning of Potentially Hazardous Drugs .
11. Ensuring Access to Unbiased Drug Information, and never fail to caution consumers
12. Build Health Literacy, Drug Literacy, Legal Literacy for consumers to protect their Right to Health, Right to Justice.
13. Always Give priority to public health concerns, using precautionary principle in withdrawal of [potentially Hazardous products for which equally effective, safe, affordable alternatives exist .
14. Use Legal Provisions to protect public Health



Dr Madhavi Yenappu

VACCINE POLICY AND REVIVAL OF PSUS

HIGHLIGHTS

1. But the current trends indicate that these other health measures are largely neglected and the focus is mainly on having vaccines for everything.
2. Current policies of liberalization and globalization and aid politics are facilitating the vaccine market expansion.
3. India has a century old history of vaccine production. But currently only three vaccine institutions are operational. Others were quietly closed down.
4. Private sector is interested in highly expensive combination vaccines.
5. Experts and civil society recommend an evidence based national policy
6. President of India in her Presidential address announced the revival of vaccine PSUs on an urgent basis.
7. The Govt. has also decided to invest around Rs 150 crore in these vaccine institutes.
8. But the Government itself procured drugs from Biological Yield Ltd, a private limited company which was not GMP compliant. The Government is still procuring vaccines largely from the private sector and only 1/10th of the vaccines are procured from PSUs.
9. While this crisis was on, the govt. planned to introduce pentavalent vaccines in the national immunization program and another PIL was admitted regarding this issue.
10. Supreme Court gave an interim order in April 2010 that Govt. should formulate a national vaccine policy. So finally the Govt. came up with a vaccine policy which was not at all an evidence based policy. A bad vaccine policy is worse than having no policy at all.

Dr. Madhavi Yenappu, Faculty NISTADS

Indian Vaccine Scenario at a glance

- Vaccines are important preventive medicine in Primary Health Care
- National health security is closely linked to self-reliance in vaccines & drugs
- Unlike curative drugs, vaccines are given to all – hence need stronger economic logic
- Vaccines constitute 2% of entire global pharmaceutical industry: growth drivers
- World vaccine market (\$22 billion) dominated by Sanofi, GSK, Merck & Wyeth
- Indian vaccine market is huge: \$ 2 billion growing at 22% per year
- India is among the largest vaccine makers and buyers globally
- 6 Primary vaccines are under GOI's EPI (TT, DT, DPT, BCG, OPV, Measles)
- Present cost of all EPI vaccines/child is Rs.30/- or Rs.750 m for 25 m newborns/pa
- Liberalization, globalization & aid politics are expanding our vaccine markets
- Many expensive new & combination vaccines are flooding the market (hep, flu etc)
- Vaccine efficacy, cost-benefit/risk-benefit are relevant only when need is proven
- Once this logic is skipped to allow one vaccine, every other vaccine would follow
- Ethics of childhood vaccination: 'coverage' more important than protection
- Taking all vaccines in India needs 27 doctor visits and Rs. 30,000/- per child <5 yrs!
- How many vaccines are adequate to prevent how many deaths & at what cost?

Before I go into the details of the status of this PIL that we filed, I want to give you some background information that will help you understand better the need for filing such an application against PSU.

As many of you are aware, vaccines are required only in the primary health care. And they are useful when used in a balance with other public health care measures. But the current trends indicate that these other health measures are largely neglected and the focus is mainly on having vaccines for everything.

There are many vaccines in the market now. Industries are promoting the vaccines in the National Immunization programs of many countries. Even International Organizations are supporting them. And the current policies of liberalization and globalization and aid politics are facilitating the vaccine market expansion.

Basically they tend to distort the national vaccine priorities irrespective of the needs and

safety of the people. This is the general background. For the success of any vaccination program local factors are very important. But they are not being considered by our country. India has strengths to boast about century old history of vaccine production. We have a policy of self reliance and self sufficiency in vaccine technology production and development. Traditionally in technology development for vaccines our strengths lies in the public sector. We were at par with other countries till the thirties. Later we were trying to catch up.

After the shutdown of PSUs there is a clear shortage of vaccines.

These are various vaccines of public sector units which cater to the needs of the national immunization program. Under our national immunization program there are six vaccines.

They have been supplied primarily by the public sector unit vaccines.

The need for filing this PIL arose when after liberalization many of these PSU vaccines were closed down which went unnoticed in the beginning. It was only when some crucial central research units were shut down. Some of these were BCG vaccine research centre, Chennai, which produced and supplied the BCG vaccine and the Pasteur Institute of Southern India that this issue came under media attention. Currently there are only three operational vaccine institutions, but I won't be surprised if they too are closed down.

Primary Vaccines Orphaned

With the declining number of companies producing primary vaccines and the closure of public sector units led to the *orphanisation* of universal vaccines in India. And Private sector organizations are more interested in new highly expensive combination vaccines. As a result there is a short supply of universal vaccines not just in India but globally also. Because of current policies public sector is no longer fashionable and these days you see more of private sector and public-private partnerships. In the end it is public who is suffering as it is not getting any benefits in spite of the growth of the private sector. In case of vaccine supplies, after the shut down of PSUs there is a clear shortage of vaccines.

There is a lot of debate on penta-valent vaccines and combination vaccines. These vaccines are being pushed nowadays because of their high interest in IPR and pricing rather than safety efficacy and need issues. International factors, alliances and slogans like universal GMP and universal laboratory practices tend to delay the national priorities with their emphasis on introduction of new vaccines and coverage themes.

Chronology

This was a general background. The chronology of events will give you a clear picture. This PIL against suspension of production of these vaccines has led to the convergence of various forms of interventions ultimately revoking the PSUs.

In January 2008 DCGA gave suspension orders to vaccine production units. Central Research Institute, Pasteur Institute and BKGVL. The consistent media reports have kept the debate alive. In April 2008 a Frontline story gave a cover story on this issue describing the closure of vaccine units as fishy. Because of the pressure generated by the media the then Health Minister appointed an expert committee on 'the future of vaccine PSUs'. But this committee fo-

The main prayers of the petition were

- a ban on the combination vaccines
- revoking the PSUs and
- formulation of a National Vaccine Policy.

cused on the possibility of converting these institutes into testing labs rather than assessing the question of their suspension and the presence of alternative sources of such universal vaccine production units.

There was consistent media reporting on the issue. Pioneer printed an article questioning the mala fide intentions of the health ministry in suspension of these PSUs. Meanwhile a PIL was filed in the Supreme Court by S.P. Shukla and others alleging that the closure of these PSUs would cause vaccine shortages leading to demand supply gaps which will affect the af-

fordable supply of universal vaccines. And this would be detrimental to child health due to its effects on the immunization program. The main prayers of the petition were a ban on the combination vaccines and revoking the PSUs and formulation of a National Vaccine Policy.

The Parliamentary Standing Committee Report was admitted two days before the PIL was filed in the Supreme Court in February 2009. Supreme Court gave notice to the Union Government on this issue. The ICMR organized a workshop on 4th June to keep the debate alive. They brought the civil society and various experts from the academic field to build a broad consensus for having an evidence based vaccine policy with a rational decision making process for vaccine use in the country for selective as well as universal immunization programs.

Return of PSUs

On the same day i.e. 4th June the President of India in the Presidential address announced the revival of vaccine PSUs on an urgent basis. The Health Ministry announced an action plan for the revival of vaccine PSUs by June 30th 2010 due to pressure from PMO which was generated by the notice issued by the Supreme Court in response to the PIL that was filed. This PIL along with the Parliamentary Standing Committee report, media reports and various other interventions converged to force the Government to relook into revival of the vaccine institutions.

Immediately in July - August some govt. officials visited these institutes and released a sum of approx. 1.1 crore and decided to invest more to meet the GMP compliance the lack of which was the reason cited for the shut down of these institutes even though they produced quality vaccines. The Govt. has also decided to invest around 150 crore in these vaccine institutes.

It should be noted here that these institutes were in the first place under the health ministry itself. But instead of providing them with the GMP compliance the ministry had preferred to close them. It did not even look for any alternate arrangements. On the contrary there were some news reports that said the Indian National Regulatory Authority would be derecognized if these institutes were not shut down. But the Government itself procured drugs from Biological Yield Ltd, a private limited company which was not GMP compliant.

The 4th Parliamentary Standing Committee report consistently put pressure on the govt. on this issue. In September 2009 the govt. set up a committee under the chairmanship of Dr. Ja-

We began the fight by demanding a rational evidence based policy and ended up getting a bad vaccine policy

ved Chaudhary. This committee indicted the govt. for suspending the PSUs and both this and the Parliamentary Committees indicted the concerns that were raised in the PIL that was filed. On 5th February Javed Chaudhary committee submitted an interim report asking the govt. to immediately revive the PSUs before they submit their final report. It was then that the health ministry sent several officials on 26th February to these institutions. Meanwhile RTI activities shone light on the increased child deaths and adverse effects on child health due to shortages in vaccine supply.

Here comes the Pentavalent

While this crisis was going on, the govt. also planned to introduce pentavalent vaccines in the national immunization program even though there was a lack of evidence on the

need and safety efficacy of these vaccines. Another PIL was admitted regarding this issue. So many things were going on simultaneously. On the pentavalent PIL Supreme Court gave an interim order in April 2010 that Govt. should formulate a national vaccine policy. So finally the Govt. came up with a vaccine policy about which many of us came to know in mid July 2011 though it was written April 2011. This was not at all an evidence based policy. It actually supports the introduction of all new vaccines. It is in fact legitimizing the market trend of pushing those vaccines which are not at all evidence based and lack any proper studies regarding their safety and effectiveness.

Before this PIL was filed, there was a CBI inquiry against the director of one of these institutes. And Dr. Mani, the director of another institute was suspended just one day before his retirement when this CBI inquiry was going on. Another PIL was filed in Kerala High Court in December 2011 against the introduction of pentavalent vaccines in Kerala. The govt. had decided to introduce these pentavalent vaccines in two states in Tamil Nadu and Kerala. So now the civil society resistance is going on against the introduction of this vaccine.

I gave this chronology of events to highlight the significance of all forms of interventions for such causes. Media consistently reported on the issue. The Pioneer newspaper was reporting on the matter daily highlighting the deliberate malfunctioning and the eventual shutting down of these PSUs. In the scientific media also a lot of debate is going on.

Industry Shapes Policy

In conclusion, the current in the country shows that the vaccine policy is intrinsically shaped by industry supply push and demand pulls are

systematically neglected. International organizations like WHO are peddling industry arguments to governments speculating financing networks and advance market commitment and exacting policies. In this current situation we have to save our national vaccine policy and public health from the vagaries of the global market. A bad vaccine policy is worse than having no policy at all.

Chronology of Events since the suspension of 3 Vaccine PSUs

- 3rd Feb 2010: PIL admitted in the Delhi High Court against pentavalent Vaccine
- 5th Feb 2010: Javed Committee submits interim report indicting govt for suspending PSUs
- 26th Feb 2010: Health ministry sends revival orders to 3 PSUs
- April 2010: High court issues interim order to govt to formulate a national vaccine policy
- 4th Aug 2010: 43rd report of the parliamentary standing committee on health raps govt.
- Sept 2010: Final Report of Javed Chowdhury committee severely indicts govt on PSUs
- 25th Sept 2011: 52nd report of the parliamentary standing committee on health still critical
- 11th April 2011: Govt's National Vaccine Policy, MOHFW released, announced in July
- Nov 2011: High court interim order to relook into Govt's vaccine policy document
- 29 Nov 2011: Mani (ex-director, CRI) suspended pending enquiry, a day before retirement
- Dec 2011: A PIL against introduction of Pentavalent vaccine was filed in Kerala High court

We filed a PIL for the revival of vaccine units and formulation of national vaccine policy. Though the units were revived they still lack the adequate working conditions. The 52nd Parliamentary Standing Committee report presents that the Government is still procuring vaccines largely from the private sector and only 1/10th of the vaccines are procured from PSUs. We began the fight by demanding rational evidence based policy and ended up getting a bad vaccine policy and so again we have to begin the fight against the new vaccine policy. The message that I want to carry forward is that academia, civil society and the legal community can be a formidable force against such issues. So health movements must be revived as the epicenter of all the interventions.



Dr. Jacob M. Puliyeel

OCCUPYING MEDICINE: VACCINES WE SHOULD NOT PAY FOR

HIGHLIGHTS

1. This is about vaccines for the 99% versus profits for the one percent.
2. Studies have shown that Hep B is very low in Asia. There is natural immunity of HiB even before vaccination which increases with age.
3. Vaccine manufacturers did their own study for 4 years and all they came up with was 125 cases in the 6 largest hospitals in 6 cities.
4. WHO did a community based study and found 7/100,00 and credited some natural immunity for the low rate of incidence.
5. The culture media is not the problem. Access to hospital not the issue.
6. The industry did a probe study in Indonesia and they found more pneumonia in those that were vaccinated suggesting that the vaccine was useless.
7. The cost of HiB vaccine is \$5.50 in the U.S the price can come down only if HiB is a part of the EPI internationally.
8. The Pentavalent vaccine has two of the useless Hib and Hep B vaccine. Wherever pentavalent has been used there have been repeated clusters of death and HHE syndrome.
9. Meningococcal costs 12,000 per child. It reduces 3.6 cases of pneumonia in 1,000.
10. When we use non-economically calculated vaccines we divert money from needed and effective vaccines.

Dr. Jacob M. Puliyeel, St. Stephens' Hospital Delhi

This presentation I have called Occupying Medicine modeled after the Occupy Wall Street movement. This is about vaccines for the 99% versus profits for the one percent.

Studies have shown that Hep B is very low in Asia. For Invasive H influenza disease (HiB) the incidence in India is very low compared to the west, it is said that there is natural immunity of HiB even before vaccination which increases with age and when children are vaccinated the titers are ten times higher in children in Asia than children in the West.

But vaccination manufacturers are not easy to convince, they have said that they don't know how to culture the bacteria. So they did their own study for 4 years and all they came up with was 125 cases in the 6 largest hospitals in 6 cities. They said this may be because of poor access to hospitals. They suggested a community based study to find the level of incidence.

WHO did the study and found 7/100,00 and credited some natural immunity for the low

It costs 12 Million to Vaccinate 1000 children

rate of incidence. The culture media is not the problem. Access to hospital is not the issue. So the pharmaceutical industry said that India over prescribes antibiotics so perhaps prior administration of antibiotics tainted the study. So they suggested probe studies to identify reduction in clinical disease after immunization.

They did the study in Indonesia and they found more pneumonia in those that were vaccinated suggesting that the vaccine was useless. The results were published but press releases said HiB protects children from pneumonia and meningitis which is a complete lie and no one has ever disputed that.

The cost of HiB vaccine is \$5.50 in the U.S, the price can come down only if HiB is a part of the EPI internationally. Where used in Canada they have eliminated H. influenza but it has been replaced with non-b H influenza which is, in some cases, worse than. H. influenza. The

Useless vaccines, like pentavalent, are being pushed at the behest of western interests.

Pentavalent vaccine has two of the useless Hib and Hep B vaccine. Wherever pentavalent has been used there have been repeatedly clusters of death and HHE syndrome. We brought this up with the government but despite this we have chosen to try the pentavalent in Kerala. One day after the pentavalent vaccine program started a child died. Tamil Nadu is supposed to start this vaccine today. Meningococcal costs 12,000 per child. It reduces 3.6 cases of pneumonia in 1,000. It doubles the sufferers of asthma in the vaccinated population. It costs 12 million to vaccinate 1000 children.

Treating four cases of pneumonia will cost 40 rupees. When we use non economically calculated vaccines we divert money from needed and effective vaccines. We need to state that efficacy must always be in absolute risk reduction. The law is the other way out, we have a PIL in the Delhi High Court which forced the government to make a policy and they have a national technical advisory group which is selected by government. In the next appeal we are asking for a three member body to select people for this group. Useless vaccines, like pentavalent, are being pushed at the behest of western interests. Some of these are dangerous as the pentavalent has repeatedly caused deaths in neighboring countries but the government is still trying it out in Tamil Nadu and Kerala.

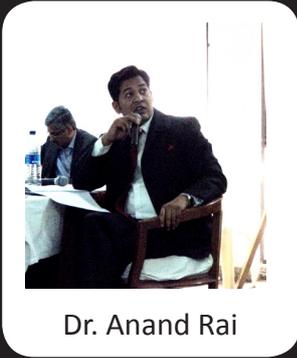
Spending Rs 12 million to save Rs 40

- Vaccine costs Rs 12,000 per child
- Vaccinating 1000 children costs Rs 12 million
- Treating 4 cases of pneumonia will cost Rs 40 if WHO recommended Septran is used

[Dabade Lancet 2009;373:2195-6](#)

If prices come down to Rs 1200/child
you will spend Rs 1.2 million to save Rs 40





Dr. Anand Rai

THE INDORE DRUG TRIALS

HIGHLIGHTS

1. Indore, surrounded by backward and predominantly tribal areas with good air connectivity has become a hub for clinical trials in India.
2. 73 trials were carried out on 3300 people out of whom 1833 were children. 81 people including 18 children suffered adverse effects which included death as a result of these trials.
3. These trials were sponsored by eight pharmaceutical companies including multinational corporations.
4. These trials were carried out by six senior doctors who were paid Rs. 5.1 crores by the companies.
5. In the MGM Memorial Medical College Ethics Committee, out of 27 members, 22 members were part of the trials and were professors in the college.
6. Basic tenets of informed consent were violated. Code of MCI Act 1958 (20A) in respect of Professional Conduct was violated.
7. Government banned all new trials in the state on 29th October, 2010.

Dr. Anand Rai, Whistle Blower Indore Drug Trials

Indore is surrounded by backward and predominantly tribal areas. A lot of poor people from such areas travel to Indore to avail the medical services and hospitals in Indore. Indore also has a good air connectivity which makes it a hub for clinical trials in India. These poor people hail from backward areas and being illiterate are easily fooled by doctors to undergo clinical trials even without obtaining their consent.

Many RTIs were filed in this regard and a lot of information was obtained. A complaint was then made to the Madhya Pradesh Economic Offences Wing which investigated the clinical trials taking place in the Maharaja Yashwantrao Hospital. It was found that 73 trials were carried out on 3300 people out of whom 1833 were children. 81 people including 18 children suffered adverse effects which included death

Ethics committees are the most corrupt and do not do their jobs.

as a result of these trials. The RTIs also showed that these trials were sponsored by 8 Indian pharmaceutical companies including many multinational corporations. These trials were carried out by six senior doctors who were paid Rs. 5.1 crores by the companies. There are other instances as well where ayurvedic trials were carried out by allopathic doctors on 116 patients. Another example is where trials of drugs for premature ejaculation were carried out on mentally retarded persons instead of healthy persons. Another example is of a kid named Yathart Naik, on whom polio trials were done, which gave him white spots. The family filed a complaint but the FIR has still not been lodged.

Name of companies who sponsored clinical trial in Indore

- 8 Indian companies and institutions sponsored these trials while multinational sponsorship was of 22 companies and institutions

Indian:

- Cipla Pharmaceuticals, Panacea Bio-Tech, Cadilla Pharmaceuticals, Ipca, Serum Institute of India, St. John's Medical College and Population Research Centre Bengaluru, Himalaya Drugs

The ethics committees for criminal trials are strangely constituted. In the MGM Memorial Medical College Ethics Committee, out of 27 members, 22 members were part of the trials and were professors in the college. Netaji Subhash Chandra Medical College and Hospital, Indore, both have ethics committees chaired by Veterinary Doctors. Ethics committees are the most corrupt and do not do their jobs. Members of the Ethics committee were the principal investigators in many trials. They failed to follow Good Clinical Practice guidelines and ICMR guidelines. Basic tenets of informed consent were violated. Code of MCI Act 1958 (20A) in respect of Professional Conduct was violated. The trial process too was not transparent.

After protests against unethical clinical trials in Indore, the MGM Medical College organised a public hearing on 30th October, 2010.

168 persons deposed before it and gave suggestions. The Government also constituted a committee headed by the Principal Secretary, Medical Education to look into irregularities, which banned all new trials in the state on 29th October, 2010.



Sandhya Srinivasan

TRIALS AND MORE TRIALS

HIGHLIGHTS

1. As of 31 December, 2010 670 trials opened for recruitment
2. Clinical trials are done through contracted research organizations (CROs). These CROs offer all kinds of services like trial design and patient recruitment. There are about 130-200 CROS in the country.
3. The majority of people come because the doctors who told them to come said they came for higher care or free care.
4. Even the best-intentioned ethics committee doesn't have the capacity to review the trials.
5. DCGI is supposed to regulate clinical trials but does not.

Ms. Sandhya Srinivasan, Indian Journal of Medical Ethics, INFOCHANGE News and Features

The Indian clinical trials are growing because of the low costs, large population and there are people who need treatment which makes it very easy to do especially where there are incentives like tax exemptions. 670 trials opened for recruitment as of Dec. 31 in 2010, the largest drug group being tested is cancer drugs. One implication is the drug industry is the major sponsor of drugs and a large number of them are foreign companies looking to make expensive cancer drugs, which would not be made available in India. People here are desperate for healthcare because public healthcare is inaccessible and private healthcare is unaffordable. There are increasing reports in the press on drug trials resulting in deaths or injuries.

There is no clear information on the deaths, no guarantees of money or medical treatment for injury or death resulting from the trials.

Clinical trials are done through contracted research organizations (CROs). These CROs offer all kinds of services like trial design and patient recruitment. There are about 130-200 CROs in the country. This is not real research that's happening, they are conducting drug research looking towards marketing.

The Subject of recruitment is the single dominant theme in the CRO meetings. They work with administrators, doctors and NGOs. They access private hospital databases and develop their own databases through health schemes like health education trainings and offers of

free services. There is a conflict of interest as well since they give about 60,000-120,000 rupees per patient recruited. Why do patients come to trials? The majority come because the doctors who told them to come said they came for higher care or free care. Doctors say people come to the trials because they can't afford quality care and some treatment is better than none. DCGI is supposed to regulate clinical trials but does not. The fact is that even the best-intentioned ethics committee doesn't have the capacity to review the trials. Some ethics committees will review trials for a fee. There has been an increase in deaths in clinical trials but very few of the deaths received compensation and only in recent years has any compensation been made. There is no transparency, all the information we have is being put together through going to the press and parliament. We need transparency on the trials because there is no clear information on the deaths, no guarantees of money or medical treatment for injury or death resulting from the trials.

Increasing reports on unethical /illegal trials

- **Bangalore:** infant with cardiac condition died in a pneumococcal vaccine trial restricted to healthy infants
- **Hyderabad:** adult died in a bioequivalence trial reportedly after participating in many such trials for the money
- **Gujarat:** charitable hospital accused of carrying out company-sponsored trials without IRB approval
- **AP and Gujarat:** 25,000 girls from vulnerable groups enrolled in vaccine trials without consent, adverse event reporting or follow-up
- **Indore:** government hospital doctors conducted 76 clinical trials on over 3,000 patients, receiving Rs 5 crore
- **Bhopal:** Gas disaster survivors enrolled in trials without consent
- **Hyderabad:** CRO administered women cancer drug without consent

Media reports

There are rough guidelines being discussed for finalization.



Anubha Rastogi

MATERNAL DEATHS: WHAT ONE JUDGEMENT CAN DO

HIGHLIGHTS

1. When a mother dies, when injustice happens, bring it into the ambit of law, file a case, go to the consumer court, do something.
2. Documentation is very, very important
3. A good case and a good judgment will have a domino effect
4. Women's reproductive rights is part of her health rights and part of her fundamental rights.
5. A home maker is a breadwinner and her family is entitled to compensation.

Advocate Anubha Rastogi, HRLN

What is most important is that irrespective of the number of mortality and mobility issues, bring it into the ambit of law, legal system. If you do not want to go to the court, you should go to either the consumer court, women rights commission, write to the collector, do something. This is to keep an account of the number of cases, which the Government will not consider but these other law bodies mentioned above will consider.

For further details on these cases and their numbers, one may refer to the HRLN website.

Let me tell you about a Delhi case, which started with a newspaper report. Shanti Devi was carrying a dead fetus in her womb and was not given medical assistance. This news was in the city edition of a newspaper. Activists went to her house to find out about every step she had followed and matched it with the constitutional rights and filed a petition. What is important is the documentation.

The Judge, Mr. Murlidhar was supportive of the movement. That made their job easier. He tried to put pressure on the Government to get this Act together but unfortunately during this period she was pregnant again and due to ill health she passed away. Yet the case was heard. Her family received compensation and the people of India received one of the finest judgments which has the domino effect.

Another case which we had documented and again was in the newspapers was in Jangpura not very far from where HRLN office is situated. A woman gave birth to a child right outside a MCD maternity centre and nobody bothered to take care of her. We added this case to the earlier one and that is what is called 'Laxmi Mandal vrs Deendayal Harinagar and others'. Copies will be supplied if necessary. The path breaking judgement made it very clear that women's reproductive rights are part of her health rights

and part of her fundamental rights. Family is entitled to compensation. Compensation for the loss of bread winner. The court considered home maker also as a breadwinner. Compensation was given to their family members. The judgment highlighted that in this case JSY was not implemented. The court held the Government accountable for non implementations.

The judgment unequivocally stated that women's right to reproductive health is part of her right to health which is further part of her fundamental right. In this case, apart from an individual monetary compensation, Shanti Devi's family got compensation under the 'National family bread winner scheme'. The connection of a woman being the bread winner for the

The connection of a woman being the bread winner for the family was thought of the first time in a judgment

family was thought of to the first time in a judgment and thus, the family got compensation on her behalf. This judgement highlighted how JSY is not being implemented and how Government under the garb of saying that there is still confusion between JSY and MBS, makes various excuses. The final outcome was that you have to give JSY and MBS and you better start giving it right away. This judgement is the best example so far and they had also quoted other law of similarly placed countries, such as Nepal, Bangladesh etc. Another case, in C.P., Delhi a woman gave birth on a street and she died. Justice Murlidhar wrote a letter to Chief Justice and said that the court should take cognizance on its own and it did so happen and Jaishri and Collin were appointed as amicus curiae. They managed to get orders to set up five shelter homes for the homeless, pregnant, lactating women. The one initial case acted like

a domino on who's one good order they are furthering their steps. In the Delhi High court, instead of somebody forcing this issue on the judges, they themselves are responding and picking up this issue.

Let me now move to the States : Deaths in Umaid Singh hospital in Jodhpur we have already discussed elsewhere in this right. We filed a PIL after all this documentation but unfortunately it has not been heard yet, as the Judge sits in Jodhpur and Jaipur, hence the delay. In this case, the documentation was very easy. Another case: Maternal deaths in Barvani, in 6-8 months there were 29 'documented' deaths in the District hospital. As comparison with the Jaipur case, the Barvani case is the most documented case. In spite of a documentation made by all the law bodies such as health ministry, civil society, state Government nothing was done. It was clear that the health infrastructure was problematic.

The Court has ordered to set up five shelter homes for the homeless, pregnant, lactating women.

Thus, we went ahead and filed a petition. Going to court is 'one' of the solutions but isn't the ultimate solution and does not mean that we give up on advocacy, pressure building or your own etc. In the Barvani case, another strategy followed was of 'Dharna'. 'Jagrit adivasi dalit committee' got together and did a dharna. A lot of cases were filed against them, FIR's got

written and we're still fighting those cases. In the Barvani case, the District collector has given a report and we are relying on his report (respondent's own report). Hence, the state cannot come and turn on us. We only want them to address the violations which they have given us in the report. There is also an Expert committee, the AGCA report, which we had filed. Recently, we have got the AGCA interim model but the court is saying that this report's guidelines have to be implemented and the state of Madhya Pradesh has to give a timeline by which the state will implement these guidelines. If they fail to implement, they will have to give an explanation.

The point to be noted here is that the Union of India has already given the funds to the state. NRHM is not a law, hence the Judges will not know about it. Therefore, we have to begin with training the Judges on how NRHM works, what it is and how it started in 2005. It was to gear up in 2007 but nothing was done and immediately the state comes and tells the court that staff have been shuffled, drugs have been purchased, hospitals have been cleaned but it was too late then. Why this is relevant is because in the court, they show the amount of work done on the affidavit whereas we come to know of the real work done by the civil society which feeds us with facts. This kind of relation is very important. The court is a part of the bigger system which is slow, and thus cases may take time. Otherwise, we can put some pressure on the judges, depending upon the nature of the case. If the case takes a lot of time, we have to maintain patience.



Dr. Narendra Gupta

MATERNAL DEATHS IN JODHPUR



Shashi Tyagi

HIGHLIGHTS

1. In a recent case, 29 women died in 15 days in two government hospitals in Jodhpur
2. Health centres in the village are either located 4 to 5 kms away from the villages or have garbage dumps or gutters next to them, thereby promoting unhealthy and unsafe environment.
3. The Government of India team found that the theory of contaminated IV fluids that was being propounded was false because about 5000 bottles of these IV fluids were supplied to different wards of the hospital. But deaths were reported only in the maternity ward.
4. In Rajasthan since the government doctors are allowed legally to do private practice, their performance in these government hospitals suffered hugely. Government doctors seem to treat government facilities as a parking place to admit their patients, and do not take their official administrative and clinical duties seriously.
5. These families were under heavy debts because the doctors had made them spend Rs. 60,000 to Rs. 3 lakh for buying useless and expensive medicines.

Ms. Shashi Tyagi is the founder of Gravis dedicated to Gandhian values and upliftment of desert regions in Rajasthan.

Between February 13 and March 18, 2011, a total of 18 women lost their lives while admitted in Umaid Hospital and the MG Hospital, Jodhpur, for medical management of their pregnancies (1). The majority of these women were from villages and all were from weak socio-economic backgrounds. Two of them belonged to families identified as being below the poverty line. Of the 14 women who died in February, eight delivered through lower segment caesarean section. Four underwent hysterectomy. One also had emergency surgery to stop excessive internal bleeding.

An investigating team constituted by the People's Union for Civil Liberties (NG was one of the team members) visited Jodhpur on March 2 and 17. The team interviewed the families of some of the women and studied documents given by family members.

What we do know

Hospital reports indicate that all the women died of excessive bleeding linked to various causes including severe infection, kidney failure, respiratory distress, pregnancy-induced hypertension, and premature detachment of the placenta.

These women came from poor backgrounds. Some of them might not have otherwise gone to a hospital. But they believed that they would get good care in a public hospital through the government's Janani Suraksha Yojana. The JSY is based on the premise that maternal mortality can be reduced only if women have access to effective emergency obstetric care and therefore encourages institutional deliveries by paying women cash incentives to have their babies in a hospital setting, as well as for transport in an emergency and for caesarean delivery if needed.

The government's response to the deaths seems to be haphazard and not based on a

thorough investigation into the deaths. A total of seven investigating teams, including those from the state and central governments, the national human rights commission and the national commission for women, have visited the hospital but no final report has been made public. These teams are apparently unable to arrive at a conclusive statement on the causes of the deaths. When laboratory tests conducted in the hospital found bacterial contamination in a batch of the intravenous fluid used in the hospital, the manufacturer, the local distributor, hospital officials and drug inspectors were arrested but then released when the lab test was found to be substandard. Three new samples were sent to a "level 3" laboratory in Kolkata and one of these three was found to be contaminated. However, deaths have been reported among women admitted well after the suspect IV fluid was removed from circulation. A fumigation machine was ordered from Delhi, implying that standard disinfection practices at the hospital are insufficient. A team from the Post Graduate Institute of Medical Research (PGIMER), Chandigarh, gave a clean chit to the doctors and hospital, but on March 17, the state government suspended three senior doctors for supervisory lapses on the basis of a report by the divisional commissioner of Jodhpur (1-5). Based on the report of the central team, the Union Health Minister wrote to the state's chief minister on March 14 asking for a ban on private practice by government doctors (7). Indeed, one should ban such private practice. Government doctors seem to treat government facilities as a parking place to admit their patients, and do not take their official administrative and clinical duties seriously.

Some questions

While these teams have been unable to clearly identify the causes of these deaths, the general background in which they have occurred is a matter of concern. We must take note of

the complex of factors influencing healthcare in hospitals like Umaid and MG: absenteeism among senior doctors who are meant to be on duty, the lack of cleanliness, and the poor quality of care.

These deaths also raise a number of questions.

First, are so many deaths in this time period uncommon in a tertiary women's hospital like Umaid Hospital? Or are these just routine? Did they just happen to catch the attention because of media reports? Umaid is a 200-bed specialty government hospital attached to the Dr SN Medical College. A number of well-qualified doctors are posted there and engaged in teaching medical students in addition to treating a large number of in-patients. The hospital

On what basis did the authorities conclude that contaminated IV fluids were the immediate cause of these deaths?

Did the women get rational treatment?

Were routine standards of infection control being followed in the first place?

has all the required equipment and facilities but it is poorly maintained, pathetically unhygienic and certainly a breeding ground for infections. There is no publicly available information on the record of post-surgical infections at the obstetrics/gynaecology departments of Umaid and MG hospitals. It is not known whether regular maternal death reporting and review processes are in place.

Second, on what basis did the authorities conclude that contaminated IV fluids were the immediate cause of these deaths? In addition

to the 18 women who died, countless others were given the IV fluid of the same batch. According to the company's statement, there were approximately 25,000 bottles of IV fluid of this particular batch. 5,000 were supplied to the three government hospitals and some shops in Jodhpur, Out of these, 2,800 were already consumed in the hospital. The remaining 20,000 were sent all over India. But the same reaction has not been seen elsewhere. These fluids were also used in other departments of the same hospital where no adverse event has been reported. Further, deaths were reported of women who were admitted to the hospital after the IV fluids were withdrawn. Third, did the women get rational treatment? A review of available reports suggests that some of the procedures were not indicated. For example, it is a common practice in big hospitals like Umaid to give IV fluids even in an absolutely normal delivery. Likewise, not all the women may have needed caesarean sections and some of those interviewed by the PUCL team suggested that junior doctors may perform unnecessary C-sections in order to get experience in the procedure. What is the C-section rate of this hospital?

Fourth, were routine standards of infection control being followed in the first place? This is the same hospital at which, about one and half years earlier, a number of children with thalassemia were infected with HIV, and others acquired hepatitis, through blood transfusion (6).

Healthcare for India's poor

The deaths also highlight the larger context of healthcare in India. Most patients who go to government hospitals like Umaid and MG do so because they cannot afford the huge expenses of private hospitals but need the super-specialty services available at tertiary care centres. But they pay for services even in public facilities. Though all the women who died

were from the poorer sections of society, their families ended up spending from Rs 60,000 to Rs 3.5 lakh. Many of them will have borrowed this money at very high rates of interest. The bulk of this money was spent on medicines. One young man spent Rs 3 lakh to save his wife but to no avail. He could manage the amount because he was from Jodhpur and because the extended community pitched in. One of the (injectable) drugs he was asked to buy, tigecycline, cost Rs 3,000 per vial. If this injection was required, the hospital's Medical Relief Society (Rogi Kalyan Samiti) should have underwritten the expense but did not do this. Instead the dead women's families have had to bear the financial burden, even in this public facility.

The Rashtriya Swasthya Bima Yojana, the government health insurance scheme, is non-functional in Rajasthan. But even if it worked, it has a piffling Rs 30,000 limit and that too for families below the poverty line (BPL). There is another scheme in Rajasthan - Mukhya Mantri Jeevan Raksha Kosh - where BPL card holders can be provided unlimited free medication. The families of two of the women who died had BPL cards but even these women were not provided free medicines. When a poor family does not have a BPL card the doctor in charge of the unit has the authority to waive the hospital's user fees and provide medicines free of cost. But this discretion in support of even the genuine poor is rarely exercised. It certainly was not exercised in the case of the women who died at the government hospitals in Jodhpur.

Another closely related question concerns the high prices of medicines. Many essential drugs escape the National Pharmaceutical Pricing Authority's price control net. Despite the government of Rajasthan's strict orders, doctors and hospital staff prescribe very expensive, branded medicines though far cheaper generic versions from the same companies are available.

Further, in the absence of any prescription audit, it is a rampant practice amongst doctors to prescribe unnecessary and expensive medicines. Some of the women were administered the drug tigecycline which cost Rs 3,200 per vial. While there are no cheaper versions available of this drug, was there a less costly alternative? In any case, we need a strong national policy on antibiotic usage.

Government policies: adding fuel to the fire

It is also common knowledge that many government doctors, especially senior doctors, are engaged in private practice after hospital hours. A large number of patients wait at these doctors' residences to consult them for a fee. The Rajasthan government allows government

One young man spent Rs 3 lakh to save his wife but to no avail. He could manage the amount because he was from Jodhpur and because the extended community pitched in. One of the (injectable) drugs he was asked to buy, tigecycline, cost Rs 3,000 per vial.

doctors to carry on private practice at their residence. This is a major cause of neglect of patients admitted in the government hospital because in an emergency government doctors are not available. Even during hospital hours, these doctors tend to care for those who have visited them during their private practice and paid fees. One major finding of the central government team which visited Jodhpur to investigate the maternal deaths was that surgical interventions were done by the junior doctors in the absence of the senior doctors. This team reportedly also commented on the poor

standards of teaching. It raises doubts as to whether parameters of quality and treatment protocols are ever followed in this hospital.

The incident also shows the lack of wisdom in propagating institutional deliveries using the carrot of money in the Janani Suraksha Yojana (JSY), the national scheme to reduce maternal mortality. The JSY has been introduced without proper preparation of hospitals at the district and taluk levels for such emergencies. Such preparation requires qualified and competent personnel and a functioning infrastructure within the hospital, as well as suitable access to it. This is one reason why, across the country, with the possible exception of Tamil Nadu and Kerala, maternal mortality seems to have increased after implementation of this institutional delivery policy. The policy has also deskilled auxiliary nurse midwives, some of whom were earlier conducting deliveries at the subcentres (no longer recognised as institutions in the JSY scheme) and marginalised traditional dais. The most vulnerable women in society are being made to abandon the tried and trusted system of dais and opt for a more modern system though the elements are not in place that will assure quality of care in this modern system. This is a letdown of the worst kind. Further, the focus on institutional delivery has come at the risk of neglecting antenatal or postnatal care.

Ensuring accountability at the top

The PGIMER panel, which visited the hospital on March 14 and March 15, 2011, did not find fault with the doctors and reportedly confirmed that it was indeed contaminated ringer lactate intravenous fluids that caused the deaths since February 13 at the hospital. Nevertheless the very next day, three doctors were suspended (7). It is unclear on what basis the doctors have been suspended. Without a proper understanding of the problems in-

involved, such an action seems to be an attempt to give the appearance of action instead of really addressing the issues. And then why only these three doctors? What about the medical superintendent? What about the medical college principal who is the head of all the hospitals in this group? Or even the health secretary, or the health minister? Nevertheless, the suspension will be salutary if it is followed by appropriate improvements in the delivery of quality healthcare and also in procurement and storage procedures being done systematically and with transparency, in these hospi-

Across the country, with the possible exception of Tamil Nadu and Kerala, maternal mortality seems to have increased after implementation of this institutional delivery policy.

tals and everywhere else in Rajasthan's public hospitals. There have also been arrests of the manufacturer, the local distributor, the drug inspector and the hospital storekeeper, as well as the trader who contracted with the hospital to supply the products of specified companies - though, curiously, the IV fluid in question was not one of the products approved in the contract. The Indian Penal Code's Section 328 (putting a person's life under threat) applies to all the actors in the system, not only the manufacturer and the local distributor. Likewise, the company under whose license the IV fluid was manufactured should also have some responsibility.

One does not know how these suspensions and arrests will eventually pan out. Probably everybody will be back in business in a few months, as happened after the children were

transfused HIV-infected blood, public memory being short. Regardless of what the investigations finally conclude, there is a need for a stricter process for checking IV fluids and parenterals in general; both the drug authorities and the company itself should be picking up random samples more frequently. Loan license of parenteral manufacturing facilities, as well as loan license and contract manufacturing in general, should be stopped.

The reaction of drug authorities at the higher levels would be to increase the quality norms by requiring more costly equipment and infrastructure. Schedule M certification (the top quality certification in the country awarded by the Drugs Controller General of India) was supposed to certify a company's quality norms in production. Missed in this effort to improve quality by adding new technology is the art of how to produce aseptic facilities and good quality medicine with optimal technology. More technology or more equipment is not the answer, as one tends to sacrifice basic commonsense about asepsis at the altar of technology.

An initial fact-finding report indicated that six of the 14 women (later the number climbed to 18) may have succumbed to "pre-existing medical conditions and natural causes." (5) If this is so, we must ask why the system did not have procedures in place to alert doctors to take additional precautions. If these pre-existing diseases cannot be managed in a tertiary level hospital like Umaid, where else can such women go? This is the second biggest women's hospital in the state of Rajasthan and equipped with all facilities.

The message has to be sent to all that most maternal deaths are preventable. And institutional delivery is only one of many indicators of maternal healthcare. Concerns about the quality of maternal healthcare start from the day that a woman conceives, actually even

before that. This is about how important the health of women is considered across the life of a woman.

The affected families in Jodhpur - and other potential future users of the health system - would like to know what systems and procedures will be put in place so that a repeat of the tragedy will not occur, adding to the statistic of the 80,000 maternal deaths every year in India. Till then the health rights of women and children - guaranteeing the availability, accessibility, acceptability and quality of such health services - stand violated.

The 39 women died during child birth. As is evident, they were in a perfectly healthy condition quite contrary to the understanding that the chief minister of Rajasthan was given

The labour room of the Umaid Singh Hospital is a picture of neglect and filth. There are no beds, no sanitation and no privacy for pregnant women. CNN-IBN Reporting on the maternal deaths in Jodhpur

about their deaths. He was told that the health condition of these women had deteriorated to such an extent that the doctors could not do much to save them. But that was not the case. This was what proved very unfortunate for them. Jodhpur Medical College is Rajasthan's second biggest medical college with which is attached this Umaid Singh Hospital for women. There is no dearth of trained human resource in this hospital.

Dr. Kirti Iyengar and I conducted a survey in this region from the families which were affected to find out from their accounts what all lapses they had found in the functioning of the doctors in the hospital.

Later on the Government of India, Ministry of Health and Family Welfare which conducted a thorough investigation into the matter, almost a sort of clinical audit and their findings were far more revealing. They found that the theory of contaminated IV fluids that was being propounded was false because about 5000 bottles of these IV fluids were supplied to different wards of the hospital. But deaths were reported only in the maternity ward.

We conducted interviews with the husbands of 16 women who had died, as a sort of maternity death autopsy.

We found that in Rajasthan since the government doctors are allowed legally to do private practice also, their performance in these government hospitals suffered hugely. They were devoting too much time to their private practice and consequently they would not give much time to teaching, or building up on their clinical skills. We have been raising this issue with the government of Rajasthan.

We were informally told by some very senior members of the government of Rajasthan that they could take some strong action only if we were able to generate a considerable amount of pressure on them through courts. Even the Union health minister holds a very strong view on this issue. One of his statements was published in the Times of India addressed to the Chief Ministers of all states that with the advent of sixth pay commission, government doctors should not be allowed to do private practice because it is a major cause of negligence in duty.

The management protocol was not followed by the doctors. When the Government of India's report came and it was found that it was adversely against these doctors, they immediately called a two member team of doctors from PGI Chandigarh who gave a two page report

giving them a clean chit. This was done just to contradict the government's report.

Shashi Tyagi adds

I am here to share with you all the existing state of maternal mortality in Jodhpur, Rajasthan. We were involved in a number of rallies spearheaded by Vinobha Ji in Rajasthan.

Our protests have been on for a year. We took up cases of several women facing problems during their pregnancy period.

During one of our rallies around village in Jodhpur, we met a woman who was going through her 8th pregnancy. We reported her case to the sarpanch and requested that her case be referred to Jodhpur hospital. The sarpanch gave his commitment to ensuring that she receives proper medical care.

The women in the villages are subjected to a lot of problems. The in-laws are harsh on them and their own families are no different. The same happened in the case of this woman. Her mother in law objected to her being taken to the hospital because that would mean no one in the house to take care of the rest.

Looking at problems emerging from such situations, we started to train mid wives. Though we are making consistent efforts at improving the village maternal conditions, the government on the other hand is obstructing our work by imposing several measures.

There existed a job of a Dai (traditional birth attendant) a few years back but the government has now stopped supporting her.

In a recent case, 29 women died in 15 days in a government hospital in Jodhpur.

Many of these women came from interior villages. The doctors on being questioned claimed that defective IV tubes caused the deaths. The

families and relatives of the victims on the other hand are convinced about negligence on part of the doctors. A group of young people in Jodhpur also expressed their support by investigating into the matter.

On 8th March, the day of International Women's day, a protest was organised and we marched to the district collector's office. When we reached his office, we were stopped from entering his office premises. A tehsildar came out to meet us. The Collector we were told was on leave.

Thankfully, the government did take notice of the matter and resulted in serious actions against Unmed hospital.

Umaid Singh hospital is the only Government hospital in Jodhpur and it conducts around 70 deliveries on a daily basis.

Looking at the increasing number of maternal deaths, the government needs to take serious steps to improve the health conditions. On coming to the city hospitals for treatment, the people from villages are ill treated and insulted. They are often neglected and denied treatment on not having enough money to afford the expenses.

If you look at the public health situation around Jaisalmer, there is a widespread lack of surgeons and gynecologists. Private practitioners are present in high numbers in villages. The number has increased to such an extent that the Dais have reported about the threats received when they carry on with their work.

The presence of ASHA hasn't really proved beneficial as she lacks technical knowledge and haven't received the required training. Also in many places health centers are not accessible.

Either they are located 4 to 5 kms away from the villages or have garbage dumps or gutters next to them, thereby promoting unhealthy

and unsafe environment. In fact one of our major initiatives was the setting up of Janani (women's) Helplines to help pregnant women.

The government forced us to close it. All of us who were part of this initiative had invested from our own pockets. The government never compensated us for it.

To act against its people has become the rule of the government. When something proves to be effective, the government wants to close it down. The high rate of political interference is another matter of concern.

The absence of the blood banks is another factor contributing to the increasing number of maternal deaths. The village health centres are in a neglected state and there is a huge lack of resources.

The condition of the cities and its hospitals is no different. There is a huge shortage of hospitals in the cities as well. This year there were 69 deaths reported due to defects in the IV fluid. Although compared to last year's statistics, there is a comparative decline in the number of deaths this year. But still there is a lot that needs to be improved.

Additional facts

1. Many of these women, in their advanced stage of pregnancy came from far-flung areas of Barmer, Jaisalmer and Jodhpur districts which lack facilities for obstetric care. Some of them had traversed more than 300 kilometres for something as basic as childbirth
2. The State has the third highest maternal mortality rate (MMR) in the country, at 388 per 1,00,000 births.
3. Umaid Hospital is overburdened. It is equipped to conduct only 40 deliveries a day but 70 deliveries take place each day that is more than 20,000 deliveries a year.

4. On some days the corridors of Umaid Hospital would be filled with patients.
5. The families of the women had to pay for medicines and for blood and plasma transfusions.
6. As many as five committees, including one by the Central government, were constituted to inquire into the incident.
7. Referral systems are totally absent in the rural areas. "There is a reason why they come here. The primary health care centres [PHCs] and the community health centres [CHCs] are not at all equipped. They have neither personnel nor infrastructure.
8. What is the point of appointing a gynaecologist at a PHC without providing for other enabling infrastructure and personnel?
9. Even if the hospital was overburdened with patients, it was common knowledge that almost all the senior doctors had a flourishing private practice, which on many occasions was conducted when they were required to be at the hospital.



Dr. Amita Dhanda

RIGHT TO MENTAL HEALTH

HIGHLIGHTS.

1. Mental health is a very neglected aspect of the right to health. For mental health there is a law but the law is flawed.
2. The Mental Health Act has only succeeded in making marginal people even more marginal than they already are.
3. The right to mental health needs to be a universal concern.
4. Mental Health Act does not address the whole issue of care.
5. The law has a process for admission into institutions; it does not have a process for exit.
6. Once you put people inside institution, a law has a process for admission; it does not have a process for exit.
7. Mental health act does not address the whole issue of care. The law is primarily talking in terms of the process by which people can be put into institutions.
8. Distinction we have made between physical and mental is in itself problematic.
9. There must be a process much more human than just say go and find the family and send the person back to the family.

Dr. Amita Dhanda is a Professor and Head, NALSAR University of Law, Hyderabad.

We are looking at this interplay between law and public health. What comes to me very strongly was one that in a number of places we are talking in terms of law being there but not being observed. So you talk of something was required to be done but was not done. "I complained here, complained there but no one heard me." This is one kind of scenario which came through in a number of presentations. The other scenario is law should have been there but it is not there. There is no control, no norms and not standards and hence no protocols either.

I want to take the third area that's how I see the whole realm of the mental health law. Yes there is a law. But the law is governed by the values which are fundamentally problematic and they are problematic because you look at people with mental illness as not subjects but as the objects of the law.

The fundamental distinction, I want you to appreciate is we are talking in terms of clinical trials being practiced on a whole range of vulnerable population and this is undesirable but this is not something given by the law. This is something which is happening where social practice is operating in a manner where the powerless because of the absence of law are being disempowered by the social medical practice.

I am talking about the situation where the powerless are further disempowered by the law. It's also true if you have a law which if gets implemented is going to make things even worse that you look at the situation you are in. How and why does law come into the field of mental health?

Law comes into the field of mental health to legitimize the use of force because if I want to compulsorily treat somebody, I cannot do so without the operation of law. So if you are going to have compulsory care, you cannot possibly do it without the authority of law and then

you go ahead and make this possible. In the sense of wanting to go ahead and say alright this happens, may be the underlying emotions are favorable one. But what you are doing by terms of law that once I get categorized as a person with mental illness, then to consult me is no longer an obligation. In other areas of health the patient is consulted. The question what is in the best interest of the patient is asked. Not so in mental health

I am not in any way downsizing the importance of the any other issues we raised in relation to access to the physical health care. The distinction one has to appreciate, that is when we are speaking in terms of access to physical health care, we are talking in terms of those ridiculous informed consent forms. At least there is need to get those forms signed.

Mental health act does not require a psychiatrist's certificate to institutionalize you. Any two doctors can give you a medical certificate and the doctor does not even have to be an allopathic doctor.

But when the law itself says that they need not take consent from this individual person but somebody else can provide this consent then evidently the person who is on the receiving end of that kind of illegal consent is much more disempowered because both social practice and the law are speaking the same language.

I am talking about the whole area of mental health care and that's what we need to be worrying about. Evidently that's the way in which the Mental Health Act has been formulated. It is forced treatment on disempowered person in the society.

The previous session was talking in terms of clinical trials demonstrating to you on very strong basis what was happening. If you do not have a law and you still want to do it and there is a lot of money driving whom do you pick up?

You pick the most disadvantage ones.

If you have a law which allows you to do it, still the most disadvantaged will get the worst of it. That's where the gender connection comes in. The last point I wish to make. The entire programme is somewhere stressing on demonstrating the fact of right to have universal concern. It is acknowledging the fact of individuality.

The right cannot be limited to having treatment that too forced treatment. You will have to see the connection between food and health. If I do not have proper nutritious food, I am going to be unhealthy. If there are disasters, if there is loss of lives, if there is violence these are all the factors which necessarily cause loss of mental health. We do not want to address those root causes.

We want the people who are mentally sick to be treated forcefully. What are we doing?? We need to speak in terms of individuality of rights, we also need to speak in terms of universality of health.

I think mental health is also everyone's need and everyone's right. We need to conceptualize the mental health in a manner where none of us should say I need mental care tomorrow and then I am a person who somewhere is inviting a lot of forced interventions myself.

Mental health laws sometimes get misused and wrong kind of people are put away in the institutions and consequently that is wrong. We need to improve implementation; we need to give good training to judges so that this kind of thing does not happen. This is the general impression. I am raising something more fundamental.

I do not think this is an implementation question. I think if you have a particular law which has got the wrong kind of values then it gets implemented that way. But evidently the very fact when you have something which has misuse written into it, if then misuse happens... why are we surprised?

Mental health act does not address the whole issue of care. The law is primarily talking in terms of the process by which people can be put into institutions. The point I am making is basically this, the way in which you are addressing the whole issue of people who have a diagnosis of mental illness is the moment the person gets a diagnosis of mental illness somewhere the person gets totally decentred from his or her own treatment and the law actually sort of proceeds on that basis the person does not have to be consulted. You can go for compulsory care.

Your second point of public health bill. The distinction of dichotomy physical and mental health is itself problematic. There is a close connection and it happens when you are not mentally well, it will have some impact on your physical health. So this distinction we have made between physical and mental is in

The reason why the women's wards are badly kept and men's wards kept in better position because the men with mentally illness get more visitors than women patients.

itself problematic. The point you were making about the wholistic health I am in total agreement. Mental health is not something that you can address as totally diagnostic category. The point you were making. I have only one problem. You were right we can use that, as per law we can use that but when a person is mentally ill then hospitals are not the only thing that can

help them. It's not difficult to go Supreme Court to ask hospital to give your money back. It is extremely important to ask further question whether you should ask for that precedent.

Once you put people inside an institution, a law has a process for admission; it does not have a process for exit. Across all the courts even high court the only think they do is go and find the family. Very often people are in institutions very far from their home because they are in conflict with their family and that sort of scenario we have to think in terms of rehabilitation and letting them as individuals find another life.

There must be a process much less complicated than just say go and find the family and send the person back to the family. We need a

programme which is more understanding and more respectful of personal dignity of people.

Mental Health Act does not require a psychiatrist certificate to institutionalize you. Any two doctors can give you a medical certificate and the doctor does not even have to be an allopathic doctor. You are talking in terms of all medication. The two certificates can be the basis of your institutionalization which often means shutting them out for ever.

If you want to go and meet a mental patient, you cannot do it. You would not get the permission to go in there. The reason why the women ward are badly kept and men's ward kept in better position because the men with mental illness get more visitors than women patients.





Dr. Shakeel Ahmed

STORY OF THE PATNA PIL

HIGHLIGHTS

1. We filed a PIL IN 2009 regarding the maternal health situation in the area
2. In Bihar we have a very weak infrastructure and that reflects in maternal mortality rates.
3. For the mothers to receive the money given under JSY (Rs. 4,000 they will have to spend 1,000 to 1200 to get this money because they have to hire the transport to get to the hospital, pay for injections etc.
4. We filed the PIL in 2009 and we are heard in 2012
5. A public health official should always be besides the lawyer while drafting the PIL.

Dr. Shakeel Ahmed is the founder of Centre for Health Resource Management.

For the PIL that has been filed in Patna I am the sole petitioner.

This PIL was initially filed by two petitioners but because the process of the hearings and documentations took a long time and during this time the other petitioner became a minister in the Government of Bihar so she withdrew her name and I was left to be the lone petitioner.

We filed a PIL regarding the maternal health situation in the area. We along with HRLN did our inquiries at District Hospitals, Primary Health Centres and Sub-Health Centres and we interviewed beneficiaries who were denied services at these hospitals.

As you know in Bihar we have a very weak infrastructure and that reflects in maternal mortality rates. Although Bihar's maternal mortality rate came down in 2010, this year the maternal mortality rate is 305.

It's not only the maternal mortality that is the issue here as there are many more denials under cash benefit schemes than deaths. We have found that for the mothers to receive the money given under JSY (Rs. 4,000 they will have to spend 1,000 to 1200 to get this money because they have to hire the transport to get to the hospital, pay for injections etc.

We have deficiencies in the primary health system to the tune of 78 of Primary Health Centres.

The provision of free ambulance service is a sham, everyone has to pay for transportation and the price of this transportation is fixed by the government.

They have to buy injections to induce labour and if the injection is not used they don't get their money back but the medicine goes back to the pharmacy. The mother has to pay money to get the umbilical cord cut and you have to give tips if it is a male child.

This is a systematic problem. These denials are happening day in and day out at least in the hospitals in Bihar. It takes a very long time to get legal redress for health issues.

We did the inquiry in 2009 and we will be heard in Jan 2012.

What could be the process so the delays could be minimized? As is, it becomes a very painful and slow movement. I request HRLN to look into this.

Also I would request that while preparing the documents for technical correction and technical facts a public health official should always be besides the lawyer while drafting the PIL.



Dr. R.N. Singh

JAPANESE ENCEPHALITIS: THE CRY FROM GORAKHPUR

HIGHLIGHTS

1. I will confine my talk to 10-12 minutes only. Encephalitis as we all know is famous in Gorakhpur and Gorakhpur is famous for encephalitis though this is a disease which is prevalent in about 21 provinces of the country.
2. Japanese Encephalitis is a disease which initially starts with high grade fever, convulses, fits, vomiting and ultimately coma.
3. Casualties under one roof BRD Medical College, Gorakhpur is about 500 to 600 per annum for the last 33 years.
4. In 2005 65 lakh vaccines were given for Gorakhpur and 3 other districts. The disease was controlled that year.
5. Our demand was to make a national program.
6. If the same vaccine would have been given just after 365 days i.e. in 2007 so many children must have been saved
7. Everybody must have a right to safe drinking water and every family must have a right for a safe way of disposal of excreta. Until we have these two things we cannot make any change in the scenario of waterborne entroviral disease.

Dr. R.N. Singh is chief campaigner encephalitis eradication movement.

Encephalitis as we all know is famous in Gorakhpur and Gorakhpur is famous for encephalitis though this is a disease which is prevalent in about 21 provinces of the country.

We have been fighting this disease for the last six and a half years. The government is also doing some good things. Our demand was to make a national program.

Casualties under one roof i.e. BRD medical college is about 500 to 600 per annum for the last 33 years. It is an irony for a country which is signing a nuclear deal, for a country which says 'Jai Ho', this is not even a political demand, but our children are dying from a disease which is preventable through proper vaccination, safe drinking water and proper disposal of excreta.

There are only two type of encephalitis found in Gorakhpur and around the whole country. 98 % of the causes lie in between them. One is Japanese Encephalitis which has lessened because of vaccination that was arranged by the then Honorable health minister when we started this movement in the year 2005. The thing that I want to share here is that the vaccine SA 1442 which is for encephalitis is known world over.

The WHO recommendation, the recommendation of the manufacturer of this vaccine and its wrapper, the international scientists have recommended two vaccinations after a gap of exactly 365 days minimum, but usually three doses are recommended, the third one after five years. That is what we have been fighting for. Here is an example. In 2005 65 lakh vaccines were given for Gorakhpur and 3 other districts. The disease was controlled that year.

But as we all know this vaccine loses its efficacy after 365 days. 2006 was good. In 2007 85 cases came to the middle college only, there must have been many other cases, in 2008 it went to about 130 cases, in 2009 it was about 300, in

2010 it was 410. I went on trying, trying, trying. Anyhow in 2010 the same vaccine was given in Gorakhpur and Basti division, an amount of about 75 lakh vaccines is good. But I want to put a question here.

If the same vaccine would have been given just after 365 days i.e. in 2007 so many children must have been saved. Again in 2010 we have the vaccine which I will take to be the first dose to all the children, if the govt. doesn't get it in the year 2011 December which is almost over now. I have been trying all the ways. I had a talk with the health minister for about 45 minutes. His body language said that he agrees on the second dose, but ultimately what they are going to do I don't know. But this is a must if

Our children are dying in large numbers from a disease which is preventable through proper vaccination, safe drinking water and proper disposal of excreta.

we want to save the children from Japanese Encephalitis which is a totally preventable disease.

And we have been demanding a national program for this disease for we have a national program for the past many years for diseases like goiter, I think nobody dies from goiter, for diseases like filaria which also hardly kills anyone. But we do not have a national program for encephalitis for which the mortality ranges between 30 % to 45 % in some countries but here in our college they have learnt that the mortality is less than 28% to 26 % in Japanese Encephalitis and it is only 15- 16 % in entroviral worm.

The main thing which I want to emphasize today in this national debate, that the second dose is mandatory right in December which is not possible I do know, but at all not possible by January also, i.e. as early as possible from the 365 days. Last year it was given on 15th December 2010. That is crucial. In fact if we want to save lives, if we want to save the public money which is spent on these vaccines which are purchased from a company in China. The tragedy is that they speak of a trial and results run in Nepal which approve of the 1 year dosage. Govt. says this is the national policy. We have asked through RTI, through the media, and written repeatedly to the government about the Japanese Encephalitis component.

Regarding Entroviral one, I want to say, my recommendation on this day is that everybody must have a right to safe drinking water and every family must have a right for a safe way of disposal of excreta. Until we have these two things we cannot make any change in the scenario of waterborne entroviral disease which is prevailing these days because though it was only 4 % this year but if the govt. does not change its attitude it will go up to 45 % in years to come.

The death rate is about 30-40%.

This Japanese Encephalitis is a disease which initially starts with high grade fever, convulsions, fits, vomiting and ultimately coma. When 300 children are infected by an infected mosquito which carries this virus, out of those 300 children 299 are subclinical cases and only one case comes out as a clinical case and this coma may persist and convulsions may cause a lot many problems. The death rate is about 30-40%. Here the main thing is that if any child is having severe headache, vomiting and fits one should have the suspicion of it being a case of Japanese Encephalitis. But the things are little different from the entero viral one

which starts with low grade fever, slight swellings in the body, later on swelling in the organs of the body-liver, kidney, spleen and the heart. There are two causes of death: one is encephalitis in the enteroviral one which is water borne disease or the other is myocarditis.

Unfortunately we do not have against the entrovirus. When there is cases then we need to do education about keeping water in the sun for 6 hours before using which would give best results 3-4 days. If the government and media publicized this, the government could save millions of lives.

A RANDOM HARVEST

From the shorter but significant presentations made at the conventions

I. Dalit Dimension of Public Health

Mark West

- Marginal groups, particularly Dalit groups, find it very difficult to access public health facilities.
- The law itself is highly discriminatory in nature.
- In a study on maternal health conducted in 68 villages in India it was found that most Dalit expecting mothers had never been paid a visit by the local healthcare worker.
- Dalits in Gujarat have not received polio vaccination.
- One legal solution is that of a rights based education. .
- There are many interventions available at the village level that are ripe for a PIL.

II. Accountability Tools

Sanjay Paul

- Every 10 minutes there india witnesses maternal death.
- Grassroots accountability is a people-centered strategy that mobilizes civil society to hold governments, policy makers, program implementers and other stakeholders accountable.
- The White Ribbon Alliance uses the platform of public hearings, verbal autopsies, and checklists as an accountability tool.
- The program brings in the collaborative efforts of chief medical officers, media, government dignitaries and community members.
- Checklists are based on international guidelines that are used for the rapid monitoring

of health services. We use the findings for advocacy and to effect change.

- Verbal autopsies are used to find the cause of death, particularly in cases of maternal death.
- We have learned that many people don't know their rights so we need to make people aware of their rights and government programs and policies. Media is also a good ally.

III. Revolving Doors

Radha Holla Bhar

Early and exclusive breastfeeding and giving Oral Rehydration Solution (ORS) contribute the most when it comes to protecting infants from dying. In 1979 a group came together as National Alliance for Nutrition in Infants and we got passed the Infant Milk Substitutes Act (IMS Act) which is a truly public health law. This Act restrains the marketing and promoting of baby food/milk substitutes for use by children of up to two years of age. A very strong law. It, however, was not implemented because no budget was assigned for implementation.

In 1994 Acash, a consumer organization found Nestle violating the IMS Act. BPNI went to court on this. Dr Arun Gupta is the petitioner. In 1995 Government took cognizance. In 2011 Government agreed to frame charges. This is the challenge before us. How do we motivate the government to accept its law?

Nestle has stopped doing what it was doing. They're no longer breaking the letter of the law but have set up National Nutrition Institutes for "continuing medical education." They claim these are not Nestle institutes, though they have a prominent place on the Nestle website. They have gone to Education and Agriculture Ministries to train young girls

in nutrition in government schools bypassing the Ministry of Health. They have also hopped onto scientific panels and medical colleges and research institutes which brings me to this issue of conflict of interest.

That also brings me to the revolving door of conflicting interests. The Advocate General of India has now become the lawyer of Novartis. Every panel has industry experts.

Nariman, who was the Advocate for Novartis, has now become Solicitor General. The lawyer for Nestle, who was there when we first filed this case, is now at the U.N. Another example is Naresh Dayal who was a Health Secretary is now with Glaxo Smithkline. Their website has this to say about him. **Mr. Naresh Dayal**

"Mr. Naresh Dayal, IAS, has worked with the Government of India for 37 years in various positions at the state and national levels. As Secretary, Ministry of Health and Family Welfare, Mr. Dayal has been responsible, among other things, for all policies and programs in Public Health, supervising National Health Authorities, assessing and devising the policies for the country's manpower requirements in health. Mr. Dayal holds a Masters degree in Arts from University of Delhi and also in Professional Studies, Agriculture, from University of Cornell, USA."

The Government of India has rules around conflict of interest with a one year ban on working for corporations related to ministerial positions. But Naresh Dayal got an exception and within two months and is working for GlaxoSmithKline.

There is a new move by UN for scaling up nutrition. Unfortunately the only evidence being gathered is around RUTF. Malnutrition means children need food. They are hungry. Governments need to find a solution for their hunger.

IV. Absence of healthcare in Bawani

Ms. Madhuri Krishnaswamy

I will speak on just a few things that emerged out of our experience in dealing with the absence of healthcare in Bawani. I don't think Bawani is much worse than other places except when it is a tribal district it is worse but its not like the normal districts are much better. Here there are a lot of women dying on the roads, dying in the hospitals because no one can perform a cesarean. The basic issues that one needs to look at here is why is this happening? One clear glaring point is that our governments are consciously dismantling the health system. There are shortages on 80% vacancies in Class One, in Class 2 more than 50% vacancies and 60% shortages in staff nurses.

No hospital has a reasonably adequate number of staff. We have PHCs where there are no doctors, more than half of them are in this situation. If you ask the government why it is happening, they say we can't recruit enough people to go to these areas. If you ask the doctors they say look at our service conditions. The doctors are not paid fixed pay commission, the living conditions are very bad.

So we have central government that is spending on all kinds of things but not on healthcare. We don't have x-ray machines, we don't have ambulances to cart the patient to where there is a doctor. There is a lot of money in NRHM, but this is public policy--get rid of everybody. Then you say the health system doesn't work And then you bring in the privatization,

V. The View from Kashmir

Dr Zubair Saleem

- We conducted a study in one of the blocks in Jammu after the implementation of the National Rural Health Mission (NHRM).

- We have been consistently working towards strengthening the public health system in J&K. What we observed initially was that people weren't aware of the vaccines at all.
- So creating awareness about the various schemes was our first step. The NHRM was implemented in Jammu and Kashmir in 2007. The JSY scheme under NHRM did wonders.
- The NHRM has definitely improved the public health system.
- The provisions of free medicines, free pick up and dropping facilities have drastically improved the public health system.
- The disparity in the sex ratio is another alarming situation. Another problem is that most chemists are not qualified pharmacists and there have been cases where they have recommended wrong medicines.
- The irrational use of drugs needs to be controlled to strengthen the public health system. Job security for employees under NHRM needs to be worked on and privatization must be strongly discouraged.

VI. Crib Deaths in West Bengal

Dr Sidharth Gupta

Crib deaths in West Bengal are a huge problem to reckon with. We have had 29 child deaths in 96 hours in the largest pediatric hospital in the State. There were 17 crib deaths in Burdwan Medical College and 12 in Bankura District. The Government's only response was that of apathy and indifference. Crib deaths are not accidental deaths in any sense of the term. Meager budgetary allocation for food and health, inequitable and improper distribution policies, corporatization and neo liberal policies are to blame for this unfortunate occurrence. Other reasons are lack of nutrition, lack of nurser-

ies, lack of nutrition rehabilitation centers and poor sanitation. West Bengal also has huge shortages in health infrastructure. Only the long term political and social changes to establish people's right to health and children's right to life is the answer.

VII. Guidelines? What Are they? The Assam Experience.

Dr. Sunil Kaul

- Most health authorities are entirely unacquainted with Government of India guidelines.
- The basic problem is lack of clarity. To take an example, the ANM says she has no idea of how many home visits she is supposed to make.
- In an NRHM survey we found that 5-7 women had died for every 100 births. The situation has marginally improved due to JSYs.
- Blood banks are located only in the towns because 70 per cent of Assam's villages lack access to electricity.
- The right to food case we launched on 8 March 2010 has met with no response of any kind whatsoever from the Government.

VIII. Some Memorable Cases

Deepika Jain

Court intervention has proved extremely beneficial in the past. Several previous cases prove the point:

1. In the Francis Coralie Mulli case, the Court held that that the right to life means right to food and clothing and health.
2. The Court then ruled in Bandhua that the right to live with human dignity includes the protection of health.

3. Consumer Education Center was a case dealing with the asbestos construction industry. The workers had filed PIL. The Court there held that the right to life includes the right to health. Medical care is a fundamental right and employers must provide emergency medical services to ensure the safety of workers.
4. The case of Paschim Bang established emergency care rights. The case was that of a person who fell from a train. He approached nine hospitals all of which refused to treat him. He had no choice but to go to private clinic. The treatment alone cost him Rs 17,000/-. The Court issued an order requiring the money to be reimbursed and said any person in an emergency, presented at a hospital, must be admitted.
5. The first reported HIV/AIDS case in India was in 1986. Antiretroviral therapy was first introduced in 1989 at 1/10 the cost. The first HIV/AIDS policy came in 2004 from this VHAP case. After this case the Government announced free anti retroviral drugs for 100,000 people. In 2010 there are nearly 2 lakh people in free treatment.

IX. Primary Health Care in Karnataka

Eddie Premdas

- We have been working on primary health care facilities for the last 5 years or so. Health clearly cannot be left to doctors alone. Karnataka is supposed to be a progressive state.
- Karnataka's maternal mortality average is 40 but in north Karnataka the average is 110. There are a lot of regional disparities.

- We surveyed 93 PHCS and found serious staff shortages, underfunded systems and a highly erratic, irrational geographical distribution of PHCS.
- We followed these surveys up with dialogues with health officials. We had mass protests, petitions, letter campaigns and mobilization of the press. In 2007, 17 districts launched a concerted 1 day protest.
- Our largest campaign was in 2010 where we printed 15,000 pamphlets on NHRM entitlements and did an intensive month-long door-to-door campaign. We also had a campaign against malnutrition.
- There are a huge number of malnourished children in Karnataka. Karnataka gets packaged food which is tasteless and not edible. Often it is expired and worms have been found in it.
- The Government has now been forced to accept that these children are severely malnourished. I would recommend guarantees of primary health care at the local level and guarantees of infrastructure at PHCs.



WHERE DO WE GO FROM HERE

Central Ideas for Action

- The fragmentation between the primary, secondary and tertiary care must be minimised as much as possible by creating a network of providers so that the referral and feedback systems become fully operational.
- The free supply of essential drugs is the first step to be taken and must be included in the 12th plan.
- At least 15 per cent of public funding must be allocated to healthcare. The State must procure all essential drugs. There should be standard treatment guidelines which must be periodically revised.
- Quality generic drugs must be ensured.
- Warehouses should be located at every district level to prevent stock outs.
- An autonomous procurement agency should be provided
- An empanelled laboratory for drug quality testing should be provided.
- Ensure the rational use of drugs.
- Set up National and State drug supply logistics corporations.
- Empower the Ministry of Health to strengthen the drug regulatory system
- Transfer the Department of Pharmaceuticals to the Ministry of Health in order that drug price control be exercised.
- Locate an adequate number of trained health care providers should be located at all levels. This would give primacy to the provision of primary health care.
- Double the number of ASHA workers from one per 1000 population to two per 1000 population in rural and tribal areas.
- In terms of the mid-level health workers we suggest that a three year program suggested by the Health Ministry should be taken up. These three year trainees are as good as MBBS doctors in addressing some of the issues related to primary health care.
- A proper training system for community health workers should be brought into prevalence. District Health Knowledge Institutes should be established. These could well become a training hub for the entire district. Training has been very fragmented and extraordinarily weak in quality. Strengthen-

ing the District Health Knowledge Institutes help in ameliorating this problem.

- Develop a National Health Information Technology Network.
- Ensure strong accountability to patients and communities.
- Establish clearly defined financing and budgeting systems.
- Using the model of Thailand there should be regular Health Assemblies which would review the performance of the Health System and enhance the role of elected representatives as well as Panchayati Raj institutions and local bodies.
- A National Health Regulatory and Development Authority needs to be developed. This Regulatory body would then support the Universal Health Care Systems by developing standard treatment guidelines, managing protocols and ensuring quality assurance.

Cross-sectoral Collaboration

- Activists and lawyers must work collaboratively to encourage recourse to legal intervention.
- Civil society groups can play a vital role by providing specific documentation.
- Legal groups should create awareness of judicial procedures. They can educate people on how to prepare documentation for an RTI or how to file a PIL.
- Activists, lawyers and civil society groups should demand a socioeconomic fact assessment before the Government takes on any public-private partnership.
- Public private partnerships need to be strengthened where the public sector is either completely absent or is very feeble.

- There should be both creation and capacity building of cadres in public health and health management. Better human resource practices for recruitment, retention, appropriate incentives and competency based professional advancement would help in the matter.
- Citizen engagement is absolutely pivotal for the success of any program. The Brazilian model of establishing health councils from the village to the national levels can well be duplicated in India. This would actually, at the village level, transform the Health and Sanitation Committee to a much more powerful participatory Health Council.
- Strengthen the role of civil society and bring into effect a formal Grievance Redressal Mechanism at the block and district levels. Effective health communication, action of social determinants, and policy level interventions which then create an environment which is conducive to health habits.

Potential Areas for PILs

- The right to clean, drinking water (the movement is dangerously fragmented) and the right to health, given the backdrop of increasing privatization.
- The recent maternal death audit guidelines need looking into. A PIL is warranted here.
- Lack of access to health care by those who are HIV positive.
- Violations of the reproductive rights of people living with HIV.
- Lack of trained workforce available for rural health care.
- Lack of accountability in rural healthcare.

- Poor quality of care, lack of medicines, lack of equipment and deprivation of care in Government hospitals.
- Violation of women's human rights.
- Lack of mechanisms of redress for various violations.
- PIL on clinical trials.
- PIL on unsafe sterilization.
- PIL on HLEG recommendations.
- PIL on Pentavalent Vaccine.
- PIL on Private Practice by Government Doctors.
- Files suits against multinational drug companies involved in human rights violations in India. To file these cases in European Courts in collaboration with ECCHR (Berlin).
- Cases on violation of PCPNDT act in collaboration with MPVHA.
- Malaria deaths in M.P.
- Crib deaths in West Bengal.



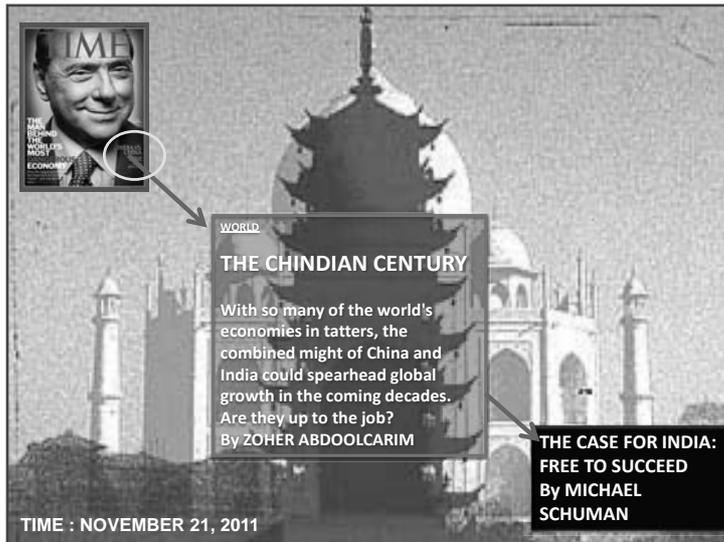
Annexures

REPORT OF THE HIGH LEVEL EXPERT GROUP ON UNIVERSAL HEALTH COVERAGE

Shrinath Reddy

REPORT OF THE HIGH LEVEL EXPERT GROUP ON UNIVERSAL HEALTH COVERAGE

**PRESENTATION TO THE
HONOURABLE MINISTER
FOR
HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA**



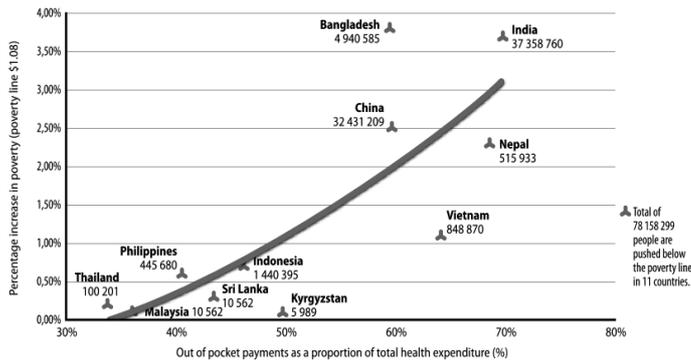
KEY HEALTH INDICATORS: INDIA COMPARED WITH OTHER COUNTRIES					
Indicator	India	China	Brazil	Sri Lanka	Thailand
IMR/1000 live-births	50	17	17	13	12
Under-5 mortality/ 1000 live- births	66	19	21	16	13
Fully immunised (%)	66	95	99	99	98
Birth by skilled attendants	47	96	98	97	99

Source: World Health Organization (2011) IMR – Infant Mortality Rate

LOW PRIORITY TO PUBLIC SPENDING ON HEALTH – INDIA AND COMPARATOR COUNTRIES 2009			
	Total public spending as % GDP (fiscal capacity)	Public spending on health as % of total public spending	Public spending on health as % of GDP
India	33.6	4.1	1.4
Sri Lanka	24.5	7.3	1.8
China	22.3	10.3	2.3
Thailand	23.3	14.0	3.3

Source: WHO database (2009)

Change in poverty (USD 1.08 per day) head count ratio by out of pocket payments in 11 countries in Asia



WHO Global Atlas on Cardiovascular Diseases Prevention and Control 2011

India's Current Health Scenario

- Largest number of underweight children (46% under 3 yrs);
- Current infant mortality rate of 50 per 1000 live births;
- Maternal mortality ratio presently 212 per 100 000 live births;
- Challenge to meet national goals of 38 per 1000 (IMR) or 100 per 100 000 (MMR) by 2015
- Rising burden of NCDs

	2011 (in Millions)	2030 (in Millions)
Diabetes	61	101
Hypertension	130	240
Tobacco Deaths	1+	2+
PPYLL Due to CVD Deaths (35-64 Yrs)	9.2	17.9

CHILD DEATHS : DISPARITY ACROSS STATES

IMR MP : 72/1000
 UP : 69/1000
 Tamil Nadu : 35/1000
 Kerala : 13/1000

**Neonatal Mortality Rate Varies
 From 11/1000 in Kerala to 53/1000 in Odisha**

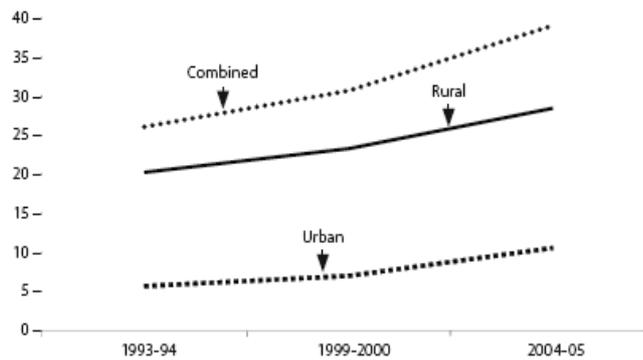
WHY IS HEALTH SYSTEM REFORM NEEDED?

- 18% of all episodes in rural areas and 10% in urban areas received no health care at all
- 12% of people living in rural areas and 1% in urban areas had no access to a health facility
- 28% of rural residents and 20% of urban residents had no funds for health care
- Over 40% of hospitalised persons have to borrow money of sell assets to pay for their care
- Over 35% of hospitalised persons fall below the poverty line because of hospital expenses
- Over 2.2% of the population may be impoverished because of hospital expenses
- The majority of the citizens who did not access the health system were from the lowest income quintiles

NSSO (2006)

Impoverishment Due to OOP Payments in India

(In Millions)



Source: Selvaraj and Karan (2009)

CURRENT SCHEMES FOR FINANCIAL PROTECTION MOSTLY DO NOT COVER

- OUT PATIENT CARE
- DRUGS
- LAB DIAGNOSTICS

Which collectively contribute to the larger fraction of OOP!

HOSPITAL BED CAPACITY, BY COUNTRY

Country	Beds/ 1000 Population
Sri Lanka	3.1
China	3.0
Thailand	2.2
Brazil	2.4
USA	3.1
UK	3.9
India	0.9
Nicaragua	0.9
Togo	0.9
Indonesia	0.6

Source: World Health Statistics (2011)

HEALTH SERVICES : URBAN RURAL DISPARITY

- 80% of Doctors
 - 75% of Dispensaries
 - 60% of Hospitals
- Are Located In Urban Areas
- Qualified Physicians:
11.3/10,000 - Urban Areas
1.9/10,000 – Rural areas

HLEG: Terms of Reference

1. Human Resource Requirements
2. Access to Health Care Services
3. Management Reforms
4. Community Participation
5. Access to Medicines
6. Health Care Financing
7. Social Determinants of Health

Our Definition of UHC

Operational Definition

“Ensure equitable access for all Indian citizens resident in any part of the country, regardless of income level, social status, gender, caste or religion, to health services (promotive, preventive, curative, and rehabilitative) that are affordable, appropriate and of assured quality.”

Definition

- *“Ensuring equitable access for all Indian citizens resident in any part of the country, regardless of income level, social status, gender, caste or religion, to affordable, accountable and appropriate, assured quality health services (promotive, preventive, curative and rehabilitative) as well as public health services addressing wider determinants of health delivered to individuals and populations, with the government being the guarantor and enabler, although not necessarily the only provider, of health and related services.”*

Guiding Principles

- Universality;
- Equity;
- Non-exclusion and non-discrimination;
- Comprehensive care that is rational & of good quality;
- Financial protection;
- Protection of patients’ rights that guarantees appropriateness of care, patient choice, portability & continuity of care;
- Consolidated & strengthened public health provisioning;
- Accountability & transparency; and
- Community participation

Our Vision

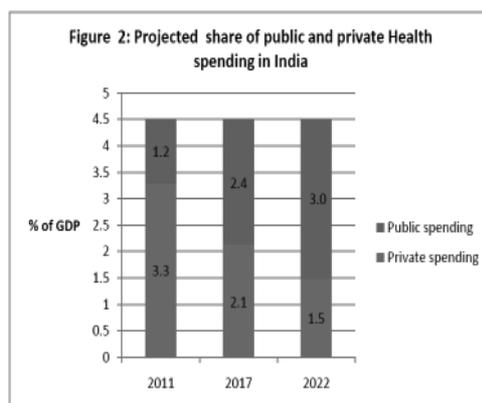
- **Universal Health Entitlement** for every citizen - to a **National Health Package (NHP)** of **essential** primary, secondary & tertiary health care services that will be funded by the government.

Package to be defined periodically by an Expert Group; can have state specific variations

Health Financing & Financial Protection

- Government (Central government and states combined) should increase public expenditures on health from the current level of 1.4% of GDP to at least 2.5% by the end of the 12th plan, and to at least 3% of GDP by 2022.
- Ensure availability of free essential medicines by increasing public spending on drug procurement;
- General taxation as principal source of health care financing – complemented by additional mandatory deductions from salaried individuals & tax payers, either as a proportion of taxable income or as a proportion of salary

Even on assuming total spending on health remains at the current level of around 4.5% of GDP, there will be a sharp decline in the proportion of private out-of-pocket spending on health - from 67% today to 33% by 2022



Health Financing & Financial Protection

- Do not levy sector-specific taxes for health financing;*
- Remove user fees for **NHP services**- this applies even for the 'non-poor'
- Introduce specific purpose transfers to equalize levels of per capita public spending on health by different states - to ensure all citizens are entitled to same level of essential healthcare;
- Accept flexible and differential norms for financing that are proposed by states, recognizing physical and socio-cultural diversities
- Integrate government insurance schemes into UHC through *India Health Card*

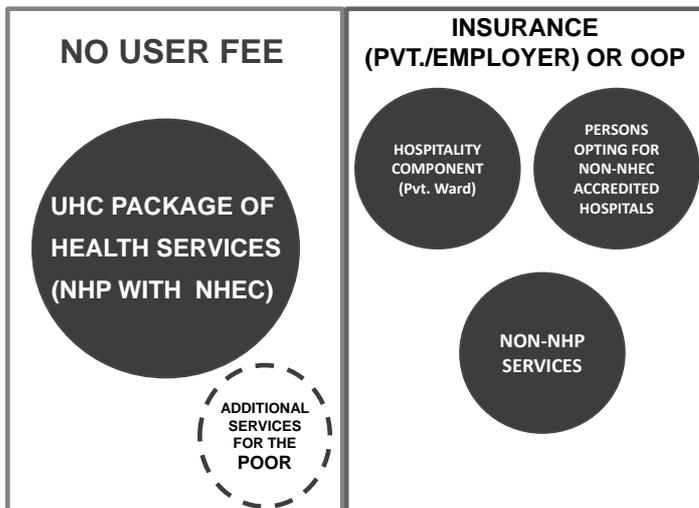
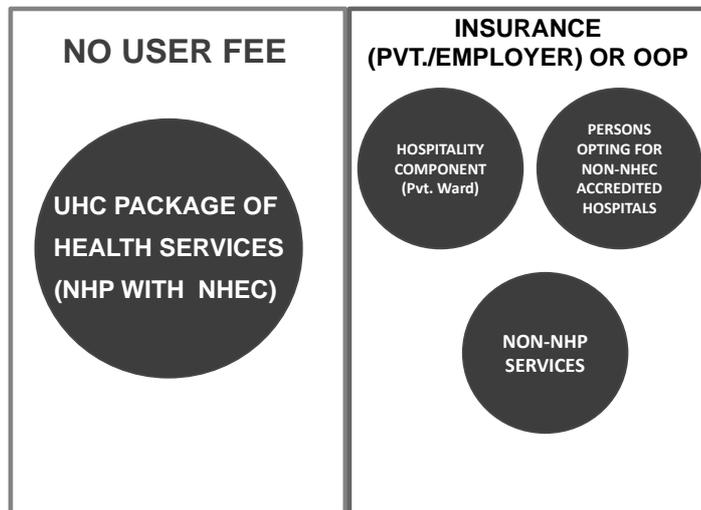
* Higher taxes on tobacco and alcohol recommended for other reasons

“User Fees for health care were put forward as a way to recover costs and discourage the excessive use of health services and the over-consumption of care. This did not happen. Instead, user fees punished the poor.”

-Dr. Margaret Chan, Director-General, WHO (2009)

“Among the ‘quick win’ strategies recommended by the Millennium Project was the removal of user fees for primary education and essential healthcare by the end of 2006.

- Dr. Jeffrey Sachs (2005)



Health Financing & Financial Protection

- Primary healthcare including preventive/curative services at primary level along with health promotion targeted towards specific risk factors, should account for 70% of all govt. healthcare expenditures
- Provide universal financial protection and access to good health care without involving insurance companies or any other independent agents to purchase healthcare services (NHP) on behalf of govt.

BECAUSE

Independent agents fragment the nature of care being provided, leading to high health care costs and lower levels of wellness at the population level

- Central and State governments should purchase services (through agencies linked to Department of Health)

Health Financing & Financial Protection

- Technical and other capacities developed by Ministry of Labour for RSBY should become the core of UHC operations – and transferred to MoHFW.
- Integrate the services provided under different programs gradually (NRHM and other vertical programs such as, HIV/AIDS);

HEALTH CARE SERVICES

GOVERNANCE

E
X
C
E
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E
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C
E

BREADTH

DEPTH

QUALITY

ACCOUNTABILITY

E
F
F
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E
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C
Y

EQUITY

PROVISION OF HEALTH CARE

- **Strengthen Public Services**

(Especially: Primary HealthCare-
Rural And Urban; District Hospitals)

- **Contract Private Providers**

(As Per Need And Availability)
– With Defined Deliverables

- **Integrate 1^o, 2^o, 3^o Care
Through Networks of Providers**

(Public; Private; Public-Private)

**Regulate
and Monitor
For Quality,
Cost And
Health
Outcomes**

Health Care Services

- Provide **essential & standard health services** as part of entitlement for every citizen to NHP at different levels of health care delivery system;
- Ensure more equitable & improved access to **functional beds** for guaranteeing secondary & tertiary care;
- Ensure adherence to & compliance with **quality assurance** in health care provision at all levels of service delivery;

KEY CHARACTERISTICS OF RELIABLE & EFFICIENT MEDICINE SUPPLY SYSTEMS

- **At least 15% allocation of public funding for health to drugs; State must procure all EDL medicines;**
- **Separate AYUSH EDL, with centralized procurement at state level;**
- **Prescription & Dispensing in accordance with Standard Treatment Guidelines (STG);**
- **A two-bid open transparent tendering process;**
- **Quality generic drugs ensured;**
- **Warehouses at every district level;**
- **An autonomous procurement agency for drugs, vaccines & diagnostics;**
- **An empanelled laboratory for drug quality testing;**
- **Enactment of Transparency in Tender Act;**
- **Prompt payments**

Access to Medicines, Vaccines & Technologies

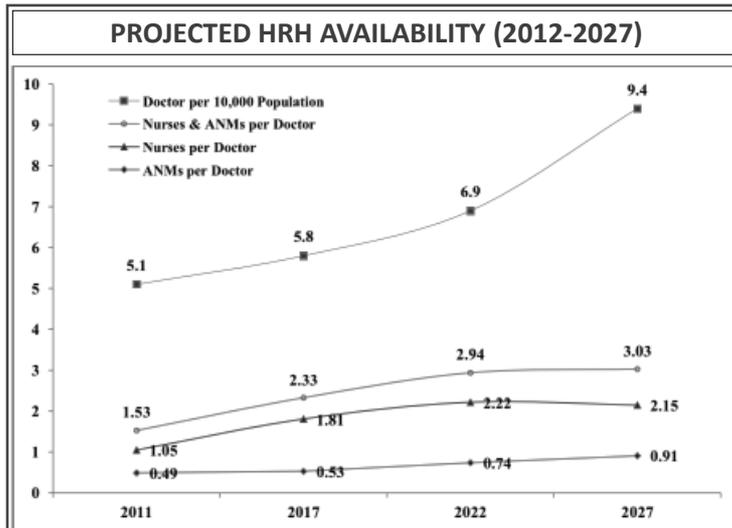
- **Ensure rational use of drugs;**
- **Set up national & state drug supply logistics corporations;**
- **Empower MoHFW to strengthen drug regulatory system;**
- **Transfer Department of Pharmaceuticals to the Ministry of Health.**

Human Resources for Health

- **Ensure adequate numbers of trained health care providers and technical health care workers at different levels – giving primacy to the provision of primary health care.**
 - **Doubling ASHAs from one per 1000 population to two per 1000 population in rural and tribal areas;**
 - **Introduction of mid-level health workers such as Bachelor of Rural Health Care (BRHC) Practitioners for recruitment & placement at rural Sub-Centres and Nurse Practitioners in urban Sub-Centres**

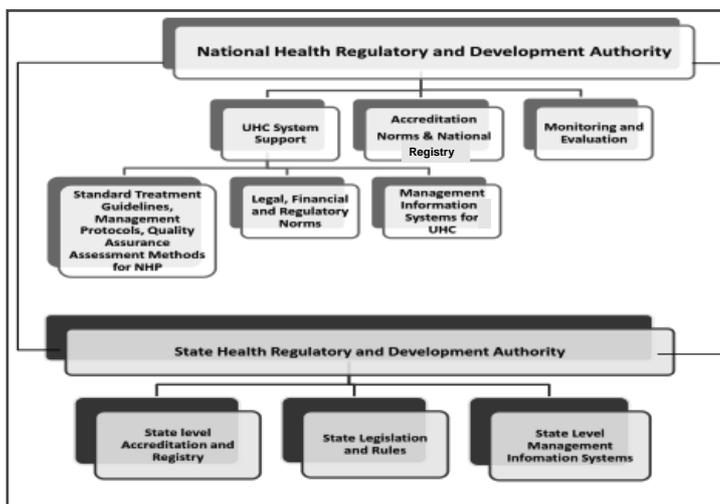
Human Resources for Health

- **Improve human resource management and supportive supervision mechanisms at block, district, state & national levels to complement health care service providers;**
- **Enhance the quality of HRH education and training by introducing competency-based, health system-connected curricula and continuous education;**
- **Invest in additional educational institutions to produce and train the requisite health workforce;**
- **Establish a dedicated training system for Community Health Workers;**
- **Establish District Health Knowledge Institutes (DHKIs);**
- **Establish the National Council for Human Resources in Health (NCHRH).**



MANAGEMENT AND INSTITUTIONAL REFORMS

- **Develop capacity and cadres for public health and health management**
- **Adopt better human resource practices to improve recruitment, retention motivation and performance; rationalize pay and incentives; and assure career tracks for competency-based professional advancement;**
- **Develop a national health information technology network based on uniform standards to ensure interoperability between all health care stake holders;**
- **Ensure strong linkages and synergies between management and regulatory reforms and ensure accountability to patients and communities;**
- **Establish financing and budgeting systems to streamline fund flow.**



COMMUNITY PARTICIPATION AND CITIZEN ENGAGEMENT

- Transform existing Village Health Committees (or Health and Sanitation Committees) into participatory Health Councils;
- Organize regular Health Assemblies;
- Enhance the role of elected representatives as well as *Panchayati Raj* institutions (in rural areas) and local bodies (in urban areas);
- Strengthen the role of civil society and non-governmental organizations.
- Institute a formal grievance redressal mechanism at the block level.

HEALTH BEYOND HEALTH CARE

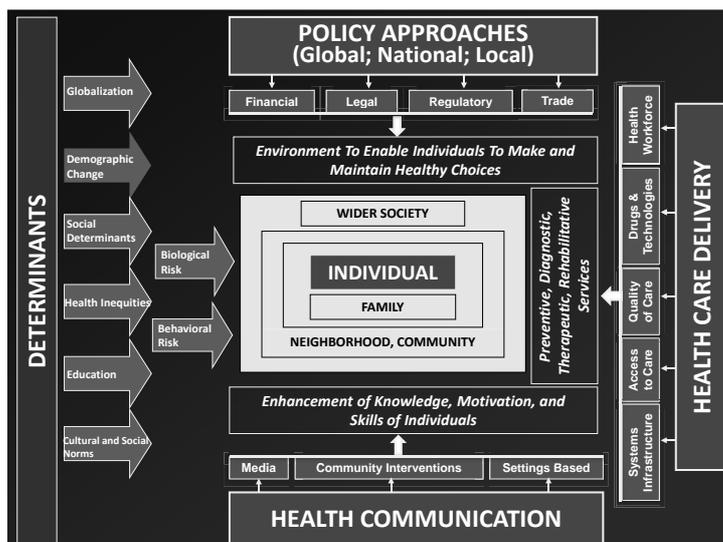
**“ Health leaps out of Science and draws
nourishment from the Society around it”**

- Gunnar Myrdal
(Swedish Economist, Nobel Laureate)

POLICIES AND PROGRAMMES IN

- Finance • Water • Sanitation • Agriculture • Food Processing
- Education • Rural Development • Urban Design • Transport
- Communications • Trade • Environment

**NEED TO BECOME SENSITIVE AND RESPONSIVE
TO PUBLIC HEALTH CONCERNS !**

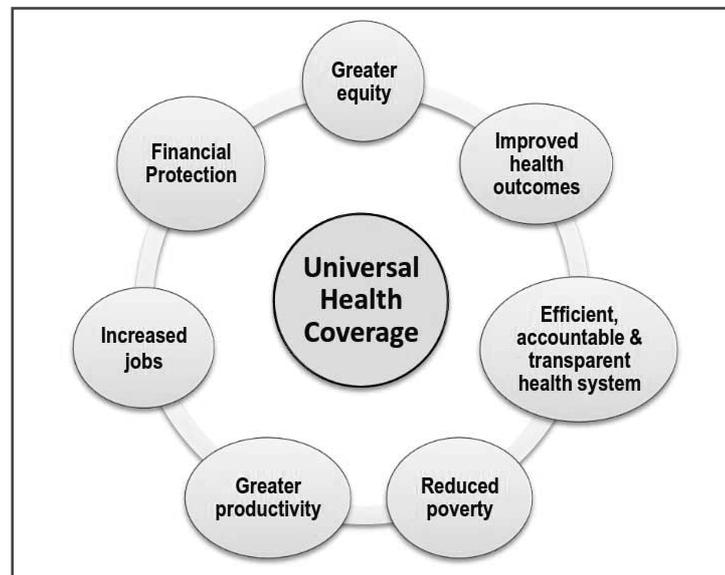


HLEG Recommends.....

Creation of National Health Promotion and Protection Trust

To Enable :

- Effective Health Communication, Dissemination and Information Sharing
- UHC Related Education to People , Patients, Providers
- Health Impact Assessment of Policies and Programs in Other Sectors (to facilitate convergent action on the Social Determinants of Health)
- Collaboration with International Partners to draw upon Best Practices, Policies, and Lessons from the Global Context



“If we don’t create the future, the present extends itself”

- Toni Morrison (Song of Solomon)

PUBLIC HEALTH SYSTEM: AN OVERVIEW

K S Jacob



Public Health Systems: An overview

K. S. Jacob
Christian Medical College, Vellore

Using Law for Public Health Conference,
New Delhi 2011

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Background and bias

- Academic background
- Convert to public health
- Field experience with the Common Review Mission of the NRHM
- Advisory role- NRHM, CCHFW, PC

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2



Public Health System scenario

- Inadequate and neglected
- Significant out-of-pocket expenditure
- Major cause of indebtedness
- Represents a crisis in health care

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National Rural Health Mission

- Refocus on health
- Prioritize rural India
- Major inputs: finance, infrastructure, personnel
- Integrate resources, programmes
- Decentralize health care management
- Flexibility for tailoring delivery
- Community participation, ownership
- A success

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Universal Health Coverage

- Recommended by High Level Expert Group
- Accepted by government
- Adopted for the 12th Five Year Plan
- Ideals backed by increased funding

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Implementing UHC

- Political, administrative and financial will to increase resources
- ? Delivery mechanism for implementation

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Unresolved issues

- Standards and regulation
 - Audit and accountability
 - Process and outcome data
 - Use of data
 - Project mode and integration
 - Competition between platforms
 - Insurance and outsourcing
 - Procurement of supplies
 - New inputs and old ethos
 - Community participation and ownership
 - Social determinants
- Governance

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Professional standards

- Regulatory authorities and engagement with medical practice
- Standard management guidelines
- Professional development and re-certification
- Ethical standards

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Audit and accountability

- Audits: institutional and individual
- Corrective action: policies, processes, procedures
- Assessments: internal and external
- Paternalistic attitudes and power differentials
- Culture of silence, complicity, collusion

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Assessment of the NRHM

- Process and outcome assessment
 - Only input and process data
 - Systemic lack of outcome data
 - Janani Suraksha Yojana and maternal and neonatal outcome
 - Hospital deliveries and duration of stay, monitoring, facilities
 - ? Correlation to National Sample Survey and National Family Health Survey data

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Use of data for system changes

- Massive data collected
- Stored and superficially analyzed
- Not employed for system correction or targeted action
- Absence of use of data at point of generation/district/state level
- Incorrect data

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Parallel health systems

- Project mode
- Minimal contribution from states
- ?Priority or lack of funds
- Parallel health systems and integration
 - Medical colleges, district hospitals, PHC
- Focus on building and infrastructure rather than efficient systems

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New platforms and old programs

- Competition not collaboration
 - VHND and ICDS
 - Anganwadis and ANMs
 - Mobile clinics and sub-centers

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Procurement of supplies

- TN Medical Supplies Corporation
- Centralized sourcing, cost, quality
- Resistance to implementation

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Insurance and outsourcing

- Health insurance and out sourcing
- Absence of gatekeepers
- Focus on rare diseases and specialist interventions in unregulated private health care
- Negative impact on public health systems
 - Diversion of funds
 - Lack of use of capacity
 - Government facilities excluded from schemes
- Private vs public insurance

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Old ethos and new inputs

- Inertia of system, discipline and morale of health staff
- Myths to cover up problems
- Internal correction and external assessments

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Community participation and ownership

- Part of blueprint
- Limited involvement on ground
 - Empowerment, monitoring, partnership, ownership
- Acceptance of poor health care

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Social determinants of health

- Reducing health to a biomedical perspective
- Biased use of evidence
- Lack of emphasis
- Absence of convergence

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Regional variation, inputs and governance

- Health, social, economic indices
- Unutilized funds, poor implementation
- NRHM governance and governance of the state/region

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Impact

- Poor quality of health care
- Variable standards
- Inefficiency and cost-ineffectiveness
- Persistent poor health indices

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Public health

- Convergence of politics, finance, social science, cultural studies, engineering, science, education, religions, legal studies, medicine
- Different frameworks, language
- Shared objectives, divergent agenda
- Ownership and delivery
- Health in all policies- “Public health lens”

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The way forward: Emphasis

- Population health as national interest
- Social and population interventions prioritized over curative medical approaches
- General health infrastructure rather than vertical programs

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The way forward: Medical practice

- Standard, regulation and accountability
- Management guidelines
- Audit and corrective action

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The way forward: Population engagement

- Information, education and empowerment
- Grievance redressal mechanism
- Engagement, inputs and partnership

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Conclusions

- UHC and NRHM ideals
- Need for adequate implementation, regulation and accountability
- Mandate a change of culture within medical fraternity, health system and government
- Using the law to deliver entitlements

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UNIVERSAL ACCESS TO MEDICINES

Sakthivel Selvaraj

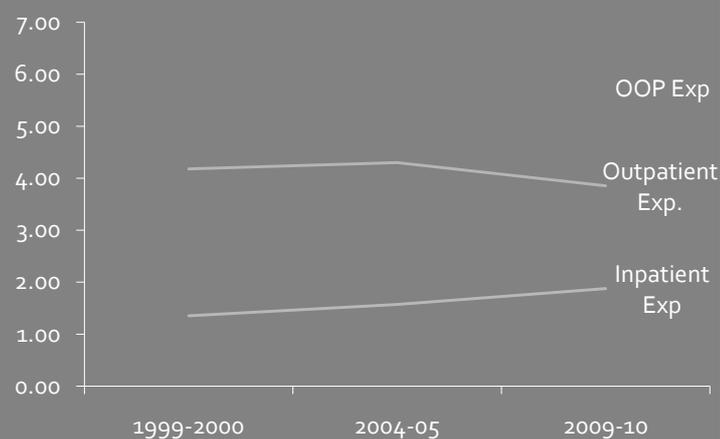
Universal Access to Medicines

By
Sakthivel Selvaraj
Public Health Foundation of India
New Delhi

Key Barriers to Access to Medicines

- Unfair health financing mechanisms;
- Unreliable supply systems;
- Unaffordable pricing;
- Irrational use of medicines;
- Inadequate funding for research in neglected diseases;
- Stringent product patent regime.

Trends in OOP Payments



Source: Respective rounds of NSSO.

Share of Households' OOP Expenditure by Quintile Groups, 2009-10

Sector	Poorest	2 nd Poorest	Middle	2 nd Richest	Richest	All
OOP Exp.	(As Percentage of Household Expenditure)					
	3.74	4.57	5.11	5.84	7.23	5.73
Inpatient Exp.	(As Percentage of OOP Expenditure)					
	26.41	30.69	32.25	34.35	33.81	32.74
Outpatient Exp.	(As Percentage of OOP Expenditure)					
	73.59	69.31	67.75	65.65	66.19	67.26
Drug Exp.	(As Percentage of OOP Expenditure)					
	75.42	72.34	70.11	66.81	65.90	68.28

Source: Unit Level Records of NSSO.

**Percentage of Households Facing
Catastrophic Expenditure on
Health, 2009-10 (>10% of HH Spend)**

Quintile Groups	OOP Expenditure	Inpatient Expenditure	Outpatient Expenditure	Drug Expenditure
Poorest	7.656	1.082	6.329	4.523
2 nd Poorest	9.875	1.980	7.394	6.012
Middle	12.237	2.770	8.848	7.392
2 nd Richest	16.197	4.496	10.979	9.591
Richest	22.456	7.954	16.207	14.852
All	13.684	3.656	9.951	8.474

Source: Unit Level Records of NSSO.

Trends in State-wise Government Drug Expenditure in India

States	State wise Government Drug Expenditure in India					
	2001-02			2010-11		
	Overall (Lakh)	Per Capita (Rs.)	Drug Exp. as % of HE	Overall (Lakh)	Per Capita (Rs.)	Drug Exp. as % of HE
Assam	1530	5.7	4.7	8635	28.5	5
Bihar	2203	2.6	3.1	13350	13.8	7
Gujarat	2693	5.3	3.7	15431	26.4	7.6
Haryana	3096	14.7	9.8	6090	24.2	5.5
Kerala	12420	38.9	17	24861	72.3	12.5
Maharashtra	20305	20.8	11.3	20882	18.7	5.2
Madhya Pradesh	7921	13.0	11.8	12213	17.1	9.3
Punjab	916	3.7	1.4	1545	5.6	1.0
Rajasthan	9045	15.9	9.3	3854	5.7	1.5
Uttar Pradesh	7104	4.2	5.2	31481	15.9	5.3
Jharkhand	NA	NA	NA	2716	8.7	3.4
West Bengal	5798	7.2	4.3	21403	24.1	6.8
Andhra Pradesh	12704	16.6	9.6	23458	27.9	10
Karnataka	7783	14.7	7.9	14831	25.1	6.3
Tamil Nadu	18097	28.9	15.3	43657	65.0	12.2
Himachal Pradesh	NA	NA	NA	1122	16.6	1.9
J & K	NA	NA	NA	4550	39.2	4.3
C. Government	72649	7	12.2	253368	21	15
All India	188903	18	9.6	503447	43	13

**District-wise Share of
Drug Expenditure in Bihar**

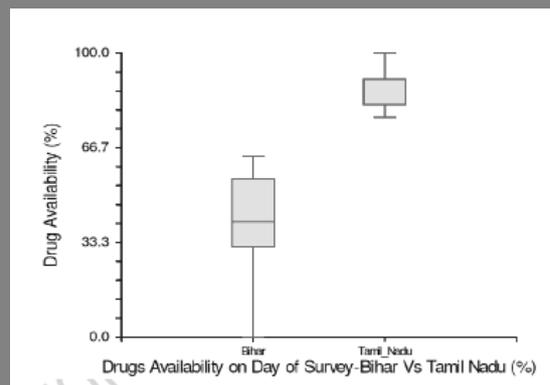
District	Drug Exp/Per capita	Drug Exp Per Illness episode (OPD visit)
Jamui	4.61	780.35
Katihar	84.53	661.08
Nawada	5.30	623.11
Samastipur	3.84	561.85
Banka	7.14	110.33
Araria	6.68	89.41
Saran	5.29	84.08
State Total	7.16	59.93
Aurangabad	6.76	15.04
Madhepur	3.16	14.70
Gaya	2.66	14.13
Khagaria	6.33	13.65
Vaishali	2.97	12.87
Muzzafarpur	1.89	11.29
Buxar	1.51	7.62

State-wise Availability of Free/Partly Free Medicines at Government Facilities during 2004

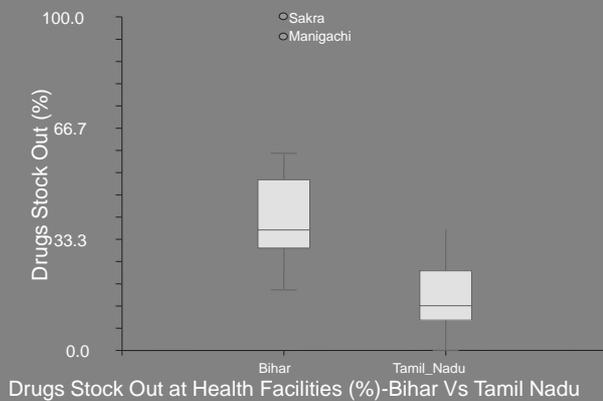


Source: Morbidity & Health Survey, NSS, 2004

A Comparative Scenario of Drug Availability in TN and Bihar



Stock-Outs at Facilities: Bihar vs Tamil Nadu (% Stock-Outs)



Irrational Medicine Use in India

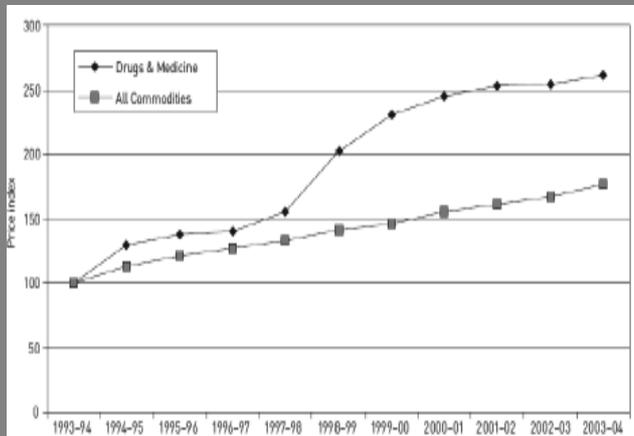
Product Rank	Product	Sales (in Crore Rs.)	Market Share	Product Description
1	COREX	135.88	0.497	Irrational cough mixture
2	PHENSEDYL COUGH	124.31	0.455	Irrational cough mixture
5	LIV-52	95.85	0.351	Useless liver drug
7	BECOSULES	92.48	0.338	Irrational vitamin combination
17	DEXORANGE	77.04	0.282	Blood tonic
18	COMBIFLAM	76.03	0.278	Irrational analgesic combination
27	DIGENE	63.49	0.232	Needless antacid
35	POLYBION	54.24	0.198	Irrational vitamin combination
38	GELUSIL-MPS	53.25	0.195	Needless antacid
40	REVITAL	53.09	0.194	Oral ginseng tonic

Source: IMS-ORG, 2006

Irrational Prescription in Public Health Facilities

	Bihar (%)	Tamil Nadu (%)
Average number of drugs per encounter	2.6	3.1
Percentage of drugs prescribed by generic name	73.5	88.0
Percentage of drugs prescribed from essential drug list	66.8	88.0
Percentage of encounters with an antibiotic prescribed	66.0	59.6
Percentage of encounters with an injection prescribed	4.9	1.4
Percentage of fixed dose combinations versus single agents	6.9	0.0
Percentage of encounters with a syrup prescribed	26.2	2.6

Trends in All-Commodity and Pharmaceutical Price Index



Draft Pharmaceutical Price Policy, 2011

Key Features:

- All 348 NELM ;
- Market Based Pricing;
- Only Formulations;
- WPI-linked increase;
- Medicines below Rs. 3 not covered;
- Patented Medicines not covered.

Implications of DPPP, 2011

Pharma market is unique because:

- Market Leader is the Price Leader - When competition exists, leading market players are expected to reduce prices substantially & yet obtain normal profits.
- Indian pharma industry behaves abnormally.
- Under a therapeutic category, hundreds of players slug it out in the Indian pharmaceutical sector, but with substantial variation in prices.
- The prices of leading players very often tend to be the highest, because of aggressive promotional campaigns.
- High margins provided by industry to stockiest & retailers encourage them to promote high priced medicines;
- Given information asymmetry that creates supplier-induced demand, pharma makers have an upper hand in pushing through medicines that are high priced.

Comparator Prices of Similar Medicines between Market Leader and Cheapest Prices

Market Leader Medicines	Active Pharmaceutical Ingredients (API)	TNMSC Prices (Rs.)	Market Leader/ Most Expensive/ Cheapest Price (Rs.)	Ratio of Market Leader to Lowest Priced Medicines	Average of 3 Highest medicine Prices (Rs.)	Average of 3 Lowest Medicines (Rs.)
Anti-Bacterial Medicines						
Monocef (1 gm inj)	Ceftriaxone	12.39	63 (Aristo); 179 (Merind); 45 (Neon)	1.4	125.3	50.3
Cifran (50mg; 10 Tabs)	Ciprofloxacin	98.26	98.6 (Ranbaxy); 98.6 (Ranbaxy); 29.7 (Hindustan)	3.3	88.6	34.6

Comparator Prices of Market Leader & Cheapest Prices

Market Leader Medicines	Active Pharmaceutical Ingredients (API)	TNMSC Prices (Rs.)	Market Leader/ Most Expensive/ Cheapest Price (Rs.)	Ratio of Market Leader to Lowest Priced Medicines	Average of 3 Highest medicine Prices (Rs.)	Average of 3 Lowest Medicines (Rs.)
Anti-Diabetes						
Amarly (1 mg; 10 tabs)	Glimepride	7.54	65 (Aventis) 65 (Aventis) 9.5 (Kopran)	6.84	59.3	10.8
Glycomet GP (1 mg- 500mg; 10 tabs)	Metformin + Glimepride	Not Availabl e	36.5 (USV); 66.2 (Aventis); 17 (Blue Cross)	2.14	52.8	25.3

HLEG Recommendations

- Scale up public spending;
- Free essential medicines to all;
- 15% of 2.5-3.0 % of GDP (Reduce OOP spending & impoverishment);
- Centralised Procurement & Decentralised Distribution;
- AYUSH medicines List – with adequate funding;

Key Principles of UHC

➤ GOVERNMENT POLICIES AND STRATEGIES MUST BE GROUNDED IN THE PRINCIPLES OF UNIVERSALITY; EQUITY; EFFICIENCY AND QUALITY.

THIS FEASIBLE & IMPLEMENTABLE, & RESULTS CAN BE DEMONSTRATED RAPIDLY & SCALED UP WITHIN A SHORT SPAN OF 1-2 YEARS, WITH MINIMUM RESOURCES AND MAXIMUM BENEFITS.

HLEG Recommendations: Drugs and Vaccine Security

- Ensure drug and vaccine security by building public sector capacity & protect capacity of Indian private sector companies to produce low cost drugs and vaccines;
- Revival of PSUs (Benchmark Cost-based pricing; Operationalise CLs; Drug security in the backdrop of acquisition);
- Reduce API import dependence;
- Revisit FDI rules;

Product Patents

- Restrict patenting of insignificant or minor improvements of known medicines (under section 3[d]);
- Make use of CL provision under TRIPS;
- Data exclusivity clause proposed by EU as part of Indo-EU trade pact needs to be removed to avoid 'ever-greening';
- Invest in neglected disease R&D by open-source drug development model.

Expected Outcomes

- Scaling up Public Spending 1-3% Reduce OOP & Reverse Private-Public spending (70:30 to 30:70);
- Cost Reductions (Private Vs Public) – Generic, economies of scale;
- Improve prescription & dispensing practices.

Overall Financial Implications

Scale Up Public Spending on Drugs (0.4-0.5% GDP):

- Current Govt: Rs. 6,000 (0.1% of GDP);
- Current HH OOP: Rs. 58,000 (0.9% of GDP);
- Likely Combined: Rs. 25,000 – 30,000 (0.5% of GDP).

Expected Outcomes:

- Reduction in OOP (reverse ratio – OOP:Govt)
- Cost Savings: Rs. 30,000 (0.5% of OOP) current scenario;
- Cost Savings: Rs. 20,000 (0.33% of OOP) current + latent demand;

Time-Frame:

- 1 year (Public Procurement & Public Distribution);
- 2-5 years (Public Procurement & Private Distribution).

USING LAW FOR PUBLIC HEALTH

Samita Sharma

Using Law for Public Health

(to make health care affordable)
A National Dialogue



Hippocratic Oath

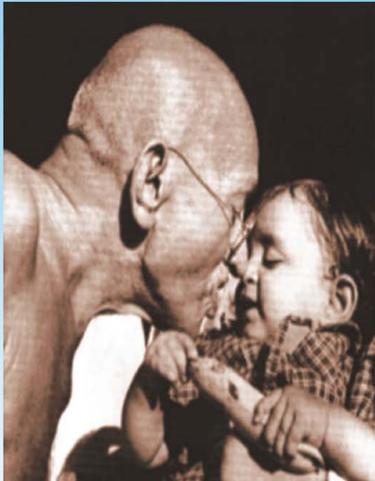


... That I will lead my life and practice my art with integrity and honor.....

.... That above all else I will serve the highest interests of my patients through the practice of my science and my art

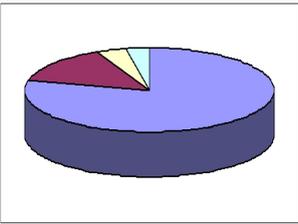
“गाँधी जी का मंत्र”

मैं आपको एक मंत्र देता हूँ
जब कभी आप दुविधा में हो या स्वार्थ प्रबल हो तो इसे आजमाएँ। आप किसी ऐसे गरीब असहाय व्यक्ति का स्मरण करें जिसे आप जानते हैं। फिर अपने आपसे पूछें क्या आपके कार्य से उसे मदद मिलेगी..... बस इतना सोचते ही आपकी सारी दुविधाएँ दूर हो जाएगी और स्वार्थ मोम की तरह पिघल कर बह जाएगा।



Where does the money for health expenditure (in India) come from?

Private out of pocket expenditure	79%
State govt.	14%
Central govt.	4%
Private investment	3%
Private insurance	0 – 1%



1. स्वास्थ्य पर होने वाला खर्च ग्रामीणों पर कर्ज भार का दूसरा सबसे बड़ा कारण है।
2. स्वास्थ्य पर होने वाले खर्च का 40 प्रतिशत से अधिक भाग दवाईयों पर खर्च होता है।
3. अस्पतालों में भर्ती 100 मरीजों में से लगभग 40 को अपना उपचार करवाने के लिए पैसा उधार लेना पड़ता है या अपने घर, जमीन, जेवर आदि बेचने पड़ते हैं।
4. 23 प्रतिशत लोग बीमार होने पर डाक्टर के पास इसलिए नहीं जा पाते क्योंकि उनके पास ईलाज हेतु पर्याप्त पैसे नहीं होते हैं।
5. दवाईयों आदि पर होने वाले खर्च के कारण प्रतिवर्ष 02 प्रतिशत से अधिक लोग ए.पी.एल. से बी.पी.एल. बन जाते हैं।

भर्ती रोगियों पर खर्च

राज्य	प्रति भर्ती रोगी का प्रतिवर्ष खर्च	दवाओं पर खर्च
राजस्थान	4382 रुपये	3187 रुपये
तमिलनाडु	255 रुपये	102 रुपये

Source :- N.S.S.O.

प्रयास द्वारा किए गए अध्ययन में अब यह बढ़कर 17620/- हो गया है।

40 प्रतिशत से अधिक भर्ती रोगियों को उधार लेकर या अपनी सम्पत्ति बेचकर अपना उपचार कराना पड़ रहा है।

भारत में :-

- विश्व के 22 प्रतिशत रोगी।
- दवा उत्पादन, विश्व की कुल दवा उत्पादन का 2 प्रतिशत।
- केवल 0.7 प्रतिशत ही आवश्यक दवाएं।
- शेष 1.3 प्रतिशत दवाएं आवश्यक की श्रेणी में नहीं।

फिर भी यह दवाएं रोगियों को दी जा रही है।

WHO के अनुसार :-

मात्र 200 से 300 आवश्यक दवाओं द्वारा 90 से 95 प्रतिशत रोगों का इलाज सम्भव है।

भारत में दवा उत्पादन की स्थिति

- लगभग 74 कम्पनियां US FDA से मान्यता प्राप्त ।
- लगभग 733 दवा कम्पनियां WHO से मान्यता प्राप्त ।
- यूरोप के देशों सहित विश्वभर में लगभग 45 हजार करोड की जेनेरिक दवाएं प्रतिवर्ष निर्यात ।
- वार्षिक उत्पादन 1 लाख करोड रूपयों से भी अधिक ।
- जेनेरिक दवाओं के निर्यात में विश्व का तीसरा (By Volume) स्थान ।

इतनी मात्रा में दवा उत्पादन के बावजूद हम गरीब मरीजों को आवश्यक दवाइयां भी उपलब्ध नहीं करवा पा रहे हैं

Factors Underlying Irrational Use of Drugs (PATHOLOGICAL PRESCRIBING)

Industry

- Unethical promotion
- misleading claims
- Keeps profit before peoples health

Prescribers

- lack of education and training
- lack of drug information
- heavy patient load
- pressure to prescribe
- generalization of limited beliefs
- misleading beliefs about efficacy

Drug Regulation

- availability of non-essential drugs
- informal prescribers

Patients

- drug misinformation
- misleading beliefs
- inability to communicate problems

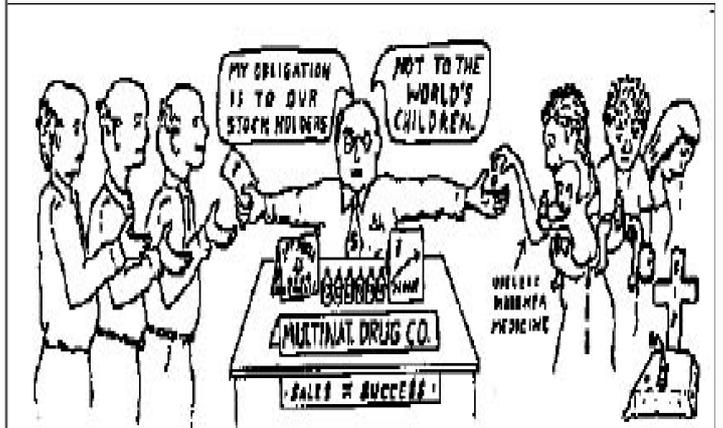
THE ROOT CAUSE OF IRRATIONAL USE



PROFIT BEFORE PEOPLE
AND IRRATIONAL PROMOTION

A REASONABLE RETURN FOR
RESPONSIBLE INVESTMENT

Balance :
Profit oriented industry v/s poor, sick & ailing



The industry orcheesters

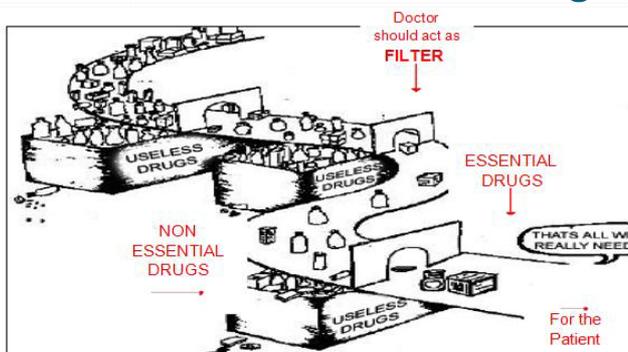
&

Doctors are used as an instrument to promote unhealthy & unethical practices of pharmaceutical industry

Unknowingly doctors help the drug companies and adversely affect the patients in three different ways :-

- Prescription of non essential drugs
- Prescription by brand name
- Irrational Prescriptions

Promotion of Non essential drugs



- **Drugs in Essential Medicines List**
 - Adequate to take care of the majority of the health needs of the population.
- **Sales of top 300 brands**
 - Only 38% of brands are of the drugs mentioned in the NLEM.
 - The other 62% brands comprise drugs that are higher priced alternatives without a clear therapeutic advantage and many are unnecessary, irrational and even hazardous.

Some of the top-selling Brands in India

as per ORG-Nielsen Retail Audit

Brand name	Uses and Remarks	Moving Annual Total in rupees crore (Oct 2003)
Corex	Cough suppressant. Abused as drug of addiction because of presence of codeine	88.18
Becosules	Multivitamin, unnecessary preparation	79.74
Liv-52	Ayurvedic liver preparation	62.67
Neurobion	Irrational Multivitamin preparation	60.27
Nise	Hazardous drug for pain relief	58.31
Dexorange	Irrational preparation for anemia	57.65

Vitamins : offer nothing to healthy people

S.N.	Brand Name	Moving Annual Total (rupees crores)
1	Becosules	79.74
2	Revital	47.64
3	Polybion	40.85
4	Zincovit	32.26
5	Cobadex Forte	26.1
6	Methycobal	21.87
7	Zincovit	21.65
8	Neogadine	21.52
9	Riconia	20.78
10	R.B. Tone	20.21
11	A to Z	19.07
12	M2tone	18.22
13	Supradyn	15.25
14	Becadexamin	14.63
15	Raricap	13.89
16	Becosules-Z	12.03
17	Optineuron	11.97

According to the Pharmaceutical Industry, Most Common Public Health Problem of India is Not Anemia. **437.68** Complex Deficiency!



I did take the tonic, sir!
But had to starve for days to buy it.

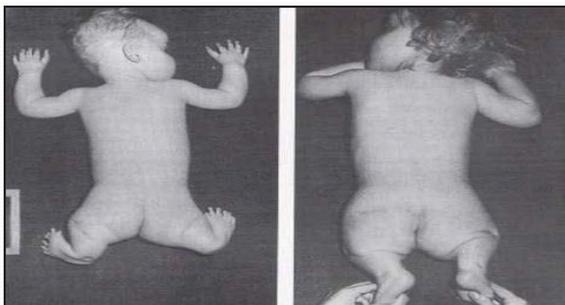
“False” Evidence-based medical practice

Evidence is selectively quoted or false evidence is produced to promote a drug. For Example:

- Glaxo Laboratories cited the authority of a British medical journal, the Lancet to promote its sales of Ostocalcium B-12 even though there was no such endorsement of the product in the Lancet.
- Boehringer-Knoll quoted UNICEF and used their logo to promote the use of streptomycin-chloramphenicol combination for diarrhoea treatment, whereas UNICEF promotes simple ORT for most diarrhoea.
- Franco-Indian Laboratories misquoted Goodman and Gilman to promote their tonic, whereas Vitamin B-12 has no role in ordinary anaemia.
- S.G. Chemicals (Indian subsidiary of Ciba-Geigy) misquoted Goodman and Gilman and Martindale to promote a combination of two dangerous drugs analgin and oxyphenbutazone, whereas in fact the texts warn against this dangerous combination.

Promotion of Hazardous, Banned and Bannable Drugs

- Thalidomide



Withdrawals from market as a result of spontaneous reporting

INN(GENERIC NAME)	REASON FOR WITHDRAWAL	YEAR OF MARKETING	YEAR OF WITHDRAWAL
Bromofenac	Serious hepatotoxic effect	1997	1998
Encainide	Excessive mortality	1987	1997
Flosequinan	"	1992	1993
Temafloxacin	Haemolytic anemia	1992	1992
Benoxaprofen	Liver necrosis	1982	1982
Mibefradil	Multiple drug interaction	1997	1998
Terfenadine	Fatal cardiac arrhythmias	1985	1998

Recently banned drugs in india

Fenfluramine Dexfenfluramine	Diseases of heart valves ,heart fibrosis
Rimonabant	Depression suicidal tendency
Sibutramine	Heart problems
Astemizole & terfenadine	Torsdes de pointes
Phenformin	Lactic acidosis
Rofecoxib ,valdecoxib	Heart attack, stroke
Rosiglitazone	Heart attack
Nimesulide for human use in children below 12 years- liver failure in viral infection	
Cisapride and its formulations for human use	
Human Placental extract - transmission of diseases	
Gatifloxacin for systemic use	

Biased Clinical Trials

Examples of Methods for Pharmaceutical Companies to get the Results they want from Clinical Trials:

- Conduct a trial of your drug against a treatment known to be inferior.
- Trial your drugs against too low a dose of a competitor drug
- Conduct a trial of your drug against too high a dose of a competitor drug (making your drug seem less toxic)
- Conduct trials that are too small to show differences from competitor drug
- Do multi centre trials and select for publication results from centers that are favorable.
- Conduct subgroup analyses and select for publication those that are favorable.
- Present results that are most likely to impress.

“Corporate Construction of Disease”

- “**halitosis**” - Listerine
- “gastro-oesophageal” reflux disease (**GERD**)” - Zantac
- “**erectile dysfunction**”- sildenafil citrate (“**Viagra**”)
- “**intellectual decay**” & “**deterioration in behavior**”

Piractecam

In India

- “intellectual decay”
- “social maladjustment”
- “lack of alertness”
- “change of mood”
- “deterioration in behavior”
- “learning disabilities in children associated with the written word”
- The drug is being promoted for use in young children
- no contraindications; no need to observe any precautions and no adverse drug reactions.

In Britain

- permitted for use in just a single indication, a rare disorder called cortical myoclonus, that too only as an adjunctive therapy
- contraindicated for adolescents under the age of 16 years.
- contraindicated in hepatic and renal impairment, during pregnancy and lactation.

In USA

- Not marketed

• Piractecam (Nootropil)

- Duration of treatment for the last indication is “entire school year” in dose of “3g per day” i.e. 6-8 capsules of 400mg daily.
- If the drug is administered for the entire school year as recommended, it will mean parents buying at least 2700 capsules at a cost of Rs. 12,775 year after year.
- **Trental 400 (pentoxifylline):**
- “The advertisement makes unsubstantiated claims of improvement in mental function.”
- This drug is marketed only for peripheral vascular disease in America and Britain
- In India it is indicated for cerebrovascular disease as well

Brain Tonics : a fiction portrayed as a fact

- Encephabol
- Hydargine
- Sermion
- Loftyl
- Sibellium

Only proven effect – placebo effect

- undesirable side effects
- transfer of money from patients pocket to pharma company's account

Appetite stimulants

Buclizine (brand Longifene in India) is being promoted as **appetite stimulant** while the drug itself is not commercially available in the US and is restricted worldwide for treatment of migraine in combination with analgesics.

- **Cyproheptadine** – Introduce in USA 1970
 - Disallowed as app. sti. In 1971 in USA
 - BNF not recommend use as app. sti.

Me too drugs

- Drugs which are similar to their predecessors are 'invented' just by making some minor change in the original drug chemical and are then patented and aggressively promoted
- higher priced alternatives of a parent drug without a clear therapeutic advantage
- In contrast to the **breakthrough drugs**, they have no significant treatment benefit, but are just created to continue to enjoy the patent protection (ever greening of patents) and thereby reap huge profits after anyhow convincing the doctors to prescribe them.

Me too drugs

- Omeprazole
- Rabeprazole
- Pantoprazole
- Esomeprazole
- Lansoprazole



Lack of Objective Drug Information

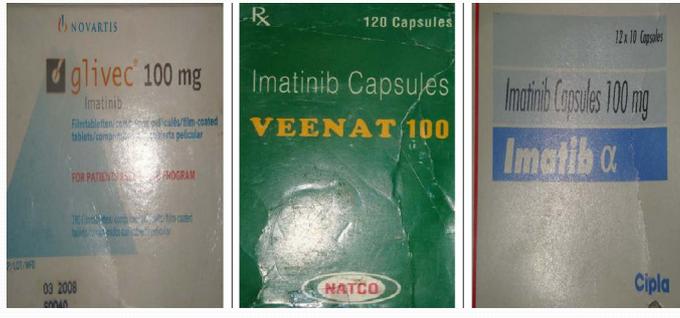
- Impartial Sources
 - Text Books – Martindale
 - Goodman & Gilman
 - Drug Bulletins
 - Drug Formularies
 - Medical Journals
 - The Lancet
 - British Medical Journal
- Commercial propaganda
 - Comes from pharmaceutical industry
 - Aimed to promote a particular product
 - Frequently biased (with rare exceptions !)
 - Examples
 - M.R.'s – Flip book
 - Advertisements in Journals
 - 'News' reports & 'Scientific articles'
 - Im(professional) journals
 - Industry sponsored 'conferences'
 - Free samples
 - Foreign 'study tours'

Prescription by brand name

Manufacturing company	(Brand Name)	(Generic Name)	(Stockiest price) One Injection	(Printed MRP)
Cadila	Amistar 500	Amikacin 500 mg	8.00/-	70/-
German Remedies	Amee 500	Amikacin 500 mg	8.00/-	70/-
Wockhardt	Zekacin 500	Amikacin 500 mg	9.90/-	70/-
Alembic	Amikanex 500	Amikacin 500 mg	8.22/-	64.25/-
Intas	Kami 500	Amikacin 500 mg	8.13/-	60/-
Unichem	Unimika 500	Amikacin 500 mg	7.80/-	72/-
Ranbaxy	Alfakim 500	Amikacin 500 mg	8.50/-	70/-
Cipla	Amicip 500	Amikacin 500 mg	7.42/-	72/-

. **RMSC tender price 5.90/-**

For example if doctor has to treat a patient of blood cancer, he may advise the salt Imatinib by various brand names. If he has prescribed brand Glivec a months course will cost **Rs. 1,14,400/-** to the patient. Whereas, the same anti cancer drug, but with a different brand name Veenat costs just **Rs.11,400/-**. And Cipla supplies the generic equivalent of this drug (@-imitib) at **Rs. 8,000/-** only, also Gelmark supplies it for **Rs. 5,720/-!** All these brands contain the same salt Imatinib, in the same quantity, conform to the same quality standards and are equally effective. [TOP](#)



Drug manufacturing company	Name given by company (Brand Name)	Salt name of medicine (Generic Name)	Rate at which drug is purchased by the chemist for 10 Tablets (Stockiest price)	Rate at which drug is sold to the customer (Printed MRP)
Cipla	Alerid	Cetirizine 10 mg	28.85/-	37.50 /-
Cipla	Cetcip	Cetirizine 10 mg	1.88/-	33.65 /-
Cipla	Okacet	Cetirizine 10 mg	1.84/-	27.50 /-



Super Distributor for Rajasthan
 M/s. Rajul Medical & Surgical Agency
 B-4, New Bypass Colony, Jaipur-302018
 Tel: 2254997, 2246211, 5539372 Mob: 98290-68768

Cipla

PRODUCT	PACK	MRP	PRICE NET	MRP-DISK	CABE
Tel Aid Surgical Tape	12x10 roll	300.00	189.31	189.30	20
Tel Aid Surgical Tape 3"	144inch	300.00	177.88	189.30	20
Tel Aid Surgical Tape 4"	12 inch	300.00	177.88	189.30	20
Tel Aid Plasters (Dress)	300	600.00	206.44	189.30	20
Acidulac 100mg/100capsule tab.	100	8.00	3.66	3.12	64
Acidulac 100mg/100capsule tab.	20x10	12.00	5.37	4.50	64
Acidulac 100mg/100capsule tab.	10x10	18.00	7.96	6.75	64
Amiclip 100 (Amikacin 100mg+Methylparaben 0.08%)	2ml Vial	20.00	4.29	3.85	800
Amiclip 250 (Amikacin 250mg+Methylparaben 0.08%)	2ml Vial	42.00	6.13	5.58	800
Amiclip 500 (Amikacin 500mg+Methylparaben 0.08%)	2ml Vial	72.00	8.27	7.42	1120
Amiprin 500 (Ampicillin Sodium 500mg (mg))	500mg	8.00	5.21	4.67	1200
Apemom Syrup/Cyproheptadine Hyd(2mg)	200ml	55.00	24.57	22.04	30
Apemom Tab/Cyproheptadine 4mg	10x6x10	10.00	3.90	3.50	80
ASIS Caps (Anti oxidant)	10	33.00	9.70	8.70	80
Asimax 250 Tab (Asthromycin Ansh250m)	10x6	60.00	35.58	31.52	80
Asimax 500 Tab	10x6	60.00	35.58	31.52	80
Burnheal cream (Silver Sulpha+Chlorhexo)	15gms	28.00	9.53	8.55	600
Castonovl condoms (Black)	3x4	12.00	6.75	6.05	720
Castonovl condoms (Purple)	3x4	12.00	6.75	6.05	720
Cefepim 250 Tab (Cefepime Azecl 250)	10x4	150.00	67.58	54.25	48
Cefepim 500 Tab	10x4	288.00	117.08	105.50	27
Cefix 100 Tab (Cefixime 100mg tablets)	10x5	180.00	51.74	46.40	30
Cefix 200 Tab (Cefixime 200mg tablets)	10x4	120.00	36.42	33.30	30
Cefix Dry (Cefixime Dry Syrup50mg/ml)	30ml	65.00	29.43	25.50	40
Cefix 1000 (Cefixime 1000mg)	10x10	300.00	73.58	66.00	40
Cephalex 125 DT (Cephalexin 125mg)	20x10	39.90	9.92	8.90	45
Cephalex 250 Capsule	10x10	69.90	17.54	15.73	144
Cephalex 250 DT Tab	20x10	79.95	20.35	18.25	36
Cephalex 500 Caps	10x10	129.95	31.78	28.50	40
Cephalex Dry Syrup	30ml	27.90	10.93	9.80	120
Cephalex Drops	10ml	35.90	12.71	11.40	120
Cetipin Tab (Cetirizine Hydro 10mg)	10x10	39.00	2.10	1.98	42
CETIPIN-L (Levocetirizine 5mg)	10x10	32.00	7.63	6.84	150
Cetipin Syrup	30ml	18.00	7.37	6.61	150
Claxton Cold Syrup(Cetirizine2mg+Para125	80ml	25.00	11.44	10.28	80
Claxton Cold Tab(Cetirizine2mg+Para500hPhenylprop	10x10	20.00	4.22	3.58	60
Claxton Dusting Powder/Povidone 9% Powder	10gm Cont	31.00	8.44	7.54	400
Claxton Ointment 20gms	20gm Tub	35.00	10.17	9.12	400
Claxton Ointment 125gm	125gm Tub	82.00	43.99	39.45	30
Claxton Ointment 250gms	250g Tub	240.00	97.20	87.50	20
Claxton Solution	100ml Bot	88.15	18.90	15.15	50
Claxton Solution	100ml Bot	180.00	66.93	60.78	30
Claxton Solution	2 Lit	450.00	216.09	193.80	8
Cipocin 1% Hydrocortisone Sodium succinate eptu	40 gm	45.00	14.12	12.65	80
Cipocin 250mg/ml (Ceftriaxone 250mg)	250mg vial	40.00	10.11	9.07	320
Cipocin 1gm Inj(Ceftriaxone 1gm)	1gm vial	135.00	23.92	21.45	30
Cipocin 500mg/ml (Ceftriaxone 500mg)	500mg vial	75.00	15.45	13.85	320
CIPLOX IV 100ml	100ml Bot	32.00	16.07	14.41	60
Ciplox 250 cap(Amoxicillin Trihydrate 250mg)	12x1x10	40.00	9.00	8.25	40

GENERIC DRUGS

- साल्ट यानि उसके मूल रसायनिक तत्व (Active Pharmaceutical Ingredient/Salt)।
- किसी रोग विशेष के ईलाज के लिए तमाम शोधों के बाद एक रासायनिक तत्व विशेष दवा के रूप में देने की संस्तुति की जाती हैं।
- जैनेरिक दवाईयों ब्राण्डेड दवाईयों की तुलना में औसतन पाँच गुना कम कीमत की होती हैं।



जैनेरिक एवं ब्राण्डेड दवाओं की तुलनात्मक दर

S.No	Name of Drug	Pack Size	RMSC Tender Price(In Rs)	Equivalent Popular Brand	MRP (In Rs)
Analgesic, Antipyretic & Anti inflammatory drugs					
1	Diclofenac Sodium Tablets IP 50 mg	10 Tab strip	Rs 1.24/10 tablets + Vat	Voveran (Novartis)	31.73
				Dicloran (Lekar)	23.43
Anti infective Drugs(Anthelminthics)					
2	Albendazole Tablets IP 400 mg	10 Tab	Rs. 6.28 + VAT	Zental (GSK)	175.00
Anti infective Drugs(Antibiotics)					
3	Azithromycin Tablets IP 500 mg	10Tab	Rs 58.80	Azithral (Alembic)	308.33

जैनेरिक एवं ब्राण्डेड दवाओं की तुलनात्मक दर

Cardio Vascular Drugs					
4	Atorvastatin Tablets IP 10mg	10 Tab Blister	Rs 2.98	Atrova (Zydus)	103.74
5	Clopidogrel Tablets IP 75 mg	10 Tab Strip	Rs 6.10	Clopidogrel (USV)	215.50
Hormones & Endocrine Drugs					
6	Glimepiride Tablets IP 2 mg	10 Tab strip	Rs 1.95	Amaryl (Aventis)	117.40
Psychotropic Drugs					
7	Alprazolam Tablets IP 0.5mg	10 Tab Blister	Rs 1.47	Anxit (Micro)	25.80
				Alprax (Torrent)	25.33

Implications of Unethical Promotion and Irrational Use of Drugs : THE SUFFERING

1. MEDICINES BECOME UNAFFORDABLE
2. INAPPROPRIATE MEDICATION
3. RISK OF ADVERSE EFFECTS
4. RISK OF ANTIMICROBIAL RESISTANCE
5. TRANSMISSION OF DISEASES THROUGH UNSAFE INJECTIONS
6. DRAIN ON FOREIGN EXCHANGE

The Solution

- Rational use of Drugs
 - Generic Prescribing
 - Adoption of essential drugs list
 - Adoption of Standard Treatment Guidelines to discourage “Luxury drugs”



The Solution

- Availability of free medicines for all
- Drug procurement by generic name through open tender system
- Distribution of essential drugs free of cost through govt. drug counters

Fair price medicine shops

- Life-line drug stores (run by RMRS)
- Co-operative Medical Stores



Market competition ensures that private medical shops also reduce their prices.



THE ULTIMATE SOLUTION: Statutory price control for all essential drugs

- Supreme Court in its interim order dated, March 10, 2003 in Gopi Nath case has directed the central government to ensure that essential and life saving drugs are kept under price control.
- At present only 74 drugs have ceiling prices. If SC orders of 10 Mar.03 are complied with, it would result in control on ceiling prices (ie control on MRP) of about 350 Essential Drugs and many other life saving drugs as well. Even if these drugs could be provided at affordable prices many more **human lives could be saved.**

HISTORY OF DRUG PRICE CONTROL IN INDIA

- In 1979 - 347 essential drugs were under control.
- In 1987 to 142 drugs.
- In 1995 this came down to 76
- At present only 74 out of over 500 commonly used drugs are under statutory price control.
- In fact only 47 bulk drugs of the 74 notified in 1st schedule of the DPCO, 1995 are under production.
- Out of 348 medicines in NLEM-2011 only 34 are in DPCO, 1995.

Draft NATIONAL PHARMACEUTICALS PRICING POLICY, 2011

• KEY PRINCIPLES

- (1) Essentiality of Drugs – NLEM, 2011
- (2) Control of Formulations prices only – API / bulk drug may not reflect the essentiality
- Control price of final end product
- (3) Market Based Pricing – Different from earlier principle of cost based pricing.

Formula for Calculation of retail ceiling price of formulation : DPCO 1995

- $R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + MAPE/100) + E.D.$
where
- "R.P." - retail price;
- "M.C." - material cost
- "C.C." - conversion cost
- "P.M." - cost of the packing material
- "P.C." - packing charges
- "MAPE" - Maximum Allowable Post-manufacturing Expenses, means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations;
- "E.D." - excise duty;

Ceiling Price will be fixed on the basis of readily monitorable

Market Based Data (MBD): 2011 Policy

- Ceiling Price = Weighted Average Price (WAP) of the top three brands by value (MAT value) of a single ingredient

Eg. Let us calculate ceiling price of cetirizine

Generic / Pharmacopoil name	Brand Name	Manufacturer	M.R.P. of 10 Tablets(in Rupees)
Cetirizine Tab I.P. (10 Mg)	Cetzine	GSK	37.50
	Alerid	Cipla	37.50
	CZ-3	Lupin	32.70
	Zyrtec	UCB India Pvt. Ltd	34.83
	Zyncet	Unichem	35.00

This means ceiling price of cetirizine would be about Rs. 35/-

- Now what is the actual price
- Cipla - Okacet - 1.84
- Cipla - Cetcip - 1.88
- Sandoz - 1.20
- Sarabhai - 1.20
- RMSC tender price - Agron remedies - 0.74 for 10 tabs.
- Would proposed price control make any difference ?

Nimesulide Tab (100 Mg)

Nise	Dr. Reddys	34.83
Nimulid	Pancea	32.00
Nimi Rapitab	Shreya	33.00
Pronim-100	Unichem	25.90
Nimutab	Centaur	31.21

Chittorgarh fair price medicine shop - 1.70/-

Diclofenac Sodium Tablets IP (50 Mg)

Voveran -50	Novartis	28.93
Dicloran	Lekar	23.43
Supance-50	Dr. Reddys	45.50
Voltaflam-50	Novartis	30.70

RMSC tender price – 1.24/-

Alprazolam Tab (0.25 Mg)

Trika 0.25	Unichem	13.60
Alprax 0.25	Torrent	15.33
Anxit 0.25	Micro Lab	16.75
Alzolam 0.25	Sun	15.00
Restyl 0.25	Cipla	10.33

RMSC tender price - 0.81/-

Discourage v/s not allowed

- The new policy (NLEM-2011) seeks to discourage non-standard strengths and dosages
- The value of 'a' is to be chosen in a manner so that companies are discouraged from manufacturing non-standard strengths.
- Accordingly, the value of 'a' is recommended as 0.5 for tablets and capsules and 0.6 for injectables.

Exemptions:

- Drugs having weighted average price less than or equal to Rs.3/- for each unit.
- For such drugs the Ceiling Price will be fixed at Rs.3/- and any such drug selling at a price higher than Rs.3/- will have to bring the price down to Rs.3/-.

:

Patented Drugs

- a separate Committee constituted by the Government order dated 21st December, 2006 for finalizing the pricing of Patented Drugs
- decisions on pricing of patented drugs would be taken based on the recommendations of the Committee

IMPACT ANALYSIS

Range of Reduction in Ceiling Price % of medicines related with NLEM 2011	
Decrease in price of Highest Priced Brand between 0-5%	52%
Decrease in price of Highest Priced Brand between 5-10%	7%
Decrease in price of Highest Priced Brand between 10-15%	5%
Decrease in price of Highest Priced Brand between 15-20%	4%
Decrease in price of Highest Priced Brand between 20%	32%

The Solution

Rational Prescription (by Doctor)

1. Prescription of drugs by generic (salt) name.
2. Prescription out of essential drugs list.
3. As per Standard Treatment Guidelines.

Low cost /free drugs made available

(at govt. medical shops)

1. Transparent procurement through open tender system.
2. Distribution of Low cost drugs through Life Line/ Coop. Store.
3. Display of Rates

Until Statutory price control for all essential drugs

Take home message

- To make treatment accessible and affordable
- To serve the ailing mankind
- TO SAVE LIVES

• THANKS

AARPGUASRO HI- THE AP EXPERIENCE

Rajan Shukla and Veema Shatrugna



Aarogyasri HI- The AP Experience

Dr Rajan Shukla
Dr Veena Shatrugna



Rajiv Aarogyasri Community Health Insurance scheme

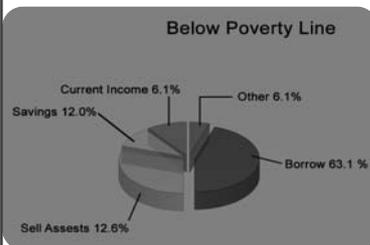
- Sponsored by: Govt. of ANDHRA PRADESH
- **The State to provide medical assistance to BPL families for the treatment of serious ailments such as cancer, kidney failure, heart and neurosurgical diseases etc., requiring hospitalization and surgery/therapy**
- **Beneficiaries: Individual, Family, Community, Women and Children**
- **The beneficiaries of the scheme are the members of below poverty line families as enumerated and photographed on the Rajiv Aarogyasri Health Card/ below poverty line Ration Card.**

Aarogyasri Scheme Coverage

- **AP has a very generous BPL criteria. 80% population BPL**
- **The benefit on family is on floater basis i.e. the total reimbursement of Rs.1.50 lakhs can be availed of individually or collectively by members of the family.**
- **An additional sum of Rs 50,000 is provided as buffer to take care of expenses if it exceeds the original sums i.e. Rs 1.50 lakhs per Individual/family.**
- **Cost for cochlear Implant Surgery is reimbursed by the Trust up to a maximum of Rs.6.50 lakhs for each case.**

Scheme Back ground

Health expenditure among BPL, by source



Source: The Institute Of Health Systems, HACA Bhavan, Hyderabad, AP-500004

✓ Escalating health care costs: leading to rural indebtedness

✓ Large proportion of BPL families borrow money or sell assets to pay for hospitalization

✓ No structured help for the poor

✓ Institutional exploitation of the poor and illiterate

✓ No proper guidance or awareness

✓ Lack of health care infrastructure

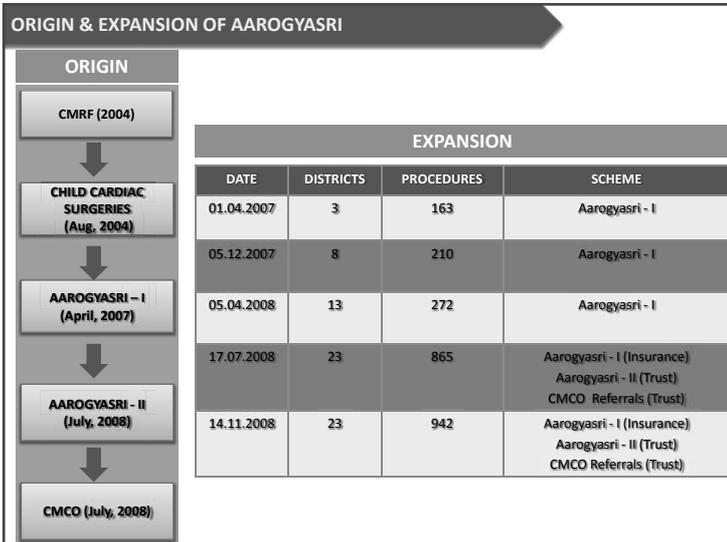
1980-2005 Hyderabad and AP emerged as corporate Health care and diagnostic Hub.

2004 – 2006, Dr Y S Rajasekhar Reddy’s political Astuteness- scheme to provide healthcare for all through corporate hospitals – A Re-election strategy.

2006- The report of the Jayati Ghosh Committee on economic distress in the agricultural sector.

2006- Manda Krishna Madiga, highlights the problems of young children with heart ailments.

May 2004 - June 2007, the CMRF had spent Rs 168.52 crore to help 55,362 BPL patients needing hospitalization.



DISEASE COVERAGE

CRITERIA OF SELECTION	SURGICAL (783 PROCEDURES)	MEDICAL (159 PROCEDURES)
<ul style="list-style-type: none"> Emergency and Life saving in nature Requiring Specialist Doctors & Special Equipment Not ordinarily available in Govt. Hospitals (Area/CHC) Verifiable Diagnostic and Post treatment Protocols Not covered by other Government schemes 942 procedures in 31 systems 	<ul style="list-style-type: none"> General Surgery ENT Ophthalmology Gynecology & Obstetrics Orthopedics Surgical Gastroenterology Cardio Thorasic surgery Pediatric Surgery Genito-Urinary surgery Neuro-surgery Surgical Oncology Medical oncology Radiation Oncology Plastic Surgery Polytrauma Prostheses Cochlear Implantation 	<ul style="list-style-type: none"> Critical care General Medicine Infectious Diseases Paediatric Intensive Care Neonatal Intensive care Paediatric General Cardiology Nephrology Neurology Pulmonology Dermatology Rheumatology Endocrinology Gastroenterology

Cashless Treatment package



Each package covers the cost of the following:

- ✓ Screening
- ✓ Testing and Diagnosis
- ✓ Medical treatment
- ✓ Medicine
- ✓ Transport
- ✓ Food
- ✓ Follow-up treatment



- Scheme lists Procedure covered, not diseases
- No protocol for determining the best modality of treating the patient, or whether the patient actually needs the procedure.
- Packages are standardized and priced in consultation with Medical experts based on procedures or surgeries.

MAIN FEATURES

UNIVERSAL COVERAGE	All BPL Families 2.03 crores
CASHLESS TREATMENT	Up to Rs 2 lakhs in a year
HEALTH WORKERS	3057 Aarogyamithras
HEALTH CAMPS	12536camps so far
SIMPLE PROCEDURE	Health card/White Card
COST	Borne by the Government
DISEASES	Identified
PACKAGES	For end-to-end treatment
CHOICE OF HOSPITALS	Left to patients
MONITORED	On-line : 24 hour basis
IMPLEMENTATION	Aarogyasri – I : through Insurance Co. Aarogyasri – II : directly by Trust CMCO : directly by Trust

Monthly Statistics

Average Monthly statistics		
SI No	Category	Total
1	Medical camps	622
2	Screened	112712
3	Cases Registered	101697
4	Out Patients	35070
5	In Patients	31149
6	Number Of Surgeries	24728
7	Claim Amount	75,71,62,435
8	Pre authorizations	26199

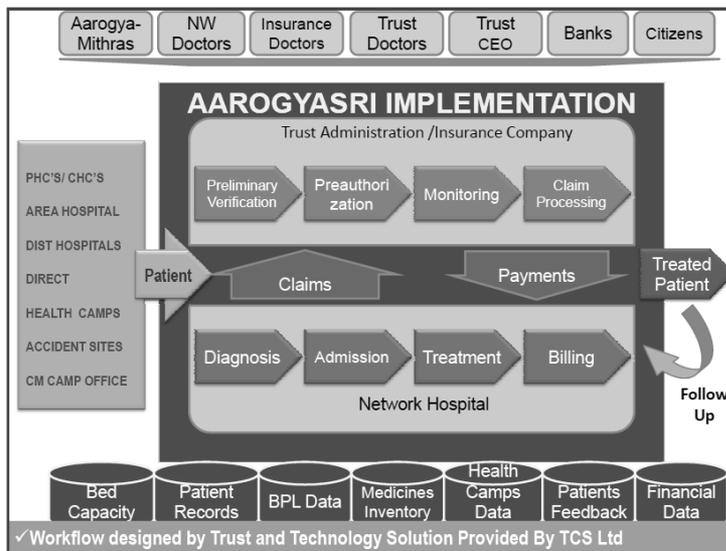


Table 11: Expenditure by Functions of Care

Functions	2004-05		2005-06		2006-07		2007-08		2008-09(RE)	
	Rs.'000	%								
Direction and Administration	824337	5.52	970903	5.98	908413	6.86	941751	3.72	1136879	3.55
Primary Health Care	8502725	56.95	8782558	54.08	9643670	51.58	11039003	43.66	12438271	38.85
Secondary Care	1824560	12.22	2001259	12.32	2774631	14.84	3343419	13.22	3534743	11.04
Tertiary Care	1992976	13.35	2506882	15.44	2984739	15.96	4742819	18.76	5156330	16.10
Medical Education	1209994	8.10	1282721	7.90	1523309	8.15	2063163	8.16	2646211	8.26
Health Statistics and Research	30391	0.20	35483	0.22	41211	0.22	54867	0.22	68921	0.22
Social Protection Schemes	64212	0.43	178970	1.10	223078	1.19	1681513	6.65	4967500	15.51
Repayment of Loans	480000	3.22	480000	2.96	598600	3.20	658460	2.60	658400	2.06
Others	0	0.00	0	0.00	0	0.00	757167	2.99	1412511	4.41
Total	14929195	100	16238776	100	18697651	100	25282162	100	32019772	100

- In 2011-12, Aarogyasri budget is Rs 925 Crore.
- 23% of states health budget (Approx Rs 4000 Crore).
- Almost 50% of State Non Plan Health Budget.

Major Treatment Categories distribution

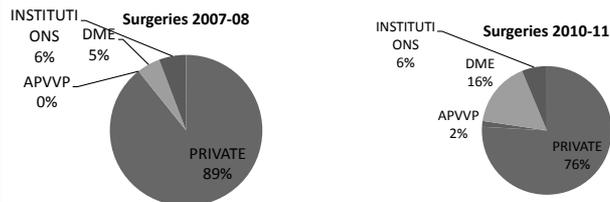
Cardiac	25.3
Cancer	22.1
Neurology	15.2
Renal	15.1
Poly-Trauma	9.1
General Surgery	4.8
Gynaecology	2.1
Paediatrics	2.4
Plastic surgery	1.1
Orthopedics	1.1
Others	1.7

Role of Insurance agency and TPA

- The Insurance agency has assured profit.
- No sharing of risk.
- 20% of total premium paid by Government as administrative cost for TPA and Insurance agency.
- Claims payment capped at 150%, after this Aarogyasri trust pays the difference.
- If unspent claims amount, Insurance agency keeps 10% of unspent and returns the rest.
- No incentive for monitoring inefficiencies, wastage, inflation of the system or checking supply side moral hazard.

Insurance a risk free business!!

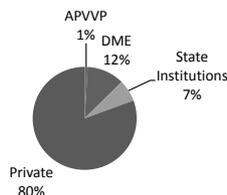
Distribution of total procedures by hospitals type



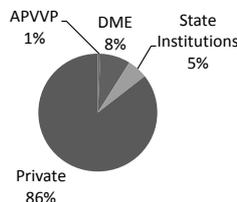
Government Hospitals participation has increased from 11% to 24% during 2007-08 to 2010-2011

Who gets the funds?

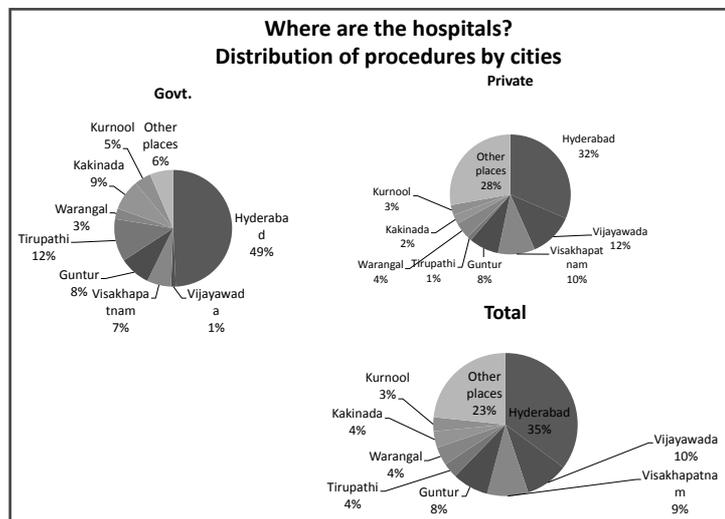
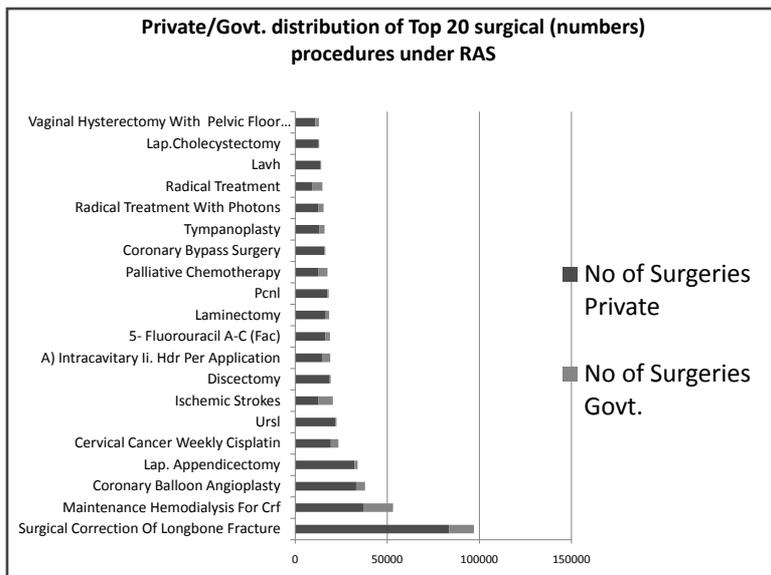
Pre Authorized Amount
Rs 2842 Cr



Claim Amount
Rs 2342 Cr



- Of the amount preauthorized, 80% has gone to private and 20% to Govt Institutions.
- Actual amount claimed by private and public sector are 86% and 14% respectively.



Positive effects

- 204 lakh BPL families covered, 12 lakh surgeries done. 80% of the population covered.
- Health on Political Agenda.
- BPL population empowered to Access health care.
- Incentivizes growth and performance in Health sector. Some public sector hospitals have also shown ↑ Performance.
- Provides a single health system handle to guide public and private sector hospitals.

Percentage change in Surgeries from 2009 to 2010

Procedure Category	Pvt hospital	DME	State Institution	APVVP
Cardiology	5	8	4	
CT Surgery	14	9	13	
General Surgery	19	33	1	9
Poly-trauma	42	28	31	9
Medical oncology	25	189	14	
Nephrology	78	546	21	
Neurology	42	51	20	
Ortho surgery	55	53	2	75
Pediatrics	22	79	-	284
OBG	-52	-5		-20

Negative effects

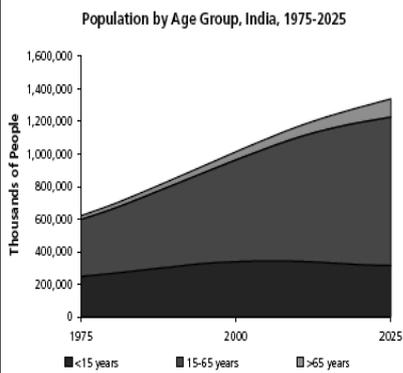
- Further Skews Public health spending towards tertiary care.
- Shifts Government health care fund from public sector to private sector.
- Stand alone scheme, not integrated with primary and secondary health care.
- Over reliance on IT technology to check frauds. Absence of Gate keeping mechanism
- Increases state health care cost with dismal impact on population health indicators.

Scope for improvement

- Map BPL health care needs.
- The scheme does not appropriately respond to cover catastrophic health care needs of BPL population.
- Still barriers to access, specially for Marginalized groups.
- Authorizations & Payments designed by technology intensive procedure rather than health conditions.
 - facilitates use by hospitals rather than patients.
 - Promotes technology intensive health care set-up, not necessarily the best health care service or easily accessible health care service.
- Lacks strategic purchasing

Strengthen Public health delivery in Primary and Secondary care.

Health Insurance – Focus Areas



- Health Insurance - potential to become a Rs.25000 crores industry by 2012.
- No. of Elderly People in the Developing World will TRIPLE in 25yrs. (WHO)
- In India, the no. of people above 60 yrs is about 8% today, with that no. expected to hit 21% by 2025. (Asia Insurance Review)

Source: NIA Library

OUT OF POCKET EXPENDITURE IN HEALTH CARE

Narendra Gupta

OUT OF POCKET EXPENDITURE IN HEALTH CARE

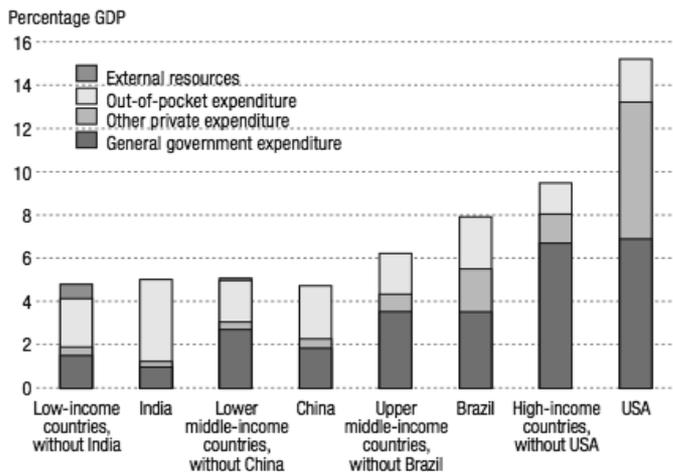
Results of study in five states of India

Study Conducted by



Prayas, Rajasthan

Figure 5.1 Percentage of GDP used for health, 2005⁴



Out of Pocket Expenditure (OoPE) in Health Care

- OoPE are non-reimbursable fees which a patient or family is responsible for paying directly to health practitioners or suppliers, without intervention of a third party. It often occurs, when publicly funded facilities are unable to provide the required health services and supplies for free or through insurance.
- India was ranked as having the 42nd highest average OoPE, with 74.4% of private expenditure being paid as out of pocket. (WHS 2011)
- OoPE accounts for an average increase in poverty by as much as 3.6 and 2.9 percent for rural and urban India respectively (Gupta 2009)

Aim of the Study

- Assess the nature of out of pocket payments of households in health care and examine its relationship with post 2004 new nation wide health initiatives viz. NRHM, RSBY and many state led programmes.

Objectives of Study

- Assess the change in out-of-pocket expenditure of households for health care between 2004-10.
- Examine the change in OoP expenditure in various social and economic groups.
- Analyse the pattern of OoP expenditure in relation to various parameters of new post 2004 national health initiatives viz. NRHM & RSBY

Research questions

- Is there any reduction or increase in out-of-pocket expenditure for households on health care post 2004?
- Is there any reduction or increase in out-of-pocket expenditure on health care in proportion to total consumption expenditure of households?
- Is there any difference in the pattern of OoP across different (a) social and (b) economic categories?
- Is there any effect of post 2004 new national health programmes on the pattern of out-of-pocket expenditure on health care?

Scale of study

- Study was carried out in rural area of 6 states of India.
- States were Assam, Bihar, Jharkhand, Rajasthan, Tamilnadu, Uttarakhand and. Data from Bihar could not be included in the study owing to technical snag.
- Criteria for selection of number of districts:
 - states up to 20 districts : 2 - Jharkhand, Uttarakhand
 - States from 21 to 30 districts : 3 - Assam, Tamilnadu
 - States from 31 to 40 districts : 4 - Rajasthan
 - States from 41 and above districts : 5

S. No.	State	District
1.	Assam	Kamrup
2.		Sonitpur
3.		Cachar
4.	Jharkhand	Sahibganj
5.		Purbi Singhbhum
6.	Rajasthan	Bharatpur
7.		Nagaur
8.		Tonk
9.		Baran
10.	Tamilnadu	Vellore
11.		Coimbatore
12.		Virudhunagar
13.	Uttarakhand	Tehri Garhwal
14.		Nainital

Sampling strategy

- Districts and village in states were selected through **PPS technique** (Probability Proportional to Size Sampling Technique).
- Sample size was fixed to 200 HH per district. This was obtained by selecting 10 villages per district and 20 households per village.

Sample design

- Stratified multi-stage design
 - The first stage units (FSU) were the 2001 census villages.
 - The ultimate stage units (USU) were households in villages. In case of large villages requiring hamlet-group (hg) formation, one intermediate stage was the selection of two hg's from each FSU.

Formation of Second Stage Strata and allocation of households

Composition of SSS		No. of households to be surveyed	
		Without hg formation	With hg formation (for each hg)
SSS 1	Households with at least one member hospitalized during last 365 days	8	4
SSS 2	From the remaining households, households having at least one child of age group 12-23 months	4	2
SSS 3	Other households	8	4

Survey tool

- Survey tool was adapted from NSSO 60th round.
- There were two schedules –
 - for listing of households and
 - for in-depth interview of selected households
- Field data of the study was collected in the months from March to May 2011

FINDINGS



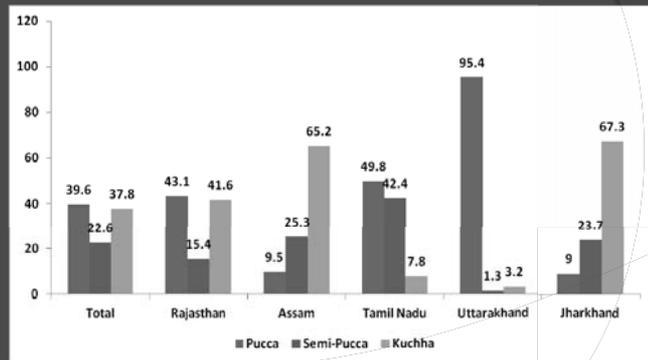
- Number of States : 5
- Number of Districts : 14
- Number of Villages : 140
- Number of Households surveyed : 2723

Profile of the sample group

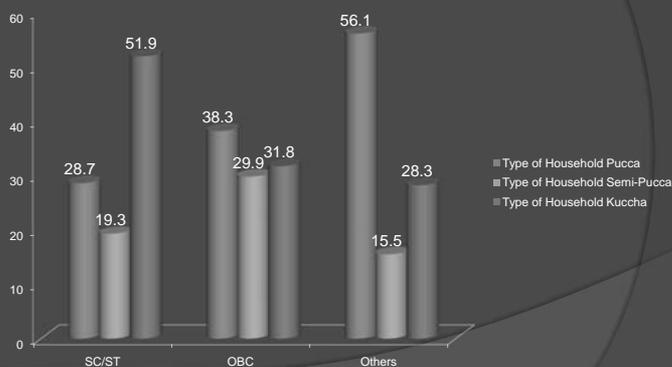
Background Variables	Percentage					
	Total	Assam	Jharkhand	Rajasthan	Tamil Nadu	Uttarakhand
Sex						
Male	50.2	51.3	50.1	52	49.4	45.3
Female	49.8	48.7	49.9	48	50.6	54.7
Age Group						
0-14	32.4	32.5	39.5	32.7	25.3	31.9
15-29	28.6	27.7	25.5	31.2	27.6	28.6
30-44	19.5	23.3	18.7	16.9	23.1	17.0
45-59	11.5	10.1	9.8	11.7	14.3	11.2
60+	8.0	6.4	6.5	7.4	9.7	11.3
Religion						
Hindu	82.5	67.1	51.2	93.9	94.5	100
Islam	11.6	27.5	23.1	6.1	2.1	-
Christian	2.2	5.4	4.1	-	3.4	-
Others	3.7	-	21.6	-	-	-
Social Group						
ST	15.2	24.9	26.4	17.6	-	0.1
SC	19.7	9.9	14.8	18.2	34.8	24.9
OBC	40.0	26.4	53.5	51.3	54.9	0.7
Others	25.1	38.7	5.3	12.8	10.9	74.2
Literacy						
Illiterate	24.2	12	34.5	27.5	12.3	15.4
Literate	75.8	88	65.5	72.5	87.7	84.6

Basic Household Amenities and Infrastructure

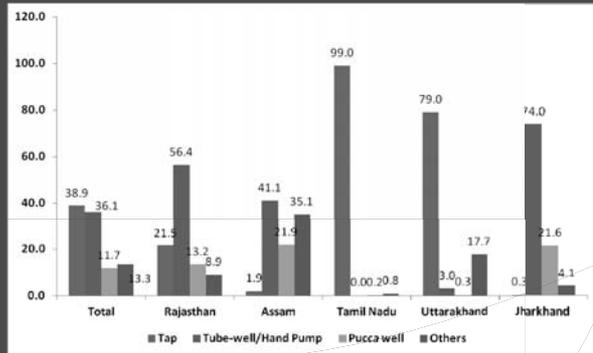
Percentage distributions of households by type of structure



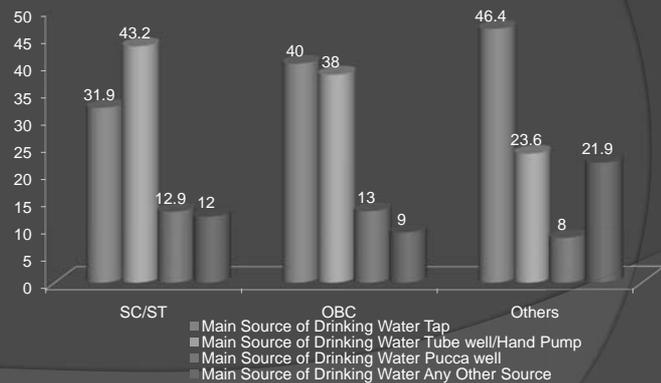
Percentage distribution of type of household by social groups



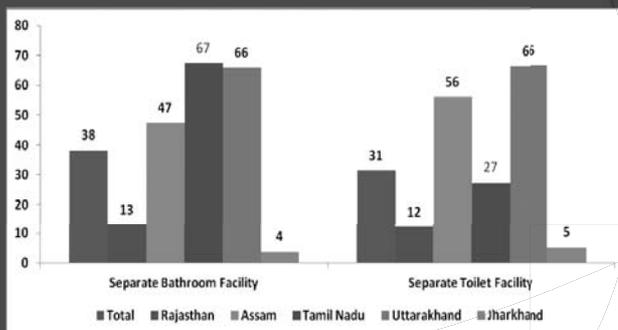
Percentage distribution of households by main source of drinking water



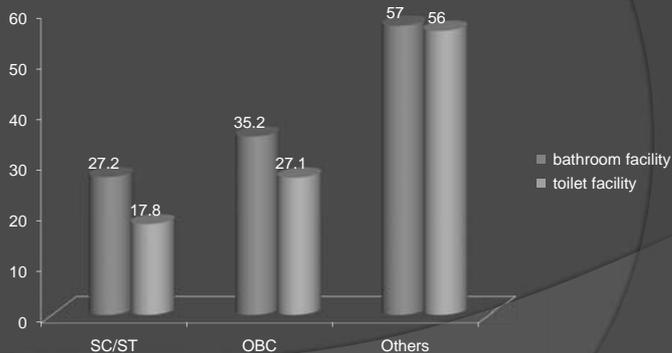
Percentage distribution of main source of drinking water by social group



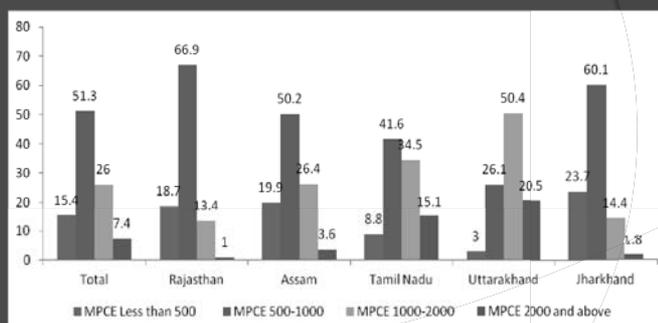
Percentage distribution of households having bathroom and toilet facility



Percentage distribution of households having bathroom and toilet facility by social group

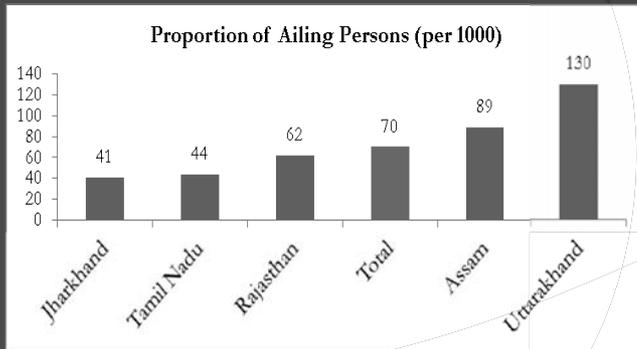


Percentage distribution of households by MPCE (Monthly Per Capita Expenditure)

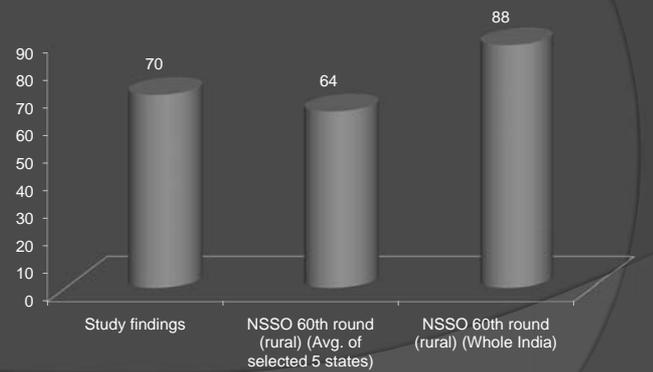


Morbidity and Health Care (Non-hospitalised case)

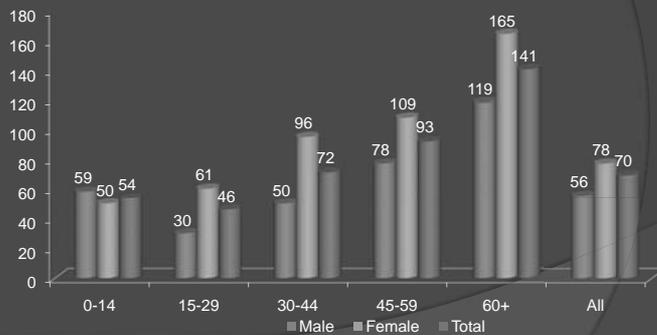
Proportion of Ailing persons (per 1000) during last 15 days prior to the survey



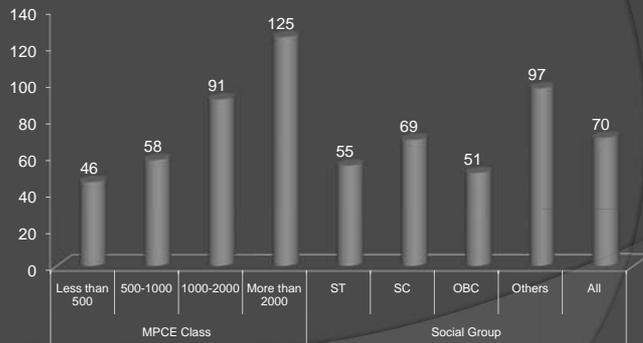
Proportion of Ailing persons (per 1000) during last 15 days prior to the survey (Comparison with NSSO 60th round)



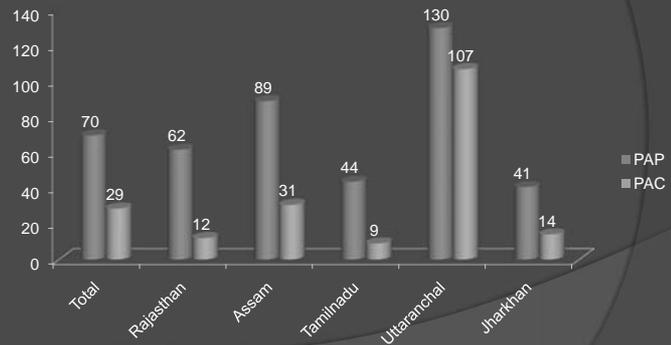
Proportion of Ailing Persons (per 1000) during last 15 days by sex and age group



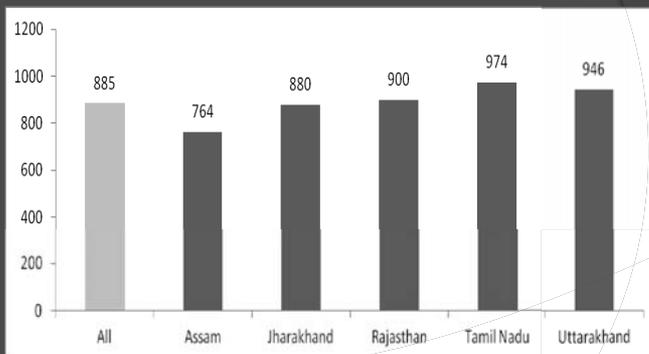
Proportion of Ailing Persons (per 1000) during last 15 days by socio-economic characteristics



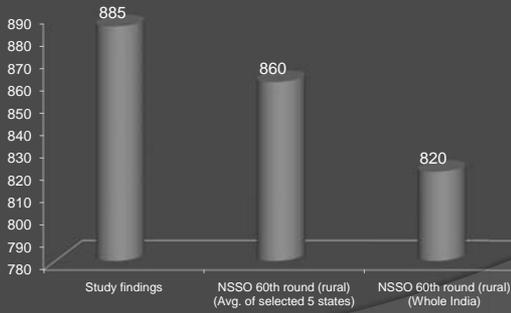
Proportion (Per 1000) of persons ailing and Proportion of persons reported commencement of ailment one day before the survey



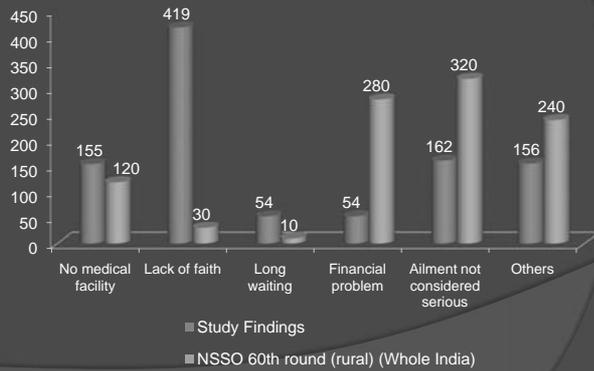
Proportion (per 1000) of ailing persons treated in outpatient



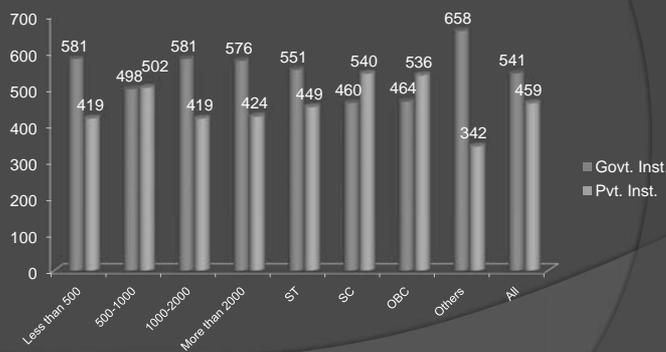
Proportion (per 1000) of ailing persons treated in outpatient (Comparison with NSSO 60th round)



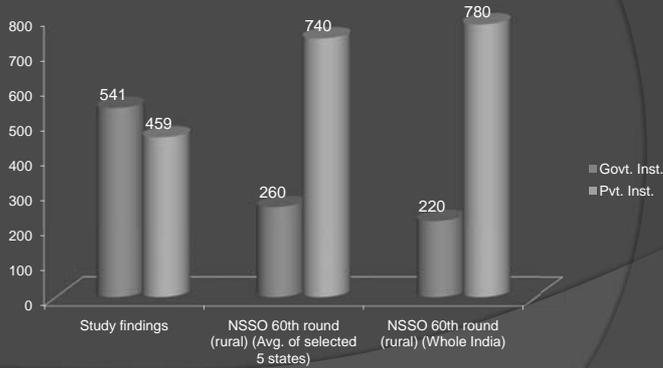
Proportion (per 1000) of untreated spells of ailment by reason for no treatment and comparison with NSSO 60th round



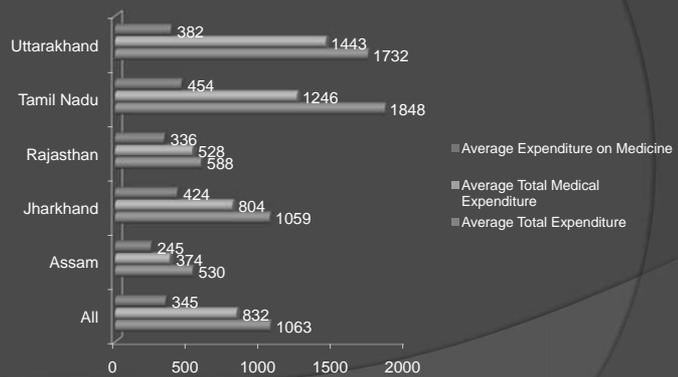
Per 1000 distribution of treated spells of ailments during 15 days by source of treatment for each MPCE class and social group



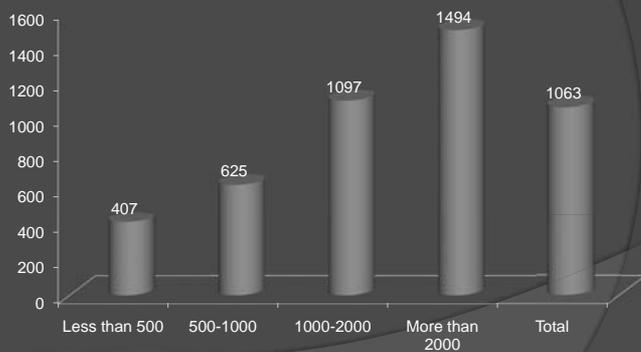
Per 1000 distribution of treated spells of ailments during 15 days by source of treatment (Comparison with NSSO 60th round)



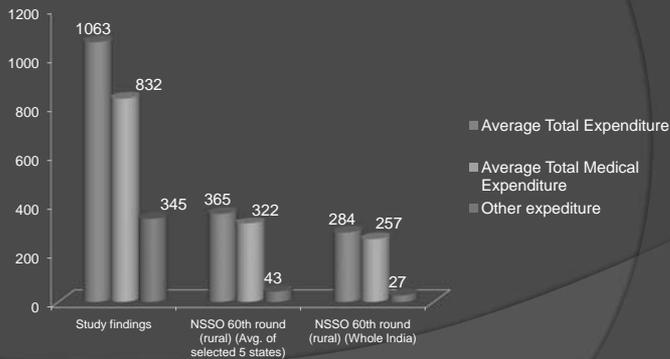
Average total expenditure (Rs.), Average total medical expenditure (Rs.) and expenditure on medicine (Rs.) for non-hospitalized treatment per ailing person during last 15 days



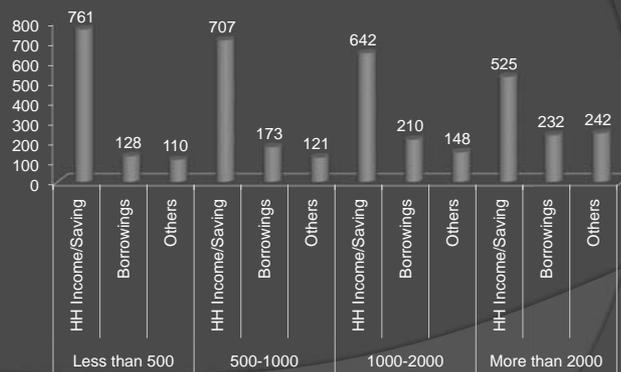
Average total expenditure (Rs.) for non hospitalized treatment for each MPCE class



Average total expenditure (Rs.) , Average total medical expenditure (Rs.) and other expenditure (Rs.) for non-hospitalized treatment per ailing person during last 15 days (Comparison with NSSO 60th round)

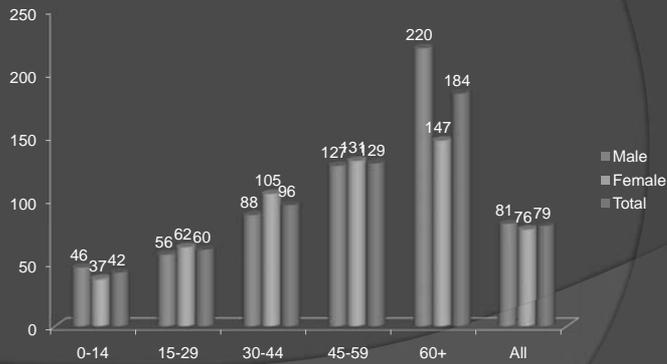


Proportion (per 1000) of household expenditure on treatment during last 15 days by source of finance for each MPCE class

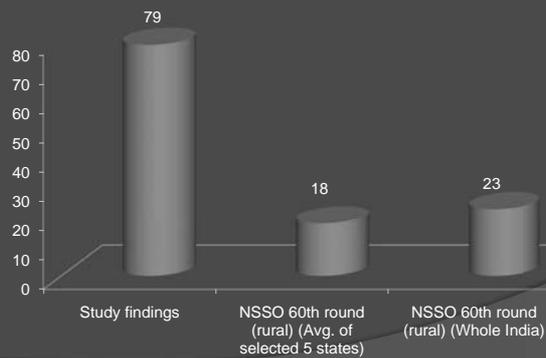


Morbidity and Health Care (Hospitalised case)

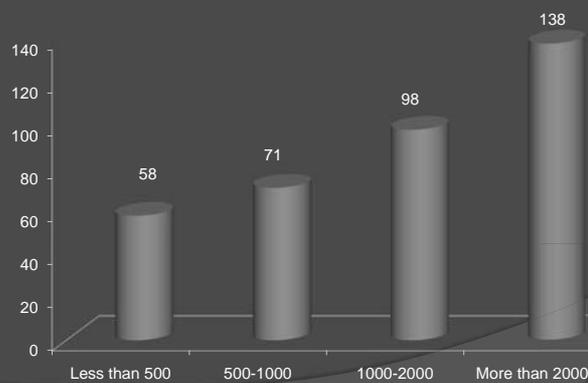
Proportion (per 1000) of population hospitalized during last 365 days



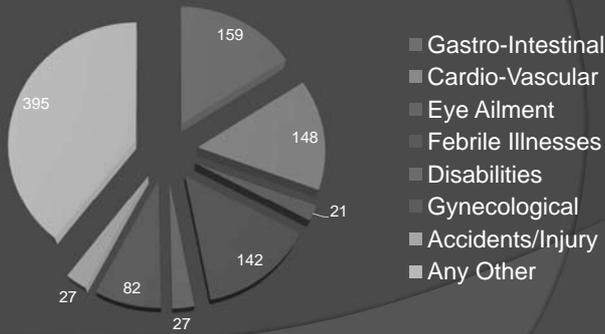
Proportion (per 1000) of population hospitalized during last 365 days (Comparison with NSSO 60th round)



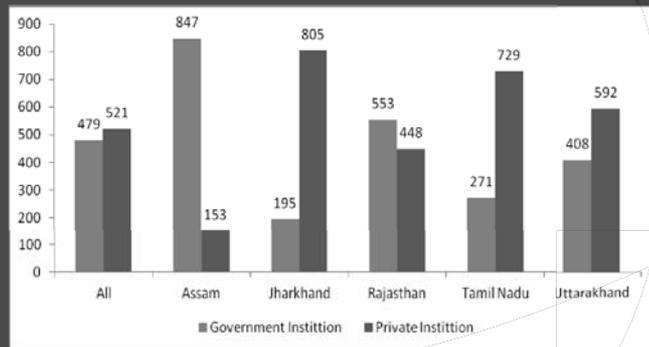
Proportion (per 1000) of population hospitalized by MPCE class



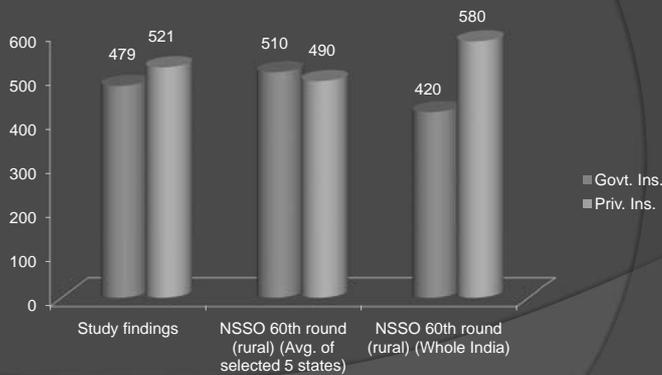
Per 1000 distribution of persons hospitalized by type of ailment



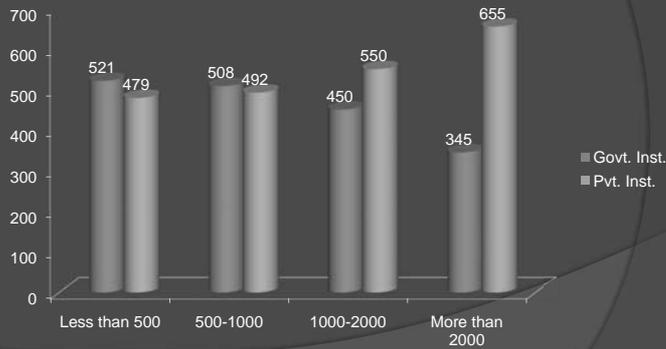
Proportion (per 1000) of hospitalized cases by type of hospital



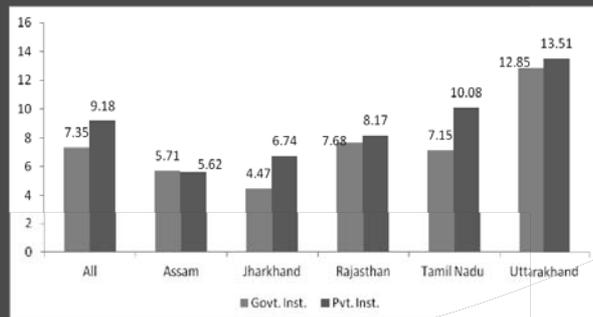
Proportion (per 1000) of hospitalized cases by type of hospital (Comparison with NSSO 60th round)



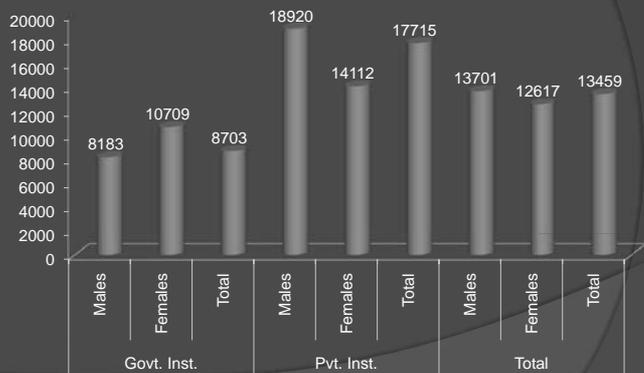
Proportion (per 1000) of hospitalized cases by type of hospital in each MPCE class

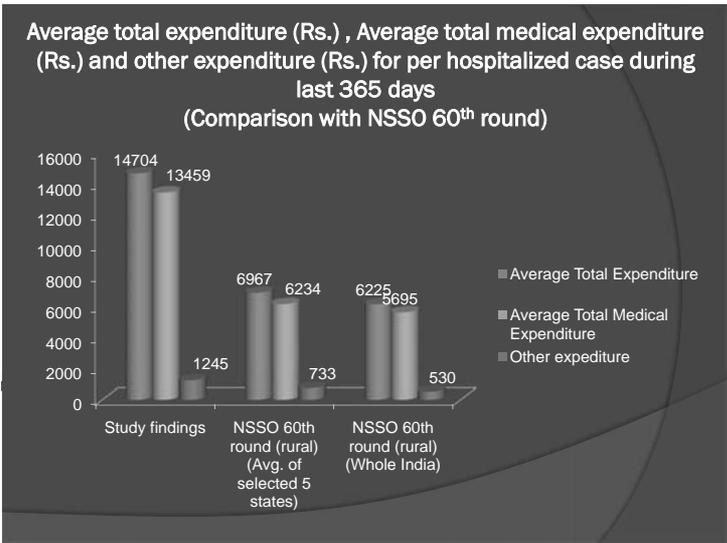
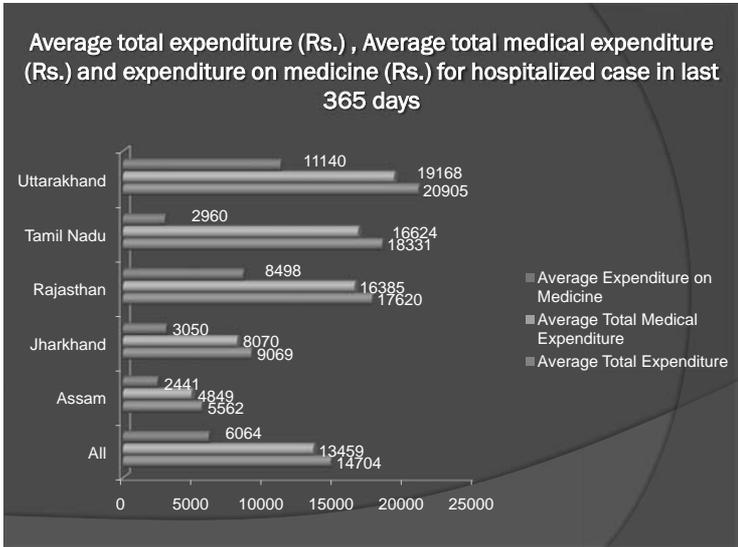
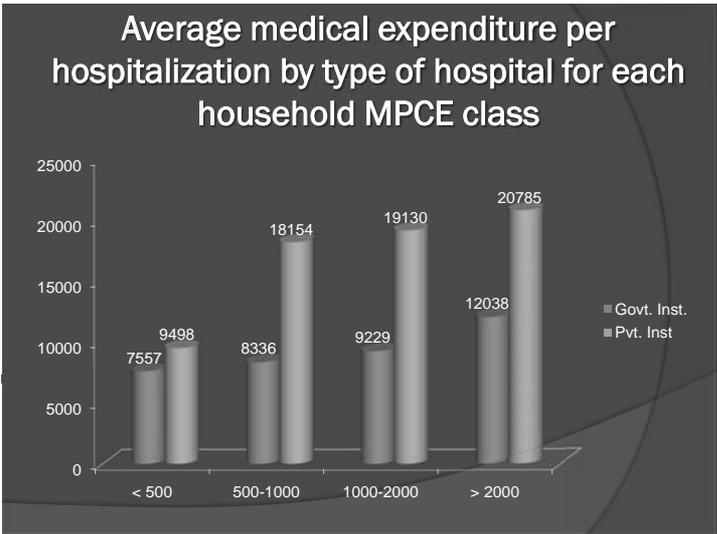


Average Duration of Stay (in days) in Hospital by Type of Hospital

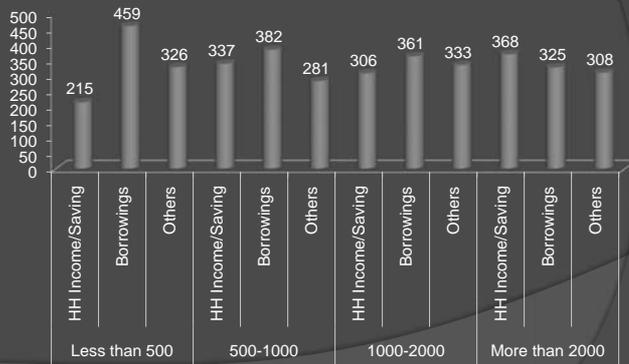


Average Medical Expenditure (Rs.) per hospitalization by sex and type of hospital



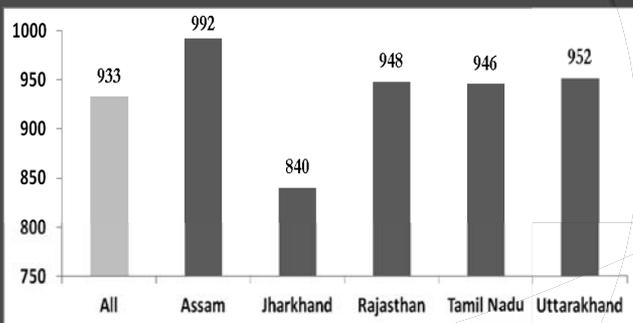


Proportion (per 1000) of household expenditure on treatment during last 15 days by source of finance for each MPCE class

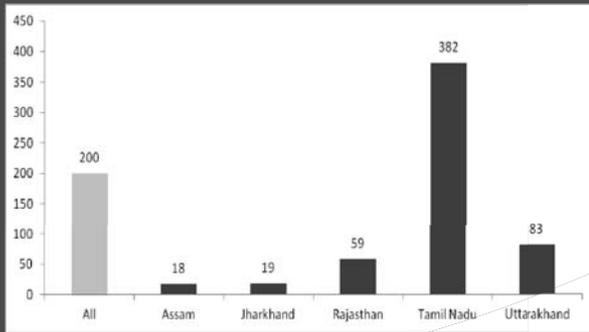


Maternal and Child Health

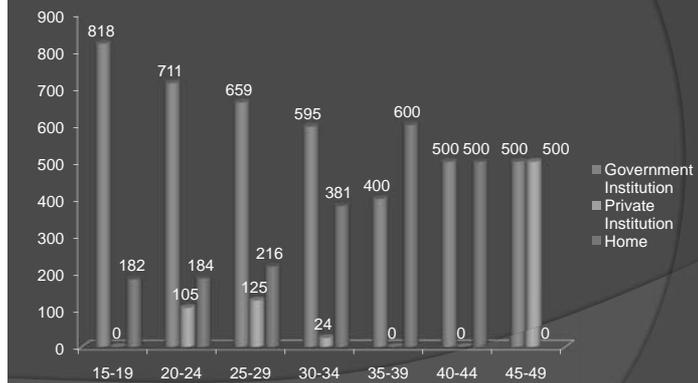
Proportion of children Immunized (per 1000)



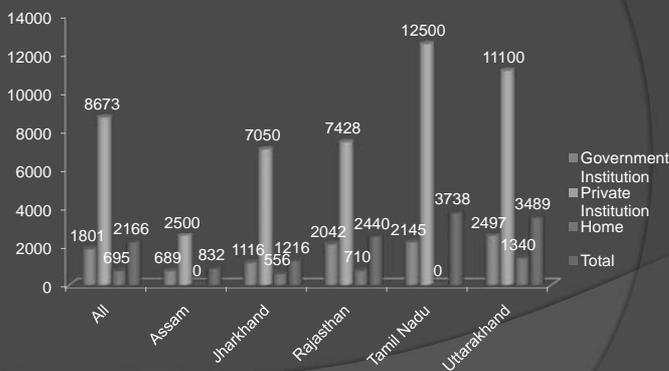
Expenditure incurred on Immunization (in Rs.)



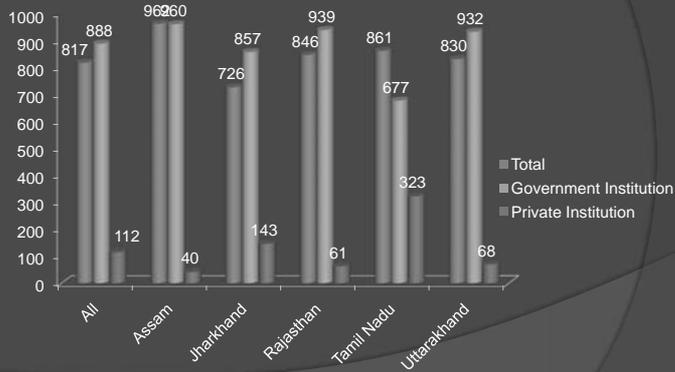
Per 1000 distribution of childbirth by place of delivery for each broad age group



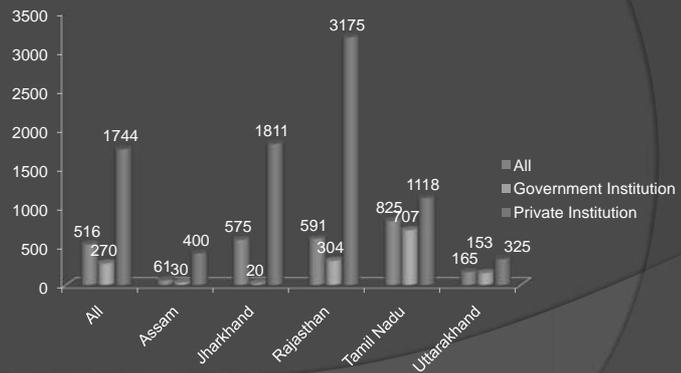
Average expenditure (in Rs.) per childbirth by place of delivery



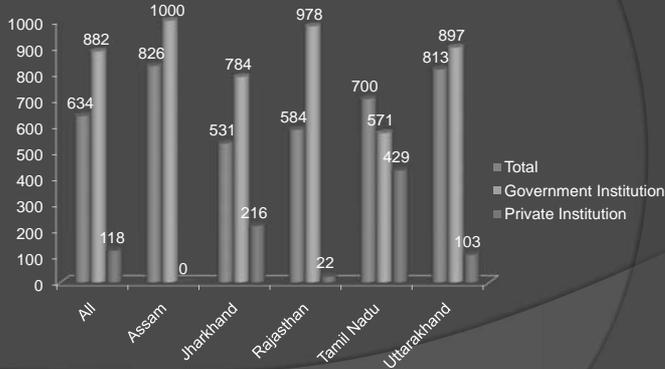
Proportion (per 1000) of women who availed antenatal care services (PWANC) by source of institution for availing the facilities



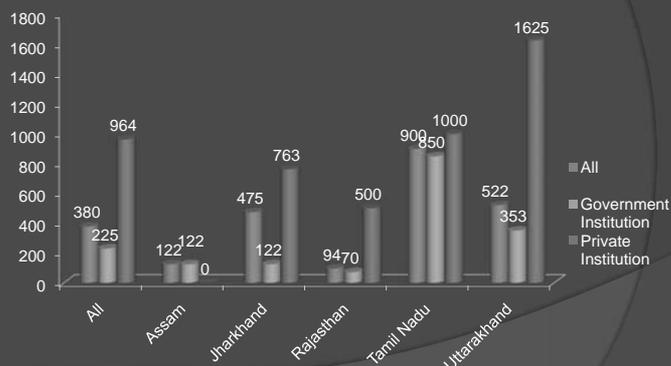
Average expenditure (Rs.) on antenatal care services (ANC) by woman by source of service



Proportion (per 1000) of women who availed post-natal care services (PWPNC) by source of institution for availing the facilities



Average expenditure (Rs.) on post-natal care services (PNC) by woman by source of service



Highlights

Indicator	Study findings	NSSO 60 th round (rural) (Avg. of selected 5 states)	NSSO 60 th round (rural) (Whole India)
Number (per 1000) of persons reporting ailment (PAP) during a period of 15 days			
➤ Male	56	-	83
➤ Female	78	-	93
➤ Person	70	64	88
PAP during a period of 15 days in broad age-groups			
➤ 0-14	54	-	72
➤ 15-29	46	-	49
➤ 30-44	72	-	78
➤ 45-59	93	-	119
➤ 60 or more	141	-	283
Number (per 1000) of persons reporting commencement of any ailment (PPC) during last 15 days in broad age-groups			
➤ 0-14	21	-	54
➤ 15-29	23	-	29
➤ 30-44	30	-	37
➤ 45-59	39	-	46
➤ 60 or more	68	-	68
➤ All ages	29	37	45
Percentage of spells of ailments treated during 15 days	89	86	82
Percentage distribution of non-hospitalized treatments by source of treatment			
➤ Govt. sources	54	26	22
➤ Private sources	46	74	78
➤ Total	100	100	100

Indicator	Study findings	NSSO 60 th round (rural) (Avg. of selected 5 states)	NSSO 60 th round (rural) (Whole India)
Percentage distribution of untreated spells of ailments by reason for no treatment			
➤ No medical facility	16	-	12
➤ Lack of faith	42	-	3
➤ Long waiting	5	-	1
➤ Financial problem	5	-	28
➤ Ailment not considered serious	16	-	32
➤ Others	16	-	24
➤ Total	100	-	100
Number (per 1000) of persons hospitalized any time during a period of 365 days			
➤ Male	81	-	23
➤ Female	76	-	22
➤ Person	79	18	23
Number (per 1000) of persons hospitalized any time during a period of 365 days in broad age-groups			
➤ 0-14	42	21	12
➤ 15-29	60	28	19
➤ 30-44	96	26	25
➤ 45-59	129	43	39
➤ 60 or more	184	73	56
Percentage distribution of hospitalized treatments by type of hospital			
➤ Govt. hospitals	48	51	42
➤ Private hospitals	52	49	58
➤ all hospitals	100	100	100
Average duration of stay (0.0 days) by type of hospital			
➤ Govt. hospitals	7.35	-	10.9
➤ Private hospitals	9.18	-	8.3

Indicator	Study findings	NSSO 60 th round (rural) (Avg. of selected 5 states)	NSSO 60 th round (rural) (Whole India)
Average medical expenditure (Rs.) for non-hospitalized treatment per ailing person during a period of 15 days	832	322	257
Average total expenditure (Rs.) for non-hospitalized treatment per ailing person during a period of 15 days			
> Medical expenditure:	832	322	257
> Other expenditure	231	43	27
> Total	1063	365	284
Average medical expenditure (Rs.) per hospitalization during a period of 365 days			
> Male	13701	-	5946
> Female	12617	-	5406
> Person	13459	6234	5695
Average total expenditure (Rs.) for hospitalized treatment per hospitalization case during a period of 365 days			
> Medical expenditure:	13459	6234	5695
> Other expenditure	1245	733	530
> Total	14704	6967	6225

Thank you

DRUG PRICING CASE OF AIDAN ET AL, PHARMA PRICING POLICY 2011

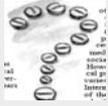
S Srinivasan

Drug Pricing Case of AIDAN et al, Pharma Pricing Policy 2011

HRLN et al meeting Dec 17, 2011, New Delhi

-S.Srinivasan ('Chinu')
LOCOST, Baroda, India
Email: sahajbrc@gmail.com





What is Wrong with India's Drug Situation? -1

- India: "Pharmacy of the World" (msf document)
- Problem of poverty amidst plenty
- Drug costs are about 40-80 percent of the health care costs
- Health care is the second most common reason for rural indebtedness.

2



What is Wrong with India's Drug Situation? -2

- There are more than 20,000 drug formulations available in the Indian market.
- A great many are irrational and unscientific.
- Too many combination drugs
- 62 percent of top-selling 300 drugs are not in the National List of Essential Medicines!
- Poor regulation by drug authorities; corruption and inefficiency

3

What is Wrong with India's Drug Situation? -3

- Because buyers and sellers have different bargaining strengths (info asymmetry)
- Sellers and doctors decide
- Buyers (patients) have little or no choice
- Buyers have to make decision usually under distress

4

What is Wrong with India's Drug Situation? –4

- Many players
- But prices of drugs have not come down
- Same drug is sold at different prices by different companies

5

“Competition” does not reduce prices!

- Same drug is sold at different prices by the SAME company too!
- Brand Leader often also the Price Leader (costliest drug is most sold).
- Therefore competition does not automatically bring down the prices.
- In fact more players seems to result in a range of prices.

6

“Free” Market?

- Drug prices are fixed as to what the perceived target market for the brand can take.
- Markets are distorted by unfair and unethical marketing practices of drug companies

7

Dates

- 1975 Hathi Committee releases its report with a list of 116 essential drugs.
- 1977 WHO releases its Model List of Essential Drugs
- 1978 Alma-Ata Charter on Comprehensive Primary Health Care of which access to Essential Drugs was one of the eight components of Primary Health Care –declaration signed by 134 Governments including India.

8

Decreasing List of Drugs under Price Control in India

- 1979 The Drug Price Control Order (DPCO) list of drugs under price control contains 347 drugs.
- 1987 The DPCO list is pruned to 142 drugs by the Ministry of Chemicals and Fertilisers.
- 1995 The DPCO list is further pruned to 74 drugs.
- 1996 The U.O.I releases the first National Essential Drugs List.

9

Pharma Policy 2002 and its Discontents

- 2002 The Ministry of Chemicals and Fertilisers releases the Pharmaceutical Policy 2002 document.
- 12.11.02 Karnataka High Court makes an order in W.P. 21618 of 2002 staying the pharmaceutical policy 2002

[on the grounds that from the list of 74 drugs found in the 1995 price control order some are likely to be omitted when the fresh list is prepared in accordance with the PP 2002.]

10

Pharma Policy 2002 and after

- 2003 WHO releases its “ WHO Model List of Essential Medicines 2003”
- 2003 U.O.I. releases its “National List of Essential Medicines 2003”. About 350 drugs in the list
- 10.3.03 SLP(C) 3668/2003 is filed by U.O.I. impugning the order of the Karnataka High Court dated 12.11.02. Notice is issued.

11

Our Writ Petition filed

- 1.8.03 SLPs 6652/2003 and 6638/2003 are filed by the Indian Drug Manufacturers Association and the Organisation of Pharmaceutical Producers of India respectively. Permission is granted to file SLPs. Notice is issued.
- 1.9.03 Our writ petition
- 10.3.2003: “Meanwhile, we suspend the operation of the order to the extent it directs that the Policy dated: 15.2.2002 *shall* not be implemented. However, we' direct that the petitioner *shall* consider and formulate appropriate criteria for *ensuring essential and life* saving drugs not to fall out of price, control and further directed to review drugs which are essential and life saving in nature till 2nd May, 2003.”
- March 2011: Govt withdraws PP 2002 case saying new policy is coming by Oct 2011

12

Our Critique of Pharma Policy 2002: 1

- Most essential and useful drugs are kept out of price control.
- Non-essential and harmful drugs like analgin, phenylbutazone, Vitamin E, sulphadimidine, mebhydrolin, diosmine panthionate and panthenols, bacampicilin, etc is under price control.
- Drugs for HIV /AIDS, cancer, hypertension, coronary artery disease, multidrug resistant tuberculosis, diabetes, iron deficiency anemia, ORS, tetanus, filariasis, vaccines (new) for rabies, hepatitis B, sera for use in tetanus, diphtheria, Rh isoimmunisation, anticonvulsants and antiepileptics, diphtheria, snake bite, suspected rabid dog bite/rabies, etc. fall outside price control (See boxes below).

13

Our Critique of Pharma Policy 2002: 2

- Price control, since it is based on market share criteria, produces only partial regulation.
- Chloroquine for malaria would be under price control but not equally important other anti-malarials
- True also for leprosy drugs and analgesics.
- Of the 300 top selling brands (as per ORG list), only 36 (that is only 12 percent) were price controlled
- The rest that is 88 percent were not

14

Post Petition (2003) Developments

- National List of Essential Medicines 2003 by Govt of India
- Attempts by Minister Paswan to reduce price by holding 'talks' with drug companies
- Sandhu Committee Report
- Pronab Sen Task Force Report – recommends all drugs be put under price control 2005
- 2005: UPA-1 Govt/Paswan comes out with new policy: recommends all drugs be put under price control. Opposed by some prominent cabinet Ministers
- PM sets GOM
- GOM holds a lot of consultations with stake holders
- UPA 2: Still no new policy
- New List of Essential Medicines 2011

15

SC order of Oct 11, 2011

- File reply within four weeks indicating therein as to within what time the revised list of National List of Essential Medicines (NLEM 2011) will be added in Schedule-I of the Drugs (Price Control) order, 1995.
- A comprehensive revised list of National List of Essential Medicines (NLEM) be also produced along with affidavit to be filed on behalf of the Ministry of Family & Welfare.

16

Our Prayers

- All essential drugs shld be under price control
- All irrational medicines should be removed
- Only rational drugs shld be marketed in India
- Free medicines for all in public sector
- Govt use CL on essential drugs under patent

17

Pricing Policy 2011 of Govt of India

- Draft policy released in Oct 2011 in anticipation of court directives
- Policy says all 348 drugs in NLEM 2011 will be under price control
- Delinks price of formulation from price of API (or bulk drug)
- Gives a procedure for calculating ceiling prices of drugs under price regulation using market based prices
- Attempts to control drugs outside NLEM, and combinations with NLEM under the same formula

18

Method of Arriving at Ceiling Price in 2011 Policy

- Ceiling Price would be fixed on the basis of Weighted Average Price (WAP) of the top three brands [para 4.7 of the draft policy]
- Dosages of essential drugs not mentioned in the NLEM 2011 to be discouraged by lowering the pro-rata (proportional) ceiling price.
- Therefore market prices of leading brands will determine ceiling prices

19

Some features of market based pricing

- The same drug is sold at a range of prices
- Higher priced equivalents are sold more largely because they are marketed aggressively to doctors and pharmaceutical traders by often unethical means.
- Doctors also believe higher priced drugs are of better quality
- Profits tend to be very high if you compare the cost of raw material used and the MRP (see Table 1)
- Lower priced equivalents are not easily available at retail pharmacies because of lower margins
- Market based prices have no relation to raw material used and as a result manufacturers end up making high profits

20

Problems with Calculating Ceiling Price using WAP for most commonly used drugs

- Brand leader is price leader in medicines that is most selling drugs tend to be the high priced ones
- WAP ceiling price will end up justifying high pricing
- As lower prices will move towards the high ceiling price
- Even now it is difficult to get cheaper equivalents of high priced drugs at retail pharmacies: in future it will be impossible
- Will also justify super-profits and the idea that higher priced drugs are of better quality
- Will lead to further impoverishment in the absence of guaranteed free quality health care by the State
- If bulk drug prices shoot up (like during Beijing Olympics), or for other genuine reasons, formulation ceiling prices will be unviable and therefore some formulations will go out of the market.

21

Table 1: A Comparison of Medicine Prices

Generic Name of Drug (1)	Unit (2)	Chittorgarh Tender Rate (3)	MRP Printed on pack/strip (4)	TNMSC Prices (5)	(Column 4/Column 5) (6)
Albendazole Tab 400 mg	10 tablets	11.00	250.00	4.55	54.94
Alprazolam Tab IP 0.5 mg	10 tablets	1.40	14.00	0.51	27.45
Amlodipine Tab 2.5 mg	10 tablets	2.30	23.00	0.41	56.01
Atorvastatin Tab 10 mg	10 tablets	9.90	65.00	2.10	30.95
Cetirizine 10 mg	10 tablets	1.20	35.00	0.49	71.42
Diazepam Tab 5 mg	10 tablets	1.40	18.00	0.55	32.72

22

Draft Policy's Exemptions from Price Regulation: Unjustified

- For drugs which are part of Hospital Supply as maintained by M/o Health and Family Welfare;
- For drugs which are part of Public Health Products as maintained by M/o Health and Family Welfare
- *This will encourage the corruption which is at present rampant in drug procurement. (Legitimises not going for lowest tender when that shld be the logical option).*
- Exemption for Drugs having weighted average price less than or equal to Rs3/-
- *Many low-priced drugs will move towards the Rs 3/- level – and it gives leeway to drugs that cost much less to produce [for example cetirizine (0.15) or iron folic acid (0.06)]*

26

Other major reasons for poor access to the right medicine at affordable prices

- Aggressive Drug Promotion by drug companies
- Inducements to doctors
- Over/under prescribing by doctors
- Cut Practice

27

Why formulation ceiling prices should not be delinked from bulk drug prices?

- Gives no idea of how much profits are being made
- MRP to raw material ratio is about 2000 % to 3000 % for many formulations (see Tables)
- In the absence of such knowledge, high prices become the normative state of affairs.
- Patient is the one who suffers in the process.
- Contradiction is clearly exposed when you compare prices of efficient government procurement agencies and market based prices. (See Table 1)

28

Why bulk drug prices should not be left to the market completely?

- Likelihood of cartelization
- In some vital drugs (like anti-TB Rifampicin) only 2-3 major manufacturers are present
- Government has no recourse if bulk drug prices shoot up without reason (or with reason).
- Only deterrent to very high pricing is availability of cheaper imports from China
- But that option is not available to smaller manufacturers for all drugs
- So they will have to rely on higher priced local manufacturers of bulk drugs
- This will render smaller manufacturers of formulations uncompetitive
- Eventual shakeout of the market will leave only bigger players
- This is not good for the country and endangers ability of government to procure drugs efficiently and at the lowest prices
- Also fewer players means production technology gets mystified and government itself has less ability to “call the bluff” when it needs to of bigger players. This is already happening to some extent in vaccines and biotech drugs.

29

So what is a better pricing policy?

- That will be one that brings down the prices of overpriced drugs and not increase it
- That has some linkage to the actual cost of production
- And therefore to the cost of the raw material, and
- Does not legitimize overpricing of drugs.
- Does not nominally reduce the price of the top-selling brands and expects prices to fall.

30

Our Suggestions for a Pricing Policy that brings down Prices

- Take as reference price the prices of well-run public procurement systems. The government says it is difficult to get cost data. Let us assume then that the selling price to the TNMSC is the cost price.
- Take a multiple, say 5, of the reference price as the ceiling price.
- Or follow the successful example of Bangladesh – operational since 1982: ceiling price would be 100-125% more than the cost of the bulk drug content in the formulation. In India’s case it could be 5-6 times the cost of the bulk drug content.
- Bulk drug price monitoring is simpler – lesser number than formulations per se.

31

USING LAW FOR PUBLIC HEALTH

Mira Shiva MD

USING LAW FOR PUBLIC HEALTH HAZARDOUS DRUGS

Dr. Mira Shiva M.D.

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Founder Coordinator & Co Convenor All India Drug Action Network

Founder Member Health Action International (Asia Pacific)

Chairperson: Consumer Education Task Force on Safety of Food & Medicine (2004-2008)
Member Health Committee: National Human Rights Commission

Founder Member & Steering Committee member People's Health Movement

17th -18th Dec 2011

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DRUG CASES –DRUG INDUCED SUFFERING

CLIQUNOL – SMON SUBACUTE MYELO

OPTIC NEUROPATHY 10,000 BLINDED & CRIPPLED .

DR OLLE HANSSON – SWEDISH PAEDIATRIC

NEUROLOGIST

Need for Effective Post Marketing Surveillance & Adverse Drug Reaction Monitoring .

Recognition of Adverse Drug Reaction not Denial by Pharma Cos that drug not absorbed therefore SMON not drug related ,

Non Denial of Unbiased Drug Information , to warn doctors & patients .

To avoid prescriptions of potentially unsafe drugs .

Timely banning of Manufacture , distribution

Consumer Awareness consumption of Potentially hazardous drugs

International Exchange about .

Hazardous Drugs: Health ,Ethical & legal challenge

KICADIS

KYOTO INTERNATIONAL
CONFERENCE ON DRUG INDUCED
SUFFERING 1979

UN CONSOLIDATED LIST OF
DRUGS & CHEMICALS BANNED&
SEVERELY RESTRICTED

UN

HAI

HEALTH ACTION INTERNATIONAL
1981

Drug Induced Sufferings ,Medical
,Pharmaceutical & Legal aspects
1980

Problem Drugs IOCU,HAI
Bad Medicine Dr Milton Silverman
Worst Pills ,Best Pills Public Citizen

- The Power to Harm Mind ,Medicine& Murder on trial John Cornwell 1996
- Banned & Bannable Drugs Dr Wishvas Rane , MS .VHAI AIDAN 1982 onwards 5 Editions 2003

HAZARDOUS DRUG – LEGAL ACTION

Hazardous Drugs THALIDOMIDE, DES
Diethylstilbestrol Stilbaestrol , High dose Estrogen
Progesterone , VIOXX, Prozac

Hazardous Devices Technology - Dalkon Shield ,

Hazardous Policies - FTAs, Counterfeit Agenda, ACTA

CASE – I EP DRUGS

EP Case FDC HIGH DOSE EP DRUGS

8th March 1982 International Women's Day EP
campaign launched.

ICMR recommendation of Ban

- Drug misused
- alternatives exist
- many countries have banned High dose EP

June 1982 DCGI Ban order

- Stay order obtained by Drug companies
- On following grounds.
 - Health State Subject – centre no right to ban
 - Violation of Industrial Regulation Act
 - Right to Trade.
- EP Campaign by Consumer, Health and Women's Groups

1983 Vincent Panikulangara PIL

Writ Petition 3492 in SC under article 32 of Constitution asked for banning of import, manufacture and sale of drugs recommended for Banning by D.C.C. and cancel licenses.

Asked for Government to constitute High Power Authority to go into **Hazards suffered by people because of Hazardous drugs** and recommend **remedial measures** including award of **compensation**.

1986 November - Supreme Court orders 4 Regional public hearings

- Chennai (5th Feb. 1987) only "Think, Tap & Press" no communication to public interest groups
- Delhi (10th April 1987)
- Calcutta (10th July 1987)
- Mumbai (19th July 1987)

E .P. CASE

- 1987, 2 SCC p. 165 S.C. in its judgment directed Government that there should be adequate representation on behalf of consuming public on DTAB and laws be amended to authorize such representation include petitioner, co-petitioner on Expert Committee.
- Organon
- Scherring
- Unichem
- Nicholas
- OPPI
-

E.P Case

- Dr. Isabel Gal's warning about association of HPT with High dose EP with congenital malformation
- Pg Submission
- With literature research
- Views of experts from HAI network
- 15th June 1988 High dose EP banned
- 30th June 1988 Ban Order – Gazette notification no. 700 E Public came to know through newspaper reports

EP Case

- Tablet estrogen per tablet
- Progesterone per tablet
- Ambiguous language in Ban Order
- Interpretation - only tablets banned, not Injectable
- Continued sale of High Dose EP drugs
- 26th July 1988 - ACASH filed Writ Petition 14/4/27 of
- 1988 Mumbai High Court against Commissioner of FDA
- High dose EP Injectables allowed
- Original Infar – Menstrogen Forte
 - Unichem – EP Forte
 - Highland Pharma – Cyclenorm
 - Sigma - S.G. Forte
 -

EP Case

- Resistance challenges all over
- Maharashtra High Court Justice Lentin ordered. Tablets, Injections will remain banned. Asked DCI to give convincing reason as to why Injectables not be banned. Stocks withdrawn
- Injectable ban

January 1989 – Monitoring by Rational Drug campaigners

- Drugs continued to be sold
- High Dose EP drugs banned
- 1983 Amendment to Drugs and Cosmetics Act 1940 Section 26
- Inclusion of Hazardous as criteria for Banning
- Warning to health and women activists in other countries about potential hazards of HPT. FDC High dose EP
- Realization of the importance , of Rational Drug Campaign with legal action .

CASE - 2

- PIL Irrational & Hazardous Drugs 693/1993 filed in Supreme Court
- DAFK, AIDAN, NCCDP Vs Union of India
- With CDMU, LOCOST intervening
- PIL against Irrational & Hazardous drugs
- Clioquinol Ciba Geigy 11000crippled & blinded in Japan because of Clioquinols induced SMON subacute myelo optic Neuropathy, (known Brands Mexaform & Enterovioform)
- Dr Olle Hansson' s Inside Ciba Geigy

- Analgin combination Hoechst Agranulocytosis
- STM Pencillin :Masking TB , Emergence of drug Resistance ,
- STM – Chloramphenicol
- Bone Marrow depression Agranulocytosis
- Phenyl butazone
- Oxyphenbutazone Agranulocytosis
- Anabolic steroids Hoechst, Ciba Geigy, Novartis, Glaxo
- Antihistaminic Codeine
- Cough Syrup
- Cough Suppressants and Cough Expectorant combinations

- Hormonal contraceptives Intervention by Saheli
- (Norplant Women's Health Groups
- Anti Fertility vaccine}
- Depo Provera, Net en
- Injectable contraceptives
- Intervention by Saheli in Hazardous drug case
- Double standard Package Insert
- List of Contraindication decreased
- Upjohn

Dalkon Shield

- Cervicitis associated with PID Infertility
- Class action US
- Dalkon shield – A.H.Robbins. cervicitis with PID & Infertility
- Between 1971 – 74 – several thousand cases of P.I.D 18 recorded deaths Class action Suite.
- By 1986 – 192000 claims filed mainly in US
- 2300 \$ million total compensation amount to pay for claim applicants through TRUST set up for the purpose

Dalkon Shield

- Not a single claim from India
- Dalkon Shield put in Family Planning Camps donation from USAID
- No medical records of women in whom Dalkon Shield put
- Women not aware of Dalkon Shield nor aware of complications
- Not aware of compensation
- Even if would have been aware getting compensation extremely difficult to get(eg. Bhopal case)
- Learning importance of Liability clause & of medical records.

UNSAFE MEDICINE

- I.V.fluid Contamination deaths in Safdarjang hospital Delhi.
- 35,000 bottles Glycerol with fungus grossly visible .
- sample tested at govt lab alleged OK

Deaths in JJ hospital Mumbai

- Glycerol adulterated with industrial Diethylene Glycol resulting in kidney failure and about 14 deaths
- Dr. N H Antia of FRCH send Communication to Justice Bhagwati about JJ Hospital Deaths on post card. This was treated as PIL
- Lentin Commission set up

Justice Lentin Commission

Report submitted within the deadline assigned .

- "These pages describe and illustrate ugly facets of the human mind and human nature, projecting errors of judgement, misuse of ministerial power and authority, apathy toward human life, corruption nexus quid pro quo between unscrupulous, license holders, analytical laboratories, elements in Industries Department controlling the awarding of rate contracts, manufacturers, traders, merchants, suppliers, the FDA and persons holding ministerial rank.
- None of this will be palatable in the affected quarters. But that cannot be helped".
- Lentin Commission report , the recommendations is a highly Recommended reading

Hazardous drugs

- Public Health Issue – Issue of unsafe medicine
- Unsafe use of medicine
- Eg. rapid administration of calcium, overdose insulin ,IV fluids
- HIV contaminated blood products
- ANTI D for Rh negative mothers
- with Rh +ve babies(testing , batch numbers)

UnSafe drugs Unsafe Use

- QUINACRINE – PIL by CHSM ,JNU & AIDWA
- Unsafe contraceptive trials stopped
- HORMONAL REPLACEMENT THERAPY
- NORPLANT contraceptive trials not allowed
- ANTI FERTILITY VACCINE trials stopped
- LETEROZOL anti Cancer Drug ,
contraindicated for Premenopausal Women
cleared for use as Fertility drug by DCGI
Challenged & now ultimately banned as
Fertility Drug .

Corporate Interest in asphyxiation of Generic Drugs

- To kill competition from cheaper equally effective drugs.
- Inclusion of Patent IPR Issue
- In definition of counterfeit
- 14 ships in Transit carrying legally made, quality ,essential Anti Retroviral drugs seized in Amsterdam. Purchased by Unitaaid for HIV /AIDS patients in Africa

IMPACT

- International Medicinal Product anti Counterfeit Taskforce (IMPACT)
- In WHO
- IMPACT using WHO Logo
- Objection raised by India, Thailand, Brazil at WHA 2010
- India Country office, Geneva
- Creation of IMPACT not asked for by any member states,
- Basically IMPACT is an initiative of IFPMA , PhRMA,

Hazardous Policies

- ACTA – Anti Counterfeit Trade Agreement being drawn up & finalized non transparently by US, EU Japan etc
- IP – protection IP MAXIMALIST AGENDA ,criminal proceedings ,seizers Destruction on mere suspicions .
- Manufacturers , transporters , label printers all to be held guilty
- Payment for lost income to the patent holder at market price
- Lack of Transparency exclusion of developing countries

PARTNERSHIP FOR SAFE MEDICINES

- PhRMA
- IFPMA initiated
- 1st india Meeting Presence of USPTO , USFDA
- Jan Aushadhi logo used
- Consumer groups , Health associations , chemicals Ministry chief brought on Board
- 4 out of 5 objectives of PSM were Counterfeit Agenda related
- Corporate interest in decision making

WHO commission on Public Health, IPR & Innovation

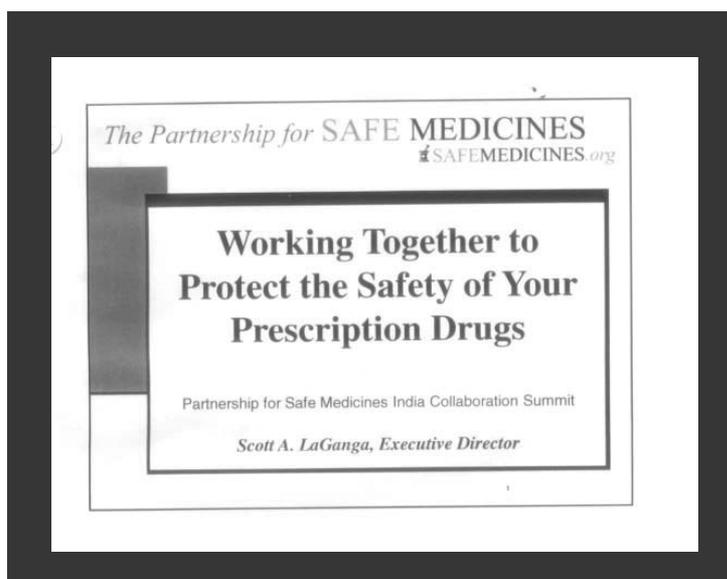
- IGWG – for implementation of recommendations of CIPIH 2006
- Inclusion of former Novartis research Chief in – R & D Paul Herrling
- R & D Financing Expert Group
- By Dr. Margaret Chan, DG WHO –
- Protests by Civil Society groups conflict of interest
- H1N1 Pandemic, role of Pharma companies in WHO expert committees .

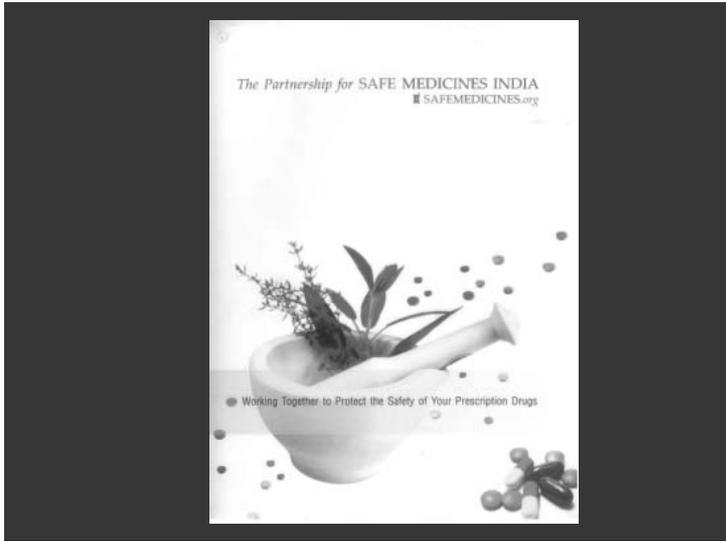
Potentially Hazardous Moves

- Information provision role of Pharma Corporate Conferences, CMEs, Direct consumer Education
- Many Patient Groups supporting Pharma.s Education & information provision role,
- HAI EU study showed those patient groups who were Supported by Pharma Cos
- Supported Pharma Corporations role in information sharing role
- Pfizer, USPTO – meeting with NGO's on IPR and Benefit sharing held in Mumbai, Delhi.

Partnership for Safe Medicine

- PhRMA
- IFMA led Initiative to push "Counterfeit Agenda"
- Back grounder for Partnership for Safe medicine
- 4 out of 5 objectives counterfeit related.
- Presence of US PTO first secretary, US FDA Chief and other staff from USFDA Delhi office







PHARMA CORPORATIONS

- Pfizer Wyeth part of Pfizer
- Largest research based pharmaceutical
- Bristol Myers Squibb –
- Eli Lilly
- Bayer
- Merck & Co (MSD) Merck Sharp & Dohme
- Abbott Labs
- Johnson & Johnson
- GSK – Glaxo Smith Kline
- Roche
- Astra Zeneca
- Novartis (former Ciba Geigy & Sandoz)

- Novartis challenging section 3 “d” of Indian Patent Act , a very important protective clause to prevent Ever Greening of Patents .
- (increasing patent protection to additional 20 years , to existing 20 earlier mere 5-7 years in IPA 1970
- Novartis chief ,chief of OPPI .
- OPPI , IFPMA & Indo EU FTA pushing for TRIPS Plus Agendas
- Data Exclusivity ,
- Patent Linkages

Health Action & Legal Action for Public Health

- Challenge Hazardous Drugs, Producers, Promoters & Protectors'.
- Challenge Potentially Hazardous Policies, Corporate Friendly measures that threaten Public Health eg TRIPS plus Agendas being pushed through Indo EU FTAs,
- Counterfeit Agendas to threaten affordable generic equivalents, IMPACT, ACTA.
- Rejecting Potentially Hazardous Drugs, Using essential /rational drugs only

Health Action Legal Action

- Reject products of Corporations indulging in potentially hazardous moves eg Novartis using every move to get section 3'd removed avoiding use of their products Calcium Sandoz, Volvuran.
- Demand Rational Drug Policy, Promotion of Rational Drug Use, Adverse Drug Reaction Monitoring, Post Marketing Surveillance
- Banning of Potentially Hazardous Drugs.
- Ensuring Access to Unbiased Drug Information, Consumer Caution

HealthAction & Legal Action

- Greater thrust to build Health Literacy, Drug Literacy, Legal Literacy for consumers to protect their Right to Health, Right to Justice.
- Giving priority to Public health concerns, using Precautionary principle in withdrawal of [potentially Hazardous products for which equally effective, safe, affordable alternatives exist.
- Using Legal Provisions to protect public Health

Pharma Corporations Acquisitions & Mergers

- **KNOWING THE PHARMA CORPORATES**
- 1947 Ciba Basel Switzerland
- 1970 Ciba Geigy AG with merger of Ciba A G & J R Geigy
- 1996 Ciba Geigy & Sandoz Merger
- Resulted in formation of **Novartis**
- **3 key Divisions**
- Pharmaceuticals
- Agriculture
- Biotechnology

Case Study Ritalin – Attention Deficit Disorder –

AD/Amphetamine

- Level II drug Attention Deficit Hyper activity Disorder ADHD
- Since 1988 Ciba Geigy giving CHADD \$ 1 million Grant Services
- Children & Adults with attention Deficit Disorder
- Insufficient research
- Group used for distributing,
- Misleading
- Information
- Promoting drug therapy
- 1990-95 6 fold increase

Ritalin

- In 1995 1.5 million Americans prescribed estimated 2 million
- 1995 J Merrau
- Investigative report
- Ritalin
- Attempt to get it Deregulated
- Potential for abuse
- When crushed into powder snorted
- Lower growth tics paranoia major long term effect
- Ritalin similar to cocaine & speed
- Youngsters attempt to harmful and addicting
- Convince guardian they had ADD / ADHD
- Ritalin being over prescribed and abused

Attention Deficit Hyperactivity Disease

- Attention Deficit Restlessness Hyperactivity many causes
- Pesticides
 - Chemicals
 - Sugar
 - MSG in food
 - Processed food
 - Short attention span because of
 - TV
 - Video games
 - Computers
 - Mobiles
 - SMS
 - Restlessness because of lack of emotional security
 - love
 - attention
 - healthy food
 - fresh air

Ciba Geigy

- 13 Dec. 1947 Ciba Pharma Pvt. Ltd wholly owned subsidiary of Ciba Ltd Basel Switzerland
- Ciba Dyes
- Ciba of India
- 1970 Ciba Geigy of India
- 1983 Hindustan Ciba Geigy
- Pesticide in Kandla Free Trade Zone

NOVARTIS

- NOVARTIS International AG Ciba & Sandoz Merger
- Basel Switzerland
- No. 3 in sales \$ 36.173 billion in 2008
- No. 6 in revenue 41.5 billion in 2009
- Profit margin of about 20%

Products of Novartis

- Main Drugs
- Clozapine Clozaril
- Diclofenac Votlaren
- Carbamazepine Tegietol
- Valsartan Diovan
- Imatinib mesylate Gleevic
- Ciclosporin Neoral Sandimmun
- Letrozole Femara
- Methylphenidate Ritalin
- Terbinafine Lamisil

NOVARTIS

- September 2008 US FDA
- Sent notice to Novartis Pharmaceuticals regarding its advertizing of FOCALINXR ADHD dr (efficacy over stated) in marketing to public medical profession.
-
- June 2009, Novartis-- declined to provide free vaccine -- during flu epidemic unlike GSK
- Influenza A H1N1 2009 Monovalent vaccine
- Guillian Barre Syndrome
- Influenza A (H1N1) 2009 monovalent vaccine
- FLUVIRIN
- ADR -allergic local reader influenza like symptoms
- 1998 Novartis (India)
- Biocron's R & D subsidiary Syngene International has entered into contract research agreement with Novartis research and Dev and Novartis Institute for Biomedical Research.
- Sandoz - Manufacturer
- Generic
- Drug
- Company owned Gerber Products Co
- Sold to Nestle in 2007
- Novartis member of IFPMA
- European Fed PMA

VACCINE PSU'S & RATIONAL VACCINE POLICY: PIL IN SUPREME COURT, SP SHUKLA & ORS VS. UNION OF INDIA

Y Madhavi and N Raghuram

**Vaccine PSUs & Rational Vaccine Policy:
PIL in Supreme Court, SP Shukla & Ors Vs. Union of India**



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NISTADS, CSIR, & GGSIPU, New Delhi, India.



National Dialogue

Using the Law for Public Health

Human Rights Law Network & LOCOST, PRAYAS, IHES, 17th –18th Dec 2011

Vishwa Yuvak Kendra, Chanakyapuri, New Delhi.

Indian Vaccine Scenario at a glance

- Vaccines are important preventive medicine in Primary Health Care
- National health security is closely linked to self-reliance in vaccines & drugs
- Unlike curative drugs, vaccines are given to all – hence need stronger economic logic
- Vaccines constitute 2% of entire global pharmaceutical industry: growth drivers
- World vaccine market (\$22 billion) dominated by Sanofi, GSK, Merck & Wyeth
- Indian vaccine market is huge: \$ 2 billion growing at 22% per year
- India is among the largest vaccine makers and buyers globally
- 6 Primary vaccines are under GOI's EPI (TT, DT, DPT, BCG, OPV, Measles)
- Present cost of all EPI vaccines/child is Rs.30/- or Rs.750 m for 25 m newborns/pa
- Liberalization, globalization & aid politics are expanding our vaccine markets
- Many expensive new & combination vaccines are flooding the market (hep, flu etc)
- Vaccine efficacy, cost-benefit/risk-benefit are relevant only when need is proven
- Once this logic is skipped to allow one vaccine, every other vaccine would follow
- Ethics of childhood vaccination: 'coverage' more important than protection
- Taking all vaccines in India needs 27 doctor visits and Rs. 30,000/- per child <5 yrs!
- How many vaccines are adequate to prevent how many deaths & at what cost?

The complexities of vaccine decisions

- Disease surveillance, pathogen variations in countries/populations
- Incidence levels of each disease that qualify for mass vaccination
- Efficacy, safety and affordability of the vaccine in the target population
- Rigorous cost-benefit analyses for each (new) vaccine
- Choice between indigenous development and/or procurement of vaccines
- The role of public vs. private sector in vaccine R&D, production
- Choice of technologies, their access and affordability
- Individual vs. Combination vaccines (cocktails or multivalent?)
- Choice of selective vs. universal vaccination
- National priorities vs. international obligations
- Personnel, logistics and resource mobilisation



Origins of the Indian Vaccine System

- Indian vaccine research & production system has a history of over a century
- Modern medical research in India began with vaccines
- India was an early bird in vaccines; a world leader in plague vaccine
- Fair institutionalisation of vaccine R&D and production under the British
- Indian govt. took lead to encourage indigenous vaccine development
- Availed international support as a member country of WHO since 1948
- Govt's official policy favoured self reliance & self sufficiency till 2005



Innovative Indian Vaccine Public Sector Institutions

Table 1. The Introduction of Vaccine Technologies in India and Elsewhere in the World

Vaccine	Techniques of Production	Year of Introduction	
		India	Elsewhere
Smallpox	Glycerinated vaccine lymph	1898	1890s
	Live attenuated freeze-dried vaccine	1965	1941
Plague	Whole-cell killed bacteria	1897	1897
Cholera	Attenuated whole-cell preparation	1892	1892
	Agar-grown heat inactivated Vibrio cholerae whole-cell vaccine	1911	1902
Hollow fever	Cholera vaccine prepared using modern techniques	Not yet	1986
	Live attenuated (passing through cell lines) virus vaccine	1965	1941
Typhoid	Heat phenolized whole-cell vaccine	1920	1915
Oral Typhoid		1994 (Marketed by private sector)	1984
Rabies	Dried cords of infected animals	—	1885
	Glycerinated cord methods	1907	1907
	Hogyes dilution method	1908	1907
	1% carbolyzed rabbit brain vaccine	1912	1911
	1% carbolyzed sheep brain vaccine	1930	—
	5% carbolyzed sheep brain vaccine (India used sheep to manage large-scale production)	1933	1930 (prepared from rabbit brain)
	5% BPL inactivated sheep brain vaccine	1959-today	1959 (prepared from mouse brain)
Tissue-culture-based anti-rabies vaccine	1977 (SII)	1977	
TT, DT, DPT	Purified toxoids inactivated with formaldehyde	1920s	1920s
TT	Purified toxoids adsorbed to aluminium phosphate	1972	1963
DT, DPT	Purified toxoids adsorbed to aluminium hydroxide	1978	1963
Bacillus Calmette-Guérin	Liquid bacterial vaccine	1951	1927
IPV	Freeze-dried bacterial vaccine	1967	1960s
	Inactivated polio vaccine (discovered by Salk)	1984 (SII)	1955
OPV	Monkey kidney cell culture vaccine	1967	1962
Improved IPV, OPV	Vero cell culture techniques	Marketed by private sector	1988-1989
Measles	Tissue-culture-based vaccine	1989	Late 1980s
Hepatitis B vaccine	Recombinant DNA technology	1997 (Shanta Biotech, Hyderabad, India)	1980s

Source: Y. Madhavi, Plos Med, 2005

No of Vaccine Institutions closed down

Vaccine Institute	Year	Vaccine/sera produced
1. Bengal Chemicals & Pharmaceuticals Ltd, Calcutta.	1901	Vaccines, sera, chemicals, synthetics & dyes (closed in 2000, being revived)
2. Vaccine Institute, Nagpur (became PSU in 1980)	1900	Smallpox, cholera (closed in 2000s)
3. West Bengal lab Calcutta (became PSU in 1980)	1980	Vaccines, Sera, synthetic dyes (closed in 2000s)
4. Bengal immunity Ltd, Calcutta	1919	TT, DT, DTP, cholera, typhoid, rabies, anti-venoms (closed in 2003)
5. Smithstrain street Lab, Chennai (PSU in 1977)	1821	Vaccines and Sera (closed in 2000s)
6. Pasteur Institute of India, Kasauli	1900	Anti-Rabies (Closed)
7. The Pasteur Medical Institute, Shillong, Assam	1917	Typhoid, cholera, anti-rabies treatment (closed down in 2006)
8. Vaccine Lymph Department, Belgaum	1904	Vaccine Lymph (closed in 1980s)
9. Vaccine lymph Department, Calcutta	1890s	Vaccine lymph (closed in 1980s)
10. Cholera vaccine Lab, Calcutta	1890s	Cholera (closed down in 1980s)
11. Pasteur Institute, Calcutta	1910	Anti-rabies (closed in 1980s)
12. The Bengal Public Health Lab, Calcutta	1900s	Cholera (stopped production in mid 1980s) converted as sterility testing lab
13. The Provincial Hygiene Institute, Lucknow	1900s	Cholera (closed in mid 2000s)
14. State Vaccine Institute, Patwada Nagar	1903	Vaccine Lymph, anti-rabies (closed in 2003)
15. The Vaccine Institute, Ranchi	1900	Vaccine Lymph, Cholera, anti-rabies, (closed in 2000s)
16. The School of Tropical Medicine, Calcutta	1921	(No vaccine production since 1980s) Epidemiological, diagnostic services
17. Institute of Preventive Medicine, Hyderabad	1870	Plague, Smallpox, Anti-rabies, TT (closed in 2005)
18. Vaccine Institute Vadodara	1973	Anti rabies (closed in 2007)
19. Public Health laboratory, Tiruvanthapuram	1937	Anti-rabies (no more vaccine production) Serves as immunology lab
20. Public Health Laboratory, Patna	1900	Cholera (closed in 2007)
21. Public Health laboratory, Bangalore	1900	Cholera (closed)
22. Indian Vaccine Corporation Ltd, Gurgaon	1989	Closed in 1992
23. King Institute of Preventive Medicine, Chennai	1898	Vaccine Lymph, TT, Typhoid, Cholera, (Production suspended in 2005)
24. Central Research Institute , Kasauli	1905	Typhoid, cholera anti-rabies, anti-snake venom (closed in Jan 2008)
25. BCG vaccine Lab , Chennai	1946	BCG vaccine (suspended in 2008)
26. Pasteur Institute of Southern India, Coonoor	1907	Anti-rabies, OPV (1967-76), DTP, dt, TT (suspended production in 2008)

Fate of DBT Public Sector Undertakings set up in 1990s

PSU	Production Targets
IVCOL	20 million doses of measles vaccine, 50 million doses of IPV and 40 million doses of DPTP
BIBCOL	aimed to produce OPV and plasma derived Hepatitis B vaccines indigenously by 1992

Source: DBT Annual Report 1987-88, GOI, New Delhi.

Annual budget allocated to BIBCOL and IVCOL by DBT (In Rs. Lakhs)

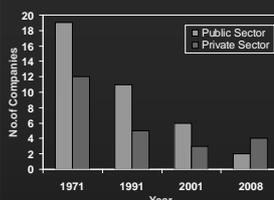
Company	1987-88	1988-89	1989-90	1990-91	1991-92	1992-93	1994-95	1995-96	1996-97	1997-98	1998-99	1999-2000	2004-2005
BIBCOL	10 (for both)	550 (for both)	453 (for both)	4.09	0.02	0.00	0.00	0.00	3.0	5.31	0.05	0.05	0.0
IVCOL				0.91	0.0	0.00	0.00	0.00	1.5	0.0	0.0	0.0	0.0

Source: Madhavi 2009, Journal of Health Studies, vol II (2):81-105.

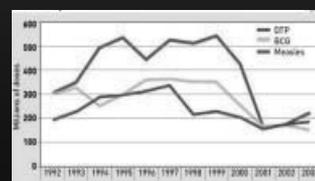
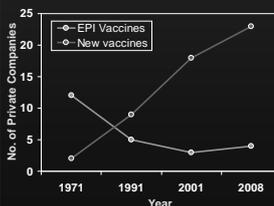
Number of Vaccine Institutions Operational

Vaccine Institute	Year	Vaccines/Sera produced
1. Haffkine Institute, Mumbai	1898	DT, TT, anti Plague, cholera, typhoid, Rabies, gas gangrene anti-toxins, anti-venoms
2. Bharat Immunologicals and Biologicals Ltd., Bulandshar	1989	OPV packaging from imported bulk
3. Indian Immunologicals Ltd. Hyderabad	1983	Measles since 2002, anti-rabies from 1998 R DNA hepatitis B, anti-rabies serum

Orphanization of Primary (EPI) Vaccines



- Decline in the firms making EPI vaccines
- Decline of production in the public sector
- Low private sector interest in EPI vaccines
- Growing demand-supply gap in EPI vaccines
- Private sector promoting expensive new vaccines
- UNICEF acknowledged global shortages for EPI
- Madhavi, 2005, PLoS Medicine



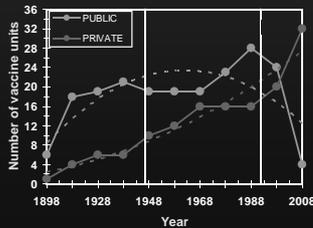
Source: UNICEF, 2003

Prices of vaccines from public & private sectors, 2008

Vaccine	Quantity	Public Sector	Private Sector
Primary Vaccines under EPI		(Indian Rupees)	(Indian Rupees)
OPV	10ml	9.22	52.11
DPT	5ml	13.75	~ 15.00 - 215.00
TT (adsorbed)	5 ml	~2.40 to 5.12	37.50
TT	5 ml	2.68	5.83
DT	5ml	5.75	-
Measles	1 ml	None	~56.84 to 1125.
New/Improved Vaccines			
Hepatitis B	Pediatric dose	None	~45.00 to 181.00
DTP-Hepatitis B conjugate	Adult dose -	None	~97.00 to 225.00
R-Vac (against rubella)	1 dose	None	36.80
MMR	0.5ml	None	66.05
Anti-Rabies	0.5ml		~147.00 to 184.50
HAVRIX	1ml	None	~294.00 to 1125.66
(for hepatitis A)	Pediatric dose	None	712.00
Meningococcal A&C	Adult dose	None	1360.00
Influenza type B	1 dose	None	48.85 to 370.00
Typhoid	0.5ml	None	~185.00 to 400.00

Attenuation of Public Sector

- Poor patronage & policy support to public sector
- Frequent changes in production profiles
- Technology at par, often used and dumped by all
- Unfashionable under liberalisation/globalisation
- WHO-GMP comes handy to suspend 3 govt units
- Private sector has a field day in vaccine park
- PPP: Carrot to private and stick to public sector
- Madhavi, 2008, Medico Friends Circle Bulletin



Other factors that affected PSUs

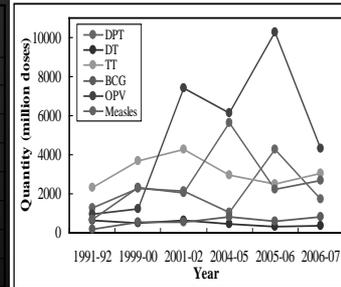
- Routine production pressures
- Declining emphasis on R&D
- Excessive dependence abroad
- Rigidities in recruitments/promotions
- Poor linkages, institutional mechanisms
- Obsolescence of R&D infrastructure
- Governmental neglect of GMP

Mounting shortages of EPI vaccines

Demand & supply of EPI vaccines

UIP vaccine	1991-92 (in lakh doses)		2006-07 (in lakh doses)	
	Demand	Supply	Demand	Supply
DPT	1320.24	1270.30	1916.96	1636.88
DT	350.00	650.82	378.01	370.29
TT	1190.00	2319.71	3651.45	2887.94
BCG	500.60	168.50	894.94	758.66
OPV*	1550.60	950.50*	4823.66	4812.48
Measles	500.00	680.00	2688.10	2688.10
Hep.B			843.83	843.83

Erratic production of EPI vaccines



Source: Compiled from Annual reports of Health Information of India 1991 to 2004-05 and national Health Profile 2007

Public sector and Private Sector meeting EPI Vaccine Supply

Vaccine	2006-07			Private Sector supply in 2008-09		
	Demand	Supply	Shortage	Demand	Supply	Shortage
DPT	1916.96	1636.88	280.08	1579.87	1163.00	416.87
DT	378.01	370.29	7.72	432.66	375.00	57.66
TT	3651.45	2887.94	763.51	1708.00	1360.00	348.00
BCG	894.94	758.66	136.28	759.21	600.00	159.21
Measles	2688.10	2688.10	0.0	391.20	450.00	58.81
OPV	4823.66	4812.18	11.48	1581.86	1530.50	51.36

Source: Compiled from National Health Profile 2007 and 34th parliamentary committee Report on Health and Family Welfare 2009.

Combination vaccines: Backdoor entry into EPI?

- Every combination vaccine combines at least one EPI with non-EPI vaccines
- Private sector produces EPI vaccines for cocktails, but doesn't supply them for EPI
- Scarcity for affordable EPI vaccines vs. flooding of costly EPI-nonEPI combinations
- For eg., the cost of DTP vaccine jumps 17 fold when combined with Hep-B
- Safety and efficacy aspects of combination vaccines not proven beyond doubt
- Are new vaccines & combinations joining the ranks of irrational drug formulations?
- Separate multivalent & cocktail vaccines
- Madhavi, 2006, Current Science



New vaccines in Indian UIP : Scientific evidence (?)

Influenza type b (Hib) Vaccine

- No actual prevalence data and no CBA studies based on Indian prevalence data
- No unambiguous evidence about its suitability in Indian Population
- Indian children acquire immunity during infancy
- Available in expensive combinations whose efficacy is doubtful

Pneumococcal Vaccine

- No reduction in clinically diagnosed pneumonia
- Reduces rare type of radiological pneumonia
- To prevent 3.6 cases of pneumonia, 1000 children need to be vaccinated
- For every 3.6 cases of pneumonia prevented 1-3 children will get Asthama
- Pneumonia can be treated & cured with antibiotics
- No evidence for its protection in Indian Population & risk of acquiring asthma

Rotavirus Vaccine

- Causes intussusception
- Can be treated with ORT like other diarrhoeal diseases
- Is it economical to introduce it in UIP?

Impact of suspending PSUs on EPI & Child Health

- Acute shortage of EPI vaccines in 23 states within 6 months
- DPT vaccination fell by 29% in Orissa and 36% in WB
- BCG vaccination fell 7.9 % in UP and 11.5 % in Punjab in 2008-09
- Incomplete immunization worsens morbidity and mortality in children
- AEFI deaths on the rise: 116 in 2009, and 128 deaths in 2010
- Sharp decline of immunization coverage in 2008-09 in India
- BCG vaccine coverage fell from 100% to 52%,
- DPT from 81% in 2007 to 43.8% in 2008.
- Pulse polio coverage dropped from 81.4% to 43%.
- Increased government procurement of EPI vaccines from Pvt. sector
- Cost of EPI vaccines appreciated by 50-70 % in 2 years
- Cost of DPT & BCG was Rs 64.29 cr in 2008-09, compared to Rs 32.2 cr in 07-08

Trans-National Global Alliances

Alliance	Year	Objective	Sponsors
CVI	1990	Global strategies for Vac D & U	UNICEF, WB, UNDP, WHO, RF, MNCs
GPV	1990	New vac D programme for purchase & Supply	Sponsors of WHO
IAVI	1996	D of anti-Hiv vacs thru PPPs	Govt.s of UK, Holland & Canada; WB, RF, BMF, Sloan F & Starr F.
GAVI	1999	Vaccine protection to every child	IFPMA, BMF, RF, UNICEF, WB, WHO, Natl Govts, PHRS
MVI	1999	D and access to malaria vacs	BMF



Emerging International Factors

- Globalization of vaccine policies, slogans and (private) industry
- New Intellectual Property Rights and World Trade Regime
- WHO-prequalification, GLP, GMP and UNICEF procurement systems
- Delinking of vaccine adoption decisions from incidence levels & other evidences
- New global alliances & influences, advance market commitments etc.
- Aid politics and loan politics tend to influence national decisions
- One vaccine fits all, one policy fits all, one 'practice' fits all
- Increasing emphasis on vaccine introduction & coverage than protection



Chronology of Events since the suspension of 3 Vaccine PSUs

- Jan 2008: DCGI ordered suspension of vaccine production in CRI, PII and BCGVL on GMP
- April 2008: Frontline cover story on "vaccine worries" attacked govt. for PSU closure
- July 2008: Health Minister Ramadoss appointed expert committee on the future of vaccine PSUs
- Aug 2008: CBI seeks ministry nod to grill PII, BCGVL Chennai lab ex-director, Elangeswaran
- Feb 2009: Supreme Court admitted a PIL against PSU closure by S P Shukla & others (HRLN)
- 18 Feb 2009: 34th parliamentary standing committee report on health attacks govt. on PSUs
- 20 Feb 2009: Supreme Court issues notice to the Union Govt. in the vaccine PIL
- 4-5 June 2009: ICMR-NISTADS workshop produced a draft National Vaccine Policy
- 4 June 2009: President of India's speech in the parliament mentioned revival of vaccine PSUs
- June 2009: Health ministry prepares an action plan to revive PSUs by 30th June 2010
- Jul-Aug 2009: Govt invests additional Rs 14 crore to make CRI GMP-compliant
- 25 Sept 2009: Govt constitutes Javid Chowdhury Committee on vaccine PSUs
- 18 Dec 2009: 38th parliamentary standing committee report on health criticizes slow PSU revival

Chronology of Events since the suspension of 3 Vaccine PSUs

- 3rd Feb 2010: PIL admitted in the Delhi High Court against pentavalent Vaccine
- 5th Feb 2010: Javed Committee submits interim report indicting govt for suspending PSUs
- 26th Feb 2010: Health ministry sends revival orders to 3 PSUs
- April 2010: High court issues interim order to govt to formulate a national vaccine policy
- 4th Aug 2010: 43rd report of the parliamentary standing committee on health raps govt.
- Sept 2010: Final Report of Javed Chowdhury committee severely indicts govt on PSUs
- 25th Sept 2011: 52nd report of the parliamentary standing committee on health still critical
- 11th April 2011: Govt.'s National Vaccine Policy, MOHFW released, announced in July
- Nov 2011: High court interim order to relook into Govt's vaccine policy document
- 29 Nov 2011: Mani (ex-director, CRI) suspended pending enquiry, a day before retirement
- Dec 2011: A PIL against introduction of Pentavalent vaccine was filed in Kerala High court

Consistent & continuous Media Reportage keeps the Debate Alive

News	Date	Source
Four Indian vaccine makers license suspended after failing GMP	12 Feb, 2008	http://www.in-pharmatechnologist.com
Vaccine Park soon at Chengelpattu	14 March 2008	The Hindu
Vaccine Worries	11 April, 2008	Frontline
4 children die of measles vaccine in TN	24 April 2008	All newspapers
Ramadosh in new controversy over vaccine deal	11 May 2008	Mail today,
Centre halts use of measles vaccine supplied by IIL	2 April 2008	Press Trust of India (PTI)
Review move to close vaccine units: Brinda	13 Apr, 2008	The Hindu Daily Newspaper
Centre decides to shut down three vaccine producing PSUs	13 May 2008	Outlook
Left turn on pharma PSU closure	18 May 2008	Business Standard
Coming soon: Five-in-one vaccination shot for kids	15 July 2009	Times of India
Government to reopen vaccine units	24 July 2009	Deccan Herald
Govt may revoke orders to halt production at 3 vaccine units	26 Feb 2009	Live Mint
Govt plans to restart state-run Kasauli vaccine making unit	6 April 2009	live mint
128 kids died after vaccine in 2010, govt can't say why	29 May 2011	Times of India

Media Reports on Vaccine PSUs

Reopening a sham? Vaccine units won't make essentials	Feb 2009	Times of India
WHO lifts vaccine embargo on India	Apr 20 2009	Livemint
India urged to use evidence in vaccine policy	June 19 2009	Scidev.net
Almost half India's children are not immunised: Govt	Jul 30, 2009	INDIAN EXPRESS
BCG Lab in Chennai gets new director	Aug 22, 2009	Pharmabiz.com
The Vaccine Mess	Jan 06, 2010	Pharmabiz.com
Health Ministry to utilise unexpired vaccines lying in closed PSU vaccine units for national immunization programme	Feb 02, 2010	Pharmabiz.com
The great Indian vaccine scam	May 12, 2010	www.mid-day.com
National vaccine policy to bring vaccines under DPCO	May 12, 2010	PHARMABIZ
Vaccination deaths: another Central team in Lucknow	Aug 24, 2010	The Hindu
Infant Deaths Cast Doubt on Vaccination Policy	Aug 27, 2010	Ipsnews.net
Health ministry continues to purchase vaccines from pvt cos, as production yet to start at PIIC and BCC Labs	Jan 25, 2011	Pharmabiz.com
Health ministry asks BCG Lab to withhold developmental works & address the issue of niacin positivity in seeds strain	Feb 22, 2011	pharmabiz.com
Critics indicate flaws in India's new vaccine policy	Sept. 01, 2011	Scidev.net

News reports in *The Pioneer* daily

Ramadoss linked to vaccine scam,	10 th May 2008
Minister armtwisted PSU head to closedown,	11th May 2008
More skeletons tumble out of Health Ministry cupboard	12th May 2008
Now, Left MP tears into Ramadoss	13 th May 2008
Ruffled Govt threatens action against whistleblower, <i>Pioneer</i> daily news	14th May 2008
Brinda ticks off Ramadoss, asks uneasy questions	15th May 2008
Scientists lash out at closure plot	16th May 2008
Health Ministry barks, doesn't bite	17 th May 2008
Ramadoss changes tack blames tobacco, liquor lobbies	18th May 2008
We pay, they profit	19th May 2008
Minister threw rules to wind	21st May 2008
Ramadoss ignored norms to put his men at helm in PSUs	22 nd May 2008
CAG report blames Govt for halting vaccine production at 3 PSUs	23 rd May 2008
Telephone booth owner becomes multi-billionaire	24 th May 2008
Workers up in arms as Director returns	27 th May 2008
Govt pays crores for 'free' seeds	30 th May 2008
Ramadoss has no answer	31 st May 2008

News reports in *The Pioneer* daily

Ministry asked to rethink on closure of vaccine Production	6 th June 2008
Ramadoss blinks, orders vaccine probe	7 th June 2008
PSUs to resume vaccine production in August , 2008	12 th July 2008
Azad smells a rat in vaccine production policy; Ramadoss steps led to Govt-run pharma companies' decline	25 th July 2009
EFC-approved vaccine comes under scanner	27 ^h June 2009

Author	Title	Bulletin/Magazine/journal	date
Y. Madhavi	Vaccine PSUs:Chonicle of an attenuation willfully caused	MFC Bulletin	329 June-July 2008
Ambedker and Singhal	Measles vaccine deaths-IAP-COI STAND	Indian Pediatrics	June 17, 2008
Anjali Puri, Pushpa Iyengar and Debarshi Dasgupta	Someone Give Him A Light :A smokescreen separates Anbumani Ramadoss from the underperforming healthcare system	OutLook (www.outlookindia.com)	19 th May 2008
Nayantara Som	On Death Bed , Apathetic regulators run the industry to the ground; India's globally acclaimed vaccine industry is gasping for its breath.	Biospectrum	September 10, 2008
<u>Bharat Dogra</u>	Sabotaging Indigenous Production of Vaccines	Mainstream	3 December 2008
G. Mudur	Activists file petition against suspension of vaccine production	British Medical Journal	7 th March 2009

Author	Title	Bulletin/Magazine/journal	date
Y. Madhavi	Vaccine PSUs: Chronicle of an attenuation willfully caused	MFC Bulletin	329 June-July 2008
Vibha varshney	Vaccine shortage to continue	Down To earth	
<u>Ankur Paliwal</u>	Policy draft backs new vaccines	Down To earth	May 31, 2011
<u>Vibha Varshney</u>	Out of Stock: Get your own vaccine (cover story)	Down To Earth	Jul 15, 2009
<u>Ankur Paliwal</u>	Licence revived, production halted	Down To Earth	Mar 31, 2011
	A vaccine for corrupt alliances	Down to Earth	Jul 31, 2009
Madhavi Y. 2009.,	Home-grown vaccines are crucial for public health. Opinions	Scidev.net,	23 September 2009
Y. Madhavi et al.,	Evidence-based national vaccine policy	IJMR	May 2010
Y. Madhavi & N. Raghuram			
Puliyel	Advance market commitment	EPW	2011

Conclusions and tasks ahead

- Vaccine policies/decisions are increasingly shaped by industry's 'supply push'
- Demand pull by disease burden and epidemiology are systematically neglected
- International agencies like WHO are also peddling industry arguments to govts
- Speculative financing and advance market commitments are hijacking policies
- Save national vaccine policy & public health from the vagaries of global markets
- A bad vaccine policy is worse than having no policy at all
- Litigations can be synergized with media, parliament and other interventions
- Academia, civil society and legal community can be a formidable force in this
- Health movements must be the revived as the epicentre of all other interventions

Tasks ahead



Thanks !

Facts from Right to Information Act

- 128 children died in 2010 due to adverse effects after immunization (AEFI). That count has risen in the past three years, with 111 such deaths in 2008 and 116 in 2009.
- The enquiry report of central team for AEFI deaths due to Measles vaccination in Chennai in 2008, in MP in 2009 and in Lucknow in 2010 is not yet ready- Ans to an RTI in March 2011.
- Health ministry procures EPI vaccines only from 2 PSUs- TT, DPT from CRI kasauli (110th of total procurement order) and Measles from IIL Hyderabad and rest of the EPI vaccines are procured from Private sector during 2010-2011, including BE Ltd., which is not WHO-GMP Complaint. JE vaccine is also procured from Chengdu institute China through HHCL.
- Only CRI kasauli supplies TT DT DPT to EPI during 15-1-2008 to 31-12-2009.
- An RTI plea to the Union Health Ministry has revealed that 522 kids died in several central government-run hospitals across the country due to a severe shortage of vaccines for BCG, DPT and Tetanus.
- 26 measles vaccine deaths in 3 years, no investigative report yet

Parliamentary Standing Committee Reports

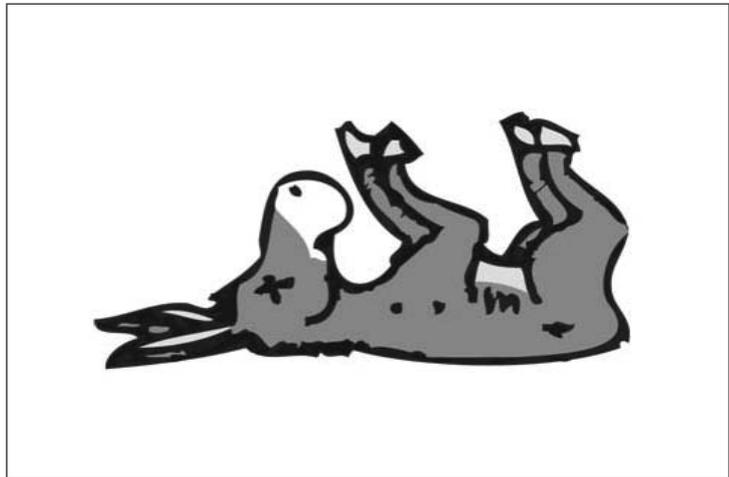
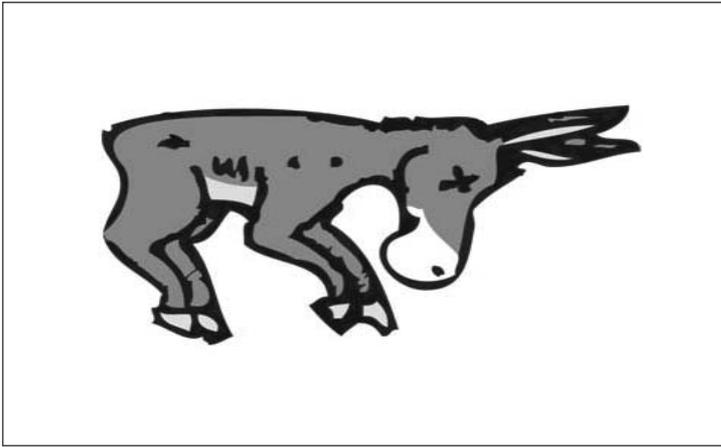
1. 34th Parliamentary Standing Committee on Health and Family Welfare, Parliament of India, Rajya Sabha, Government of India, New Delhi; 18th Feb 2009: zReasons for closure
 2. 38th Parliamentary Standing Committee on Health and Family Welfare, Parliament of India, Rajya Sabha, Government of India, New Delhi; 18th Dec 2009 :notes that action taken by the ministry still unanswered
 3. 43rd Parliamentary Standing Committee on Health and Family Welfare, Parliament of India, Rajya Sabha, Government of India, New Delhi; 4th Aug 2010
 4. 52nd Parliamentary Standing Committee on Health and Family Welfare, Parliament of India, Rajya Sabha, Government of India, New Delhi; Feb 2011
 5. Javid Chowdhury Committee Report, 2010. Interim Report of the Committee set up to determine the reasons for the suspension of the manufacturing license of CRI Kasauli, PII Coonor, and BCGVL Guindy, and to draw the road-map for the revival of the three units, Feb 2010; vindicates the concerns expressed in the petition and it indictes health ministry and DCGI for the current crisis and recommends immediate revivsl od vaccine units
 6. Javid Chowdhury Committee Report, 2010. Final Report of the Committee set up to determine the reasons for the suspension of the manufacturing license of CRI Kasauli, PII Coonor, and BCGVL Guindy, and to draw the road-map for the revival of the three units, Sept 2010.
- Questions in LokSabha and Rajya sabha on vaccine psu revival and status

OCCUPY MEDICINE USEING THE LAW

Jacob M Puliyel

Occupy
Medicine
+ Using the
Law
Vaccines for 99%
versus
profits for the 1%

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Raffle of a dead donkey

Cost	\$ 100
500 tickets @ \$2 each	\$ 1000
Refund	\$ 2
Profit	\$ 898

250,000 death in India each year due to Hepatitis B

Miller et al Health Economics 2000;9:19-35

ICMR data suggests about 5000 die

Dhir et al Ind J of Gastroenterol 1998;17:100-3

Model Used

Model 'stratified by income group and geographic region' was used and it was available on the CDC web site:

<http://nihfic.cit.nih.gov/research>

No model on web site

Model using data from Taiwan Males

25% Male hepatitis B carriers die in Taiwan
World Record

300% of mortality in Taiwanese female carriers

Beasley Cancer 1988;61:1942-56

It is 17 times higher than mortality in Canadian carriers

Villeneuve et al Gastroenterology 1994;106:1000-5

Extrapolation Taiwan Male Mortality

4% population are carriers in India

If 1 in 4 carriers die of the disease

1% of deaths in India must be due to
Hepatitis B

1% of deaths among India's 1 billion
population is 250,000!

Puliyel JM. Lancet 2004;363:659

Health Economics publishes call for retraction of paper

Model used by Miller must be published or the
paper retracted

Puliyel JM Health Economics 2004;13:1147

Miller has replied that the model was lost

Miller MA Health Economics 2004;13:1147-8

The paper has NOT been retracted yet

Invasive H. Influenza B (Hib) disease

Incidence of invasive disease with Hib is very
low.

Incidence:

9/100,000

Asia

109/100,000

Western Pacific

Levine Pediatr Infect Dis J 1998;17:S95-113

Is Hib really needed in Asia?

Editorial in Bulletin of WHO

Lau YL Bulletin WHO 1999;77:867-8

Natural Immunity in Asia

1. High antibody levels pre-vaccination at 6 weeks
2. Not passive immunity
Without immunization: Increasing antibody titers with increasing age

Tastan Ind Pediatr 2000;37:414-7

Natural Immunity in Asia: Vaccine Booster Effect

3. After vaccination, antibody levels increase ten times higher than normal suggesting that child was immune before vaccination

Acharya Ind Pediatr 1997;34:9-15
Kumar Ind J Pediatr 1997;64:839-47

Natural Immunity to Hib

Animal model: E coli cross-reactive antigens
against Hib

Schneerson Inf and Immunol 1971;4:397-401

Bradshaw Lancet 1971;1095-98

Petrie Br J Exp Path 1971;13:380-94

Infection with organisms like E Coli may
protect Asians against Hib

Puliyel Vaccine 2001;19:4592-4

Inappropriate-Media Hypothesis for Low Culture Rate

Chocolate agar supplemented with
Isovitalex

Gellert Lancet. 1994 ;344:959

Invasive Bacterial Infection Surveillance Group (IBIS) Study

- Continuous surveillance for 4 years
- 6 of the largest hospitals in 6 cities
- Appropriate culture techniques
- Findings: 125 cases in 4 years!

Small numbers?

Access to the hospital is perhaps a problem

Solution: Community studies needed.

IBIS Group Clinical Infect. Dis 2002;34:949-57

WHO Prospective Community Study Hib Meningitis

Incidence Hib meningitis 7/100,000

(Levine had estimated 9/100,000 invasive disease)

Low rate of Hib in children in this region:

- (a) genetic factors
- (b) early exposure to bacteria with cross-reacting antigens
- (c) low bacterial virulence

Minz et al IJMR 2008;128:57-64

New Ideas Low Incidence of Hib

- Culture media not the problem:
IBIS Study
- Access to hospital not the issue:
Mitz Community Study

Perhaps prior antibiotic use problem

Probe study for areas with Low Culture Rate

Probe studies to identify reduction in
clinical disease after immunization

No culture proof needed

The Hib initiative.

www.hibaction.org/research.php#vaccine_probe.

Indonesia Lambok Study

55000 children:

- Double blind
- Hamlet randomized
- Active case surveillance

Gessner Lancet 2005;365:43-52

Vaccine Effectiveness (Vaccine preventable Hib disease)

Disease manifestation	Vaccine Effectiveness (Incidence Unvaccinated – Vaccinated)
Alveolar Consolidation/ Effusion	- 43 (95% CI -185 to 98)

Bangladesh Probe 2007

- Not randomized. No blinding
- Incident case-control study
- Population 68,000
- 35% received Hib vaccine
- 475 Pneumonia.

Baqui Ped Infect Dis 2007;26:565-71

Bangladesh Probe
Vaccine Effectiveness - 3 doses
 Baqui Ped Infect Dis 2007;26:565-71

Disease	Community Controls (matched for age , sex, season and distance from hospital)
Meningitis	40% (95% CI -138 to 85)
Pneumonia (WHO protocol)	20% (95% CI -10 to 43)

Press release
WHO Dhaka , 28 June 2007

**New study shows Hib vaccine protects children
 from significant burden of life-threatening
 pneumonia and meningitis**

Press release signed by WHO, GAVI, USAID, Johns
 Hopkins

Puliyel Demanding Accountability. BMJ 2010; c4081
 Puliyel Eu tu WHO. IJMR 2010;131:588-9

No Hidden Agenda

- Cost of Hib in the USA is \$5.60 (1998 prices)
- Price can come down only if Hib is part of EPI internationally

Nossal Nature Medicine 1988;5:475-6
 Steinhoff Lancet 1993 ;342:630-1

Poor countries must use the vaccine so the price of
 the vaccine in the West can come down

Puliyel Vaccine 2001;19:4592-4

Hib eliminated:

Replacement by other invasive strains of H. influenza

Proportional increase in non-B H. influenza strains, including non-serotypeable strains, causing invasive H influenza disease in the post-Hib vaccine era in Canada

Tsang et al Clin Infect Dis. 2007;44:1611-4.
Brown et al Clin Infect Dis 2009;49:1240-1243

Pentavalent Vaccine

- DPT costs Rs 15/child
- 50% don't receive these vaccines

- DPT + (useless) Hep b and Hib
Rs 525/child

Pentavalent deaths

- Bhutan 8
- Pakistan 4
- Sri Lanka 4
- Japan (DPT+Hib) 4

- Kerala vaccination started 14/12/11
1 death already!

Brighton Classification (WHO)

- Certainly related (Re-challenge)
- Probably related (No other explanation)
- Possibly related (Also other explanation)
- Unrelated (Other explanation only)

Pneumococcal vaccine

Cost

Rs 12,000 per child

Benefit

Reduce 3.6 cases of pneumonia /1000 children vaccinated

Madhi WHO Bull 2008;86

Pneumococcal Vaccine Harm: Risk of Asthma Doubled

1.4 additional cases of Asthma for every 3.6 cases pneumonia avoided (per 1000 children vaccinated)

Klugman K. NEJM 2003;349:1341-8

Spending Rs 12 million to save Rs 40

- Vaccine costs Rs 12,000 per child
- Vaccinating 1000 children costs Rs 12 million
- Treating 4 cases of pneumonia will cost Rs 40 if WHO recommended Septran is used

Dabade Lancet 2009;373:2195-6

If prices come down to Rs 1200/child
you will spend Rs 1.2 million to save Rs 40

Cure is Worse than Disease

Strain Replacement

Invasive pneumococcal infections increased
after PCV 7

Serotype 19A isolated, one third of which
were resistant to multiple antibiotics.

Kaplan Pediatrics 2010;125: 429-436

Rota Virus in India

- Continuous reassortment of bovine and human strains.

Ramani S. IJMR 2007;125:619-32

- No study on reduction in diarrhoea among vaccinated in India

Community Perspective: Allocative Efficiency

Hypothetical Case Study

1. Rota virus control costs Rs 200 crores
Saves 1 life year per Rs 20,000
2. Polio control costs Rs 350 crores
Saves 1 life year per Rs 10,000
3. TB control costs Rs 700 crores
Saves 1 life year per Rs 5000

Rank Incremental Cost-Utility Ratios Budgetary Constraint: Rs 1000 crores

1. TB control costs Rs 700 crores
Saves 1 life per Rs 5000
2. Polio control costs Rs 350 crores
Saves 1 life per Rs 10,000
3. Rota virus control costs Rs 200 crores
Saves 1 life per Rs 20,000

50% of the population don't receive
the basic

EPI vaccines costing Rs 30

- HPV Rs 9000/child
- Rotavirus Rs 2000/child
- Pneumococcal vaccine Rs 12000/child

Community Perspective
Newer vaccines: Are they ethical?

Pneumococcal Vaccine: Perspective of the Individual

Exorbitantly expensive

Cost per child Rs 12,000

MRP includes incentive to doctor Rs 3000

- Very small benefits (3.6/1000 pneumonia)
- Individual risks - Asthma (1.4/1000)
- Community risks - Antibiotic Resistant Strains

Can it be prescribed ethically to rich?

Another Half Truth

Pneumococcal vaccine protection against
vaccine-strain invasive-disease (VS-IPD) 80%
(CI 58% to 90%, P < 0.0001)

Cochrane meta analysis . Lucero 2009

The other half of the truth

No reduction in all-cause mortality

[OR 11% (95% CI -1% to 21%, P = 0.08)]

Incidence of vaccine strain invasive disease was
so low - the absolute risk difference (ARR) is only -
0.002 (CI: -0.004 to -0.000)

Number Needed to Prevent One Case 500.

Puliyel Microbiology and Infection 2011

Misleading Statistics

- Risk reduction (RR) of 50% sounds good for a vaccine

Patients and doctors are easily convinced

Suppose Risk comes down from 4% to 2%

- RR is 50%
- It affords 2% reduction in absolute risk.

Unlikely to convince patients to take the treatment

Morgan Clinical Oncology 2004;16:549e560

Yellow fever

- 100% Protection
- ARR ZERO
(As disease non-existent India)

RR and ARR

	Die	Live	Total	
RR = $R_2/R_1 = (0.0001/0.0002) = 50\%$	Control	2	998	1000
ARR = $R_1 - R_2 = 0.0002 - 0.0001 = 0.0001$	Vaccine	1	999	1000
NNT = $1/ARR = 1/0.0001 = 1000$	Total	3	1997	2000

Efficacy as 'absolute risk reduction' to calculate cost benefits easily

- Impressive sounding reductions in relative risk can mask much smaller reductions in absolute risk.
- Clinical decisions based on absolute risk (AR) rather than relative risk (RR).

Godlee F 2008. Absolute risk please. BMJ

How to avoid buying a dead donkey

What can we do



Resolution for WHA: Intervention to enhance child survival

Efficacy must ALWAYS be reported in terms of 'absolute risk reduction'

NOT Relative risk (RR)

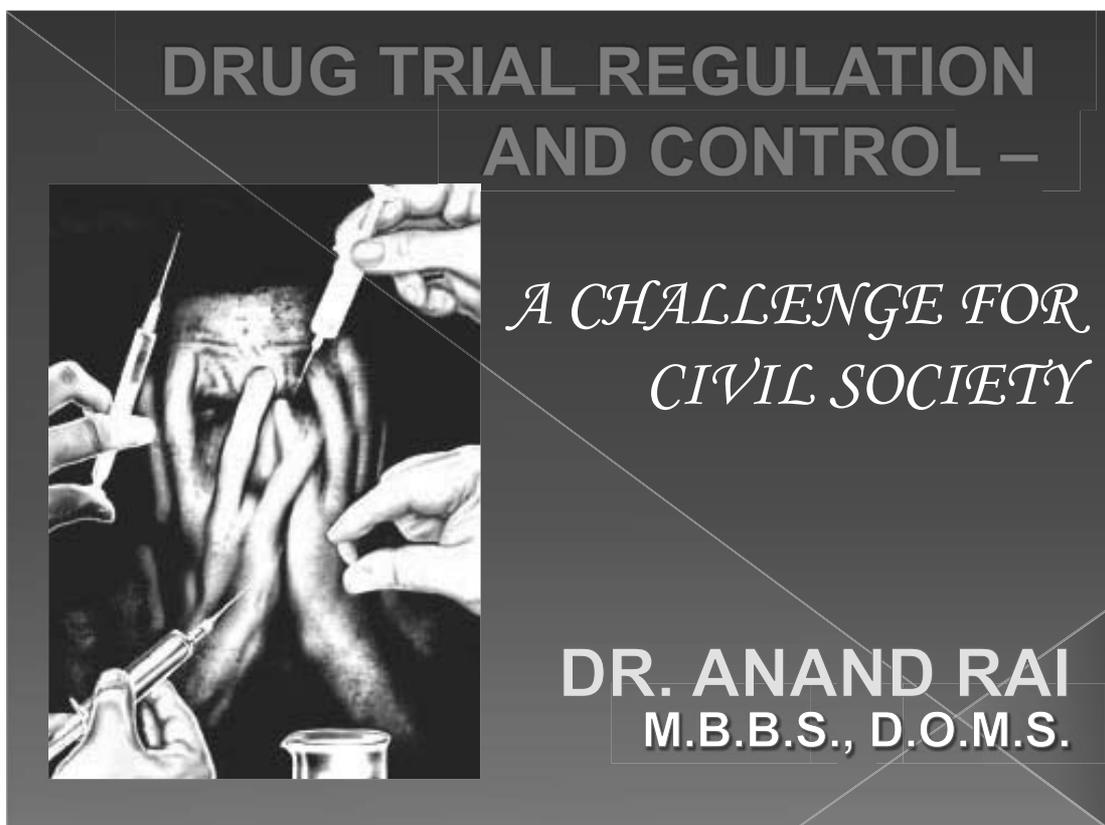
so that Member States can calculate cost benefits easily

The Law Court

- PIL Delhi High Court
- PIL now in Kerala High Court
- Useless vaccines being pushed at behest of vested interests
- Dangerous vaccines being pushed on unsuspecting children

DRUG TRIAL REGULATION AND CONTROL – A CHALLENGE FOR CIVIL SOCIETY

Dr. Anand Rai



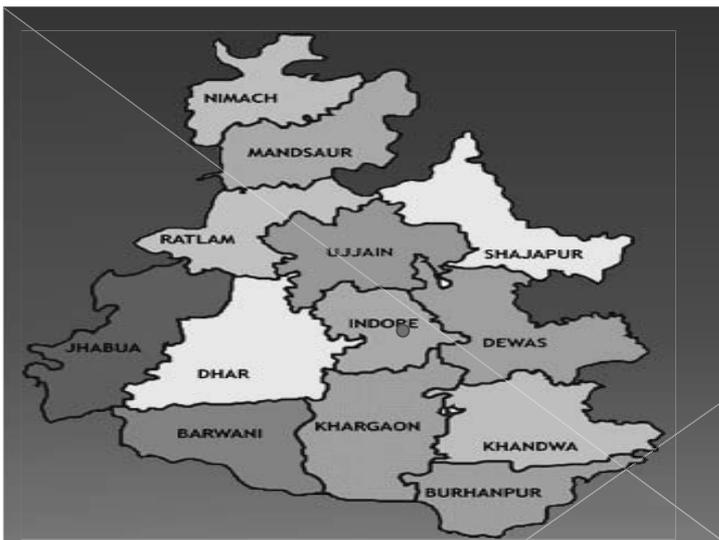
- Disturbed patients afraid of their surroundings, Doctors above the law and a government on siesta ... the story of India.
- The doctors go through their day ignoring the Hippocrates oath they took when they started their careers.
- Many doctors in M.P. give more importance to their earnings than to the life of their patients. Lured by the offers of big Pharma companies these doctors have deliberately violated all regulations and have reduced clinical trials to a money spinning exercise.



GUINEA PIG

INDORE : A case study

- Indore – the commercial capital of Madhya Pradesh is surrounded on all sides by backward and predominantly tribal districts. Poor patients from surrounding districts flock to Indore for secondary and tertiary care.
- Indore has hospitals, great air connectivity and has transformed itself into a clinical trial hub.



- M.P. Government's Economic Offences Wing investigates clinical trials in Maharaja Yeshwant Rao Hospital, government teaching hospital – in all 73 trials were carried out on nearly 3300 patients that included 1833 children.
- The trials were carried out by six senior doctors who received Rs 5.1 crores from drug companies.
- 81 including 18 children patients suffered serious adverse effects which included death.
- In the private sector 60 trials were carried out involving 40 doctors – the number of patients not disclosed. In CHL Apollo hospital there were five deaths.



Dr. Apoorva
Pauranik



Dr. Ashok
Bajpayee



Dr. Anil
Bharani



Dr. Puspa
Varma



Dr. Salil
Bhargava



Dr. Hemant
Jain



Name of companies who sponsored clinical trial in Indore

- 8 Indian companies and institutions sponsored these trials while multinational sponsorship was of 22 companies and institutions

Indian:

- Cipla Pharmaceuticals, Panacea Bio-Tech, Cadilla Pharmaceuticals, Ipca, Serum Institute of India, St. John's Medical College and Population Research Centre Bengaluru, Himalaya Drugs

Name of companies who sponsored clinical trial in Indore

Multinational:

- Boehringer Ingelheim, Schering Plough Research Institute, Theravance Inc, Speedal, Eli=Lilly, Australian Medical Council, MacMaster University, Servier, Duke Medical University, Daiichi-Sankyo-Phaema Development, Novaartis, Schwarz Biosciences, Merck, Eisai, Pfizer, Biogen Idec, Crucell, Bayer, Thrombosis Research Institute, GlaxoSmithKline, Johnson and Josnson, Alcon, Servier

Drugs and indications for which the trials were conducted

Name of the drug	Indication
◉ Ipratropium Salbutamol inhaler	Chronic obstructive pulmonary disease
◉ B1 1744 CL & Fordil	Chronic obstructive pulmonary disease
◉ Momentosone Furate/Formetrol	Chronic obstructive pulmonary disease
◉ Telavancin v/s Vancomycin	Hospital acquired pneumonia
◉ Avocsantan	Diabetic Nephropathy
◉ Prasugrel & Clopidogrel	Unstable angina
◉ Aggrenox v/s Clopidogrel With and without Micardis	Second Stroke
◉ Dabigatran Etexilate with Open label Warfarin	Prevention of Stroke
◉ Apixaban v/s Warfarin	Nonvalvular Atrial fibrillation
◉ Ivabradine v/s Amlodipin	Stable angina
◉ Apixaban v/s Aspirin	Stroke

Drugs and indications for which the trials were conducted

Name of the drug	Indication
⊙ Aliskerin	Heart failure
⊙ Pramipexole ER	Parkinsonism
⊙ Pramipexole ER L-Dopa	Parkinsonism
⊙ Rotigotin	Parkinsonism
⊙ Donepezil SR	Dementia
⊙ Pregablin	Epilepsy
⊙ BG 9928 Adenosone Antagonist	Acute decompensated heart failure
⊙ E-5555 PDGF Antagonist	Acute coronary syndrome
⊙ Rameltonv/s Zolpidem	Insomnia
⊙ Telmisartan, Dipyremidol, & Clopidogrel	AspirinSecond stroke
⊙ Quetiapine	Schizophrenia
⊙ Desvenlafaxine Succinate ER	Major depressive disorder
⊙ Clonazopam v/s Paroxetine Hydrochloride	Depression and Anxiety

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⊙ Clonazopam v/s Paroxetine Hydrochloride	Depression and Anxiety

Drugs and indications for which the trials were conducted

Name of the drug	Indication
⊙ Depoxetine	Premature Ejaculation
⊙ IN-AQUL-001	Primary Insomnia
⊙ Armodofinil v/s Modafinil	Shift work disorder
⊙ Remelton v/s Zolpidom	Insomnia
⊙ Asinapin v/s Risorpidon	Schizophrenia
⊙ AL-46383 A Ophthalmic Solution	Adenoviral conjunctivitis
⊙ Moxifloxacin AF Ophthalmic Solution	Bacterial conjunctivitis
⊙ Ophthacare	Conjunctivitis

Trials of drugs and vaccines on children

Name of Drug/ vaccine	Sponsor	No. of children involved
Hib Conjugate Vaccine	Panacea Biotech	24
Easy five vaccine	Panacea Biotech	50
I/V Montelukast	Merck	05
Quadrivalent study	L.G. Life Science	100
Men ACWYTT Conjugate vaccine	GlaxoSmithKline	194
DTWP Vaccine	Panacea Biotech	100
VALSARTAN	Novartis	05
Bivalent OPV vaccine	WHO	400
Pentavalent	L.G. Lifescience	160
Rabeprazole	Johnson & Johnson	03
Imovax Polio Vaccine v/s Panacea Biotech vaccine	Sanofi Pasteur	65
12AH1N1 Vaccine	Serum Institute of India	50
12BH1N1 Vaccine	Serum Institute of India	50
HPV Multivalent vaccine V-503	Merck and Dome	44
Hepatitis A	Crucell	90
Bivalent oral polio vaccine	Panacea Biotech	100
	Total	1838

Hazardous adjuvant used in vaccine trial

Adjuvant Name	Side Effect & Details
(1) THIOMEROSAL Adjuvant used in Hib-vaccine, Easy Five Vaccine, Quadrivalent Study by LG Life science, Pentavalent Study LG Life Science (on 100 Trial Subject & 60 Trial Subject), H1N1 Vaccine; combination vaccine of Diphtheria, Tetanus, whole cell pertusis, Hepatitis B; Combination vaccine LBVF0101 H ₁ N ₁ influenza vaccine & many more trials done at CNBC, Indore.	It is 49.6% mercury by weight and is metabolized in to Ethyl mercury and Thiosalicylate. US FDA banned THIOMEROSAL since 1999 In special condition Maximum recommended Dose is 1 Micro Gram Per DOSE but in CNBC Hospital, Indore 25 micro gm per dose used. Side Effect: - (1) Neurodevelopment disorder (2) Autism, (3) Attention deficit Hyper Activity disorder (ADHD) (4) Speech or language delay.

Hazardous adjuvant used in vaccine trial

Adjuvant Name	Side Effect & Details
(2) ALLUMINIUM PHOSPHATE GEL / ALLUMINIUM HYDROXIDE GEL / AMORPHOUS ALLUMINIUM HYDROXY PHOSPHATE SULPHATE (AAHS) As adjuvant used in: - Easy five vaccine, Hib vaccine, DTWP, Pentavalent study by LG Life Science (On 100 and 60 trial subject), HPV vaccine, combination vaccine – Deptheria, Tetanus, Patuisis, Hep-B, LBVF0101, V503 Multivalent HPV vaccine & many more, Vaccine trials done at CNBC Indore (M.P.)	SIDE EFFECTS: Alluminium is particularly dangerous Neurooxin. It has the ability to slip fast your body's natural defenses and enters, brain potentially causing brain damage, alzheimers disease, Dementia, convulsions & coma, Alluminium can even cause nerve death.



Yatharth Naik

DISTANT AND STRANGELY CONSTITUTED ETHICS COMMITTEES

- **MGM Memorial Medical College has 27 members as opposed to 12 laid down. No layman representation. Of the total 22 are professors in the college**
- **Netaji Subhash Chandra Medical College has an Ethics Committee chaired by a Veterinary Doctor**
- **Bombay Hospital, Indore also has an Ethics Committee chaired by a Veterinary Doctor**

List of Ethics Committees that approved drug/vaccine trials in Indore

- Ethics and Scientific Review Committee, MGM Medical College Indore
- Clinicom Ethics Committee, Bengaluru
- Aditya Ethics Committee
- Shatabdi Hospital Ethics Committee
- Cerebral Ethics Committee
- Unique Independent Ethics Committee
- Independent Ethics Committee, Consultant, MGM College and MY hospital, Division of Cardiology, Indore
- North Maharashtra Ethics Committee, Jalgaon
- Kotbagi Hospital Ethics Committee
- Independent Ethics Committee, Dhanasree Hospital, Pune
- Ethics Committee of Diabetes, thyroid hormone research Institute Pvt. Ltd., Indore
- C.H.L. Apollo Hospital Ethics Committee, Indore
- Choithram Hospital Ethics Committee. Indore
- Bangalore Central Ethics Committee
- Naitik Independent Ethics Committee
- Manav Independent Ethics Committee

These committees are not independent as in most cases the chairperson is part of the institution. None have representation of lay persons.

Economic irregularities established by EOW, M.P. in clinical trials in Indore

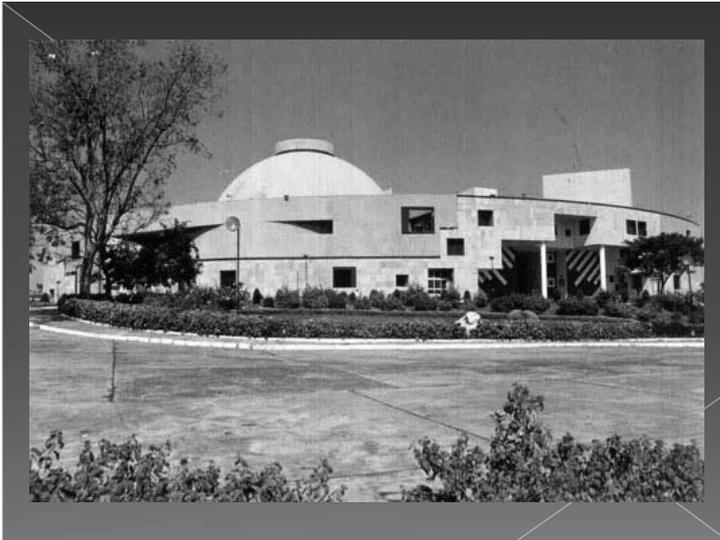
- Members of Ethics committee MGM Medical College were the principal investigators in many trials. The Secretary of the Committee Dr. Anil Bharani failed to follow the GCP guidelines and the ICMR guidelines.
- Principal investigators failed to fulfil their responsibility in cases of serious adverse events
- The basic tenets of informed consent were violated.
- Code of MCI Act 1958 (20A) in respect of Professional Conduct was violated.
- Patients enrolled for clinical trials stated that the process was not transparent.
- Insurance provisions for patients suffering serious adverse events were violated. Consent was not taken properly.
- 10% stipulated income for trials has not been deposited with the institution

Protests & outcome

- Protests against unethical clinical trials in Indore resulted in the state government appointing a committee headed by the Principal Secretary, Medical Education to look into the irregularities. This committee banned all new trials in the state on 29th October 2010.
- A public hearing was organized by the committee in MGM Medical College on 30th October 2010. 168 persons made deposition before it and gave their suggestions.
- M.P. Government, Department of Public Health and Family Welfare made the following suggestions to the DCGI on 22nd March 2011.
 1. Representative of the state government should be included in granting permission and licences under Rule 21(B) of the Drugs and Cosmetics Act.
 2. Any drug trial taking place within the state must have the clearance of the state government also before it is approved by the DCGI
 3. Serious adverse events must be reported to the CMHO within 24 hours by the Principal Investigator.
 4. Director Health/Medical should have the right to audit and monitor the records relating to drug trials.

Agencies investigating unethical drug trials in M.P.:

Agency	Complainant
1. NHRC through SHRC	Dr. Anand Rai
2. Lokayukt, M.P.	Mr Rajendra Gupta
3. State Economic Offences Investigation Bureau	Dr. Anand Singh Raje
4. DCGI	Mr Ajay Naik
5. MCI through M.P. Medical Council	Mr Rajendra Gupta & Mr. Sharad Gite
6. CBI through MCI Vigilance officer	Mr. Rajendra Gupta
7. M.P. Police, Sanyogitaganj, Indore	Mr. Ajay Naik
8. Health Minister, M.P. Government	Mr Sharad Gite
9. Joint Director Health, Indore Division	Dr. Anand Rai



Questions raised in M.P. Assembly on drug trials

Date/Q.no.	Name of M.L.A	Subject
July 23,2010 Q.No. 540	Mr. Pratap Grewal	Trials on patients of government hospitals
July 30, 2010 Q 1369	Mr. Paras Sakhlecha	Foreign travel of doctors organized by trial sponsor
July 30, 2010 Call attention Motion 284/507/533	Ajay Singh, Mr. Paras Sakhlecha, Mr. Pratap Grewal	Discussion on Drug and and vaccine trials
Nov 23, 2010 Qno 544	Mr. Paras Sakhlecha	Hazardous vaccine trials on girls
Nov 30, 2010 Q no 1193	Mr. Pradumn Tomar	Deaths during trial
Nov 30, 2010 Q no. 2692	Mr. Arif Akeel	Action against erring officials
Nov 30, 2010 Q. no. 2748	Mr. Paras Sakhlecha	Enquiry into drug trials and and making rules for them
Nov 30, 2010 Q.No.2794	Mr Umang Singhar	Action taken on complaints of trial victims
Nov 30, 2010 Q. No. 2793	Mr Umang Singhar	MY Hospital Supdt. in trials at Gyan Pushpa Research Centre

Questions raised in M.P. Assembly on drug trials

Date/Q.no.	Name of M.L.A	Subject
March 10, 2011 Q.No. 3505	Mr. Pratap Grewal	Trial with Pigvalin in Neurology Dept.
March 10, 2011 Q.No 1795	Mr Sanjay Shah	Victimization of whistle blower
March 17, 2011 Q.No. 5715	Mr. Pratap Grewal	Trials and Ethics committees in private hospitals
March 30, 2011 Q.No. 6790	Mr. Paras Sakhlecha	Tadalafil, PDE-5 inhibitor being tried in PAH patients
March 31, 2011 Q.No. 5626	Mr. Paras Sakhlecha	Trials on mental patients
July 12, 2011 Q.No 519	Mr. Paras Sakhlecha	Adverse effects of drug trials
July 12,2011 Q. No 521	Mr. Paras Sakhlecha	On information provided during Call attention motion on trials
July 19,2011 Q.No.182 & 2165	Mr. Shrikant Dube, Mr. Paras Sakhlecha	On complaints about drug trials
July 19,2011 Q.No.1850	Mr. Pratap Grewal	Info on deaths during trials in govt. and private hospitals
July 19,2011 Q.No. 554	Mr. Mahendra Singh	On drug trials

Questions Raised in Parliament (Rajyasabha) About Drug Trial

Date and Question No.	Name of M.P.	Subject of Question
15.03.2011, Q.No. 2117	Smt. Kusum Rai	Carrying out of clinical Trial
15.03.2011, Q.No. 2082	Shri N.K. Singh	Irregularities in studies of HPV vaccine.
15.03.2011, Q.No. 2113	Shri. T.M. Selvaganapati	Rejection of HPV vaccine project by PHFI
15.03.2011, Q. No. 269	Shri K.N. Balgopal	Development of Biomedical Stents for cardiovascular Treatment
02.08.2011, Q.No. 241	Shri Mahendra Mohan	Mechanism for monitoring clinical trials of drugs.
02.08.2011, Q.No. 249	Shri Mahendra Mohan	Safety & Ethical issues in clinical trails of drugs.
09.03.2011, Q.No. 137	Shri purushotham Khodabhai Rupala	Protection of patients under going clinical trials.
09.03.2011, Q.No. 1037	Shri. K.E. Ismail	Death during clinical trials of drugs.
09.03.1064, Q.No. 1046	Shri Mahendra Mohan	Illegal clinical trails of drugs

Suggestions for regulating clinical trials

- ⦿ An empowered committee should work out the necessity of clinical trials in the country based on the death toll and disease burden. Only such trials should be allowed in the country.
- ⦿ A new drug proposed to be introduced in the country should be cost effective. All trials should be sponsored by/through the government.
- ⦿ Placebo control trials should be stopped.
- ⦿ Concurrent trials should not be allowed and only those drugs from outside India should undergo trials which are already licensed in the home country.

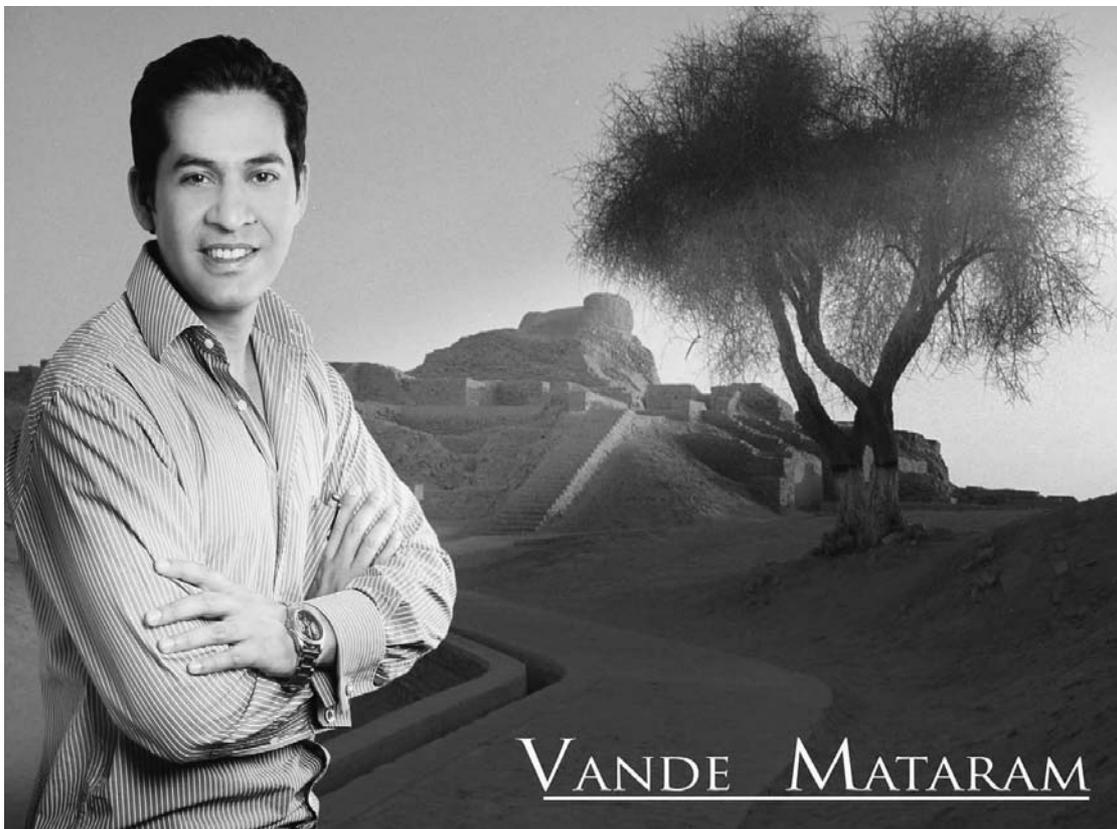
Suggestions for regulating clinical trials

- ⦿ There should be no restriction on publishing results of a trial and in fact publication of results in reputed scientific journals should be a requirement for the benefit of patients.
- ⦿ An independent apex agency needs to be established to oversee the functioning of the DCGI office and various Ethics committees.
- ⦿ The office of the DCGI should be strengthened professionally to have more technical persons and inspectors. DCGI should have regional centres so that trial sites can be monitored effectively. Help lines must be set up for complainants.

All Ethics committees should be registered with the Gol. When they fail to carry out their duty properly their registration should be cancelled.

Suggestions for regulating clinical trials

- Failure to carry out their duties in respect of ethical clinical trials should result in punishment to Principal Investigator, Drug companies, chairman of the ethics committee and contract/clinical research organization which should include fine and imprisonment.
- Funds for clinical trials should be channelled through institutions and not privately.
- A copy of the informed consent form, patient information sheet and clinical trial liability insurance policy should be given to each trial participant for the ultimate protection of her/his well being.
- If a drug is granted a licence after the trial, trial subjects must be given a share of the profit.



THE CLINICAL TRIAL SCENARIO IN INDIA: ISSUE AND CONCERN

Sandhya Srinivasan

The clinical trial scenario in India

Issues and concerns

Sandhya Srinivasan

*Indian Journal of Medical Ethics
Infochange News & Features*

Using the law for public health: national dialogue
New Delhi, December 17-18, 2011

Summary: government policy on drug trials

- The Indian clinical trials industry is **growing** in size and importance in the region
- **The “India advantage”**: low costs, treatment-naïve population with acute and chronic diseases of interest to the industry, and high recruitment rates in clinical trials
- **Promoted by changes in the law starting 2005**
- **Incentives and promises**: tax exemptions, fast-track approval, timelines for ethics review

Summary: snapshot of drug trials in India

- 670 trials open for recruitment as of December 31, 2010
- Drug company sponsored: **456/670**
- Foreign sponsors: **292/670**
- Single largest drug group -- **cancer drugs 125/670**
- Placebo controlled trials: **190/670**
- Phase 3 or 4 (for marketing approval) **477/670**

Clinical Trials Watch, *JME*, 2011

Implications

- Research agenda driven by drug industry
- Large number of foreign companies (plus collaborations?)
- Research focus on expensive drugs
- Large number of placebo controlled trials – depriving participants of effective drugs?
- Vast majority phase 3 / phase 4 trials for regulatory approval – any contribution to India’s research capacity?

Research environment

- People desperate for healthcare
 - Public healthcare inaccessible
 - Private healthcare unaffordable
- Health system and doctors willing collaborators
- Regulation for participant protection weak or non-existent
- Industry confidence: no fear of punishment

Increasing reports on unethical /illegal trials

- **Bangalore:** infant with cardiac condition died in a pneumococcal vaccine trial restricted to healthy infants
- **Hyderabad:** adult died in a bioequivalence trial reportedly after participating in many such trials for the money
- **Gujarat:** charitable hospital accused of carrying out company-sponsored trials without IRB approval
- **AP and Gujarat:** 25,000 girls from vulnerable groups enrolled in vaccine trials without consent, adverse event reporting or follow-up
- **Indore:** government hospital doctors conducted 76 clinical trials on over 3,000 patients, receiving Rs 5 crore
- **Bhopal:** Gas disaster survivors enrolled in trials without consent
- **Hyderabad:** CRO administered women cancer drug without consent

Media reports

Growth of subcontracted research

- Clinical research undertaken by contract research organisations
- **Estimated: 130-200 CROs** operate in the country (some CROs entered much before 2005)
- Offer 'turnkey' services to drug companies from trial design to recruitment, site monitoring, collecting data and filing regulatory applications...
- Seem to be data collectors, do not increase research capacity

Unethical patient recruitment practices

- Collusion with hospital administrations, doctors, NGOs
- Participant databases compiled from access to hospital databases
- Independent databases developed from
 - physician referrals
 - health camps
 - "patient education" programmes
 - "community outreach" through NGOs

Recruitment incentives: conflicts of interest

Recruitment incentives in the private sector

- Rs 60,000-120,000 per patient recruited
- Principal investigator: sponsored trips to conferences "etc"

Recruitment incentives in government hospitals

- Institution gets 15% of budgeted expenses
- Department equipment and investigators' salaries
- Principal investigator: sponsored trips to conferences "etc"
- **Are investigators incentivised to induce patients?**

Exploiting desperation

CRO survey on why people enter a clinical trial

Exploiting inequity in doctor-patient relationships

- 75%: PI is primary physician
- 21% referred by primary care physician

Seeking better or free care

- For higher quality care: 16%
- For free drugs/care: 10%

For the money: 5%

Excel Life Sciences, 2008

Physicians' promotion: "trials for treatment"

As treatment

"If they can't afford [standard treatment] they go untreated. Then it's **better to give something**"

Investigator in cancer drug trial

For free care

In private hospitals, "there is an opportunity for the patient to get treatment ...and investigations free"

Investigator in psychiatric drug trial

For better care

In public hospitals, "a lot of poor people go [to public hospitals]. With the limited number of beds...entering a trial gets them priority"

Investigator in psychiatric drug trial

Regulation of clinical trials: DCGI's office

- DCGI's office is expected to review applications and monitor ongoing trials
- Understaffed, overworked?

Regulation: the ethics committee

- Charged with reviewing proposals and monitoring research
- Many improperly constituted, poorly trained, ill-equipped
Mudur 2005; WHO/ICMR 2007
- Trials that cleared ethics committees
 - Placebo-controlled trials of psychiatric drugs depriving seriously ill patients of standard care
 - Cancer drug trial on treatment-naïve cancer patients desperate for treatment
 - HPV vaccine trial on 15,000 poor girls without parental consent

Regulation: the “independent” ethics committee

- **Numbers:???**
- Industry sponsored, to review proposals for a fee
- Conflict of interest: may be inclined to approval proposals since they benefit from the fees
- Delink research from institutions and ability to monitor research
- Ethics committee shopping: refused by one, go to another

Regulation: no compensation in trial injury

- Increase in deaths in clinical trials
 - 132 (2007), 288 (2008), 637 (2009), 670 (2010)
- 25 /670 deaths deemed related to research participation
- Compensation initially received in only five deaths
- Treatment expenses paid or reimbursed only for eight participants

PIB, 2011, press reports

Regulation: inadequate knowledge of treatment and compensation requirements

Study of knowledge and practices on compensation and medical treatment

- 47% of investigators 26% of ethics committee members unaware of/ did not understand requirements
- Compensation policies to provide immediate medical relief /reimburse expenses, **not** compensate for disability / death
- Informed consent forms
 - Did not mention compensation
 - Reimbursement **only** if treatment was not already covered by other insurance, or after insurance was exhausted

Thatte et al, 2009

Lack of transparency

- Information on the industry **pieced together** from press reports on rights violations, investigations of advocacy organisations, studies, laws and guidelines, and the nascent clinical trials registry
- Information that should be in the public domain – even templates of documents such as the informed consent form – is withheld
- **Government:** withheld details sought under the Right To Information Act, on trials purportedly conducted in the public interest with government support -- as "proprietary information"
- **Industry:** Refused requests for interviews, or to part with information on the argument that they are answerable only to the authorities.

Clinical trials in India: issues and concerns

- **Research agenda:** industry profit not community needs
- **Recruitment practices**
 - exploit unequal physician-provider relationship
 - exploit needs of poor people seeking healthcare
- Research designs that put participants at risk of harm
- Research violations resulting in harm
- No guarantee of post-trial access to the community
- An industry without regulation, transparency or accountability to the public
- **Plans for high risk phase 1 trials of foreign drugs**

SOCIAL ACCOUNTABILITY OF MATERNAL HEALTH

Sanjay Kumar Paul



Social Accountability of Maternal Health

Sanjay Kumar Paul
CEDPA India
And

White Ribbon Alliance for Safe Motherhood, India

Every 10 minutes
witness
a maternal death in India

WRA India

- ▣ Established in 1999,
- ▣ is a coalition of individuals and organizations with 1500+ organizational members
- ▣ formed to promote increased public awareness of the need to make pregnancy and childbirth safe for all women and newborns...
- ▣ Works with communities around ensuring entitlements
- ▣ People Centered Advocacy

Grassroots Accountability



..is a 'people-centered' strategy that mobilizes civil society to hold governments, policy makers, program implementers and other stakeholders accountable to their commitments.....



.....to translate maternal and newborn health commitments and policies into improved access to services.....

....relies on civic engagement, i.e., in which ordinary citizens and citizen groups participate directly or indirectly in exacting accountability



The White Ribbon Alliance for Safe Motherhood, India has been using strategies to mobilize citizens to effect change.....

.....some grassroots accountability techniques to facilitate accountability for MNCH commitments

....so that information can be collected on local situations, and to highlight progress on implementation of key programs and policies

These grassroots accountability techniques are ways of understanding, reporting and ultimately improving access to services and information

An effort to help narrow gaps between vision/goal/policy and reality/action on the ground

It is also an effort to disseminate information on entitlements

It involves participation of stakeholders, employees, volunteers, clients, community etc

Accountability Tools for Grassroots Advocacy

Multitude of tools

- Participatory Budgeting
- Social Audits
- Participatory Planning
- Public Expenditure Tracking Surveys
- Citizen Report Cards
- Budget Analysis
- Citizen-based Vigilance Committees

What we have used

- Public Hearings
- Checklists
- Verbal Autopsy

Public Hearings



Public Hearing is a process in which interested parties/ stakeholders and any other persons who may be affected by the issue have the opportunity to make submissions, ask questions , or register objections

.....these hearings become forums for women to share their stories and demand change

.....and influence service providers, policymakers, the media, and women and their families...

.....Identify issues and look at local solutions

Public Hearings

Issues-

- Provision/quality of services
- High instances of referral
- Issues of accountability
- Non-provision of blood/ minimum medicines during child birth in the facilities

Results:

- Vigilance committee represented by SHG of women and media was formed
- A defunct sub-centre in remotest location was functional
- Blood bank operational in district head quarter hospital

Positive experiences

- Commitment to Action -but this is restricted to local level and limited to the authority/decision making power of those present
- Follow up on commitments-challenging
- Participation of providers and government officers - imperative but difficult

Checklists



A method for rapid monitoring of the maternal health situation in facilities

Facilities and quality of services are assessed at the district hospital, referral and primary level through quick surveys using checklists and individual interviews of beneficiaries

Findings can be used as a baseline and use it after time interval to measure changes that take place- for tracking implementation

Using the findings

The findings collated and report shared with all stakeholders including policy makers and media

Used for constant advocacy on improving quality MCH services at the local level

Instrumental in shaping state/local specific advocacy on safe motherhood



Total 204 Community and Sub-centre, 102 FRU/PHC and 12 district hospitals were assessed using these checklists in the 12 focus districts of Orissa

*Supply of equipments and drugs – example- weighing machine available with 48% of the ANMs and BP instruments with 45%. Stethoscope is available with only 8.1% in the pre public hearing checklist used

Out of 24 FRUs, Gynecologists are available in only 13 FRUs

Blood transfusion facility with power back up is available in only 6 FRUs

Pediatrician available in only 06 FRUs

Out of 78 24x7 PHCs, labour room is available in only 63 facilities

Conducting verbal autopsy of recent maternal deaths

Identify causes of a particular maternal death,

.....educating community members on birth planning and available entitlements

.....sensitizing stakeholders on their roles and responsibilities

Case Study: Kalahandi – Namis Sabar

- ❑ Namis Sabar was 24 years old and lived in a remote area of the district of Kalahandi where the only accessible healthcare is the Sub Centre
- ❑ Prolonged labour, family not aware of impact of prolonged labour and waited a number of hours to see if the birth would progress normally
- ❑ Finally after hours, when decision was taken to take her to a facility, the first stop was a sub centre which was not equipped to handle an obstetric complication, referred to a district hospital and transportation arranged, and she died on the way to the district hospital
- ❑ Combination of lack of preparedness and access to transport led to mother's death
- ❑ Findings shared with the community –emphasizing Birth preparedness, Complication readiness and recognizing danger signs

What Have We Learnt:

•**Information on policies and programs:** Need to demystify government procedures, policies, programs, rights and entitlements in order to strengthen citizens' voice and promote social accountability

•**Gathering evidence for grassroots advocacy is challenging:**
Accessibility and "legitimacy": Who has the information and how does one get the information?

Redressal vs Reprisal : There has to be some assurance of outcomes, that citizens can trust the government to enforce sanctions in response to their action.....because citizen participation and engagement is contingent on this assurance...and that there will be no reprisals

Marginalized groups can make their voices heard, and can be brought into the movement to create social change

What Have We Learnt:

- ❑ Lack of key systemic and timely improvements lead to frustration among people
- ❑ Acceptance of accountability mechanisms not universal in the state system – confrontation vs engagement/dialogue

Recommendations:

- ❖ Working with networks to collaborate in the planning and execution of social accountability initiatives
- ❖ Government officials ownership of social accountability as a useful means to improve services
- ❖ Bring leaders in front of their own communities and constituencies to engage in a dialogue with citizens who can provide personal stories and make problems with the health system more difficult to ignore
- ❖ Use mass media outlets to spread awareness to policymakers and community members
- ❖ Hold governments accountable to fulfilling their commitments, it is equally important to recognize and highlight the positive outcomes of steps they take toward implementation
- ❖ Efforts to improve social accountability for maternal health must be pursued in tandem with more systemic efforts to empower women and ameliorate gender power dynamics

**IN THE NAME OF ONE WHO
CREATED ALL THAT EXISTS**

Dr Zubair Salim

**IN THE NAME OF
ONE WHO CREATED
ALL THAT EXISTS**



Public Health in Jammu & Kashmir

*Dr. Zubair Saleem
MD, PGDGM, FGSJ
Consulting Geriatrician
Zonal Medical Officer, Budgam, Kashmir*



Overview

- Health Scenario
- NRHM (MMR and IMR)
- Challenges for a doctor
- Deficiencies in health policies
- Recommendations

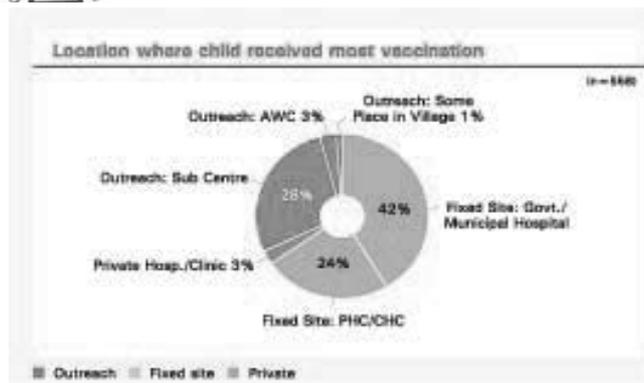




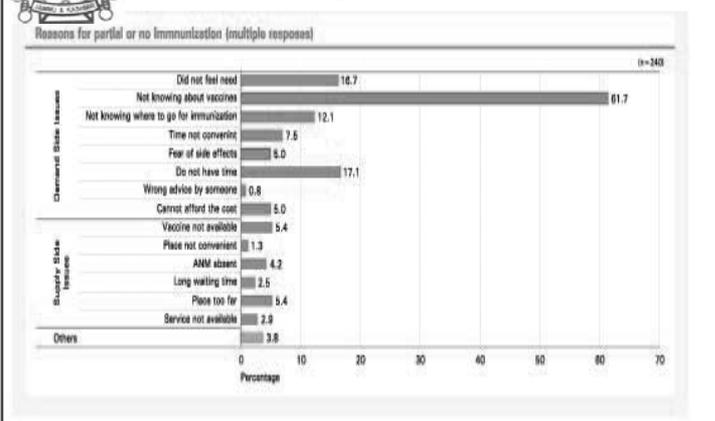
Booster: DPT 42% OPV 39%



Child received most vaccination in public sector 96%



Common reason for no immunization: not knowing about vaccine



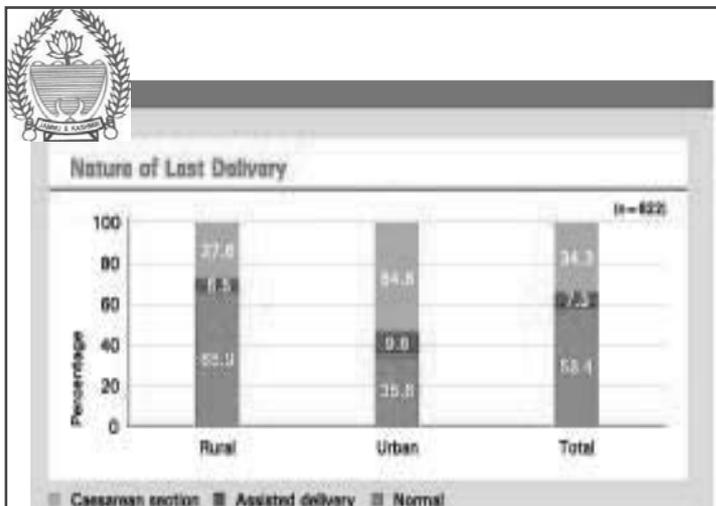
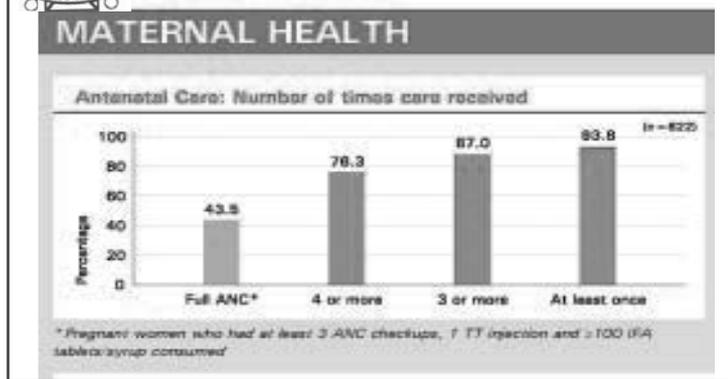


NRHM Implementation

- In 2007
- Primary goal: to decrease MMR & IMR
- Well integration with state health system
- JSY (ANC, Free investigations, etc)
- RKS
- ASHA
- JSSK (Maa Tujhe Salam)
- Rtn

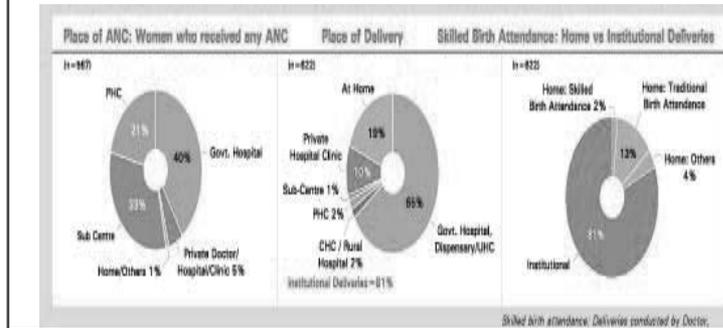


87% pregnant received 3 ANC's





Institutional deliveries >81%
Deliveries in public sector >85%



Post NRHM implementation MMR

- The MMR in J&K as per the data available from the death records of Directorate and Economics and Statistics after necessary adjustments works out to be 100. The internal Health Management Information System of the National Rural Health Mission also collects and maintains information related to Maternal Deaths but has not been in a position to record many such deaths because of low prevalence.



IMR

- IMR also declined in past few years to around 45 but still needed to decrease in order to meet the goal of NRHM
- Thus JSSK was launched:
 - Free medical facilities upto 30 days of newborn
 - Free drugs/consumables to mother in hospital
 - Free food to mother in hospital
 - Free pick and drop at the time of delivery/illness of newborn



- **Sex ratio (Females per 1000 males): 822 according to census 2011**
PNDT act enforced
- **Trans-genders have equal rights for health**
- **Intact RNTCP (DOTS) for TB**
- **Leprosy Programme**
- **Diagnosis of HIV/AIDS and treatment**



Challenges for a doctor

- Most of the drugs available are manufactured by private companies: avoid writing salt names
- Patient demands dose convenient drugs (combined drugs)
- Lack of proper expertise among chemists
- Lack of health awareness/education in patients eg. Treating simple diseases/antibiotics, leads to
 - Malpracticing
 - Irrational prescriptions
 - Percentage system



DEFICIENCIES IN HEALTH POLICIES

- Dependent policies
- Job insecurity
- Minimal salary
- Lack of Health Education/Awareness
- Rural population > Urban
Remote areas, no proper roads/infrastructure
- Lack of budget
- Infrastructural Deficiencies
- Deficiencies are augmented with armed conflict



Armed Conflict & Public Health

- Health care providers hesitate to go to remote areas resulting in mushrooming growth of quack practicing
- All the people are directly or indirectly affected mentally/physically
 - PTSD Kunanposhpora mass rape
 - Forced disappearances/mass graves
 - Custodial deaths/fake encounters
 - Mass migration



Recommendations

- Further strengthening NRHM
- Job security for NRHM employees
- More strict audit/accountability for RKS funds
- Involvement of local panchayat bodies for spending RKS funds
- Enhancing the salary of NRHM employees
- Against privatization of public health
 - 10% IPD 25% OPD
 - Vaccine
 - ANC
 - Treatment in outbreaks
- Rapid resolution of armed conflict in Kashmir



NRHM and law in Kashmir

- NRHM guidelines are the words of Gospel for any health care provider and if anyone violates it, is accountable before the court of law, and if found guilty will face punishment by the law and the concerned department.
- JSY given on filing RTI and official concerned suspended
- BMO suspended for using ambulance to go to his home from the hospital after a commoner filed RTI
- ISM Doctor suspended for writing allopathic drugs

THANK YOU

QUALIFIED VERSUS QUACKS DUCKING THE REAL ISSUES?

Satya Sivaraman and Dr Siddhartha Gupta

Qualified versus Quacks Ducking the Real Issues?

Satya Sivaraman

And

Dr Siddhartha Gupta

Trained Medical Personnel in India

- Medical Colleges (modern medicine): 266
- Dental colleges: 268
- MBBS doctors/year : 30,290
- Dental surgeons/year: 20,080
- Nursing colleges: 1,597
- GNM/year: 59,138
- Pharmacy colleges: 461
- Degree/ Diploma Pharmacists: 27,735

India: Shortage of Medical Manpower

- o Population: 1.21 billion
- o Allopathic doctor to patient ratio: 1:1722
- o Including non-allopathic doctors: 1:781
- o Ratio in rural India: 1:25,000
- o Doctor Patient ratio in Cuba: 1:170

Health Personnel Shortage

- o Estimated shortage of doctors: 600,000
- o Estimated shortage of nurses: 1,000,000

Major killer and other diseases in India

Disease	Patients	Death
Tuberculosis	15 million	0.5 million/year
Diarrhoeal diseases	4 million/year	0.8 million/year (mostly <5 yr)
Acute Respiratory Infection	5.5 million/year	1 million/year (approx)
Typhoid Fever	0.3 million/year	N.A.
Malaria	15 million/year	20,000/year
Leprosy	Total 0.5 million	N.A.

Some Health Indices of India

- Maternal Mortality Rate (MMR): 301 per 1, 00,000
- Infant Mortality Rate (IMR): 57 per 1000
- Under 5 Mortality Rate: 72 per 1000

Some Health Indices of India (continued)

- Malnourished Babies: 53%
- Anemia in Women: 52%
- Children under 5 yrs dying of malnutrition related diseases: 2.5 million

Poverty/ lack of basic facilities

- o People below poverty line (BPL): 27.4% (calculated on the price of food grain with 2200 calorie)
- o Daily earning less than US\$1: 35%
- o Daily earning less than US\$2: 74%
- o Households with Electricity, Drinking water and Sanitation (all three): 28.65%

The Fragile Infrastructure

- Formal medical education is unable to solve the problem of man power, particularly in rural areas
- Most of the villages are dependent of quacks or non qualified rural practitioners, unskilled dais, religious healers & witch doctors
- Health facility is almost non existent in many urban slum areas, labor colonies around sick/ closed factories, resettlement areas of displaced persons

The Fragile Infrastructure (contd.)

- Estimated 75 lakh non-qualified practitioners in the country
- 31 % of Indian population practices self-medication
- Number of pharmacies in India: 550,000

NRHM document (2005 – 2012)

“The goal of the mission is to improve availability of and access to quality health care by people, especially for those residing in the rural areas, the poor women and children”.

Primarily it aims about 650 million people in 18 states.

It realizes that the Herculean task cannot be done by mobilizing the qualified doctors and other health workers only.

Also the approach should be ‘Bottoms up’ rather than ‘Top Down’ i.e. participation of the target population through Panchayati Raj Institutions (PRI).

Integral part of core & supplementary strategies of NRHM

- Introduction of *Accredited Social Health Activists (ASHA)* for immunization, RCH service, sanitation, assistance in delivery and use of formulations (drugs) for common ailments.
- Reorientation of formal medical education to support rural health issues including regulation of medical care and medical ethics.

Health Worker Training



Health worker training programme

Pilot Training Program in 2006

No. of trainees – Five.

From Swadhikar, an NGO working in tea gardens of Kalchini, Jalpaiguri.

From Madan Mukherji Smriti Janaswasthya Kendra, Beliatare, Bankura.

From Calcutta Ahead Centre for Inter-disciplinary Research. Working in Medinipur Village: Pathar Pratima Block, South 24 Pgs.

Regular program from 2008

- *Mid-July, 2008 to mid-September, 2008*
No. of trainees – Ten. Five boys from Tripura Plant-growers' Co-operative Society. Five girls from People's Union for Development and Research, an NGO working in Kadamtala, Howrah.
- *Mid-November, 2008 to mid-January, 2009*
No. trainees – Ten. Five girls from Tripura Plant-growers' Co-operative Society. Five girls from People's Union for Development and Research, an NGO working in Kadamtala, Howrah.

Regular program from 2008 (continued)

- *Mid-June, 2009 to mid-August, 2009*
No. of trainees – Eleven. Nine boys from United Milli Forum, a peoples' organization working in Jharkhand. Two girls from Sambhavana Trust, an NGO working among the gas-affected people of Bhopal, Madhya Pradesh.
- *Mid-August 2009 to Mid-October 2009*
No. of trainees – Nine
Four boys and 5 girls from different blocks and lands of Sunderbans ravaged by cyclone and flood.

Regular program from 2009 (continued)

- *November 2009 to December, 2009*
No. of trainees – Five Four boys from United Milli Forum, a peoples' organization working in Jharkhand. One from Delhi.
- *January 2010 to October 2010*
No. of trainees – Sixteen
Twelve girls from United Milli Forum and Four girls and One boy from JOAR, Jadugoda, Jharkhand.

Health workers' training program

Trainers: *Skin, Eye, ENT specialist*

Gynecologist

Psychiatrist

Pathologist

Optometrist

Dentist

Pharmacologist

Physiotherapist

Health workers



Curriculum of Health worker program

- Anatomy & physiology of human body
- Pathological basis of diseases
- Different organ systems & common ailments prevalent in rural India
- Diseases related to child birth & child health
- Dental care
- Psychological disorders
- Skin & venereal diseases

Curriculum of Health worker program (contd)

- Basic pharmacology, use of formulations & their side effects
- First aid training
- Basic laboratory investigations
- Practical training on patient examinations
- Injection, transfusion, bandaging, plastering, suturing of wounds

Pre & post training assessment is done

Working with rural practitioners

A training camp for Rural Practitioners (quacks) from 5 districts of West Bengal



Our View

- ✦ Medicine developed as an occult science for use of a small group of people
- ✦ In a capitalist system it is always a tool for oppression of the common people
- ✦ The benefit of science did not reach the vast majority
- ✦ Only in erstwhile Soviet Union, Communist China, Cuba and recently Venezuela there has been mass participation in health care delivery for all.

Our View (continued)

- Formal Medical education in our country is completely dissociated from the interest of commoners
- Demystification of medical science & stress on non formal education can solve the health problem in India
- Total revamping of curriculum of medical education & peoples' participation is the need of the day

Thank You!



CRIB DEATH IN GOVERNMENT HOSPITALS IN WEST BENGAL: WHO'S SIN?

Dr/ Siddhartha Gupta

Crib Death in Government Hospitals in West Bengal: Who's "Sin"?



Speaker:
Dr. Siddhartha Gupta
Shramajibi Swasthya Udyog



Series of events

- ▶ 29 child death in 96 hours (24th to 27th October, 2011) in Dr. B.C. Roy Child Hospital, the **LARGEST PEDIATRIC HOSPITAL** in the state.
- ▶ 17 child death on 29th & 30th October, 2011 in Burdwan Medical College
- ▶ 12 crib death in Bankura District Hospital from 29th October to 18th November, 2011
- ▶ 23 cot death in Maldah District Hospital from 8th to 2011 (14th November: Children Day)



Past Records of Dr. B.C. Roy Child Hospital

- ▶ 30th June, 2011; 19 crib death in 36 hours
- ▶ August, 2006: 23 deaths in 72 hours
- ▶ September, 2002: 30 deaths in 24 hours



Government response (Quick, objective, apathetic & disgusting)

- ▶ Such child deaths in large number are quite normal. I do not know why such an uproar”
Director of Medical Education
- ▶ “No fault of hospitals. We give them clean chit.”
Expert committee after a disproportionately quick probe
- ▶ It is pure media hype. The fault lies in improper referral system to the city hospitals from districts. Had the children died in the periphery in the same number, there would have been no news. Our state performance is much better than any other state.

Health Secretary



Government response (continued)



- ▶ “The babies were extremely sick and referred in terminal conditions. No hospital in the world could save them”.
Superintendent, Dr. B.C. Roy Hospital
- ▶ Self Certification by respective Superintendent themselves
(In 12 – 24 hours)
- ▶ Clean Chits by Central Minister of State (Health) & Central cabinet Minister of Health

Striking similarity

- ▶ This child death is not unnatural. This can happen any time. Our records are much better than other state.”
Health Minister of Left Front Government in 2002
- ▶ “Do not criticize the Health Minister. He is an asset of my cabinet”.
Chief Minister in 2002
- ▶ “Child death is painful but we are not at fault. We have taken many measures and shall take more. These are all trial & lynching by media. IMR & MMR are much better in West Bengal”.
Health Minister, 2006



Child death in India

- ▶ Under 5 child in India:240 million
- ▶ Child death / year: 2 million (25% of world child death)
- ▶ Child death / day: 5000
- ▶ Death from malnutrition:46%
(2 child/ minute)



Comparative data



Health indices	USA	CHINA	CUBA	INDIA
IMR /1000	07	17	05	50
Under 5 mortality/1000	08	13	07	72
MMR/ lac	21	48	12	254
Life expect	75	72	75	64
Allopathic doctors/ 1000	2.56	1.5	5.5	0.7

Main causes of child death

- ▶ Diarrhea: 15%
- ▶ Birth asphyxia: 18%
- ▶ Birth trauma/ abnormalities: 26%
- ▶ Malaria: 10%
- ▶ Measles: 5%
- ▶ HIV: 4%
- ▶ Sepsis: 12%



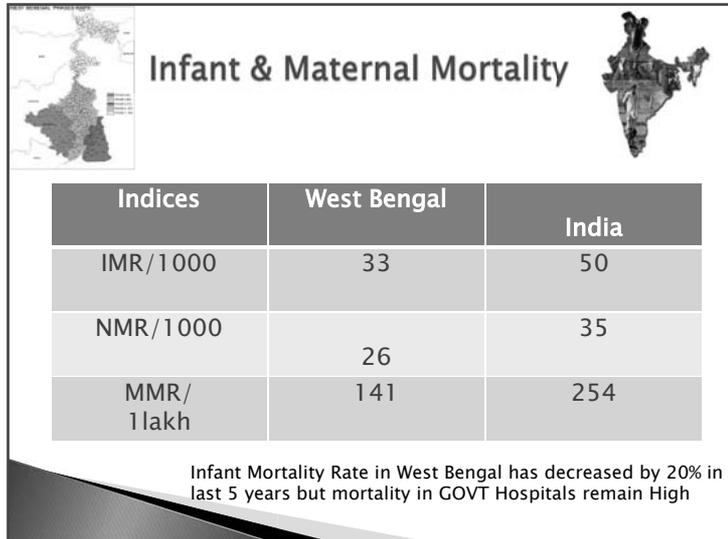
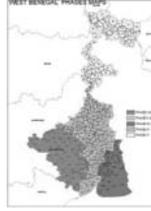
State of West Bengal

- ▶ Area: 88.5 thousand sq km (2.8% area of India)
- ▶ Population: 9.2 crores (7.5% of India)
- ▶ Population density (1030/ sq km (India: 363/ sq km)
- ▶ GDP: 4th in India
- ▶ GDP per capita: 12th in India
- ▶ BPL: 27.04%
- ▶ S.C. population: 1.85 crores, S.T. population: 0.45 crores, Religious minorities: 30%
- ▶ Rural population: 72%



State of West Bengal (continued)

- ▶ Rural electrification:34.9%
- ▶ Portable drinking water in villages: 30.6%
- ▶ Rural Sanitation:45%
- ▶ Patient: Doctor:2022:1 (India: 1700:1)
- ▶ Patient: Doctor (Rural Area): 4747:1
- ▶ Child birth per year: 1.1 million
- ▶ Children requiring SNCU/ NICU care in state: Above 1 lakh per year
- ▶ Number of SNCU/ NICU in state: Only 7 (against 32 as proposed in NRHM)
- ▶ Unutilized NRHM fund in last 5 years :668.5 crores (NFHS II & III; Health on the March, 2009)



Underlying Causes

- ▶ Maternal Malnutrition
- ▶ Low birth weight
- ▶ High Percentage of Non Institutional Delivery
- ▶ Inadequate hospital beds and delivery facility
- ▶ Lack of nursery/ SNCU at RH, CHC & District Hospitals
- ▶ Lack of nutritional rehab center at BPHC/CHC
- ▶ Inadequate manpower: doctor, nurses etc
- ▶ Poor Sanitation & cleanliness in GOVT Hospital





Average food intake

Food item	Daily need	West Bengal	India
Sugar (gm)	30	12	25
Pulse (gm)	40	14	24
Fruit (gm)	50	19	23
Milk (gm)	150	46	146
Egg (gm)	45	2.7	0.7

National Nutrition Monitoring Bureau

Average Food intake for children & women



Group	Protein (in gm)		Energy (Calorie)	
	Needed	Available	Needed	Available
1 - 3 yr	22	18.3	1240	693
4 - 6 yr	30	25.7	1690	1008
7 - 9 yr	41	29.6	1950	1220
Pregnant women	65	45.3	2175	1664

Other Health Statistics of West Bengal



Indices	West Bengal	India
Anemia in under five children	78%	74%
Anemia in rural children	82%	79%
Severe malnutrition in children	23%	-
Average height	150 cm	151.2 cm
Average BMI	19.7	20.3
BMI below 18.5	43.7%	35.9%
Anemia in pregnancy	63%	52%

Source: WB Human Development report 2004
National Health Profile 2009

Health Infrastructure (Primary care)

Infrastructure	Required	Present
SSC	12101	10356
PHC/ BPHC	1993	924
CHC	498	349
Female health worker	11280	6051
Male health worker	10356	4215
Gynecologist	349	38
Pediatrician	349	25
Physician	349	107
All specialists	1396	486
All technicians	1622	568
Pharmacists	1273	830



INADEQUATE PUBLIC FUNDING

- Out of pocket expenses: 88%
- Catastrophic shock for health expenses in poor families: 35-51%
- Long waiting in Govt Hospitals for IPD admission & operations



Conclusions

- Crib deaths: Not Accidents but incidents
 - Knee Jerk reactions by politicians & administration
- "Main Culprit": Meager Budgetary allocation for food & health
 - Inequitable & improper distributions
 - Neoliberal Policies, corporatization & PPP

**NO SHORT TERM MEASURE CAN STOP
THE CHILD DEATH IN WEST BENGAL OR
INDIA. LONGTERM POLITICAL & SOCIAL
CHANGES TO ESTABLISH PEOPLES'
RIGHT TO HEALTH AND CHILDRENS'
RIGHT TO LIVE IS THE ANSWER.**

**Let us work together for a
changed scenario**



LEADING JUDGMENTS ON PUBLIC HEALTH IN INDIA

Dr. Dipika Jain

LEADING JUDGMENTS ON PUBLIC HEALTH IN INDIA

Dipika Jain
Assistant Professor/Assistant Director, Centre for
Health Law, Ethics and Technology.
Jindal Global Law School, Sonipat
India

PILs on Public Health?

- Plethora of cases arising out of PIL's have been filed in order to secure proper health services. Many judgments pronounced in these cases have had a profound effect as they have resulted in effective policy making and better execution of services.
- PILs have been filed on a wide array of health issues involving fundamental right to health, right to food, reproductive rights, rights of workers to occupational health and safety, right to clean environment, right to adequate drugs, medical negligence, right against medical malpractice, right to emergency health care, HIV/Aids and public health care.

Initial Recognition of right to health by the Courts:

Francis Coralie Mullin v Union Territory of Delhi 1981(1) SCC 608.

- The Indian Supreme Court since 1970's onwards started reiterated in several of its decisions that the Right to Life guaranteed in Article 21 of the constitution in its true meaning includes the basic **right to food, clothing and shelter.**
- **More than mere animal existence**

Bandhua Mukti Morcha etc Vs. Union of India and Ors. AIR 1984 SC 802

- THE Court addressed the types of conditions necessary for enjoyment of health. The Court held that right to live with human dignity also involves right to “protection of health”

Parmanand Katra v. Union of India,(1989)4 SCC 286

- The petitioner filed a writ petition under Article 32 of the Constitution where in it requested the Union of India to include a direction where it is made mandatory to treat every injured individual instantly so as to preserve the life and the procedural criminal law should be followed after that so as to prevent any negligent deaths to occur.
- ISSUES: The issue that was dealt in this case was regarding the moral and professional duties and obligations of a medical practitioner.
- The court held that every medical practitioner is professionally obligated to treat emergency cases with expertise and cannot refuse to offer treatment to such cases. The government hospitals further cannot refuse any kind of treatment unless it requires more technical expertise that too not without giving primary treatment. It also held that no legal procedures as prescribed under Criminal Procedure Code should act as a hindrance for a doctor to treat an emergency case and hence all the fulfillment of these legal formalities should be a secondary action and that of saving a person's life should be the primary action.

Consumer Education and Research Centre v. Union of India(1995)3 SCC 42

- The Supreme Court for the first time explicitly held that '[t]he right to health . . . is an integral fact of [a] meaningful right to life.'
- **Facts**--This case was concerning the occupational health hazards faced by workers in the asbestos industry.
- **Court Held**--Reading Article 21 with the relevant directive principles guaranteed in articles 39 (e), 41 and 43, the Supreme Court held that the **right to health and medical care is a fundamental right and it makes the life of the workman meaningful and purposeful with the dignity of person.**

LANDMARK CASE--This recognition established a framework for addressing health concerns within the rubric of public interest litigation and in a series of subsequent cases, the Court held that it is the obligation of the state not only to **provide emergency medical services but also to ensure the creation of conditions necessary for good health**, including provisions for basic curative and preventive health services and the assurance of healthy living and working conditions.

Paschim Banga Khet Mazdoor Samity and Ors., vs. State of West Bengal-1996(4) SCC 37

- **Facts**--In this case, Hakim Sheikh, a member of the Paschim Banga Khet Mazdoor Samity, fell off a train and suffered serious head injuries. He was brought to a number of state hospitals, including both primary health centres and specialist clinics, for treatment of his injuries. Seven state hospitals were unable to provide emergency treatment for his injuries because of a lack of bed space and trauma and neurological services. He was finally taken to a private hospital where he received his treatment. Feeling aggrieved by the callous and insensitive attitude of the government hospitals in Calcutta in providing emergency treatment the petitioner filed this petition in the Supreme Court and sought compensation.
- The issue presented to the Court was whether the lack of adequate medical facilities for emergency treatment constituted a denial of the fundamental right to life under Article 21.
- **Court Held**--Article 21 of the Constitution casts an obligation on the state to take every measure to preserve life. **The Court found that it is the primary duty of a welfare state to ensure that medical facilities are adequate and available to provide treatment and due to the violation of the right to life of the petitioner, compensation was awarded to him.**
- The Court recognized that substantial expenditure was needed to ensure that medical facilities were adequate. However, it held that a state could not avoid this constitutional obligation on account of financial constraints.

Murli Deora v Union of India and Ors, (2001)8 SCC 765

- In a public interest litigation, the Supreme Court prohibited smoking in public places in the entire country on the grounds that smoking is injurious to health of passive smokers and issued directions to the Union of India, State Governments as well as the Union Territories to take effective steps to ensure prohibiting smoking in all public places such as auditoriums, hospital buildings, health institutions, educational institutions, libraries, courts, public offices and public conveyances, including railways.

VHAP Vs. Union of India No. 349/2003.

- Despite a steady rise in the rate of HIV infection, prior to 2004, the Government of India only had an AIDS prevention policy. Treatment was not part of its duty. In 2003, HRLN filed a petition on behalf of the Voluntary Health Association of Punjab (VHAP) calling upon the government to provide free ARV drugs to HIV positive persons.
- Soon after the petition was filed, the Government announced free ARV drugs for 100,000 people in six high prevalence States: Maharashtra, Andhra Pradesh, Nagaland, Manipur, Tamil Nadu and Karnataka, with the objective of providing free anti-retroviral treatment to 100,000 PLHAs by the end of 2005, and to provide treatment to an additional 15-20 percent of AIDS cases each year, thereafter, for a period of five years.

Petition demanded:

- Provide universal and equal treatment to people living with HIV/AIDS (PLHAs)
- Supply of free Anti-Retroviral Therapy (ART) in easily accessible centres
- Supply CD4 testing machines in every district
- Supply nutritional supplements to all PLHAs
- Train medical personnel and counsellors
- Provide second line drugs to those who have developed resistance to first line drugs
- Publicise the treatment policy in every corner of the country.

THANK YOU

..

Right to Health recognition by Courts?

- The substantive recognition of the right to health as essential to living with human dignity has thus allowed the judiciary to directly address human suffering by guaranteeing the social entitlements and conditions necessary for good health.

DAVAN GERE DISTRICT ANAJI PHC PHOTO (2010)

Eddie Premdas (Adv) RTH karnataka

Davangere District Anaji PHC Photos (2010)



Davangere District Bilichod PHC (2010)



JANAAROGYA ANDOLANA KARNATAKA (JAAK) Right to Healthcare Campaign



Eddie Premdas (Adv)
Public Health Law Consultation
10th December 2011

KARNATAKA- PEOPLE & HEALTH

- IMR
- MMR
- % of anemic women
-

Health Services

- Subcentres: 8143
- Primary Health Centres (PHC): 1676 + 9 (urban)
- Community Health Centres (CHC): 249
- Primary Health Units (PHU): 583
- 22,000 practicing doctors in the State
- bed strength 43,479

The Goal & Process of the Campaign

- Goal: to revitalise PHCs and to strengthen people's right to primary health care
- People's mobilisation, Training, documentation of the status of sub-centres – PHCs, CHCs, District Hospitals;
- Public hearings, documentation of the denial of health rights cases; mobilising local media; continuous dialogue; struggle
- To advocate for **HEALTH AS CITIZEN'S FUNDAMENTAL HUMAN RIGHT**



KARNATAKA STATE PEOPLE'S HEALTH ASSEMBLY



2000 – Davangere
2005 BANGALORE
2007 Bangalore
2007 National Health Assembly



Public Hearing with NHRC - 2004 on right to health (denials)

Access to
 essential drugs,
 right to food,
 right to health.....



RPHC AS PEOPLE'S CAMPAIGN (2006 -2011)



RPHC - CONTEXT

- **BACKGROUND:** No improvement in PHCs despite NRHM, lethargy in implementing basics of NRHM, not even using funds allotted by central govt.,
- Increasing denials to health services and deaths, etc. (2007)
- 93 PHCs surveyed - in 12 districts (2006-07)

Findings of survey - Systemic problems affecting PHCs

- Severe staff shortage (doctor, nurse, other health human resources)
- Under-funded health system - shortage of essential medicines, equipments)
- Poor or absent infrastructure (water, toilets, electricity etc.)
- Rampant corruption



PHCs FAILING, UNATTENDED, NEGLECTED PUBLIC HEALTH SYSTEM.. Required diagnosis and treatment

- 
- Irrational geographical distribution of PHCs
 - No basic facilities to the Health Staff
 - Neglect by the Government - lack of political will
 - Lack of awareness among people about health rights
- 

Follow up of the study



- Dialogue with the Health system to revitalise PHCs
 - Mass protests and petitions
 - Signature campaigns & letter campaigns
 - Mobilisation of Press with stories
- 

Demanding Right to Health /Healthcare...



PHC at Haveri, Karnataka (2007)



Demanding Health Rights Statewide Coordinated Action in 17 districts - Feb.1, 2007



2nd Statewide Mass Action for Right to Health in 17 districts - 29 Oct 2007



DEMANDING RIGHT TO PRIMARY HEALTH CARE 29 Oct., 2007



Health and Human Rights Trainings for Activists in Districts

- 2 day workshops for health activists in 13 districts
- 450 health activists trained
- 10 state level workshops held on

health rights



Electoral advocacy in 2008 for National Health Bill

- JAAK prepared health policy brief
- Context of state elections - Met contesting candidates to put health on their electoral campaigns
- Issues raised in the policy brief discussed in the Legislative assembly
- Advocacy extended to candidates participating in GP and BBMP elections to add health issues in their manifestos

ಜನಾರೋಗ್ಯ ಆಂದೋಲನ - ಕರ್ನಾಟಕ
JANAAROGYA ANDOLANA KARNATAKA (JAAK)
 ಸಾರ್ವಜನಿಕ ಆರೋಗ್ಯ ಸಾಧನೆ ಎಂಬ ಗುರಿಗಾಗಿ ಜನರ ಆರೋಗ್ಯ ಚಳುವಳಿ!

ಆರೋಗ್ಯದ ನೀತಿ ಪತ್ರ

ನೀರ ಕೊಡುವ ಸ್ಥಳವನ್ನು "ನಿರೀಕ್ಷಿಸಿ ಕರ್ನಾಟಕ"ದ ಸಾರ್ವಜನಿಕ ಆರೋಗ್ಯ ವ್ಯವಸ್ಥೆ!
 "ಆರೋಗ್ಯ ಕ್ಷೇತ್ರದಲ್ಲಿ ಭಾರತದಲ್ಲಿಯೇ ಅತ್ಯಂತ ಕಡಿಮೆ ವಿಸ್ತರಣೆ ಕಂಡುಬಂದಿರುವ ರಾಜ್ಯ ಕರ್ನಾಟಕ" ಎಂದು
 ಮಾನ್ಯ ಪ್ರಧಾನ ಮಂತ್ರಿಗಳು 2007ರಲ್ಲಿ ಪೋಲಿಸ್ ಸಚಿವರುಗಳಿಗೆ ಸ್ವಾಭಾವಿಕವಾಗಿ ನೀಡಿ ವಿಧಿಸಿದರು.....

Health Policy Brief

ಚಿತ್ರ 1. ಕರ್ನಾಟಕದ ಉದ್ದೇಶದ ಸಾರ್ವಜನಿಕ ಆರೋಗ್ಯ ವ್ಯವಸ್ಥೆಯ ಸಾರ್ವಜನಿಕ ಆರೋಗ್ಯ ಸಾಧನೆಗಾಗಿ ಸಿದ್ಧತೆ

ಚಿತ್ರ 2. ವಿವಿಧ ಜಿಲ್ಲಾ ಆರೋಗ್ಯ ಸಾರ್ವಜನಿಕ ಆರೋಗ್ಯ ವ್ಯವಸ್ಥೆಯ ಸಾರ್ವಜನಿಕ ಆರೋಗ್ಯ ಸಾಧನೆಗಾಗಿ ಸಿದ್ಧತೆ

STATE PUBLIC HEARING

31-03-09

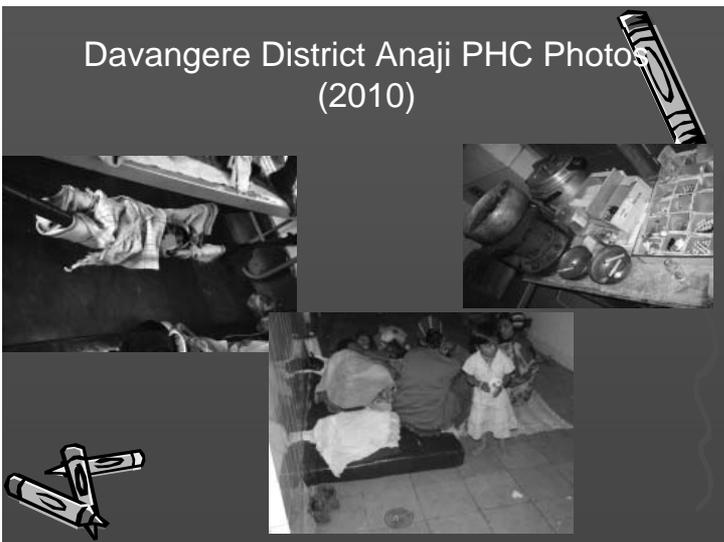
- Documentation/Research of the situation of Public Health
- Presented cases of people experiencing denial of health services
- Video documented cases presented on cases of deaths, discrimination etc.
- Testimonies by members of various vulnerable communities on experiences of public health services - PWD, mental health, PLHAs, Women, Dalits





District Public Hearings 2009-10

- Organised in 8 districts
- Process:
 - 6 - 8 month long process in each district
 - Consultation -orientation, Training and Capacity Building
 - Fact finding and inquiries on the PHCs
 - Collation of data and documentation
 - Recording Testimonies of people
 - Organising the Public Hearing
 - Follow up to improve the PHCs (delegations, mass actions etc)
- Documented the status of 114 PHCs, 54 CHCs, 55 specific gross denials to health rights which led to death or debt



Davangere District Bilichod PHC (2010)



ROPING IN LOKAYUKTA FOR DENIAL, DISCRIMINATION IN HEALTH SYSTEM



- 24x7 helpline of lokayukta
- Formal complaint forms are circulated on denial of health care and corruption
- Over 50 complaints lodged with Lokayukta on mal-administration, corruption, non functioning of health centres, theft of babies, infant deaths due to negligence
- Investigations done and some are on

Moving SHRC for health

- Case studies of 114 PHCs, 54 CHCs and 55 specific case studies of denials have been submitted to SHRC as formal complaints with evidence & photographs
- Over 100 formal complaints filed with SHRC
- SHRC has given orders to the state govt - no action from Govt



Campaign Against Malnutrition

- As part of the Right to Primary Health Care, JAAK is now focusing on the issue of malnutrition of children and women
- Focus on the issue of packaged food outsourced by Govt - the number of children with severe malnutrition is on the rise and also deaths



Issues & Reflections

- Voluntary team work and people's participation is a great strength
- legal options



Issues not addressed

- Secondary and tertiary care level issues
- Barriers which cause inaccessibility or denial: User fees, lack of grievance redressal, privatisation of services within public sector, autonomous insti., clinical trials, non-availability of essential medicines,
- Issue of private sector with 78% stake in public health of the country - rationalisation of services and costs, irrational treatment, lack of standard treatment protocols, getting them under the ambit of regulatory authority etc



Health For All at least
NOW!!



ABBREVIATIONS

ACASH	– Asian Centre for Advocacy and Social Health
AGCA	– Advisory Group on Community Action
AMRI Hospital	– Calcutta Hospital
ANC	– Ante-Natal Care
ANM	– Auxiliary Nurse Midwife
API	– Annual Parasitic Index
ASHA	– Accredited Social Health Activist
AYUSH EDL	– AyurvedicUnani Siddha Homeopathic Essential Drug List
BCG	– Tuberculosis vaccine
BMI	– Body Mass Index
Booster DPT	– Diphtheria Pertussis Tetanus
BPL	– Below Poverty Line
BPNI	– Breast Feeding Promotion Network of India
BSIS	- govt scheme (outpatient care)??
CBI	– Central Bureau of Investigation
CDMO	– Central Drug Manufacturing Organisation
CGHS	– Central Government Health Scheme
CHC	– Community Health Centre
CIC	– Central Information Commission
CL	– Compulsory License
CM	– Chief Minister
CME	– Conference on Medical Education
CMO	– Chief medical Officer
CRO	– Chief Research Officer

Crore	– Ten Million
DCGI	– Drug Controller General of India
DFID	– Department for International Development
DG	– Director General
DHKI	- District Health Knowledge Institutes
DM	– District Magistrate
DN	– medical education?
DOTS	– Directly Observed Treatment Schedule
DPCO	– Drug Price Control Order
EBIS	– Evasive Bacterial Infection Surveillance Group
EIA	– Environment Impact Assessment
EP Drugs	– EastrogenProgestrone drugs
EPI	– Essential Programme of Immunisation
EPI	– Essential Programme of Immunisation
EPW	– Economic Political Weekly
FDA	– Food & Drug Administration
FDI	– Foreign Direct Investment
FIR	– First Information Report
FRCH	– Foundation for Research in Community Health
FRU	– First Referral Unit
FSU	– First Stage Unit
GDP	– Gross Domestic Product
GMP	– Good Manufacturing Practices
GOM	–Group of Ministers
GSK	– GlaxoSmithKline
Hg	– Hamlet – Group
HH	– Households
HIB	– some type of infection?
HIV	– Human Immuno Deficiency Virus
HLEG	– High Level Expert Group
HPV	– Human Pappiloma Virus
IAP	– Indian Academy of Paediatrics
ICDS	– Integrated Child Development Scheme
ICMR	– Indian Council of Medical Research
IMPACT	– International Medicinal Product Anti Counterfeit Taskforce
IMR	– Infant Mortality rate
IMS Act	– Infant Milk Substitution Act
IPD	– In-Patient Department

IPR	– Intellectual Property Regime
IQ	– Intelligence Quotient
ISM doctor	– Indian Systems of Medicine doctor
J&K	– Jammu & Kashmir
JSSK	– JaniniShishsuSurakshaKaryakram
JSY	– JananiSurakshaYojana
Kuchha	– is a dwelling made of clay and thatch
Lakh	– One Hundred Thousand
MCD	– Municipal Corporation of Delhi
MCI	– Medical Council of India
MGM	– Mahatma Ghandi Medical College
MIMS	– Monthly Index of Medical Specialities
MMR	– Maternal Mortality Rate
MoHFW	– Ministry of Health and Family Welfare
MP	– Member of Parliament
MPCE	– Monthly Per Capita Expenditure
MRP	– Maximum Retail Price
NCHRH	– National Council for Human Resources in Health
NGO	– Non-Government Organisation
NHP	– National Health Package
NHRC	– National Human Rights Commission
NISTAD	– National Institute of Science Technology and Development
NLEM	– National List of Essential Medicines
NMBS	– National Maternity Benefit Scheme
NRHM	– National Rural Health Mission
NSSO	– National Sample Survey Organisation
NTAGI	–National Technical Advisory Group of India
OBC	– Other Backward Castes
OoPE or OoP	– Out of Pocket Expenditure
OPV	– Oral Polio Vaccine
PAN	– Permanent Account Number
PCPNDT	– Preconception Prenatal Diagnostics Techniques Act
PF	– Plasmodium Falciparum
PGI Chandigarh	– Post-Graduate Institute Chandigarh
PHC	– Primary Health Centre
PIL	– Public Interest Litigation
PMO	– Prime Minister’s Office

PPP	– Private Public Partnership
PPS Technique	– Probability proportional to Size Sampling Technique
PSM	– Partnership for Safe Medicines
PSU	–Public Sector Unit
Pucca	– is a concrete dwelling
PWD	– Public Works Department
R&D	– Research and Development
RCH	– Reproductive Child Health
RKS	– RogiKalyanSamiti
RNTCP	– Revised National Tuberculosis Control Program
RSBY	– RashtriyaSwasthyaBimaYojana (some type of govt scheme)
RTI	– Right to Information
RUTF	– Ready to Use Therapeutic Food use in malnutrition
SC	– Scheduled Caste
SC	– Supreme Court
SDM	– Sub-Divisional Magistrate
Semi-Pucca	– is a dwelling made with a mixture of concrete and clay and other material
SHRC	– State Health Resource Centre
SLP	– Special Leave Petition
SRS	– Sample Registration System
SSS	– Second Stage Strata
ST	– Scheduled Tribe
STD	– Sexually Transmitted Disease
TB	– Tuberculosis
TILS	– legal strategy?
UHC	– Universal Health Care
UN	– United Nations
UNICEF	– United Nations International Children Emergency Fund
UOI	– Union of India
USA	– United States of America
USU	– Ultimate Stage Unit
VRS	– Voluntary Retirement Scheme
WHO	– World Health Organisation
WRAI	– White Ribbon Alliance of India

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