



WHO role in moving the agenda for viral Hepatitis control in India



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GLOSSARY OF TERMS USED

ADR	- Adverse Drug Reaction
CHAI	- Clinton Health Access Initiative
CHC	- Community Health Centre
DAA	- Direct Acting Antivirals
FIND	- Foundation for Innovative Diagnostics
HAV	- Hepatitis A Virus
HBV	- Hepatitis B Virus
HCV	- Hepatitis C Virus
HDV	- Hepatitis D Virus
HEV	- Hepatitis E Virus
HIV	- Human Immunodeficiency Virus
IDU	- Injection Drug Use
MMHCRF	- Mukh Mantri Punjab Hepatitis C Relief Fund
MSF	- Médecins Sans Frontières
MSM	- Men having sex with men
NACP	- National AIDS Control Programme
NAT	- Nucleic Acid Test
NGO	-Non Government Organizations
NHM	- National Health Mission
NPSP	- National Polio Surveillance Project
NVHCP	- National Viral Hepatitis Control Programme
PLHIV	- People living with HIV
PWID	- People who inject drugs
RUP	-Re use prevention syringes
SAC	-State AIDS Control Society
SVR	- Sustained virologic response
TI	-Targeted Interventions
UN	- United Nations

EXECUTIVE SUMMARY

This report focuses on an evaluation of role of WHO country office in moving the viral hepatitis agenda which was conducted through systematic review of available literature, key interview of major stakeholders and reviewing the programme declarations and guidelines. For this evaluation no field visits were undertaken to hospitals and labs, or patient care and facility data were collected.

In spite of the high disease burden and available prevention and treatment interventions, hepatitis has not received the same attention as other diseases such as HIV, TB or malaria. In India there is a paucity of reliable data on the burden of the disease. The Central Bureau of Health Intelligence (CBHI) publish its annual National Health Profile (NHP) with burden of disease data for some diseases, every year. NHP place the annual burden of viral hepatitis around 105 hundred thousand.

During 2011–2013 period, 804,782 hepatitis cases and 291 outbreaks were reported by IDSP. The virus type was unspecified in 92% of cases. Among 599,605 cases tested for hepatitis A, 44,663 (7.4%) were positive, and among 187,040 tested for hepatitis E, 19,508 (10.4%) were positive. Overall prevalence of 3.7%; that of non tribal population at 3.0% and that amongst tribal population at 11.85%. A 2015 study found, 1.0% prevalence in pregnant women, IDU prevalence 51.2%, thalassaemics 22.7%, haemophilics 14.3% and in liver disease patients 19.7%. In an active survey based population study in Ludhiana district of Punjab in 2012, the authors found 5.2% positivity for HCV antibody.

The WHO global strategy for viral hepatitis sought to reduce the incidence of chronic hepatitis infection from the 2015-16 estimate of 6–10 million cases of chronic infection to 0.9 million infections by 2030, and to reduce the annual deaths from chronic hepatitis from 1.4 million to less than 0.5 million by 2030. The WHO supported Hepatitis control programme in Punjab came into being since 2013. The programme came initially as a fund to support diagnosis and treatment of Hepatitis C cases and went on to become Mukha Mantri Hepatitis C Relief Fund (MMHCRF) in 2016 providing for diagnosis to treatment of HCV. The programme was supported by WHO from the very beginning and also by other partners like FIND, CHAI and MSF.

The national hepatitis control programme was launched in July 2018, was championed through media campaign, set up a programme management unit, incorporated MMHCRF as part of it and went on to procurement, training and other pre launch activities to operationalize the actions in districts and states in phases beginning this year. The programme used prevalence data and WHO technical guideline extensively in devising the plan and modelling care and support network. The components of the programme include awareness generation, immunization of Hepatitis B for birth dose, high risk groups, health care workers, safety of blood and blood products, injection safety, safe socio-cultural practices, safe drinking water, hygiene and sanitary

toilets, as preventive measures.

Various estimates are there for prevalence of HBV/HCV in PWID, all of them quite high, in the range of 30% or higher. The PGI study of 2010-12 found 31.8% positive for HCV antibody and 3.5% positive for HBV, in its drug deaddiction and treatment centre.²³ Elsewhere in Punjab a higher rate of HCV prevalence with 38.1% was recorded. Ensuring blood and blood product safety is important programme component in NVHCP. A seven year study in Delhi has shown a prevalence of 1.61% HBV and 0.73% HCV in donated blood, and suggested a somewhat descending trend of HBV prevalence over time. The sheer vastness of blood donors at about 1% of the population and the number of blood banks and agencies collecting and testing these blood units make it challenging to regulate for transfusion transmitted infections like viral hepatitis. As the programme is not fully operational, looking into its needs and support system is yet to be seen. The existing operations of the Punjab and Haryana Government programme and the FIND and MSF activities in Delhi, Meerut and Imphal with its success stories and lessons help the new programme with lessons.

One in 5000 male birth is likely to be haemophilia major and 1 in 10000 a haemophilia minor, so the approximation of 50000 in the country is likely an underestimate. The prevalence of HBV and HCV infections are much higher among people - Hemophilia with HBV infection occurring in 5-10% and HCV infection in 30-35% of multiple transfused patients. Estimates indicate that there would be around 100,000 patients with a b thalassemia syndrome and around 150,000 cases of sickle cell disease in this vast country.

The prevailing scenario in India can be better comprehended by the situation in Punjab and some other states where active diagnosis and treatment programme is in place. Punjab till end of April has screened a number of cases for HCV and put 63000 under treatment, according to the statistics given by the State programme officer. Haryana has put somewhere between 10 and 15 thousand in similar care with state government initiatives which has made treatment of Hepatitis C cheapest in India the package being inclusive of diagnostics, Delhi has started 3 different models of care and has put some 15000 cases under treatment this year under the FIND project, MSF in Meerut has covered approximately 3000 cases over the last one year or so and in Manipur has covered some 7000 cases under a community driven model. Treatment efficiency or sustained SVR is estimated at above 90%, but not much evidence on ADR monitoring as is planned for the national programme or any direction obvious for the 2-5% cases that would persist viral load after 12 or 24 weeks.

WHO and its partners have been able to advocate the right quarters and the programme is launched and under implementation, the latest being the national action plan that came into being in February 2019. At a country level WHO has helped organize national and local awareness raising events, promoted by popular celebrities, such as celebration of World Hepatitis Day in India. WHO has engaged in policy dialogue and provided the direct technical support to undertake situation assessments, meta-analysis of existing seroprevalence studies for improved burden of disease estimations and cost-effectiveness studies on DAA and RUPs to inform the

investments in HCV elimination, negotiate better DAA prices, develop decentralized service delivery models for hepatitis testing and treatment, strengthen of laboratory capacity and mobilize communities to act and demand for treatment. Two WHO technical support groups have been created in India and used to support situation analysis, economic and operational research and capacity building. When the National viral hepatitis control programme was launched in July 2018, WHO country office contributed to the development of national guidelines for diagnosis and treatment and national training materials, based on WHO Global guidance.

When it comes to HBV/HCV control, the programme is geared to have its initial turf detecting HCV cases and treating them. Most of the HCV cases in the community being likely non icteric getting a grip over the same would be tricky, unless a large scale and sectoral high risk screening is offered and popularized and finally making knowledge of one's HCV/HBV status a popular aspiration. Hepatitis B vaccine was universalised nationwide in 2011. The actual coverage of HBV birth dose is about 70% in those born in Government facilities and less than 20% in the private ones, as per NPSP data.

2012 estimates put the number of injection use in India at 3 billion a year or 2.9 per person per year. 82.5% of this is for curative purposes and 63% of all unsafe. NVHCP recognize that, unsafe health care practices by health care providers/ traditional healers/ quacks pose a major challenge and risk for transmission of HBV and HCV and that there are gaps in implementation of bio-medical waste management rules, leading to sharps injuries and increased risk of infections. It propose to roll out re-use prevention (RUP) syringes, addressing prescriber practices. It took a long time to switch over to AD syringes in the immunization sector, it would be a much greater challenge to replace the injection instruments for the whole of health care sector with RUP and SIP syringes.

Targeted Interventions (TI) for key and bridge populations had been a core prevention strategy under NACP, NVHCP propose to adopt the same approach in targeting the people who inject drugs (PWID) in India. Currently needle syringe exchange program and opioid substitution therapy are provided for prevention of HIV among PWID. There are some disturbing figures regarding the prevalence of HBV/HCV in the PWID. Some of the work done by organizations like BMGF and MSF in Manipur report very high prevalence. The experience of Manipur has shown that not only the PWID but their spouse and partners need to be brought under the lens for inclusion in the test and treat group.

World wide prisoners have been found to be having a higher prevalence of HBV/HCV and this is supported by the Indian studies. This is a population where health infrastructure is traditionally poor. It would be a challenge to address the programme implementation in this sector without a concrete and probably innovative planning. The viral hepatitis prevalence rate amongst the prison population is higher than in the community and there need to be specific programme interventions to address this group, with or without the support of NACP run initiatives targeted at testing and bringing the prison population positive for HIV under care.

In addition to the key population under NACP, there are other focus groups that need to be attended to under the NVHCP. These focus groups include close first degree relatives and family members of infected person : mother, siblings, spouse and children. The other populations for both hepatitis B and C include those who have received blood or blood products specially before implementation of hepatitis C testing at a large scale in India; i.e. before 2001, recipients of multiple blood transfusion, person exposed to unsafe injection practices by informal health care providers, etc. The blood product recipients, dialysis underdoers and similar category of population are at much higher risk for contracting HBV/HCV and need to be strategized for early control.

The prevalence of HBV/HCV is higher in the tribal and indigenous groups, both due to their genetic make-up and specific cultural and social attributes. The number of blood dyscrasia and haemoglobinopathies are also a larger burden on this population. Added to this is the lack of access to the tribal population because of the backwardness and inadequacy of the health facilities accessible to them. Unless there is specific strategies worked out and additional programme inputs placed, there is no reason to expect a result better than what IDSP has contributed towards the burden estimate and transmission dynamics of viral hepatitis. WHO has great role to play in this area and set the path right from the beginning. Forty nine districts in the country have more than 75% of ST population. NFHS 3 data (2005-06) showed institutional delivery rate in ST population at 17.7% and fully immunized children at 31.3%. The health infrastructure in the high tribal population areas have more temporary facilities, lesser human resources and cover wider geographic area. There is the scope and need of addressing the needs in the programme for a people who are less than 10% of population but will need more and dedicated efforts to be controlled for viral hepatitis.

The programme is new and has countrywide plans of implementation, with a secretariat of 3 officers and 2 consultants. The programme manager, was acutely aware of this inadequacy and quite open to accommodate hands to make the programme operational. Providing technical and logistic support is crucial, and WHO can avail this opportunity to place personnel in running the NVHCP to render technical and managerial support.

BACKGROUND

This report is the result of an exercise undertaken by the School of Public Health of Manipal Academy of Higher Education for evaluating the role of WHO country office in moving the viral hepatitis agenda in India. It was conducted through systematic review of available literature, key interview of major stakeholders and reviewing the programme declarations and guidelines. A framework questionnaire based on the Global Health Sector Strategy was used for the interview, as relevant to the role the interviewee or her/his institution.¹ All contact, scheduling of interview was done with help of WHO country office and the members interviewed are listed below.

List of personnel interacted with/interviewed : 29Apr-7May2019		
Shri Vikas Sheel	Joint Secretary	Department of Health and Family Welfare, Government of India
Dr R S Gupta	Deputy Director General	National AIDS Control Organisation, Government of India
Shri E R Babu	Country Project Manager - HCV	FIND (Foundation for Innovative New Diagnostics)
Shri Siddharth Sindhwani	Manager	Clinton Health Access Initiative
Ms Leena Menghaney	Access Campaign, South Asia	Medico sans Frontier
Prof R K Dhiman	Professor & Head, Dept. of Hepatology	PGIMER, Chandigarh
Dr Gagandeep Grover	Programme officer, NVHCP, Punjab	Government of Punjab
Dr Paul P Francis	Technical Officer, planning	WHO Country Office
Dr Pankaj Bhatnagar	National Professional Officer (NPO), NPSP	WHO Country Office
Dr Chandrakant Lahariya	NPO, Healthcare, Access and Protection	WHO Country Office
Dr Madhur Gupta	NPO, Pharmaceuticals	WHO Country Office
Dr Vimlesh Purohit	NPO, HIV and Hepatitis	WHO Country Office
Ms Rina Sinha	NPO, Communications	WHO Country Office

The Prasanna School of Public Health of Manipal Academy of Higher Education, Manipal was awarded APW (Regn. 2019/892090-0; 2019/892090-0; Purchase Order 202246104) for evaluation of role of WHO country office in moving the viral hepatitis agenda forward in India. We did not undertake field visits to hospitals and labs, or collect patient care and facility data for this evaluation.

1. World Health Organization : Global Health Sector Strategy on Viral Hepatitis, 2016–2021; WHO, Geneva, 2016.

THE BURDEN

Sustainable Development Goals have recognized Hepatitis as one of the major global health concern due to the high burden of the diseases across the globe. The major contributors globally being Asia, North Africa, East Africa and West Africa. In spite of the high disease burden and available prevention and treatment interventions, hepatitis has not received the same attention as other diseases such as HIV, TB or malaria. In India there is a paucity of reliable data on the burden of the disease. The Central Bureau of Health Intelligence (CBHI) publishes its annual National Health Profile (NHP) with select burden of disease data every year. NHP places the annual burden of viral hepatitis around 105 hundred thousand. The data available for the last 4 years is placed below at table 1.

Table 1 : Number of cases of viral hepatitis reported in India				
Year	2014	2015	2016	2017
Cases	138554	133625	146970	159675
Deaths	400	397	451	507
Source : National Health Profile 2018 and 2016; http://www.cbhidghs.nic.in/WriteReadData/1892s/Before%20Chapter1.pdf ; https://www.cbhidghs.nic.in/ . accessed 4 March 2019.				

The Integrated Disease Surveillance Programme (IDSP) of National Centre for Disease Control (NCDC) publishes weekly outbreak report from its event based reporting system. The data reported on these outbreaks gives an overview of the disease outbreaks every year. Table 2 summarizes the viral hepatitis data for the last 5 years.

Table 2 : Viral Hepatitis outbreaks reported by IDSP 2014-2018					
Outbreaks/Year	2014	2015	2016 ¹	2017 ²	2018
Hepatitis A	21 (27.2)	40 (38.8)	47 (45.6)	33 (45.2)	23 (33.8)
Hepatitis B	0	1 (0.9)	0	0	1 (1.4)
Hepatitis C	0	2 (1.9)	1 (0.9)	0	0
Hepatitis E	29 (37.6)	37 (35.9)	37 (35.9)	32 (43.8)	13 (19.1)
All viral Hepatitis Laboratory confirmed	50 (64.9)	80 (77.6)	85 (82.5)	65 (89.0)	37 (54.4)
Total outbreaks of Jaundice/ viral Hepatitis	77	103	103	73	68
Total cases reported during outbreak	3123	5817	5266	2414	1823
Total deaths reported during outbreak	10	26	15	3	2
Total States reporting outbreak	15 (41.6)	18 (50.0)	16 (44.4)	17 (47.2)	15 (41.6)
Total Districts reporting outbreak	50 (7.0)	66 (9.3)	71 (10.0)	47 (6.6)	47 (6.6)
1. In 2016, data for 15th week could not be retrieved.					
2. In 2017, data for 4th week could not be retrieved					
Weekly data from IDSP Weekly report on outbreaks available at https://idsp.nic.in/index4.php?lang=1&level=0&linkid=406&lid=3689 ; accessed 4-8 March 2019.					

Weekly data on occurrence of viral hepatitis is collected by IDSP. During 2011–2013 period, 804,782 hepatitis cases and 291 outbreaks were reported by IDSP. The virus type was unspecified in 92% of cases. Among 599,605 cases tested for hepatitis A, 44,663 (7.4%) were positive, and among 187,040 tested for hepatitis E, 19,508 (10.4%) were positive. During June–September of each reporting year, a 17% increase in the total number of reported hepatitis cases above baseline was observed.

During the 3-year period, 291 hepatitis outbreaks involving 15,601 cases and 58 (4%) deaths were reported to IDSP. Outbreak-related cases accounted for 1.9% of all reported hepatitis cases. At least one hepatitis outbreak report was received from 23 (66%) of 35 Indian states. Two-thirds of outbreaks were reported from rural areas. Among 163 (56%) outbreaks with known aetiology, 78 (48%) were caused by hepatitis E, 54 (33%) by hepatitis A, 19 (12%) by both hepatitis A and E, and 12 (7%) by hepatitis B or hepatitis C. There is discernible seasonal peak around June to September, typically monsoon season.²

A 2006 study suggested a prevalence of 2.4% amongst non tribal population and that for tribal population at 15.8% for HBV³. This prevalence data was derived after reanalyzing the data in different cross sectional studies and adjusting the observed prevalence to its denominator population size, before extrapolation. In a later study the group modified their analysis on the basis of population data and gave an overall prevalence of 3.7%; that of non tribal population at 3.0% and that amongst tribal population at 11.85%.⁴ A 2015 study found, 1.0% prevalence in pregnant women, IDU prevalence 51.2%, thalassaemics 22.7%, haemophiliacs 14.3% and in liver disease patients 19.7%.⁵ In an active survey based population study in Ludhiana district of Punjab in 2012, the authors found 5.2% positivity for HCV antibody.⁶

2. Tripurari Kumar, Aakash Shrivastava, Anil Kumar, Kayla F. Laserson, Jai P. Narain, Srinivasaraghavan Venkatesh, Lakhbir S. Chauhan, & Francisco Averhoff : Viral Hepatitis Surveillance — India, 2011–2013. *Morbidity and Mortality Weekly Report (MMWR)* July 24, 2015 / 64(28);758-762. Centers for Disease Control and Prevention, USA.
3. Ashish Batham, Dherian Narula, Tanmay Toteja, V Sreenivas and Jacob M Pulliyel : Systematic Review and Meta-analysis of Prevalence of Hepatitis B in India. *Indian Pediatrics*. Vol 44, Sep 17, 2007.
4. Ashish Batham, Manoj Anand Gupta, Pallav Rastogi, Shubham Garg, V Sreenivas & Jacob M Puliyel : Calculating prevalence of Hepatitis B in India : Using Population weights to look for publication bias in conventional meta-analysis. *Indian Journal of Pediatrics*, Vol 76, Dec 2009.
5. Priya Madan Yabaji, Aruna Shankar Kumar & Kanjaksha Ghosh : A silent killer (Hepatitis C virus) in India: A review of prevalence from all available data. *International journal of current research*; vol 7 issue 09 Sep 2015. <http://www.journalcra.com>
6. Ajit Sood, Shiv Kumar Sarin, Vandana Midha, Syed Hissar, Neena Sood, Pankaj Bansal & Manu Bansal : Prevalence of Hepatitis C virus in a selected geographical area of northern India : a population based survey. *Indian J Gastroenterol* (Sep-Oct 2012) 31 (5) : 232-236. DOI 10.1007/s12664-012-0251-8.

There is wide variation in prevalence of various types of viral hepatitis in the country and also amongst the various population groups and high risk groups. All taken together a base value of 2% prevalence and or carrier rate seems on the lower side of plausibility. Following inclusion of Hepatitis B in the child immunization schedule there is some reduction in HBV prevalence but HCV prevalence have increased in this period amongst blood donors.⁷

GLOBAL CONTEXT

The World Health Organization adopted resolutions on viral hepatitis control in 2010 and in 2014, included Hepatitis control under the Sustainable Development Goals of the UN by 2030 and came with a strategy document for viral hepatitis control in 2016. The strategy sought to reduce the incidence of chronic hepatitis infection from the 2015-16 estimate of 6–10 million cases of chronic infection to 0.9 million infections by 2030, and to reduce the annual deaths from chronic hepatitis from 1.4 million to less than 0.5 million by 2030. The region devised strategy for hepatitis control in 2013, following the earlier initiative of WHO headquarter in 2012⁸.

Major endemic states in the world were devising ways of having control over viral hepatitis in general and Hepatitis B and C in particular, those being high burden on the health system in the long run. Egypt came out with its plan to control HCV growth by using domestically licensed direct acting antivirals⁹; Pakistan continues its programme on HCV control complementing Government efforts with NGO initiatives¹⁰. Malaysia's decision on compulsory license for DAA after 2017 makes them the first country to use government use license for HCV treatment.¹¹

The strategy was to improve the service coverage targets of viral hepatitis diagnosis and treatment to achieve the impact target of high reduction in mortality and bringing all known and hitherto undetected cases within the reach of the health-care delivery system and improve the diagnostic and treatment abilities of medical institutions.

Between 2015 and 2017, China went for a plan combining pre marital counselling for Hepatitis B carrier status, strong compliance of birth dose Hep B vaccination, and surveillance for active infection with antivirals state expenses and insurance to bring down the prevalence to a

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7. P K Gupta, H Kumar, D R Basannar & M Jaiprakash : Transfusion transmitted infections in Armed Forces: Prevalence and Trends. Medical Journal Armed Forces India, 2006; 62 : 348-50.
 8. WHO SEARO : Regional strategy for the prevention and control of viral hepatitis, 2017.
 9. Omran D et al . : Towards HCV elimination in Egypt. World J Gastroenterol 2018 October 14; 24(38): 4330-4340. DOI: 10.3748/wjg.v24.i38.4330.
 10. Al Kanaani Z, Mahmud S, Kouyoumjian SP, Abu-Raddad LJ. 2018 The epidemiology of hepatitis C virus in Pakistan: systematic review and meta-analyses. R. Soc. open sci. 5: 180257. <http://dx.doi.org/10.1098/rsos.180257>.
 11. MSF: web posting on Access to care. (<https://msfaccess.org/malaysias-compulsory-licence-sofosbuvir-positive-step-public-health-and-innovation>)

manageable one and surpassing the global 2020 target for the country¹². WHO's Hepatitis B strategy combines use of birth dose vaccine with targeted coverage for adults in high risk and care and support for chronic cases and carriers^{13,14}.

IMPETUS FOR A NATIONAL HEPATITIS CONTROL PROGRAMME

There were local initiatives in the country to rein in the epidemic of viral hepatitis. The WHO supported Hepatitis control programme in Punjab came into being since 2013. The programme came initially as a fund to support diagnosis and treatment of Hepatitis C cases and went on to become Mukha Mantri Hepatitis C Relief Fund (MMHCRF) in 2016 providing for diagnosis to treatment of HCV.¹⁵ The programme was supported by WHO from the very beginning and also by other partners like FIND, CHAI and MSF.¹⁶

These institutions, namely WHO, FIND, CHAI and MSF were advocating for a national programme for control of viral hepatitis, and simultaneously aided and supported local initiatives for viral hepatitis or HCV control in the States of Punjab, Haryana, Uttar Pradesh and Manipur. Much of this came as a spin off from the Punjab experience, but independent needs were being felt at many such places as a problem of access for chronically sick viral hepatitis cases in the backward or socially isolated communities like Injection drug users.

Their leadership in making nucleic acid based rapid detection kit for viral hepatitis diagnosis, procuring directly acting antivirals at a much reduced rate, designing Clinical Record Forms, operations planning, training HR for specific roles in hepatitis control including laboratories and developing operational manuals and guidelines, support in operationalizing Technical Resource Group, were stellar and coordinated.

12. Jue Liu, Wannian Liang, Wenzhan Jinga & Min Liu : Countdown to 2030: eliminating hepatitis B disease, China. Bull World Health Organ 2019;97:230–238 | doi: <http://dx.doi.org/10.2471/BLT.18.219469>

13. Yvan Hutin, Shalini Desai & Marc Bulterys : Preventing hepatitis B virus infection: milestones and targets. Bull World Health Organ 2018;96:443–443A | doi: <http://dx.doi.org/10.2471/BLT.18.215210>.

14. Kate Whitford, Bette Liu, Joanne Micallef, J Kevin Yin, Kristine Macartney, Pierre Van Damme & John M Kaldor : Long-term impact of infant immunization on hepatitis B prevalence: a systematic review and meta-analysis. Bull World Health Organ 2018;96:484–497. doi: <http://dx.doi.org/10.2471/BLT.17.205153>.

15. WHO SEARO : Punjab's Hepatitis C initiative brings hope to life; media centre, WHO SEARO, 2017.

16. Radha K. Dhiman, Sandeep Satsangi, Gagandeep S. Grover and Pankaj Puri : Tackling the Hepatitis C Disease Burden in Punjab, India. J Clin Exp Hepatol. 2016 Sep; 6(3): 224–232. PMCID: PMC5052426.

WHO also helped in bringing out research findings like the effectiveness of HCV treatment as a cost effective programme option¹⁷ and compiling evidence on prevalence estimates of viral hepatitis in India.^{18,19}

Other than these, WHO and its partners had been working very closely in moving the agenda for availability of direct acting antivirals in the country at affordable price, and supported the organization of first world conference on access to medical products and international laws on trade.²⁰ WHO also supported injection safety that helped move forward the agenda of hepatitis control in Punjab and the country.²¹⁻²³

NATIONAL VIRAL HEPATITIS CONTROL PROGRAMME OF GOVERNMENT OF INDIA

The national hepatitis control programme was launched in July 2018, was championed through media campaign, set up a programme management unit, incorporated MMHCRF as part of it and went on to procurement, training and other pre launch activities to operationalize the actions in districts and states in phases beginning this year.

The programme used prevalence data and WHO technical guideline extensively in devising the plan and modelling care and support network.

The existing operations of the Punjab and Haryana Government programme and the FIND and MSF activities in Delhi, Meerut and Imphal with its success stories and lessons help the new programme.

17. Aggarwal R, Chen Q, Goel A, Seguy N, Pendse R, Ayer T, et al. (2017) Cost-effectiveness of hepatitis C treatment using generic direct-acting antivirals available in India. PLoS ONE 12(5): e0176503.
<https://doi.org/10.1371/journal.pone.0176503>.
18. Amit Goel, Nicole Seguy and Rakesh Aggarwal : Burden of hepatitis C virus infection in India: A systematic review and meta-analysis. Journal of Gastroenterology and Hepatology. First published: 03 September 2018 <https://doi.org/10.1111/jgh.14466>.
19. Dhiman RK, Satsangi S, Grover GS, Puri P : Tackling the Hepatitis C Disease Burden in Punjab, India. J Clin Exp Hepatol. 2016 Sep;6(3):224-232. Epub 2016 Sep 7.
20. World Health Organization (India) : First World Conference on Access to Medical Products and International Laws on Trade, 2017.
21. IPEN Study Group : Injection practices in India. WHO South-East Asia Journal of Public Health 2012;1(2):189-200 189.
22. World Health Organization (India) : India Injection Safety Implementation Project 2016-18.
23. Pankaj Bahuguna et al : Cost-effectiveness of safety engineered syringes for therapeutic use in India. Journal of clinical and experimental hepatology. July 2018. Vol 8 suppl 1, p S 118. DOI: <https://doi.org/10.1016/j.jceh.2018.06.492>

The programme is aimed at country wide elimination of Hepatitis C by 2030; reduction in morbidity and mortality associated with Hepatitis B and C in the infected population, and reduce the risk, morbidity and mortality due to Hepatitis A and E. NVHCP has taken a baseline prevalence for HAV as 10-30% of acute hepatitis being caused by it and 5-15% of acute liver failure cases. For HEV it is 10-40% of acute hepatitis and 15-45% of acute liver failure.

HBV surface Antigen (HBsAg) positivity in the general population has been summed up as between 1.1% to 12.2%, with an average prevalence of 3-4%. Anti-Hepatitis C virus (HCV) antibody prevalence in the general population is estimated to be between 0.09-15%, as summed up by the programme operational guideline. It is estimated that about 40 million people are chronically infected with Hepatitis B and 6-12 million people with Hepatitis C.

Also, high risk population for viral hepatitis include close first degree relatives and family members: mother, siblings, spouse and children, of persons affected with viral hepatitis. The other populations for both hepatitis B and C include those who have received blood or blood products specially before implementation of hepatitis C testing at a large scale in India; i.e. before 2001.

The components of the programme include awareness generation; immunization of Hepatitis B for birth dose, high risk groups, health care workers; ensuring safety of blood and blood products; implementing injection safety at every level of health care, promoting safe socio-cultural practices, collaborating to assure drinking water safety, hygienic and sanitary toilets, as preventive measures, to mention a few.

On coping up with cases it adopted an approach of diagnosis and treatment at programme cost, by screening pregnant women for HBsAg in areas with low institutional delivery, free screening, diagnosis and treatment for both hepatitis B and C, provision of linkages with private sectors and others as required and engagement with community to ensure adherence to treatment and demand generation. Procurement of drugs and diagnostic kits are under way, first level of cascade training is over and state level programme officers have been designated.

The programme would be implemented in a phased manner and have annual targets and strategies. Management and procurement would be centralized under NHM and implementation and operations would be with the states and districts in the usual model of NHM working from shared finances. Model treatment centres would be established at the district and designated towns and gradually the programme operations would be devolved to the CHC level.

BURDEN OF HEPATITIS IN OTHER VULNERABLE POPULATIONS

Also, key and bridge population groups under the NACP for HIV infections are especially vulnerable to viral hepatitis infections too. These include groups like recipients of multiple blood/blood products transfusion, patients on hemodialysis, People Who Inject Drugs, MSM, female sex workers, sexual partners of infected people, prisoners, migrants and truckers etc.

Injection drug users are a large group who are vulnerable to HBV and HCV among other things because of the needle and syringe sharing. Various estimates are there for this prevalence, all of them quite high, in the range of 30% or higher. The PGI study of 2010-12 found 31.8% positive for HCV antibody and 3.5% positive for HBV, in its drug deaddiction and treatment centre.²⁴ Elsewhere in Punjab a higher rate of HCV prevalence with 38.1% was recorded.²⁵ The increasing trend of IDU, even in children adds to the importance of this sector in hepatitis control.²⁶ In this light the NACO estimate of 200 000 IDU in India may be an underestimate.

Use of safe injection and correct disposal of the used injection devices have attracted a lot of attention in this millennium. A lot of studies still find a high percentage of unsafe injection, use of unsafe injection practices giving rise to outbreaks including that of HBV and HCV.²⁷ Basic injection safety practices even in medical graduates in the hospital setting is quite poor.²⁸ The compliance in grass roots health care workers and the Ayush practitioners is lesser. And probably the least amongst the rural practitioners of medicine who do not have a formal training.

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24. Debasish Basu, Arun Kumar Sharma, Sunil Gupta, Naresh Nebhinani & Vineet Kumar: Hepatitis C virus (HCV) infection & risk factors for HCV positivity in injecting & non-injecting drug users attending a de-addiction centre in northern India. *Indian J Med Res* 142, September 2015, pp 311-316 DOI:10.4103/0971-5916.166596.
 25. Mahajan P, Singh M, Garg A, Garg PD, Singh G (2016) Prevalence of Hepatitis-C Viral Infection among Opioid Dependent Injectable Drug Users: A Study Conducted at Swami Vivekananda Drug De-Addiction and Treatment Centre, Amritsar. *Dual Diagn Open Acc* 1:6. doi: 10.21767/2472-5048.100006
 26. Dhawan A, Pattanayak RD, Chopra A, Tikoo VK, Kumar R. Injection drug use among children and adolescents in India: Ringing the alarm bells. *Indian J Psychiatry* 2016;58:387-93.
 27. WHO India : India Injection safety implementation project, Ibid.
 28. Peethala S et al. : A study on assessment of safe injection practices among interneers in government general hospital, Kakinada, Andhra Pradesh, India. *Int J Community Med Public Health*. 2017 Nov; 4(11):4321-4325. DOI: <http://dx.doi.org/10.18203/2394-6040.ijcmph20174852>.

Ensuring blood and blood product safety is an important programme component in NVHCP. A seven year study in Delhi has shown a prevalence of 1.61% HBV and 0.73% HCV in donated blood, and suggested a somewhat descending trend of HBV prevalence over time but ascending prevalence for HCV.²⁹ other studies have found higher prevalence, and a rising one in younger population.³⁰ Considering the window period infection transmission and use of tests other than NAT for detection, actual problem may be larger.

Also there is a sizeable group of people who needs transfusions and injections for survival, like the thalassaemics, haemophiliacs and those on dialysis. Injection safety for these groups are of paramount importance and they need to be compulsorily brought under the ambit of test and treatment for viral hepatitis. One in 5000 male birth is likely to be haemophilia major and 1 in 10000 a haemophilia minor, so the approximation of 50000 in the country is likely an underestimate.³¹ The prevalence of HBV and HCV infections are much higher among certain population groups -Haemophilia with HBV infection occurring in 5-10% and HCV infection in 30-35% of multiple transfused patients.³²

Estimates indicate that there would be around 100,000 patients with a b thalassemia syndrome and around 150,000 cases of sickle cell disease in this vast country. However, in the absence of National Registries of patients, the exact numbers are not known. The March of Dimes Global Report on Birth Defects has estimated that the prevalence of pathological hemoglobinopathies in India is 1.2 per 1000 live births. It has been suggested that there would be 32,400 babies with a serious hemoglobin disorder born each year based on 27 million births per year in India.³³

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29. Akanksha Rawat, Preeti Diwaker, Priyanka Gogoi & Bharat Singh : Seroprevalence & changing trends of transfusion-transmitted infections amongst blood donors in a Regional Blood Transfusion Centre in north India. Indian J Med Res 146, November 2017, pp 642-645 DOI: 10.4103/ijmr.IJMR_468_15.
 30. Sonam Kumari : Prevalence and trends of hepatitis B virus, Hepatitis C virus, Human immunodeficiency virus 1, 2 and syphilis infections among blood donors in a regional transfusion center in Punjab, India: A 3 years study. Ind Journal of STD and AIDS. DOI: 10.4103/0253-7184.196887.
 31. Anita Kar, Supriya Phadnis, Sumedha Dharmarajan, and Juhi Nakade: Epidemiology & social costs of haemophilia in India. Indian J Med Res. 2014 Jul; 140(1): 19–31. PMCID: PMC4181156 PMID: 25222774.
 32. Hemophilia Federation of India : <https://www.hemophilia.in/>
 33. Roshan Colah, Khushnooma Italia, Ajit Gorakshakar : Burden of thalassemia in India: The road map for control. Pediatric Hematology Oncology Journal 2 (2017) 79e84.

India has a huge network of blood banks, that has gone through considerable reforms and regulations in the last few decades. During January 2015 to December 2015, the annual blood collection from all the blood banks that reported was 11,645,791 of which 71.9% (8,378,692) units were through voluntary blood donations and the remaining were from replacement donations.

The average annual collection of blood units of all the blood banks in the country was 4789 units. The average annual collection of NACO supported blood banks was found to be higher (6,219 units) than the Non-NACO blood banks (3,583 units). Between January and December of 2015, 0.87% of this blood were positive for HBV and 0.34% for HCV.

For HCV, the states of Punjab, Mizoram, Manipur, Haryana, Uttarakhand, Chandigarh, Puducherry, Delhi, West Bengal, Uttar Pradesh, Meghalaya and Daman & Diu had higher prevalence going up to 1.37% in Punjab. For HBV, Puducherry, Dadra & Nagar Haveli, Bihar, Andhra Pradesh, Tripura, Rajasthan, Madhya Pradesh, Delhi, Maharashtra, Mizoram, Karnataka, West Bengal and Uttar Pradesh had higher prevalence, topped by Puducherry at 2.12%.³⁴

One other group that is vulnerable to HBV/HCV with higher risk are the prisoners. As of end 2015, the total number of jail inmates in India was more than 4 00 000³⁵. Jail inmates are evidenced to carry higher prevalence of HBV/HCV³⁶. One Indian study done in Chennai also found considerable prevalence of HBV/HCV. The study enrolled 1381 inmates, 1258 of them male. While 3.89% men and 1% women were positive for HBsAg 1.27% men and none of the women, were found to be positive for anti-HCV antibodies.³⁷

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34. National AIDS Control Organization/National Blood Transfusion Council : Assessment of Blood Banks in India -2016.
 35. Government of India : National Crime Records Bureau -Prison Statistics India, 2015. in India, 2015.
 36. Aaron M. Harris et al : An evaluation of the hepatitis C testing, care and treatment program in the country of Georgia's corrections system, December 2013 – April 2015. BMC public health. Harris et al. BMC Public Health. Vol 19, supplement 3. <https://bmcpublichealth.biomedcentral.com/articles/supplements/volume-19-supplement-3> <https://doi.org/10.1186/s12889-019-6783-4>.
 37. M Ramamurthy et al : Risk factors and prevalence of hepatitis B virus and hepatitis C virus among prison inmates, Chennai, India, 2015. Int Journal of Inf Dis 53S (2016) 4-163.

In a study in Delhi's Tihar jail, the investigators found of the 50 acute cases of hepatitis 34 % were positive for HBV and 16% were positive for HCV, in the wake of an outbreak reported in the jail.³⁸ A study that investigated the Ghaziabad jail found 11.7% positive for HBV and 5% for HCV amongst the 240 inmates, all of whom were male.³⁹

Because of the recent initiatives of NACP IV, there is now targeted intervention in the prison inmates for HIV control. Specific programme components with NGO support has been launched in the states of Punjab, Haryana, Chandigarh and the North East. NACO surveillance data from these components showed that in the 13282 prisoners covered a prevalence of 31.9% of HCV was detected.⁴⁰

BACKWARD AND DISADVANTAGED -THE TRIBALS

The tribal population of the country, as per 2011 census, is 10.43 crore, constituting 8.6% of the total population. 89.97% of them live in rural areas and 10.03% in urban areas. Broadly the STs inhabit two distinct geographical area – the Central India and the North- Eastern Area. Forty nine districts in the country have more than 75% of ST population. NFHS 3 data (2005-06) showed institutional delivery rate in ST population at 17.7% and fully immunized children at 31.3%. The health infrastructure in the high tribal population areas have more temporary facilities, lesser human resources and cover wider geographic area.⁴¹ All these pose a challenge to delivering service under any health programme, particularly so for NVHCP where continued care, repeated visit and long term follow up would be essential.

Several studies have consistently shown higher prevalence of HBV/HCV in the tribal populations in India. Many of these populations also possess genetic make up making them more vulnerable to haemoglobinopathies and blood dyscrasias, adding to their problem. These population live in the most health backward districts, a large part of which are difficult to reach and have poor health infrastructure.

Bringing this population within the coverage of NVHCP would be a challenge and putting the positive under continued and followed up would be a challenge.

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- 38. P Kar et al : Analysis of serological evidence of different hepatitis viruses in acute viral hepatitis in prisoners in relation to risk factors. Indian J Med Res. 112, October 2000, pp 128-132.
 - 39. Sarman Singh, Rajendra Prasad and Alok Mohanty MD : High prevalence of sexually transmitted and blood-borne infections amongst the inmates of a district jail in Northern India. International Journal of STD & AIDS Volume 10 July 1999. pp 475- 478.
 - 40. National AIDS Control Organization : Annual Report 2017-18. Pp 362-363.
 - 41. Government of India : Statistical Profile of Scheduled Tribes in India. Ministry of Tribal Affairs, Statistics division, 2013.

EFFECTIVENESS OF HCV DIAGNOSIS AND TREATMENT

The actual roll out of the programme is yet to happen. But the operations guideline and other manuals are very explicitly oriented towards the path and goals of global WHO hepatitis control strategy. The expectations from the broad operational targets of the global or regional strategy to be achieved, are more but there is optimism that once rolled out the pace will pick up and achievement of milestones would be faster.

The prevailing scenario in India can be better comprehended by the situation in Punjab and some other states where active diagnosis and treatment programme is in place. Punjab till end of April has screened a number of cases for HCV and put 63000 under treatment, according to the statistics given by the State programme officer.

Haryana has put between 10 and 15 thousand in similar care with state government initiatives which has made treatment of Hepatitis C cheapest in India the package being inclusive of diagnostics, Delhi has started 3 different models of care and has put some 15000 cases under treatment this year under the FIND project, MSF in Meerut has covered approximately 3000 cases over the last one year or so and in Manipur has covered some 7000 cases under a community driven model.

Treatment efficiency or sustained SVR is estimated at above 90%, but not much evidence on ADR monitoring as is planned for the national programme or any direction obvious for the 2-5% cases that would persist viral load after 12 or 24 weeks.

PREVALENCE DATA OF RECENT TIMES -HBV and HCV

The prevalence data of recent times for both Hepatitis B and C do not show any specific pattern or decline. Till now the viral hepatitis situation is probably similar to what the multicentric WHO supported prevalence study used by the national programme observed. Individual studies are regional and time and target specific and some of them are listed here. The population prevalence of HBV is around 1% in most of the studies (Table 3) and that of HCV is lesser (Table 4).

Table 3 : Hepatitis B prevalence estimated by studies								
Sl No.	Study Investigator	Site	Study Group	Year of Study	Year Published	Sample size	Prevalence rate	Demographics (Predominance)
1	Sathiyakala R et al.	Kancheepuram, Tamil Nadu	Pregnant women	2014 – 2016	2017	1282	1.01%	26-30 yrs
2	Ray G	India	Review		2018	Pregnancy	0.9% - 1.1%	
						Hepatocellular carcinoma	43%	South India: 42% North India: 39-69% West India: 82%
						Children (<12 yrs)	4.3–7.2%	Contribution of vertical transmission
						PLHIV	0.2–8%	Kolkata: 11.3% - Mumbai: 16.7% Hyderabad: 15% Chennai: 79.9% Delhi: 5.3%
						Haemodialysis & renal transplant	5.2–18.7%	
						Injectable drug use	2.7–10.8%	
						Tribal	Up to 65%	
3	Kulandhai LT et al.	Chennai	Eye donors	2005 – 2017	2019	7136	1.09%	
4	Shanmugam RP et al.	Tamil Nadu	Population based	2014 - 2017	2018	18589	1.63%	Male Rural area

								Theni dist. (5.56%) Cuddalore dist. (3.3%)
5	Nanhi N et al.	Jammu and Kashmir	Hospital Based (Surgery)	2018	2019	9252	1.91%	
6	Modi GB et al.	Gujarat	Blood Bank	2015 – 2018	2019	3155	0.6%	Replacement donors (1.5%)
7	Sharma B et al.	Himachal Pradesh	Population Based	2015	2018	4231	22.8%	Hyperendemic area, Physical proximity to Tibet
8	Harsh P et al.	AIIMS, New Delhi	Inflammatory Bowel disease patients	2004 – 2016	2017	829	2.4%	Intestinal TB: 5.9%
9	Stevens K et al.	Bylakuppe, Karnataka	Tibetan refugees	2013	2016	2769	8.9%	Born in Tibet (12.4%) 30–59 yrs
10	Basak S et al.	Kolkata, West Bengal	Cornea donors	2011 – 2016	2017	4300	0.88%	
11	Patil SR et al.	Karad, Maharashtra	Hospital Based	2010 – 2012	2016	25193	1.87%	
12	Raaj A et al.	Chennai, Tamil Nadu	Pregnant Women	2010 – 2011	2016	2772	5.86%	21-25 yrs (Higher Prevalence compared to Countrywide mean)
13	Tiewsoh JBA et al.	Mangalore	HIV	2013 – 2015	2017	137	6.6%	
14	Khatoon R et al.	Sitapur, Uttar Pradesh	Hospital Based	2015 – 2016	2016	1537	3.9%	
15	Patel PH et al.	Valsad, Gujarat	Hospital Based	2015 – 2016	2016	11145	2.67%	21-30 yrs

16	Kondareddy S et al.	Nellore, Andhra Pradesh	Blood Bank	2013 – 2017	2018	11234	1.8%	
17	Dinesha TR et al.	Chennai, Tamil Nadu	High Risk Group	2009 – 2010	2018	1612	8.1%	Heterosexual risk: 2.3% Intravenous drug use: 10.2% HCV: 38.3%

Table 4 : Summary of recent Hepatitis C prevalence studies

Sl No.	Study Investigator	Site	Study Group	Year of Study	Year Published	Sample size	Prevalence rate	Demographics (Predominance)
1	Sood A et al.	Punjab	Population based	2013-14	2018	5543	3.6%	Male Rural area 40-49 yrs
2	Goel A et al.	India	Systematic Review and Meta-analysis		2019	Blood donors	0.44%	Mizoram 1.24% Punjab 1.24% Manipur 1.29%
						Pregnant women	0.88%	Punjab 2.06%
						PLHIV	3.51%	
						Injectable drug use	44.71%	
						Hemodialysis	19.23%	
						High risk behavior	4.06%	
						STI	4.10%	
3	Saini PA et al.	Indore, MP	Blood Bank	2011 - 2015	2017	58998	0.07%	31-40 years

4	Shanmugam RP et al.	Tamil Nadu	Population based	2014 - 2017	2018	18589	0.3%	Male Rural area Theni dist. (4.16%) Salem dist. (1.86%)
5	Nanhi N et al.	Jammu and Kashmir	Hospital Based (Surgery)	2018	2019	9252	1.05%	
6	Modi GB et al.	Gujarat	Blood Bank	2015 – 2018	2019	3155	0.32%	Replacement donors (0.7%)
7	Sarvaiya AN et al.	Gujarat	Blood Bank	2016	2017	1658	0.21%	
8	Roy P et al.	Pune, Maharashtra	Hemodialysis	2014	2019	250	18.8%`	
9	Ramya E et al.	Tamil Nadu	Irula Tribe community		2018	372	5.1%	Female, 31-40 yrs Tattooing, migrations and sexual promiscuity
10	Basak S et al.	Kolkata, West Bengal	Cornea donors	2011 – 2016	2017	4300	0.84%	
11	Barman B et al.	Meghalaya	Chronic Liver disease	2015 - 2016	2018	196	21.9%	
12	McFall Am et al.	Northeast India	People who Inject Drugs		2017	6457	30.4%	Longer injection duration, Sharing needles/syringes Larger PWID network
13	Tiewsoh JBA et al.	Mangalore	HIV	2013 – 2015	2017	137	0.7%	

PREVALENCE DATA OF RECENT TIMES -HAV and HEV

For the data on Hepatitis A and E, the outbreak data from Integrated Disease Surveillance Programme gives some sort of an estimate. The data is not indicative of any direction in the prevalence of either outbreak and or burden and probably a mix of surveillance function and outbreak burden, with detection capacity. The outbreaks, cases reported in the outbreaks, seasonality and state reporting are given in the following tables and charts.

Table 5 : Hepatitis outbreaks reported in IDSP by year (Jan 2016 to Dec 2018)		
Year	No. of outbreaks	Number of Hepatitis cases
2016	99	4569
2017	67	2317
2018	71	1972
Grand Total	237	8858
Source : Weekly outbreak data from IDSP, Government of India.		

Generally there is a decreasing trend, both in terms of number of outbreaks and the number of cases reported in these outbreaks.

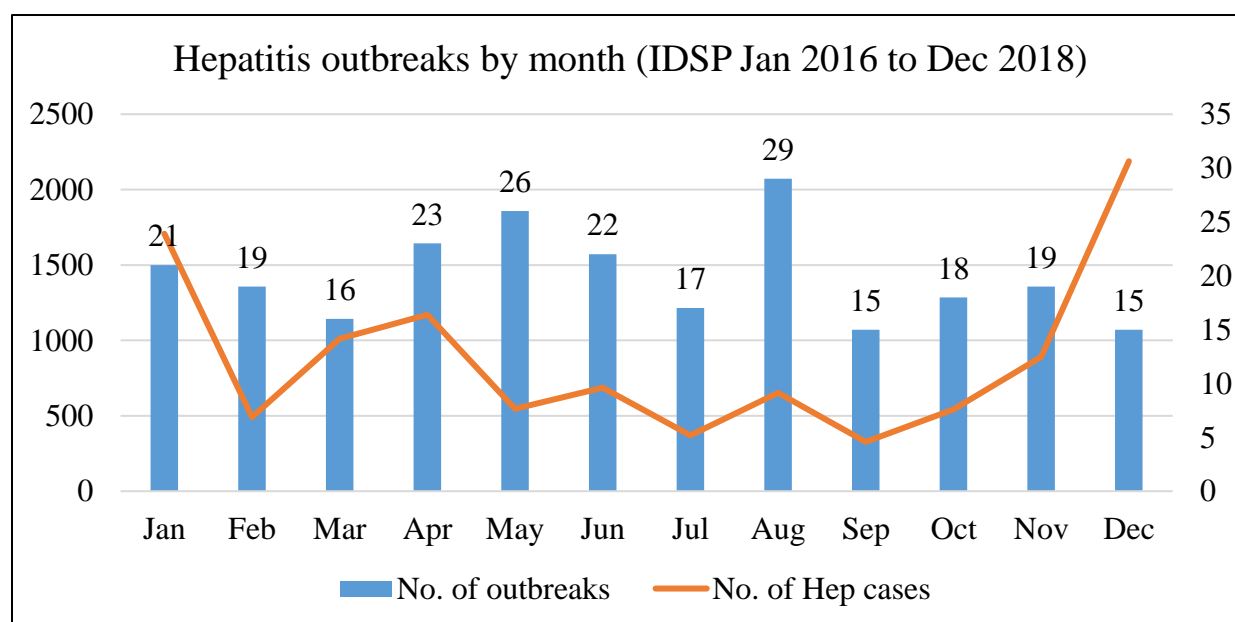


Figure 2: Seasonal trend of hepatitis outbreak in India -IDSP

Table 6 : Hepatitis outbreaks by month (IDSP Jan 2016 to Dec 2018)

Month	No. of outbreaks	Number of Hepatitis cases
Jan	21	1707
Feb	19	491
Mar	16	1012
Apr	23	1171
May	26	547
Jun	22	686
Jul	17	371
Aug	29	652
Sep	15	327
Oct	18	542
Nov	18	859
Dec	13	493
Grand Total	237	8858

Most of these outbreaks were jaundice or hepatitis outbreaks of A and E, wherever confirmed. Less than 5 outbreaks of HBV and HCV has been reported by the IDSP in the last 3 years. Overall May to August is the high season when most of the outbreaks are reported, roughly aligned to the monsoon season.

Table 7 : Hepatitis outbreaks by state (IDSP Jan 2016 to Dec 2018)

State	No. of outbreaks	Number of Hepatitis cases
Arunachal Pradesh	1	18
Assam	3	29
Bihar	2	102
Chandigarh	1	17
Chhattisgarh	4	245
Dadra and Nagar Haveli	1	22
Goa	1	13
Gujarat	29	1794
Haryana	2	100
Himachal Pradesh	2	611
Jammu & Kashmir	31	914
Jharkhand	1	25
Karnataka	10	167
Kerala	62	2268
Maharashtra	14	519
Madhya Pradesh	1	15

Odisha	29	644
Punjab	19	599
Rajasthan	6	199
Tamilnadu	8	155
Uttarakhand	7	172
Uttar Pradesh	2	163
West Bengal	1	67
Grand Total	237	8858

Most of the cases have been reported in these years by the states of Himachal Pradesh, Kerala, Gujarat, Jammu and Kashmir, Odisha, Punjab, Maharashtra, Chhattisgarh, Rajasthan and Karnataka. And, Kerala, Gujarat, Jammu and Kashmir, Odisha, Punjab, Maharashtra, Chhattisgarh, Rajasthan and Karnataka also reporting the maximum number of outbreak.

AGENDA MOVED FORWARD BY WHO

WHO and its partners have been able to advocate the right quarters and the programme is launched and under implementation, the latest being the national action plan that came into being in February 2019.

At a country level WHO has helped organize national and local awareness raising events, promoted by popular celebrities, such as celebration of World Hepatitis Day in India. WHO has engaged in policy dialogue and provided the direct technical support to undertake situation assessments, meta-analysis of existing seroprevalence studies for improved burden of disease estimations and cost-effectiveness studies on DAA and RUPs to inform the investments in HCV elimination, negotiate better DAA prices, develop decentralized service delivery models for hepatitis testing and treatment, strengthen of laboratory capacity and mobilize communities to act and demand for treatment.

WHO focal points have been created in India and used to support situation analysis, economic and operational research and capacity building. When the National viral hepatitis control programme was launched in July 2018, WHO country office contributed to the development of national guidelines for diagnosis and treatment and national training materials, based on WHO Global guidance.

CONCLUSIONS AND RECOMMENDATIONS

- I. The programme is geared to have its initial turf detecting HCV cases and treating them. Most of the HCV cases in the community being likely non icteric getting a grip over the same would be tricky, unless a large scale and sectoral high risk screening is offered and popularized and finally making knowledge of one's HCV/HBV status a popular aspiration. It adopted a hub and spoke model, the way Punjab programme is functioning, with 22 district hospital and 3 medical colleges and dishing out service delivery with screening, viral load testing, cbc and biochemical tests for fitness for administration of directly acting antivirals and treatment with follow up including viral load testing again and if necessary repetitively. Part of this is paid service, most of it being free. There are currently different models being fine tuned to get the best of fit.

As FIND is trying to find a way of making the whole thing a single package not making the care seekers cue up at different departments and care providers, and also trying to make follow up supply of drugs a predictable time bound affair in lines with the AIDS ART collectors. MSF is trying to bring down the cost of medicine by another 5 dollars per regimen using different procurement route for generics in UP and making spouse and community part of the client group to ensure long term care and follow up in Manipur. CHAI is trying to troubleshoot a lot tracking of the patients for follow up, incorporating each of the client screened and at the same time ensuring individual privacy, in a multimodal care and support set up including private operators like private laboratory for designated tests. FIND's Delhi model of 15 urban hospital with 3 feeder spoke is yet another model and apparently has the ability to capture more cases quickly and efficiently bringing the eligible under treatment.

It is to be seen whether the NVHCP is flexible enough to adopt and adapt from these operations research and capture more faster and effectively make a quick dent on the huge number of chronic cases and carrier.

- II. In India, the estimated burden of hepatitis is very high, necessitating focus on prevention and control measures to mitigate morbidity and mortality arising out of hepatitis. Hepatitis B vaccine was universalised nationwide in 2011, though a large number of states were pushing birth dose of HBV since 2008, following a Government order. The UIP schedule recommends hepatitis B birth dose to all infants within 24 hours, followed by three doses at 6, 10 and 14 weeks to complete the schedule. The NVHCP in its base line data accepted that, hepatitis-B birth dose coverage among the total live births was 45% in 2015 and 60% in 2016. Missed opportunity was about 40%. The coverage amongst institutional deliveries for Hepatitis -B birth dose was reported to be 76.36% as of December 2017. The actual coverage of HBV birth dose is about 70% in those born in Government facilities and less than 20% in the private ones, as per NPSP data. Poor communication on the immunization division, poor understanding of wastage restrictions and reluctance of health workers to open a vial of 10 dose vaccine

whenever a child is born in an institution, and lack of categoric surveillance for HBV birth dose missing in the fully immunized, all contributed to low coverage of HBV birth dose.⁴²

A facility based survey in Maharashtra found 40% of medical staff, 57% of medical staff working in Government institutes and 31% of medical staff working in Private institutes were aware that birth dose of hepatitis B should be given within 24 hours. Categorically, 44% hospital nurses, 35% of ANMs and 39% of medical doctors were aware Hepatitis B birth dose should be given within 24 hours of birth. In the absence of screening for newborn and care other than vaccine, adds to high chronicity and consequent load on the system for eliminating Hepatitis B. The programme does mention but currently there is no plan for adult HBV vaccination for high risk groups, health care workers and members of the larger populace.

There needs to be a way of increasing the birth dose of HBV in the Government facility as well as the private ones. NVHCP has to devise a way of ensuring this coverage handled currently by another line department which are likely placed higher in the hierarchy of public health officials. The programme propose to strengthen routine immunization services to achieve and sustain the desired coverage of the timely birth dose followed by three doses of hepatitis B vaccine; coordinate with the Universal immunization programme for mandatory immunization of all healthcare workers; and provision of vaccination for health care workers should be followed one month later by testing for protective hepatitis B antibody levels (anti HBs>10 IU/ml). This approach need to be implemented on the ground to provide protection to the healthcare workers against contracting hepatitis B accidentally, and also help detect and support the positive HCWs.

The IPEN study cited before, puts the number of injection use in India at 3 billion a year or 2.9 per person per year. 82.5% of this is for curative purposes and 63% of all unsafe. NVHCP recognize that, unsafe health care practices by health care providers/ traditional healers/ quacks pose a major challenge and risk for transmission of HBV and HCV and that there are gaps in implementation of bio-medical waste management rules, leading to sharps injuries and increased risk of infections. It propose to roll out re-use prevention (RUP) syringes, addressing prescriber practices with adequate concessions to community preference for injections while respecting the socio-cultural practices like tattooing, religious ceremonies (e.g. mundans), ear/body piercing etc. However, recently NACO has come out openly in favour of screening and banning the non compliant tattoo outlets for ensuring safety.

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42. Chandrakant Lahariya, B. P. Subramanya, Stephen Sosler : An Assessment of Hepatitis B Vaccine Introduction in India: Lessons for Roll out and Scale up of New Vaccines in Immunization Programs. Indian Journal of Public Health, Volume 57, Issue 1, January-March, 2013.

The programme recognize the importance of moving on to safety engineered syringes and Reuse Preventable syringes and needles. WHO has done quite a bit in advocating its importance and the Government of Punjab has now adopted the policy of moving for a full scale switch for health care injections in all Government facilities by RUP only. The same is not palpable in the programme yet, notwithstanding the Government adopted National Patient Safety implementation framework (2018-2025) and India Injection Safety Implementation Project 2016-18.

In its demonstration project on switch over to RUP in the Government health sector, led by WHO, Punjab adopted a resolute stand on the same in July 2016. As of early 2019 it is still to reach full switch. The cost difference between AD syringes and for that matter disposable syringes and RUP or SIP syringes is less than 20-40% and likely to become more even as the volumes go up and the manufacturers and facilities are all domestic.

- III.** Targeted Interventions (TI) for key and bridge populations had been a core prevention strategy under NACP, NVHCP propose to adopt the same approach in targeting the people who inject drugs (PWID) in India. Currently needle syringe exchange program and opioid substitution therapy are provided for prevention of HIV among PWID. The programme propose to coordinate with NACP for including prevention/management of hepatitis B and C in the package of prevention services for the key and bridge population. Work in this area would not only involve NACP but also a host of NGOs currently working in the sector. Strategies need to be devised, as the states affected may not be the ones with strong SACs and a lot needs to be done to go beyond traditional HIV HRGs.

There are some disturbing figures regarding the prevalence of HBV/HCV in the PWID. Some of the work done by organizations like BMGF and MSF in Manipur report very high prevalence. Also these entities have brought in collaborations and community rooted initiatives like Community Network for Empowerment and their success in bringing in the affected under care and support. WHO can play a stellar role in bringing in the best practices from such experiences and help the programme steer in the right direction.

- IV.** In addition to the key population under NACP, there are other focus groups that need to be attended to under the NVHCP. These focus groups include close first degree relatives and family members of infected person: mother, siblings, spouse and children. The other populations for both hepatitis B and C include those who have received blood or blood products specially before implementation of hepatitis C testing at a large scale in India; i.e. before 2001, recipients of multiple blood transfusion, person exposed to unsafe injection practices by informal health care providers, etc. Identification of hot spots of hepatitis B and C should also be one of the priorities of the NVHCP. A lot needs to be done to cover the PLHIV, groups of people needing blood and blood

products like the haemophiliacs and the thalassaemics, or those undergoing dialysis. With the more than a million blood units and a close number of donors in the country having a HBV-HCV combined prevalence of more than 1% makes this task daunting. It is also noteworthy that this prevalence data comes from different blood banks testing HBV and HCV prevalence by different laboratory test, not all of them using the more sensitive NAT, which is also expensive in comparison. Specific strategy needs to be drawn to popularize voluntary testing and treatment seeking for HBV and HCV.

As for others, NVHCP has recognized the especially vulnerable group of prison inmates and their high prevalence of HCV and other body fluid transmitted infections. The initiative to bring in HIV Target Intervention approach for jail inmates has given rich dividends and the NVHCP plans to collaborate with NACP on implementation of its HCV control in the same go, together. But exact modalities need to be drawn, including shared areas of work, support systems for surveillance and treatment needs to be strategized.

- V. The prevalence of HBV/HCV is higher in the tribal and indigenous groups, both due to their genetic make-up and specific cultural and social attributes. The number of blood dyscrasia and haemoglobinopathies are also a larger burden on this population. Added to this is the lack of access to the tribal population because of the backwardness and inadequacy of the health facilities accessible to them. The role of Equity in WHO activities including that on ensuring access to the disadvantaged population in Hepatitis control is of added importance. It's one area where the NVHCP has not devised a strategic approach yet and WHO can build up a consensus for the same and ultimately ensure that the most disadvantaged get the benefit the care and support of a dedicated programme.
- VI. The NVHCP has proposed to work with IDSP to enhance and streamline outbreak reports of viral hepatitis. This is a voluminous task add to our knowledge of burden of Hep A and E in the country. The exact strategy is not clear in the guideline and calls for a review of existing reporting system of IDSP for hepatitis outbreaks as well as indicator and now case based reporting on the same as well. The data that NVHCP is going to collect through its M& E system is also going to be entrusted to IDSP for analysis. Unless there is specific strategies worked out and additional programme inputs placed, there is no reason to expect a result better than what IDSP has contributed towards the burden estimate and transmission dynamics of viral hepatitis. WHO has great role to play in this area and set the path right from the beginning.

Surveillance is crucial not only for programme management but also aid and help operational research in the area. The scenario of viral hepatitis control is an emerging one, with newer diagnostics, therapeutics and programme management models still being worked into. It would be absolutely essential to make the TRG and the supporting institutions be a support for the programme in detecting problems early, in finding out

and selecting interventions in time and in a manner to suit the finances available for maximizing benefits. WHO is now overall establishing its leadership in science in its work areas, and this can be one of its regular engagement area.

- VII.** Currently the NVHCP has a secretariat with 3 regular personnel and 2 consultants supporting the programme in implementation. The programme is acutely aware of its inadequacy as the programme is rolled out in all its components spread across all 36 States and Union Territories. The programme unit is acutely aware of this inadequacy and sought for more hands to run the programme as well as continued technical support. Providing technical and logistic support is crucial, and WHO can avail this opportunity to place personnel in running the NVHCP to render technical and managerial support.

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