medico
318- friend
319 circle bulletin

August-November 2006

Data Exclusivity: Another Self-Goal and a Trade Barrier

-S.Srinivasan

The Government of India is currently thinking of amending the Drugs and Cosmetics Act to introduce "data exclusivity": a provision that would preclude for a period of years both generic manufacturers and the Drug Controller from relying on clinical trial data submitted by an originator company to prove the safety and efficacy of the drug. Data exclusivity (DE) guarantees additional market protection for originator pharmaceuticals by preventing health authorities from accepting applications for generic medicines during the period of exclusivity. India's amended patent provisions are silent on data exclusivity.

Basically this would delay the entry of affordable generic equivalents in the market. And by requiring generic manufacturers to reinvent the wheel, the drug would become more costly, defeating the idea of affordable generics.

MNCs (represented by OPPI and Nicholas Piramal among Indian companies) are advancing a self-serving argument that once the country accepts patent, then "data accompanying patent information" is deemed to be accepted and hence exclusivity is also accepted. Legally it is not a valid argument. MNCs are now demanding that unless data exclusivity is ensured they would not conduct clinical trials in India.

However even TRIPS does not require this change: influential ministries of the Government of India think such a change is required under Article 39.3 of TRIPS (for the text of the article see box below). While all that is required is that clinical data relating to "new chemical entities" that require "substantial effort" in generating be protected from "unfair commercial use." There is no mention of any period of exclusivity.

Introducing data exclusivity would require intending generic manufacturers to conduct their own duplicate trials – a process guaranteed to add further costs. The immediate entry of competitors after exclusive rights end is essential in reducing the price of a product in the market.

In effect data exclusivity would delay and probably discourage new entrants – another form of trade barrier in a "free market" economy. As has been pointed out:[1]

> The earliest point in the career of the drug when one obtains a glimpse as to which its adverse effects might be is, without doubt, the phase of pharmacological and toxicological studies in animals. Very properly, the community requires of the pharmaceutical industry that the work performed at this stage be conscientiously carried out and painstakingly reported when the drug is submitted to Drug Control Authorities…Very improperly, the the community then goes on to tolerate a situation whereby these reports, having been used for this purpose, are then commonly deposited in confidential archives where they are inaccessible to the medical world at large…It follows that when the first clinical evidence of a particular and unexpected side effect reaches us there is often no simple and direct means of comparing it with what has been reported in dogs, rabbits and mice. If these data were public property, it might be simpler to identify at an early stage those adverse reaction reports from the clinics which, because they run parallel to animal findings, deserve particular attention…

What is interesting is that the move is being opposed by even the usual free market protagonists in the media and the pharma industry. There are some diehards however. The redoubtable Dr Mashelkar is pitching for a three-year data exclusivity period even as the Commissions he was a member of – the WHO's Commission on Intellectual Property Rights,

[1] Dukes, M.N. Graham, (1977), "The moments of truth", *Side Effects of Drugs Annual*, 1, Wxcerpta Medica, Amsterdam and Oxford. Quoted in: Carlos Correa. *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement.* South Centre in collaboration with the Department of Essential Drugs and Medicines Policy of the World Health Organization, June 2002.

Innovation and Public Health and the UK's Commission on Intellectual Property Rights – have been unambiguous about the negative effects of TRIPS as well as of TRIPS Plus (more than what TRIPS Agreement requires) provisions like data exclusivity.

Forgotten in the media clamour is that this affects not only pharma but all other sectors like agriculture, seeds and pesticides too.

Let us recollect Article 1.1 of the TRIPS provisions:

Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

Article 1.1 clearly provides that Members are only obliged to implement a minimum level of protection. So why should India be TRIPS-Plus?

TRIPS Article 39: Agreement on Trade-Related Aspects of Intellectual Property Rights

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices(a) so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Note (a): For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

Difference between Data "Protection" and Data "Exclusivity"

Data "protection" is a general obligation for WTO member states to provide protection against a) unfair commercial use b) for "undisclosed" information only. The TRIPS agreement does not specify a timeframe for data protection.

TRIPS Article 39.3 provides data protection to all producers of new chemical entities (pharmaceutical or agricultural chemicals; not only patent-holders or other inventors) against unfair commercial use of undisclosed data (for example, confidential information that they have provided to drug regulatory authorities in a drug registration dossier).

A drug regulator, who refers to a registration dossier of an originator product while assessing a generic drug application, does so in the interest of public health; most experts do not see this as being unfair commercial use or a violation of data protection.

Drug companies themselves have recently announced that they want all clinical data to be public (see IFPMA statement at <http://clinicaltrials-dev.ifpma.org/>.

So there should be no conflict between data "protection" and clinical trials.

Data "exclusivity" is a TRIPS Plus condition, often found in developed countries or in Free Trade Agreements, which goes far beyond data protection. Data exclusivity actively disallows regulatory authorities to consider generic drug applications for a number of years after the marketing approval of the originator drug.

Data exclusivity also blocks market access to generics if:

- The original product is not patented,
- The country does not have to grant patents yet (e.g., LDCs until 2016), or

➢ The country has issued a compulsory license.

Data exclusivity might even block a generic if the originator is not even marketed, depriving patients of access to an effective drug.

USA, EU and several Free Trade Agreements include data exclusivity periods of 6-10 years. This is a TRIPS Plus condition, and should be avoided by developing countries.

Generic companies in Europe accepted a data exclusivity clause, in exchange for a Bolar clause. There is no obligation for developing countries under TRIPS to do so.

I hope this clarifies the confusion?

Wilbert Bannenberg, Public Health Consultant
(a non-lawyer, so please correct me if I am wrongly interpreting TRIPS!) Email: wjb@wxs.nl

Quoted from e-forum <http:/ www.essentialdrugs.org/edrug/archive/200502/msg00043.php>)

mfc bulletin Editor's Comment: While this is as well, the term "data protection" is used in EU and covers DE as well; whereas in the US, there is only DE which includes DP of all kinds.

Medico Friend Circle Letter to PM on DE

July 2006

Subject: Proposed Amendment to the Drugs and Cosmetics Act – the risks arising out of 'Data Exclusivity'

Dear Mr. Prime Minister,

We write to you on behalf of the Medico Friend Circle (a 35-year-old all-India body of persons and professionals concerned with appropriate health policy) with regard to the proposed Amendment to include 'data exclusivity' in the Drugs and Cosmetics Act. It is our assertion that the proposed amendment is a TRIPS-plus measure – not only is it not required, but it will have disastrous public health implications. This assertion of ours comes after intense consideration at MFC's national meeting at Sewagram, Wardha on 7th and 8th July 2006.

As a participant organisation in the *Jan Swasthya Abhiyan* (national people's health campaign), MFC stands by their position that:

- The TRIPS Agreement does not mandate data exclusivity, mentioning only 'data protection against unfair commercial use'.
- 'Data exclusivity' would mean preventing generic competition, restricting access to cheaper medicines with disastrous consequences for the Indian people.

➢ Making it mandatory (as amended) to conduct fresh clinical trials on drugs which have already been shown to be effective and safe is unsustainable and unethical.

➢ Including 'data exclusivity' is an unrequired 'TRIPS-plus' agenda clearly against the Indian people's interest.

In addition, the MFC emphasises the following points:

1) India has already amended its Patent Act according to the WTO-imposed TRIPS conditionalities, and this is sure to hike up new drug prices for Indian consumers, as seen all over the world. In this light, agreeing to this TRIPS-plus proposal is especially unwarranted.

2) All clinical trials must be registered, and it should be made mandatory that data generated through pre-clinical and clinical trials, whether positive or negative, or equivocal be made available in the public domain (peer reviewed, scientific journals and open access web sites). From the time a patent is granted, all data generated through scientific studies providing the basis of the approval for marketing should be in the public domain and not under the exclusive knowledge of the innovator company or the drug regulatory authority. This is so that other researchers will have the option of independently scrutinising the data and assessing for themselves the scientific merit. Further, this open system will enable other experts to assess whether the approval granted for registration by the drug regulatory authority was scientifically justified or not. This open system will in no way undermine the requirements of fair competition. These guidelines are in line with the CONSORT as well as the ICMR guidelines.

3) On the contrary, 'data exclusivity' would mean that after patent expiry, if any other company is to make and market the generic version of the same medicine, it will be forced to repeat the full range of clinical trials. Not only would this delay manufacture of the generic version, and thereby cheaper drug availability to the

people, but in case of diseases for which there is no other effective and safe medicine, data exclusivity would mean repeating mandatory trials comparing it with the drug whose patent has expired, and that would be an absurd thing to do. On the other hand, such trials would be unethical if done with the placebo control as it would violate the national and international ethical guidelines currently in force. It would unethically withhold a proven medicine from patients in the placebo arm of the trial.

Finally, we wish to state that proactive steps taken in the past by the Indian Government led to the creation of a generics-based industry which displayed a dramatic increase in access to essential medicines and lowered healthcare costs. For instance, generic anti-retroviral drugs (ARV drugs for HIV/AIDS) lowered the therapy cost by over 95%. The increasing use of generics worldwide provides a countervailing force against monopolistic pricing practices of 'innovator' companies even after patent expiry. Without generics, even for off-patent drugs, patients in India would have to pay 10-100 times more for treatment. Since a great proportion of Indians subsist in poverty, drug price increases affects the people gravely. Here let us recall that, unlike in developed countries, families in India spend more than 50% of their healthcare costs on medicines.

In the light of these concerns, we urge you to refrain from amending the Drugs and Cosmetics Act, and further from including 'Data Exclusivity' in any other legislation.

Thanking you for your serious consideration of our submission,

Sd/- Sincerely yours,
Dr. Ritu Priya, Convener

(followed by names of members of EC of mfc)

Editor's Note: It has been pointed out by Advocate Kajal Bharadwaj that point 3 above is not accurate. To quote her: "Data exclusivity can operate both during and after the patent period depending on the regulations and not only after the expiry of the patent period. More importantly, data exclusivity applies for non-patented drugs effectively introducing an exclusive marketing time period for molecules that are not even new. This was the main concern about the press release. While mfc's letter in para 3 also makes a reference to a molecule who's patent has expired, it does so after making the point about data exclusivity and repeating clinical trials generally."

The Benefits of Openness of Drug Information

... Almost no new element of knowledge emerges suddenly; as a rule it begins with impressions and hypotheses. Where these arise – for example, in reports of possible serious side effects in the journals – all existing relevant information will need to be mobilized to verify or discount this evidence so that the trust can be established as quickly as possible. Much of the information needed for that purpose, including data on both animal and human experience, is unpublished and lies only within the files of agencies. By using it, the truth can be established much more quickly than if one is reliant purely on published evidence.

Consequences of excessive secrecy in drug regulation

If a substantial part of the information existing on drugs remains hidden within regulatory agencies, and sometimes fragmented between them, the development of knowledge will be impeded. This is particularly dangerous where suspicion arises of a hitherto unknown risk.

Malpractice can be hidden from view; legal discovery in the course of litigation has for example revealed cases of falsification or suppression of unfavorable data by certain companies, or submission of inconsistent files on the same drug to different agencies. Secrecy facilitates the circulation and use of sub-standard drugs.

Where a drug is subject to negative findings, the failure of a drug agency to explain its conclusions or provide background data, can leave the way clear for the sometimes very different and emphatic account given from the manufacturer. In a climate of secrecy and mistrust, the public is unlikely to believe even accurate and meticulously prepared official statements – assuming that they cannot be taken at face value and that some relevant information has probably been withheld.

The incomplete availability and irregular release of information promotes a climate in which suspicion is generated and in which sensational and poorly founded stories on drugs break in the popular press, their reliability cannot be checked and unnecessary panic can be caused...

[1]Extracts from the Statement of the "International Working Group on transparency and accountability in drug regulation "(Uppsala, 11-14 September, 1996). Quoted in: Carlos Correa, June 2002, op.cit.

Data Exclusivity in International Trade Agreements: What Consequences for Access to Medicines?

(MSF technical brief, May 2004)

"Data exclusivity" is a term covering measures some governments, especially the US, are seeking to include in bilateral and regional trade agreements. The implications of such measures need to be understood, because they could have far-reaching ramifications for access to medicines.

Data exclusivity refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine. Data exclusivity is completely separate from patents. In fact, the strongest impact may be felt in a country where there is no patent for a medicine - if data exclusivity is granted this will provide a monopoly for a set period (e.g. five years).

This short briefing paper outlines the consequences of data exclusivity for access to medicines and explains why countries are not obliged to agree to it.

What kind of data are we talking about?

"Data exclusivity" refers to test and other data that a pharmaceutical company must provide to a drug regulatory authority (DRA) in order to get first-time registration for a ny new medicine it wishes to market in a country. This test data is necessary to demonstrate the efficacy and safety of the drug. Registration - or marketing approval – by the DRA is needed before a medicine can be marketed in a country.

When generic manufacturers later apply to register another version of an already-registered medicine, they only have to demonstrate that their product is therapeutically equivalent to the original. To fulfil the efficacy and safety requirements, the drug regulatory authority relies on the registration file of the original manufacturer.

So what kind of exclusivity is it?

In order to delay competition from generic manufacturers, multinational companies have been pushing hard to obtain exclusive rights over their test data. During this period of "data exclusivity", the DRA is not authorised to rely on information in the originator dossier to approve/register generic versions of a medicine. This period of exclusivity may vary from five years in the US to eight-10 years in the EU and can be found in developed countries mostly in medicines legislation. Such legislation also exists in a limited number of developing countries.

Practically, data exclusivity prevents DRAs from registering generic versions of a medicine during a limited period, unless the generic manufacturer independently carries out its own tests showing the safety and efficacy of the medicine.

What are the consequences of data exclusivity for access to generic medicines?

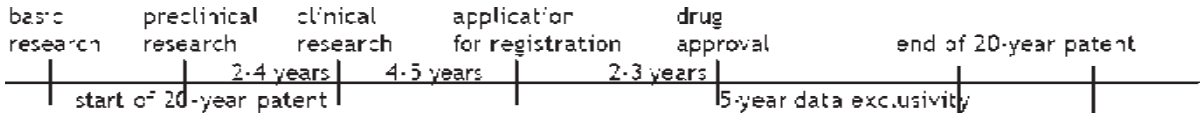
The biggest impact of data exclusivity is on medicines that are not patented in some countries, as a result of pre -TRIPS patent laws excluding pharmaceutical patents. This is the case of most antiretroviral medicines in Guatemala for instance,[1] where generic manufacturers will now have to wait five years from the date of approval of the original medicine in Guatemala before obtaining registration of their own version of the medicine.[2] In other words, even when a medicine is not protected by any patent, multinational pharmaceutical companies are assured a minimum period of monopoly in countries that provide data exclusivity. This is clearly going beyond the TRIPS Agreement (see further below).

In other situations, where a medicine is protected by patents, data exclusivity may constitute a barrier to the use of compulsory licenses. If a generic manufacturer is granted a compulsory license to overcome the patent, it will not be able to make effective use of the license if it has to wait for the expiry of data exclusivity before it can get its generic version approved by DRA and put on the market. Therefore, countries will need to ensure that the use of compulsory licences are not restricted by data exclusivity.

Data exclusivity is a means of impeding generic competition, and maintaining artificially high prices, thereby restricting access to medicines. Moreover, it

[1]This is because Guatemala only introduced patent protection for pharmaceuticals in November 2000. Consequently, all medicines which were applied for patent protection before this date cannot be patented in Guatemala (except for new improved versions that meet the patentability criteria). See MSF report *Drug patents under the spotlight –Sharing practical knowledge about pharmaceutical patents*, May 2003.

[2] In accordance with Decree 09-2003, and the recently signed Central America Free Trade Agreement (CAFTA) with the United States.



could be considered unethical to require generic manufacturers to conduct their own safety and efficacy trials with proven effective compounds. Clinical trials could expose patients to sub optimal treatment.

Proof of therapeutic equivalence should be sufficient.

What is the relationship between data exclusivity and patents?

Patent application is made well before the application for drug registration, at the stage of basic research, but since patents now last for 20 years, they usually expire after the data exclusivity period.

The schematic graph above illustrates the interference of patents and data exclusivity.

Is data exclusivity another kind of intellectual property right?

Compared to more traditional intellectual property rights such as patents and copyrights, data exclusivity is very unusual since it does not require any inventive activity for it to be granted. Data exclusivity protection is instead only based on the fact that an investment has been made by the originator in carrying out the necessary tests to demonstrate the safety and efficacy of their new medicine. Although the TRIPS Agreement now requires some protection for this sort of data, it does not require that exclusive rights be granted in the same way as patents or copyright.

What does TRIPS say about test data?

Developed countries pushed very hard during the TRIPS negotiations to have data exclusivity included in the TRIPS Agreement as a new kind of IPR. They succeeded *in part,* as test data are mentioned in Section 7 of the TRIPS Agreement, but *not entirely,* as TRIPS does not talk about "exclusivity" as such.

There is only one article in the TRIPS Agreement that talks about test data: Article 39.3, which states that

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

In simple words, what TRIPS says is that WTO Members should protect "undisclosed test or other data" against "unfair commercial use" and "disclosure". Nowhere does TRIPS state that countries should provide *exclusive* rights to the originator of the data for a *given* period. Rather, TRIPS simply refers generally to the need for "data protection", without answering the question of how such protection should occur.

As for other forms of IP, Article 39.3 of the TRIPS Agreement only provides a minimum international standard for the protection of the submitted undisclosed information required for market approval of a pharmaceutical product. Since the wording of Article 39.3 is very general, Members maintain substantial flexibility when determining how submitted test data should be protected. WTO Members do *not* have an obligation under Art. 39.3 to confer exclusive rights to test data, whether it is for three years, five years, or 10 years, as pointed out by many experts.[3]

Data exclusivity is no more than "TRIPS-plus" and is designed to delay the introduction of generic competition, creating a barrier to access of medicines, in particular where there are no patent barriers.

What will be the effect of data exclusivity in bilateral and/or regional trade agreements given TRIPS flexibility?

Countries that are members of the WTO do *not* have to grant data exclusivity, as specified under TRIPS Article 39.3. However, if they agree to grant data exclusivity in a trade agreement signed after the TRIPS Agreement, they are bound by the later agreement, in accordance with the rules of international law, and will have to implement this obligation at national level.

Countries that have agreed to data exclusivity provisions in free trade agreements with the US include: Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Morocco, Nicaragua and Singapore.

---

[3] See Carlos Correa, 2002, op. cit. Available at <http://www.southcentre.org/publications/pubindex.htm#books>. See also the Report of the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, London, September 2002, pp.50-51 and 163.

IDMA (Indian Drug Manufacturers' Association) on Data Protection (DP) and Data Exclusivity (DE)

➢ The Committee to examine 'Data Protection' (chaired by Ms Satawant Reddy, Secretary, C&PC) is understood to be divided on granting DP in Pharmaceuticals. There are good reasons for that.

➢ Data Protection (DP) as envisaged by TRIPS Art 39.3 is our international obligation. However, we feel that by virtue of several changes in Drugs and Cosmetics Rules and the introduction of new Schedule 'Y', India fully meets these requirements.

➢ However, the MNCs are pressing for a higher level of protection - a three to five years of exclusive monopoly in market or Data Exclusivity (DE). The MNCs are actively supported by their governments particularly the USA.

➢ The USTR continues to show India on 'Priority Watch' list under US Trade Law Section 301. There is incessant pressure from the US Government upon India to agree to grant DE.

➢ There is no complaint either from the TRIPS Council or WTO or any other country. This is basically a US agenda and they are pursuing it relentlessly.

➢ During the final phase of the Uruguay Round, both in Brussels Ministerial as well as in the Marakkash Conference, the US proposal asking for a five-year DE was rejected. Instead, a consensus article on 'protection of data' only (the present TRIPS Art 39.3) was accepted. Not satisfied, USA now wants to go beyond TRIPS and is trying to get its demand on DE implemented by all Member States. They are even putting it as a clause in regional and bilateral Free Trade Agreements. Please note that TRIPS does not use the term 'Data Exclusivity'.

➢ In the opinion of eminent economist Prof. Carlos M. Correa, Data Exclusivity does not come under the purview of TRIPS and is tantamount to TRIPS PLUS. Obviously, Members are not required to accept any TRIPS PLUS demand.

➢ It is true that bowing to the US pressure, Russia, China and many developing countries have accepted it. However, Brazil has not accepted the demand in the case of Pharmaceuticals. We should follow the Brazilian example in this matter.

➢ The surest result of Data Exclusivity will be rise in prices of critical drugs. It will restrict competition and create additional monopoly rights. It will delay generic production which is considerably cheaper and good for the masses. Thus, it will affect peoples' right to life and access to medicine. This is politically unwise.

➢ The MNC lobby in India is arguing that by accepting DE, R&D and foreign direct investment will flow into India. Nothing is farther from the truth. It is a canard spread by MNCs to allure developing countries to accept DE. DE and R&D are not connected. So is FDI which does not depend upon whether a country has or has not accepted DE. R&D and FDI basically depend upon things such as the economic environment in the country, the economic policies of the Government etc., - not on acceptance or non-acceptance of DE. For example, considerable FDI has been flowing into China since 1978 when they changed their economic policies, two decades before they agreed to DP. (Even their agreeing to grant DE was for gaining entry into WTO.)

➢ Unlike a patent, which is a reward for invention, 'data exclusivity' is a monopoly reward for investment involved in clinical trials and other tests. It is public knowledge that the claims relating to expenses on clinical trials and tests etc are highly exaggerated.

➢ The demand of Data Exclusivity is aimed at earning increasingly higher profits. It is based on corporate greed and therefore, against public interest.

➢ DE in Insecticides - It is disturbing to learn that the Ministry of Agriculture have accepted the idea and that they are recommending a three year Data Exclusivity Regime for Pesticides. If this is accepted, the price of this vital farm input is bound to go up adversely affecting the production cost of our produce and further reduce the already slim margin for the farmer.

➢ DE in Pharmaceuticals - However, in the case of Pharmaceuticals, we urge that the best course is to follow the example of Brazil. The Government should not accept this demand.

➢ If for political reasons the Government is forced to agree upon granting DP/DE, the following safeguards are suggested -

➢ Consider DP only, not DE.

➢ Negative List - It is of utmost importance not to allow minor variations, derivatives, metabolites, change of form etc to be a ground for DP or DE. This is regardless of whether a fresh application for marketing approval is required. A provision similar to the negative list applicable to a new patent (section 3d of the Patents' Act) should be introduced in public interest. If this precaution is not taken, everybody, poor or rich, you and me including, will be paying ten times the generic medicine's cost for ever.

➢ Let there be aprovision for a 'pre-grant opposition' as in Patents.

- There should also be a provision for over-riding DP/DE through Compulsory Licence or take over the drug in public health emergencies. Further it should not affect the powers of the Government under Para 6 of Doha Declaration (where medicines are required urgently by countries which do not have manufacturing capability)
- There should be no bar for anyone to generate the same data afresh. In short, DE should not expand into 'market exclusivity', an even higher level of protection.
- The term (period) should be co-terminus with the term of patent. It should not go beyond the patent term.
- The term (period) should start from the date of the First Marketing Approval of the original molecule anywhere in the world - not just from the date of application filed in India.
- The entry of generic medicines in market should not be delayed. All loop holes to extend monopoly (ever greening) should be adequately plugged.
- Clearly define the law in terms of Constitutional validity and in light of Right to Information Act. The benefits to DP holder should be commensurate with evidence based Cost Data. The filing of cost data should be compulsory.

COMPARATIVE

	WTO TRIPS	United States	European Union (Post 2004)
Date protected	Only undisclosed data which involves considerable effort to originate and the submission of which was required	No mention	No mention
Kind of protection	No Unfair Commercial use / disclosure	Granting of exclusive rights No use/disclosure + no reliance permitted	Granting of exclusive rights No use/disclosure + no reliance permitted
New drug protected	Only New Chemical Entity	New Chemical Entities (NEC) + New indications/uses	New Chemical Entities (NEC) + New indications/uses
Minimum period of protection	No mention	5 years data exclusivity for NEC (non disclosure/reliance) + 3 years market exclusivity for new indications (non disclosure)	8 years data exclusivity (non disclosure/reliance) + 2 years market exclusivity (non disclosure) + 1 years market exclusivity for new indications (non disclosure)

Reproduced from: Judit Rius Sanjuan. CPTech Discussion Paper No. 1. *U.S and E.U Protection of Pharmaceutical Test Data,* April 12, 2006. <http://www.cptech.org/ip/health/dataexcl/index.html>

Safeguards if Decision by Govt to Introduce DE

➢ **DE for not more than three years**

➢ No protection to be provided for new indications. Restrict exclusive rights to New Chemical Entities. Article 39.3 is after all aimed at protecting data, which is the result of "considerable effort". Subsequent data relating to new indications, routes of administration and dosages - should not receive a separate period of data protection. In fact in a particular case (*Generics)*, the European Court of Justice was not persuaded either that a separate period of data exclusivity ought to be provided for new indications associated with "major therapeutic innovation" (*R v. The Licensing Authority established by the Medicines Act 1968, ex p. Generics (U.K.) Limited, R v. The Licensing Authority established by the Medicines Act 1968, ex p. The Wellcome Foundation Limited, R v. The Licensing Authority established by the Medicines Act 1968, ex p. Glaxo Operations U.K. Limited and Others*, ('*Generics*'), Case C-368/96 [1999] 2 C.M.L.R. 181).

➢ **The protection period in India should begin on the date of marketing approval in the first country recognized by India (US, Canada, EU, etc). Also to qualify for DE they will have to register the product in india within one year of registration elsewhere (i.e. no DE without registration in India).** Thus the data exclusivity clock could be set running by a registration in another country. This means that in practice India will have a period of marketing exclusivity that is always less than stipulated. Such a system would positively encourage originators to expedite registration in that developing country, so as to benefit from the longest possible period of protection. In the EC legislation on data protection under Directive 65/65/EEC, although data exclusivity rights are provided for, they are stipulated to run from the date of first registration in the EC. For example if a medicine is first registered in Germany and only registered in the UK seven years later, then only three years of data protection would be left in the UK.

➢ If for a patented drug compulsory licence is granted then a provision for accompanying compulsory licence for the necessary data is needed so that the licenced drug can be given marketing authorisation. To do otherwise would render empty the value of a compulsory licence. India will need to ensure that the use of compulsory licences are not restricted by data exclusivity. The EC has recently indicated that they would regard it as reasonable to make both the relevant patent and the relevant data the subject of compulsory licences so that the purpose of the compulsory licence is not frustrated. Also ensure an independent provision on compulsory licensing of test data, as it can be very useful when required agreement on the sharing of data is not possible.

➢ Review of the second applicant's application is permitted to take place during the period of exclusive rights. A generic product could be approved during the latter period of exclusive rights and placed on the market the first day after the expiry of the market exclusivity period. If this were not permitted, their period of exclusivity would include the specified term plus the amount of time that it would take a generic firm to gain marketing approval based on their filing their application on the first day after the expiry of that period.

➢ DE to be capped by the expiry of a relevant patent.

➢ Ensure that health and safety data would be immediately available to the public. Also the DCGI in public interest should be authorized to use and disclose any data turned over to it by an applicant for registration.

➢ What if the pharmaceutical company even despite DE decides not to supply the market after all? Again, could India be left with neither branded originator nor generic drugs? Should a 'working' requirement be considered by analogy with patent law, where the originator has to market the relevant product after obtaining regulatory approval, failing which they forfeit their exclusive rights.

Patents and Welfare Loss

A study by a World Bank economist and two Yale University economists estimates that in the presence of price regulation the total annual welfare losses to the Indian economy from the withdrawal of the four domestic product groups in the fluoroquinolone sub-segment alone would be on the order of Rs 20.16 billion. Out of which profit loss for Indian drug companies would be Rs. 2.3 billion. "…the loss incurred by producers - Rs. 2.3 billion on an annualized basis - pales in comparison to the decrease in consumer welfare … under the same scenario - Rs. 17.81 billion annually."

Source: *Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India.* Shubham Chaudhuri, The World Bank; Pinelopi K. Goldberg, Dept. of Economics, Yale, NBER and BREAD; and Panle Jia, Dept. of Economics, Yale, March 2006. Paper available at <http://www.econ.yale.edu/~pg87/TRIPS.pdf>

On "Unfair Commercial Use"[1]

A. The TRIPS Agreement text

One of the crucial interpretative issues in Article 39.3 is whether the reliance by a national authority on data submitted by one company (the "originator") to evaluate a subsequent application by another company (a "follower"), constitutes an "unfair commercial use" of the information.

The expression *"unfair commercial use"* is not defined in Article 39. Pursuant to Article 31 (1) of the Vienna Convention, its interpretation should be based on the ordinary meaning of the terms of the treaty in their context and in the light of the agreement's object and purpose.

1. "Unfair"

Ladas concludes his treatise's discussion of the issue by indicating that:

> We look for a standard by which we may judge the act complained of. This is an objective standard: the honest practices in the course of trade in the particular community and at the particular time" (Ladas, 1975, p. 1689).

Given this diversity, it is likely that different countries will judge certain situations differently, depending on their values and competitive advantages. Some countries may consider it an "unfair practice" for a "follower" company to commercially benefit from the data produced by the originator, via a marketing approval system based on "similarity"; or hold that such commercial benefit gives rise to claims of "unjust enrichment" leading to a compensation for the use of the data. In others, it may be regarded as the legitimate exploitation of an externality created during legitimate competition in the market. As noted by Kamperman Sanders,[4]

> "Where exploitation of another's achievements becomes inequitable, unfair competition law acts provides a remedy. This means that the mere fact that another's achievement is being exploited does not call for any impediment on the basis of unfair competition provisions. On the contrary, appropriating and building on others' Proscribed Acts of Unfair Commercial Use 27 achievements is the cornerstone of cultural and economic development. The axiom of freedom to copy epitomizes the principles of the free market system".

Certainly, specific regulations could be adopted at the international level in order to harmonize the treatment of these cases. The United States made such a proposal in the TRIPS negotiations,[1] but it was not incorporated into the final text of the TRIPS Agreement. The U.S. proposal would have obliged countries to prevent any use of test data, without the consent of the right holder or on payment of "the reasonable value of the use", if that use led to the "commercial or competitive benefit of the government or of any person". This provision would have obliged countries to prevent *any* practice that would create such benefit. The final proposal, by contrast, used the term "unfair commercial practices". The rejection of the US proposal indicates that the negotiating parties deliberately opted under Article 39.3 to mandate regulation of certain *types* of practices (those that are commercially *unfair*) and not to prevent any practice based on its possible *effects* on benefits allocation.

In other words, Article 39.3 only applies when a competitor obtains a benefit or advantage from the use of the originator's testing data *as the result of unfair commercial practices*. It is the qualification of the practice that counts, not the mere existence of an

advantage or benefit. Such qualification is left to Members' discretion; it is part of the room for manoeuvre that they retained when signing the Agreement.

There are many instances in which the production of goods, notably intangibles, in a competitive environment generates externalities that benefit competitors. In describing the nature of competition, Ladas has noted that:

> "it is an undeniable fact of modern business life that successful manufacturers or traders have to cope with the danger of having the goodwill of their business, their connection with the purchasing public, interfered with by competitors...In a competitive economy is it to be expected that each manufacturer or trader necessarily seeks to maintain and improve his market position by obtaining the benefit of a public demand, even though this demand be created by other manufacturers or traders ...
>
> "…where does lawful competition end and unlawful competition begin? The fact that a competitor may derive a profit from his act of competition or cause monetary loss to another is not, in itself, unlawful. The dictum "no one should reap where he has not sown" requires delicate application. Progress would be paralyzed and monopoly would become general if we should attempt to prevent persons from using the work or experience of others. We must encourage people in the same trade or industry to compete for the

---

[1] Excerpted in public interest from *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, by Carlos Correa, June 2002, pp 25-33. Available also at: <www.southcentre.org/publications/protection/toc.htm>

[2] *The Concise Oxford Dictionary*, Seventh Edition, Oxford University Press, Oxford, 1989.

[3] Ladas, Stephen, (1975), *Patents, Trademarks, and Related Rights. National and International Protection*, vol. III, Cambridge.

[4] Kamperman Sanders, Anselm (1997), *Unfair Competition Law,*1997, Clarendon Press, Oxford.

[5] See below the history of the negotiation of article 39.3. *(not in this extract – editor)*

custom of the public on the most favorable terms. The issue is whether the means employed in such competition are fair and lawful. An act may lack tact or taste but not be dishonest" (Ladas, 1975, pp. 1676, 1677 and 1689).

Many countries do not treat commercialization of a "similar" product approved by reference to a previous registration, or by reliance on data submitted by the originator company, as an unfair commercial practice, but some do. Under Article 39.3, each approach is valid. Article 39.3 mandates protection against "unfair commercial practices", but permits Member countries to determine which practices will be deemed commercially unfair. As mentioned, differences among countries are likely to exist, consistent with Article 10*bis* of the Paris Convention.

2. "Commercial"

Article 39.3 only covers "commercial" uses. This requirement clearly excludes use by the government, notably by the national health authority to assess the efficacy and toxicity of a pharmaceutical or agrochemical product.

In the view of the European Union, however, there is a substantial difference between the underlying principle in Article 39.1, which refers to relationships between competitors and Article 39.3, which includes governmental acts:

"The main question of interpretation is what is meant by "unfair commercial use". Clearly, this concept is different from the concept of "unfair competition", as used in Article 39.1 with a reference to Article 10bi of the Paris Convention on the protection of Industrial Property, and which relates to behaviour among competitors. Protection of registration data is a government function. Article 39.3 does not indicate whether the notion of "unfair commercial use" refers to unfair commercial use by generic manufacturers to those who have submitted the data (usually research-based pharmaceutical industry) or to use by regulatory authorities of these data to the benefit of competitors. Protecting data against "unfair commercial use" is also different from protecting them from disclosure, since the latter is a separate and distinct obligation under Article 39.3" (EU, 2001, p.3).[6]

The EU argument, however, disregards that Article 39 *develops* and does not add to Article 10bis of the Paris Convention. It only incorporates *examples of the general principle contained in paragraph (2) of Article 10bis*.

In addition, though the use by the governments will *indirectly* have commercial consequences (the entry of a competitor in the market), it does not represent a *commercial* activity as such, but a legitimate State practice. In order to be "commercial", the use of the information should be made by an entity which is actually in commerce.

As also noted by Ladas,

"The general clause of Article 10bis, in establishing as its foundation "honest usages," looks to the relations between competitors and to the interests of customers, and these provide an objective test which reflects an evolving pattern of competition in most of the present world...By definition, competition in commerce refers to the efforts of two or more persons, acting independently, to secure the 30 Protection of Data for the Registration of Pharmaceuticals: Implementing Standards …custom of third parties, with the results that one may increase the sale of his goods and reduce the sale of the goods of the other" (Ladas. 1975, p. 1688).

The same concept underlies the WIPO "Model Provisions on Protection against Unfair Competition" which, in relation to data protection, suggests the adoption by national laws of the following provision:

"Use or Disclosure of Secret Information Submitted for Procedure of Approval of Marketing: Any act or practice, in the course of industrial or commercial activities, shall be considered an act of unfair competition if it consists or results in an unfair commercial use of secret test or other data, the origination of which have been submitted to a competent authority for the purposes of obtaining approval of the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities" (emphasis added) (WIPO, 1996).[7]

3. "Use"

Finally, for Article 39.3 to apply, there must be "use" of the information submitted by the originator.[8]

4. Analysing "Unfair Commercial Use"

Thus, given the flexibility inherent in Article 39.3, and depending on the applicable legal system, national laws can follow different approaches for the approval of a second-entry marketing application.

They may:

a) require the second-entrant to produce its own testing and other data or to obtain an authorization of use from the "originator" of the data;

b) allow the second-entrant to rely on the "originator's" data against payment of a compensation to the "originator" (when the "originator" has not given his consent for the use of the data);[9]

c) examine and rely upon the data submitted by the "originator" to evaluate the second-entrant application;

d) approve a second entry marketing application without examining or otherwise relying upon confidential information submitted by the originator.

In all cases, the authorities will normally require that

[6]European Union (EU), (2001), *Questions on TRIPs and data exclusivity. An EU contribution*, Brussels.

[7] WIPO, (1996), *Model Provisions on Protection Against Unfair Competition*, Geneva.

the second entrant prove that his product is similar or "essentially similar" to the already registered product (in terms of its physical and chemical characteristics and attributes).[10] Different types of bioequivalence studies are generally required for this purpose.[11]

In cases a) and b) the data receive specific protection, either on the basis of exclusivity or compensation. In case c) the second entrant does not *use* the data; it is the authority who examines and relies on the data in its possession. In case d), finally, there is no "use" at all, since the authority does not use the testing and other data (which it may not even possess); it merely relies on public information and/or on the existence of a prior (domestic or foreign) marketing approval.

Neither in cases c) or d) is there a "commercial use" of the data. A contrary interpretation holds that even indirect reliance on data by a national authority constitutes a form of commercial use.

Under this interpretation, the competent authority must be proscribed from "using" the data to support, clear or otherwise review second entrant applications for marketing approval for a set amount of time unless authorized by the "originator" (WHO, 2000, p. 39).[12]

According to this interpretation, national authority reliance on the data submitted by the originator in order to assess a subsequent application constitutes "unfair commercial use", even when neither the authority nor the competitor actually "use" the data without the originator's authorization (for instance, when approval is given without any re-examination of the data). In the U.S. complaint against Australia, for instance, the USA argued that relying on the innovator's data allowed free-riding by generic drug companies on *"the innovator company´s investment in developing the test data and thus puts the innovator company at a competitive disadvantage... The U.S. claims that Article 39 para.(3) means that generic companies are not allowed to derive commercial benefit from the innovator´s test data"* (Priapantja, 2000, p.6).[13]

Under this view, the fact that a competitor obtains a commercialbenefit or advantage constitutes an "unfair commercial use" of the data, notwithstanding that actual use may not occur and that the practice as such may not be "dishonest" or contrary to a country's prevailing values of morality or fairness in commercial activities.

This latter interpretation, however, clearly goes beyond what the provision mandates. It does introduce an obligation not negotiated during the Uruguay Round that, in practice, would limit legitimate competition and thereby erect barriers to the access to medicines.

---

[8] In one of the texts under consideration by the negotiating parries in July 1990, the broader concept of "exploitation" was proposed (but not finally adopted). The text read: "3Aa. Parties, when requiring the publication or submission of undisclosed information consisting of test [or other] data, the origination of which involves a considerable effort, shall protect such data against unfair exploitation by competitors. The protection shall last for a reasonable time commensurate with the efforts involved in the origination of the data, the nature of the data, and the expenditure involved in their preparation, and shall take no account of the availability of other forms of protection".

[9] This compulsory licence approach is the one applicable, under certain circumstances, in accordance with the U.S. FIFRA. See Annex I. (in the complete document – editor)

[10] See, e.g., article 4.8 (a) (ii) of the EC Directive 65/65/EEC.

[11] In some countries, bio-availability studies are also required for the approval of generic versions of existing products.

[12] WHO, (2000), *The TRIPS Agreement and Pharmaceuticals. Report of an ASEAN Workshop on the TRIPS Agreement and its Impact onPharmaceuticals*, Jakarta, 2-4 May 2000.

[13] Priapantja, Priapantja, (2000), *Trade Secret: How does this apply to drug registration data?*, paper presented at "ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals", Department of Health and World Health Organization, Jakarta, 24 May 2000.

Forthcoming in October 2006

The Revised

A Lay Person's Guide to Medicines

What is in them and what is behind them

LOCOST, Vadodara, 2006, 600 pp, hardbound, Rs 250/-

Postage free if ordered before October 15, 2006.
Email: <locost@satyam.net.in>

Ricardo and "Free Trade"[1]

-Utsa Patnaik

… It is often accepted as an unquestioned truism by economists, including economists from developing ex-colonized countries, that the freest possible international trade, is necessarily a good thing for everyone participating in that trade. For over two centuries now the ideology of free trade has been so thoroughly dinned into the heads of students, via the textbooks and in today's world also via the conventional wisdom filtering through the print and electronic media, that any systematic alternative viewpoint which stresses the costs of 'free trade' is hardly ever encountered. The ideology of free trade dates back to Adam Smith and David Ricardo, and it is no accident that both theorists should be from Britain and have written at a time when that country was in the process of grasping the land and resources of other civilizations, and launching on the world's first Industrial Revolution after creating a conducive economic environment for it by forbidding its colonies to manufacture anything and forcing them to specialize in producing the wage goods and raw materials its own industry needed. Neither theorist was English, for Smith was a Scotsman while Ricardo's forebears came originally from Spain. Yet both were the quintessential theorists of the emerging manufacturing bourgeoisie in Britain in the last quarter of the 18th century and the first quarter of the 19th century respectively. The free trade that they advocated has been much misunderstood; it was the freeing of British trade from its own monopoly trading companies, but very much while retaining control of subjugated colonies; hence the freedom to Britain to continue to industrialize at the expense of other nations and peoples, and definitely not a general freedom for any potential rival to do likewise. Thus Adam Smith, in a passage in The Wealth of Nations which is never quoted, strongly opposed the idea of North America developing its own manufactures rather than relying on importing manufactures from Europe:

"It has been the principal cause of the rapid progress of our American colonies towards wealth and greatness that almost their whole capitals have been employed in agriculture. They have no manufactures, those household and coarser manufactures excepted which.are the work of the women and the children in every private family. The greater part both of the exportation and the coasting trade of America is carried on by merchants who reside in Great Britain. Were the Americans, either by combination or by any other sort of violence, to stop the importation of European manufactures, and, by thus giving a monopoly to such of their own countrymen as could manufacture the like goods, divert any considerable part of their capital into this employment, they would retard instead of accelerating the further increase in the value of their annual produce, and would obstruct instead of promoting the progress of their country towards real wealth and greatness."[2]

Here was the first clear articulation by a metropolitan economist, of the now familiar and self-serving argument that the colony's best interests lay in remaining an agricultural exporter, leaving the manufacturing and trade to be done by the metropolis.

These words, published in 1776 were famous last words, for after winning independence less than a decade later, from 1783 North America's European settlers went on precisely to do the opposite of Adam Smith's advice, namely they erected protective barriers against the inflow of manufactures from Britain and Europe and built up their own industry in a process of import substitution. Because they did so the USA is today the world's leading capitalist country: had they listened to Adam Smith's version of 'free trade' it would have been at most an Argentina. As the leading capitalist and imperialist country in the world the USA follows today in turn policies to encourage its own growth at the expense of the third world's freedom to industrialize, a question I propose to discuss later.

Of course, the modern theory of international trade is associated above all with David Ricardo and is an elaboration and development of Ricardo's theory of comparative advantage.[3] The essence of the ideology of international free trade can be said to reside in this theory, for it says that specialization and trade is necessarily of mutual benefit to both parties entering into trade as long as relative cost differences in producing goods exist, even where one country may produce all goods at a lower absolute cost than does the other. The theory has been immensely influential and has been used to explain not only the trade between countries of equal economic strength, e.g. intra-European trade, but also the pattern of international trade in which the colonies and subjugated areas came to specialize in agriculture while the European countries specialized in manufactures; and to argue that not only the colonizer but the colonized too benefited from this pattern of specialization and trade. Comparative advantage is the reason given, for example, by Professor K N Chaudhuri in the Cambridge Economic History of

---

[1] Extract from Utsa Patnaik. "The Cost Free Trade: The WTO Regime and the Indian Economy," *Social Scientist,* V.27: No.11-12 November December 1999 #318-319. Reproduced with permission of author. A complete version is available online at <http://www.macroscan.com/anl/feb00anl200200Costs_Free_Trade_1.htm>

[2] Adam Smith. *The Wealth of Nations.* Books 1-111 (First published 1776, quoted passage on p.466 of Penguin Books 1986, Ed. Andrew Skinner)

[3] David Ricardo. *Principles of Political Economy and Taxation.* (Vol.1 of *The Works and Correspondence of David Ricardo* edited by Pierro Sraffa with the collaboration of M H Dobb, Cambridge: CUP 1951), Ch.VII "On Foreign Trade.''

India to explain why from being the world's largest exporter of cotton textiles in the pre-colonial era, India turned into an importer of cotton manufactures from Britain and an exporter of agricultural products like raw cotton, jute, opium, indigo and so on.[4]

No argument can be more fallacious than Ricardo's theory. Why it should have been necessary to use military force to induce countries like Portugal, China or India to trade, if it was so beneficial for them, is not explained. Even more important, the theory is internally logically fallacious. A fallacy in a theory can arise either because the premise is incorrect, or because the argument is incorrect. In the case of the comparative advantage theory applied to Northern trade with warmer lands, the premise itself is incorrect. The premise is that in the pre-trade situation (assuming the standard two-country two-commodity model) both countries can produce both goods. Given this premise, then it can be shown that both the countries gain by specializing in that good which it can produce at relatively lower cost compared to the other country, and trading that good for the other good: for compared to the pre-trade situation, for a given level of consumption of one good a higher level of consumption of the other good results in each country. This mutual benefit arising from comparative advantage, is adduced as both the reason for and the actual outcome of specialization and trade.

The reality was that the tropical or sub-tropical regions with which Britain, Netherlands France etc. initiated forced trade using military power, were bio-diverse and could, and did, produce a much larger range of goods than the N. European countries could, including tropical crops which could never be produced under field conditions in the temperate regions. In tropical regions crops can be grown all the year round and multi-cropping of the same physical unit of land is possible. Not only is the output vector much larger but it is a qualitatively different output vector, for it contains elements which are not present in cool temperate lands at all. Moreover since it is agriculture which provides not only food for subsistence but raw materials for manufacture, fibres for clothing and traditional materials for housing, the better resource base and lower costs of subsistence in a bio-diverse tropical region led to abundant supply and lower costs of all these elements vital for the standard of life.

While Portugal which is a warm temperate land could produce both cloth and grape-based wine on a large scale, Britain could produce only cloth but not grapes under field cultivation, for the latter requires land within a mean July isotherm of at least 19 degrees Celsius or 66 degrees Fahrenheit, which no part of Britain (except perhaps Cornwall) possessed. Similarly while India, Burma or China could produce both cotton cloth as well as raw cotton/ sugarcane/ indigo/tea/jute/ rubber etc., Britain, Netherlands, Germany and France could produce only cloth and none of the other crops, and so on. The cost of production of raw cotton, indigo, tea, coffee, jute, rubber etc thus cannot even be defined for cool temperate Britain, Germany, or Canada. If absolute cost is not definable, then ipso facto relative cost is not definable. The premise of the theory does not hold, namely that both countries can produce both goods, hence the conclusion does not hold, that specialization and trade is necessarily mutually beneficial. (Certainly the country with the poorer output vector benefits by acquiring goods it cannot produce; but the country with the superior output vector does not necessarily benefit : specialisation and enforced trade can lead to very adverse welfare outcomes such as falling mass nutrition levels, as we will show below). Yet economists have continued to make logically untenable hence nonsensical statements like the following: Britain exported cloth and imported tea/ indigo/cotton from India because it had a comparative advantage in cloth production while India had a comparative advantage in the crops specified. How does one at all talk of production, or cost of production of tea and indigo in Britain? This absurd fairy tale masquerading as serious theory continues to hold sway in trade theory to this day, modified only to say - the labour-abundant country produces labour intensive (primary or simple manufactured) goods while the capital abundant country produces capital intensive (advanced manufactured) goods.

The lack of satisfaction of the basic and crucial premise - homogeneous productive capacities across countries - in history, itself was the positive real reason for this important segment of trade: thus adopting the premise, amounts to assuming away the real reason for this trade. The basic motive of forced trade was for the temperate lands to gain access to tropical bio-diversity and to inexpensive manufactures like textiles of mass appeal and mass consumption which were based on using the unique and cheap resources of these regions. In the course of the three centuries since 1700 the consumption basket and standard of living of the Northern populations has altered beyond recognition. It is based on importing goods from all over the world, the major part being goods not producible at all in the temperate lands.

While Ricardo's explanation was superficially extremely clever, he did a signal disservice to the cause of objectivity and science, by pretending in effect that all trade including forced trade, was freely chosen trade determined by technologically determined, neutral cost factors. Trade patterns which had been in reality the outcome of trade wars, genocide and political subjugation, were discussed in such a way as to ignore this historical reality of 'capitalism's blustering violence' (to use a memorable phrase first employed by Rosa Luxemburg;[5] and by focusing only on value-neutral cost factors - necessarily in a fallacious manner - Ricardo provided an intellectual justification for, and hence an apologetic for forced trade. 'Capitalism's blustering violence' was neatly sanitized into the theory of relative costs. All subsequent mainstream trade theory has been similarly tautological and apologetic in

[4]K N Chaudhuri. "Foreign Trade and the Balance of Payments'' in *The Cambridge Economic History of India.* Vol.11 edited by Dharma Kumar and Meghnad Desai (Orient Longman 1985).

[5]Rosa Luxemburg. *The Accumulation of Capital* (London:1963)

character, and has talked of mutual gains from trade as the necessary cause and result of all observed patterns of specialization- not simply that between countries of similar economic strength.[6] 'Factor endowments' are talked of while completely ignoring the real differences in productive capacities in the same 'factor', land, in different countries. Many generations of third world economists have been fooled into believing that somehow being involved in a particular pattern of primary sector specialization, was unavoidable in terms of pure cost-of -production logic and was to the ultimate benefit of their countries.

But why blame Ricardo alone? It is more than that: we in the third world remain mentally and intellectually colonised even when we are politically independent: we do not dare to question the most nonsensical of theories as long as they come from the centres of academic hegemony and power, we do not dare to point out that the Emperor is naked. This is not accidental: as long it is not the search for objective truth which guides us, as long as it is professional publications and professional recognition in metropolitan centres which remain our implicit aim, in short as long as third world academics continue to suborn themselves, intellectually dishonest theorizing will continue to hold sway.

What was the historical cost to the countries like ours of being involved in 'free trade' as defined and implemented by the colonizing powers? I am here not talking of the well known costs by way of the genocide and decimation of entire peoples, their numbers running into millions, involved in colonial conquests. I would like to focus on the mechanisms of free trade in more recent times.

There have been two very important types of cost historically, which have again come to the forefront in the present era of loan-conditional liberalization and WTO discipline : the first is the re-emergence of an inverse relation between agricultural exports and domestic food availability, and the second is de-industrialisation. To understand the first type of cost we have to conceptualise tropical land as akin to a non-renewable resource. Usually it is the fossil fuels alone and the minerals which are thought of as being non-renewable. But we have to recognise that land is not homogeneous in productive capacity, and that the earth's bio-diversity and botanic diversity is concentrated in the tropical lands. It is clear that there is a limited supply of these lands, for unlike in the 19th century when cultivable wastes existed, by now there are no open frontiers, the limits of physical expansion have been reached and only the vast tropical rainforests remain whose ongoing destruction carries serious adverse environmental implications. In big countries like India and China total cultivated area is no longer expanding, in fact it is shrinking. Our land now is virtually like a non-renewable resource. It is not completely non-renewable: sown area can still be expanded if enough investment is pumped in, especially into irrigation. But the regime of neo-liberalism is precisely one of macroeconomic contraction, 'withdrawal of the state' and falling productive investment, and in this context tropical land must be conceptualized as non-renewable.

But the global asymmetry of demand, established over two centuries ago, continues: the world's rich countries which account for 75% of global income although they have hardly 16% of world population [7], cannot produce in their own countries anything but a small fraction of the highly diversified consumption basket on which their populations have come to depend, and they want access to our more productive, bio-diverse but limited lands on the one hand, and on the other hand access to our markets for the few primary goods they can succeed in producing,(notably foodgrains), and for their manufactures. Their high living standards are crucially dependent on the physical availability of our products. A typical Northern supermarket in W. Europe or USA carries on average 12,000 items of food alone in raw and processed form [8] and at least 60-70 percent of the items have a wholly or partly tropical to subtropical import content. If these goods were to disappear from the supermarket shelves the standard of life of Northern populations would plunge to a near- medieval level, that prevalent three hundred years ago.

The solution developed earlier under colonial and imperial systems where there was direct political control, was simple: first, protect metropolitan industry through trade barriers to the inflow of cheaper manufactures based on ample supply of raw materials, from countries like ours; second, promote in the colonies the export of the wage-goods and raw materials required for running metropolitan industries; third, keep the colonial markets completely open to the flooding in of manufactures from the metropolis, and fourth, monopolize invisible incomes (at that time, from shipping and financial services). This remains the basic agenda of the advanced imperialist countries today although the economic mechanism has changed to debt-conditional policies and a trade discipline operating through international organizations, (while invisible incomes have changed to modern forms of financial and communication services, the electronic entertainment industry, and returns to research in pirated bio-resources). Advanced countries continue to protect their own producers, continue to demand that we export tropical primary products or at most simple labour-intensive manufactures and continue to seek market access for their manufactures, their surplus temperate crops and for invisible services...

[6] Joan Robinson is an exception. In her "Reflections on the Theory of International Trade" *(Collected Economic Papers,* Vol.V Oxford: 1975) she points out that "In Ricardo's example Portugal was to gain as much from exporting wine as England from exporting cloth, but in real life Portugal was dependent on British naval support, and it was for third reason that she was obliged to accept conditions of trade which wiped out her production of textiles and inhibited industrial development, so as to make her more dependent than ever."

[7] These figures relate to the USA, Canada, EEC and Japan taken together.

[8] Harriet Friedman, "The Origin of Third-World Food Dependence'' in Bernstein, Crow et.al. Eds. *The Food Question*.

Medico Friend Circle Letter to PM on Drug Pricing

July 2006

The Honourable Prime Minister
Government of India
Nirman Bhavan
New Delhi

Dear Mr. Prime Minister,

Medico Friend Circle is a national body of health professionals, health workers, which has been for the last 35 years exploring and advocating appropriate health policy measures for the benefit of the Indian people.

We write to you at a time when a ***Draft Pharmaceutical Policy*** has been submitted to the Cabinet for discussion and approval. This matter was discussed during the national Executive Committee meeting of the Medico Friend Circle at Sewgram,Wardha on 7th and 8th July and we hereby share our concerns with you. Civil society organizations have represented the concerns of public interest and public health to a succession of committees, taskforces which have deliberated on the issue of pharmaceuticals and their pricing. We even approached the Supreme Court to intervene when the previous government virtually abolished the regulation of drug prices in its pharmaceutical policy. We would be happy to share with your office the detailed arguments we have put forth during these various submissions. Here we would very briefly summarize our points.

Here we briefly **summarize the rationale for price control of the essential drugs** –

- Medicines are the only commodity in which the payer (the patient) does not decide what to buy and at what cost. The doctor prescribes and the patient pays.
- Unlike in case of other commodities the purchaser of medicines is extremely vulnerable as he/she is seeking immediate relief from suffering. This special nature of drugs is the reason why even in so-called market economies all issues related to drugs including their prices are the subject of regulation by their Governments. The only exception is the USA.
- In India, unlike in the developed countries, expenditure on medicines constitutes a large proportion (>50%) of total medical expenditure. 90% of this expenditure is out-of-pocket expenditure by the people since the government spends a very small proportion on medicine procurement
- Unlike in the developed countries, most Indians patients face the drug industry as hapless individuals because most are not covered by insurance or social security mechanisms.
- Majority of Indians are below or near poverty-line, yet they are forced to spend on unnecessarily costly medicines. This unnecessary expenditure on medicines is a very important cause for indebtedness after hospitalization.
- Lastly, the track record of the drug industry in India as regards to pricing is extremely reprehensible. The following examples would illustrate this point:
- The same drug in the same strength manufactured by two trusted companies can vary from 2 times to 20 times in their prices, which has no credible explanation other than overpricing. Levofloxacin used in infections is sold by CIPLA is 7 rupees per tablet, while Aventis sells it at Rs. 95 per tablet. What is worse is that costlier drugs most often sell more because of more aggressive promotion.
- Committees constituted by the Government have clearly documented abnormal rises in prices of drugs after they were taken off the list of price-controlled drugs, e.g. price deregulation in 1995 the price of some TB drugs rose by 250%. Yet no action has been taken.

The pharmaceutical industry can afford to spend an estimated Rs. 5300 crores a year on drug promotion which actually means pampering doctors with gifts, big and small, and sponsoring lavish dinners and conferences in five star hotels, and even overseas visits.

When the pharma companies can afford to sell a drug at 10% of its MRP to the government and 20% of its MRP to the pharma trade why does it not question the abnormally high MRP itself? Even in quality conscious bulk procurement processes like in Delhi and Tamil Nadu, the tender rates of drugs are as low as 2-20% of the market rate When the government cannot provide essential drugs to the people, then is it not its primary responsibility to ensure that they are not being cheated with overpriced drugs in the market?

Thanks to the Indian Patents Act 1970, the Indian pharmaceutical companies have demonstrated that the western companies were vastly overpricing drugs. This has led to a worldwide questioning of drug prices. However, these same Indian companies which grew under Governmental protection are now joining the choir of MNCs in singing paeans to the free market and creating an uproar whenever protection of consumer interests in India is brought up. They are

resisting any attempts to question drug prices at home.

We agree that the industry is involved in business and not philanthropy and is entitled to fair returns on its investment. However it is a myth that regulation of prices is incompatible with profitability of the pharmaceutical sector. Is a 150-200% margin on the post-manufacturing cost of a drug produced in India that is being contemplated in this policy less for any commodity by any stretch of the imagination? The industry with s clout is peddling myths, half-truths and what is worse, even threats in its attempt to abolish regulation of drug prices, and looking at the intervention being made by your office, seems to be succeeding.

The pharma policy has to balance the public interest with economic interest, at this juncture after being skewed in favor of the industry for over the last 3 decades over which the list of drugs under price control have steadily declined from 347 to the present 74. If, the government bows again to the industry and neglects public interest, it shall be labelled complicit in the rising graph of drug prices, healthcare costs and people's miseries.

We hope you will give serious consideration to the above submission.

Thanking you,
Sincerely yours,
Dr. Ritu Priya, Convenor

---

mfc annual meet

Minutes of the 32nd Annual Meet

Sneha Deepam, Vellore, Jan 27-28, 2006

The meet began with a worship song in Tamil by Sara Bhattacharji followed by a celebration song by Manisha Gupte, Eddie, and Sarojini. This was followed by an introduction by Ritu Priya, the present convener. Ritu said that she was heartened to see so many young people present this time which could perhaps be attributed to the venue of the meeting (Vellore), the theme, as well as the mfc group and the body of work it is associated with.

Day 1: Jan 27, 2006

Session 1: "Role of the Health Care System from a Public Health Perspective: An Introductory Overview" - Coordination Team: Ritu Priya and Anand Zachariah

Anand Zachariah, representing the local host group from CMC, welcomed the participants. He stated that as part of a medical college he saw that it was far away from the mfc ideals. At CMC, the trend has been to move in the direction of advanced technology which is far removed from the mfc ethos; however, CMC was deeply concerned by this trend and was constantly on the lookout for alternatives. His hope from this meet was that it would focus on issues of critical importance in the clinical/medical world and help CMC in its exploration towards a viable alternative. He too expressed his happiness at the large presence of "freshers".

Sarojini N B, the previous convener, introduced mfc as an organisation/network in existence for more than 30 years with a nationwide link. The organisation is non-funded and has stood as a sharing platform for dialogue and debate of common concerns in public health. She spoke about the structure, activities including publications. The last few years has seen the emergence of a stimulating e-forum which keeps the group alive. She concluded that unlike other networks which become dysfunctional over a period of time, mfc has contributed for more than three decades and continues to be a secular, pluralist and pro-people group.

Dr Chandy, Director, CMC, presented CMC's perspective on quality and costs in health care. While he was in Addis Ababa the previous year he had realised the strength that was India. He is of the opinion that the answer to the problem of medical care is to have one General Practitioner (GP) in each village.

The goal of CMC has been to:

- Provide high quality education with minimal cost; and
- Ensure that it reaches people, along the lines provided by the CHAD team and Sara's work.

Dr Chandy gave a brief history of the setting up of CMC hospital by Dr Ida Scudder who started by providing medical care at road side clinics. External funds are taken to a limited extent only so that freedom in decision making is not interfered with. In the 1940s, there was an attempt to bring in expertise in areas the institution lacked in. The present day's model is based on the model of "teach people and work with them". The evolution of CMC was based on the two principles: education is the key and somebody has to pay. CMC is committed to the marginalized/underprivileged to provide low-cost effective care. The central concern is how to innovate for a better care without charging the patients more. This year has been declared as the year of compassion by the institution. The worry was with an inflation of 7% to 10%, how can costs be met. To cut on costs, the numbers had to be increased. Dr Chandy went on to explain the "both-and" model where they build on the numbers as a cost cutting measure reaching out to the bottom of the pyramid. As mentioned by Prof. Prahlad (of "core competence" fame), there are ways in which to reach out to large numbers. He cited the examples of successful models such as Amul, Arvind eye hospital, etc., which could be replicated if high technology care is provided at a central point and made available to all. Looking at these models from sustainability point of view also, in the last year's budget of CMC Vellore, 20% was set aside for the poor patients and 98% of the income came from the patients. He concluded that if large numbers of people are served, revenue will be generated to serve more poor and the model will be sustainable.

Anant Phadke then introduced the theme of the meet. Mfc as an organisation and several members within it have been working on the 'right to health care' which is that every citizen in this country should get affordable health care as a right guaranteed under the constitution. Given the huge morbidity load in the country, it is difficult to provide essential care to everyone and hence one needs to look at quality and cost of care from a rights based perspective. In the previous mfc meetings there has been much focus on primary health care; however in this meeting there is a shift to even looking

at secondary and tertiary health care. Good quality care is to be made available to everyone and we need to have cost-cutting mechanism to have high quality care at low cost. We also need to focus on preventive, curative, symptomatic, and rehabilitative care as part of the debate. In addition to clinical criteria of efficacy, safety and acceptability, public health criteria of social conditions, social mechanisms accessibility and costs needs to be taken into consideration. Hence along with the cost issues of every aspect of health care, issues like humaneness, doctor patient relationship etc. must be taken into consideration during discussions. He emphasised that it may not be possible to come to a consensus in all the discussions but the debates would clarify issues which was important for working towards a consensus at a later point.

Binayak Sen followed with reflections from the field (already published in the previous issue of the bulletin). He spoke about the current situation of India where he described issues ranging from expropriation of the poor of human rights by citing conflicts and violence in Kalinga, Bastar Mumbai etc. He expressed concern over the fact that common property resources, and livelihood resources are being snatched from the poor at gunpoint and further, the Supreme Court of India has acted as an agent of globalisation which is clear from the various judgements it has passed against common people. Significantly he mentioned that according to National Nutrition Monitoring Bureau, 34% of adults in India have BMI below 18.5 (including 60% SCs and 50% STs); and if more than 40% population have BMI less than 18.5 it is a famine situation, according to the WHO. Therefore India is on the verge of a permanent famine.

Binayak mentioned that though Standard Treatment Guidelines were formulated in Chattisgarh, they have been negated although this program is the base for NRHM. There should be some institutional and judicial mechanism whereby cost and quality measures can be given mandatory path rather than only recommendatory status.

Session 2: Quality of Public Health (Coordination team: Anant Phadke, coordinator, Anant Bhan, Sarojini)

The meeting on the theme started with brief presentations by the authors summarising the salient points in their paper. After a set of papers relevant to a specific topic was presented, the participants were given time to discuss the several issues outlined in the presentations/papers. It is to be noted that this method of organising the two-day meet was quite successful, particularly since the number of papers for the meet was large and had arrived late; the participants had therefore been unable to go through all of them before the meet.

The first presentation was by Prachin G, "Quality of Health Care - Trends in Assessments." According to him, the major trends in quality control came from the industry. The evolution of a system of quality assessment initially used the structure indicator, then adding process and outcome indicators. He opined that the medical fraternity needs to react to the fact that outcome is based only on mortality and morbidity indicators. Although there has been some research on disease mechanism and new therapies there has been little on how to deliver existing therapies which would have defined quality with a health care perspective; however now industrial sector defined quality from the market perspective. We would need to look at quality of care from critical strategic and normative aspects, as well as access, cost effectiveness, efficiency and expectations of the patients while spelling out the health attributes. There is disadvantage in using outcome as the only indicator and pointed out that structure, process, patient statistics and accessibility need to be considered. Further, for critical quality dialogue between all sectors have to be encouraged.

Alpana Sagar presented her paper, "Quality of Care- Public *vs* Private." In her opinion, the measurement indices of quality in public sector should not be based on that adapted from the private sector. There was a need to look behind the intangibles of the tangible indicators of structure, process and inputs. The falling in inputs affects referral services, for instance, when health personnel are not in place because of which the output is not up to the mark. It is not just the input but also the attitude of doctors that affects the public sector whose services continue to have an epidemiological impact. She expressed concern over the fact that RMPs provide maximal out reach, yet they do not get any assistance from the government in comparison to the support that corporate sector gets from the government. She questioned the current standards for quality care set by the private sector, and whether it would mean that similar "five star" standards are expected in the public health sector for cost effective coverage and how was it possible within India's social and economic context. Here she cited the example of use of malarial slide versus the dip stick and the use of MRI.

Ritu Priya followed this with her paper, "The Social Moorings of Health Services: Issues of Quality and Cost and the Case of Iodine Deficiency Disorders." She emphasised that not only access or universal coverage by the health system is important but the content of services needs to be looked into while making an assessment of quality. She traced the developments in public health policy/system from the Bhore committee, Sokhey Committee, Chopra Committee, the Bombay Plan, the People's plan and the Gandhian-Nehruvian models to explain the search for universal, technological solutions, by minimising the context. The standards for content came from institutions like AIIMS, which the public sector could not fulfil; therefore the private sector filled this gap. On the reverse, dialogue on combining the alternative systems has been marginalized in society.

Ritu spoke of the Kangra valley study which showed high prevalence of goitre and iodine deficiency diseases which led to the policy of universalisation of the iodised salt as was done earlier in USA and Canada. She explained, with data, that use of iodised salt was the sole reason for a decrease in iodine deficiency diseases has really not been proven; that other factors such as the bacterial content in water etc were not taken into account while assessing impact. The link of rise in auto immune thyroid diseases with iodisation cannot be ruled out. Her conclusion was that universalisation of iodised salt and Pulse Polio are classic cases of scientifically flawed programmes.

Sathyamala presented on "Issues in Public Health Programmes: the Case of Polio Eradication." This has to be seen in the context of both epidemiological impact and rational use of resources. The programme was promoted as a preventive approach in contrast with the clinic approach to the disease, more people centric, economically better (as it would save scarce resources) and was based on the principle of herd immunity. She traced the evolution of the programme with the initiation by Rotary International, taken up by the WHO, UNICEF and CDC Atlanta. The disease was not a public health priority in the country had been imposed by the global community and had moved from a donor supported programme to a program relying on World Bank loans which are based on conditionalities such as global tenders etc. Today, almost the entire expenditure under child health in the plan budget is allocated for the pulse polio program (and another wasteful universal hepatitis B program). She pointed out that children in many parts of the country have received at times more than 25 doses of the polio vaccine and the consequences to their health were not spelled out at all. Neither was the possibility of serious impact, such as explosive epidemics in future have been evaluated. There is a need to examine whose interests the programme is serving. Since donor fatigue has set in now, who will deal with the future adverse affects

of the programme? She concluded that to turn what a French Queen had said once "If they do not have bread why don't they eat cake," today we have the situation, "if they do not have water, give them polio drops."

Dr. Jacob John who had kindly consented to attend this meet was asked to respond as the expert and pioneer of the pulse polio strategy in the country. He said that the terms like "eradication" and "elimination" were technically not different and that "eradication" was not specific to polio alone but a generic issue as could be seen from the example of the TB control program of 1962. He said that in the government sector nobody takes responsibility and avoiding accountability on the part of the government is the critical issue that needs to be looked at. He also expressed that though the goals could not be faulted, the "tactics" are wrong, and it is these "tactics" that are unscientific, not public-health friendly and not economically viable. The Global Polio Eradication Initiative (GPEI) was unscientific because exclusive use of OPVs in the program is inefficient, and unsafe; further it is not public health friendly because plunging into eradication without control was the wrong strategy and money for UIP was wasted in providing OPV. He further opined that the Government of India did not know where to go from 2006 onwards; polio cannot be eradicated without use of IPV, as OPV cannot really bring about herd immunity. There were questions from the house on countries where polio was eradicated to which he replied that in about 120 countries in the world wild polio virus was not found and in Bangladesh since last five years there has been zero incidence of wild or vaccine virus caused cases. However in an Indonesian island, 45000 children were infected by the vaccine virus out of which 45 cases were detected. He did not respond to the question of the political implication of eradication in a post-9/11 world.

The group broke up for lunch animatedly discussing the morning presentations.

Session 3: Post-Lunch

The post-lunch session began with Ravi Duggal on, "NRHM: Quality and Cost Issues." The National Rural Health Mission (NRHM) came as a promise of the new coalition government in the centre, as part of its stated commitments; only that people did not ask why the word "rural" was being used. There was really nothing new in NRHM, except that the public health sector was being reorganised with the World Bank strategy of selective targeted care, which opposes the principle of universal care. There is no universality of healthcare and the *Rogi Kalyan Samithi*, taken from the Madhya Pradesh experience, he considered, was a risk. The new dimension of NRHM could also be seen as an opportunity in its engagement with civil society. The *Jan Swasthya Abhiyan* (JSA) has recently got involved in the monitoring of NRHM.

Ravi presented a summary of Rajib Dasgupta's study and said that the Indian Public Health Standard (IPHS) component focuses only on the 30-bed Community Health Centre. The Bureau of Indian Standards has already set standards for hospitals of various types, but the IPHS does not talk about standards for the private sector at all. NRHM further talks of assured services, but does it become a justiciable right, he asked? Critical quantity is the first dimension of quality. Therefore basic minimum quantum of services needs to be established; to talk of quality and not just talk of isolated programmes is not very meaningful. The present allocation for health, which is less than 1% of GDP, is not enough. Health being a state subject, the increase in budget has to be both central and state government. The household burden of spending is 5-6% of GDP, and mostly goes to the private sector out of which at least half is irrational, wasteful expenditure. In the context of developing countries, there is need to remember that health is a public good and the role of the state is very central to making this (public health services) available.Regulating and organising the private sector as a part of public health should be the responsibility of the state. Various means like health cess, health insurance, etc. should be used to pool resources. It is seen that private companies like ICICI are promoting community health insurance in states like Assam and Kerala, but they have no mandate to assure health care for all.

Anand Zachariah followed with, "Access to health care for all: what can we learn from AIDS?" He emphasised on the issue of disease categories and said that there was a culture around disease categories in medical knowledge and among people. Post-Traumatic Stress Disorder (PTSD) was a political response of the US government to legitimise the sufferings of the war veterans of Vietnam. This later became universalised and included in DSM III (Diagnostic and Statistical Manual of the US). However, in most of these categories, the historic origin is not visible. Culture around medical knowledge offers scope for change. For example, AIDS in 1981 was associated with the gay community, which is a stigmatised community, but now it is gradually changing. It has become imperative to provide free ARVs and AIDS has become political issue. This was possible because of people's initiative, and in this the role played by the gay lobby was crucial. He quoted the examples of Brazil, Thailand, South Africa and Indian pharmaceuticals in bringing down the costs of ART. Finally he stressed on the fact that treatment should be made affordable and that there should be a will to provide treatment.

Session 4: Plenary Discussion, Day 1

(The following section contains the highlights of the discussions after the presentations on the first day of the mfc Annual Meet, Jan 27, 2006. The section contains details of the opinions expressed, questions asked and summaries of discussions).

There was a question whether the scope of discussion was confined to *healthcare or* included *health* also. The response was that the discussion was related to health care and public health initiatives.

Regarding access to healthcare, it was pointed out that the average monthly income of many families was below Rs. 1000 per month, and they could not even afford the cost of LOCOST medicines for illnesses like TB. Hence *improvement in economics and education was required to improve health*.
Another issue that came up was about the *linking mechanisms* that existed at the lower levels like hamlet level and between levels. It was felt that linking mechanisms do not exist as people do not talk to each other and do not trust each other. Hence there was a lack of linkages between them. An example of some linkages given was that quality care would be expensive, but it did not mean that those in need had to bear the costs. Somebody else could pay for it, if proper linkages were made and systems worked out to make the linkages work. A question was raised by another participant about the need for looking at linkages outside when an existing system of primary health care is a linkage which is very much within. It was also pointed out that our efforts need to be put into making that linkage work.

While talking of quality, it was pointed out that there were *individual responses of excellence but the system did not respond to it*.

A participant pointed out the example of AMUL and self-sufficiency in food production (cited in one of the presentations) could not be a parallel in healthcare, because it was found that these advancements increased the production of milk and food but did not enable the capacity of large numbers of people to buy these products. And *in health care it was found that even the lowest possible level of care could not be afforded by the poorest and*

they have to take loan to access it.

Regarding the issue of quality standards, it was found that the *standards set by the private sector were not necessarily the best* and it should not be blindly replicated in the public sector. An example given was the overmedication happening in the private sector.

A participant stated that there were *very little epidemiological data in India*, and that US and UK data was quoted whenever we spoke of a disease. *In the absence of data the decision regarding what to treat and how much does it cost was difficult*.

The participant said that while the need for having low cost solutions was important, it was very difficult to know the quality of a low cost drug or surgical equipment bought as there was *no regulatory mechanism*.

A participant spoke of the present global scenario, where privatisation was increasing in all spheres, and so also in India. He felt that the *public sector allocation for health would continue to reduce*, and wondered whether new initiatives like NRHM would be of any use? Drugs were also not available to the health centre, so *would NRHM be able to do anything*? One participant felt that the National Rural Health Mission (NRHM) was trying to ensure that health services were accessible to people. Certain goals were set to be met by 2012. If they were met, more than 90% of our problems would be met. Hence *the meeting of the goals of NRHM needs to be monitored*. The participant said that NRHM is trying to bring the vertical programmes together. PPP is talked about but *regulation both in quality and cost is not addressed*. As mfc, we have to present our own alternatives, but if universalisation of access to health care is to be done, we need to work out the costs and see how it can happen in an accountable manner. The entire issue of segmentation has to be addressed. Another participant said that the basics should be carefully laid out. He said that *the structure was primarily doctor-centric and there was limited role for other healthcare professionals*. Hence there was a need to question the structure. We need to critically examine how the public healthcare framework model was built in India.

Regarding polio vaccine, a participant felt that it was *much more important to attend to the sanitation and water treatment needs rather than giving more importance to OPV or IPV as the mode of transmission could be taken care of*.

In Indian public health policymaking process, there was *no reliance on sound data or information*. *Quality often assumes rationality, but that is questionable*. We need to question the process of decision making. The outcome indicators need to be questioned. There are no standard indicators, though attempts have been made.

One of the main learning we can take from the HIV/ AIDS campaign is that *infected people have fought for their rights and have been a part of the decision making process*. The mental block of being superior because you are not infected has to be removed. Everyone has to work together.

A participant asked about the privatisation of health care and asked if there had been regulation of private sector in any country.

Another participant brought the group's attention to the social situation that was grim. *The social determinants of health have worsened in the last decade*. Non-availability of nutrition and employment has reversed the gains. Poverty has to be considered and poor people need to be provided for, if we need to make a change. We see all sorts of anomalies in having access to Below Poverty Line (BPL) card, which is one of the last social insurance existing in the country. Even from a health and health care perspective, we need to work on the issue of access to BPL card and the criteria set for obtaining one. A discussion about *minimalist package for the poor* took place where a participant stated that it had not worked. In a hegemonic rural society, people of higher class and caste will access the cards. The BPL cards distribution system has systematically reduced the number of people having access to BPL cards. The poor are left to fend for themselves when they are ill. The private medical insurance that we have, don't leave many of us who go to the public health services or access social insurance. The basic quality of the public system won't change, because of the segmentation.

Another problem was the *selective tackling of disease in a war or campaign mode*. We need to question things like tubectomy camps. *People setting targets like pathogens eliminating themselves by 2005 or so is ridiculous*. Where are these targets coming from? We need to critically look at all the programmes and the targets.

In popular public policy making, *people's participation and people's perspective have a role to play*. Another participant wondered about how we could talk of quality when a poor person went to a public health structure which was functioning improperly or not functioning at all?

A participant opined that while talking of conceptual framework, it was important to look at "*Quality from whose perspective"*? The users' perspective has to be taken. People may want injections or sex-selective abortions. There is an interface here, and the questions of ethics and rationality come into play here. There is a concern that the number of medical students studying with government colleges have come down from 688 to 320 in Karnataka due to the reduction of seats. This causes a *reduction in the number of politically active and socially conscious doctors to come down*. Speaking about medical education, one participant felt that If Bangalore Medical College (BMC) shuts down, the public health scenario will not change because it does not ensure that people go to work in rural areas. This point was contested as other participants felt that students paying Rs. Thirty lakhs were unlikely to go to serve in rural areas. Number of seats in government sector has decreased, and doctors on payment seat do not go to the rural areas but go abroad or set up private practise. It is found that students who are poor and come from reserved seats are more likely to go back to smaller places from where they come.

Mass program funds and donors get hijacked by political persons or some others with certain interests. In this context we need to build up grassroots organisations like cultural and religious organisations and educate the grassroots.

We need to recognise people's role in policy making and how the rights of the powerful get attention as seen in the case of AIDS like the positive groups of gay white men who were instrumental in bringing AIDS to the centre stage.

When *we say segmentation of health services we assume that the rich are getting the best and poor getting the worst*; but if you look at the number of times the polio drops are given in a universal manner it affects both classes. In the iodine study, people did not buy iodised salt even in endemic areas because of their choice based on their life situation — as technical people we need to understand this.

The quality of health care needs to be seen from the *perspective of providers* also. They work in the absence of any facilities. They are also trained in irrational and inappropriate technology during their student days. How can we then expect them to work rationally? *Mfc should get involved in re-writing the medical education textbooks*.

When we talk of medical education and quality of health care, we need to examine what is the *quality of training to providers*. The numbers of colleges training students in alternative systems of

medicine are also going up. The colleges are set up to earn money and the students join the course as they won't go unemployed. Many of them get into public health system because they do not have any other options. And they join on recommendation of politicians. *Mfc should look at involving students* as in this stage they can be inspired and taught about rational drugs, right to health and health for all. A participant gave her own example and said that she had come from a students' movement herself and that she was inspired during her student days.

Where do the Rural Medical Practitioners (RMPs) fit in when we speak of quality in healthcare? People who can not afford proper doctors go to them and others who are less than fully qualified. We need to think of them too, when we talk of quality. The Government of India is trying to standardise hospitals including the rural private hospitals and those run by NGOs and other charitable institutions. Many of these standards are not appropriate for the kind of rural services available. This will increase the cost of health care. The Association of Rural Surgeons of India is trying to fight these. Would mfc be interested in joining them?

Lobbying is not ideal for health issues as commercial sector also lobbies and we cannot dream of beating them in this game. *It is also not comparable to a democratic process*. *Lobbying has often come to replace collective struggle*. This leads to us getting what others allow us to have, and not necessarily what people need.

The HIV patients were being used by people (NGOs) and it was not a people's movement. Even if health care is affordable, there is no guarantee that they may be accessed by the poor.

Health financing has to be seen not as a percentage of GDP because of the rise in GDP, and it could be misleading.

Quality of healthcare should be linked to Right to Information so that data like outcomes of treatment can be made public.

There appears to be only two options before the poor – either to die or to kill their whole family and die. The poor go to the RMPs and they have to take loans at high rates of interest from the local money lender, to meet their medical costs and finally they lose land. In this context, what kind of quality are we taking about.

The Government awards war veterans of Kargil, but *nobody spares a thought for the mother who loses her life*, in giving birth, due to lack of infrastructure in Government hospitals.

There is a misconception that buying low cost drugs is below their dignity as they *equate low cost with low quality*. People need to be sensitised regarding this.

Demanding increased budget as a percentage of GDP without bothering about where it is being allocated is an empty demand. There has to be some demand on the systems whereby the money is getting spent. The unutilised funds go back, and there won't be adequate allocation the following year.

There is a need for decentralisation as now money lies on one side and power to use the money lies on the other. People at the periphery are confused. The people at the level who can spend money do not have the capacity to spend the money. *What is essential is the implementation of policy and not just the formulation of fantastic policies*, as they already exist. But policies are not happening because orders have to come from the centre and *health personnel at the lower levels are demoralised*.

It often happens that money is released from the Government treasury only in March, and the department is expected to spend the money by March. This leads to a lot of problems. *In the public health system there is a lot of corruption, negligence and inhuman treatment of patients*, 12 case studies were documented under the right to health care campaign.

We need to agitate about the destruction of the public sector Indian drug industry.

There was reference to the quality of public health policy making and a participant brought the group's notice to Dr. Ekbal's paper where it was reported that 40% budget in Kerala was transferred to the *Panchayati Raj Institutions* (PRI). Village has done mapping, etc. According to this model, our theoretical framework should be revisited and *people's voices must be heard, as health is a sense of well being of the people*. Ten years back PRI was not part of popular discourse, unlike now. The debate must be enlarged and more people must be involved.

Role of the midwife is very important but our policies are wiping out her role.

Government has withdrawn from providing anti-rabies vaccine where new policies are leading to increase in costs and inaccessibility.

A participant was of the opinion that having people's say in policy decision can become a reality *when the opinions of people get a mandatory status*. This would assure that policy decisions really address the voice of people and not merely by universalising the Mitanin program as ASHA for the entire country.

Making a reference to the JSA charter, a participant felt that most of it was covered in the new NRHM, but the problem lay in the implementation of these policies. He asked the group to contribute to getting them implemented.

Day 2, January28, 2006

Session 5: Cost and Quality of Health Care at Primary, Secondary and Tertiary Levels (Coordination team: Anand Zachariah, Sara Bhattacharji and Renu Khanna)

Eddie began the session with a Kannada song. The formal sessions began with two presentations.

Anant Phadke, presenting his paper "Excessive Use of Screening and Diagnostic Tests," spoke about the great deal of money being wasted on medical investigations that are unnecessary. He gave the example of "stress test" as of being little value when conducted in general population for a screening. It is more than likely that even when a person does not have the disease s/he might get labelled as a patient of Ischemic Heart Disease (IHD) because of its low predictive value and then be burdened with medication. He also added that there is a tendency to refer patients for unnecessary investigations. He was of the opinion that diagnostic and screening tests have to be applied only when they are absolutely essential, in high-risk groups. It is the commercialisation of health care which is leading to the violation of scientific principles such as the Bayesian theorem. How can the cost of intervention (without reducing the quality of essential care), as well as how cost of essential care be reduced needed to be considered. He opined that there has to be some rationality about the fees of surgeons and physicians and a need for mechanism for regulation needs to be evolved.

Prabir Chatterjee presented a paper ("The Business of Healing") by Sathyamala, which was written around a narrative of an activist doctor[1] (paper entitled "Misplaced Faith?") who in her efforts to seek a rational, safe and effective treatment during an episode of *status asthmaticus*. Her experiences in a nursing home run by

[1]Arti Sawhny, the author of "Misplaced faith?" initially did not want her identity to be revealed but later decided to publish it in her name and this has been published in the previous issue of the bulletin.

missionaries, a public sector hospital (both in a small town) and a private trust hospital in the capital, all showed that irrespective of the nature of the institution, the "care" she received was uniformly bad; in one, it was the inappropriate treatment and in another it was the callous attitude of the health professionals. This was despite the fact that she was a doctor (and therefore knowledgeable) and had lived a life struggling against injustices in society. Finally, she was also landed up with a huge bill.

Sathya's narrative was about her experiences as a medical student, the reasons for her moving away from clinical care, her journey through the voluntary health sector and the evolution of ideas regarding public heath. Some of the observations made in her paper were that there is a clear class/caste hierarchy in the health personnel in the country; medical students learn on the bodies of the poor; and patients are subjected to humiliation in hospital (for example, when the nurses and other staff treat them with contempt and doctors discuss about them in a language not understood by them). She mentioned some myths popularised about patient behaviour like - patients do not seek care at the earliest because they are uneducated, they throw away the medicines if it is provided "free", TB patients "default" as they do not want to continue and complete the treatment regimen, etc. The critical issue, she asked, in assessing quality of care, was whose perspective should prevail: the doctors' or the patients'? And who is to decide?

Venkatesan presented "The General Practice Approach - the Age-Old Strategy to Limit Cost," a paper by the team at the Low Cost Effective Care Unit (LCECU), CMC, on their experiences of working with an alternative model for poor patients. He introduced the concept of cost effective care in health. Patients were seeking care from the medical college hospital where all types of specialised care are available but this turns out to be unaffordable. It is therefore necessary to remember the cost effectiveness of general practice care, though the advanced investigation is required at times. General practice can play the "gatekeeper's" role in the system. With this, 30% of the referrals have come down. Specialists have to exclude certain difficult cases and hence suggest advanced investigations. For instance, in the hospital, even in a case of headache, the neurologist would suggest MRI to rule out complicated diagnosis. Care for diabetes by specialist is - Consultation charges: Rs.240; Lab tests: Rs.1225; 3 visits for the patients, whereas, by a generalist in LCECU is - Consultation charges: Rs.65; Lab tests: Rs.270 and only 2 visits. Similarly, for childhood pneumonia, costs in specialist care: Investigations: Rs.1150 and admission for 5 days, whereas, generalist care in LCECU: costs for Investigations is Nil and admission x 3 days. In their assessment, for cost effectiveness early diagnosis has a major role to play. All Western countries have taken this up and it has proved to be a very cost effective method, in which the GP provides comprehensive care, health education, personalised (individualized) care. The vision that he stated was: GPs in India should be trained in family medicine, communication skills, and appropriate use of lab tests. And Family Medicine should be included in the undergraduate curriculum.

Vinod Shah presented a paper on "Some Strategies to Cut Health Care Costs." Distance education, was important in improving quality of care in a situation where there is a lack of multi-competent doctors. At present, GPs cannot take care of 60 to 70% of medical conditions. He quoted statistics on the number of medical practitioners in the country as per the MCI. In our country, there is nothing like re-licensing of doctors. Doctors in most hospitals do not have a culture of continued learning and rarely if ever read journals. He said that trained medical practitioners have to compete with the quacks and practitioners of other systems (who practice allopathy despite not being trained in it). This is exploitative towards the patients because of the unfair competition. And private practitioners are a very important cause for pushing people below poverty line. He said that Family Medicine as a discipline could be proposed in two ways: intensive, which can produce good family physicians but not serve the mass needs of the country and extensive which can train thousands of doctors by distance education and contact programmes. He stated that the advantages of distance education are that it is low cost, covers large numbers and can be as effective as traditional training methods (since those who participate in them are highly motivated people). However, a major disadvantage in this process was the high drop out rate. In the training programme they conduct, the approach is problem based rather than system based and this has a professional impact and makes the practice more rational. Many medical practitioners are not aware of ethical practices and this approach can address this issue. It can also create sensitivity towards gender issues. There could be a public health impact by working with the government. The quality of care can also be improved by training doctors to improve their bed-side manners too. He stated that he was working towards a decentralised model and was in the process of negotiating with ISRO for satellite mentoring.

Anurag Bhargava spoke about access to health care by the poor in the paper prepared by the JSS team, "Health Care In India: Looking Behind the Smoke Screen of Access, Quality and Cost." His chief concern was: How did the situation of private and public sector mix get legitimised? He despaired of being able to change the system. What do the following terms mean: primary, secondary and tertiary care in Indian context, BPL and APL, NHP, etc., he asked. He stated that the requirements for public health facility are doctors, diagnostic sources, drugs and procedures. He gave the example of malaria control intervention which is not sensitive to the local needs/situation and the case of a boy who had a fall and altered sensorium and weaknesses in lower limbs and was referred to PHC and district hospital but could not get appropriate care anywhere.

Biswaroop, spoke about the laboratory run by their organisation, , which can be best suited for a rural area. There is a referral centre with OPD, a ward with 15 beds and 2 OTs. Three outreach clinics per week are conducted in forest fringe and forest villages. The lab supports all three levels of service, including the village health programmes. Some of the key messages that Biswaroop, who is incharge of the laboratory at JSS, conveyed were:

-Microscope is the most cost effective investment of small lab and can be used for dozens of tests.
-Use defined test panels for special symptoms to save time.
-Lab is not a panacea for quality care; it must be linked with standard treatment guidelines.
-If a particular treatment strategy is not required it need not be done. He gave an example of how "lab reaches the patients and not merely wanting the patients to reach the lab."

Anurag discussed the findings of expenditure on health from their study at JSS "Is Curative Health Care Possible without a Welfare State? Lessons from a Non-Profit Community Health Programme in Rural Chhattisgarh." He concluded that the poor fall ill more often and for them even a low cost health care is not affordable. Substantial part of their health care is on transport. The study showed that 35% of the population was not accessing care from any provider at all.

These presentations were followed by discussion. The main points were summarised and put up in flip charts (See box 1).

Box 1: Issues for Discussion

• Lab:
– Identify need for diagnosis criteria in a remote setting
– Costing of investigations
– Equipment for investigations
– Quality control in lab
• Nursing Care standards
• Cost-effective interventions - quality/protocols
• Financing/"Robinhood
• Medical education: lab testing - cost-effectiveness
• Cost to patients - opportunity
• Loss of earning
• Doctor shopping
• "Quacks"
• Role of locally trained health workers
• Clinical competence - skills/ethics
• Over specialization - general practice
• Traditional medicine vs mainstream medicine
• Other low cost options
• Quality of medicine
• Caste - sex
• Professional authority
• Role of distance education/Appropriate education
• Transparency of medical charges "Accountability
• Under utilization and over utilization of technology / cost
• Who is the poor?/BPL
• Referral system - gate keeping
• Govt. subsidy to private sector
• Basic care access to all not only for poor
• Aging population - chronic diseases
• How can a "disempowered person" deal with system/ professional authority even for "empowered person"
• Low cost labelling resulting in? Dichotomy
• What is Rationale therapeutic care?
• What determines referral? Managing without referral
• Emergency Medicine

Session 6 (day 2, pre-lunch)

Shamanna spoke about his institute, AV Prasad Eye institute, at Hyderabad ("Eye Care Service Delivery for Rural Area, Comprehensive and Sustainable Approach: The LV Prasad Eye Institute Rural Eye Care Model"). This is a tertiary care institute with a top to down approach for providing high quality eye-care. It is working to provide better care for its patients, and realised that the quality of training of the ophthalmologists was very poor in the country so have been conducting number of training programmes also. The Institute gives fellowship training, has established centres that provide basic eye-care facilities and has a centre for rehabilitation and eye enhancement and also invests in non-economically viable inputs required for eye care. For instance, it does not provide spectacles that are available in the market but is involved in providing cornea, magnifiers, etc., that are not available, as they are not profit-making devices. Against the camp approach of previous eye-care units, the Institute has established permanent or semi-permanent setup within, or close to, the communities, called the "Vision Centres" and have the trained "Vision Guardians" drawn from the local community – ensuring the sustainability of the centre and enhancing the local awareness level. The Institute does not use government subsidies, the reason being the government system is corrupt and non-functional that does not provide the ground for effective financial collaboration, besides it is easily possible for them to gets their funding from external agencies – "leaving the subsidies for those who actually need them." They adopt the modern "Robin Hood" approach to cover the 60% of the patients who cannot pay.

Prof. Chandy spoke about his way of providing care of leukaemia patients ("An Approach to the Management of Leukaemia in the Developing World"). He has worked out three different treatment protocols for patients with leukaemia by categorizing them into three groups on the basis of their income and accordingly prioritising the treatment. Although there could be an ethical concern as they are "unequal" treatment schedules, this concern can be answered by fact that there are already existent economic inequalities in the society.

Mathew spoke about his experiences in rural surgical care. Regi too presented on his rural surgery experience.

Jacob John spoke about the reducing cost in his paper "Cost Containment in Trauma Care Services - Limited Experiences." He presented the various innovations, improvisation and adaptations in surgical procedures and critical care that makes surgical care more cost-effective. The use of mosquito nets for hernia repair, use of home made preparations for parenteral nutrition therapy and highly restricted use of antibiotics in various surgeries, even in serious trauma cases (including skull fractures and craniotomies) were some of them. The suggested methods have been tested for their effectiveness and it was seen that they can cut the costs up to 40-60% and moreover, at times, less interventionist. Effective training of the nurses and junior doctors in early management of trauma patients, such as intubations, also brings about better outcome of therapies.

Karthik's experience in working in a rural community has shown the presence of a large number of cases of hypertension and diabetes in the population with whom he works. Such problems amount to 50% of their total case load. The people in the area are the poor and weigh not more than 40-50 kg. It was also observed that they do not have the stated risk factors for these non-communicable diseases. In their centre, they could manage hypertension with relatively inexpensive drugs but insulin becomes unaffordable. These 'lifestyle" diseases and others like cataracts make the people unable to work and lead to social exclusion. Kartik is planning on a study to understand the link between malnutrition/stress and the problems of Hypertension & diabetes. He would send the study design on request.

There was a comment that consumption of industrial salt is very common in low-income groups, which could give rise to epidemic of hypertension. And now with the ban on non-iodised salts its consumption would only increase.

Issues recognised:
- Demystification of super-specialist knowledge in health care, e.g., use of banana leaves for burn dressing and putting the burn and leprosy cases in the same ward by Dr. Antia.
- Mainstreaming the "low cost" care strategies
- Indigenous systems of medicines
- Dissemination of information about various treatment protocols developed by various community-centred and tertiary care centres that e.g., protocols that depend on low antibiotic doses, or are low cost.

Discussion

The session was summed up by Anant Phadke who proposed that the following session should flesh out the issues thrown up in the two days, the "learnings" we got and where and how do we go from here. The following issues were then identified and the participants were divided into sub-groups to discuss each of these issues in depth (See Box 2)

Box 2: Enhancing the Caring Aspect Of Health Care

- Training, peer examples, role of consumer organizations,
- Reducing Class, caste, ender, urban bias
- Curbing commercialization, professional arrogance
- Non-allopathic practices
- Needs of old people

Cost Saving Measures

A) Investigations
- Minimizing unnecessary investigations
- Minimizing COST of necessary investigations
- Cost-audit of labs
- Use of lab to avoid costly shot gun therapy, State of the art technology is not always necessary, for example, more, better use of the microscope,
- Using more investigations at PHCs – glucometer, urinary HCG test for detecting pregnancy

B) Training
- Role of general practioner, of para medics, reducing unnecessary referrals
- Distance Education
- Better clinical training for generalists, including a better understanding of Baysian principle
- Better training about more cost-effective interventions, cost effective protocols
- Health education to break the myth "Higher the price, better the quality"

C) Reduction in treatment cost
- High cost "State of the art" technology is not always necessary, "State of the art" technology can be cheaper than conventional
- Reduction in building cost, equipment,
- Cost – effective materials – sutures, mosquito nets, reusable, glass syringes, nylon sutures, innovative use of Ryles tube etc.
- Proper training of Paramedics, demystification
- Avoidance of unnecessary medicines, irrational medicines, cleanliness in peri-operative care to avoid unnecessary use of anti-microbials, alternative to conventional spacers for asthma patients, use of low cost standard medicines
- Non-allopathic medicines
- Mainstreaming of these innovations, universal protocols adaptation

D) Special issues
- Epidemic of diabetes and hypertension amongst the rural poor
- Chronic diseases

The highlights and conclusions reached by the sub-groups were then presented in the plenary in the post-lunch session. These are given below:

Sub-Group 1: Caring Aspects: Enhancing Caring Aspects in Health Care

- Not only treating disease but also healing the person.
- Both tangible and intangibles.
- Caring environment - both structural and cultural: Providers and users.
- Patient Rights: incorporation within the model of caring.
- Myth: Users don't want information which arises from the expectation that patients have very low expectations from the providers.

Components
- Client-Provider Relationship.
- Communication: Verbal and non-verbal. Training and communication:
- Manner of communication should be rooted in a particular cultural context.
- Patient's Rights: Information, choice, ask questions, raise expectations.
- Training/Textbooks: promote, teach, model of caring along with treating.
- Emphasis on technology: loss of acumen and personal skills.
- Professional arrogance: caste, class, gender, age.
- Non-allopathic systems also have similar biases.
- Use of too much technology with reduced interaction between the health provider and use, leading to loss of skills.

Strategies

Mechanism/Tools such as:
- Making of institutional charter along with community; this is dynamic process-to make institutions more transparent and accountable.
- Role of MCI: re-examine and re-structure.
- Demystification and transparency by medical practitioners by People's Access to knowledge systems.
- Treatment protocol, both allopathic and non-allopathic, in terms of ethical practice, consent etc be prepared.
- Make information culturally more sensitive, and relevant
- Need alternatives to current trend of commercialised health care that increases disparities and privileges dominant socio-economic groups.
- A parallel process to make such mechanisms/ tools more accountable on the one hand and increase awareness on the other.
- Access to knowledge systems
- Community should be given space for sharing their expectations from the institutions. This can then feed into institutional charters.

Sub-Group 2: Investigations and Technology

What are the ways to minimise unnecessary investigations was the question the group started with.

- By taking a good clinical history and a good clinical examination.
- Creation of standard test panels: Critically look at the existing test panels. For example, in surgery for hernia, is it necessary to go through the battery of tests that patients are subjected to.
- Reducing different kinds of "cuts and commissions" to others would ensure lower costs.
- Dissemination of information among the general public.
- Improve doctor- patient relationship would reduce concerns about "consumer litigation" and hence not pressurise the doctor to prescribe high number of tests.
- Access to GP at all times, at geographically available locations.
- Sensitise medical students about poverty and cost issues.

Limiting the Cost of Necessary Investigations
- Use centralised facilities for those tests where the economics of scale operates.
- Ensure greater accountability on the part of laboratories in the public sector.
- Have regulatory mechanisms for the private sector. Ask LOCOST to make lab consumables.
- Cost accounting of laboratories
- Infrastructure
- Consumables
- Overheads
- Maintenance and depreciation of instruments
- Salaries

Training of staff and upgrading are other important areas.

The group was emphatic about the need to carry out this exercise

in different part of the country and its different levels of health care.

Sub-Group 3: Issues in Current Medical Training

- Communication: Psychology, sensitivity, socio-economic conditions, gender sensitivity are not taught in medical colleges.
- Textbooks not relevant (foreign authors and contexts). For example, one professor for community medicine for the entire state of Karnataka.
- Continuing medical training after finishing degree (re certification).
- Not able to question professors, doctors (lack of courage professional arrogance).
- Taught generic names of drugs in college (positive), but brand names in practice.
- Declining government seats, high tuition in private institutions.

Where do we go from here?

- Introduction of community medicine early in training.
- 50% of the training should be outside hospital.
- Role of voluntary, multipurpose health workers needs to be recognised.
- Provide reading materials to sensitise about socio-economic status about challenges, needs of community.
- Providing role models for students, mentoring. mfc members should visit medical institutions and teachers can visit rural areas.
- Students can and should form their own mfc at college and state level.
- Recognise alternative systems of healthcare – their incorporation into the health system.

Sub-Group 4: Reducing Cost of Healthcare

- Building infrastructure, local material, simple structure, local human resources' involvement.
- Training, simple, long intensive with miniature of local people (many successful models).
- Rational care needs minimal equipment.
- Management systems and planning in detail - data record systems for local needs derived from protocols and other evidences.
- Medical care as a turnover industry. If more frequent turnover costs is less. Economic principle.

Sharing of experiences of people in group

- For reducing costs – reduce costs of infrastructure.
- In case of training, what is important is quality of care and quality of training is of higher importance than formal degree/ qualification. So even a class V educated person from the community can be trained effectively and ensure quality of care.
- The question of infrastructure, and what is the basic/ minimum for running a quality care need to be ascertained
- Rationale care with basic infrastructure, basic equipment is possible
- Management issues/ processes from the industry model can be humanised and used in case of health care because health care is a industry working on economy of scale based on principle number of turnover
- Adaptation of standard universal protocol according to locally relevant needs

One comment on the presentations were that the whole dynamics of GP question need to be taken into account – the model of Britain, Australia could be followed and a separate National Board for General/ Family Practice be made. It was also felt that health care delivery at any level should focus on competence of the professionals, institutions and right behaviour by health professional both at professional and human level. The tools to achieve this is to use better management procedures to maintain infrastructure, training, techniques for managing process and other resources.

The concluding session began with Sathyamala summarising the key issues that had been culled out from the discussions of both the days of the meet.

These were:

❖ Principles on quality of services and patient care to be applicable to both within the public and private sector and which standard should prevail?

❖ What are the principles that can be used to guide assessment of quality of services? These could be on the basis of efficacy, safety, cost, regularity/sustainability, and access and provider-user interaction. Quality of health care from a public health perspective, including but not relying upon clinical criteria alone for assessment.

❖ Is "low cost" synonymous with cost for the poor? Is optimal care to be different for the rich and the poor? Or is reducing cost only as it relates to the economic status of patient or is it part of rational therapeutics? And how to *mainstream* low cost as the rationale for care. Quality and cost of health care in the context of the goal of universal access. Would one compromise the other or can they both co-exist?

❖ Are we thinking of reforming the existing system or supporting the formation of alternative models of health care delivery as oasis/ places of excellence, not possible to replicate? Sub-group 2 was for centralisation. How do we see de-centralisation in this context?

❖ Economics of cost: large numbers and large turnovers of patients are said reduce unit cost (hence the idea of putting a hospital in a "catchment" area). That is why big hospitals were built. But excessive turnover can affect the quality of care for want of adequate time to give appropriate attention to patient's needs. Regulation, auditing and cost accounting is another key issue. But how is to be operationalised? Who will do it? What about social accountability to the communities where we are situated in?

❖ How does one apportion scarce resources? At the community level, at the national level? Where does one draw the line in terms of technological sophistication?

❖ Is the demand to increase the allocation to the health sector in itself sufficient? Should we not also outline how it should be spent? Otherwise will it not be wasted away as in the polio eradication programme?

❖ Issues of training- Medical education are the key. Training inputs at all levels of medical education, levels of health personnel. What of continuing education? How can the work being carried out as experiments in the alternate sector be fed back into medical education? Who will re-orient (and how) the doctors already out there?

❖ Caring to be considered not merely as good "bedside" manner but as central to therapeutics. Not just treating the disease but *healing* the patient is critical. The use of terminology and the change in terminology - patient/doctor, user/provider, client/provider need to examined critically. David Werner in his *Where There is no Doctor*" does not use the word patient even once.

❖ Should care consist of only the modern system of medicine or how does one integrate other "pathies". Is integration of other systems only to reduce costs or are they to be promoted as valuable and at times better systems of healing.

❖ Finally, the selection, training and the role of medical/ health professional has to be seen in the current social context of increasing violence, poverty, deprivation and privatisation

Sathya then opened the floor for discussion which was to be free flowing.

- A participant explained the term "scale of economy" being generally related to the industry but the principle is to do

more work per unit. Similarly increase in the number of patients ensures more cost effectiveness. Turnover health care is a turn over industry and we need to manage it. Therefore more turnover frequency the cost is less.

•There was opinion expressed that people's involvement ensured a shift from top down to a bottom-up approach. We should be able to look at mainstreaming the alternative cost effective interventions. Indian protocols need to be shared; given the anarchy of technology, may be mfc can look at this as a work to be carried forward. The way forward for mfc was then discussed where it was felt that small groups should be set up to document the alternative cost effective interventions taking place all over the country. Effective campaign should be carried out by mfc to regulate the private sector. The rationale for appropriate cost needs to be developed, which in turn can create social demands. Rational guidelines of standard treatment should be based on indications. Also important to develop systems of social regulation. *"If the oasis does not spread through the desert, the desert will overcome" was what one participant put graphically.* Therefore there is a need to move out of isolation and identify strategies to impact others. Although advocacy is important, it maybe more useful to impact neighbouring individual, groups, organisations through individual efforts. Need to address the pathologies in private sector with mechanisms like Consumer Protection Act and need to work with legal networks. The pharma policy needs to be closely monitored and requires intervention as 70% of costs of health care is due to drugs and has a tremendous effect on health care. However, it is important to continue to address problems in the public system as a larger majority of people continue to access it. Strengthening public health systems (PHCs) by actually using them by mfc members; holding them accountable.

- In response to Anant's suggestion that initiatives, training, etc., should be documented; Regi from Dharmapuri said that they had done a lot of work but had no time to document the work. Therefore external support in doing this would be welcome.
- Alternative cost-effective system that could be incorporated into the public health system.
- Increase in privatisation which is also apparent in medical education. About Rs 30 lakh fees can automatically lead to unethical practices of recovery. There was a need to regulate technology - like CT scan - and laboratory services in a given geographical area. New medical technologies need to / can be regulated by Drugs and Cosmetics Act. The existing paradigm of quality might have discrepancies with that of the people and mfc.
- mfc has an important role to play in demystification but with rapid technological advancements, it would be extremely essential to evolve new ways to keep up with them. Cost effective experiences that were shared should be disseminated through journals, bulletins and incorporated in training for medical students. Teleconference as a possibility at the PHC to assist doctors.
- Strategy to disseminate mfc concerns using visual media, to counter existing "unacceptable", "problematic", media campaigns. Visual media is not expensive to create and can also be used to highlight the experiences of alternative models of health care.
- Formation of smaller groups (cells) within mfc to address different concerns -public policy, documentation of experiences, protocols, etc.
- Issues of user fees need to be taken in consideration as it has been shown that quantum of morbidity increases with increase in user fees. If a premium institution like AIIMS introduce user fees this will be replicated at various other levels.

Reporting coordinated by C. Sathyamala and Sathyashree. Rapporteurs: Sathyasree, Neeta, Sarika, Jyothi, Naveen, Williams Rachna, Asha, Deepa, Manjir, Sashwati, and Preeti. Comments on minutes by Ritu Priya.

---

mfc GBM

Minutes of the 31st GBM of Mfc

Sneha Deepam, Vellore, Jan 29, 2006

Attendees included: Alpana Sagar, Anand Zachariah, Anant Bhan, Anant Phadke, Anurag Bhargava, Binayak Sen, C. Sathyamala, Dhananjay Kakde, Jyoti Gupta, M. Sivakami, Manmohan Sharma, Manisha Gupte, Manjir Mukherjee, Mira Shiva, N. Kannan, Neeta S. Rao, Prabir Chatterjee, Prachin Kumar, Preeti Nayak, Ravi D'Souza, Ravi Duggal, Renu Khanna, S. Srinivasan (Chinu), Sangita Kumbhar, Sarojini N.B., Saswati Bhattacharya, Sathyashree, Shekhar Saha, William Rachna.

Meeting conducted by the convenore Dr. Ritu Priya

The meeting began with a feeling of well being as this mfc meet was well attended with enthusiastic participation, there had been a large number of background papers, from the local organizers had done a commendable job in terms of board/lodging hospitality and other support arrangements, and there were many new comers, particularly medical students who had become a rarity in the mfc meet. Anant congratulated the convener, the organizing team and local hosts for the wonderful meet. The following account gives a summary of the discussions and decisions taken during the GB.

Follow-Up of the Current Meet

1. Anant went on to suggest that as a follow up of this meet, mfc could evolve a critique of Public Health Policy in India. The suggestion was that the body of work that has been presented in the meet and that exists in India could be taken forward either as mfc or as part of a different network, such as the JSA (*Jan Swasthya Abhiyan*). Whether the issues can be converted into a mass campaign needed to be seen. Both Anurag and Kalantri had felt that taking up rationality of diagnostics as a campaign issue would be difficult. Standardised protocols for surgery etc exist and despite all this there is gross irrationality in the private sector. There was a need to prepare a good document and put it in the public platform and put the private sector on the defensive; this document to be on pre-operative work-ups, screening tests etc, to be used in public hearings after getting consensus from the doctors. There was a need to ask for a ban on advertisements such as "Rs 650, all organs in the abdomen." Alpana Sagar brought up the irrational use of ultrasound tests in pregnancy which had not been discussed in the meet. Decision taken was, a sub-group (Alpana Sagar Anurag, Kalantri, Sathya, Sarojini and Manjari) to look at diagnostics including that in obstetrics.

Anant felt that issues of quality raised on the first day of the meet needed a lot of work and conceptualization. The meet barely touched on the issue of cost. There needed to be some way of comparing experiences with the objective of mainstreaming the experiences. There needs to be transparency regarding costs. What goes into the making of "costs", what is minimum cost; can the idea of cost be put to open debate. One of the most powerful statement made during the meet was, you cannot bring down cost to the level poor people can afford – what does this mean? Prachin raised the question: Is cost factor not part of quality issue and why

was it during the meet these two were being discussed as independent entities? Should cost not be part of rational therapeutics? Mira Shiva said that this time no one seemed to be talking about "false constraints". What should be the priority in health budget? Cost reduction without sacrificing quality has always been the part of rational drug movement. Sub-group was formed to write up the experiences of several groups that had presented their work in this meet. Renu volunteered to visit Regi's place in Dharmapuri district and Anant Bhan volunteered to go with her to document their experiences.

- Sub-group to document experiences: Anand Zachariah, Anant Bhan, Renu Khanna.
- Sub-group on protocol standardization: Ravi D'Souza (convener), Anurag and Binayak with Anand Zachariah as the sounding board.

- Sub-group on Tuberculosis particularly in the light of the 2003 WHO guidelines which have not been made public (Mira Shiva will check from Ministry): Mira Shiva (convener), Binayak, Mira Sadgopal, Anurag and Thelma.

2. Polio was another issue that needed to be taken up for campaign. Anant felt that compared to mfc, JSA was in a better position to launch a nation wide campaign. Sathya reported that Onkar Mittal had written and spoken to Amit Sengupta, one of the convener s of JSA to take up the polio issue right from the time of the people's health assembly meeting in Mumbai in January 2004. But no interest was taken and the issue was not given space during the meet. Later attempts too had been met with less than enthusiasm. Anant reported that Abhay Shukla (who was not present at the GB) wanted to take up issues such as iodisation of salt, polio, and leprosy as part of JSA and had asked Anant to find out whether mfc would be interested in contributing to it. JSA was meeting on 24/25 Feb in Bangalore to finalise decisions on JSA publications. Manmohan Sharma stated that JSA was not always very welcoming and when they had planned to go to the Lucknow meeting last year they were told not to come. There was a discussion about 'credits' if mfc were to work with JSA. Anant said that he was not sure as to JSA policy and if mfc materials were to be used, JSA's decision may be to not use individual names as it was the JSA policy. Sathya pointed out that this was rather strange as the names of the several convener s of JSA figured in published materials of JSA. Anant said that he had in any case given a definite commitment to work with JSA on these issues. Mira Shiva felt that mfc should not get eclipsed and due acknowledgements should be given to those involved in preparing the material. Renu Khanna suggested that Anant should communicate to mfc whatever the decision of JSA is regarding acknowledgements. Irrespective of involvement with JSA in this issue, it was decided that mfc will publish a document on vaccination policy this year. Sathya said that she has already been working towards this and had been collecting materials for this. This monograph and the anthology on infectious diseases (of an earlier meet) will be published this year. Manisha Gupte said that this should be the year of publications for mfc.

- Sub-group on vaccine policy will consist of Sathyamala (convener), Prabir Chatterjee, Alpana, Anant Bhan, Anant Phadke and Ritu.

Discussion on the Theme for the Next Meet

Anurag Bhargava suggested the review of the epidemiology of communicable and non-communicable diseases and what should be the public health response. Anant Phadke reported that Abraham had suggested Medical education as the theme and had offered to host the meet in Hyderabad. Abraham is a former CHC fellow though currently does not have an organizational affiliation, but said that he has a lot of contacts in AP and has offered to work for several months if needed to organize the meet. However, this is the first meet he has attended and only if other members of mfc from Hyderabad are involved then it could be a possibility. Ravi D'Souza commented that mfc has already had a meet on medical education but Anant pointed out that it was 20 years ago. Ritu Priya said that other themes that had come earlier (apart from medical education and epidemiology of diseases), were environmental health, health sector reforms, NGOs and health care. Chinu said that there was need to take up agriculture and seeds, what does it mean for health, and link it up with environmental health. Manmohan said that this issue was particularly important as it is being seen as the reason for increase in incidence of cancers. Sathyashree said that environmental health, pesticides, impact of big dams (150 new dams are being proposed) need to be seen together. Dhananjay said that the biodiversity report of Kalpavriksh had shocked the ministry. Sathyashree suggested that a letter could be written to the health ministry about making health assessment of these projects mandatory.

- Sathyashree to write a note and circulate it to Alpana and then others. Environmental sub-group will also consist of Ravi D'Souza and Manmohan.

After much discussion, it was decided that there was a clear demand for inputs into medical education particularly from the medical students and interns who had attended the meet. **The theme for the next annual meet would be "Public Health Education in India" and the theme for the one after that would be "environment and its**

Anand Zachariah mentioned a consultation that was held in Vellore last year on medical education. If education had to adhere to health care then it was important to look at general practice; that there was nothing called "true" medical knowledge and what did it mean for India. It was important to look at the culture of medical knowledge which has a history. Several background papers were circulated during this consultation. Subsequently he and a few others from CMC have initiated a dialogue with an NGO, Anveshi, in Hyderabad. The project has been in one year in progress He was not sure how it will progress but they could contribute a paper.

Sathya said that Padma has already published a paper on gender dimensions of the Text Book on Preventive and Social Medicine (PSM) (Park) and this could be a background paper. Ritu mentioned that clinical research has become important in India and this should also be looked into. Anant said that public health is not only PSM but it is also about clinical medicine. Renu mentioned that as part of the Achutha Menon's Centre, she (and others) has been visiting medical colleges (12 to 15) to sensitize students on gender and making deliveries safe. There is work happening in the other fora too and this can be brought into the mfc meet. It was reported that Ravi Narayan is involved with the setting up of five public health schools in India.

- Decision: Ritu will write the concept note, and the group working on the theme will consist of Prabir, Renu, Anand, Anant, and Alpana. Renu Khanna and Sukanya.volunteered.

Venue and Date for Mid-Annual Meet: July 7-8, 2006, Wardha
Venue and Date for Annual Meet: December 29-30, 2006, Bangalore (1st preference; if not Hyderabad could be explored). Bangalore was the choice because of CHC and as so many medical students from Bangalore had attended this meet.

Discussion on "Cells"

Many of the cells did not seem to be functioning such as the primary health cell (convener, Shyam Ashtekar), women & health cell (convener, Neha Madhiwalla), infectious diseases cell (convener, Yogesh Jain). Only decision taken was to revive women and health cell (which had not met for more than two years as Neha has not attended mfc meet fro two years running). Sarojini, Manisha, Alpana, Sathyashree, Renu, Sivakami, Manjit will work out something in the near future. No convener was chosen but Sarojini accepted to be functional coordinator till the group came to a

decision.

Drug cell also has not been functioning well. Anant reported about the AIDAN meeting held on the 26th, the day before the mfc meet. Mira Shiva and Gopal Dabade were to be co-conveners. Chinu and Anurag were to be joint conveners. Mfc is one of the founder members of AIDAN and the GB endorsed mfc being part of the AIDAN. Anant had been the convener of the rational drug cell with help from Ulhas Jajoo. There was a discussion about having a new convener as Anant felt that he will not be able to give time to the mfc work. Mira's name was suggested but there was an objection that she could not be convener of two networks at the same time. It was also pointed out that Sarojini had been the convener of both mfc and JSA at the same time and this had not been considered a problem then. Manisha felt that mfc members should not cut off their links with mfc and Renu pointed out that it was a classic struggle of wearing different caps. Ritu said that this was bound to happen as many members of mfc were also active members of other networks. Anant finally decided to be the convener of mfc drug cell as for him mfc was still a priority although he warned the group, not much work will be done by him as he was overburdened with work.

- Rational drug policy cell: Anant (convener, till such time another one is found)), Mira, and Ulhas.

The cell on "Violence as a Public health Issue" (coordinator, Renu Khanna) was not discussed.

Gujarat Issue

Sarojini reported on the case filed by mfc in the Medical Council of India against Togadia. They referred it to Gujarat. She also said that because Lakshmi Sehgal had signed the petition it had made all the difference. She felt the issue should be revived particularly since the government had changed. He felt that there was no need to collect any more signatures. Togadia had issued three press releases and said that mfc doctors were all crazy. He also said that he was proud to be a Nazi doctor and that Muslims in India should remember what happened to the Jews. He had also said that he was not bothered if his name was struck off the register as he could always take up to farming. The group unanimously agreed that mfc should continue with this issue and bring it. Manisha felt that this was particularly important as history will be watching us. However, it was pointed out by Ravi D'Souza that because many from CMC Vellore had signed the petition, it appeared as though it was a petition by CMC and gave it a different colour. There was a discussion about writing to the President but Manisha pointed out that the President (APJ Abdul Kalam) had given prizes to a NRI doctor who was an RSS. There was more discussion on taking it up with the NHRC, Nanavati Commission, PUCL, etc. Renu suggested that since JSA had also signed the petition, 2-3 persons could sit together and work out a plan. Manisha said that mfc should take the lead as it had initiated it. Sarojini also reported that Murali (lawyer in the Supreme Court) had said that the petition was weak and would not hold. It was decided that Indira Jaising will be approached for legal advice. Ritu said that mfc should work with JSA on this.

- Sub-group on petition against Togadia: Sarojini (convener), Renu, Ravi D'Souza , Dhananjay, Chinu, Manisha, Sathya, Ritu, Anand Zachariah, Binayak, Prabir and Anant Phadke.

Bulletin/e-forum

Ritu thanked the editor for bringing out the bulletin on a regular basis. Manisha suggested that 2 pages could be brought out on a regular basis: aspirations of student and life journey of people in mfc and the factors that influenced them. Sathyashree reported that Ravi Narayan had been thinking about documenting mfc and she wanted to interview mfc members on it. There was discussion on personalized accounts and open narratives. Dhananjay said that young people facing certain questions needed these kinds of biographies. Renu was quite open to be interviewed. Anant B said that interview and organic writing will be different. Chinu was opposed to the idea because he felt that within mfc, several are part of each other's narrative and this may not be a good idea when everyone is still around. No decision was taken on this.

Sathya mentioned that her article on tsunami had been cut by Chinu without consulting her and she felt that there should be a clear policy on this.

Anant B said that the editorial committee and the executive committee are a two way process and very few from these were attending the GB. Renu said that it was sad that people come for the two day meet; get an intellectual "kick" out of it but then do not put effort into the organization. It was felt that all members of both the committees should attend the organizational part of the meet both at mid annual and annual meets.

Anant B said that some funds needed to be found for travel for those who could not come because of financial constraints. Prabir said that Mona Saxena Fund was available and many including himself had benefited from it. Manisha suggested an annual meet traveler kitty and collect funds from those who would like to contribute for supporting students etc. Eligibility criteria should be evolved.

Website

Ritu pointed out that the web site needed to be looked into. For instance, mfc is being termed as a "health NGO" which is not the way we perceived ourselves. Currently Nobhojit was handling it. Anant communicated that Amar Jesani had offered to help with funds but was not sure if mfc will accept foreign funds. The group appreciated Amar's offer but felt that it could be managed without any funding. Ravi D'Souza had offered to help but both Nobhojit and Arun Dolke (handling the e-form) had not responded to his offer. Prabir offered to work with Ravi to help upload stuff and patch up gaps. There was a discussion on who formed the mfc e-group. There are 93 members and Ravi reiterated that he felt certain decorum and norms needed to be maintained while communicating within the e-group. Ritu said that Arun Dolke was not very communicative.

- Website cell: Ravi D'Souza, Nobhojit, Anant B & Prabir

The brochure was discussed and Sarojijni reported that it had been finalized quite sometime ago with the feedback received from others. Ritu and Sarojini will look into this.
All anthologies and back copies of the bulletin were to be sent to the head office.

Executive Committee

- Manisha, Chinu, Neha and Anant B retire from the EC.
- Mira Sadgopal, Abhay, Sarojini and Ritu to continue till 2007.
- New members: Anant Phadke (Drug cell convener), Sathyamala (Vaccine policy cell convener), Anand Zachariah, Binayak Sen and Prabir Chatterjee.
- Re-elected: Manisha (Trust office), Chinu (editor).

The accounts for the previous year were passed around.

Manisha reported that PAN number has been obtained and also the Section 80 G exemption. There is a deficit for the bulletin but it was coming out regularly. There is a deficit of approximately Rs 10,000/ per year. In the previous meet at Mumbai, there was a huge deficit as collections were less than what had to be paid for venue etc. The deficit was met from mfc funds. Some members (Sunil Nandraj, for instance) had donated money this time but there was need to get more donations/contributions. In the 2004 minutes, it had been agreed that those with life subscriptions before 2001 should give an additional amount of Rs 500/- each and life subscription is for 10 years only.

The meeting ended with a vote of thanks to all present.

(Minutes by C. Sathyamala).

Counting the Gains: Stakeholders' Consultation on One Year of NRHM

- Abhijit Das

The Government of India announced the National Rural Health Mission (NRHM) in April 2005, as a mechanism to deliver public health programmes to its citizens through a comprehensive and coordinated approach. This new approach was a departure from the past in that it acknowledged many of the gaps in the earlier fragmented verticalised approach. In addition it also included provisions for greater quality of services, transparency of approach and accountability at all levels.

It is important to recall the processes through which the evolution of NRHM took place to understand the different factors that have influenced its formulation and implementation in the first year. The Reproductive and Child Health (RCH 2) project was already on the anvil when the UPA government came into power. The UPA government's mandate included a strong support from the rural poor across the country and the Common Minimum Programme (CMP) emerged as an important tool for distributive justice. Through the CMP the new government promised to increase the budgetary allocation on health from a meager 0.9% of the GDP to a more substantial 2 –3 % of the GDP (but still below the WHO recommended 5%). However the CMP also promised a "sharply targeted population control programme" in the 150 districts with poor demographic indicators. Finally when the decision to put together a Health Mission was shared publicly for the first time in September 2004, there were two concept notes – one primarily focusing on a community based health worker and the other concerned with population "stabilization". This confusion enabled the civil society and public health experts to intervene in a substantial manner. Task forces were set up to deliberate different aspects of the mission and finally the NRHM was announced with a much more progressive outlook and integrated approach than probably had never been done before since independence.

The NRHM completed one year in April 2006. It must also be remembered that 2005-2006 was also the first year in which the Finance Minister introduced the Outcome Budget and NRHM had promised few outcomes for the first year – selection and training of 40% ASHA, upgrading of selected number of PHCs (to 24*7) and CHCs (to IPHS standards), disbursing untied fund (of Rs 10,000) to Sub-Centres and launching of the Janani Suraksha Yojna. Thus the most important dynamics which influenced the NRHM in its first year were its holistic vision which was mediated by the desire to achieve the outcome budget indicators and the integrated and community oriented approach which was often times at conflict with the already designed RCH2 project implementation plans. Further, the States that are supposed to own and implement the vision of NRHM did not have the opportunity to evolve their own SRHMs and these were formulated by executive dictat.

The NRHM has been well designed and includes provisions which enable better access and quality of services. It also has a bottom-up approach encouraging participation, transparency and accountability. Keeping these in mind, a group of civil society organizations across 8 of the high focus states (Rajasthan, UP, MP, UA, Bihar, Jharkhand, CG and Orissa) conducted a brief review of the fulfillment of reproductive health needs and rights through the NRHM in its first year. Starting from state level workshops and followed through with community level documentation exercises this process culminated in a Stakeholders Consultation in Delhi on September 26-27, 2006. This consultation was co-organised by the Advisory Group on Community Action, a standing committee of the NRHM that has been constituted at the national level to give inputs and feedback on how to strengthen community processes within it.

The Consultation was very well attended with over a hundred participants representing civil society organizations and networks from ten states, public health experts from across the country, International NGOs involved in implementing Reproductive Health projects, or funding local NGOs, International Donors and Technical support organizations like WHO, UNICEF, UNFPA, World Bank, DFID and EC, Indian and International Foundations and senior bureaucrats from the Ministry.

Sandeep Dixit, Member of Parliament, chaired the first session that presented a broad overview of the NRHM – both its provisions and its implementation. In his concluding remarks he mentioned that it was unfortunate that issues like maternal or infant health, which were crucial development issues remained as peripheral political issues. It was not as if health was not a political issue because in the recent past the doctors' strike, the termination of the services of the Director of the AIIMS, demands for AIIMS like institutions in different states had been of immense political significance both in the national as well as

state capitals. It was a challenge for us to engage with politicians and political parties and create an interest among on these crucial issues. He gave the example of the National Rural Employment Guarantee Act and huge financial commitment that had been made because of political championship of the issue at the highest level.

In subsequent sessions, different aspects of the NRHM, particularly those with respect to reproductive health needs and rights were discussed. These included the ASHA selection and review process, the mechanism for improving maternal health outcomes, decentralized planning and monitoring mechanisms and innovations like Public-Private-Partnerships, addressing adolescents and so on. Each session had presentations from civil society representatives, public health experts, the government and technical support agencies. The consultation concluded by drawing up a list of recommendations for the government as well as for the members of the civil society. An interim list of recommendations was presented to Ms S Jalaja, Mission Director, NRHM, who attended the session on the second day. The Advisory Group on Community Action will hand over the final list of recommendations to the Government.

All stakeholders present at the Consultation appreciated the progress that has been made over one year through the NRHM at the National, State, District and Village levels. There was evidence that the ASHA selection and training process had begun, and many states had also introduced local innovations. A substantial number of Sub Centres had received the untied funds, and some expenditures had also started. The JSY payments had started in many states and some states (like MP or Gujarat) had also started special schemes for maternal health. CHCs had been identified for upgradation and district planning had been initiated across some states.

However some gaps were also noted. The most important hurdle was seen as the lack of ownership of the NRHM vision among the states that tended to see NRHM as a new package of schemes. The lack of involvement of Panchayati Raj institutions was also a large gap. The ASHA selection and training process also needed to be made more robust and rigorous. The speed of implementation was seen as an impediment to institutionalizing new processes. Community involvement, including the involvement of NGOs and CBOs in planning and monitoring had not yet become operational. MNGOs were seen as the most prominent health NGOs and this was not always true. The Consultation noted with satisfaction the innovations that had been introduced within NRHM like addressing adolescents or harnessing the resources of the private but also cautioned that private provisioning of services should not lead to privatization or private funding of services. The norms and regulations for private engagement needed to be developed as soon as possible and made mandatory.

The consultation ended with the resolve that there was a great need to share people's experiences and aspirations as well as the programme provisions and successful experiences. This process of sharing needed to take place at all levels so that all stakeholders could play a creative role in making NRHM successful and contribute towards improving the health status of the country as a whole.

The names of participants, programme details, presentation and detailed report are available at <http://www.chsj.org/activities_update1.htm>.

VIOLENCE AGAINST WOMEN AND ROLE OF HEALTH CARE PROVIDERS

A NATIONAL LEVEL COURSE FOR HEALTH PROFESSIONALS

CEHAT, research centre of Anusandhan Trust is pleased to announce a course on "Violence against women and role of health care providers (HCP)" for health professionals. The course is designed to provide participants an understanding on Violence against Women (VAW) as a health and human rights issue and train them to respond to specific needs of victims of violence. Doctors, Nurses, Researchers, Health activists, are encouraged to participate.

COURSE DATES: Dec 11 – Dec 19, 2006

FACULTY: Amar Jesani, Aruna Burte, Manisha Gupte, Renu Khanna, Seema Malik

COURSE COORDINATOR: Padma Deosthali

Medium of the course: English and Hindi

Deadline for submission of application NO LATER THAN 15th Oct 2006 For details, see <www.cehat.org>

Coalition for Maternal-Neonatal Health and Safe Abortion

Statement of Purpose

Vision

A society that ensures maternal-neonatal health care and safe abortion for all, and especially for the poor, in India.

Why? Because in India

- With a ratio of 540 maternal deaths per 100,000 live births, one woman dies every five minutes. This results in 136,000 women dying every year due to complications related to pregnancy, childbirth and unsafe abortion.
- Although infant mortality rates have declined, neonatal deaths have stagnated. At the rate of 44 per 1000 live births, neonatal deaths account for up to 46 % of under-five child mortality.
- Unsafe abortion causes 9-18 % of all maternal deaths and 24-67 % of complications from unsafe abortion result in significant morbidity.
- 75% of life-threatening maternal complications occur at the time of childbirth or soon after delivery. 75% of deaths among newborns occur in the first week, with 25-50% occurring on the first day. 61% of maternal morbidity occurs mainly during childbirth or after delivery. Yet 59% of women give birth without a skilled attendant and 83% of women do not receive any postnatal care at all.

The great majority of maternal deaths are needless. They can be avoided if skilled attendance at birth is available and if referral linkages to emergency obstetric care and safe abortion are effective and affordable. Nonetheless maternal health is not only about preventing maternal deaths through obstetric services. Its essence requires affirming women's well-being and rights to be pregnant on their own terms and to carry through with their pregnancy, childbirth and motherhood with no adverse consequences to themselves or their children. Discrimination that warps women's rights to maternal health must be addressed and crucial linkages to neonatal health and safe abortion must be made.

Governments, despite their responsibility to ensure women's rights to maternal-neonatal health and safe abortion, fail to support health care providers and the health systems they belong to. Limited antenatal services and institutional deliveries of poor quality are the norm, along with few linkages to specialist services and little follow-up during the postnatal period. At the same time unregulated and privatised health care services encourage irrational medical interventions leading to iatrogenic risks and financial indebtedness. Considering this context, to ensure good maternal-neonatal health care and access to safe abortion services for all, a focus on integrated, accountable and equitable health systems that provide accessible, affordable and effective services is essential.

For our vision to be a reality, advocacy is required not only with policymakers at national and state capitals, but with key actors at various levels: health service providers within the public and private sectors; among researchers; civil society organisations working on health; members of local government at village, taluk and district levels; and at community level with individual women, men and children, as well as with families and other social groups. Without such mobilisation and engagement, progressive policies and legislations that are developed and adopted, flounder at the stage of implementation.

Mission

- To raise visibility about the unacceptably high numbers of preventable mortality and morbidity among mothers and newborns, and the lack of access to safe abortion, especially among the disadvantaged.
- To mobilise advocates from different constituencies who will collectively generate pressure in a deliberate, organised and systematic effort to

a. ensure effective implementation of relevant policies and programmes

b. develop new policies and change existing ones when needed

c. bring about change within communities, health care providers, researchers, administrators, elected representatives and the media.

Strategy

- Bring together individuals and organisations who share our vision across various states and from diverse backgrounds and areas of expertise
- Identify priority areas and pool together ideas, knowledge and skills to develop and implement key advocacy interventions (with the actors and levels mentioned above)
- Create a space for members to

a. enhance their knowledge and skills by sharing different kinds of expertise and sustaining peer review mechanisms

b. provide solidarity to bolster ingenuity, creativity and persistence for effective advocacy.

Aimed Activities

- Individual evidence based advocacy projects focussing on specific problems from across the country supported by the coalition.
- Training courses for different groups of stakeholders, on advocacy, research skills or specific content areas.
- Preparation of regular report cards on the state of maternal-neonatal health and safe abortion in different states, along with analysis on state specific policies.
- Consolidation and dissemination of latest information (especially in local languages) aimed at health providers, decision-makers and key actors at the community level.
- Organising thematic meetings and conferences and systematic reviews to highlight specific themes in

conjunction with other allies.

- Providing study tours, learning exchanges and documentation of innovations and good practices within the public sector, private sector and the NGO sector.

Current Steering Committee Members

All members are equal, with steering committee member only serving to administer the coalition. Steering committee members are listed below, in alphabetical order:

Asha George, Consultant, IIM-Bangalore; Subodh S. Gupta, MGIMS, Sewagram, Wardha; Sharad and Kirti Iyengar, ARTH, Udaipur, **Coalition Secretariat;** Renu Khanna, SAHAJ, Baroda; Dileep Mavalankar, IIM-Ahmedabad; T.K. Sundari Ravindran, Honorary Professor, Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

Membership

Please email cmnhsa@yahoo.com for an application form or write to TK Sundari Ravindran, Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Medical College P.O, Trivandrum- 695 011

Subscription Rates

	Rs. Indv.	Inst.	U.S$ Asia	Rest of world
Annual	100	200	10	15
Life	1000	2000	100	200

The Medico Friend Circle bulletin is the official publication of the MFC. Both the organisation and the Bulletin *are funded solely through membership/ subscription fees and individual donations.* ***Cheques/ money orders/DDs payable at Pune, to be sent in favour of Medico Friend Circle,*** *addressed to Manisha Gupte, 11 Archana Apartments, 163 Solapur Road, Hadapsar, Pune - 411028. (Please add Rs. 15/- for outstation cheques). email: masum@vsnl.com*

MFC Convener

Ritu Priya, 147-A, Uttarakhand, JNU,
JNU Campus, New Delhi -110 067. Email: <convenor.mfc@vsnl.net>
MFC website:<http://www.mfcindia.org>

Contents

Editorial Committee: Anant Bhan, Neha Madhiwalla, Dhruv Mankad, Amita Pitre, C. Sathyamala, Veena Shatrugna, Chinu Srinivasan. **Editorial Office:** c/o, LOCOST, 1st Floor, Premananda Sahitya Bhavan, Dandia Bazar, Vadodara 390 001 email: editormfc@yahoo.com. Ph: 0265 234 0223/233 3438. **Edited & Published by**: S.Srinivasan for Medico Friend Circle, 11 Archana Apartments, 163 Solapur Road, Hadapsar, Pune 411 028.

Views and opinions expressed in the bulletin are those of the authors and not necessarily of the MFC. Manuscripts may be sent by email or by post to the Editor at the Editorial Office address.

MEDICO FRIEND CIRCLE BULLETIN
PRINTED MATTER - PERIODICAL

Registration Number: R.N. 27565/76

If Undelivered, Return to Editor, c/o, LOCOST,
1st Floor, Premananda Sahitya Bhavan
Dandia Bazar, Vadodara 390 001