Introduction

It is 45 years since the beginning of the Medico Friend Circle (MFC). It began in the mid-1970s as a churning among a group of young doctors and others concerned about public health, with doctors specially trying to make sense of their dilemmas, the mismatch between what their education prepared them for and the needs for basic health care on ground. These dilemmas and discussions led to the circle of friends, the cyclostyled bulletin, the annual meetings, the study cells. The other factors that influenced these young health activists were the JP movement, the emergency and after, the trends of medical education at that time and the inability of the government to provide basic health care.

In the intervening time so much as has changed. Health care and medical education have become an industry. Successive governments have not invested adequately in strengthening basic primary care. Responsibility for curative health care has more or less shifted to private players through government supported insurance. The hospital-based sector has expanded in cities with specialty hospitals. The parallel increase in cost of care causes more impoverishment. All these are leading to lack of access to basic health care.

In the last few years we have witnessed a significant upsurge of young members who have attended the annual meetings. The increasing number of young people could reflect the effort of programmes such as NIRMAN (of SEARCH, Gadchiroli) and mentoring by NGO organisations. Or it could be that youngster are disillusioned with mainstream medicine in the current scenario and are looking for alternatives?

The annual meeting in February 2019 had a lot of young, inquisitive and raw faces who wanted to understand things beyond their academic textbooks. They participated in the discussions in the meet, tried to keenly observe and learn from the experienced and senior members of the group. Many youngsters raised different questions pertaining to their professional career. They had an intense desire to work for the society, for the underserved population but seemed to have number of concerns. To go for PG or not, when to apply for the coaching classes, how to convince parents and resolve their worries and plenty more. It was in this background that the theme chosen for the mid-annual meeting was ‘Dilemmas of Young Health Professionals’.

In this Background Paper, we have tried to understand and represent the dilemmas of varied health professionals in their own language and as experienced by them. Many members representing different health professions have vividly described individual dilemmas faced by them.

Dialogue

The backgrounder takes the shape of a conversation between a few allopathic doctors working in primary care, an Ayurvedic doctor, a homeopathic doctor, a nurse, a medical sociologist, a health writer, a former pharmaceutical writer, a public health dentist, a community medicine MD, a group of friends...
intending to start an independent organization, and a medical teacher. The background paper begins by setting the stage for the conversation within a medical college and the life and experience of a medical student, Subbu. Subbu’s sees that life around him is governed by NEET coaching. A clinical case discussion regarding a TB patient with undernutrition forces him to ask the question, ‘Are antibiotics enough to treat and reduce TB in the society?’ This question initiates a wider discussion among the young professionals from different backgrounds on ‘the dilemmas of our respective fields and to understand other professionals dilemmas as well’. This initial scene firmly situates the dialogue in the medical college system, the overarching influence of NEET and the concerns of students who despite all this are seriously thinking about the health needs of society.

Pankaj, a primary care physician in Chhattisgarh narrates his quest to work for people of rural India. After finishing MBBS he was not confident of practising medicine and he joined Jan Swasthya Sahyog to work in the hospital and the community. His first dilemma was whether to undertake a formal postgraduation in family medicine. He decided to continue to work and simultaneously completed his distance education course in family medicine from CMC Vellore. He talks about the tussle between the needs of the organisation and his interest to work with the community. His financial requirements with marriage and supporting his parents were significant issues that he faced. Through his work with the government he was able to overcome his cynicism about government programmes. As his experience grew, he was given significant decision-making responsibilities and is now leading a project.

Smitha an ayurvedic doctor and public health specialist writes about her own dilemmas as a ‘Vaidya’ and dilemma of AyUSH practitioners in general. ‘There the difference in the philosophical approaches and disparities in the approach to specific clinical conditions and their treatment. There is the lack of ‘evidence-based research’ to guide practice. The amount of allopathy that is learnt in AyUSH courses varies from state to state. There is the perception that their training is less equal to MBBS which affects their training and career opportunities. Should AyUSH practitioners also practice allopathy? There is a philosophical aspect to this question but also an economic aspect which forces AyUSH practitioners to combine practice in order to survive. How should allopathy be combined with other pathies? Another aspect is gender and patriarchy issues where women vaids are not able to prepare medicines during their menstrual periods. With environmental changes, there is increasing scarcity of medicinal plants which affects practice.

Nishigandha is a homeopathic postgraduate student. She writes about the inadequacy of undergraduate training in providing knowledge and skills and patient exposure. This forces students to undertake postgraduate training which in her own experience has not provided her with more practical training. Another issue that she faces are the misconceptions about public about homeopathy which makes it difficult for practitioners to gain the trust of patients. There is the ethical issue of not being able to provide emergency care at primary level because of legal restrictions on prescribing emergency drugs. She says that very few homeopaths are working at the community level.

Roopa, a nurse writes about the lack of social orientation in nursing training and the exposure to role models of nurses working in the community. She says that working with NGOs does not provide credit for clinical and teaching work experience which dissuades nurses from joining such organisations. She felt there was lack of autonomy and leadership opportunities in nursing. There was a limited recognition of the potential role that nurses can play in primary health care level.

Nidhi a medical sociologist trained at CMC Vellore writes about the lack of understanding of her profession by other health professions which leads them to be referred to as ‘social workers’. There is gap between theory that she learnt during her course and being able to use it in her practice. She writes, ‘I am still trying to figure out where exactly the gap is? Is it with the curriculum and training or the hospital environment which focuses on physical care at the expense of addressing psychological and social issues’.

Nishitha, a health reporter writes about the challenges of health reporting. She says that there is tendency to sensationalise stories in order to have them published. Editors lack of understanding of health issues and this prevents them from publishing stories from health reporters. She writes about the ‘demanding deadlines to come up with x number of health stories every day’ which puts ‘health reporters under immense stress’. When the Nipah virus epidemic happened she thought, ‘11 deaths are good enough to report for today,’ and that was her ‘first wakeup call that she was turning out to be an insensitive and, goal driven reporter’. She feels that
journalists are being lost between ‘the triad of being sensitive, being indifferent, being a performer’.

Priya has written about the dilemmas of working as a medical writer for pharmaceutical company working in South East Asian countries. She writes, ‘I no longer derived any meaning in the work and was burnt out from it; the long hours coupled with the continual pressure of deadlines and the need to be profitable, made it necessary for me to take a break to gain back my mental health’. She had to promote lung cancer drugs, but at the same time the company not willing to address environmental pollution that was causing lung cancer. In China she observed that there was first class care for the privileged and a lesser standard for ordinary people. This made her feel that there was ‘something inherently morally wrong with determination treatment quality according to a person’s economic status’. She writes that, ‘pharmaceutical companies lure doctors by sponsoring their attendance at fancy conferences and meetings that are held in attractive destinations … I am sure that this does influence [doctors] treatment decisions to a certain degree’. She writes that ‘it is on account of my questioning of the ethicality of the incidents around me that led me to move away from the bio-medical diagnosis, treatment and management mindset. I hope that being surrounded by like-minded folk will provide some clarity, comfort, and reassurance on the day-to-day ethical dilemmas that we all face in our jobs in the healthcare industry’.

Rajeev is a public health dentist. He writes that ‘Oral health in India lacks priority from both policy circle as well as the community. A Union Health Secretary told him, ‘We are dealing with bigger problems such as TB, AIDS, Cancers. I understand dental care requires attention but where is the money? All the money goes to bigger diseases.’ Rajeev writes, ‘For a middle-aged Adivasi male whom I met in one of my village visits in Gudalur, tooth pain is a near non-existent issue as compared to other bigger problems he faces’. He mentioned, ‘how does it matter to have a tooth or not, I want to simply get it removed’. He further added, ‘where do I get the money from to get my tooth repaired?’ The affordability of oral diseases’ treatment is a major challenge. There are very few insurances or payment plans in India that cover dental treatment. With a minute percentage of primary health centres offering dental services in India, the poor and the neediest are left with minimal chances of treatment. Very few community-based organisations recognise the importance of oral health needs and are catering to it. The social determinants of oral health and diseases are the same ones which cause other diseases too and cannot be ignored if one has to work on oral health betterment. Many young and enthusiastic dentists who are interested in community dental health themselves clueless and opt for other areas of interest in public health. He said that one of the biggest challenges faced by public health dentists is that of mentorship. He was able to learn about the oral hygiene practices practiced by the Adivasis in Gudalur …. For example, the use of Neem or Meswak twigs for oral hygiene practices is as beneficial as plastic tooth brushes. It was a Eureka like moment when I found a simple and acceptable solution for affordability issue’.

Priyadarsh, who has just completed MD in Community medicine has written about his existential dilemma, ‘We want to work for the people and work with the people … We love to work for the people because it brings happiness to us, along with satisfaction, respect and also some good name … We don’t have grand dreams of understanding equity, corporate exploitation, biased World Banks and shrewd politics. we don’t at all want to measure our work … the baseline, the intervention, the end line, the impact, the behaviour change…. how to be leader and bring change without manipulating the community? … Where should the free birds amongst us go and what’s their solace?’

Sangeetha, a primary health doctor initiated a discussion on ‘dilemmas of young health professionals at the rural sensitisation programme at the Tribal Health Initiative, Sittilingi, which was attended by about 20 medical students from Chennai. The rural sensitisation programme is a 3-day camp to expose medical students and young doctors to health needs in rural areas. The main dilemmas that were discussed could be summarised as follows.

- The students felt that the way medicine is being practised in tertiary care centres made them fear that they may lose empathy towards patients.
- The question of why ethics is totally ignored in medical curriculum.
- In reality the problems which patients face are poverty, marginalization, accessibility and other socio-political factors. In current context of specialty medicine, which specialty would give them training and skills to address the real problems?
- The focus of both private and public health care was on tertiary care hospitals and not on
community based primary care centres, which gives very few options for the young doctors.

- Why is MBBS considered not enough? Why do doctors feel insecure even after completing undergraduation? Is specialty necessary to give appropriate care to the patients?
- Competitive exams (NEET, Institution exams) are blinding us from taking bolder decisions to come out of the rat race. How to reassure ourselves?
- Will I be the doctor I want to be? And bring changes in the society? Or will I become another ordinary person in future who had many dreams?
- How to balance personal and work life if we decide to work for the society?

Sangeetha herself has worked for 3 years in THI, Sittilingi. She talks about her experience of working in rural area has affected her. She had numerous dilemmas which have crept up after her rich experience in the rural health. She says: ‘The only advantage is we get to know more people and more institution who has brought a change in some way. But still it doesn’t give us the clarity of where we fit in. The only reassurance is, the experience gives the confidence that we can exist with dilemmas till we find out what is our path, which will be fruitful if it’s a combination of both public health and clinical medicine.’

Dhiraj and his group of friends have just beginning to make their dream a reality. They are a group of about 8 friends who are now ‘aspiring to create an organization of our own. This group of ours intends to contribute meaningfully in sector of rural health. Our group includes family physicians, some MBBS graduates intending to study further and couple others who are public health masters. This group has always talked about how we could contribute to the poor and the needy, and this stream of thoughts really brought us together. We went through period of extensive exploration in different setups in rural areas and meeting experienced senior members who have done work in such challenging areas. Meeting inspirational people all around these places and our own learning experience enhanced our capacities and helped in knowing ourselves further. We deep down realized that friendship must be strengthened first and only that can help us to stay grounded in this field of non-profit social service. To start an organization everything had to be started from scratch. Legalities and financial aspects are certainly the most important issues bothering us. Under what provisions we should register our organization? From where will money come from which will sustain ourselves? Where do we setup the organization? And plenty more. As profit making is never top priority, financial sustenance and thereby limitations to be considered for the group is of utmost importance. We cannot do everything as providing medical facilities of every kind is simply not possible in this setting. We understand, thankfully, that life is more than just work and service. Life also is personal needs, friends and family. A salary to sustain, quality time with life partner and attending family responsibilities simply cannot be compromised. We realise we must give due importance to these too. In midst of work and service, we do not forget that at the end of the day we, the group members, are friends.

Anand, a medical teacher talked about his dilemmas as a young doctor, service obligation after MBBS and having to work closely with patients under the guidance of good teachers helped him to clarify his interest in clinical medicine. ‘My own experience has taught me that the only way to sort out your dilemmas of medicine, are to become involved in the care of patients, taking responsibility for their lives and working with people who can teach you and open your mind to different ways of thinking and possibilities’.

An issue that came significantly into the discussion was NEET and its impact on students minds. In an increasingly consumerist society where wealth is equated to success, students feel that they need higher degrees for high paying jobs. Because of this, students have to clear PG-NEET and so they skip clinical postings to attend coaching classes. There is also the fake panic induced by the coaching classes. Two recent incidents that relate to the theme are the death of Dr. Payal Tadvi, postgraduate in Mumbai due to caste-based discrimination that she faced and the violence against interns at the NRS Medical College in Kolkata.

Concluding remarks

The theme of this mid-annual meet is different in the sense that dilemmas are largely personal. We need to remember that personal dilemmas need to be expressed and discussed and solutions need to be found through informal discussions, connection and bonding. What the younger group in MFC is probably seeking is guidance, mentorship and even friendship from a like-minded group. Therefore, the bulletin as well as discussions regarding this theme needs to be as informal as possible with an attempt to arrive at a conclusion of some kind!
Need for Reforms in MFC?

The personal accounts of dilemmas which span different streams in health care, different age groups have both similarities and differences. But together they provide a weave and texture of the problem that is being confronted by young health professionals. On the one hand there is curative medicine that is propelled in a certain direction. On the other hand, there are a large number of young doctors who came into medicine with the dream of addressing the health needs of society. Young health professionals are caught in the quagmire of the system, and their dilemmas reflect the difficulty in addressing these contradictions.

If we imagine that 1% of each graduating batch are seriously concerned about the country’s health, that would translate into 5000 potential graduates every year who are facing similar dilemmas. We usually think that dilemmas are personal and it is up to the individual to resolve these. But if dilemmas are systemic, then what can we in MFC do to support individuals and groups to address and resolve these dilemmas.

We have to try and understand, what these questions from the younger group means at this historical juncture and in the current social and political setting. What are youngsters looking for from MFC, and how can the organisation adapt and re-form itself to meet these expectations?

It is quite clear that the only way forward for young health professionals to clarify their dilemmas is to engage with actual issues on the ground. This could be through programmes such as NIRMAN or rural sensitisation programmes. Could MFC think of itself as a parallel educational space, providing the discussion, resources, thinking and guidance which youngsters are looking for and which the medical, dental, nursing or AYUSH colleges do not seem to be able to provide.

An initial list of suggestions that could be explored in this regard are:

1. Reviving the idea of MFC study cells
2. Experiential learning tours of organisations working in health and development.
3. Involving the younger group in different levels of MFC advocacy
4. Thinking about how the bulletin should change to meet the younger groups requirements
5. Career guidance and mentoring by the for interested youngsters

Summary of issues that have emerged in the discussion

A. Medical Education

1) Is medical education causing students to lose their empathy towards other humans?
2) Is the focus of the education system towards providing tertiary care rather than primary care?
3) Is medical education helping the students to understand the larger socio-political realities impacting health?
4) Is medical education enabling students to acquire necessary skills for practice?

B. Postgraduation

1) Why isn’t an MBBS degree adequate for practicing medicine? Why the rat race for a post-graduate seat?
2) In order to gain experience and learn about the health problems in rural areas, what is a better choice? To work or pursue higher education?
3) If we are interested in rural medicine or primary care, what kind of post-graduation should we pursue: medicine, surgery, obstetrics and gynaecology, paediatrics or family medicine, community medicine, public health?

C. AYUSH

1) Where do AYUSH practitioners stand, when their philosophies are different from mainstream ‘allopathy’?
2) When majority of people that prefer AYUSH medicines reside in cities, can an AYUSH practitioner expect to make a financially sufficient career in a rural area?
3) How do deforestation and climate change affect the availability of various herbs that are required for medicinal preparations under AYUSH practices?
4) How to deal with perceived sense of inefficiency due to lack of proper education, facilities and clinical skill awareness imparted at undergraduate level as well as at the postgraduate level?
5) Also lack of interest in alternative medicine amongst rural population and inadequate availability of modern medicines in emergencies makes it difficult for AYUSH practitioners to practice independently in rural areas.
6) How to deal with factors that makes AYUSH students feel inferior to their MBBS counterparts?
7) There are inadequate job opportunities for AYUSH graduates (and those available are in
majority contractual) for which they are forced into doing post-graduation and even in that seats are meagre. What can be done further in this regard?

D. Nursing

How to deal with the triple A problems (lack of awareness, depriving autonomy, work without adequate acknowledgement) that cause the nursing community to largely stay away from the social service area?

E. Medical Sociology

1) How to overcome the apparent gaps in the curriculum, training and actual application of Medical sociology?

2) As the focus is mainly on physical care, social and emotional components are easily side-lined, how do we make people acknowledge the need of this emerging and evolving workforce?

F. Health Reporting

1) For a health reporter, how far is the editorial decision as to what is newsworthy a barrier to effective reporting?

2) Is health reporting becoming elitist?

3) How to find a balance between being sensitive while also being a performer?

G. Pharmaceutical Sector

1) How do jobs in the pharmaceutical industry that ignore patient rights, animal rights and the conduct of ethical research affect the mental health of its workers? What can be the possible solutions to handle it?

2) The extremes in generic drugs: On one hand overwhelmingly projected as less efficacious and on the other, a high percentage of drugs going through poor pharmacovigilance process.

3) How do doctors we should deal with the increasing influence of Pharma industry knowing or unknowingly?

H. Dental Medicine

1) How to prioritize oral health over the seemingly bigger (What is big? Who decides it as big?) Public health crises?

2) How to deal with the issue of imparting dental care which is highly commodified and costly?

3) Lack of mentorship and opportunities for dentists in community-based organizations. This leads to numerous clueless enthusiastic dentists to go for alternative branches of interest in public health.

I. Income and Family Issues

1) Can the income from working with non-governmental organizations fulfill the financial requirements of an individual along with supporting his/her family needs, that may include spouse, aged parents, etc.?

J. Miscellaneous

1) For several young health professionals, lack of a dilemma is itself a dilemma. If they don’t measure their impact, does this mean they are not successful?

2) How to be leader and bring change without manipulating the community? How to behave in most trustful manner where we don’t have to fake emotions or hide truth from the people about where this project or intervention is going to lead them to? Whether we need some goal or just being there will be the most natural course taken? What are the solutions to these dilemmas?

3) When working for an organization, how to balance between our own interests and the needs of the organization?

4) How to deal with transitions in roles when working for the organization?

5) What are the possible pros and cons of working in each sector i.e. NGO, Government or Private?

6) Will this knowledge of each sector (NGO, Government, and Private) in some detail reduce the bias one has regarding a particular sector?

7) How can public health and clinical medicine be integrated in study and practice?

K. Dilemmas while working in groups/organizations

1) What are the prerequisites for friends to become work partners?

2) What are the legal formalities which are to be considered when starting an organization?

3) What are financial issues one must face and various means and ways to achieve financial sustenance effectively while working in rural setup?

4) Where should we limit ourselves in terms of organization, needs of the rural population in the area and ultimate goals and objectives of the organization?

5) How to maintain work life balance to sustain in the long run and to avoid clashes between group members who are primarily friends before anything else?
This paper discusses the judgment of the Delhi High Court on the ban by the Government on Oxytocin; and the subsequent judgment of the Supreme Court as the matter went on appeal. Para numbers cited in Sections 1 and 2 refer to the Delhi High Court judgment.

1. The Ban

Oxytocin is an essential and life-saving drug frequently used for women during delivery, for induction and augmentation of labour, to make childbirth safe and prevent death from postpartum haemorrhage (PPH). In India PPH contributes to 38%, approximately a total of 32,000 maternal deaths, of all maternal deaths occurring every year in India. The guidance note of the Maternal Health Division, Ministry of Health and Family Welfare on prevention and management of Postpartum Haemorrhage recommends AMTSL for prevention and PPH and states that: “Oxytocin remains the uterotonic of choice for AMTSL. Oxytocin (10 IU, IM) is the preferred uterotonic based on studies on the safety and effectiveness of uterotonics. It also is the recommended uterotonic drug for PPH prevention during caesarean sections.” (A uterotonic, is an agent used to induce contraction or greater tonicity of the uterus.)

In April 2018, the Government of India banned private production of Oxytocin and decreed that henceforth the public sector unit KAPL (Karnataka Antibiotics Pvt Ltd) will make Oxytocin for the entire country and will directly sell on its own, or through government outlets like Jan Aushadhi, to registered hospitals and clinics in public and private sector. The immediate trigger for the order series of orders leading up to the ban was its purported misuse and dangers to the health and well-being of milch cattle. Cattle injected with Oxytocin was feared to have Oxytocin residues in the milk produced which was therefore feared to be harmful to human health. The related measures proposed by the Government included not allowing retail or wholesale chemists to stock Oxytocin in their shops in any form or name.

Several affected manufacturers, and civil society, represented by AIDAN (All-India Drug Action Network), appealed against the ban. After hearing detailed arguments, the Delhi High Court bench of Justices Ravindra S. Bhat and A.K. Chawla pronounced on December 14, 2018 its final order on Oxytocin quashing the ban. Petitioner AIDAN cited studies by scientists from the Indian Council of Agricultural Research (ICAR) and National Dairy Research Institute (NDRI), that showed that there was no evidence for the apprehensions of oxytocin residues in milk and any harm thereof.

The AIDAN petition also argued that Oxytocin, an essential and life-saving medicine, needed for preventing deaths of mothers, during and immediately after delivery, and that was relatively easily available, would become scarce after the ban. In a country where more than half of all pregnant women are anaemic and with several states still unable to assure blood availability at all major delivery points, this would make women even more vulnerable and would lead to many more maternal deaths. The order was therefore entirely out of proportion to the alleged harms. Never before any essential drug included in WHO Essential Drug List and in National List of Essential Medicine (NLEM) has been meted such biased, adverse treatment and with such insouciance.

The other petitioners who were manufacturers – BGP Products Operations GMBH (a subsidiary of Mylan) and others – invoked Article 14 (right of equality before law) and Art 19 (1) (g) (right to practise any profession, or to carry on any occupation, trade or business) of the Constitution of India and submitted the impugned notifications were violative of these provisions, arguments essentially accepted by the Hon’ble Delhi High Court as we shall see.

The Union of India preferred to fall back upon Article 19(6) of the Constitution of India to justify its reservation of Oxytocin manufacture to the public sector even as it tried to highlight the supposed dangers to cattle and vegetables, and girl children in sex trafficking.

Influential Animal Rights Lobby Leads to a Bad Decision

The several minutes of the Drug Technical Advisory Board (DTAB) and the Drugs Consultative Committee (DCC) (available at https://cdsco.gov.in/openems/openems/en/dcc-dtab-committee) nowhere recommend the ban of private manufacture.
and sale of Oxytocin nor suggest confining it to PSUs or for that matter to a single PSU. Neither could the Union of India produce satisfactory evidence of ‘widespread misuse’ of Oxytocin. All the statutory body meetings “recommended against the ban of sale of Oxytocin having regard to its beneficial medical effects….” The 67th and 70th meetings of the DTAB; the 49th and 69th meetings “consistently and clearly stated that Oxytocin could not be banned or prohibited as it has a defined use for therapeutic purposes.” (Para 123 (iv) and (v)).

The decision to ask KAPL to be the sole manufacturer of Oxytocin in India was despite several notings in the Government files requisitioned by the Delhi High Court to be produced – these notings doubted the capability and viability of KAPL to execute the role of the sole manufacturer of Oxytocin formulations.

Smt. Maneka Gandhi, the then Minister for Women and Child Development Ministry of the NDA Government, used her political clout in the matter to influence various levels of decision making. On 16.10.2015, the 49th meeting of the DCC was addressed by Smt. Maneka Gandhi highlighting the negative consequences of misuse of Oxytocin for milch cattle.

2. Legal Issues in the Delhi HC Final Order

The Delhi High Court bench of Justices Bhat and Chawla while quashing the ban, decided in its wisdom the following questions worthy for determination in the batch of writ petitions challenging the Oxytocin ban and related restrictions:

1. Does the ban, namely, GSR 411(E) dated 27.04.2018, fall within the scope of Article 19(6) of the Constitution of India?
2. Is the ban notification ultra vires the provisions of the Drugs (and Cosmetics) Act?
3. Whether the impugned notification is arbitrary and therefore, unsustainable?

Ban Notification and Scope of Article 19(6) of the Constitution of India

Art 19 outlines six freedoms. And specifically Art 19 (1) (g) asserts the right to trade/any profession/business. The proposed ban would have shut down domestic Oxytocin production and sales of all licensed private sector manufacturers. And with it the right enshrined in Art 19 (1) (g) would have been infringed. An exception is however made through Art 19 (6) (ii) which asserts the right of the State to reserve, in public interest, certain products/business/trade for the public sector as part of ‘reasonable restrictions’ on the right to trade, etc. Art 19 (6) (ii) basically legitimises State Monopoly and seemingly puts its beyond judicial review. Government counsel cited several related cases in support of the restrictions/ban on the manufacture/sale of Oxytocin which de facto led to State monopoly over manufacture and sale of Oxytocin formulations. While the judgment interrogates the logic and relevance of these cases cited by the Government and its appropriateness to the argument, it does not question in anyway the right of the Government to create such a monopoly. The judgment also appears to quote in approval certain case laws that argue that public interest is to be assumed, unless the contrary is shown, if the action of the State results in monopoly.

The ban notification cites Section 26 A of the Drugs and Cosmetics Act to promulgate the prohibition of private manufacture. However as the judgment points out after detailed examination, “no provision in the enactment (Drugs and Cosmetics Act) per se authorizes the taking over of the drug business or an entire line of business for monopoly production by one licensee – even if it were a State monopoly.” (Para 79)

And further:

“.... Any provision or law which does not enable the creation of a monopoly either directly or authorize the creation of State monopoly, therefore, does not fall within the productive ambit of Article 19(6)(ii). In the present case, this Court is of the opinion that Section 26A does not and cannot be considered by any standard or interpretation as a law that creates State monopolies or enables the creation of State monopolies. Consequently, the Union’s arguments on this score are unsustainable and have to fail.” (Para 82 of the order)

So the instant case the State cannot – per the order – claim immunity under Art 19 (6).

Reading Sec 26 A Further

Even if examined in the light of particular clauses of Section 26 A of the Drugs and Cosmetics Act, the ban does not hold water. Section 26 A talks of prohibiting (that is banning), restricting or regulating a drug only if it has unacceptable safety (risk to human beings or animals), or efficacy (does not have the therapeutic value claimed/purported to be claimed), or the content of the drug has no therapeutic justification. And it needs to use relevant material in determining so, and such actions have to be in public interest.

From relevant material examined by the Court (see Paras 100-102) including several minutes of DTAB/DCI, and after noting that it is part of the NLEM and the WHO Essential Medicine List, as
also WHO recommendations for prevention and treatment of postpartum haemorrhage,\(^9\) and after taking into account Oxytocin’s vital role on saving lives of pregnant women in PPH, the Hon’ble Court observed:

“... it is apparent, that the materials on record, as well as the materials produced in the form of official files, do not point to any known or established risk to human or animal life, on account of Oxytocin use. On the other hand, its use for medicinal and therapeutic purposes is known and recognized .... As to the beneficial use – even necessity of Oxytocin, the (maternal mortality) figures, in a sense speak for themselves ...... The Central Government stated, in Parliament, that the largest cause of maternal deaths is haemorrhaging which accounts for 38% of all maternal deaths. According to UN data, India is estimated to account for 15% of the total global maternal deaths. It would be a fair, or reasonable assumption that ease of access to Oxytocin was one of the reasons for the significant decline in maternal deaths due to haemorrhaging.” (Paras 103-105)

The impugned notification therefore cannot be seen to be valid in the light of the provisions of Section 26A and powers exercisable thereof.

The Delhi High Court also examined the scope of judicial review of the ban, claimed as a legislative decision by the Govt of India. Whatever be the scope of such decisions, the Court said the ban order would be inadmissible because of its gross unreasonableness and bad faith if one considers the disastrous public health impact on women giving birth that it would have had, a irresistible fact that the discourse of the Union of India repeatedly sought to elide despite advice to the contrary of its own committees and experts.

The learned judges observed that the “predominant consideration which runs like a common thread through the government’s decision making process is that Oxytocin had been misused in the past, resulting in adverse impact on the health of animals. In a case like this assuming the respondents had a good case to conclude Oxytocin was a risk to cattle health nevertheless in the nature of things its therapeutic benefit to humans could not have been overlooked or given less importance.”

In the end, the Court quashed the notification as both unreasonable and arbitrary as the Union of India did not “adequately weigh” on inter alia what banning private manufacture, and restricting manufacture and supply of a life saving drug, could do to “increase in maternal fatalities, during childbirth, impairing lives of thousands of innocent young mothers. ... For these reasons, this court is of the opinion that the conclusions recorded by this court – to quote the Supreme Court – do not transgress the arena of permissible judicial review, but rather “enough for us to say that the present case is on the right side of any line that could reasonably be drawn.” (itals in original)

3. Appeal by the GOI in the Supreme Court

Instead of letting the matter rest, the Government took the quashing of the ban as a prestige issue. The Union of India, during February 2019, filed a Special Leave Petition (SLP) in the Supreme Court against the Delhi High Court Order.

Again the respondents to the petition in the Supreme Court were the manufacturers and AIDAN. Almost the same arguments were traversed again. The GOI laid more emphasis on the legislative nature of the decision to ban and argued that the Courts cannot review such a decision.

The Supreme Court bench of Justices A.M. Sapre and Indu Malhotra that heard both sides, refused to opine in favour of either party. Instead they identified, in their final order of August 22, 2019,\(^{10}\) seven issues that need to be deliberated further by a larger three-judge bench as these issues have larger implications.\(^{11}\) At least one of them, issue (vii), certainly does: “Whether the exercise of power (to regulate, restrict or prohibit a drug) by the Central Government under Section 26A of the Drugs and Cosmetics Act, 1940 is legislative or executive in nature?”

The Government had argued that the Oxytocin ban on private sector production was legislative in nature and hence beyond judicial review, or at least required judicial restraint.

“Unfortunately or fortunately, the scope of judicial review either over an administrative action or over legislative action or over quasi-judicial action, is not defined in India by any statute, but is mostly judge made, based to a great extent, upon Western precedents,” according to the learned judge of the Madras High Court in para 88 of the Macleods vs Union of India (2012) judgement.

If scientific issues, like the ban of Oxytocin production in private sector, or say a ban of irrational fixed dose combination (FDCs) medicines, were beyond judicial purview because it was based on a legislative decision, the court must nevertheless (after the Delhi HC judgment on the matter) check for arbitrariness. A process that may involve taking a call on whether the scientific exercise leading up to a legislative decision was logical or not and whether it was bereft of arbitrariness. However,
courts opining on scientific matters, is a slippery terrain. But to concede scientific expert judgement as necessarily beyond bias and unreasonable ness is also unacceptable, as scientists and technocrats can be doctrinaire in their world view. The opinion of the proposed three-judge bench, any which way, will be far-reaching, and hopefully settles the issue for some time at least.

For lack of space, we cite two other questions, of the seven, flagged by Justices Sapre and Malhotra:

(iii) Whether the classification made by the impugned notification between licensed public sector and private sector companies, in the manufacture of the drug Oxytocin for domestic use, would achieve the object and purpose of preventing the unregulated and illegal use of the drug?

(iv) Whether it would be in public interest to restrict the manufacture of a lifesaving drug for domestic use, to a single public sector undertaking, to the complete exclusion of the private sector companies, particularly in view of the high maternal mortality rates in the country?

The answer in our humble opinion is a firm no to both questions. The ban needs to go in the interests of safe delivery and reduction of maternal mortality.

**Endnotes**


5Art 19 (1) (g) says: “All citizens shall have the right to practice any profession, or to carry on any occupation, trade or business.” This right is subject to Art 19 (6):

“Nothing in sub-clause (g) of the said clause shall affect the operation of any existing law in so far as it imposes, or prevent the State from making any law imposing, in the interests of the general public, reasonable restrictions on the exercise of the right conferred by the said sub-clause, and, in particular, nothing in the said clause shall affect the operation of any existing law in so far as it relates to, or prevent the State from making any law relating to:

(i) the professional or technical qualifications necessary for practicing any profession or carrying on any occupation, trade or business,

(ii) the carrying on by the State, or by a corporation owned or controlled by the State, of any trade, business, industry or service, whether to the exclusion, complete or partial of citizens or otherwise.

6For instance M/s. Daruka & Co. v. UOI and Ors. (1973AIR SC 2711)

Section 26A in the Drugs and Cosmetics Act, 1940 is about Powers of Central Government to prohibit manufacture, etc., of drug and cosmetic in public interest.

Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the official Gazette, [regulate, restrict or prohibit] the manufacture, sale or distribution of such drug or cosmetic.

7Recommendations for prevention and treatment of postpartum haemorrhage (available on its website http://apps.who.int/iris/bitstream/handle/10665/75411/9789241548502_eng.pdf?sequence=1)

8As quoted in Collector of Central Excise, New Delhi v. Ballarpur Industries Ltd. 1989 (4) SCC 566


10Delineated in Para 12 of the order as “substantial questions of law” arising for consideration:

(i) Whether a drug included in the National List of Essential Medicines published under Schedule 1 of the Drugs (Prices Control) Order, 2013 notified under Section 3 of the Essential Commodities Act, 1955 would be subject to the provisions of Section 26A of the Drugs and Cosmetics Act, 1940?

(ii) Whether the impugned notification has resulted in creating a monopoly in favour of public sector companies, to the complete exclusion of private sector companies, and if so, whether it would be protected by Article 19(6)(ii) read with Article 14 of the Constitution?

11See main text of this article.

12See main text of this article.

(iii) Whether there was relevant and objective material before the Central Government to form the basis of satisfaction to exercise the power to prohibit the manufacture of the drug by the private sector companies for domestic use, under Section 26A of the Drugs and Cosmetics Act, 1940?

(iv) Whether the object of curbing the clandestine manufacture and unregulated use of the drug Oxytocin, which is covered by Section 18 of the Drugs and Cosmetics Act, 1940, can be achieved by taking recourse to Section 26A by imposing a ban on the manufacture of licensed drugs by private sector companies?

(vii) See main text of this article.
Book Review


Read Books Limited. Downloadable from https://www.e-bookdownload.net/search/exploring-the-dangerous-trades-the...

-Jagdish Patel

Alice Hamilton was born in the same year as Mahatma Gandhi - in 1869. At age 101, she died in 1970 – the year President Nixon signed the Occupational Safety & Health Act, a revolutionary law. Her autobiography was first published in 1943. Alice Hamilton was an American physician, research scientist, and author who is best known as a leading expert in the field of occupational health and a pioneer in the field of industrial toxicology. She was also the first woman appointed to the faculty of Harvard University. Her scientific research focused on the study of occupational illnesses and the dangerous effects of industrial metals and chemical compounds. In addition to her scientific work, Hamilton was a social-welfare reformer, humanitarian, peace activist, and a resident-volunteer at Hull House in Chicago. I had known about the work of Alice Hamilton but had no opportunity to read about her. When I was visiting Mark Catlin, head of safety & health department of Service Employees International Union (SEIU) in his Washington office on November 28, 2007, during discussion we came across Alice Hamilton and I said that I have not read any book on her work. He immediately rose up, opened the cupboard behind and took out a book and marking his autograph he presented me this autobiography.

This 427-page book, Exploring the Dangerous Trades: The Autobiography of Alice Hamilton, M.D. is nothing less than superb. This autobiography takes us through the by lanes of American society, politics and history. “Protection of workers in dangerous trades is the chief but not the only subject of this book.”

She attended International Conferences in 1933 and 1938 in Europe which were days of the Second World War. Her descriptions of the mindset of German people, and persecution of German Jews, is disturbing. One is inclined to compare with our own present situation in India, when we read how German intelligentsia supported the persecution of Jews.

She agrees that, “I should never have taken up the cause of the working class had I not lived at Hull House.” Hull House was established in 1889, 3 years after the Haymarket “riot”, by Jane Addams (September 6, 1860 – May 28, 1936), the American settlement activist, and a leading name in the history of social work and women’s suffrage in the United States and an advocate for world peace. “At Hull house one got into the labor movement as a matter of course, without realizing how and when...I cannot remember when I began to see the working world through the workers’ eyes …. It was also my experience at Hull House that aroused my interest in industrial diseases.” This was the time when American middle class had begun taking interest in the lives of the poor.

When she was 15 years, going on 16, she had decided to become a doctor. In 1893 she became a medical graduate. Thereafter she did her post-graduation in Pathology and Bacteriology in Germany. She became tutor in 1919 at Harvard University and that too, on her terms.

At the age of 40, in 1910, her career in Occupational Health began. She started working on a subject on which no American had worked earlier. When complaints of lead poisoning started pouring from Illinois she accepted to inquire. She had no literature on the subject, and no experience. In Europe the subject was researched but not in America. “This ignorance and indifference was not confined to the medical profession - employers and workers both shared it. The employers could, if they wished, shut their eyes to the dangers their workmen faced, for nobody held them responsible, while the workers accepted the risks with fatalistic submissiveness as part of the price one must pay for being poor.”

Remembering the days of lawlessness, she writes that a manufacturer of lead once asked her how is he responsible for the toxic effects on his workers.

Sharing her experience, a Hungarian woman visiting Hull Hose said that her husband met with an accident at a steel mill and he was hospitalized for treatment where visitors, not even his wife, were not allowed. There were no laws for worker compensation those days. Under the guise that worker had knowingly accepted the hazard, damages were not paid. This was USA in 1910. In America those days, employers were giving treatment expenses to the accident victims. But today in 2019 hundreds of workers in India are not fortunate to get even treatment expenses following accident at work, let alone compensation.

Workers meet with accidents because they are careless, American (and Indian) employers argued, and still argue, to justify their action (or lack of it). Workers get sick because they are drunkards, it used to be said by America’s employers. We are not responsible, they used to say those days in US. Till 1922, American workers had to work for 12 hours, 7 days a week. Wages paid were least possible. The book tells you...
how efforts by American workers to get organized were cheaper by their employers. Migrant workers were cheaper and were more obedient and hence were preferred over local workers. And when the migrant worker would become a victim of accident or occupational disease, employers would not shoulder any responsibility. Migrant workers were doing the most hazardous work including the heavy lifting and handling of very hot materials in uncomfortable shop floors. Those dying in construction or steel mills were migrant workers. Workers from European countries were flocking to US and hence there was no dearth of migrant workers. We have a similar situation today in many parts of the world.

When she was studying toxicity of lead there were many plants of National Lead Company in areas surrounding Chicago. She was deeply hurt by what she saw in these plants during her visits. “I visited them and found much dangerous work going on in all of them. One of the vice-presidents, Edward Cornish, later President, came to Chicago and I went to see him in the Sangamon Street works. He was both indignant and incredulous when I told him I was sure men were being poisoned in those plants. He had never heard of such a thing; it could not be true; they were model plants. He went to the door and shouted at a passing workman to come in. “Did the lead ever make you sick?” he demanded. The man, a badly scared Slav, stammered, “No, no never sick.” “Any other man sick?” demanded Mr. Cornish. “No, no, all good.” and the poor man escaped quickly. “There,” said Mr. Cornish, “you see!” “But I do not see,” I answered.” Your men are breathing white-lead dust and red lead and litharge and the fumes from the oxide furnaces. They are no different from other men; a poison is poison to them as is to any man.” He thought a moment and then he said, “Now, see here. I don’t believe you are right, but I can see you do. Very well then, it is up to you to convince me. Come back here with your proof that my men are being leded and I give you my word I will follow all your directions, even to employing plant doctors.”

Alice accepted the challenge; it was not easy to present the evidence, because you would not find records either in factory or hospital. After great deal of hard work she could produce evidence of 22 workers suffering from lead toxicity and who required treatment. Edward kept his promise and made huge changes in the plant. Later, he appointed doctors as suggested by Alice. Alice writes, “I have met many admirable men in industry throughout these thirty-two years but my warmest gratitude and admiration goes to Edward Cornish.”

After one year of publication of her report “The Survey of Occupational Diseases”, laws were enacted in 1911 in Illinois to pay compensation to the workers affected by occupational diseases. The reforms that followed the passage of this law were swift and drastic, she notes. By 1937 all important industrialized States in USA had enacted the law. After that study she was assigned the job of Federal Survey. She would find lead poisoning among enamel workers in the ceramic industry. After getting sick, workers would go back to their native areas which made investigation difficult. We have the same situation today in India among migrant workers. When she went back in 1929 to the same units after a lapse of 17 years, lead poisoning had not remained a big hazard. But silicosis was a big hazard then in ceramic units.

In Joplin in Missouri state, an employer was insisting that Alice visit his lead smelting plant. Alice went to the plant site, but she first visited the village Smelter Hill and met with the workers first. People asked her if she is the same Washington lady! She was shocked and surprised, as to how they knew her! Everyone in the village knew that she would be visiting. They told her how employer was ‘preparing’ to welcome her. Sick workers were instructed not to attend duty for a few days when she came visiting. The plant was cleaned hastily. She understood that she would not get to know the real picture. She then visited the plant next day and told the employer to maintain such cleanliness always. She told three young employers of the plant the information that she had collected the earlier day from the village and clarified that she will include all that in her report. Employers “gaily admitted the fraud”. They promised to take necessary action. 62.5% workers had toxic effects and 3 of the affected had died already.

During the first world war, the demand for explosive chemicals had gone up. Production of chemicals like picric acid, dinitrobenzol, nitroglycerine, TNT, gun powder, etc., had increased. Alice was assigned this job to inquire the effect of war chemical manufacture on the workers and engineers and give recommendations. But no one would give her the information as to who were the manufacturers and where were they, not even the army or navy. She started with whatever little information she had. Then the factories itself would speak for themselves. “I was also helped by the great clouds of yellow and orange fumes, nitrous gases, which in those days of crude procedure rose to the sky … sometimes it would be a group of ‘canaries’ who would guide me to the plant. These were men who were so stained with yellow picric acid that they were dubbed canaries.” She describes incidents like that of the two stained workers she met in a small railway station in New Jersey who told her that they were working in Canary
Islands making picric acid for the French. Workers there would die of toxic anemia and toxic jaundice. “But it was impossible to overcome of arrogance of employers and contempt of the trade unions for the non-members.”

She found lung diseases among the granite and marble cutters. She notes that it took 20-30 years to prove workers were right. She got complaints that fingers get numb (dead fingers) in this trade while using air hammer. “The clear waters of truth are so often muddied by mutual antagonisms, quarrels over wages and hours and over unionization, and also, I am afraid, by the intense class consciousness of not a few physicians”, she notes.

There was no information on silicosis among granite cutters in Vermont. “In Barre, a cutter would say, Sure I know it will get me. It got my father, it’s got my older brother, it’s only a question of time when it will get me.” These workers were carving grave stones and for their death too. This reminded me of our Kambhat workers. Deeply grieved, Alice appealed to the audience at a public meeting in Baltimore not to insist on granite for tomb stones. The Sun newspaper carried this appeal prominently next day with the title “Wants to abolish granite tombstones”. American Granite Association immediately wrote to her, denying stone cutting was “bad for the men’s health.” But the Government constituted a Committee to look into the TB incidence among the workers in dusty occupations. The Committee observed that in Vermont incidence of TB mortality was 1.5 per 1000 among males above age of 40. Among Barre stone cutters, this incidence was as high as 60.6. By then it was 30 years that these units were using machines to cut the stones. After the report of the Committee, changes took place in a big way.

There are references to carbon monoxide poisoning as well as mercury poisoning. Mercury mine workers used to take mercury on their clothes and as a result family members also were exposed. We keep reading of the mercury poisoning among hat makers but here we find this information in minute details. When she made her inquiry in 1920-21, she found 43 affected among 100 hat makers. But by that time serious consequences were largely under control. After First World War, the situation had improved a lot. Hat-making was a home-based industry in Russia then. But before the Bolshevik revolution it had developed a process replacing mercury with caustic potash. When Alice told them their newer hats are of inferior quality, “I was told severely that in Soviet Russia human lives were more precious than pretty hats. I felt justly rebuked.”

In 1924, she worked on toxic effects of benzene. While talking of benzene she also talks of toxicity of solvents. She narrates incidence of di-ethylene dioxide which was also known as Dioxan. This was believed to be safer because before the concentration reaches to dangerous levels, there would be enough irritation of throat and eyes to give ample warning. Then there was a report from England that just before Christmas five workers were working overtime in a factory, to earn extra money. Employers wanted to finish the orders quickly. Workers kept working though the exhaust was out of order and in spite of burning eyes and throat and dizzy spells. Within two weeks all 5 fell sick and died following liver and kidney damage (hemorrhagic inflammation in liver and kidneys.)

In 1937-38 she studied toxic effects of carbon sulfide in Viscose rayon factories. She narrates stories she used to receive on the victims and the problems she faced during inquiry.

Surprisingly there is no reference to asbestos hazards. Also, we do not find any reference to the 400 deaths due to silicosis in 1929 during construction of the Gauley bridge tunnel built by Union Carbide. We should not forget however that this is an autobiography and not a history of occupational diseases.

Alice was a progressive individual. She advocated protective labor laws. She disliked inequalities in American society. Her commitment for social change went well beyond her profession. She endorsed many controversial causes like birth control when it was opposed by most medical professionals. She became pacifist during World War I but her abhorrence of Hitler led her to support American efforts in World War II. In later years she opposed cold war and in1963 at the age of 94 she advocated withdrawal of US troops from Vietnam.

Till the end of her life she believed that evils were largely the result of ignorance rather than malfeasance. She believed in the capacity of individuals, once informed of the facts of any situation, to take positive action. She has described in the book the changes brought about by voluntary action by the employers rather than coercive Government action. Comparing our experiences in India of laws for health and safety not being implemented with the voluntary changes when laws were absent, we cannot decide how far laws have helped protect workers. She supported strong compensation laws when it was opposed by employers. Human behavior is complex and beyond prediction. Reading this autobiography we can understand that for a conflict prone subject like occupational health, human sensitivity is the only lighthouse.
Critical Public Health Practice – Imparting or Sharing Knowledge?

- Kaaren Mathias

What is the prevalent practice for sharing knowledge?

Public health practice in most corners of the world seeks to build give health-promoting information to people in communities. A typical community sensitisation meeting might involve a ‘team’ (NGO or government) going to a community where they already have relationships and connections. Thirty to sixty minutes are spent gathering people together (driving around with a loud speaker or telling the community-based workers to call all the people in the vicinity) and sitting them down (some on chairs and others on the ground). The community health team then imparts knowledge by giving a talk, doing a ‘natak’ or using a flip chart. Sometimes if it is a smaller meeting or a larger hall, a movie clip or powerpoint presentation could be used. Knowledge is imparted. There may be a discussion at the end. Satisfied, more or less, the community members then drift back to their homes and the ‘team’ head back to their offices or the town.

The practice of building knowledge stands on several assumptions such as: the people paid as health workers know more about a topic than community members. People in the community will be benefited by the information. Didactic teaching methods lead to increased knowledge on a topic. Increased knowledge on a topic leads to a change in behaviour. There are obvious leaps of faith embedded in each of these assumptions.

What is wrong with imparting knowledge?

It is hard to dispute the utility of knowledge that could be life-extending or life-saving (symptoms of sepsis in a baby, there is blood-thickening-iron in green leafy vegetables) yet knowledge delivered into a context we do not know intimately, is often not relevant. For example, last year, our community mental health team in Dehradun district implemented an income generation programme which involved donating a pregnant nanny goat to a high-need family impacted by disability. Our urban community health workers arranged that the goats would be impregnated to deliver kids in March, spring being the most appropriate season for goats to be born. Community members however disputed this timing vigorously and explained that as goat milk is sold at a premium price in August and September (during the dengue season when it is a highly favoured local treatment), they wanted the nanny goats to deliver in July, so that they had maximum milk production during the dengue season post-monsoon. They had contextual knowledge that made this a far more rational time for goat reproduction.

A one-way approach to knowledge (the expert has the knowledge and the community member is a grateful recipient) raises valid concerns around ‘whose knowledge counts?’ Coercive or exploitative flows of power often accompany ‘building knowledge’ interventions (1). Explanatory frameworks which describe the unique perspective of a person or a community to understand ill-health, are often part of the collectively owned community knowledge in a given cultural context. Yet most commonly, allopathic and bio-medical explanatory frameworks are considered to trump local explanatory frameworks (2).

The following paragraph from my doctoral thesis (3) explores this further, referencing the idea of mental health literacy: “The seemingly innocuous concept ‘mental health literacy’ cannot be simply addressed by experts delivering education sessions to passive community members (4), which can have negative impacts. Evidence from both India and other countries suggests that promoting Western biomedical explanatory models of mental illness may actually increase stigma in some settings (5). Literacy and knowledge does not only flow unidirectionally, and poor communities also use external knowledge and power to advance their own interests (1). Campbell describes knowledge production as most effective in a relational process through alliances, networks, collaborations, and social movements (6).”
What are the alternatives?

There are promising pathways forward. The first, is to make sure knowledge exchange occurs in a dialogue where professional and community expertise are given equal status (7). In supporting knowledge exchange in our community mental health project in Uttarakhand, we use ‘corner conversations’ as a key process. A community worker sits with a group of four to eight local community members, and knowledge on depression, anxiety or Government health services is shared and debated to enable the integration of often unfamiliar medical knowledge with local frames of reference. This is supported by approaches of ‘dawa aur dua’ (medicines and prayers) which seem promising as a way to increase treatment and care of PPSD and respect their explanatory frameworks for ill-health. Examining how to facilitate respectful dialogues is something that we all need to do more of.

Another key pathway forward is the process of coproduction which is a knowledge production model that strongly represents the perspectives of ‘experts by experience’ (EBE) (who are traditionally on the receiving end of medical research). A recent publication that used participatory action research (8) summarises the value of this approach: “Growing evidence demonstrates the value of a co-production process that collaboratively builds on the knowledge of EBE with the knowledge of health professionals, to thus rerespect the right of people to participate in any knowledge creation that ultimately affects their lives (9-11). Benefits of co-production include improved quality and responsiveness of services, more effective and cost-efficient services, strengthened social capital and citizenship (10) and further, space for dialogue between service users and service providers which can increase the possibility for critique of bio-medical discourses which have dominated interventions for the last century (11).”

Conclusions

Living in an era of unprecedented access to information and new ways of understanding how knowledge is produced, we are also obliged to be critically reflective. We should build knowledge using processes that are most likely to lead to self-determination and ownership, and which also better supports new attitudes, relationships and practices. Dialogue, equal power relations, participation and coproduction are key concepts to make sure we share knowledge for good.

References

The world of developing countries is very vast, and spreads across multiple continents. Among these countries we can see wide variety of political systems, governance, economic situations, demography, culture, labor laws and its enforcement, numbers of workers in formal and informal sectors and difficulties in recording and reporting of accidents and occupational diseases. This leaves a narrow range for comparison.

Among developing countries, some are better in collecting data on occupational accidents and diseases while some are very poor.

*From the data available, a wide gap is observed in the ratio of illnesses to injuries recorded between developed and developing countries.*

**Reporting of fatal and non-fatal injuries at work:**

Laws for safety and health at work in India have provisions to report the accidents and occupational diseases, but enforcement is so weak that there is a huge gap between the estimated fatal and non-fatal accidents reported by ILO for India, and the figures reported to ILO by the Indian Government. The average rate of reported fatal accidents in Indian-registered factories per 1,000,000 workers employed in the years 2010-2013 was 20.85, while it was 1.53 for the European Union in the same period. Based on occupational injury rates estimated by the World Bank, the risk of fatal and non-fatal occupational injury in China and India is about two and a half times higher than in the Economic Established Market region (basically Europe and North America). This difference is five times higher in the Sub-Saharan Africa economic region. Countries with developed economies have the lowest rates. Fatal rates in Sweden and the United Kingdom are 1.9 and 0.8 per 100,000 workers, respectively, while in Mozambique or Kenya the fatality rates are 21.6 per 100,000 workers, similar to that in Bolivia, where the fatality rate is 21.9. (2007 report)

**Reporting of occupational diseases:**

Some data on accidents are available but there is paucity of data on occupational diseases. Diagnosis of occupational disease is still such a rare event that in many developing countries even the first case is not reported. Medical professionals in public and private sectors are not reporting cases of occupational diseases for several reasons. The Ministry of Labor of the Government of India published data for occupational diseases in India for years 2014, 2015 and 2016. In these three years, 132 cases of occupational diseases were notified by only 5 states of India. The rest either did not diagnose or failed to report.

**Why cases are not being reported:**

Private medical practitioners are sometimes hesitant to notify occupational diseases because they are concerned that the victim may loss his/her job, or that no one will take care for his/her rehabilitation or compensation. Thus notification may push the victim to the corner. Also, notification may not help reduce recurrence as the law enforcement agency may not take any action to improve the work environment. Each elected Government has their pressing issues, priorities and political compulsions. Elected Governments drive the policy and influence law enforcement and administration. In different

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countries, local issues are different, but the common thread is, generating resources will always have the top most priority. Industry is sometimes given leeway, which impacts notifications against employment generation. In public life and execution, persona gains in mutual interest impact enforcement in general, and for notifications in particular.

**Social environment and government policies:**

In India, there are still thousands of people who do not know where they were born and when. The literacy rate in India stands at 74% (2011) which may be an indicator, though it does not assure that people know their legal rights. Unionization is very weak and existing trade unions have further weakened in the last two decades. Society is riddled with divisions on the lines of religion, caste, color, region and language. Social and economic inequality, poor governance, rule of the mighty, legacy of feudal thought, and huge economical gaps are hindrances in achieving labor rights. And now under the “ease of doing business,” labor laws are further liberalized to push more workers out of the purview of the law. Vacancy in state and central labor ministries is mounting. State and central governments are curbing powers of enforcement agencies by amending policies for inspection of workplaces. Overall, it does not provide a conducive social environment for reporting of accidents and occupational diseases.

**Health care services:**

Diagnosis and reporting of occupational diseases is benighted. In India, 80% of health care is provided by the private sector, which is not monitored under any law. In rural parts, health care is provided by unqualified medical practitioners who do not have knowledge of occupational health. Incomprehension of legal provisions and occupational health among rural and private medical professionals is egregious. The state is not investing in making the legal provision known.

**Whose responsibility:**

Dissonance prevails between the labor department and the health department about their duties. Setting up a separate cell on occupational health within the health department and making them responsible to monitor the health of workers in all economic sectors may be a solution.

**The situation is changing slowly:**

*In the last two decades, we have observed change, though slowly.*

Despite all odds there are some positive stories of change. Setting up a clinic for screening or organizing diagnosis camps at irregular time periods have been used successfully by grass root groups to generate scientific data on occupational diseases like silicosis and asbestosis. Data so generated have been presented before the National Human Rights Commission to get directions from the commission for the State on prevention, rehabilitation and compensation. In South Africa, the State Compensation Board organized diagnosis camps for past gold mine workers not only in South Africa but also neighboring countries from where workers used to migrate. Activists have successfully helped victims of occupational diseases by bridging the information gap between the doctor and the victim by collating information on exposures and locating probable materials causing the disease. In some cases, state policy was positively influenced by grass root organizations to set up a system to confirm occupational disease and pay compensation. In the days to come, technology may help ease notifications, which may encourage experts to report the cases they come
across. Public hospitals may set up a system for diagnosis of occupational diseases following public pressure. Though at low speed, positive changes have also been witnessed in countries like Vietnam, Indonesia, Pakistan, Tanzania, Thailand and Malaysia.

What can be done:

1. The state has a major role to play. Let it invest in propagating legal provisions. Associations of medical practitioners can also be encouraged. Workers, trade unions and non-profits may be educated on notifiable occupational diseases.

2. The government can provide assistance to industry to improve the work environment.

3. The central government should name one single competent authority for all cases notified from mines, manufacturing, services and other sectors. Amend the law to empower any citizen to notify a case.

4. The notifications should be online and should be accessible to the public so that possibility of changing the record by the authority can be minimized or diminished.

5. Anonymity of the notifier should be allowed. Confidentiality should be respected at all levels.

6. Multiple approaches are needed – surveillance, data collated from research, data from social security and compensation claims.

7. Out-patient departments may be opened in all public hospitals for diagnosis of occupational diseases. Private hospitals also may be encouraged.

8. Encourage medical colleges to diagnose and report occupational diseases. Medical boards should confirm reported cases, and should be set up in all medical colleges. A system for appeal should also be set up for review and appeal.

9. Demonstration projects may be taken up in hospitals to set up systems to diagnose and report occupational diseases. Under the project, paramedical staff may be trained to record occupational history, and experts should be encouraged to use them.

10. Training programs may be developed to train personnel in recording occupational history.

11. There should be legal provisions for qualified occupational health professionals to submit annual updates of the cases they may have seen.

12. Society, in general, should invest more in occupational safety and health rights including diagnosis and notifications of occupational diseases and accidents.

Future of work:

In India and some other developing countries, one can see the change happening and that the process of change continues to progress and strengthen further. As developing countries get economically stronger, governance may improve, reflected by better data on occupational injuries and diseases. People with more political power may lead to develop technology and a social atmosphere where reporting of occupational diseases will be easier. With technological advancement, working conditions may improve which would reduce occupational diseases. On the other hand, global warming, use of modern technology like robots, driverless vehicles, 3D printing, artificial intelligence may generate joblessness or an increase in unemployment in developing countries. The population in democratic countries votes to choose the Government they want in power. They have to choose between con-servative and progressive political parties. The choice impacts overall life including labor rights and notifications.

Preface
I had earlier written a reflection on the 2018 crisis of the Cochrane collaboration leading to the hounding of Peter Gotzsche which was published in the IJME. The essay had drawn the attention of a senior adviser in the WHO, Geneva, who had gotten in touch with me about some of issues I had raised in that reflection. This letter was the response. For reasons not known to me (perhaps including having other more urgent things to do), further correspondence stopped from that side after a Skype conversation suggesting ways to follow up on my suggestion below. This was a year ago. I am now putting this letter out for some consideration and thought since it took quite some time and work to write it.

17 November 2018

Dear (friend),

Three statements from your email will guide this note:

a) how do we strengthen models of local knowledge and sharing of insights that benefits from global evidence but appraised and improved for local use.

b) WHO wants to improve the way it promotes synthesis of global evidence from all sources, and ensure it is packaged and channelled to people who make/should make decisions – in local settings.

c) There needs to be disruption and innovation to get this to scale, and clearly WHO will not be doing this alone.

Evidence Synthesis in the Broadest Sense


Note on Meaningful Action by WHO to Strengthen and Share Local Medical Knowledge

Evidence Synthesis coming after EBM, and as a corrective to its abstraction (i.e., lack of emphasis on local variation) would have a specific task and objective: to synthesize evidence regarding current medical practice in different contexts. What does the formal EBM search for global evidence miss and dismiss as unacademic? What goes under the radar and why? What is practice in specific situations?

Examples

1) In the state of Bihar, a health NGO working with government found that one dramatic way to reduce localized infant and maternal mortality is to go on a brush, soap and water scrubbing mission to remove layers of caked blood and placental fluid from the delivery tables in the government hospital labour rooms. This level of ‘trivial’ action doesn’t find its way into medical research. It points to the need for research on social practices that defy the current academic imagination.

2) In the Mumbai slums, a doctor treating gastroenteritis had a choice between two antibiotics both of which took the same time to halt the infection. One of them also reduced the frequency of diarrhoea during this period. While in the abstract both antibiotics could have been used, it made sense to choose the latter considering the real difficulty of going to the public neighbourhood toilet several times a day when ill.

3) A doctor (who was a retired head of medicine in a teaching hospital) examining a 60-year-old patient who came after five days of suffering with cyclical fever and chest symptoms decided to treat her with both anti-malarial drugs and antibiotics to tackle pneumonia. Rather than wait for X-ray and lab results (which he ordered) to make a differential diagnosis, he took the tacit decision to medically confront both possibilities given the risk attendant upon age and the late presentation.

4) There is reason to believe that there has been a silent reduction in infant mortality across
Bihar over the past two decades to levels below the other EAG states of India even though the public health system has, if not all but collapsed, at least not improved. Informed opinion is willing to consider the possibility that this is because informal (unlicensed) ‘grey’ market practitioners across the state treat gut infections and pneumonia in children successfully. They also seem to physically ‘refer’ critical cases of illness to more informed doctors by taking the child and parent on their own motorcycles for further treatment.

5) Informal practitioners make twice daily rounds of villages to take care of small health problems among the people in the villages and towns of the state of Chhattisgarh – these services are usually on credit and payment is made after the harvest. The better among them also refer the more serious patients to more qualified doctors.

If we look at these examples (and several others) one can understand why policy and governmental institutions are beginning to demand evidence-based guidelines that are relevant, practical and effective in very specific conditions.

The findings of Evidence Synthesis in the above sense will vary depending on the location of its application – it will be different in private general practice, government health centres and secondary hospitals, in mission hospitals in remote tribal locations, in tertiary care and teaching hospitals and in corporate hospitals. No doubt from WHO’s global perspective, such differences will be even wider in the specific health care systems that have come to work in different countries. However, each of these locations will have their tensions and differences (beyond the simple power and ego trips against authority), with respect to the following (and more):

• how research on locally relevant, but globally marginalized health problems is often starved of funding;

• how courses of treatment under the local conditions that impose specific constraints are delegitimized by global norms;

• how very specific and important issues in the local context don’t find significance in the globally defined priority list of diseases;

• how global drug and immunization recommendations are made with scant regard for the specific constraints in the circumstances in which they are to be used.

• how the methods and documents currently providing RCT based practice guidelines are opaque and comprehensible only to those who have adequate training and special access to the analytical tools.

The task of evidence synthesis will be to begin to address such experienced shortfalls. This will clearly involve learning from the local context about what needs to be done at the global level, how what has already been done may in instances be wrong, and how to improve what has been done. In short, this will involve transforming the architecture of expertise in relation to the local. At stake is a new understanding of what a “universal” solution means. Also at stake is a robust on the ground medical care and research programme that is driven by need and appropriateness.

One should not romanticize the local as the root of all true knowledge, since after all, drugs and pharmaceuticals are, as of now, universal solutions designed as globally applicable to human beings, and without the manufacturer telling the GP how and for what to use the drug, the latter wouldn’t have a clue. There would also be some completely unacceptable local practices that may be downright wrong and would need correction. However, one should also recognize the abstract and limited knowledge in global norms about all the contexts in which they are applied. The problem is to understand how to apply the norm in relation to the local, i.e., see it as a broad suggestion for practice based on global evidence, to be modified according to the sense of the practitioner of the local situation in which she seeks to use it. The norm cannot be an unforgiving law, and institutions like the WHO (multilateral), Cochrane (standards watchdog) or even BMGF (philanthropic) for that matter cannot be unquestioned authorities if they are to intervene effectively at the local level. There is a need for global bodies to learn what the local is saying.

Suggestion with respect to General Practitioners

I will in the rest of this note develop a small suggestion regarding your question 3 (innovative methods, overturning paradigms) with respect to the
largest, most intractable and diverse medical care group in India – the rural, urban and metropolitan private general practitioners. Would they count as a ‘health system’? Perhaps they would if we extend the meaning of the term system to cover an organic self-sustaining entity which cannot easily be governed.

Different Regimes of Practice

There are very different social conditions in which general practice is conducted – availability or not of drugs; living conditions; emergency medical infrastructure for side effects; cost of treatment; availability of nutritious food and safe drinking water; wage-days lost/ family and domestic responsibilities that contribute to lack of follow up visits by patients: all these are factors in each local context and have a bearing on how the doctor decides to treat the patient who comes to the clinic. There is an irreducible and tacit element of ‘sense making’ that informs such practice. Under these conditions, treatment practices can be very different from those prescribed by the global norm. Often, these methods are labelled as irrational or illegitimate – yet some of us estimate that they constitute a large fraction of medical care in India and perhaps in other resource poor regions of the world too. Such methods will often also be deeply appreciated by senior doctors who have had a stint of experience in resource poor situations.

In the larger scheme of things, these practical insights if proven true will show up the profile of illness, the issues that handicap people’s effort to earn a livelihood, and the intersectoral factors overburden the inequity of disease in resource poor conditions. They will also likely provide specific links between the purely biomedical problem and other socio-political conditions of life (in India, the problem of intersections between caste and tribe, community and gender will be key factors to investigate). All these will need to be examined and analysed by formal research. However, they exist in the medical transaction long before such an examination of their truth value is undertaken.

Social Media

How could the WHO tap into and begin a conversation with these practices?

My specific recommendation here is seemingly a very mild one: WHO should experiment with social media to engage in conversations about local general medical practice and provide critical inputs to it.

Reasons

1. It is important to have an open conversation and I think social media will provide a platform. While the technology of social media is new, the phenomenon is clearly recognizable as a twenty-first century global avatar of the original agora. The problem is to figure out how to meaningfully invite the general practitioners to join such social media groups.

2. The media chosen should be multidirectional rather than top down (in the existing manner of websites, online pamphlets and blogs). However, WHO’s IRIS portal, the District Hospital Improvement programme in Nepal and the Social Determinants of Health initiative among many such others, all engage with the needs of small practitioners and hospitals. Such initiatives should be strengthened, and their geographical and social reach widened.

3. Some forms of social media, like Facebook or even better WhatsApp, provide for short responses from mobile phones, which permits critical engagement for people with little time and no patience to write long essays (like this one!). It should be possible to float opinion surveys on medical practice topics on these social media platforms to get quick opinions or positions that could be followed up with other detailed methods.

4. Facebook or WhatsApp also permit attachments, long texts and ways for WHO or other institutions to put in locally relevant, timely and useful guidelines in simple language for specific treatments, e.g., a gastroenteritis outbreak or heatstroke epidemic. There could also be regular inputs reproduced from WHO’s diverse initiatives on general medical problems and useful protocols to deal with them.

5. It is impossible to be the controlling authority in social media. Guidelines will be commented on and criticized if not appropriate to the situation – thus providing the basis for further correction according to the spirit of true Evidence Synthesis.

6. And yet, the question remains of separating the useful inputs from empty opinion and pure
wrongheadedness. This will be a challenge of the back up system of these platforms.

7. It is likely there will be attempts to ‘take over’ such media spaces by pharmaceutical industries, by other power players, even by political hatemongers, but my sense is that professional community and commitment will survive. In addition, the fact that the social media groups will be large and diverse will make it much more difficult to control opinion and outcomes than it is in today’s specialist global knowledge environment.

8. All these inputs and the many conversations will be chaotic and will need some form of guidance and governance – some form of systematization. However, these forms of governance will have to engage with the reality on the ground. On the other hand, there will be leaders who will emerge and govern the conversation, moderating it and anchoring it to reality. This seems to happen in even the most chaotic egroups and social media groups I belong to and there is no reason why it should not with a group of medical practitioners.

9. In one way, this is not a new idea – if we search the internet for any medical guidelines for patient or doctor advice, we find several websites where different doctors and specialists enter a conversation with the patient. I have seen a few where doctors too talk to each other. To my understanding WHO has used Facebook to put out guidelines too. However, looked at from a different perspective, inviting criticism from practitioners and engaging in a two-way learning conversation with them is completely new.

Such social media groups should be local to towns and cities. This will make the conversation meaningful and contextually relevant to the participants. At least this is what I hope/assess will be the case.

Some speculations on further steps:

- Experimentation is required to figure out whether such multidirectional social media groups are possible, scalable, what the platform should be and what kind of knowledge-based self-governance will need to take root.

- What are the complications introduced by local language conversations on these groups? Even trained doctors often prefer to converse in the local language of their region – and other experience teaches us that such conversations will be the most effective and comfortable in sharing experience, offering opinions and taking stands.

- Next, would it be possible to integrate these local social media groups into larger aggregations and if so, what would the mechanism be?

- Finally, if the knowledge of medical care is to grow in a useful manner based on these inputs, WHO should foster the development of regional or local committees of experienced practitioners who can help decide what inputs to concentrate on, synthesize and generalize for broader reference among the social media groups of professionals. They could also be a core group which meets once in a while to discuss specific issues. It would also be necessary to see how to get broader concurrence from these ‘member’ practitioners on accepted practices which are locally relevant.

- These kinds of democratic initiatives would have to be worked out for the other domains of health care such as remote mission hospitals, government health centres and secondary/teaching hospitals, etc. In each case a specific kind of instrument will have to be worked out in practice.

These are the thoughts I would like to share with you and if you want to take this further, we could set up a Skype session some time.

I would like to acknowledge the following practitioners/activists/thinkers I had conversations with in drafting this letter: Anand Zachariah, Veena Shatrugna, Mithun Som, Lakshmi Kutty, Susie Tharu, KS Jacob, Chinu Srinivasan, Anurag Bhargava, Sridhar Srikanthiah, Rakhal Gaitonde, Amar Jesani, Vasanta Duggirala, A Suneetha, Jacob Tharu, Ravi Duggal, Prabir Chatterjee, KR Antony, Dhruv Mankad and Sunil Kaul. The inputs these persons have provided through their wide experience are crucial to my suggestions and have enriched my own somewhat academic understanding. However, errors are mine. This note does not commit these people to work on what WHO proposes – that would need a direct request to each of them.

Best wishes, Srivatsan
First and foremost, as civil society, patients and consumers using medical devices we have been alarmed and deeply distressed over the developments of the past month regarding price control measures on medical devices being subject to trade negotiations between the United States and India. Health should never be on the negotiating table in trade agreements especially when it creates impediments in our pathway for self-reliance in health technologies and affordability and accessibility of health services.

We also note with distress the haphazard manner in which consultations on this drastic move by the Indian government took place before the Honourable Prime Minister’s visit to the United States. We are taken aback that civil society and patients did not form any part of the formal consultative process held by the Ministry of Commerce on critical issues that affect our lives and health directly. In this regard we welcome the statement made by the Hon’ble Prime Minister at the United Nations High Level Meeting on Universal Health Coverage that “In our efforts to ensure affordable healthcare, we have slashed the cost of stents by 80% and cut down the cost of knee implants by 50 to 70%.”

We therefore call on the Ministry of Commerce to uphold the Prime Minister’s message and promise to ensure that not even an inch of India’s sovereignty to deal with the prices and affordability of medical devices is on the negotiating table in the ongoing trade talks with the US.

Towards instituting a patient-oriented regulatory regime for medical devices, we believe there is a need to bring in urgent regulations and reforms in the following broad areas:

- strengthen regulatory systems for ensuring product safety through adequate testing and laying down of norms for clinical trials and related investigations particularly for high-risk devices and implants
- approval of foreign made devices: examine critically the data submitted by the manufacturers and relied upon by the foreign regulators for approval of devices before deciding to waive trial and testing requirements in India, and in general stop over-reliance on foreign regulatory authorities for granting licenses in India statutory provisions to check unethical business practices in the marketing and promotion of medical devices that cover manufacturers, traders and institutions and greater scrutiny of conflicts of interest of doctors hired by manufacturers to promote or develop devices
- standard treatment protocols for common procedures involving the use of medical devices and medical audits to curb irrational treatment
- consistent post-marketing monitoring of performance of devices, particularly high-risk devices, including institution of patient registries
- urgent need for revamping regulations pertaining to reporting and collection of adverse events and instituting systems to ensure responsiveness of the regulatory agency in dealing with device failures, including public awareness, statutory recalls and cancellation of licenses
- provisions for compensation to victims of faulty implants
- affordable pricing: instituting ceiling price caps on devices regulated under the Drugs and Cosmetics Act and commonly used consumables in order to make these critical devices accessible, reduce financial burden of patients to curb corrupt practices that are driving up the costs of healthcare
- institutionalizing patient registries

Each of the above points needs detailed discussion with civil society and patient groups before policy decisions are taken.

In the wake of public health disasters such the Johnson & Johnson ASR metal-on-metal hip implants and global withdrawals due to safety concerns of pacemakers, bioresorbable stents, pelvic mesh, breast implants, etc., there is a growing recognition of the need for strengthening of our medical devices regulatory systems so as to avert risks to patients from faulty and untested devices.

Therefore, we are dismayed at the decision of the CDSCO’s DTAB to further relax the provisions in the Medical Devices Rules, 2017 for granting approvals.
to imported devices based on marketing approvals by foreign regulatory bodies and extend the waiving of clinical investigations for products approved in the EU through CE certification, in addition to regulatory approvals in US, UK, Australia, Canada or Japan.

CE approval for medical devices, particularly high-risk devices and implants, is a deeply flawed system and must not be used as the basis for allowing inadequately tested devices into the Indian market. Failed devices such as Abbott’s bioresorbable scaffold ABSORB and Johnson & Johnson’s ASR hip implants, among others were approved in India through CE approvals. The International Consortium of Investigative Journalists (ICIJ) has extensively highlighted the flawed system for CE marking approvals of high-risk devices, including weak clinical data requirements, in its recent investigation[1].

We find this development extremely disturbing and cause for grave concern to vulnerable patients in India, that are being exposed to devices that may not have proven safety profiles due to loopholes and corruption in foreign regulations. These devices are being made available solely based on approvals provided by foreign agencies, which neither are accountable to domestic customers, nor can be influenced by our regulatory organizations. The misery of patients is compounded by the fact that laws governing medical devices are toothless, especially when it comes to providing for patient care and support in case of failure of such devices, making reflied available for affected patients and bring erring manufactures to book for transgressions.

A move in this direction, especially at a time when the country is witnessing hundreds of patient’s lives ruined by ASR metal-on-metal hip implants developed by Johnson & Johnson is completely unwarranted and goes against the duty of the government to protect patients.

Finally, we end with a call for better participation and consultation of civil society and patients in the framing and implementation of government laws and policies on medical devices and in the regular work of the medical device committees charged with approvals and monitoring of medical devices.

In Conclusion

We are deeply uncomfortable and principally opposed to consultative processes organised by the government in collaboration and with joint funding from industry. Instead, we support the Government in holding public consultations which engage all stakeholders on a level platform.

There are critical issues before the government, NPPA, CDSCO and medical device committees that require inputs from and proper consultations with civil society and patients. These consultations must take place in an open and transparent manner and through platforms free from even the appearance of industry influence or the appearance of greater weight being given to industry stakeholders and voices.

We once again urge the government to address speedily and urgently our concerns on price controls, approvals and post-marketing regulation of medical devices. In nearly every case of device failures or faults we see an inexcusable time lag between actions taken by foreign regulators and those taken by Indian regulators. This must be remedied as a matter of urgency. As we have pointed out earlier, the collection and response to adverse events in India is equally critical. With the recent developments of price control of medical devices ending up as a negotiating tool for the government and concerns over the framework for approvals and regulations, we regret that rather than patient safety and care, industry safety and care seems to be central to the government’s policies on medical devices. Patients and the health of millions in this country must be at the centre of government action.

(The following people were involved in drafting the statement, in consultation with HIPS & AIDAN members-Kajal Bhardwaj, Malini Aisola, S. Srinivasan, Rajagopal Viswanathan, Avaneesh Akhoury and Vijay Vojhala.)

We visited the Kashmir Valley between 5th and 9th October 2019. We spoke to a cross section of people in three different regions......

**Overall Impressions**

....Of the approximately 75 plus people we spoke to in these five days, not a single person we met was happy with the reading down of Article 370 and abolition of Article 35A, as well as the conversion of the state into a UT. Almost every single person wanted azadi, though what they mean by this varies between full independence, i.e not being with either India or Pakistan, to full merger with Pakistan. The constituency for Pakistan has increased drastically, along with those who regard Hurriyat leader Geelani as their main leader. There are no takers for the so-called full integration that the Government of India is promising post-370, especially given that this promise has come with a communication blockage, heavy military presence, severe repression, and the denial of fundamental rights which are in theory available to every Indian citizen.

We met one old Pandit man who had stayed back in the valley who was ambivalent about azadi, saying “My children are in Delhi so I can’t stay apart from them”. But he added, “the people here will never accept in their hearts being part of India.” He too was unhappy about the abrogation of 370, though he felt “the Government may be able to ride it out, since Pakistan is not a match for India.” He too was unhappy about the abrogation of 370, though he felt “the Government may be able to ride it out, since Pakistan is not a match for India.” One group of NC supporters in Handwara felt ‘normalcy’ may return if Article 370 is restored, but they also said, “who doesn’t want azadi?” A Gujjar sarpanch, who recognized that they were a minority as STs in Kashmir said, “even animals want azadi.” One shopkeeper in Srinagar said that 370 had been so hollowed out that it made little difference, but “still, it was our identity.” Regardless of their specific views, however, everyone felt they had lost their identity, and had been humiliated by not being consulted on their own future. People are resisting in the only way possible – through satyagraha or non-violent civil disobedience. There is a complete hartaal across the state, despite severe economic and educational losses. Since the entire leadership is in jail – from mainstream parties to the separatist parties, this satyagraha is being carried out by the people themselves. There is some societal coercion, but by and large, this is entirely voluntary. This is not happening on the direction of militants, contrary to the advertisements now being run by government. People compare the situation in 2019 to that in 2016 after the killing of Burhan Wani. The major differences are that first, now there is no leadership and people are acting on their own, second, the resistance is across the valley (earlier it was mostly South Kashmir), and third, even those who were earlier with the Indian government are now completely alienated. The Government claim that the major difference is that there is no open resistance and no loss of life is a.) untrue, since people have been killed even if fewer, b.) temporary – till the people figure out new strategies. The communications blackout and the mass arrest of mainstream leaders is new and unprecedented. While people hate the Indian government, they displayed enormous hospitality and graciousness to us as ordinary Indians. They have no problem with Indians, so long as they are not from the media. The Kashmir press is heavily censored, with Orwellian claims that everything is normal and people are happy. The Government runs full page advertisements every day telling people the
benefits of not having 370. The national television media is simply a disgrace since they are collaborating with the government in the pretence that everything is normal. The correspondents for national media report abuses and torture faithfully but the news is not always carried. They remarked that in over two months, there has not been a single editorial in Kashmir on Article 370. Everyone feels that they are being pushed back to the stone age without phones and internet.

The High Court is hardly functioning. Lawyers told us that some 300 habeas corpus petitions had been filed but the court gave generous time to the government by which time the petitions became infructuous. There were hardly any private lawyers.

Even a cursory visit to Kashmir’s villages show a level of prosperity that is much higher than many parts of India. The Swachh Bharat Abhiyan, Ujjwala Yojana, Housing Schemes etc. are quite unnecessary here, since everybody already has pukka houses, toilets, gas cylinders etc.

In the long run it appears that the Modi government’s precipitous step will result in a long term Palestine-like occupation, with heavy costs not just to the Kashmiris but also to the Indian economy and polity, unless there is enough international pressure to introduce some changes.

The mainstream leadership is by and large completely discredited. Repeatedly we heard that if the government can jail even their favoured stooge, Farouq Abdullah, then what is a common person to expect. They also repeatedly pointed out that the government had not even spared Hindu religious sentiments by sending back the Amarnath yatris midway. There is no going back from this step.

**Economic Losses**

People are facing huge economic losses due to the curfew-turned-hartal. Although there are now officially no restrictions, the uncertainty over where the government has re-imposed restrictions continues. For instance, journalists informed us that the government announces that they have removed restrictions from 20 police precincts without specifying which ones, so people are never fully certain. The heavy deployment of the military also continues so people feel unsafe.

One taxi driver who was earlier employed at Rs 8000 pm is now earning Rs. 5000. “370 knocked 3000 of my monthly income” he said. An auto driver said he used to run a hotel with 16 rooms but since there were no tourists he was now driving an auto.

Shops are open only from 7-9 am. The hartal is largely voluntary but there is also some social enforcement. For instance, we were told that a vegetable seller in Soura who kept open all day found his shack burnt down, a milk man was given a “last warning” for keeping his shop open half day, an apple grower who sold his fruit found six trees cut overnight. An auto driver said he no longer drives downtown for fear of random stones, so he parks his auto at night at his in-laws and walks home 2 km to downtown. He plies only for a short while in the evening.Apples which have been pre-sold due to advance agreements are being transported under government security, so there is some fear of militants also.

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On the 9th, we found a couple of establishments (restaurants) had started staying open all day. It may be that people will slowly inch back to keeping open their businesses, out of compulsion. However, one apple grower we met said he was “willing to lose 9-10 lakhs every year by not harvesting and selling his apples, if it gets us azadi.” (see section on apple trade)

Houseboat owners, workers and everyone dependent on tourism have been particularly badly hit. One houseboat owner with a five room houseboat said he lost 7 lakhs this year. A
shopkeeper who sells perfumes sourced from Gujarat to tourists on houseboats said that due to the communications blackout, he was not able to contact his suppliers, and anyway, what would be the point since there were no buyers.

Weddings are going on, but the amount of food consumed and numbers invited are much lower than usual. The head of one NGO, Aash, which organizes mass weddings for orphans, said that last year they had served biryani, this year they could only serve kahwa.

Several people, in both Srinagar and the villages, told us that Kashmiris are able to survive the blockades and hartal because of community traditions of support and co-operation, which get strengthened in conflict situations. Those who cannot afford it are helped with rations. In places like Aanchar in Srinagar where they have barricaded themselves in, many people are agriculturists and have enough paddy stocks.

**Apple Trade**

We visited the Shopian and Sopore fruit mandis. The Shopian fruit mandi was completely closed with not even trucks parked outside. One grower we met said he was prepared to lose lakhs if the hartal helped to get azadi.

The Sopore fruit mandi was also closed, but the Horticulture dept office where NAFED was purchasing fruit was open. The NAFED officials said that while normally 300 trucks leave the Sopore fruit mandi per day, they had managed to send out only 3 trucks since September 15 when the Market Intervention Scheme (MIS) was announced. However, they said that a.) those who had already signed agreements with traders from Azadpur mandi were sending it directly, b.) that some informal trading was taking place outside the mandi. Inside the mandi, however, it is clear that there is complete hartal.

Last year the mandi turnover was 1000 crore. Only 586 farmers out of 94,000 farmers in District Baramulla had registered with NAFED to sell. Out of these 586, only 46 growers had actually sold. This came to 30 metric tonne which was sent out in 3 trucks (as mentioned above).

While MIS is pitched as beneficial for apple growers, in practice because of the sorting into different grades they are losing out. Earlier each crate contained a mix of grades, which were sold at the highest grade.

In Handwara, people are fulfilling their agreements, but those who had not made agreements are suffering. They have to sell their apples against the challans of their neighbours with agreements, and since there is no communication have no idea what rates they are getting for their apples.

**Religious Restrictions**

This year Eid was hardly celebrated. Around Qalamabad in Kupwara, the police went around villages and told people not to gather in Idgahs and not to use loudspeakers. People offered eid namaz in their local mosques. There was no namaz in the Qalamchakla Idgah either.

**Educational losses**

While schools are technically open, no children are going to school. The teachers mark attendance for a couple of hours a day, sometimes 2-3 times a week. A six year old girl in Soura Srinagar said she was scared to go to school because “police uncle goli marenge”. Parents don’t want to send their children to school with such heavy militarization and without phones. We were told that the CRPF had occupied SP Higher Secondary school since August 5th but could not personally verify this. Rural schools are shut. Even if it’s within the locality, the armed forces are everywhere and people are scared they may be some incident/shootout.
An 11th standard girl in Parigam village, Pulwama who was studying for medical entrance tests in a coaching college in Srinagar had now returned home to her village. Exams have been announced for end November but she said she didn’t know how they would do it since they have not been taught the course; they could only revise whatever had been covered, the new material was difficult to study on their own. She didn’t know how she would be able to give the entrance test.

One school teacher in a middle class Srinagar school said they distribute assignments to all those children whose addresses they have but don’t know how to reach the rest.

A college teacher said that she and other colleagues have been going periodically to college but no students come. On 9 October when colleges officially opened, there were almost no students that we could see. There is no public transport so it is hard to see how school or college students would get to the educational institution.

**Arrest of children/minors**

Small children, some as young as six years, are being picked up and kept for a day to several days, or asked to report morning to evening for several days. Most often there is no record of their detention. In most cases, their fathers or other relatives are asked to report every day to the thana, as some kind of surety/hostage. Children are picked up on charges of playing resistance taraanas through mosque loudspeakers or pelting stones. This has happened even before August 5th as one of our cases showed but the pace has intensified.

Both in Pulwama and Srinagar, we were told that children are scared to sleep in their own homes at night lest they are picked up. They sleep at a grandmother’s or other relative.

For a year or more, the army has been carrying out a census of households in villages. After August 5th, it was thus easy for them to target families with youth.

We met the following cases:

**SS village, Shopian district**

20 children (approx.) between the ages of 12 and 20 were picked up and kept for 15-20 days. One 12 year old child, SN, class VII, was picked up on August 10 and released on September 25 to a juvenile justice home. There are 6 cases against him – of stone pelting, damaging houses and vehicles. We were unable to meet his parents and get the exact details.

Other children detained from the village include:

1. SAM, age 14/15; class X student
2. ABS, age 14/15 years; class X student
3. AF, age 16 years
4. IAP. He is from a poor family, so was doing mazdoori.

They were picked up from their houses on 10th and 20th August around 2 am. They were released in batches of 2-3 from 20th to 25th September. Apart from SN, none have been charged.

The police charged their families Rs. 100 per day for food while the children were kept in the thana. They were allowed to meet their families for 10-15 minutes every day. There is huge overcrowding in jails, making it difficult for the children to lie down and sleep.

We did not meet the children themselves – we were told they were out plucking apples (which may or may not have been the case), but we met members of their families and village elders.

**SB village, Shopian district**

In this village, children had been picked up in May 2019 and released. We met some of them and their parents.

1. SF, age 12, Class V
2. AM, age 9, class IV
Two men in civil clothes came on a scooter around 3 pm to AY house and took him. Then they came to FF house and summoned him to the thana. He went with his mother. Then they went to AM and AS houses and summoned them too. Police left the younger kids off at night and they had to go back the next morning. They were kicked a couple of times and made to do sit ups holding their ears (murga). AM had been picked up in 2016 as well when he was only six.

FF was inside for 5 days along with two other boys. They were quite badly beaten up. His father also said when he went to meet him he was told to come back later and could see he was being beaten. The boys were picked up for playing taraana on the Hanfi mosque loudspeakers, SB village. The Police confiscated their IPad and the mosque loud speakers. FF was sent away from SB village to his aunt’s for a few months and had only just returned.

Srinagar

We spoke to one child who had been picked up and released. Six year old H was picked up from the mosque on 17th August at 3 pm, along with T, age 12, class VII, and taken to the thana. They were released at midnight. After that T’s father and H’s grandfather had to report in the thana from morning to evening for several days. H is now interested in playing with guns and thinks of them all the time.

Torture Cases

Parigam Village, Pulwama

Parigam village has two army camps close by. The high school has been shut for two months. Earlier while the army would pass through the village, they did not bother the residents. However, after August 5th, they have randomly picked up youth whose houses lie along the main road and tortured them to instill fear. On the night of August 6th, the army picked up 9-11 youth between the ages of 20-30 from 8 houses, getting one person to knock on the door of another in a chain.

We met two brothers, Shabir Ahmad Sofi, aged 25 and Muzaffar Ahmad Sofi, aged 23 years, along with their father Sanaullah Sofi, at their home in Parigam village, Pulwama. The family runs a nanwai (bread) and bakery. On the night of 6th August the army first knocked on the door of the chowkidar, Abdul Ghani, and told him to call a man called Qayoom Ahmad Wani who runs a kirana (groceries) shop. Qayoom was then used to show them the way to the baker’s house. When Sanaullah opened the door, the army asked for his sons (they knew them because of the prior census, the boys had not had any previous charges).

The 9-11 youth (the Sofi brothers; Qayoom Ahmad Wani; Yasin Ahmad Bhatt, Muzaffar Ahmad Bhatt; Abdul Ghani’s son) were taken to a spot outside the mosque and beaten with cables and sticks on the road from 12.30 am to 3 am approximately. They were also given electric shocks to revive them after falling unconscious. The boys crawled home on all fours. They have been unable to move for the last two months, leave alone work.

When the families of the youth tried to intercede they were turned back. The Army threatened to beat the youth more if anyone tried to stop them. The next morning the youth were taken to the Government Hospital for Bone and Joint Surgery, Barzulla, Srinagar. The families wanted to file an FIR in Pulwama thana but the thana has been closed off with barbed wire.

Sanaullah’s bakery has been shut for the last two months. He incurred a loss of Rs. 2 lakh on the goods he had prepared for Id, which could not be sold, since the bakery was shut. Now he survives on the morning nanwai. Earlier his monthly income was about 25-30,000 per month. Now it is almost nothing.
Arrests/Preventive Detention

The number of arrests and preventive detention cases has increased since August 5. People with old FIRs against them are being picked up and kept in the police stations. Sometimes they are released and some of them are charged under PSA and kept in Srinagar central jail or taken to Agra. Families are scared that if they protest or speak to the press, the detenues will be charged with PSA.

Parigam village, Pulwama

Five men were arrested and taken to Pulwama PS after August 5th (date unknown). The army hit two girls (one of them is a nursing student) for protesting while their relatives were being taken away. We were unable to talk to this family.

Karimabad village, Shopian

This is a known militant village, with 11 graves in a martyrs’ graveyard. The army has twice demolished the graveyard but people have rebuilt it and put paper flowers on the graves. Here too, the army has picked up youth as part of preventive detention measures and sent them to Agra even though they have nothing to do with the militancy personally.

Those arrested include:

1. Mamoon Ahmad Pandit, aged 17 years, 2nd year student of the degree college, Pulwama, arrested on 7th August, and lodged in Agra central jail under PSA. His sole crime is that he is the youngest brother of well-known militant Nasir Ahmad Pandit who died in 2016.

   We met his mother who said the army men jumped over the gate, asked for Suhail, and dragged him out by his neck and hair. The sister and mother were pushed inside the house; the army fired twice on the cement floor and later took the cartridges away. We saw the holes in the floor. Munirul had been previously taken away in July also; his hair was cut and he was beaten. At the police station, the family was told he would be released after August 15, but on August 14 they heard he was being taken to hospital. The family met him at Pulwama PS, but immediately after he was taken to Srinagar central jail and then Agra jail.

2. Munirul Islam, age 20, aka Suhail, s/o Bashir Ahmad Pandit, arrested on 8th August at 2.45 am. We met his sister who said the army men jumped over the gate, asked for Suhail, and dragged him out by his neck and hair. The sister and mother were pushed inside the house; the army fired twice on the cement floor and later took the cartridges away. We saw the holes in the floor. Munirul had been previously taken away in July also; his hair was cut and he was beaten. At the police station, the family was told he would be released after August 15, but on August 14 they heard he was being taken to hospital. The family met him at Pulwama PS, but immediately after he was taken to Srinagar central jail and then Agra jail.

3. Bilal Ahmad Dar (father of two small children). We did not meet anyone from his family, so have no details.

The charges against all three appear to be stone pelting, breaking cars, helping militants. But we have not seen any papers and the families have not yet been to Agra or engaged lawyers.

Prongroo village, Handwara

3 men have been arrested from this village and are still in jail. We met their families

1. Mohd Shafi Mir, s/o Mohd Maqbool Mir, age 35
2. Asgar Maqbul Bhat
3. Nadeem Mohd Sheikh

On 3rd September the police came to their houses and told them to come to Qalmabad PS in connection with an FIR of 2018. When Mohd Shafi Mir went with his father they were told he was wanted for stone pelting and attending the funeral procession of Manan Wani. His remand kept being extended.

Zahoor Ahmad, age 25 was wanted by the police. Since he wasn’t home, they picked up his 17 year old brother Danish and kept him in the thana for 3 days till Zahoor came. Zahoor was inside for 18 days before he was released. He was accused of sloganeering.
Srinagar

Arrest of OM, age 18, studies in class 12 Govt High School. 2nd October. OM was released on October 8th.

We met OM’s family. 17 police cars came to the locality and the police jumped over the courtyard gate and forced the door open when they need only have knocked. They beat the women present with rifle butts and forcibly took away OM who was going upstairs to get his ID. OM’s father was shoved to the wall and cracked his forearm and chest. The police also used pepper gas and tear gas.

Community bond system: Once a person is arrested, people in the community are asked to give surety. In OM’s case, 20 elders from the area were summoned on a daily basis. Their IDs are taken and they have to spend 1-2 hours, sometimes the whole day in the police station.

Arrest for speaking to media

Inayat Ahmad of Soura, shopkeeper, was arrested on 29th August for speaking to Al Jazeera and participating in protests. After 15-16 days in the thana he was taken to Srinagar central jail where he has been charged under PSA. The chargesheet said that he was involved in stone throwing on 7th August, which is not at all likely since he is the father of two kids. The first FIR was filed on 7th August (for stone pelting); A second FIR was filed on 30 August 2019 for participating in procession and shouting pro-Pak slogans.

Custodial Death

3rd September 2019: Death of Riyaz Ahmad Thikri, Nandpora Bhandi ward of Bhandi village. Age approximately 20 years.

Bhandi is a Gujjar village and there are many forest cases against the Gujjars here. The villagers say the forest staff take bribes of 10-20,000, plus they have to pay the lawyers Rs 500 per appearance. With travel etc. it comes to Rs 1000 per appearance.

One man said he has been attending court since 2005. Since 2010, the forest department has barred Gujjar routes with barbed wire.

Riyaz Ahmad had just returned from labour in Ladakh when the police came on 2nd September and summoned him to the thana in connection with a year-old timber smuggling FIR. On the 3rd the police went to his uncle, Jamaldeen Shabangi’s house and took him to the PS. There they informed him that his nephew had committed suicide with the drawstring of his salwar.

Jamaldeen and others, however saw that Riyaz’s nose was broken and the right side of his body from shoulder to hip was blue and bruised. A post mortem was conducted in Handwara hospital but the family has not been given a copy.

Riyaz’s mother, Shirina Begum, is blind. He has three brothers, two younger who are now doing mazdoori. He was the main bread earner.

After Riyaz died in police custody there was a procession from Heral to Varpura, Qalmabad, but the police fired tear gas. They then seized the dead body and forcibly got it buried near his home before anyone could come. His uncle Jamaldeen was hit on the face during the protest.

Conclusion

Had the Supreme Court intervened earlier – and it may still do so – to restore Article 370 and revert J & K to its former status as a State of the Union, some of the anger may have been assuaged. However, like everyone else in Kashmir and outside, we are uncertain as to what the future will hold for Kashmir and India.

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