



REPORT NO.

119

**PARLIAMENT OF INDIA
RAJYA SABHA**

**DEPARTMENT-RELATED PARLIAMENTARY STANDING
COMMITTEE ON HEALTH AND FAMILY WELFARE**

ONE HUNDRED AND NINETEENTH REPORT

On

DEMANDS FOR GRANTS 2020-21 (DEMAND NO. 43)

OF THE

DEPARTMENT OF HEALTH RESEARCH

(Ministry of Health and Family Welfare)

(Presented to the Rajya Sabha on 3rd March, 2020)

(Laid on the Table of Lok Sabha on 3rd March, 2020)



**Rajya Sabha Secretariat, New Delhi
March, 2020/ Phalguna, 1941 (SAKA)**

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सत्यमेव जयते

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March, 2020/ Phalguna, 1941 (SAKA)**

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* to be appended at the printing stage

COMPOSITION OF THE COMMITTEE
(2019-20)

1. Prof. Ram Gopal Yadav - **Chairman**

RAJYA SABHA

2. Shri A.K. Antony
3. Dr. L. Hanumanthaiah
4. Shrimati Kahkashan Perween
5. Shri Suresh Prabhu
6. Dr. Santanu Sen
7. *Vacant
8. Shri K. Somaprasad
9. Dr. Subramanian Swamy
10. Shrimati Sampatiya Uikey

LOK SABHA

11. *Vacant
12. Ms. Bhavana Gawali (Patil)
13. Ms. Ramya Haridas
14. Dr. Chandra Sen Jadon
15. Shrimati Malothu Kavitha
16. Shri P. K. Kunhalikutty
17. Dr. Sanghamitra Maurya
18. Shri Arjunlal Meena
19. Shrimati Pratima Mondal
20. Dr. Pritam Gopinath Munde
21. Dr. Mahendrabhai Kalubhai Munjpara
22. Dr. Bharati Pravin Pawar
23. Adv. Adoor Prakash
24. Shri Haji Fazlur Rehman
25. Dr. Rajdeep Roy
26. Dr. Subhas Sarkar
27. Shri D. N. V. Senthilkumar S.
28. Shri Anurag Sharma
29. Dr. Mahesh Sharma
30. Dr. Sujay Radhakrishna Vikhepatil
31. Dr. Krishna Pal Singh Yadav

SECRETARIAT

Shri P.P.K. Ramacharyulu	Secretary
Shri J. Sundriyal	Joint Secretary
Shri V.S.P.Singh	Director
Shri Bhupendra Bhaskar	Additional Director
Shrimati Harshita Shankar	Under Secretary
Shri Rajesh Kumar Sharma	Assistant Committee Officer
Ms. Monika Garbyal	Assistant Committee Officer
Shri Parth Gupta	Assistant Research Officer

(i)

* Shri Udayanraje Pratapsingh Bhonsle, Member resigned from the membership of the Lok Sabha w.e.f 14th September, 2019.

* Chaudhary Birender Singh, Member resigned from the membership from the Rajya Sabha w.e.f 20th January, 2020

PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, hereby present this 119th Report of the Committee on the Demands for Grants for the year 2020-21 (Demand No. 43) of the Department of Health Research, Ministry of Health and Family Welfare.

2. The Committee, in its meeting, held on 13th February, 2020 examined the detailed Demands for Grants (2020-21) of the Department of Health Research and heard the Secretary (Health Research) and other Officers thereon.

3. The Committee while making its observations/recommendations has mainly relied upon the following documents:—

- (i) Detailed Demands for Grants of the Department of Health Research for the year 2020-21;
- (ii) Annual Report of the Department for the year 2019-20;
- (iii) Detailed Explanatory Note on Demands for Grants of the Department of Health Research for the year 2020-21;
- (iv) Output-outcome monitoring framework for CS & CSS scheme with outlays less than 500 crore during 2020-21;
- (v) Projection of outlays for the schemes to be undertaken by the Department during the Financial Year 2020-21;
- (vi) Written replies furnished by the Department to the Questionnaires sent to them by the Secretariat; and
- (vii) Presentation made by the Secretary (Department of Health Research) and other concerned officers.

4. The Committee, in its meeting held on 2nd March, 2020, considered the Draft Report and adopted the same.

5. For facility of reference and convenience, observations and recommendations of the Committee have been printed in bold letters in the body of the Report.

NEW DELHI
March 3rd 2020
Phalguna 13, 1941 (Saka)

Prof. Ram Gopal Yadav
Chairman,
Department-related Parliamentary Standing Committee on
Health and Family Welfare

CHAPTER I

INTRODUCTION

1.1 The Department of Health Research (DHR) was created on the 17th September, 2007 as a separate Department within the Ministry of Health & Family Welfare by an amendment to the Government of India (Allocation of Business) Rules, 1961, however, the Department became functional from November 2008. The aim of the DHR is to bring forth modern health technologies for the people through research activities and innovations related to diagnosis, treatment methods and vaccines for prevention; to translate clinical trials and operational research into processes and products and to forge synergy with organizations concerned and introduce these innovations into public health system.

1.2 Mandate of DHR

1.2.1 The Department of Health Research has been allocated the following functions:

(i) Promotion and co-ordination of basic, applied and clinical research including clinical trials and operational research in areas related to medical, health, biomedical and medical profession and education through development of infrastructure, manpower and skills in cutting edge areas and management of related information thereto.

(ii) Promote and provide guidance on research governance issues, including ethical issues in medical and health research

(iii) Inter-sectoral coordination and promotion of public – private – partnership in medical, biomedical and health research related areas

(iv) Advance training in research areas concerning medicine and health, including grant of fellowships for such training in India and abroad

(v) International co-cooperation in medical and health research, including work related to international conferences in related areas in India and abroad.

(vi) Technical support for dealing with epidemics and natural calamities.

(vii) Investigation of outbreaks due to new and exotic agents and development of tools for prevention.

(viii) Matters relating to scientific societies and associations, charitable and religious endowments in medicine and health research areas.

(ix) Coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department and for the promotion of special studies in medicine and health.

(x) Administering and monitoring of Indian Council of Medical Research (ICMR).

1.2.3 The Committee takes into account the cherished objectives of setting up of Department of Health Research for translating modern health technologies and

innovations into public health system through in-depth research and investigation pertaining to diagnosis treatment methods and transforming the same into the products. The Committee believes that the Department would perform its enshrined functions and responsibilities through Management by Objectives (MBO) and not merely through Management by Activities (MBA). The Committee, however, recommends that the Department must keep on evaluating its performance vis-a-vis entrusted responsibilities and introduce organisational interventions for substantial performance improvement in order to accomplish its set vision and mission.

1.3 With a view to fulfil its mandate, the DHR had formulated following new schemes which had been rolled out in 2013-14.

(i) Establishment of Network of Research Laboratories for Managing Epidemics and Natural Calamities (VRDL)

1.3.1 In order to enhance the capacity for early identification and diagnosis of all viral infection, the Department of Health Research launched the scheme of establishment of network of Viral Research & Diagnostic Laboratories (VRDLs). The scheme is in the mid phase for setting up of new VRDLs and creating high quality systems for existing /re-emerging viral pathogens at an early stage and prevent spreading of epidemics. During the 14th Finance Commission, a network of 106 functional VRDLs has been laid down. It is now proposed to strengthen this network by augmenting the quality parameters for consistent, reliable and high-quality diagnosis; initiate event-based surveillance for fast detection of outbreaks; strengthen coordination of VRDLs with the State public health system, Integrated Disease Surveillance Program (IDSP) and National Vector Borne Disease Control Program (NVBDCP); initiate structured research projects which could translate into information for drafting/refining public health policies.

(ii) Establishment of Multidisciplinary Research Units (MRUs) in Govt. Medical Colleges

1.3.2 To promote and encourage quality medical research in the country and provide assistance to medical colleges to set up appropriate research facilities, the Department of Health Research rolled out the MRU scheme in the year 2013-14 during 12th Five Year Plan and was extended for the 14th Finance Commission period i.e. 2017-18 to 2019-20 with total estimated cost of the project of Rs. 394.86 crores. The Government has further extended the scheme for 2020-21. The scheme aims to provide infrastructural support, in terms of civil works, equipment and recurring expenditure, to carryout research focussed on non-communicable diseases to various State Government Medical Colleges across the country in phased manner.

(iii) Establishment of Model Rural Health Research Units (MRHRUs) in States.

1.3.3 Keeping in view a gap that exists between Primary Health Centre and CHC and tertiary care hospitals with state-of-art facilities created by the Centre and also by some of the State Government, the Department of Health Research has rolled out a scheme for Establishment or Model Rural Health Research Units (MRHRUs) in the States under the initiative of infrastructure development of health research in the country. The MRHRU will be an interface between patient, health providers and health researcher to provide latest/sophisticated technology for diagnosis and management of disease in rural areas. The activity will be entirely supported by DHR for its sustenance. In total, 25 MRHRUs are to be established during the 14th Finance

Commission period. Each MRHRU has to be linked to the nearest ICMR institute to mentor and guide the research activities of MRHRU relevant to local needs.

(iv) **Human Resource Development (HRD) for Health Research**

1.3.4 The Human Resource Development Scheme of Department of Health Research is intended to create a pool of talented health research personnel in the country by upgrading skills of faculty of Medical Colleges/Institutes, mid-career Scientists, medical students, etc., by specialized training in priority areas of health research in leading national and international institutions, encourage and support the trainees to develop and take up research projects for addressing critical national and local health problems and financial assistance to institutions for up-gradation of infrastructure to enable such institutions to provide training with state of art technologies.

(v) **Grants in Aid Scheme (GIA) for inter-sectoral convergence & promotion and guidance on research governance issues.**

1.3.5 The scheme launched during 2013-14 aims at providing support in the form of grant-in-aid for carrying out research studies to identify the existing knowledge gap and to translate the existing health leads into deliverable products. There will be special focus on encouraging innovation, their translation and implementation by collaboration and cooperation with other agencies by laying special stress on implementation research so that there is a better utilization of available knowledge.

1.3.6 The scheme was originally approved by Cabinet Committee on Economic Affairs (CCEA) on 6th February, 2014 at a total cost of Rs. 1242 crore for the 12th Plan period. Continuation of the scheme beyond 12th Plan period, from 2017-18 to 2019-20 was approved on 18th September, 2017 at a total estimated cost of Rs. 297.08 crore.

New Initiatives of Department of Health Research

1.4 Annual Report (2019-20) of the Department mentions the following initiatives of the Department of Health Research:-

(i) **Preparation of standard treatment workflow**

1.4.1 Standard treatment workflow (STW) for 53 common and serious medical and surgical conditions had been prepared that entails simple, self-explanatory treatment algorithms. STW comprises of symptoms, signs, diagnostics, treatment etc. for concerned diseases. A dissemination strategy is being planned for putting these up in all Medical Colleges, District Hospitals, Primary Healthcare Centres across the country for the benefits of medical practitioners. The Committee was informed that a high-level stakeholders meeting was organized in January which was attended by NITI Aayog, Department of Health and Family Welfare, WHO, UNICEF and a few identified States.

(ii) **National List of Essential Medicines (NLEM)**

1.4.2 The Secretariat of the Standing national Committee on Medicines and other Health Care Products (SNCM) is housed by the DHR. The core Committee, through a series of meetings and consultations with experts from across the country deliberates and revises the National List of

Essential Medicines (NLEM) from time to time. DHR provides administrative and IT support to the SNCM. Medicines in NLEM are categorised according to the therapeutic class and listed with doses forms and references to the levels of healthcare, namely, Primary (P), Secondary (S) and Tertiary (T).

(iii) **The India-TB Research Consortium:**

1.4.3 ICMR took a lead and initiated a new flagship Programme to establish India TB research and development Consortium that aims to bring together all major national players (with international collaborators) to address overarching scientific questions to tackle TB in a mission mode. Different trials in the area of TB drugs and vaccine have been initiated. It is proposed to coordinate and monitor the activities at the Department of health Research to ensure effective and timely completion of the project for TB Elimination by 2025.

1.5 Establishment Expenditure of the Centre (Secretariat)

(In crores)

	Actual 2018-19	BE 2019-2020	RE 2019-2020	BE 2020-21
Revenue Allocation	25.43	38.00	38.00	42.00

1.5.1 Notes on Demands for Grants (2020-21) mentions the provision for Secretariat expenditure of the Department of Health Research. The actual revenue/establishment expenditure was to the tune of Rs.25.43 crore in 2018-19 that increased to Rs.38.00 crore in 2019-20 and is estimated to Rs.42.00 crore in BE 2020-21. The major increase in allocation in 2019-20 and 2020-21 over the allocation for 2018-19 is on account of provision of payment of rent in respect of the additional floor hired by the Department in the Indian Red Cross Society Building to accommodate the additional staff and normative increase in office expenses and other heads due to increase in its activities and taking up of new initiatives, like Health Technology Assessment, Standard Treatment Workflows, work relating to Surrogacy (Regulation) Bill, National List Essential Medicines (NLEM), National Ethics Committee Registry for Biomedical and Health Research, etc.

1.5.2 The Committee sought to know the economic measures being taken by the Department to rationalize the revenue expenditure and the outcome of the measures so undertaken. Responding to that the Department mentioned that various economic measures taken by the Department to rationalise the revenue expenditure includes streamlining and complementing the working between the Department of Health Research and ICMR in respect of certain important areas of functioning, making all procurements through GeM Portal, implementation of e-Governance system like development of Dashboard for review of projects, implementation of Direct Beneficiary Module (DBT) and making use of computerized portal for receipt and processing of proposals under the various schemes.

1.5.3 The Committee is in agreement with the provision for the Secretariat which is recurring revenue expenditure. The Committee also appreciates the operating mechanism of the Department i.e. adherence to modern accounting practice; adoption of the technological and advancement/development for rationalizing the revenue expenditure under the Head ‘Secretariat’ and ensuring a transparent system.

1.5.4 The Committee sought to know about the existing strength of Human Resource in the Department and whether the in position strength against the sanctioned strength in the Department is sufficient for meeting the functional requirement of the Department, the DHR informed the Committee that out of the total sanctioned strength of 42 regular posts, 23 posts are vacant. The work of the Department is, therefore, largely met by way of engaging about 100 contractual employees at all levels, viz. administrative and technical (scientific). To fulfil its mandate, the Department has rolled out 05 schemes. Over the years, the activities of the Department have increased significantly. Apart from the above activities, presently the Department is also looking after (i) Health Technology Assessment, (ii) Standard Treatment Workflow, (iii) National List of Essential Medicines, (iv) India TB Research Consortium, etc.

1.5.5 While the work of the Department has increased tremendously, the manpower requirement has not been commensurately met. As a result, there is a big gap between the activities being discharged by the Department and the availability of manpower. The work of the Department is, therefore, largely met by way of engaging contractual employees at all levels, viz. administrative and technical (scientific). The issue of filling up of the vacant sanctioned slots is under consideration in consultation with the M/o Health & Family Welfare and the DoPT.

1.5.6 The Committee observes that the Department of Health Research has been entrusted vital responsibilities that need to be accompanied by adequate, efficient and effective staff and professionals in order to carry out those responsibilities. The Committee, therefore, recommends the Department to evaluate and assess the requirement of human resources and project the requisite budgetary allocation to meet the revenue expenditure in consonance with requirement of manpower.

CHAPTER II

MACRO- ANALYSIS OF BUDGETARY ALLOCATION TO THE DHR

(DEMAND NO. 43)

2.1 The Committee observes that the actual Gross Revenue outlay for the Department of Health Research during the year 2018-19 was to the tune of Rs.3175.73 crore, having a component of Rs.1447.85 crore as recoveries from National Investment Fund (NIF). Out of the total outlay for the Department of Health Research in 2018-19, Ministry of Finance had indicated to the Department of Health Research that the entire allocation for ICMR would be met from the proceeds of National Investment Fund. Hence, certain adjustment heads were opened like “**Inter Account Transfer**” and “**Recoveries from NIF**” with the approval of Ministry of Finance and Controller General of Accounts. These are only adjustment entries without involving any financial implications. Net actual revenue expenditure was **Rs. 1727.88 crore** (Rs. 3175.73 – Rs. 1447.85) i.e. adjustment of NIF recoveries from gross outlay.

(In Crores)

	Actual 2018-19	Budget 2019-20	Revised 2019-20	Budget 2020-21
Gross	3175.73	3374.65	1950.00	2100.00
Recoveries	-1447.85	-1474.65	-	-
Receipts	-	-	-	-
Net	1727.88	1900.00	1950.00	2100.00

2.1.1 The Committee notes that the Gross Revenue outlay for the Department in BE 2019-20 was to the tune of Rs.3374.65 crore with component of Rs.1474.65 crore as recoveries and Rs.1900.00 crore as budgetary allocation. This budgetary allocation was however, enhanced to Rs.1950.00 crore at RE stage. The DHR apprised the Committee that the budgetary allocation in 2019-20 has been increased from the BE provision of Rs.1900.00 crore to RE provision of Rs.1950 crore for meeting additional requirements of ICMR towards funding of various research activities like Research Support for Diseases identified for Elimination (Fast-tracking TB elimination, Strengthening Malaria Elimination Efforts); Indian Cancer Research Consortium and Bio-bank Facility, etc. The DHR was indicated by the Ministry of Finance that there would be no allocation for Department of Health Research under NIF in RE 2019-20 and, therefore, there will be no recoveries from National Investment Fund (NIF) and the Net Outlay will be of Rs.1950.00 crore.

2.1.2 The Committee desired to know the reasons for variation in Revenue outlay in BE 2020-21 that amount to Rs.2100.00 crore in comparison to Rs.1950.00 crore in RE 2019-20 and why the amount of recoveries from NIF has not been indicated in BE 2020-21. The Department replied that the enhanced allocation of Rs.2100.00 crore in BE 2020-21 in comparison to the RE 2019-20 allocation of Rs.1950.00 cores is to meet the additional requirements for schemes of DHR and ICMR as follows:

Component	RE 2019-20	BE 2020-21
Secretariat Expenditure	38.00	42.00
Schemes	230.00	262.39
ICMR	1552.22	1795.71
Bhopal Memorial Hospital & Research Centre (BMHRC)	129.78	-
Total	1950.00	2100.00

2.1.3 No provision has been made under the Head “Recoveries from NIF” both under RE 2019-20 and BE 2020-21.

2.1.4 To a query as regards the reasons for budgetary allocation only for revenue expenditure and not for capital expenditure, the Department responded that presently, no separate Head of Account for “Capital Outlay” has been created for the Department of Health Research since it is not incurring any departmental expenditure to acquire, upgrade, and maintain physical assets such as property, buildings, plant& machinery and high value equipment. The entire expenditure on schemes as well as for the ICMR and Bhopal Memorial Hospital & Research Centre is being met by release of grants to the concerned agencies and there is already a separate head of account “Grant for Creation of Capital Assets” under Revenue Head for the ICMR, as per the normal practice.

2.1.5 The Committee finds that marginal increase in the budgetary allocation to DHR during the last two years is not commensurate with the responsibilities entrusted to the Department to deal with the magnitude and incidence of diseases in the country and considerable amount of fund required to broadbase the research activities which facilitates the policy maker to formulate health policy in the right direction. The outcome of the health research also support the executive to sketch suitable strategy in combating the health challenges. The Committee, therefore, recommends higher budgetary allocation to DHR to achieve the set objective missions enshrined in National Health Mission and National Health Policy, 2017. The Committee, in this regard, lend its support to DHR to approach the Ministry of Finance for seeking higher budgetary allocation at the RE stage for promoting health and well being of the people of the country.

2.2 During the discussion on Demands for Grants on 13th February, 2020, the Chairman of the Committee sought to know the justification behind projected demand, the adequacy of actual allocation 2020-21 and the way out to meet the requirement of the schemes/projects/institutions of DHR. Responding to that DHR formulated its reply on the basis of the following information:-

Projected demand and actual allocation in BE 2020-21

Rs.in crores			
Component	Projected Demand	Allocation in BE 2020-21	Shortfall
Schemes	305.50	262.29	43.21
ICMR	2300.00	1795.71	669.51
Bhopal Memorial Hospital & Research Centre (BMHRC)	165.22		
Total ICMR+BMHRC	2465.22		
DHR Sectt Expenditure	42.00	42.00	0.00
Grand Total	2812.72	2100.00	712.72

2.2.1 It was informed that the shortfall in allocations under the schemes would affect the establishment of new Viral Research & Diagnostic Laboratories; Multi Disciplinary Research Units in Medical Colleges (MRUs) ,Model Rural Health Research Units (MRHRUs) in States and funding of projects under the schemes of Human Resource & Capacity Development.

Projected demand and actual allocation in RE 2019-20 & BE 2020-21 in respect of ICMR

(Rs. In Cr.)			
	Projected Demands	Actual Allocation	Shortfall
2019-20 RE	1861.83	1552.22	309.61
*2020-21 BE	2465.22	1,795.71	669.51
Rs.2300 Cr. : ICMR			
Rs.165.22 Cr. :BMHRC			
*for 2020-21 BMHRC has been merged with ICMR.			

2.2.2 More funds were demanded at RE stage (2019-20) for following activities:

Priority Projects in pipelines:

S. No.	Major Programs	Amount
		(Rs. In Cr.)
1	Managing outbreaks/Epidemics/Research on emerging/re-emerging infections like ZIKA, NIPAH, Dengue, etc. (Strengthening National Health Security)	30.00
2	Aligning Research Support to Ayushman Bharat: Cost-effective technologies Treatment and Management algorithms Essential Medicines(Supporting National Health Systems)	35.00
3	Research Support for Diseases identified for Elimination Fast-tracking TB elimination (Steer forward the activities of India TB Research Consortium)	40.00
4	Establishment of Medical Device Mission Secretariat (MDMS) and Innovation and Translational Research	30.00
5	Fight against Double Burden of Malnutrition and anemia	20.00
6	Mission Mode Medical Research to address Health needs of Tribal Areas	25.00
7	Indian Cancer Research Consortium	20.00
8	New Areas of Medicine	20.00
9	Bio-bank Facility	30.00
	Total	250.00

2.2.3 On the basis of allocation of Rs.1552.22 Cr. for the year 2019-20 at RE stage, funds will be used proportionately in respect of aforesaid activities. The Department has argued that the funds allocated for the year 2020-21 are not sufficient to meet research requirements meant for the year 2020-21. A number of research projects will suffer due to shortfalls. Details of projects which will suffer are as under:

S. No.	Major Programs	Amount
		(Rs. In Cr.)
1	Medical Device Mission Secretariat to be set up at IITs	150.00
2	India Cancer Research Consortium	50.00

3	Assistive Technologies Centres with AIIMS and IITs	120.00
4	Malaria Elimination Research Alliance	28.00
5	National Data Quality Forum	15.00
6	Triple Drug for Lymphatic Filariasis	27.00
7	India TB Research Consortium	100.00
8	Vector Borne Diseases like Dengue, Chikungunya	25.00
9	Clinical Trial Registry of India	55.00
10	Outbreak / Epidemic Investigations	27.00
11	Nutrition Related Programmes (double burden of malnutrition and anemia)	65.00
12	Technological Innovations (Shigella Vaccine, Hepatitis E Virus, Chandipura Virus IGM ELISA etc)	25.00
	Total	687.00

2.2.4 The Committee expresses its deep concern over lower budgetary allocation during 2020-21 vis-à-vis projected demands under various components of DHR schemes/ICMR. Against the projected demand of Rs. 305.50 crore over various schemes, the actual allocation in BE 2020-21 is to the tune of Rs. 262.29 crore thus leaving a shortfall of Rs. 43.21 crore. Similarly against the projected demand of ICMR and BHMRC to the tune of Rs. 2465.22 crore, actual allocation in BE 2020-21 is to the tune of Rs. 1795.71 crore thus leaving a considerable budgetary gap of Rs. 669.51 crore. Only the revenue outlay to the tune of Rs. 42.00 crore for the DHR Secretariat expenditure is as per the projected demand. Thus as a whole, against the projected demand of Rs. 2812.72 crore only Rs. 2100.00 crore in BE 2020-21 has been earmarked for DHR thus there is huge financial gap of Rs. 712.72 crore. The shortfall in allocations under the schemes would sever impact the establishment of new Viral Research & Diagnostic Laboratories; Multi Disciplinary Research Units in Medical Colleges (MRUs), Model Rural Health Research Units (MRHRUs) in States and funding of projects under the schemes of Human Resource & Capacity Development. Similarly, shortfall of Rs. 669.51 crore in BE 2020-21 in respect of ICMR would affect the number of research projects which inter-alia includes Medical Device Mission Secretariat to be set up at IITs, assistive Technologies Centres with AIIMS and IITs, India Cancer Research Consortium, India TB Research Consortium, Nutrition Related Programmes, Technological Innovations, Vector Borne Disease like Dengue and Chikungunya, etc. The Committee laments inadequate budgetary allocations to DHR meant for the financial year 2020-21.

Comparative Position of allocations for Health Research vis-a-vis other Scientific Departments

2.3 The Committee has been apprised about the comparative budgetary allocation to DHR viz-a-viz other scientific departments which are as under:-

<i>Rs. in crores</i>	
S&T Departments	Allocation in BE 2019-20
Department of Agriculture Research & Education (DARE)	8079
Department of Science & Technology (DST)	5580
Department of Scientific & Industrial Research (DSIR)	4896

Department of Biotechnology (DBT)	2580
Ministry of Earth Sciences (MoES)	1901
Department of Health Research (DHR)	1900

2.3.1 The Committee understands that Department of Health Research, mainly through the Indian Council of Medical Research (ICMR) and its 26 research institutes engaged in promoting health research and innovations in the priority areas of national health, by way of strengthening health research infrastructure and human resource and capacity development programs/activities across the country. However, the Committee is constrained to express its concern that the allocations for Health Research have been lowest compared to the allocations for similar departments engaged in R&D activities.

2.3.2 The Committee would like to draw the attention of Government to enhancement in allocations of DHR, ICMR endorsed by General Council of NITI Ayog in its meeting on 15th June, 2019 chaired by Honble Prime Minister. The relevant recommendation is reproduced below:-

“While appreciating that the actual expenditure of the Department of Health Research including Indian Council of Medical Research (ICMR) has been consistently growing for the last 10 years, the Committee are disheartened to note that the allocation of budget on health research works out to be 2.3 per cent only, i.e. allocation of Rs.1800 crore out of the total allocation of RS.77,069 crores for the Ministry of Health and Family Welfare. As such, the Committee recommend that allocation on health research may suitably be enhanced so that the R&D on health sector do not suffer for want of money thereby furthering the prospects of women participation in Research and Development activities of Health and Family Welfare.”

2.3.3 The Committee, is in agreement with the recommendation of General Council of NITI Aayog that Central outlay on health research needs be suitably increased for meeting the national health priorities and development of new technologies, diagnostics and treatments including development of new vaccines, etc.

Utilisation of fund earmarked during 2019-20

2.4 The DHR informed the Committee about the utilization of fund against the allocation made during 2019-20 which is enumerated below:-

Statement indicating the allocations made in 2019-20 and utilisation

<i>Rs. in Crores</i>						
Sl.No.	Scheme/Programme	BE 2019-20	RE 2019-20	Cumulative expr. upto <u>10.02.2020</u>	% of expr in respect of BE	% of expr in respect of RE
1.	Establishment of Network of Viral Diagnostic & Research Laboratories for Managing Epidemics.	80.00	73.00	59.21	74.01%	81.11%

	Separate Budget line “Development of Tools to prevent outbreaks of epidemics”	7.35	6.00	6.00	81.63%	100.00%
2.	Establishment of Multidisciplinary Research Units (MRUs) in Govt. Medical Colleges.	58.00	55.00	42.05	72.50%	76.45%
3.	Establishment of Model Rural Health Research Units (MRHRUs) in the States	15.00	19.00	9.43	62.87%	49.63%
4.	Human Resource Development for Health Research	33.00	30.00	26.56	80.72%	87.74%
5.	Grant-in-aid Scheme for inter-sectoral convergence and Coordination for Promotion & Guidance on Health Research	28.00	18.00	15.58	55.64%	86.56%
6.	Research Governance	25.00	23.00	20.18	80.72%	87.74%
7.	International Cooperation	1.00	6.00	0.38	38.00%	6.33%
<i>Total of DHR Schemes (A)</i>		<i>247.35</i>	<i>230.00</i>	<i>179.39</i>	<i>72.52%</i>	<i>78.00%</i>
8.	Indian Council of Medical Research (ICMR)	1474.65	1552.22	1474.65	100.00%	95.00%
9.	Bhopal Memorial Hospital & Research Centre, Bhopal (BMHRC)	140.00	129.78	129.79	92.70%	100.00%
<i>Total (ICMR+BMHRC) (B)</i>		<i>1614.65</i>	<i>1682.00</i>	<i>1604.43</i>	<i>99.37%</i>	<i>95.39%</i>
10.	Secretariat Expenditure (C)	38.00	38.00	17.76	46.74%	46.74%
Total (A+B+C)		1900.00	1950.00	1801.58	94.82%	92.39%

2.4.1 The Committee is perturbed to observe under utilization of allocated funds by DHR which reflects weakened absorption capacity of implementing agencies of the scheme and programmes being executed under DHR. The Committee notes subtle under utilization of funds during 2019-20 with respect to projects like establishment of network of VDRLs for managing epidemics (74.01% of BE); Establishment of MRUs i.e. (72.50% of BE); Establishment of MRHRUs (49.63% of RE); HRD for Health Research (80.72% of BE); Grants in Aid Scheme (55.64% of BE); Research Governance (80.72% of BE);

International Cooperation (6.33% of RE); thus indicating overall utilization of 72.52% of BE allocation and 78% of RE allocation over the total DHR schemes. The Committee further observes that while ICMR has been able to spend upto 95% of BE allocation the revenue expenditure is to the tune of 46.74% of RE and BE allocation. It is worth reminding here that the DRSC on Health & Family Welfare has consistently recommended higher allocation to DHR keeping in view of the incidence of diseases in the country affecting large chunk of population. The Committee, therefore, strongly recommends that DHR must strengthen the absorption capacity of the implementing agencies of the schemes and programmes for optimal utilization of the allocated funds at BE stage so that the Ministry of Finance does not reduce allocated fund at the RE stage.

Projected demand funds allocation and actual utilization to the Department

(Rs in crores)

Year	Schemes/ Projects	Projected Demand	Fund Allocation (BE)	Reasons for revision at RE stage	Actual Utilization	Reasons for underutilization of earmarked funds
2018-19	Setting up of nationwide network of laboratories for managing epidemics and national calamities	130.00	70.00	RE reduced to Rs 55.00 crore by Ministry of Finance (MoF)	52.14	Due to reduction in budget at RE stage and less utilization of provision under NER component.
	Development of tools/support to prevent outbreaks of epidemics	5.00	5.00	No revision at RE stage	4.96	Due to receipt of less number of proposals.
	Development of Infrastructure for	170.00	63.00	RE reduced to Rs 47.00	46.01	Due to reduction in
	Promotion of Health Research			Crone by MoF		budget at RE stage. Saving against RE was mainly under NER component.
	Human Resource and Capacity Development	156.00	72.00	RE reduced to Rs 28.01 crore by MoF	23.77	Due to receipt of less number of proposals for fellowship/training.

2019-20	Setting up of nationwide network of laboratories for managing epidemics and national calamities	130.00	80.00	RE reduced to Rs 73.00 crore by MoF	59.21	Expenditure is upto 10.2.2020. Further expenditure is still in progress.
	Development of tools/support to prevent outbreaks of epidemics	5.00	7.35	RE reduced to Rs 6.00 crore by MoF	6.00	-
	Development of Infrastructure for Promotion of Health Research	118.00	73.00	RE increased to Rs 74 crore for meeting additional requirements	51.48	Expenditure is upto 10.2.2020. Further expenditure is still in progress.
	Human Resource and Capacity Development	101.00	87.00	RE reduced to Rs 77.00 crore by MoF	62.70	Expenditure is upto 10.2.2020. Further expenditure is still in progress.

2.4.2 Replying to a query as to the schemes whose implementation has been affected due to the short fall in allocation of funds during 2019-20 and the impact of shortfall in the fund on the accomplishment of physical and financial targets alongwith the steps that were taken by the Department to overcome the shortfall, the Ministry submitted that the implementation of the schemes has been managed within the RE allocation by suitable re-allocation of funds under the various schemes and prioritising the expenditure for release of funds to the ongoing projects and postponing funding of some of the new projects under the schemes to next financial year.

2.4.3 On a query as to whether the Budgetary allocation for different components of the Department for 2020-21 is as per the projected requirements and the extent to which schemes/projects would be affected as a result of the shortfall, the Ministry replied that suitable schemes wise allocations have been made within the allocated funds and the additional requirements if any based on the progress of expenditure will be projected at the RE stage. Replying to another query seeking to know other sources of Revenue or means of mobilization besides the budgetary allocation, the Ministry replied in the negative.

2.4.4 The Committee understands that under utilization of funds by the DHR not only reflects the lack of resilient monitoring mechanism over optimum utilization within stipulated timeframe work but also indicates lackadaisical approach of Department in achieving the set objectives of the schemes. The Committee, therefore, recommends the DHR to improve the monitoring mechanism for timely execution of schemes/programmes undertaken that would give legitimate claim to approach the Ministry of Finance for

higher budgetary allocation as per the projected demand to meet the expenditure on projects pertaining to research activities as originally conceived at the projection stage.

2.5 The Ministry furnished the physical and financial performance of the following schemes/projects as against the targets set for the Department of Health Research during the year 2019-20 (as on 31st January, 2020) :-

(1) **Setting up of Nation -wide Network of Laboratories for Managing Epidemics and National Calamities:**

I. Financial Performance	<i>(Rs in crores)</i>
BE 2019-20	80.00
RE 2019-20	73.00
Actual Expenditure (upto 31.1.2020)	59.21
II. Physical Performance:	
Total Scheme Target:	125 VRDLs
Already Achieved upto 2018-19	95 VRDLs
Target for 2019-20	30 VRDLs
Achievement during 2019-20(Upto January, 2020)	11 VRDLs

2.5.1 The Committee was given to understand that the main reasons for shortfall in achieving the set physical target for establishing Viral Research & Diagnostic Laboratories (VRDLs) include time taken by State Government to submit proposals and MoUs, long time taken by the concerned Institutes/medical colleges in identifying the requisite space, etc. The Committee is constrained to observe that though there was a backlog in establishment of VRDLs, the proposals for establishment of 5 additional VRDLs are under various stages of consideration. The Committee, strongly recommends the DHR for persuading the State Government to their proposals for resolving the problem of undue delay in identifying the requisite place for establishing VRDLs. The Committee strongly believes that DHR would not leave any stone unturned in achieving the physical target of establishing VRDLs from now onwards.

2. **Development of Infrastructure for Promotion of Health Research**

- (i) Establishment of Multi-Disciplinary Research Units (MRUs) in Government Medical Colleges/Research Institutions:

I. Financial Performance	<i>(Rs in crores)</i>
BE 2019-20	58.00
RE 2019-20	55.00
Actual Expenditure (upto 31.1.2020)	42.05
II. Physical Performance:	
Total Scheme Target:	90 MRUs
Already Achieved upto 2018-19	79 MRUs
Target for 2019-20	11 MRUs
Achievement during 2019-20	1 MRUs

2.5.2 The Committee observes that the main reason for delay in establishing MRUs in government medical colleges is the undue time taken by State Governments in submitting proposals and MoUs and long time taken by the concerned Institutes/medical colleges in identifying the requisite space. The Committee takes note of the proposals for establishment of 18 new MRUs that are at various stages of consideration. The Committee, therefore, recommends that DHR should play pro-active role in persuading the State Government for submitting proposals for establishing MRUs on time after signing MoUs. The Committee also recommends that the Government should give green signal for approving 18 new MRUs that are at various stages of consideration.

- (ii) The following details of financial and physical progress in Establishment of Model Rural Health Research Units (MRHRUs) in States has been shared with the Committee:

I. Financial Performance	(Rs in crores)
BE 2019-20	15.00
RE 2019-20	19.00
Actual Expenditure (upto 31.1.2020)	9.43
II. Physical Performance:	
Total Scheme Target:	25 MRHRUs
Already Achieved upto 2018-19	18 MRHRUs
Target for 2019-20	7 MRHRUs
Achievement during 2019-20	5 MRHRUs

2.5.3 The Committee expresses its displeasure over non achievement of physical targets set in establishment of MRHRUs due to delay in processing of the proposals for technical evaluation. Against the physical target for setting up of 25 MRHRUs during 2018-19 only 18 MRHRUs were set up and while during 2019-20 against the target of 7 MRHRUs, 5 MRHRUs have been set up. The Committee was apprised that two proposals, one each in A&N Islands and Telangana are already in the pipeline. The Committee understands that MRHRUs provide a platform for interface amongst patient and health researchers which helps in providing latest and sophisticated technology for diagnosis and management of diseases in rural areas. The Committee, therefore, recommends that DHR, while considering to enhance the objective of setting up of larger number of MRHRUs in the rural areas make realistic assessment of financial requirement for the purpose and accordingly, approach the Ministry of Finance for allocating the requisite fund.

(2) Development of Tools/Support to Prevent Outbreaks of Epidemics

I. Financial Performance	(Rs in crores)
BE 2019-20	7.35
RE 2019-20	6.00
Actual Expenditure (upto 31.1.2020)	4.16

2.5.4 Apprising about the physical performance under Model Rural Health Research Units (MRHRUs), the Committee was informed that there was no pre-planned targets under this scheme. Funds are released against specific proposals received from the State Governments/medical colleges/research institutes, etc for supply of diagnostic kits, training of staff, collection of samples, procurement of reagents for testing of samples, research activities,

etc on case to case basis. Funds to the tune of Rs.1.07 crore have been disbursed to ICMR-National Institute of Research in Tribal Health (NIRTH), Jabalpur for TruNat diagnostic device for TB in tribes of Madhya Pradesh. Rs. 48.00 lakhs have been released to King George Medical College (KGMU) Lucknow for EQAS activity on Scrub Typhus. An amount of Rs. 4.04 crore have been released to NIV Pune (Rs.96.39 lakhs, Rs.1.15 crore, Rs.29.20 lakhs and Rs. 1.63 crore) for purchasing diagnostic kits for detection of high risk viruses like Coronavirus (2019-nCoV) and for capacity building for conducting workshop for BSL3 Auditors. Funds to the tune of Rs.14.80 lakhs to Government Medical College, Guwahati for renovation/modification of BSL3 laboratory and Rs.25.93 lakhs to JIPMER, Puducherry have also been released.

2.5.5 The Committee notes with concern that the DHR has made actual expenditure to the tune of Rs. 4.16 crore against the BE allocation of Rs. 7.35 crore that was reduced to the tune of Rs. 6.00 crore at RE stage. The Committee understands that budgetary allocation is reduced at the RE stage keeping in the light of the progress of the scheme. The Committee observes that had the DHR been able to make expenditure commensurating to the progress of the scheme as per allocated fund at BE stage, the Ministry of Finance would not have reduced the allocation at RE stage. The actual expenditure is only to the tune of Rs. 4.16 crore till 31st January, 2020 which is again a matter of concern to the Committee.

(3) Human Resource and Capacity Development

(i) Human Resource Development for Health Research:

I. Financial Performance	(Rs in crores)
BE 2019-20	33.00
RE 2019-20	30.00
Actual Expenditure (upto 31.1.2020)	26.35
II. Physical Performance:	
Total Scheme Target:	
Already Achieved upto 2018-19	247 fellowships including projects
Target for 2019-20	65 Fellowships, 30 startup projects and support to 12 institutes
Achievement during 2019-20	72 fellowships, support to 2 Institutes and 30 startup projects

2.5.6 The Committee was given to understand that the physical achievements under the scheme of Human Resource Development for health research depend on the availability of budget vis-à-vis number of quality applications received under the scheme. The Committee, therefore, strongly recommends that the DHR must encourage the fellow researcher to undertake research projects so that the outcome of the research projects yield in translation of product development for combating the challenges of emerging and re-emerging viruses. The Committee also recommends that the HRD scheme of DHR must accomplish the objective of creation of pool of talented health research personnel in the country through optimal utilization of the earmarked budgetary allocation.

(ii) Grant in Aid Scheme:

I. Financial Performance	(Rs in crores)
BE 2019-20	28.00
RE 2019-20	18.00
Actual Expenditure (upto 31.1.2020)	15.45
II. Physical Performance:	
Total Scheme Target:	Not Applicable
Already Achieved upto 2018-19	243 Research Projects
Target for 2019-20	41 projects
Achievement during 2019-20	13 Research Projects

2.5.7 The Committee underlines the need of inter-sectoral convergence and coordination for promotion and guidance on health research and recommends that DHR must make all efforts to identify the existing knowledge gap and promote research projects that would yield in extracting the health leads which would ultimately translate into deliverable products. Since the physical achievement of target set under the scheme is dependent upon the availability of budget and number of quality applications received, the Committee, strongly recommends the DHR to approach the Ministry of Finance for allocating requisite fund for the scheme and also encourage/induce the health researcher to undertake the research projects.

(iii) Health Technology Assessment:

I. Financial Performance	(Rs in crores)
BE 2019-20	25.00
RE 2019-20	23.00
Actual Expenditure (upto 31.1.2020)	20.18
II. Physical Performance:	
Total Scheme Target:	Not Applicable.
Already Achieved upto 2018-19	2 Guidelines completed and issued.
Target for 2019-20	10 Guidelines and selection of 30 new topics for HTA.
Achievement during 2019-20	3 Guidelines completed and issued and 8 studies completed.
Reasons for shortfall:	Target is likely to be achieved by 31.3.2020.

2.5.8 The Committee is given to understand that Health Technology Assessment in India (HTAI) undertakes activities to analyze evidence related cost effectiveness and clinical effectiveness for deployment of health technologies covering medicines, devices and health programmes, which in turn ensures effective and optimal utilization of health budget and easy access to quality healthcare at the minimum cost. The Committee, therefore, recommends optimal utilization of allocated funds in order to minimize the cost for quality healthcare, especially in rural, urban slums and tribal areas.

International Cooperation

2.5.9 Provisions under this Head of Account are made to facilitate and accelerate international cooperation in medical and health research by providing contributions for international conferences, participations abroad, organizing international conferences in India, and meeting foreign travel expenses on official visits abroad. The BE allocation of Rs.1.00 crores under this Head has been increased to Rs.6.00 crores at RE stage towards payment of share amounting to Rs.5.00 crores to the Department of Science & Technology for organising the India International Science Fair-2019 at Kolkata. Actual Expenditure as on 10.02.2020 is Rs 0.38 crore and Rs 5.00 crore is proposed to be released to ICMR towards contribution of IISF, 2019. The International Conference schedule on 27-28 February, 2020 on Health Technology Assessment has been postponed due to travelling restrictions of international participants due to Corona Virus epidemic.

2.5.10 The Committee is of the view that international cooperation in medical and health research provides an opportunity and platform for the indigenous health researcher to interact with the health researchers in various parts of the world and therefore it helps in bridging the knowledge gap and skill development in the field of the health research. The Committee, therefore, recommends for encouraging the fellow health researchers to participate in the international conference to understand the global standard and practices in the health research that would in turn up-scale the health research in the country. Accordingly, provision for adequate fund be made to meet the expenditure incurring on international cooperation in the field of health research.

Output-Outcome Framework for Schemes 2020-21

2.6 The Committee came across about the output-outcome framework for schemes for DHR which envelops financial outlay, targets sets for outputs and outcome during 2020-21. The details are enumerated below:-

(i) Setting up of nationwide network of laboratories for managing epidemics and national calamities (CS)

FINANCIAL OUTLAY (Rs in Cr)	OUTPUTS 2020-21			OUTCOME 2020-21		
	Output	Indicators	Targets 2020-21	Outcome	Indicators	Targets 2020-21
83.00	1. Enabling Environment: Infrastructure, research and training to manage and investigate outbreaks/epidemics and	1.1. Number of multi-centric research studies conducted by the network of labs	2	1. Timely diagnosis of epidemics and availability of trained Viral	1.1. Number of labs verified for Quality parameters	50

FINANCIAL OUTLAY (Rs in Cr)	OUTPUTS 2020-21			OUTCOME 2020-21				
	2020-21	Output	Indicators	Targets 2020-21	Outcome	Indicators	Targets 2020-21	
		emerging and/re-emerging viruses	during the year		Research & Diagnostic Professionals at Medical College, State Level and regional level Laboratories.			
			1.2. Number of labs monthly reporting results to the apex authority (NIE Chennai)	105			1.2. Number of virology personnel trained per year	50
	2. Catalytic Change: Presence of research and training labs at regional and state level		2.1. Number of regional level labs built.	2				
			2.2. Number of State level labs built.	3				
			2.3. Number of medical college level labs built.	10				
			2.4. No. of labs which have the capacity to identify major viruses for public health importance					
			(i) Regional	9				
			(ii) State	22				
			(iii) Medical College	74				
			2.5. No. of outbreak investigation done	100				
		2.6. Number of samples tested per year	150000					

2. Development of Infrastructure for Promotion of Health Research (CS)

FINANCIAL OUTLAY (Rs. in Cr)	OUTPUTS 2020-21			OUTCOMES 2020-21		
	2020-21	Output	Indicator(s)	Target 2020-21	Outcome	Indicator(s)
80.00	1. Establishment of Model Rural Health Research Unit: Creation of infrastructure and enabling environment for research at rural areas.	1.1. Number of MRHRUs established	5	1. Establishment of Model Rural Health Research Unit: Operationalization of Model Rural Health Research Units	1.1. Increase in Health Research studies/projects at Rural Areas.	10
		1.2. Number of research studies/projects under taken at each MRHRU	25		1.2. Increased in transfer of new technologies for improving the quality of health services to rural population.	0
		1.3. Number of research studies/projects completed at MRHRUs.	6			
		1.4. Number of research papers published/presented/patents filed on new clinically/public health relevant knowledge generated.	4			
		1.5. Number of transfer of new technologies	1			
	2. Establishment of Multi Disciplinary	2.1. Number of MDRUs	10	2. Establishment of Multi Disciplinary Research Unit at	2.1. Increase in Health Research	25

FINANCIAL OUTLAY (Rs. in Cr)	OUTPUTS 2020-21			OUTCOMES 2020-21			
	2020-21	Output	Indicator(s)	Target 2020-21	Outcome	Indicator(s)	Target 2020-21
	narily Research Unit at Medical College: Creation of infrastru cture and enabling environ ment for research at Medical Colleges	establi shed at Medic al Colleg es			Medical College : Operationalizatio n of Multi- Disciplinary Research Units at Medical Colleges	ch activiti es at Govt. Medic al Colleg es/Res earch Institio ns.	
		2.2. Num ber of MDR Us functi onal	56			2.2. Initiatio n to develop ment of Diagno stic kits/tec hnologi es for Non- commu nicable & Commu nicable disease s	0
		2.3. Numb er of researc h studies / project s undert aken at each MDR U	120				
		2.4. Numb er of researc h studies /projec ts compl eted at MDR Us	25				
		2.5. Numb er of researc h papers publis hed/ present ed/ patents filed	38				

FINANCIAL OUTLAY (Rs. in Cr)	OUTPUTS 2020-21			OUTCOMES 2020-21			
	2020-21	Output	Indicator(s)	Target 2020-21	Outcome	Indicator(s)	Target 2020-21
			on new clinically/public health relevant knowledge generated				
		2.6.	Number of new technologies developed for introduction into the public health system	1			
		2.7.	Number of leads converted into patents/products/process for used in public health services	1			

3. Human Resource and Capacity Development (CS)

FINANCIAL OUTLAY	OUTPUTS 2020- 21			OUTCOMES 2020-21		
	2020-21	Output	Indicator(s)	Target 2020-21	Outcome	Indicator(s)
92.00	1. Enabling Environment for Research	1.1. No. of fellowships awarded. (HRD)	HRD : 100	1. Training to develop and take up research projects on major health problems	1.1. % of completion of research studies (i) GIA (ii) HRD	GIA: 95% HRD: 85%
		1.2. No. of start-up projects undertaken by trainees / fellows (HRD)	HRD: 5		1.2. % of start-up projects undertaken by fellows : HRD	HRD: 60%
		1.3. No. of researchers trained by the institutes supported. (HRD)	HRD: 100		1.3. No. of evidence based guidelines issued on Health Technology Assessment (HTA)	HTA: 10
		1.4. No. of research projects undertaken. (i) GIA (ii) HRD	GIA: 20 HRD: 80		1.4. No of new topics for Health Technology Assessment	HTA: 30

FINANCIAL OUTLAY	OUTPUTS 2020- 21			OUTCOMES 2020-21			
	2020-21	Output	Indicator(s)	Target 2020-21	Outcome	Indicator(s)	Target 2020-21
			D				
			1.5. No. of research projects completed. (i) GIA (ii)) H R D	GIA: 105 HRD: 20			
			1.6. No. of research paper published/ presented on new clinically/public health relevant knowledge generated. (i) GIA (ii)) H R D	GIA: 15 HRD: 30			
			1.7. No. of leads converted into patents/products/ process for used in public health services (i) GIA (ii)) H R D	GIA: 3 HRD: NA			
			1.8. No. of Cost effective and indigenous diagnostic kits developed (i) GIA (ii)) H R	GIA: 3 HRD: NA			

FINANCIAL OUTLAY	OUTPUTS 2020- 21			OUTCOMES 2020-21			
	2020-21	Output	Indicator(s)	Target 2020-21	Outcome	Indicator(s)	Target 2020-21
			D				
		1.9. No. of guidelines for protocols /devices developed in major identified diseases. (i) GIA (ii)) H R D	GIA: 1 HRD: NA				

4. Development of tools/support to prevent outbreaks of epidemics (CS)

FINANCIAL OUTLAY	OUTPUTS 2020-21			OUTCOMES 2020-21		
	2020-21	Output	Indicator(s)	Target 2020-21	Outcome	Indicator(s)
7.29	1. Providing Diagnostic Kits and reagents to investigate outbreaks/ epidemics of emerging and/re-emerging viruses	1.1. Number of labs which have provide confirmation of etiology of the outbreak during the year	40	1. Providing diagnostics for non-viral infectious pathogens	1.1. Number of labs strengthen for diagnosis of non-viral pathogens	50
		1.2. Number of etiological agent for which diagnostic kits to be supplied to each labs	6			
	2. Providing Training to labs for capacity building	2.1. Number of trainings to be imparted by RC	5			

	by Resource Centre (NIV, Pune)					
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2.6.1 The Committee takes note of the various details of output-outcome framework for the schemes 2020-21. The Committee hopes that the financial outlay earmarked for various schemes would create the enabling environment and bring forth cataleptic change in the basic infrastructure for carrying out bio-medical and health research. The Committee is of the considered view that network of VRDLs, MRUs and MRHRUs would definitely enhance the operational and professional efficiency of health researchers. The Committee believes that all the projects undertaken during 2020-21 would be completed without time and cost overrun. The Committee recommends DHR to strengthen the monitoring mechanism to oversee the execution of research projects and to ensure that physical targets set during the year must be achieved. The Committee also recommends DHR to undertake annual performance evaluation of each scheme and programme through cost benefit analysis and SWOT analysis. The Committee desires that DHR should formulate output-outcome framework for remaining years of 15th Finance Commission in order to have a holistic overview of the schemes under DHR.

2.6.2 The Committee, while taking into account the financial and the physical achievement under various schemes of DHR, recommends the following interventions for improvements :-

- (i) Advance planning to be made for completion of various formalities so that the process of sanctioning and release of funds for the various projects be started in the beginning of the next financial year.**
- (ii) More workshops and review meetings to be organized for addressing the issues in the implementation of the schemes.**
- (iii) More field visits to be organized for onsite appraisal of progress of implementation of the schemes.**
- (iv) Dashboard for online monitoring of schemes and programmes.**

CHAPTER – III

SCHEMES/PROJECTS OF DHR

MICRO ANALYSIS OF CENTRAL SECTOR SCHEMES/PROJECTS

SETTING UP OF NATION WIDE NETWORK OF LABORATORIES FOR MANAGING EPIDEMICS AND NATIONAL CALAMITIES

(In crores)

	Actual 2018-19	BE 2019-2020	RE 2019-2020	BE 2020-21
Revenue Allocation	52.14	80.00	73.00	83.00

3.1 Notes on Demands for Grants (2020-21) stipulate that the objective of setting up of nationwide network of laboratories for managing epidemics and national calamities is to ensure timely diagnosis and management of viral epidemics and emerging/re-emerging viral infections. The Committee, however, notes decrease in allocation of fund for the purpose from Rs.80.00 crore in BE 2019-20 to Rs.73.00 crore in RE 2019-20. The actual expenditure incurred is Rs. 59.21 crores as on 07.02.2020. However, the DHR claimed that the entire amount Rs. 73.00 crore allocated in RE 2019-20 shall be fully utilised by 31.03.2020.

3.1.1 The DHR further informed the Committee that the demand for the year 2020-21 has been projected as Rs. 83.00 crore. The amount of allocation of Rs. 83.00 crore will be utilised for setting up of new VRDLs and to meet the recurring expenditure of the existing 106 VRDLs. However, if there is an additional requirement of funds, the same will be asked for at RE stage. The Committee desired to know whether any Research Project got affected due to lower allocation at RE stage and the quantum of actual expenditure incurred in the year 2019-20. The DHR replied that reasons for decrease from Rs.80.00 crore in BE 2019-20 to Rs.73.00 crore in RE 2019-20 are non-receipt of viable proposals from implementing agencies adhering to conditionality of scheme guidelines; long-time taken by State Govt. signing of MoUs and in identifying the space, undertaking civil works, procurement of equipment and engagement of staff etc. by the concerned Institutes/medical colleges. The BE of Rs.83.00 crore for the year 2020-21 is proposed keeping in view to meet the requirement of setting up new VRDLs and to strengthen the existing network and to meet the recurring expenditure of existing 106 VRDLs.

3.1.3 The Committee expresses serious concern over decrease of funds for setting up of nationwide network of laboratories for managing epidemics and national calamities. The Committee finds that Budgetary allocation to the tune of Rs. 80.00 crore in BE 2019-20 was reduced to Rs.73.00 crore in RE 2019-20 and the actual expenditure incurred as on 7th February, 2020 is to the tune of Rs. 59.21 crore. The Committee understands that lower budgetary allocation for erecting nationwide network of basic infrastructure pose a serious challenge in managing epidemics and national calamities that result into loss of mankind. The Committee, therefore, is of the considered view that the stumbling blocks in the wake of successful implementation of the project viz. non-receipt of viable proposals from implementing agencies adhering to conditionality of scheme guidelines; long-time taken by State Govt. signing of MoUs and in identifying the space, undertaking civil works, procurement of equipment and engagement of staff etc. by the concerned Institutes/medical colleges need to be tackled through administrative acumen by the executive concerned with

the implementation of the scheme. At the same time, the Committee recommends that the DHR must project its demand for the scheme keeping in view the width and breadth of the country, size of population of the country vulnerable to epidemics and national calamities and frequency of incidence of epidemics and calamities for efficient management and effective control.

3.1.4 The Committee wanted to know the contingent Plan for managing emergent epidemics such as Coronavirus and whether the network of laboratories in the country is well equipped to tackle/contain any epidemic including coronavirus. The DHR responded that all VRDLs are routinely engaged in providing serological and molecular diagnosis of common viruses like dengue, Chikungunya, measles, rubella etc. However, selected VRDLs which are located strategically and have a state-of-art infrastructure, have been trained by the NIV, Pune which is apex lab and resource centre for VRDLs for handling viruses under high bio-safety and bio-security requirements. Such labs are capable of handling any epidemic due to new and emergent virus such as 2019-novel Coronavirus. These labs are equipped with kits, reagents and test protocols for timely detection of any new and emergent virus.

3.1.5 The Committee has been apprised that in the wake of 2019-nCoV outbreak, 14 VRDLs in the country viz. Bangalore Medical College and Research Institute, Bengaluru, National Institute of Virology Field Unit, Kerala, National Institute of Virology Field Unit, Bangalore, King Institute of Preventive Medicine and Research, Chennai, Sawai Man Singh Medical College, Jaipur, King George's Medical University, Lucknow, Gauhati Medical College and Hospital, Guwahati, BJ Medical College, Ahmedabad, Indira Gandhi Government Medical College & Hospital (IGGMCH), Nagpur, All India Institute of Medical Sciences, New Delhi, Kasturba Hospital for Infectious Diseases, Mumbai, Gandhi Medical College & Hospital, Secunderabad, ICMR-National Institute of Cholera and Enteric Diseases, Kolkata, NCDC, Delhi (Department of Health & Family Welfare) have started testing for the virus. These Labs have tested a total of 1435 samples as on date 07-February, 2020. DHR/ICMR has the capacity to scale up testing to another 35-40 Influenza testing laboratories under the VRDL network, depending upon the need. It is seen from this experience that the network of laboratories in the country is well equipped to tackle/contain any epidemic including Coronavirus. Furthermore, 10 BSL-3 labs are being commissioned at regional VRDLs. The ICMR has recently issued guidelines for BSL-3 labs and these guidelines will be adhered to for commissioning of the new BSL-3 labs. The availability of BSL-3 labs will ensure safe handling of any highly virulent virus that may emerge.

3.1.6 The Committee has been apprised that measures are also being taken to ensure deployment of manpower and shipment of test reagents and samples. In compliance with its mandate of tackling emerging / re-emerging viral infections, ICMR-NIV, Pune pre-emptively stocks primers/probes and reagents for viruses which have a potential to cause epidemics in India (Yellow Fever, Ebola, MERS, SARS etc.). The capacity for testing such pathogens is immediately scaled up in VRDLs as per need.

3.1.7 The Committee is of the firm view that the Government should formulate a concrete contingent plan for managing epidemics that do not outbreak with prior notice and for which the state of preparedness must be resilient enough to contain the outbreak of epidemics and calamities so that lives of people be saved. The Committee, therefore, strongly recommends the government to undertake measures to strengthen the contingent plan for managing epidemic and National calamities. In this regard, the Committee recommends that each VRDL must be trained in Good Clinical Laboratory Practices (GCLP). The Committee further recommends the government to undertake bio-security

and bio-safety measures so that any new and emergent virus is contained and controlled within shortest span of time. The Committee further recommends that the personnel engaged in handling the virus must be trained in bio-safety modules that include acquainting workers about wearing personal protective equipment to protect them from exposure to unknown virus.

3.1.8 The Committee acknowledges the vital role of VRDLs in surveillance diagnosis and detection of outbreaks of epidemics and calamities. The Committee notes that most of the VRDLs provide diagnosis within 24 to 48 hours, however, it is felt that turnaround time may further be reduced with the use of latest technology and medical device.

DEVELOPMENT OF INFRASTRUCTURE FOR PROMOTION OF HEALTH RESEARCH

3.2 Notes on Demands for Grants (2020-21) stipulates that the provision under the development of infrastructure for promotion of health research envisages establishment of Multi-Disciplinary Research Units in Government Medical Colleges and Model Rural Health Research Units in States.

(In crores)

	Actual 2018-19	BE 2019-2020	RE 2019-2020	BE 2020-21
Revenue Allocation	46.01	73.00	74.00	80.00

3.2.1 Apprising the Committee about the existing status and adequacy of basic infrastructure for promotion of Health Research in the country, the DHR replied that till few years back, bio-medical research was being carried out by a few Medical colleges /Institutions as they had access to the requisite data of patients and their diseases for carrying out bio-medical research. However, realizing the importance of bio-medical research and its impact on providing quality and cost effective patient care/treatment and also to ensure quality research work, Government introduced dedicated Bio-Medical Research Schemes namely (i) Establishment of Multidisciplinary Research Units (MRU) in Government Medical Colleges and (ii) Model Rural Health Research Units (MRHRU) in the rural areas in the State under the mentorship of nearest institute of Indian Council of Medical Research (ICMR). The main objectives of these two schemes are as under:

Objectives MRU Scheme

- (i) Encourage and strengthen an environment of research in Medical colleges.
- (ii) Bridge the gap in the infrastructure which inhibits health research in the Medical Colleges
- (iii) To ensure pan India geographical spread of health research infrastructure.
- (iv) To improve the overall health status of the population by creating evidence-based application of diagnostic procedures/processes/methods.

3.2.2 Till December, 2019, MRUs have been established in 80 Government Medical Colleges. As per MCI list there are approximately 384 Government Medical colleges in various States and

the long term objective of the Scheme is to set up an MRU in each of them in a targeted manner. Accordingly, the budgetary requirements are included in the annual budget of the Scheme itself to meet the targets.

Objectives of MRHRU Scheme

- (i) To create infrastructure and transfer technology at the rural level for improving the quality of health services.
- (ii) To develop research priorities based on the assessment of the local disease burden.
- (iii) To ensure pan India geographical spread of MRHRUs.
- (iv) The long term plan is to establish MRHRU in all States and Union Territories. Accordingly, the budgetary requirements are included in the annual budget of the Scheme itself to meet the targets.

3.2.3 The Committee notices the increase in allocation under this head from Rs.46.01 crore in 2018-19 to Rs.74.00 crore in RE 2019-20 and further increase to Rs.80.00 crore in BE 2019-20. The Ministry, in this regard, submitted before the Committee as under:-

“The MRU/MRHRU schemes envisage budgetary support for both recurring (Salary/Contingencies/Consumables etc.) and Non-recurring (Civil work/Equipments) expenditure. Annual budgetary requirement of the MRUs/MRHRUs are worked out as per the requirements under these heads. Besides providing for recurring /non-recurring costs of the existing MRUs/MRHRUs, funds are also required for establishing new units approved during the year. The number of MRUs/MRHRUs is progressively increasing since inception of the schemes in 2013-14 and so is the budgetary requirement. This trend is likely to continue with the setting up of progressive targets under the scheme. Hence the increase in the budgetary allocation over the years.”

3.2.4 On a query seeking details of the utilisation status of funds allocated in 2019-20 under this head and the reasons for under utilization, the DHR informed that against allocation of Rs. 73.00 crore in BE and Rs. 74.00 in RE, a total of Rs. 51.48 crore has been utilized till January, 2020. The Department has received proposals for establishing new units and also for meeting the recurring /non-recurring funds requirement of the existing units. It is expected that the RE allocations for these two schemes for the year 2019-20 will be fully utilized.

3.2.5 Regarding the outcome of the funds so utilised during 2019-20, the DHR stated that the outcome of funds utilized during 2019-20 is as under:

Scheme	Major Areas of research	Number of Publications
MRU	57 Research Projects on Cancer, Diabetes Mellitus and hypertension, Cardiovascular disease, Mental Health, Environmental Health/ occupational health, Stroke and neurological disorder, Diabetes, Metabolic disorders, Chronic Kidney disease and liver disorders, etc.	7

MRHRU	5 Research Projects on “Improving health and nutritional status of vulnerable segment of population by implementing multi-component health and nutrition education intervention as sustainable model of intervention”. “Snake Venom as Potential Inflammation Inhibitor and anti-venom activity of plant extract”. Projects relating to the Maternal Child health, Dengue fever, Prevalence of diarrhoea etc.	4
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3.2.6 As regards the details of projected demand and actual allocation made during the last five years for development of infrastructure for promotion of Health Research, the DHR furnished the following figures:-

(Rs in crores)

Financial Year	Projected Demand	Actual Allocation	
		BE	RE
2016-17	171.40	30.25	30.25
2017-18	194.50	45.00	56.00
2018-19	170.00	63.00	47.00
2019-20	118.00	73.00	74.00
2020-21	92.00	80.00	-

Implementation Status of the Scheme is as under:-

Year	MRUs		MRHRUs	
	Target	Achievement	Target	Achievement
2013-14 to 2018-19	80	79	21	18

Year	MRUs		MRHRUs	
	Target	Achievement	Target	Achievement
2019-2020	10	1	4	5

3.2.7 Against the target of establishing 90 MRUs till March, 2020, a total of 80 MRUs have been established till December, 2019 and it is expected that the target of establishing 90 MRUs will be met by 31.3.2020. Similarly, against the target of establishing 25 MRHRUs till March, 2020, a total of 23 MRHRUs have been established till December, 2019. The Department has received 4 proposals from State Governments which are being processed and the deficiencies therein are being sorted out in consultation with medical colleges/State Government/ICMR Institute. It is expected that the target of establishing 25 MRHRUs will be met. It is proposed to establish 7 more MRHRUs upto 2021-22. Efforts will be made to cover all the States while proposing further continuation of the Scheme for the 15th Finance Commission period.

Geographical distribution of development of Health Research infrastructure in the country

3.2.8 The Ministry apprised the Committee about the following geographical distribution of development of Health Research infrastructure in the country:-

Region	ICMR Institutes (26)	VRDLs (106)	MRUs (80)	MRHRUs (23)	Total (235)
North	4	19	20	6	49
Central	5	15	13	2	35
East	3	15	10	3	31
West	5	15	7	2	29
South	8	32	25	5	70
NER	1	10	5	5	21

3.2.9 The Committee observes that establishment of MRUs in government medical colleges and Model Rural Health Research Units in the rural areas are two pillars of basic infrastructure for biomedical research schemes in the country. The Committee finds that the MRHRU scheme is comparatively more diversified in its approach towards Bio-medical Research as it intends to transfer the requisite technology also to the rural areas to serve the affected persons as they do not, otherwise, have access to such technologies. The Committee, therefore, is of the firm view that there is urgent need for strengthening of basic infrastructure for health research in the country by allocating the fund as investment through budgetary provision to strengthen the network of research institutes for carrying out bio-medical research for ensuring bio-security not only against the emerging and re-emerging life threatening viruses but also providing a protecting umbrella against bio-terrorism.

DEVELOPMENT OF TOOLS/SUPPORT TO PREVENT OUTBREAKS OF EPIDEMICS

3.3 The following budgetary provision has been kept for development of tools/support to prevent outbreaks of epidemics to mobilize additional resources during outbreaks/epidemics:-

(In crores)

	Actual 2018-19	BE 2019-2020	RE 2019-2020	BE 2020-21
Revenue Allocation	4.96	7.35	6.00	7.29

3.3.1 The DHR has mentioned that on the suggestion made by Ministry of Finance the scheme was rolled out in 2015-16 by creating a separate budget line for mobilization of additional resources during emergency situations of outbreaks. Funds are released against specific proposals

received from the State Governments/medical colleges/research institutes, etc for supply of diagnostic kits, training of staff, collection of samples, procurement of reagents for testing of samples, research activities, etc on case to case basis. Requirement under this head is projected based on the past trend of expenditure and in case need arises, additional funds are sought at RE stage.

3.3.2 To the Committee's query about the projected demand, the variation in allocation of RE stage and impact of reduced allocation at BE 2020-21, the DHR clarified that the requirement was met within the RE allocation, without affecting the implementation of the scheme by prioritising the expenditure on essential activities and postponing the new activities to the next financial year.

3.3.3 The Committee expresses deep anguish over lower projection of Rs. 7.35 crore in BE 2019-20 by DHR for an important healthcare scheme envisaging development of tools/support to prevent outbreak of epidemics. Unfortunately the same was further reduced to Rs. 6.00 crore as a result of which DHR had no alternative financial options to undertake new initiatives but adhering to imprudent prioritisation of the expenditure on essential activities and postponing the crucial new activities to the next financial year. The Committee notes with concern that against the projected demand of Rs. 8.00 crore only an allocation of Rs. 7.29 crore has been earmarked for the said purpose. Needless to say, the DHR should appreciate that epidemics possess the potential for large scale casualties in case the same is not controlled and contained in time. The Committee, therefore, strongly recommends the DHR to approach the Ministry of Finance for higher allocation for development of tools/support to prevent outbreaks of epidemics.

3.3.4 The Committee strongly recommends the DHR that the allocated funds for development of infrastructure for promotion of Health Research must be optimally utilized by adhering the following strategy in order to achieve the physical target:-

- (i) Simplification of procedure and processes for sanctioning and release of funds for the various projects**
- (ii) Proper planning, efficient coordination and effective financial controlling while executing the scheme.**
- (iii) Strengthening of monitoring mechanism and organizing workshops and review meetings for addressing the issues in the implementation of the schemes. Adherence also to dashboard for online monitoring of progress of Scheme/ Programme.**
- (iv) Regular field visits for onsite appraisal of progress of implementation of the schemes.**

HUMAN RESOURCE AND CAPACITY DEVELOPMENT

3.4 The budgetary provision under Human and Resource and Capacity Development is meant for (i) fellowships for training in health research under the scheme of Human Resource Development of Health Research; (ii) Grant in aid Scheme for inter-sectoral convergence for health research & governance issues including Health technology Assessment and (iii) International Co-operation in Medical & Health Research including work related to International Conferences. The status of allocations under the scheme is as follows:-

(In crores)

	Actual 2018-19	BE 2019-2020	RE 2019-2020	BE 2020-21
Revenue Allocation	23.77	87.00	77.00	92.00

3.4.1 On the sharp increase in allocation from Rs.23.77 crore in 2018-19 to Rs.87.00 crore in BE 2019-20, the DHR has submitted that higher projection was demanded for FY 2019-20, to support 100 fellowship programs under HRD scheme, 41 research projects and finalisation of 10 evidence based guidelines under Health Technology Assessment (HTA) in various fields of biomedical/health sciences. On the reduction in allocation to Rs.77.00 crore at the RE stage during the year 2019-20, it was clarified that same is attributed to reduction in receipt of less number of proposals from the NER. The actual expenditure as on 10.02.2020 is Rs. 62.70 crore as against Rs. 77.00 crore at RE stage. It was also added that the proposals for utilizing the remaining amount is in pipeline for financial concurrence and it is expected to be fully utilized in the current financial year. The DHR apprised the Committee that the allocation to the tune of Rs. 92.00 crore has been earmarked in 2020-21 to support a total of 100 fellowships, 20 research projects and nearly 10 evidence bases guidelines under HTA in addition to funding of ongoing fellowships, research studies resource centres, multi centric studies including DIAMOnDS.

3.4.2 The Committee does not agree with Department's plea for lower projection at RE level on account of reduction in receipt of less number of proposals from the NER. The figures of actual expenditure to the tune of Rs. 62.70 crore in 2019-20 under the head are also not encouraging. The Committee disapproves the casual approach of the DHR for not adhering the desired cannons of fiscal discipline. The Committee is of the considered view that unless there is adequate budgetary allocation followed by optimal utilization of allocated fund, the DHR would not be in a position to constitute a pool of talented and trained medical researchers. The Committee, therefore, strongly recommends that DHR must approach the Ministry of Finance for adequate budgetary provision for Human Resource and Capacity Development. The Committee further underlines the importance of capacity building by providing financial assistance to health researchers in various areas of bio-medical/health science.

3.4.3 Projected demands vis-à-vis actual allocation made during the last five years for Human Resource and Capacity Development are as follows:-

(Rs in crores)

Financial Year	Projected Demand	Actual Allocation	
		BE	RE
2016-17	63.00	28.25	28.25
2017-18	106.10	46.00	63.00
2018-19	156.00	72.00	28.01
2019-20	101.00	87.00	77.00
2020-21	115.50	92.00	-

3.4.4 The DHR elaborated its Human Resource Policy which seeks empowerment of available human resource pool of the country by way of advanced training in the emerging areas of the biomedical sciences and providing financial assistance to implement the research ideas into

workable project. The main objectives policy are as follows:-

- (i) To increase the overall availability of trained personnel for health research from Medical Colleges across the country through Fellowships and career advancement, etc. for faculty and young medical doctors and other Scientists to take up medical and health research as a career.
- (ii) To focus on the creation of a cadre of trained medical/health researchers in specific identified priority areas of health research viz., Clinical Trials; Toxicology; Good Clinical Practices (GCP); Good Laboratory Practices (GLP); Quality Control (QC) & QA; Genomics; Proteomics; Clinical Psychology, Geriatrics; Modern Biology; Biotechnology; Stem cells; Genetics; Drugs chemistry; and operational research etc.
- (iii) To create, support, nurture and encourage the trainees from Medical Colleges to forge linkages with other Scientists from universities, research Institutes etc. to develop multidisciplinary and multi-sectoral teams necessary for addressing critical national and local health problems.
- (iv) To establish suitable online teaching and learning facilities to facilitate training in health research in various subjects in a more effective manner and for promoting biomedical/health research.

3.4.5 The scheme provides for Fellowship Programmes for Women Scientists, Fellowship Programmes for Young Scientist, Support to Institutes for Imparting training, Long Term / Short Term Fellowships for Training in Indian Institutes, Long Term / Short Term Fellowships for Training in Foreign Institutes, Start-up grant for fellows undergone long term / short term training supported by DHR etc. Regular national & international level training workshops / exposure visits are also provided to various categories of Scientists and personnel in the Department. The smooth implementation and the achievement of the time-bound outcome in respect of the research projects supported under the Scheme are ensured through rigorous review and monitoring mechanism with the help of subject specific technical committees.

3.4.6 The following ICMR-HRD Fellowships/Programs/Schemes are also under implementation for capacity and skill development in the country:-

S. No.	Fellowships/Programs/Schemes
A.	FELLOWSHIPS/SCHEME
1	Junior Research Fellowship (JRF)
2	ICMR Centenary Post-Doctoral Fellowship (PDF)
3	MD-MS/Ph.D. Fellowship
4	ICMR Chairs for Sr. retired medical/biomedical teachers/scientists
5	Short Term Studentship (STS)
6	Nurturing Clinical Scientists (NCS) Scheme
7	ICMR-Emeritus Scientist (IES)

8	Adjunct Faculty Scheme
B.	FINANCIAL SUPPORT PROGRAMS/SCHEMES
1	MD/MS/DM/MCh/MDS thesis support
2	International Travel Grant to non-ICMR scientists
3	DHR-ICMR Funded Workshops on Clinical Training/Translational Research
C.	MISCELLANEOUS PROGRAMS
1	ICMR Awards & Prizes

3.4.7 Besides, emoluments/fellowships of many ICMR Programs like JRF, STS, PDF, MD-PhD. and IES *etc.* have been increased from time to time by ICMR and also the number of seats in the STS Programs have been increased so as to encourage more young researchers/scientists and medical students to take biomedical research in their future career. Many new Schemes like Adjunct Faculty have also been introduced recently by ICMR to ensure more research opportunities for young medical graduates and Senior Scientists respectively. The Prize money for all the ICMR-Awards has also been increased by ICMR in 2019, to thereby strengthen a more talented pool of both young and senior Scientists in India to undertake good and valuable research in future.

3.4.8 The Committee is of the considered view that DHR must devise robust strategy for the capacity building of the global standard for its manpower to ensure better achievement of set objectives. The Committee, in this connection, recommends the DHR to have realistic assessment of the requirement of health care systems and of bio-medical science and accordingly devise appropriate strategies for imparting trainings / exposure visits / workshops in various reputed international organisations. Moreover, the Committee recommends for upgrading the existing knowledge of human resources in the various fields of biomedical/ health sciences in various areas viz. Toxicology, Genomics, Proteomics, Geriatrics, Stem Cell Research, Clinical Trials, Good Clinical Practices (GCP), Biotechnology, Genetics, Operational Research, Health Informatics, Medical Ethics, Health Economics, Health Policy, Biomedical imaging and processing, Health Informatics, Environment and Health etc.

INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR), NEW DELHI

3.5 Indian Council of Medical Research is the APEX body to formulate, conduct, coordinate and promote biomedical and health research in India The ICMR plays its mandated role in different disease specific areas through its intramural network of 26 institutes/centres and attached field units across the country involving about 600 scientists and by supporting extramural research in medical colleges, universities, institutions and not for profit organizations. The mission objectives and prime task of ICMR is as follows:

- (i) GENERATE, manage and disseminate new knowledge.
- (ii) INCREASE focus on research on the health problems of the vulnerable, the disadvantaged and marginalized sections of the society.

- (iii) HARNESS and encourage the use of modern biology tools in addressing health concerns of the country.
- (iv) ENCOURAGE innovations and translation related to diagnostics, treatment, methods/ vaccines for prevention.
- (v) INCULCATE a culture of research in academia especially medical colleges and other health research institutions by strengthening infrastructure and human resource.

3.5.1 The following table highlights the budgetary allocation for ICMR:-

(In crores)

	Actual 2018-19	BE 2019-2020	RE 2019-2020	BE 2020-21
Revenue Allocation	1447.85	1474.65	1552.22	1795.71

3.5.2 On seeking the details of the variation in allocation, the DHR informed the Committee that the budgetary allocation for ICMR in 2019-20 has been increased from Rs.1474.65 crore to Rs.1552.22 crore at RE stage for meeting additional requirements of ICMR towards funding of various research activities like Research Support for Diseases identified for Elimination (Fast-tracking TB elimination, Strengthening Malaria Elimination Efforts), Indian Cancer Research Consortium and Bio-bank Facility, etc. The allocation for 2020-21 includes the requirement of Bhopal Memorial Hospital and Research Centre, Bhopal, which has been merged with ICMR. The actual expenditure upto 31.1.2020 is to the tune of Rs. 1330.34 crore upto 31st January, 2020.

3.5.3 On being asked as to justify the adequacy of allocations and their impact on various schemes/projects, the DHR clarified that as against additional allocation of Rs.387.18 crore at Revised Estimate stage Rs.77.57 crore has been allocated and the activities have been planned accordingly.

3.5.4 The projected demand and actual allocation for last five years are as follows:

(Rs in crores)

Financial Year	Projected Demand	Actual Allocation		Grant Released to ICMR	Actual Expenditure by ICMR
		BE	RE		
2015-16	1715.91	863.17	893.74	883.37	879.33
2016-17	1460.10	894.00	1094.00	1077.40	1062.97
2017-18	2308.00	1150.00	1413.60	1413.60	1390.46
2018-19	2487.00	1416.00	1447.85	1447.85	1436.62
2019-20	2100.00	1474.65	1552.22	1474.65	1330.34 (upto 31.01.2020)

3.5.5 Replying to the Committee's query whether the Department through ICMR generates any funds internally, the DHR replied that internal Fund is generated through laboratory fees charged by the Institutes for conducting various tests, sale of publications, income from consultancy/contract research etc. Income from internal funds generation during the year 2018-19 was about Rs.2.00 crores.

3.5.6 The Committee acknowledges the pivotal role of Indian Council of Medical Research (ICMR) as an apex body in the field of bio-medical and health research in the country, however, the lower allocation/release of fund to ICMR viz-a-viz its projected demand is a matter of great concern. The figures of actual allocations against the projected demands of Department during last five years have witnessed a huge gap and the Department could not get its justifiable share of budget. The Committee terms the said allocation highly inadequate keeping in view the vast responsibilities entrusted to ICMR. The Committee cautions the Government that it is only through the in-depth health research, the country can be free from life threatening diseases, therefore, strongly recommends for higher budgetary allocation to ICMR keeping in view its projected demand so that ICMR can implement its originally conceived schemes/programmes without any procrastination. At the same time, the Committee also recommends the ICMR for enhancing the absorption capacity of its schemes and programmes so that allocated fund is optimally utilized during the same financial year, otherwise, the Ministry of Finance may not express its willingness for higher allocation to ICMR despite the dire necessity of the schemes/programmes rolled out by ICMR even if that are meant for life saving.

Major Achievements of ICMR

3.5.7 The Committee has been apprised of the major achievements of ICMR in its various field of activities which are enumerated below :-

1. Health Research

- (i)** Established 'RESEARCH - Regional Enabler for South East Asia Research Collaboration for Health' in collaboration with WHO and 9 countries of South- Asian region. It will work to effectively combat emerging and re-emerging infectious diseases in South East Asia region.
- (ii)** Crimean Congo Hemorrhagic Fever virus (CCHF) outbreak confirmation in Gujarat and Rajasthan 2019
- (iii)** India TB Consortium:
- (iv)** National TB Prevalence Survey Initiated Vaccine and drug trials against TB ongoing
- (v)** Validated the now WHO Recommended TrueNAT: indigenous, cost-effective, PHC friendly TB diagnostic test.
- (vi)** MERA India: Brought national and international stakeholders on one platform, identified gaps and sent calls for proposals to address those gaps.

2. Nutrition

- (i)** Awareness, knowledge and acceptance of Mid-day Meal (MDM)
- (ii)** Nutrition Surveillance System (NSS)
- (iii)** Mobile App on 'Dietary Guidelines For Indians: The App is based on the Recommended Dietary Allowances (RDAs) for Indians prescribed by NIN.
- (iv)** Fortified Food to Fight Malnutrition: ICMR has come up with a micronutrient mix that is being considered by government for its flagship programmes.

- (v) Release of Indian Food Composition Tables: The new “Indian Food Composition Tables-2017”, comprising of data of 586 varieties of Indian foods and their nutritive values, was released.
- (vi) Nutrition Surveillance System (NSS)- launched in six states under Poshan Abhiyan Studies

3. Non Communicable Disease (NCD)

- (i) India Cancer Research Consortium (ICRC)
- (ii) National Registries: Cancer, Stroke, Young diabetes, Heart Failure
- (iii) Set up 10 Centres for Advances Research in the areas of non-communicable diseases like acute myeloid leukemia (AML), young diabetes, intestinal diseases, kidney diseases, heart failure etc.
- (iv) India Hypertension Management Initiative: This will accelerate the implementation of quality hypertension treatment for over 15 crore population over the next four years.
- (v) Release of a white paper by ICMR on use of e-Nicotine products has led to banning of ENDS (electronic Nicotine Delivery Systems) through The Prohibition of Electronic Cigarettes (Production, Manufacturing, Import, Export, Transport, Sale, Distribution, Storage & Advertisement) Bill, 2019, thus saving a generation from the ill effects of nicotine.
- (vi) Mission DELHI for early diagnosis and treatment of heart attack patients by trained motorcycle first respondent paramedics is covering 20-25 lakh population in the national capital.

4. Basic Research

- (i) Isolation and characterization of Nipah virus from the clinical samples of NiV cases from 2018 Kozhikode outbreak.
- (ii) Genetic analysis showed evidence of recent evolution of ZIKV in India and circulation of two strains, the reported mutation linked to fetal microcephaly (S139N) and higher transmissibility (A188V) was not observed. ZIKV was isolated from Jaipur, Rajasthan.
- (iii) Rota virus G12P[11] unusual strain was detected for the first time from India in neonates.
- (iv) First time described Natural Killer cell degranulation defect as
- (v) a cause for impaired NK-cell cytotoxicity and hyper inflammation in Fanconi Anemia patients. This finding will
- (vi) have a significant impact on the management of complications in FA patients.
- (vii) Quantitative proteomic analysis led to identification of 57 proteins with altered levels in Gall bladder Carcinoma (GBC) cases, with a potential to be used as biomarkers for post treatment surveillance.
- (viii) First time reported that in children from eastern Uttar Pradesh the inflammatory genes (TNF α -308, G/A genotype and CCL2
- (ix) -2518 A/Ggenotype) was significantly associated with the susceptibility to Japanese encephalitis virus-infection.

5. Tribal Health

- (i) Intervention with 35 mobile TB diagnostic vans in 17 Tribal- hard- to reach districts in 5 states in India (Jharkhand, Gujarat, Rajasthan, Madhya Pradesh, Chhattisgarh) brought the out of pocket expenditure of patients to zero and increased the case finding.
- (ii) Development of Malaria Elimination Model leading to 85% decrease in malaria cases in Mandla district.
- (iii) Setting up of “Centre for Research, Management, and Control of Hemoglobinopathies” at Chandrapur, Maharashtra.
- (iv) Estimation of TB burden in tribal population of North Eastern Region.
- (v) Health profiling of particularly vulnerable tribal groups (PVTG).

6. Traditional Medicine

- (i) Phase IV (Randomized, double-blind, clinical trial on the developed product) of the task Force project on “Development of Nardostachys Jatamansi and Withania somnifera formulation (SDA-217) for treatment of sleep disorders” has been initiated.
- (ii) Another Task Force on Development of a standardized formulation of Trigonella Foenum-Graecum seeds for preventing or delaying the development of type-2 diabetes in subjects with pre-diabetes is ongoing.
- (iii) A Joint Phytopharmaceutical Drug Development Programme of ICMR, CSIR and DBT as an effort of inter-ministerial cooperation for promotion and facilitation of innovative research on Phytopharmaceuticals” in the country has been initiated. Under this programme 9 leads
- (iv) were initially identified, out of these 3 leads have been prioritized, which will be initiated in near future.

7. Publication & Dissemination of Information

- (i) Special Issue of Indian Journal of Medical Research on
- (ii) Gandhi and Health@150 (also the Hindi Version)
- (iii) Participation in India International Science Festival (IISF), Indian Science Congress and other exhibitions to showcase and display ICMR Activities and Achievements through exhibits, live demonstrations and films.
- (iv) Organization of Health Research Conclave during IISF in November, 2019 at Kolkata. Eminent speakers delivered talk on emerging and re-emerging infections, nutrition, tribal health, Anti-microbial resistance, palliative care and innovations.
- (v) Mission SHAKTTI – a special program carried out in 36 Delhi Schools to educate students about the healthy lifestyle following the ideology and philosophy of Mahatma Gandhi like cleanliness, Hygiene, sanitation, nutrition, physical fitness, mental health etc.
- (vi) New volumes on Phytochemical Reference Standard of Indian Medicinal Plants and Reviews of Indian Medicinal Plants were also brought out.

- (vii) Dissemination activities were carried out to share the research finding of the papers on non-communicable diseases like cancer, mental health, air pollution, malaria, ENDS and malnutrition with media and other stakeholders.
- (viii) Opinion Editorials on important health topics were also published in leading news dailies.
- (ix) ICMR Activities and achievements were published in Reference India, Science Reporter, India Series, etc

3.5.8 The Committee acknowledges the major achievements of ICMR in the specified areas viz. health research, nutrition, tribal health, tradition medicine and publication and dissemination of information and hopes that ICMR would continue to achieve the milestones in these battle fields. The Committee recommends that the mobile app on ‘Dietary Guidelines for Indians’ must be popularized especially in rural, urban slums and tribal areas. Nutrition Surveillance System need to be further strengthened and must yield result on the grass-root level. The Committee recommends the Government to undertake Fortified Food to fight malnutrition as the flagship programme for which the Government should transform the research activity in ICMR into Government policy and a suitable course of action must be chalked out for its implementation on the ground level. The Committee also recommends that the Mission SHAKTI be incorporated in school syllabus to educate students about the healthy lifestyle following the ideology and philosophy of Mahatma Gandhi like cleanliness, Hygiene, sanitation, nutrition, physical fitness, mental health, etc.

Specific Areas to be funded in respect of ICMR

3.5.9 The Committee sought to know the specific areas proposed to be funded under the head of ICMR and the details of physical and financial achievements of all on-going research projects on health, nutrition, non-communicable diseases, basic research, tribal health and traditional medicine and publication and dissemination of information. Specific areas proposed to be funded are mentioned as under:-

Major Areas

Annual Action Plan of ICMR for 2020-21

I. Tuberculosis

- (i) National TB Prevalence Survey
- (ii) New proposals under India TB Consortium would be funded to fast track end TB by 2025.
- (iii) Prevalence and Determinants for TB disease among contacts of TB patients: A Bi directional study.
- (iv) Research activities aiming towards bringing down TB cases in Saharia tribes of Madhya Pradesh and Rajasthan.
- (v) Elimination of tuberculosis from the island of Car Nicobar.
- (vi) TB vaccine & indigenous molecular diagnostic kit ‘TruNat’ to be implemented.

II. Vector Borne Diseases like Dengue, Chikungunya/JE and Malaria

- (i) Research activities directed towards elimination of Vector- borne diseases-Malaria, Filariasis and Kala Azar will be fast tracked; Support to diagnostics for Visceral Leishmaniasis (VL) and Post Kala-Azar Dermal Leishmaniasis (PKDL) developed by National Institute of Pathology (LAMP Assay); Lymphatic filariasis: M & E protocol implementation and morbidity management; Dengue/chikungunya: Scale-up of Wolbachia carrying Aedes mosquito releases to control Aedes-borne diseases; Evaluation of Public Health Pesticides (PHPs): GLP quality trials of Public Health Pesticides.
- (ii) Climate change (CC) impact on human health with emphasis on vector borne diseases
- (iii) Filariasis elimination by scaling up of supplementing Mass Drug Administration (MDA) with diethylcarbamazine (DEC) fortified salt in Nancowry group of islands.
- (iv) Clinical trials on new indigenous, cost-effective, safe and efficacious drugs for treatment of VL, PKDL and co-infected cases.
- (v) New tools for vector control in view of changed vector bionomic.
- (vi) Public Health Emergency Operation Centre for outbreak epidemic management like nCov, Zika, Nipah etc.
- (vii) Advancing multi-country research through the Regional Research Platform: Activities related to strengthening of Regional Platform for outbreak & epidemics developed recently in collaboration with 10 countries.

III. Vaccines & Vaccine Preventable diseases

- (i) To develop of clinical trial sites for Nipah monoclonal antibodies, dengue and Zika vaccine.
- (ii) Interchangeability study of the two JE vaccines: SA-14-14-2 Chinese JE vaccine and JENVAC of Bharat Biotech International Ltd.
- (iii) It is proposed to initiate the monitoring of human influenza virus activity in all north eastern Border States of India, which pose danger of cross border transmission of highly pathogenic respiratory viruses from Southeast Asian countries.
- (iv) “Estimation of burden of cholera followed by oral cholera vaccine implementation: Way forward for cholera control in India”. The TF project is planned to be initiated with ICMR-NICED Kolkata in current financial year to achieve the “End Cholera” goals in India by 2030.
- (v) HIV Estimation in India

IV. Non- Communicable Diseases Centres for Advanced Research and Excellence to be set up in following areas:

- Artificial Intelligence
- Disability and Assistive Technologies
- Elderly Care

Studies will be undertaken on the following:

(a) Oncology

- Diet and Cancer
- Oral Cancer

(b) Cardiovascular Diseases

- Digoxin in patients with rheumatic heart disease - a randomized placebo controlled trial
- Neuro developmental outcomes in infants undergoing surgery for congenital heart defects
- Role of exosomal cargo (miRNAs) in rheumatic heart disease pathogenesis.

(c) Neurology

- Development of pathways for Epilepsy Care
- Development and Networking of Brainbank in India to facilitate neuroscience research
- Registry of Multiple Sclerosis and other allied demyelinating disorders

(d) Diabetes

- Incidence Rates, Complications, Mortality Rates and Secular trends in Prevalence and Prevention of Diabetes through mHealth (INDIAB)
- A Multi-level Community Based Behavioral and Environmental Change Intervention for Reducing Diabetes Risk among Adult Population in India (INDIAB)
- Youth Diabetes Registry (YDR)-Phase III.
- ICMR Bio-bank

(e) Snake Bite

- Nationwide Survey to estimate incidence, mortality, morbidity and economic burden due to snakebite in India.
- ICMR National Snakebite Project (INSP) on capacity building of health system on prevention and management of snakebite envenomation including its complications

(f) Mental Health

- Assessment of impact of severe mental disorders on caregivers and development of a psycho-educational package to reduce the negative caregiving consequences are under process

(g) Disability

- WHO Collaborating Centre (WHO-CC): The process to create WHO-CC on Disability & Rehabilitation has been initiated by WHO SEARO on the recommendations of WHO Hqrs.
- National List of Essential Assistive Technologies (NLEAT): As a part of Policy Briefs for ATs, NLEAT will be prepared by involving all the stakeholders.

(h) Gastroenterology

- Prevalence and Incidence of Acute and Chronic Pancreatitis in Rural and Urban Population in India
- The Indian Metabolic and Liver Disease (IMELD) Study

(i) Tobacco and substance abuse

- Analysis of substance use habits among commercial motorists in India
- Co-relation of lesser known tobacco products with Oral Premalignancy and Malignancy

V. Anti-Microbial Resistance

- AMR Diagnostics Task Force (TF) to validate the indigenously developed diagnostics has been initiated. This TF will validate diagnostics for use at different levels of health care system.

VI. Nutrition

- (i) To support ongoing Task Force studies on Nutrition; Iodine Deficiency Disorders (IDD); Fluorosis, High Fat, Sugar and Salt foods (HFSS) and Vitamin A.
- (ii) To promote research activities and develop R&D facilities in less representative states/ areas and especially in medical colleges and institutes located in inaccessible/ difficult/ tribal dominated areas as well as in North-east regions.
- (iii) To review Global Hunger Index
- (iv) To carry out a pilot study on Conditional Cash Transfer for Take Home Ration under POSHAN Abhiyaan
- (v) To address issues related to food safety concerning to general population

Basic Medical Sciences/ Nanomedicine/Pharmacology/ Rare Disease

- (i) To initiate 17 projects under Task Force on Nanomedicine in following topics: Nano-drug delivery, Nano-enabled point of care devices, Nano-biosensor, Nano-enabled system for Regenerative Medicine & Wound Healing, Nano- immunotherapeutics&

Nano-adjuvant Imaging & Theragnostics, Nano-enabled emerging technologies like, Photodynamic Therapy (PDT), Nanorobotics etc

- (ii) To initiate 29 projects under Task Force on Rare diseases.
- (iii) Pharmacogenomic registry and networking.
- (iv) Studies will be initiated under Task Force on Omics in Health and Disease in the areas of Airway diseases, Neglected tropical diseases, Inborn metabolic disorders, Neonatal stunting, Lifestyle diseases (Obesity, Non-alcoholic fatty liver disease and cardio-metabolic disease).
- (v) Research proposals will be invited in area, such as gene therapy:
 - 1. Inherited genetic diseases affecting any organ heart diseases (familial cardiomyopathy, channelopathies, etc), etc, including syndromes. B. Treatment of multifactorial diseases such as cancers, diabetes, lung diseases, neurologic diseases etc.
- (vi) **Guideline will be prepared for Stem Cell Therapy.**
- (vii) **Good Clinical Laboratory Practices Guidelines, 2008 of ICMR will be revised.**
- (viii) **Ongoing Centres of Advanced Research (19), Task Forces (63), Ad-hoc projects (146), fellowships (444) in the areas of**
- (ix) **Basic Medical Sciences will be continued.**

VII. Reproductive Biology, Maternal and Child Health

The following task force studies will be initiated.

- (i) Phase-III Multicenter, Randomized, Double-Blind Placebo- Controlled Study to evaluate efficacy of probiotics supplementation for prevention of neonatal sepsis in 0-2 months old low birth weight infants in India - A UKRI, MRC, JGHT study
- (ii) National Registry for Rare and other Inherited Disorders in India
- (iii) Establishment of health and demographic surveillance system in Cuttack district, Odisha (Cuttack –HDSS)
- (iv) India Pediatric HIV Cohort follow up (Phase III) study"
- (v) Proposal for developing consortium of all HDSS in India to generate programme relevant data and inform policy
- (vi) Follow up of babies born through Assisted Reproductive Technology
- (vii) Classification of Indian pregnancies as late preterm, term and post-term based on adverse perinatal outcomes as function of gestational age/gestational length.
- (viii) Clinical Trial Phase-III b study with intravascular injectable male contraceptive RISUG
- (ix) Development of cost-effective indigenous reagent red cell panels for identification and characterization of blood group alloantibodies in North east India
- (x) A multicentric study on Systemic Lupus Erythematosus (SLE) from the North Eastern Region of India: Early diagnosis to research potential for understanding disease pathogenesis

- (xi) To study spectrum of Primary Immunodeficiency Diseases in North East India and establishment of diagnostic facilities for PID
- (xii) Draft national guidelines for accreditation, supervision and regulation of ART Banks in India (in the process of finalization).
- (xiii) ICMR is in process of revising the existing guidelines entitled “National guidelines for accreditation, supervision and regulation of ART Clinics in India (Published in 2005).

VIII. Tribal Health

- (i) It is proposed to upscale the Tribal health Research forum (THRF) activities and to setup a nation-wide research program in the form of Tribal Health Research Consortium of India (THRCI), involving all stakeholders particularly the MoTA and its states Tribal Research Institutes (TRIs) / Centers (TRCs), together with the Tribal Welfare Departments including local tribal representatives and other public institutions as well as private industries and NGOs, to develop joint collaborations and partnerships, in advancing preventive / curative needs to the indigenous peoples. This will pave the way for improving the overall tribal health in India and their quality of life more than before.
- (ii) To develop “Elimination model for soil-transmitted helminth (STH) in remote tribal area: A community based health model”. This project has a potential to generate data which could complement Government programme and will be extended for the benefit of tribal/rural population.
- (iii) The project “Tribal Microbiome – An Indian Perspective” will be undertaken.
- (iv) A mission-oriented research project on “Towards improving tribal health in central India through integrated research approach” is planned to be undertaken
- (v) A research project on “Health Assessment of 75 Primitive Vulnerable Tribal Groups (PVTGs) of India” has been proposed in collaboration with ICMR-RMRC, Bhubaneswar.
- (vi) Connecting the unconnected: An incentive-based model to connect the traditional healers to public health system.
- (vii) Studies in the areas of Malaria, Sickel-Cell, Anemia, Glucose-6- phosphate dehydrogenase and TB with respect of tribal population.

Technological Innovations

- (i) Medical Device & Diagnostic Mission Secretariat will be strengthened.
- (ii) Clinical Validation of medical devices.

IX. Human Resource Development/ Health Research Capacity Strengthening Fellowships

1. ICMR-STs (Short-Term Studentship) for MBBS/BDS students
2. ICMR-Nurturing Clinical Scientists (NCS) Scheme for MBBS/BDS graduates
3. ICMR-Junior Research Fellowship (JRF)
4. ICMR-Centenary PDF (Post-Doctoral Fellowship)
5. ICMR-MD/MS-PhD Fellowship

6. ICMR Chairs for Sr. retired medical/biomedical teachers/scientists
 7. ICMR-Emeritus Scientists (IES)
- Financial Support
 1. ICMR-MD/MS/DM/MCh/MDS thesis support
 2. International Travel Grant to non-ICMR scientists
 3. DHR-ICMR funded Workshops for Clinical Training/Translational Research
- X. Traditional Medicine
- (i) **National Task Force Project “Development of Nardostachysjatamansi and Withaniasomnifera formulation (SDA-217) for treatment of sleep disorders”**
 - (ii) **National Task Force Project “Development of A Standardized Formulation of *Trigonellafoenum-graecum* Seeds (PDP-117) For Preventing or Delaying The Development of Type-2 Diabetes in Subjects With Pre-Diabetes”-**
 - (iii) **Joint Phytopharmaceutical Drug Development Programme of ICMR, CSIR and DBT**
 - (iv) Cannabis based Phytopharmaceutical drug (THC: CBD ratio, 1:1) in management of cancer pain.
 - (v) Cannabis based Phytopharmaceutical drug (CBD content>80.0%) in treatment of resistant pediatric epilepsy
 - (vi) Boswellia based Phytopharmaceutical drug for treatment of osteoarthritis
- XI. International Health
- (i) **ICMR/AU-STRC Capacity Building Scheme (Training Courses in India 2020) For African Health Practitioners/Researchers:** 14 training courses
 - (ii) **Collaborative Research Programme under India Africa Health Sciences Platform:** Call for Proposals 2020 in thematic areas of Cancer, HIV/AIDS and Tuberculosis
 - (iii) **Newton Bhabha Researcher Link workshops:** In partnership with British Council, UK.
 - (iv) **New MoUs under process with the partnerse.g. NHRC Nepal; DMR Myanmar; BMGF USA and WHO.**
 - (v) International Health Division is the Secretariat for Heads of International (Biomedical) Research Organizations (**HIROs 2020**)**meeting** scheduled to be held on 12-13th March, 2020 in New Delhi. ICMR and DBT will jointly co-host the Annual Meeting of the HIROs.
 - (vi) **ICMR International Fellowship Programme for scientists belonging to developing countries**

XII. New Infrastructure development

- (i) NIIH- Centre for Hemoglobinopathies, Chandrapur
- (ii) ICMR National Centre for Assistive Technologies @ IIT/AIIMS
- (iii) National Biobank at NICPR, Noida
- (iv) NIV-Centre for One Health, Nagpur

XIII. IEC/ IJMR/ In house- publications/Policy, Planning and Communication

- (i) **Monograph Publications “Review monographs on Indian Medicinal Plant”- volumes 21 & 22**
- (ii) **Monograph Publications “Safety Reviews of Selected of Indian Medicinal Plants”- 2nd volume**
- (iii) Publication of ICMR Patrika , and VarshikPrativedan, the Hindi version of ICMR Annual Report 2018-19.
- (iv) A special issue on “Women’s health with reference to breast cancer and cervical cancer” has been initiated for the early 2020.
- (v) History of Medicine.

3.5.10 The Committee takes into account the Annual Action Plan of ICMR for the year 2020-21 enveloping research projects in 13 specific areas for which an amount to the tune of Rs. 1795.71 crore has been earmarked. The Committee believes that ICMR would undertake National TB Prevalence Survey and implement TB vaccine and indigenous molecular diagnostic kit ‘TruNat’ in order to eliminate TB by 2025. The Committee also believes that research activity directed towards elimination of vector borne diseases would yield desired outcome. The Committee considers the research activities undertaken by ICMR pertaining to climate change impact on human health, especially vector borne diseases would go a long way in containing the life threatening diseases. The Committee feels that ICMR must undertake extensive clinical trials on new indigenous, cost effective, safe and efficacious drugs for treatment of VL, PKDL an co-infected cases. The Committee expects ICMR to continue for strengthening public health emergency operation centre for epidemic management like nCov, Zika, Nipah, etc. The Committee desires the ICMR to have HIV estimation in India and undertake research activities for its treatment. The Committee believes that ICMR would achieve the ‘End Cholera’ goals in India by 2030. The Committee strongly believes that the outcome of research activities undertaken by ICMR in the field of Oncology, Cardiovascular diseases, Neurology, Diabetes, Mental Health, Disability, Gastroenterology would relieve large chunk of people through assured treatment. The Committee would like ICMR to undertake new initiatives to improve the position of India in global hunger index and address issues pertaining to iodine deficiency disorder, POSHAN Abhiyan, nanomedicine, pharmacology/rare diseases, reproductive biology, maternal and child healthcare. The Committee recommends the ICMR to galvanize the Tribal health Research forum (THRF) activities and to setup a nation-wide research program in the form of Tribal Health Research Consortium of India (THRCI). The ICMR also needs to strengthen medical device and diagnostic mission secretariat and ensure clinical validation of medical devices. The Committee recommends the ICMR to promote the traditional medicine, promote participation in international health conference to have a glance over global health index and parameters and to implement the same in India. The call for “centre for one health” would require a network of new infrastructure

development. The Committee would like the dissemination of collected research information/analysis and outcome to the lower rungs of the country for the benefit of the general masses.

Major research projects on traditional medicine undertaken by ICMR and follow-up action for bringing the achievements thereof

3.5.11 Following projects are ongoing Major Research Projects on Traditional Medicine at ICMR National Institute of Traditional Medicine, Belagavi:

SI No.	Project title	Funded by	Status Note	Follow up action planned
1.	A Randomized Controlled Clinical Study to evaluate the Safety and Efficacy of an ayurveda formulation - PJ7 in the management of Dengue fever and prevention of its complications	CCRAS, Ministry of AYUSH	150 patients recruited, Laboratory investigations and data analysis are ongoing, to be completed by March 2020	If the formulation is found effective, ICMR will be approached for further necessary steps
2.	Evaluation of analgesic and anti-inflammatory activities of <i>Plumbago zeylanica</i> root paste in osteo-arthritis patients	ICMR Extramural	120 patients recruited, Laboratory investigations and data analysis are ongoing, to be completed by March 2020	If the formulation is found effective, ICMR will be approached for further necessary steps
3.	Evaluation of AYUSH- GMH in the subjects of mild to moderate non- alcoholic fatty liver disease (NAFLD) - a double blind randomized control clinical study	CCRAS, Ministry of AYUSH	Project sanctioned, funds and interventional medicines awaited.	Project yet to be initiated

3.5.12 The Committee notes the details of major research projects on the traditional medicine undertaken by ICMR alongwith timeframe for its for the completion of the undertaken projects such as (i) evaluation of the safety and efficacy of an Ayurveda formulation PJ7 in the management of the Dengue fever (ii) funded by the Ministry of AYUSH and to be completed by March, 2020 (iii) evaluation of analgesic and anti-inflammatory activities of *Plumbago zeylanica* root paste in osteo-arthritis patients, funded by ICMR under extramural provision and (iv) non- alcoholic fatty liver disease (NAFLD) – A double blind randomized control clinical study, funded by Ministry of AYUSH. The Committee is of the view that research projects on the traditional medicine would go a long way for the treatment of various diseases and therefore, all on-going projects must be completed without time and cost overruns. Again the projects that could not be commenced be initiated on priority basis so that desired outcome can be harnessed without cost overrun and further delay.

3.5.13 Number of publications, patents filed and technology developed are as follows:

Year	Papers Published	Patents Filed	Patents Granted	Technologies developed
2018-19	823	17	7	13
2019-20 (till Dec 19)	567	18	4	23

3.5.14 The major research leads that have been translated to health benefits are:

1. Shigella Vaccine: Technology has been transferred to Hilleman Laboratories.
2. Point-of-Care Nipah Diagnostic Test: A rapid diagnostic test has been developed for Nipah Virus in collaboration with industry.
3. TrueNAT: A cost-effective, PHC friendly TB diagnostic test, validated in collaboration with DBT and industry, has been endorsed by WHO after successful completion of a multi-country trial.
4. MIP Vaccine against Leprosy: ICMR has validated the Made in India vaccine and is being implemented in National Leprosy Elimination Programme
5. Point of Care Diagnostic Test for Blood Disorder: INR 50 test developed for detection of blood disorders, Haemophilia A & von Wilerbrand disease.

Technologies under pipeline for commercialization are as under:

1. Method and kit for diagnosis of Hemophilia A and Von Willebrand Disease.
2. Development and validation of a PCR based technology for detection of Yq microdeletions in diagnosis of male infertility.
3. Improved process for the production of Cyclosporin A using the fungus *Tolypocladium* sp.
4. Novel Immunogenic Antigens of Shigella
5. Recombinant vaccine for Hepatitis E.
6. A novel *Salmonella typhi* protein as subunit vaccine.
7. Nano-engineered bioresorbable polymer composite for bone-soft tissue fixation application.

3.5.15 The Committee appreciates ICMR for publishing 823 research papers /research documents during 2018-19 including 17 patents filed out of which 7 were granted and 13 technologies were developed. Similarly, during 2019-20 (till December, 2019) 567 research documents were published, 18 patents were filed, 4 patents were granted and 23 technologies were developed. The Committee hopes that research conclusions would be disseminated to the ground level and benefits reach to the patient at the primary health centre. The Committee applauds the achievements of ICMR in exploring major research leads that have been translated to various health products in the interest of health benefits of the public. The Committee further believes that the technologies as developed through major research activities undertaken by ICMR, sooner than later, would foster into commercialization and thereby yield the desired results in maintaining the public health.

3.5.16 Keeping in view the overall functioning of ICMR vis-à-vis its financial and physical achievement, the Committee recommends suitable and adequate measures by way of regular monitoring of ongoing activities and utilization of funds earmarked; creating dashboard of major ongoing activities and periodical analysis for specific recommendations for corrections and incentivizing/rewarding good performers be taken to improve the financial and physical performance of ICMR.

BHOPAL MEMORIAL HOSPITAL AND RESEARCH CENTRE, BHOPAL

3.6 Bhopal Memorial Hospital & Research Centre (BMHRC) was set up in 1998 under the Bhopal Memorial Hospital Trust (BMHT) for treatment of Bhopal Gas Victims. BMHRC has now been merged with Indian Council of Medical Research (ICMR). The status of allocation is as under:-

(In crores)

	Actual 2018-19	BE 2019-2020	RE 2019-2020	BE 2020-21
Revenue Allocation	127.72	140.00	129.78	--

3.6.1 On being asked to spell the reasons for reduction in allocation from Rs. 140 crore in BE 2019-20 to Rs. 129.78 crore at the RE stage and the actual expenditure figures for 2019-20 under this head, the DHR mentioned that an amount of Rs.140 crores was allocated to BMHRC for the financial year 2019-20 shared the following reasons:-

- (i) When the budget under this head was projected, the proposal for filling up the vacant posts of doctors through UPSC was under process. After notification of Recruitment Rules, DHR had taken up the proposal with the Union Public Service Commission for making recommendations of candidates for recruitment to the posts of Professors (4) Assistant Professors (16) and Specialists (10), UPSC issued advertisement for these posts. However, UPSC had recommended only 7 Assistant Professors and 2 Specialists (Medicine) so far. Hence recruitment of doctors could not be made as projected.
- (ii) Procurement of number of equipments are under process at various stages. Installation of all equipments and release of payment may not materialize in the current financial year. Hence, at the RE stage, the funds requirement has been reduced.

3.6.2 The Committee wanted to know the reasons for merger of Bhopal Memorial Hospital & Research Centre, Bhopal with Indian Council of Medical Research (ICMR) as the Committee in its 111th Report had strongly recommended that Bhopal Memorial Hospital & Research Centre, Bhopal be merged with AIIMS, Bhopal. The Committee desired to know the benefits that are likely to accrue due to the merger of BMHRC and ICMR. The DHR clarified that the Department of Health & Family Welfare constituted a Core Group under the Chairmanship of Prof Nitin M Nagarkar, Director, AIIMS, Raipur and Former Director, AIIMS, Bhopal in connection with proposed merger of BMHRC, Bhopal and AIIMS, Bhopal. The Core Group, while recommending the proposal, has highlighted certain difficulties in the integration of staff working in two institutes due to difference of pay scales, allowance, provisions under Recruitment rules, etc. The Department of Health & Family Welfare forwarded the report of the Core Group to

Department of Health Research (DHR) with a request to consult all the stakeholders including employee's/doctors' association and confirm acceptability of the recommendations. Accordingly, a meeting was convened with the stakeholders under the Chairmanship of Secretary, DHR on 02.01.2019 at ICMR. Most of the participants representing different categories of the staff of BMHRC expressed their apprehension about losing their seniority, re- designation of their posts on merger and demanded protection of job of each employee.

3.6.3 The issue of merger of BMHRC, Bhopal and AIIMS, Bhopal was subsequently discussed in the meeting of Governing Council of Indian Council of Medical Research (ICMR) held on 25.01.2019 chaired by the then Hon'ble HFM. The Governing Council, after detailed discussion decided that a High Power Committee under the Chairmanship of Secretary, DHR meet at the earliest and decide the modalities for smooth functioning of BMHRC. Accordingly, a High Power Committee comprising 11 members and Chaired by Secretary DHR, was constituted vide orders issued by DHR on 23rd April, 2019. The Committee discussed the options regarding merger of BMHRC with AIIMS, Bhopal, making it an autonomous body or transfer to ICMR.

3.6.4 Views of the Committee are summarized as under:

“In view of the difficulties, especially regarding incorporation of staff of BMHRC with the existing cadres of AIIMS, Bhopal mainly due to disparities in the pay structures of employee, the members were of the view that merger may lead to problems in the matter of personnel administration, hierarchy & seniority, etc, which may eventually result in litigation, both from the staff of AIIMS and BMHRC and, therefore, the Committee did not recommend the option of the merger of BMHRC with AIIMS, Bhopal. There were two options viz. to make BMHRC an autonomous body and affiliation with Sree Chitra Tirunal Institute of Medical Sciences & Technology, Trivandrum, Kerala for PG courses or Transfer of BMHRC to ICMR as one of its constituent units.”

3.6.5 The Committee was of the view that the ultimate goal was to make BMHRC as an Institute of Excellence. The Committee was also of the view that autonomy to the hospital will facilitate quick decision on proposals and filling up of vacant posts of doctors and other staff at the hospital level. In addition to the BMHRC will also be able to put in greater efforts into Research and innovations in medical education and public health areas.

3.6.6 With a view to realize these objectives the consensus view of the members of the Committee was that BMHRC may be transferred back to ICMR and the same has been accepted by the Competent Authority.

3.6.7 On a query about immediate measures that are being taken and would further be taken to revive the hospital, the DHR replied that taking over the administrative control of BMHRC in the year 2015, Govt. of India has extended the benefits of 6th as well as 7th CPC and scales of pay to the employees of Bhopal Memorial Hospital & Research Centre as admissible as per the Central Government Rules. Recruitment Rules of Medical Doctors (Professor, Associate Professor, Assistant Professor), Specialists were notified in the Gazette of India dated 13.02.2018 and 17.04.2018. The Recruitment Rules for the other posts at BMHRC were also notified in Gazette of India in 2018 and 2019.

3.6.8 After notification of Recruitment Rules, DHR had taken up the proposal with the Union Public Service Commission for making recommendations of candidates for recruitment to the posts of Professors, Assistant Professors and Specialists. UPSC issued advertisement for these posts. UPSC recommended only 7 Assistant Professors and 2 Specialists (Medicine). Out of these, only two Assistant Professors joined in 2019. One of them has resigned due to personal reasons.

3.6.9 The administrative control of BMHRC was transferred from DHR to ICMR vide orders issued on 29.11.2019. ICMR has already scheduled interviews for Selection to various posts of faculties from 8th to 11th February, 2020. It may be added that ICMR has been able to select 8 faculty Doctors (7 Assistant Professor and 1 Associate Professor). Promotions due to all eligible doctors have been given as per rules and guidelines. All the requisite equipments for proper patient care are functional and are being maintained regularly. Purchase of new equipments is also a regular process.

3.6.10 Recapitulating the recommendations of the Department-related Parliamentary Standing Committee on Health & Family Welfare in its 111th Report on the Functioning of new AIIMS (Phase-I) under the Pradhan Mantri Swasthya Suraksha Yojana (PMSSY), the Committee noted that BMHRC has witnessed seven handovers in 10 years. The Committee notes the view of the High Power Committee, constituted with the terms of reference for deciding the fate of BMHRC, in order to achieve the goal for improving the functioning of BMHRC in conjunction with ICMR, there is urgent need for enhancing the capacity building by way of improved availability of Doctors, commencement of PG courses in medical education, optimal utilization of resources, undertaking new activities etc. The Committee believes that efficient and effective operational and functional synergy would be integrated between BMHRC and ICMR for multiplying professional proficiency of BMHRC. The Committee appreciates that DHR has already undertaken initiatives for the filling up of the vacant posts and procurement of tools and equipments for proper patient care. The Committee, however, would like to be apprised of the cost benefits analysis and ultimate outcome of transfer of BMHRC to ICMR alongwith performance audit report indicating the operational ratio and other accounting practices.

NORTH EASTERN AREAS

3.7 The Department of Health Research has been allocating 10% of the budgetary allocations under the Central Sector Schemes for the NE Region as per the existing guidelines on the subject. Besides this, budgetary provision is also made by the ICMR for meeting the expenditure on its institute, namely, the Regional Medical Research Centre (RMRC), Dibrugarh and for various research activities in the NER. The budgetary allocations for NER are tabulated below:-

(In crores)

	Actual 2018-19	BE 2019-2020	RE 2019-2020	BE 2020-21
Revenue Allocation	--	103.00	101.00	104.00

3.7.1 The Committee notes that a Revenue allocation of Rs.101.00 crore was made in RE 2019-20 for projects/schemes of North Eastern Areas. Actual expenditure as on 10.02.2020 is Rs 88.14 crores, which includes Rs 8.14 crores under the Central Sector Schemes of DHR and

release of Rs 80.00 crore to ICMR. A Revenue outlay of Rs.104.00 Crore has been earmarked in 2020-21. The Committee desired to know how the revenue allocation of Rs.104.00 crore proposed to be utilised in 2020- 21 and whether the revenue allocation is sufficient and if not what reasons have been proposed by the Department to offset the effect of short fall of funds, if any. The DHR informed that the allocation of Rs. 104.00 crores in 2020-21 accounts for Rs.24.00 crores for the Central Sector Schemes of DHR and Rs.80.00 crores for ICMR. The funds will be utilised for the projects already sanctioned.

3.7.2 The following schemes/projects have been funded with the allocations made in 2019-20 in the NER:

(1) Establishment of Network of Research Laboratories for Managing Epidemics and Natural Calamities.

S.No.	Name of State	Name of Viral Research & Diagnostic Laboratory (VRDL)
1	Assam	Regional Medical Research Centre (RMRC), Dibrugarh (ICMR)
		Guwahati medical College, Guwahati
		Tezpur Medical College & Hospital, Tezpur
		Jorhat Medical College & Hospital, Jorhat
		Fakruddin Ali Ahmed Medical College, Barpeta
		Silchar Medical College, Silchar
2	Manipur	Regional Institute of Medical Sciences, Imphal
		J N Institute of Medical Sciences, Imphal
3	Meghalaya	North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences, Shillong
4	Tripura	Government Agartala Medical College, Agartala

(2) Establishment of Multi-disciplinary Research Units (MRUs) have been approved in the following Government Medical Colleges / Research Institutions in the NE region:

Sl. No.	Name of the State	Name of the Medical College sanctioned the MRU
1	Assam	Silchar Medical College and Hospital, Silchar
		Fakruddin Ali Ahmed Medical College, Barpeta
		Jorhat Medical College, Jorhat
2.	Manipur	Regional Institute of Medical Sciences, Imphal
3.	Tripura	Agartala Govt. Medical College, Agartala

(3) Establishment of Model Rural Health Research Units (MRHRUs) have been approved in the following States of the NE Region:

Sl. No.	State	Location of MRHRU	ICMR mentor Institute/Centre	Linked Medical College
1.	Assam	PHC Chabua	RMRC, Dibrugarh	Assam Medical College and Hospital, Dibrugarh
2.	Tripura	Kherengbar Hospital Khumulwung	RMRC, Dibrugarh	Agartala Government Medical College
3.	Nagaland	PHC, Niuland, Dist: Dimapur	RMRC, Dibrugarh	--
4.	Meghalaya	Sohra CHC ,East Khasi Hills	RMRC, Dibrugarh	District Surveillance Officer EKH(IDSP)
5.	Arunachal Pradesh	CHC Sagalee Papum Pare	RMRC, Dibrugarh	Tomo Riba Institute of Health & Medical Sciences (TRIHMS), Neharlagun

(4) Human Resource Development for Health Research: The number of fellowships funded under the scheme in the NE region is as follows:

2013-14 to 2017-18		2018-19		2019-20	
Name of the State	No. of Fellowships granted	Name of the State	No. of Fellowships granted	Name of the State	No. of Fellowships granted
Assam	8	Assam	5	Assam	2
Tripura	1	Tripura	1		
Manipur	5	Nagaland	3		
Nagaland	1				
Total	15		9		2

3.7.3 The Committee is constrained to express its displeasure over lower actual expenditure to the tune of Rs. 88.14 crore as on 10th February, 2020. The Committee hopes that projects/schemes undertaken during 2019-20 viz. establishment of network of VRDLs, MRUs, MRHRUs and Human Resource Development for Health Research would yield the desired outcome in the interest of maintaining public health in NER. The Committee also hopes that allocation would be fully utilized for the intended purpose on the projects already sanctioned in the interest of public health in NER.

3.7.4 ICMR has a permanent Institute, namely, the Regional Medical Research Centre (RMRC) at Dibrugarh for addressing various health issues of the regional importance. Besides, it has a NIMR Field Station at Guwahati. Also, Three Task Force projects have been initiated recently in north east by ICMR as mentioned below:

- (i) Rickettsial diseases in states of Nagaland, Meghalaya and Mizoram in Northeast India: Epidemiology, disease burden and vectors.
- (ii) Systematic study of Acute Encephalitis Syndrome (AES) in NE states of India for clinical, aetiological and epidemiological aspects.
- (iii) Monitoring of insecticide resistance in malaria vectors in endemic States of India (VBDSF) including North East Region.

3.7.5 As a part of the efforts to improve the expenditure profile on health research activities in the NE region, it has been decided to establish a Bio Medical Research Centre at Guwahati.

3.7.6 The Committee wanted to know about the action Plan that can be undertaken to disseminate the benefits of Health Research in NER to local dwellers as well as to meet the health requirement of the people countrywide. The DHR mentioned that a network of MRHRUs has been created in the NER for transfer of technology at the rural level for providing better treatment to the local population. This infrastructure is also catering the research needs on local disease burden and the technology from lab to the field. The Multi-disciplinary Research Units (MRUs) in the government medical colleges are also engaged in research on non-communicable diseases which will ultimately benefit the patients in the area. The network of viral research and diagnostic laboratories are engaged in identification of new and emerging viruses for managing epidemics/outbreaks. Meeting with all stakeholders including Health and WCD officials, local communities, North East Hill Council, Ministry of DoNER, etc will be held not only to disseminate the findings of research but also to brainstorm and prioritise areas for health research in collaboration with them.

3.7.7 The Committee has been given to understand ICMR is playing the pivotal role in NER and three task force projects viz. Rickettsial diseases, Acute Encephalitis Syndrome (AES) and Monitoring of insecticide resistance in Malaria vectors are underway. The Committee, in this connection, recommends DHR that the decision to establish Bio-medical Research Centre at Guwahati be implemented on the ground level without delay.

3.7.8 The Committee also recommends for dissemination of benefits of health research in NER to the local dwellers by providing cost effective healthcare services. The Committee, in this regard, recommends that DHR should formulate strategy for focusing on the following course of action in NER:

- (i) Reduction of risk factors for cancer and lifestyle related diseases (diabetes, and Cardiovascular diseases)**
- (ii) Hypertension control by reduction of salt consumption.**
- (iii) Improving maternal and child health**
- (iv) Effort to halt and spread of Antimicrobial drug resistance**
- (v) Reduction of TB in NE, elimination of malaria and food borne diseases**
- (vi) Developing network for data sharing platform for Surveillance and early containment of outbreaks.**

CHAPTER- IV

ISSUE RAISED

4.1 During the course of examination of Demands for Grants (2020-21), the Committee deliberated on various issues on the various provisions and implications of Demands pertaining to DHR. These following issues deserve to be part of this report:-

I. Separate budgetary allocation for common diseases like Kidney Diseases, Diabetes, Cancer, High BP, etc.

4.2 The DHR apprised the Committee that a separate earmarked budget was used for setting up the ICMR-Indian Cancer Research Consortium wherein Rs.25.00 crores was allocated for this activity. In addition Rs.75.00 crores were allocated to the Division of Non-communicable Diseases of which the major diseases are cancer, Diabetes, Hypertension and stroke. ICMR has a dedicated institute ICMR-National Institute of Cancer Prevention and Research in Noida which focuses of prevention and early detection of cancer. This institute has also developed a device which assists in early detection of cervical cancer in women.

4.2.1 Taking into account various budgetary provisions and institutional arrangements meant for combating common diseases Kidney Diseases viz. Diabetes, Cancer, High BP, etc, the Committee recommends that DHR, in tandem with ICMR, would make concerted efforts for undertaking research activities to translate its outcome to develop product for treatment of common diseases for up-keeping of public health. The Committee would like the ICMR-NICPR to undertake further research to develop device for early detection of various emerging forms of Cancer.

II. 24x7 Crisis Management team at National Level for addressing the situations during outbreak of epidemics

4.3. The Committee has been informed that the Emergency Medical Relief (EMR) Cell of Ministry of Health & Family Welfare has been entrusted with the responsibility of mobilizing Central Teams in the event of any public health emergency. EMR coordinates with various arms of the Health Ministry as well as other ministries / departments of the Govt. to ensure an appropriate response to any unforeseen public health event like outbreaks of infectious diseases, health issues emerging as an aftermath of floods, earthquakes etc. EMR also convenes various ministries / departments to build the country's preparedness plan in times of Public Health Emergencies of International Concern (PHEIC). Besides, NCDC Delhi is the focal point for implementation of International Health Regulations (IHR) 2005.

4.3.1 ICMR works closely with EMR & NCDC to support the preparedness for unforeseen public health events. The assignment covering laboratory support, deputing epidemiologists and microbiologists are undertaken by ICMR through its National institutes located near the site and a nationwide network of 106 virus research diagnosis laboratories (VRDLs). The National Institute of Virology (NIV), Pune is a resource centre for VRDLs, which provides training and reorientation to the VRDLs. Additionally, it is involved in providing reagents for testing as well as undertaking quality assurance and quality control in the VRDLs. This network is currently used for undertaking surveillance of certain organisms of public health importance such as zika virus and influenza nationally. The findings from influenza surveillance are utilized for selecting

the strains of influenza virus in its vaccine every year. The dreaded high-risk pathogens such as Nipah virus and zika virus have been detected of recent through these VRDLs. A network of 14 different laboratories is involved in providing support to the Health Ministry for providing diagnostic support against novel Coronavirus currently.

4.3.2 The Committee was given to understand that the network of VRDLs can detect the high risk pathogens identified by R & D blueprint of the World Health Organisation such as Ebola virus, SARS, MERS-CoV, Zika virus, Yellow fever, Nipah virus, SARS-CoV-2 (novel coronavirus) etc. These pathogens are associated with high risk of death, high transmissibility and a potential to be used to as agents of bioterrorism due to non-availability of effective vaccine or cure.

4.3.3 Considering these issues, ICMR proposes to expand the viral labs network by establishing these laboratories in Command Hospitals under Indian Army and the Armed Forces Medical College, Pune. This will ensure that Army will be able to detect any pathogen that can be used in bioterrorism and act upon it. In order to enhance our preparedness to handle these high risk pathogens, ICMR proposes to develop modules and undertake training to create a pool of master trainers in Bio-simulation. These Master trainers can propagate the training to other VRDL labs. ICMR proposes to expand the mandate of a select few willing VRDLs by enhancing the capacity to undertake research on fungi and certain bacteria that are of public health of importance due to drug resistance and non-availability of therapeutic modalities. ICMR has upgraded four VRDLs for fungal surveillance during this year. Antimicrobial resistance is emerging as a major cause of death and by 2050, the predominant cause of death in intensive care units due paucity of antibiotics. Additionally, ICMR proposes expansion of the team at VRDLs to undertake quality outbreak investigations in coming years. These activities will require additional fund allocation to ICMR.

4.3.4 The Committee is of the considered view that in order to have 24x7 Crisis Management team at National Level for addressing the situations during outbreak of epidemics, there is an urgent need to strengthen the government's preparedness plan and to galvanise the role of NIV, Pune- a resource centre for VRDLs, NCDC, Delhi and enhancing the capacity building of VRDLs. The Committee, in this regard, recommends that VRDLs can be re-oriented to detect the dreaded high-risk pathogens that can be used in bio-terrorism. The Committee, in this context, appreciates the proposal of ICMR to develop modules and create pool of master trainers in Bio-simulation, who, in turn, can propagate the training to researchers engaged in VRDL labs. The Committee, therefore, strongly recommends that adequate budgetary allocations be made to ICMR for expansion of VRDLs to undertake research on fungi and certain bacteria as the antimicrobial resistance as antimicrobial resistance is said to be emerging major cause of death. The Committee calls upon the government to direct the research institutes to be proactive in their approach and act upon before an outbreak of epidemics rather than acting post aftermath of the outbreak.

Awareness about preventive measures against the spread of viral outbreaks and other communicable and non communicable diseases

4.4 The Committee has been informed that ICMR is supporting a project on creating sustainable community intervention strategies for Acute Encephalitis Syndrome in Muzaffarpur, Bihar. This project is expected to lead to the development of an innovative community engagement strategy. The same model can be replicated in other States. The Department of Health Research will take up the matter with the Ministry of Human Resource Development to

explore the feasibility and appropriate age inclusion of such chapter in the course book of school children.

4.4.1 The Committee recommends that there is a need to undertake awareness program about the preventive measures like hand-washing, sterilization, smoking, weight loss, dietary habits, etc. against the spread of viral outbreaks and other communicable and non communicable diseases. In this connection, the Committee recommends that the Ministry of Human Resource Development may consider to incorporate the study material in the curriculum of school children.

Elimination of TB by 2025

4.5 The Committee has been informed that ICMR has set up 'India TB research Consortium' a flagship programme of ICMR which is working towards the development of new tools for diagnosis, treatment and prevention of TB which could subsequently be taken up by Ministry of Health & Family Welfare for use under NTEP so that the elimination target could be achieved. A new cost effective point of care molecular diagnostic test developed with support from ICMR, has been recommended to the Ministry of Health & Family Welfare for use under NTEP and is also recommended by WHO for detection of TB/MDR-TB. The test can easily be widely used at PHC level, rural areas, hard to reach areas for detection of TB/MDR-TB thus helping in early diagnosis and treatment. Besides evaluation of new shorter treatment regimens for TB/MDR-TB are ongoing and a Phase- III vaccine trial using two vaccines in a single trial is ongoing for prevention of TB disease

4.5.1 The Committee feels that there is a trumpet call for intensification of research work under 'India TB Research Consortium' of ICMR for development of new pools for diagnostic treatment to enable the Department of Health and Family Welfare to achieve the target of elimination of TB by 2025 i.e. 'Desh Jitega, TB Harega.

Making availability of TB Van in Rural Areas

4.6 The Committee was informed that during 2016-2017, ICMR under the Global Fund project has used 35 mobile TB diagnostic vans fitted with digital X-rays and smear microscopy in 17 Tribal districts in 5 states (Chhattisgarh, Madhya Pradesh, Jharkhand, Gujarat and Rajasthan) to diagnose TB in tribal population and it had increased the case finding and has led to almost zero out of pocket expenditure by the TB cases. The vans were handed over to the Central TB Division for further use under programme and in currently being used by State Govts.

4.6.1 Currently, ICMR is undertaking the National Tb Prevalence survey with support from CTD and WHO to estimate the national as well as state level of prevalence of TB. The survey would cover a total population of 500000 in 625 clusters across India except Andamans and Lakshadweep using 25 state of Art buses fitted with digital Chest X-rays and Molecular TB diagnostic test. The other tests like HB, Blood sugar, BP etc. are also being measured under the survey. The 625 clusters would include select rural, urban, semi urban, tribal areas across the country.

4.6.2 The Committee takes note of the efforts made by ICMR for innovating mobile TB diagnostic vans fitted with digital X-rays and smear microscopy and handing over to the Centre TB Division for use by the State Government with almost zero impact on out of pocket expenditure by the TB cases. The Committee hopes that under the National Tb

Prevalence survey, to estimate the national as well as state level of prevalence of TB, would use the state of Art buses fitted with digital Chest X-rays and Molecular TB diagnostic test in all the identified 625 clusters that would cover select rural, urban, semi urban, tribal areas across the country with support from CTD and WHO.

India at 102 position in the Global Hunger Index, 2019 out of 117 countries

4.7 The Committee has been informed by the DHR that the Global Hunger Index (GHI) is a tool designed to comprehensively measure and track hunger at global, regional, and national levels. GHI scores are calculated each year to assess progress and setbacks in combating hunger. The GHI was initially published by the US based International Food Policy Research Institute (IFPRI) and Germany based Welthungerhilfe. In 2007, the Irish NGO Concern Worldwide also became a co-publisher. In 2018, IFPRI stepped aside from its involvement in the project and the GHI became a joint project of Welthungerhilfe and Concern Worldwide. The Index is calculated based on following indicators:

Factors	Indicators
UNDERNOURISHMENT	share of the population that is undernourished (that is, whose caloric intake is insufficient)
CHILD WASTING	share of children under the age of five who are wasted (that is, who have low weight for their height, reflecting acute under nutrition)
CHILD STUNTING	share of children under the age of five who are stunted (that is, who have low height for their age, reflecting chronic under nutrition).
CHILD MORTALITY	Mortality rate of children under the age of five (in part, a reflection of the fatal mix of inadequate nutrition and unhealthy environments).

India's Global Health Index (GHI) Score

YEAR	GHI SCORE	RANK
2014	17.8	55/76
2015	29.0	80/104
2016	28.5	97/118
2017	31.4	100/119
2018	31.1	103/119
2019	30.3	102/117

4.7.2 The DHR has expressed that it is important to examine the computation of GHI in the Indian context because of recent media reports leading to misdirected stigma, and advocacy for hunger alleviating policies. In order to review the appropriateness of Global Hunger Index to measure 'Hunger', Secretary, DHR has constituted an Expert Committee with terms and reference that inter-alia includes (i) Appropriateness of the indicators used in Global Hunger Index; (ii) Methodological issues in the computation of GHI and (iii) Suggest a way forward. The ICMR Expert Committee is working on the '*White Paper*' on Global Hunger Index and the same will be released.

4.7.3 The Committee draws satisfaction from the fact that DHR has constituted an Expert Committee to examine the appropriateness of the indicators used in Global Hunger Index, methodological issues in the computation of GHI and to suggest a way forward. In addition, the ICMR Expert Committee is also working on the 'White Paper' on Global Hunger Index. The Committee would like to be updated on the recommendations of the said Expert Committee alongwith the response of DHR thereon.

Need to develop policies to stop irrational use of antibiotics

4.8 The DHR has admitted that reducing antimicrobial use among humans is important given the relationship between hospital and community infections. It was stated that studies undertaken in other countries concluded that the prevalence of pathogens in the community was predicted by hospital drug resistant rates of those pathogens. In one study, Stewardship activities within the community were associated with 32% reduction in community Methicillin-resistant Staphylococcus Aureus (MRSA), while hospital-based interventions were responsible for an additional 37% reduction in community MRSA. ICMR through the treatment guidelines and its Antimicrobial Stewardship Program (AMSP) program is making an effort to rationalize and reduce antimicrobial use in hospitals which will also have an impact on community rates. Research initiatives can guide policies on antimicrobial use in the health care systems. ICMR will support such research initiatives.

4.8.1 ICMR had initiated discussion on colistin ban with ICAR and Drugs Controller General of India (DCGI) which came into effect in 2019. DCGI also banned sale of fixed dose combinations of improper antibiotics in 2018, on the suggestions of ICMR and introduced H1 schedule to regulate sale of certain classes of antibiotics. ICMR would be undertaking research studies to document the effectiveness of these initiatives in discouraging improper antibiotic use.

4.8.2 The Committee has been given to understand that reducing antimicrobial use is the necessity of the day keeping in view the intrinsic relationship between hospital and community infections. In this regard, the Committee applauds the treatment guidelines and antimicrobial Stewardship Programme of ICMR that aims to rationalize and reduce antimicrobial use in hospital. Keeping into consideration the given fact, the Committee, strongly recommends formulation of policy both in hospitals and communities to reduce antimicrobial use in the Health care System.

Telemedicine and tele-radiology as well as taking the Mobile CTs and Mobile MRIs to rural sectors

4.9 The DHR apprised the Committee that ICMR is making attempts to develop the Artificial intelligence tools which can be used in a rural area for screening of TB using Chest X-rays. The teleradiology is currently being used to read X-rays done in mobile survey vans under the National TB Prevalence survey. A pilot project has been initiated in Tezpur and Dibrugarh in Assam to check the feasibility of using a mobile CT scan in semi-urban and rural areas. The findings of the study will provide some indications as to how such an effort can be scaled up to other areas of the country

4.9.1 The Committee appreciates the efforts being made by ICMR in developing the artificial intelligence tools for screening TB using chest x-ray in rural areas. The Committee, in this connection, recommends that efforts should also be made to give a nationwide rural coverage of screening TB through the artificial intelligence. The

Committee further recommends that the successful model of pilot project, as initiated at Tejpur and Dibrugarh at Assam, to verify the feasibility of using a mobile CT scan in semi-urban and rural areas can be replicated in all semi and urban rural areas in the country. The Committee would, therefore, like the ICMR to make assessment of financial requirement and approach the Ministry of Finance for allocation.

Mission DELHI (Delhi Emergency Life Heart-Attack Initiative)

4.10 In reply to a query whether the “Mission DELHI (Delhi Emergency Life Heart-Attack Initiative)” in a range of 3KM around All India Institute of Medical Sciences (AIIMS) launched by the Indian Council of Medical Research (ICMR) as a Pilot Project is proposed to be extended to other states also, the DHR submitted that this program has recently been initiated on a Pilot Basis in Delhi and based on the success and results in Delhi, it would be considered for expansion in other states as well.

4.10.1 The Committee strongly recommends that “Mission DELHI (Delhi Emergency Life Heart-Attack Initiative)” launched by the Indian Council of Medical Research (ICMR) as a Pilot Project should be extended to other States as well for it has the capacity to save lives of many needy persons.

Advanced medical technologies to people’s doorsteps.

4.11 Establishment of Model Rural Health Research Units (MRHRUs) in close proximity to the PHCs/CHCs is a great initiative to take advanced medical technologies from lab to field for the benefit of the local population. DHR will make further attempts to review these technologies and develop implementation research projects around them.

4.11.1 The Committee underlines the need to extend the benefits of scientific and technological advancement accessible and affordable to all, especially the people living in rural and tribal areas for which the advance medical technologies under MRHRUs can be made available at the people’s door steps.

Circulation of the Standard Treatment Workflows (STWs) to every Primary Health Centre and the subsidiary health centers

4.12 The DHR informed the Committee that dissemination strategy is being formulated to circulate the Standard Treatment Workflows (STWs). The Department is also looking into the various channels of dissemination of the STWs to the Primary Health Centers, Community Health Centres & the District Hospitals. The detailed plan in the regard is also under discussion with various stakeholders.

4.12.1 The Committee understands the utility of Standard Treatment Workflows (STWs) in Public Health Care and recommends that strategic course of action with regard to dissemination to the Primary Health Centers, Community Health Centres & the District Hospitals must be translated on the ground level in the interest of patients, doctors, etc.

Status of Zika virus

4.13 Cases of Zika virus were reported from Ahmadabad, Gujarat (2017); Tamil Nadu (2017); Jaipur Rajasthan (2018), Bhopal, MP (2018). ICMR is conducting surveillance of ZIKV at 35 different locations in India. Besides a follow up study of babies born to infected mothers in 2018 Jaipur outbreak has also been conducted. No further cases of ZIKV have been reported.

4.13.1 The Committee takes note of the efforts made by the ICMR in conducting surveillance of ZIKA and in fact no cases of ZIKA have been reported.

Monitoring Leprosy in certain States

4.14 The DHR informed the Committee that the special emphasis to find out the patient suffering from the leprosy is expected to flush out more hidden cases, especially amongst women, children. In addition to continuous administering of MDT to patients, new preventive approaches such as chemoprophylaxis and immuno-prophylaxis are being considered to break the chain of transmission and reach zero disease status.

4.14.1 The Committee hopes that administration of MDT, new preventive approaches such as chemoprophylaxis and immuno-prophylaxis would break the chain of transmission and reach zero disease status.

Criteria for establishment of Viral Research & Diagnostic Laboratories (VRDLs)

4.15 The scheme entitled “Setting up of Nation-wide Network of Laboratories for Managing Epidemics and National Calamities” is mandated to establish a three tier structure of Viral Research & Diagnostic Laboratories (VRDLs):

- (i) Regional Level VRDLs with state of art facilities including BSL-3 facility –to be established in AIIMS or AIIMS like Institutes;
- (ii) State Level VRDLs with BSL2+ facility – in Government Medical Colleges; and
- (iii) Medical College Level VRDLs with BSL-2 facility – in Government Medical Colleges.

4.15.1 The proposal for the Regional Level is to be forwarded to Department of Health Research by the Director/ Head of Medical College/Institute with duly signed Memorandum of Agreement. The proposal for State Level and Medical College Level Viral Research & Diagnostic Laboratories (VRDLs) along with duly signed Memorandum of Agreement is to be forwarded by the State Health Department to Department of Health Research. The proposal is then screened and evaluated by Technical and Evaluation Screening Committee including findings of its site visits. The proposals duly recommended by the Technical and Evaluation Screening Committee as sent for final approval by Approval Committee, Chaired by Secretary, DHR.

4.15.2 The Committee, taking into account the Criteria for establishment of Viral Research & Diagnostic Laboratories (VRDLs), recommends that procedure for establishment of VRDLs must be simplified and transparent. The procedure should not take in due time to be completed.

DHR-ICMR Advanced Molecular Oncology Diagnostic Services (Diamonds)

4.16 DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMOnDS) is an integrated approach towards molecular oncopathology, where molecular oncopathology diagnostic services and molecular onco-pathology research will run parallel and in sync with each other. Data generated through diagnostic services will become the basis for diagnostic research, generating further information and insight for the cancer pathology and better management.

4.16.1 Through the first phase of DIAMOnDS initiative, nine zonal molecular onco-pathology labs along with one centre for data management has been set up across four zones of the country to provide free of cost, basic as well as high-end oncopathology diagnostic services to cancer patients. Along with the diagnosis, these labs will also be performing basic, translational and clinical research activities as diagnostics and research go hand in hand in a laboratory set-up. These laboratories are entrusted with responsibility of analyzing the scientific and technology areas, in research and diagnostics, along with the task of capacity building through specialization courses, hands on trainings and interactive workshops. The initiative has been started as a pilot project and based upon its learning, there shall be an endeavor to expand the network of DIAMOnDS labs in more number of states of the country. This will definitely require more budgetary allocation.

4.16.2 The Committee understands that DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMOnDS) is vital for the treatment of cancer. The Committee is of the view that in-depth research in the field of molecular oncopathology diagnostic services and molecular onco-pathology research would go a long way in the elimination of cancer. The Committee is of the view that the expansion of the network of DIAMOnDS in various States of the country requires the budgetary allocation. The Committee, therefore, recommends DHR to make assessment of the financial requirement for the said purpose and accordingly approach the Ministry of Finance for requisite allocation.

Collaboration with other Ministries, including AYUSH to come up with certain cheaper drug options for cancer treatment

4.17. The DHR apprised the Committee about a Randomized Controlled Clinical Study to evaluate the safety and efficacy of an ayurveda formulation - PJ7 in the management of Dengue fever and prevention of its complications ICMR-NITM, Belagavi in collaboration with Dept of AYUSH. ICMR is also engaged in various other studies related to traditional medicines. A Joint Phytopharmaceutical Drug Development Programme of ICMR, CSIR and DBT as an effort of inter-ministerial cooperation for promotion and facilitation of innovative research on Phytopharmaceuticals” in the country has been initiated. Under this programme 9 leads were initially identified, out of which 3 leads have been prioritized.

4.17.1 The Committee is of the considered view that collaboration with the other ministries including AYUSH would help to invent cheaper drug option for treatment of various diseases, including cancer. The Committee, in this regard, appreciates the joint efforts of ICMR, CSIR and DBT in taking initiatives and facilitation of innovative research on Phytopharmaceuticals. The Committee feels that the Randomized Controlled Clinical Study to evaluate the Safety and Efficacy of an Ayurveda formulation - PJ7 would go a long way in the management of Dengue fever.

NESTLE CASE

4.18 The Committee sought to know the course of action being contemplated against NESTLE in view of the finding of a Committee an alleged violation of law in company's sponsorship of a five hospital on the study of infant milk substitutes. It is learnt that the Breastfeeding Promotion Network of India (BPNI), notified by the Government to monitor compliance of the Infant Milk Substitute (IMS) Act, had brought a five hospital study to the notice of the Ministry of Health and Family Welfare and ICMR on July, 17, 2019. The DHR replied that the Committee of ICMR reported that 'the complaint is well founded' and the study is violative of section 9(2) of the IMS Act that it was 'funded and sponsored by NESTLE India, it is a producer/supplier distributor on Infant Milk Substitute defined under the Act. The ICMR Committee recommended that the study should be terminated immediately by the appropriate authority. Based on the recommendations of the ICMR committee, the Clinical Trial Registry of India (CTRI) has advised the investigators to change the CTRI registration status to 'terminated' citing the reasons for the same.

4.18.1 The Committee notes that the Clinical Trial Registry of India (CTRI) has terminated NESTLE's sponsorship of a five hospital study on violation of Section 9(2) of the Infant Milk Substitutes Act on the recommendation of Committee constituted by ICMR for the purpose.

REGISTRATION OF CANCER CASES

4.19 Taking notice of the Media reports that each and every case of cancer will be registered by the ICMR to assess actual disease burden, the Committee sought to know from DHR as to what was being done in this regard and by when will this registry be operational. The DHR submitted that the systematic collection of data on cancer is being carried out by various Population Based Cancer Registries (PBCR) across India under the National Cancer Registry Programme (NCRP) of ICMR since 1982. The NCRP operates through a network of 36 Population Based Cancer Registries (PBCRs) and 236 Hospital Based Cancer Registries (HBCRs) which covers nearly 10% of Indian population. Since cancer is not yet a notifiable disease, registration of each case is not mandatory. The quality data collected by the registries on a regular basis across the country gives a more complete assessment regarding the burden of cancer. The data collected by PBCRs is published periodically in form of consolidated reports by ICMR-NCDIR. The reports are shared with MoHFW from time to time and are readily accessible on the website www.ncdirindia.org.

4.19.1 The Committee also took notice of recent media reports which indicated that a Kerala Institute, namely, Shree Chitra Tirumal Institute of Medical Sciences has earned US patent for turmeric based cancer treatment. ICMR has supported the development of this technology and the product is likely to be transferred to industries for clinical trials and commercial use. The Committee, therefore, desired to know the plan of action to make available this course of treatment to ailing cancer patients. The DHR stated that SCTIMST and ICMR have won a joint US patent for developing a drug delivery patch for curcumin based cancer treatment. ICMR has supported the development of this technology. Currently, SCTIMST is in the process of identifying an industry partner for validation of the technology. Based on the clinical validation results and regulatory clearances the drug delivery patch will be available for the use.

4.19.2 The Committee underlines the need of registration of each and every case of cancer by the ICMR to assess actual disease burden. In this regard, the data collected by Population Based Cancer Registries (PBCR) and 236 Hospital Based Cancer Registries (HBCRs) would be quite useful. The Committee believes that the data so collected would be used in the further research work for developing products for treatment of cancer.

ANIMAL FREE TEST METHODS

4.20 The ICMR has recognized the need for alternatives to animals in experimentation and called for modern, animal free test methods to replace animal research. The Committee sought to know the measures/initiatives that have been taken to replace animal experimentation. The DHR referred to a white paper on “Indian Road Map for Alternatives to Animals in Research: Past, Present and Future” prepared by Expert Group set up by D.G ICMR.

4.20.1 The Committee has been informed that under bio-medical research the following key areas have been identified for regulation of animal free test method:-

- i. Building on the strengths, such as boosting collaborations and networking in the national as well as the international arena should be promoted. The existing expertise in in vitro methodologies as alternatives to animal testing needs to be fairly expanded and research efforts, especially regarding chronic toxicity endpoints, increased.
- ii. Use of cell cultures should be adopted in parasitic diseases and encouraged in lifestyle diseases as well.
- iii. Use of stem cells may be seriously considered in development of tissues and organoids for use in basic, applied research and accelerating drug discovery research.
- iv. Bioinformatics and computational tools should be used extensively in drug discovery and development to accelerate the process.
- v. All available models where organoids will be used on chip should be encouraged for use by researchers.
- vi. Centers having the expertise of stem cell developed organoids should to share the technology with researchers.
- vii. Facilitation and providing guidance on validation criteria and processes.
- viii. Plan of action needs to be prepared for the new validated in vitro tests dissemination to all the investigators in the academia in universities, medical institutes, and national centers.
- ix. To compile a repository of validated in vitro tests available nationally (and internationally) and initiate training investigators, covering scientists who are using animals in the country.
- x. Plan for training scientists on 3D organoids or animal/human-on-a-chip or other similar tests used abroad with the help of international agencies and then to disseminate the same to drug development centres in the country.

4.20.2 The Committee has further been apprised of the regulatory toxicology as enumerated below:-

- i. To develop new toxicity testing strategies, with an emphasis on high throughput technologies to establish toxicological ‘fingerprints’ or reveal toxicological pathways of chemicals, complex mixtures, and pharmaceuticals.
- ii. Building on our strengths, such as boosting collaborations and networking in the national as well as the international arena and intensifying our efforts at the OECD level.
- iii. Intra- and inter-laboratory reproducibility of test methods should be examined with the aim of predicting of toxicity in humans.

4.20.3 The Committee takes note of the White Paper prepared by Expert Group set up by ICMR on development of alternatives to animals in key areas of bio-medical research and regulatory toxicology. The Committee, however, recommends that DHR may constitute an Executive Group to formulate guidelines in consonance with the recommendation of White Paper Roadmap for harmonization across various research institutions of the country. The Committee is of the considered view that there is an urgent need for promotion of general awareness for making use of alternative to animals in all bio-medical research process. The Committee also recommends that DHR must evolve the monitoring mechanism to oversee the regulation of the same guidelines. The Committee further desires that necessary follow up action be undertaken, as and when required, to pursue the mission provisions as contained in the White Paper and guidelines on the subjects pertaining to animal free test method.

PFIZER AS A PARTNER FOR ITS COLLABORATION TO COMBAT ANTIMICROBIAL RESISTANCE (AMR)

4.21 The Committee sought the rationale for identifying Pfizer as a partner for its collaboration to combat Antimicrobial Resistance (AMR) in the name of public private partnership. The Committee also desired to know the details of nodal agency dealing with Antimicrobial Resistance, the role of ICMR and how has it got involved in it. On a query to the conflict of interest of Pfizer, the Department informed that ICMR-Pfizer signed an MoU in 2017 to partner on building capacities in Antimicrobial resistance surveillance and stewardship in secondary levels of health care and undertake communication and awareness activities on AMR. For this Pfizer contributed Rs 4.47 crore from its CSR fund and National Control for Disease Control (NCDC) is nodal agency for surveillance of AMR.

4.21.1 The Committee has been given to understand that ICMR is currently leading the entire AMR research initiative in Indian hospitals which includes improving surveillance of AMR, understanding mechanisms of resistance and building structure and process of Antimicrobial Stewardship. This initiative is currently limited to tertiary care hospitals as the infrastructure and human resource capacity to undertake these activities in secondary level hospitals do not exist. ICMR decided to utilise the Pfizer fund for capacity building and education and awareness activities. The DHR has assured the Committee that although funds have been received from Pfizer, ICMR is the face for undertaking all activities. The activities are being driven through the core team of ICMR or the ICMR network of hospitals. Pfizer does not influence the decision making process at ICMR and has given a written undertaking that it will not claim any right on any intellectual property arising out of this project as the funds are coming from the CSR fund of Pfizer.

4.21.2 The Committee observes that though the Pfizer company has contributed from Corporate Social Responsibility (CSR) fund under an MoU as a partner for its collaboration to combat Anti-Microbial Resistance (AMR) with ICMR, still the DHR should ensure that the company is not allowed as lobbying group to influence the decision of the policy maker and no rights on the intellectual property arising out of the project be claimed by Pfizer.

STEM CELL THERAPY

4.22 As per media reports, ICMR is planning to bring in regulations for stem cell therapy and prevent misuse and lay standards for research, clinical use and storage. The move comes in wake of several complaints by patients about the misuse of stem cell therapy. On a query as to the kinds of complaints filed regarding misuse of this therapy and the norms envisaged to be laid down help in regulation for stem cell therapy, the DHR submitted that the last decade has witnessed a spurt in translational research using different types of stem cells. It was hoped that like the well-established hematopoietic stem cell transplantation (HSCT) with clearly defined clinical indications, other stem cell based therapies too will be integrated into routine clinical practice. However, this did not happen due to lack of systematic clinical research using common protocols and objective outcome evaluation. This still remains the major impediment in the process of translation from the bench to bedside. Parallel to these scientific developments, the field is unfortunately witnessing rampant malpractice, posing challenges for the regulatory authorities worldwide. In India too, science and the medical practice is at the crossroad. Clinical research is struggling to cope with the regulatory requirements, industry sponsored clinical research is gaining momentum, but seeks greater clarity and direction. Meanwhile, unscientific or unethical stem cell therapy continues to pose a threat to the well-being of patients and other vulnerable individuals. ICMR has received complaints from NGOs, Patient groups and individual patients that how they were mislead and promised cure through stem cell therapy for their incurable or genetic disorder with no outcome or improvement.

4.22.1 The Guidelines for Stem Cell Research and Therapy in 2007 was a step towards this commitment, which were revised after public consultations and released as National Guidelines for Stem Cell Research (NGSCR-2013). The National Guidelines for Stem Cell Research, 2017 which is an outcome of concerted efforts of different stakeholders has been formulated taking into account several new scientific and technical advancements as well as the perceived challenges in the field. Efforts were made to bring together all concerned ministries/agencies to chalk out strategies to curb rampant unethical practices of banking and therapeutic application. The recommendations of the Inter-Ministerial/Inter-Agency have helped to shape these guidelines. Detailed and extensive consultation with stakeholders were held and their suggestions taken into account before finalization. Most importantly, the guidelines have been harmonized with existing rules and regulations resulting in a comprehensive document.

4.22.2 The 2017 guidelines, stipulate that any stem cell use in patients, other than that for hematopoietic stem cell reconstitution for approved indications, is investigational at present. Accordingly, any stem cell use in patients must only be done within the purview of an approved and monitored clinical trial with the intent to advance science and medicine, and not offering it as therapy. In accordance with this stringent definition, every use of stem cells in patients outside an approved clinical trial is unethical and shall be considered as malpractice. The document provides important definitions for and elaborates upon levels of manipulations. A list of approved indications for HSCT has been provided. The mechanism for review and monitoring of clinical research has been strengthened by making CDSCO approvals mandatory prior to initiation of any clinical trial. Some major amendments include:

- i. Mandatory registration of Institutional Committee for Stem Cell Research (IC- SCR) and Institutional Ethics Committee (IEC), with National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and CDSCO respectively;
- ii. Undertaking clinical trials only at institutes with registered IC-SCR, IEC, and only at Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) certified

facilities;

- iii. Research undertaken by medical professionals registered with the Medical Council of India (MCI) and an MCI approved post graduate qualification in the domain area of the specific trial.

4.22.3 Taking cognizance of the challenge of regulating unethical practices in the country that the doctors are misleading vulnerable population and offering unproven (without validating safety and efficacy) stem cell therapy for various genetic and other debilitating incurable conditions, Secretary (HFW), ICMR was entrusted to develop Guidelines for Stem Cell Therapy. The same are under finalisation and will be released soon after taking comments and suggestions from the stakeholders. To develop evidence based Stem Cell Therapy guidelines, ICMR invited Level I and Level II evidences, from various professional societies as well as from other entities through open call on ICMR website, ICMR is in process of collating the information received to frame the said guidelines. The document will have clear demarcation on approved and unapproved stem cell therapies.

4.22.4 The Committee takes note of the fact that ICMR has been entrusted with the responsibility of formulating evidence based Stem Cell Therapy guidelines. It is felt that there is an urgent requirement for facilitation of safe and regulated translational and clinical stem cell research. The Committee is of the view that while framing the guidance document, utmost care needs to be taken to ensure that stem cell research does not in any way compromise the safety of patients and vulnerable individuals. The Committee also feels that the guidelines would need harmonization with existing rules and regulations with a view to frame a comprehensive document specifying that every use of stem cell in patients outside an approved clinical trial is unethical, and therefore, shall be considered as malpractice and henceforth punishable under the relevant law.

TREATMENT OF CORONAVIRUS

4.23 As per media report, ICMR has set up an expert Panel duly approved by the DGGI to develop drug mix in line with Chinese Protocol for treatment protocol for coronavirus. The Committee desired to be apprised of the details of the measures undertaken to combat the threat of corona virus in India and whether any research project has been undertaken for treatment of coronavirus. The DHR informed that till date there is no available drug or vaccine for treatment of novel Coronavirus (nCoV) infection. However, there is limited evidence of effectiveness of anti-retroviral drug, boosted lopinavir in treating nCoV infected patients. ICMR has obtained approval of CDSCO for restricted public health emergency use of boosted lopinavir in nCoV infected consenting patients. Till date, the drug has not been used in any nCoV infected patient in India.

4.23.1 At a time when rapid spread of Coronavirus raises fear of global pandemic with deaths and infection engulfing Europe, the Middle East and Asia, there is urgent need for in-depth research activities for treatment and containment of the Coronavirus. The Committee, in this regard, feels that the Coronavirus has the potential to have an adverse impact on the global economy, thereby, affecting the international trade. The Committee hopes that ICMR would play pivotal lead role to deflect the impact of the virus on the Indian economy through international collaboration and cooperation.

SUBMISSION OF SECRETARY, DHR

4.24 During the Committee's meeting held on 13th February, 2020, the Secretary, DHR, urged the Committee to consider the following issues:-

- (i) Projected Budget for DHR during 2020-21 is to the tune of Rs.2800.00 crore against which the Department has been allocated Budgetary grant to the tune of Rs.2100.00 crore to meet the revenue expenditure. The said budgetary allocation to DHR constitute approximately 3% of total health budget, however, the Governing Council of NITI Aayog has recommended allocation of fund to DHR atleast 5% of health budget;
- (ii) 15th Finance Commission (2020-21 to 2024-25), now extended upto 2025-26) has recommended that out of the budgetary allocation to National Health Programmes, viz, tuberculosis, malaria, leprosy, etc. certain percent of fund be earmarked for research purposes. Enhanced budgetary allocation is also required to give impetus to Anti Microbial Research and health research in rural areas;
- (iii) Additional budgetary allocation is required to upscale projects on Non Communicable Diseases Control;
- (iv) National Bio-security is a burning issue now-a-days which requires the immediate attention of the Government. Enhanced budgetary allocation is all the more necessary to implement a programme/scheme/project on bio-security; and
- (v) Need for in-depth research and investigation on emergence/re-emergence of WHO's blue-print viruses that requires high-end diagnostics, high-end treatment either through vaccines or immunoglobulins or monoclonals. Such research and investigation, in turn, involve huge financial allocation.

4.24.1 The Committee took into consideration the submission of the Secretary, DHR made on 13th February, 2020 regarding enhancement of budgetary allocation for implementing the schemes by the department. The Committee has already recommended for enhancement of budgetary allocation to DHR under various programmes in the preceding chapter and allocation of budgetary support as per the projected demand of DHR for implementation of schemes during 15th Finance Commission in the succeeding chapter. The Committee hopes that the Ministry of Finance would consider the recommendations of the Committee, positively.

4.24.2 The Committee is in agreement with the plea of the Secretary to give impetus to the issue of Bio-security which in turn need the immediate attention of the Government. The Committee, in this regard, recommends DHR to formulate National Bio-security Policy, encompassing potential threat of various viruses, its implications on human beings and on the economy in general, course of action required to combat the menace of bio-warfare and requirement of fund to implement the various components of the program on bio-security, etc.

CHAPTER –V

FUTURE OUTLOOK OF HEALTH RESEARCH

5.1 The Committee understands the high value of health research for the individual and the society at writ large. The health research entails in-depth investigation provides vital information about disease trends and risk factors, outcomes of treatment or public health interventions, functional abilities, patterns of care, and health care costs and use. The approaches to health research encompasses complementary insights and clinical trials for significant information about the efficacy and adverse effects of medical interventions by controlling the variables factors. However, feedback from real-world clinical experience is also crucial guidelines for comparing and improving the use of drugs, vaccines, medical devices, and diagnostics. Tracking clinical experience with the drug is important for identifying relatively rare adverse effects and for determining the effectiveness in different populations or in various circumstances. It is, therefore, vital to record and assess experience in clinical practice in order to develop guidelines for best practices and to ensure high-quality patient care. The Committee, therefore, is of the firm view that various forms of health research would lead to significant discoveries for development of new therapies, and improvement in health care and public health.

Need for enhancing budgetary allocation to DHR

5.2 The Ministry has furnished the following information about the actual expenditure in Health Research during last five-years vis-a-vis budgetary allocation on Health Sector.:-

The budgetary allocation of Health Research in comparison with budgetary allocation of Health for last five years are as follows:(Rs in crores) Financial Year	Budgetary Allocation of Health Research	Budgetary Allocation of Health & Family Welfare	% of Budgetary allocation of Health Research against Health & Family Welfare
2016-17	1144.80	37061.55	3.09%
2017-18	1500.00	47352.51	3.17%
2018-19	1800.00	52800.00	3.41%
2019-20	1900.00	62659.12	3.03%
2020-21	2100.00	65011.80	3.23%

5.2.1 The Committee takes into account that the budgetary allocation to the Health Research is merely about 3% of budgetary allocation of Ministry of Health and Family Welfare which is abysmally low compared to requirement of funds needed for Health Research. The Committee is of the view that Health Research is vital component to make the country disease free and therefore, expenditure on Health Research needs to be much higher compared to present allocation. Keeping in view the large population of the country and need for further investment on the health research, the Committee recommends the government to earmark atleast 10% of allocation be made to the Department of Health & Family Welfare.

5.2.2 The Committee, therefore, recommends that the Central outlay on health research needs be suitably increased for meeting the national health priorities and development of new technologies, diagnostics and treatments including development of new vaccines, etc.

Revised projections for 2021-22 to 2025-26

5.3 The committee in this regard would like to place the Revised Projections for the period 2021-22 to 2025-26 as reflected in the Table :-

<i>Rs. in Crores</i>						
S.NO.	Particulars	2021-22	2022-23	2023-24	2024-25	2025-26
1.	DHR schemes	433.50	484.50	506.50	557.50	592.00
2.	ICMR	2579.80	2841.80	3204.50	3568.00	4042.00
3.	Secretariat Expenditure	44.00	50.00	55.00	60.00	70.00
4.	Total	3057.30	3376.30	3766.00	4185.50	4704.00

Note: Due to the transfer of management of Bhopal Memorial Hospital & Research Centre (BMHRC) to the ICMR, the budgetary requirements of BMHRC have been merged with the ICMR

5.3.1 The Committee was given to understand that the Department of Health Research is not implementing any Centrally Sponsored Scheme (CSS). All Schemes being implemented by the DHR are the Central Sector Schemes which do not involve any transfer of funds direct to the State Governments.

Details of Requirements for 15th Finance Commission period (2021-22 to 2025-26) in respect of Department of Health Research

S.N.	Scheme/ Programme	2021-22	2022-23	2023-24	2024-25	2025-26
1.	Establishment of Network of Viral Diagnostic & Research Laboratories for Managing Epidemics (VRDL)	115.00	125.00	145.00	166.00	170.00
2.	Development of Tools to prevent outbreaks of epidemics	6.00	6.50	7.00	7.50	8.00
3.	Establishment of Multidisciplinary Research Units (MRUs) in Govt. Medical Colleges	146.00	166.00	150.00	160.00	170.00
4.	Establishment of Model Rural Health Research	19.00	24.00	26.00	30.00	35.00

	Units (MRHRUs) in the States					
5.	Human Resource Development for Health Research (HRD)	61.00	66.00	71.00	76.00	80.00
6.	Grant-in-aid Scheme for inter-sectoral convergence and Coordination for Promotion and Guidance on Health Research (GLA)	50.00	55.00	60.00	65.00	70.00
7.	Research Governance – MTAB/ HTA	30.00	35.00	40.00	45.00	50.00
8.	International Cooperation	6.50	7.00	7.50	8.00	9.00
	Scheme Total (A)	433.50	484.50	506.50	557.50	592.00
9.	Bhopal Memorial Hospital & Research Centre, Bhopal (BMHRC)*					
9.1	Grant in aid General	50.80	54.30	58.00	62.00	70.00
9.2	Grant in aid Creation of Capital Assets	10.00	10.00	10.00	10.00	12.00
9.3	Grant in aid Salaries	119.00	127.50	136.50	146.00	160.00
	Total of BMHRC (B)	179.80	191.80	204.50	218.00	242.00
10.	Indian Council of Medical Research (ICMR)					
10.1	Grant in aid General	1400.00	1500.00	1700.00	1900.00	2100.00
10.2	Grant in aid Creation of Capital Assets	300.00	350.00	400.00	450.00	500.00
10.3	Grant in aid Salaries	700.00	800.00	900.00	1000.00	1200.00
	Total of ICMR (C)	2400.00	2650.00	3000.00	3350.00	3800.00
11.	Secretariat Expenditure (D)	44.00	50.0	55.00	60.00	70.00
	Grant Total (A+B+C+D)	3057.30	3376.30	3766.00	4185.50	4704.00
<i>Note : Due to the transfer of management of Bhopal Memorial Hospital & Research Centre (BMHRC) to the ICMR, the budgetary requirements of BMHRC may be merged with the ICMR</i>						

5.3.2 The Committee notes that the vision of the DHR provides “to bring modern health technology to the people through innovations related to diagnostics, treatment methods and

vaccines for prevention; to translate them into products and processes and in synergy with concerned organizations introduce these innovations into public health systems.” The Committee opines that the course of actions outlined above need to be focussed to achieve the vision of DHR. Needless to say, the Government urgently needs creation and expansion of infrastructure for promoting research in medical colleges and rural areas, creating trained human resources in various areas of health research, interventions for containing outbreaks/epidemics through establishment of network of viral research and diagnostic laboratories across the country and support for pursuing research in areas relevant to the health priorities of the nation. The Committee recommends concrete action for effective and efficient research governance, regulatory and evaluation framework through development of appropriate regulations, guidelines, authorities to protect and strengthen ethic based biomedical research and to develop expertise to assess cost effective technologies for reduction in out-of-pocket expenses on health care.

New initiatives of Department of Health Research & Indian Council of Medical Research to make country Biosecure

5.4 The Committee has been apprised that establishment the network of Viral Research & Diagnostic Laboratories (VRDLs), duly supported by National Institute of Virology (NIV), Pune with BSL-4 facility, are capable of tackling outbreak investigations in the country by developing vaccines and diagnostic kits. ICMR has been instrumental in timely detection and successful containment of the recent Zika (ZiV) and Nipah Virus (NiV) outbreaks.

5.4.1 The Committee believes that with expanding network of VRDLs, ICMR would serve as an important platform for diagnosis and surveillance of existing as well as emerging viral infections and thus make the country bio-secured against life-threatening viruses and the menace of bio-terrorism.

Establishment of RESEARCH (Regional Enabler for South East Asia Research Collaboration for Health) platform

5.4.2 This regional platform on infectious diseases of public health importance in the South East Asia region was established in August, 2019 with participation from Bangladesh, Bhutan, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor Leste. The Committee has been given to understand that the Regional Platform ‘RESEARCH would help in tackling emerging and re-emerging infections like dengue, ZIKA, NIPHA, novel Corona Virus etc and also strengthen the Viral Research Diagnostics Labs established across the country.

5.4.3 The Committee is confident that ICMR, through (RESEARCH) platform would provide leadership to effectively combat emerging and re-emerging infectious diseases in South –East Asia region. The Committee, however, recommends that ICMR should formulate definite course of action and circulate the same among all partners of RESEARCH in order to achieve the objective of combating against the infectious diseases. The Committee believes that ICMR would make the country bio-secured and play the role of a global leader in biomedical and health research for tackling emerging infections.

Support to Ayushman Bharat: Standard Treatment Workflow: INFOGRAPHICS:

5.4.4 The Committee observes that INFOGRAPHICS on standard treatment workflows for different disease conditions are being made for different disease conditions. These workflows will comprise of symptoms, signs, diagnostics, treatment etc. for concerned diseases. The

infographics will be put up in all Medical colleges, District Hospitals, Primary Healthcare Centres, etc. across the country. Support is also being provided through the National Costing Study conducted through HTAIn for reviewing/regionalizing the reimbursement benefit packages under Ayushman Bharat.

5.4.5 The Committee believes that since Ayushman Bharat is a flagship program of the government which will get its expression and expansion throughout the country in due course of time. The Committee feels that there would be need for percolation and proliferation of Standard Treatment Workflow: INFOGRAPHICS on the ground level for ensure treatment of the people. The Government has to undertake requisite steps for adherence to standard treatment workflow INFOGRAPHICS to assist/help in the implementation of Ayushman Bharat.

Expanding role of Multi Disciplinary Research Units (MRUs) in Government Medical Colleges/Institutes

5.4.6 The Committee feels that since the scheme aims at creating requisite infrastructure and environment Government Medical Colleges for undertaking research in Non-Communicable Diseases, therefore, the Committee recommends intensification of the role of MRUs. The Committee observes that Major Health Research activities initiated by the MRUs in the domain of Cancer, Diabetic Mellitus and hypertension, cardiovascular disease, Mental Health, Environmental Health/ occupational health, Stroke and neurological disorder, Diabetes, Metabolic disorders, Chronic Kidney disease and liver disorders are vital for treatment for these diseases.

Fight against Double Burden of Malnutrition

5.4.7 The Committee believes that the country is in the need for best possible, affordable and viable solutions to fight the double burden of malnutrition in the form of persistent under-nutrition and coexistent obesity through convergence of multi-sectoral interventions. Several studies addressing problems of under-nutrition, flurosis, IDD, Vitamin A deficiency have already been initiated in over 70 districts of the country. Studies have also been initiated to tackle adolescent anaemia and developing nutri-smart villages under inter-sectoral collaboration. The Committee recommends the Government for making the scheme a flagship program.

Vector Borne Diseases: MERA India

5.4.8 The Committee notes that Malaria Elimination Research Alliance (MERA) aims to bring multiple stakeholders both at (national and international) levels under one umbrella with a view to eliminate the disease. The Committee is of the considered view that MERA India would play a vital role in the elimination of victor borne disease.

National Leprosy Vaccination Program: 110 Districts

5.4.9 Based on the successful trial of MIP, an indigenous leprosy vaccine, in 6 districts of Bihar and Gujarat, it is planned to launch it on a national scale to attain the vision of leprosy-free India.

5.4.10 The Committee recommends the Government to launch National Leprosy Vaccination Program nationwide to free India from leprosy within the set time frame and help remove the social stigma being faced by the patient suffering from leprosy.

Vision of DHR the 15th Finance Commission period (2020-21 to 2024-25)

5.5 The Committee has been apprised of the physical targets of various schemes for the period of 15th Finance Commission which are enumerated below:-

Establishment of MRUs

5.5.1 The DHR has proposed to establish 40 new MRUs to cover the unserved areas/States/UTs during the 2020-21 to 2024-25.

5.5.2 The Committee is of the considered view that the Scheme would result into creation of necessary infrastructure in the Government Medical Colleges and also encourage and strengthen an environment of research. The network of MRUs will also bridge the gap in the infrastructure and improve the health status of the population by creating evidence based application of diagnostic procedures/processes/methods.

Establishment of MRHRUs in the States

5.5.3 The Department has proposed to set up 10 new MRHRUs during the 15th Finance Commission to cover all the States and UT in the next four years.

5.5.4 The Committee understands that the scheme would provide special support for creating infrastructure at the periphery level for transfer of technology to the rural level for improving the quality of health services to rural population. The Committee believes that implementation of new and modern technologies in the rural settings and taking technologies from Lab to field would result in a better health care to the rural population.

Establishment of Network of VRDL during 15th Finance Commission Period (2020-21 to 2024-25)

5.5.5 The DHR has already rolled out a scheme for “Establishment of a Network of Laboratories for Managing Epidemics and Natural Calamities” with the target to establish three tier network of 160 Viral Research & Diagnostic Laboratories (VRDLs) across the country. The DHR has shared the following vision for VRDL

- (i) establishment of 35 new VRDLs during the 15th Finance Commission period to achieve the total target of setting up of 160 Viral Research and Diagnostic Laboratories (Regional level – 10; State Level-50 and Medical College Level-100) upto 2024-25;
- (ii) Upgradation of existing Medical College Level VRDLs to State Level VRDLs.
- (iii) Improvement in functionality and quality of VRDLs. NABL Accreditation of 10 Regional and 50 State Level VRDLs.
- (iv) Establishment of five Centres of Excellence (CoE) on basis of etiological agents:
 - a. Centre of excellence for Arboviral Diagnosis and Research
 - b. Centre of excellence for Respiratory Viruses Diagnosis & Research
 - c. Centre of excellence for Hepatitis Diagnosis and Research
 - d. Centre of excellence for Viral Diarrhoeal Diagnosis & Research
 - e. Centre of excellence for Unknown emerging viruses Diagnosis & Research

5.5.6 The Committee has further been apprised of the following steps for development of Holistic Diagnosis approach for Acute Febrile Illness in the Network- Ambit for diagnosis for few bacterial infections like enteric fever, scrub typhus and leptospirosis.

- (i) Development of core capacity for effective and regular monitoring of VRDLs
- (ii) Multi-centric research activities
- (iii) Calibration and maintenance of equipment would be taken care of.
- (iv) Recurring budget under VRDL Scheme would be enhanced and would be taken care of till 2025 for all VRDLs.
- (v) Development of Electronic Reporting System (ERS) for VRDLs.
- (vi) Strengthening of Resource Centre VRDL at NIV, Pune
- (vii) Budget for diagnostic kits and reactions for dengue, chikungunya, Japanese Encephalities (JE), Zika and Influenza viruses may be earmarked for Resource Centre VRDL due to huge load of diagnosis during the season.

5.5.7 The Committee is of the considered view that the scheme would broadbase the coverage nationwide for timely diagnosis/identification of viruses during outbreaks of epidemics, generation of data about viral diseases for facilitating quick deployment of resources and measures to save the human lives.

Human Resource Development for Health Research during 15th Finance Commission period (year-wise)

5.5.8 Physical targets for the 15th Finance Commission period (year-wise) are given in the table below:

S.N.	No. of Fellowships/ Projects	2020-21	2021-22	2022-23	2023-24	2024-25	Total
1.	Short Term Fellowship abroad	30	40	50	60	70	250
2.	Long Term Fellowship abroad	40	40	40	40	40	200
3.	Short term Fellowship at Indian Institutes	40	50	60	70	80	300
4.	Long Term Fellowship at Indian Institutes	30	40	40	40	40	190
5.	Women Scientists who have had break in career Category 'A' Category 'B'	20	20	30	40	50	160
6.	Scholarship/ Fellowship Programme to young scientists	20	20	30	30	40	140

	in newer areas for three years						
7.	To encourage health research personnel (NRIs/PIOs/OCI) to come back to India	10	10	10	20	20	70
8.	Support to institution	8	9	10	12	15	54
9.	Start-up grant/No. of projects	30	40	50	60	70	250
10.	New schemes to be planned	40	50	60	70	80	300

5.5.9 The Committee appreciates concerted efforts of the government in creation of a pool of talented health research personnel with upgraded skills of faculty of medical colleges, mid-career scientists, medical students, etc. The Department, however, needs to chalk out specialized training course and support the trainees to take up research projects for addressing critical national and local health problems.

Grant-in-aid Scheme for Inter-Sector Convergence & Promotion and Guidance on Health Research

5.5.10 The DHR has proposed that Bone Health, Reproductive complications and infant's health, Trauma, High Altitude Health, Rare Genetic Disorders, Regenerative Medicine may be included under GIA Scheme during 15th Finance Commission period for health research. The Committee has been given to understand that scheme would yield in identifying the existing knowledge gap and to translate the health leads into deliverable products.

5.5.11 The Committee recommends that the scheme must focus on encouraging innovation, its translation and also the implementation of research so that there is a better utilization of available knowledge. The Committee believes that the country will be benefitted once the initiative taken under the scheme result into integrated solutions for the promotion of health; generation of joint inter-departmental/ inter-agency projects on health problems; and development of more affordable and cost effective technologies for public health use; besides developing indigenous technologies for advanced health care.

MALARIA ELIMINATION RESEARCH ALLIANCE (MERA) INDIA

5.5.12 This alliance is being formed to develop a common platform for developing research strategies to accelerate malaria elimination efforts in India. It will bring together independent research organizations, and capitalizing on the strengths, will reinforce trans-institutional research that will have impact on policies. The budget projection under the project are tabulated below:-

Rs. In Crores					
	2020-21	2021-22	2022-23	2023-24	2024-25
	15.00	17.00	19.00	21.00	22.00

Revisiting the role of Indian Council of Medical Research (ICMR)

5.6 The Committee has been apprised that ICMR has drafted a new Strategic Research Plan to contribute towards improvement in health outcomes in India. The ICMR Strategic Plan 2017-24 envisages capacity building, data management, leveraging traditional medicine, evidence to policy and strengthening program implementation through research.

5.6.1 The ISP- 2017-24 was supported by a comprehensive research performance evaluation by external agencies. Domestic and foreign external stakeholders have always appreciated ICMR's global recognition and brand value as well as its vital contribution into outbreak investigation and timely intervention. The recommendations of various committees that have reviewed ICMR's work, recent WHO guidance on elimination of diseases and sustainable development goals and a plan to leverage the strength of ICMR institutional network form the foundation on which ISP201-24 have been built formulated. Its core aim is to deal with health challenges faced by the country with reference to non-communicable diseases, anti-microbial resistance, emerging infections, maternal and child health and issues related to health systems and health care delivery. ISP-2017-24 is based on 5 major pillars and 15 target oriented goals as expressed under:-

Strengthen Health Research Capacity	Data Systems and Research Platforms	Leveraging Traditional Medicine	Enable Evidence to Policy Translation	Strengthen Program Implementation through Research
Develop Programs and customized courses for enhancing skills and introduce high end schemes with a focus on mentorship for established and new researches to enable them to undertake basic, clinical, implementation and translational research	Develop and implement ICMR Policy for sharing and access to health/biomedical research data	Identify key researchable areas in traditional medicine and provide training for traditional medicine researchers in pre-clinical and clinical research and frame guidelines	Build capacity for evidence based health policy development	Identify gaps in health programmes at both national and state levels and undertake research to address them to improve programme implementation in the country
Provide infrastructural and menioring support to select institutions and	Setup disease-specific/thematic repositories and warehouses of health/biomedical	Establish national level inter-disciplinary research	Establish national level health technology assessment	Promote innovations in health systems and health care delivery

medical colleges and individuals to undertake actionable research	research data	facility and a network for traditional medicine research	mechanism for use in health policy	
Establish regional virtual as well as physical centres of excellence which will act as hubs of mentorship and capacity building	Promote ICMR research data warehouse by various stakeholders for improving research and public health	Conduct collaborative research on identified researchable areas in traditional medicine	Knowledge Translation (KT) by engaging with stakeholders to share relevant, reliable and timely research evidence and syntheses	Disseminate and advocate successful models/pilot interventions for introduction in health programmes

5.6.2 The Strategic Plan will focus on capacity building organizing data systems, leveraging traditional medicine, evidence to policy and strengthening programme implementation through research. Implementation of ISP 2017-24, ICMR would play a greater role in improving the health of the people of India. As a knowledge generating body, it will position itself to provide critical feeds for policy making and program strengthening and improvement. The reviewed focus on innovation and translation of research into products and schemes of mass benefit is expected to touch the lives of the people of India.

5.6.3 The Committee appreciates ICMR’s global recognition and brand value with significant contribution during outbreak of epidemics and in-depth investigation in the field of bio-medical research and health research. However, the Committee expects ICMR to make SWOT- analysis of its working in order to capitalize on its strength and opportunities and make strategy to overcome its weaknesses and threats. The Committee believes that ICMR should chalk out strategies/course of action in the areas requiring improvement viz. focus on development of new technologies, new drugs and devices; more effective use of communication tools such as social media, mass media, public exhibitions, wide spread research dissemination initiatives and ICMR website; the other policy prescription for ICMR could be greater engagement with private sector, need to strengthen facilities and opportunities for medical research in the country and emphasis on operations research to strengthen health infrastructure.

Progress towards Sustainable Development Goals (SDG)

5.7 The Committee has been apprised that ICMR is committed to work towards attainment of Sustainable Development Goals (SDGs) of UN for health. In fact, ICMR has recently released its strategy document, “ICMR Strategic Plan and Agenda 2030” which has been designed in tune with the National Health Policy 2017 and Sustainable Development Goals (SDGs) of UN for health. ICMR’s research priorities correlate with the national health priorities. ICMR has identified mission-mode projects in key areas of communicable and non-communicable diseases, maternal and child health, nutrition as well as understanding the critical importance of capacity building in health research in the whole country. Focus is also on evidence to policy translation

and strengthening program implementation for overall improvement of health and prevention and control of diseases.

5.7.1 The Committee believes that ICMR can significant contribute in achieving the objectives set in Sustainable Development Goals through proper planning, standard formulation, smooth coordination, effective implementation and perceptile promotion of biomedical and Health Research. The Committee would like the ICMR to undertake biomedical and health research aimed to improving health services, health policies, newer modalities of diagnostics, guidelines for management of infectious and non-communicable diseases etc. with public, public-private and NGO partnerships, etc.

Upcoming Legal frame-work of the Department of Health Research

5.8 The Committee has been apprised of the following important legislations being piloted by the Department of Health Research:

The Surrogacy (Regulation) Bill, 2019

5.8.1 The Committee is aware of the fact that the Surrogacy (Regulation) Bill, 2019 as passed by the Lok Sabha on the 5th August, 2019, was placed in the Rajya Sabha on the 6th of November, 2019 for consideration and on 21st of November, 2019 referred to the Select Committee of Rajya Sabha for reporting thereon. The Select Committee presented its Report on The Surrogacy (Regulation) Bill, 2019 on 5th February, 2020 which has been approved by the Cabinet on 20th February, 2020.

5.8.2 The Surrogacy (Regulation) Bill, 2019 proposes to regulate surrogacy in India by establishing National Surrogacy Board at the Central level and the State Surrogacy Boards and Appropriate Authorities in the States and Union Territories. The major objectives of the Bill are to regulate surrogacy services in the country, to provide altruistic ethical surrogacy to the needy Indian couples, to prohibit commercial surrogacy including sale and purchase of human embryo and gametes, to prevent commercialization of surrogacy, to prohibit potential exploitation of surrogate mothers and protect the rights of children born through surrogacy.

The Assisted Reproductive Technology (ART) Regulation Bill, 2020

5.8.3 The Committee has been given to understand that the Assisted Reproductive Technology Regulation Bill, 2020 has been framed to establish the national Board, the State Boards and the national Registry for the Regulation and Supervision of assisted reproductive technology clinics and the assisted reproductive technology banks, for prevention of misuse and for safe and ethical practice of assisted reproductive technology services in the Country. The Cabinet has approved the Assisted Reproductive Technology (Regulation) Bill, 2020 on 19th February, 2020. The proposed legislation intends to ensure effective regulation of Assisted Reproductive Technology services and procedures in India.

5.8.4 The Assisted Reproductive Technology Services Bill needed mainly to protect the affected Women and the Children from exploitation. The oocyte donor needs to be supported by an insurance cover, protected from multiple embryo implantation and children born through Assisted reproductive technology should be provided all rights equivalent to a Biological Children. The cryopreservation of sperm, oocytes and embryo by the RT Banks needs to be

regulated and the bill intends to make Pre Genetic implantation Testing mandatory for the benefit of the Child born through assisted reproductive technology. Another action intended is the proper registration of the ART Clinics and Banks.

Broadbasing Health Technology Assessment (HTA) in India

5.8.5 The Committee feels that there is need to broaden functional domain of HTA in for analyzing evidences related to cost-effectiveness, clinical-effectiveness and equity issues regarding the deployment of health technologies viz. Medicines, devices and health programmes by means of HTA in India. The objective of arriving at evidence-informed decision making for an efficient use of existing health resources is to provide people affordable, accessible and quality healthcare. The Committee acknowledge the pivotal role of HTA in maximizing health, reducing Out of Pocket Expenditure (OOP) and minimizing inequality in healthcare services. The Committee believes that HTA would lead to developing systems and mechanisms to assess new and existing health technologies based on available data on resource use, cost clinical effectiveness and safety. It will also ensure healthcare accessibility and usefulness to inform health policy. The Committee hopes that the dissemination of research findings and resulting policy decisions will educate and empower the public to make better informed decisions for health. HTA could be a useful tool in taking India towards Universal Health Coverage.

5.8.6 The Committee believes that the intention of Department of Health Research in setting up of Health Technology Assessment Unit (HTA) is to evolve guidelines for evaluation of appropriateness and cost effectiveness of available and new health technologies in the country. The Committee is also of the view that scheme has the potential for development of standardized cost effectiveness guidelines/interventions to reduce the cost and variations in patient care and streamline the medical reimbursement procedures. The Committee is of the considered view that institutionalization of the process and structure in DHR would lead to assured accomplishment of the set mission objectives and actualization of visions of the Department.

5.8.7 The Committee has also been given to understand that the DHR is in the process introducing a Bill on HTA for constitution of Board thereon to streamline its functioning. The Committee would like to be apprised of the progress made in this regard.

EMERGING PRIORITY AREAS OF DHR

A. Quality Assurance in Health Care

5.9 The DHR has proposed to undertake activities related to Healthcare Quality and Safety (HQS) to improve the quality of healthcare in India working on the following objectives:

- (i) To promote the dissemination of knowledge and skills of monitoring and improving healthcare quality and safety.
- (ii) To facilitate creation of institutional mechanisms of quality monitoring and improvement at health faculties.
- (iii) To build a pool of experts who will guide and steer the quality improvement work in country

- (iv) To promote research in creating new knowledge about methods of quality improvement and in implementation of quality improvement methods in different context of healthcare provision.

B. Affordable Indigenous Technologies

5.10 The Committee has been given to understand ICMR has recently developed a Point-of-care diagnostic kit for Nipah virus in partnership with industry. Also shigella vaccine has been transferred for commercialization to Hillman. Other such low cost, indigenous medical innovation may help in better healthcare delivery in coming years. Moreover, Health research needs to focus on providing affordable and accessible health care services so as to maximize health, reduce out of pocket expenditure and reduce inequality with the help of Health Technology Assessment in India (HTAIIn).

C. Sustainable Universal Health Coverage

5.11 The Committee notes that Standard Treatment Workflows (STWs), for 50 disease conditions, for all levels of healthcare systems have been recently launched which along with Health Technology Assessment and National List of Essential Medicine & Diagnostics are providing support to *Ayushmaan Bharat* towards Universal Health Coverage. All these programmes along with mission mode initiative for tackling communicable and non-communicable diseases in collaboration with central and state health departments would lead to realizing the goal of “Health for All” within economic means of the nation.

D. Forging National

5.12 The Committee believes that in order to strengthen the health research capacity of the nation, there is need to engage with multiple stakeholders (national and international; public and private) viz.

Inter-ministerial collaborations

- (i) ICAR: in the areas of zoonosis, antimicrobial resistance and nutrition
- (ii) MHRD: in the areas of innovation and technology development.
- (iii) DBT: in the areas of bio ethics, stem cell research, commercialization of technology, innovation.
- (iv) ISRO: in the areas of early warning systems and impact of climate change on health.
- (v) AYUSH: in the areas of traditional medicine

Public Private Partnerships

- (i) Tata Trusts: in the area of TB
- (ii) Sun Pharma: in the area of malaria
- (iii) Pfizer: in the area of anti-microbial resistance
- (iv) Emami Limited: in the area of herbal product development for sleepdisorder and pre-diabetes

E. International Collaborations

5.13 The Committee has been apprised that 40 Mission Mode Projects have been initiated for TB (ITRC), Malaria (MERA India), Cancer (ICRC) to bring together all major national players (with international collaborators) to address overarching scientific questions. MoUs have been signed with NIH, African Union (AU) to strengthen research capabilities.

F. Other Key Areas

5.14 The Committee has been apprised that besides priority areas on non-communicable diseases, pollution, new and emerging technologies including Artificial intelligence, nanotechnology, gene and stem cell therapy, etc have been identified for research keeping in view the Country's health program and policies.

5.15 Taking cognizance of the key priority areas of DHR for bio-medical and health research and new areas of research, the Committee believes that higher budgetary allocation for the said purpose is essential. The Committee, therefore, strongly recommends that the Department of Health Research must make realistic assessment of requirement of budgetary allocation in the light of future outlook of Health Research in the country and chalk-out specific course of action for transforming and advancing the bio-medical and health research to global quality and standard in order to yield desired results.
