Demand for Grants 2021-22 Analysis

Health and Family Welfare

The Ministry of Health and Family Welfare has two departments: (i) the Department of Health and Family Welfare, and (ii) the Department of Health Research. The Department of Health and Family Welfare is responsible for functions including: (i) implementing health schemes, and (ii) regulating medical education and training. The Department of Health Research is broadly responsible for conducting medical research. This note analyses the financial allocation trends and key issues concerning the health sector.

Budget speech highlights 2021-22

The Finance Minister, Ms. Nirmala Sitharaman stated that health and well-being is one of the key pillars for the budget. Key highlights in the budget regarding health and well-being include:

- Urban Swacch Bharat Mission 2.0 will be implemented with a capital outlay of Rs 1.4 lakh crores over five years (2021-26). The objectives of the Mission include: (i) complete faecal sludge management, (ii) reduction in single use plastic, (iii) source segregation of garbage, and (iv) reduction in air pollution.
- A new central scheme PM AtmaNirbhar Swasth Bharat Yojana will be launched with an outlay of Rs 64,180 crore over six years. The scheme will be focused on: (i) developing primary, secondary, and tertiary healthcare systems, (ii) strengthening existing national institutions, and (iii) creating new institutions for detection and cure of new diseases.
- Rs 35,000 crore has been allocated for COVID-19 vaccine under the Ministry of Finance.

Apart from the budget allocation to the Ministry of Health and Family Welfare: (i) Rs 13,192 crore has been allocated as finance commission grant for health, (ii) Rs 36,022 crore has been allocated as finance commission grant for water and sanitation.

Overview of finances

Overall, India's public health expenditure has increased from 0.9% of GDP in 2015-16 to 1.1% of GDP in 2020-21.[1,2,3,4] The Economic Survey 2020-21 observed that India ranks 179th among 189 countries in prioritising healthcare in the government budget. Note that the National Health Policy, 2017 aims to increase public health expenditure to 2.5% of the GDP by 2025.

In 2021-22, the Ministry has an allocation of Rs 73,932 crore (an annualised growth of 7% over the actual expenditure in 2019-20).[5] Under the Ministry, the **Department of Health and Family Welfare** accounts for 96% of the Ministry's allocation at Rs 71,269 crore whereas the **Department of Health Research** has been allocated Rs 2,663 crore (4% of the allocation).

As 2020-21 had extra-ordinary expenditure on account of Covid-19, we have used annualised increase over the 2019-20 figures for comparison across all our Tables.

Table 1: Budget allocation for the Ministry of Health and Family Welfare (in Rs crore)

Item	2019-20 Actuals	2020-21 RE	2021-22 BE	Annualised Change (Actuals 2019-20 to BE 2021-22)
Health & Family Welfare	62,397	78,866	71,269	7%
Health Research	1,861	4,062	2,663	20%
Total	**64,258**	**82,928**	**73,932**	**7%**

Note: BE – Budget Estimate; RE – Revised Estimates.
Sources: Expenditure Budget 2021-22; PRS.

The revised estimate in 2020-21 (Rs 82,928 crore) includes Rs 14,217 crore for COVID-19 emergency response and health system preparedness package, and COVID-19 vaccination for healthcare and frontline workers. Table 2 details the main heads of expenditure under the Ministry allocated for the year 2021-22.

Table 2: Main heads of expenditure (in Rs crore)

Major Heads	2019-20 Actuals	2020-21 RE	2021-22 BE	Annualised Change (Actuals 19-20 to BE 21-22)
National Health Mission (total)	34,660	35,144	36,576	3%
Autonomous Bodies	9,601	9,882	10,924	7%
PMJAY	3,200	3,100	6,400	41%
PMSSY	4,683	7,517	7,000	22%
National AIDS & STD Control Programme	2,813	2,900	2,900	2%
Family Welfare Schemes	489	496	387	-11%
RSBY	57	29	1	-87%
Others	8,755	23,860*	9,744	5%
Total	**64,258**	**82,928**	**73,932**	7%

Note: * Includes Rs 14,217 crore for COVID-19 emergency response and vaccination of healthcare and frontline workers; BE - Budget Estimate; RE - Revised Estimates; PMJAY: Pradhan Mantri Jan Arogya Yojana; PMSSY- Pradhan Mantri Swasthya Suraksha Yojana; RSBY: Rashtriya Swasthya Bima Yojna; Autonomous Bodies include AIIMS, and ICMR.
Sources: Expenditure Budget 2021-22; PRS.

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COVID-19 vaccine

On January 3, 2020 DCGI approved two vaccines (Covishield and COVAXIN) for restricted use in emergency situation.[6] Restricted use in emergency situation refers to approving the use of vaccines only for people who are in urgent need considering their vulnerability to the virus.

Table 3: Status of COVID-19 vaccine candidates in India

Company	Name	Clinical Stage
Bharat Biotech	COVAXIN	Phase 3 ongoing (received restricted use authorisation)
Serum Institute of India/ICMR	Covishield (AstraZeneca/ Oxford)	Phase 3 completed (received restricted use authorisation)
Zydus Cadilla	ZyCoV-D	Phase 2 ongoing; Phase 3 approval granted
Dr Reddy's Laboratories and Sputnik LLC	Sputnik	Phase 2 ongoing
Biological E	Biological E	Phase 1 / 2 ongoing

Notes: *ICMR: Indian Council for Medical Research.
Sources: COVID-19 Vaccines undertrial in India, Indian Council for Medical Research, Ministry of Health and Family Welfare.

Note that some countries such as United States of America issued emergency use authorisation for COVID-19 vaccines.[7] Emergency Use Authorisation (EUA) refers to approving the use of unapproved medical products, or unapproved uses of approved medical products during public health emergencies (such as COVID-19 pandemic).

The Standing Committee on Home Affairs (2020) noted that in India no EUA has been given in the past by CDSCO. The Committee recommended that proper consideration and caution should be taken in case of issuing any EUA. The Committee added that the provision of EUA should be used in the rarest of rare cases.[8]

Development and financing: In 2020-21, the Ministry of Health and Family Welfare supported the development of approximately 30 COVID-19 vaccine candidates.[9]

In 2020-21, ICMR was allocated Rs 25 crore for studies and research on the development of a vaccine, and the Department of Biotechnology spent Rs 75 crore to support eight proposals for vaccine development by private industries and academia. In November 2020, the Department of Biotechnology received a grant of Rs 900 crore in form of a stimulus package (Mission COVID Suraksha) from the Ministry of Science and Technology. The Department of Science and Technology supported three projects (committed expenditure: Rs 3.2 crore; sanctioned expenditure: Rs 22.3 lakh), under Intensified Research in High Priority Areas (IRHPA), on COVID-19 vaccine.

Further, an expenditure of Rs 2,475 crore was approved by the central government under the World Bank funded India Covid-19 Emergency Response and Health System Preparedness Package for procurement of various components such as testing kits, testing machines, and reagents for COVID-19.[10]

In 2020-21, it is estimated that overall, the Ministry of Health and Family Welfare will spend Rs 13,857 crore on COVID-19 Emergency Response and Health System Preparedness Package and Rs 360 crore on COVID-19 vaccination for healthcare workers and frontline workers.

Distribution: The central government, in coordination with the state governments, identified the priority group for vaccination.[11] The priority group comprised of two groups: (i) first group of one crore healthcare workers and two crore frontline workers, and (ii) second group 27 crore adults over 50 years of age and persons below 50 years of age with comorbidities.[12]

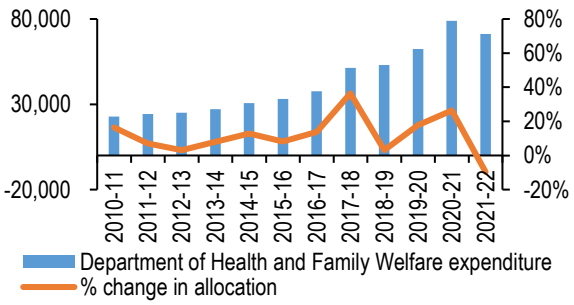
The Standing Committee on Health and Family Welfare (2020) had noted that an approach of smart vaccination may be opted for immediate control of pandemic provided the entire population is vaccinated eventually.[28] Smart vaccination refers to a strategy in which the people of India are divided into three groups: (i) core group, (ii) bridge group, and (iii) general population. Once the core group is vaccinated, with all preventive measures such as wearing masks the pandemic may be contained without vaccinating the entire population of the country.[28]

Trends in allocation and expenditure

In the last 16 years, the allocation to the Department of Health and Family Welfare has increased from Rs 11,366 crore in 2006-07 (revised estimate) to Rs 71,269 crore in 2021-22 (budget estimate). Over the period 2006-22, the Compound Annual Growth Rate (CAGR) has been 13%. CAGR is the annual growth rate over a certain period of time.

The utilisation has been over 100% in the last five years, i.e., the Department exceeded its budget estimates. In 2020-21 (revised estimates), the Department is expected to exceed the budget estimate by 21%. Overall, the Ministry is expected to have an additional spending of Rs 15,817 crore at the revised stage in 2020-21. Out of this, Rs 14,217 crore will be spent for COVID-19 emergency response and health system preparedness package, and COVID-19 vaccination for healthcare and frontline workers.

Figure 1: Allocation to the Department of Health and Family Welfare (2010-22) (in Rs crore)



Note: Revised Estimate has been 2020-21; For 2021-22, % change in allocation is 2021-22 BE over 2020-21 RE; BE – Budget Estimate; RE – Revised Estimate.
Sources: Union Budgets, 2006-07 to 2021-22; PRS.

Table 4 indicates the actual expenditure of the Department of Health and Family Welfare compared with the budget estimates of that year (2010-11 to 2020-21).

Table 4: Comparison of budget estimates and the actual expenditure (2010-21) (in Rs crore)

Year	BE	Actuals	% Utilisation (Actuals/BE)
2010-11	23,530	22,765	97%
2011-12	26,897	24,355	91%
2012-13	30,702	25,133	82%
2013-14	33,278	27,145	82%
2014-15	35,163	30,626	87%
2015-16	29,653	33,121	112%
2016-17	37,062	37,671	102%
2017--18	47,353	51,382	109%
2018-19	52,800	52,954	100%
2019-20	62,659	62,397	100%
2020-21	65,012	78,866*	121%

Note: BE – Budget Estimates; *Revised Estimate.
Sources: Union Budgets, 2010-21; PRS.

Major schemes and issues

National Health Mission

The National Health Mission (NHM) consists of two sub missions, the National Rural Health Mission (NRHM) (focused on rural areas) and the National Urban Health Mission (NUHM) (focused on urban areas). NHM aims at strengthening public health systems and healthcare delivery.

The various components under NHM include: (i) reproductive, maternal, newborn and child health services (RCH Flexi Pool), (ii) NRHM Flexi Pool for strengthening health resource systems, innovations, and information, (iii) immunisation including the Pulse Polio Programme, (iv) infrastructure maintenance, and (v) National Disease Control Programme.

The allocation for NHM in 2021-22 (Rs 36,576 crore) is 4% higher than the revised estimates of 2020-21. Under the NHM, the rural component, i.e., the National Rural Health Mission has been allocated Rs 30,100 crore, (0.2% annual increase over 2019-20). The allocation for National Urban Health Mission is Rs 1,000 crore in 2021-22 (8% annual increase over 2019-20).

Note that, significant funding for NHM is done through flexible pools, such as RCH flexible pool, and flexible pool for communicable diseases. The rationale for creating of the flexible pool is to allow more financial flexibility in allocation of funds among RCH services and efficient distribution of funds to obtain desired health outcomes. In 2021-22, Rs 8,451 crore was allocated towards the flexible pools, which is 8% annual decrease over 2019-20.

The Phase-I results of National Family Health Survey-5 indicate certain improvements as compared to those in National Family Health Survey-4. These include: (i) expeditious increase in full immunization coverage, (ii) increase in households with improved sanitation facility and clean cooking fuel across 22 states, and (iii) increase in institutional births.[13]

Table 5: Allocation towards flexible pools in 2021-22 (in Rs crore)

Major Heads	2019-20 Actuals	2020-21 RE	2021-22 BE	Annualised Change (Actuals 2019-20 to BE 2021-22)
Flexible Pool for Communicable Diseases	3,357	2,110	2,178	-19%
Flexible Pool for Non-Communicable	675	404	-	-100%
RCH Flexible Pool	5,902	-	6,273	3%
Total	9,934	2,514	8,451	-8%

Note: RCH flexible pool includes Routine Immunization Programme, Pulse Polio Immunization Programme and National Iodine Deficiency Disorders Control Programme.
Sources: Expenditure Budget 2021-22; PRS.

Table 6 shows the status of some key targets under the NHM framework.

Table 6: Status of some key targets of NHM

Targets (2012-20)	Latest Status
Reduce IMR to 25	IMR has reduced to 32 in 2018.
Reduce MMR to 100/1,00,000 live births	MMR has reduced to 113 in 2016-18.
Reduce TFR to 2.1	TFR has reduced to 2.2 in 2018.
Annual Malaria Incidence to be < .001	Annual Malaria Incidence is 0.02 in 2019.
Less than 1 % microfilaria prevalence in all districts	Out of 256 endemic districts, 99 have reported incidence less than 1% till 2018.
Reduce annual prevalence and mortality from Tuberculosis by half	Incidence reduced from 300 per lakh in 1990 to 204 per lakh in 2017.

Note: IMR-Infant Mortality Rate; MMR-Maternal Mortality Rate; TFR-Total Fertility Rate.
Source: Health and Family Welfare Statistics 2019-20; Special Bulletin on maternal Mortality in India 2016-18; National Family Health Survey-4 (2015-16); Unstarred Question No. 4335, Ministry of Health and Family Welfare, Lok Sabha, December 13, 2019; PRS.

Health infrastructure and enhancing service delivery by training human resources in healthcare are crucial for achieving objectives of the National Health Mission. Healthcare infrastructure in India can be categorised into *physical infrastructure* and *human resources* who provide medical services.

Physical infrastructure

Depending on the level of care required, healthcare in India is broadly classified into three types. This classification includes primary care (provided at primary health centres), secondary care (provided at district hospitals), and tertiary care institutions

(provided at specialised hospitals like AIIMS). Primary health care infrastructure provides the first level of contact between health professionals and the population.[14]

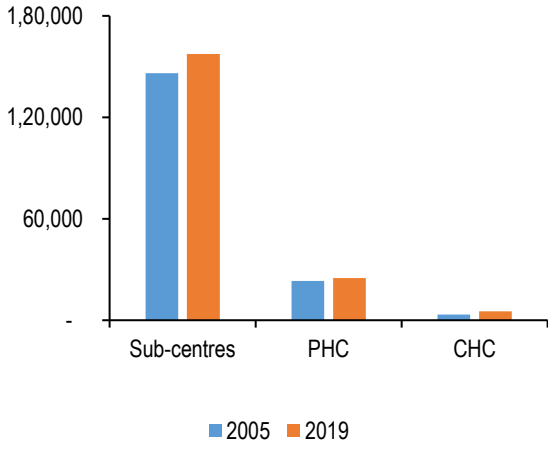
Broadly, based on the population served and the type of services provided, primary health infrastructure in rural areas consists of a three-tier system. This includes Sub-Centres (SCs), Primary Health Centres (PHCs), and Community Health Centres (CHCs).[15]

The High Level Group on Health Sector (2019) and the report of 15th Finance Commission on Ayushman Bharat have observed that focus on prevention and early management of health problems can reduce the need for complicated specialist care provided at the tertiary level.[17,20] It recommended that the focus of healthcare provision in the country should be towards providing primary healthcare.

The Finance Minister announced that PM AtmaNirbhar Swasth Bharat Yojana will be launched with an outlay of Rs 64,180 crore over six years. The scheme will be focused at: (i) developing primary, secondary, and tertiary healthcare systems, (ii) strengthening existing national institutions, and (iii) creating new institutions for detection and cure of new diseases.

The number of SCs, PHCs, and CHCs in 2005 and 2019 respectively across rural and urban areas are given in Figure 2.

Figure 2: Number of Sub Centres, PHCs, and CHCs (2005 and 2019)



Note: PHC – Primary Health Centre; CHC: Community Health Centre.
Source: Comparative Statement, Rural Health Statistics 2017-19; PRS.

The government plans to transform 1.5 lakh sub healthcare centres, primary health centres and urban primary health centres into Health Wellness Centres (HWCs) by 2022. HWCs will provide various range of services beyond maternal and child healthcare services. These services will include: (i) care for non-communicable diseases, (ii) rehabilitative care, (iii) mental health services, (iv) first level care for emergencies and trauma, and (v) free essential drugs and diagnostic services.[16]

Further, the High Level Group noted that India has 1 bed per 1,000 people, which is significantly less than the global average of 2.9 beds.[17,18] The National Health Policy, 2017 plans to increase this to 2 beds per 1,000 people.[17] This could be achieved by creating 3,000 to 5,000 hospitals with 200 beds each by 2025.[17]

Human resources in health

The Economic Survey 2020-21 observed that the aggregate density of health workers is 23 per 10,000 population, which is significantly lower than that recommended by World Health Organisation (WHO) (44.5 health workers per 10,000 population) to achieve the Sustainable Development Goals (SDG) targets by 2030.[4] As of 2019, there is 1 doctor per 1,511 people and 1 nurse per 670 people, which is lower than the WHO standard of 1 doctor per 1,000 people and 1 nurse per 300 people.[17] Note that despite the increase in total number of health workers, there is shortfall of doctors, specialists, and surgeons. For example, the number of health workers (female) (including auxiliary nurse midwives) has increased from 1,33,194 in 2005 to 2,19,326 in 2018.[15] As of 2018, 11% positions of doctors are vacant in primary health centres, and only 60% of total required specialists have been approved for appointment in primary health centres.[15]

Pradhan Mantri Jan Arogya Yojana (PMJAY)

The Ayushman Bharat programme - PMJAY was launched in September 2018.[19] It aims to provide an insurance cover of Rs five lakh per family per year to 10.7 crore poor families.[19] The scheme subsumed two centrally sponsored schemes, namely, Rashtriya Swasthya Bima Yojana (RSBY) and the Senior Citizen Health Insurance Scheme.

Benefits: The scheme provides insurance coverage for secondary and tertiary healthcare. The scheme provides 1,350 medical packages such as surgery, cost of medicines, day care treatments, and diagnostics. In addition, the scheme provides for pre- and post-hospitalisation expenses.

Allocation: In 2021-22, PMJAY has been allocated Rs 6,400 crore, which is double the actual spend two years ago (Rs 3,200 crore in 2019-20).

A study report by the 15th Finance Commission on Ayushman Bharat (2019) estimated the demand and expenditure on PMJAY for the next five years. It stated that the total costs (centre and states) of PMJAY for 2019 could range from Rs 28,000 crore to Rs 74,000 crore.[20] This estimate considers: (i) the assumption that all targeted beneficiaries will be covered (approximately 50 crore people), (ii) hospitalisation rates over time, and (iii) average

expenditure on hospitalisation. Further, it noted that these costs could go up to between Rs 66,000 crore and Rs 1,60,089 crore in 2023 (accounting for inflation).

Implementation: The Economic Survey 2020-21 notes that PMJAY enhanced health insurance coverage. The proportion of health insured households increased by 54% in states that implemented PMJAY and decreased by 10% for states which did not implement it. The infant mortality rate also decreased by 20% in states with implementation whereas in states without implementation the mortality rate declined by 12%.

Table 7 shows details regarding the implementation of the Ayushman Bharat programme which includes PMJAY and Health and Wellness Centres.

Table 7: Status of implementation of Ayushman Bharat - PMJAY (as of September 2020)

Indicators	All India
Beneficiary families covered (in crore)	13.13
Funds disbursed to states/UTs for implementation (in crore)	5,474
Total hospital admissions authorised (in crore)	over 1.24#
Health and Wellness Centres	59,307*

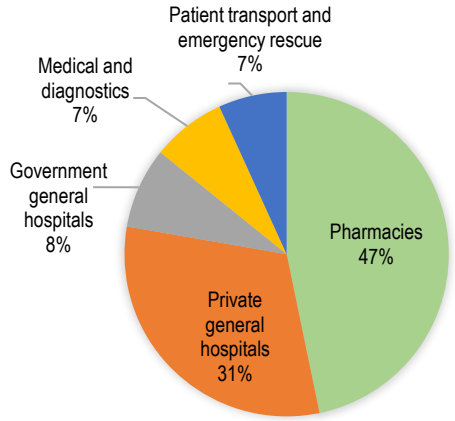
Note: #Includes 5.13 lakh hospital admissions for testing and treatment of COVID-19; *As on February 10, 2021.
Sources: Press Information Bureau (September 23, 2020) Ministry of Health and Family Welfare; Lok Sabha Unstarred Question No. 2081, Ministry of Health and Family Welfare, answered on September 23, 2020; HWC Portal, Ayushman Bharat; PRS.

Note that, the Standing Committee on Health (2018) and a study report of the 15th Finance Commission (2019) had noted that PMJAY is just an extension of RSBY which provided for coverage of up to Rs 30,000 per family per annum.[20,21] Hence, to ensure proper implementation of the scheme, an analysis of the failures and inadequacies of RSBY should be done. This would look at whether: (i) RSBY covered all potential beneficiaries, (ii) hospitalisation rates increased under the scheme, and (iii) insurance companies were profitable under the scheme. The key challenges identified in the implementation of RSBY include: (i) low rate of enrolment of beneficiaries, (ii) increase in out-of-pocket expenditure, and (iii) issues in empanelment of healthcare service providers.[22]

The Standing Committee on Health and Family Welfare (2020) noted that PMJAY faces various implementation challenges. These challenges include issues in: (i) identification of beneficiaries, (ii) non-inclusion of numerous eligible people, (iii) empanelment of healthcare providers, and (iv) hospital transaction system.[23]

Out-of-pocket expenditure: While PMJAY provides coverage for secondary and tertiary levels of healthcare, most of the out-of-pocket expenditure made by the consumers is on pharmacies (47%), private general hospitals (31%), government general hospitals (8%), medical and diagnostics (7%), and towards patient transport and emergency rescue (7%) (See Figure 3).[24]

Figure 3: Major heads for which out-of-pocket expenditure is made (May 2020)



Sources: NITI Aayog (May 1, 2020); PRS.

Out-of-pocket expenditure is the payment made directly by individuals at the point of service where the entire cost of the health service is not covered under any financial protection scheme.

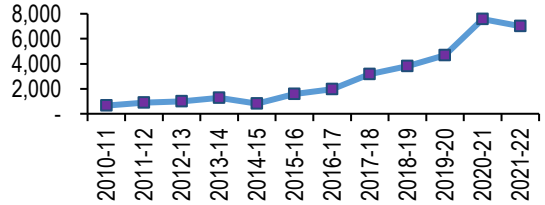
The Economic Survey 2020-21 observes that the overall out-of-pocket expenses in India on healthcare are 60% of the total expense on public health (which is one of the highest in the world). The survey highlights that increasing the spending on public health from 1% of the GDP to 2.5-3% of GDP will help in reducing the out-of-pocket expenses from 60% to 30%.[4]

Pradhan Mantri Swasthya Suraksha Yojana

Pradhan Mantri Swasthya Suraksha Yojana (PMSSY) was introduced in 2003 with objective of: (i) correcting regional imbalances in the availability of affordable and reliable tertiary healthcare services, and (ii) augmenting facilities for quality medical education in the country. This includes establishing AIIMS like institutions and upgrading certain state government hospitals. Over the years, the scheme has been expanded to cover 20 new AIIMS and 71 state government hospitals.

In 2018, the Comptroller and Auditor General (CAG) noted that all new AIIMs overshot their completion time by almost five years.[25] There were similar delays observed in the upgradation of state government hospitals. Further, it was found that the Ministry had estimated the capital cost for setting up six new AIIMS in Phase 1 to be Rs 332 crore per institute. After four years, this cost was revised to Rs 820 crore per institute, on account of shortcomings in planning and assessment of requirements. The Standing Committee on Health and Family Welfare (2017 and 2018) noted that this indicates poor assessment of time and cost which have left the allocated funds unused.[21,26]

Figure 6: Yearly allocation to PMSSY (2010-22) (in Rs crore)



Notes: Values for 2020-21 and 2021-22 are revised estimate and budget estimate respectively
Sources: Union Budget 2010-11 to 2021-22; PRS.

In 2021-22, the allocation to PMSSY has been decreased by 7% over the revised estimates of 2020-21 at Rs 7,000 crore. Allocation towards PMSSY increased from Rs 654 crore in 2010-11 to Rs 6,020 crore in 2020-21 (24% annual increase). In 2020-21, the revised estimate for PMSSY (Rs 7,517 crore) was 25% higher than the budget estimate (Rs 6,020 crore). This was due to the capital allocation (Rs 2,448 crore) for PMSSY at the revised stage.

Health research

In 2021-22, the Department of Health Research has been allocated Rs 2,663 crore (20% annual increase over 2019-20). The revised estimate in 2020-21 is 93% higher than the budget estimate for the year (Rs 2,100 crore).

The Standing Committee on Health and Family Welfare (March 2020) noted that the allocation to Department of Health Research is low compared to the requirement of funds needed for health research. The Committee recommended that at least 10% of the budget for the Ministry of Health and Family Welfare should be allocated towards health research.[27]

The Standing Committee on Health and Family Welfare (November 2020) noted that the budgetary allocation of Department of Health Research has been one of the lowest in 2019-20 (Rs 1,900 crore) as compared to the budgetary allocation of other departments involved in scientific research.[28] The Committee reiterated its recommendations to increase the budgetary outcomes of the Department of Health Research. The Committee noted that shortfall of funds may adversely impact the establishment of new Viral Research & Diagnostic Laboratories; Multi-Disciplinary Research Units in Medical Colleges (MRUs), and Model Rural Health Research Units (MRHRUs) in states.[28]

Further, the Committee noted that there is inadequate investment on public health research, as India invests only 0.65% of GDP on overall research and development activities in the country across various sectors. The Committee recommends that the Ministry of Health and Family Welfare should at least increase its spending on health research to the world average of 1.72% of GDP within two years.[28]

The Standing Committee on Health and Family Welfare (2018) had noted the huge, persistent, and recurring mismatch between the projected demand for funds and actual allocation to the Department of Health Research.[29,30] The Committee also noted that the Department had reported shortfall of funds for implementation of projects and on the other hand, there was underutilisation of funds released.

This mismatch between demand and allocation has led to impact in terms of restrictions in the sanctioning of new labs, providing recurring grants to the ongoing projects, and upgradation of health research infrastructure.[29] This also led to repercussions in the medical research output. For example, in two years i.e., 2015 and 2016, only 1,685 research papers have been published by the Indian Council of Medical Research and three patents have been granted against the 45 patents filed.[29]

Regulation of healthcare sector

The Economic Survey 2020-21 noted that information asymmetry is one of the key reasons which exposes the healthcare sector to market failures. It noted that patients in India rarely know the value of information they receive in the healthcare sector. For example, in case of certain medical services such as preventive care or mental health, patients may never know about the quality of the services they received. The Survey recommends setting up a sectoral regulator (specifically in private healthcare): (i) for supervision and regulation of the healthcare sector, and (ii) to prevent information asymmetry in the sector. Further, the Survey noted that mitigating information asymmetry in the healthcare sector will help in achieving lower insurance premiums and better welfare of people.

Drug regulation

In India, the import and manufacture of new drugs (including vaccines) is regulated under: (i) the Drugs and Cosmetics Act, 1940, (ii) Drugs and Cosmetics Rules, 1945, and (ii) New Drugs and Clinical Trials Rules, 2019.[31,32,33] The 1940 Act provides for the regulation of import, manufacture, sale, and distribution of drugs. Although the DCA is a central legislation, it is implemented by the states. The 2019 Rules provide for testing and approval for new drugs (including vaccines) in India.

The Mashelkar Committee Report (2003) highlighted the following challenges of the drug regulatory system: (i) inadequacy of trained and skilled personnel at the central and state levels, (ii) lack of uniformity in the implementation of regulatory requirements and variations in regulatory enforcement, and (iii) inadequate or weak drug control infrastructure at the state and central level.[34]

Expert committees have recommended several steps to address these concerns regarding drug regulation in the country.[34,35,36] They include: (i) a new

independent and professionally run regulatory body, Central Drug Administration, reporting directly to Ministry of Health and Family Welfare, (ii) categorising the states in terms of scale of industry (manufacturing and sale) and investment in their regulation accordingly, (iii) the revision and imposition of higher fees for drug applications, clinical trials, and registration of imported drugs and foreign manufacturers, and (iv) establishment of technical expert committees for new drug approvals.

The National Medical Commission Act, 2019 (NMC Act)

Parliament passed the NMC Act in 2019 to replace the Medical Council of India (MCI). The NMC will oversee medical education and practice in India.

Functions of the NMC include: (i) framing policies for regulating medical institutions and medical professionals, (ii) assessing the requirements of healthcare related human resources and infrastructure, (iii) ensuring compliance by the State Medical Councils of the regulations made under the Act, (iv) framing guidelines for determination of fees for up to 50% of the seats in private medical institutions and deemed universities which are regulated under the Act.

Currently, the Central Drugs and Standards Control Organisation (CDSCO), which is headed by the Drugs Controller General of India (DCGI), regulates the approval of new drugs (including vaccines) that are introduced in the country, grants permission to conduct clinical trials, and registers and controls the quality of imported vaccines.[33] It also approves licenses for the manufacture of new drugs (including vaccines) and coordinates these activities with states across India.[37]

In 2015, the Ministry of Health and Family Welfare constituted 25 panels of experts under the CDSCO in various medical areas such as vaccine, cardiology, and antiviral. These Subject Expert Committees evaluate the application of clinical trials, new drugs, and medical devices in their areas of expertise.[38] They are composed of 8 medical experts each. For example, the evaluation process for emergency authorization of a COVID-19 vaccine is being conducted by the Subject Expert Committee examining COVID-19 drugs and vaccines.[39]

Quality of drugs

The Standing Committee Report (2013) found that in India the prevalence of not-of-standard drugs is 7-8 % and the prevalence of spurious drugs is 0.5%.[40]

A not-of-standard drug refers to drug which do not meet Indian pharmacopoeia standards. The specifications under these standards include: (i) name of pharmacopoeia, (ii) quality of bonding agent, (ii) quality of colouring agent, and (iii) dissolution time. A drug is deemed to be 'spurious' if: (i) it is manufactured under a name which belongs to another drug, (ii) if it is an imitation of another drug, or (iii) if it has been substituted wholly or partly by another drug, or (iv) if it wrongly claims to be the product of another manufacturer.[41]

The extent of 'non-standard quality' drugs in the National Drug Survey between 2014 and 2016 was 3.2%.[42] The extent of 'spurious' drugs during the same period was 0.02%.[42]

With regard to quality of drugs, the Mashelkar Committee recommended that: (i) states should take more samples to check the quality of drugs manufactured and sold in the market, (ii) states should also monitor the source of purchase and quality of drugs stocked by registered medical practitioners, and (iii) number of drug inspectors and their skills must be upgraded according to the load of work of inspections and monitoring.[34]

Drug pricing

The National Pharmaceutical Pricing Authority (NPPA) monitors the availability and pricing of drugs in the country. NPPA fixes the prices of drugs/devices included in Schedule I of Drugs (Prices Control) Order (DPCO), 2013 after their notification under National List of Essential Medicines (NLEM). NLEM, 2015 consists of 3,754 medicines in total. Wherever instances of manufacturers/ importers charging prices higher than the prices fixed by the NPPA are reported, these cases are examined in detail. Since the inception of NPPA in 1995 till 2019, 2,038 demand notices have been issued to pharmaceutical companies for having overcharged patients on the sale of formulations at prices above the ceiling prices notified by NPPA.[43] An amount of Rs 5,477 crore is still remaining to be paid and an amount of Rs 4,033 crore is under litigation.[43]

In January 2019, the Standing Committee on Affordable Medicines and Health Products (SCAMHP) was constituted.[44] The Committee acts as a recommending body to NPPA regarding prices of drugs and health products. In addition, the Committee is authorised to examine a matter, suo-moto or on request of NPPA or Department of Health and Family Welfare.[44]

Annexure

Table 8: Allocations to the Ministry of Health and Family Welfare for 2021-22 (in Rs crore)

Major Heads	2019-20 Actuals	2020-21 BE	2020-21 RE	2021-22 BE	Annualised Change from 2019-20 Actuals to 2021-22 BE
Department of Health and Family Welfare	**62,397**	**65,012**	**78,866**	**71,269**	**7%**
Department of Health Research	**1,861**	**2,100**	**4,062**	**2,663**	**20%**
Pradhan Mantri Swasthya Suraksha Yojana (PMSSY)	4,683	6,020	7,517	7,000	22%
Family Welfare Schemes	489	600	496	387	-11%
National AIDS and STD Control Programme	2,813	2,900	2,900	2,900	2%
National Health Mission	**34,660**	**33,400**	**35,144**	**36,576**	**3%**
-National Rural Health Mission	29,987	27,039	28,367	30,100	0.2%
-National Urban Health Mission	850	950	950	1,000	8%
-Tertiary Care Programs	241	550	312	501	44%
-Strengthening of State Drug Regulatory System	206	175	130	175	-8%
-Human Resources for Health and Medical Education	3,376	4,686	5,386	4,800	19%
Infrastructure Development for Health Research	148	170	169	177	9%
Rashtriya Swasthya Bima Yojna (RSBY)	57	29	29	1	-87%
Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (PMJAY)	3,200	6,400	3,100	6,400	41%
Autonomous Bodies	9,601	9,616	9,882	10,924	7%
Others	8,607	7,976	9,474	9,567	5%
COVID-19 Emergency Response and Health System Preparedness Package	-	-	13,857	-	
COVID-19 vaccination for healthcare workers and frontline workers	-	-	360	-	
Total	**64,258**	**67,112**	**82,928**	**73,932**	**7%**

Sources: Demand for Grants, Ministry of Health and Family Welfare, Union Budget, 2021-22; PRS.

State-wise numbers on the health sector

Table 9: Comparison of key health indicators across states

State	Population (Million) 2011	Crude Birth Rate 2017	Total Fertility Rate, 2018	Under 5 mortality rate, 2010-15	Infant Mortality Rate (per 1000 live Births) 2018	Underweight children (%) 2015-16	Life Expectancy at Birth (Years) 2014-18	Maternal Mortality Ratio 2016-18
		Number of live births per 1,000 in a population.	Number of children born to a woman in her lifetime	Death between 0-5 years, per 1,000 live births	Number of infants who die before reaching one, per 1,000 live births	% Children below 5 years of age who are underweight	How long a new-born can expect to live, on existing death rate	Number of maternal deaths, per 1,00,000 live births
Andhra Pradesh	49	16	1.6	41	29	32%	70	65
Assam	31	21	2.2	57	41	30%	67	215
Bihar	104	26	3.2	58	32	44%	69	149
Chhattisgarh	26	23	2.4	64	41	38%	65	159
Gujarat	60	20	2.1	44	28	39%	70	75
Haryana	25	21	2.2	41	30	29%	70	91
Jharkhand	33	23	2.5	54	30	48%	69	71
Karnataka	61	17	1.7	32	23	35%	69	92
Kerala	33	14	1.7	7	7	16%	75	43
Madhya Pradesh	73	25	2.7	65	48	43%	67	173
Maharashtra	112	16	1.7	29	19	36%	73	46
Odisha	42	18	1.9	48	40	34%	69	150
Punjab	28	15	1.6	33	20	22%	73	129
Rajasthan	69	24	2.5	51	37	37%	69	164
Tamil Nadu	72	15	1.6	27	15	19%	72	60
Telangana	35	17	1.6	32	27	29%	70	63
Uttar Pradesh	200	26	2.9	78	43	40%	65	197
West Bengal	91	15	1.5	32	22	32%	72	98
Arunachal Pradesh	1	18		33	37	19%		
Delhi	17	15	1.5	42	13	27%	74	
Goa	1	13		13	7	24%		
Himachal Pradesh	7	16	1.6	38	19	21%	73	
Jammu & Kashmir	13	15	1.6	38	22	17%	74	
Manipur	3	15		26	11	14%		
Meghalaya	3	23		40	33	29%		
Mizoram	1	15		46	5	12%		
Nagaland	2	14		37	4	17%		
Sikkim	1	16		32	7	14%		
Tripura	4	13		33	27	24%		
Uttarakhand	10	17	1.8	47	31	27%	71	99
Andaman & Nicobar Islands	0	11		13	9	22%		
Chandigarh	1	14		38	13	25%		
Dadra & Nagar Haveli	0	24		42	13	39%		
Daman & Diu	0	20		34	16	27%		
Lakshadweep	0	15		30	14	23%		
Puducherry	1	13		16	11	22%		
All India	**1,211**	**20**	**2.2**	**50**	**32**	**36%**	**69**	**113**

Sources: Census Data 2011; Sample Registration System 2019; Health and Family Welfare Statistics 2017; Special Bulletin on maternal Mortality in India 2016-18; National Family Health Survey-4 (2015-16); PRS.

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