THE HCFI ROUND TABLE ON HEALTH AND WELLNESS: BUILDING CONSENSUS

AGENDA FOR THE THIRD MEETING TO BE HELD ON 21ST JUNE, 2019 AT 4 PM, AT THE PHD CHAMBERS OF COMMERCE AND INDUSTRY, PHD HOUSE, SIRI FORT INSTITUTIONAL AREA, AUGUST KRANTI MARG, NEW DELHI 110016

AGENDA NO. 1

PRIMARY HEALTH CARE ACROSS INDIA NEEDS URGENT ATTENTION

Preamble

The overall allocation to health sector accelerated to ₹61,398 crores in the Interim Budget for 2019-20, which is a moderate 13% increase over the previous year (2018-19). This Round Table notes that over 60% of this increase is on account of higher allocation to the flagship scheme, Pradhan Mantri Jan Arogya Yojana (PMJAY). The related focus area of Ayushman Bharat, namely strengthening primary care through health and wellness centres, has received a mere Rs.1,600 crore in 2019-20 as against a revised estimate of ₹1,400 crore in 2018-19. While additional resources could be forthcoming, the message clear and loud is that primary healthcare can wait.

The good news is that healthcare is upfront on the country's political agenda, and the significant state intervention with Ayushman Bharat is encouraging. However, all of this could fall short in the absence of an equivalent push for primary health care.

In October, 2018, health funders, policymakers and practitioners came together in Astana, Kazakhstan to celebrate the 40thanniversary of the 1978 Alma-Ata

Declaration and reaffirm their commitment to primary health care as *the* most equitable and sustainable strategy to achieve health for all. Across India, primary health care identified as an urgent priority, is possibly the weakest link in the health system. With significant segments of our population lacking access to essential health services, most of which can be delivered through strong primary health care, we have an opportunity and responsibility to act now.

A FICCI-Feedback Consulting Report, 2015 has analysed that the abnormally high out of pocket expenditures (OOPE), annually incurred by consumers of health services across India is almost entirely due to the existing skewed primary healthcare system in India, which also reflects the lowest primary health care visits, coupled with the highest incidence of hospitalisation. And it does not help that successive governments have omitted to effectively regulate private hospitals so that instances of mismanagement and massive over-charging of patients, such as the tragic case of Adya Singh in a hospital in Gurgaon continue to surface.

Problems in existing primary health care system in India:

- Primary health care services in India are located too far from the populations they serve, provide too little services, and have too little resources.
- Primary health care in India suffers from inadequate public investments. Per capita public expenditure on health in India is US $43.8, as opposed to US $268 in Thailand. Not surprisingly then, IMR of Thailand stands at 9.9/1000 live births, as opposed to 44/1000 live births in India.
- Each PHC in India is supposed to serve a population of 25-30,000 which makes them too far for many families to reach, and for the providers to provide continued care. In many parts of the world, there is a functional primary health care facility at a population of 2000-3000.
- Primary Health care services in India rely too heavily on the presence of doctors, despite having a shortage of doctors nationally. Since many doctors do not often live in the rural areas, especially in remote areas, the primary health centres become dysfunctional.

- There is no cadre of primary care providers in the country, unlike many Western countries, where General Physicians and Nurse Clinicians are the certified primary care providers. MBBS doctors are by default the primary care providers in India with no additional training. Nurses are only supposed to assist the doctors.
- Lack of primary health care services in India is also one of the reason for increasing cases of violence and assault against the doctors in the country which is an alarming situation.

Press Information Bureau, Government of India, Minsitry of Health and Family Welfare in Year Ender 2018: Ministry of Health and Family Welfare has given details about Ayushman Bharat scheme of the Union Government which is reproduced hereunder :

AYUSHMAN BHARAT

Ayushman Bharat is a centrally sponsored programme anchored in the Ministry of Health and Family Welfare (MoHFW). It is an umbrella of two major health initiatives, namely Health and Wellness Centres (HWCs) and Pradhan Mantri Jan Arogya Yojna (PMJAY). Brief details of these components are as following:

Ayushman Bharat-Health & Wellness Centres (AB-HWC)

Delivery of comprehensive primary health care services through Health &Wellness Centres is a critical component of the newly announced Ayushman Bharat scheme. It places people and communities at the center of the health care delivery system, making health services responsive, accessible and equitable.

Nearly 1.5 lakh Sub-Centres and Primary Health Centres would be transformed as Health & Wellness Centres by 2022 to provide comprehensive and quality primary care close to the community while ensuring the principles of equity, affordability and universality.

Till date i.e. December, 2018, 4503 HWCs have been operationalized in various states.

Key components of AB-HWC:

- **Additional Human Resource** - New cadre of health care professional- referred to as the Mid-Level Health Provider- who is a nurse or an Ayurvedic Practitioner trained and accredited for a set of competencies related to primary health care and public health. Mid-Level Health Provider will lead the team of MPWs and ASHAs at SHC level
- **Multiskilling/ Training** of existing service providers - upgrading skills to provide expanded package of services
- **Efficient logistics** system to ensure availability of wide range of drugs and point of care diagnostics
- **Robust IT system** – to create unique health id and longitudinal health record of all individuals and provision of tele-consultation services

- Provision of services related to **indigenous health system and yoga** etc for promotion of wellness

- **Linkages** with schools to train Health and Wellness Ambassadors to enable creating healthy habits in schools

The **package of services** envisaged at AB-HWC are:

1. Care in pregnancy and child-birth.
2. Neonatal and infant health care services
3. Childhood and adolescent health care services
4. Family planning, Contraceptive services and other Reproductive Health Care services
5. Management of Communicable diseases including National Health Programmes

6. Management of common communicable diseases and outpatient care for acute simple illness and minor ailments.
7. Screening, Prevention, Control and Management of non-communicable diseases.
8. Care for Common Ophthalmic and ENT problems
9. Basic Oral health care
10. Elderly and palliative health care services
11. Emergency Medical Services
12. Screening and Basic management of Mental health ailments

Key benefits for community under AB-HWC:

- Expanded package of primary care services –ranging from maternal and child health, communicable diseases to non-communicable diseases (universal screening, prevention, control and management of five common communicable diseases: hypertension, diabetes and three common cancers – those of the oral cavity, breast and cervix, primary health care for diseases for the eye, oral health, ENT, mental health, provision of palliative care and care for the elderly, and medical emergencies)
- Wide range of free drugs
- Point of care diagnostics at the centres.
- Tele-consultation services with Medical Officers for complications
- Continuum of care ensured through referral linkages and protocols
- Unique health id – longitudinal health record for each individual
- Services related to indigenous health system and yoga for promotion of wellness.

Ayushman Bharat- Pradhan Mantri Jan Arogya Yojana (AB-PMJAY)

Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (PMJAY) aims to cover over 10 crore poor and vulnerable families (approx. 50 crore beneficiaries) providing coverage up to Rs. 5 lakh per family per year for secondary and tertiary hospitalization.

PMJAY has been launched on September 23, 2018. After the launch of PMJAY, RSBY and SCHIS got subsumed in it.

Key features:

- PMJAY is an entitlement based scheme. This scheme covers poor and vulnerable families based on deprivation and occupational criteria as per SECC (Socio-economic caste census) data.

- As on 30.12.2018:
    - Number of Hospitals Empanelled: 16,112
    - Beneficiaries Admitted: 6,81,825
    - E-cards Issued: 39,48,496

- PMJAY provides cashless and paperless access to services for the beneficiary at the point of service in any (both public and private) empanelled hospitals across India. All beneficiary families of RSBY and SCHIS are entitled for benefits under PMJAY.

- Under PMAJY, the States are free to choose the modalities for implementation. They can implement the scheme through insurance company or directly through the Trust/ Society or mixed model.

- There is no restriction on family size, ensuring all members of designated families specifically girl child and senior citizens get coverage.

- At National level, National Health Agency (NHA) in the form of Society has been registered under the Societies Registration Act, 1860, to implement the scheme. NHA is responsible for all operational matter of PMJAY. NHA is functioning w.e.f. 11.05.2018.

- MoU has been signed between National Health Agency, Government of India and 31 States/UTs namely, Uttar Pradesh, Andaman & Nicobar Island, Lakshadweep, Dadra & Nagar Haveli, Daman & Diu, Chhattisgarh, Mizoram, Jharkhand, Bihar, Puducherry, Madhya Pradesh, Assam, Haryana, Uttarakhand, Jammu & Kashmir, Manipur, Meghalaya, Gujarat, Himachal Pradesh, Chandigarh, Tripura, Nagaland, Arunachal Pradesh, Sikkim, West Bengal, Rajasthan, Goa, Maharashtra, Tamil Nadu, Karnataka and Andhra Pradesh.

- Out of these 31 States/UTs, 25 states/UTs namely Arunachal Pradesh, Tripura, Chhattisgarh, Mizoram, Manipur, Gujarat, Nagaland, Sikkim, West Bengal, Dadra & Nagar Haveli, Himachal Pradesh, Tamil Nadu, Daman & Diu, Haryana, Jharkhand, Assam, Uttar Pradesh, Chandigarh, Maharashtra, Uttarakhand, Goa, Bihar, Lakshadweep, Madhya Pradesh, Andaman & Nicobar have launched PMJAY on 23.09.2018.

- Ayushman Bharat National Health Protection Mission Council, as an Apex body has been set up to provide policy direction to the scheme.

- More than 1350 packages have been finalized by an expert committee headed by Director General, Health Services and peer reviewed by NITI Aayog.

- Operational Guidelines on various operational matters of PMJAY, Model tender documents etc are in place. Details are available on official website i.e. www.abnhpm.gov.in.

For Deliberation

Suggestions to the Union Government for making Ayushman Bharat a success for Primary Health Care:

1. Health Governance: Government should invest in developing health governance system for transparent and accountable system with greater multiple Stakeholder participation at all levels.

2. Evidence based decision making system

3. Integrated health information system

4. Easily available health information at all levels.

5. Health Finance:

    a. increasing public private participation
    b. encouraging private sector investment
    c. preferential public financing

6. Imparting health education

7. Focussing more on skill training competence

8. How to attract all states to adopt Ayushman Bharat in their state.

AGENDA NO. 2

UTILISING THE SKILLS / TRAINING OF TECHNICIAN AND PARA-MEDICS (CERTIFIED BY RMPS), TO BRING THEM ON PAR WITH QUALIFIED TECHNICIANS.

Definition of Problem

On the one hand we look for, encourage and applaud excellence as much at the level of surgical assistants, as at the level of the surgeon herself. On the other hand, we also see models of healthcare delivery being developed wherein some initial training of selected non-medical personnel is bolstered by constant testing and rigorous supervision amidst a "practice make perfect" approach. And this is gaining traction. It has increased the availability and supply of para-medical staff, and simultaneously reduced drastically the cost of healthcare.

From the relevant literature, we learn that a blacksmith may train and build skills among a cohort of trainees, but only those among the group will go on to become blacksmiths who are screened, tested and certified by the Guild of Blacksmiths. And certainly no blacksmith can, after 10 years in the field, aspire to become known as a mechanical engineer.

Further, Clause 7.10 of the Indian Medical Council Regulations, 2002, stipulate that:

" A registered medical practitioner shall not issue certificates of efficiency in modern medicine to an unqualified, or non-medical person

(Note: The foregoing does not restrict the proper training and instruction of bona fide students, midwives, dispensers, surgical attendants, or skilled mechanical and technical assistants and therapy assistants under the personal supervision of physicians.)".

For Discussion

(i) In exercise of the powers conferred under section 20A read with section 33(m) of the Indian Medical Council Act, 1956 (102 of 1956), the Medical Council of India, with the previous approval of the Central Government, hereby makes the following regulations relating to the Professional Conduct, Etiquette and Ethics for registered medical practitioners.

(ii) **Section 20A in The Indian Medical Council Act, 1956:** *Professional conduct. –*

(1) The Council may prescribe standards of professional conduct and etiquette and a code of ethics for medical practitioners.

(2) Regulations made by the Council under sub-section (1) may specify which violations thereof shall constitute infamous conduct in any professional respect, that is to say, professional misconduct, and such provision shall have effect notwithstanding anything contained in any law for the time being in force.

(iii) Clause 7.10 was incorporated in Code of Ethics by Medical Council of India while prescribing standards of professional conduct, etiquette and code of ethics for medical practitioner.

(iv) As per the provisions of Clause 7.10, a registered medical practitioner shall not issue certificates of efficiency in modern medicine to an **unqualified, or non-medical person** which means that the medical practitioners are prohibited from issuing any certificate of efficiency to any person who is not qualified or to any person who is non-medical.

(v) However, with the said provision there is a note which states that ***The foregoing does not restrict the proper training and instruction of bona fide students, midwives, dispensers, surgical attendants, or skilled mechanical and technical assistants and therapy assistants under the personal supervision of physicians.)***.

(vi) From the provisions of Clause 7.10, it is clear that the medical practitioner is restricted from issuing any certificate of efficiciency to any person who is either unqualified or is not a medical person. But the medical practitioner can issue certificate of efficiency to a person who is qualified like doctors or who is a medical person likeis allowed to give training and instructions to :

- ***bona fide students,***
- ***midwives,***
- ***dispensers,***
- ***surgical attendants,***
- ***or skilled mechanical and***
- ***technical assistants and***
- ***therapy assistants***

(vii) There is a disjoint in the said provision as the medical practitioner is not allowed to issue certificate of efficiency to a person who is unqualified or is a non medical person. And the medical practitioner is only allowed to give training and instrucitons to ***bona fide students, midwives, dispensers, surgical attendants, or skilled mechanical and technical assistants and therapy assistants under the personal supervision of physicians.*** **Now these people are not qualified as MBBS doctors but they are medical persons who have sufficient training and knowledge and instructions.**

(viii) **Now, according to the second part of the provsions of Clasue 7.10 the medical practitioner should be allowed to issue certificate of efficiency to a person who is a medical person who has undergone sufficient training under the personal supervision of the medical practitioner.**

(v) The current proposal is not consistent with that goal of seeking excellence in the implementation and delivery of health services. unless we need to build in sufficient checks and balances. For this reason, external validation becomes an essential requirement. The freshly minted technician / surgical assistant must be subject to external examination testing, as part of continuing medical education.

(vi) While there cannot be any restriction on enhancing skill sets and imparting proper instruction and training to technical assistants, surgical attendants, midwives, therapy assistants, and dispensers, it is counter-intuitive that they should not be subject to an external examination in a series of continuing medical education.

(vii) The aspect of being treated on par will arise only in keeping with the recruitment rules for the particular skill set. Should we be subjecting unsuspecting patients to the care of persons who have gained a backdoor entry, and have since then, never been subject to external testing of any kind. It can happen anywhere, but since this highly motivated technician is not fully acquainted with the relevant theory, he could inadvertently jumble up the protocols to be followed.

Recommendations

A review of the literature shows that the developed countries are finding this a unique solution. Clearly, in India, we need checks and balances, and cannot arrive at any consensus unless all aspects are deliberated in detail.

AGENDA No. 3

Electronic Medical Devices: Problem Definition

Preamble

India's drug controller, DCGI, has issued an advisory for patients and health care providers against Medtronic's Astra pacemakers after a US FDA alert about a battery-related malfunction in the device on May 7.

As per the FDA alert, three medical device reports in USA, in which a Medtronic implantable pacemaker or cardiac resynchronization therapy pacemakers (CRT-P) battery had fully drained because of a crack in the device's capacitator, without any warning to the patients or health care providers. If a capacitator in an implanted pacemaker is cracked, it can create an electric short that can cause a battery to drain earlier than expected. DCGI has issued the advisory to warn people concerned against the reported malfunction.

As on date, 1,850 such devices have been imported to India, of which 1,600 have been sold. The adverse events were reported in the USA within one year after patients were implanted with the pacemaker. They were reported on average within seven months of the device getting implanted.

The advisory informs that those involved should be aware of sudden battery levels drop during follow up visits. Patients must watch out for signs such as feeling lightheaded, dizzy, chest pain, severe shortness of breath.

The pacemakers (and possibly other medical devices, similarly implanted), have a defined battery life which needs to be checked periodically. Some users are advised on the same. Some pacemakers also give an alert. We need to deliberate some of

these essential gaps, in anticipation that we in India will begin to adopt and abide by global standards and quality metrics.

Comments of Dr KK Aggarwal

1. 1600 is a small number

2. All 1600 patients should be tracked and evaluated for the battery. There is no need to give a National advertisement for the same.

3. Once found ok their battery should be checked every month (normally it is one a year)

4. If they require implant it should be free by the company

5. Adequate compensation should be given to the patient in case of any default

6. Any failure of pacemaker resulting in complete heart block and death will end up with huge liability for the doctor, hospital and the company.

7. Once you know about a possible complication and do not act in time, any fatality will attract 304A.

8. Once you call the patient, check the pacemaker, and inform about future precautions. then only you safeguard your liability.

For Discussion

(i) This RT should immediately demand the REGISTRY for all such critical medical implants/devices used by patients on the recommendation of the Medical Practitioners.

(ii) We need to deliberate on following points:-

a. Who shall be custodian of that registry?

b. Should registration be incumbent upon the medical practitioner?

c. Should registration be mandatory for the patient or voluntary?

d. What benefits does the registration confer on the patient?

e. Who is eligible for the implant? Standard protocols need to be in the public domain, so that the medical practitioner is accountable, and also the patient is confident that she is being adequately advised.

f. In the event of an emergency, what is the role of the patient, and of the medical practitioner/ medical centre that has placed the implant?

g. Does the patient have access to a Card detail, at all times?

h. in case of emergency they should carry a card detail which provides immediate access to the center which is put in the implant

i. Should the HCFIRT submit a memorandum to DCGI on this subject?

AGENDA NO. 4

Regulatory Guidelines on Electronic Nicotine Delivery Systems

Background

The tobacco epidemic in India has also reached alarming levels. As per the latest estimates there are nearly 106 million people in India who smoke combustible cigarettes and 32 million who smoke as well as chew tobacco. India is home to roughly 11.2% of the combustible cigarette smokers in the world and 1.3 million people in the country die every year due to tobacco related illnesses.

As per the Global Tobacco Atlas, the economic cost of smoking in India is Rs.181,869 crore ($27.93 billion) as of 2018. This includes both direct cost of healthcare and the indirect cost of lost productivity from early death and illness. This is roughly 1% of India's GDP and arguably one of the largest burdens on the Government of India today.

Public Health strategy of Harm reduction has been used in medicine and social policy to minimize harm that accrues from behaviors that cannot be completely avoided or prevented. Today, technological innovation in the field of tobacco harm reduction offers an opportunity to significantly reduce the risk caused by tobacco consumption.

Electronic Nicotine Delivery Systems (ENDS) products heat a solution (e-liquid) to create an aerosol which frequently contains flavourants, usually dissolved into Propylene Glycol or/and Glycerin. The premise of these products is that combustion leads to most of the harm and once one removes combustion from the product, they can act as a tobacco harm reduction tool. The emergence of Electronic Nicotine

Delivery Systems (ENDS) and subsequent improvements to product characteristics have the potential to ensure that India reaches its tobacco control goals.

Currently, ENDS remain unregulated therefore necessitating that steps be taken by the concerned authorities to enact regulations that will ensure its safety and quality in the market.

Law/Rules/Polices relating to ENDS

i. ENDS or any vaping product is not covered under the provisions of Drugs and Cosmetics Act and Rules. This has been duly confirmed by the DGHS vide reply dated 30.11.2018 to HCFI in reply to HCFI's RTI application in which the DGHS has specifically stated that:

> "*Point No. 1 to 20: It is to inform that the proposal of regulation of e-cigarettes has already been deliberated in 48th Drugs Consultative Committee (DCC) meeting held on 24.07.2015 and DCC opined that e-cigarettes cannot be regulated under the provisions of the Drugs and Cosmetics Act, 1940, as e-cigarettes are not covered under the definition of the term "Drug"."*

ii. Vide letter dated 22.02.2019 the DCGI has requested all states and UTs in the country to ensure that ENDS are not sold (including online sale), manufactured, distributed, traded, imported and advertised

iii. On 28.08.2019 Ministry of Health and Family Welfare had issued Advisory on ENDS including e-cigarettes, heat not burn devices, vape, e-sheesha, e-nicotine, flavoured hookah and the like product to all States and UTs to prevent initiation of ENDS

Developing a Robust Regulatory Regime

1. As medical practitioners, our advice to patients should always be to quit smoking, but in cases where patients are unable or unwilling to quit without alternatives, it is imperative that they have access to less harmful tools, such as ENDS. Government's stance to bring ENDS under the ambit of the Drugs and Cosmetics Act and impose a ban on these alternatives will leave these smokers who intend to switch away from cigarettes without a viable alternative.

2. Moreover, prohibiting legal sale and distribution of these products will limit the degree of control the Government and regulators can impose on the availability of ENDS, as it is no secret that banned items quickly resurface through a grey market. This channel would pose particular risk in the case of ENDS, which, while being significantly less harmful than cigarettes, are not risk-free. ENDS are meant for use by adult smokers as an aid to reduce their dependence on cigarettes, and these should not be made available to non-smokers or youth as nicotine is an addictant. Moreover, smuggled items are often of questionable quality and may pose serious health and safety risks to users.

3. Earlier this year, HCFI, along with 80 public health experts, had written to the Ministry of Health and Family Welfare with a consensus statement seeking regulation of ENDS, so that these products are made available only to adult smokers and their sale is subject to appropriate age verification. In addition, regulation would help the government control and monitor quality, manufacturing standards, and nicotine levels, and also frame appropriate rules for labelling, packaging and promotion of these products. Regulations on these lines have been imposed in several countries, including, Canada, UK, USA, New Zealand, and even the UAE, and have been followed by encouraging declines in smoking rates and prevalence in these countries.

4. Most of these countries have regulated the product under their relevant tobacco legislation by creating a separate set of rules for ENDS within such enactments. To this end, we strongly urge that the Government of India take into account the mounting positive evidence supporting the use of ENDS to supplement tobacco control measures and frame a risk-proportionate regulatory framework rather than imposing a ban on the category, as has been done in several developed economies.

5. ENDS provide an opportunity to reduce India's tobacco burden, and lower the socio-economic costs associated with tobacco use. Moreover, these products give smokers a chance to reduce their exposure to harmful chemicals and toxins associated with smoking.

6. We hope that the Government will take into account the views of all stakeholders involved, including those of medical practitioners and experts like us, the scientific community, global experts and policy makers, and only after careful consideration of the newer evidence, take a decision in this matter, so that the country's adult smokers are not deprived of a harm reduction alternative to smoking. We also request that, in the meanwhile, the Government encourage and support further research on ENDS, so that our policy making is backed by science and sound evidence.

7. A scientific summary of positive evidence on ENDS from leading global medical research institutions is provided below for your reference.

Scientific Summary

Health impact vis-a-vis cigarette smoking	**Public Health England (PHE)** ● In its independent evidentiary review, **Public Health England (PHE)** has categorically concluded that

	"Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. The previous estimate that, based on current knowledge, **vaping is at least 95% less harmful than smoking** remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping." ● It has further observed that "To date, the levels of metals identified in e-cigarette aerosol do not give rise to any significant safety concerns, but metal emissions, however small, are unnecessary." ● On assessment of exposure to harmful constituents PHE has observed that "biomarkers of exposure assessed to date are consistent with significant reductions in harmful constituents and for a few biomarkers assessed...similar levels to smokers abstaining from smoking or non-smokers were observed." **National Academies of Sciences, Engineering and Medicine (NASEM)** ● NASEM concluded that "there is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicant and carcinogens present in combustible tobacco cigarettes" and there is substantial evidence that completely switching from

	regular use of combustible tobacco products to vaping results in reduced short term adverse health outcomes in several organs systems." ● They concluded that "e-cigarettes pose less risk to an individual than combustible tobacco cigarettes" and "complete switching from combustible tobacco cigarettes to e-cigarettes would be expected to reduce tobacco-related health risk." Lead authors of the NASEM report on vaping, Dr. Eaton and St. Helen, also published a follow-on Evidence to Practice article, which recommended that, "if a smoker's initial treatment has failed or not been tolerated, or if the smoker refuses to use approved medications and counselling and wishes to use e-cigarettes to aid quitting, physician should encourage the smoker to switch completely to e-cigarettes. We agree with Public Health England that behavioral support should be provided to smokers who want to use e-cigarettes to help them quit smoking, and that health professionals should receive education and training in use of e-cigarettes in quit attempts." The **Royal College of Physicians** ● Opined that "Toxin levels inhaled from vaping products under normal conditions are likely to be well below prescribed threshold limit for occupational exposure, which make the probability of significant long-term harm unlikely."[1]

[1] Supra note 1

	The **American Cancer Society** ● Issued a statement that stipulates that the use of vaping is less harmful than smoking cigarettes. It has further observed that despite clinical advice, many smokers "...will not attempt to quit smoking cigarettes and will not use FDA approved cessation medications. These individuals should be encouraged to switch to the least harmful form of tobacco product possible; switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products." The **American Heart Association** ● Observed that "E-cigarettes either do not contain or have lower levels of several tobacco- derived harmful and potentially harmful constituents compared with cigarettes and smokeless tobacco. In comparison with NRTs, e-cigarette use has increased at an unprecedented rate, which presents an opportunity for harm reduction if smokers use them as substitutes for cigarettes." **David B. Abrams from the College of Global Public Health, New York University**, April 2018 issue of Annual Review of Public Health ● Stated that "A diverse class of alternative nicotine delivery systems (ANDS) has recently been developed that do not combust tobacco and are substantially less harmful than cigarettes. ANDS have the potential to

	disrupt the 120-year dominance of the cigarette and challenge the field on how the tobacco pandemic could be reversed if nicotine is decoupled from lethal inhaled smoke. ANDS may provide a means to compete with, and even replace, combusted cigarette use, saves more lives more rapidly than previously possible." **Stephan WE** ● Risk assessment analysis of toxic emissions from e-cigarettes concluded that the carcinogenic risk of e-cigarettes is 0.4% that of smoking.[2]. **Celerion Labs** ● A lab experiment conducted by Celerion Labs to examine changes, relative to baseline, in primary urine and blood BOEs in 90 adult smokers showed that all eight non-nicotine urine BOEs were reduced by an aggregate of 85.3% in the abstinence group compared to 85.0% aggregate reduction in the ENDS group. **Polosa, et al** ● A recent study evaluated the effects of e-cigarette use in a small group of never smoking adults followed up for 3.5 years, and no adverse effects were observed in the respiratory and cardiovascular system[3]
Risk posed by	**International Agency for Research on Cancer (IARC)**

[2] Stephens WE. Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke. Tob Control. 2017 Aug 4. Pii: tobaccocontrol-2017-053808

[3] Polosa R, Cibella F, Caponnetto P, Maglia M, Prosperini U, Russo C, et al. Health impact of E-cigarettes: a prospective 3.5-year study of regular daily users who have never smoked. Sci Rep. 2017;7(1):13825.

Nicotine	• Nicotine has a low risk profile and is currently not classified as a carcinogen by the International Agency for Research on Cancer and does not promote obstructive lung disease.[4]
Harm to non-users	• The Excess Lifetime Cancer Risk (ELCR) in order of magnitude is lower in e-cigarette users compared to smokers and negligible in people exposed to e-cigarette aerosol as bystanders (second-hand exposure)[5] • Poor materials and build quality, lack of quality control and improper use of ENDS can give rise to a fire hazard. However, with technological advancement and optimum safety features, these concerns can be addressed. A regulation is necessary for maintaining safety standards and prohibition only increases the risk of counterfeit and unstandardized products flooding the market[6]
Gateway to smoking addiction and smoking	**Prof. RN Sharan et al** • ENDS usage was found to be higher in former smokers than among non-smokers by nearly 4.13 fold, signifying that they were a useful aid in helping smokers switch. Also, use of ENDS was 7.53 times higher in current smokers than in non-smokers, which indicates ENDS are not a gateway to nicotine use but

[4] IARC. Tobacco smoke and involuntary smoking. IARC Monographs on Evaluation of Carcinogenic Risks to Humans 2004; 83: 1–1438

[5] Scungio M, Stabile L, Buonanno G. Measurements of electronic cigarette-generated particles for the evaluation of lung cancer risk of active and passive users. J Aerosol Sci. 2018;115:1-11.

[6] Das, S., Choudhury, Y., Vaiphei, S., & Sharan, R. (2019). A Systematic Review and Meta-analysis on the Health and Safety Implications of Electronic Nicotine Delivery Systems. Indian Journal Of Clinical Practice, 29(11).

	are more commonly used by smokers to switch from smoking.[7] **PATH (Population Assessment of Tobacco and Health) study** • In the US, data coming from the largest, longitudinal study of youth smoking initiation, viz. the PATH (Population Assessment of Tobacco and Health) study, which includes two waves of observations on nearly 11,996 U.S. youth, shows a different picture. The investigators were unable to report a single youth out of the 11,996 in the sample who was a cigarette naive, regular ENDS user at baseline who progressed to become a smoker at follow-up[8]

Executive Summary

A Systematic Review and Meta-analysis on the Health and Safety Implications of Electronic Nicotine Delivery Systems

Sharan et al.

A systematic review of 299 published scientific literature was performed by Prof. R. N. Sharan (North-Eastern Hill University), Dr. Sambuddha Das (Assam University), Dr. Yashmin Choudhury (Assam university), and Dr. S. Thangminlal Vaiphei (Central University of Rajasthan) has been published in the Indian Journal of Clinical Practice (IJCP) in order to compare the toxicities of nicotine, other chemicals, and metal ions produced during cigarette smoking and ENDS use, and to evaluate the

[7] Ibid

[8] Berry KM, Reynolds LM, Collins JM, Siegel MB, Fetterman JL, Hamburg NM, et al. E-cigarette initiation and associated changes in smoking cessation and reduction: the Population Assessment of Tobacco and Health Study, 2013-2015. Tob Control. 2019;28(1):42-9.

health and safety aspects of ENDS. The study indicates that ENDS pose minimal health and safety concerns when compared to conventional cigarettes:

- Toxic chemicals such as class 1 carcinogens, respiratory toxins, and carcinogenic metal ions were found to be present in significantly higher quantities in conventional cigarette compared to ENDS vapor. For instance, metal ion Cadmium, which is a Class 1 carcinogen, a respiratory toxin and reproductive and developmental toxicant, was found to be 1369.37 fold higher in cigarette smoke than ENDS vapor. Similarly, lead and chromium which are Class 2b probable carcinogens were 12.02 fold and 13.71 fold more common in cigarette smoke than in ENDS vapor.
- Cigarette smoke was also found to contain significantly higher levels of carcinogens such as formaldehyde (8.31 fold), benzene (22 fold), and probable carcinogens such as acetaldehyde (91.17), and toluene (53.07 fold) which were found to be negligibly present or absent in e-cigarettes.
- The study also evaluated the safety implications of nicotine, and found that the risk of acute toxicity from direct ingestion of nicotine would not arise due to e-cigarette use, as ENDS deliver about 1mg of nicotine in blood (equivalent to a cigarette), whereas the toxic level is in the range of 30-60mg. It also took into consideration risks arising from the physical makeup or design of ENDS devices. Poor materials and build quality, lack of quality control and improper use of ENDS can give rise to a condition called "thermal runaway" in lithium rechargeable batteries and potentially lead to fire hazard. However, with technological advancement and optimum safety features, these concerns can be addressed.
- Use of ENDS was 7.53 times higher in current smokers than in non-smokers, which indicates that, contrary to perception, e-cigarettes are not a gateway to nicotine use but are more commonly used by smokers to reduce harm or quit smoking.

Objective

The focus is to develop a regulatory framework which will be drafted in endeavoring to protect the public health of its citizens by ensuring:

- access to quality-controlled ENDS products as a less harmful alternative to smoking for adult smokers;
- protect young persons from inducements to use ENDS products;
- disseminate accurate information on ENDS and its potential health impact.

Recommendations

The following are the salient focus areas for regulating ENDS in India:

1. Points of Sale

1.1. Regulate by licensing point of sale outlets for ENDS under the following conditions:

a. No sale is made to minors below 18 years of age;

b. Prohibit sale within 100 meters of educational institutions;

c. Online sale of ENDS products shall be permitted only under robust age verification system that prevents minors from purchasing such ENDS products.

2. Product Standards and Quality Assessment

2.1 Ensure approval of products as ENDS products only if they work in such a way that no combustion of tobacco or nicotine mixture occurs during the entire process of consumption when used as intended.

2.2 Ensure product standards that could prevent any injuries, including:

a. A potential product standard to prevent ENDS manufacturing defects and adulteration;

b. Product standard to address concerns about children's exposure to liquid nicotine;

2.3 As part of the standard, the government shall also consider, among other things, levels of toxicants and impurities in e-liquids.

3. Labelling

3.1. Ensure that the product must contain mandatory health warnings that must comply with the requirements in terms of content, location etc.

3.2. Ensure that the location, measurements of it cannot be redrafted or altered. The warnings must be irremovably printed or stickered, indelible and fully visible to the reader.

4. Youth Access

4.1 Ensure that all ENDS products will be sold in exclusive age-restricted locations and platforms.

4.2 Ensure that all persons are required to show proof of age at the time of purchase of the product.

4.3 Ensure removal from the market of those ENDS products that are marketed to children and/or appealing to youth. This could include using popular children's cartoon or animated characters, or names of products favored by kids like brands of candy or soda.

5. Testing Claims on Harm Reduction

As per available scientific evidence ENDS products may make a harm reduction claim.

5.1 The state shall ensure the claim be may only be made if:

a. The manufacturer can support the claim with scientific tests; or

b. The manufacturer can support the claim with evidence demonstrating significant reduction in the level of biomarkers of exposure to HPHCs.

6. Public Outreach

6.1. Outreach efforts to ensure that ENDS are not attractive to the youth, vulnerable sections of the population or never smokers.

6.2. Ensure restricted advertisement to ensure:

a. no advertisement that appeals minors;

b. it does not undermine quit- tobacco and no smoking campaigns and encourage non-nicotine/ non- smokers to smoking.

7. Implementation and Monitoring through an ENDS Oversight Committee

7.1 Ensure governance and enforcement of regulatory guidelines through an ENDS Oversight Committee chaired by the Principal Secretary of the Department of Health and Family Welfare. It shall be constituted to monitor and review the implementation of these guidelines.

8. Advisory Council

8.1 The ENDS Oversight Committee shall create an Advisory Council having one (1) representative from each of the following:

a. [the State Police, not below the rank of Deputy Inspector General;

b. a government medical institution, not below the rank of Professor;

c. the Department of Consumer Affairs, not below the rank of Director; and

d. the Department of Women and Child Welfare, not below the rank of Director].

8.2. The Advisory Council shall be responsible for providing inputs to the Oversight Committee on potential gaps in the implementation of these Guidelines or scientific assessments regarding the health and societal impact of ENDS products.

9. Scientific Assessment through Centre for Tobacco Harm Reduction

9.1. The government shall establish a Centre for Tobacco Harm Reduction (Centre) in an academic institution in the State. The Centre shall be responsible for conducting routine scientific assessments relating to the toxicity, efficacy, relative safety and harm reduction potential of ENDS products.

9.2. An annual scientific review on ENDS products shall be submitted by the Centre to a relevant oversight committee in order to ensure increased efforts in scientific studies and analysis of such products in helping smokers quit the habit and work on evaluating access to, and use of, regulated nicotine products.

10. Tax

10.1 As demand for nicotine products responds to changes in price, tax policy shall be crafted to encourage switching for adult smokers. Accordingly, combustible products shall be taxed at a higher rate than ENDS products. Government should aim to levy specific excise tax of cents per milliliter for ENDS products

AGENDA NO. 5

OFF-LABEL USE OF DRUGS, DISPOSABLES AND DEVICES

Definition of Off Label Use of Drugs

Off label use of drugs is the use of pharmaceutical drugs (drug, device, disposable) for an unapproved indication or in an unapproved age group, dosage, or route of administration.

Marketing of pharmaceuticals for off-label use is usually prohibited. But, both prescription drugs and over-the-counter drugs (OTCs) can be used in off-label ways, although most studies of off-label use focus on prescription drugs.

Off-label use is generally considered legal across the world legal unless it violates ethical guidelines or safety regulations.

More than 50% of all drugs are prescribed off-label based on available scientific and safety evidence and amongst psychiatrists and children, the number is even higher.

Why the need to work on the subject: off label use of drugs"?

In the matter of **Balram Prasad vs Kunal Saha & Ors** on 24 October, 2013, the Hon'ble Apex Court said *"73. …….. In fact punitive damages are routinely awarded in medical negligence cases in western countries for reckless and reprehensible act by the doctors or Hospitals in order to send a deterrent message to other members of the medical community. In a similar case, the Court of Appeals in South Carolina in Welch Vs. Epstein [31]* ***held that a neurosurgeon is guilty for reckless therapy after he used a drug in clear disregard to the warning given by the drug manufacturer causing the death of a patient.*** *This Court has categorically held that the injection Depomedrol used at the rate of 80 mg twice daily by Dr. Sukumar Mukherjee was in clear violation of the manufacturer's warning and recommendation and admittedly, the instruction regarding direction for use of*

the medicine had not been followed in the instant case. This Court has also made it clear that the excessive use of the medicine by the doctor was out of sheer ignorance of basic hazards relating to the use of steroids as also lack of judgment. ***No doctor has the right to use the drug beyond the maximum recommended dose."***

Government Policy/Rule/Law

There is no mention of the term "Off Label" use of drugs in Drugs and Cosmetics Act and Rules in India. Nor there is mention of the term "Single or Reuse of the medical devices" neither in Drugs and Cosmetics Act and Rules nor in Medical Devices Rules, 2011.

For understanding, the law relating to off lable use of drugs and reuse of single use of medical devices and disposables, the Heart Care Foundation of India (HCFI) had filed RTI applications .

As per the reply received by HCFI to an RTI filed HCFI/March/2019/042 dated 18th March 2019 , the CDCSO vide reply Z-28020/233/2019-DC dated 3rd May 2019 replied as under "*Medical devices notified under drugs and cosmetic act 1940 are regulated as per the provisions of Medical Device rules, 2017. As per rule 44 (k) of medical device rules 2017, if the device is intended for single use, it should be labeled appropriately. Further there is mention in medical device rule that to label the devoice appropriately if the device is intended for single use.*

Penalty in case of violation of any provisions of drugs and cosmetic act 1940 and medical device rules 2017 will be as prescribed as per the said act and rules.

Refurbishing of medical devices and disposables does not come under the purview of CDSCO. *However, refurbishing of medical equipment comes under the m ministry of Environment, Forest and Climate change."*

Has DCGI allowed off label use of drugs?

The government can ban off-label use of any drug as it did in the case of bevacizumab. On January 21, 2016, the DCGI took the bold step of prohibiting the use of intraocular bevacizumab as off-label treatment for various retinal diseases. Unfortunately, DCGI's decision put a large portion of the population at risk of denial of access to treatment for common blinding retinal diseases. But, after 2 months, the DCGI agreed to withdraw the alert notice, enabling retinal surgeons to again use bevacizumab.

This decision may be a landmark judgment for India and other countries around the world to look at evidence-based off-label use of drugs.

Can a doctor be held liable for mere deviation from normal practice?

- The Hon'ble Supreme Court of India in the matter titled as ***"Jacob Mathew versus State of Punjab"*** has held that:

> *"A mere deviation from normal professional practice is not necessary evidence of negligence. Let it also be noted that a mere accident is not evidence of negligence. So also, an error of judgment on the part of a professional is not negligence per se. Higher the acuteness in emergency and higher the complication, more are the chances of error of judgment."*
>
> *…..The degree of skill and care required by a medical practitioner is so stated in Halsbury's Laws of England (Fourth Edition, Vol 30 Para 35): " …… and a person is not liable in negligence because someone else of greater skill and knowledge would have prescribed different treatment or operated in a different way; nor is he guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art, even though a body of adverse opinion also existed among medical men."* [Jacob Mathew Supreme Court]

- In the matter titled as **Achutrao Haribhau Khodwa vs State of Maharashtra, 1996 SCC (2) 634, the Hon'ble Supreme Court has held that:**

  "The skill of medical practitioners differs from doctor to doctor. The very nature of the profession is such that there may be more than one course of treatment which may be advisable for treating a patient. Courts would indeed be slow in attributing negligence on the part of a doctor if he has performed his duties to the best of his ability and with due care and caution. Medical opinion may differ with regard to the course of action to be taken by a doctor treating a patient, but as long as a doctor acts in a manner which is acceptable to the medical profession, and the Court finds that he has attended on the patient with due care skill and diligence and if the patient still does not survive or suffers a permanent ailment, it would be difficult to hold the doctor to be guilty of negligence."

- The opinion has to be by authentic body. In the matter titled as ***"Vinitha Ashok versus Lakshmi Hospital***, AIR 2001 SC 3914", the Hon'ble Supreme Court has held that:

  "[28] Thus in large majority of cases, it has been demonstrated that a doctor will be liable for negligence in respect of diagnosis and treatment in spite of a body of professional opinion approving his conduct where it has not been established to the courts satisfaction that such opinion relied on is reasonable or responsible. If it can be demonstrated that the professional opinion is not capable of withstanding the logical analysis, the court would be entitled to hold that the body of opinion is not reasonable or responsible."

- In the matter titled as "***Kusum Sharma & Others versus Batra Hospital & Medical Research Centre***, 2010 (3) SCC 480 the Hon'ble Supreme Court of India has held that:

"In the realm of diagnosis and treatment there is scope for genuine difference of opinion and one professional doctor is clearly not negligent merely because his conclusion differs from that of other professional doctor".

"The medical professionals are entitled to get protection so long as they perform their duties with reasonable skill and competence and in the interest of the patients. The interest and welfare of the patients have to be paramount for the medical professionals."

- **IPC - Section 92** - Act done in good faith for benefit of a person without consent: "Nothing is an offence by reason of any harm which it may causes to a person for whose benefit it is done in good faith, even without that person's consent, if the circumstances are such that it is impossible for that person to signify consent, or if that person is incapable of giving consent, and has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing to be done with benefit;

- **IPC - Section 88** - Act not intended to cause death, done by consent in good faith for person's benefit: "Nothing, which is not intended to cause death, is an offence by reason of any harm which it may cause, or be intended by the doer to cause, or be known by the doer to be likely to cause, to any person for whose benefit it is done in good faith, and who has given a consent, whether express or implied to suffer that harm, or to take the risk of that harm."

<u>Law on off label use of drugs in the US and UK</u>

- **In the United States**, the law permits a physician or other healthcare practitioner to prescribe an approved medication for other uses than their specific FDA-approved indications. Pharmaceutical companies are not allowed to promote a drug for any other purpose without formal FDA approval. However, once a drug has been approved for sale for one purpose,

physicians are free to prescribe it for any other purpose that in their professional judgment is both safe and effective, and are not limited to official, FDA-approved indications.

This off-label prescribing is most commonly done with older, generic medications that have found new uses but have not had the formal (and often costly) applications and studies required by the FDA to formally approve the drug for these new indications. However, there is often extensive medical literature to support the off-label use.

- **Regulation in the United Kingdom**: Physicians in the United Kingdom can prescribe medications off-label. According to General Medical Council guidance, the physician must be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate safety and efficacy. Prescribing may be necessary when no suitably licensed medicine is available to meet the patient's need (or when the prescribing is part of approved research).

HCFI Round Table on Off Label Use of Drugs

On 27th May, 2019, HCFI Experts Round Table was held on off label use of drugs and reuse of single use of medical devices in which following concensus statement was passed:

RT Sutra: **" In absence of any unethical considerations or a safety issue AND in presence of strong International or National scientific evidence; approved off-label indication in other country; Guideline or Consensus statement; prevalent use in the clinical practice WITH no reported side effects under PVPI and the drug is not under RISK MAP category THEN the use of the available DCGI approved drug (including medical devices and disposables) is justified for off label indications under implied consent. In all other situations, one needs to take an informed consent."**

Recommendation

Clearly, there is a need for an off label policy.

The pharmaceuticals cannot promote or advertise legally. The onus therefore falls on the medical profession to "certify" the off-label use of drugs.

Time has come to formulate guidelines. We need to build a baseline document and draft suggestions to be sent to medical specialty societies cum associations and/or all medical stakeholders before sending it to the regulatory authorities.

Dileberation

Few examples of off label use

- Metformin in India is an off-label use for PCOD, which is used by gynecologists across the country; FOGSI, Indian Menopausal Society, Endocrine Society of India recommend this use in their guidelines. For its use no consent needs to be taken, but it is not DCGI-approved for this indication. Use of metformin-myoinositol combination in PCOD is also an off-label use.
- Amlodipine is approved for use only for mild and moderate hypertension, but it is also being used for severe hypertension, which is an off-label use.
- Aspirin in acute myocardial infarction: This is not a DCGI-approved indication.
- Using injection methotrexate for sarcoidosis, one may need to take an informed consent.

"Anticipate and prepare ourselves"

- To begin with, sensitize the medical profession on this issue. Most doctors are unaware of off-label use.

- Identify situations in which drugs can be used; supported by strong scientific evidence; being used for the said indication for years and PvPI has not recorded any adverse effect with the drug.

- Seek recommendations from professional associations and societies as they understand safety issues and scientific evidences.

- Sensitize the ethic committees of institutions regarding this issue

- National workshops: Invite specialists with scientific data; organize round tables in different zones of the country. Points to be discussed:

    - Safety and ethics of off-label use
    - Is the drug used anywhere else in the world or in India for the off label indication?
    - Is the drug approved for off label indication/s in other countries?
    - Are there enough international/national studies on the off-label use?

- Invite government participation

- Include off-label use as part of informed consent; hospitals must have their individual "ethics committee guidelines" on this till a national policy is available.
- Phase 4 post-marketing trials should be regulated. Adverse events should be reported. This will strengthen PvPI.

- Robust data including level of evidence is needed along with risk-benefit analysis.

- Commercial bias and conflict of interest needs to be taken care of.

- Expert evidence by peer group is accepted by the Courts as "prevalent practice", "peer group recommendations" or "society recommendations" unless there is a national existing policy. Till a law is formulated, this can be followed.

- Submit the draft to DCGI with copy to Health Ministry and other regulatory bodies; follow up with RTIs; file PIL if no satisfactory reply.

Guidance on reuse of cardiovascular catheters and devices in India

- Each medical establishment should have its own off label, *list of devices which can be* reprocess, number of times can reuse, reprocess, reuse, re-sterilise committee consisting of doctors, infection control officers, microbiologists, nurses, and administrators which should oversee central sterilisation, re-processing, infection control, biomedical engineering and cost accounting.

- The above committee should have institutional ethics committee approval.

- The in-house committee should take responsibility for the protocol linked to safety issues.

- The medical establishment should provide adequate space for reprocessing, trained personnel and other consumables that are required.

- Standard and validated written protocols should be followed for reprocessing for each type of single used device.

- Establishment should Ensure mechanism for tracking of such devices

- There should be a periodic review and audit.

- Cardiology and other specialties reusing catheters should formulate common guidelines and standard operating procedures for reuse. These guidelines should include the list of items that can be reused, the number of recommended reuses, the procedure for reuse, and validating effectiveness of reprocessing procedures, to ensure sterility and intact functionality of these devices and ensure quality control.

- An adverse event record should be maintained for all reused devices and there should be a periodic review and audit.

- Third party reprocessing units should be encouraged and need to be stringently regulated and accountable for quality control.

- The reused catheters/devices should not be billed on the new item rate to the patient as the reuse policy is primarily done to reduce the cost.

- The cost of sterilization process should be accounted for in the catheterization laboratory charges and or should not exceed 10% of the original cost of the catheters.

- Reused cardiac implantable electronic devices should not be charged.

- Made or make in India concept for these single used devices should be encouraged and facilitated to offset the cost, issues related to reuse and improve penetration of therapy.

- Engagement with the health regulatory authorities and price control for all imported medical devices should be addressed. Sealing the maximum retail price (MRP) based on the landing price with a well-defined formula for different medical single used device should be established.

- ICMED: There is a basic policy on reprocessing of single use devices (SUDs); it needs to be expanded. This assumes significance given the waste generated causing environmental hazard, an important public health problem today. Three important issues to be taken care of with regard to SUDs: Identify which SUDs can be reused safely; benefit of cost has been passed over to the consumer and consent.

AGENDA NO. 6

MEDICAL COLLEGES IN INDIA

Background and Problem Definition

India has among the largest number of medical colleges in the world (422), with an annual production of over 57, 000 doctors and 25, 000 specialists. However, India's average annual output of graduates per medical college is much less as compared to 149 in Western Europe, 220 in Eastern Europe and 930 in China. Simultaneously, the private medical colleges have increased exponentially, but found unaffordable by large segments of the student population. Hence it becomes necessary to periodically augment MBBS seats in government medical colleges. By opening new government medical colleges via upgrading and re-inventing by existing district hospitals, part of the problem is addressed.

Aiming to strengthen the supply and availability of trained human resources for the health sector, Ministry of Health has recently proposed to convert 75 district hospitals into medical colleges, as part of the centrally sponsored scheme for "establishment of new medical colleges by upgrading district or referral hospitals" preferably in underserved districts of the country. This proposal has been sent for approval to the Expenditure Finance Committee (EFC), and if approved, it will be sent to the Cabinet. Under the scheme, the states put in a proposal earmarking hospitals in underserved districts to be converted into medical colleges keeping the criteria in mind that the district should have no other private or government medical college.

Government had previously approved the conversion of first, 58 and subsequently, an additional 24 district hospitals into medical colleges. Of these 39 hospitals have become functional while the remaining are still under construction.

Medical colleges are unevenly spread across urban and rural areas of India, with wide disparities in the quality of education. This has skewed the distribution of health workers such that vulnerable populations in rural, tribal and hilly areas continue to be extremely underserved. To address the requirements of Universal Health Coverage (UHC) there is need for improvement in the country's present doctor population ratio from 0.5 per 1000 persons to one doctor per 1000 persons by the end of the year 2027.

This Scheme aims to create an additional 10,000 MBBS and 8,000 PG seats in the country. This will bridge the gap and shortages in availability of seats, mitigate the shortage of doctors and medical faculty in India, and could begin to address and achieve the desired doctor-population ratio.

However, it is also necessary to liberalise some MCI norms and only thereafter the current number of MBBS seats would be substantially increased, and affordable medical education would become more widely available.

For Discussion

(i) With respect to this item, there is currently, diverse news coming in from state governments: (a) MCI has re -approved the increase of 50 MBBS seats in Amritsar and Patiala medical colleges, augmenting the total number of MBBS seats in Punjab from 150 to 200. (b) The state government of Kerala has decided to allot 15% seats as all India merit seats from this academic year *in their private medical colleges*. All these years only government colleges have had all India merit seats. The self-financing medical colleges of Kerala have a 15% NRI quota. That will remain. From the remaining 85% seats, 15% seats will be allotted to any student from outside Kerala who makes it to the merit list.

(ii) While -re-inventing district hospitals into medical colleges,

utilise this as an opportunity to install HMIS and e Hospital protocols, in one/more newly minted medical college at a time, so that we build on the agenda of health reform.

Recommendations

Topic suggested by Dr. Anil Kaitan

AGENDA NO. 7

Damaging for India s reputation but what's MoH & CDSCO doing to silence the critics?

1 - report of spurious/ counterfeit medicines ?

2- Same report highlighted poor quality of product being sold and consumed in India by licensed mfrs. specially to Public Health - Corrective Action ? As u can't sweep this under carpet

3- How can quality Accreditation/ Certification be incentivized beyond so called minimal compliance that varies state to state?

4- Role of 3rd party certification for Quality by accredited CB to go beyond minimal compliance or even for minimal compliance .

5- MoH makes Policy , CDSCO implements regulations with help of State Liscensing Authorities but where's oversight for harmonized implementation?

6- Unlicensed units run with impunity of medical devices that's unfair for the licensed units - action taken on some orthopedic unlicensed mfrs. by CDSCO n Maharashtra FDA but follow up ? Conclusion?