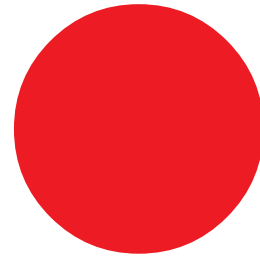


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October 2005 - January 2006

Why we do not need to give Hepatitis B Vaccine for all newborns : Letter to Health Minister

Dr. Anbumani Ramadoss,
Cabinet Minister, Ministry of Health & Family
Welfare, Government of India,
Nirman Bhavan, New Delhi-110011

Dear Dr. Ramadoss,

Through the news in the *Times of India* (6th September) 'Hepatitis-B threat bigger than AIDS' we came to know about the decision of the Health Ministry to launch the programme throughout India to give hepatitis B vaccine to all newborns by including it in the National Immunization Programme.

This decision seems to be based on the impression that "hepatitis B is a bigger problem than AIDS" and the news says, "Ministry records also say that one in every 20 people in India is a carrier of this deadly virus". As socially concerned experts working in the field of Public Health, and Rational Drug Policy in India, we would like to point out the following -

1) The claim that 4.7% of the Indian population is chronically infected with hep.B virus is gross overestimation based on a paper, which has surprisingly made an elementary arithmetical mistake and also has unscientifically assumed that all those who are found to be positive for hep.B infection are chronic carriers of this infection. Using the same data correctly the actual 'hep.B carrier rate' works out to be

only 1.42%. (1) The WHO has recommended hep-B vaccination of all newborns only for countries where this carrier rate is more than 2%. (2).

2) Hepatitis B is much more infectious than HIV. However, whereas untreated HIV infection is 100% fatal, in case of Hepatitis B infection only 10% of infected adults become chronic carriers and the average fatality rate due to Hepato Cellular Carcinoma is much lower than what has been claimed (3). About 90% of infected infants become carriers. But carriers eliminate the hep B infection at an annual rate of up to 2% (4) and the overall incidence of the damage due to hep B infection -acute hepatitis, chronic persistent hepatitis (CPH), chronic active hepatitis (CAH), cirrhosis and hepato-cellular carcinoma (HCC) is much less than what is generally believed. (5)

3) Newborns who get hep.B infection at birth from their hepB positive mothers have the highest risk of getting HBeAg infection which the most infectious variety of hep.B infection and which has the highest chances of becoming carriers. (6,7) Prevention of this perinatal (vertical) transmission from hepatitis-B positive mothers requires that newborns at risk be given the first dose of the vaccine within 12 hours of birth. (8) Hence the WHO, the American Academy of Pediatrics have recommended that for such newborns, the first dose of hep.B vaccine must be given not later than 48

hours after birth. In India, since 77% births take place at home, the first dose of hep.B vaccine would not be given immediately after birth but 6 weeks after birth with the first dose of the triple vaccine in the National Programme. Hence in this programme 77% of the newborns will not be protected from the mother- to-child mode of infection, which is the most dangerous type of infection.

4) If we want to take up Hepatitis B vaccination programme at all then the Selective Vaccination Strategy should be used like in other low prevalence countries like Japan, U.K. Netherlands. The Selective Vaccination strategy which consists of identifying the HBsAg positive mothers through antenatal screening and vaccinating their newborns within 24 hours of birth. In India 2-3 % of mothers are hep.B positive, and this selective strategy would protect about 40% of the newborns from the risk of HBeAg positivity by vaccinating only the 3% of the newborns, and this programme would cost one fourth of the Universal Strategy.(9) The cost-efficacy of HB Vaccination should be measured in terms of cost per highly infectious carriers (HBeAg positive) prevented and not HBsAg positive carriers prevented. This is because as mentined above, HBeAg positive carriers are far more dangerous to public health, as they are far more infectious and are far more likely to develop serious chronic liver disease later than mere HBsAg positives. In India, only 65% of women get any health-care during pregnancy. This highly cost-effective selective vaccination programme will not be very effective even for control of Hep. B. infection, (leave aside, it's eradication from India) unless this coverage is substantially improved. Secondly, it will not eradicate hep B infection. But any way even if all newborns are vaccinated in the Universal Vaccination Programme, it will take at least 65 years to eradicate hepatitis-B infection in India.

5) With 25 million babies being born every year in India, even assuming that the cost of hepB vaccine per child in this programme to be only Rs. 50/, (i. e. much less than the current price), it would cost Rs. 125 crores annually for the vaccine alone. This is equal to our budget for TB-control programme (the number one killer of Indian adults) and is almost equal to the combined cost of other 6 vaccines given to infants. The cost-efficacy of this programme is also unfavourable - about Rs. 700 per life year saved (10) compared to around Rs. 20 per life year saved for the measles vaccination. (11)

6) Those medical professionals who come in close contact with blood, patients in need of dialysis/ repeated blood transfusion and persons exposed to

unsafe sexual relations should be vaccinated against hep.B on a priority along with newborns of hepatitis positive mothers. Giving this vaccine to all newborns, that too 6 weeks after birth, is neither effective in preventing the most dangerous, mother-to- child transmission nor is it good economics. It will primarily benefit the manufacturers of this vaccine who have succeeded in convincing a section of the medical professionals through their usual techniques.

In view of the very serious, substantial issues mentioned above, we request you to stall your decision to include the hepatitis B vaccination in the National immunization Programme, invite us for a detailed discussion with the concerned officials/experts in your Ministry and initiate a public debate on this issue before taking a final decision.

Sincerely yours, etc.

cc. The Secretary, Ministry of Health & Family Welfare

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*A move to bail out the “ailing” vaccine industry***Heptatitis-B firms get a shot in the arm: Centre’s move to include vaccine in national immunisation plan to boost demand 300%.**

C H Unnikrishnan / Mumbai September 15, 2005, *Business Standard*, Sep 15, 2005

Domestic Hepatitis-B vaccine manufacturers, which were on the verge of closing down their huge capacity manufacturing plants owing to adverse market conditions, have a reason to smile.

The Union health ministry has decided to include the vaccine in the national immunisation programme, which would increase the demand for the vaccine by more than 300 per cent in the first year and an annual growth of at least 25 per cent to 30 per cent in the following years.

The central health minister Anpamani Ramdoss said that as a special focus on the preventive health programme, which is part of the National Health Mission 2005, the government has decided to include Hepatitis-B vaccine in the programme.

By including the vaccine in the immunisation scheme, the government would procure large quantity of vaccine, which would be approximately 100 million doses per annum.

The current manufacturing capacity with the leading five manufacturers in India is estimated to be about 400 million doses. The companies in the segment are Serum Institute of India, GSK India, Shanta Biotechnics, Wockhardt and Bharat Biotech, Panacea Biotech, Unichem and Intas Pharma.

Since the market for Hepatitis B vaccine in India is in a bad shape owing to tepid demand and falling prices, manufacturers were in dilemma whether to remain in the business or not.

The industry is now, however, buoyant about the government’s decision V Kapre, executive director, Serum Institute of India, the largest manufacturer of Hepatitis B vaccine and the only manufacturer of DPT Hep-B combination vaccine in the country, said though the decision was delayed, the industry should appreciate the move, which will not only help manufacturers but also improve public health in the country.

Many players, including multinational Pfizer and domestic major Cadila Healthcare which had launched the vaccine in India, have, however, already discontinued the product.

Many more have shifted their focus to other vaccines and new generation combination products.

Sighted

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- 9) The WTO now has a URL and a link to their excellent new FAQ on compulsory licensing. TRIPS AND HEALTH: FREQUENTLY ASKED QUESTIONS
<http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm>

*Background paper for Annual Meet Jan 2006***Cost and Quality Issue in Hospital Care***-Anant Phadke¹*

In the MFC Annual Meet in January 2005 on the Right to Health Care, one of the important issues that emerged was to concretely assess the cost and quality implications of providing health care to every citizen as a matter of right. To provide health care to all, the private sector would also have to be involved in a system of social insurance. The cost, quality of health care will have to be debated in this context. The theme of the forthcoming annual meet needs to be seen in this context.

The cost and quality issue in case of preventive, promotive services would require a separate paper. In this current piece I have tried to outline the various components of hospital-based care in order to raise issues related to the objective of reducing cost without reducing the quality of care.

Even if we exclude Intensive Care Unit care, the average bill for the hospitalised patient in a large city turns out to be around thousand rupees a day! Today, we do not know how much of this is because of high pricing by the equipment manufacturers and how much is due to high priced unnecessary interventions by doctors. If every citizen is to get hospital-based quality care, when needed, the existing bill for hospital care has to substantially come down. We need to learn from any experiments, traditions, which have provided good quality care at much lower cost than what is commercially available.

‘Good quality’, ‘reasonable quality’ ‘minimum standards’ are not self-evident terms. But yet we will have to use these by means of consensus by specifying our understanding of these terms. By minimum standard in a particular country in a particular period, I mean the standard below which patient’s interests get palpably, unacceptably sacrificed. We cannot make a compromise on ‘minimum standards’, but as we go for higher standards of care, we have to decide about some trade off between quality and cost. Which trade off we are going to accept has to be decided through a dialogue between the different stakeholders in health care. In this MFC meet we would like to learn from various experiments, traditions in providing ‘good quality low cost health care’ about how in their set up, this trade off was decided, by whom?

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There are various components of hospital-based health care and we need to discuss these somewhat systematically. In this note I have only outlined the issues by giving some illustrative examples. It is hoped that various experiences in good quality low-cost hospital health care would be shared in response to this note.

1) Setting and Infrastructure

In a big city, the land cost is two to five times the construction cost and hence the cost of the hospital building is very high. This is true to a lesser extent in other cities also. If city hospitals get substantial concession in land cost, can the cost of health care come down? How much?

Because of some stereotyped understanding of quality of construction, construction cost goes up. Have there been experiences of good quality, lower cost construction for hospitals?

2) Medical Technology

Higher quality equipments/technology give better results albeit at higher costs. But at primary and secondary level care, since the level and type of intervention is anyway limited, isn’t it possible to use some less sophisticated equipment without sacrificing the quality of care? Are there such examples? For example, what quality of sonography machine is adequate at a rural secondary level centre? What is the cost – saving by not opting for the state of art machine?

In some instances, modern diagnostic techniques need to be made available at PHC level even if it means higher costs. For example, blood sugar estimation by glucometer, pregnancy test by urinary HCG, use of nebuliser to administer a bronchodilator in acute bronchial asthma, etc. etc. Are there any experiences about such quality enhancement through appropriate modernisation; at what cost?

3) Protocols for Cost-effective Investigations

Unnecessary investigations are quite a widespread phenomenon. Routine HIV testing for all hospitalised

patients; routine pre-operative testing for Hepatitis-B; complete lipid profile instead of selective markers' routine lipid profile testing annually; doing all Liver Function Tests when only serum bilirubin and SGPT would do; all Pulmonary Function Tests when only peak flow measurement would suffice... these are some of the examples. Are there any examples of keeping medical investigations to the minimum as a policy of a hospital, without sacrificing the quality of care? How? Which protocols are used in such settings?

The issue is not always very simple. Doctors, especially in tertiary care settings tend to do more investigations to rule out rarer diseases and to 'play safe'. Thus for example, a CT Scan will be ordered for every case of head injury not with the intention of making money on CT Scan, but to play safe. Can such expenses be reduced without reducing the quality of care? Have any protocols been used to achieve such cost reductions? Can we use cost per Quality Adjusted Life Year gained as a parameter to assess how 'costly' is an investigation?

Ideally investigations are to be made only to achieve on one of the following - to establish or rule out a diagnosis; to decide prognosis; to decide the type of treatment to be given; to assess the impact of the treatment, including side-effects. If any investigation is not necessary to achieve any of the above, that investigation is unnecessary. But the tricky issue is about investigations done to rule out a small chance of having a serious disease. How can expenses on such investigations be reduced without affecting the quality of care?

4) Protocols or Methods of Cost-effective Interventions

In case of many interventions, there are options for choosing a cheaper modality without reducing the quality of care. laparoscopic surgeries generally means less surgical trauma, less post-operative morbidity, hospitalization, but much higher costs than 'open' surgery. (This assumes that the surgeon is quite skillful). In the West, where the costs of stay in hospital are very high, shorter hospital stay offsets the higher cost of laparoscopic interventions. In India, however, laparoscopic surgeries tend to be much costlier. Hence, shall we have a policy of restricting laparoscopic surgeries only for very specific situations? (Laparoscopic tubectomy may be an exception in govt.hospitals. Because here the salaried surgeon's fees per patient turns out to be very low and the woman can go back home to

her village early, reducing a great deal the family's expense.)

Less use or reuse of disposables is one area where cost reduction can be achieved substantially. Have there been examples of doing this? The range can be quite wide - reuse of certain disposables in cardiac surgery to use of glass syringes in OPD. One more common example is: in a clean, non-emergency surgery, to implement the standard prescription for preoperative antimicrobial prophylaxis of giving a single intravenous dose of an appropriate antimicrobial just at the onset of the surgery. But very few centres follow this policy in India. Are there examples in India of centres, which follow this textbook protocol? How much is the average saving per operation?

Things are not so straightforward in other instances. For example anaesthesiologists say that intra-operative use of pulse oxymeter to monitor oxygenation of blood considerably reduces the incidence of deaths due to sudden intra-operative cardiac arrhythmias. Even if it means increased cost, should we not consider this use as essential at least for bigger operations even in otherwise poorer Indian conditions? Similarly, should we not have an ultrasound in every Rural Hospital primarily for obstetric care?

In public hospitals superior, newer type of material is not used (from suturing material to cannulas to adhesive tapes) because more convenience and less trouble to patients as an objective of health care is sidelined on the grounds of cost- considerations. Shouldn't this change even if it means higher expenses?

5) Cost-effective Use of Medicines

Medication is a subtype of medical intervention. But it needs special mention in Indian conditions. A lot of money is wasted in India on account of use of medicines of doubtful value, more fashionable but very costly medicines and branded products when very cheap, good quality generics are available. Are there any studies/ examples of avoiding such expenses? What are the results?

There are also examples of the drug treatment as given in a standard textbook is not followed in India because we cannot afford it. For example, until recently, all these years the obsolete Semple vaccine was used in India in Public Hospitals after suspected rabid dog bite, because the Cell Culture Vaccine was considered too

costly. Similarly unlike in the West, anti-rabies serum is hardly ever used, because it is 'too costly'. How do we decide what is too costly in Public Health Care in Indian settings? Has any work been done on this aspect?

6) Fees of Doctors and Other Professionals

Doctors' fees form a substantial proportion of cost of health care in surgical hospital care in private sector. When we want to include private hospitals in social insurance and want have social control on the pricing of health care in such setting, doctor's fees especially surgeon's fee would be the contentious issue. Today in a bigger city the surgeon's charges for various surgical procedures are as follows: Caesarean Rs. 5,000-10,000; cataract surgery including IOL implant around Rs. 5,000; TUR for prostate-enlargement around Rs.

10,000. These surgeries take around half an hour (cataract surgery is a 10 minute job). Have any financially self-sustainable centres been able to charge much less without reducing the quality of care? Can we have reasonable, fixed rates for surgeon's fees for different types of surgeries and years of experience of the surgeon?

To summarize, I have touched upon various components of hospital-based care to address the issue of cutting down unnecessary costs without reducing the quality of care. Sharing of Indian experiences, experiments by participants of the MFC meet in this regard would go a long way in concretely assessing the cost implications of providing minimum hospital care to all citizens, when needed.

Local Production of Oseltamivir (Tamiflu): Options

"This note briefly summarises the action to be initiated by the Government; the provision in the Indian Patents Act, 1970; and list potential manufacturers of the drug.

Roche holds patent for oseltamivir, the known most effective drug used in the treatment of avian flu. With the winter setting in, warmer countries fear that migratory birds may bring the virus. This has created panic across the countries, fearing out break of epidemic. Hence, almost all countries are looking for alternative sources of supply. However, it is known that Roche is unable to meet the surge in global demand. Besides, its very high price of the drug is beyond the reach of many developing countries. It is therefore imperative for India that it uses flexibilities in the TRIPS Agreement, as incorporated in its Patents Act and capabilities of its pharmaceutical industry to augment the supply of drug and be ready to offer to other developing countries at reasonable prices, besides being prepared for any untoward health problem in the country.

To this end, it is suggested that the Department of Chemicals and Petrochemicals (C & PC), as part of the nodal ministry responsible for the availability of medicines, may initiate the following actions forthwith:

1. Seek from the Department of Industrial Policy and Promotion (DIPP) details of patent applications, if any, filed by Roche for oseltamivir. Most likely these applications may be in the Mail Box, pending

examination and clearance.

2. Request DIPP for early examination and determination of the patent status to decide on the need for use of compulsory license to augment supply.

3. Also, approach Drugs Controller General of India (DCGI) to ascertain status of application, if any, filed by Roche for the new drug (oseltamivir) approval in India. If the originator has not filed an application for the marketing authorisation, the DCGI may be requested to spell out the data required from the generic companies for granting marketing authorization to oseltamivir, in the special circumstances.

4. Simultaneously, initiate dialogue with the local industry to ascertain its preparedness to manufacture oseltamivir, capacity in terms of quantity, and time lines for commercial production of API and the finished dosage forms. Ascertain the status of their applications for the manufacturing/marketing approval in the country.

5. As regards monopoly rights of Roche under the patent and the use of compulsory license, the Department of C & PC has two options as under:

Option 1: Section 84

- a. Section 84 of the Indian Patents Act, 1970, permits an application for a compulsory license three years after the sealing of the patent. The general

principles embodied in the Act note that patents are granted to encourage inventions and to make the benefit of patented invention available at 'reasonably affordable prices to the public', to secure that these are worked in India, and not to enable patentees to enjoy monopoly power by importing. That the patent right is not abused by the patentee and the patentee does not 'resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology' (Section 83).

b. An application for a compulsory license can be made under Section 84 on the following grounds: that the 'reasonable requirements of the public' have not been satisfied, or that the product is not available at a 'reasonably affordable price', or that the patented invention is 'not worked in the territory of India'. However, this is constrained by the provision that it can be sought only after three years from the sealing of the patent.

c. Moreover, the wording of the grounds for granting compulsory licenses in Section 84 is not amenable to easy interpretation and is not operationally useful and the procedure specified is cumbersome. The procedure is open-ended without any time limit imposed for the grant of compulsory licenses. A copy of the application for compulsory license will have to be advertised in the official gazette, though this is not required under TRIPS Agreement. The patentee or any other person may oppose the application and will have to be given adequate time for doing so. The Controller will decide only after giving both the parties an opportunity to be heard. A compulsory license granted by the Controller can be opposed. Such appeals will be considered by an Appellate Board before a compulsory license is ultimately permitted. The grounds of 'reasonable requirements of the public' or 'reasonably affordable price' can easily be challenged by the patentees. The entire process is excessively legalistic and provides the patentees the opportunity to buy time through litigation. The huge legal expense involved in fighting the MNC holding the patent may dissuade the local companies from applying for a license in the first place.

d. Hence, in the given situation, this option is ruled out.

Option 2: Section 92

a. Article 31 of the TRIPS Agreement, dealing with the compulsory licensing, provides for special provisions 'in the case of a national emergency or other circumstances of extreme emergency or in case of public non-commercial use'. For any such use, the government is not required to negotiate with the patent owner. Nor is the latter provided any injunctive relief. All that it can expect is payment of compensation for the use.

b. The government can notify that it is satisfied that in circumstances of national emergency, extreme emergency, or public non-commercial use, it is necessary to grant a compulsory license for oseltamivir. Anytime thereafter, an application for a compulsory license be made by a local company under Section 92. The procedure described herein above (Option # 1) is not mandatory for the 'public health emergency' and thus provides an easy and workable solution.

c. It is further suggested that instead of adopting a case by case approach, the government may notify the list of medicines eligible for compulsory licenses in public health crisis. It can thus find a solution for imatinib mesylate (Glivec), also which is subject of dispute in several courts.

d. This is the best option in the given situation. It will enable the country to protect, not only its citizens, but also help the poor of the developing countries, as the Indian Patents Act incorporates provision of Article 31(f) allowing export of 'non-predominant' part of the production.

6. The companies that have made known their ability to produce oseltamivir are Cipla, Ranbaxy and Hetro.

If you need any further clarification or information on the subject, please feel free to call."

D G Shah

(DG Shah has been with the Indian Pharmaceutical Alliance. Copied here for fair use from IP-Health e-forum exchange, Oct 27, 2005)

Creation Myths

Does innovation require intellectual property rights?

- Douglas Clement¹

This article attempts to explain the results of an interesting paper, "Perfectly Competitive Innovation", by Michele Boldrin and David K. Levine, first published as a report by the Federal Reserve Bank of Minneapolis (see also their paper at <<http://levine.sscnet.ucla.edu/papers/pci23.pdf>>). The authors, who are economists, argue that copyrights, patents, and similar government-granted rights serve only to reinforce monopoly control, with its attendant damages of inefficiently high prices, low quantities, and stifled future innovation. More to the point, they argue, economic theory shows that perfectly competitive markets are entirely capable of rewarding (and thereby stimulating) innovation, making copyrights and patents superfluous and wasteful. See also conclusions of their paper "The economics of ideas and intellectual property" in *Proceedings of the National Academy of Sciences of the United States of America (PNAS)*, January 25, 2005, vol. 102, no. 4.

The most forceful performance at last year's Grammy ceremony was a speech by Michael Greene, then president of the National Academy of Recording Arts and Sciences. Speaking not long after the 9/11 attacks, Greene gravely warned of a worldwide threat - "pervasive, out of control, and oh so criminal" - and implored his audience to "embrace this life-and-death issue."

Greene was not referring to international terrorism. "The most insidious virus in our midst," he said sternly, "is the illegal downloading of music on the Net."

Greene's sermon may have been a bit overwrought, but he's not alone in his fears. During the last decade, the captains of many industries - music, movies, publishing, software, pharmaceuticals - have railed against the "piracy" of their profits. Copyright and patent protections have been breached by new technologies that quickly copy and distribute their products to mass markets. And as quickly as a producer figures a way to encrypt a DVD or software program to prevent duplication, some hacker in Seattle, Reykjavik, or Manila figures a way around it.

The music industry has tried to squelch the threat, most conspicuously by suing Napster, the wildly popular Internet service that matched patrons with the songs they wanted, allowing them to download digital music files without charge. Napster lost the lawsuit and was liquidated, while similar services survive.

But the struggle over Napster-like services has accented a much broader issue: How does an economy best promote innovation? Do patents and copyrights nurture or stifle it? Have we gone too far in protecting intellectual property?

In a paper that has gained wide attention (and caught serious flak) for challenging the conventional wisdom, economists Michele Boldrin and David K. Levine answer the final question with a resounding yes. Copyrights, patents, and similar government-granted rights serve only to reinforce monopoly control, with its attendant damages of inefficiently high prices, low quantities, and stifled future innovation, they write in "Perfectly Competitive Innovation," a report published by the Federal Reserve Bank of Minneapolis. More to the point, they argue, economic theory shows that perfectly competitive markets are entirely capable of rewarding (and thereby stimulating) innovation, making copyrights and patents superfluous and wasteful.

Reactions to the paper have been mixed. Robert Solow, the MIT economist who won a Nobel Prize in 1987 for his work on growth theory, wrote Boldrin and Levine a letter calling the paper "an eye-opener" and making suggestions for further refinements. Danny Quah of the London School of Economics calls their analysis "an important and profound development" that "seeks to overturn nearly half a century of formal economic thinking on intellectual property." But UCLA economist Benjamin Klein finds their work "unrealistic," and Paul Romer, a Stanford economist whose path-breaking development of new growth theory is the focus of much of Boldrin and Levine's critique, considers their logic flawed and their assumptions implausible.

"We're not claiming to have invented anything new, really," says Boldrin. "We're recognizing something

¹This article originally appeared in Reason Online at <<http://www.reason.com/0303/fe.dc.creation.shtml>>. Douglas Clement is a senior writer for The Region, a magazine published by the Federal Reserve Bank of Minneapolis. A version of this article appeared in The Region's September 2002 issue. Reproduced here for fair use.

that we think has been around ever since there has been innovation. In fact, patents and copyrights are a very recent distortion." Even so, they're working against a well-established conventional wisdom that has sanctioned if not embraced intellectual property rights, and theirs is a decidedly uphill battle.

The Conventional Wisdom

In the 1950s Solow showed that technological change was a primary source of economic growth, but his models treated that change as a given determined by elements beyond pure economic forces. In the 1960s Kenneth Arrow, Karl Shell, and William Nordhaus analyzed the relationship between markets and technological change. They concluded that free markets might fail to bring about optimal levels of innovation.

In a landmark 1962 article, Arrow gave three reasons why perfect competition might fail to allocate resources optimally in the case of invention. "We expect a free enterprise economy to underinvest in invention and research (as compared with an ideal)," he wrote, "because it is risky, because the product can be appropriated only to a limited extent, and because of increasing returns in use."

Risk does seem a clear roadblock to investment in technological change. Will all the hours and dollars spent on research and development result in a profitable product? Is the payoff worth the risk? The uncertainty of success diminishes the desire to try. Much of Arrow's article examines economic means of dealing with uncertainty, none of them completely successful.

The second problem, what economists call inappropriability, is the divergence between social and private benefit - in this case, the difference between the benefit society would reap from an invention and the benefit reaped by the inventor. Will I try to invent the wheel if all humanity would benefit immeasurably from my invention but I'd get only \$1,000? Maybe not. Property rights, well-defined, help address the issue.

The third obstacle is indivisibility. The problem here is that the act of invention involves a substantial upfront expenditure (of time or money) before a single unit of the song, formula, or book exists. But thereafter, copies can be made at a fraction of the cost. Such indivisibilities result in dramatically increasing returns to scale: If a \$1 million investment in research and development results in just one unit of an invention,

the prototype, a \$2 million expenditure could result in the prototype plus thousands or millions of duplicates.

This is a great problem to have, but perfect competition doesn't deal well with increasing returns to scale. With free markets and no barriers to entry, products are priced at their marginal cost (that is, the cost of the latest copy), and that price simply won't cover the huge initial outlay - that is, the large indivisibility that is necessary to create the prototype. Inventors will have no financial incentive for bringing their inventions to reality, and society will be denied the benefits.

Increasing returns therefore seem to argue for some form of monopoly, and in the late 1970s Joseph Stiglitz and Avinash Dixit developed a growth model of monopolistic competition - that is, limited competition with increasing returns to scale. It's a model in which many firms compete in a given market but none is strictly a price taker. (In other words, each has some ability to restrict output and raise prices, like a monopolist.) It's a growth model, in other words, without perfect competition. The Dixit-Stiglitz model is widely used today, with the underlying assumption that economic growth requires technological change, which implies increasing returns, which means imperfect competition.

Stanford's Paul Romer formalized much of this work in the 1980s and 1990s, in what he called a theory of endogenous growth. The idea was that technological change - innovation - should be modeled as part of an economy, not outside it as Solow had done. The policy implication was that economic variables, such as interest and tax rates, as well as subsidies for research and technical education, could influence the rate of innovation. (See "Post-Scarcity Prophet," December 2001.)

Romer refined the ideas of Arrow and others, developing new terms, integrating the economics of innovation and extending the Dixit-Stiglitz growth model into what he called "new growth theory." In a parallel track, Robert Lucas, a Nobel laureate at the University of Chicago, elucidated the importance of human capital to economic growth. And just prior to all this growth theory work, Paul Krugman, Elhanan Helpman, and others integrated increasing returns theory with international trade economics, creating "new trade theory." Similar theories became the bedrock of industrial organization economics.

Central to Romer's theory is the idea of nonrivalry, a

property he considers inherent to invention, designs, and other forms of intellectual creation. "A purely nonrival good," he wrote, "has the property that its use by one firm or person in no way limits its use by another." A formula, for example, can be used simultaneously and equally by 100 people, whereas a wrench cannot.

Nonrivalrous goods are inherently subject to increasing returns to scale, says Romer. "Developing new and better instructions is equivalent to incurring a fixed cost," he wrote. "Once the cost of creating a new set of instructions has been incurred, the instructions can be used over and over again at no additional cost." But if this is true, then "it follows directly that an equilibrium with price taking cannot be supported." In other words, economic growth - and the technological innovation it requires - aren't possible under perfect competition; they require some degree of monopoly power.

Undermining Convention

Economists prize economic growth but distrust monopoly, so accepting the latter to obtain the former is a Faustian bargain at best. With "Perfectly Competitive Innovation," Boldrin and Levine vigorously reject the contract.

Innovation, they argue, has occurred in the past without substantial protection of intellectual property. "Historically, people have been inventing and writing books and music when copyright did not exist," notes Boldrin. "Mozart wrote a lot of very beautiful things without any copyright protection." (The publishers of music and books, on the other hand, sometimes did have copyrights in the materials they bought from their creators.)

Contemporary examples are also plentiful. The fashion world - highly competitive, with designs largely unprotected - innovates constantly and profitably. A Gucci is a Gucci; knock-offs are mere imitations and worth less than the original, so Gucci - for better or worse - still has an incentive to create. The financial securities industry makes millions by developing and selling complex securities and options without benefit of intellectual property protection. Competitors are free to copy a firm's security package, but doing so takes time. The initial developer's first-mover advantage secures enough profit to justify "inventing" the security.

As for software, Boldrin refers to an MIT working paper

by economists Eric Maskin and James Bessen. Maskin and Bessen write that "some of the most innovative industries today - software, computers and semiconductors - have historically had weak patent protection and have experienced rapid imitation of their products."

Moreover, U.S. court decisions in the 1980s that strengthened patent protection for software led to less innovation. "Far from unleashing a flurry of new innovative activity," Maskin and Bessen write, "these stronger property rights ushered in a period of stagnant, if not declining, R&D among those industries and firms that patented most." Industries that depend on sequential product development - the initial version is followed by an improved second version, etc. - are, they argue, likely to be stifled by stronger intellectual property regimes.

"So examples abound," says Boldrin. "That's the empirical point: Evidence shows that innovators have enough of an incentive to innovate." But he and Levine are not, by nature or training, empiricists. They build mathematical models to describe economic theory. In the case of intellectual property, they contend, current theory says innovation won't happen unless innovators receive monopoly rights, but the evidence says otherwise. "So what we do is to develop the theoretical point to explain the evidence," says Boldrin.

Rivalry Over Nonrivalry

A fundamental tenet of current conventional wisdom is that knowledge-based innovations are subject to increasing returns because ideas are nonrivalrous. Boldrin and Levine argue that in an economy this has no relevance. While pure ideas can be shared without rivalry in theory, the economic application of ideas is inherently rivalrous, because ideas "have economic value only to the extent that they are embodied into either something or someone." What is relevant in the economic realm is not an abstract concept or formula - no matter how beautiful - but its physical embodiment. Calculus is economically valuable only insofar as engineers and economists know and apply it. "Only ideas embodied in people, machines or goods have economic value," they write. And because of their physical embodiment, "valuable ideas...are as rivalrous as commodities containing no ideas at all, if such exist."

A novel is valuable only to the extent that it is written down (if then). A song can be sold only if it is sung, played, or printed by its creator. A software program -

once written - might seem costless, Boldrin and Levine write, but “the prototype does not sit on thin air. To be used by others it needs to be copied, which requires resources of various kinds, including time. To be usable it needs to reside on some portion of the memory of your computer....When you are using that specific copy of the software, other people cannot simultaneously do the same.”

In each instance, the development of the initial prototype is far more costly than the production of all subsequent copies. But because copying takes time - a limited commodity - and materials (paper, ink, disk space), it is not entirely costless. “Consider the paradigmatic example of the wheel,” they write. “Once the first wheel was produced, imitation could take place at a cost orders of magnitude smaller. But even imitation cannot generate free goods: to make a new wheel, one needs to spend some time looking at the first one and learning how to carve it.”

The first wheel is far more valuable than all others, of course, but that “does not imply that the wheel, first or last that it be, is a nonrivalrous good. It only implies that, for some goods, replication costs are very small.”

Economic theorists generally have assumed that the dramatic difference between development and replication costs can be modeled as a single process with increasing returns to scale: a huge fixed cost (the initial investment) followed by costless duplication. Boldrin and Levine say this misrepresents reality: There are two distinct processes with very different technologies. Development is one production process involving long hours, gallons of coffee, sweaty genius, and black, tempestuous moods. At the end of this initial process, the prototype (with any luck) exists and the effort and money that produced it are a sunk cost, an expense in the past.

Thereafter, a very different production process governs: Replicators study the original, gather flat stones, round off corners, bore center holes, and prune tree limbs into axles. Stone wheels roll off the antediluvian assembly line. In this second process, the economics of production are the same as for any other commodity, usually with constant returns to scale.

As Boldrin and Levine develop their mathematical model, they assume only that, “as in reality,” copying takes time and there is a limit (less than infinity) on the number of copies that can be produced per unit of time. These “twin assumptions” introduce a slim

element of rivalry. After it’s created, the prototype can be either consumed or used for copying in the initial time period. (Technically, it could be used for both, but not as easily as if it were used for just one or the other.)

While others simply have assumed, with Romer, that the prototype of an intellectual product is nonrivalrous, Boldrin and Levine argue that the tiny cost of replicating it undermines the conventional model. Production is not subject to increasing returns, they argue, and competitive markets can work. “Even a minuscule amount of rivalry,” they write, “can turn standard results upside down.”

Britney Gets Her Due

Still, the central question is whether innovators will have enough incentive to go through the arduous, expensive invention process. Since the 1400s, when the first patent systems emerged in Venice, governments have tried to provide incentive by granting inventors sole rights to their creations for limited periods. The U.S. Constitution gives Congress the power “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”

Economists long have recognized that such exclusive rights give creators monopolies, allowing them to set prices and quantities that may not be socially optimal. But conventional thinking says these costs are the necessary tradeoff for bringing forth creative genius. Today, the legal realities and economic conventions have assumed the air of incontrovertible fact: If inventors can be “ripped off” - copied as soon as they create - why would they bother?

In arguing for competitive innovation rather than the monopolistic variety, Boldrin and Levine emphasize that they are not saying creators don’t have rights. On the contrary, they stress that innovators should be given “a well defined right of first sale.” (Or, more technically, “we assume full appropriability of privately produced commodities.”) And creators should be paid the full market value of their invention, the first unit of the new product. That value is “the net discounted value of the future stream of consumption services” generated by that first unit, which is an economist’s way of saying it’s worth the current value of everything it’s going to earn in the future.

So if Britney Spears records a new song, she should be

able to sell the initial recording for the sum total of whatever music distributors think her fans will pay for copies of the music during the next century or so. Distributors know her songs are in demand, and she knows she can command a high price. As in any other market, the buyer and seller negotiate a deal. The same rules would hold for a novelist who writes a book, a software programmer who generates code, or a physicist who develops a useful formula. They get to sell the invention in a competitive market. They're paid whatever the market will bear, and if the market values copies of their song, book, code, or formula, the initial prototype will be precious and they'll be well paid.

In fact, says Boldrin, "in a competitive market, the very first few copies are very valuable because those are the instruments which the imitators - the other people who will publish your stuff - will use to make copies. They're more capital goods than consumption goods. So the initial copies will be sold at a very high price, but then very rapidly they will go down in price."

What creators won't get, in Boldrin and Levine's world, is the right to impose downstream licensing agreements that prevent customers from reproducing the product, modifying it, or using it as a stepping stone to the next innovation. They can't prevent their customers from competing with them.

But will the market pay the creator enough? That depends on the innovator's opportunity costs. If the price likely to be paid for an invention's first sale exceeds the opportunity costs of the inventor, then yes, the inventor will create. If a writer spends a year on a book, and could have earned \$30,000 during that year doing something else, then her opportunity cost is \$30,000. Only if she guesses she can sell her book for at least that much is she likely to sit down and write.

"What we show in the technical paper is that the amount [a book publisher] gives me is positive, and in fact, it can be large," says Boldrin. "Then it's up to me to figure out if what society is paying me is enough to compensate for my year of work."

But what happens as reproduction technologies improve: as printing presses get quicker, or as the Internet lets teenagers share music files faster and farther? Won't that drive authors and musicians into utter poverty?

In fact, Boldrin and Levine argue, the opposite should occur. Increasing rates of reproduction will drop

marginal production costs and, therefore, prices. If demand for the good is elastic - that is, if demand rises disproportionately when prices drop - then total revenue will increase.

And since creators with strong rights of first sale are paid the current value of future revenue, their pay will climb. "The point we're making is the invention of things like Napster or electronic publishing and so on are actually creating more opportunities for writers, musicians, for people in general to produce intellectual value, to sell their stuff and actually make money," says Boldrin. "The costs I suffer to write down one of my books or songs have not changed, so overall we actually have a bigger incentive, not smaller incentive."

Conventional wisdom admits that monopoly rights impose short-term costs on an economy. They give an undue share of the economic pie to those who own copyrights and patents; they misallocate resources by allowing innovators to command too high a price; they allow innovators to produce less than the socially optimal level of the new invention. But these costs are all considered reasonable because innovation creates economic growth: The static costs are eclipsed by dynamic development.

Boldrin and Levine say this is a false dilemma. Monopoly rights are not only unnecessary for innovation but may stifle it, particularly when an innovation reduces the cost of expanding production. "Monopolists as a rule do not like to produce much output," they write. "Insofar as the benefit of an innovation is that it reduces the cost of producing additional units of output but not the cost of producing at the current level, it is not of great use to a monopolist." Monopolists, after all, can set prices and quantities to maximize their profits; they may have no incentive to find faster reproduction technologies.

More broadly, producers are likely to engage in what economists call "rent-seeking behavior" - efforts to protect or expand turf (and profits) by fighting for government-granted monopoly protection - and that behavior is likely to stifle innovation. Expensive patent races, defensive patenting (in which firms create a wall of patents to prevent competitors from coming up with anything remotely resembling their product), and costly infringement battles are common functions of corporate law departments. Such activity chokes off creative efforts by others, particularly the small and middle-sized firms that are typically more innovative.

The Critics

Like any radical innovation, Boldrin and Levine's argument has its critics. "We've been presenting it in quite a few key places, and I have to admit that every time there was a riot," says Boldrin. "There was a riot at Stanford last Thursday. It was a huge riot at Chicago two weeks ago. I know it was a riot at Toulouse when David presented it."

A "riot" among economists might not call for crowd control, but the paper does evoke strong reactions. UCLA's Klein says the paper is "unrealistic modeling with little to do with the real world." In a paper with Kevin Murphy of the University of Chicago and Andres Lerner of Economic Analysis LLC, Klein writes that Boldrin and Levine's model works only under the "arbitrary demand assumption" that demand for copies is elastic, so that as price falls over time output increases more than proportionately and profit rises. In the case of Napster and the music industry, this "clearly conflicts with record company pricing. That is, if Boldrin and Levine were correct, why are record companies not pricing CDs as low as possible?"

Romer has a broader set of objections. As a co-author and graduate school classmate of Levine's and a former teacher of Boldrin's at the University of Rochester, Romer has no desire to brawl with his respected colleagues. Moreover, he agrees that property rights for intellectual goods are sometimes too strong; in some cases, society might benefit from weaker restrictions. Music file sharing, for example, might increase social welfare even if it hurts the current music industry. And he stresses that alternative mechanisms for bringing forth innovation - government support for technology education, for example - might well be superior to copyrights and patents. Nonetheless, Romer does have serious problems with the new theory.

First of all, the first-sale rights Boldrin and Levine would assign to innovators "would truly be an empty promise." In their model, if a pharmaceutical firm discovers a new compound, it can sell the first pills but not restrict their downstream use. A generic drug manufacturer could then buy one pill, analyze it, and start stamping out copies.

"So what Boldrin and Levine call 'no downstream licensing' is instant generic status for drugs," Romer complains. And while they argue that the inventor "can sell a few pills for millions of dollars," this is unrealistic if everyone who buys a pill can copy it. "You can make

a set of mathematical assumptions so that this is all logically consistent," says Romer, "but those assumptions are wildly at odds with the underlying facts in the pharmaceutical industry."

If Boldrin and Levine are unrealistic about appropriability, they are even more at sea regarding rivalry, Romer adds. While it's true that ideas must be embodied to be economically useful, it's false to say that there is no distinction between the idea and its physical instantiation. A formula must be written down, but the formula is far more valuable than the piece of paper on which it's written. In a large market, the formula could be so valuable that "the cost of the extra paper is trivial - so small that it is a reasonable approximation to neglect it entirely." If Romer's approximation is right - if it truly is reasonable to neglect that "trivial" cost - then out goes the slim element of rivalry on which the Boldrin/Levine argument rests.

Romer also objects to the contention that competition can deal well with sunk costs. And he suggests that Boldrin and Levine are wrong to object to copyright restriction of downstream use, since perfect competition allows sellers and buyers to enter contracts that impose such restrictions. "What justification is there," says Romer, "for preventing consenting adults from writing contracts that limit subsequent or downstream uses of a good?"

Boldrin's quick e-mail re-sponse: "We never say anything like that!! Patents and copyrights are NOT private contracts; they are monopoly rights given by governments."

Romer counters: "The legal system creates an opportunity for an owner to write contracts that limit how a valuable good can be used....The proposal from Boldrin and Levine would deprive a pharmaceutical company or the owner of a song of the chance to write this kind of contract with a buyer."

According to University of Chicago's Lucas, "There is no question that Boldrin and Levine have their theory worked out correctly. The issue is where it applies and where it doesn't." Their strongest examples, Lucas argues, are Napster and the music industry. "If we do not enforce copyrights to music, will people stop writing and recording songs?" he asks rhetorically. "Not likely, I agree. If so, then protection against musical 'piracy' just comes down to protecting monopoly positions: something economists usually oppose, and with reason."

But Lucas cautions that their theory may not apply everywhere. "What about pharmaceuticals?" he asks, echoing Romer. "Here millions are spent on developing new drugs. Why do this if the good ideas can be quickly copied?"

Refining the Theory

Solow suggests that Boldrin and Levine should enrich their "very nice paper" by testing its robustness. What happens, for example, if the time interval between invention and copying is shrunk? And - echoing Arrow - "does anything special happen if you introduce some uncertainty about the outcome of an investment in innovation?"

Boldrin and Levine recognize that work remains to be done to strengthen their theory. They have begun to examine the effect of uncertainty on their model, as Solow suggests, and they say the results still broadly obtain. The difference is that a large monopolist may be able to insure himself against risk, whereas competitors will need to create securities that allow them to sell away some of the risk and buy some insurance.

As for pharmaceutical research and development, Boldrin and Levine contend that their critics are misrepresenting the industry's economics. Much of the high cost of pharmaceutical R&D, Boldrin argues, is due to the inflated values placed on drug researchers' time because they are employed by monopolists. Researchers are paid far less in the more competitive European drug industry.

In addition, Levine says, pharmaceuticals aren't sold into a competitive market: "They are generally purchased by large organizations such as governments and HMOs." If inflated drug prices are viewed more realistically, these economists argue, the development costs of new drugs would not be nearly as insurmountable as commonly believed.

Moreover, copying a drug takes time and money, providing the innovative drug company with a substantial first-mover advantage. "It's not obvious that the other guys can imitate me overnight," says Boldrin. "The fact that you are the first and know how to do it better than the other people - it may be a huge protection."

Still, they admit, there are cases of indivisibility where the initial investment may simply be too large for a

perfectly competitive market. "We have argued that the competitive mechanism is a viable one, capable of producing sustained innovation," they write. "This is not to argue that competition is the best mechanism in all circumstances." Indivisibility constraints may keep some socially desirable innovations from being produced; the situation is similar to a public goods problem. The authors suggest that contingent contracts and lotteries could be used in such cases, but "a theory of general equilibrium with production indivisibility remains to be fully worked out."

Some economists have already begun work on the next stages. Quah at the London School of Economics has pushed Boldrin and Levine's model in a number of directions to test its robustness and applicability. In one paper, he finds it works well if he tweaks assumptions about the consumption and production of the intellectual assets, but it falters if he changes time constraints.

In another paper, Quah contends that Boldrin and Levine's potential solutions to indivisibility constraints may not actually resolve the problem. "What is needed," he writes, "is the capability to continuously adjust the level of an intellectual asset's instantiation quantity." Roughly translated: We need the ability to come up with half an idea. That might be a problem.

More studies like Quah's will be needed to poke, prod, refine, refute, and extend Boldrin and Levine's theory. And empirical work will be needed to see whether it is indeed a more apt description of innovation. The theory is part of an intellectual thicket, and economists who work that thicket tend to render it impenetrable by adopting different terms or defining identical terms differently.

What is clear, though, is that Boldrin and Levine have mounted a formidable assault on the conventional wisdom about innovation and the need to protect intellectual property. That it has met with opposition or incredulity is to be expected. What matters are the next steps.

"The reaction for now is surprise and disbelief," Boldrin says. "We'll see. In these kinds of things, the relevance is always if people find the suggestion interesting enough that it's worth pushing farther the research. All we have made is a simple theoretical point."

*Document***Drug Pricing Task Force Report: Executive Summary¹**

A Task Force was constituted on the 29th November 2004 to explore various options other than price control for achieving the objective of making available life saving drugs at reasonable prices. The Report of the Task Force is now in the public domain and its major recommendations are as follows (reproduced from the Executive Summary of the Report, the full report is uploaded at the mfc website www.mfcindia.org).

1. The Strategic Approach

The Task Force recommends that price regulation should be on the basis of 'Essentiality' of the drug and it should be applied only to formulations and not to upstream products, such as bulk drugs. No effort should be made to impose a uniform price, and only a ceiling price should be indicated. The ceiling price of essential drugs should normally not be based on cost of production but on readily monitorable market based benchmarks. Other drugs falling into selected therapeutic categories should be brought under a comprehensive price monitoring system with mandatory price negotiations system, if necessary. The regulatory mechanism should be significantly strengthened both at the Centre and in the States. A process of active promotion of generic drugs should be put in place including mandatory debranding for selected drugs. Public Sector Enterprises (PSEs) involved in the manufacture of drugs should be revived where possible and used as key strategic interventions for addressing both price and availability issues. The drug regulator must maintain a data base of brands and their compositions and no change should be permitted in the composition of a given brand. There should be bulk purchases of drugs by Government agencies, co-operatives or consumer bodies through public-private partnership and insurance companies should be encouraged to extend health insurance covering medicines.

2. Drugs and Therapeutics (Regulation) Act

A new legislation viz, Drugs and Therapeutics (Regulation) Act (DATA) should be enacted for price control on drugs. Under DATA Government should be empowered to impose a price or limit the increase in price, and to clearly lay down the principles governing or the reasons leading to imposition of any such price control and to seek or compel disclosure of any information or data relevant to its functioning. The powers

and provisions of the DATA would be in addition to those contained in the Drugs and Cosmetics Act, 1940 and Essential Commodities Act, 1955.

3. National Authority on Drugs and Therapeutics

As a long term objective, the Task Force endorses the proposal made by the Planning Commission in the Mid-term Appraisal of the Tenth Five Year Plan to establish a National Authority on Drugs and Therapeutics (NADT), as an independent regulatory agency integrating the offices of the Drugs Controller General of India, the Central Drugs Standard Control Organisation (CDSCO) and the National Pharmaceutical Pricing Authority (NPPA) along with all the powers and functions of these bodies. In the interim, a dual regulatory system comprising of the National Drug Authority (NDA) and the NPPA is proposed with standing arrangements for resolution of over-lapping responsibilities.

4. Other Regulatory Issues

Consistent with the strengthening of the Central Drug regulatory system, the state's supervisory and regulatory capacity should also be strengthened. The Centre should financially support State Governments to bring their state drug control formations to a threshold level, especially as far as the price monitoring functions are concerned. The recommendations of the Mashelkar Committee 2003 report should be adopted as a blue print for this purpose.

5. Principles of Price Regulation

The Task Force recommends that the National List of Essential Medicines (NLEM) 2003 should form the basis of drugs for price control/monitoring. To support the process the Government should announce the ceiling price of all drugs contained in the NLEM on the basis of the weighted average price of the top three brands by value of single ingredient formulations prevailing in the market as on 1.4.2005. In cases where there are less than three brands, the average of all existing brands would be taken. The ORG-IMS data can be used for this purpose initially with a retail margin of 20%. For drugs which are not reflected in ORG-IMS data, the NPPA should prepare the necessary information based on market data collection. In the case of formulations which involve a combination of more than one drug in the NLEM, the ceiling price would be the

weighted average of the applicable ceiling prices of its constituents. Excise duty should continue to be payable on the actual MRP of the individual medicines. In the case of drugs not contained in the NLEM, intensive monitoring should be carried out, for any new formulations based on existing APIs, manufacturer concerned would be required to submit its intended price along with application for marketing approval to the regulator, which would be granted only if the indicated price is consistent with relevant ceiling price. The NLEM should be revised every three years.

6. Patented Products

All patented drugs and formulations should compulsorily be brought under price negotiation prior to the grant of marketing approval. The reference price to be used for such negotiations will be the prevailing price of the closest therapeutic equivalent in the domestic market/lowest price at which the drug is marketed internationally.

7. Bulk Procurement

Bulk purchase mechanism should be streamlined to ensure that the current malpractices are curbed so that the prices reflect the true value of quality drugs. In order to reduce the financial burden of public health system it would be appropriate that a lower ceiling price is fixed for the bulk procurement by Government.

8. Promotion of Generics

Public procurement and distribution of drugs through the public health system should mainly be for generic drugs. Quality certification may be provided free to dedicated generic drug manufacturers and there should be no control on price or distribution margins specified for generic drugs.

9. Access Arrangements

The low volume high priced drugs such as cancer drugs, anti AIDS/HIV drugs may be exempted from the payment of excise duty, custom duty, octroi and other levies if any. This benefit should be passed on to the patients.

10. Public Sector Undertakings

The role of PSUs producing drugs should be recognized and all Departments of Central Government must be advised to first procure their drugs from the PSUs at prices approved by NPPA for the drugs covered under the essential category. For other drugs produced by these PSUs, procurement may be done at prices worked out by a committee constituted for this purpose.

11. Scheme for BPL families

The Central Government has set up a National Illness Assistance Fund (NIAF) under which assistance to states upto 50% of their share is provided out of this fund in the State illness Fund (SIF) set up by respective states. A BPL patient is provided financial assistance upto Rs.1.50 lakhs. The Task Force feels that there is an imperative need for the states to set up the SIFs and revolving funds in all Government hospitals for making available medicines free of cost to BPL families.

12. Excise Duty Relief

The Task Force has recommended to reduce the excise duty on all pharmaceutical products from 16% to 8%. In order to mitigate the rigors faced by and to provide a level playing field for small scale pharma units to enhance the exemption limit of small scale units from the present Rs.1 crore to Rs.5 crore.

13. Research and Development

Keeping in view the introduction of Product Patent Regime in India the Task Force has recommended that fiscal incentives should be granted over a much longer period of time, say 10 years, rather than the limited period extensions that are being made presently. The corpus of Rs.150 crore under the Pharmaceutical Research and Development Support Fund (PRDSF) needs to be sufficiently increased over the next 5 years.

14. Facilitating Schedule M Implementation

A special fund should be created for providing interest subsidy on borrowings to small scale pharma units adopting Schedule M implementation. This assistance should be in addition to any other financial assistance.

15. Public Awareness

To create public awareness and to educate the people, a dedicated web site needs to be created in addition to other possible modes of enhancing public awareness like public literatures, booklets, newsletters/magazines etc.

16. Settlement Commission as a Device for funding Certain Activities

A Settlement Commission on the lines of constituted by the Income Tax Department needs to be constituted for settling the cases of past and future arrears of over charging from the drug companies. All on-going court cases should be brought before the proposed settlement commission and efforts be made to arrive at some workable settlement.

Prolonging Death: Capitalism and Old Age

T. Vijayendra¹

I. Who wants Old People?

I'd like to be working up to 3 days before I die. But I am not likely to. I envied my father because he died at the age of 80 and still was managing his affairs on his own. On the other hand my mother was incapacitated for many years and the last few months she developed bedsores and died in misery, and every one was happy to see her go! I am 62 year old and it scares me (like it does so many of us) that I may have the same fate as my mother had. From the age of 50 I have been on asthma medicine, from the age of 60, I am on blood pressure and cholesterol medicine and now my knees are getting really painful. What triggered this essay was the news coverage of deaths in France.

Deaths in France

Sometime back about 15,000 old people died in France during an unusually hot summer. France has a longevity figure of 84 years. Most of these old people lived in old age homes. Most doctors and relatives had gone for vacations to 'hotter' climates. The bodies stayed in morgues for weeks. Even after return many relatives did not want to claim these bodies and let the state arrange the funeral. Everybody blamed everybody including global warming. One unstated loud fact was that everyone was relieved that they died, perhaps including some of the old people themselves.

What happened in France is of course an extreme case. In most affluent countries the number old people is increasing at an alarming rate. In developing countries, too, the rich and the middle class are living longer. India has an average longevity figure of 67 years. Communities are dying and so are the traditional support systems for the old people. There are not enough old-age homes and few of them are adequate.

Old Age is a New Phenomenon

Till the 19th century most people died before they reached the age of 50. Even today most poor people

in Asia, Africa and Latin America die early. Thus the longevity figure of 67 years for India actually means that the affluent here are living much longer than 67 years and that the poor are still dying before they reach 50 or so. Today, in India, there are about 75 million old people above the age of 60 years, which is about 7.5 % of India's population. In the 'developed' countries this percentage is higher and in the poorer countries it is lower.

These old people on the whole are a burden on the earth (this includes the present author also). Most of them are pure consumers. And since they are from affluent societies, their consumption levels are far above average. In the market it is the young who are sought after. Older people are forced to retire. They do not find any productive or meaningful work. But now the reverse is also true in the West – because of the pensions crisis people are being warned they will have to work till 70, like it or not! Possibly the pension fund managers want people to die before they can claim their pensions!

A few old people are of course very rich and powerful. Most of these are corrupt politicians and business people. At the other end, there are a few old people who are 'nice' people, that is, wise, caring, lovable and respected. But the overwhelming majority of old people are ordinary, unwanted people!

II. Old Age is a Racket!

Medico-Industrial Complex

Old age is a racket created by the medico-industrial complex. This is the second largest business after the armament industry. Both control people and nations. The medico-industrial complex controls people and nations by creating dependencies. Just as the military-industrial complex survives on small-scale continuous warfare, the medico-industrial complex also survives on rich people having prolonged illnesses, involving expensive treatment, but not dying. People above 60 years of age ideally suit this purpose and they pay nearly 70% of the medical bills. This is a nexus of loot between the health care system, medical technology, drug industry, pension and insurance

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schemes and housing industry. Britain is an exception, where the National Health provides health services free at the point of delivery.

Capitalism survives on individualism and insecurity. A fear of old age is generated right from the day one starts work. Social security, pension and insurance scheme vultures arrive with one's first paycheck. Credit cards, loans for consumer durables and housing loans follow. A big chunk of one's paycheck vanishes into pension and insurance scams. Lovely media images are created as to how a wise old man is enjoying his old age with children and grandchildren! Now each of these is a well-known racket. Everyday somewhere or the other a pension or insurance scam is being exposed.

When old age actually arrives the problems show up. The house has to be repaired regularly because the construction is poor. Every breakfast you are swallowing half a dozen pills to keep this or that symptom under control. And your pension is not enough.

And as we said above the old people are unwanted, lonely, unhealthy, depressed and unhappy. They are living in what the naturalists call 'zoo conditions'. For example in nature a sparrow lives about 3 years. In a cage however it can live upto 13 years! But a bird in a cage is also lonely, unhealthy, depressed and unhappy. Just like our old people.

The Abuse of Medical Ethics

Books have appeared about how rapacious is the drug industry. Irrational tests and surgical procedures take a big toll on money, health and sometime life too. However it is in the interest of the industry to keep the patient ill but alive.

One of the worst abuses of the health care system is prolonging death. As Ivan Illich has said, death is defined as the stage when the patient is unable to pay. A new culture has come into being saying that life per se is precious and that a person has to be kept alive no matter how much he is suffering or whether he himself wants to live such a life. Some time, the converse can also be true. Recently a man with incurable disease went to the Court of Human Rights to make sure that doctors don't stop life support systems. In other words he wants to go on existing, even in a vegetable state. In this, the religious organizations, and particularly the Catholic Church, have played a powerful role. This has led to an enormous amount of suffering to the patients and their families. In many cases it has also financially broken

the families. On the other hand, millions of young people are dying all over the world from 'curable' diseases like malaria, tuberculosis, leprosy, cholera and diarrhoea. But they cannot pay and hence they have to die!

III. A 'Natural' Life!

A Typical Life

What is a typical natural life? We just have to see a tribal family, which is not yet seriously affected by 'modern' life. Up to the age of five or so the child stays near mother and the family. Many children died at childbirth or a few years later if they were weaklings. Then the child starts going out with the elders and helps in some activities that helps the family. This can be food gathering, carrying and fetching. It is also an apprenticeship. The child learns a lot. By twelve years s/he starts venturing alone or 'gangs' of children begin moving on their own, exploring, learning and getting to be self-sufficient. By eighteen, the young adults start their own families, by thirty all the children are born and by the time they are forty they are ready to go! Most 'old' people in their forties continue to work till a few days before they die. They usually die with very few days' illness or none. The causes of death are more 'natural' and not 'zoo condition' deaths of contemporary old people. These can be hunger and famine, encounters with wild life, poisonous insects, reptiles, bacterial and viral disease and accidents.

Such a life does not face the diseases of our time, such as cancer, heart attack, backache, diabetes or even menopause. Most of these occur after 50 and are related to lifestyle patterns. Their life cycles are similar to other living beings in nature. Most people till the 19th century lived this kind of life. Until 200 years ago, there was no population problem. In 10,000 B.C. the population of humans on earth was less than a million!

Lessons from the Past

What was the basis of life in the past? One was that every one was working, although they worked much less than we do. This was so because there was no leisured class (which consumed enormous resources) to be supported, and the natural resource base available was much higher. Today there are huge wasteful industries such as armament, pharmaceuticals, cosmetics, tobacco, alcohol and so on, which guzzle natu-

ral resources. They also demand human labour and consumerism all of which cause much of our problems today. Secondly, individualism and consumerism in modern society is breaking down communities. In the past, the family and community provided much of the caring needed in illnesses. Physical labour, reviving communities and reducing consumerism is the main lesson we can learn from the past.

IV. Living with Dignity

Reviving Communities of a New Type

To revive communities, first we have to understand why communities are breaking down. They are breaking down because the old society was unfree in many ways and curbed people's aspirations. Now that cannot be reversed. Old type of communities have to go.

The driving forces are individualism and cash economy. If you have money in your pocket you are free to do what you want to do! Now individualism has come to stay because people cannot give up freedom they have achieved. But dependence on cash economy and consumerism can be reduced. The need for community will always be there because the human species is social species. What we need is new type of community. A community not based on power and authority but on freedom. A free association of free people! In such a situation the insecurities will be less and one can avoid to a large extent the rapacious nexus of medical industrial complex, insurance scams and housing loans.

A Rational Health Care

The rational health care will essentially be based on community care. It will be based on caring and not fleecing. It will be based on a healthy life style – a good mix of mental and manual outdoor work, a healthy diet and a stress-free, peaceful tranquil life! Illnesses and diseases can and will still occur but they can be more effectively dealt with in such a situation.

In health care there are three components – knowledge-based reassurance, relief and cure – in decreasing order of importance. A well-trained and experienced doctor can indeed play a very important role. However he will be much more effective in delivering health care in a community based health care system than in the present market based system.

V. Dying with Dignity

Doctors and Death

Most classics in medical literature, in all systems of medicine, ask the doctor to respect people, reduce their sufferings and when death is inevitable, not to prolong the misery. However, as we have seen above, a new culture has come into being where prolonging life at all costs has become a lucrative business at the cost of the patients and their families. Often doctors are helpless because of the pressure of this culture and the possibility of the patient's families taking them to court. Family members in turn feel helpless lest their neighbours say that to save money these people let the patient die! We need to restore the concept of living and dying with dignity.

Euthanasia and the Living Will

There are many cases where it is no longer good to prolong life, which in fact amounts to prolonging death. In some countries medically assisted death is legal. However in most countries it is not and many may not want it. For such cases, a 'Living Will / Advance Directive' is useful. It is made when the person is of sound mind and gives his/her directive to doctors, relatives and friends for such situations. Essentially it asks them not prolong their death with medical intervention or treatment, not to put them on life support systems and manage their last hours with painkillers only, even if it shortens their life.

Cultural and Religious Traditions

In most societies there is a tradition and ritual of meeting death with dignity and peace. In essence it is similar to the living will. However here it is not solely dependent on individual will but there is a community support. The Christian tradition of Hospice comes closest to the living will, where medical care is provided to reduce suffering but not to prolong death. Some Hindus build a cottage next to a holy river and spend their last days peacefully. Jains have a tradition of systematic fasting to death with religious rituals. Some tribes in Fiji believe that after death they will live eternally at the age at which they died. So they prefer to die in their prime! In the polar region some communities send their old on a boat with provisions. It is possible to build secular traditions too. In Hyderabad there is an old-age home run by the Communist Party!

ADD LIFE TO YOUR YEARS AND NOT YEARS TO YOUR LIFE

Minutes of MFC Mid-Annual Meet Sewagram, 9th-10th July, 2005

Participants: Anant Phadke, C. Sathyamala, Ulhas Jajoo, S.P.Klantri, Binayak Sen, Dhruv Mankad, Jyoti Gupta, Ravi D'Souza, Ritu Priya.

At the outset it was collectively decided to begin the MAM with the two substantive campaign issues, the proposed universal ban on iodised salt and the polio eradication initiative, and the theme for the annual meet 2006, then to discuss the thematic cells and finally other organizational issues. Despite the small number, the discussion on all subjects was as lively as always.

Iodine Deficiency Disorders (IDD) and Universal Iodisation of Salt

The e-group discussion on the subject had been consolidated and a print out was available for reference. Anant, Dhruv and Ritu led the discussion, with queries and comments from all others. The issues raised can be summarized as follows:

- I. The Epidemiology of IDD and impact of universal salt iodisation
 - Magnitude of the problem?
 - Evidence of positive impact?
 - Evidence of negative consequences?
- II. The Political Economy of salt and its iodisation
- III. Choice/rights of citizens vs. compulsory consumption of iodised salt.

Available information and technical data related to (I.) was discussed and, even after consideration of opinions to the contrary by MFC members on the e-groups, led to questioning of the scientific basis of such a public health intervention.

For II, the information supplied (on the e-group) by Dhruv of the available US and Indian production processes available for Potassium iodate and then using it to iodate common salt was found very useful. Small-scale iodation plants had become feasible with the Indian technology; the US one being much more expensive.

The issue of choice/rights of citizens versus compulsory consumption of iodised salt was discussed at some length and two views were expressed: (i) that compulsion by the state was not acceptable at all and (ii) that compulsion was not acceptable for measures of individual protection but justified if the freedom to choose was likely to violate other's rights or harm others. It was thought that the second statement is open to abuse and "a 100 questions need to be asked before any such step is taken". Ulhas pointed to the need to differentiate ethics, morality and spirituality. The consensus formulation reached after discussion was "We question the use of compulsion in any public health intervention."

In view of the intensive discussion, it was thought that Dhruv would formulate the objection to the ban from MFC, in a manner that it accommodated all views and would be acceptable to all MFC members. The request to Sridhar to do a review on the

subject for MFC was to be repeated.

Theme and Structure of Annual Meet 2006

The theme decided at the GBM, Jan. 2005 was 'Quality and Costs of Health Care: Social Regulation in the context of Universal Access'. Ritu briefly presented the main points of the background note circulated by her on the e-group (and published in the bulletin). A long session of brainstorming followed through the second half of the first day and on to the second morning. Recapturing the whole discussion is difficult, however to give a sense of it, the major issues are given below :

- I. That diverse perspectives exist on the issue:
 - i. The issue of quality and cost as reflected in the National Health Policy was brought up by Anant.
 - ii. The CII statements were pointed out by Ritu.
 - iii. The Management approach was articulated by Dhruv:
 - Minimum infrastructure standards Patient satisfaction.
 - Incremental upgradation
 - iv. The views of communities and peripheral level workers were considered important to incorporate

II Formulating the Minimum standards:

- Ulhas started the discussion on this from his experience of a community health programme — For a Primary Health Care Hospital, focusing on the personnel and specialties required.
- S.P. Kalantri spoke of 122 criteria set for a rural hospital by the Maharashtra Health Systems Development Project, which included criteria for infrastructure, referral, safety mechanisms levels of technology and personnel.
- Ravi D'Souza suggested that we should not think of personnel by specialties but by the minimum services needed and what all one doctor can provide. The issue of standards for the private sector was raised.

III Public/Private Sector and Regulatory Mechanisms

- Ritu suggested that we think of criteria for public health services as first priority and then how they can be met by all kinds of private sector services as well.
- Sathya emphasised the need to look at the issue systemically, e.g. how can we envisage doctors coming to work in public health services when medical education is to involve high fees and medical tourism affects the orientation of medical institutions?
- Anant brought in the issue of primary level care providers in sectors, the CHW and the private practitioners. The public system standards are available, so we can start with them. The issue of universal access will have to be addressed for the private sector.
- Sathya added the importance of setting criteria for use of diagnostics e.g. ultrasound in pregnancies.
- Dhruv pointed out that, with public hospitals becoming corporations, same criteria and mechanisms as for the private sector will have to be applied.

· Ulhas brought up the role of the community in controlling quality and cost. One model could be that the government provides the infrastructure and the doctor is paid by the community. The Gram Sabha should be involved in tariff negotiations.

· Anant pointed to the Canadian model of social insurance with the municipal body and communities playing a role.

IV. Quality Criteria for Public Health Programmes

· Anant wanted discussion on the issue of standards for public health programmes, as raised in the background note. He raised the issue of defining the 'desirable' standard and the simultaneous need to compromise on them due to economic constraints, for instance, even with .0001% cretinism, he thought it desirable to do screening of all neonates, but would not consider it a priority for our health services at this stage.

· Ritu questioned whether this is a 'desirable'. We need to think at what point of prevalence do we let nature take its course. Magnitude of the problem, level of technology needed and optional measures available to tackle each problem as well as cost at societal level — not only financial but in the Illichian sense— have to be taken into consideration.

· Binayak posed the question – how do we address the issue of dealing with epidemics and the endemic conditions that lead to mass ill health, e.g., improving water supply? In this context, Ritu pointed to the importance of recognising the role of the public health system in highlighting the causality of disease in society, through surveillance, monitoring and initiation of societal action.

Finally, the following tentative structure was worked out for the Meet:

Session I

Role of the Health Care System from a Public Health Perspective

[One or Two Overview Papers as Backgrounders with brief presentation of main points.

+

Open Discussion]

Session II

Quality of Public Health Care

- a) Surveillance / monitoring at district level
 - content
 - inputs required (costing, expertise etc.)
- b) Programmes
 - priority setting
 - criteria for quality
 - wasteful expenditure

Background papers + in-depth discussion on one/two control programme(s) (e.g. IDD control and Polio Eradication which are already under discussion within MFC).

Session III

Quality Standards for Community Level and institutional Primary Level, Secondary & Tertiary Level Service Delivery

- Services required at each level

- Criteria/parameters for quality [for professional medical care, Paramedics and community providers, Institutions (Public and private), teams]

- Inputs needed to reach those levels (finances, technology, human) for public health system & for private sector.

Backgrounders of specific experiments and experiences should form the basis for discussion, e.g.:

Low Cost Effective Care Centre, Vellore; Community-based Palliative Care Network, Manjeri, Kerala; Arvind Eye Care Centre, Hyderabad; Jan Swasthya Sahyog, Bilaspur; Trauma Centres; Drug Procurement System - Tamil Nadu.; Glass vs. Disposable Syringes; Dais vs. Institutional Deliveries; Mitamin Programme, Chhatisgarh.

Session IV

Structures Required for Social Regulation

· Accreditation and rating systems?

· Social insurance systems?

· Community structures

· Lessons drawn from the experience of case studies discussed in the previous session.

(All the examples given were illustrative and not exhaustive)

Date & Venue

The two dates proposed at the GBM (21st-22nd Jan & 27th - 28th Jan.) were discussed and the second preferred since it gave people the day of 26th to travel.

Venue: The convener informed others of the communication with Dr. Ekbal about organizing the 2006 meet in Kerala. It was felt that another option should also be explored. Vellore was proposed, and Ravi D'Souza and Binayak volunteered to contact Anand Zachariah and other friends to sound them out about the possibility.

Vellore was thought to be a good option because of the medical setting and possibility of interaction with 'socially conscious people' interested in the theme outside MFC. It has several experiments with developing quality of care suited to local context, and there are several possible venues there - CHAD/ Karigiri/ the main college campus.

The Polio Eradication Initiative

Sathya initiated the discussion by tracing the sequence of events of how the issue got taken up: it was initiated by Dr Onkar Mittal who worked on gathering data/literature since 2002 and Sathya joined in this endeavour in December 2003. A letter was sent to WHO by her and Dr. Mittal asking questions about the polio eradication initiative, a memorandum was sent to the MOHFW/UNICEF/WHO in April 2004, MFC members endorsed the memo, and we are still waiting for a response from these bodies. The decision not to go to public in the World Health Assembly and media was so as not to cause confusion in the public mind. Subsequently, an article co-authored by Sathyamala, O. Mittal, R.Dasgupta and R. Priya has been pub-

lished in the IJHS, as also a response to an article in the EPW on the subject. Now it is time to think of going into campaign mode. In the ensuing discussion, additional points were raised and some others corroborating the critique were cited.

· Dhruv provided information of an estimated cost worked out to Rs.30, 000 / per child protected, with a lot spent on the advertising.

· Anant reported Dr. Deodhar's critique that eradication is technically not feasible since sub-clinical infections persist and water supply safety is not being dealt with.

Anant also reported Dr. Kale and Dow's point that reversion of virus is possible and vaccine associated paralytic polio (VAPP) is 25% of all cases in India today.

· He quoted Dr. Jacob John in Jan. 2004, *Ind. J. of Paediatrics*, acknowledging the limitations of the present strategy and advocating for injectable polio vaccine (which is 150 times the price of the oral one).

It was generally felt that a campaign should now be undertaken and a sequence of steps planned for it. Several different approaches to the campaign were proposed, including mobilization/networking with existing critics, larger mobilization and information dissemination, demanding compensation for children who get paralysis despite having been immunised, demanding full information etc.

Everyone volunteered varying degrees of input in the campaign. Existing papers could be used for going to academics but briefs and other documents would have to be prepared for the larger campaign. Further discussion for the campaign was left till the annual meet.

Organisational Issues

1. MFC brochure: Decision taken that the convener will get the brochure printed, after updating information and life-subscriber charges, etc.

2. Thematic Cells: No one was sure whether they were in suspended animation or dead! It was proposed to check with the conveners of each cells if they wished to revive them or saw the possibility of that. The following thematic cells and their conveners as per memory of those present:

<i>Theme</i>	-	<i>Convenor</i>
Women & Health Cell	-	Neha Madhiwala
Health Policy Cell	-	Abhay Shukla
Primary Health Care Cell	-	Shyam Ashtakar
Infectious Diseases Cell	-	Yogesh Jain

[Any others?]

3. MFC Books & Reports - In Search of Diagnosis, the Medical Education Anthology, Under the Lens, Depo-Provera, Bhopal, Gujarat.

· We need to collect complete information about the present stock of each one- from previous conveners, the registered office, Cehat Mumbai, CHC, Sathyamala.

· An earlier proposal to upload them on the website was repeated and welcomed by all. Anant remembered that Amar had

offered to get it done. It was proposed that this be followed up. It was also proposed that members with the competence could be asked to volunteer time to do the uploading. Nobhojit Ray has been doing it for the MFC bulletins, but it is too much work for one person.

4. Functioning of the MFC e-group was discussed and it was felt that some rules decided upon earlier need to be reiterated —

· Introduction of all new members must be given by the introducer.

· The ground rules need to be sent on the e-group every month to remind them periodically.

· The detailed discussion at the Bhopal GBM was recalled and it was felt that the issues spelt out there need to be taken up.

5. Follow-up on Gujarat and the Togadia case- The convener reported her communication with the Amnesty International Asia desk, whose network had also represented to the MCI on the need for investigating the role of doctors during the post Godhra carnage. The MFC report had been used for this. Exchange of information of our respective cases with the MCI had been decided upon.

· It was decided to discuss the case at the annual meet when more people involved were present.

· Members recalled that at the Gujarat meet it had been decided that MFC would develop a curriculum on Communalism for doctors and a curriculum on Health and Violence. A workshop was organised in 2003 at Pune. No one had any information about further follow-up of either curricula.

· Anant reported that Cehat (Sunita, Neha, Abhay and Jaya Velankar) had done on analysis of the post-mortem reports. The analysis may be available with Sunita??

6. It was pointed out that minutes of the Gujarat meet and the last 2 meets had not been published in the MFC bulletin. Neither had the audited statement been published for the past 2 years. It was felt that this should be rectified.

7. Sathya reported that she had been appointed by the Supreme Court as a member of the advisory committee on the Bhopal case, chaired by Prof. Ganguli, Director ICMR. Unfortunately, the issues raised by her and others in the Committee in favour of the surviving victims were misrepresented in the minutes. Despite bringing this to the Chair's notice corrections were not made and the minutes were submitted by Prof Ganguly to the Supreme Court with minor changes. So an affidavit had to be filed in the SC against him. Prof Bhargava, who is also a member of the advisory committee too agreed to the contentions raised by Sathya.

8. Recent publications on the Bhopal Gas Tragedy had completely blacked out the MFC reports — e.g., *Seminar's* special issue and a publication co-authored by Sathya & Ward Morehouse.

These issues brought the discussion around to two perennial questions: (i) members' sustained interest and time commitment to MFC, and (ii) marginalisation of MFC perspectives by the mainstream trends and the need to articulate and disseminate these more effectively. It was thought important that attempts be made to address these issues when planning the forthcoming annual meet and other activities.

Alice Thorner: A Personal Tribute

-Sujata Patel¹

Alice Thorner, my friend and collaborator died in Paris on Wednesday 24th August 2005. She was 87. She will be missed by many - Alice had wide contact with four generations of scholars, activists and journalists with whom she observed, and joined forces to assess the manifold changes occurring in contemporary India.

Though born an American, she was passionate about all things Indian. This passion was first instilled in 1939, when she met Indian liberal-left students in England where her husband, Daniel was doing research in the India Office Library on the railway system in India. She and her husband were part of a group of liberal and leftist intellectuals who looked with hope towards India when the Second World War was over with the death of fascism as a site for a new kind of social transformation, neither capitalist nor communist.

She first visited India in 1945, and later came back in 1952 when Daniel took a sabbatical to do research on the agrarian situation in India. This visit meant for a year stretched out till 1960, when Daniel was asked to testify against himself and that of his colleagues by the Senate Investigative Committee, during the McCarthy years. When he refused to do so, his job and fellowship slipped out of his hands as did his passport.

They remained in India and made it their home till 1960, when they shifted to Paris. In this period they did their best work as social scientists.

Alice and Daniel were consistent dissenters without ever being ideologically close minds. This criticality fuelled all their work done on India including the masterpiece that they wrote titled, *Land and Labour in India* (now being reprinted as a new edition). These eight years of self-exile in Bombay were for Alice the most joyous and happy years together being her most creative. Singly and together with her husband, she researched on many aspects of Indian society and created concepts, categories and theories in the arena of demography, agricultural economics, and urban and industrial development.

After Daniel's death in 1974, Alice started coming to

India every year for at least three months. She collaborated with Indian social scientists and was affiliated to many Indian research institutes. From Paris she integrated three continents of scholars on India, the American, the European and the Indian. Her home became a salon where intellectuals could meet and discuss important issues and ideas regarding India, especially after the seventies when there was a serious rethinking being attempted in understanding whether India had indeed gone through a third path of development.

In this context Alice started a new life, as a single woman and a professional and built a new research agenda-to study urban processes in India and to participate with other women scholars in understanding the gender question in India. Earlier she and Daniel had written for and were closely associated with the *Economic Weekly*, later called the *Economic and Political Weekly*. Now she urged the editor of EPW, to initiate a special thematic section titled, 'Review of Women's Studies'. This marked a threshold in the growth of women's studies in India. The first set of papers from the Review has been published as *Ideals, Images and Real Lives: Women in Literature and History*.

In early 1990 Alice approached me when I was in the Department of Sociology at the SNDT Women's University to organise a conference on Bombay. She had lived in Bombay and was interested in understanding how communities constructed the city in the 19th and 20th centuries and gave it a modern and secular identity. This conference was held in interregnum between the two phases of violence that occurred in 1992-3 and which initiated a pogrom against the Muslims in the city that questioned Bombay's secular character. Volumes from the conference (*Bombay: Metaphor of Modern India and Bombay Mosaic of Modern Culture*), which I co-edited with her, reflected these concerns.

Being a historian she remained an optimist all her life - yet she had been very disturbed by the developments of Hindutva forces in the last few years. She remained a humanist committed to liberal ideas and critical thinking and found it difficult to appreciate the new changes taking place in India.

(continued on page 24)

¹ Professor of Sociology, University of Pune

(continued from page 23)

For the last fifteen years Alice and I have collaborated on many issues and concerns. Over time we have moved from being collaborated to being intimate friends. In her passing away, I personally, and all of us have lost a dear friend and a mentor. She will always remain a role model for many of us - of a competent professional and a compassionate thinker who believed in ushering in social change that can reorganise inequalities in India.

I was in Paris last week - on Wednesday and Thursday, 18th and 19th August and stayed with her. I was on the way back from the US where I had attended two conferences. Despite being weighed down by physical difficulties she was interested in engaging with me and debating my arguments in these papers. As was her nature, she insisted I invite one colleague from Paris, whom I had met in one of the meetings. Over tea and cakes, she vigorously defended the argument that in France inequalities were on the rise. As I kissed her goodbye the next day, she reminded me to send her my papers of the conference. On Monday night, she was taken to the hospital with breathing difficulties and passed away on Wednesday morning at 11.30 am. Alice went as she lived - an intellectual who cared.

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Next Annual Mfc Meet

Next annual meeting theme will be on "Social regulation of Costs and Quality of Care in the Context of Universal Access to Health Care". The suggested dates for the annual meet are Jan 27-28, 2006 and will be in Vellore, Tamil Nadu. GBM on Jan 29th.

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*Supplement to Issue 313-314***The Iodised Salt Issue: Exchanges on the mfc e-forum**

June 20, 2005

Dear All,

This is a mail from Dr. Banerji on iodine addressed to JSA and copied to me among others. I am circulating it at the mfc eforum with the request that this issue also be taken up at the mid-annual meet for discussion. I also heard over the grape wine that Ramdoss plans to introduce iodine plus iron fortified salt, which will cost Rs20/kg!

Sathya

 Dear JSA Friends,

I realise that JSA and PHM are “coalitions” — with a common minimum programme. But when we call ourselves as an Andolan or Movement, at least some of us are concerned about the people as a whole, particularly about the unserved and underserved. It is in this context that I am raising three issues:

1. The iodine fortification of common salt has been led by the AIMS since 1950s. I do not think we have reasonably reliable all-India data on iodine deficiency diseases (IDD). Then, why did we launch compulsory iodisation of salt and, thus, unwittingly or otherwise, give a golden opportunity of penetration to commercial firms like Tata and Cooks into the salt market? In this process we deprived hundreds of thousands of exceedingly poor salt producers of their meager livelihood. Have the exponents of compulsion any data to show that the subsidised iodation had led to the decline in the IDDs? Then, are there data to show that the incidence of the IDD explosively increased after the compulsion was lifted and the authorities were impelled to re-impose compulsion? I THINK IT IS A QUESTION OF HUMAN RIGHTS OF THE LOCAL SALT PRODUCERS. I note that this did not attract the attention of at least some in the Andolan. Then, what is the Andolan for?

2. I noted in *The Pioneer* of a few days back that the NAC member, Shri Jai Prakash Narayan, while calling for an investment Rs 100,000 crores for health, pleaded for “compulsory” immunization of children with what he calls MMR. He seems to have “forgotten” the Indira Gandhi Programme of Universal Immunization, started

in 1985.

3. I still remember the document produced by Dr Abhay Shukla to start discussion to elaborate National/People’s Health Charter. As far as I know, there was little response from JSA.

I think it is worthwhile to bring in these issues when we are planning to meet for the global PHA-II. The poor Health for All seems to have receded for yet another four years and a half!

Sincerely yours,

 Debabar Banerji, Ph 91-011-26490851

June 30, 2005

Dear All,

I heard that the Gazette notification for this ban has been issued and if there are any objections, these need to be filed within a month; otherwise the ban will be enforced from July 15th. Any one would like to take up this challenge?

International Council for Control of Iodine Deficiency Disorders - ICCIDD - has been spearheading a campaign to control Iodine Deficiency Disorders thru universal salt iodisation.

We need substantial scientific evidence if we are to oppose this. About 20 years back MFC had opposed it and the booklet by KSSP, which had critiqued the universal salt iodisation, was very useful. But that was 20 years back. New studies have been done and they need to be reviewed. Has anybody done that?

One paper notes the risks of this programme. But says that the risk can be minimised by careful monitoring. One does not know how. It says, “In 1995, ICCIDD was involved in the monitoring of an iodine-induced hyperthyroidism (IIH) outbreak in Zimbabwe following salt iodisation. The problem subsided after three years but there was some mortality from heart complications. Avoiding excessive iodine intake can minimize IIH. In a well-controlled study the incidence of hyperthyroidism increased by 27% in one year after iodine intake increased from 90 gm per day to the recommended

value of 150 gm per day. Subsequently there was a steady decrease in the incidence of the disorder. The problem of IHH demonstrates the need for careful monitoring of the iodine intake of populations after salt iodisation has been initiated. This can be done by determining the median urinary iodine level for 40 samples from school- children or preferably from pregnant women. The benefits of correcting iodine deficiency for an entire population far outweigh the risks, which can be minimized by careful monitoring. (Source: Hetzel BS. "Eliminating iodine deficiency disorders—the role of the International Council in the global partnership". *Bull World Health Organ.* 2002; 80(5):341.)

The main issue is - is IDD so widespread in India? Secondly so-called inedible salt would be available everywhere, people can use this and hence the ban would not be implemented.

Anant Phadke

Thu, 30 Jun 2005

Dear Drs Sathyamala and Phadke,

The onus to produce data to re-introduce compulsion in iodisation lies with those who want it. Otherwise, there was free choice. Compulsion without database smacks of an authoritarian mindset. "They" are unable to deliver the goods promised to the poor. Banning of smoking scenes in the cinema and re-induction of compulsion in iodisation indicate the desperation of a tottering government.

Regards, D Banerji

It was Dr. KP Aravindan, Prof of Pathology and the current Chairperson of the Health Subcommittee who did the original KSSP pamphlet on Iodisation of the salt. It was argued then that Universal Iodisation through common salt is not necessary and iodisation should better be confined to places where there are large numbers of risk groups are residing. We at that time argued further that universal iodisation will only help the big industries that have the resources and technology to market refined iodised salt. The small-scale industry will be forced to close down. The unethical marketing practices of refined iodised salt manufacturers were also highlighted (that iodised salt will increase intelligence, etc.) We can have a second look at the present situation. But the original argument against universal iodisation still looks

strong.

Ekbal

Dear Friends,

I fully agree with Ekbal's position. All this is part of a micronutrient lobby (initially of Canadian inspiration) which would like to iodise all salt; then ironise it as well, then add zinc to ORT; and zinc fortification of cereal products; then copper, then more metals or micronutrient.... There is money for industry if they shift emphasis from food and nutrition security issues and the Right to Food campaign, which deals with the crux of the malnutrition and under nutrition epidemic to micronutrient deficiency. With fortification of food, especially for these "poor hungry children" (!) who will be retarded without all our micronutrients - distributed through corporate social responsibility (!) where will the world be in 2010. There are enough corporate linked medical professionals to promote this. JSA and MFC must take the old position strongly - "from Micronutrients back to Malnutrition" - from Malnutrition back to Right to Food!!

Ravi Narayan

July 1, 2005

Dear All,

Here is some information about incidence of IDD in India. ORIGINAL ARTICLE IN *Indian Journal of Pediatrics*. Year: 2004 | Volume : 71 | Issue : 1 | Page : 25-8 "Iodine deficiency disorders in 15 districts of India." Toteja GS, Singh P, Dhillon BS, Saxena BN Central Co-ordinating Unit, Indian Council of Medical Research, New Delhi, India. *Abstract* METHODS: A multicentre study to assess iodine deficiency disorders (goitre and deaf-mutism/cretinism) in 1, 45, 264 children (6 - <12 years old) from 15 districts of ten states was carried out during 1997-2000. Urinary iodine excretion was also determined in 27481 children, while iodine content was estimated in 5881 samples of edible salt. The sampling methodology followed was a "30 cluster survey". RESULTS: The overall prevalence of goitre was 4.78% (4.66% of grade I and 0.12% of grade II) amongst the children examined. The highest prevalence of 31.02% goitre was observed in Dehradun district, while the lowest prevalence of 0.02% goitre was recorded in Bishnupur and Badaun districts. The overall prevalence of cretinism among children examined from seven districts was 0.072% whereas that of deaf-mutism was 0.27% among children

examined from 8 districts. Median urinary iodine values was marginally less than the WHO cut-off values only in children of the 3 out of the 15 districts surveyed. Iodine content was found to be adequate in 55.45% of the salt samples. CONCLUSION: The results suggested a significant decline in the prevalence of goitre in most parts of the country.

Dhruv Mankad

July 1, 2005

Dear All,

This Ban is based on NIN's (National Institute of Nutrition's) report (2003) on the prevalence of IDD (iodine deficiency disorder) in 40 select districts of various states of India where maximum prevalence of goitre had been reported by the central goitre cell, DGHS, between 1959 and 1999. The report states that there was a marked reduction in the prevalence of TGR (total goitre) in all the regions except the eastern region. The goitre rate had come down drastically in the north east as well as a result of the ban, but IDD was still endemic in about half the districts surveyed, etc., etc. The survey did the following: 1) Urinary iodine excretion 2) Iodine estimations in the common salt at the household and the shops 3) Clinical exam for goitre

There are no simple correlations (naturally because of the presence of goitrogens) but the results are convincing that iodised salt works (it has worked in the North east, south and even the northern region...). I can share the report with anyone (I have limited copies).

But that is not my point, I would like to submit that this is the first time in India that the scientists from the upper classes are willing to consume a nutrient like iodine even though they may not need it...to make sure that mothers do not give birth to cretins. Phooh! Laudable I would say.... The NGOs, Gandhians and Health groups on the other hand are protesting because they would like to exercise their right to choose...! Individual good vs. community good...!

About multinational organizations...they are there everywhere, and it is another question...!

About small producers...apparently the technology for iodisation of small amounts of crystal salt is also available.

Veena Shatrugna

July 2, 2005

Two things:

The data quoted seems to support the policy of iodised salt - if now goitre is much less of a problem now as compared to before. Ofcourse you have to rule out secular decrease etc. if at all. But as a policy maker I would take the risk of continuing with the iodisation of salt at the expense of appearing to force the issue on unaffected populace - even now uniodised salt is available in big cities after all this ooh ha.

Secondly about "SSIs will close down": most of the salt in Gujarat (60 percent of the salt of India is supposed to come from Gujarat which incidentally also has 2/3rd of India's coastline) is actually made by poor agharia families who literally brave the heat and cold for 6 (non-monsoon months) of the year for a pittance — 5 paise per kilo they get for salvaging the salt from the likes of the Little Rann of Kutch. The land itself is leased by middlemen who make 25 paise per kilo selling to industry for packaging and refining. The point is that nobody is - really none of these middlemen are - going to close down and have not closed down to the best of my knowledge after UI of salt was introduced.

Chinu

July 2, 2005

Veena,

Is the report available in electronic form? I have been looking for this report ever since the press report on it and would very much like to have a copy—to satisfy my academic curiosity, among other things. But I am not a researcher—so if you have only a few copies perhaps you can send a copy to CEHAT library?

Padma

Dear Padma,

Yes I can send you the report on Goitre Prevalence, and you could perhaps make photocopies for others in Mumbai.... and give it to the Cehat Library too...

Veena

On the iodised salt story, we could discuss the possibility of tracking "long term side-effects of iodised

salt intake” on the lines of the adverse drug actions monitoring system (of course nonexistent in India), we may push the Govt. and the UNICEF to becoming accountable in this country.

Veena

This - Veena's suggestion - I like. Can we not form a group to collate all research-based information regarding effects/long-term side effects of intake of iodised salt and other related studies? This way we will also be putting together a dossier —which we could upload on the mfc website. The dossier would not only have the research studies but also comments on them, by those of us who have looked into the issue and point to areas where there is no information...

Padma

...I would like to point out here, that perhaps what we are dealing with in case of both Pulse Polio and Iodised salt might be viewed in the context of the Law of diminishing returns of many public health interventions. Many standard public health interventions - though none of them are ideal - can prove quite effective for control, in situations or locations of high prevalence of a public health problem. However, as they continue to be applied and generalised, paradoxically due to their very success, the magnitude of the problem decreases, and further application of the same intervention yields less and less additional benefit - while its negative effects (due to application on such a large population, often universal) begin to outweigh the benefits of additional incremental efforts... Historically, if we look at the graph of inputs versus benefits, while the first part of the curve moves upwards, the second part of the curve plateaus off, and the third part of the curve may actually begin to move downward.

...Probably we need to look at Iodised salt in such a context - where do we stand on the input-benefit curve (first, second or third part?), what are the negative impacts, and what are the alternative approaches available? I agree with Veena's idea to try to put together the evidence in a coherent manner, at least to bring the policy under public scrutiny and debate.

Abhay Shukla

July 3, 2005

.... I personally think that we cannot back out of the Pulse polio thing as a responsibility of being a global citizen. If we do not cooperate or engage in a dialogue, we may be responsible for getting back the polio to many parts of the world once again. On the other hand, I do think that we are being taken for a ride by the authorities who do not wish to say that the emperor has no clothes. The system is not working in India and I think it is crazy to keep giving the Polio drops on and on and on...

On the other hand, about iodisation, it doesn't seem to be a bad idea, but I am sure the poor should get a better deal not just in salt manufacture but in many other things. The increase in prices of salt is not related to iodisation but the same usurious profit-market system that works in drugs or other things. The MRP system on labour just doesn't seem to work anywhere. The Chhattisgarh Mukti Morcha has helped the Miners get Rs 261/- as daily wages as of last month!! Can we all try that in our own areas??

Sunil Kaul

July 4, 2005

Some more interesting info regarding iodated salt! Kindly look at the rates in USD.

Dhruv

IODISATION OF SALT SMALL SCALE (matter available on mfc website.)

July 5, 2005

... I wonder whether there are some small local economies that subsist on small-scale salt production?

Neha

July 7, 2005

Dear All,

.... I have been reading mails related to OPV and salt iodisation. In one-way or another, I have been/am involved in both programs, although never directly, and have explored issues involving both programs in various ways - deliberately and inadvertently. I have

wanted to respond in some detail, and finally your deadline made me sit and write. I will try and summarize my views on both:

OPV

I have been (had been) conversing with Sathya and others on this. While I have personally not had the time to delve completely into the merits of all arguments and evidence, I have tried to understand them and have sent our papers / petitions / references to colleagues in India and abroad who have been involved in immunization programs, are each respected for their contribution to the field, have worked for WHO at one point as consultants or employees, who personally know people at the helm of polio affairs, and whose views I respect. Their considered view as of last year was that there can always be a question about whether a global polio eradication campaign was justified, and whether this came from affluent countries' self-concern. However, none of them took seriously the possibility that there was something technically impossible about such a campaign, well conducted, being able to eradicate polio globally. None was an academic, and so they preferred to hold their final counsel on this issue. All of them were anguished at the way in which the campaign was operationally messed up in so many countries, and about (as they saw it) the way the campaign had completely sidetracked routine immunization. Nigeria and India are luminous examples of how difficult and corruption-prone the campaign can be on the ground - it is remarkable achievement of organizations involved to have brought down polio cases to a handful in India (they are said to be reasonable true figures). The target-approach in polio campaigns has become the gold-standard example of false upward reporting of coverage data involving every level in the government. My own views on what we can do -

1. Probe, by all means, the evidence available to figure out what possible harm the campaign bodes for the future (such as, are there possibilities of explosive epidemics coming back? what can be done to prevent that? etc.)

2. Those of us who can, help the Government, WHO, UNICEF (since their stated intentions are at least noble and no one else has the reach, ability and commitment of resources that they have, and each is influenced by democratic norms) make sense of the campaign and its effects on other programs (not just immunization), and put in place alternative approaches. Yes, there are many more who will listen than we imagine there are.

PS: People have noticed the IJHS article by Sathya and others. One of the persons referred to above forwarded the published article to me, saying "FYI only. I have not read yet, just the abstract and conclusion. I am sure that this will be much discussed in India."

Salt Iodisation

It was only when the campaign began (seemingly centered in Gujarat) to revoke the ban on sale of uniodised salt some years ago that I realized there might be issues worth probing. After medical college days, I had seen but a rare goitre, and at first thought, the need for iodisation seemed questionable. To find references about the effectiveness, efficacy and toxicity of iodine I had to excavate long-buried WHO documents and monographs of the 50's to 70's - since these seemed to be currently non-issues for nutritionists. There was nothing there to suggest that iodine was harmful, and examples of many countries - including some of the most affluent ones - who had been iodizing salt (or flour, as I remember) since decades. For evidence of goitre prevalence, I spoke to the PSM dept at Surat, who had conducted numerous goitre surveys over years - and had consistently found early goiters in most places. I got to the Gandhians and asked what their arguments were, and found nothing substantial - other than the accusation that multinationals were marginalizing small-scale producers as a part of a global conspiracy. The market share of MNCs and large producers, individually, then quoted (by the campaigners), was small, and the sums quoted as profits from salt sales were laughably so - compared to similar investments in other industries. Global MNC-led conspiracy did not seem to make commercial sense. The absolute difference in living expenses imposed on poor families forced to buy private / MNC salt (a few rupees a month) was small, and in some places uniodised salt anyway continued to be available. The campaigners were not convinced; the ban was revoked suddenly, without assigning sufficient cause. Academics and others protested feebly. Life went on.

Some time later (4 years ago) I happened to stumble upon the office of the Secretariat of the ICCDDB, which was then situated at the School of Public Health at Emory University, Atlanta. I was there on a fellowship (as a consequence of which we had a wonderful convenor in Sarojini, doing more than her due share of duty!) and one of the Professors on the International Policy course I was taking, was an office-bearer. I spoke to him and his senior colleague about the revoking of the ban in India and the campaign, of which they were aware. They gave me a lot of material, and I chose to

study the issue formally for the course. Many details escape me, but this is what I understood about the “technical” aspects of the issue:

1. Iodine deficiency seems to induce neuronal damage at all levels and ages, including at levels insufficient to cause goitre. Cretinism is only an extreme form. The best evidence thus far seems to indicate that there is a difference in average IQ scores of about 10-15 points between school children who are iodine sufficient and deficient. This was sufficient evidence to foreclose conducting randomized control studies; hence we do not have more “definitive” evidence. While one may contest the worthiness of IQ as an indicator, the significance of 10-15 points and conclusiveness of evidence, the implication of this, if true, is that a community of iodine deficient people is losing out “geniuses” in the right tail of the distribution curve, and as a country we might be concerned about that. Much of the material on the issue is in a monograph collating conference papers on various aspects of iodine deficiency, edited by Prof Carl Taylor, published sometime in the 90’s. As for goitres, they may just be the tip of the iceberg, like Bitot’s spots in Vitamin A deficiency.

2. Iodine deficiency is by nature patchy and unpredictable, depending on who is consuming natural produce from which kind of soil (iodine deficient or otherwise) - for instance, I have no way of saying if the vegetables and cereals I consume were grown in iodine deficient soils.

3. No evidence of toxicity has been found for levels at which salt is iodised. The safety margins are huge, since salt cannot be consumed in large quantities. Experience over many decades of use in affluent countries does not indicate any cause for concern.

On the operational front, the picture is a fascinating - and sickening - complex maze involving many players internationally and nationally, each trying to get his pound of flesh. The total amount of the iodine compound required to iodise all salt globally is so small, that it does not make commercial sense for one or two mines to produce it. (If India was to produce iodine, it would have to be a loss-making venture - hence imports). There is intense inter-state rivalry in India (Gujarat vs TN, I think) that gets very nasty at times. The bane of salt pans is the FDA inspections. A lot of the cost iodised salt has to do with packaging costs (cannot be exposed to air) and middlemen’s commissions - not all producers’ profits. I do not remember finding evidence of a global conspiracy, though. Technology

for small-scale iodisation continues to evolve, and maybe something is available by now.

I wrote a paper or two for the course, which I will try to dig out. I remember bringing back to India some of the reference material, which also I will try and hunt down.

I write this from memory alone, so there could be errors and omissions. If there is contrary evidence, I will be glad to stand corrected on any of these issues. Otherwise, my views on what we can do –

1. Encourage those of us who can, to find sensitive, ethical, effective methods to describe the problem of iodine deficiency in India - beyond goitre surveys. Once we have hard data, we might be able to take rational decisions on public health interventions - and whether and when laws of diminishing returns apply here.

2. Until we have such evidence, consider access to iodine - and in the absence of a viable alternative, access to iodised salt - the right of every child in the country. If we cannot think of feasible, practical ways of providing iodised salt to every family free of cost, let us support the ban.

We were also required to submit a power-point presentation on policy implications of our study at the end of the course. It was end of term, and I was in no mood to submit an elaborate, evidence-based presentation one day before Christmas break. I mulled over the mindlessness of it all, and produced a light-hearted story. I happen to have it here on an email attachment of four years ago. Am sending it to Arun to upload it on the group website, for those of you who might be interested. It takes a dig at many, including us, but I hope it does not hurt. The file is titled “The Story of Rita”. (Available at the mfc eforum yahoo briefcase)

Sridhar

July 08, 2005

I have followed the I-salt debate at various times and was at IAPSM recently where I heard CS Pandav make the case again. I am generally convinced that unless there is evidence of I-salt causing serious morbidity/side effects in populations that are not deficient for Iodine; there is no public health reason to oppose I-salt universalisation. Many areas have varying degrees of Iodine def in natural resources and some areas may not have it. But goitre and Cretinism are serious

problems in many areas and others can jolly well suffer I-salt unless it is harmful.

1. There is no evidence now that I-salt has side effects on non-def populations, despite use in several countries. (Please correct me if there is any.)
2. I do not buy the personal freedom point of view in this issue because the at-risk population has no access to great choices when goitre/cretinism strikes.
3. Is there anyway to make a non-ban policy work at district level so that Iodine is still available to people at risk?
4. There is no reason to oppose it on the bogey of Corporate/MNC versus SSIs. First of all, SSIs can do it, the SSI-technology, I am given to understand, is there already. Secondly, I am not opposed to the idea of MNC itself. If we have MN presence in science, research, ideas, and the larger politics, I have no problem with MNC-in trade per se. When I switch on my mobile I am already hitting an MNC solution. None of us is against it. In fact I am for freer trade policies.
5. The cost of I-salt per day is so small that it is difficult to oppose it on any economic grounds. For those people who cant afford even that, we anyway need to have general anti-poverty economic programmes, which is a separate matter.

Shyam Ashtekar

Dear MFC Friends,

The issue of the ban on non-iodated salt was discussed extensively at the recent MFC mid-annual meet at Wardha. The views of members not present at the MAM were also taken into consideration in the preparation of a draft statement, which will be finalised and submitted by the 15th of July 2005.

Kindly note the use of the terms "iodated" and "non-iodated" which are the correct terms to be used instead of "iodised" and "non-iodised".

Please go through the draft below and send your comments and suggestions to the convenor (Ritu Priya) at this address <convenor.mfc@vsnl.net>. Please note that these should reach the convenor by today evening (the 12th).

Ravi D'Souza

Resolution at the Mid-Annual Meet held at Wardha on the 10th July 2005

Medico Friend Circle opposes compulsory use of iodated salt by banning common salt. Its opposition to making the iodated salt compulsory is on the following grounds:-

1. Small IDD affected population in India

- 1.1 Only a small section of the population in selective areas in India suffer from Iodine Deficiency Disorders (IDD) like goitre, mental retardation and cretinism in children.
- 1.2 The people residing in these areas have iodine deficient diets.
- 1.3 The iodated salt should be made available at a lower cost through ration shops and the open market in the endemic areas.
- 1.4 The people should be encouraged to have the cheaper iodated salt by making them aware of the effects of iodine deficient diets.

2. Compulsory iodated salt is hazardous

- 2.1 Making everyone consume iodated salt compulsorily is hazardous for some persons.
- 2.2 The hyperthyroidism caused in an area with introduction of iodated salt is documented to have lead to deaths due to heart disease.
- 2.3 A small population has hyperthyroidism and they are advised to take a low iodine diet. If iodated salt is made compulsory, they would have to consume it even though it is hazardous to them.
- 2.4 There is no direct one-to-one correlation showing that most IDD are caused by low content of iodine in the diet alone. Therefore the other causes need to be identified and addressed as well.

3. Banning common salt is impractical

- 3.1 Banning common salt is not only an infringement of the choice of what salt should be consumed by the people, it is also difficult to implement.
- 3.2 The salt used for industrial purposes (commercial sodium chloride) would be available anyway. It would be difficult to ensure that it is not consumed by the people.
- 3.3 All goitres are not due to iodine deficiency. Iodine replacement is an answer only in goitres with normal thyroid physiology. Therefore it is not logical to ban common salt. Further, the relationship between goitre and cretinism is unclear.
- 3.4 There is a paucity of evidence about the magnitude and spread of IDD in India in the published literature. Therefore, MFC is not convinced about the rationale of universalisation of iodisation of salt.
- 3.5 This is especially true when an alternative mode of ensuring availability of iodated salt in the endemic areas is recommended.

Saturday, July 29, 2000

The Hindu, Editorial Page

The Science & Politics of Iodised Salt

By Ritu Priya & Imrana Qadeer

A PUBLIC debate on the issue of lifting the ban on non-iodised salt, including the involvement of political parties in it, is a welcome development. However some critical epidemiological questions have yet to be answered in order to weigh the possible benefits and negative consequences of universal iodisation of salt in our country. Among the initial protests to a universal ban on non-iodised salt was a scientific critique by Dr. K. P. Aravindan published as a booklet by the Kerala Shastra Sahitya Parishad in 1989. Questions on the rationale of universal iodisation have been raised by Prof. D. Banerji of the Centre of Social Medicine & Community Health, Jawaharlal Nehru University, since 1985. The Sarv Sena Sangh, a group of leading radical Gandhians, has been at the forefront of a mass mobilisation campaign on the issue since 1997. Their meetings with the Prime Minister on the issue in 1998 ended with assurances of a review that did not materialise.

Are we to centralise identification of public health problems and universalise solutions in this day and age when “decentralisation” is the key to good governance? Or, should we locate priority problems of each region and sub-region and find solutions most suited to the local context? The protest against the universal ban of non-iodised salt is simply asking for the latter, i.e. use of iodised salt where iodine deficiency is really a problem and leaving people the choice in other regions. Its proponents say a ban in just the severely-affected regions has proved unsuccessful. Without analysing the reasons for this failure they prescribed universalising the ban. The programme documents acknowledge the crucial problem of a higher price of iodised salt and therefore the role of traders in flouting the localised ban. However, they do not recognise what they see as a ‘marginal difference’ to be of serious significance for the majority of people living under severe economic stress. The refusal to pay the extra cost in regions which have been identified as highly affected also means that either the problem is not of real significance for the people, or, the programme has not adequately tried to convince them of the risk of iodine deficiency and the value of using iodised salt. This speaks of

the high level of alienation of our health service from those it is meant to benefit. Ignoring these reasons for their failure, the technocrats enforced “their solution” by legal provisions. And, to be effective, it had to be enforced all across the country, on even those who did not have a problem to be solved!

The scientific argument for universal iodisation of salt is itself on weak ground. What has propelled the whole campaign for universal iodisation is the “evidence” that a high level of goitre (enlargement of the thyroid gland in front of the neck) in a population indicates high risk of “invisible” mental retardation of varying degrees and cretinism (a severe form of congenital physical and mental retardation in newborns). However, the data presented by its proponents on the prevalence of goitre and mental retardation exhibit several limitations. Extrapolation from findings in severely iodine-deficient pockets to all other population groups across the country is one flaw. Use of laboratory evidence of iodine deficiency in blood with no evidence of low thyroid hormone levels in the same persons or actual manifestation of any deficiency signs in them is another lacuna. The I.Q. tests used to assess levels of mental retardation are also highly questionable; they incorporate grave biases of cultural and socio-economic background, weighted against accomplishments of the poor and the rural people. The diagnosis of small size goitre itself depends entirely upon the subjectivity of the investigator. These weaknesses in the data presented in favour of universal iodisation leaves its proponents open to charges of exaggeration of the problem.

While problems of methodology, diagnostic tools and generalisation for whole populations are genuine in epidemiological research, the way to establish the validity of the findings is their verification. Unfortunately, the entire research in India has been undertaken primarily by only one group of scientists. Their initial steps at studying the problem in highly affected communities were pioneering. However, the lack of resources necessary for epidemiological research and the international patronage to a technocratic view did not encourage other units to undertake research in the area and provide alternative data. This single group then created the dominant

perspective on the problem in the country. The imperative of a scientific approach requires that the work of even these very respected scientists should, at least, be put under scrutiny of other, including dissenting, health scientists.

From the perspective of scientific public health planning, several questions still need to be answered convincingly. One, what is the epidemiological extent of mental retardation and cretinism due to iodine deficiency in most of the districts labelled as “endemic”? If this is not a major problem then the goitre is basically a cosmetic problem. Goitre is known to be a normal, physiological condition during growth periods, puberty, pregnancy etc. Cretinism does not necessarily and naturally follow goitre. The figures for various districts covered by the ICMR’s “Epidemiological Survey of Endemic Goitre and Endemic Cretinism” in 1989 show this. For instance, the prevalence of goitre in Dibrugarh and West Manipur was 65.8 per cent and 19.8 per cent respectively, while prevalence of cretinism was 2.2 per cent and 6.1 per cent. Cretinism has also not been noticed to be increasing in most areas even where iodine deficiency is increasing. Is this because certain critical levels of deficiency have to be reached before cretinism occurs and that kind of deficiency is absent in most parts of the country? In the 1989 ICMR survey report, the level of goitre estimated by the AIIMS team to indicate a significant prevalence of endemic cretinism (20 per cent of 10-19 year olds with grade II goitre) was not found in any district in the country! Alternatively, is it that a combination of other factors (organic or chemical) in the environment and diet have led to the goitre and cretinism found in a few pockets of the population?

The second question is of the negative effects of

excess iodine, especially in areas where it is already adequate in the diet. The consensus statement of a “scientific National Consultation on Benefits and Safety of Iodised Salt” organised in 1999 at Jaipur, tells us that “with consumption of salt at the average Indian level of 10g, the iodised salt as manufactured will provide 500 mcg per person per day”. This is half the prescribed “maximum safe daily intake of 1000 mcg” and well above the “generally accepted desirable adult intake of 100-300 mcg/day”.

A third question is for soil and agricultural scientists to answer - why is iodine deficiency now spreading to geographical areas which were free from it earlier? If the current agricultural practices, including use of chemical fertilizers, are responsible for the increasing iodine deficiency, then that is where we need to focus to prevent further spread and reverse the process. As most public health problems have their root cause in environmental and social conditions, a scientific public health approach demands that their identification and management through non-medical correctives be an integral part of the strategy. Isolated universal iodisation of salt goes contrary to this principle.

There are optional approaches available to deal with the problem in highly affected areas. Participatory community programmes of iodisation of salt or water at local level is one that has been tried successfully in countries such as Thailand. Supplying subsidised iodised salt in these areas so that it is cheaper than non-iodised salt is another option.

(The writers are, respectively, Assistant Professor and Professor, Centre of Social Medicine & Community Health, Jawaharlal Nehru University, New Delhi.)

July 12, 2005

Dear All,

I wanted to respond to Sridhar’s e-mail about polio-eradication and ban on common salt; but could not manage. I am writing this one in the train on my way back from the MAM.

About Polio Eradication, it will be better if he can spare some time to respond to the specific arguments that Sathya, others and myself have provided.

About the ban on un-iodated salt, he may not have got any substantial evidence to oppose the ban from the

Gandhians he met. But even the newspaper article by Imrana and Ritu, indicates that much more solid arguments have been made against the ban. It will be better if Sridhar or Shyam respond to these arguments. To ensure the supply of iodised salt to the needy the easier option is that the government thru the ration shops and others should subsidizes sale of iodised salt in areas of proven endemicity of Iodine Deficiency. Instead, the government is asking everybody to consume iodised salt compulsorily so that it does not have to spend anything from its pocket! Subsidizing salt for vulnerable populations would ensure that the right of every child in such areas (to which Sridhar has referred) to get iodine supplementation is respected.

Without considering this option, I am surprised that Sridhar has so easily agreed to the compulsive use of iodised salt for all Indians! Conventional types of experts are not much bothered about the state indulging into undemocratic precedents. But MFC experts should certainly be bothered about such 'on-scientific' issues.

Even if it is proved that a particular intervention is beneficial for health of a people, it is no ground to make it compulsory. It is necessary that people drink only potable water or wear helmets etc. etc. But that does not mean that these things be made compulsory! We should make a distinction between making iodised salt universal and making it compulsory.

Though the attendance was very poor, the Mid Annual Meet discussions were good.

Anant Phadke

July 12, 2005

Anant Phadke says inter alia:

"Even if it is proved that a particular intervention is beneficial for health of a people, it is no ground to make it compulsory. It is necessary that people drink only potable water or wear helmets etc. etc. But that does not mean that these things be made compulsory! We should make a distinction between making iodised salt universal and making it compulsory."

So there is no moral ground/justification for doing policy advocacy or asking for changes in the system? And if a thing is made universal, it is in a way compulsory —is it not? You do not have a choice except that you don't use the universally available thing.

Chinu

July 12, 2005

Dear Ravi, Ritu, Sathya and Jyoti,

First, the draft statement enclosed is in a clearer form with only minor and necessary edition in the statement I had handed over at the end of the MAM. I endorse the changes made in the draft document.

The discussion amongst the small group present was

very fruitful though some differences still exist about what would mean in reality if iodated salt is 'universalised' but common salt is not banned.

Dhruv

July 13, 2005

Dear All,

I have finally found the gazette notification tucked away in a corner of the ministry website, under the PFA! I could send it to anyone interested and unable to find it.

It was notified on the 27th May and gives us until the 27th July to put in our objections.

Veena, could you please send the reports from NIN so that they can be put onto the website and a more informed response can be sent? Sridhar, what about the Carl Taylor studies and other material? Sridhar, could you also review these? At the MAM, we have decided to send the resolution that Ravi D'Souza has already put on the eforum (with any urgent changes suggested) saying that we will be sending supporting documents shortly. It was thought that someone would put a review together using the studies referred to in the various emails. Sridhar was the first choice.

Ritu

July 14, 2005

Dear Anant,

I am responding to your assertion that I must respond to specific arguments provided by several friends on the OPV and iodation issues. My earlier mail is in fact my response overall to what I believe we should be doing, given where we are today. While I am not sure which specific arguments you want me to respond to, I am happy to get the opportunity to review again your letter to IP, our memorandum, the IJHS article, your and Ritu's write-ups on iodation and the IDD petition, and state my position on some of the central issues. I reiterate that I have not had the luxury of going through original articles of late, and am basing my comments on these documents and on the discussions with immunization experts that I referred to in my previous mail.

OPV

I have been of the opinion that, purely from the point of view that the pulse polio program is disruptive of our even-otherwise floundering public health programs (it has set us back by a decade now), the campaign should never have been launched. This must have been the case with many other developing countries, and together we should have taken the stand that global eradication of polio cannot be at the costs that we are required to bear. I had predicted this would happen when the campaign began, and am sorry to see that prediction come so true. While some may argue that freedom from polio is a worthwhile goal, I could never see the sense of disrupting a host of other important programs to prevent a few thousand cases of paralysis (which eventually would have been largely achieved through routine immunization), and a handful of deaths. This is not to belittle individual tragedy and loss, but to be wise in investing resources.

I had also been skeptical about the ability of WHO / UNICEF / Government to ever reach universal coverage in repeated pulses. I admit to be pleasantly surprised that the campaigns could achieve even what they have achieved.

I have also been uncomfortable with assertions that polio is safe in the face of the HIV epidemic, as in some African countries.

Having said that, I have been also skeptical about the assertion that there is a glaring fundamental conceptual flaw in the campaign design, in that the poliovirus can never be eradicated, even given a well-implemented campaign (at least sufficiently enough to be of no consequence). I do find the logic of our arguments formidable, particularly those related to eradication vs. elimination, in the face of poor sanitation. Yet, I am not convinced:

1. I find it difficult to believe that in a competitive academic world, a global campaign could be planned and launched, using huge amounts of public funds from the West (common citizens contributed hundreds of millions of dollars in donations for the cause) and yet such fundamental, simple flaws could escape notice.

2. I find it equally difficult to believe that it was a conspiracy of silence in the vast community of researchers, academics, program managers, funders, politicians, et al.: I see no common force that could clamp down on such a large and varied intelligentsia,

often with conflicting and competing interests. For instance, there are large numbers of "routine immunization experts" who are feeling marginalized under the onslaught of the polio campaign, and would have gladly used these arguments to fight it.

3. I find it difficult to believe that WHO and others would have dared to launch the biggest global campaign after smallpox eradication without sufficient thought to the soundness of strategy - the loss of credibility would be almost irreparable. I see no motivation sufficient for them to take such a risk. In this context, it would be useful to re-examine what exactly WHO and others promised countries in terms of eradication - what exactly were we told, by whom / thru what channels, about the possibility of discontinuing OPV after a certain time? What was the sequence of events / circumstances under which such promises were made?

4. The nearest convincing explanation I can think of is that some crucial pieces of knowledge (such as about significant proportions of revertant strains) came to light much after the campaign was underway - and I am not sure we understand the full implications of these findings on polio eradicability.

5. The circumstantial evidence - of AFP cases coming down to zero in scores of countries, and to very low levels in India - should also make us look again. If AFP surveillance in all countries is equally false and faulty, that would be a surprise. (I believe AFP could still be a good marker for a public health program to get rid of polio - will argue out some other time that the problem is not so much with the adequacy of the marker as with the sloppiness of implementing the program).

With a little more thought, one could probably list other questions that we must ask ourselves before we accept readily that it was just so much a sloppy job. Perhaps, we could start with a careful review of WHO's written response to Sathya and others last year - I remember reading it and thinking of several of their explanations as sensible, but I do not remember the details. I had shared some of these misgivings with her even then.

The rest of the arguments - such as about changing definitions and deadlines, apparent plateaus in AFP trends, etc - can all have more benign explanations - such as poor implementation, which I see no harm in honestly admitting. I would therefore also slightly reword the assertion - "The failure of the eradication campaign is due not to a lack of proper implementation but to a basic flaw in the strategy itself." as "The lack

of proper implementation can hardly be blamed for failure of eradication, when the basic strategy was in itself flawed.”

I would have liked to examine evidence myself to make sure we have missed nothing, but that is not possible. I will await defense from the progenitors of the campaign. If no viable defence comes forth, and if the emperor has indeed no clothes, I will be well and truly stunned and shocked.

But not unhappy ... it will spell a quicker end to the mindless campaign, and we can get back to the basics: routine immunization and putting the rest of the programs back on track, as Anant has also suggested. Incidentally, I realize that this is all I had said in the previous mail.

Iodated Salt

Without referring to each argument of yours and Ritu's, I had responded to most of them. I also have the petition now to respond to.

Overall, I face a dilemma: how important is the issue of iodine deficiency, really? Is it something we should be spending much breath on? Since I am not sure, I will take the conservative view that we must hope for the best but be prepared for the worst - and argue for how best to tackle the problem.

My understanding of iodine deficiency is that its causation is unpredictable - and thus not localizable. It is said to arise primarily from consuming natural produce from iodine deficient soils. Particularly in today's world where even villagers consume produce that is not their own - think of PDS, of urban slums, of migration, to mention some factors that affect primarily the poor - how does one delimit iodine deficiency geographically? And monitor this temporally? If we indeed wish to provide iodine only to those who genuinely need it, the need would be to identify iodine deficient diets - or urine - on a continuous basis for each individual or family of community - as relevant - and thus be extremely impractical. Universal availability of iodated salt (or equivalent vehicle) is the only answer. I see this as the major problem with our petition. If there is a flaw in this part of my understanding, a number of the rest of my arguments could be weakened.

I had not come across the Zimbabwe study that showed evidence of IHH. Textbooks and websites still maintain that IHH is rare. We must define this problem for India - a careful study should be an easy matter, given the

large number of people already consuming iodised salt, and the fair number who yet do not. Almost any research institution could do it. A survey of recent literature for case reports and any trends from hospital data for IHH may help. But I am not sure if we right in describing the hazard the way it is worded in the petition - it does not sound consistent with the abstract quoted by Anant, besides being based on one single study - have we assessed its quality and external validity? We might at most call for a stay on the ban until the possibility of hazard is investigated. But then someone must take on the responsibility of investigating and reporting this. Even if there is some evidence of toxicity, it may be worth considering iodation at lower doses, or the feasibility or effectiveness of monitoring urine samples. After all, it is ultimately a balance between good and bad effects that we are striving for. We must also look closely at the experience of those countries that have used iodated salt since long.

The cost of iodated salt can never be lower than simple salt. Subsidizing it is the only way to bring down the price. I personally believe that we are over-doing the issue of the price of salt (at most, a few rupees extra per month per family, at the rate of consumption of 10 g per capita per day). There are other, hugely more suffocating price issues (fuel, food grains, vegetables, oil) that we have yet to settle, due to which we are among the most undernourished of the world's people. Besides, can we really depend on our PDS to deliver this? Particularly when the alternative is at a rather small cost? But I won't push this point ... if we can ask for a viable mechanism of delivering cheap/free iodated salt to every household, I will be happy for the poor.

It is nobody's case that all goitres are due to iodine deficiency or that the prevalence of goitres and cretinism, or of cretinism and other mental retardation should parallel each other. Each is multi-factorial, and the absence of a one-to-one correlation proves or disproves nothing.

As for the question of how extensive the problem is, I have already suggested that this must be thoroughly and convincingly defined, in its entire spectrum of manifestations. This is fraught with methodological and ethical issues, however, and can be quite a handful to accomplish. We may at the end be left to take decisions based on less than convincing evidence. But I am not sure if it will be wise to wait to reach that point before we act. Also, until such time, on what basis do we assert, as we have done in the petition, “only a small section of the population in selective areas of India suffers from IDD”?

Patients who know they are hyperthyroid could surely be legally spared some non-iodated salt from the surplus industrial sodium chloride available, even if the ban is well enforced! Those who do not know could suffer, of course - let us define this problem and see if there is a way to help such people get diagnosed and treated adequately - which we ought to have been doing anyway.

That brings us to the question of the ban itself. I am aware that I am on slippery ground when I advocate that we accept the ban: it is tantamount to forcing people to consume iodated salt. I would not accept a ban if it were shown that iodated salt had significant hazards. I would not accept the universal ban if it is shown that localised measures are sufficient. I would certainly not accept the ban if it is shown that iodine deficiency might not be much of an issue after all. Also, a ban is a crude way of doing something that ought to have been done with more love and care. But, for me, at least for now, the ban passes the test of Gandhi's talisman: all things considered, I am convinced it will be for the better of the children of the poorest person I can think of. Until we find a more effective mechanism of reaching iodated salt to all people who need it, let us accept the ban as the currently most effective mechanism (not perfect, not fully effective - just the most effective as of now). And let us insist on the PDS supplementing this effort to the extent it can (I do not know of any other ways to even try to make subsidised salt available to all who need it).

To an extent, arguing that this impinges on freedom of choice is like making the same argument about smoking. Smoking affects the health of others who inadvertently smoke, and thus cannot be granted as a right in public. Making non-iodated salt available freely to the public because a few do not wish to consume it is hazardous to those who need it but do not know of its utility - in the Indian context. Of course, it would be ideal and lovely if informed choice could be the principle guiding all this. How come millions of families do not exert the choice of feeding home-available foods to their children and just watch them become malnourished? Why have we as a nation failed to provide even this simple information to these millions? In the face of numerous such failures, with what face do I tell our talisman that this time I will not fail to inform him? This is troubling.

Finally, will we be setting a dangerous precedent by invoking such a ban? Perhaps. But let us trust ourselves to be alive to such a possibility and tackle each case on its merit.

I hope I have covered all points. I would be happy to learn more.

Sridhar

July 14, 2005

Dear MFC members

I agree with Sridhar and would like to state that at this point I find it difficult to oppose the ban for the following reasons:

1) As newer areas of Iodine deficiency crop up every year.

2) In the sample of 40 districts surveyed from different states (2 districts per state) by the NIN last year the goitre rates ranged from 3% to 40%. The Eastern region had a prevalence of 22 to 40%. All the regions except Dubri, Aizawl and Surat had a TGR of more than 5%, a cut off level to define endemicity.

3) This is the first time that the middle and upper classes including scientists are willing to consume a nutrient (iodine) for the sake of the poor living in inaccessible areas and tribal areas in the country. On the other hand the NGOs, Health activists, Gandhians, etc., are concerned about individual rights...there is a contradiction here and it worries me quite a bit

4) It is well known that anything targeted to the poor never works ... think of all those Govt. programmes for the BPL ...it humiliates them and further reduces them to becoming Beggars....); however programme which include the well off have a wider reach...The iodated salt never reached Nagaland, Manipur, Meghalaya, Sikkim, Uttranchal, Adilabad Bhadrachalam, etc. These areas are NOT IMPORTANT for the MNCs or even Business ...It will amount to the poor being asked to wait till all the research questions are answered...no one is going to consider our demand for targeting subsidised salt seriously...they have not done it for 50 years, there is no reason to believe that it will happen now...in any way major structural changes are not round the corner

5) There is a contradiction in the petition, when we say

1.2 "The people residing in these areas have iodine deficient diets" and 2.4: "There is no direct one-to-one correlation showing that most IDD are caused by low content of iodine in the diet alone." And advocating Points 1.3 and 1.4 which state

1.3 The iodated salt should be made available at a lower

cost through ration shops and the open market in the endemic areas.

1.4 The people should be encouraged to have the cheaper iodated salt by making them aware of the effects of iodine deficient diets.

Sounds a bit patronizing...why should this "encouraged to have the cheaper iodated salt" thing come up again and again

6) China and India started out together...and goitre has virtually disappeared from China...cant say that about India

7) At some time it would be good for us to have tribals from the North East, debate issues of "Science" ...as ban on non Iodated salt raises questions of citizenship.

...(At NIN we have Dr. Longvah, a serious scientist from Nagaland who is part of this recommendation. He was the first one to show that Goitre rates have come down in the NE after compulsory iodisation...It is another matter that the credit was not given to him.... understandably!)

8) Finally I would stick my neck out and say that we at MFC should welcome and volunteer to consume Iodised salt if it helps the country tackle this problem Obviously I do not agree with the petition

Veena

July 15, 2005

Dear All

I support Sridhar's and Veena's statements and find it difficult to go with the mfc resolution on I-salt. However I am on my wrong foot (due to public health grounds) when Anant's is siding with personal liberties and I am not found with. This said, I feel we cannot support the stand 'ask at-risk people in hills and other places to exercise informed choice between two salts'. When even ANC care is barely utilised by informed consent, I-salt is an unlikely possibility in this situation.

It is not like helmets either. Like smoking affects also others who do not smoke, IDD affects unborn children without their consent or information. Even the adults in many such districts are not able to exercise their own decisions. The delay in getting the message all over will affect many more lives. I think we are stretching

the informed consent and freedom issue too far. We have imposed a ban on PNDDT earlier, not left it to discretion of families or providers when the case for public awareness and informed decision was stronger than in this issue. In public health we do face such dilemmas and not all can be resolved completely.

If there are serious and sizeable ill effects of I-toxicity due to I-salt, I will reconsider my stand on ban.

Whether the ban itself will work in India is a different issue, and such a case applies to PNDDT and many other public health matters in India.

Shyam

July 15, 2005

Indeed, I too was trying to get the difference between 'ban on Sati', 'compulsions for helmet', 'ban on sex selection' and 'compulsions for iodated salt'!! Could not find any.

Incidentally, some time back Deva had thrown in a question re. health ministers' initiative for 'ban on smoking' - and closer at home 'ban on dancing bars' - well these are I guess all shades of the same theme! we have to either accept that the government has to play a 'paternal role' - 'welfare state' - or then fight for total liberty. Anything in between is bound to cause problems.

Deepti (Chirmulay)

July 15, 2005

Dear All,

I quite see the relevance of Veena's and Sridhar's points of view and arguments. Since there are obviously many issues here that need to be discussed and understood I would not like mfc to send this petition right now. Can we not pursue the suggestion that has been made earlier that we put up all the papers and studies - or those that are available - and take a look at them? Perhaps there are questions to be asked about some of these studies, perhaps not. By saying this I am not ignoring or sidelining the fact that there was considerable discussion at the MAM. But since some members who have followed the issue have raised some questions, we need to be clear on the content of the petition and the demands that we are making.

Padma

July 17, 2005

One more consideration for universalising:

In Gujarat among the the problem areas is Bharuch and some nearby 'tribal' areas — adivasis migrate considerably to towns like Baroda where non-iodated salt would be available if there were no universalisation. Which goes against the intention of a policy of 'compelling/persuading' those likely to be affected to use iodated salt.

Chinu

July 18, 2005

Here I present IDD situation in Orissa, hope it would help the ongoing debate.

The National Iodine Deficiency Disorders Control Programme started in Orissa State since Dec '1989 & it is a 100% centrally sponsored scheme.

BAN NOTIFICATION ON SALE OF NON - IODISED SALT:

There is complete Ban for Sale & manufacture of common salt for human consumption other than Iodised Salt in the State of Orissa since 18.10.2001 vide notification no. 12544 dated. 18.10.01 under P.F.A Act - 1954.

The following districts have been surveyed so far on I.D.D Control Programme:

<i>Year</i>	<i>District</i>	<i>Population Surveyed</i>	<i>I.D.D Prevalence Rate</i>
1989	Puri	6762	19.34%
1989	Sundargarh	-	33.5%
1998	Cuttack	11066	21.61%
1999	Keonjhar	7821	14.9%
2001	Nuapada	2467	14.4%
2001	Balasore	35002	0.83%
1995 to 1999	Baragarh	-	10.8%
2002	Baragarh (Resurvey)	7949	7.66%
2003 - 04	Ganjam	40333	15.79%
- do -	Kandhamal	7108	27.79%

IDD PREVALENCE SURVEY:

The quantum of IDD in Orissa is yet to be identified. Only 9 districts have been surveyed and Gajapati & Bolangir are under survey during the current financial year.

MONITORING

1. All the Chief District Medical Officers, all Health Officers of Municipal Corporations / Municipalities of Orissa have already been instructed vide this Directorate letter No.12191/27.12.2003 to enhance collection of the Salt Samples by the Food Inspectors at least 2 (two) salt samples in each month as per f PFA Act, and 4 (four) salt samples beyond PFA Act and send to state public Health laboratory for analysis of Iodine for monitoring purpose of IDD Control Programme.

2. A review Monitoring cum Workshop for all the food inspectors of the state will be undertaken ensuring proper monitoring of the programme through testing of salt samples in January 2005.

Regards, Rajan

July 19, 2005

... Just look at Rajan's figures, an average of 10-15 percent. And these are not exactly mountainous belts - just the Eastern Ghats and part of the Chotanagpur plateau. And some at MFC are worried about precipitating hyperthyroidism! I think we have to differentiate between clinical medicine (the maximum benefit for the individual) and public health (the optimum benefit for the population). Personally I am not in favour of this petition at all.

Regards, Deva

July 19, 2005

Dear Rajan,

Just a clarification - what are the types of IDD identified in the 9 districts and their relative proportions in different age groups?

This is crucial information to interpret this data, since one component of the debate is about the methodological problems in identifying IDD and its public health implications.

Regards, Ritu

July 19, 2005

Dear All,

All bans if and when they are done in public interest, (in fascism, dictatorships so many things are banned!) have something in common - preventing harm to the individuals or to the society at large. But to be sure, banning a criminal, murderous activity like Sati is different from helmet compulsion! Any scientific analysis has to grasp both - the commonalities and the differences.

It is necessary that the State has to make certain things compulsory to protect the interests of the society at large. However, the question is what is the basis of making such compulsion so that it is ensured that the ban does not unnecessarily encroach upon people's democratic rights and the state is a welfare state and not a draconian one. About compulsory saltiodisation as such, I am sending a separate mail to try clarifying my position.

Anant Phadke

July 19, 2005

I would point out that Zimbabwe was not an exception. Other African countries were subjected to higher doses of iodation by Western Experts and faced similar problems. I quote from Charles Todd's note – "Eliminating iodine deficiency: applause and questions", in the *Bull World Health Org* vol.80 no.5 Geneva 2002, Round Table Discussion, "The challenge ahead: iodised salt on every table forever".

He says: "Finally, there is the question of whether we should be in such a hurry to eliminate IDD, given the recognized danger of an increased incidence of hyperthyroidism following the introduction of iodine supplementation (Stanbury JB, Ermans AE, Todd C, Oken E, Tonglet R, Vidor G, et al. Iodine-induced hyperthyroidism: occurrence and epidemiology. *Thyroid* 1998; 8:83-100.). This has proved particularly controversial in poor developing countries where there may be extremely limited access to treatment for hyperthyroidism, but it is just those communities, in which iodine deficiency is so severe, that will benefit the most from supplementation. What is important is to provide physiological amounts of iodine. Early recommendations for Africa called for a standard level of 100 parts per million (ppm) of iodine (as potassium iodate) in all salt for human consumption. This level proved far too high for many countries. Following

reports of increased hyperthyroidism in the Democratic Republic of the Congo and Zimbabwe, WHO, UNICEF and ICCIDD carried out a special study in seven African countries and subsequently lowered the recommended level of salt iodisation to 20-40 ppm (3). Regrettably, the evidence base for the initial recommendation had been weak, and it was only through close monitoring of the impact of salt iodisation that the danger was uncovered.

Anant Phadke

July 19, 2005

Dear All,

...To begin with let me clarify my overall position about banning/prohibiting a thing or making things mandatory for citizens. When a citizen's action is harmful to others or harms the larger social interests, the state can justifiably prohibit such action. For example, smoking in public space, sex-selective abortions, driving under the influence of alcohol etc. There is a second kind of social compulsion, which the State imposes, which requires some active participation by the citizens. For example, mandatory registration of births and deaths, participation in National Immunization programme or other interventions to control of communicable diseases like malaria. Such a compulsion can also be justified if it is indispensable to achieve the specific larger public good. The problem starts when the social benefits of a compulsion are not overwhelming as compared to the social cost in terms of erosion of democratic culture, leave aside the effort and resource cost to the state and the individual. Compulsory use of helmets or of iodated salt belongs to this third category.

In case of helmets all scooterists are at risk, whereas in case of iodated salt, there is not even any claim that every citizen is at risk. Hence the case for compulsion of iodated salt becomes weaker. This does not mean that supply of iodated salt cannot be ensured to the needy areas. The Goiter Control Programme 1962 failed because iodated salt was not subsidized. If the Govt. subsidizes iodised salt to make cheaper than common salt, people too would choose iodated salt. Public education, propaganda (not as much as pulse polio!) would do the rest. If the manufacturers, traders are not going to incur any losses by manufacturing or selling iodated salt, there is no reason, why they would not do so in the endemic areas provided a market has been created for it. The main point is who is going to foot the bill to subsidize iodated salt?

Today, iodated salt is costlier by Rs.5/- per kg. An

individual requires about 300 gms of salt a month i.e. 3.6 kg per year. To make iodated salt cheaper, the per capita annual subsidy would be Rs.6 X 3.6 = Rs.21.6. If half of India is found to be endemic, it would cost additionally about Rs.1060 crores annually to provide subsidised iodated salt to the 50 crore population in endemic areas. But if common salt is banned and hence if all 100 crore Indians have to buy iodated salt, the people would have to spend additional Rs.1800 crores annually, from their pocket. Instead of this, the citizens would prefer to pay through taxes Rs.1060 crores for the benefit of the people in the endemic areas. If there is a political will to implement the subsidization of iodated salt, the subsidization strategy can be implemented by overcoming whatever administrative and other difficulties that may arise. The trouble is, the subsidization strategy has not been even attempted! Well-meaning bureaucrats and experts have suggested the strategy of banning the common salt as this is the convenient option for the bureaucrats! It is the responsibility of the state to ensure that iodated salt is universally available at a subsidised rate in the endemic areas. The govt. is carrying it out in a manner suitable to itself, manufacturers and traders.

Sridhar has said "Until we find a more effective mechanism of reaching iodated salt to all people who need it, let us accept the ban as the currently most effective mechanism (not perfect, not fully effective - just the most effective as of today)". I would put it the other way round. Unless it is convincingly shown that the subsidization strategy is unworkable in practice, the common salt should not be banned.

Veena may note that since the endemic areas are now claimed to be much more wide spread than remote/tribal areas, the subsidization strategy would involve not only the poor in remote areas but people from all strata of the society in different areas. The Wardha draft statement of the mid annual meet says that in the endemic areas, subsidised iodated salt should be made available both through ration-shops and others. So in endemic areas iodised salt would be universally available without banning the common salt. (Chinu may note that there is clear difference between Universalisation and compulsion. Universalisation of iodated salt does not mean that the common salt cannot be sold.)

In the above paragraphs I have deliberately kept away from the scientific issues like the more reliable, consensus level about proportion of 'population at risk' for IDD; or the issue of risk of hyperthyroidism due to universalisation of iodated salt. I have no first

hand knowledge of the related recent literature. However, it was reported by Ritu in the mid-annual MFC meet that in the published literature the details of the many of the studies on prevalence of Iodine Deficiency in India are not available. In view of the methodological problems related to the earlier such studies, we felt that we cannot accept the conclusions quoted from these studies in absence methodological details.

In the MAM it was decided to request Sridhar to go through the available literature. This is necessary to fine-tune our argument. But I feel that today we are justified in registering objection to the gazette notification of banning common salt on the grounds that 100% of the Indian population is not at risk of IDD and that the 'subsidization strategy' has not even been tried.

Before people or the Govt. start spending around a thousand crores annually, will it not be possible to do ID prevalence study in every district to find out which districts are endemic?

I have suggested some copy editing of the Wardha draft. But I think that the Wardha draft is basically OK and be endorsed by all after making the necessary improvements in it. The convenor can suggest a process of coming to some consensus decision.

Anant Phadke

July 19, 2005

Dear All

Have been following this debate and it gets interesting by the day. While the discussion has not clarified for me what side I should take what prompted me to pitch into the debate is Anant's economics. If universalisation of I-salt does not cause great harm for those who get iodine from other sources as well like fish etc., then instead of talking about subsidies why dont we let I-salt be produced in such large quantum so that economies of scale brings the price of I-salt almost to the level of common salt and this could be helped by the public sector or cooperative sector playing a substantially larger role so that oligopoly in the salt sector which fixes prices is curtailed. And I also agree that universalisation of I-salt should not mean banning non-I salt. Trust I have not compounded the confusion and I guess I missed great debates by not attending the MAM

Ravi Duggal

July 20, 2005

Dear All,

Though, banning of common salt is difficult to implement and can also affect a section for whom iodine would be harmful, the problem is about the fact that unlicensed producers pack common salt without iodation and could sell under similar brand name to dupe the needy consumer OR would compete with iodated salt for lower price in area where iodine deficiency is endemic. This needs to be controlled. Apparently it has not succeeded. Example quoted is experience in Nepal about Indian manufacturers..

Free flow is not just a cosmetic quality. It is to ensure that salt is not caked while iodation mixing is done. Iodation with spraying KIO₃ (in India and developing countries and KI₃ in Developed ones) after crystallization makes it sure to remain iodated.

Finally, since 70% of salt consumed in India is anyway iodated, the economics of scale may not have major effect. since the cost is the iodation includes the method of production - spray mixing method. Simple techniques are available of mixing powdered salt with KIO₃, calcium carbonate and magnesium carbonate. - dry mixing method which reduces the cost.

I would just like to point out that KIO₃ was subsidized till recently. Also, it is the branding and packaging - the mark up for which the company justifies high price. (like any pharmaceuticals) Any subsidy offered would subsidise TATA etc ad cost!

A Bangladesh study in 1992 (ref <http://www.micronutrient.org/Salt_CD/4.0_useful/4.1_fulltext/pdfs/4.1.1.pdf>) recommended withdrawal of subsidy because the increase in price was at the mark up level (advertisement, packaging etc.) and at the production level it was a marginal increase.

In fact, a price control by making sure that uniodated and iodated salt is available at the same price giving an edge to the iodated one where really required! This would be a more effective strategy rather than subsidy.

My argument is that its economics is not adverse enough to oppose universalisation of iodated salt, it is an ethical and to some extent medical argument which points to reconsider its legalisation. Economic issues could be better settled through hard negotiations and allow justifiable price.

Regards, Dhruv

July 20, 2005

Dear All,

In a separate mail I have clarified my position on the banning of common salt issue. Let me also respond to Shyam as he has misunderstood my mail. Even Sridhar in his otherwise well written mail (I would respond to the other issues he has raised, separately) has brought in this confusion when the subsidization strategy we are suggesting is not based on informed choice in the endemic areas but making available subsidised, cheaper iodated salt in endemic areas.

I have said:

“To ensure the supply of iodised salt to the needy the easier option is that the government thru the ration shops and others should subsidize sale of iodised salt in areas of proven endemicity of Iodine Deficiency. Instead, the government is asking everybody to consume iodised salt compulsorily so that it does not have to spend anything from its pocket! Subsidizing iodised salt for vulnerable populations would ensure that the right of every child in such areas (to which Sridhar has referred) to get iodine supplementation is respected. Without considering this option, I am surprised that Sridhar has so easily agreed to the compulsive use of iodised salt for all Indians! Conventional types of experts are not much bothered about the state indulging into undemocratic precedents. But MFC experts should certainly be bothered about such ‘on-scientific’ issues.

Even if it is proved that a particular intervention is beneficial for health of a people, it is no ground to make it compulsory. It is necessary that people drink only potable water or wear helmets etc. etc. But that does not mean that these things be made compulsory! We should make a distinction between making iodised salt universal and making it compulsory. “

Its gross misunderstanding when Shyam responds to this by saying “I feel we can not support the stand ‘ask at-risk people in hills and other places to exercise informed choice between two salts’. When even ANC care is barely utilised by informed consent, I-salt is an unlikely possibility in this situation.”

When one says that through ‘subsidization strategy’ iodised salt be made universally available cheaper by say a rupee a kg in endemic areas, one is not relying on the people in remote areas or in other Iodine Deficient areas making an informed choice. But to be sure all new health interventions requiring

people's co-operation would require a lot of health education and propaganda.

Anant Phadke

July 20, 2005
Dear All,

Reply to Anant: I shall try to take up a few points...about targeting to areas, which require the salt: targeting was supposed to be happening before the law came in..... BUT there were real problems....

... Railway Wagons at Gujarat were supposed to be specially deployed for the supply of I-salt to the NE ...these wagons were never given priority for obvious reasons...On the way to the NE they languished for days in the railway yards in UP, Bihar, Bengal almost everywhere and reached the North East months later, in the meantime uniodised salt would come in from Bihar, UP Bengal Orissa almost anywhere. We have a unique situation where every person handling the wagons decided that the NE was NOT a priority. I am sure they believed that the NE deserved to be neglected because of "Insurgents" or God knows what else. Difficult to lay your fingers on any one reason. There are so many other such stories...

Since the Govt had fixed the amount of I Salt necessary for the Goitre areas and even subsidised it...It was discovered that the actual production was far below the requirements, and fudged figures used to be sent to the Govt every month...the hassle of producing the salt and then transporting it across the country was not worth it ...

Veena

July 20, 2005

Thanks Anant, I got your point. Sorry for misunderstanding. Then that means both the salts are available in the needy districts-fine. We will have to unfortunately also address the epidemiological and administrative issue of borderline areas. In fact the ban idea came partly because the unmanageable mix up on borderline areas and largely because 'no harm from this level of I-salt in euthyroid' assumption.

Shyam

July 22, 2005
Dear All,

I agree that with Dhruv that it is not enough to subsidise the iodated salt. There should be price control also. Otherwise the govt. would be doling out subsidy into the profit-box of the concerned companies.

Veena's narration does not convince me about the impossibility of iodated salt reaching the needy people in these remote areas. It would reach the needy people in remote areas if the manufacturers and traders get their usual margin and thanks to a subsidy, the people get it cheaper by say a rupee a kg compared to the common salt. The earlier attempts failed because the iodated salt was costlier than the common salt.

As of today most of us have not been thru the NIN study report and the time is running out. Since Veena has gone thru the NIN report, she can tell us in some detail what proportion of the Indian population is at risk for IDD, based on the NIN and other studies. I would argue that so long as a substantial proportion of population lives outside the endemic zones, the 'subsidization' strategy should be adopted to provide iodated salt cheaper than common salt in endemic areas.

Sridhar/Veena can tell us, based on the experiences in other countries whether iodisation at lower concentration — around 40 ppm results in much lower incidence of Iodine Induced hyperthyroidism.

Based on the prevalence of IDD and of IIH we can decide whether we are for the 'subsidization strategy' or for the banning strategy. We need to take a decision at the earliest so that in case we decide against the banning strategy, objection to the notification can be filed before 27th deadline. The EC can take a decision based on the e-mail debate. The convenor can initiate the decision making process.

I do not agree with Gopal Dabade and others' arguments who have circulated a letter in opposition to the ban though I am, as of today opposed to the ban on common salt.

Anant Phadke

July 23, 2005
Dear Ritu,

Sorry for the delay in responding to your clarifications on methodology of IDD survey, although it was well

narrated by one Cuttack medical college faculty who was involved with it...but I rather waited to get access Govt document on it for unambiguity and authenticity. Hence the delay

Regards, Rajan

Yes! on methodology query. here is how it goes :

Samples Survey conducted on random sampling basis. Sample collection as follows:

- ◆ 5% of all categories of school children, both boys and girls in equal proportion from all the schools in each block of the district.
- ◆ 1% of the village population - all ages and both sexes in each bloc of the districts.

Technique of examination From clinical point of view, the diagnosis of the goiter is based entirely on inspection and palpation of neck...(.rest of the paragraph is about mode of palpation, position of examiner in children and adult etc etc)

Classification of Goitre As per recent WHO publication (1994), the previous five grade of goiter namely Grade-0, Grade-1A, Grade-1B, Grade-II, and Grade-III have been classified into three grades:

- a) Grade-0 (No palpable/visible goitre)
- b) Grade-1 (mass palpable but not visible in normal position. It moves upwards in the neck as subject swallows)
- c) Grade-2 (A swelling in the neck that is visible when the neck is in a normal position and is consistent with an enlarged thyroid when the neck is palpated/Goitre visible and palpable)

Data Collection Format This is one page sheet with a stratified table indicating: Age groups (0-4, 5-9, 10-14,15-19, 20 & above, Grand Total); Sex (Male and Female); Grades of Goitre (0, 1st & 2nd Grade); Total cases of Goitre Percentages.

The data I had shared earlier was over all snapshot. Age-Sex disaggregated data is definitely accessible and made available if we collectively agree to collate state level info across the country if it helps to strengthen petition...when done, may shed new light...may be we be forced to give a fresh look at some points in the petition..quite possible.

July 25, 2005

Dear All,

I have been trying to put together all the arguments based on the review of studies undertaken at our centre in JNU to input into the mfc debate, but we are still in the process of finalising it. I will try to share the main points of the CSMCH response to the ban by this afternoon.

Can everyone interested, and the EC members, please take a look and be available for consultations in the evening so that we can take finale decisions on the mfc response?

I have not seen the NIN study on the website. Padma and Nobhijit, can it be put in by the evening?

Regards, Ritu

July 25, 2005

Some thoughts on the Comments of Anant Phadke inter alia: "To begin with let me clarify my overall position about banning/prohibiting a thing or making things mandatory for citizens. When a citizen's action is harmful to others or harms the larger social interests, the state can justifiably prohibit such action."

I think one factor we need to introduce is time - some consequences of our actions are immediately 'obvious' and some not so.

Also we need to constantly redefine boundaries of individual and social freedom and social responsibility. And integrate it with our idea of just society.

A related question is obvious to whom - some consequences of certain actions are only obvious to the so-called educated and experts (eg: mosquitoes lead to malaria). Ofcourse some social consequences are not obvious to the experts in the field (eg. Narmada dam). Some are obvious only to a subset of experts (say where do I throw the nuclear waste from a reactor - relevant in the current hoopla about "concessions" wrangled by our PM Manmohan Singh).

Some other examples chosen randomly: :

- 1) Helmets - negative consequences obvious although it constricts the space around my brain. Helmet free driving is worthy of ban - so I think.
- 2) Injectable contraceptives: no unanimous opinion (I feel) - because of conflict about interpretation of risks and benefits among experts. So we end up taking positions depending on how you interpret data. And your politics.
- 3) Sex determination tests - not obvious to many in this country but still ban advocated by many of us concerned about democratic space.
- 4) Mandatory regn. of births and deaths - very obvious to epidemiologists but not others.
- 5) Smoking, pollutant gases, polluting industries, etc. : case for some kind of restriction obvious to medical experts and some laymen. Not obvious to many. Do we wait till more people die?
- 6) Drugs (narcotics) and alcohol: Damage obvious to experts but not to say non-expert males.
- 7) Harmless/useless/dangerous medicines: Not

obvious to even many experts. And forget things like fancy combinations/generic drugs, etc. Seen as violation of clinical and business freedom if you advocate ban. Somewhat akin to euthanasia (shld we or shld we not?), at the risk of oversimplification.

8) Then they are other things, which are macro level causal phenomena like free trade and globalisation (and benefits thereof). Benefits obvious to even experts like Amartya Sen but not to some of us. Shld I ban free trade?

9) Then there are norms - like not lying, not manipulating the truth. These are apparently obvious to many (all?) but seldom practiced all the time by say business persons, diplomats, lawyers, advocates of many social causes.

Even our idea of truth and normatively acceptable radically changes over the years - sometimes in minutes, the so-called epiphanies and paradigm shifts..

Is there a thing called objective truth (an extreme example: a person is dead?)? Looking at it very fundamentally - many things appear to be difficult to prove absolutely. They are conditional. Even three angles of a triangle equal to 180 degrees is a bit subjective (not in the post-modernist sense) but as against consensual truth.

Then there are some truths, which are not provable, and some provable things not true. Is democratic space a sine qua non for justice as in getting my required roti, kapda, makaan? I do not know. If a hungry person in a desert - hungry for many years along with his starving/dying daughter - is given a choice of food for rest of life versus restrictive freedom, I guess he/she would prefer food. I might. Especially if it is either/or.

So the best we can do is take positions hoping to integrate them with our idea of how a (faultily) benign and just society should be.

Iodine salt ban - ahem, without knowing much of the recent literature which I probably would not understand - seems to be a good idea in my world view and I think I am as democratic as the average Indian (which is probably not saying much).

Consistency of means and ends? Is it always worth striving for?

Chinu

July 25, 2005

Dear All,

Given below is the executive summary of the CSMC review and submission to the Ministry. Please advise about mfc's position.

Regards, Ritu

Objections to the Ban on Sale of Non-Iodised Salt and a Proposed Rational Public Health Approach for the National Goitre Control Programme

Executive Summary

I. We propose use of iodised salt in populations where iodine deficiency is convincingly found to be a public health problem and leaving people the choice in other regions. Its proponents say a ban in just the severely affected regions has proved unsuccessful. Without analysing the reasons for this failure they prescribed universalising the ban. The programme documents acknowledge the crucial problem of a higher price of iodised salt and therefore the role of traders in flouting the localised ban. There are optional approaches available to deal with the problem in highly affected areas. Participatory community programmes of iodisation of salt or water at local level is one that has been tried successfully in countries such as Thailand. Supplying subsidised iodised salt in these areas so that it is cheaper than non-iodised salt is another option, which directly addresses the problem without adding the negative health consequences of the intervention.

II. A systematic review was carried out by a team at the Centre of Social Medicine & Community Health, Jawaharlal Nehru University, with the aim of analyzing available evidence and providing inputs to policy makers and program formulators regarding the entire issue of iodine deficiency disorders. A total of 121 studies and documents were reviewed starting from year 1930 till 2004. The studies were categorized based on their study design (community and hospital based studies which were cross sectional studies, randomized trials, or experimental field studies). They were analysed for their predominant research question, hypothesis and methodology. The four aspects examined in-depth from the findings of these were: the magnitude of problem of IDD; the causality and determinants of goiter, cretinism, and hypothyroidism; evidence of effectiveness of intervention; and the harmful effects of iodisation.

III. The scientific argument for universal iodisation of salt was found to be on weak ground. Some critical epidemiological questions have yet to be answered in order to weigh the possible benefits and negative consequences of universal iodisation of salt in our country. What has propelled the whole campaign for universal iodisation is the 'evidence' that a high level of goitre (enlargement of the thyroid gland in front of the neck) in a population indicates high risk of 'invisible' mental retardation of varying degrees and cretinism (a severe form of congenital physical and mental retardation in newborns). However, the data presented by its proponents on the prevalence of goitre and mental retardation exhibit several serious limitations. The review brought out four salient issues as given below. Our reasons for reaching these conclusions are also indicated.

1. Possible over-estimation of the problem of IDD

- (a) Methodological errors due to use of subjective clinical methods recognized universally by all endocrinologists in estimation of prevalence and severity.
- (b) Rationale for identification of 'hidden IDD' not explained
- (c) Arbitrary and changing criteria used for the identification of endemic areas
- (d) Not taking cognizance of physiological goiter
- (e) Extrapolation from findings in severely iodine-deficient pockets to all other population groups across the country.

2. Causal linkages have not been considered despite evidence that they play an important role

- (a) Evidence from earliest studies (1927) and also from recent studies have identified multiple causes for IDD, but these have not been considered
- (b) Evidence for decrease in the problem without Iodine supplementation in sub-populations in India as well as other countries has been ignored
- (c) Persistence of the problem despite years of continued use of Iodine supplementation in India as well as other countries has not been given due cognizance
- (d) Failure to convincingly demonstrate negative consequences of goiter per se, especially its links with cretinism

3. Flawed assessment of the impact of intervention

- (a) Studies based on assumptions of effectiveness of interventions without corroborating evidence
- (b) Lack of comparability of groups and indicators in the samples studied
- (c) Different classifications used by various researchers

4. Harmful effects of Iodine not given due cognizance

- (a) Ignoring possible links of increased iodine intake leading to anemia, hyperthyroidism and goiter despite evidence from the studies

IV. Thus, evidence from this scientific, systematic review of empirical studies demonstrates enough bases to question the current dominant view and reveals that opposing research findings were ignored. The studies available do not provide evidence about the effectiveness of universal iodisation of salt as a measure that leads to

decreasing goiter and other IDD by itself. Further, there is evidence of negative impacts on health itself like increase in anemia, goiter and hyperthyroidism.

July 25, 2005

Dear All,

I have made several changes (mainly editing) in the Wardha-meet resolution that was circulated after the MAM. The revised version is pasted below. The EC may accept/reject/modify this statement.

Anant Phadke

Medico Friend Circle opposes compulsory use of iodated salt by banning common salt. Its opposition to making the iodated salt compulsory is because it is not established that the benefits of compulsory salt iodisation are overwhelming compared to the risk it entails, both to health of the population especially in non-endemic areas and to democratic ethos in India. Our grounds can be summarized as follows:

1. Only a section in India lives in IDD affected areas

1.1 Only a section of the population in selective areas in India suffers from Iodine Deficiency Disorders (IDD) like goitre, mental retardation and cretinism in children. In the published literature there is a paucity of evidence about universal spread of IDD in India.

1.2 There is no direct one-to-one correlation showing that most IDDs are caused by low content of iodine in the diet alone. Other causes need to be identified and addressed as well.

1.3 All goitres are not due to iodine deficiency. Further, there is no one to one relationship between goitre and mental retardation.

2. Alternative strategy is available

2.1 The iodated salt should be made available at a lower cost through ration shops and in the open market in the endemic areas.

2.2 In addition in such areas, the people should be encouraged to use the cheaper iodated salt by making them aware of the effects of iodine deficient diets.

3. Compulsory iodated salt can be hazardous

3.1 Making everyone consume iodated salt compulsorily is hazardous for some persons.

3.2 The issue of how much is the risk of Iodine Induced Hyperthyroidism if all one hundred crores population starts consuming iodated salt has not been settled. The hyperthyroidism caused in an area with introduction of iodated salt is documented to have lead to deaths due to heart disease.

3.3 A small population has hyperthyroidism and they are advised to take a low iodine diet. If iodated salt is made compulsory, they would have to consume it even though it is hazardous to them.

4. Banning common salt is impractical

The salt used for industrial purposes (commercial sodium chloride) would be available anyway. It would be difficult to ensure that it is not consumed by the people.

July 26, 2005

Re the edited stt by Anant: "The iodated salt should be made available at a lower cost through ration shops and in the open market in the endemic areas."

You have not answered questions about migrant population - migrant for atleast 6 months of the year - as is the case with affected population here in Gujarat. How will you ensure that they consume only iodated salt in Baroda or Ahmedabad or Surat where they usually migrate to? ...

Chinu

July 26, 2005

Somebody please explain this to me.

While we started discussing iodisation after the mfc MAM had structured a memorandum on it, there were many who raised issues on the stand taken and some who said they did not see their way to agreeing to it.

If the discussions are still on why this revised version of the statement? I understand the 'urgency', but there are people who disagree. Should we not then decide that no matter what the urgency we need to take a look at the issue more thoroughly?

By rushing into making a statement, we are simply falling into the timetables set by the state. Instead, we should, as Gopal Dabade's letter says point out the need for more time to debate the issue. This is too important issue to be decided upon in such a short time. And I am strongly resistant to being pushed into taking a position just because the state has issued a notification. Let us even give the authorities the benefit of the doubt ... that they did not realise that so many issues still needed resolution.

Mfc, as a socially committed body seriously working on health issues for many years should request/demand that the issue of iodisation and banning etc should be put up for public discussion for which due process be followed and deadlines set.

This I think is the important stand to take.

We should not be hassled into taking a position, especially when some people will refrain from agreeing to it because they see the need for more discussion, and others who have expressed specific reservations

will simply fall silent. I really object to this process.

But as I have said earlier there is something that I have missed, please do clarify.

I am a bit uncomfortable at what's happening and don't want to be part of this process - that is, unless I have somehow misunderstood the process.

Padma Prakash

July 26, 2005

Thanks Padma, I got the same feeling when I read the fresh statement. I keep wondering whether we are more loyal to ideologies than the poor people of India. Do we miss the woods for the trees?

I also agree with Veena that we are trying to give a scientific tinge to something political. It seems that we do not like to push things down people's throats and that is great, we need to defend that. But as Sridhar brought out, the cost factor should not bother us at all - we don't seem to take stands on many things while this 2 rupees extra bit a month vexes us. I would still love to hear the continued debate about the benefit analysis and Anant's piece seemed to stymie the debate.

Sunil

July 26, 2005

IDD (Iodine Deficiency Disorder) is not Science; it is Politics for sure...! Let us not stretch the science bit too much. Thus far we (the elite) were not too worried about Malaria, IDD, mortality due to gastroenteritis (of whatever cause), STDs and others, as they were contained, because they occurred in tribal belts...The rest of India did not have to do much ...not any more...IDD has stopped respecting borders (Pilot investigations carried out by me in the city of Hyderabad show that breast milk samples in over 100 women have very low iodine levels...unfortunately I don't have urinary iodine values or the details of type of salt intake). In addition newer areas of IDD are being seen ...so is it possible that the elite are taking notice and would like to prevent this epidemic occurring nearer home.... maybe they are not doing anyone a favour by their willingness to use iodised salt.

The parallel with AIDS is there...thus far women's white

discharge was NON SPECIFIC...it was not an area for research and no one listened to women - but with AIDS so close to our lives the Govt, Bill Gates and Clinton are interested in RTIs and even REPRODUCTIVE RIGHTS...Phooh please don't give the credit to the Women's movement.

About hyperthyroid cases...yes we could ask for adverse drug (iodine) reaction monitoring system...and propagate information that if the salt is left open...iodine levels come down to nil very soon. Maybe in 15 to 30 days (from 30ppm to nil). Hyperthyroid cases can use this salt

About pricing ... We are not able to do much with privatization of Schools, Hospitals, Water supply, and Highways etc. The private sector and MNCs are in control good or bad...but why do we want the tribal areas to retain their pristine purity when it comes to their needs? After 50 years of Govt failure with iodised salt distribution in endemic areas the private sector might do better and sell iodised salt there.....provided they are assured a larger Indian market...and that seems to be happening with the elite agreeing to participate in this projectThe Govt can still subsidize it in the endemic areas...after all Tamil Nadu is selling the iodised salt at Rs.2 through the PDS

There are many other issues of course and I agree with Padma. Let us discuss it. But ...not just as Science...!

Veena

July 26, 2005

Dear All,

Thanks to Veena I got the photocopy of the NIN study last evening. Unfortunately it only corroborates the methodological critique in the CSMCH submission, the executive summary of which I had put in my email yesterday afternoon.

Rajan's reply to my queries, giving methodological details of the Orissa study gives similar pointers.

However, since mfc works on consensus and should continue to do so, we do not seem to be in a position to send the MAM resolution to the ministry as mfc response to the ban notification. Some members have clearly expressed their opinion in favour of the ban in the egroup debate.

Since today is the last day for submission of objections, I would suggest that anyone who thinks it important

should send individual emails or from other organisations to the Secretary, Ministry of Health & Family Welfare, Shri P. Hota. Both the mfc mam resolution and the CSMCH-JNU exec summary are there for consideration and use.

I do not have Shri Hota's email id right now. Could anyone who does have it please share it stat.

For mfc, I think what will be important is to continue the debate on two issues:

1) the importance of epidemiological data and its critical appraisal for specific choice of interventions and programme formulation, and

2) democratic norms/coercion in relation to public health interventions. Chinu's latest mail raises important issues that need to be followed through.

We should continue to actively put all the data relevant to the iodisation issue on the mfc website. Also pursue with Sridhar to go on with the review. Rajan and others who are ready to share data could all fed into the data base.

Few studies of those cited for districts studied for prevalence by official documents were available and so one of the demands made in the CSMCH-JNU submission to the ministry is that all data be put in the public domain. If others who think THIS is important could also reiterate this it would be good.

We could take up the debate in the coming annual meet as a question of what are the criteria for defining quality of a public health programme.

Regards, Ritu

PS: Some of us have received copies of letters from Dr. C.S.Pandav, at AIIMS, community Medicine and deeply involved with the National Goitre Control Programme, congratulating the Minister for the ban notification, written by himself, Dr. Karmakar, chief of the International Council for Control of IDD, and by the AIIMS director. He has requested that other professional organisations send similar letters to the ministry!

July 26, 2005

Dear All,

The Secretary H & FW's email id -
<secyhth@nb.nic.in>.

Thanks to Anant for revising the MAM resolution, but my own view and that of the EC members I was able to consult- Manisha, Sarojini and Neha (I have not been able to get to Renu, Chinu and Anant Bhan on phone)- is that mfc is not in a position to state a common view.

I absolutely agree with Chinu and Veena about the politics of data/'science' and hope that we can discuss that with concrete examples, such as of the iodistion universalisation issue.

Regards, Ritu

July 26, 2005

Dear All,

We have had some amount of discussion on e-mail after the MAM. The executive summary of the JNU's CSMCH's review, I thought, clearly shows inadequate scientific evidence about universal spread of IDD in India. The economico-political and social-ethical arguments have also been exchanged. Based on all this, I felt that there would be consensus (after some modifications in it) about the revised draft I have circulated. But if people feel that this revised draft is basically unacceptable we can decide not to take decision immediately. I do not know who are the E.C. members, but if after whatever discussion has taken place so far, if people feel that as of now MFC should not take any position on this issue, E.C. can so decide. Alternatively, we can file an objection to the Gazette Notification, by saying more public debate is necessary and back up this position with arguments, facts. For this purpose, the revised draft that I have circulated can be suitable modified. I do not know whether any general plea to the State asking for more time will be heeded to. Filing objection to Gazette notification is a definite space available and its better to use it. Let us note that it will be very difficult to reverse the ban once it is effected after the due process of Gazette notification has been followed. There is a need to stall the govt. decision. However, I do see that as MFC, we have certain limitations. Let us accept those and also its consequences. In any case, EC has to take SOME decision, as its already very-very late.

Anant Phadke

July 26, 2005

Dear All,

I just got hold of a recent WHO publication on I def. It shows most of India map as having optimal dietary Iodine based on urinary iodine levels (the surveys are called subnational, which means they are partial and spread, not total national). The Himalayan areas are in def zones. UI is the most dependable parameter for ID.

The full report is available on www3.who.int/whosis/micronutrient. The contact address is <micronutrients@who.int>.

That lays to rest the worries of those who wanted a ban on common salt (incl me).

Shyam

July 26, 2005

Dear Dr. Sham Ashtekar,

It is true that in most areas of the country urinary iodine excretion which reflects iodine intake is OK, but that is because there is a ban on the sale of non-iodised salt since the last few years in the whole country (except Kerala, and for sometime in Gujarat) However these bans had been in place as a result of state notifications. Now since iodisation comes under the central PFA Act (Prevention of Food Adulteration Act), it is the duty of the centre to issue the notification under the act, since states do not have any power under the PFA act. But the states had been acting on behalf of the centre. That is all...so lifting the ban would change the iodine status of the Population.

Veena

July 27, 2005

Shyam, can you please give us a reference for the map you refer to?

The link you provided leads us to an excellent database (Thank you!) but that seems to only show how widely fluctuant the problem is - at a rough count, around 15 districts of peninsular India seem to have median UI values less than 100 and about another 15 are at the borderline figure of 100. Around 6 districts have more than 20% of the sample at less than the cut-off mark for severe deficiency. In fact, data from samples of

sub-Himalayan states shows much lesser degrees of deficiency! A lot of the data is from school children, which leaves much to be desired in terms of representativeness. One would also need to look at whether these populations were consuming iodised salt, as Veena has pointed out (the southern states are known to have been poor users of iodised salt as of 1998 - NFHS 2).

I am not sure if this data can really rest our worries. Let us look further, now that the debate is not closed.

Sridhar

July 27, 2005

Dear All,

Sunil's mail is a little unfair. Secondly, he is requested to come forth with concrete arguments and not mere tendentious remarks.

Anant Phadke

July 27, 2005

Sorry Anant if it hurt. Your letter did seem to abruptly end the debate. I agree I do not get to read many scientific papers but enjoy what I get served on the mfc network. The debate was clearly showing that there were different ways in which people were taking stands based on the same data. What does that show - that we are taking sides irrespective of the science that is visible to us. That is politics or ideological, and although I do not mind people sticking to their ideology and bargaining hard, the tendency to stop the debate by clearly wording what was not being agreed by many who were voicing their views - for time's sake or whatever - seemed too authoritarian, worse than feeding people iodised salt as far as I am concerned. I am sorry for the outburst and my regards for you and the mfc group remain unfazed

Sunil

July 29, 2005

Dear Veena,

All of us would agree that like any other policy issue, the IDD-banning of common salt issue needs to be discussed from both the angles - science and politics,

not to mention other dimensions - economics, socio-cultural etc.

Is more information available on the Tamil Nadu experience that you have mentioned?

It is nice to know that if the salt is left open...iodine levels come down to nil very soon. Maybe in 15 to 30 days (from 30ppm to nil). Thus despite compulsory production of iodated salt, hyperthyroid cases would have a space to get non-iodated salt!

Your remark "why do we want the tribal areas to retain their pristine purity when it comes to their needs?" is perhaps based on a little misunderstanding. I do not think that anybody MFC is arguing against supply of iodated salt in endemic areas thru open market. What is being argued is the subsidization to make it cheaper than common salt in the endemic areas.

Anant

July 29, 2005

Dear Sunil,

Please read carefully the explanation in my 26th July e-mail about why I circulated the revised draft. Also take note that the very purpose and context of my e-mail of 30th June about compulsory iodisation was the deadline created by the gazette notification.

In any organization, after a round of debate, the issue of taking a decision has to be taken up. In my experience in an organization, though people argue about various nuances of an issue, there is many times an agreement about a particular resolution. Secondly, when people argue out positions, their positions get modified through the process of debate; such give and take is expected in any debate! Therefore my revised draft contained some important changes compared to the original Wardha-draft. If people felt that there is no consensus about it, its fine. But it is unfair to talk about somebody stymieing the debate or being "authoritarian" when somebody tries to push forward the issue of taking a decision. Its one thing to say that there is no consensus and hence a particular draft should not be sent and other thing to talk about somebody styming the debate or being "authoritarian".

Please note that I have been suggesting that we decide about/ initiate a decision-making process thru the convenor/EC (I am not on the EC). Let me quote from my e-mails:

19 th July - "The convenor can suggest a process of coming to some consensus decision."

22nd July - "We need to take a decision at the earliest so that in case we decide against the banning strategy, objection to the notification can be filed before 27th deadline. The EC can take a decision based on the e-mail debate. The convenor can initiate the decision making process."

26th July afternoon, - "if after whatever discussion has taken place so far, if people feel that as of now MFC should not take any position on this issue, E.C. can so decide."

Though obviously I was very keen that MFC contributes in thwarting/postponing the decision of banning common salt, I have tried to follow the democratic traditions of debate and decision-making in MFC. And yet your repeat assertion of being authoritarian!

That I have been hurt by your outburst is secondary issue. It is more important to continue the debate in a healthy manner. Your statements like - "I keep wondering whether we are more loyal to ideologies than the poor people of India ... we don't seem to take stands on many things while this 2 rupees extra bit a month vexes us." do not serve a positive purpose.

Incidentally at least in Pune the iodated salt is costlier by Rs. 5/- kg and not by Rs. 2. Anyway its not a great amount and we have not made an issue whether people can afford it not. The issue as I had put it is, "...if common salt is banned and hence if all 100 crore Indians have to buy iodated salt, the people would have to spend additional Rs.1800 crores annually from their pocket. Instead of this, the citizens would prefer to pay through taxes Rs.1060 crores for the benefit of the people in the endemic areas." (assuming half of our population lives in the endemic area)

My request would be: Please respond specifically to the arguments put forth in the debate and not make general, insensitive remarks.

Anant

July 31, 2005

Dear All,

People from endemic areas who migrate for months together to non-endemic areas would, during these

months, consume diets, which are not deficient in iodine. Iodised salt is not a therapeutic measure and hence is not needed when the diet is not iodine deficient during the migration to non-deficient area. I hope, this fact would take care of Chinu's concern about the needs of the migrant population.

Anant

August 1, 2005

Dear Anant,

Those of us in Iodine deficient areas are aware that any non-iodised salt in India will make its way to tribal areas. Iodised salt in 100kg bags also loses its iodine rapidly if exposed to sunlight. We are in favour of compulsory iodisation. Kindly do not take an MFC decision without considering our point of view.

Prabir

August 18, 2005

Dear All,

Copied below is an open letter on the issue of iodised salt. We are seeking individual endorsement and anyone willing to be a signatory may please let me know by Saturday (20th) night. Dr. Ekbal, Imrana Qadeer, Anant Phadke, D. Banerji, Alpana Sagar, C. Sathyamala, Ritu Priya, are those who have presently endorsed the letter.

Some pieces have appeared in the national press, English and Hindi, in favour of the ban. We hope some papers will publish this opinion too.

Regards, Ritu

(see below revised version of letter - editor)

Sep 9, 2005

Dear All,

The letter circulated earlier was initially written with the information from the newspapers that the ban was going to be announced on the 15th Aug. Since that has not happened and the ministry is waiting because of the objections, it seems appropriate to redraft the letter somewhat. The main issues remain the same, and the questions just as relevant if the

ministry is to give serious consideration to the objections. Therefore, while the modifications are minor, the redrafted letter is copied below for information of those who have endorsed it earlier. Any others who would like to add their names now can also do so.

Anyone wanting to add or delete names may please write by 6th morning, after that the letter will be sent to the ministry with 4 contact persons names and addresses (Anant Phadke, Dhruv Mankad, C. Sathyamala and Ritu Priya) and the complete list of 233 signatories.

Regards, Ritu

Open Letter to the Ministry of Health & Family Welfare /Letter to Editor

Subject: Universal Ban on Sale of Non-iodised Edible Salt

Sir,

As persons concerned about public health in India, we appeal to the Ministry of Health & Family Welfare to take heed of scientific evidence relating to the issue of iodised salt before instituting a measure that will affect each and every citizen of our country. We refer to the proposed universal ban on sale of non-iodised salt. The Ministry needs to answer the following questions urgently:

1 Most of the district level data cited in support of the ban is not available in the public domain. Why?

2. The studies that are available in the public domain provide only weak evidence in support of the universal ban.

◆ The prevalence and seriousness of the problem both appear overestimated to us, especially given that some qualified analysts have pointed out methodological flaws. For instance, goitre is known to be difficult to assess, and it can exist as a physiological (normal) condition as well as a disease condition, but the studies do not account for this.

◆ The studies assessing impact of salt iodisation programmes appear to have assumed effectiveness of the programme approach, even though findings of

several studies demonstrate varying impact. Some studies show little impact despite high use of iodised salt in such areas, thus pointing to the multifactorial origin of IDD. In other areas goitre has declined despite little use of iodised salt!

◆ The potential negative consequences of compulsory use of iodised salt have been demonstrated by other studies, gaining importance when applied on a mass scale.

What has been done to weigh the costs - in terms of health side-effects and financial expenses - against the benefits?

3. We understand that several objections were filed against the ban in the stipulated two-month period, and some questioned the ban on scientific grounds. What note or action has been taken on these objections?

4. In some locations and sub-populations, iodine deficiency disorders (IDD) do constitute a public health problem. Local measures to deal with the problem are known, for instance, subsidizing the iodised salt so that it becomes available at lower prices than non-iodised salt, promoting small-scale production in the endemic pockets and encouraging its use there. Therefore, what is the rationale for instituting a universal ban on non-iodised salt?

5. Non-iodised salt will continue to be available at cheaper prices for 'non-edible' purposes (industrial, etc.) and can be consumed as edible. How does the government propose to enforce the ban in light of this?

6. From the information being given to the public, it appears that goitre is only due to 'natural' iodine deficiency in the environment. However, other causes have been identified from the 1920s onwards, including contaminated water, chemical pollution of soil and water, and dietary 'goitrogens'. In the endemic areas, what measures are being taken to deal with these factors?

This withholding of information, misinformation and the intense industrial pressure that is known to underlie decisions about such measures compels us to raise these issues for public examination and open debate.

Yours sincerely,

40 signatories from different organisations/institutions, in alphabetic order plus 192 signatories from Christian Medical College, Vellore.