Process evaluation and Implementation Challenges of National Patient Safety Implementation Framework in Selected Public Healthcare Facilities in Tamil Nadu – A Mixed Method Study

Operations Research Report

Tamil Nadu Health Systems Reforms Program

By

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DEPARTMENT OF COMMUNITY MEDICINE

FINAL PROJECT REPORT

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Submitted to

The TNHSRP – Operational Research

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LIST OF ABBREVIATIONS

ADR	Adverse Drug Reaction
BMW	Biomedical Waste
CSSD	Central Sterile Supply Department
DCGI	Drugs Controller General of India
GH	Government Hospital
HCAI	Healthcare associated infections
HCW	Healthcare Worker
HDI	Human Development Index
HICC	Hospital Infection Control Committee
ICMR	Indian Council of Medical Research
ICU	Intensive Care Unit
IPD	Inpatient Department
ISO	International Standardisation Organisation
JCI	Joint Commission International
MoHFW	Ministry of Health and Family Welfare
MS	Medical Superintendent
NABH	National Accreditation Board for Hospitals & Healthcare Providers
NACO	National AIDS Control Organization
NPSIF	National Patient Safety Implementation Framework
NQAS	National Quality Assurance Standards
OPD	Outpatient Department
OT	Operation Theatre
PPE	Personal Protective Equipment
PvPI	Pharmacovigilance Programme of India
RMO	Resident Medical Officer
SOP	Standard Operating Procedures
WHO	World Health Organization

Process evaluation and Implementation Challenges of National Patient Safety Implementation Framework in Selected Public Healthcare Facilities in Tamil Nadu – A Mixed Method Study

INTRODUCTION

"Patient Safety is Everyone's Responsibility"

What is Patient Safety?

Patient safety is one of the fundamental elements of the healthcare delivery.[1] However, occurrence of avoidable adverse reactions, errors and risks associated with healthcare delivery remains a major challenge for the patient safety globally. World Health Organization (WHO) has defined patient safety as the "reduction in unnecessary harm associated with the health care to an acceptable minimum".[2] It has emerged as a discipline with evolving complexity in health care delivery systems and the resulting increase in the patient harm across the healthcare facilities.[1] A mature healthcare system will consider the higher level of complexity in the healthcare settings that makes the humans more vulnerable to mistakes. Patient safety (as a discipline) now consists of a "*framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make errors less likely and reduce the impact of harm when it does occur*."

Patient safety also represents the "quality" dimension of healthcare provided by the system, an essential component of universal health coverage (UHC).[3] There is a clear consensus that the "quality" healthcare services across the world should be safe, effective, and people centred. To realize the benefits of "quality" healthcare, health services should be equitable, integrated, timely, and efficient. To ensure the successful implementation of patient safety related strategies; clear set of policies, skilled healthcare professionals, data driven safety

improvement, leadership capacity, and effective involvement of the patients in their own care, are all required.[1]

Patient safety – Global scenario:

Globally, the burden of unsafe care was estimated to be 10%, i.e., 1 in 10 patients are globally harmed while receiving the healthcare.[4] Available evidences have suggested that around 134 million adverse events due to unsafe care occur in healthcare facilities in the low- and middle-income countries, responsible for around 2.6 million deaths globally every year.[5,6] According to the recent estimates, the societal cost of the patient harm has been valued at around US $1 trillion to 2 trillion per year.[5]

Below, we have listed some of the patient safety situations that are causing the most concern:

Medication errors are the leading cause of avoidable harm and injury in healthcare delivery systems globally. The cost associated with the medication errors has been estimated to be US $42 billion per year.[7]

Health care-associated infections (HCAIs) occurs mainly due to the patient safety errors among the hospitalized patients. Approximately 7% of patients in developed countries and 10% in developing countries acquire HCAIs and patient safety errors were touted to be one of the major reasons for such high burden.[4,6]

Unsafe surgical care procedures cause complications of varying severity in about 25% of the surgical patients. Almost 7 million patients suffer from the significant complications annually, and almost 1 million of them die during or immediately after the surgery.[8]

Unsafe injections practices in the hospital settings can be responsible for the transmission of infections, like HIV, hepatitis B and C, posing direct danger to the patients and the healthcare workers. This accounts for nearly 9.2 million years of life lost due to disability and mortality worldwide.[9]

Diagnostic errors can occur in about 5% of the adults visiting the outpatient care settings, and more than half of them have the potential to develop serious harm. Most people are likely to suffer from a diagnostic error at least once in their lifetime.[10]

Unsafe transfusion practices expose the patients to risk of adverse transfusion reactions and also transmission of serious infections like HIV or Hepatitis B.[11] Data on the adverse transfusion reactions from 21 countries has shown an average incidence of about 8.7 serious reactions per 100,000 distributed blood components.[12]

Radiation errors involve an overexposure to the radiation and the cases of wrong-patient or wrong-site identification.[13] A comprehensive review of nearly 30 years of published data on the safety in radiotherapy has estimated that the overall incidence of radiation errors is around 15 per 10,000 treatment courses.[14]

Sepsis is a condition that is not diagnosed early enough frequently, making it difficult to save that patient's life. These infections are also often resistant to antibiotics, leading to deteriorating clinical consequences. It was estimated to affect about 31 million people worldwide, resulting in over 5 million deaths every year.[15]

Venous thromboembolism is one of the most common causes of preventable patient harm, contributing to about one-third of the complications attributable to hospitalization. Every year, an estimated 3.9 million cases of venous thromboembolism occur in high-income countries and 6 million cases in low- and middle-income countries.[16]

Factors contributing to patient safety problems:

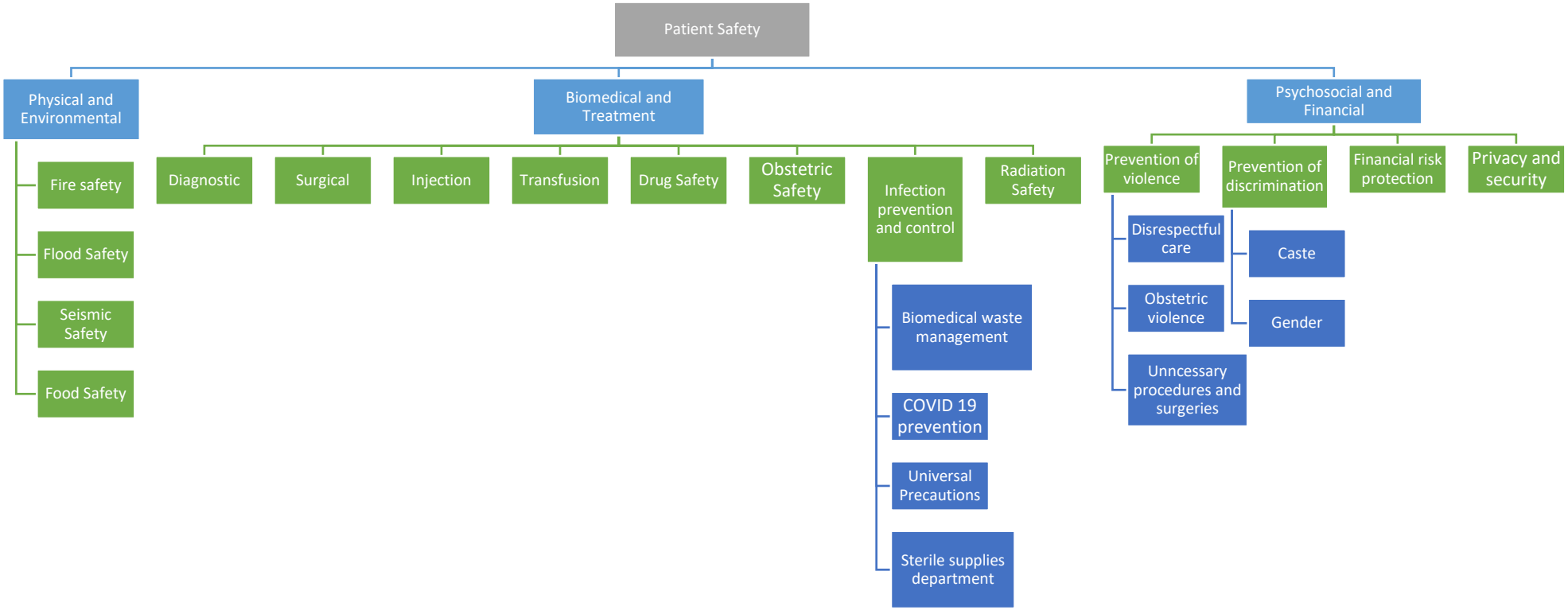
"To err is human" and expecting a flawless performance from the human beings working in a complex and high-stress environment is very unrealistic. Assuming that the individual perfection is possible will not improve the level of patient safety.[17] Humans are usually guarded from making any mistakes, while placed in an error-proof environment with the well-designed systems, processes and tasks in the working environment.[18] Therefore,

focusing on the healthcare system that allows the harm to occur is the starting point of improvement, and this can occur only in a transparent and open environment where the safety culture prevail.

Figure 1 shows the various factors contributing the patient safety problems across healthcare facilities. Patient safety encompasses both medical & non-medical reasons for patient safety problems such as error in patient communication, management, or clinical performance. Several aspects threatening the patient safety are errors in diagnosing a patient, surgical errors, adverse events following administration of any drugs or application of any medical devices, unsafe injection practices, blood products and improper biomedical waste management (BMW) system. These are not restricted only to the in-patient or hospitalization services but are also commonly found during the out-patient care services. It has been reported that more than 15% of all the hospital admissions are related directly to the adverse events during the patient's treatments.

Simple precautions such as hand hygiene, proper waste disposal, personal protective measures, clean hospital environment and patient etiquette are some of the cost-effective interventions to ensure patient safety and reduce the burden of HCAIs and other adverse events associated with patient safety.[5] Therefore, there is a need to make investments for enabling the hospitals and healthcare facilities to be safe for the patients. Making the hospitals safe can also substantially reduce the associated healthcare costs and improve the patient satisfaction and experiences.

Figure 1: Various factors contributing to the patient safety at healthcare settings



Global Initiatives for Patient Safety:

The "Seventy-second World Health Assembly" (72nd WHA) in the year 2019 has adopted a resolution WHA72.6 on the global action on patient safety and mandated for the development of a "global patient safety action plan". This global action plan was later adopted by the "Seventy-Fourth World Health Assembly" (74th WHA) in the year 2021 with the vision of making "a world in which no one is harmed in health care, and every patient receives safe and respectful care, every time, everywhere" (**Figure 2**).[5]

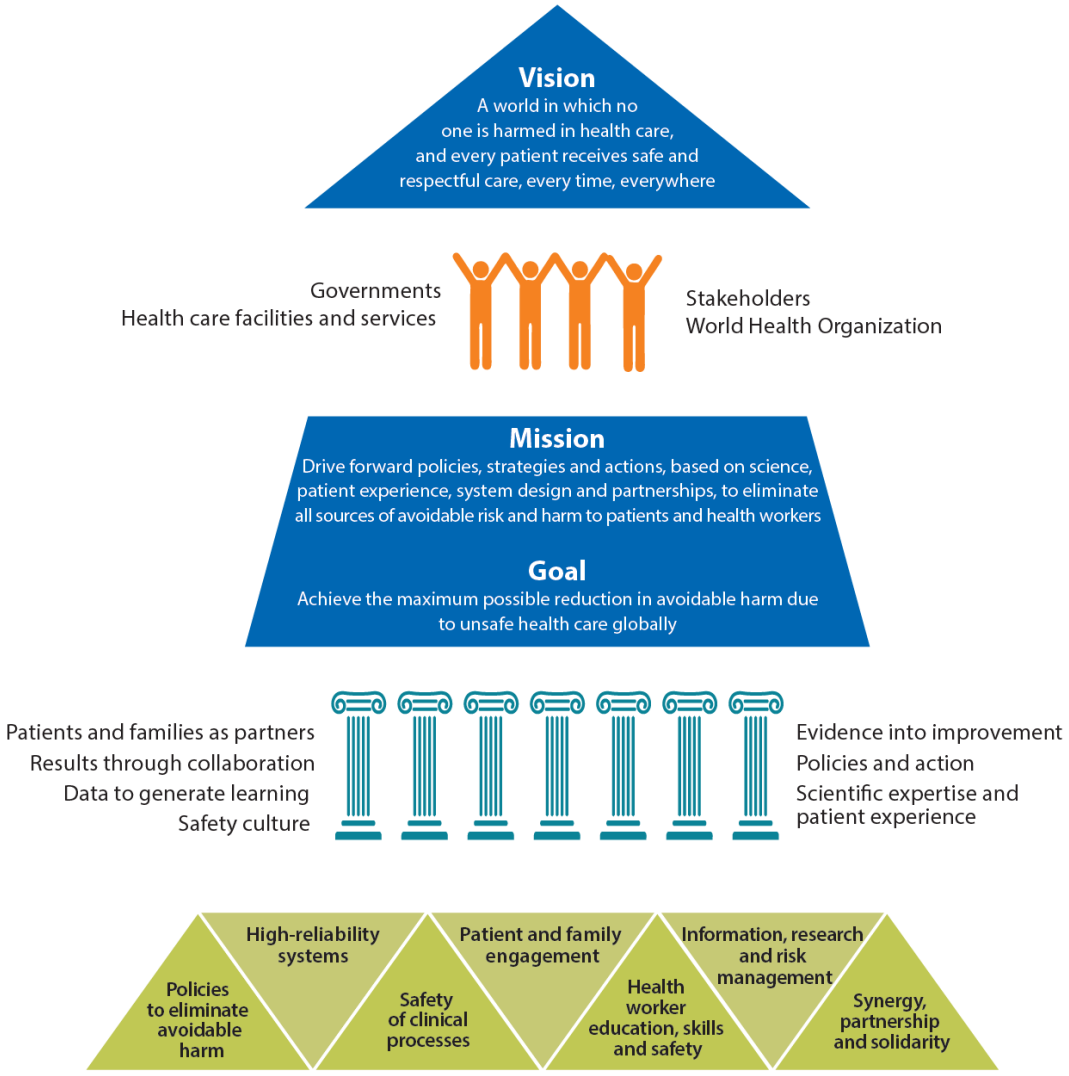


Figure 2: Overview of the Global Patient Safety Action Plan (2021-2030).

The purpose of this action plan was to provide a strategic direction for all the stakeholders to eliminate the avoidable harm in the health care settings and improve the patient safety in the different practice domains through various policy actions on the quality and safety of healthcare services, as well as implementation of the recommendations at the point of care. This action plan also provides a framework for all the countries to develop their own national action plans on the patient safety, and align them to their existing strategic instrument for the improvement of patient safety in all the clinical and health-related national programmes. A favourable ecosystem in government and point-of-care is required with guidance coordination for the smooth implementation of the action plan across various countries (**Figure 3**).[5]

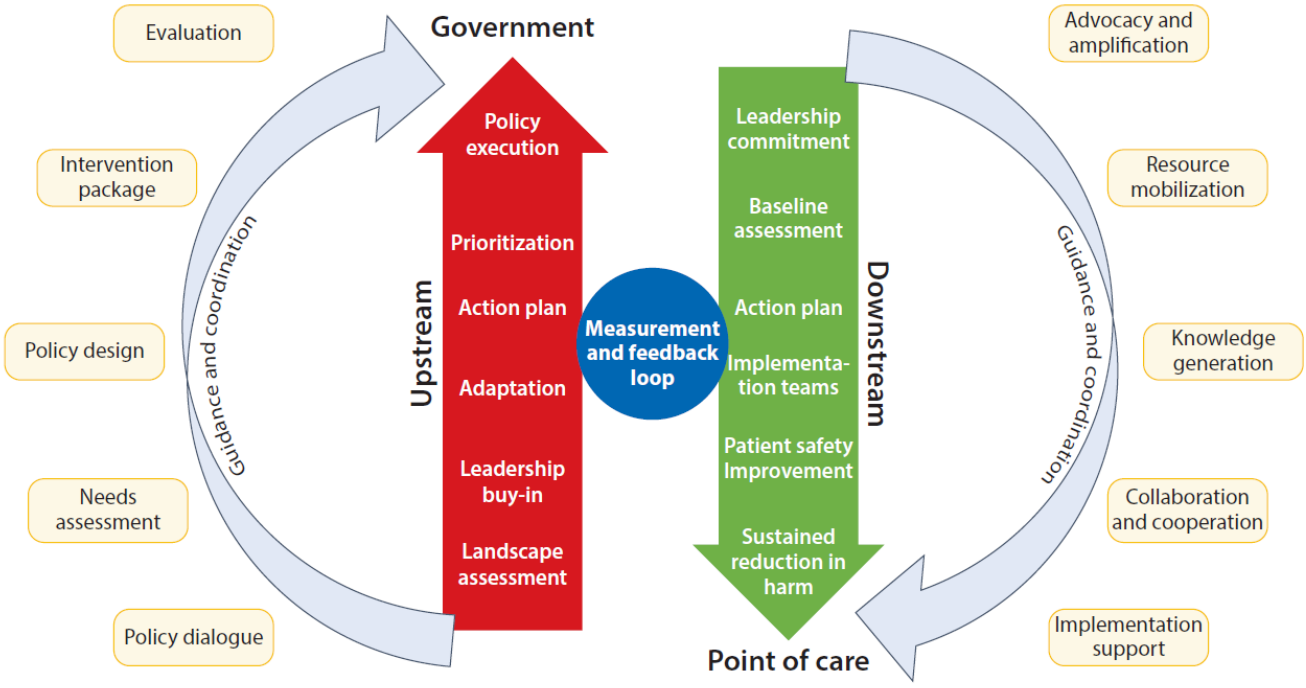


Figure 3: Ecosystem for Implementation of Global Patient Safety Action Plan (2021-2030)

The WHO has recommended several other key initiatives to advance the patient safety agenda. "Clean Care is Safe Care" is an initiative focused at reducing hospital acquired infections.[19] "Safe Surgery Saves Lives" initiative is dedicated to reducing surgical risks and harms.[20] "The Medication without Harm" initiative is directed towards drug safety and

pharmacovigilance.[21] These biomedical safety initiatives are very important in making hospitals safe spaces. In addition, it must be understood that hospitals and health facilities are social institutions. They are spaces of intense social interactions. Therefore, interpersonal safety, prevention of discrimination, prevention of violence and protection of equity are important dimensions of patient safety.[5,22]

Indian Initiative for Patient Safety – "*National Patient Safety Implementation Framework*":

In spite of availability of several data management systems in India, there has been little to no documentation of the errors, HCAIs, negligence or adverse events occurring to the patients during their hospitalization in our country. Taking cognizance of the patient safety challenges and to harmonize the several initiatives in the country, Ministry of Health and Family Welfare (MoHFW) has introduced the "National Patient Safety Implementation Framework (NPSIF)" to ensure the patient safety at different levels of healthcare delivery system in both public and private facilities.[23]

It aims to improve the patient safety at all levels of healthcare across all the modalities of healthcare provision, including the prevention, diagnosis, treatment and follow-up within the overall context of improving the quality of care and progressing towards universal health coverage in the coming decades. Being a cross-cutting concept in nature, the scope of topic "patient safety" applies to all the national programmes and it envisages collaboration of the wide range of national and international stakeholders, both within & outside the health sector. Key strategic objectives of the NPSIF are depicted in **Figure 4**.

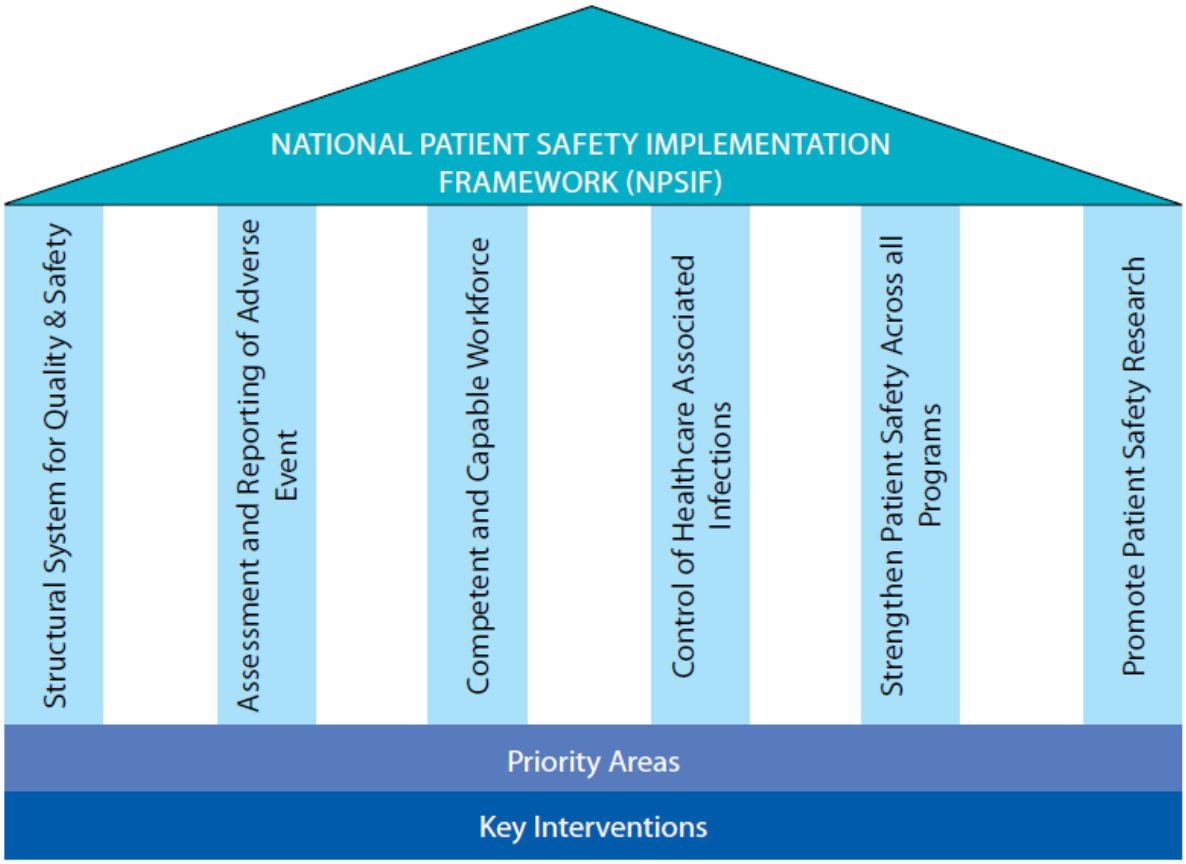


Figure 4: Key Strategic Objectives of the NPSIF

The framework provides the list of key strategic objectives, priority areas and key interventions across six domains to ensure the proper implementation of patient safety practices across the country.

Rationale for the study:

Despite the availability of the framework, there has been any attempts done to check the status of implementation of this framework in any part of the country. Evaluating the status of implementation, checking the feasibility, challenges and obtaining the suggestions for improvement are the key factors necessary for proper implementation and sustainability of any national health programs, schemes or framework.

Hence, there is a need to evaluate the proper implementation of the patient safety practices mentioned in the framework across the public healthcare facilities. Tamil Nadu is one of the best performing states in terms of health indicators and healthcare delivery in India. It is also important to know whether the state is better performing in terms of its patient safety practices and good quality service delivery. Hence, we will do the process evaluation of National patient safety implementation framework across the public healthcare facilities in Tamil Nadu. We will also try to explore the challenges in implementation of this framework and suggestions to overcome the same through qualitative interviews.

Objectives:

Among the public health care facilities (secondary and tertiary) in the state of Tamil Nadu,

- To evaluate the process of National patient safety implementation framework
- To explore the challenges in implementing the framework and suggestions to overcome the same.

METHODS

Study design:

We have conducted a sequential explanatory mixed method study, with quantitative part involving a cross-sectional survey of public health facilities and patients attending the facilities, while the qualitative part involves the key informant interviews [KIIs] and in-depth interviews [IDIs] of healthcare workers/officials in the surveyed facilities.

Quantitative components:

- Process evaluation of the public health facilities about the implementation of NPSIF
- Patient safety assessment among OPD and IPD patients of public health facilities
- Hand hygiene & Biomedical waste management observations among healthcare professionals in public health facilities

Study setting

Healthcare services in the state of Tamil Nadu are provided by a three-tier structure delivery system. At the primary level, sub-centers (SCs) and primary health centers (PHCs) are responsible for provision of healthcare delivery. In secondary level, community health centers (CHCs) and district hospitals (DHs) are responsible for providing specialist secondary services and in tertiary level, medical colleges/hospitals are responsible for tertiary care services.

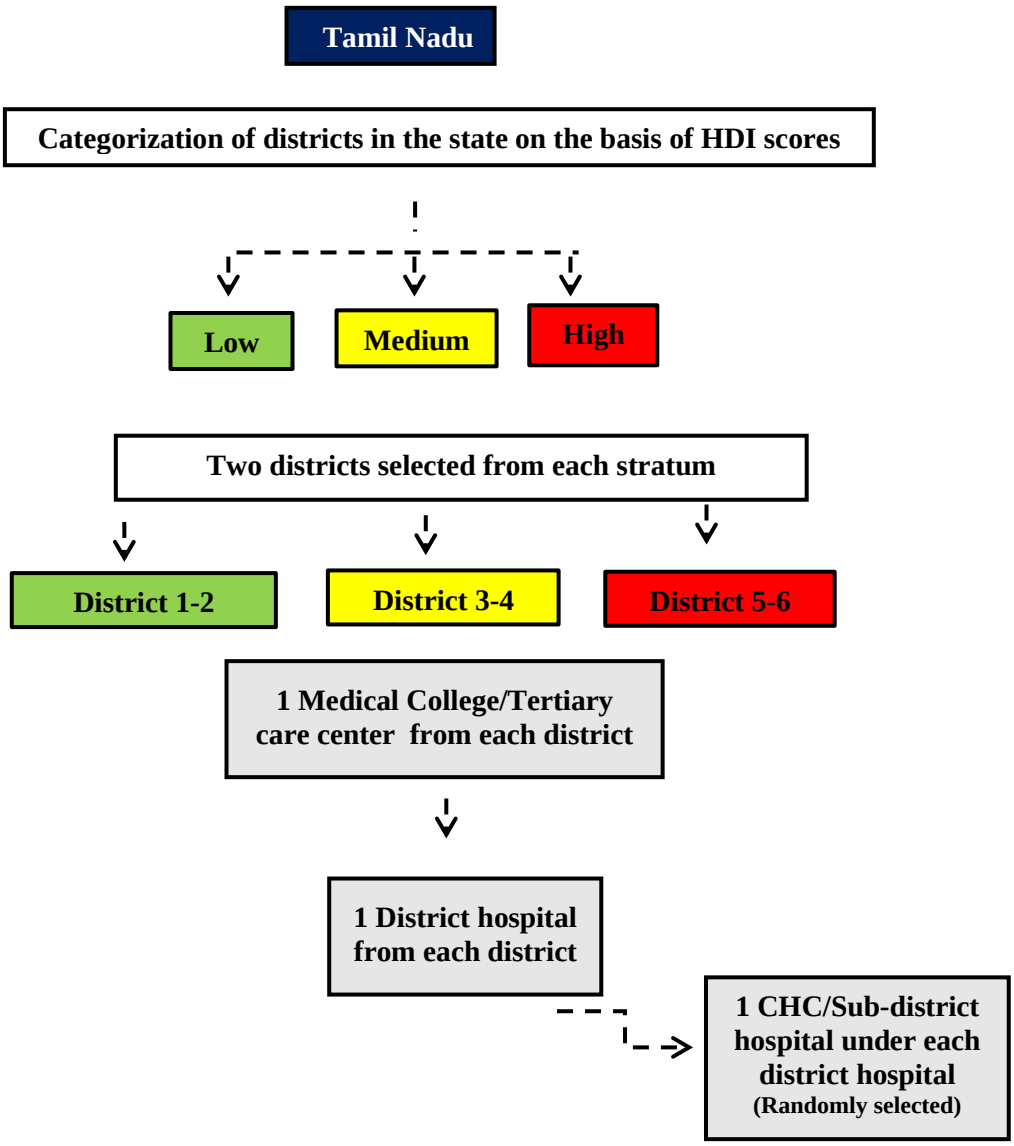
Sampling strategy

Patient safety implementation framework is mainly concerned with secondary and tertiary care facilities in the country and hence, only these two levels of healthcare facilities will be

sampled. A two-stage stratified random sampling was performed for the selection of public health facilities.

Stage 1: In the first stage, all the districts were stratified into three categories (low, medium and high) based on their human development index (HDI) scores.[7] The reason for choosing HDI to stratify the districts was that the indicators in HDI were representative of important demand side characteristics explaining the health status, healthcare seeking behavior and utilization of services. Two districts from each of these strata were selected randomly. Selection of districts was done randomly using lottery method.

Figure 5: Sampling strategy for the selection of districts and facilities



Stage 2: In the second stage, a total of 18 public health facilities were selected covering the secondary and tertiary care levels of healthcare delivery. The selected facilities were 6 tertiary care hospitals/medical colleges (on the basis of patient load) in each selected district, 6 DHs (one from each district), 6 CHCs (under each selected DH), summing up to 18 public healthcare facilities in Tamil Nadu (**Table 1**).

Table 1: District-wise list of health facilities sampled for the study

District	HDI	Tertiary Hospital	Secondary Hospitals
Tirunelveli	High	Government Tirunelveli Medical College and Hospital	• Government Headquarters Hospital, Tenkasi • Government Hospital, Ambasamudram
Tiruchirappalli	High	KAP Vishwanathan Government Medical College and Hospital	• Government Hospital, Srirangam • Government Hospital, Musiri
Salem	Medium	Government Mohan Kumaramangalam Medical College and Hospital	• Government Hospital, Attur • Government Hospital, Omalur
Pudukkottai	Medium	Government Pudukkottai Medical College and Hospital	• Government Hospital, Aranthangi • Government Hospital, Ilupur
Villupuram	Low	Government Villupuram Medical College and Hospital	• Government Hospital, Tindivanam • Government Hospital, Vikravandi
Theni	Low	Government Theni Medical College and Hospital	• Government Hospital, Bodinayakanur • Government Hospital, Periyakulam

Sample size

For patient safety assessment in outpatient department (OPD) and inpatient department (IPD) patients, assuming that at least 50% of the patients feel they are safe for >90% patient safety domains, with absolute precision of 5%, confidence level of 95% and design effect of 2, the minimum sample size was estimated to be 768 in each district. To round it off, we took 800 patients from each of the district.

To make the sample more representative of the distribution of OPD and IPD patients across the facilities, we took 500 patients from the OPD and 300 patients from the IPD in each district. For OPD patients, 250 patients were selected from the medical college and 125 patients in each of the two GH in the selected district. The total sample size to be taken from all the six districts were 3000 OPD patients (500 in each district). For IPD patients, 200 patients were selected from the medical college and 50 patients in each of the two GH in the selected district. The total sample size to be taken from all the six districts were 1800 IPD patients (300 in each district).

For hand hygiene observations, sample size was calculated based on the previous study with a 22% non-compliance rate to hand hygiene[24], 10% relative precision, the minimum number of hand hygiene opportunities to be observed will be around 2700. Since we have a sample of 18 facilities, we must observe 150 hand hygiene opportunities from each facility (150x18=2700). Same number of observations was also done for biomedical waste management observations also.

Data collection

Training of data collectors

A team of field assistants and research assistants were recruited as data collectors for this survey. In total, 6 Field Assistants and 2 Research Assistants will be recruited. Before starting the data collection process, a week-long training was provided to familiarize them on data collection methods, tools, and the patient safety implementation framework at the facility level. The field assistants were then asked to collect data from both secondary and tertiary care facilities. They were monitored periodically by the Research Assistants, the Principal Investigator and Co-Investigators.

Process evaluation

Development of tool for process evaluation of public health facilities

Implementation status of National Patient safety guidelines was assessed using a tool containing the set of indicators developed using NPSIF framework, literature search, standard guidelines, and expert opinions (**Annexures**). In total, nearly 100 indicators under six domains were used to assess the selected secondary and tertiary care facilities in the state. The indicators were split across six domains as mentioned under the NPSIF. Indicators under Domain 1 (Structural support for quality & safety), Domain 2 (establish system for reporting & learning), Domain 3 (competent and capable workforce for patient safety) was developed based on the key priority areas mentioned under these domains in NPSIF and relevant literature search. Indicators under Domain 4.1 (Infection prevention and control) was developed based on the key priority areas in NPSIF, and policy document on "ICMR Hospital Infection Control Guidelines"[25] and "WHO Guidelines on Core Components of Infection Prevention and Control Programmes at the National and Acute Health Care Facility

Level".[26] Domain 4.2 (Sterile equipment supply) and Domain 4.3 (Biomedical waste management) was developed based on the key priority areas in NPSIF, literature search and opinion from public health experts. Indicators under Domain 5.1 (Blood Safety) was developed based on the key priority areas in NPSIF and policy document on Standards for Blood Bank & Blood Transfusion Services.[27] Indicators under Domain 5.2 (Antimicrobial Safety) was developed based on the key priority areas in NPSIF, policy document on antimicrobial stewardship practices in India and literature search.[28] Indicators under Domain 5.3 (COVID-19 Safety) was developed based on the WHO Hospital readiness checklist for COVID-19.[29] Indicators under Domain 5.4 (Medication Safety), Domain 5.5 (Medical device Safety), Domain 5.6 (Injection Safety), Domain 5.7 (Safe surgical care), Domain 6 (Patient Safety Research) were devised using the key priority areas mentioned under these domains in NPSIF and relevant literature search.

These initial set of indicators underwent two rounds of revision before finalization. The first round of revision was done following the review of indicators by a panel of public health experts. The purpose of the review is to check the indicators for its completeness, correctness, relevance, consistency, and importance. Following the first round of revision, Research Assistants were trained and oriented on the tool and its application. Then, the second round of revision was done after piloting the tool in our tertiary care centre by the Research Assistants. The purpose of the piloting is to check the indicators for its applicability, understanding, build familiarity and find the best way to implement the tool. During this round, we obtained valuable inputs from the administrative heads (Medical Superintendent), and experts in various departments such as Pharmacology, Microbiology, and Pathology. Following the feedback obtained during the piloting, the tool was again reviewed by the PI, Co-PI and Research Assistants and the set of indicators for data collection were finalized.

Data collection process

Research Assistants visited the selected public health facilities and relevant officer in charge (Dean/Medical Superintendent/Resident Medical Officer)/healthcare personnel/respective committee heads were interviewed to record the information about each of the domains and indicators. In addition to the interview, the indicators were confirmed by the direct observation of the activities, review of records, registers, or logs. Only after verification, the activity or indicator was considered as performed or present. Hence, both primary (through interviews) and secondary data (through record review) were collected during the survey.

Perception of patients on the patient safety hospital care in hospitals (OPD & IPD)

A consecutive sample of 250 OPD patients and 200 IPD patients from medical colleges and 125 OPD patients and 50 IPD patients from each of two GHs were interviewed about the patient safety hospital care in the hospital during their visit. We developed a semi-structured questionnaire to assess the patient's perception on the patient safety hospital care in the hospital. The questionnaire was developed based on literature search and consultation with team of public health experts. Two separate questionnaires (one for OPD and another one for IPD interviews) were developed. Both the questionnaires were piloted by the field assistant and modified the questionnaire for its relevance, understanding and difficulty in any items and final version was confirmed after consensus between PI, Co-PI and Research Assistants. The final form of questionnaire (both versions) consisted of three sections (**Annexures**):

Section I consisted of sociodemographic details of the patients (age, gender, education, occupation, marital status, socioeconomic status, reason for OPD/IPD visit, duration of hospitalization if applicable, previous OPD/IPD visit to the same hospital)

Section II consisted of questions related to patient safety hospital care in the hospital (questions were split based on four domains – Communication between patient and healthcare providers, procedural safety, environmental safety, COVID-19 appropriate behaviour)

Section III consisted of questions related to disrespectful care, patient satisfaction, quality of care and recommendation rating to the hospital.

Hand hygiene and biomedical waste management observations

We also performed the work sampling technique and observed the performance of hand hygiene and biomedical waste management by healthcare professionals (doctors/nurses/ technicians etc.) in the selected healthcare facilities. Observation checklists were made after consensus with the subject experts and literature search (**Annexures**).

Hand hygiene compliance was assessed during five moments of hand hygiene (as defined by WHO)[30]:

1) Before touching a patient,
2) Before clean/aseptic procedures,
3) After body fluid exposure/risk,
4) After touching a patient,
5) After touching patient surroundings

This additional layer of observation will increase the robustness of the obtained results and ensure whether there is proper compliance to the activities under the framework.

Qualitative part

Participants

Following the survey, KII and IDI were conducted among the Relevant officer in charge (Dean/Medical Superintendent/Resident Medical Officer)/respective committee heads/healthcare workers of varied experience and cadres. The composition of participants consists of dean, medical superintendent, resident medical officer, representatives from matron office, hospital infection control committee (if available), biomedical waste management committee (if available), construction and maintenance department, CSSD incharge (if available) and the representatives from para-clinical and clinical departments such as Pharmacology, Microbiology, Community Medicine, General Medicine, General Surgery, Obstetrics and Gynaecology, Paediatrics, Orthopaedics and Blood bank/Transfusion Medicine. Participants were selected from all the 18 sampled public health facilities.

Interview procedure

At least 5-6 in-depth interviews were conducted from each of the purposively selected healthcare facilities or till the point of data saturation is achieved. An interview guide was developed after the quantitative survey (based on its findings) to collect information regarding the facilitating factors or challenges faced in the implementation of patient safety framework across all the strategic objectives. We also asked them about the recommendations to overcome the challenges. Interview was conducted by the trained set of data collectors who are fluent in the local language, formally trained in a qualitative research workshop and has previous experience in qualitative data collection process.

Interview was started after obtaining the informed consent and explaining the purpose and motive of the study. Privacy of the information was ensured by conducting the interview in

an isolated room without presence of any non-participants. Participants were ensured about the confidentiality of the information obtained through the interview. The interviews were audio-recorded only for participants providing consent. Field notes were taken during the interview. At the end of the interview, summary was presented to the participants for validation of the data collected.

ANALYSIS PLAN

Quantitative

Data was entered into EpiCollect5, and analysis was performed using STATA software version 14.2 (StataCorp, CollegeStation, TX, USA). Continuous variables were summarized as mean and standard deviation (SD) and categorical variables as proportions. All the process indicators, hand hygiene, biomedical waste management observations and various domains of patient safety hospital care in the hospital were summarized descriptively as frequency and percentages.

The various indicators of process evaluation were assigned scores as per the following range:

Domain 1: To improve structural systems to support quality and efficiency of healthcare and place patient safety at healthcare facility level (Maximum: 16 points; Minimum: 0 points)

1.1. National Quality Assurance Standards (NQAS) accreditation:

Present - 4 points; Absent – 0 points;

1.2. National Accreditation Board for Hospitals & Healthcare Providers (NABH) accreditation:

Present - 4 points; Absent – 0 points;

1.3. Kayakalp certification:

Present - 2 points; Absent – 0 points;

1.4. LAQSHYA certification:

Present - 2 points; Absent – 0 points;

1.5. Additional certifications/ accreditation (1 points for each certification/ accreditation):

Maximum - 4 points; Minimum – 0 points;

Domain 2: To assess the nature and scale of adverse events in healthcare and establish a system of reporting and learning (Maximum: 4 points; Minimum: 0 points)

2.1. SOPs/Checklist related to patient safety:

Present - 1 point; Absent – 0 points;

2.2.Standard protocol for duty handing over and taking over rounds:

Present - 1 point; Absent – 0 points;

2.3.Anonymous reporting system (complaint/suggestion box) for hospital staff, students, residents, patients or families:

Present - 1 point; Absent – 0 points;

2.4.Registered and functional patient groups for development of policies, strategies or plans in hospitals:

Present - 1 point; Absent – 0 points;

Domain 3: Competent and capable workforce aware and sensitive to patient safety (Maximum: 2 points; Minimum: 0 points)

3.1.SOP/Practice guideline for training of healthcare workers on patient safety:

Present - 1 point; Absent – 0 points;

3.2.Conduct of training for healthcare workers on patient safety:

Present - 1 point; Absent – 0 points;

Domain 4: To prevent and control healthcare associated infections (HCAI)

Subdomain 4.1.: Strengthening infection prevention and control structure & program across all healthcare services & levels of care (Maximum: 10 points; Minimum: 0 points)

4.1.1. Hospital infection control committee (HICC)/Microbiology department:

HICC – 1 point; Microbiology department – 0.5 points; None – 0 points;

4.1.2. Composition of HICC as per recommended guidelines

(Chairperson: Head of the Institute (preferably)

Member Secretary: Senior Microbiologist

Members: Representation from Management/Administration (Dean/Director of Hospital; Nursing Services; Medical Services; Operations)

Relevant Medical Faculties

Support Services: (OT/CSSD, Housekeeping/Sanitation, Engineering,

Pharmacologist, Store Officer / Materials Department)

Infection Control Nurse (s)

Infection Control officer)[31]

Present - 1 point; Absent – 0 points;

4.1.3. Conduct of regular HICC meeting:

Present - 1 point; Absent – 0 points;

4.1.4. SOP for Hospital Infection Prevention and Control:

Present - 1 point; Absent – 0 points;

4.1.5. Environmental surveillance:

Present – 0.5 points; Absent – 0 points;

4.1.6. OT surveillance and swabs:

Present – 0.5 points; Absent – 0 points;

4.1.7. ICU surveillance and swabs:

Present – 0.5 points; Absent – 0 points;

4.1.8. Inspection/Monitoring of sterilization and disinfection practices:

Present – 0.5 points; Absent – 0 points;

4.1.9. Autoclave check:

Present – 0.5 points; Absent – 0 points;

4.1.10. Water quality check:

Present – 0.5 points; Absent – 0 points;

4.1.11. Monitoring of antimicrobial sensitivity and resistance patterns:

Present – 0.5 points; Absent – 0 points;

4.1.12. Conduct of training on hand hygiene practices:

Present – 0.5 points; Absent – 0 points;

4.1.13. Awareness sessions on hand hygiene practices for general public/patients:

Present – 0.5 points; Absent – 0 points;

4.1.14. Reporting of HCAI from microbiology/HICC to hospital administration:

Present – 0.5 points; Absent – 0 points;

4.1.15. Reporting of HCAI from hospital to HAI surveillance:

Present – 0.5 points; Absent – 0 points;

4.1.16. Set of monitoring indicators for infection prevention and control:

Present – 0.5 points; Absent – 0 points;

Subdomain 4.2.: Providing appropriately cleaned and disinfected or sterilized equipment for patient care as required (Maximum: 10 points; Minimum: 0 points)

4.2.1. Central Sterile Supply Department (CSSD):

Present – 1 point; Absent – 0 points;

4.2.2. SOP for cleaning, disinfection or sterilization of equipment for patient care:

Present – 1 point; Absent – 0 points;

4.2.3. Logs for monitoring sterilization practices:

Present – 1 point; Absent – 0 points;

4.2.4. Regular cleaning, decontamination or fumigation practices:

Present – 1 point; Absent – 0 points;

4.2.5. Culture for checking quality of disinfection:

Present – 1 point; Absent – 0 points;

4.2.6. Trained staff for cleaning, disinfection/sterilization of equipment for patient care:

Present – 1 point; Absent – 0 points;

4.2.7. Maintenance and repair system in place for all the equipment:

Present – 1 point; Absent – 0 points;

4.2.8. Periodic servicing of equipment:

Present – 1 point; Absent – 0 points;

4.2.9. Periodic internal audit:

Present – 1 point; Absent – 0 points;

Subdomain 4.3: Providing a safe and clean environment by improving the general hygiene, sanitation, and management of healthcare waste in healthcare facilities

Biomedical waste management: (Maximum: 10 points; Minimum: 0 points)

4.3.1. Biomedical waste management committee:

Present – 1 point; Absent – 0 points;

4.3.2. Regular meeting of biomedical waste management committee:

Present – 1 point; Absent – 0 points;

4.3.3. SOP for Biomedical waste management:

Present – 1 point; Absent – 0 points;

4.3.4. Training of hospital staffs on biomedical waste management:

Present – 1 point; Absent – 0 points;

4.3.5. Provision of personal protective equipment for handling biomedical waste:

Present – 1 point; Absent – 0 points;

4.3.6. Mechanism for reporting needle stick injuries to hospital administration:

Present – 1 point; Absent – 0 points;

4.3.7. Mechanism for reporting needle stick injuries to National AIDS Control Organization (NACO):

Present – 1 point; Absent – 0 points;

4.3.8. Biomedical waste storage facility:

Present – 1 point; Absent – 0 points;

4.3.9. Bins and trolleys for transporting biomedical waste safety to the storage facility:

Present – 1 point; Absent – 0 points;

4.3.10. Facility has a link to any common treatment facility:

Present – 1 point; Absent – 0 points;

Domain 5: To implement global patient safety campaigns and strengthening Patient Safety across all programmes

Subdomain 5.1: Blood safety: (Maximum: 9 points; Minimum: 0 points)

5.1.1. Hospital transfusion committee/Blood bank:

Hospital transfusion committee – 1 point; Blood bank – 0.5 points; None – 0 points;

5.1.2. ***Composition of transfusion committee as per recommended guidelines:***

(Chairperson – Dean/Medical Superintendent of the institute

Convenor – Head of transfusion medicine department

Members – Representatives from medicine, surgery, obstetrics, and gynecology, orthopedics and nursing superintendent)[32]

Present – 1 point; Absent – 0 points;

5.1.3. Regular meeting of transfusion committee:

Present – 1 point; Absent – 0 points;

5.1.4. SOP for Blood bank and Blood transfusion services in facility:

Present – 1 point; Absent – 0 points;

5.1.5. Frames appropriate policies and procedures for blood transfusion in the facility:

Present – 0.5 points; Absent – 0 points;

5.1.6. Committee reviews policies and procedures:

Present – 0.5 points; Absent – 0 points;

5.1.7. Committee revises policies and procedures whenever required:

Present – 0.5 points; Absent – 0 points;

5.1.8. Committee monitors blood transfusion practices:

Present – 0.5 points; Absent – 0 points;

5.1.9. Committee conduct audits to review the appropriateness of blood and its components for blood transfusion:

Present – 0.5 points; Absent – 0 points;

5.1.10. Committee evaluates the incidence of adverse transfusion reaction:

Present – 0.5 points; Absent – 0 points;

5.1.11. Committee reports the adverse donor and transfusion reaction to the hospital administration:

Present – 0.5 points; Absent – 0 points;

5.1.12. Committee reports the adverse donor and transfusion reaction to NACO:

Present – 0.5 points; Absent – 0 points;

5.1.13. Facility promotes the voluntary non-remunerated blood transfusion:

Present – 0.5 points; Absent – 0 points;

5.1.14. Facility requires replacement donor for blood transfusion:

Present – 0.5 points; Absent – 0 points;

Subdomain 5.2 Antimicrobial Safety: (Maximum – 10 points; Minimum – 0 points)

5.2.1. Antimicrobial stewardship committee:

Present – 1 point; Absent – 0 points;

5.2.2. Composition of committee as per recommended guidelines

(Infectious disease physician, Clinical Pharmacologist/Pharmacist, Clinical Microbiologist, Infection Control Nurse and Hospital Administrator)[33]:

Present – 1 point; Absent – 0 points;

5.2.3. Regular meeting of the committee:

Present – 1 point; Absent – 0 points;

5.2.4. Updated antibiotic formulary:

Present – 0.5 points; Absent – 0 points;

5.2.5. Antibiotic formulary based on National Essential Drugs list:

Present – 0.5 points; Absent – 0 points;

5.2.6. Adequate stock of all the antimicrobials in the formulary:

Present – 0.5 points; Absent – 0 points;

5.2.7. Local antibiotic guidelines based on local antibiotic susceptibility to assist with antibiotic selection for common clinical conditions:

Present – 0.5 points; Absent – 0 points;

5.2.8. Restrictions for prescription of antimicrobials:

Present – 0.5 points; Absent – 0 points;

5.2.9. Facility has a copy of ICMR standard treatment guidelines for antimicrobial use in common syndromes:

Present – 0.5 points; Absent – 0 points;

5.2.10. Facility has a written antimicrobial stewardship policy guideline:

Present – 0.5 points; Absent – 0 points;

5.2.11. Facility has a post-prescription review:

Present – 0.5 points; Absent – 0 points;

5.2.12. Doctors in the facility had undergone training on antimicrobial prescription and antimicrobial resistance:

Present – 0.5 points; Absent – 0 points;

5.2.13. Conduct of periodic OPD prescription audits:

Present – 0.5 points; Absent – 0 points;

5.2.14. Conduct of periodic IPD prescription audits:

Present – 0.5 points; Absent – 0 points;

5.2.15. Results of antibiotic audits communicated directly with prescribers:

Present – 0.5 points; Absent – 0 points;

5.2.16. Facility monitors antibiotic use by grams (Defined Daily Dose or counts of antibiotics by patients per day):

Present – 0.5 points; Absent – 0 points;

5.2.17. Facility has an electronic drug ordering system:

Present – 0.5 points; Absent – 0 points;

5.3. **COVID-19 Safety** (Maximum: 5 points; Minimum: 0 points)

5.3.1. Nodal officer for COVID-19 safety:

Present – 0.5 points; Absent – 0 points;

5.3.2. Facility has COVID-19 triage procedure:

Present – 0.5 points; Absent – 0 points;

5.3.3. Facility has separate COVID-19 suspect and isolation ward:

Present – 0.5 points; Absent – 0 points;

5.3.4. Facility has trained health workers in the use of personal protective equipment (PPE) and COVID-19 appropriate behavior:

Present – 0.5 points; Absent – 0 points;

5.3.5. Facility has rational use of PPE:

Present – 0.5 points; Absent – 0 points;

5.3.6. Whether patients are placed in single rooms:

Present – 0.5 points; Absent – 0 points;

5.3.7. Facility ensures 1-metre distance between beds regardless of whether patients are suspected of having COVID-19:

Present – 0.5 points; Absent – 0 points;

5.3.8. Facility has exclusive staff for doing COVID-19 duty:

Present – 0.5 points; Absent – 0 points;

5.3.9. Facility limits the visitors into suspected and confirmed COVID-19 ward:

Present – 0.5 points; Absent – 0 points;

5.3.10. Facility ensures visitors follow COVID-19 appropriate behaviour:

Present – 0.5 points; Absent – 0 points;

5.4. **Medication Safety** (Maximum: 4 points; Minimum: 0 points)

5.4.1. Pharmacovigilance committee:

Present – 1 point; Absent – 0 points;

5.4.2. Composition of committee as per recommended guidelines

(Chairman – Dean/Medical Superintendent of the institute

Nodal officer/Member secretary – Faculty from Pharmacology department/Pharmacist

Members - Representatives from medicine, surgery, obstetrics, and gynecology, paediatrics, orthopedics, and nursing superintendent)[34]

Present – 1 point; Absent – 0 points;

5.4.3. Regular meeting of the committee:

Present – 1 point; Absent – 0 points;

5.4.4. Reporting of adverse drug reactions to National Coordination Centre for Pharmacovigilance Programme of India:

Present – 1 point; Absent – 0 points;

5.5. **Medical device safety** (Maximum: 2 points; Minimum: 0 points)

5.5.1. Facility uses non-mercury devices:

Present – 1 point; Absent – 0 points;

5.5.2. Facility has access to dedicated biomedical engineer:

Present – 1 point; Absent – 0 points;

5.6. **Injection safety** (Maximum: 4 points; Minimum: 0 points)

5.6.1. Facility has dedicated room for giving injections:

Present – 1 point; Absent – 0 points;

5.6.2. Facility has dedicated staff for giving injections:

Present – 1 point; Absent – 0 points;

5.6.3. Facility has handbook for giving safe injections:

Present – 1 point; Absent – 0 points;

5.6.4. Facility has trained manpower for giving safe injections:

Present – 1 point; Absent – 0 points;

5.7. **Surgical safety** (Maximum: 1 point; Minimum: 0 points)

5.7.1. Facility has safe surgical checklist:

Present – 1 point; Absent – 0 points;

Domain 6: To strengthen capacity for and improve patient safety research (Maximum: 2 points; Minimum: 0 points)

6.1.Facility undertakes research on questions related to patient safety:

Present – 1 point; Absent – 0 points;

6.2.Facility has research repository on questions related to patient safety:

Present – 1 point; Absent – 0 points;

Assessment of patient safety care in OPD (Maximum: 3 points; Minimum: 0 points)

Facilities with >75% patients answering strongly agree/agree for all the questions – 3 points

Facilities with >75% patients answering strongly agree/agree for > 75% questions – 2 points

Facilities with >75% patients answering strongly agree/agree for 50-75% questions – 1 point

Facilities with >75% patients answering strongly agree/agree for < 50% questions – 0 points

Assessment of patient safety care in IPD (Maximum: 3 points; Minimum: 0 points)

Facilities with >75% patients answering strongly agree/agree for all the questions – 3 points

Facilities with >75% patients answering strongly agree/agree for > 75% questions – 2 points

Facilities with >75% patients answering strongly agree/agree for 50-75% questions – 1 point

Facilities with >75% patients answering strongly agree/agree for < 50% questions – 0 points

Hand hygiene assessment: (Maximum: 3 points; Minimum: 0 points)

Facilities with >75% HCWs compliant to hand hygiene practices – 3 points

Facilities with 50-75% HCWs compliant to hand hygiene practices – 2 points

Facilities with 25-50% HCWs compliant to hand hygiene practices – 1 point

Facilities with < 25% HCWs compliant to hand hygiene practices – 0 points

BMW disposal assessment: (Maximum: 3 points; Minimum: 0 points)

Facilities with >75% HCWs compliant to BMW disposal practices – 3 points

Facilities with 50-75% HCWs compliant to BMW disposal practices – 2 points

Facilities with 25-50% HCWs compliant to BMW disposal practices – 1 point

Facilities with < 25% HCWs compliant to BMW disposal practices – 0 points

The final scores were computed after summing all these components, and each health facility was given an overall score for patient safety ranging from 0 to 100. Based on the scores, the facilities were classified as high performing (score > 75), medium performing (score 50-75) and low performing (score < 50) in terms of patient safety.

Qualitative

Transcription of the interview was performed in verbatim format within the same day of interview (to prevent the loss of information). Transcripts were reviewed by another person to decrease the bias and increase the interpretive credibility. Manual descriptive content analysis was performed to derive the themes and sub-themes. Codes were derived using hybrid approach (inductive and deductive). The findings were reported by using consolidated criteria for reporting qualitative research (COREQ).[35]

Ethical Considerations:

The study was reviewed and approved by the Institutional Ethics Committee of the ESIC Medical College and PGIMSR, KK Nagar, Chennai 600078 on 04.05.2021 through the IEC No. IEC/2021/1/12. Written informed consent was obtained from all the patients in both the outpatient and in-patient settings. Adequate privacy was provided during the interviews. Confidentiality of the patient data was maintained throughout the study. Name and personal identifying information were not collected during the interview.

RESULTS

In total, 18 facilities were surveyed with 6 medical colleges and 12 GH across six districts of Tamil Nadu. **Table-2** shows the basic details about the surveyed healthcare facilities.

Table-2: Details about the healthcare facilities across six districts in Tamil Nadu during the survey period (August-November 2021) (n=18)

District	Facility Name	Overall Bed capacity	Average bed occupancy during survey period (%)	Average OPD visits per day at the time of survey
Tirunelveli	Tirunelveli Medical College	2047	1453 (71)	2173
Tirunelveli	Government hospital, Ambasamudram	125	80 (64)	650
Tirunelveli	Government hospital, Tenkasi	557	375 (67.3)	1250
Tiruchirappalli	Tiruchirappalli Medical College	1703	500 (29.4)	5000
Tiruchirappalli	Government hospital, Srirangam	157	90 (57.3)	600
Tiruchirappalli	Government hospital, Musiri	68	55 (80.9)	400
Salem	Government Mohan Kumaramangalam Medical College	1642	1642 (100)	3500

Salem	Government hospital, Omalur	62	62 (100)	600
Salem	Government hospital, Attur	300	250 (83.3)	1800
Pudukkottai	Government Medical College, Pudukkottai	1635	1000 (61.2)	1200
Pudukkottai	Government hospital, Ilupur	104	20 (19.2)	800
Pudukkottai	Government hospital, Aranthangi	225	200 (88.9)	800
Villupuram	Government Medical College, Villupuram	1500	1500 (100)	3000
Villupuram	Government Hospital, Vikravandi	60	15 (25)	400
Villupuram	Government Hospital, Dindivanam	50	50 (100)	1200
Theni	Government Medical College, Theni	826	800 (96.8)	500
Theni	Government Hospital, Bodinayakanur	296	35 (11.8)	700
Theni	Government Hospital, Periyakulam	86	80 (93)	1400

The results of the study are presented in the following seven sections:

Section-I: Process evaluation of implementation of NPSIF in public health facilities across Tamil Nadu

Section-II: Patients' perception on safe hospital care in OPD settings of public health facilities across Tamil Nadu

Section-III: Patients' perception on safe hospital care in IPD settings of public health facilities across Tamil Nadu

Section-IV: Hand hygiene practices by healthcare workers employed in public health facilities across Tamil Nadu

Section-V: Biomedical waste management practices by healthcare workers employed in public health facilities across Tamil Nadu

Section-VI: Scoring system for the NPSIF implementation across public health facilities in Tamil Nadu

Section-VII: Qualitative findings on the facilitating factors, challenges faced, and possible suggestions for effective implementation of NPSIF in public health facilities at Tamil Nadu

Section-I: Process evaluation of implementation of NPSIF in public health facilities across Tamil Nadu

Domain 1: To improve structural systems to support quality and efficiency of healthcare and place patient safety at healthcare facility level

We found that 7 out of 18 facilities (1 medical college – Villupuram and 6 GHs) had NQAS accreditation, about 8 out of 19 facilities had Kayakalp certification (1 medical college – Villupuram and 7 GHs), half of the surveyed facilities (4 medical colleges and 5 GHs) had LaQshya certification, while none of the facilities had NABH, JCI or ISO accreditation (**Table-3**).

Domain 2: To assess the nature and scale of adverse events in healthcare and establish a system of reporting and learning

We found that 7 out of 18 facilities (1 medical college – Salem and 6 GHs) had patient safety related SOPs/checklists, almost all the facilities except Theni Medical College had anonymous reporting system for patients, families, and healthcare providers for raising patient safety concerns and 8 out of 18 facilities (2 medical colleges – Salem and Villupuram, 6 GHs) had registered and functional patient groups for development of policies, strategies or plans in hospitals (**Table-3**).

Domain 3: Competent and capable workforce aware and sensitive to patient safety

We found that one-third of the facilities (1 medical college – Salem and 5 GHs) had SOPs for training of HCWs on topics related to patient safety, while majority of the facilities (2 medical colleges – Pudukottai and Salem, 11 GHs) were conducting training for HCWs on topics related to patient safety (**Table-3**).

Table-3: Distribution of the healthcare facilities based on the findings for the Domain 1, 2 and 3 of the NPSIF (n=18)

	Pudukkottai Medical college	*Ilupur GH*	*Aranthangi GH*	*Trichy Medical college*	*Srirangam GH*	*Musiri GH*	*Tirunelveli Medical College*	*Ambasamudram GH*	*Tenkasi GH*	*Salem Medical College*	*Omalur GH*	*Attur GH*	*Theni Medical College*	*Bodinayakanur GH*	*Periyakulam GH*	*Villupuram Medical College*	*Vikravandi GH*	*Tindivanam GH*
Domain 1: To improve structural systems to support quality and efficiency of healthcare and place patient safety at healthcare facility																		
NQAS accreditation	No	Yes	Yes	No	Yes	Yes	No	No	No	No	No	No	No	No	Yes	Yes	No	Yes
NABH accreditation	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Kayakalp certification	No	Yes	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	Yes	No	No
LAQSHYA certification	No	No	Yes	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes
JCI accreditation	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
ISO accreditation	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
National building code	Yes	No	No	No	No	No	No	No	No	Yes	No	No	No	No	Yes	No	No	No
Fire safety certification	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes
Seismic safety certification	No	No	No	No	Yes	No	No	No	Yes	Yes	No	No	No	Yes	No	No	No	No
Domain 2: To assess the nature and scale of adverse events in healthcare and establish a system of reporting and learning																		
Patient safety SOP/checklist	No	No	Yes	No	No	No	No	Yes	Yes	Yes	No	Yes	No	No	No	No	Yes	Yes
Anonymous Reporting System	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes

Functional Patient Groups	No	No	Yes	No	Yes	No	No	No	No	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes
Domain 3: Competent and capable workforce aware and sensitive to patient safety																		
SOP for training of HCWs on "patient safety"	No	Yes	No	No	No	No	No	No	Yes	Yes	No	Yes	No	No	Yes	No	No	Yes
Training for HCW on "patient safety"	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes

Domain 4: To prevent and control healthcare associated infections (HCAI)

Subdomain 4.1.: Strengthening infection prevention and control structure & program across all healthcare services & levels of care

Almost all the facilities except Bodinayakanur GH had a separate HICC. Half of the facilities had a separate microbiology department. Majority of the facilities (16 out of 17) had the composition of the committee as per regulations and met monthly (14 out of 17) and updated logs regularly (11 out of 17). About 11 facilities (5 medical colleges except Theni Medical College and 6 GHs) had SOP for infection prevention and control practices. Majority of the facilities were regularly performing environmental surveillance (10 facilities), OT surveillance (17 facilities), ICU surveillance (10 facilities), inspection/monitoring of sterilization and disinfection (16 facilities), autoclave check (17 facilities) and water quality check (14 facilities) (**Table-4**).

Subdomain 4.2.: Providing appropriately cleaned and disinfected or sterilized equipment for patient care as required

More than half of the facilities (10 out of 18 facilities – all 6 surveyed medical colleges and 4 GHs) had a separate CSSD. Only 8 out of 18 facilities had SOP for cleaning, disinfection, or sterilization of equipment for patient care. Half of the facilities had logs for monitoring sterilization practices. Majority of the facilities (16 out of 18) had maintenance and repair system in place and regular fumigation (14 out of 18) and periodic servicing of equipment (16 out of 18). Only 5 facilities had trained staff for performing these activities and performed periodic internal audit (**Table-4**).

Table 4: Distribution of the healthcare facilities based on the findings for hospital infection prevention and control measures (n=18)

	Pudukkottai Medical college	*Ilupur GH*	*Aranthangi GH*	*Trichy Medical college*	*Srirangam GH*	*Musiri GH*	*Tirunelveli Medical College*	*Ambasamudram GH*	*Tenkasi GH*	*Salem Medical College*	*Omalur GH*	*Attur GH*	*Theni Medical College*	*Bodinayakanur GH*	*Periyakulam GH*	*Villupuram Medical College*	*Vikravandi GH*	*Tindivanam GH*
Domain 4.1. Strengthening infection prevention and control structure & program across all healthcare services & levels of care																		
Separate HICC committee	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Composition as per regulations	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
Monthly meeting	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	No	Yes
SOP for infection prevention & control	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	No	Yes
Environmental surveillance	Yes	Yes	No	Yes	No	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No
OT surveillance	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
ICU surveillance	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No
Inspection/Monitoring of sterilization and disinfection	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Autoclave check	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Water quality check	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	No	Yes
Monitoring of antimicrobial sensitivity and resistance pattern	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes	No	No	No	No	Yes	Yes	No	No

HCW hand hygiene training	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hand hygiene awareness session	No	Yes	No	Yes	Yes	No	No	No	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes
Reporting Healthcare Associated Infections to Hospital Administration	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes
Reporting Healthcare Associated Infections to surveillance system	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	No	No	No
Monitoring indicators	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No
Domain 4.2. Providing appropriately cleaned and disinfected or sterilized equipment for patient care as required																		
Separate CSSD	Yes	Yes	No	Yes	Yes	No	Yes	No	No	Yes	No	No	Yes	No	Yes	Yes	Yes	No
SOP for sterile equipment supply	No	Yes	No	No	Yes	Yes	Yes	No	No	Yes	No	No	Yes	No	Yes	No	No	Yes
Logs for monitoring sterilization practices	No	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	No	Yes	No	No	No
Cleaning/decontamination/fumigation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes
Swabs taken for culture to check quality of disinfection	Yes	No	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	No	Yes	Yes	No	Yes
Training of staff	Yes	No	No	No	No	Yes	Yes	No	No	Yes	No	No	No	No	Yes	No	No	No
Maintenance & repair system	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Periodic equipment service	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	No	Yes
Periodic internal audit	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes	No	No	No

Subdomain 4.3: Providing a safe and clean environment by improving the general hygiene, sanitation, and management of healthcare waste in healthcare facilities

Majority of the facilities (15 out of 18 facilities – all 6 surveyed medical colleges and 9 GHs) had a separate BMW management committee. Almost all these facilities having BMW committee met at least once a month (except Salem Medical College). Regarding the BMW practices, all the 18 facilities provide PPE for BMW handlers, BMW storage facility and availability of bins and trolleys for transporting of BMW. Majority of the facilities (15 out of 18) had SOP for BMW practices, conducted training for staffs on BMW practices (14 out of 18), mechanism for reporting needle stick injuries to the hospital administration (14 out of 18) and linkage to common treatment facility (13 out of 18) (**Table-5**).

Table 5: Distribution of the healthcare facilities based on the biomedical waste management practices (n=18)

	Pudukkottai Medical college	*Ilupur GH*	*Aranthangi GH*	*Trichy Medical college*	*Srirangam GH*	*Musiri GH*	*Tirunelveli Medical College*	*Ambasamudram GH*	*Tenkasi GH*	*Salem Medical College*	*Omalur GH*	*Attur GH*	*Theni Medical College*	*Bodinayakanur GH*	*Periyakulam GH*	*Villupuram Medical College*	*Vikravandi GH*	*Tindivanam GH*
Domain 4.3: Providing a safe and clean environment by improving general hygiene, sanitation, & management of healthcare waste in healthcare facilities																		
Separate BMW management committee	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes
Monthly meeting	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes	No	Yes
SOP for BMW management	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Training of staffs	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes
PPE for BMW handlers	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Reporting needle stick injuries to administration	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Reporting needle stick injuries to NACO	No	No	Yes	No	No	No	Yes	No	No	No	Yes	Yes	No	No	Yes	Yes	No	Yes
BMW storage facility	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Availability of bin & trolley	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Link to treatment facility	Yes	Yes	No	No	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Domain 5: To implement global patient safety campaigns and strengthening Patient Safety across all programmes

Sub-domain 5.1: Blood Safety:

More than half of the facilities (10 out of 18 facilities – 4 medical colleges and 6 GHs) had a separate hospital transfusion committee. Majority of the facilities having transfusion committee (7 out of 10 facilities) had composition as per regulations and half of them met at least once a month. However, less than half of the facilities performed their functions appropriately. Majority of the facilities (14 out of 18 facilities – all surveyed medical colleges and 8 GHs) had blood bank. Almost all the facilities having blood bank promotes voluntary blood donation and requires replacement donor for transfusion (**Table-6**).

Table 6: Distribution of the healthcare facilities based on the blood safety or blood transfusion practices (n=18)

	Pudukkottai Medical college	*Illupur GH*	*Aranthangi GH*	*Trichy Medical college*	*Srirangam GH*	*Musiri GH*	*Tirunelveli Medical College*	*Ambasamudram GH*	*Tenkasi GH*	*Salem Medical College*	*Omalur GH*	*Attur GH*	*Theni Medical College*	*Bodinayakanur GH*	*Periyakulam GH*	*Villupuram Medical College*	*Vikravandi GH*	*Tindivanam GH*
Domain 5.1: Blood Safety																		
Separate Transfusion committee	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No	Yes	No	No	Yes
Composition as per regulations	No	No	Yes	Yes	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes
Blood bank	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
Frames policies and procedures	No	No	No	Yes	Yes	No	Yes	No	No	No	No	No	No	No	Yes	No	No	Yes
Reviews policies and procedures	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	Yes	No	No	No
Revise policies and procedures	No	No	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No
Monitors blood transfusion practices	No	No	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	Yes	No	No	No
Audits to review appropriateness of blood & blood transfusion	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	Yes	No	No	No
Evaluate incidence of adverse transfusion reaction	No	No	Yes	Yes	No	No	Yes	No	No	No	No	No	No	No	Yes	No	No	No

Reporting adverse transfusion reactions to hospital administration	No	No	Yes	No	No	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No
Reporting adverse transfusion reactions to NACO	No	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	Yes	No	No	No
SOP for Blood bank	Yes	No	No	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes
Promotion of voluntary non-remunerated blood donation	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	No	Yes
Replacement donor requirement	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No

Subdomain 5.2 Antimicrobial Safety:

Only one facility (Theni medical college) had a separate antimicrobial stewardship committee, and the composition of the committee was as per regulations and meets at least once a month. Almost all the facilities (except Vikravandi GH) had an antibiotic formulary, and amongst the facility having antibiotic formulary, all the facilities except Theni medical college had the formulary based on the National Essential Drugs List. All the facilities except Theni medical college did not have stockout of antibiotics. Half of the facilities had local antibiotic guidelines based on local antibiotic susceptibility. Only 2 facilities (Aranthangi and Musiri GH) had written antimicrobial stewardship guidelines. Only 5 facilities conduct post-prescription review and conducts training for doctors on antimicrobial prescription. More than half of the facilities conduct periodic OPD (11 facilities) and IPD audits (10 facilities) for antimicrobial use and 9 out of 11 facilities (except Omalur GH, Trichy Medical College) conducting the audit communicate the results to the prescribers. Only 3 facilities (Salem medical college, Omalur and Tindivanam GH) conduct monitoring of antibiotic by grams (DDD) (**Table-7**).

Table 7: Distribution of the healthcare facilities based on the antimicrobial practices (n=18)

	Pudukkottai Medical college	*Ilupur GH*	*Aranthangi GH*	*Trichy Medical college*	*Srirangam GH*	*Musiri GH*	*Tirunelveli Medical College*	*Ambasamudram GH*	*Tenkasi GH*	*Salem Medical College*	*Omalur GH*	*Attur GH*	*Theni Medical College*	*Bodinayakanur GH*	*Periyakulam GH*	*Villupuram Medical College*	*Vikravandi GH*	*Tindivanam GH*
Domain 5.2: Antimicrobial Safety																		
Antimicrobial Stewardship Committee	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No
Composition as per regulations	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No
Monthly meeting	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No
Presence of Antibiotic formulary	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Antibiotic formulary as per NEDL	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes
Stock-out of antibiotics	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Local antibiotic guidelines based on local antibiotic susceptibility	No	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	No	No	Yes	No	Yes
Restriction for prescription	No	No	Yes	Yes	No	No	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes	No	No	No
ICMR standard treatment guidelines copy	No	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	No	No	Yes	Yes	No	No
Antimicrobial stewardship policy guideline	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No
Post prescription review	No	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	No
Training doctors on antibiotic prescription	No	No	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	No	No	Yes	No	No

Periodic OP audits	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	No	No	Yes	No	No	Yes
Periodic IP audits	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	Yes	No	No	Yes	No	No	Yes
Communicating audit results with prescribers	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	No	Yes	No	No	Yes	No	No	Yes
Monitoring of antibiotic use by grams (DDD)	No	No	No	No	No	No	No	No	No	Yes	Yes	No	No	No	No	No	No	Yes
Electronic drug ordering system	No	Yes	Yes	Yes	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes	No	Yes

***Subdomain 5.3: COVID-19 safety*:**

All the surveyed 18 facilities had a separate nodal officer for coordination of COVID-19 control activities, separate triage system for identifying COVID-19 suspect patients visiting the facility and provided training for wearing PPEs during COVID-19 duty. Almost all the facilities (except Omalur and Vikravandi GH) had a separate COVID-19 suspect and isolation wards. Except Tirunelveli, Villupuram and Theni medical colleges, Ambasamudram GH and Vikravandi GH, all other facilities ensure 1-metre distance between the beds in wards. More than half of the facilities limit the visitors into suspect or isolation ward for COVID-19 patients. Almost all the facilities (except Bodinayakanur and Aranthangi GH, Villupuram Medical College) ensured that the visitors follow COVID-19 appropriate behaviour (**Table-8**).

Table 8: Distribution of the healthcare facilities based on the COVID-19 safety practices (n=18)

	Pudukkottai Medical college	*Ilupur GH*	*Aranthangi GH*	*Trichy Medical college*	*Srirangam GH*	*Musiri GH*	*Tirunelveli Medical College*	*Ambasamudram GH*	*Tenkasi GH*	*Salem Medical College*	*Omalur GH*	*Attur GH*	*Theni Medical College*	*Bodinayakanur GH*	*Periyakulam GH*	*Villupuram Medical College*	*Vikravandi GH*	*Tindivanam GH*
Domain 5.3: COVID-19 safety																		
COVID-19 Nodal Officer	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
COVID-19 Triaging system	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Separate suspect and isolation wards	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes
Training for use of PPE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Practicing rational use of PPE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Single rooms for COVID-19 patients	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
One meter distance between the beds	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes
Exclusive staffs for COVID duty	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Limit visitors inside suspect wards	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No	Yes
Limit visitors inside isolation wards	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	No	Yes
Ensuring visitors to follow COVID appropriate behaviour	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes

***Sub-domain 5.4. Medication Safety*:**

Only 5 facilities (2 medical colleges – Tirunelveli and Theni and 3 GHs – Tindivanam, Srirangam and Periyakulam) had a separate pharmacovigilance committee. All the 5 facilities had composition of the committee as per regulations and 4 out of 5 facilities meet at least once a month. 3 out of 5 facilities (Tirunelveli, Theni medical colleges and Tindivanam GH) reports the adverse drug reactions to National Coordination Centre for Pharmacovigilance Programme of India (**Table-9**).

Subdomain 5.5: Medical device safety

About 10 out of 18 facilities are using only non-mercury devices. Only Tirunelveli Medical College had a dedicated biomedical engineer for their facilities, while all other facilities have a biomedical engineer only at district level (**Table-9**).

Subdomain 5.6. Injection safety

All the facilities had dedicated room for giving injections, while all the facilities except Salem medical college and Attur GH had dedicated staff for their injection rooms. Only 7 out of 18 facilities conducts training for HCWs on the safe injection practices (**Table-9**).

Subdomain 5.7. Surgical safety

All the facilities except Theni medical college, Vikravandi and Attur GH had safe surgical checklist (**Table-9**).

Domain 6: To strengthen capacity for and improve patient safety research

Only 2 facilities (Tirunelveli and Salem medical college) conduct research on patient safety and allied themes, while none of the facilities had a repository of materials related to patient safety and allied themes (**Table-9**).

Table 9: Distribution of the healthcare facilities based on the procedural and device safety and patient safety research (n=18)

	Pudukkottai Medical college	*Ilupur GH*	*Aranthangi GH*	*Trichy Medical college*	*Srirangam GH*	*Musiri GH*	*Tirunelveli Medical College*	*Ambasamudram GH*	*Tenkasi GH*	*Salem Medical College*	*Omalur GH*	*Attur GH*	*Theni Medical College*	*Bodinayakanur GH*	*Periyakulam GH*	*Villupuram Medical College*	*Vikravandi GH*	*Tindivanam GH*
Domain 5.4: Medication Safety																		
Pharmacovigilance Committee	No	No	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes
Composition as per regulations	No	No	No	No	Yes	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	Yes
Monthly meeting	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	Yes	No	No	Yes
Reporting adverse drug reactions to National Coordination Centre for Pharmacovigilance Programme	No	No	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No	No	No	Yes
Domain 5.5: Medical device safety																		
Dedicated biomedical engineer	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No
Using only non-mercury devices	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes
Domain 5.6: Injection safety																		
Dedicated injection rooms	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dedicated staff for injection rooms	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes

Handbook on safe injection practices	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No
Training on safe injection practices	No	No	No	Yes	No	No	No	Yes	Yes	Yes	No	Yes	No	No	Yes	No	Yes	No
Domain 5.7: Surgical safety																		
Safe surgical checklist	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	No	Yes
Domain 6: To strengthen capacity for and improve patient safety research																		
Research on patient safety	No	No	No	No	No	No	Yes	No	No	Yes	No	No	No	No	No	No	No	No
Repository for research on patient safety	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No

Section-II: Patients' perception on safe hospital care in OPD settings of public health facilities across Tamil Nadu

Table-10 shows the sociodemographic details of the study participants. The mean (SD) age of the study participants were 42.7 (19.8) years. There was almost equal distribution of males and females in the sample. Majority of the study participants (45.5%) were employed. Almost three-fourth of the participants (71.2%) were currently married. The most common comorbidity reported among the participants were hypertension (17%) followed by diabetes mellitus (16.6%) and coronary artery disease (2.8%). Almost three-fourth of the participants (72%) had previous OPD visit to the same facility.

Table 10: Sociodemographic details of the participants involved in assessment of patients' perception on safe hospital care at OPD level across public health facilities in Tamil Nadu (n=3090)

Characteristics	Categories	Frequency (%)
Mean (SD) age of the participants = 42.7 (19.8) years		
Gender	Male	1594 (51.6)
	Female	1496 (48.4)
Occupation	Employed	1406 (45.5)
	Unemployed	1387 (44.9)
	Not applicable[#]	297 (9.6)
Marital status	Never married	398 (12.9)
	Currently Married	2201 (71.2)
	Separated/Widowed/Divorced	231 (7.5)
	Not applicable*	260 (8.4)

Comorbidities[$]	Diabetes	512 (16.6)
	Hypertension	524 (17.0)
	Coronary heart disease	88 (2.8)
	Asthma	60 (1.9)
	Chronic kidney disease	42 (1.4)
	Chronic obstructive pulmonary disease	27 (0.9)
Districts & Hospital		
Tirunelveli	Tirunelveli Medical College	250 (8.1)
	Government hospital, Ambasamudram	250 (8.1)
	Government hospital, Tenkasi	249 (8.1)
Tiruchirappalli	Tiruchirappalli Medical College	125 (4.1)
	Government hospital, Srirangam	128 (4.1)
	Government hospital, Musiri	124 (4.0)
Salem	Government Mohan Kumaramangalam Medical College	125 (4.1)
	Government hospital, Omalur	126 (4.1)
	Government hospital, Attur	127 (4.1)
	Government Medical College, Pudukkottai	203 (6.6)

Pudukkottai	Government hospital, Ilupur	125 (4.1)
	Government hospital, Aranthangi	125 (4.1)
Villupuram	Government Medical College, Villupuram	128 (4.1)
	Government Hospital, Vikravandi	130 (4.2)
	Government Hospital, Dindivanam	125 (4.1)
Theni	Government Medical College, Theni	250 (8.1)
	Government Hospital, Bodinayakanur	250 (8.1)
	Government Hospital, Periyakulam	250 (8.1)
Department	General Medicine	2438 (78.9)
	General Surgery	68 (2.2)
	Obstetrics & Gynecology	307 (9.9)
	Pediatrics	212 (6.9)
	Orthopedics	65 (2.1)
Previous OPD visit to same facility	Yes	2226 (72.0)
	No	864 (28.0)

[#]*Students/Paediatric patients*

[*]*Patients aged less than legal marriage age*

[$]*Multiple responses possible*

Figure 6 shows the distribution of participants based on their responses to the assessment of patients' perception on safe hospital care during their visit.

Domain 1: Communication between the patient and healthcare workers

More than 80% of the participants had agreed or strongly agreed that they were well-informed about their current medical condition and medications prescribed for their condition during their current visit.

Domain-II: Procedural Safety

In total, 2038 participants underwent some form of investigation (blood/urine/sputum/pus) during their OPD visit. Amongst them, more than 90% had agreed or strongly agreed that they felt safe while undergoing the investigation. In total, 1724 participants were given injection during their OPD visit. Amongst them, more than 85% had agreed or strongly agreed that they felt safe while getting the injection. In total, 1675 participants were applied some form of medical devices during their OPD visit. Amongst them, nearly 90% had agreed or strongly agreed that they felt safe while undergoing the procedure with medical devices during their visit.

Figure 6: Perception of patients towards patient safety culture (OPD level) across public health facilities in Tamil Nadu (n=3090)

Domain-III: Environmental Safety

More than 80% of the participants had agreed or strongly agreed that the hospital environment was clean during this hospital visit, while more than three-fourth of the participants felt that the wastes are disposed of properly during this hospital visit.

Domain-IV: COVID appropriate behavior

About 70% of the participants had agreed or strongly agreed that the social distancing norms were followed properly during this hospital visit, while nearly three-fourth of the participants felt that the hand hygiene norms were followed properly during this hospital visit. More than 80% of the participants had agreed or strongly agreed that everyone in the hospital wore mask properly during this visit.

Disrespectful care, patient satisfaction, recommendation, and quality of care

About 6.2% of the participants felt that they were made to feel disrespected; about 5.9% reported that the health provider shouted at or scolded them; about 3.8% reported that the health providers made negative or disparaging comments about them. Nearly 95% of the participants reported they were satisfied with the care provided during their current visit and will recommend the facility to their friends/family (**Table-11**). More than three-fourth of the participants had rated the quality of care as excellent to good (**Figure 7**).

Table 11: Disrespectful care, patient satisfaction, recommendation of the facility by the study participants (OPD level) across public health facilities in Tamil Nadu (n=3090)

Domain	Categories	Frequency (%)
Disrespectful Care	Whether the patient was made to feel disrespected?	192 (6.2)
	Whether the health provider shouted at or scolded them?	183 (5.9)
	Whether the health providers made negative or disparaging comments about them?	116 (3.8%)
Patient Satisfaction	Very Satisfied	1033 (33.4)
	Satisfied	1868 (60.5)
	Dissatisfied	179 (5.8)
	Very Dissatisfied	10 (0.3)
Recommendation to family/friends/ relatives	Strongly recommend	1250 (40.4)
	Recommend	1659 (53.7)
	Not recommend	159 (5.2)
	Not at all recommend	22 (0.7)

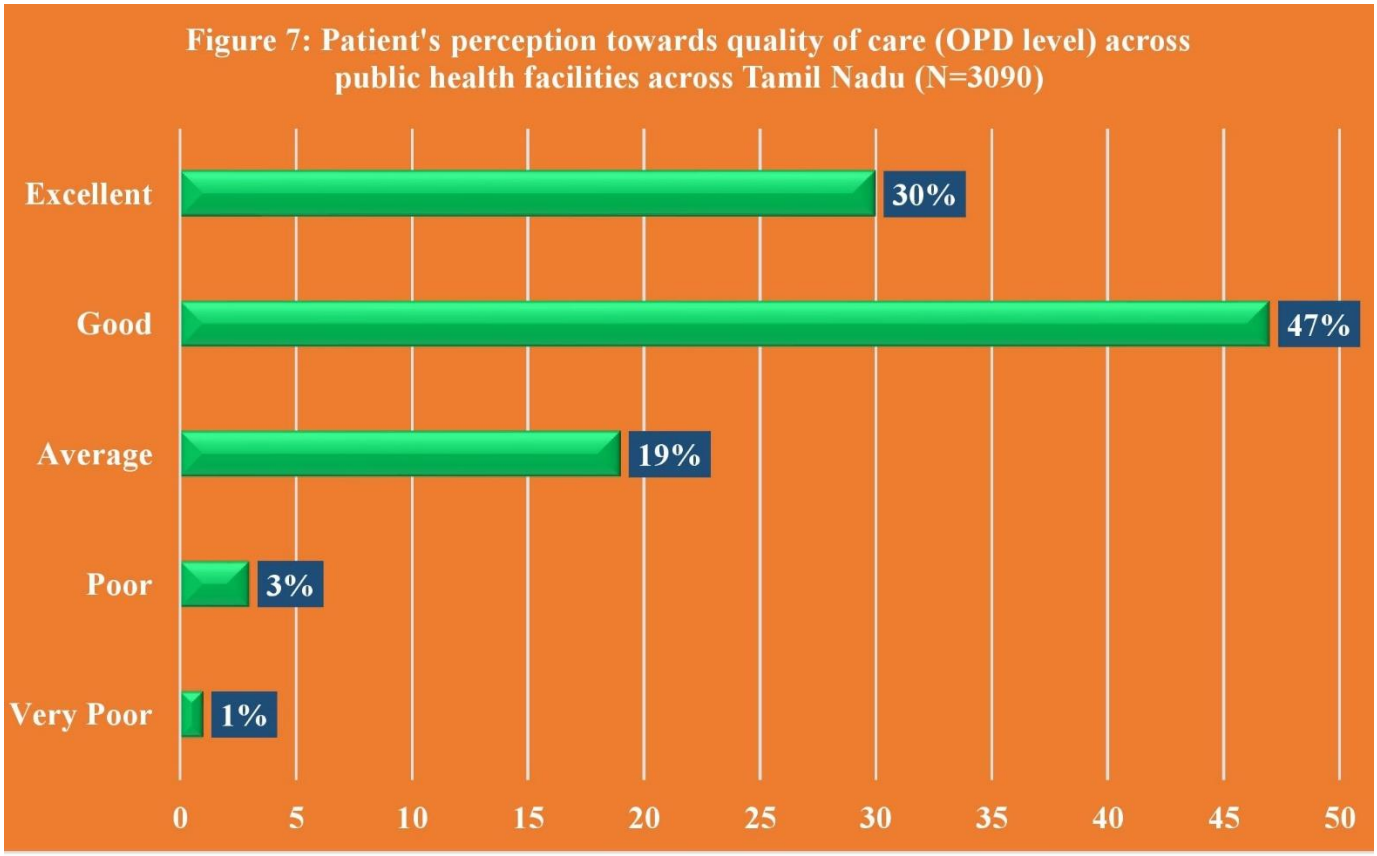


Figure 7: Patient's perception towards quality of care (OPD level) across public health facilities across Tamil Nadu (N=3090)
Excellent
30%
Good
47%
Average
19%
Poor
3%
Very Poor
1%
0
5
10
15
20
25
30
35
40
45
50

Section-III: Patients' perception on safe hospital care in IPD settings of public health facilities across Tamil Nadu

Table-12 shows the sociodemographic details of the study participants. The mean (SD) age of the study participants were 35.4 (20.3) years. There was almost equal distribution of males and females in the sample. Majority of the study participants (44.2%) were unemployed. More than two-third of the participants (69.0%) were currently married. The most common comorbidity reported among the participants were hypertension (10.1%) followed by diabetes mellitus (9.8%) and coronary artery disease (2.9%). Almost one-fifth of the participants (18.3%) had history of previous hospitalization in the same facility.

Table 12: Sociodemographic details of the participants involved in assessment of patients' perception on safe hospital care at IPD level across public health facilities in Tamil Nadu (n=1827)

Characteristics	Categories	Frequency (%)
Mean (SD) age of the participants = 35.4 (20.3) years		
Gender	Male	916 (50.1)
	Female	911 (49.9)
Occupation	Employed	762 (41.7)
	Unemployed	807 (44.2)
	Not applicable[#]	258 (14.1)
Marital status	Never married	249 (13.6)
	Currently Married	1260 (69.0)
	Separated/Widowed/Divorced	104 (5.7)
	Not applicable*	214 (11.7)

Comorbidities[$]	Diabetes	179 (9.8)
	Hypertension	184 (10.1)
	Coronary heart disease	53 (2.9)
	Chronic kidney disease	44 (2.4)
	Chronic obstructive pulmonary disease	36 (2.0)
	Asthma	25 (1.4)
Districts & Hospital		
Tirunelveli	Tirunelveli Medical College	200 (11.0)
	Government hospital, Ambasamudram	50 (2.7)
	Government hospital, Tenkasi	50 (2.7)
Tiruchirappalli	Tiruchirappalli Medical College	200 (11.0)
	Government hospital, Srirangam	50 (2.7)
	Government hospital, Musiri	50 (2.7)
Salem	Government Mohan Kumaramangalam Medical College	214 (11.7)
	Government hospital, Omalur	50 (2.7)
	Government hospital, Attur	75 (4.1)
	Government Medical College, Pudukkottai	187 (10.2)

Pudukkottai	Government hospital, Ilupur	50 (2.7)
	Government hospital, Aranthangi	45 (2.5)
Villupuram	Government Medical College, Villupuram	201 (11.0)
	Government Hospital, Vikravandi	50 (2.7)
	Government Hospital, Dindivanam	55 (3.0)
Theni	Government Medical College, Theni	200 (10.9)
	Government Hospital, Bodinayakanur	60 (3.3)
	Government Hospital, Periyakulam	40 (2.2)
Department	General Medicine	500 (27.4)
	General Surgery	356 (19.5)
	Obstetrics & Gynecology	436 (23.9)
	Pediatrics	282 (15.4)
	Orthopedics	253 (13.8)
Previous hospitalization in the same facility	Yes	335 (18.3)
	No	1492 (81.7)

[#]*Students/Paediatric patients*

[*]*Patients aged less than legal marriage age*

[$]*Multiple responses possible*

Figure 8 shows the distribution of participants based on their responses to the assessment of patients' perception on safe hospital care during their inpatient admission.

Domain 1: Communication between the patient and healthcare workers

More than 90% of the participants had agreed or strongly agreed that they were well-informed about their current medical condition and medications prescribed for their condition during their current visit.

Domain-II: Procedural Safety

In total, 1720 participants underwent some form of investigation (blood/urine/sputum/pus) during their hospitalization. Amongst them, 90% had agreed or strongly agreed that they felt safe while undergoing the investigation. In total, 1721 participants were given injection during their hospitalization. Amongst them, more than 90% had agreed or strongly agreed that they felt safe while getting the injection. In total, 1570 participants were applied some form of medical devices during their hospitalization. Amongst them, more than 90% had agreed or strongly agreed that they felt safe while undergoing the procedure with medical devices during their visit. In total, 521 patients underwent blood transfusion during their hospitalization. Amongst them, nearly 95% had agreed or strongly agreed that they felt safe while undergoing the blood transfusion. In total, 467 patients underwent some form of surgery during their hospitalization. Amongst them, nearly 95% had agreed or strongly agreed that they felt safe while undergoing the surgery. In total, 292 patients had childbirth during their hospital stay. Amongst them, more than 90% had agreed or strongly agreed that they felt safe while undergoing the surgery.

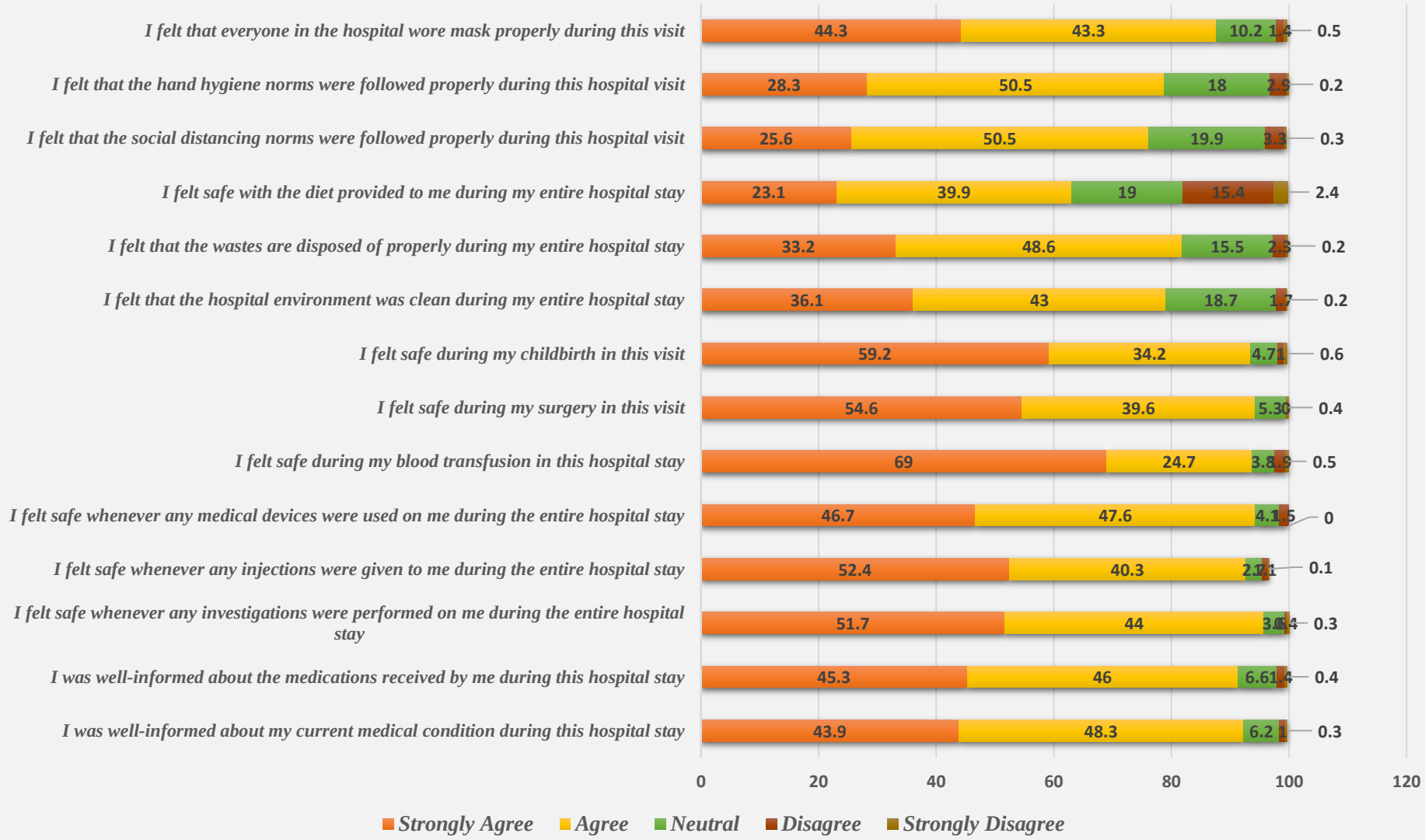
Domain-III: Nutrition and Environmental Safety

Nearly 80% of the participants had agreed or strongly agreed that the hospital environment was clean, and the wastes are disposed of properly during this hospital stay. However, nearly one-fifth of the participants felt unsafe taking the diet provided during their hospitalization.

Domain-IV: COVID appropriate behavior

More than three-fourth of the participants had agreed or strongly agreed that the social distancing and the hand hygiene norms were followed properly during this hospital stay. Nearly 90% of the participants had agreed or strongly agreed that everyone in the hospital wore mask properly during this hospital stay.

Figure 8: Perception of patients towards patient safety culture (IPD level) across public health facilities in Tamil Nadu (n=1827)



Disrespectful care, patient satisfaction, recommendation, and quality of care

About 10% of the participants felt that they were made to feel disrespected; about 4.3% reported that the health provider shouted at or scolded them; about 1.4% reported that the health providers made negative or disparaging comments about them. More than 95% of the participants reported they were satisfied with the care provided during their current hospital stay and will recommend the facility to their friends/family (**Table-13**). More than three-fourth of the participants had rated the quality of care as excellent to good (**Figure 9**).

Table 13: Disrespectful care, patient satisfaction, recommendation of the facility by the study participants (IPD level) across public health facilities in Tamil Nadu (n=1827)

Domain	Categories	Frequency (%)
Disrespectful Care	Whether the patient was made to feel disrespected?	183 (10.0)
	Whether the health provider shouted at or scolded them?	80 (4.4)
	Whether the health providers made negative or disparaging comments about them?	27 (1.5%)
Patient Satisfaction	Very Satisfied	535 (29.3)
	Satisfied	1225 (67.1)
	Dissatisfied	59 (3.2)
	Very Dissatisfied	8 (0.4)
Recommendation to family/friends/ relatives	Strongly recommend	578 (31.6)
	Recommend	1186 (64.9)
	Not recommend	52 (2.9)
	Not at all recommend	11 (0.6)

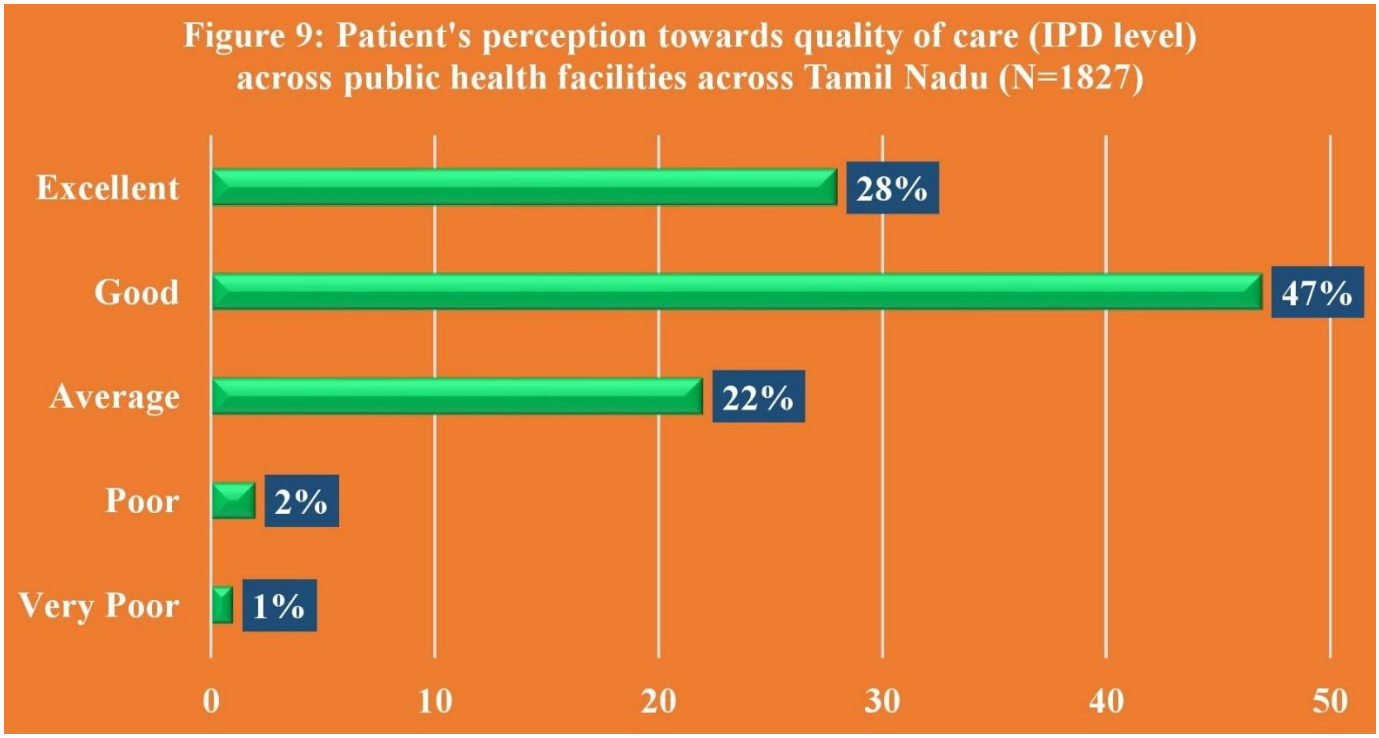


Figure 9: Patient's perception towards quality of care (IPD level) across public health facilities across Tamil Nadu (N=1827)
Excellent
28%
Good
47%
Average
22%
Poor
2%
Very Poor
1%
0
10
20
30
40
50

Section-IV: Hand hygiene practices by healthcare workers employed in public health facilities across Tamil Nadu

Table-14 shows the details about the hand hygiene observations made amongst the healthcare workers in public health facilities across Tamil Nadu. Majority of the observations were made amongst the nurses (56.8%) followed by doctors (32.5%) and other allied staffs (10.7%). More than half of the observations were made in general medicine department. Almost half of the observations were made in IPD (47.5%) followed by general OPD (31.6%) and injection OPD (16.3%). Majority of the observations were made before and after touching the patients amongst the "5 moments of hand hygiene". Only during one-fifth (19.4%) of the observations, hand washing was done by the healthcare workers. Amongst the 530 observations during which hand washing was done, only during 201 (37.9%) of the observations, hand washing was done appropriately by following all the essential steps of hand hygiene.

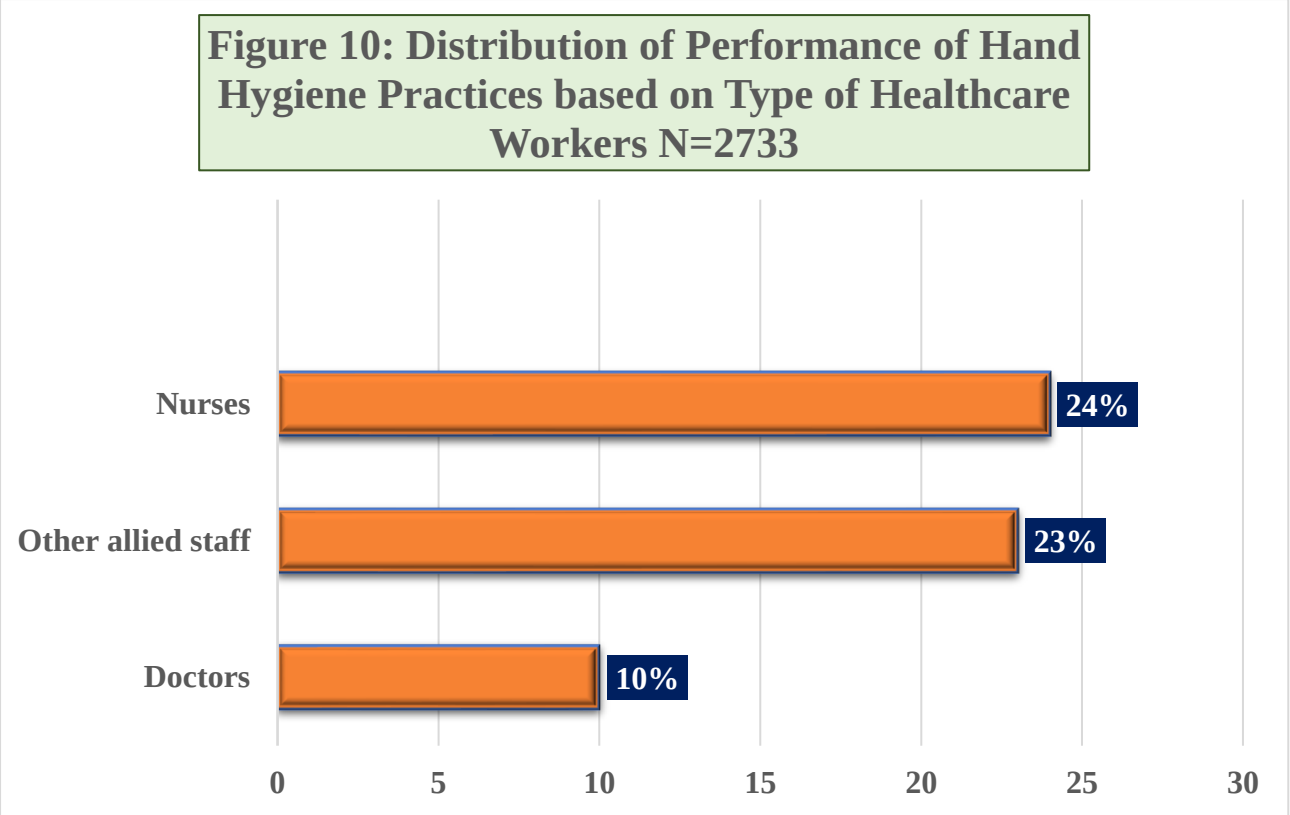
Table 14: Hand hygiene observations across public health facilities in Tamil Nadu (n=2733)

Characteristics	Categories	Frequency (%)
Designation	Doctor	887 (32.5)
	Nurse	1552 (56.8)
	Other allied staffs[#]	294 (10.7)
Department	General Medicine	1475 (54.0)
	General Surgery	251 (9.2)
	Obstetrics & Gynecology	350 (12.8)
	Pediatrics	333 (12.2)
	Orthopedics	324 (11.8)

Division	Outpatient department	863 (31.6)
	Inpatient department	1297 (47.5)
	Injection OPD	447 (16.3)
	Procedure room/Operation theatre/Intensive care unit	126 (4.6)
Districts & Hospital		
Tirunelveli	Tirunelveli Medical College	149 (5.4)
	Government hospital, Ambasamudram	150 (5.5)
	Government hospital, Tenkasi	152 (5.6)
Tiruchirappalli	Tiruchirappalli Medical College	150 (5.5)
	Government hospital, Srirangam	148 (5.4)
	Government hospital, Musiri	150 (5.5)
Salem	Government Mohan Kumaramangalam Medical College	151 (5.5)
	Government hospital, Omalur	149 (5.4)
	Government hospital, Attur	201 (7.3)
	Government Medical College, Pudukkottai	151 (5.5)

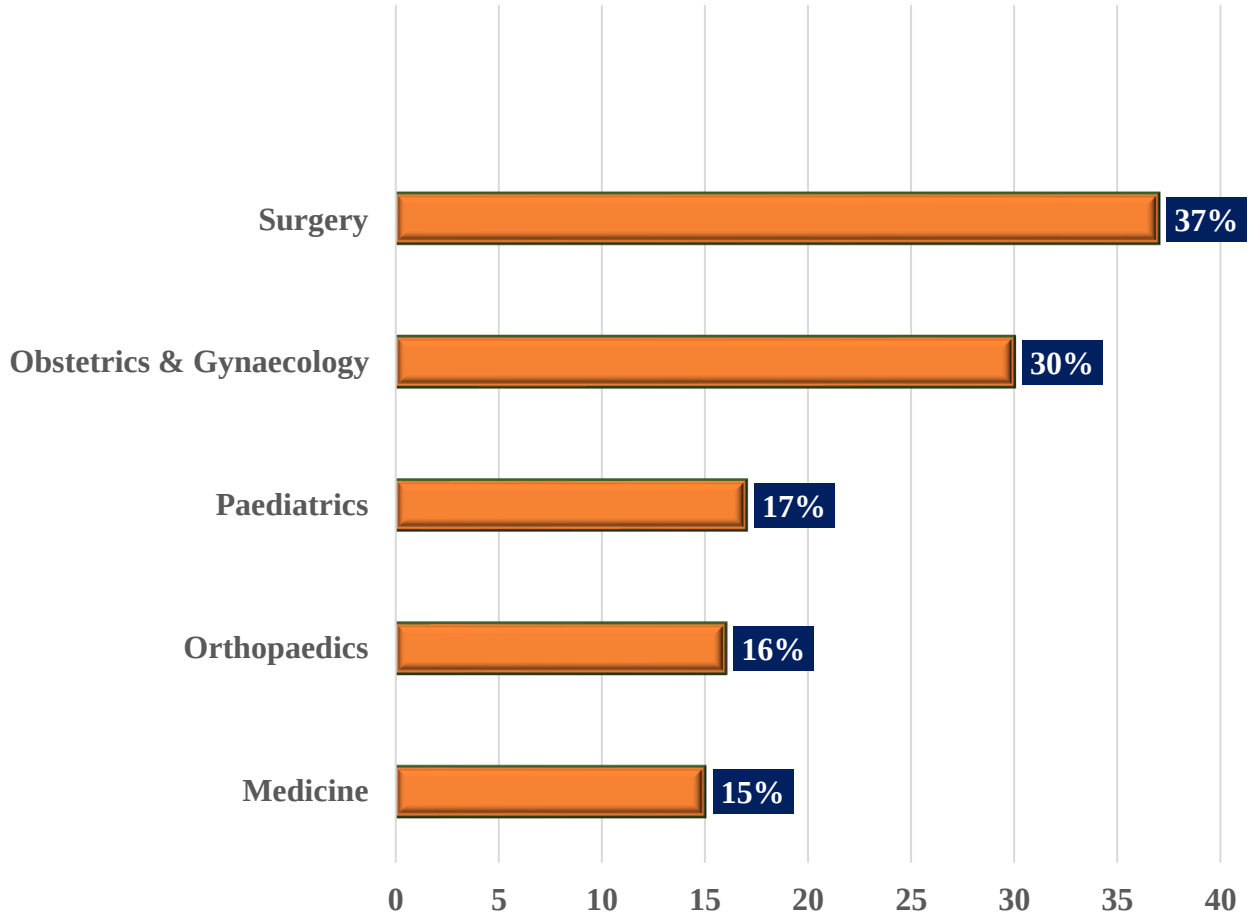
Pudukkottai	Government hospital, Ilupur	149 (5.4)
	Government hospital, Aranthangi	150 (5.5)
Villupuram	Government Medical College, Villupuram	142 (5.2)
	Government Hospital, Vikravandi	143 (5.2)
	Government Hospital, Dindivanam	148 (5.4)
Theni	Government Medical College, Theni	150 (5.5)
	Government Hospital, Bodinayakanur	150 (5.5)
	Government Hospital, Periyakulam	150 (5.5)
Which of the "5 moments of hand hygiene" was observed?	After body fluid exposure	47 (1.7)
	After touching the patients	1033 (37.8)
	After touching patient surroundings	483 (17.7)
	Before clean or aseptic procedure	69 (2.5)
	Before touching patients	1101 (40.3)
Whether hand hygiene was performed during the event	Yes	530 (19.4)
	No	2203 (80.6)
Whether hand hygiene was performed appropriately during the event (n=530)	Yes	201 (37.9)
	No	229 (62.1)

[#]lab technicians, pharmacists, sanitary workers

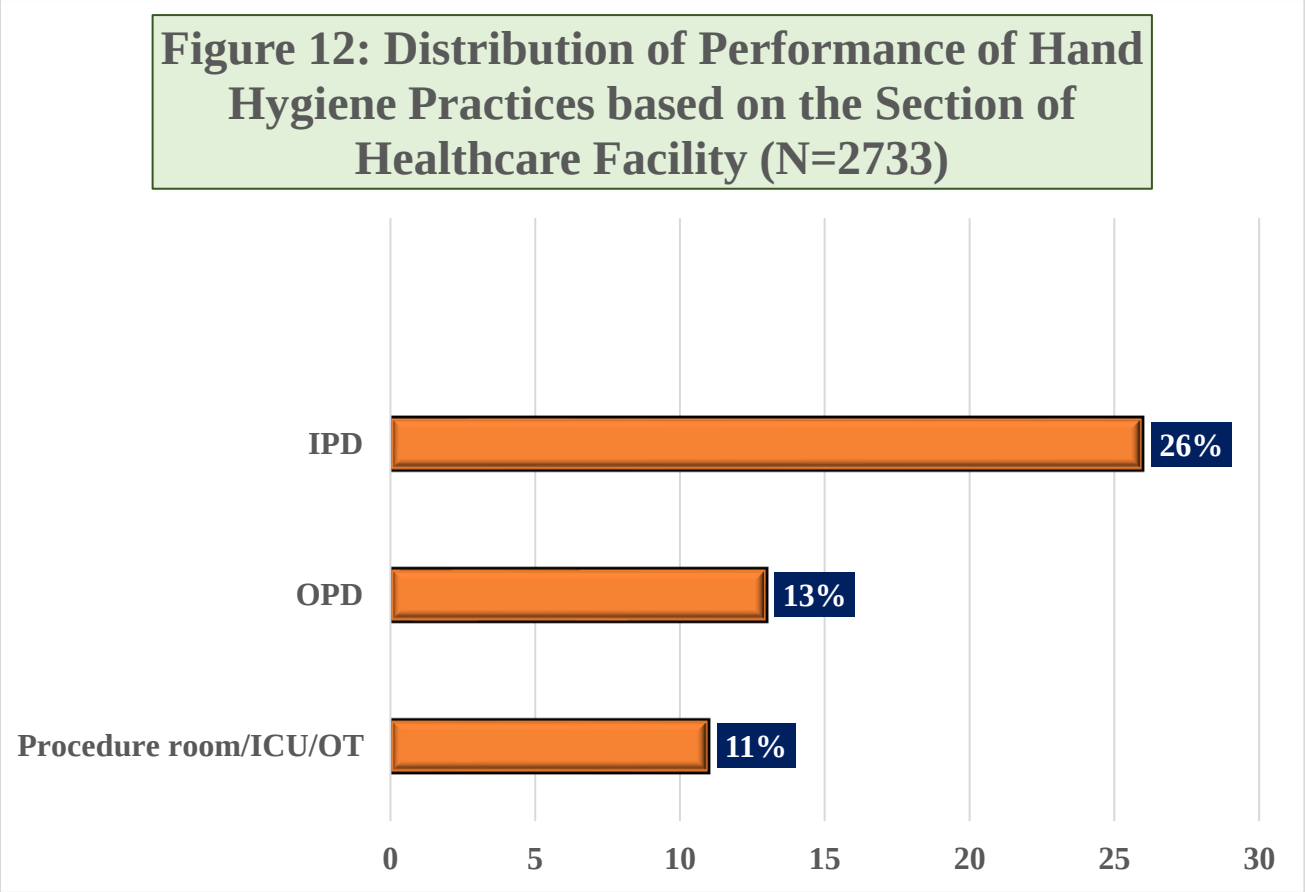


Amongst the different cadres of healthcare workers, nurses (24%) were more compliant to hand hygiene practices followed by other allied healthcare staff like laboratory technicians, sanitary workers etc. (23%) and doctors (10%) **[Figure 10]**.

Figure 11: Distribution of Performance of Hand Hygiene Practices based on the Department (N=2733)



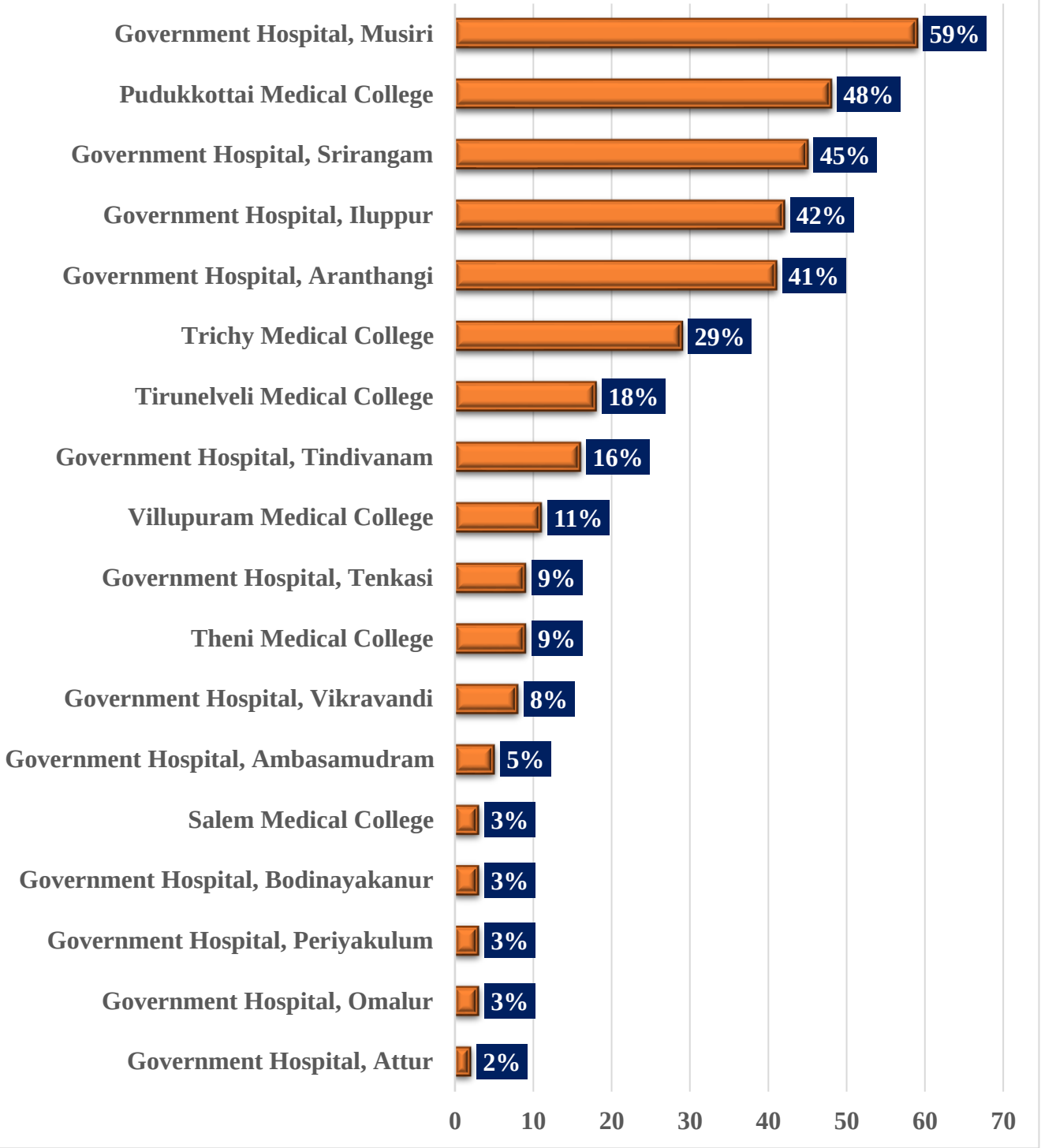
Amongst the various clinical departments, HCWs in Surgery department (37%) had the highest compliance to hand hygiene practices followed by Obstetrics & Gynaecology department (30%) **[Figure 11]**. HCWs in medicine department had the least compliance to hand hygiene practices (15%).



Amongst the various section of healthcare facilities, IPD (26%) had the highest compliance to hand hygiene practices followed by OPD (13%) **[Figure 12]**. HCWs in procedure room/ICU/OT had the least compliance (11%) to hand hygiene practices.

Amongst the various healthcare facilities surveyed, HCWs belonging to facilities in Trichy and Pudukkottai had the highest compliance to hand hygiene practices. HCWs from Musiri GH (59%) had the highest compliance to hand hygiene practices followed by Pudukkottai Medical College (48%). HCWs belonging to facilities in Theni and Salem had the least compliance to hand hygiene practices. HCWs from facilities such as Attur GH, Omalur GH, Salem Medical College, Periyakulam GH and Bodinayakanur GH had compliance ranging from 2-3% to hand hygiene practices **[Figure 13]**.

Figure 13: Distribution of Performance of Hand Hygiene Practices based on the Healthcare Facility (N=2733)



Amongst the five moments of hand hygiene, HCWs who had exposure to body fluids (74%) had the highest compliance to hand hygiene practices followed by HCWs prior to performing any clean or aseptic procedure (57%). HCWs had least compliance to hand hygiene practices before touching any patient (13%) or after touching patient surroundings (13%) **[Figure 14]**.

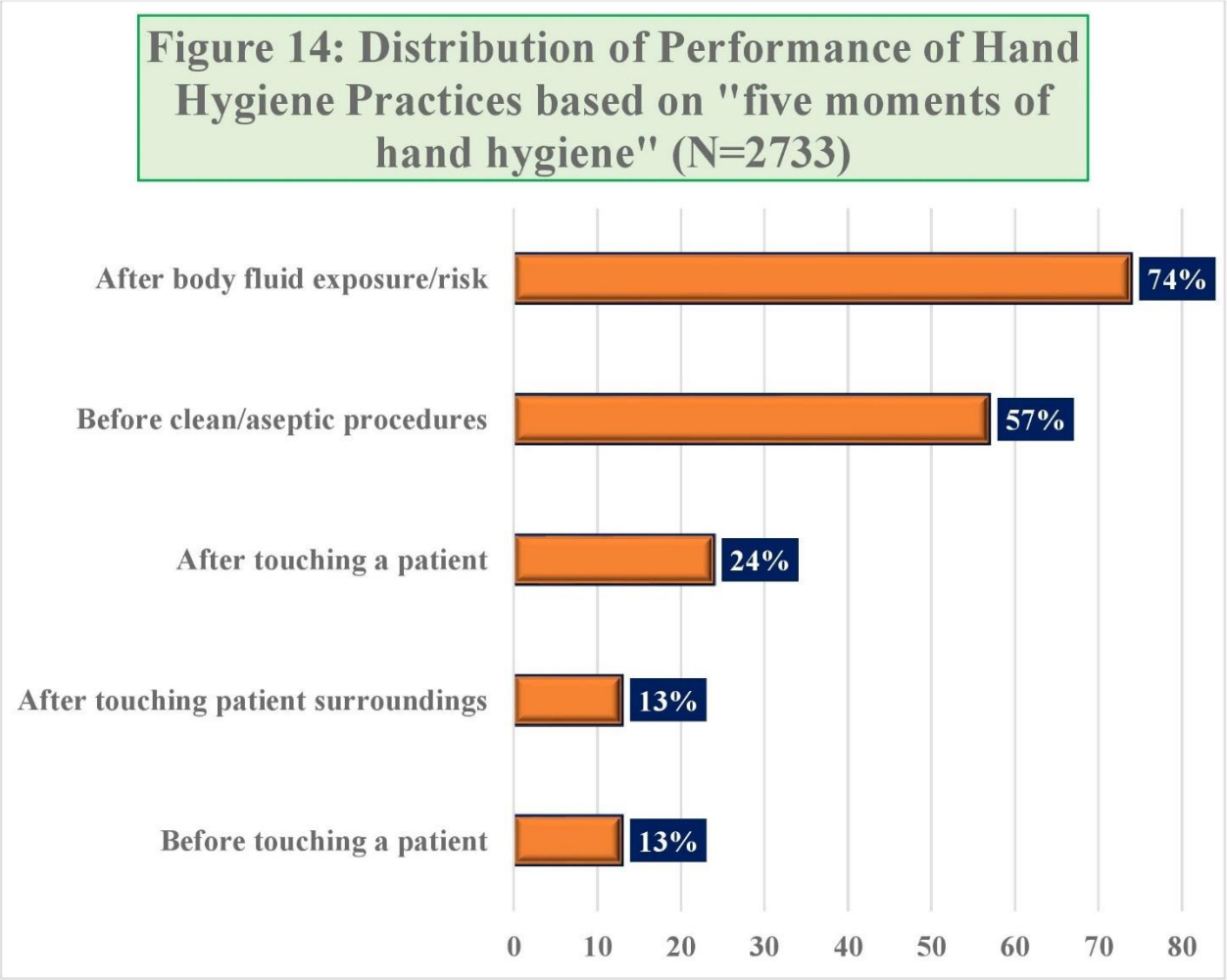
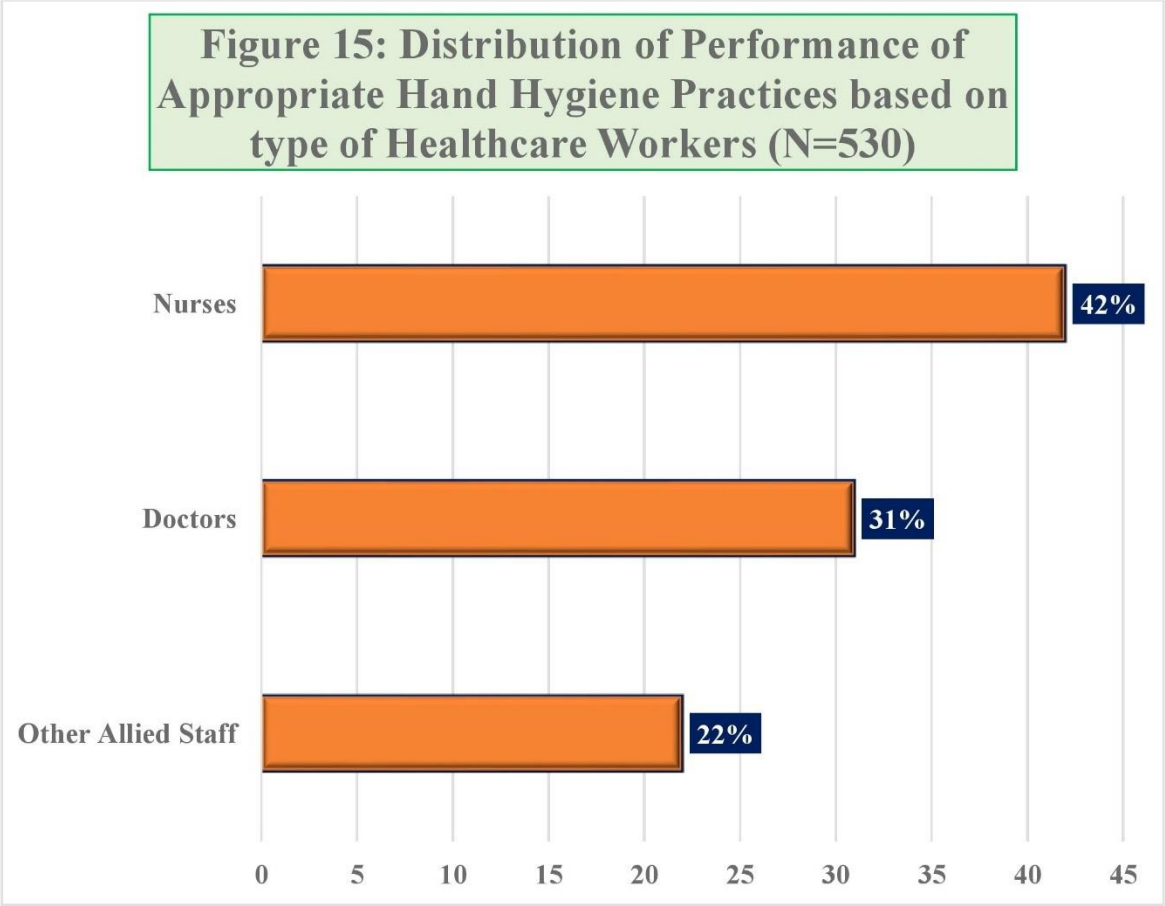
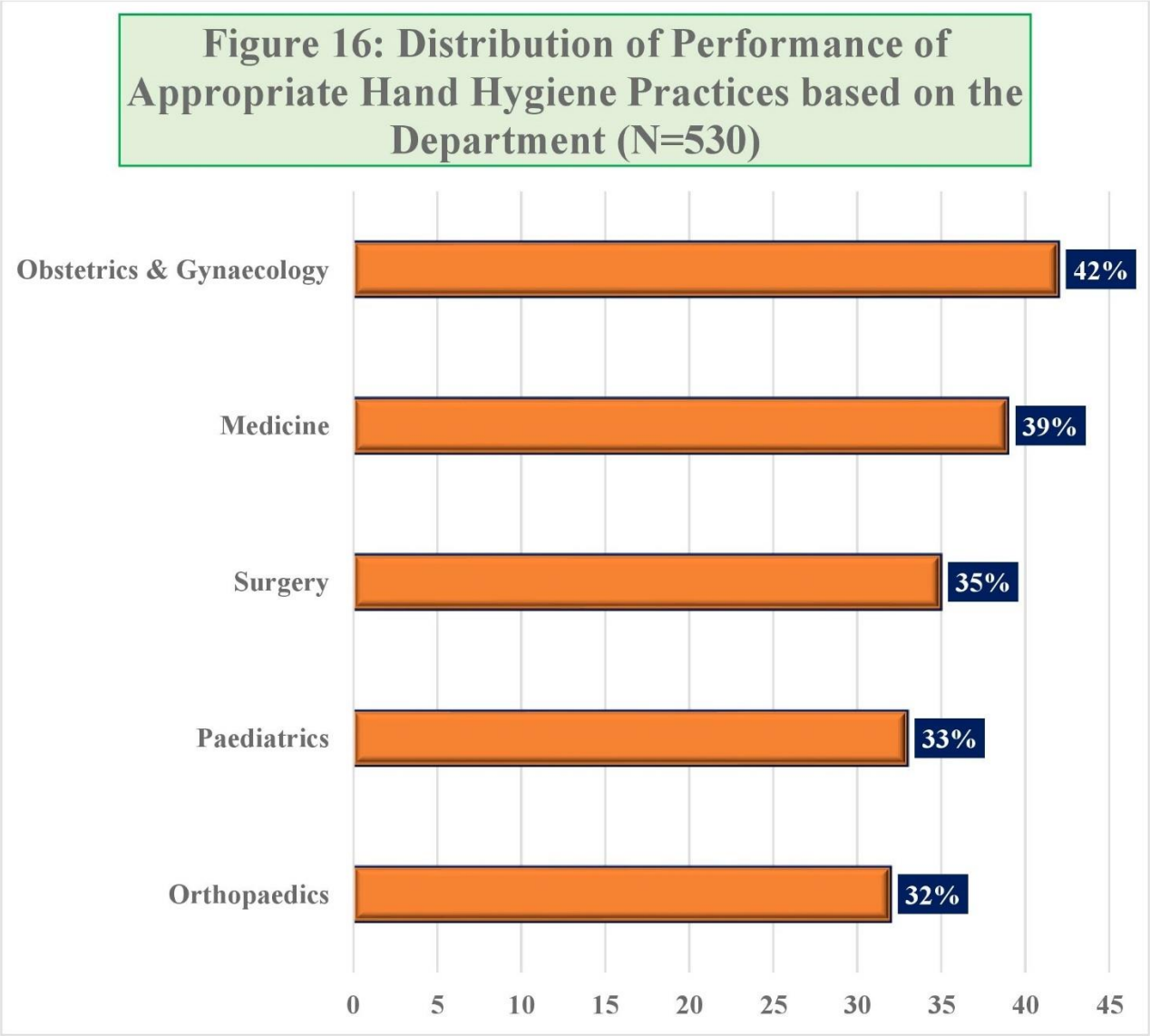


Figure 15-19 shows the distribution of appropriate performance of hand hygiene based on the cadre, department, division, healthcare facility and moment of hand hygiene.

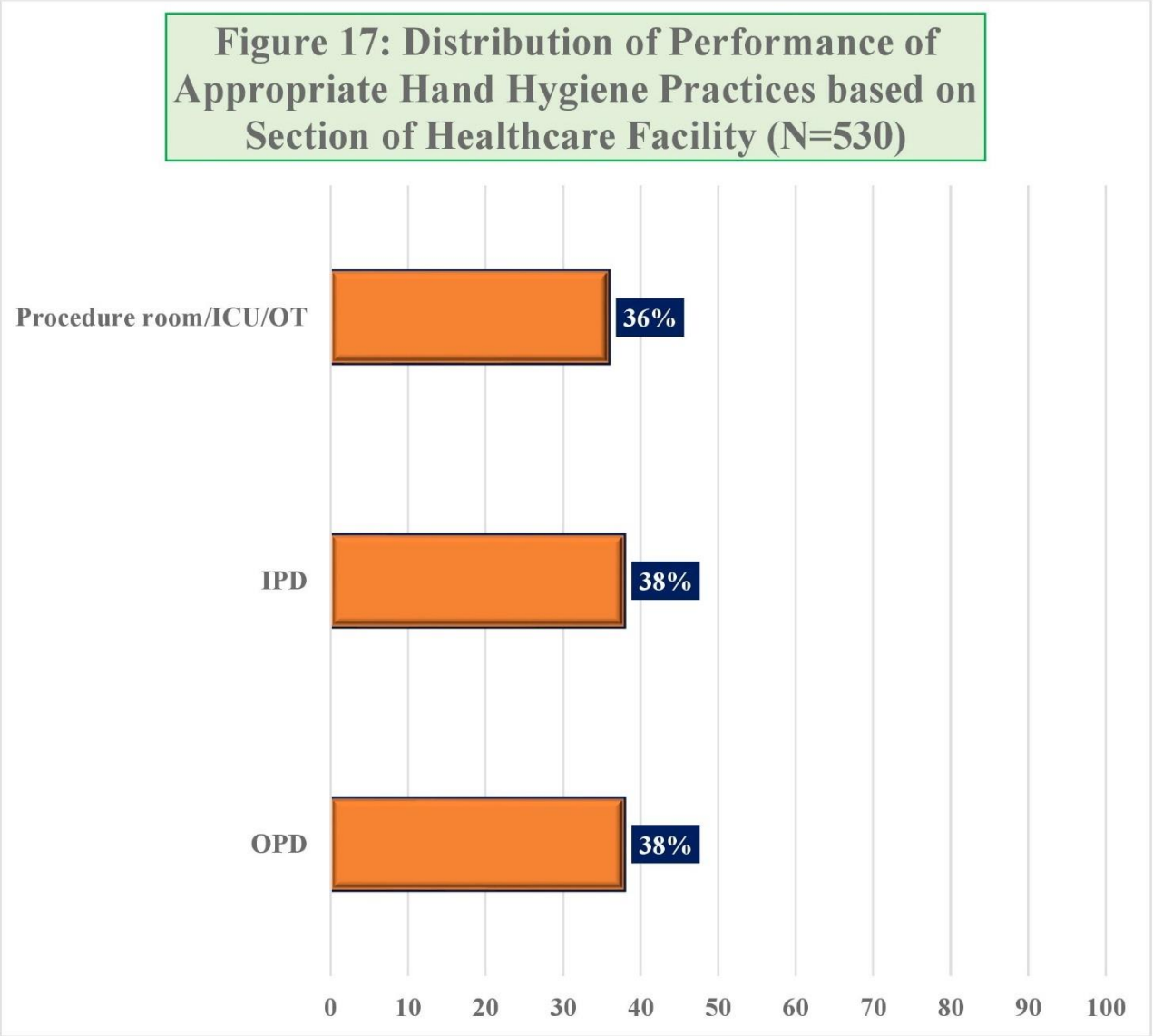
Amongst the different cadres of healthcare workers, nurses (42%) were more compliant to appropriate hand hygiene practices followed by doctors (31%) and other allied healthcare staff like laboratory technicians, sanitary workers etc. (22%) **[Figure 15]**.



Amongst the various clinical departments, HCWs in Obstetrics & Gynaecology department (42%) had the highest compliance to appropriate hand hygiene practices followed by General Medicine department (39%) **[Figure 16]**.

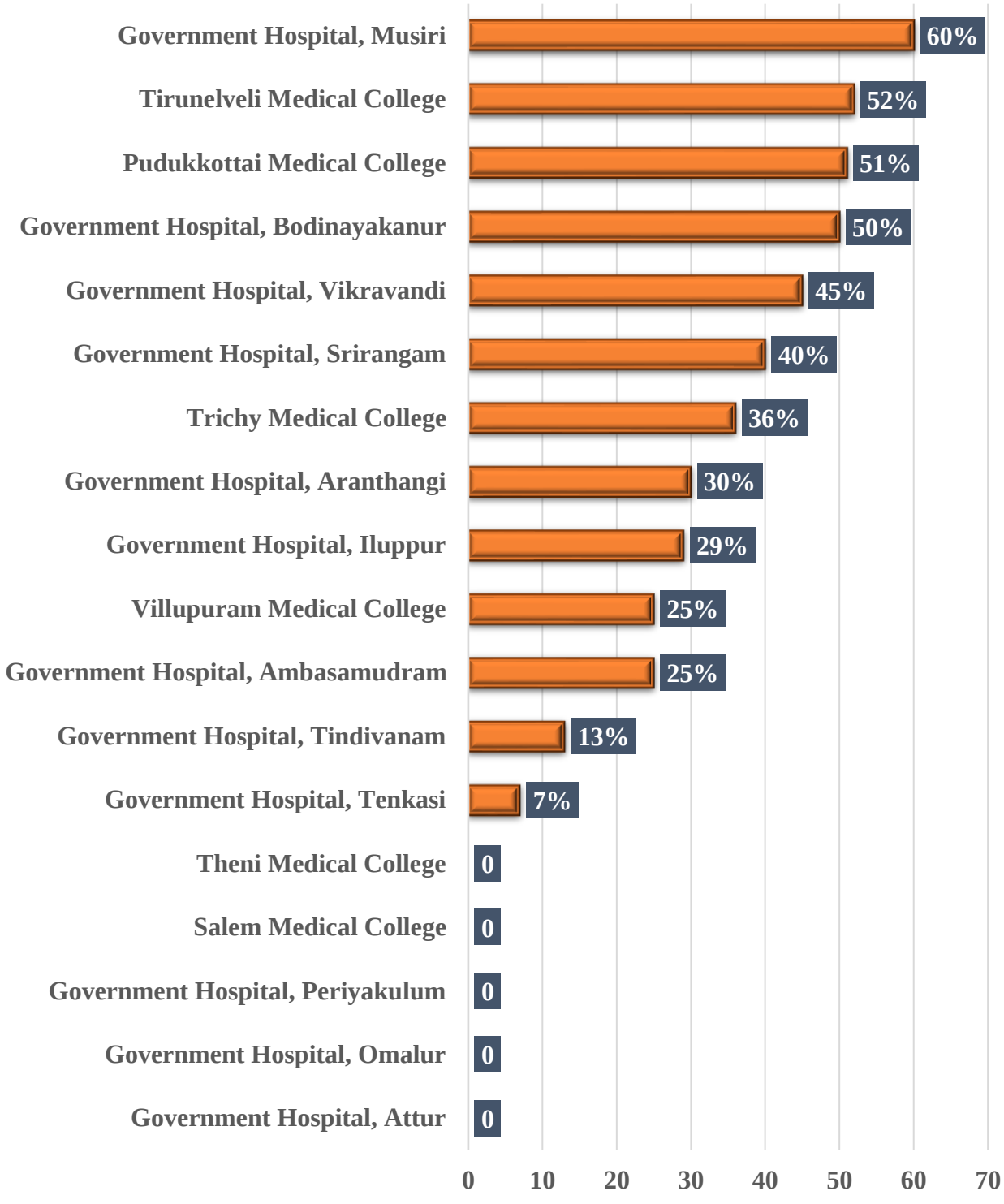


There was almost equal distribution of appropriate hand hygiene practices across various section of healthcare facilities **[Figure 17]**.

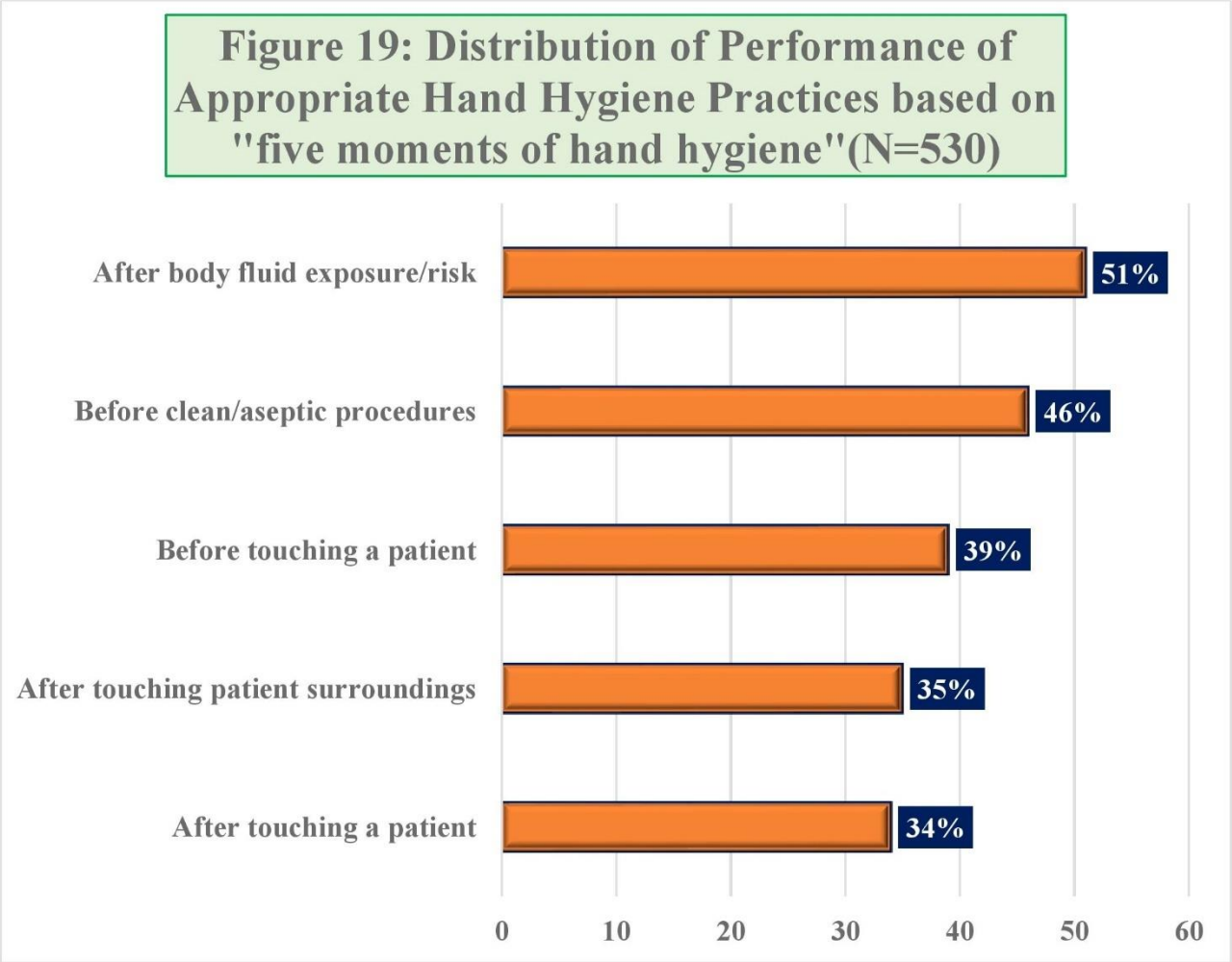


Amongst the various healthcare facilities surveyed, HCWs from Musiri GH (60%) had the highest compliance to appropriate hand hygiene practices followed by Tirunelveli Medical College (52%). HCWs belonging to facilities in Theni and Salem had the least compliance to appropriate hand hygiene practices. HCWs from facilities such as Attur GH, Omalur GH, Salem Medical College, Periyakulam GH and Theni Medical College had 0% compliance to appropriate hand hygiene practices **[Figure 18]**.

Figure 18: Distribution of Performance of Appropriate Hand Hygiene Practices based on Healthcare Facility (N=530)



Amongst the five moments of hand hygiene, HCWs who had exposure to body fluids (51%) had the highest compliance to appropriate hand hygiene practices followed by HCWs prior to performing any clean or aseptic procedure (46%). HCWs had least compliance to appropriate hand hygiene practices after touching any patient (34%) or after touching patient surroundings (35%) **[Figure 19]**.



Section-V: Biomedical waste management practices by healthcare workers employed in public health facilities across Tamil Nadu

Table-15 shows the details about the BMW management observations made amongst the healthcare workers in public health facilities across Tamil Nadu. Majority of the observations were made amongst the nurses (66.3%) followed by doctors (22.2%) and other allied staffs (11.5%). More than half of the observations were made in general medicine department. Almost half of the observations were made in IPD (44.7%) followed by general OPD (28.3%) and injection OPD (19.2%). During nearly three-fourth of the observations (73%), the BMW was disposed of appropriately.

Table 15: Biomedical waste management observations across public health facilities in Tamil Nadu (n=2593)

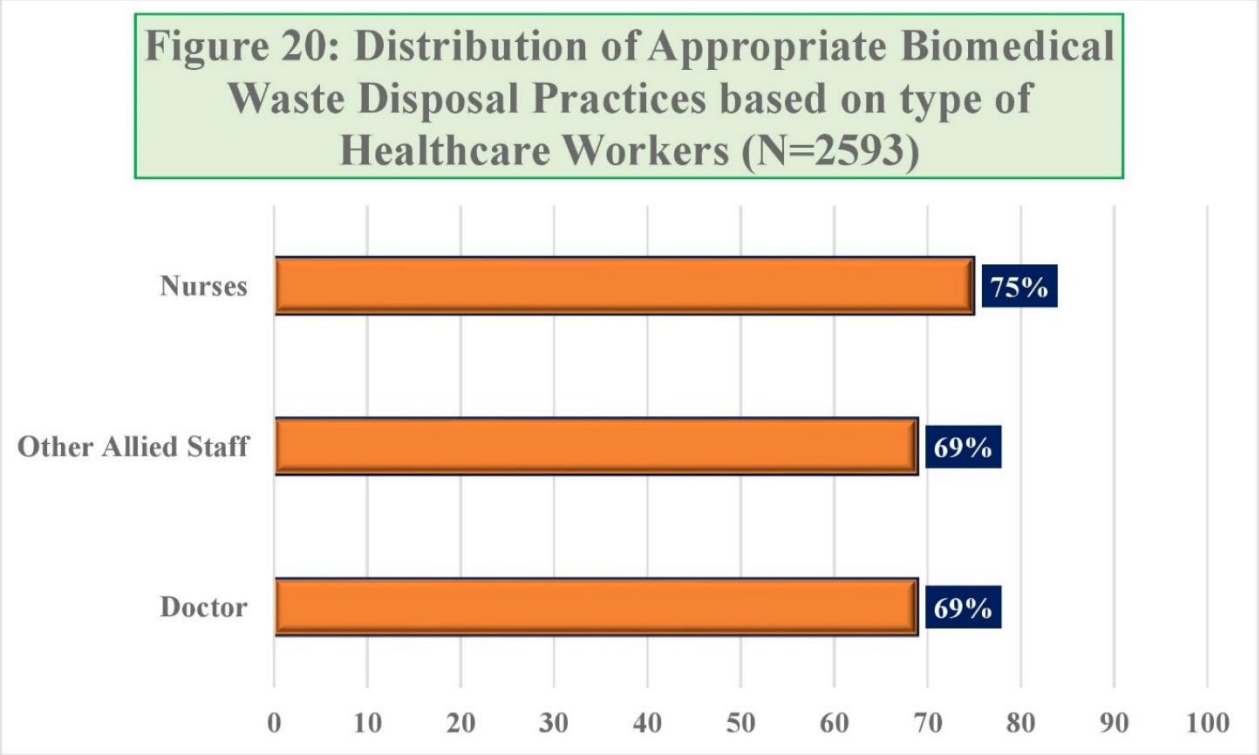
Characteristics	Categories	Frequency (%)
Designation	Doctor	575 (22.2)
	Nurse	1719 (66.3)
	Other allied staffs[#]	299 (11.5)
Department	General Medicine	1611 (62.1)
	General Surgery	272 (10.5)
	Obstetrics & Gynecology	276 (8.8)
	Pediatrics	260 (10.0)
	Orthopedics	224 (8.6)
Division	Outpatient department	734 (28.3)
	Inpatient department	1159 (44.7)
	Injection OPD	498 (19.2)

	Procedure room/Operation theatre/Intensive care unit	202 (8.0)
Districts & Hospital		
Tirunelveli	Tirunelveli Medical College	150 (5.8)
	Government hospital, Ambasamudram	154 (5.9)
	Government hospital, Tenkasi	146 (5.6)
Tiruchirappalli	Tiruchirappalli Medical College	140 (5.4)
	Government hospital, Srirangam	100 (3.9)
	Government hospital, Musiri	150 (5.8)
Salem	Government Mohan Kumaramangalam Medical College	148 (5.7)
	Government hospital, Omalur	154 (5.9)
	Government hospital, Attur	197 (7.6)
Pudukkottai	Government Medical College, Pudukkottai	150 (5.8)
	Government hospital, Ilupur	150 (5.8)
	Government hospital, Aranthangi	151 (5.8)

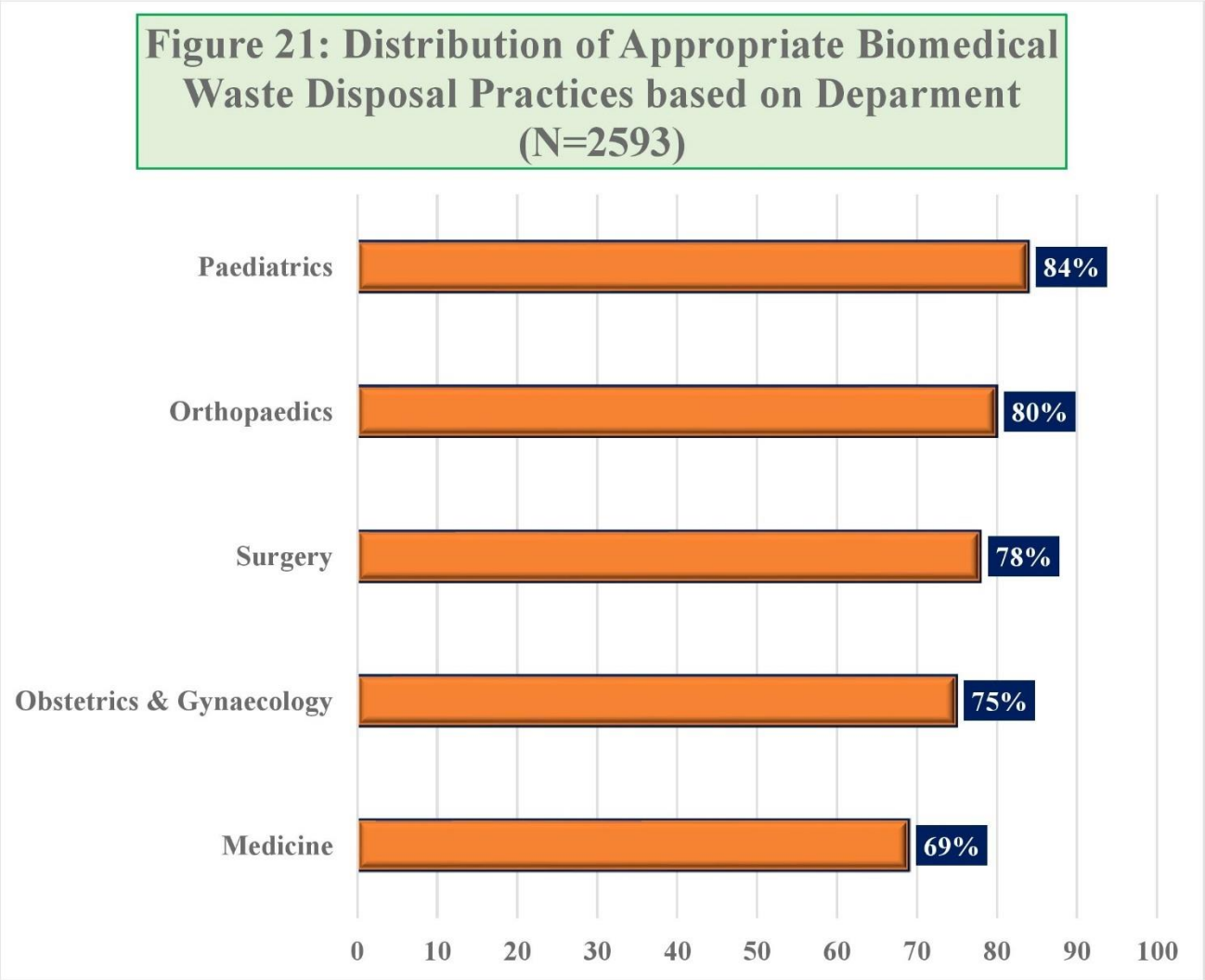
Villupuram	Government Medical College, Villupuram	151 (5.8)
	Government Hospital, Vikravandi	145 (5.6)
	Government Hospital, Tindivanam	146 (5.6)
Theni	Government Medical College, Theni	63 (2.4)
	Government Hospital, Bodinayakanur	149 (5.7)
	Government Hospital, Periyakulam	149 (5.7)
Whether BMW was disposed of appropriately during the observation	Yes	1893 (73.0)
	No	700 (27.0)

[#]Laboratory technicians, sanitary workers

Figure 20-23 shows the distribution of appropriate disposal of BMW based on the designation, department, division, and healthcare facility. Nurses (75%) had the maximum compliance to appropriate BMW disposal practices followed by doctors (69%) and other allied staffs (69%) **[Figure 20]**.

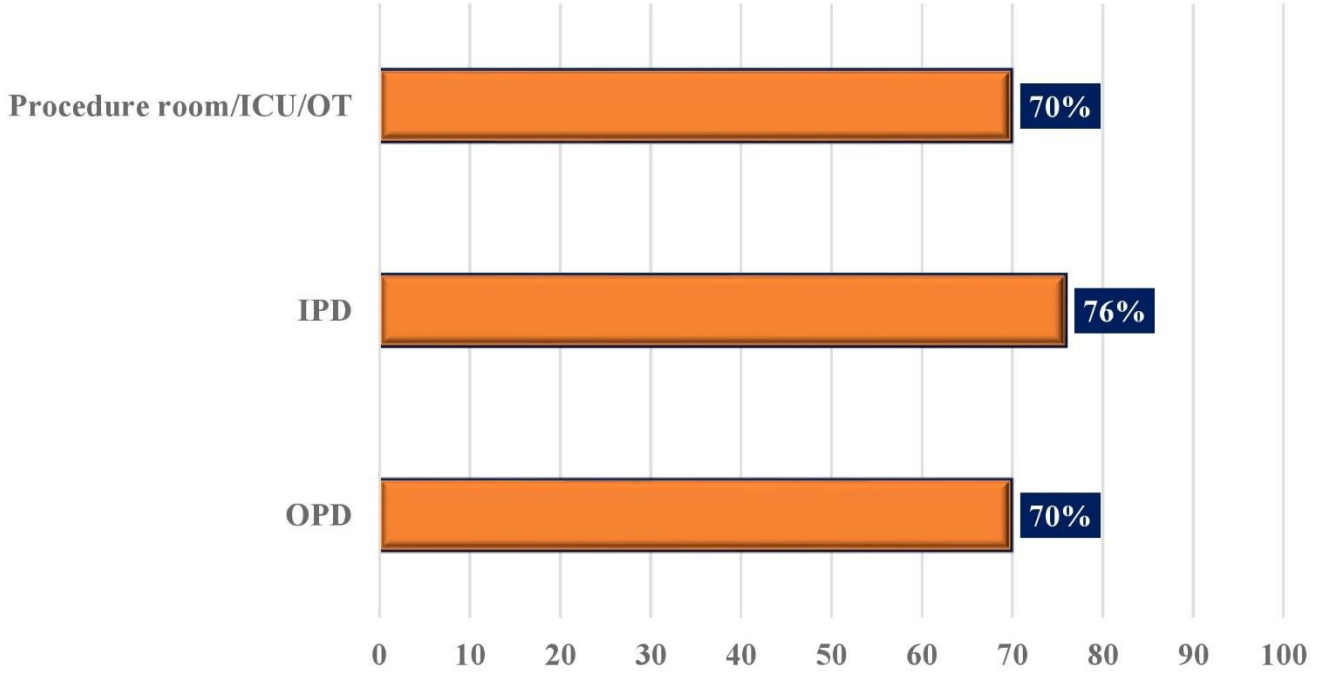


Amongst the various clinical departments, HCWs in Paediatrics department (84%) had the highest compliance to appropriate BMW disposal practices followed by Orthopaedics department (80%). HCWs in medicine department had the least compliance to appropriate BMW disposal practices (69%) **[Figure 21]**.



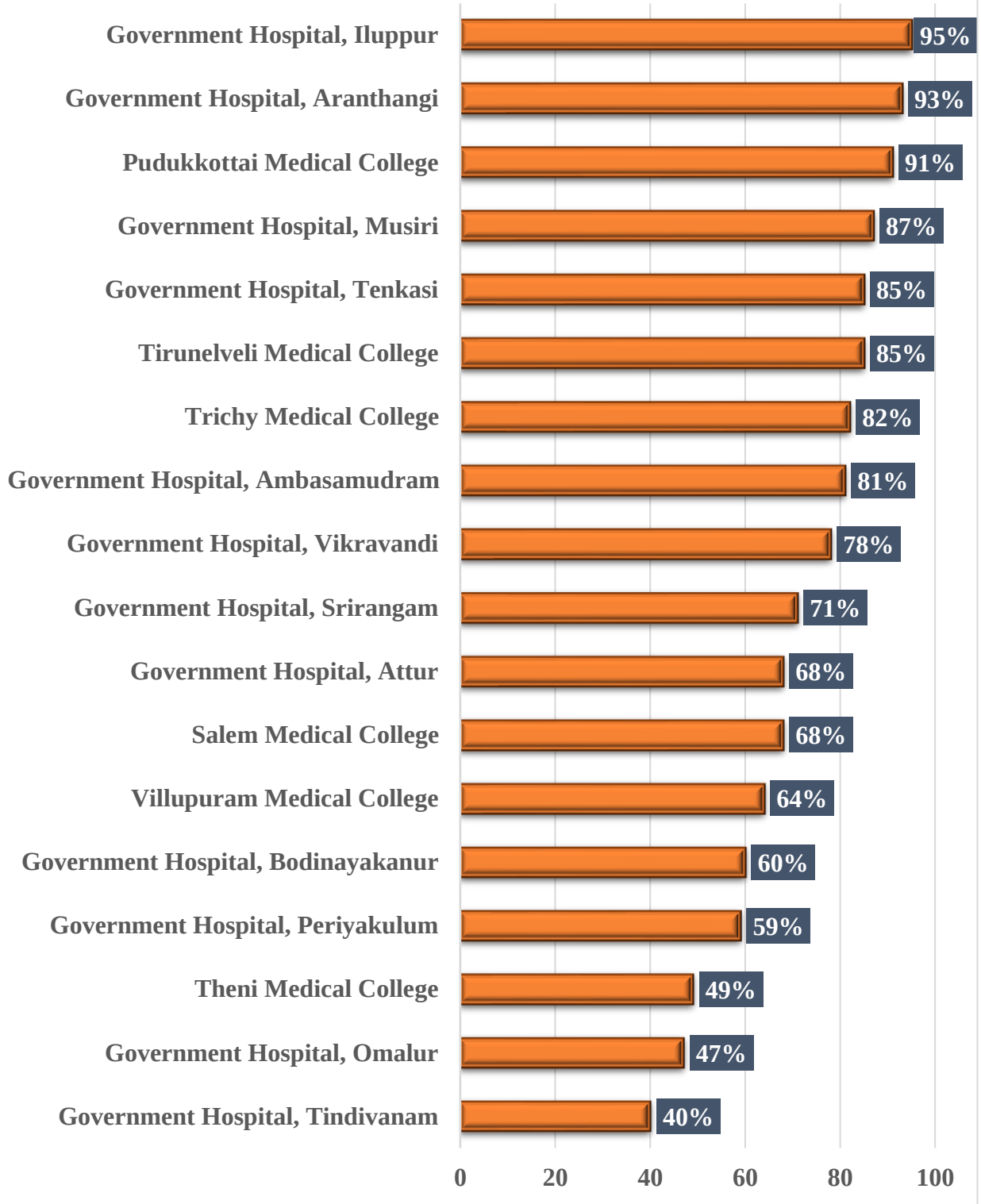
There was almost equal distribution of appropriate BMW disposal practices amongst the various section of healthcare facilities **[Figure 22]**.

Figure 22: Distribution of Appropriate Biomedical Waste Disposal Practices based on Section of Healthcare Facility (N=2593)



Amongst the various healthcare facilities surveyed, HCWs belonging to facilities in Trichy and Pudukkottai had the highest compliance to appropriate BMW disposal practices. HCWs from Illupur GH (95%) had the highest compliance to appropriate BMW disposal practices followed by Aranthangi GH (93%) and Pudukkottai Medical College (91%). HCWs belonging to facilities in Theni, Villupuram and Salem had the least compliance to appropriate BMW disposal practices. HCWs from Tindivanam GH (40%) had the least compliance to appropriate BMW disposal practices followed by Omalur GH (47%) and Salem Medical College (49%) **[Figure 23]**.

Figure 23: Distribution of Appropriate Biomedical Waste Disposal based on Healthcare Facility (N=2593)



Section-VI: Scoring system for the NPSIF implementation across public health facilities in Tamil Nadu

Final scores were compiled after considering the results of process evaluation indicators, patients' perception on safe hospital care (OPD and IPD level), hand hygiene and BMW disposal practices for each individual facility. Periyakulam GH was the only facility belonging to high-performing category with score of 75.5 for patient safety practices.

About 11 facilities (4 medical colleges and 7 GHs) belonging to medium performing category. Amongst them, Tindivanam GH had the highest score amongst the medium performing facilities with a score of 64. Tirunelveli Medical College was the best performing medical college with a score of 61 for patient safety practices.

Six facilities (2 medical colleges – Theni and Pudukkottai, 4 GHs – Bodinayakanur, Vikravandi, Omalur and Ambasamudram) belonged to low-performing category in terms of patient safety. Amongst them, Bodinayakanur and Vikravandi GH were the least performing facilities with score of 29.5 for patient safety practices (**Figure 24**).

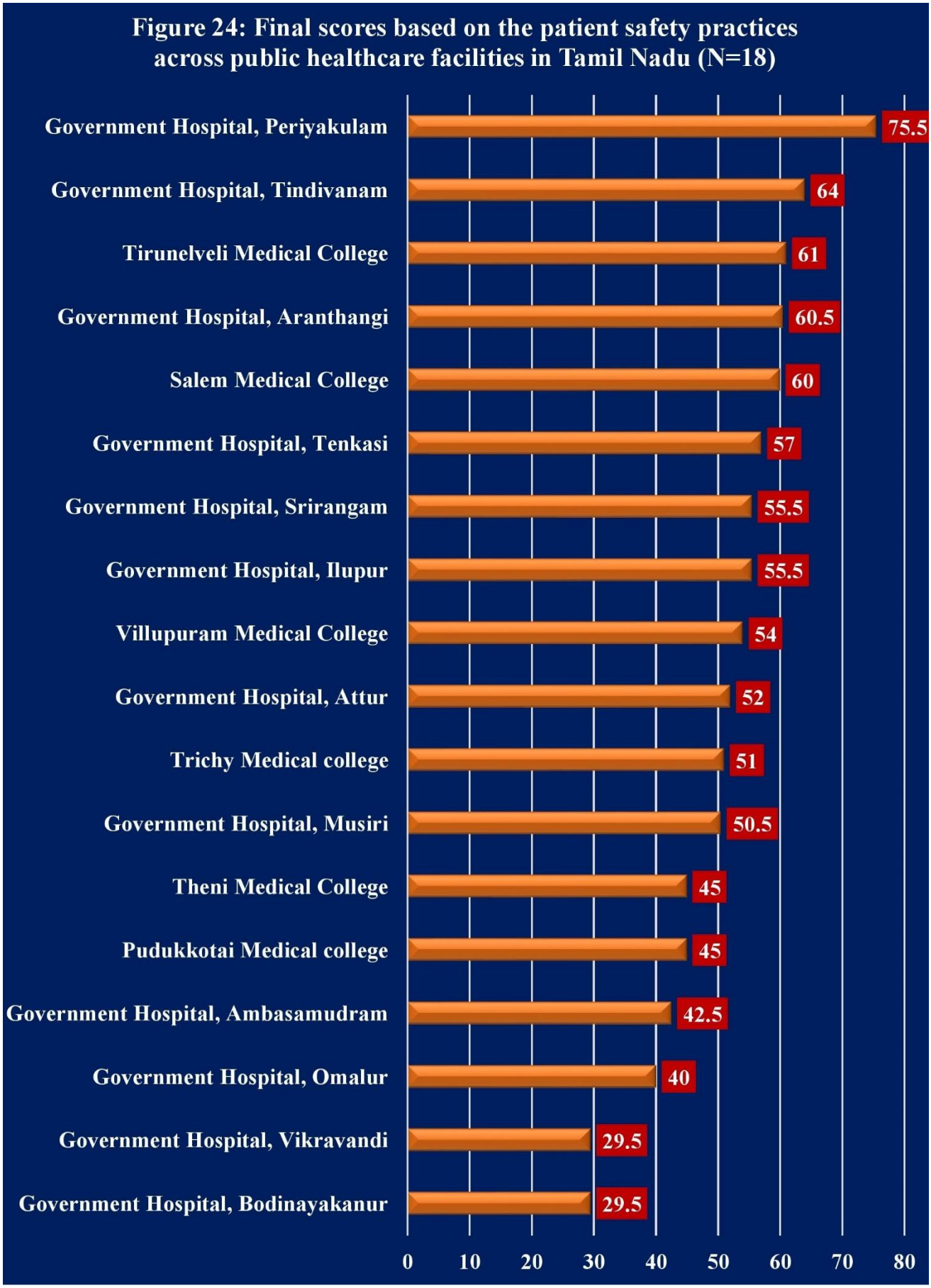


Figure 24: Final scores based on the patient safety practices across public healthcare facilities in Tamil Nadu (N=18)
Government Hospital, Periyakulam
75.5
Government Hospital, Tindivanam
64
Tirunelveli Medical College
61
Government Hospital, Aranthangi
60.5
Salem Medical College
60
Government Hospital, Tenkasi
57
Government Hospital, Srirangam
55.5
Government Hospital, Ilupur
55.5
Villupuram Medical College
54
Government Hospital, Attur
52
Trichy Medical college
51
Government Hospital, Musiri
50.5
Theni Medical College
45
Pudukkotai Medical college
45
Government Hospital, Ambasamudram
42.5
Government Hospital, Omalur
40
Government Hospital, Vikravandi
29.5
Government Hospital, Bodinayakanur
29.5
0
10
20
30
40
50
60
70
80

Protocol for assigning sampling weights for estimation of patient safety score at district:

Weight assigned for Medical College = 1 (as there is only one medical college in each district)

Weight assigned for District Hospital = Total no. of district hospitals in the district / 2 (Sampled district hospitals)

The number of district hospitals in each of the districts were - Trichy (5), Tirunelveli (6), Salem (12), Villupuram (7), Theni (5), Pudukkottai (13)

The final weights for each district were calculated using the following formula (**Table-16**):

Weighted score of patient safety practices in a district = Proportional weight of Medical College * Patient Safety Score in Medical College + Proportional weight of District Hospital * Average Patient Safety Score of two District Hospitals

Table 16: Weight calculation for patient safety practices in a district

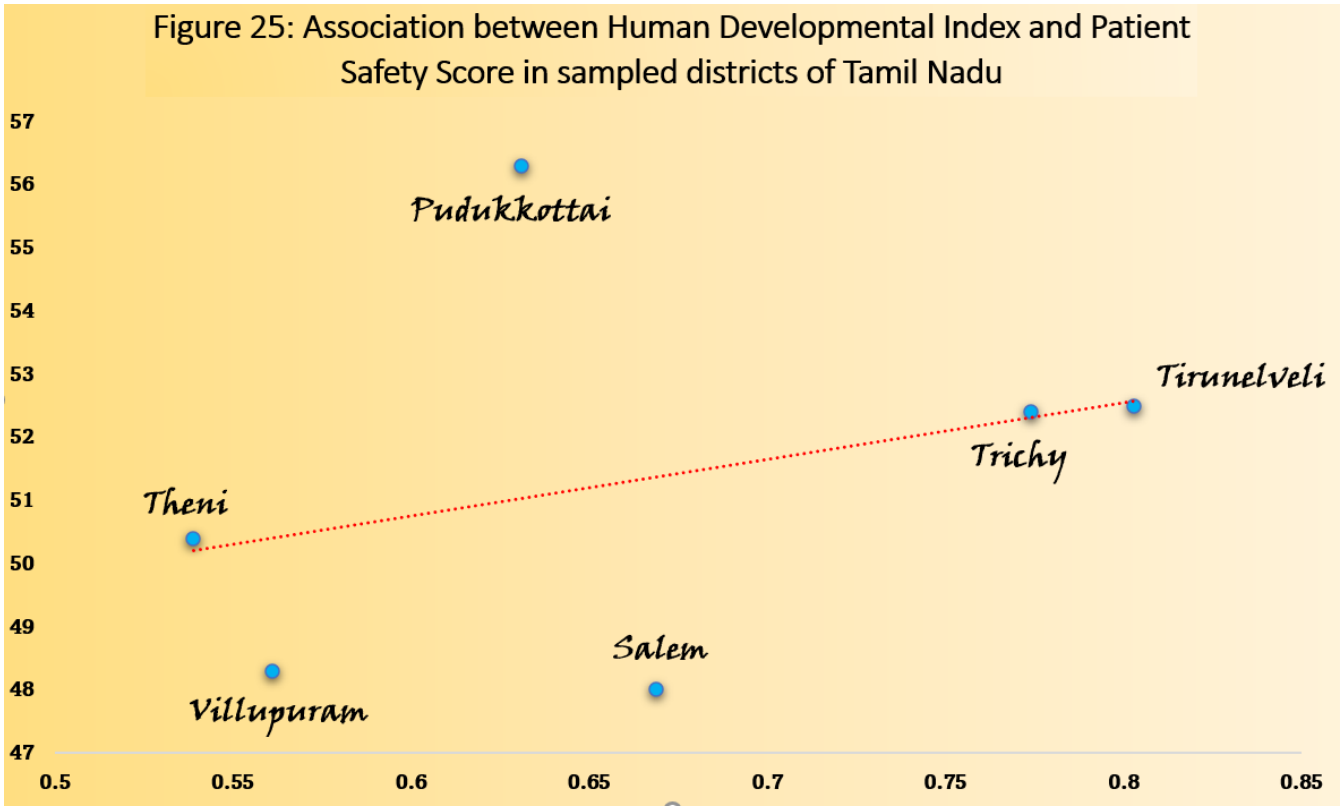
District	Weight calculated for Medical College	Weight calculated for District Hospital	Total Weight	Proportional Weight of Medical College	Proportional Weight of District Hospital
Tirunelveli	1	3	4	0.25	0.75
Tiruchirappalli	1	2.5	3.5	0.28	0.72
Salem	1	6	7	0.14	0.86
Pudukkottai	1	6.5	7.5	0.13	0.87
Villupuram	1	3.5	4.5	0.22	0.78
Theni	1	2.5	3.5	0.28	0.72

After adjusting for weights, we found that Pudukkottai (56.3) was the best performing district followed by Tirunelveli (52.5) and Tiruchirappalli (52.4). Salem (48) was the least performing district followed by Villupuram (48.3) (**Table-17**).

Table 17: Weighted score for patient safety practices in districts

District	Health facility	Facility-wise patient safety score	District-wise patient safety score
Tirunelveli	Tirunelveli Medical College	61	**52.5**
	Government hospital, Ambasamudram	42.5	
	Government hospital, Tenkasi	57	
Tiruchirappalli	Tiruchirappalli Medical College	51	**52.4**
	Government hospital, Srirangam	55.5	
	Government hospital, Musiri	50.5	
Salem	Government Mohan Kumaramangalam Medical College	60	**48**
	Government hospital, Omalur	40	
	Government hospital, Attur	52	
	Government Medical College, Pudukkottai	45	

Pudukkottai	Government hospital, Ilupur	55.5	**56.3**
	Government hospital, Aranthangi	60.5	
Villupuram	Government Medical College, Villupuram	54	**48.3**
	Government Hospital, Vikravandi	29.5	
	Government Hospital, Tindivanam	64	
Theni	Government Medical College, Theni	45	**50.4**
	Government Hospital, Bodinayakanur	29.5	
	Government Hospital, Periyakulam	75.5	



We assessed the association between the HDI and patient safety score between the sampled districts (**Figure 25**). We found that the overall district level score of patient safety score that were present in the health facilities increased with increasing HDI values. Therefore, a pattern of association between the level of development of the district and patient safety practices at the secondary and tertiary care facilities were observed.

Section-VII: Qualitative findings on the facilitating factors, challenges faced, and possible suggestions for effective implementation of NPSIF in public health facilities at Tamil Nadu

In total, 80 qualitative interviews were conducted with administrative heads and healthcare workers across 18 public healthcare facilities in Tamil Nadu. **Table-18** shows the details of participants who were interviewed for qualitative part of the study.

Table 18: Details of the participants interviewed for qualitative part of the study (n=80)

Characteristics	Categories	Frequency (%)
Mean age of the participants = 48 years		
Gender	Male	27 (33.7)
	Female	53 (66.3)
Type of HCW	Doctor	44 (55.0)
	Nurse	34 (42.5)
	Other allied staffs[$]	2 (2.5)
Designation	Dean/MS/RMO/NS	32 (40.0)
	Head or staffs under HICC/CSSD/BMW/ Microbiology Department	26 (32.5)
	Head or staffs under transfusion committee/ blood bank/ immunohematology	7 (8.8)
	Head or staffs under pharmacovigilance committee/ Pharmacology Department	9 (11.3)
	COVID-19 nodal officer	4 (5.0)
	Head or staffs under antimicrobial stewardship committee	1 (1.2)

	Others[#]	1 (1.2)
Districts & Hospital		
Tirunelveli	Tirunelveli Medical College	4 (5.0)
	Government hospital, Ambasamudram	4 (5.0)
	Government hospital, Tenkasi	5 (6.0)
Tiruchirappalli	Tiruchirappalli Medical College	4 (5.0)
	Government hospital, Srirangam	6 (7.5)
	Government hospital, Musiri	5 (6.0)
Salem	Government Mohan Kumaramangalam Medical College	5 (6.0)
	Government hospital, Omalur	6 (7.5)
	Government hospital, Attur	4 (5.0)
Pudukkottai	Government Medical College, Pudukkottai	3 (3.7)
	Government hospital, Ilupur	5 (6.0)
	Government hospital, Aranthangi	6 (7.5)
Villupuram	Government Medical College, Villupuram	5 (6.0)
	Government Hospital, Vikravandi	2 (2.5)
	Government Hospital, Tindivanam	5 (6.2)
Theni	Government Medical College, Theni	6 (7.5)
	Government Hospital, Bodinayakanur	1 (1.2)
	Government Hospital, Periyakulam	4 (5.0)

[$]Pharmacists, HMIS staff

[#]OG Professor – in charge of LAQSHYA and HMIS

We had three predetermined themes (facilitating factors, challenges, and suggestions for overcoming challenges), nine subthemes (Structural Support for Quality & Safety, Hospital Infection Control, Biomedical Waste Management, Blood Safety, Antimicrobial Stewardship, COVID-19 Safety, Medication Safety, Procedural and Device Safety, Patient Safety Research). Each theme and its subtheme were explored through four categories (patient, HCW, hospital administration and health system level) **(Table 19-21)**.

Theme 1: Facilitating factors for implementation of NPSIF activities across public health facilities in Tamil Nadu:

Subtheme 1.1: Structural Support for Quality & Safety

First, positive feedback received from the patient side was reported as a major facilitating and motivating factor for the hospitals to work towards accreditation process. Motivated workforce with multi-tasking ability and sense of reputation was the prominent facilitating factor found at HCW level.

A 48-year-old female RMO in a GH has said that,

"Reputation of the institution is one of the reasons which motivate to work efficiently so that the care is up to the mark"

Initiatives undertaken by hospital administration such as provision of LAQSHYA training for their staffs has helped in increasing the awareness about various protocols among HCWs and placing complaint boxes throughout the hospital and constitution of patient welfare committee for grievance redressal of patients helped in understanding the patient safety concerns and improved the hospital services. At health system level, conduct of training dedicated towards the accreditation process has been reported as an important facilitating factor.

A 45-year-old female OG Professor in a Medical College has said that,

"LAQSHYA training for the staffs has helped in increasing awareness about various protocols & improved services"

A 54-year-old male Medical Superintendent in a GH has said that,

"We have complaint boxes throughout the hospitals; patients put their concerns in the box and it gets rectified immediately"

Subtheme 1.2: Hospital Infection Control

The ongoing COVID-19 crisis has acted as a facilitating factor for hospital infection control as the fear/threat of COVID-19 led to patients realizing importance of hand hygiene and its compliance during their visit to hospitals and in general. For healthcare workers, satisfaction of doing public service for infection control, recognition to their facility in terms of kayakalp certification has been a major motivating factor for performing the hospital infection control activities.

A 51-year-old female Nursing Superintendent in a GH has said that,

"Public service is our satisfaction, Infection prevention and kayakalp certification motivate us to work well in a challenging field"

The hospital administration has also undertaken measures like provision of hand hygiene and personal protective equipment (PPE) training to their staffs considering the ongoing COVID-19 pandemic situation.

A 50-year-old female Nursing Superintendent in a Medical College has said that,

"After COVID we have improved our hand hygiene practices and also trainings are frequently given"

Widespread depiction of IEC materials throughout the hospital on the hygiene and sanitation activities, regular meeting of the HICC committee and resolution of problem discussed in the meeting immediately, training sanitary workers on innovative practices for cleaning the hospitals, digitalization of data through "WHO NET software" for automated data entry and review and work sampling for monitoring the hand hygiene practices are few other facilitating factors implemented through hospital administration for infection prevention and control practices. The directorate has also been helpful by providing standard protocols for facilitating the hospital infection prevention and control measures.

A 42-year-old female staff nurse working under CSSD department in a GH has said that,

"We have shifted from registers to WHO NET and is easy for the review"

A 52-year-old male head of the HICC in a GH has said that,

"Standard protocols are provided to us on hospital infection control practices by the government"

Subdomain 1.3: Biomedical Waste Management

At patient level, especially those coming from urban areas and highly educated, are aware about the hazards of biomedical wastes, enabling them to follow proper waste practices in the hospital. HCWs has reported that they have a sense of responsibility to prevent hospital acquired infection for the patients and follow standard BMW practices. At hospital administration level, regular audits, monitoring and practice sessions, provision of rewards for staffs following proper BMW practices are some of the facilitating factors for BMW management.

A 42-year-old female staff nurse under BMW management committee in a GH has said that,

"Appraisal, appreciation and rewards are our motivating factors"

Subdomain 1.4: Blood Safety

Local community support to blood donation camps has been an important facilitating factor reported at patient level. At HCW level, job satisfaction, commitment, and provision of counselling on blood donation were major facilitating factors.

A 52-year-old female blood bank officer in a GH has said that,

"Regular meetings are held, and the staffs are 100% involved in these meeting"

At hospital administration level, allowing patient representation in framing blood safety policies, conducting awareness programs and application of latest technologies were some of the facilitating factors in ensuring blood safety.

A 52-year-old female blood bank officer in a GH has said that,

"We have representation from patients in our transfusion committee; This makes us know about their point of view and frame patient-friendly policies"

Subdomain 1.5: Antimicrobial Stewardship

Crosschecking the prescriptions of higher-level antibiotics by the respective department heads has acted as a major facilitating factor for proper antimicrobial practices. At hospital administration level, monitoring the antimicrobial practices (as part of accreditation) and conducting regular seminars, continuing medical education (CMEs) and case discussions were major facilitating factors. Health system in few districts has initiated training for doctors on appropriate antibiotic practices in terms of dose, duration, frequency, and indication.

A 50-year-old male Medical Superintendent in a Medical College has said that,

"Directorate conducts training for doctors and nurses on dose, duration, dosing interval of antibiotics for facilities applying for certifications"

Subdomain 1.6: COVID-19 Safety

Patients are willing to comply the COVID-19 safety measures and appreciate the HCWs for doing COVID-19 duty during these tough times. This encourages the HCWs to perform their duties more devotedly.

A 54-year-old male Dean in a Medical College has said that,

"*Patient's attitude towards doctors have changed post COVID in a positive way"*

HCWs had a sense of responsibility, satisfaction, and providing selfless service to the community during these tough times. Hospital administration has taken steps like triaging system to prevent the mixing of COVID and non-COVID patients, ensuring the visitors follow COVID appropriate behaviour and providing appropriate quarantine for staffs doing COVID-19 duty.

At health system level, support for outsourcing of staffs and equipment, advanced IEC materials using audiovisual aids and providing psychological support to patients through provision of mobile phones to talk with their family members were few of the facilitating factors for ensuring COVID-19 safety measures.

A 50-year-old male Medical Superintendent in a Medical College has said that,

"District collector has arranged 50 mobile phones for the COVID patients to talk to their families; This was helpful in providing psychological support to patients"

A 54-year-old male Resident Medical Officer in a GH has said that,

"Local administration has helped us immensely in outsourcing the sanitary workers and equipments like ventilators during COVID times"

Subdomain 1.7: Medication Safety

At HCW level, interest in conducting pharmacogenomic studies might help in developing effective and safer medications and the doses can be tailored to the person's genetic makeup. Hospital administration across various facilities have also taken certain initiatives for medication safety like regular meeting and audits of pharmacovigilance committee, regular training on handling emergency adverse drug reactions (ADR) and having a standardized "10 R" checklist for safe drug administration to their patients. At health system level, clinical pharmacology wings have been set up in few districts, which helps in monitoring the ADR across all the facilities in the district.

A 52-year-old female head of pharmacology department in a medical college has said that,

"I ask my assistant professors to take up pharmacogenomic studies; relation between area and drugs; So, if we can do that for the patients it will be good"

A 44-year-old male head of pharmacovigilance committee in a medical college has said that,

"Every staffs go through repeated training to handle adverse reactions"

Subdomain 1.8: Procedural and Device Safety

Mother's satisfaction following delivery in LAQSHYA certified health facilities were reported. At hospital administration level, initiatives like conduct of recruitment and refresher training on standard procedures, accreditation process, mercury spill kit and availability of standard protocol for major procedures, has helped in maintaining procedural and device safety in their facilities.

A 50-year-old female nursing staff in a GH has said that,

"We have a ready-to-use mercury spill kit in case of emergencies like accidental leakage of mercury devices; We are also given training on how to handle such situations"

Subdomain 1.9: Patient Safety Research

Patient's cooperation and participation during the satisfactory survey has helped the healthcare facility to monitor the quality of services provided by them. Faculties in most of the medical colleges have also reported that they are highly motivated to conduct research on patient safety theme, given the support from hospital administration and health system.

A 57-year-old male Medical Superintendent in a medical college has said that,

> *"We want to carry out research on patient safety related questions, if we are given the required support from administration"*

Table 19: Facilitating factors for implementation of National Patient Safety Implementation Framework across public healthcare facilities in Tamil Nadu

Theme: Facilitating factors for implementation of National Patient Safety Implementation Framework			
Subthemes	**Categories**	**Codes**	**Quotes**
Structural System for Quality & Safety	**Patient**	➢ Positive feedback from patients	*"Some patients provide good feedback about our hospital; This motivates us to apply for certification process and provide quality services, par with private hospitals"*
	Healthcare workers	➢ Motivated workforce with multi-tasking ability ➢ Sense of reputation and identity	*"Reputation of the institution is one of the reasons which motivate to work efficiently so that the care is up to the mark"*
	Hospital Administration	➢ LAQSHYA training ➢ Patient welfare committee ➢ Compliant boxes/Anonymous reporting system ➢ Infant monitoring system	*"LAQSHYA training for the staffs has helped in increasing awareness about various protocols & improved services"* *"We have complaint boxes throughout the hospitals; patients put their concerns in the box, and it gets rectified immediately"*

	Health System	➢ Training for NQAS accreditation	*"District administration has taken initiative to provide training for the hospitals on obtaining NQAS certifications"*
Hospital Infection Control	**Patient**	➢ Fear/Threat of COVID-19	*"COVID-19 fear led to patients realizing importance of hand hygiene"*
	Healthcare workers	➢ Job Satisfaction for performing public service ➢ Teamwork and supportive supervision	*"Public service is our satisfaction; Infection prevention and certifications motivate us to work well in challenging field"*
	Hospital Administration	➢ COVID-19 crisis led improvement in hand hygiene & PPE training ➢ Widespread depiction of IEC materials ➢ Regular HICC meeting with rapid problem solving ➢ Innovative cleaning practices ➢ Utilization of "WHO NET software" ➢ Work sampling & observations for monitoring the hand hygiene practices	*"After COVID we have improved our hand hygiene practices and also trainings are frequently given"* *"We use three bucket system for ensuring a clean surface; Zig Zag method of mopping is taught to our sanitary workers"* *"We have shifted from registers to WHO NET and is easy for the review"*

	Health System	➢ Standard protocol for hospital infection prevention & control measures	*"Standard protocols are provided to us on hospital infection control practices by the government"*
Biomedical Waste Management	**Patient**	➢ Understanding the hazards of biomedical wastes	*"Patients who are literate and coming from urban areas understands the seriousness of hazards of biomedical waste and follow proper protocol"*
	Healthcare workers	➢ Sense of responsibility & contribution	*"All of us have a sense of responsibility to prevent infections for patients by following proper waste disposal practices"*
	Hospital Administration	➢ Regular audits and practice sessions ➢ Appraisal, appreciation, and rewards ➢ Work sampling to monitor BMW practices	*"Appraisal, appreciation and rewards are our motivating factors"*
Blood Safety	**Patient**	➢ Local community support in blood donation camps	*"People from local community around hospitals support us & voluntarily donate blood during blood donation camps"*
	Healthcare workers	➢ Job satisfaction for saving patient's lives ➢ Counselling for blood donation	*"Job satisfaction and I feel happy that a life is saved"*

		➢ Commitment of healthcare workers	*"Regular meetings are held, and the staffs are 100% involved in these meeting"*
	Hospital Administration	➢ Patient representation to frame blood safety policy ➢ Awareness program on blood donation practices ➢ Application of latest technologies (Gel card technique, apheresis)	*"We have representation from patients in our transfusion committee; This makes us know about their point of view and frame patient-friendly policies"* *"Awareness programs like rallies on blood donation are conducted regularly"*
	Health System	➢ Political support for blood donation camps	*"Counsellors and other local politicians motivate their party members and general public to voluntarily donate blood during blood donation camps"*
Antimicrobial Stewardship	**Healthcare workers**	➢ Counterchecking prescription of high-level antibiotics	*"In IPD... if any house surgeon prescribes a higher antibiotic, they get countersigned by HOD"*
	Hospital Administration	➢ Monitoring antibiotic practices as part of accreditation process ➢ Regular CME, Seminars & Case discussions	*"Applying for certification makes it mandatory for our hospital staffs to properly follow antimicrobial practices"*

	Health System	➢ Directorate-initiated appropriate antibiotic use training for HCWs	*"Directorate conducts training for doctors and nurses on dose, duration, dosing interval of antibiotics for facilities applying for certifications"*
COVID-19 Safety	**Patient**	➢ Willingness to comply COVID-19 measures ➢ Appreciating HCWs for doing COVID-19 duty	*"Most of the patients are compliant in following our advises regarding cleaning hands and masking"* "*Patient's attitude towards doctors have changed post COVID in a positive way"*
	Healthcare workers	➢ Sense of responsibility, satisfaction, selfless service to the community	*"We have a sense of responsibility and do selfless service to our community during this tough time"*
	Hospital Administration	➢ Security personnel monitoring visitors for COVID appropriate behaviour ➢ Triage system to identify COVID-19 suspects ➢ Quarantine for HCWs as per protocol	*"We have separate triaging system to screen the patients for COVID-19 related symptoms and refer them for testing before sending to non-COVID areas of hospital"* *"Our hospital provides quarantine for minimum 10 days post-COVID duty; This makes us not to get overwhelmed with the caseload or work tension"*

	Health System	➢ Support in outsourcing manpower & equipment ➢ Advanced IEC materials for awareness sessions ➢ Mobile phones for patients to communicate with their family	*"Local administration has helped us immensely in outsourcing the sanitary workers and equipments like ventilators during COVID times"* *"District collector has arranged 50 mobile phones for the COVID patients to talk to their families; This was helpful in providing psychological support to patients"*
Medication Safety	**Healthcare workers**	➢ Interest in undertaking pharmacogenomic studies	*"I ask my assistant professors to take up pharmacogenomic studies; relation between area and drugs; So, if we can do that for the patients it will be good"*
	Hospital Administration	➢ Regular meeting and audits of pharmacovigilance committee ➢ Regular training for handling emergency ADR ➢ "10R" checklist for drug administration	*"Every staffs go through repeated training to handle adverse reactions"*

	Health System	➢ Clinical pharmacology wings at district level	*"Clinical pharmacology wing has been set up in districts; They will monitor the drug reactions happening in all the facilities"*
Procedural and Device Safety	**Patient**	➢ Satisfaction among delivered mothers in LAQSHYA certified facilities	*"Mothers who undergone delivery in our facility were very much satisfied with our quality of service; LAQSHYA certification helped in achieving this and it might even shift the patient's attitude towards government facility from private hospitals if we get some additional certifications"*
	Hospital Administration	➢ Recruitment and refresher training on safe procedural practices ➢ Mercury spill kit and training ➢ Standardized protocol for major procedures ➢ Knowledge about standardized procedures through accreditation process	*"We conduct training for all the staffs who are newly recruited and also refresher training every year to ensure that all the medical procedures are conducted safely on our patients"* *"We have a ready-to-use mercury spill kit in case of emergencies like accidental leakage of mercury devices; We are also given training on how to handle such situations"*

			"We didn't know there is a protocol for everything but, after this (Laqshya), we got to know many things e.g., Temperature charts should be there etc., we were doing things before but now it is in a more organized manner"
Patient Safety Research	**Patient**	➢ Patients Cooperation	*"Patients are cooperative in taking part of research studies and satisfactory surveys"*
	Healthcare workers	➢ Motivated Faculties in medical colleges to conduct patient safety research	*"We want to carry out research on patient safety related questions, if we are given the required support from administration"*

Theme 2: Challenges in implementation of National Patient Safety Implementation Framework across public healthcare facilities in Tamil Nadu:

Subtheme 2.1: Structural Support for Quality & Safety

First, poor cooperation from the patient side was reported as a major barrier for the hospitals to obtain the accreditation process. HCWs have reported that they are overburdened with the clerical works associated with the certification process, rendering them unable to give 100% in patient care.

A 53-year-old male Nursing Superintendent in a GH has said that,

"We are overloaded with clerical works, so we are not able to give our 100% to patient care"

Challenged faced by hospital administration to obtain accreditation were the lack of infrastructure, basic facilities like canteen, toilet, spacious wards, disabled and elderly friendly facilities, equipment, manpower necessary for accreditation. HCWs from some facilities have also reported that they did not see any structural or technological improvement over the past few years.

A 57-year-old male Medical Superintendent in a medical college has said that,

"We did not have any improvement in terms of facilities, infrastructure or technology in our facility since 2016"

At health system level, there are many vacancies that are left unfilled, and the staffs are also being rotated between the facilities after provision of necessary training. This interrupts the flow of care and accreditation process across the various healthcare facilities.

A 45-year-old female OG Professor in a Medical College has said that,

"We have received LAQSHYA certificate but sustaining it becomes challenging especially with shortage of staffs. Nurse whom we train here for a good time by the time they learn properly they get rotated and it becomes difficult for us"

Subtheme 2.2: Hospital Infection Control

Crowding and lack of cooperation from the patient side has been a major challenge in maintaining the infection control practices at healthcare facilities.

A 50-year-old female head of HICC in a medical college has said that,

"Patient cooperation is must; people get crowded inside ICU"

Challenges faced from the HCW side are their difficulty in adapting to newer protocols/guidelines, and lack of time to review the records and registers. Some staffs in HICC department are reported to be unaware of their job responsibilities. At hospital administration level, major barriers were the ongoing COVID-19 crisis, which lead to difficulty in coordinating the routine HICC activities and surveillance.

Lack of manpower provision for HICC activities and paper-based reporting system were reported as the major challenges at the health system level.

A 55-year-old female Head of Microbiology department in a Medical College has said that,

"If they give four technicians, I can do a good job. we are overworked. these documentation need manpower…"

Subdomain 2.3: Biomedical Waste Management

Though patients from urban areas are aware about the hazards of biomedical wastes and reported as a facilitating factor, patients visiting from rural areas are unaware about such hazards, doesn't understand the seriousness of BMW and are responsible for constant littering around the hospital campus.

A 45-year-old female OG Professor in a Medical College has said that,

"Despite the rule of one or two attenders many people come and crowd the ward areas they litter and do not bother to keep the place clean"

At the HCW level, lack of motivation to attend the BMW management training, non-compliance to standard BMW guidelines, and job insecurity were reported as some of the challenges in maintaining proper BMW management practices in the hospital.

A 55-year-old female Head of Microbiology department in a Medical College has said that,

"They are not interested or overworked we put training for ten people but four turn up"

At hospital administration level, lack of monitoring system for BMW practices and absence of sewage treatment plant was reported as the major challenges. At health system level, there is insufficient supply of materials required for BMW management like buckets, covers, closed bins, gloves, bags & masks. Hospitals also face challenges in solid waste management as it comes under the municipality.

A 55-year-old female Head of Microbiology department in a Medical College has said that,

"This (solid waste management) is under municipality here... so they have to dump in a village... sometimes the villagers come and fight for this... this affects proper management... if it was under a corporate thing... this won't be an issue"

Subdomain 2.4: Blood Safety

Donors engaging in high-risk behaviors like alcohol intake, drug use or sexual promiscuity and professional donors selling the blood for monetary benefits has been the most important challenge in blood safety reported at patient level.

A 52-year-old female head of transfusion committee in a medical college has said that,

"Some people who come for blood donation engage in high-risk behaviors like alcohol, drugs, sexual promiscuity"

She also went on to say that,

"*There are professional donors who sell blood for money, people still fear for blood donation they go for professional donors*"

Poor maintenance of records and logs by the staffs have been reported as a challenge at HCW level. At hospital administration level, COVID-19 crisis has led to failure in conducting blood donation camps. patient representation in framing blood safety policies, conducting awareness programs and application of latest technologies were some of the facilitating factors in ensuring blood safety.

At health system level, poor supply of blood transfusion materials like blood bag & pouches, tubing & other blood collection materials and non-allocation of manpower dedicated to blood transfusion services and availability of only blood storage facility in some GHs were reported as the major challenges presenting to maintain the blood safety practices.

A 49-year-old female staff nurse working as blood storage in-charge in a GH has said that,

"Currently we have storage facility alone, we can do better if we have blood bank so that we do not wait for the other facility"

Subdomain 2.5: Antimicrobial Stewardship

Major challenge in antimicrobial practices presenting from the patient side was the self-medication with higher level antibiotics. It in turn can present as a major factor responsible for antimicrobial resistance. HCWs present certain challenges in antimicrobial practices as they were reported to be non-compliant to ICMR guidelines for antibiotic prescription and mostly prescribe high-end antibiotics.

A 55-year-old female head of microbiology department in a Medical College has said that,

"Some of them (doctors) think higher antibiotics will work and ask the patients to take from local purchase"

Challenges reported at hospital administration level were the frequent stock-out of antimicrobials, no prescription audits, and no facility to check the culture sensitivity for antibiotic prescription. Health system also presents certain challenges like non-supply of high-end antibiotics and keeping deadline to empty the stock of antibiotics.

A 50-year-old female Medical Superintendent in a GH has said that,

"We are pushed to a situation to give out the antibiotics supplied to us"

Subdomain 2.6: COVID-19 Safety

Major patient level challenges in COVID-19 safety measures were unwillingness of patients to undergo triaging, visitors' entry into suspect/isolation ward and COVID-19 positive patients going back home against the doctor's order during their infectious period.

A 35-year-old female Chief Medical Officer in a GH has said that,

"*COVID positive patients are not staying in hospital and going back to home without listening to our orders and come back whenever they feel like"*

Challenges faced by HCWs were the hectic work schedule and excess workload while doing COVID-19 duties. At hospital administration level, there was no dedicated staffs for doing COVID-19 duty, leading to mixing of staffs between COVID and non-COVID area of the hospital. At health system level, non-compliance to instructions from hospital was reported during this COVID-19 crisis.

A 50-year-old male Medical Superintendent in a Medical College has said that,

"Some field staffs do not comply to our instructions, especially transporting the positive patients even when we say that we do not have beds for them"

Subdomain 2.7: Medication Safety

At patient level, discontinuing the medications following any ADR without informing the consulting doctor was reported as a major challenge in ensuring safe medication practices. At HCW level, unwillingness to follow standard protocol and staffs not reporting the near-expiry or expired drugs on time to the hospital administration were reported as important challenges to medication safety. At hospital administration level, there was lack of awareness about the reporting of ADR in some GHs. At health system level, there was a delay or even non-monitoring of ADR reported from the facilities.

A 59-year-old male Chief Medical Officer from a GH has reported that,

"We neither did not know that we need to report adverse reactions nor procedure to do it"

A 52-year-old female Head of Pharmacology from a medical college has reported that,

"Because of ignorance they (patients) will not know that the problem they are facing is because of the drug (they take) and they will be taking alternate medicines or alternate medical treatment"

Subdomain 2.8: Procedural and Device Safety

Patient's obsession towards unnecessary treatment and procedures has been a major challenge in ensuring procedural and device safety. Like medication and antimicrobial safety, non-compliance of HCWs to standard guidelines is a major hindering factor in ensuring procedural and device safety. At hospital administration level, lack of manpower and equipment were mentioned as the major challenge. At health system level, there is only one biomedical engineer for each district. This led to overburdening of work and delay in servicing or repair of equipment in OT. It was also reported that there is lack of infrastructure, staffs, and servicing of equipment under CSSD.

A 31-year-old female doctor from microbiology department in a GH has said that,

"We don't have enough infrastructure to carry out CSSD activities; We don't even have an autoclave; In our hospital, only a signage of CSSD is present for NQAS purpose"

A 31-year-old female physician in a GH has said that,

"Patients are obsessed in demanding for injection & CT scan"

A 54-year-old male head of anaesthesia department in a medical college has said that,

"There is one biomedical engineer for whole district…quality of work reduces due to availability"

Subdomain 2.9: Patient Safety Research

Though faculties in medical colleges are motivated to conduct research, major hindering factors to initiate the process were lack of awareness about the theme "patient safety", lack of support from hospital administration, lack of facilities or funds for conducting the research.

A 57-year-old male Medical Superintendent in a medical college has said that,

"We are not given any funds to conduct research on any topics, leave alone patient safety theme"

Table 20: Challenges in implementation of National Patient Safety Implementation Framework across public healthcare facilities in Tamil Nadu

Theme: Challenges in implementation of National Patient Safety Implementation Framework			
Subthemes	**Categories**	**Codes**	**Quotes**
Structural System for Quality & Safety	**Patient**	➢ Poor patient cooperation	*"Lack of patient cooperation to adhere to certain guidelines makes the certification process difficult for us"*
	Healthcare workers	➢ Overburdened with clerical works	*"We are overloaded with clerical works, so we are not able to give our 100% to patient care"*
	Hospital Administration	➢ Lack of infrastructure necessary for accreditation ➢ Lack of basic facilities (*spacious wards, canteen, toilet, ramps for disabled, non-slippery floors and rails for elderly*) ➢ Lack of equipment necessary for accreditation ➢ Shortage of manpower necessary for accreditation ➢ Fund spending within deadline	*"We have enough funds but carry over option would be a better option; we can perform better when the funds don't come with the expiring date"* *"We did not have any improvement in terms of facilities, infrastructure or technology in our facility since 2016"*

		➢ No structural/technological improvement ➢ No stress management classes for staffs	
	Health System	➢ Rotation of staffs between facilities ➢ Unfilled vacancies of various posts ➢ Delay in funding	*"Only one lab technician will go here & there, he will do everything. With the new future of NABH if they give a couple of lab technician then it can be easier"* *"We have received LAQSHYA certificate but sustaining it becomes challenging especially with shortage of staffs. Nurse whom we train here for a good time by the time they learn properly they get rotated and it becomes difficult for us"*
Hospital Infection Control	**Patient**	➢ Overcrowding and uncooperative patients	*"Patient cooperation is must; people get crowded inside ICU"*
	Healthcare workers	➢ Difficulty in adapting to newer protocols ➢ No time to review records and logs ➢ HICC staffs unaware of job responsibilities	*"Suddenly, some new guidelines come up and we have to adapt immediately to that protocol; this is difficult especially during the initial few weeks"*

	Hospital Administration	➢ COVID-19 crisis affects HICC coordination	*"We are not able to meet regularly for HICC meetings due to COVID-19"*
	Health System	➢ Manpower shortage for HICC ➢ Paper based reporting system for HICC	*"If they give four technicians, I can do a good job. we are overworked. these documentation need manpower…"*
Biomedical Waste Management	**Patient**	➢ Poor awareness about hazards of biomedical waste ➢ Patient crowding & littering inside hospital campus	*"Even after repeated instructions, patients and their attenders still keep facility unclean and throw wastes throughout hospital campus"* *"Despite the rule of one or two attenders many people come and crowd the ward areas they litter and do not bother to keep the place clean"*
	Healthcare workers	➢ Lack of motivation to attend BMWM training ➢ Non-compliance to standard guidelines ➢ Job insecurity among contractual workers ➢ Outsourced staff intake alcohol during duty hours	*"They are not interested or overworked we put training for ten people but four turn up"* *"Most of them are aware, even our students are aware but only staff nurse and lower cadre people follow it, to my knowledge the house surgeon can do*

			better by segregating the waste at the place of collection"
	Hospital Administration	➢ Irregular inspection for appropriate BMW disposal ➢ Lack of sewage treatment plant	*"We are already overburdened with so much administrative work; We don't have enough staffs to allot for monitoring the biomedical waste disposal in our hospital"*
	Health System	➢ Insufficient supply of BMW management materials (buckets, covers, closed bins, gloves, bags & masks) ➢ Challenge in solid waste management under municipality ➢ Lack of manpower to transport BMW to storage facility	*"We don't have separate manpower to take the biomedical wastes to storage facility"* *"This (solid waste management) is under municipality here... so they have to dump in a village... sometimes the villagers come and fight for this... this affects proper management... if it was under a corporate thing... this wont be an issue"*
Blood Safety	**Patient**	➢ Blood donors engage in high-risk behavior ➢ Professional donors selling blood for money	*"Some people who come for blood donation engage in high-risk behaviors like alcohol, drugs, sexual promiscuity"*

			"*There are professional donors who sell blood for money, people still fear for blood donation they go for professional donors*"
	Healthcare workers	➢ Poor logs and record maintenance by staffs	*"Staffs usually put new registers at the start of the year and maintain it for only few days at the start of year; after that, nothing will be entered in the registers"*
	Hospital Administration	➢ COVID-19 crisis led failure in blood donation camps and manpower training	"*Because of COVID blood donation camps are not being conducted, so we have to go for replacement donors"*
	Health System	➢ Shortage of manpower for transfusion services ➢ Only blood storage facility available in some GHs ➢ Poor supply of blood transfusion materials (*blood bag & pouches, tubing & other blood collection materials*)	*"Currently we have storage facility alone, we can do better if we have blood bank so that we do not wait for the other facility"*
Antimicrobial Stewardship	**Patient**	➢ Self-medication with high level antibiotics ➢ OOPE due to unavailability of high-end antibiotics	*"Some patients do not follow doctor's advice and take some high-end*

			antibiotics from their local pharmacy if the symptom persists for even two days"
	Healthcare workers	➢ Non-compliance to ICMR antibiotic guidelines ➢ Lack of awareness about prescription audits	*"Some of them (doctors) think higher antibiotics will work and ask the patients to take from local purchase"*
	Hospital Administration	➢ Frequent stock-out of antimicrobials ➢ Lack of facilities to perform culture sensitivity ➢ No prescription audits	*"We don't have lab facility to look for the cultures and treat patients accordingly"*
	Health System	➢ Non-availability of high-end antibiotics ➢ Antibiotic supply with a deadline to empty stocks	*"We are pushed to a situation to give out the antibiotics supplied to us"*
COVID-19 Safety	**Patient**	➢ Restless patients during triaging ➢ Visitors entering COVID-19 suspect/isolation ward ➢ COVID patients goes home against doctor's orders	*"By the time I provide bed, there is a complaint lodged against me with administration or dean that they are not providing bed because we triage the patients depending upon the severity of the patient"* *"COVID positive patients are not staying in hospital and going back to*

			home without listening to our orders and come back whenever they feel like"
	Healthcare workers	➢ Excess workload and hectic duty schedule	*"We have excess workload and hectic duty schedule due to COVID-19 positivity of many staffs"*
	Hospital Administration	➢ No dedicated staff for doing COVID-19 duty	*"There are no dedicated staffs for doing COVID duty; we have to return back to non-COVID area after a week; this exposes more number of staffs and patients to be exposed"*
	Health System	➢ Non-compliance to instructions from hospitals	*"Some field staffs do not comply to our instructions, especially transporting the positive patients even when we say that we do not have beds for them"*
Medication Safety	**Patient**	➢ Discontinuing medications following ADR	*"Because of ignorance they (patients) will not know that the problem they are facing is because of the drug (they take) and they will be taking alternate medicines or alternate medical treatment"*

	Healthcare workers	➢ Unwillingness to comply with standard guidelines ➢ Non-reporting of near expiry or expired drugs to hospital administration	*"Doctors are not willing to follow the standard guideline as they follow their own clinical practice"*
	Hospital Administration	➢ Lack of awareness about ADR reporting in GHs	*"We neither did not know that we need to report adverse reactions nor procedure to do it"*
	Health System	➢ Delay or non-monitoring of ADR events	*"Even when we report about any adverse drug reactions on time to district health authorities, the monitoring and subsequent action for those events are either delayed or not happening at all"*
Procedural and Device Safety	**Patient**	➢ Obsession towards unnecessary injections & procedures	*"Patients are obsessed in demanding for injection & CT scan"*
	Healthcare workers	➢ Unwillingness to comply with standard guidelines ➢ CSSD staffs unaware of job responsibilities	*"Doctors are not willing to follow the standard guideline as they follow their own clinical practice"*
	Hospital Administration	➢ Lack of manpower in CSSD ➢ Shortage of equipment ➢ Delayed repair/servicing of the equipment	*"We require medical equipment, because of the shortage we are not able to perform some procedures or provide complete care to the patients"*

		➢ Rotation of CSSD staffs after training ➢ Lack of infrastructure for CSSD activities	*"CSSD staffs are rotated to other departments after training; This makes us to give excess undue training to new set of staffs; monitoring can happen effectively if they are kept in one place"* *"We don't have enough infrastructure to carry out CSSD activities; We don't even have an autoclave; In our hospital, only a signage of CSSD is present for NQAS purpose"*
	Health System	➢ Non-availability of biomedical engineer	*"There is one biomedical engineer for whole district…quality of work reduces due to availability"*
Patient Safety Research	**Healthcare workers**	➢ Lack of awareness about patient safety theme ➢ Lack of motivation to conduct research	*"We are unaware about the theme "patient safety" and hence we have not undertaken research on this topic"*
	Hospital Administration	➢ No communication about undertaking research on patient safety theme ➢ Lack of administrative support	*"Though, we are interested in doing research on patient safety related topics, we do not have the administrative support to do research"*

		➢ Lack of facility or setup to conduct research	*"We do not have enough facilities to do some advanced patient safety related studies like pharmacogenomic studies"*
	Health System	➢ Scarcity of funds for conducting research	*"We are not given any funds to conduct research on any topics, leave alone patient safety theme"*

Theme 3: Suggestions to overcome the challenges in implementation of National Patient Safety Implementation Framework across public healthcare facilities in Tamil Nadu:

Subtheme 3.1: Structural Support for Quality & Safety

Major suggestion reported at HCW level during the interviews were the proper maintenance of records and logs to ensure smooth accreditation process. To overcome the challenge posed by lack of poor cooperation, HCWs were suggested to follow "service with a smile" during service delivery as it will help to reduce the mental stress of the patients.

A 56-year-old male Dean in a medical college has said that,

"Good communication between doctor and patient should be there, they(doctors) should try to reduce mental pressure of patients (regarding any disease or treatment); "Service with a smile" should be the motto"

At hospital administration level, the following suggestions were provided to ensure structural support for quality & safety: working towards NQAS and NABH accreditation, conducting patient satisfactory survey, proper Health Management Information System (HMIS), CME & training, and signage board with list of available services to help the patients understand the service delivery of the hospital.

A 50-year-old female Medical Superintendent in a GH has said that,

"NQAS, NABH acts like an indicator to improve patient safety in a facility, so it is very essential achieving those standards"

At health system level, the common suggestions provided were filling the existing vacancies across all the facilities and recruiting additional manpower for the purpose of accreditation, filling posts like Dean/MS/RMO with doctors having qualification & experience in hospital

administration, regularly conducting CME/Workshops/Trainings on any newer updates or frameworks, carryover option for funding, separate wing for each domain of the patient safety and finally addition of "patient safety" theme in the medical, dental and allied sciences curriculum.

A 57-year-old male Medical Superintendent in a Medical College has said that,

"Separate wing can be made at district level for all these domains of patient safety; they can regularly monitor the proper implementation of services under that particular domain"

Subtheme 3.2: Hospital Infection Control

Regular surveillance by a team of HCWs was suggested to tackle the challenges on hospital infection control practices. At hospital administration level, it was suggested that the infection control measures taken during COVID-19 crisis like installing hand wash basins, placement of hand sanitizers in various places of hospital campus should be sustained during the post-pandemic period also. In addition, it was suggested to undertake measures like audiovisual demonstration of infection control practices in patient waiting area, automated based data handling and review, root cause analysis and brainstorming for problem solving. At health system level, it was recommended to have a separate panel of experts at district level to monitor and supervise the hospital infection control measures.

A 54-year-old male Resident Medical Officer in a GH has said that,

"We can conduct root cause analysis and brainstorming as a part of HICC activity to undertake corrective and preventive actions for hospital infection control"

A 55-year-old male Resident Medical Officer in a GH has said that,

"The hygiene practices implemented during COVID times like putting wash basin at main gate and using sanitizers are good habits and should be continued"

Subdomain 3.3: Biomedical Waste Management

Recommendations at patient level was that the patient should follow "no waste littering policy" and should be made aware of "Our Hospital" concept. It was also suggested that it is the responsibility of HCWs to educate the patients on the seriousness of the BMWs. Recommendations at hospital administration were continuous training, support, and provision of exclusive staffs for BMW management. At health system level, uninterrupted supply of BMW management materials like buckets, covers, closed bins for trolleys, gloves, bags, masks were suggested.

A 47-year-old female staff nurse under BMW management committee has said that,

"We need some exclusive staffs for collecting and transporting biomedical wastes"

Subdomain 3.4: Blood Safety

At patient level, recommendations suggested for ensuring blood safety practices was the representation of patients in blood transfusion committee. This will enable the hospital to frame patient friendly blood safety policies and cooperation during blood donation camps and awareness sessions. At HCW level, the major recommendation was to educate the patients about the importance of blood donation.

A 52-year-old female head of transfusion committee in a medical college has said that,

"There can be representation of patients in the transfusion committee to frame patient-friendly policies"

At hospital administration level, recognition of blood donors and ensuring medico-legal safety for blood handlers were the major recommendations. At health system level, it was suggested that a separate medical officer-in-charge can be recruited for the blood transfusion services in all the secondary and tertiary care facilities.

A 45-year-old male blood bank medical officer in a medical college has said that,

"In organ donation, the recipient knows the donor and they will feel properly acknowledged, but in blood donation, the recipient patient will not know who donated the blood and saved their lives. Hence, blood donors should also be acknowledged as a life-saviour"

Subdomain 3.5: Antimicrobial Stewardship

Recommendation at patient level was to ensure that the patients trust their doctors and take only prescribed antibiotics in dose, duration and interval for antibiotic use and avoid unnecessary use. At HCW level, the major recommendation was to check the appropriateness of antibiotic usage using pill count method during the follow-up visit of patients.

A 48-year-old male head of pharmacovigilance committee in a Medical College has said that,

"Doctors should follow pill count method to ensure that the patients complied to their advice and used antibiotics appropriately"

Recommendations reported at hospital administration level were to send a directive for all the clinical departments regarding appropriate antibiotic usage, regularly updating the antibiotic formulary and regular training on antibiotic prescription. Health system can also undertake certain innovative practices like digitally monitoring the antibiotic usage through a separate wing of experts and staffs, inclusion of antimicrobial stewardship in medical, dental, and allied health sciences curriculum.

A 48-year-old male head of pharmacovigilance committee in a Medical College has said that,

"Antibiotic usage in all the government hospitals should be monitored through any app or software"

Subdomain 3.6: COVID-19 Safety

Recommendation at patient level challenges in COVID-19 safety measures were creation of patient testimonials on the care provided in government hospitals for COVID-19 treatment. Displaying such testimonials might motivate other suspect patients to seek care immediately without any hesitancy on quality of care at government hospitals. Health system should also recognize the service provided by GH & medical colleges for the handling of COVID-19 crisis through appreciation and rewards.

A 56-year-old male Medical Superintendent in a GH has said that,

"Recognition of the service provided by us especially for not referring back any patients even during such high caseload would further motivate us"

Subdomain 3.7: Medication Safety

At patient level, health literacy ("*ability to get, process, understand and apply health information and services in order to make appropriate health decisions"*) is an important factor necessary for ensuring medication safety. HCWs should educate the patients about ADR before prescribing any medications. This will enable the patients to anticipate the possible ADR and understand what need to be done or when to seek care from healthcare facility. This will also increase the compliance to medications as the patients skipping the dose of medications due to ADR was reported as a major challenge in ensuring medication safety.

A 48-year-old female head of pharmacology from a medical college has reported that,

"Patient should also be educated about the possible adverse reaction whenever any drugs are prescribed for them"

Several recommendations were provided at hospital administration level like cross-checking high end antibiotic prescription, celebrating pharmacovigilance week to improve the awareness among patients and HCWs about medication safety, repeated training on handling ADR, and electronic drug ordering system.

A 52-year-old female Head of Pharmacology from a medical college has reported that,

"Celebrating pharmacovigilance week once a year will increase its awareness among the patients, staffs and public"

At health system level, the following initiatives can be taken to ensure medication safety: developing a reporting system/surveillance system for minor ADR, ensuring uninterrupted & sufficient antibiotic stocks, and making high-end antibiotics available at secondary and tertiary care facilities.

A 52-year-old female Head of Pharmacology from a medical college has reported that,

"From the hospital side, they are only reporting serious reactions, so they should be encouraged to report even the milder reaction what we routinely see as some patients are dropping out due to such minor reactions also"

Subdomain 3.8: Procedural and Device Safety

Recommendations for ensuring procedural and device safety at hospital administration level were utilizing a standardized safe surgical checklist, ensuring proper calibration of all the electronic BP apparatus, annual maintenance of equipment and arranging clinical society meeting for doctors to update themselves on the challenges faced during major procedures across specialties. Health system can also allot one biomedical engineer per facility instead of one engineer per district to ensure regular servicing of the equipment and overcoming the delay in repairing any equipment necessary for major procedures.

A 56-year-old male Medical Superintendent from a GH has said that,

"One Biomedical engineer for entire district hence, workload is increased… If we have one biomedical engineer for each government hospital, we can improve the quality of service we provide"

Subdomain 3.9: Patient Safety Research

Hospital administration should ensure enough support and encouragement for the HCWs to undertake research in area of patient safety. Health system should also allocate funds or grants for the government hospitals/medical colleges to conduct research on any topics under the patient safety theme.

A 57-year-old male Medical Superintendent in a medical college has said that,

"Though, we are interested in doing research on patient safety related topics, we do not have the administrative support to do research… If we have enough support from the administration, we will perform patient safety studies"

Table 21: Suggestions to overcome the challenges in implementation of National Patient Safety Implementation Framework across public healthcare facilities in Tamil Nadu

Theme: Suggestions to overcome the challenges in implementation of National Patient Safety Implementation Framework			
Sub-themes	**Categories**	**Codes**	**Quotes**
Structural System for Quality & Safety	**Healthcare workers**	➢ Proper maintenance of records, registers, logs ➢ "Service with smile"	*"Good communication between doctor and patient should be there, they(doctors) should try to reduce mental pressure of patients (regarding any disease or treatment); "Service with a smile" should be the motto"*
	Hospital Administration	➢ Working towards NQAS and NABH accreditation ➢ Conducting patient satisfactory survey ➢ Proper HMIS system ➢ Continuing Medical Education & Training ➢ Signage board with list of available services	*"NQAS, NABH acts like an indicator to improve patient safety in a facility, so it is very essential achieving those standards"* *"Patient satisfactory survey will help us to know our performance level"*
	Health System	➢ Improving doctor-patient & nurse-patient ratio ➢ Filling vacancy & recruiting additional manpower	*"Initiatives should be taken to regularly update or train doctors on these newer*

		➢ CME/Workshops/Trainings on newer updates ➢ Permanentize trained contractual staffs ➢ Manpower to handle clerical works & data entry ➢ Carryover option for funding ➢ Incentivization/increment for quality-related work ➢ Separate wing for each domain of patient safety ➢ Conflict management & stress management classes ➢ Making all the GHs into training centre ➢ Filling posts like Dean/MS/RMO with doctors having qualification & experience in hospital administration ➢ Addition of "patient safety" theme in curriculum	*guidelines like NPSIF at directorate level"* *"Dedicated data entry operator for handling data and management so that we can focus on patient safety better"* *"Funding is not sufficient for us. It will be good if we have increment or provided with the incentives for the additional quality related work we do"* *"Separate wing can be made at district level for all these domains of patient safety; they can regularly monitor the proper implementation of services under that particular domain"* *"Every GHs should be turned into a training centre; This will make everyone know about newer updates/guidelines"*

Hospital Infection Control	**Healthcare workers**	➢ Surveillance by team of HCWs on daily basis	*"Committee should form a team and they should monitor every day the hand hygiene practices, biomedical waste disposal and CSSD equipment"*
	Hospital Administration	➢ Sustaining COVID-19 infection control measures ➢ Audiovisual demonstration of infection control practices in patient waiting area ➢ System based data handling ➢ Root cause analysis and brainstorming	*"The hygiene practices implemented during COVID times like putting wash basin at main gate and using sanitizers are good habits and should be continued"* *"We can conduct root cause analysis and brainstorming as a part of HICC activity to undertake corrective and preventive actions for hospital infection control"*
	Health System	➢ District-level panel of experts for monitoring & supervision	*"A separate panel of experts at district level can be made to monitor and supervise the hospital infection control practices in all the facilities in district"*
Biomedical Waste Management	**Patient**	➢ Follow "no waste littering policy"	*"Patients should comply to no waste littering policy during their visit"* *"Patient should be made aware to the concept of "our hospital"*

	Healthcare workers	➢ Awareness generation about hazards of BMW	*"Staffs should generate awareness among the patients regarding the harm of bio-medical wastes during their visit"*
	Hospital Administration	➢ Continuous training, encouragement, and support ➢ Exclusive staffs for biomedical waste management	*"We need some exclusive staffs for collecting and transporting biomedical wastes"*
	Health System	➢ Uninterrupted supply of BMW management materials	*"We need uninterrupted supply of buckets, covers, closed bins for trolleys, gloves, bags, masks"*
Blood Safety	**Patient**	➢ Patient representation in transfusion committee	*"There can be representation of patients in the transfusion committee to frame patient-friendly policies"*
	Healthcare workers	➢ Educating patients about voluntary blood donation	*"Patients should be educated about blood donation and properly encourage voluntary blood donation"*
	Hospital Administration	➢ Acknowledgement & recognition of blood donors ➢ Ensuring Medico-legal safety for blood handlers	*"In organ donation, the recipient knows the donor and they will feel properly acknowledged, but in blood donation, the recipient patient will not know who donated the blood and saved their lives.*

			Hence, blood donors should also be acknowledged as a life-saviour"
	Health System	➢ Recruitment of separate medical officer-in-charge	*"There should be a separate medical officer for blood bank, one person should not be held responsibilities of 2 departments"*
Antimicrobial Stewardship	**Patient**	➢ Trust in doctors	*"Patients should trust their doctors and comply with the dose, duration and interval for antibiotic use and avoid unnecessary use"*
	Healthcare workers	➢ Pill count during patient follow-up	*"Doctors should follow pill count method to ensure that the patients complied to their advice and used antibiotics appropriately"*
	Hospital Administration	➢ Directive to follow ICMR guidelines ➢ Regularly updating antibiotic formulary ➢ Regular training on antibiotic prescription	*"All the doctors should be ordered strictly to follow ICMR guidelines while prescribing antibiotics"*

	Health System	➢ Digitally monitoring the antimicrobial usage ➢ Curriculum focusing on antimicrobial stewardship	*"Antibiotic usage in all the government hospitals should be monitored through any app or software"*
COVID-19 Safety	**Patient**	➢ Patient testimonials	*"Patient testimonials about their hospital experience, importance of seeking care might help in reducing the delay in treatment seeking behaviour and help build trust in government hospital for COVID care"*
	Health System	➢ Recognition and appreciation of medical colleges/GHs	*"Recognition of the service provided by us especially for not referring back any patients even during such high caseload would further motivate us"*
Medication Safety	**Patient**	➢ Health literacy	*"People should enable themselves to understand their health situation and follow doctor's advice on appropriate services for condition; This can prevent them from having unnecessary procedures"*

	Healthcare workers	➢ Educating patients about adverse drug reactions ➢ Pharmacogenomic studies	*"Patient should also be educated about the possible adverse reaction whenever any drugs are prescribed for them"* *"I ask my assistant professors to take up pharmacogenomic studies… so if we can do that for the patients it will be good"*
	Hospital Administration	➢ Cross-checking high end antibiotic prescription ➢ Celebrating pharmacovigilance week ➢ Repeated training on handling ADR ➢ Conducting prescription audit ➢ Electronic drug ordering system	*"Celebrating pharmacovigilance week once a year will increase its awareness among the patients, staffs and public"* *"Every staff should go through repeated training to handle adverse reactions"*
	Health System	➢ Reporting system/Surveillance of minor ADR ➢ Uninterrupted & sufficient antibiotic stocks ➢ Availability of high-end antibiotics ➢ Generic drug prescription by private practitioners	*"From the hospital side, they are only reporting serious reactions, so they should be encouraged to report even the milder reaction what we routinely see as some patients are dropping out due to such minor reactions also"* *"Even for the private practitioners we should ask to write the generic*

			(medicines) so that it is easy and will reduce medication errors"
Procedural and Device Safety	**Hospital Administration**	➢ Standardized safe surgical checklist ➢ Proper calibration of BP apparatus ➢ Annual maintenance of equipment ➢ Clinical society meeting for doctors	*"All the hospitals should have uniform safe surgical checklist; the surgeons and theatre staffs should be trained on the checklist"*
	Health System	➢ Dedicated biomedical engineer ➢ Multi-storage & engineering support system for repairing/servicing equipment	*"One Biomedical engineer for entire district hence, workload is increased… If we have one biomedical engineer for each government hospital, we can improve the quality of service we provide"*
Patient Safety Research	**Hospital Administration**	➢ Encouragement and support to faculties	*"Though, we are interested in doing research on patient safety related topics, we do not have the administrative support to do research… If we have enough support from the administration, we will perform patient safety studies"*
	Health System	➢ Fund allocation/grants	*"If we have enough fund to do the projects, we are very much willing to do studies on patient safety theme"*

Table-22 shows the best and innovative practices followed by the surveyed public health facilities in Tamil Nadu. Most of the surveyed facilities had some best or innovative practices that can be adopted across all the secondary and tertiary care facilities in Tamil Nadu. First, we have discussed the best practices amongst the medical colleges.

Tirunelveli Medical College was the only facility having dedicated biomedical engineer stationed inside the college campus. Trichy Medical College was the only facility utilizing the WHO NET software for automated data entry and review in microbiological practices. This has enabled them to ease the process of data entry & review and avoid the burdens associated with manual entry. Salem Medical College had performed research on the topics related to the patient safety theme. Pudukkottai Medical College had a core committee monitoring the activities of all the committees in hospital. This can be readily converted into patient safety committee of the hospital and ensure proper implementation of NPSIF in their facility. In Villupuram Medical College, the competency of staffs in handling institutional deliveries are assessed through Dakshata checklist (developed based on WHO Safe Childbirth Checklist). Theni Medical College was the only facility with dedicated antimicrobial stewardship committee. They also have the unique HMIS version 2.0 and the first ICMR sponsored VRDL laboratory in South India.

Tenkasi and Tindivanam GH perform regular patient satisfactory survey to understand and improve their quality of services. Ambasamudram GH had patient representation in framing the blood safety policies of the hospital. Srirangam GH had liaison with community organizations like Rotary and Lions Club for conducting blood donation camps, awareness campaigns, mask distribution drives and coordination of outreach activities in the hospital. Musiri GH has dedicated staff for coordination of NQAS activities, while Periyakulam GH has a dedicated quality control team. In Musiri and Attur GH, advanced managerial techniques like root cause analysis and fish bone diagram are applied to identify the problems

and take corrective and preventive actions to address the identified problems. For example, the pharmacy in Attur GH has a fish bone diagram depicting the possible reasons for long waiting time in the pharmacy. The diagram also contains the corrective and preventative actions to be taken to reduce the waiting time of patients. Attur GH also utilize the "10R" checklist (10 rights checklist – "right patient, right reason, right drug, right route, right time, right dose, right form, right action, right documentation, and right response") for safe multidisciplinary drug administration. Omalur GH has a mercury spill kit, that are useful in handling emergency situations like accidental mercury leakage from medical devices.

Table-22: Best and Innovative Practices Across Surveyed Public Health Facilities in Tamil Nadu

District	Facility Name	Best /Innovative Practices
Tirunelveli	Tirunelveli Medical College	*"Dedicated biomedical engineer at the facility"*
	Government Hospital, Tenkasi	*"Patient satisfactory survey"*
	Government hospital, Ambasamudram	*"Patient representation in framing the blood safety policies of the facility"*
Tiruchirappalli	Trichy Medical College	*"Utilization of WHO NET software for automated data entry and review in microbiological practices"*
	Government Hospital, Srirangam	*"Liaison with community organizations like Rotary & Lions Club for outreach activities like blood donation camps, awareness campaigns & drives"*
	Government Hospital, Musiri	*"Dedicated staff for coordinating NQAS accreditation"* *"Root cause analysis for corrective and preventive actions"*
Salem	Salem Medical College	*"Conducts research on questions related to patient safety theme"*
	Government Hospital, Omalur	*"Mercury spill kit for accidental leakage from devices"*
	Government Hospital, Attur	*"Utilization of "10R" checklist for safe drug administration"*

		"Fish bone diagram exploring the long waiting time in pharmacy depicted"
Pudukkottai	Pudukkottai Medical College	*"Core committee monitoring the activities of all the committees in hospital"*
Villupuram	Villupuram Medical College	*"Applying Dakshata checklist to assess staff competency in safe childbirth"* *"Daily surveillance of hand hygiene practices in the hospital"*
	Government Hospital, Tindivanam	*"Patient satisfactory survey"*
Theni	Theni Medical College	*"Antimicrobial stewardship committee"* *"Celebrating pharmacovigilance week"* *"Utilization of HMIS version 2.0"* *"First ICMR sponsored VRDL laboratory in South India"*
	Government Hospital, Periyakulam	*"Dedicated quality control team"* *"Repeated training for staffs in handling adverse drug reactions"*

Figure 26-28 shows the tree map diagram made for depicting the top ten facilitating factors, challenges and recommendations reported during the qualitative interviews (depending on the frequency of the reported findings).

Obtaining/working towards obtaining the NQAS/NABH/Kayakalp certification was found to be the most common facilitating factors reported across majority of the interviews (26 out of 80) in the implementation of NPSIF. It was mainly described as the facilitating factor as it enables the hospital administration and staffs to understand the various domains of quality & safety components of patient care. This was followed by the regular training of staffs across various domains of patient safety like hand hygiene, BMW management, medications, and procedures (15 out of 80 interviews). Self-motivation of the HCWs (14), hospital administration support (13), sense of responsibility and satisfaction among HCWs (12), availability of standard protocol/SOP/checklist for patient care (8), political support in hospital activities (6), government rewards for best performing hospitals, doctors, and staffs (6), appreciation from patients (6) and anonymous patient reporting system (5) were the other factors reported under the top ten facilitating factors for NPSIF implementation (**Figure 26**).

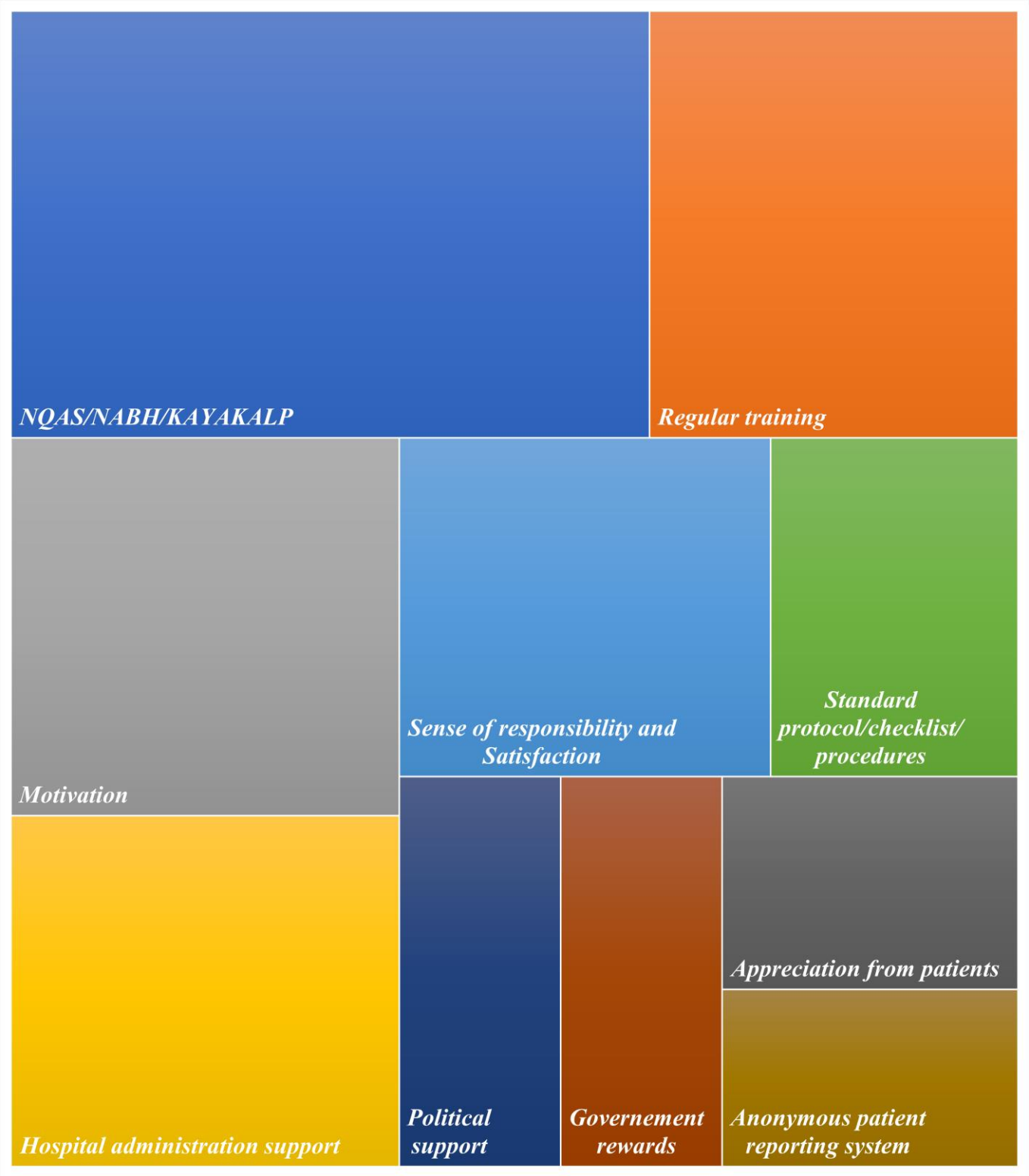


Figure 26: Treemap diagram summarizing the top ten facilitating factors reported during the qualitative interview in the application of National Patient Safety Implementation Framework across public health facilities in Tamil Nadu

Lack of manpower was the most frequently reported challenge as it was mentioned during 54 out of 80 qualitative interviews. This manpower issue comprises of the unfilled vacancies, additional manpower requirement for data entry, quality control, accreditation process, biomedical engineer etc. The next most reported challenge was the poor patient compliance (24 out of 80 interviews). This issue comprises of the poor compliance of patients towards waste disposal practices, COVID-19 appropriate behaviour (hand hygiene, mask usage and social distancing), crowding in wards/ICU/OPD, and medication intake etc. The third most reported challenge was the lack of infrastructure in terms of basic facilities like toilet, spacious wards, canteen, disabled and elderly friendly rails, ramps, and non-slippery floors, and infrastructure/building/facilities necessary for NQAS/NABH accreditation. This was followed by the funding issues (17 out of 80 interviews). Though majority of the facilities tell that they receive adequate funds, the main issue reported were the associated deadline with the funds and not able to carryover the balance funds, and delay in receiving funds. The next most common challenge reported was the overburdening of the staffs with clerical works (16 out of 80 interviews), hindering them from focusing on the patient care. The other commonly reported challenges were equipment issues like lack of equipment and delayed servicing/repairing of existing equipment (15), poor record maintenance (12), non-compliance to standard guidelines by HCWs (12), lack of training on patient safety domains (8) and non-availability of high-end antibiotics (8) (**Figure 27**).

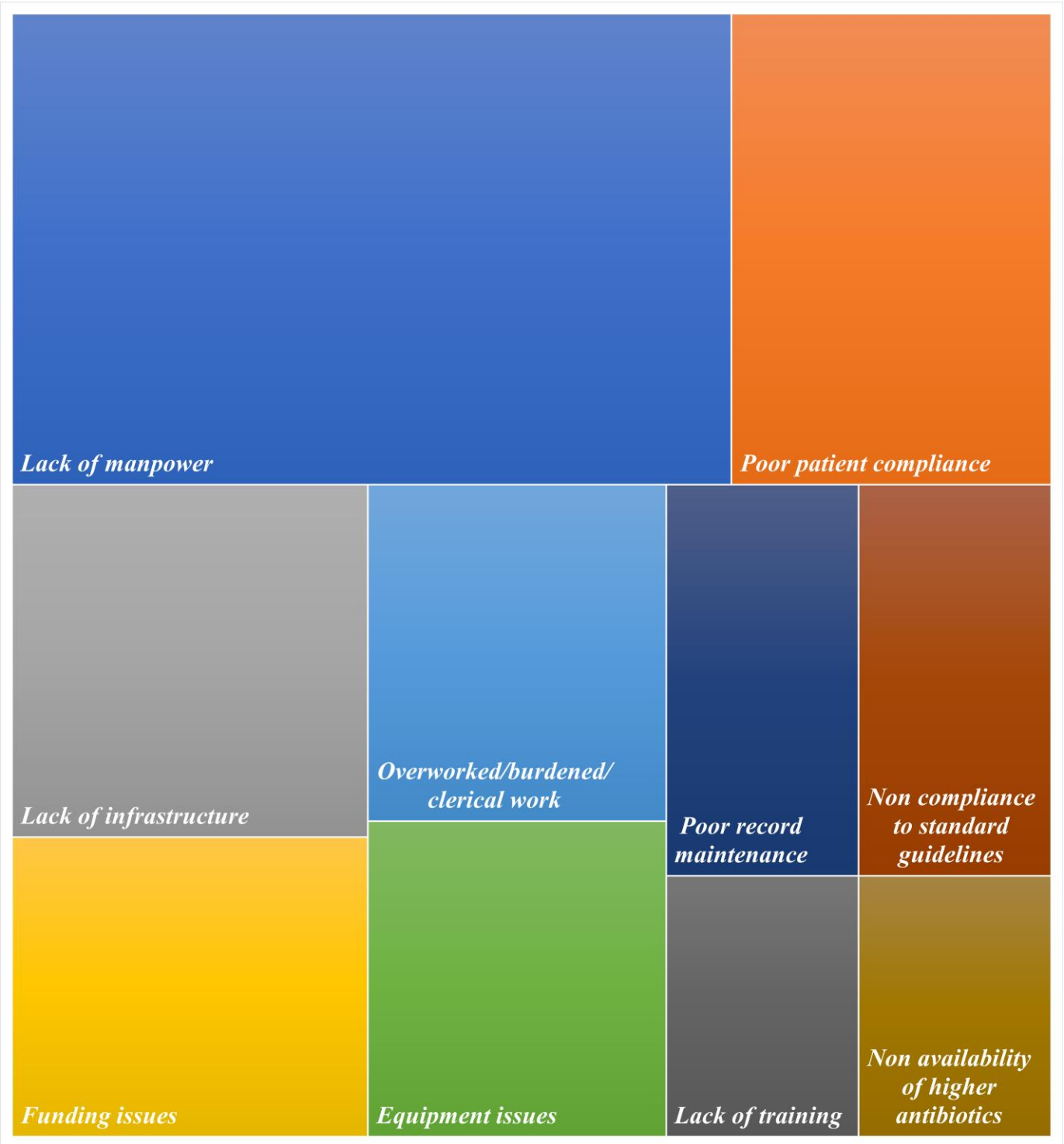


Figure 27: Treemap diagram summarizing the top ten challenges reported during the qualitative interview in the application of National Patient Safety Implementation Framework across public health facilities in Tamil Nadu

Providing IEC to the patients was the most reported recommendation with 61 out of 80 interview participants mentioning it. This recommendation consists of generating awareness among patients regarding the importance of BMW, COVID-19 appropriate behaviour, antibiotic usage, ADR reporting, available services in the facility etc. The next most common recommendation was to conduct regular CME/training/workshop/case discussions/clinical society meeting for all the doctors and staffs in the facility. This was mainly recommended as majority of the participants told they were unaware about the patient safety theme and regular orientation on the latest updates and guidelines will enable them to develop knowledge and understand the importance of the topic. This was followed by recommendation on proper record maintenance as it is one of the factor hindering the facilities to work towards major accreditation process like NQAS, NABH etc. The other recommendations were dedicated staff or team (12) and surveillance system setup for patient safety (11), dedicated staff for data entry to reduce the burden of staffs and provide safe patient care (11), disabled and geriatric friendly infrastructure (10), dedicated biomedical engineer for each facility to avoid delay in servicing/repairing of equipment (6), filling all the existing vacancies (5), and carryover option for funding (4) (**Figure 28**).

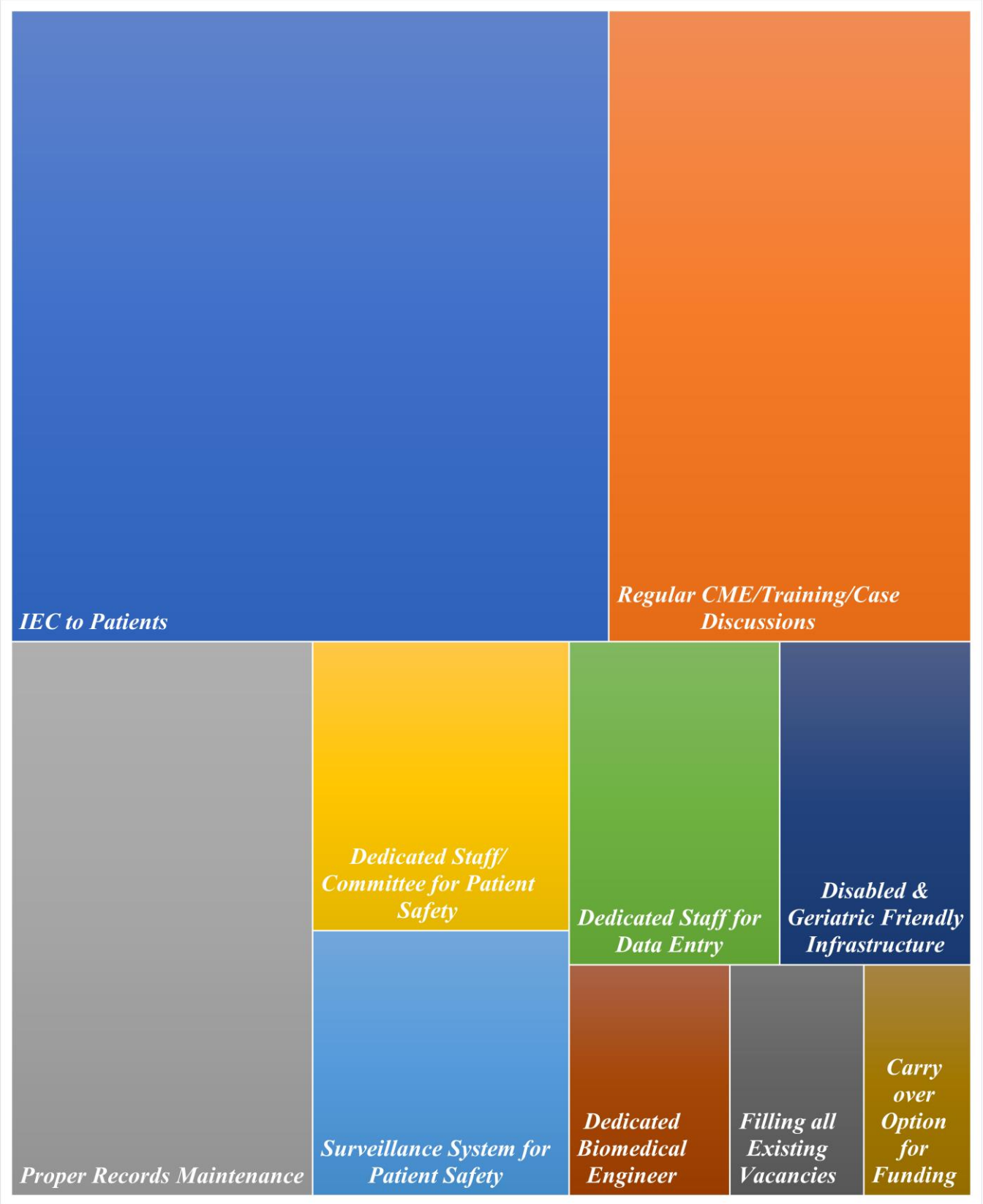


Figure 28: Treemap diagram summarizing the top ten recommendations reported during the qualitative interview in the application of National Patient Safety Implementation Framework across public health facilities in Tamil Nadu

We have developed a conceptual framework based on the six pillars of health system strengthening for depicting the major challenges and recommendations reported during the qualitative interviews (**Figure 29**).

Under the first pillar "*Leadership & governance*", the major challenge reported was the absence of patient safety committee or domain specific committee at the directorate level. The recommendation provided for that challenge was to setup a separate patient safety wing along with subcommittee for each of the domain in patient safety.

Under the second pillar "*Healthcare Financing*", funding of the facilities with deadline for spending the total amount, lack of funds for patient safety research and no additional benefits for doing the patient safety related work. The suitable recommendations reported during the interview were to develop a carryover option for funding, awarding grants for best research proposals on patient safety theme on yearly basis to public health facilities in Tamil Nadu, and performance-based incentives to staffs based on the improvement in patient safety indicators.

Under the third pillar "*Health Workforce*", major challenges reported were the unfilled vacancies, lack of training on patient safety, overburdening with clerical works, and rotation of staffs after training. The possible recommendations provided by the participants for these challenges were to immediately fill all the existing vacancies in all the public health facilities, organize a CME/workshop/training on patient safety in a phased manner, dedicated manpower for data entry to ensure that the existing staffs can focus purely on the patient care, and avoiding the unnecessary rotation of staffs from a department/facility after getting trained and oriented towards a particular line of work.

Under the fourth pillar "*Medicines, equipment and technologies*", the major challenges reported were the lack of high-end antibiotics availability, lack of equipment necessary for

patient care, and delay in servicing/repair of equipment. The recommendations provided to overcome these challenges were regularly updating the antibiotic formulary with high-end antibiotics based on the local needs, provision of necessary equipment and dedicated biomedical engineer for each of the secondary and tertiary care facilities.

Under the fifth pillar *"Health Information Systems",* the major challenges reported were the lack of awareness about ADR reporting system, manual maintenance of records and lack of surveillance system for patient safety indicators. The possible recommendation to overpower these challenges were conversion of manual to automated system-based data handling for entry, analysis, dissemination and review, directorate-initiated orientation program for all the GHs on ADR reporting system and establishment of patient safety surveillance system with suitable indicators at the state and district level.

Under the sixth pillar "*Service Delivery*", the topmost challenges reported were the non-compliance of HCWs to standard guidelines in terms of clinical care, procedures, and prescription practices. These challenge can be overcome by sending a strict directive from directorate and hospital administration level for full compliance to all the recommended standard guidelines on the clinical and patient care practices. Failing to comply should lead to some form of consequence to the respective HCWs. It was also reported that there was lack of preventive and promotive service provision by majority of the facilities. Hence, it was recommended that all the facilities should conduct regular outreach sessions in the form of awareness sessions, rallies, camps, drives and campaigns for the community.

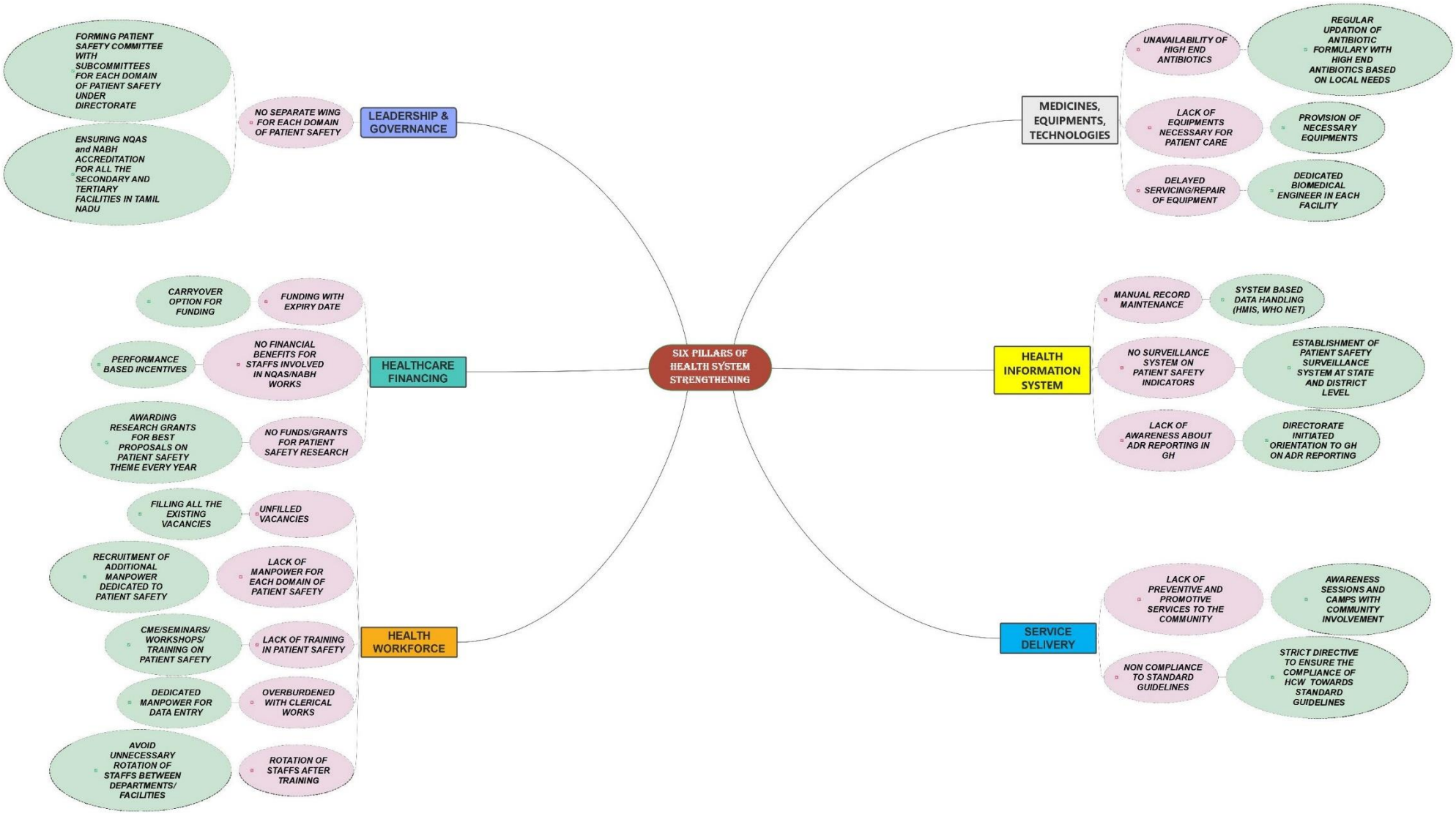


Figure 29: Conceptual framework based on the six pillars of health system strengthening depicting the challenges and possible recommendations for the application of National Patient Safety Implementation Framework across public health facilities in Tamil Nadu

DISCUSSION

Key findings of the study:

This study evaluated the status of implementation of NPSIF in a sample of public health facilities of Tamil Nadu under six main headings namely, process evaluation using a set of indicators, patient safety culture in OPD & IPD, Hand hygiene & BMW disposal practices and qualitative interviews assessing the facilitating factors, challenges, and recommendations for implementation of NPSIF across public health facilities of Tamil Nadu.

- Seven out of 18 facilities (1 medical college – Villupuram and 6 GHs) had NQAS accreditation
- Eight out of 19 facilities had Kayakalp certification (1 medical college – Villupuram and 7 GHs)
- Half of the surveyed facilities (4 medical colleges and 5 GHs) had LaQshya certification
- None of the facilities had NABH, JCI or ISO accreditation
- Seven out of 18 facilities (1 medical college – Salem and 6 GHs) had patient safety related SOPs/checklists
- All the facilities except Theni Medical College had anonymous reporting system for patients, families, and healthcare providers for raising patient safety concerns
- Eight out of 18 facilities (2 medical colleges – Salem and Villupuram, 6 GHs) had registered and functional patient groups for development of policies, strategies, or plans
- One-third of the facilities (1 medical college – Salem and 5 GHs) had SOPs for training of HCWs on topics related to patient safety,
- 13 out of the 18 facilities (2 medical colleges – Pudukkottai and Salem, 11 GHs) were conducting training for HCWs on topics related to patient safety

- All the facilities except Bodinayakanur GH had a separate HICC, while half of the facilities had a separate microbiology department.
- Ten out of 18 facilities (all 6 surveyed medical colleges and 4 GHs) had a separate CSSD, while 15 out of 18 facilities (all 6 surveyed medical colleges and 9 GHs) had a separate BMW management committee.
- Ten out of 18 facilities (4 medical colleges and 6 GHs) had a separate hospital transfusion committee, while 14 out of 18 facilities had their own blood bank.
- Only one facility (Theni medical college) had a separate antimicrobial stewardship committee. All the facilities except Vikravandi GH had an antibiotic formulary, and amongst the facility having antibiotic formulary. Only 2 facilities (Aranthangi and Musiri GH) had written antimicrobial stewardship guidelines.
- All the surveyed 18 facilities had a separate nodal officer for coordination of COVID-19 control activities, separate triage system for identifying COVID-19 suspect patients visiting the facility and provided training for wearing PPEs during COVID-19 duty.
- Only 5 facilities (2 medical colleges – Tirunelveli and Theni and 3 GHs – Tindivanam, Srirangam and Periyakulam) had a separate pharmacovigilance committee, while 3 out of these 5 facilities (Tirunelveli, Theni medical colleges and Tindivanam GH) reports the adverse drug reactions to National Coordination Centre for Pharmacovigilance Programme of India
- Ten out of 18 facilities are using only non-mercury devices.
- Only Tirunelveli Medical College had a dedicated biomedical engineer for their facilities, while all other facilities have a biomedical engineer only at district level
- All the facilities had dedicated room for giving injections, while all the facilities except Salem medical college and Attur GH had dedicated staff for their injection rooms.

- All the facilities except Theni medical college, Vikravandi and Attur GH had safe surgical checklist
- Only 2 facilities (Tirunelveli and Salem medical college) conduct research on patient safety and allied themes, while none of the facilities had a repository of materials related to patient safety and allied themes
- At OPD level, assessment of patient's perception on the safe hospital care revealed that more than 80% of the patients strongly agreed or agreed that they felt safe across almost all the domains except compliance to COVID-19 appropriate behavior inside hospital.
- At IPD level, assessment of patient's perception on the safe hospital care revealed that more than 80% of the patients strongly agreed or agreed that they felt safe across domains like communication with healthcare providers and during procedures, while there was some amount of disagreement in terms of nutrition, environmental safety, and compliance to COVID-19 appropriate behavior inside hospital.
- At OPD level, 8.3% of the participants felt that they faced some form of disrespect (felt disrespected/received shout or scold/received negative or disparaging comments), while the survey at IPD revealed that 12.2% felt that they faced some form of disrespect.
- Only during one-fifth of the observations, hand washing was done by the HCWs. Amongst these observations during which hand washing was done, only 37.9% did the hand washing appropriately by following all the essential steps of hand hygiene.
- HCWs belonging to facilities in Trichy (Musiri GH - 59%) and Pudukkottai (Pudukkottai Medical College - 48%) had the highest compliance to hand hygiene practices, while HCWs belonging to facilities in Theni and Salem had the least compliance to hand hygiene practices.

- HCWs from facilities such as Attur GH, Omalur GH, Salem Medical College, Periyakulam GH and Bodinayakanur GH had compliance ranging from 2-3% to hand hygiene practices
- HCWs from Musiri GH (60%) had the highest compliance to appropriate hand hygiene practices followed by Tirunelveli Medical College (52%).
- HCWs from facilities such as Attur GH, Omalur GH, Salem Medical College, Periyakulam GH and Theni Medical College had 0% compliance to appropriate hand hygiene practices.
- During 73% of the observations, the BMW was disposed of appropriately.
- HCWs belonging to facilities in Trichy (Illupur GH - 95%) and Pudukkottai (Aranthangi GH - 93% & Pudukkottai Medical College - 91%) had the highest compliance to appropriate BMW disposal practices.
- HCWs belonging to facilities in Theni, Villupuram and Salem had the least compliance to appropriate BMW disposal practices.
- After compiling the overall patient safety scores in a hospital, Periyakulam GH was the only facility belonging to high-performing category (75.5), 11 facilities (4 medical colleges & 7 GHs) belong to medium performing category (score 50-74) and 6 facilities (2 medical colleges – Theni & Pudukkottai, 4 GHs – Bodinayakanur, Vikravandi, Omalur & Ambasamudram) belong to low-performing category (score < 50).
- During the qualitative interviews, commonest facilitating factors for implementation of NPSIF reported were obtaining/working towards obtaining the NQAS/NABH/Kayakalp certification, regular training of staffs across various domains of patient safety like hand hygiene, BMW management, medications, and procedures, self-motivation of the HCW, hospital administration support, sense of responsibility and satisfaction among HCWs, availability of standard protocol/SOP/checklist for

patient care, political support in hospital activities, government rewards for best performing hospitals, doctors, and staffs, appreciation from patients and anonymous patient reporting system.

- Commonest challenges for implementation of NPSIF was lack of manpower, poor patient compliance, lack of infrastructure, funding issues, overburdening of the staffs with clerical works, equipment issues, poor record maintenance, non-compliance to standard guidelines by HCWs, lack of training on patient safety domains and non-availability of high-end antibiotics.
- Commonest recommendations for successfully implementing NPSIF was providing IEC to the patients, regular CME/training/workshop/case discussions/clinical society meeting, proper record maintenance, dedicated staff or team and surveillance system setup for patient safety, dedicated staff for data entry, disabled and geriatric friendly infrastructure, dedicated biomedical engineer for each facility, filling all the existing vacancies, and carryover option for funding.

Readiness of public health facilities for implementation of NPSIF:

NPSIF is a unifying framework to bring together various diverse programmes that are being already implemented and give better expression of patient safety elements. This framework covers various important aspects of patient safety such as legal, regulatory aspects, nature & scale of adverse events, external quality assessment, hospital infection prevention & control, competent and capable workforce, building patient safety campaign and capacity to conduct patient safety research. The plan of this framework was to ensure the implementation of the programme over 2018 to 2025.[23] However, our study showed the lack of readiness to implement the activities mentioned under NPSIF across almost all the surveyed public health facilities in Tamil Nadu (only Periyakulam GH belonged to high performing category).

One of the prime reason for such low score for other facilities were lack of maintenance of records, registers, or logs. This is because many activities under the framework have been told to be performed in the facilities. However, there was no record or registers to physically verify the claim, leading to lower scores. Hence, all the activities performed in the hospital should be manually or digitally documented and updated regularly in a separate set of records or database. We have also assessed the level of implementation, and its challenges and recommendations under the following set of themes:

- *Structural support for Quality & Safety*
- *Hospital infection control policies & its implementation*
- *BMW management policies & its implementation*
- *COVID-19 safety policies & its implementation*
- *Medication safety policies & its implementation*
- *Blood safety policies & its implementation*
- *Antimicrobial policies & its implementation*
- *Procedural and Device safety policies & its implementation*
- *Patient Safety Research*

Structural system for Quality & Safety

Quality control mechanism in the form of various accreditations system, might help in ensuring patient safety, rights, benefits, hospital infection prevention and control, and placement of proper protocols in terms of special care for critically ill, vulnerable groups, leading to better & controlled clinical outcomes.[36] A systematic review of literature has also revealed that there is a consistent evidence on the impact of accreditation program in improving the quality of care and clinical outcomes in healthcare facilities.[37] The accreditation process has this ability to influence the quality of care through three mechanisms: *"coherence, organizational buy-in and*

collective quality improvement action".[38] The existing accreditation systems such as NQAS/NABH and quality related frameworks in India are relatively robust and comprehensive.[39,40] Hence, it is pertinent to adopt these standards across all the public health facilities in Tamil Nadu.

However, the lack of readiness to implement NPSIF was mainly seen with respect to structural support for quality (national or international accreditation) & safety of the healthcare facilities. The major challenges responsible for the non-attainment of accreditation was the lack of infrastructure, manpower, equipment, facilities, structural or technological improvement, financing issues and overburdening of HCWs required for the accreditation process. A systematic review assessing the attitude of various stakeholders involved in accreditation process (doctors, nurses, hospital administration) has also revealed reasons like our study (financial concerns, demanding manpower etc.) as the major factors responsible for non-attainment of accreditation system in their respective facilities.[41]

To overcome these challenges, major suggestions provided were to fill the existing vacancies and recruitment new manpower for quality control process, incentivization of staffs (if existing staffs are involved in quality control work), proper maintenance of records, registers, logs, CME/Workshops/Trainings on newer updates and guidelines and filling administrative posts like Dean/MS/RMO with doctors having qualification & experience in hospital administration. In addition, all the public health facilities in Tamil Nadu can adopt certain best practices from some of the surveyed facilities like dedicated staff for coordinating NQAS accreditation (Musiri GH), dedicated quality control team (Periyakulam GH), establishment of core committee (like patient safety committee) to monitor the activities of all the committees in hospital (Pudukkottai Medical College), and regularly conducting patient satisfactory survey (Tindivanam and Tenkasi GH). These are readily actionable points as they have already been adopted by some of the public health facilities.

Though, such accreditation system is highly helpful in ensuring patient safety practices in hospital, it is not always associated with quality of care or patient satisfaction. A survey conducted in Kerala has revealed that there was no significant difference in patient satisfaction or their perception on quality depending on the accreditation process.[42] Our study also revealed similar finding as the patient satisfaction and perception on quality of care was almost equal across all the surveyed health facilities.

Hence, in addition to the accreditation systems, it is necessary to assess whether the hospitals can comply with the patient safety standards across all the domains under NPSIF. Also, training and education should be provided to the staffs on patient safety practices and instructions on successful implementation of the patient safety standards. Our study revealed that majority of the facilities are lacking in this aspect as they did not have proper checklist/SOP/training to staffs on patient safety.

Suggestions provided to overcome this challenge was the establishment of separate wings for each domain of patient safety at directorate level and add the "Quality & Patient Safety" into curriculum of medical, dental, and allied health professionals. Secondary healthcare facilities must be transformed into patient safety centers through rhetoric action of authorities through concerned and organized efforts. In addition, it is important to include or augment the "patient safety" as a key aspect of accreditation standards & award criteria.[5] Though the latest NQAS accreditation process includes a patient safety component, it is necessary to cover all the aspects of patient safety mentioned under NPSIF.[39] The facilities can also address the patient safety requirements through international accreditation standards like JCI certifications.[43]

Hospital infection prevention and control policies and their implementation

Healthcare-associated infection (HCAI) is one of the most common complications associated with healthcare management.[44] It is a serious complication as it can lead to high rate of morbidity and mortality, length of hospital stay, and costs associated with it.[44] Hence, implementation of effective infection prevention & control practices is central to the provision of high-quality care for the patients and HCWs in hospitals.

WHO has released the "guidelines on core components of infection prevention and control programmes at the national and acute health care facility level" in the year 2016.[26] This guideline was intended to support the improvement of infection, prevention, and control practices at national and health facility level (both public and private hospitals). This document provides guidance to policy makers responsible for monitoring of infection, prevention and control programs and delivery of action plans for antimicrobial resistance at national level. At the health facility level, this document provides guidance to the hospital administrators and in charge of HICC.[26] This guidelines has reported eight core component for infection prevention and control (six components applicable to both national and facility level & two components applicable to facility only). The eight core components are as follows[26]:

- Infection prevention and control programmes
- Infection prevention and control guidelines
- Education and training
- Surveillance
- Multimodal strategies
- Monitoring/audit of infection prevention and control practices and feedback
- Workload, staffing and bed occupancy
- Built environment, materials, and equipment

The Hospital Infection Control Guidelines was released by Indian Council of Medical Research with a main objective of preventing the HCWs and hospital environment from transmitting the infections.[25] It had a total of ten components (overlapping with the WHO guidance of core components):

- Basic infection control measure – standard & additional precaution
- Education and training of HCWs
- Protection of HCWs
- Identification of hazards & minimizing the risks
- Surveillance
- Outbreak investigation
- Incident monitoring
- Aseptic techniques
- Using single use devices, reprocessing of equipment and instruments
- Antibiotic use, management of exposure to blood/body fluids, handling the blood products, and hospital waste management practices

We have combined these WHO & ICMR core components and assessed the relevant HICC activities in the surveyed health facilities. We found that majority of the facilities were better performing in terms of many major indicators (except monitoring of antimicrobial resistance pattern and reporting of HCAI to surveillance system). All the facilities except Bodinayakanur GH had a separate HICC, which acted as a major facilitating factors for such satisfactory performance in terms of hospital infection, prevention, and control measures. The ongoing COVID-19 crisis has actually had a positive impact on the infection control measures as most of the public health facilities has conducted training to HCWs on hand hygiene, PPE use and installed hand washing stations with sanitizers and awareness sessions for the patients.

Compliance to these practices was also heavily scrutinized during this period, which might have also influenced the positive finding with respect to these indicators. This shows that the public health facilities in Tamil Nadu are working towards the positive direction in handling infection control practices. However, the sustainability of these measures is important, and a future survey on the same set of indicators post the pandemic period might give an idea on the hospital infection control practices in normal situations. Despite such positive findings, one area of concern with many facilities were the non-reporting of HCAIs to surveillance system. Hospital infection control is a key component of patient safety and non-availability of data on the outcome related to infection control practices, might make it difficult to determine the impact of the implementation of various hospital infection, prevention, and control practices across the public health facilities in Tamil Nadu.

Improper hand hygiene practices

We have also conducted a direct observational survey of hand hygiene practices amongst various set of HCWs in the surveyed public health facilities. Despite such positive findings with respect to implementation of HICC activities, including regular hand hygiene training sessions to the staffs in almost all the facilities, only during one-fifth of the observations, hand washing was done by the HCWs and less than 10% did hand washing appropriately by following all the essential steps of hand hygiene. This finding was similar to previous studies in Southern India and other similar setting.[45-50] However, few studies showed at least 30-60% compliance to hand hygiene practices, representing a wide variation in the compliance to hand hygiene practices across public health facilities.[51-53] Nonetheless, findings from our study is a primary area of concern, given that the WHO has cited the hand hygiene as one of the crucial components of COVID-19 containment, and for which overall compliance was less than 20% and appropriate practice was less than 10%. We further explored the hand hygiene compliance

and appropriateness across several factors to understand the pattern of non-compliance and generate workable recommendations.

In our study, we found that the nurses were more compliant to hand hygiene opportunities and appropriate hand hygiene practices than doctors or allied healthcare staffs. This was also found to be similar to previous study findings across Indian setting and other low middle income countries.[49,50,52,54,55] There might be various factors responsible for such poor compliance to hand hygiene among doctors, like work pressure, high caseload, and possibility of superiority complex or following Monkey's rule (i.e., "why should I follow when others are not Following"), which makes them less receptive and learn from other HCWs—especially nurses.

We found that the compliance to hand hygiene was better in IPD compared to OPD and procedure room/OT/ICU. However, there was no significant difference in terms of appropriate hand hygiene practices across the setting. This again reiterates the fact that lack of time, work pressure and high case load as the possible reasons for lower compliance of hand hygiene practices at OPD. However, the worrying finding is the lack of hand hygiene compliance in highly sterile settings like procedure room/OT/ICU. But the number of observations in these setting was very low, given the lack of accessibility during the survey.

We have also assessed the hand hygiene compliance and appropriateness based on the five moments of hand hygiene. We found that HCWs who had exposure to body fluids had the highest compliance to hand hygiene practices followed by HCWs prior to performing any clean or aseptic procedure, while the least compliance was found before touching any patient or after touching patient surroundings. This finding was similar to the results reported in previous evidence in Indian setting.[52,56,57] The probable reason for such difference could be the attitude of HCWs to practice hand hygiene more when they perceive that they are at risk of contracting infections from the patients, i.e., exposure to bodily fluids. Performance of hand hygiene has

been a routine practice before performing any clean or aseptic procedure for a longer period of time. Hence, the compliance was better during these moments. However, such attitude should be changed and HCWs should understand that every moment (as per WHO five moments of hand hygiene) is equally important in preventing the transmission of infection in health facility. However, a further root cause analysis should be done to identify the possible reasons for the lower compliance and the difference identified across various factors. From the policymakers' perspective, these data indicate what type of health worker, at which setting and what moment of hand hygiene should be prioritized in designing and targeting the infection prevention & control interventions.

BMW management policies and their implementation

The safe & sustainable management of the BMWs is a legal and social responsibility of all the people involved in provision or utilization of healthcare services (i.e., patients, families, HCWs, hospital administration and health system). WHO has proposed the core principles to achieve such safe & sustainable BMW management in the year 2007. The proposal has stressed up on the necessity of right investment in resources with complete commitment to reduce level of harmful effects for the people and environment due to BMWs.[58] WHO also released the second edition of "The Blue Book" in the year 2014, adopting newer practices compared to the first edition published in 1999.[58]

Government of India has also released the first BMW management guidelines around the same timeline (in the year 1998), which was subsequently amended in 2000, 2003 and 2011.[59] The latest BMW management guidelines was published in the year 2016.[60] The BMW Rules, 2016 (further amended in 2018 & 2019) is a joint product of research made by agencies such as Centre for Chronic Disease Control, Health Care without Harm, and Centre for Environmental Health under Public Health Foundation of India.[61] This guideline was introduced to bring out

a stringent and elaborate set of rules and bring a change in the way BMWs are managed in India. Monitoring the activities in health facility and its compliance to the standard guidelines is important as proper compliance to BMW practices ensures safety to patients and HCWs. Though surveys were conducted on BMW practices across healthcare facilities in India[62-64], there is limited evidence on the assessment based on the latest guidelines.

In addition, the ongoing COVID-19 crisis has drastically changed the practice of BMW generation and management. One such major change is the use of PPEs during the COVID-19 pandemic. Before this crisis, the commonly used PPEs were gloves and masks. But, the COVID-19 pandemic has brought out a landslide shift in the behavior of HCWs, patients and general public. Everyone has started using various forms of PPE. Masks, gloves, face shields, visors, full body suits, and splash-proof aprons, are available for use to general public also.[65] The waste generation is bound to increase due to such practices and hence, the assessment of BMW practice is essential more than ever to determine whether the public health facilities are in line with the standard guidelines and has the ability to withstand the paradigm shift during the ongoing COVID-19 crisis.

Similar to HICC, most of the surveyed facilities were better performing in terms of almost all the BMW management practices (except reporting of needle stick injuries to NACO). Similar findings were reported in previous survey conducted in an Indian setting regarding the satisfactory adoption of latest BMW guidelines in secondary and tertiary care setting.[62] Almost all the facilities except Omalur, Vikravandi Bodinayakanur GH had a separate BMW management committee, which acted as a major facilitating factor for such satisfactory performance in terms of BMW management measures. Similar to HICC, the ongoing COVID-19 crisis might have influenced a positive change in the waste disposal practices as most facilities has conducted training to HCWs on BMW disposal practices and management. Compliance to these practices was also heavily scrutinized during this period, which might

have also influenced the positive finding with respect to these indicators. This shows that the public health facilities in Tamil Nadu are working towards the positive direction in handling BMW management practices.

Similar to HICC, one area of concern with many facilities were the non-reporting of needle stick injuries to NACO. This again makes it difficult to determine the impact of BMW management practices implemented across the public health facilities in Tamil Nadu, as the ultimate aim or objective of any intervention is to achieve the desired outcome. Another major challenge reported during the qualitative interview was the non-compliance of patients to waste disposal practices. This is an important issue as the general public, patients or their families are no longer responsible for generation of only general wastes. They have also started using wide range of personal protective devices, which comes under BMWs.[65] Improper disposal of these wastes pose threat to all the HCWs and visitors to health facilities. Hence, it is necessary to create awareness among the general public regarding the hazards and threats associated with BMWs. The recommendations suggested during the interviews to tackle this problem were to utilize audiovisual demonstration of BMW disposal practices in all the OPDs & wards, outreach sessions to general public and counselling by HCWs during the routine check-up or follow-up of patients. BMW disposal practices should reach every person in the community, for their own safety and their surroundings.

Till now, policies on BMW management focusses primarily on the medical community and health facilities. However, BMWs are generated in every household by the general public due to the home isolation for COVID-19, surge in door-to-door sample collection, and home-based care for chronic disease/elderly patients. Hence, future policies, programmes, and regulations should also focus on the BMW collection, segregation and disposal practices in general population outside the hospitals. In addition, the standard guidelines on the BMW management should be updated time-to-time considering the nature of the pandemic. Future research studies

can be conducted to assess the BMW disposal practices of general public, as the surveys conducted till now primarily focuses on assessing the BMW disposal practices by HCWs.

Improper BMW disposal practices

We have conducted a direct observational survey of BMW disposal practices amongst various set of HCWs in the surveyed public health facilities. In contrast to the poor hand hygiene compliance, BMW disposal practices was significantly better as nearly three-fourth of the observations followed appropriate BMW disposal practices. HCWs in all the surveyed facilities of Pudukkottai has reported more than 90% compliance to BMW disposal practices. Similar finding was found in previous studies assessing the BMW disposal practices across various cadres of HCWs.[66,67] Such positive findings is encouraging given that the COVID-19 pandemic has raised the amount of BMW generated and ability of the virus to remain active on different surfaces for a variable period of time has made them hazardous.[68] In addition, fomite transmission has also been described as one of the modes of COVID-19 transmission.[69] Hence, there is always a scope for improvement despite the positive findings obtained in our survey, as some of the facilities had compliance as low as 40%. All the HCWs handling BMW across all the facilities should take utmost care and training or additional interventions should be targeted towards these facilities with compliance less than 50%.

Depending on the type of HCWs, nurses had better compliance when compared to doctors or other allied staffs, though the difference was relatively smaller. This finding was also similar to previous studies in Southern India and other similar setting, as the doctors and nurses had almost similar BMW disposal compliance or slightly better compliance amongst nurses.[66,67,70,71] Possible reason for such finding could be high amount of responsibility on BMW management practices are assigned to nurses in public health facilities of Tamil Nadu. In addition, nurses have better access to BMW management training, guidelines and equipment

compared to doctors. However, such practice should be changed and all the HCWs are equally important in preventing the transmission of infection in health facility. Though, training programs are conducted for every HCWs in the health facility, the doctors are not motivated enough to attend the training as reported during the qualitative interviews. Hence, the training on BMW management should be made as a strict mandate for all the hospital staffs. Attendance of staffs during the training programs should be considered for the annual appraisal or promotion of staffs.

COVID-19 safety policies and their implementation

During epidemics or pandemics of any disease condition, it is the health system (especially the hospitals), that face major challenges in patient and staff management. The situation was similar during this ongoing COVID-19 pandemic. The number of reported cases consistently rises across the world, making it exceedingly difficult and challenging for health system to adopt to such rising needs. The situation was more challenging for a resource constrained setting like India. During the disastrous second wave of the pandemic in India, the health system was almost at the brink of a collapse.[72] This was mainly due to the unexpected nature of such catastrophic event and lack of preparedness across most public health facilities in the country. Hence, hospital preparedness activities are the crucial components of disaster

preparedness for any mass casualty incidents and the need to address all the possible hazards, including any infectious disease outbreaks and pandemics.[73]

Though, COVID-19 safety is not one of the component of NPSIF (given the non-existence of the disease during the period of framework development), the global patient safety action plan has emphasized that the ongoing pandemic brought out some important patient safety implications, giving a heightened impetus to the efforts that promote safe care at every level.[5] Despite the vast number of negative effects associated with COVID for patients, HCWs, health

facilities and health system, the action plan has also highlighted some positive effects of COVID-19. The pandemic has provided short-term benefits in some key areas that can function as a catalyst for the subsequent improvement strategies.

The shared commitment & responsibility have united the stakeholders and HCWs like never before, as highlighted from our study findings during the interviews. Many facilities have spontaneously adopted some key safety attributes such as collaboration, active communication, transparency, and rapid adoption of newer patient safety practices (like implementing new hand hygiene strategies & facilities). However, the settings in which these measures are implemented, responded that they do not want this to be only temporary measures, but sustain and further strengthen it over the period of time. The forthcoming years are the time to build a safer health system that minimizes the avoidable harm to the patients and HCWs.

Contemplating how the COVID-19 situation adds to the patient safety context will help in harvesting newer patient safety lessons from both the pandemic failures and transformations. All these components are a part of the urgent requisite to "build back better" and "hardwire" the positive changes to promote the coverage of the safety innovations and strategies and make a resilient health systems to the impact of any forthcoming catastrophic events (outbreaks or pandemics) than ever before.[5] Due to the key role of the hospital preparedness, especially, in response to pandemics, it is necessary to focus on the hospital and HCW preparation.[74] This findings will not only help till the end of this pandemic, but also make sure the readiness of health facilities during any forthcoming epidemics or pandemics, that has critical patient safety implications.

We assessed the COVID-19 safety practices by adopting the WHO hospital preparedness checklist across the surveyed public health facilities in Tamil Nadu. We found that almost all the facilities were better performing in terms of many major indicators (except separate room

for patients and exclusive staff for COVID-19 duty). The major facilitating factors responsible for such satisfactory performance in terms of COVID-19 safety indicators were the sense of responsibility, satisfaction, and selfless service by the HCWs, appreciation from patients further motivating the HCWs to provide service tirelessly and strong pollical and health system support in terms of infrastructure, facilities, and equipment. This shows that the public health system in Tamil Nadu is trending towards the positive direction in handling emergency situations. However, it is important to convert such temporary support to a permanent resilient, scalable, adaptable and efficient system to ensure that any forthcoming pandemic do not overburden the HCWs, facilities or the health system. However, one major area of concern with many facilities were the inability to limit the visitors inside the COVID-19 suspect and isolation ward. It was even reported that *"some positive patients go home and come back to ward whenever they feel like"* as per the qualitative interviews. Hence, strict mandate should be given to avoid such unfortunate incidents in the future.

Medication safety policies and their implementation

Medication errors and unsafe medication practices (like incorrect dosages/infusions, use of abbreviation, unclear instructions, inappropriate/illegible prescriptions) are one of the leading causes of avoidable harm in healthcare setting globally.[75] Worldwide, the economic burden associated with the medication errors has been estimated to be US$ 42 billion annually.[76] To tackle this problem, WHO has identified the theme *"Medication Without Harm"* for the third Global Patient Safety Challenge in the year 2017.[75] It was proposed to bring out solutions for addressing many obstacles the world faces in ensuring safe medication practices. The main aim of this challenge was to reduce the severe and avoidable medication related harms by 50% worldwide in the next five years. The key action areas proposed under this challenge fall into three categories: Early priority actions, Development programmes and global action.[77]

Pharmacovigilance system in India was initiated almost four decades ago (in the year 1986) with a formal ADR monitoring system, under the supervision of DCGI. India joined the WHO programme for International Drug Monitoring in the year 1998.[78] However, these initial systems were highly unsuccessful. Later, National Programme of Pharmacovigilance was launched in the year 2005, which was later renamed as Pharmacovigilance Programme of India (PvPI) in the year 2010, to ensure a robust pharmacovigilance system in India.[78] The PvPI works towards safeguarding the health of Indian population, by ensuring that the benefits associated with medicines significantly outweighs the risk associated with the use. The programme was primarily intended to work towards building trust between doctors and patients, thereby increasing the patient safety, in addition to detection of prescribing, administration and dispensing errors and substandard medicines.[79] The Indian Pharmacopoeia Commission (IPC)-PvPI has become a "WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services".[80] Despite these achievements, the PvPI is still facing challenges in terms of ADR reporting across the facilities in the country.

Our study has explored these pharmacovigilance practices and challenges faced in this process across public health facilities in Tamil Nadu. We found that only five out of 18 facilities had a pharmacovigilance committee, while only three facilities (Tirunelveli and Theni Medical College, Tindivanam GH) did regular reporting of ADR to NCC for PvPI. The major reason for such weak or non-existent implementation of pharmacovigilance practices were reported to be the lack of awareness about the presence of such reporting system among HCWs and administrative heads (mainly in GHs). It is necessary to orient all the health facility on the importance of forming a pharmacovigilance committee and the regular ADR reporting practices. Amongst the facilities reporting the ADR, it was suggested that minor ADR should also be reported under state/national level surveillance system. This was mainly suggested as many patients are stopping the medications on their own, even for minor ADR, which goes

unnoticed most of the times. It was also suggested that regular training should be provided to HCWs on medication safety practices i.e., practicing safe drug administration, management of ADR etc.

WHO has also released a document on "The 5 Moments for Medication Safety" i.e., starting, taking, adding, reviewing, and stopping the medication during the third WHO global patient safety challenge for ensuring safe drug administration.[81] These are the key moments during which the action by patient/caregiver can significantly reduce the risk of harm associated with the medication use. Each moment consists of five critical questions (some being self-reflective for patients and some requiring support from HCWs for answering and reflecting upon correctly).[81] Health facilities can adopt this practice and make the patients and HCWs aware about such checklist for safe drug administration. A best practice adopted by one of the surveyed facility (Attur GH) follows "10R" checklist for safe drug administration ("right patient, right reason, right drug, right route, right time, right dose, right form, right action, right documentation and right response").[82] Adoption of this checklist advocates the need for knowledge of causes of the medication errors, process of implementing the strategies to reduce medication errors, ensure safe practices throughout the medication journey (from chemical preparation to monitoring outcomes and response). This can be adopted by all the public health facilities in Tamil Nadu as it has already been tried and tested in a GH.

Blood safety policies and their implementation

Blood safety has been an evolving area of focus for most countries over the past few decades. The WHO is promoting the efforts to improve access of safe blood transfusion and blood products across the globe. Safety of the blood products begin with the recruitment of blood donor and includes[83]:

1. Emphasis on the pre-donation information collection,

2. Collection, preparation, and testing of the blood components,

3. Emphasis on the post-donation information collection,

4. Labeling of blood products for distribution,

5. Handling of blood products in hospital inventory,

6. Blood transfusion into patient by the hospital staff, and

7. Concluding with the hemovigilance and the clinical quality improvement care to ensure the patient safety and reduce the morbidity & mortality associated with the blood transfusion.

The WHO has also recommended that all the activities in relation to the collection, testing, processing, storage, and distribution of blood be coordinated at national level through an effective organization and integrated network of blood supply.[84] The national blood safety system should be governed by the policy and legislative framework for the blood safety to promote the uniform implementation of consistency and standards in the safety and quality of blood & blood products.[84]

In India, NACO has been made primarily responsible to ensure the provision of safe blood for the country since the year 1992.[85] NACO supports the network of blood banks across India in more than 600 districts. Government of India has adopted the National Blood Policy (NBP) in the year 2002. This policy aims to create a nationwide system to ensure an easy access to safe and adequate blood supply.[85] National Blood Transfusion Council (NBTC) was constituted under NACO with an objective of promoting voluntary blood donation, safe blood transfusion, infrastructure to the blood centres, and develop human resources. It is a policy making apex body for issues pertaining to operation of blood centres. NBTC has also released compendium of National Blood Policy and Guidelines in the year 2016.[86]

At health facility level, it is the responsibility of hospital transfusion committee to carry out the roles and responsibilities stated under the NBP. This committee consists of a multi-disciplinary team, involving all the departments that provide and prescribe blood and blood products in the health facility. It acts as a watchdog for the promotion of safe & appropriate blood transfusion and its components. This committee is responsible for setting appropriate policies & procedures, reviews, revise them and monitor the practices against them. This committee also plays a vital role in dealing with the hemovigilance system and risk management, providing advocacy and leadership for the safer transfusion practices and coordinate the multi-disciplinary teams with quality, clinical, and risk management tools.[32]

In this study, we tried to assess the activities of this committee along with the blood safety practices in the public health facilities of Tamil Nadu. We found that though 10 out of 18 facilities had a separate hospital transfusion committee, most of the important blood safety interventions were weak or non-existent in the public health facilities that were surveyed. Only two facilities (Tirunelveli Medical College & Periyakulam GH) have performed all the activities recommended under the policy document of "Standards for Blood Banks and Blood Transfusion Services".[25] Only four facilities were evaluating the incidence of adverse transfusion reaction and reporting this reactions to hospital administration and only three of them were reporting it to NACO. This indicated that the concept of hospital transfusion committee and its practices was in a very nascent stage in the public health facilities of Tamil Nadu. Four facilities (Ilupur GH, Musiri GH, Bodinayakanur GH, Vikravandi GH) did not even have a blood bank and had only blood storage facility. Even in facilities with blood bank, there was lack of manpower and supply of blood transfusion materials. These factors were reported as some of the major challenges regarding blood safety in the healthcare facilities. The major recommendations suggested during the interviews were to provide a dedicated medical officer-

in-charge for blood bank, uninterrupted supply of materials and establishment of blood bank in all the secondary and tertiary care facilities of Tamil Nadu.

Professional donors selling blood for monetary benefits was reported as a major challenge. Supreme Court of India has already mandated for the removal of professional blood donation.[85,86] However, as per the findings from our interview, it is clear that this practice is still ongoing. In addition, the practice of replacement donor is still present in 13 out of 18 facilities. The WHO has reported that elimination of family/replacement donor and paid donor system is a key component in establishing a safe blood transfusion service.[87] Hence, it is important to eliminate these practices and promote the non-remunerated voluntary blood donation practices (which was still lacking in 5 out of surveyed 18 facilities) across all the public health facilities in Tamil Nadu. However, the trend in voluntary blood donation practice was further worsened due to the ongoing COVID-19 crisis. This was mainly because the HCWs were already burdened with provision of clinical care to the high caseload of COVID-19 patients. Hence, all the facilities can follow a good practices followed by Srirangam GH, where a liaison with community organization can be made to conduct blood donation camps and create awareness campaigns to promote the knowledge about the importance of voluntary blood donation among general public.

Antimicrobial policies and their implementation

Antimicrobial resistance is one of the leading causes of morbidity and mortality around the world. A recent study published in Lancet has estimated that there were about 4.95 million deaths associated with the bacterial antimicrobial resistance in the year 2019, including approximately 1.27 million deaths attributable to the bacterial antimicrobial resistance.[88] The study also highlighted the global disparity in the burden, drawing the global attention towards the antimicrobial resistance threat in Asian and African countries. The observed data and the

modelled estimates for proportion of the resistant pathogen isolates by country and territory has showed that India had one of the highest burdens of antimicrobial resistance. India stood out in the burden amongst most countries in the Asian region, exhibiting maximal resistance trends.[88]

To tackle the problem of such high magnitude, the Antimicrobial Stewardship, Prevention of Infection and Control (ASPIC) program by the Indian Council of Medical Research was put together to bring clinical pharmacologists, clinical microbiologists, and other clinicians together to work towards antimicrobial stewardship. The main goals of this ASPIC program are to prevent the emergence of antimicrobial resistance and to prevent hospital acquired infections. The program involves training the experts from these specialties from 20 different institutions each year to carry out the activities to achieve these goals.[33]

A study conducted by the Indian Council of Medical Research in 2014 showed that though many public and private hospitals had the antimicrobial stewardship policy documents with them, the practice of these policies was rare. Antimicrobial audits were not performed routinely by the facilities.[89] The ASPIC was established in the same year. A systematic review done in 2020 showed that even after implementation of the ASPIC and widespread awareness about antimicrobial resistance and stewardship activities, the implementation of antimicrobial stewardship is still in an extremely poor state in the country.[90]

Several other important interventions have also been performed in India to ensure antimicrobial stewardship and reduction of antimicrobial resistance. The Chennai Declaration was signed in 2012 by the Clinical Infectious Diseases Society in which it was decided to adopt a national level policy to tackle the problem of antimicrobial resistance. The declaration stated the need for an easy to implement national level policy to handle antimicrobial resistance.[91]

The National Action Plan on Antimicrobial Resistance was drafted by the Core Working Group on Antimicrobial Resistance constituted by the Ministry of Health and Family Welfare of the Government of India in 2016. The strategic objectives of the NAP-AMR were aligned with the GAP-AMR objectives of the WHO. The core objectives of the NAP-AMR include:

1. Improving awareness and understanding of AMR through effective communication, education, and training

2. Strengthening knowledge and evidence through surveillance

3. Reducing the incidence of infections through effective infection prevention and control activities

4. Optimizing the use of antimicrobials in health, animals, and foods

5. Promoting investments for AMR activities, research, and innovation

6. Strengthening India's leadership on AMR

This study is focused on the fourth objective which is optimizing the use of antimicrobials in health. The NAP-AMR has drafted the following activities for optimizing the use of antimicrobials in health care.

Ensure uninterrupted access to high quality antimicrobials: The NAP-AMR envisages strengthening drug regulation, regulation of sale of antimicrobials over the counter, regulation of the manufacture and distribution of substandard antimicrobials, and establishing quality management systems in antimicrobial production and distribution. The NAP also focuses on strengthening the logistics and supply chain of antimicrobials to ensure uninterrupted supply to all health facilities.

Establishment of National Surveillance System for Antimicrobial use: Surveillance of antimicrobial use at health facilities and at district, state and national levels, surveillance of antimicrobial consumption among humans, animals, and agricultural sector, monitoring the consumption of antimicrobials in health facilities.

Antimicrobial stewardship in human health: Establishment of antimicrobial stewardship committees in all health facilities, develop national guidelines for antimicrobial use, developing resources for antimicrobial stewardship programs, training of health facilities for antimicrobial stewardship, establishing a monitoring and evaluation framework for antimicrobial stewardship in health facilities, improving antimicrobial use at the community level.[92]

The Antimicrobial Resistance Surveillance and Research Network (AMRSN) was set up by the ICMR in 2013. It collates the incidence of drug resistant infections and patterns of antimicrobial resistance among pathogens of human importance. This network focuses on six main pathogenic microbes and their resistance namely Enterobacteriaceae causing sepsis, Gram negative non fermenters, Enteric fever pathogens, Diarrheagenic bacteria, Gram positive staphylococci and enterococci, and fungal pathogens. The main goals of AMRSN are to establish a network of hospitals to monitor the trends of antimicrobial susceptibility and testing, molecular testing and gene mapping of resistance pathogens, dissemination of information on drug resistant pathogens to stakeholders and creation of data management system for data collection and analysis. The Nodal centres in this network are AIIMS, New Delhi, PGI, Chandigarh, JIPMER, Puducherry and CMC, Vellore. In addition, there are 15 regional centres.[93]

The Indian Council of Medical Research released the Antimicrobial Stewardship Programme guidelines in 2017. Some of the stewardship strategies proposed by this guidelines include ensuring appropriate antimicrobial therapy, ensuring appropriate surgical prophylaxis,

developing and implementing standard treatment guidelines, performing prospective audits and providing feedback to prescribers, maintaining a strict antimicrobial formulary at facility level and ensuring that it adheres to the National Essential Drugs List, pre-authorization of certain Watch and Reserve antimicrobials, education and training of prescribers, ensuring establishment of good microbiology laboratory support and effective monitoring and evaluation. Other supplemental stewardship initiatives include measures of antimicrobial consumption in DDDs per hospital performance indicators and monitoring them, escalation / de-escalation of antimicrobials, switch from parenteral to oral therapy at the earliest possible time, and optimization of dose and duration of therapy.[28] The ICMR also released the Standard Treatment Guidelines for antimicrobial use in common syndromes in the year 2019.[94]

In this study it was found that most of the important interventions of antimicrobial stewardship were weak or non-existent in the public health facilities that were surveyed. Only one facility (Theni Medical College) had antimicrobial stewardship committee. This indicated that antimicrobial stewardship was in a very nascent stage in the public health facilities in Tamil Nadu. The only strategies that were present in almost all the facilities was a robust drug formulary of antimicrobials that adhered to the national essential drugs list and keeping the stock of antibiotics up to date in the facility. All the other interventions were rare in the surveyed facilities.

We tried to explore the reasons for such weak antimicrobial system through qualitative interviews. We found that there was lack of awareness among HCWs about prescription audits as it was not being conducted by the hospital administration. HCWs were also reported to be non-compliant to standard ICMR guidelines as they follow their own clinical practice. There was also lack of facilities reported in some facilities to conduct culture sensitivity, which makes it difficult to follow the appropriate antimicrobial practices. These factors in combination with non-availability of high-end antibiotics in public health facilities ultimately burdens the

patients visiting the public health facilities. They are prescribed antibiotic to purchase outside in private pharmacy, leading to significant out-of-pocket expenditure. Some suggestions identified during the interviews were to mandate a strict directive for all the HCWs to comply with the ICMR guidelines while prescribing antimicrobials. Regular training/CME/workshops can be conducted to ensure that all the HCWs are aware about the antimicrobial prescription and resistance. At health system level, it was suggested that the antimicrobial stewardship should be made as a core competency into the curriculum of medical, dental, and allied health sciences.

Procedural and device safety policies and their implementation

For surgical safety, NPSIF has specifically mentioned that there is no national level policy and plan for the surgical services at various levels of healthcare.[23] The framework has mentioned that the safe surgical checklist is not uniformly implemented in the country. However, this is not the case as per the findings in our study. We found that almost all the surveyed public health facilities in Tamil Nadu except Theni Medical College, Attur GH and Vikravandi GH had a safe surgical checklist in their facility.

For injection safety, National Centre for Disease Control (NCDC) has released a handbook on safe injection practices and WHO has also released a policy guidance on safe injection.[95] Despite the availability of such materials, only one facility (Salem Medical College) had a handbook on safe injection practices in their facility. Only 7 out of 18 facilities conducts training on safe injection practices for their staffs regularly. Similar findings were reported in previous surveys and reports i.e., most facilities did not have injection safety guidance document or regular training to their staffs on patient safety.[96]

We also observed safety practices followed in injection OPD and found that only during 18.1% of the events, HCWs have performed hand hygiene in injection OPD, with least compliance

after touching the patient (17%) or his surroundings (11%). Highest compliance to hand hygiene in injection OPD was before giving injections (40%). However, this proportion was still less as every HCW should perform hand hygiene before giving injections as reported by a previous study in India.[97] However, some studies in countries like Cambodia (22%) and Iran (19%) have also reported lower compliance to hand hygiene during injection practices (similar to the current study finding).[98,99] Major reasons reported in the literature for such lower compliance were lack of training, supervision, and access to hand hygiene facilities.[100,101] An interventional study conducted in Cambodia has revealed that developing and implementing a setting-specific training program for HCWs might improve the compliance of hand hygiene from 22% to 80% during injection practices.[98] Hence, it is important to develop a setting specific training program and implement it across all the public health facilities in Tamil Nadu.

We also found some positive findings with respect to injection safety practices, where 100% of the observations had used sterile needle/syringe for injection. We also found that 75% of the times, staffs from injection OPD followed proper waste disposal practices. These findings were also in line with the previous evidence in India and similar low middle income settings.[97,102-104] Unsafe waste disposal practices during injections, like inappropriate collection or disposal of sharp wastes puts the HCWs, waste handlers and community at risk of having sharp injuries leading to blood-borne infections. Hence, high compliance to such practices might help in reducing such serious infectious diseases. However, apart from this information, additional indicators such as needle recapping, utilization of newer injection devices, Hepatitis B vaccination coverage of HCWs, proportion of HCWs with exposure to needle stick injuries and postexposure prophylaxis should be collected for conducting a comprehensive assessment of injection safety practices across all the public health facilities in Tamil Nadu.[105]

Good practices at the hospital administration level in the surveyed facilities were the reporting of needle stick injuries to hospital administration (14 out of 18 facilities). This shows there is

excellent surveillance system in place for needle stick injuries across public health facilities in Tamil Nadu. Amongst these facilities conducting surveillance, only half of them report these events to NACO. This shows that the data is kept internal and the larger picture of the burden of needle stick injuries are not available. This is one of the major occupational hazards in healthcare setting and compiling this data on national level is very important. This was also reported as challenge in the framework for patient safety, necessitating a prompt attention to this issue.

For medical device safety, Drugs Controller General of India (DCGI) has few national regulatory and monitoring programmes, but extent of its implementation, practice and coverage are very limited. Despite the lack of importance towards medical device safety in India, Health Technology Assessment (HTA) Division has been established and it was designated as a WHO Collaborating Centre. Safe medical devices as per the Good Manufacturing Practices (GMP) and WHO standards for infection prevention & control and patient safety exists. NPSIF focuses primarily on key priority areas under medical device safety: utilization of non-mercury devices and dedicated biomedical engineer at facilities. Though, 10 out of 18 facilities has transitioned to use of non-mercury devices, only one facility (Tirunelveli Medical College) had a dedicated biomedical engineer. This has led to several challenges in these facilities like delayed servicing or repair of the equipment necessary for procedures or clinical care. This in turn led to interruption of patient care services in these facilities at times. One of the commonest suggestion identified during the qualitative interview was the appointment of dedicated biomedical engineer for each facility. This helps to overcome such barriers and ensure safe procedural and device practices. Facilities that are still using mercury devices can adopt the good practice followed in Omalur GH, where a *"mercury spill kit"* and proper training to staffs for accidental leakage from devices are provided.

Apart from these findings, major challenges faced in terms of overall procedural and device safety across these facilities were the patient's obsession towards unnecessary treatment and procedures (injections, scans etc.), non-compliance of HCWs to standard guidelines, lack of manpower, infrastructure, and equipment. Such challenges require interventions at multiple levels (patient, HCW, facility and health system). It is the responsibility of the HCWs to communicate and teach the patients about necessary medications/diagnostic/therapeutic procedures and consequences of undergoing such unwanted practices. Patients should also be responsible and trust the advice of HCWs & should not demand such unwanted procedures. Health facility and health system should also provide the necessary infrastructure, facilities, manpower and equipment to ensure safe and uninterrupted clinical care to the patients.

Patient safety research

Despite the considerable progress found in some areas of patient safety, infrastructure & funding for patient safety research was found to be very sparse as only two facilities (Tirunelveli and Salem Medical College) were conducting patient safety related research and none of the facilities had a repository on patient safety or allied themes. Similar findings were also reported by previous reports and publications.[106,107] Consequently, HCWs in other areas of clinical research were less aware of the information gaps in the field of patient safety, and the competences needed to tackle them. This hinders the development of multidisciplinary research teams, that are vital to create the evidence base for supporting safer care.[108]

Fostering research requires a significant effort to strengthen the research capacity, as the underdevelopment of this research field was attributed to the lack of support, funding and encouragement from the administration and health system level. Hence, it is important to encourage and motivate the researchers in public health facilities about the primary purpose of patient safety research, which is to produce the interventions and solutions for safer patient

safety policies and practices.[109] It is necessary to develop a set of professional leaders, who will be able to drive the change through monitoring and research.[110]

Inclusion of the patient safety theme into the curriculum might help to create more professionals focusing on this area of research. WHO has released a guide for developing training programmes on patient safety research.[108] Adopting this guide might help in addressing such limited capacity in the field of patient safety research and translating the results of the existing research. This guide helps to develop the leaders in patient safety research, implementation, and change management. This is especially important in a developing and transitional setting like India, where the need for cost-effective & locally acceptable interventions is more critical.[111,112]

Patient's positive perception towards safe hospital care

In ''To Err is Human'' released by the Institute of Medicine Committee on Quality of Health Care, it was emphasized that it is important to establish a safety culture in the hospitals and ensure that the patients are not inadvertently harmed by the errors.[113] Several studies have assessed the patient safety culture from the HCW's point of view in hospitals around the world.[114-117] Though patient safety culture can be assessed from the HCWs working in the facility, it is ultimately the patients' perception that finally decides the overall quality and safety of hospitals. Previous surveys conducted in Indian setting have tried to assess the patient satisfaction, respectful and quality care.[118-122] However, patients' perception on safe hospital care was not explored in any of these studies. Hence, we developed a questionnaire based on the patient safety domains assessed during the process evaluation and interviewed the patients visiting the OPD and IPD of the surveyed health facilities. We assessed the patients' perception on safe hospital care across various domains along with other quality related indicators such as

patient satisfaction, respectful care, quality of care and future recommendation to family/friends were assessed during this survey.

Our study showed that patients' visiting the surveyed health facilities had highly favourable perception about majority of the domains in both OPD and IPD settings, especially with respect to the communication between patient and HCWs and procedural safety. This is an encouraging finding given that despite the high caseload and work pressure in public health facilities, patients are clearly communicated about their disease condition & medications given to them and feeling safe during all the procedures (ranging from drawing blood for investigation to undergoing surgical procedure/childbirth).

However, there was slight negative or neutral perception towards nutrition & environmental safety, especially with the diet provided to the patients during their hospital stay. This should be further investigated as diet is an important part of recovery for any hospitalized patients. Patients' perception towards diet influences their eating habits during their hospital stay. Inadequate food intake can lead to malnutrition during hospitalization, leading to prolonged hospital stay and additional disease burdens.[123,124] Hence, further qualitative exploration should be undertaken to have a deeper understanding about the problem and recommend corrective actions.

At least one in five patients visiting OPD or IPD has reported that they felt unsafe with respect to compliance of COVID-19 appropriate behaviour (i.e., hand hygiene, social distancing and masking) inside the hospital. However, qualitative exploration of COVID-19 safety revealed that the non-compliance to COVID-19 appropriate behaviour by the visitors has contributed to this finding, with even the COVID-19 patients going home and come back to hospital whenever they feel like. Hence, more stringent rules and regulations should be laid down and strict action should be taken against the non-complying set of patients and visitors in the hospital.

Another positive finding found in our study was the high level of patient satisfaction and positive perception about the quality of care in both OPD and IPD settings across all the surveyed public health facilities. This was significantly higher than previous studies conducted in public health facilities across different parts of India.[118,119,125] High level of satisfaction and quality of care has led to more than 90% of the patients reporting that they will recommend the facility to their family/friends.

Though that was such a positive finding, the minor proportion who were not satisfied with the care had faced some form of disrespect (felt disrespected/received shout or scold/received negative or disparaging comments) during their hospital visit/stay. This has made them to feel dissatisfied with the service and not recommend the facility to others. The disrespectful care was significantly higher among the hospitalized patients when compared to those visiting OPD. This can negatively impact the patient outcomes and delay the recovery time. These factors further burden the patients, HCWs and facilities. Though minor proportion has felt such disrespect or abuse, it is a burning issue that has been widely discussed all over the world.[126] However, till now, the studies have focused on assessing the respectful maternity care, while the patients admitted/visiting the facility for other reasons are neglected from this area of research.[127-130] Hence, the findings from our study should be taken up and further qualitative exploration to identify the reasons for such disrespectful care and corrective solutions should be suggested.

Level of socioeconomic development and patient safety practices

In our study, it was observed that districts such as Tirunelveli and Tiruchirappalli which are more developed as per the Human Development Index had better patient safety scores compared to Salem which had medium HDI and Theni, Villupuram, which had lower HDI (Pudukkottai was the only outlier with the best patient safety score, despite being a medium

HDI district). This pattern of socio-economic development having an impact on patient safety has been observed in previous studies and reports.[112] Increasing socio-economic development means the availability of funds for focusing on the quality and patient safety measures will also be high. Therefore, the health system practices on patient safety are higher in these better developed districts. Moreover, stricter regulatory mechanisms and policies are present in these better developed districts as observed in this study. This directly translates to a better score on patient safety system.

Strengths and Limitations of the study:

Strengths

1. This was the first study to assess the level of implementation of patient safety framework in public health facilities of Tamil Nadu.
2. Adoption of mixed methods approach has enabled us to explore the challenges faced by these facilities and provide recommendations in a more comprehensive manner.
3. We did a comprehensive evaluation of patient safety framework implementation using nearly 100 indicators, developed through the policy document, literature search, expert opinion and validated through panel of experts and piloting of the tool.
4. We have utilized a validated tool or standard framework/guidelines (released by Government of India/WHO/CDC or other reputed organizations) for developing the process evaluation indicators or survey on hand hygiene, BMW disposal and assessment of patients' perception on safe hospital care.
5. We did data triangulation by confirming the findings for most indicators of process evaluation. Data triangulation was done through multiple sources & the information obtained during quantitative or qualitative interviews were physical verified through records, registers, or logs. This further enhances the credibility of the study findings.
6. We have also conducted a survey on hand hygiene and BMW disposal practices in all the surveyed health facilities across different settings (OPD/IPD/Procedure room/Injection OPD/ICU/OT) and type of HCWs (doctors/nurses/allied staff).
7. Relevant stakeholders (patients, HCWs, hospital administrative heads) were interviewed during the qualitative component of the study, which helped us to explore the ground level challenges in implementation of framework and communicate the findings to health system.

8. We have also adopted a geographically representative sampling strategy, which might increase the external validity of our study findings. This model strategy can be adopted by other regions for the assessment of patient safety framework implementation in the respective states of the country.
9. Higher sample size for both quantitative & qualitative components,
10. High response rate and cooperation from patients, HCWs and administrative heads of the facilities were added strengths of the study.

Limitations

1. Observer bias was possible during the hand hygiene and BMW disposal observations, as the Dean/MS/RMO were informed that such observations will be made on the HCWs in a defined period of time. Hence, the communication of this information to all the HCWs in the facility might have influenced their practices during the survey.
2. Possibility of desirability bias as the HCWs might tend to under-report the unfavourable findings and over-report the favourable information about their own health facility.
3. We were not able to physically verify the safe practices of some clinical care procedures like surgical safety, obstetric safety, radiation safety and injection safety due to feasibility and resource constraints.
4. Restriction of access to some wards in the facilities made it difficult to physically verify some of the process evaluation indicators (especially related to COVID-19 safety)
5. Given the current COVID-19 situation, some of the indicators especially in infection prevention and control and coordination of non-COVID activities might be influenced in a positive or negative way. Hence, a repeat survey post the pandemic situation might give a better picture of public health facilities out of COVID-19 context.

Recommendations:

Based on the findings from this study, we propose several important recommendations to enable the implementation of patient safety framework across secondary and tertiary health facilities in Tamil Nadu. Recommendations were provided at the following four levels:

1. *Health facility level,*
2. *Health system level.*
3. *Healthcare worker level,*
4. *Patient level*

Recommendations at Health Facility level:

1. Each facility should set up its own patient safety committee, along with sub-committees such as HICC, BMW management committee, CSSD, hospital transfusion committee, antimicrobial stewardship committee, pharmacovigilance committee and quality control committee (for NQAS/NABH/any other accreditation processes).
    a. Composition of Patient Safety Committee in Medical Colleges:

    Medical Superintendent, Clinical Microbiologist, Clinical Pharmacologist, Transfusion Medicine specialist, Community Medicine specialist, General Medicine specialist, General Surgery specialist, Obstetrics and Gynecology specialist, Paediatrics specialist, Pharmacist, Quality Consultant, Nursing Superintendent and representatives from patients and families

    b. Composition of Patient Safety Committee in District Hospitals:

    Medical Superintendent/Resident Medical Officer, Microbiologist (if available), Blood bank-in-charge, General Medicine specialist, General Surgery specialist, Obstetrics and Gynecology specialist, Paediatrics specialist, Pharmacist, Nursing Superintendent, representatives from patients and families

2. This patient safety committee along with subcommittees must meet monthly. It must have a documented minutes of meeting each month. Subcommittees should have their own meeting for coordination of their activities before this harmonized meeting. Patient safety committee should have received and went through the monthly audit reports of all the committees before the harmonized meeting. The purpose of harmonized meeting is as follows:
    a. To discuss the important findings in monthly audit reports.
    b. To review the progress and understand the challenges faced in the implementation of activities under each subcommittees.
    c. To ensure whether the problems discussed in the previous meeting were resolved.
    d. Discussion about the progress/trend of process and outcome indicators of patient safety practices
3. Standard Operating Procedures, Checklists, Training modules should be kept in place by the patient safety committee and the subcommittees on their respective department. These documents can be adopted based on the available standard guidelines and subsequent modifications can be made based on their local needs.
4. Regular audits on process indicators for implementation of patient safety framework (adopt the tool from this study or develop based on the six domains of NPSIF) should be conducted by the respective sub-committees with an overall coordination and supervision by the patient safety committee.
5. Regular audits on outcome indicators of patient safety practices (HCAIs, ADR, adverse transfusion reaction, needle stick injuries, diagnostic or medication errors, radiation harm, unsafe surgical care, venous thromboembolism, and sepsis) should be conducted

by the respective sub-committees with an overall coordination and supervision by the patient safety committee.

6. The audit findings of both process and outcome indicators should be made accessible for all the HCWs working in the hospital.
7. The audit findings should also be communicated to the relevant national/state level surveillance system as follows (e.g., needle stick injuries & adverse transfusion reaction to NACO and ADR to NCC for PvPI).
8. Adoption of system-based or electronic data handling system like WHO NET software (implemented in a phased manner) for data entry, analysis, and review of all the activities under patient safety committee and sub-committees of the hospital.
9. The Patient Safety committee must prepare a timetable for organizing monthly training to the relevant staffs including doctors, nurses, and other allied health staffs on each of the sub-themes under patient safety. A topic under each sub-theme can be selected for a month and the training can be conducted by the respective sub-committee with overall coordination and supervision by the patient safety committee. A model timetable can be developed as follows:
    a. January – Patient Safety committee (Training on the concept of patient safety)
    b. February – Quality control committee (Training on NQAS/NABH/ Kayakalp)
    c. March – HICC (Training on Hand hygiene practices based on "WHO 5 moments of hand hygiene")
    d. April – BMW management committee (Training on BMW management & disposal practices as per latest guidelines)
    e. May – CSSD (Training on SOP/guidelines for sterile equipment supply, monitoring & audit)

f. June – Hospital Transfusion committee (Training on adverse transfusion reaction reporting & management)
g. July – Pharmacovigilance committee (Training on ADR reporting & management)
h. August – Antimicrobial stewardship committee (Training on antimicrobial prescription, antimicrobial resistance, and antimicrobial stewardship)
i. September – General Surgery department (Training on Safe Surgical Checklist)
j. October – Obstetrics & Gynaecology department (Training on LaQshya & Dakshata checklist)
k. November – General Medicine department (Training on safe injection practices)
l. December – Community Medicine department (Training on research methodology)

In addition to these regular training sessions, special training sessions should be conducted by the patient safety committee on the newer updates in guidelines/new policy document/new program/scheme/service implementation in the hospital.

10. Patient satisfaction survey can be conducted at quarterly intervals in the OPD and IPD of all the departments. The findings of the survey should be communicated to the respective departments. Quality control team can assess the trend in patient satisfaction across each of the departments and explore the reasons for non-satisfaction, if found in any survey. However, a standard tool at the state level should be developed for conducting the patient satisfaction survey. This enables the comparison of findings between facilities and dilution in the criteria can be avoided.
11. All the secondary and tertiary public health facilities should feed information back to the state & district health administration on the ways in which the facilities' licensing,

regulatory or accreditation system could be improved for facilitating the achievement of highest standards of the patient safety.

12. Observation of "World Patient Safety Day" on 17th September every year to create awareness about patient safety among patient, families, HCWs and general public.
13. Application of Dakshata checklist for assessing the staff competency in childbirth can be done in all the public health facilities.
14. Hospital administration is responsible for providing constant encouragement, support (in terms of infrastructure, facilities, or equipment) and allocation of intramural funds for conducting research on patient safety and allied issues.
15. Patient safety champions for each aspect can be identified in each facility and can be made responsible for his/her expert area. This can ease the implementation of patient safety framework at the healthcare facilities.
16. Hospital administration should liaise with their local community organizations for providing preventive and promotive services like outreach sessions, awareness campaigns, blood donation camps, and mass vaccination drives.

Recommendations at Health System level:

1. A State level Core Multidisciplinary Expert Committee must be formed along with sub-committees (for each domain of patient safety) to discuss and provide recommendations on the implementation of patient safety practices across all the public health facilities in Tamil Nadu. The committee would bring out the directives and standards for implementation at the healthcare facility level and can also monitor the facilities by reviewing their reports and undertake various forms of audits and assessments.
2. This core committee must comprise of experts in the field of infectious diseases, microbiologists, pharmacologists, transfusion medicine specialists, public health specialists, surgeons, physicians, obstetricians, intensivists, health professional with qualification and experience in hospital administration and/or quality control and representatives from patients and families (patient safety advocates and champions).
3. This multidisciplinary expert committee must be given the task of arriving at a consensus decision on implementation of patient safety interventions in the health facilities, actively involved in framing, reviewing, and revising the policy and procedures under the framework and identification of indicators for regular monitoring and evaluation of implementation of patient safety framework and its outcomes.
4. This multidisciplinary expert committee should also frame Standard Operating Procedures, Checklists, and Training modules for each domain of patient safety. These documents should be circulated to all the public health facilities and the facilities should be instructed to strictly comply to these standard guidelines. The committee can be given the responsibility to undertake periodic monitoring and supervision of compliance to these guidelines.
5. State and district level surveillance of patient safety practices, implementation of patient safety framework and its outcomes must be established at Nodal Centres and several

smaller regional centres. This surveillance data must be used to review and update the patient safety guidelines. This surveillance system should consist of the following outcome indicators: HCAIs, major and minor ADR, adverse transfusion reaction, needle stick injuries, diagnostic or medication errors, radiation harm, unsafe surgical care, venous thromboembolism, and sepsis.

6. Creating a statutory requirement & accountability mechanism for all public health facilities to operate in a transparent manner, ensure minimum patient safety standards and publish an annual report on the patient safety.
7. Establish a state and district level patient safety charter that includes the institutional standards and the rights and responsibilities of patients and HCWs with respect to various domains of patient safety.
8. Funding to the public health facilities can be provided with a carryover option to the subsequent time period.
9. Filling up the existing vacancies across all the public health facilities can be done.
10. Hospital administration posts like Dean or Medical Superintendent can be assigned to doctors with additional qualification or experience in the field of hospital administration.
11. Dedicated quality control team consisting of a quality consultant (with qualification and experience in hospital administration/quality assurance/ public health), infection control nurse, laboratory technician, pharmacist, biomedical engineer, OT staff, can be framed for medical colleges and government hospitals.
12. District quality control team should conduct periodic audits of all the public health facilities under their control to identify the required infrastructure, facility, and equipment for achieving NQAS/NABH accreditation process. The same should be communicated to the state health department for supply of required materials and fast track the accreditation process across all the secondary and tertiary care facilities.

13. Dedicated biomedical engineer should be appointed for each of the tertiary care facilities and if possible, for each or cluster of secondary public health facilities in Tamil Nadu.
14. Establishment of Geriatric and Disabled friendly rails, floors and ramps in all the public health facilities should be done.
15. High-end antibiotics should be made available in public health facilities based on the local susceptibility patterns and requirements. This will reduce the OOPE among the patients and drastically reduce the need to seek private health facilities for bacterial infections resistant to low-end antibiotics.
16. Piloting of electronic medication system (computer-based system enabling the prescribing, supply, and/or administration of medicine) can be done to reduce the medication error and associated harm reduction. If found to be effective, it can be implemented in all the public health facilities.
17. Call for proposal on *"Patient Safety theme"* can be done on yearly basis (exclusively for the public health facilities in Tamil Nadu) and best research proposals can be awarded grants/funds to do their study.
18. National Medical Commission can incorporate the knowledge about patient safety as a core competency under the curriculum of medical, dental, and allied health sciences.

Recommendations at HCW level:

1. Training courses on each domain of patient safety must be developed specifically for the Indian context in collaboration with ICMR and this must be made mandatory for all government medical officers. This can be implemented in two phased manners:
    a. Phase 1: Mandatory offline training for all the members of the DIRECT PATIENT CARE TEAM must be implemented.
    b. Phase 2: HCWs newly recruited for the DIRECT PATIENT CARE must mandatorily undergo this training program as part of their induction training.
2. Proper maintenance of records, registers and logs by the staffs working under all the committees in a hospital. Every activity conducted by the committees or hospital administration should be documented to assess the progress in the implementation of patient safety practices in hospital.
3. All the HCWs involved in prescribing or dispensing the medications should adopt the *"10R checklist for safe drug administration"* or *"six moments of medication safety"* during their routine practice.
4. All the doctors working in secondary and tertiary public health facilities should mandatorily undergo the course on *"ICMR Online Prescribing Skills Course For Indian Medical Graduates (IMG)"*.
5. COVID-19 nodal officers/representative from each of the public health facility can undergo *"COVID-19: Learn & Lead",* an online course created by the National Institute of Epidemiology, Indian Council of Medical Research in collaboration with the Centre for Disease Control, United States. This course is dedicated towards enabling the HCWs on handling a pandemic situation and sustaining routine clinical services based on the real-life field experiences. However, this recommendation can be revisited depending on the trend of the disease or emergence of newer variants.

Recommendations at Patient level:

1. Audiovisual demonstration of health education messages should be telecasted in all the major OPDs & IPDs for raising awareness amongst the patients regarding the various domains of patient safety practices. The topics that can be considered are as follows: infection control, waste disposal measures, six moments of medication safety, harms of self-medication practices (especially antimicrobial resistance), voluntary blood donation, safe surgical and obstetric care, and COVID-19 appropriate behaviour.
2. Patient testimonials can be created by each of the secondary and tertiary care facilities to build the trust amongst general population to seek public health facilities.
3. Establishment of patient safety advocates & champions networks should be done at facility, district, and state level. This network should consist of patients and families who has experienced adverse events in hospitals, in order to utilize their experience of safe & unsafe care positively and build safety & harm-minimization strategies.
4. Patients and their families can be involved at all possible levels of healthcare delivery, ranging from the policy making & planning related to patient safety till the performance oversight, and shared decision-making at each level of care. However, the patients need to be educated first as involvement before proper education can result in conflict within the healthcare facilities. Hence, this should be considered as the last item of implementation in the patient safety framework.

Recommendations for Future Research:

Though we have tried to comprehensively assess the level of implementation of patient safety framework, challenges and recommendations, there is always some areas for improvement, which can be utilized for future research questions on patient safety practices in Tamil Nadu. The recommendations are as follows:

1. We have captured only the patients' perception on patient safety culture in public health facilities. Future studies can focus on HCWs' safety (violence against HCWs, mental health, ergonomics, conflict management etc.) and HCWs' perception on patient safety culture in hospitals.
2. Additional domains of patient safety like radiation safety, immunization safety, direct observation of surgical, obstetric and injection safety practices can be undertaken in the future patient safety studies in Tamil Nadu.
3. Qualitative interview with state & district level policymakers can be conducted to understand the feasibility of implementation of the proposed recommendations and challenges faced at state & district administration level to implement NPSIF.
4. We have included only secondary and tertiary care health facilities as the NPSIF was focusing primarily on the higher level of care. However, patient safety is a universal concept applicable at all the levels of healthcare in both private and public facilities. Hence, future studies should also include primary healthcare facilities and private healthcare facilities (clinics, hospitals, and tertiary care centres) in the sample.
5. The survey data collection was done during the ongoing COVID-19 crisis, which might have influenced certain process indicators and response to interviews. Hence, similar study with above-mentioned modification can be done post the pandemic period to understand the patient safety practices, framework implementation and its challenges in non-COVID-19 context.

6. We have conducted only process evaluation to assess the level of implementation of NPSIF. Future studies can also capture the outcome indicators for NPSIF implementation (HCAIs, ADR, adverse transfusion reaction, needle stick injuries, diagnostic or medication errors, radiation harm, unsafe surgical care, venous thromboembolism, and sepsis). This will be helpful to assess the trend in the outcome indicators and understand the impact of implementation of various activities mentioned under NPSIF in a phased manner across public health facilities in Tamil Nadu.

CONCLUSION:

This study assessing the implementation status of NPSIF across public health facilities in Tamil Nadu found that majority of the facilities were still underprepared to implement the patient safety framework in their facilities. Structural support for quality & safety (accreditations), antimicrobial practices, blood safety, patient safety research are the major domains in which the facilities were lacking in terms of NPSIF recommended practices. The major challenges reported for the implementation of the framework were shortage in manpower, infrastructure, facilities, equipment, lack of awareness about patient safety, non-compliance to standard guidelines and lack of patient cooperation. However, the study also reports the recommendations suggested to overcome these challenges and best practices followed in the surveyed facilities. Therefore, the study concludes that based on the current situation of patient safety practices in public health facilities, it will be difficult to perform full-fledged implementation of patient safety framework by the year 2025. However, as a first step, a core patient safety committee can be formed at the state level and this team can come up with a Gantt chart for this framework implementation based on the priorities during this three years' time. There is an immediate need to intervene and establish rigorous patient safety committee at state, district level involving the health facilities at the ground level to ensure the phased implementation of patient safety framework across the public health facilities in Tamil Nadu.

REFERENCES:

1. World Health Organization. Patient safety. 2019. [Internet] [cited 22 Mar 2021]. Available from: https://www.who.int/news-room/fact-sheets/detail/patient-safety
2. Runciman W, Hibbert P, Thomson R, Van Der Schaaf T, Sherman H, Lewalle P. Towards an International Classification for Patient Safety: key concepts and terms. Int J Qual Health Care. 2009; 21(1):18-26
3. Puras D. Universal Health Coverage: A Return to Alma-Ata and Ottawa. Health Hum Rights. 2016; 18(2):7-10
4. World Health Organization. Patient safety – Healthcare association infections Fact Sheet. 2017. [Internet] [cited 2022 Jan 23]. Available from: https://www.who.int/gpsc/country_work/gpsc_ccisc_fact_sheet_en.pdf
5. World Health Organization. Global patient safety action plan 2021–2030: towards eliminating avoidable harm in health care. Geneva: World Health Organization; 2021. [Internet] [cited 2022 Jan 23]. Available from: https://www.who.int/publications/i/item/9789240032705
6. Gardam MA, Lemieux C, Reason P, van Dijk M, Goel V. Healthcare-associated infections as patient safety indicators. Healthc Pap. 2009; 9(3):8-24
7. Aitken M, Gorokhovich L. Advancing the Responsible Use of Medicines: Applying Levers for Change. Parsippany (NJ): IMS Institute for Healthcare Informatics; 2012. [Internet] [cited 2022 Jan 23]. Available from: https://ssrn.com/abstract=2222541 (Accessed 26 December 2021).
8. WHO guidelines for safe surgery 2009: safe surgery saves lives. Geneva: World Health Organization; 2009. [Internet] [cited 2022 Jan 23]. Available from: http://apps.who.int/iris/bitstream/handle/10665/44185/9789241598552_eng.pdf?sequence=1 (Accessed 26 December 2021)

9. ha AK, Larizgoitia I, Audera-Lopez C, Prasopa-Plaizier N, Waters H, W Bates D. The global burden of unsafe medical care: analytic modelling of observational studies. BMJ Qual Saf Published Online First: 18 September 2013. https://doi.org/10.1136/bmjqs-2012-001748
10. Singh H, Meyer AN, Thomas EJ. The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. BMJ Qual Saf. 2014;23(9):727–31. https://doi.org/10.1136/bmjqs-2013-002627
11. Clinical transfusion process and patient safety: Aide-mémoire for national health authorities and hospital management. Geneva: World Health Organization; 2010. [Internet] [cited 2022 Jan 23]. Available from: http://www.who.int/bloodsafety/clinical_use/who_eht_10_05_en.pdf?ua=1 (Accessed 26 July 2019)
12. Janssen MP, Rautmann G. The collection, testing and use of blood and blood components in Europe. Strasbourg: European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe; 2014. [Internet] [cited 2022 Jan 23] (https://www.edqm.eu/sites/default/files/report-blood-and-blood-components-2014.pdf, accessed 26 December 2021).
13. Boadu M, Rehani MM. Unintended exposure in radiotherapy: identification of prominent causes. Radiother Oncol. 2009; 93(3):609–17. https://doi.org/10.1016/j.radonc.2009.08.044
14. Shafiq J, Barton M, Noble D, Lemer C, Donaldson LJ. An international review of patient safety measures in radiotherapy practice. Radiother Oncol. 2009; 92:15-21 https://doi.org/10.1016/j.radonc.2009.03.007

15. Fleischmann C, Scherag A, Adhikari NK, et al. Assessment of Global Incidence and Mortality of Hospital-treated Sepsis. Current Estimates and Limitations. Am J Respir Crit Care Med 2016; 193(3): 259-72. https://doi.org/10.1164/rccm.201504-0781OC https://www.ncbi.nlm.nih.gov/pubmed/26414292
16. Raskob E, Angchaisuksiri P, Blanco N, Buller H, Gallus A, Hunt B, et al. Thrombosis: A major contributor to global disease burden. Thrombosis Research. 2014; 134(5): 931–938
17. Systems Approach. In: Patient Safety Network [website]. Rockville (MD): Agency for Healthcare Research and Quality; 2019. [Internet] [cited 2022 Jan 23] (https://psnet.ahrq.gov/primers/primer/21, accessed 23 December 2021).
18. Leape L. Testimony before the President's Advisory Commission on Consumer Production and Quality in the Health Care Industry, November 19, 1997.
19. Squeri R, Genovese C, Palamara MA, Trimarchi G, La Fauci V. "Clean care is safer care": correct handwashing in the prevention of healthcare associated infections. Ann Ig. 2016 Nov-Dec;28(6):409-415. doi: 10.7416/ai.2016.2123. PMID: 27845475.
20. García-París, J., Coheña-Jiménez, M., Montaño-Jiménez, P. et al. Implementation of the WHO "Safe Surgery Saves Lives" checklist in a podiatric surgery unit in Spain: a single-center retrospective observational study. Patient Saf Surg 9, 29 (2015). https://doi.org/10.1186/s13037-015-0075-4
21. Donaldson LJ, Kelley ET, Dhingra-Kumar N, Kieny MP, Sheikh A. Medication Without Harm: WHO's Third Global Patient Safety Challenge. Lancet. 2017 Apr 29;389(10080):1680-1681. doi: 10.1016/S0140-6736(17)31047-4. PMID: 28463129.
22. Mitchell PH. Defining Patient Safety and Quality Care. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD):

Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 1. Available from: https://www.ncbi.nlm.nih.gov/books/NBK2681/

23. Ministry of Health & Family Welfare. National Patient Safety Implementation Framework (2018-25) New Delhi: MoHFW, Government of India; 2018. [Internet] [cited 2022 Jan 23]. Available from: https://www.who.int/docs/default-source/searo/india/antimicrobial-resistance/national-patient-safety-implementation-framework.pdf?sfvrsn=7f5c38a4_2
24. Chavali S, Menon V, Shukla U. Hand hygiene compliance among healthcare workers in an accredited tertiary care hospital. Indian J Crit Care Med 2014; 18:689-93.
25. Indian Council of Medical Research. Hospital Infection Control Guidelines. [Internet] [cited 24 Jan 2022]. Available from: https://main.icmr.nic.in/sites/default/files/guidelines/Hospital_Infection_control_guidelines.pdf
26. World Health Organization. Guidelines on Core Components of Infection Prevention and Control Programmes at the National and Acute Health Care Facility Level. [Internet] [cited 24 Jan 2022]. Available from: https://www.who.int/gpsc/core-components.pdf
27. National AIDS Control Organization. Standards for Blood Banks and Blood Transfusion Services. 2007. [Internet] [cited 24 Jan 2022]. Available from: http://naco.gov.in/sites/default/files/Standards%20for%20Blood%20Banks%20and%20Blood%20Transfusion%20Services.pdf
28. Walia K, Ohri VC, Madhumathi J, Ramasubramanian V. Policy document on antimicrobial stewardship practices in India. The Indian journal of medical research. 2019;149(2):180–4.

29. World Health Organization. Hospital readiness checklist for COVID-19. 2020. [Internet] [cited 24 Jan 2022]. Available from: https://www.who.int/publications/i/item/WHO-2019-nCoV-hospital-readiness-checklist-2020.1
30. Chou DT, Achan P, Ramachandran M. The World Health Organization '5 moments of hand hygiene': the scientific foundation. J Bone Joint Surg Br. 2012 Apr;94(4):441-5. doi: 10.1302/0301-620X.94B4.27772
31. National Centre for Disease Control. Hospital infection prevention and control guidelines. [Internet] [cited 24 Jan 2022]. Available from: https://ncdc.gov.in/WriteReadData/l892s/File571.pdf
32. Kaur G, Kaur P. Hospital transfusion committee: Role and responsibilities. Indian J Pathol Microbiol 2014; 57:352-4
33. Chandy SJ, Michael JS, Veeraraghavan B, Abraham OC, Bachhav SS, Kshirsagar NA. ICMR programme on Antibiotic Stewardship, Prevention of Infection & Control (ASPIC). Indian J Med Res. 2014 Feb;139(2):226-30. PMID: 24718396; PMCID: PMC4001333.
34. Lihite RJ, Lahkar M. An update on the pharmacovigilance programme of India. Frontiers in pharmacology. 2015 Sep 23;6:194.
35. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007; 19(6):349-57
36. Gopal KM. Strategies for Ensuring Quality Health Care in India: Experiences From the Field. Indian J Community Med. 2019 Jan-Mar;44(1):1-3. doi: 10.4103/ijcm.IJCM_65_19.

37. Alkhenizan A, Shaw C. Impact of accreditation on the quality of healthcare services: a systematic review of the literature. Ann Saudi Med. 2011 Jul-Aug;31(4):407-16. doi: 10.4103/0256-4947.83204
38. Desveaux L, Mitchell JI, Shaw J, Ivers NM. Understanding the impact of accreditation on quality in healthcare: A grounded theory approach. Int J Qual Health Care. 2017 Nov 1;29(7):941-947. doi: 10.1093/intqhc/mzx136.
39. National Health Mission, Ministry of Health & family Welfare, Government of India. National Quality Assurance Standards for Public Health Facilities 2020. [Internet] [cited 2022 Jan 23]. Available from: http://qi.nhsrcindia.org/sites/default/files/National%20Quality%20Assurance%20Standards%202020.pdf
40. National Accreditation Board for Hospitals and Healthcare Providers (NABH). Accreditation Standards for Hospitals (5th edition) April 2020. [Internet] [cited 2022 Jan 23] Available from: https://www.nabh.co/images/Standards/NABH%205%20STD%20April%202020.pdf
41. Alkhenizan A, Shaw C. The attitude of health care professionals towards accreditation: A systematic review of the literature. J Fam Community Med 2012; 19:74-80
42. Joseph S. Impact assessment of accreditation in primary and secondary public health-care institutions in Kerala, India. Indian J Public Health. 2021 Apr-Jun;65(2):110-115. doi: 10.4103/ijph.IJPH_827_20.
43. Joint Commission International. International Patient Safety Goals 2017. [Internet] [cited 2022 Jan 23]. Available from: http://www.jointcommissioninternational.org/improve/international-patient-safety-goals

44. World Health Organization. Healthcare associated infections: FACT SHEET. [Internet] [cited 24 Jan 2022]. Available from: https://www.who.int/gpsc/country_work/gpsc_ccisc_fact_sheet_en.pdf
45. Tyagi M, Hanson C, Schellenberg J, Chamarty S, Singh S. Hand hygiene in hospitals: an observational study in hospitals from two southern states of India. BMC public health. 2018 Dec;18(1):1-9.
46. Nair SS, Hanumantappa R, Hiremath SG, Siraj MA, Raghunath P. Knowledge, attitude, and practice of hand hygiene among medical and nursing students at a tertiary health care centre in Raichur, India. International Scholarly Research Notices. 2014;2014.
47. Bathke J, Cunico PD, Maziero EC, Cauduro FL, Sarquis LM, Cruz ED. Infrastructure and adherence to hand hygiene: challenges to patient safety. Revista gaucha de enfermagem. 2013; 34:78-85.
48. Onyedibe KI, Shehu NY, Pires D, Isa SE, Okolo MO, Gomerep SS, et al. Assessment of hand hygiene facilities and staff compliance in a large tertiary health care facility in northern Nigeria: a cross sectional study. Antimicrob Resist Infect Control. 2020; 9(1):30
49. Bharara T, Gur R, Duggal S, Chugh V. Evaluation of hand hygiene compliance over the years, in an intensive care unit of a north Delhi hospital preparing for accreditation: A 3-year study. J Family Med Prim Care. 2020 Apr 30;9(4):1939-1943.
50. Powell-Jackson T, King JJ, Makungu C, Spieker N, Woodd S, Risha P, Goodman C. Infection prevention and control compliance in Tanzanian outpatient facilities: a cross-sectional study with implications for the control of COVID-19. The Lancet Global Health. 2020 Jun 1;8(6):e780-9.

51. Sureshkumar D., Ramasubramanain V., Abdulghafur K., Nagvekar V. Hand hygiene compliance in India. BMC Proceedings. 2011;5(suppl 6):259.
52. Sastry AS, Deepashree R, Bhat P. Impact of a hand hygiene audit on hand hygiene compliance in a tertiary care public sector teaching hospital in South India. American journal of infection control. 2017 May 1;45(5):498-501.
53. Anargh V, Singh H, Kulkarni A, Kotwal A, Mahen A. Hand hygiene practices among health care workers (HCWs) in a tertiary care facility in Pune. Med J Armed Forces India. 2013 Jan;69(1):54-6. doi: 10.1016/j.mjafi.2012.08.011.
54. Pittet D, Mourouga P, Perneger TV. Compliance with handwashing in a teaching hospital. Infection Control Program. Ann Intern Med 1999;130:126-30.
55. Karaaslan A, Kepenekli Kadayifci E, Atıcı S, Sili U, Soysal A, Çulha G, et al. Compliance of healthcare workers with hand hygiene practices in neonatal and pediatric intensive care units: overt observation. Interdiscip Perspect Infect Dis 2014; 2014:1-5.
56. Shukla U, Chavali S, Menon V. Hand hygiene compliance among healthcare workers in an accredited tertiary care hospital. Indian J Crit Care Med 2014; 18:689.
57. Mathai A, George S, Abraham J. Efficacy of a multimodal intervention strategy in improving hand hygiene compliance in a tertiary level intensive care unit. Indian J Crit Care Med 2011; 15:6.
58. Chartier Y, Emmanuel J, Pieper U, Prüss A, Rushbrook P, Stringer R, editors. Safe Management of Wastes from Health-Care Activities. 2nd ed. Geneva, Switzerland: WHO Press; 2014. p. 1-146.
59. The Gazette of India Biomedical Wastes (Management and Handling) Rules, India: Ministry of Environment and Forests, Government of India. Notification Dated; 20th July, 1998.

60. Bio-Medical Waste Management Rules, 2016. Published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (i), Government of India Ministry of Environment, Forest and Climate Change. Notification; New Delhi, the 28th March, 2016.
61. Central Pollution Control Board. Pictorial Guide on Biomedical Waste Management Rules 2016. [Internet] [cited 24 Jan 2022]. Available from: https://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/Pictorial_guide_covid.pdf
62. Devi A, Ravindra K, Kaur M, Kumar R. Evaluation of biomedical waste management practices in public and private sector of health care facilities in India. Environ Sci Pollut Res Int. 2019 Sep;26(25):26082-26089. doi: 10.1007/s11356-019-05785-9.
63. Chethana T, Thapsey H, Gautham MS, Sreekantaiah P, Suryanarayana SP. Situation analysis and issues in management of biomedical waste in select small health care facilities in a ward under Bruhat Bengaluru Mahanagara Palike, Bangalore, India. J Community Health. 2014 Apr;39(2):310-5
64. Dixit AM, Bansal P, Jain P, Bajpai PK, Rath RS, Kharya P. Assessment of Biomedical Waste Management in Health Facilities of Uttar Pradesh: An Observational Study. Cureus. 2021 Dec 2;13(12):e20098. doi: 10.7759/cureus.20098.
65. Capoor MR, Parida A. Biomedical Waste and Solid Waste Management in the Time of COVID-19: A Comprehensive Review of the National and International Scenario and Guidelines. J Lab Physicians. 2021 Jun;13(2):175-182
66. Basavaraj, T.J., Shashibhushan, B.L. & Sreedevi, A. To assess the knowledge, attitude and practices in biomedical waste management among health care workers in dedicated COVID hospital in Bangalore. Egypt J Intern Med 33, 37 (2021).

67. Dalui A, Banerjee S, Roy R. Assessment of knowledge, attitude, and practice about biomedical waste management among healthcare workers during COVID-19 pandemic in a health district of West Bengal. Indian J Public Health 2021; 65:345-51
68. Rowan NJ, Laffey JG. Unlocking the surge in demand for personal and protective equipment (PPE) and improvised face coverings arising from coronavirus disease (COVID-19) pandemic – implications for efficacy, re-use and sustainable waste management. Sci Total Environ 752. 2021.
69. World Health Organization. Modes of transmission of virus causing COVID-19: implications for IPC precaution recommendations. [Internet] [cited 24 Jan 2022]. Available from: https://www.who.int/news-room/commentaries/detail/modes-of-transmission-of-virus-causing-covid-19-implications-for-ipc-precaution-recommendations.
70. Dey P, Das B. Knowledge, attitude, and practices about biomedical waste management as per 2016 rules among resident doctors and nursing staff in a tertiary care specialty hospital: A cross-sectional study. J Med Soc 2020; 34:31-5
71. Imchen T, Kumari R, Singh JV, Srivastava K, Singh A. Study of biomedical waste management among healthcare personnel at a Tertiary hospital in Lucknow district. Int J Community Med Public Health 2017; 4:1483-7.
72. Malik MA. Fragility and challenges of health systems in pandemic: early lessons from India's second wave of coronavirus disease 2019 (COVID-19). Glob Health J. 2022 Jan 19. doi: 10.1016/j.glohj.2022.01.006. Epub ahead of print. PMID: 35070474; PMCID: PMC8767801.
73. Rebmann T. Assessing hospital emergency management plans: a guide for infection preventionists. Am J Infect Control. 2009; (9):708–14. e4. doi:10.1016/j.ajic.2009.04.286

74. Seyedin H; Moslehi S; Sakhaei F; Dowlati M. Developing a hospital preparedness checklist to assess the ability to respond to the COVID-19 pandemic. East Mediterr Health J. 2021(2):131-141 https://doi.org/10.26719/2021.27.2.131

75. World Health Organization. Medication Without Harm. 2017. [Internet] [cited 24 Jan 2022]. Available from: https://www.who.int/initiatives/medication-without-harm

76. Aitken M, Gorokhovich L. Advancing the responsible use of medicines: applying levers for change. Parsippany (NJ), United States of America: IMS Institute for Healthcare Informatics; 2012 Available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2222541

77. World Health Organization. Medication Without Harm: WHO Global Patient Safety Challenge. 2017. [Internet] [cited 24 Jan 2022]. Available from: https://apps.who.int/iris/bitstream/handle/10665/255263/WHO-HIS-SDS-2017.6-eng.pdf?sequence=1&isAllowed=y

78. Kalaiselvan V, Srivastava S, Singh A, Gupta SK. Pharmacovigilance in India: Present Scenario and Future Challenges. Drug Saf. 2019 Mar;42(3):339-346. doi: 10.1007/s40264-018-0730-7. PMID: 30269244.

79. Pharmacovigilance Programme of India. Introduction & functions. 2017. [Internet] [cited 24 Jan 2022]. Available from: http://www.ipc.gov.in/PvPI/about.html.

80. Pharmacovigilance Programme of India. IPC, NCC-PvPI as WHO Collaborating Centre. 2017. [Internet] [cited 24 Jan 2022]. Available from: http://www.ipc.gov.in/PvPI/about.html

81. World Health Organization. 5 moments for medication safety. 2019. [Internet] [cited 24 Jan 2022]. Available from: https://www.who.int/publications/i/item/WHO-HIS-SDS-2019.4

82. Edwards S, Axe S. The 10 ‘R's of safe multidisciplinary drug administration. Nurse Prescribing. 2015 Aug 2;13(8):398-406.

83. Harris JC, Crookston KP. Blood Product Safety. [Updated 2021 Aug 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK539826/

84. World Health Organization. Blood safety and availability. 2020. [Internet] [cited 24 Jan 2022]. Available from: https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability

85. National AIDS Control Organization. Access to Safe Blood. 2017. [Internet] [cited 24 Jan 2022]. Available from: http://naco.gov.in/access-safe-blood

86. National Blood Transfusion Council. Compendium National Blood Policy and Guidelines 2016. [Internet] [cited 24 Jan 2022]. Available from: http://nbtc.naco.gov.in/assets/resources/policy/commonResource_1517222887.pdf

87. World Health Organization. Blood safety. 2009. [Internet] [cited 24 Jan 2022]. Available from: https://www.who.int/bloodsafety/transfusion_services/en/Blood_Safety_Eng.pdf

88. Murray CJ, Ikuta KS, Sharara F, Swetschinski L, Aguilar GR, Gray A, Han C, Bisignano C, Rao P, Wool E, Johnson SC. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet. 2022 Jan 19. Epub ahead of print. https://doi.org/10.1016/S0140-6736(21)02724-0

89. Walia K, Ohri VC. Antimicrobial stewardship activities in India: Current scenario. International Journal of Infectious Diseases. 2014 Apr;21:214.

90. Sahni A, Bahl A, Martolia R, Jain S, Singh S. Implementation of antimicrobial stewardship activities in India. Indian Journal of Medical Specialities. 2020;11(1):5

91. Ghafur A, Mathai D, Muruganathan A, Jayalal J, Kant R, Chaudhary D, et al. The Chennai declaration: A roadmap to tackle the challenge of antimicrobial resistance. Indian Journal of Cancer. 2013;50(1):71.
92. Ministry of Health and Family Welfare G of I. National Action Plan on Antimicrobial Resistance. New Delhi; 2017.
93. Indian Council of Medical Research. India's Antimicrobial Resistance Surveillance and Research Initiative. 2019.
94. Indian Council of Medical Research. Treatment guidelines for antimicrobial use in common syndromes. New Delhi; 2019.
95. National Center for Disease Control. Handbook on Safe Injection Practices. [Internet] [24 Jan 2022]. Available from: https://ncdc.gov.in/WriteReadData/l892s/Handbook%20on%20Safe%20Injection%20Practices.pdf
96. Gyawali S, Rathore DS, Kc B, Shankar PR. Study of status of safe injection practice and knowledge regarding injection safety among primary health care workers in Baglung district, western Nepal. BMC Int Health Hum Rights. 2013 Jan 3;13:3
97. Chaudhuri SB, Ray K. Safe Injection Practices in Primary Health Care Settings of Naxalbari Block, Darjeeling District, West Bengal. J Clin Diagn Res. 2016 Jan;10(1):LC21-4. doi: 10.7860/JCDR/2016/15668.7132. Epub 2016 Jan 1. PMID: 26894097; PMCID: PMC4740625.
98. Kanagasabai U, Singh A, Shiraishi RW, Ly V, Hy C, Sanith S, Srun S, Sansam S, SopHeap ST, Liu Y, Jones G, Ijeoma UC, Bock N, Benech I, Selenic D, Drammah B, Gadde R, Mili FD. Improving injection safety practices of Cambodian healthcare workers through training. PLoS One. 2020 Oct 30;15(10):e0241176. doi: 10.1371/journal.pone.0241176. PMID: 33126238; PMCID: PMC7599083.

99. Yusefzadeh H, Didarloo A, Nabilou B. Provider knowledge and performance in medication injection safety in anesthesia: A mixed method prospective crosses sectional study. PLoS One. 2018 Dec 5;13(12):e0207572

100. Erasmus V, Daha T, Brug H, Richardus J, Behrendt M, Vos M, et al. Systematic Review of Studies on Compliance with Hand Hygiene Guidelines in Hospital Care. Infect Control Hosp Epidemiol. 2010;31(3):283–94. pmid:20088678

101. Marra AR, Guastelli LR, Manuela C, Araujo P De. Positive Deviance: A New Strategy for Improving Hand Hygiene Compliance. 2010;(1).

102. Arora NK. Injection practices in India. WHO South-East Asia J Public Health 2012;1:189-200

103. Anwar, M.M., Mohamed Lotfy, A.A. & Alrashidy, A.A. Safe injection awareness and practices among nursing staff in an Egyptian and a Saudi hospital. J. Egypt. Public. Health. Assoc. 94, 21 (2019). https://doi.org/10.1186/s42506-019-0018-5

104. Al Awaidy S, Zayed B, Ramadan M, Hsairi M. Assessment of safe injection practices in health facilities in Oman. East Mediterr Health J. 2018 Jun 25;24(4):351-359. doi: 10.26719/2018.24.4.351. PMID: 29972229.

105. World Health Organization (WHO) best practices for injections and related procedures toolkit. March 2010. WHO/EHT/10.02 ISBN 978 92 4 159925 2. Available at https://apps.who.int/iris/bitstream/handle/10665/44298/9789241599252_eng.pdf;jsessionid=0DB0C5CCD2A5D71190B064DFE5DA4F45?sequence=1

106. Meyer GS, Eisenberg JM. The end of the beginning: the strategic approach to patient safety research. Qual Saf Health Care. 2002; 11(1):3-4.

107. Wachter RM. Patient safety at ten: unmistakable progress, troubling gaps. Health Aff (Millwood). 2010 Jan-Feb;29(1):165-73.

108. World Health Organization. Patient safety research: a guide for developing training programmes. 2012. [Internet] [cited 24 Jan 2022]. Available from: https://www.who.int/publications/i/item/9789241503440

109. Pronovost PJ, Berenholtz SM, Needham DM. Translating evidence into practice: a model for large scale knowledge translation. BMJ. 2008 Oct 6;337:a1714. doi: 10.1136/bmj.a1714.

110. Carpenter KB, Duevel MA, Lee PW, Wu AW, Bates DW, Runciman WB, Baker GR, Larizgoitia I, Weeks WB; Methods & Measures Working Group of the WHO World Alliance for Patient Safety. Measures of patient safety in developing and emerging countries: a review of the literature. Qual Saf Health Care. 2010 Feb;19(1):48-54

111. Bates DW, Larizgoitia I, Prasopa-Plaizier N, Jha AK; Research Priority Setting Working Group of the WHO World Alliance for Patient Safety. Global priorities for patient safety research. BMJ. 2009; 338: b1775

112. Wilson RM, Michel P, Olsen S, Gibberd RW, Vincent C, El-Assady R, et al; WHO Patient Safety EMRO/AFRO Working Group. Patient safety in developing countries: retrospective estimation of scale and nature of harm to patients in hospital. BMJ. 2012; 344: e832. doi: 10.1136/bmj.e832.

113. Institute of Medicine. To Err Is Human: Building a Safer Health System. Washington, DC: National Academy Press; 1999

114. Azyabi A, Karwowski W, Davahli MR. Assessing Patient Safety Culture in Hospital Settings. Int J Environ Res Public Health. 2021 Mar 3;18(5):2466. doi: 10.3390/ijerph18052466. PMID: 33802265; PMCID: PMC7967599.

115. Khoshakhlagh, A.H., Khatooni, E., Akbarzadeh, I. et al. Analysis of affecting factors on patient safety culture in public and private hospitals in Iran. BMC Health Serv Res 19, 1009 (2019). https://doi.org/10.1186/s12913-019-4863-x

116. Reis CT, Paiva SG, Sousa P. The patient safety culture: a systematic review by characteristics of hospital survey on patient safety culture dimensions. International Journal for Quality in Health Care. 2018 Nov 1;30(9):660-77.

117. Waterson P, Carman EM, Manser T, Hammer A. Hospital Survey on Patient Safety Culture (HSPSC): a systematic review of the psychometric properties of 62 international studies. BMJ Open. 2019 Sep 4;9(9):e026896

118. Rajkumari B, Nula P. Patient's satisfaction with care in a government health facility in North East India: A cross-sectional study. J Med Soc 2017;31:94-8

119. Verma M, Rana K, Kankaria A, Aggarwal R. Assessment of patient's satisfaction visiting a tertiary health care institute in north India. J Pharm Bioall Sci 2020;12:252-61

120. Bhattacharya S, Sundari Ravindran TK. Silent voices: institutional disrespect and abuse during delivery among women of Varanasi district, northern India. BMC Pregnancy Childbirth. 2018 Aug 20;18(1):338

121. Rajkumari B, Devi NS, Ningombam J, Ingudam D. Assessment of respectful maternity care during childbirth: Experiences among mothers in Manipur. Indian J Public Health 2021;65:11-5

122. Joseph. K. J. V, Mozumdar A, Lhungdim H, Acharya R (2020) Quality of care in sterilization services at the public health facilities in India: A multilevel analysis. PLoS ONE 15(11): e0241499.

123. Agarwal E., Ferguson M., Banks M., Batterham M., Bauer J., Capra S., Isenring E. Malnutrition and poor food intake are associated with prolonged hospital

stay, frequent readmissions, and greater in-hospital mortality: Results from the Nutrition Care Day Survey 2010. Clin. Nutr. 2013;32:735–745

124. Kontogianni M.D., Anna K., Bersimis F., Sulz I., Schindler K., Hiesmayr M., Chourdakis M. Exploring factors influencing dietary intake during hospitalization: Results from analyzing nutritionDay's database (2006–2013) Clin. Nutr. ESPEN. 2020;38:263–270. doi: 10.1016/j.clnesp.2020.04.001.

125. Chakraborty SN, Bhattacherjee S, Rahaman MA. A cross-sectional study on patient satisfaction in an Urban Health Care Centre of Siliguri Municipal Corporation, Darjeeling, West Bengal. Med J DY Patil Univ 2016;9:325-30

126. Organization WH. The prevention and elimination of disrespect and abuse during facility-based childbirth: WHO statement. Geneva: WHO; 2014.

127. Bowser D, Hill K. Exploring evidence for disrespect and abuse in facility-based childbirth. Boston: USAID-TRAction Project, Harvard School of Public Health; 2010.

128. Kassa, Z.Y., Husen, S. Disrespectful and abusive behavior during childbirth and maternity care in Ethiopia: a systematic review and meta-analysis. BMC Res Notes 12, 83 (2019). https://doi.org/10.1186/s13104-019-4118-2

129. Begley, C., Sedlicka, N. & Daly, D. Respectful and disrespectful care in the Czech Republic: an online survey. Reprod Health 15, 198 (2018).

130. Ansari H, Yeravdekar R. Respectful maternity care during childbirth in India: A systematic review and meta-analysis. J Postgrad Med 2020;66:133-40

APPENDIX – 1: PROCESS EVALUATION QUESTIONNAIRE

Unique ID for the facility:

Name of the healthcare facility:

Bed capacity of the healthcare facility:

Average number of outpatients per day:

Average number of inpatients per day:

Average bed occupancy rate over the past one week:

DOMAIN 1: Structural systems to support quality and efficiency of healthcare (expect Question 8, all other questions are Yes/No type)

1. Does the facility have National Quality Assurance Standards (NQAS) certification?

   Oral report: Yes/No Verified: Yes/No
2. Does the facility have National Accreditation Board for Hospitals & Healthcare Providers (NABH) certification?

   Oral report: Yes/No Verified: Yes/No
3. Does the facility have Joint Commission International (JCI) certification?

   Oral report: Yes/No Verified: Yes/No
4. Does the facility have International Organization for Standardization(ISO) certification?

   Oral report: Yes/No Verified: Yes/No
5. Does the facility have National Building Code (NBC) certification?

Oral report: Yes/No Verified: Yes/No

6. Does the facility have Fire safety certification?

   Oral report: Yes/No Verified: Yes/No

7. Does the facility have Seismic safety certification?

   Oral report: Yes/No Verified: Yes/No

8. If any other certification obtained, please specify_____

   Oral report: Yes/No Verified: Yes/No

9. Does the facility have SOPs/Checklist related to patient safety?

   Oral report: Yes/No Verified: Yes/No

10. Does the hospital have a standard protocol for duty handing over and taking over rounds?
11. Does the facility have anonymous reporting system (complaint box/suggestion box) to be used by healthcare facility staff, students, residents, parents and families?

    Oral report: Yes/No Verified: Yes/No

12. Are there any registered and functional patient groups who are involved in the development of policies, strategies or plans in the respective healthcare facility?

    Oral report: Yes/No Verified: Yes/No

DOMAIN 3: Competent and capable workforce is aware and sensitive to patient safety (Both the questions are Yes/No type)

1. Does the facility have practice guideline/SOP for training of healthcare workers on the theme “patient safety”?

   Oral report: Yes/No Verified: Yes/No

2. Does the facility conduct training for healthcare workers on theme “patient safety”?

   Oral report: Yes/No Verified: Yes/No

3. If yes, how often does the training is conducted?
4. When was the last training conducted? (dd/mm/yyyy)

DOMAIN 4a: Prevent and control healthcare associated infections (HCAI) – KAYAKALP

(First two questions are Yes/No type)

1. Whether the facility is Kayakalp certified?

   Oral report: Yes/No Verified: Yes/No

2. Whether the facility has made an initiative to implement the good practices mentioned under the Kayakalp program?

   Oral report: Yes/No Verified: Yes/No

   If NO, Answer next question as Nil

   If YES, mention the list of initiatives in the next question

3. What are the initiatives taken?

DOMAIN 4b: Prevent and control healthcare associated infections (HCAI) –

COVID Safety (All the questions are Yes/No type)

1. Does the facility have a nodal officer for COVID safety?

   Oral report: Yes/No Verified: Yes/No

2. Does the facility have COVID-19 triage procedure?

   Oral report: Yes/No Verified: Yes/No

3. Does the facility have a separate suspect and isolation ward for COVID-19?

   Oral report: Yes/No Verified: Yes/No

4. Has the facility trained health workers in the use of personal protective equipment (PPE) and COVID-19 appropriate behaviour?

   Oral report: Yes/No Verified: Yes/No

5. Does the facility practice rational use of PPE?

Oral report: Yes/No Verified: Yes/No

6. Whether the patients are placed in single rooms?
7. When single rooms are not available, whether the COVID-19 suspect patients are grouped together?
8. Does the facility ensure a 1-metre distance between beds regardless of whether patients are suspected of having COVID-19?

   Oral report: Yes/No Verified: Yes/No
9. Are there exclusive staffs for doing COVID-19 duty?

   Oral report: Yes/No Verified: Yes/No
10. Does the facility limit the visitors inside the suspected COVID-19 ward?
11. Does the facility limit the visitors inside the confirmed (isolation) COVID-19 ward?
12. Does the facility ensure that visitors follow COVID-19 appropriate behaviour?

    Oral report: Yes/No Verified: Yes/No

DOMAIN 5: Implement global patient safety campaigns and strengthening Patient Safety across all programmes (All are Yes/No questions)

1. Does the labour room in the facility Laqshya NQAS certified?

   Oral report: Yes/No Verified: Yes/No
2. Does the maternity OT in the facility Laqshya NQAS certified?

   Oral report: Yes/No Verified: Yes/No
3. Does the facility have a dedicated biomedical engineer?

   Oral report: Yes/No Verified: Yes/No
4. Does the facility use non-mercury devices and equipment?

   Oral report: Yes/No Verified: Yes/No

DOMAIN 6: Strengthen capacity for and improve patient safety research (All are Yes/No type questions)

1. Does the facility undertake research on questions related to patient safety?

   Oral report: Yes/No Verified: Yes/No

2. Does the facility have repository of good quality research on patient safety and other allied themes?

   Oral report: Yes/No Verified: Yes/No

Does your facility have microbiological laboratory/division within the hospital?

Oral report: Yes/No Verified: Yes/No

If no, does your facility have access to microbiological services outside the hospital?

Oral report: Yes/No Verified: Yes/No

Does the facility have a Hospital Infection Control Committee?

If answer is yes, proceed to HICC Domain

If answer is no, skip all the 10 questions in HICC Domain

HICC (All the questions are Yes/No type except question 6 & 7):

1. What is the composition of HICC committee?

_____

_____

_____

2. How often does it meet?
3. When did the committee meet last? (dd/mm/yyyy)
4. Whether the agenda and minutes maintained for the last conducted meeting?
5. Does the HICC have a log?
6. If present, Is the log updated?

---

1. Is there a microbiology department in the hospital?
2. Is there a SoP for infection prevention and control in the facility?

   Oral report: Yes/No Verified: Yes/No
3. Whether Environmental surveillance are carried out in the facility?

   Oral report: Yes/No Verified: Yes/No

   If yes, how often it is done?

   When was the last time this activity was carried out? (dd/mm/yyyy)
4. Whether OT surveillance and swabs are carried out in the facility?

   Oral report: Yes/No Verified: Yes/No

   If yes, how often it is done?

   When was the last time this activity was carried out? (dd/mm/yyyy)
5. Whether ICU surveillance and swabs are carried out in the facility?

   Oral report: Yes/No Verified: Yes/No

   If yes, how often it is done?

When was the last time this activity was carried out? (dd/mm/yyyy)

6. Whether Inspection/Monitoring of sterilization and disinfection practices are carried out in the facility?

   Oral report: Yes/No Verified: Yes/No

   If yes, how often it is done?

   When was the last time this activity was carried out? (dd/mm/yyyy)

7. Whether Autoclave check are carried out in the facility?

   Oral report: Yes/No Verified: Yes/No

   If yes, how often it is done?

   When was the last time this activity was carried out? (dd/mm/yyyy)

8. Whether Water quality check are carried out in the facility?

   If yes, how often it is done?

   When was the last time this activity was carried out? (dd/mm/yyyy)

9. How many blood cultures have been tested in the past year?

10. Do you monitor the antimicrobial sensitivity and resistance patterns of bacteria in your facility?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

    When was the last time this activity was carried out? (dd/mm/yyyy)

11. Whether all the healthcare workers undergo training on hand hygiene practices in the healthcare facility?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

    When was the last time this activity was carried out? (dd/mm/yyyy)

12. Does the facility conduct awareness sessions on the hand hygiene practices for the general public/patients?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

When was the last time this activity was carried out? (dd/mm/yyyy)

13. Does the HICC/microbiology department report the healthcare associated infection to the hospital administration?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

    When was the last time this activity was carried out? (dd/mm/yyyy)

14. Does the facility report the healthcare associated infection to the HAI surveillance?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

    When was the last time this activity was carried out? (dd/mm/yyyy)

15. Does the HICC/microbiology department has set of monitoring indicators for infection prevention and control?

    Oral report: Yes/No Verified: Yes/No

16. If yes, what are the indicators used? _____ (**If no to above question, mention Nil**)

17. Does the health facility have a dedicated CSSD/Sterilization department?

    Oral report: Yes/No Verified: Yes/No

18. Is there a standard operating procedure for the CSSD?

    Oral report: Yes/No Verified: Yes/No

19. Are there logs for monitoring sterilization practices?

    Oral report: Yes/No Verified: Yes/No

    If yes, when was the last time the log was updated? (dd/mm/yyyy)

20. Whether the cleaning, decontamination or fumigation of the CSSD done?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often?

    When was it last done? (dd/mm/yyyy)

21. Are swabs taken for culture to check quality of disinfection?

    Oral report: Yes/No Verified: Yes/No

If yes, how often?

When was it last done? (dd/mm/yyyy)

22. Have staff of the CSSD undergone training?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often?

    When was it last done? (dd/mm/yyyy)

23. Is there a maintenance and repair system in place for all the equipments?

    Oral report: Yes/No Verified: Yes/No

24. Are equipment serviced periodically?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often?

    When was it last done? (dd/mm/yyyy)

25. Is there a periodic internal audit of the CSSD?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often?

    When was it last done? (dd/mm/yyyy)

Biomedical waste management (All are Yes/No type questions):

1. Is there a separate biomedical waste management committee?

   Oral report: Yes/No Verified: Yes/No

   (If No, skip the next five questions)

2. How often does the committee meet?
3. When did the committee meet last? (dd/mm/yyyy)
4. Whether the agenda and minutes maintained for the last conducted meeting?
5. Does the BMWC have a log?

6. If present, Is the log updated?

---

7. Is there a SoP for biomedical waste management ?

   Oral report: Yes/No Verified: Yes/No

8. Are all staff trained in biomedical waste management?

   Oral report: Yes/No Verified: Yes/No

   If yes, how often it is done?

   When was the last time this activity was carried out? (dd/mm/yyyy)

9. Are staff handling biomedical waste provided PPE?

   Oral report: Yes/No Verified: Yes/No

10. Is there a mechanism for reporting needle stick injuries to hospital administration?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

    When was the last time reporting done? (dd/mm/yyyy)

11. Is there a mechanism for reporting needle stick injuries to NACO?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

    When was the last time reporting done? (dd/mm/yyyy)

12. Is there a biomedical waste storage facility in the hospital?

    Oral report: Yes/No Verified: Yes/No

13. Are there bins and trolleys for transporting biomedical waste safely to the storage facility?

    Oral report: Yes/No Verified: Yes/No

14. Does the facility have a link to any common treatment facility?

    Oral report: Yes/No Verified: Yes/No

    If yes, what is the name of the common treatment facility_____

Nursing Superintendent:

1. Does the facility have safe surgical checklist?

   Oral report: Yes/No Verified: Yes/No

2. Does the facility have a dedicated room for giving injections?

   Oral report: Yes/No Verified: Yes/No

3. Does the facility have a dedicated staff for giving injections?

   Oral report: Yes/No Verified: Yes/No

4. Does the facility have a handbook on safe injection practices available?

   Oral report: Yes/No Verified: Yes/No

5. Does the facility conduct training on safe injection practices for the hospital staffs?

   If yes, how often is it done?

   When was it last done? (dd/mm/yyyy)

---

1. Does the facility have established transfusion committee?

   Oral report: Yes/No Verified: Yes/No

2. What is the composition of the committee?

_____

_____

_____

3. Does the hospital transfusion committee have a log?

   Oral report: Yes/No Verified: Yes/No

   If yes, how often it is updated?

   When was it last updated? (dd/mm/yyyy)

4. How often does the hospital transfusion committee meet?

   Oral report: Yes/No Verified: Yes/No

   When was the last meeting conducted? (dd/mm/yyyy)

5. Agenda and minutes maintained for the last meeting?

   Oral report: Yes/No Verified: Yes/No

6. Whether the committee follows appropriate policies and procedures for blood transfusion?

   Oral report: Yes/No Verified: Yes/No

7. Whether the committee reviews the policies and procedures?

   Oral report: Yes/No Verified: Yes/No

8. Whether the committee revise the policies and procedures?

   Oral report: Yes/No Verified: Yes/No

9. Whether the committee monitors the blood transfusion practices?

   Oral report: Yes/No Verified: Yes/No

   If yes, how often it is done?

   When was it done last? (dd/mm/yyyy)

10. Whether the committee conduct audits to review the appropriateness of blood and its components for blood transfusion?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

    When was it done last? (dd/mm/yyyy)

11. Whether the committee evaluate incidence of adverse transfusion reaction (incorrect blood components transfused)?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

    When was it done last? (dd/mm/yyyy)

12. Does the hospital transfusion committee report the adverse donor and transfusion reactions to the hospital administration?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

    When was it done last? (dd/mm/yyyy)

13. Does the hospital transfusion committee report the adverse donor and transfusion reactions to the NACO?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often it is done?

    When was it done last? (dd/mm/yyyy)

---

1. Does the facility have blood bank?

   Oral report: Yes/No Verified: Yes/No
2. Is there a SoP for Blood Bank and Blood Transfusion services in the facility?

   Oral report: Yes/No Verified: Yes/No
3. Does the facility promote the voluntary non-remunerated blood donation?

   Oral report: Yes/No Verified: Yes/No
4. Does the facility require replacement donor for blood transfusion?

   Oral report: Yes/No Verified: Yes/No

Does your facility have a functioning committee on pharmacovigilance?

If no to above question, skip the pharmacovigilance committee related questions (next 4 questions)

---

1. What is the composition of the committee?

   _____

   _____

   _____
2. How often does the committee meet?

   Oral report: Yes/No Verified: Yes/No
3. When did the committee meet last? (dd/mm/yyyy)

   Oral report: Yes/No Verified: Yes/No

4. Does the committee report the adverse drug reactions to National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI)?

   Oral report: Yes/No Verified: Yes/No

   If yes, how often it is done?

   When was it done last? (dd/mm/yyyy)

Does your facility have an antimicrobial stewardship committee?

If No, skip the next three questions

1. What is the composition of the committee?

_____

_____

_____

2. How often does the committee meet?

   Oral report: Yes/No Verified: Yes/No

3. When did the committee meet last? (dd/mm/yyyy)

   Oral report: Yes/No Verified: Yes/No

Anti-Microbial Stewardship: Policy and Practices for appropriate use of antimicrobials

1. Does your facility have an antibiotic formulary (including unrestricted and restricted antibiotics) updated?

   Oral report: Yes/No Verified: Yes/No

   If yes, how often is the updating done?

   When was it done last? (dd/mm/yyyy)

2. Is your antibiotic formulary based on the National Essential Drug List?

   Oral report: Yes/No Verified: Yes/No

3. Do you have stock of all the antimicrobials in your formulary today?

Oral report: Yes/No Verified: Yes/No

4. If you are out of stock of any antimicrobials today, could you list them?_____

   _____

   _____

5. Are your local antibiotic guidelines based on local antibiotic susceptibility to assist with antibiotic selection for common clinical conditions?

   Oral report: Yes/No Verified: Yes/No

6. Do you have any restrictions in place for prescription of antibiotics? (e.g., only authorized persons can sign antibiotic prescriptions, only certain antibiotics can be prescribed by certain groups of doctors, all antibiotic prescriptions must be signed by prescribing doctor and an authorized person etc.)

   Oral report: Yes/No Verified: Yes/No

7. Does you facility have a copy of the ICMR standard treatment guidelines for antimicrobial use in common syndromes?

   Oral report: Yes/No Verified: Yes/No

8. Do you have any other STG for antimicrobial use?

   Oral report: Yes/No Verified: Yes/No

9. Does your facility have a written antimicrobial stewardship policy guideline?

   Oral report: Yes/No Verified: Yes/No

   If NO, skip questions 10 to 14

10. Does your facility have a written policy to document diagnosis while prescribing antibiotics?

    Oral report: Yes/No Verified: Yes/No

11. Does your facility have a written policy that requires ordering appropriate microbiological tests before prescribing antibiotics?

    Oral report: Yes/No Verified: Yes/No

12. Does your facility have a policy that encourages conversion from parenteral to oral antibiotics as early as possible?

Oral report: Yes/No Verified: Yes/No

13. Does your facility have a policy that encourages minimizing the overall duration of antibiotic use?

    Oral report: Yes/No Verified: Yes/No

14. Does your facility have a policy of authorization by designated persons of prescription of restricted antimicrobials?

    Oral report: Yes/No Verified: Yes/No

15. Is there a 48-hour antibiotic review procedure (post-prescription review)?

    Oral report: Yes/No Verified: Yes/No

16. How is this implemented?

    Details?_____

    _____

    _____

17. Have your doctors undergone training on antimicrobial prescription and antimicrobial resistance?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often is the training done?

    When was it done last? (dd/mm/yyyy)

18. Have your nurses undergone training on antimicrobial administration and antimicrobial resistance?

    Oral report: Yes/No Verified: Yes/No

    If yes, how often is the training done?

    When was it done last? (dd/mm/yyyy)

19. Does your facility conduct periodic audits of OP prescriptions to check for appropriate use of antimicrobials?

    Oral report: Yes/No Verified: Yes/No

20. Does your facility conduct periodic audits of IP prescriptions to check for appropriate use of antimicrobials?

Oral report: Yes/No Verified: Yes/No

21. Are results of antibiotic audits or reviews communicated directly with prescribers?

    Oral report: Yes/No Verified: Yes/No

22. Does your facility monitor antibiotic use by grams (Defined Daily Dose [DDD]) or counts (Days of Therapy [DOT]) of antibiotic(s) by patient per day?

    Oral report: Yes/No Verified: Yes/No

    If NO, skip question 23

23. Is monitored antibiotic use reported by hospital activity denominator (by number of admissions/discharges or by number of bed-days/patient-days)?

    Oral report: Yes/No Verified: Yes/No

24. Do you have electronic drug ordering system in your hospital?

    Oral report: Yes/No Verified: Yes/No

Hand hygiene Observation checklist

Does the facility have charts/boards depicting the correct hand hygiene practices in the following areas?

a. Outpatient department Yes No
b. Operation Theatre Yes No
c. ICU Yes No
d. Wards Yes No
e. Injection OP Yes No
f. Procedure Rooms Yes No
g. Labour Room Yes No

Biomedical waste management Observation checklist

1. Are prominent posters and panels displayed in key spots indicating the biomedical waste disposal mechanisms?
2. Are there colour coded biomedical waste disposal bins available in

a. Outpatient department	Yes	No
b. Operation Theatre	Yes	No
c. ICU	Yes	No
d. Wards	Yes	No
e. Injection OP	Yes	No
f. Procedure Rooms	Yes	No
g. Labour Room	Yes	No

APPENDIX – 2: ASSESSMENT OF PATIENT PERCEPTION ABOUT THE PATIENT SAFETY CULTURE IN THE HOSPITALS (OPD)

Section-I: Sociodemographic details:

Unique ID for the patient:

Hospital Name:

Age:

Gender:

Education:

Occupation:

Marital status:

Monthly income:

Monthly household expenditure:

Total number of family members:

Reason for OP visit:

Duration of visit (in hours):

Previous OPD visit in the same hospital: Yes/No

If yes, how many times: _____

Sought care from which department: General Medicine/General Surgery/Obstetrics and Gynaecology/Paediatrics/Orthopaedics

Section-II: Perception about the Patient safety culture in Hospital:

Domain-I: Communication between the patient and healthcare workers:

1. I was well-informed about my current medical condition during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

2. I was well-informed about the medications received by me during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

Domain-II: Procedural Safety *(applicable only to those patients who have undergone the respective procedure)*

3. I felt safe whenever any investigations were performed on me during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

4. I felt safe whenever any injections were given to me during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

5. I felt safe whenever any medical devices were used on me during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

Domain-III: Environmental Safety

6. I felt that the hospital environment was clean during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

7. I felt that the wastes are disposed off properly during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

Domain-IV: COVID appropriate behavior

8. I felt that the social distancing norms were followed properly during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

9. I felt that the hand hygiene norms were followed properly during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

10. I felt that everyone in the hospital wore mask properly during this visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

DISRESPECTFUL CARE:

During this OPD visit,

1. Whether the patient was made to feel disrespected? Yes/No
2. Whether the health provider shouted at or scolded them? Yes/No
3. Whether the health providers made negative or disparaging comments about them? Yes/No

If the patient answers "Yes" to any of these three questions, they will be considered to have received disrespectful care.

PATIENT SATISFACTION:

Based on this recent outpatient visits, the patients will be asked to:

1) rate their satisfaction with the health facility on a four-level scale

a) very satisfied

b) satisfied

c) dissatisfied

d) very dissatisfied

2) rate the quality of care at the health facility on a five-level scale

a) excellent

b) good

c) average

d) poor

e) very poor

3) state how likely they will recommend the facility to friends/family on four-level scale

a) strongly recommend

b) recommend

c) not recommend

d) not at all recommend

Each indicator will be dichotomized at the most positive level to represent the goal of the health system. For example, for satisfaction we will categorize the responses as either ‘very satisfied’ or ‘not very satisfied’

APPENDIX – 3: ASSESSMENT OF PATIENT PERCEPTION ABOUT THE PATIENT SAFETY CULTURE IN THE HOSPITALS (IPD)

Section-I: Sociodemographic details:

Unique ID for the patient:

Hospital name:

Age:

Gender:

Education:

Occupation:

Marital status:

Monthly income:

Monthly household expenditure:

Total number of family members:

Reason for hospitalization:

Duration of hospital stay:

Previous admission in the same hospital: Yes/No

If yes, How many times?

Sought care from which department: General Medicine/General Surgery/Obstetrics and Gynaecology/Paediatrics/Orthopaedics

Section-II: Perception about the Patient safety culture in Hospital:

Domain-I: Communication between the patient and healthcare workers:

3. I was well-informed about my current medical condition during this hospital stay

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

4. I was well-informed about the medications received by me during this hospital stay

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

Domain-II: Procedural Safety *(applicable only to those patients who have undergone the respective procedure)*

3. I felt safe whenever any investigations were performed on me during the entire hospital stay

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

4. I felt safe whenever any injections were given to me during the entire hospital stay

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

5. I felt safe whenever any medical devices were used on me during the entire hospital stay

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

6. I felt safe during my blood transfusion in this hospital stay

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

7. I felt safe during my surgery in this visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

8. I felt safe during my childbirth in this visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

Domain-III: Nutrition and Environmental Safety

9. I felt that the hospital environment was clean during my entire hospital stay

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

10. I felt that the wastes are disposed of properly during my entire hospital stay

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

11. I felt safe with the diet provided to me during my entire hospital stay

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

Domain-IV: COVID appropriate behavior

12. I felt that the social distancing norms were followed properly during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

13. I felt that the hand hygiene norms were followed properly during this hospital visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

14. I felt that everyone in the hospital wore mask properly during this visit

a) Strongly Agree (1)

b) Agree (2)

c) Neutral (3)

d) Disagree (4)

e) Strongly Disagree (5)

DISRESPECTFUL CARE:

During the entire period of hospital stay,

4. Whether the patient was made to feel disrespected? Yes/No
5. Whether the health provider shouted at or scolded them? Yes/No
6. Whether the health providers made negative or disparaging comments about them? Yes/No

If the patient answers "Yes" to any of these three questions, they will be considered to have received disrespectful care.

PATIENT SATISFACTION:

Based on this recent hospitalization, the patients will be asked to:

4) rate their satisfaction with the health facility on a four-level scale

e) very satisfied

f) satisfied

g) dissatisfied

h) very dissatisfied

5) rate the quality of care at the health facility on a five-level scale

f) excellent

g) good

h) average

i) poor

j) very poor

6) state how likely they will recommend the facility to friends/family on four-level scale

e) strongly recommend

f) recommend

g) not recommend

h) not at all recommend

Each indicator will be dichotomized at the most positive level to represent the goal of the health system. For example, for satisfaction we will categorize the responses as either ‘very satisfied’ or ‘not very satisfied’

APPENDIX 4 - QUALITATIVE INTERVIEW GUIDE

Title of the study: **Process evaluation and Implementation Challenges of National Patient Safety Implementation Framework in Selected Public Healthcare Facilities in Tamil Nadu – A Mixed Method Study**

Research question: What are the challenges in implementation of National Patient Safety Implementation Framework (NPSIF) in selected public healthcare facilities in Tamil Nadu?

Information in italics indicates a note to the interviewer and should not be read aloud.

***Interview details* (Interviewer: please be sure to complete each question below):**

Interviewer's Name: _____
Note taker's name (if present): _____
Location of interview: _____
Date of interview (DD/MM/YYYY): _____/_____/_____
Start time: _____
End time: _____

General Instructions: *Most questions below have probes that are follow-up questions. Please be sure to read the first question and allow the participant to respond before asking additional questions. Do NOT read the question and probes at one time. These are to be asked if the participant has not yet discussed the question in the probe. If they have, please skip that probe and go on to the next one. If a participant begins to get annoyed at the probes for a given question, please say "let's move on". Please ask additional questions when the participants provide unusual or interesting responses.*

Please read the following to the participants:

Thank you for taking the time to meet with [me/us] today. We would like to ask you some questions and discuss about the facilitating factors, possible challenges faced by your institute in implementing the national patient safety implementation framework, any suggestions on overcoming the barriers and for improving the services. The interview should take about 60-90 minutes. [I/We] will be recording the conversation because [I/we] don't want to miss any of your comments. [I/we] may also take some notes. All your responses will be kept confidential. This means that your interview responses will only be shared with research team members and we will ensure that any information we include in our report does not identify you as the respondent. Remember, you don't have to talk about anything you don't want to and you may end the interview at any time. We appreciate your answering these questions as honestly as possible. Please feel free to ask me if you have any questions or if you do not understand any question.

Are you ready to begin?

If yes, begin. Stop to answer any questions people may have before starting.

Interviewer: if a participant seems unwilling to answer any question, please ask: "It seems you would rather not answer this and want to move on. Is that right?" (That way, we will have this on the audio-tape and understand why a question may not be answered.)

A. Demographic data:

1. Age of subject in years: ___

2. Gender: Male___ Female___

3. Educational qualification:

4. Current position in the institute: MS___ RMO____ Microbiologist_____ Others_____

B. General knowledge about the patient safety:

5. What do you think are the requirements to ensure patient safety in your facility?
   Probe questions: probe about the importance of NQAS standards, ask about importance of separate checklist/SOP for patient safety, ask about importance of having anonymous patient safety reporting system, having separate patient groups for discussing the patient safety related policy making in the institute, having a separate patient safety surveillance system, training the healthcare workers on patient safety, having a separate HICC, CSSD, BMW committee, hand hygiene programme, kayakalp certification, safe surgical care, safe obstetric care, safe injection, medication safety, blood safety, medical device safety, patient safety research.

C. Facilitating factors in implementation of NPSIF:

6. What are the facilitating factors in successfully implementing the patient safety related activities in your institute?
   Probe questions: (ask about only the activities already implemented in the particular facility – obtained from process evaluation)
   probe what are the facilitating factors for each of the activities found to be already implemented in the healthcare facility in the following list: NQAS standards, separate checklist/SOP for patient safety, anonymous patient safety reporting system, separate patient groups for discussing the patient safety related policy making in the institute, separate patient safety surveillance system, training the healthcare workers on patient safety, HICC, CSSD, BMW committee, hand hygiene programme, kayakalp certification, safe surgical care, safe obstetric care, safe injection, medication safety, blood safety, medical device safety, patient safety research
   - probe at different levels, facilitating factors at patient level, healthcare worker level, hospital administration level, directorate level, political level

D. Challenges in implementation of NPSIF activities:

7. What are the challenges you are facing to sustain the activities after implementation?
   Probe questions: (ask about only the activities already implemented in the particular facility – obtained from process evaluation)
   - probe at different levels, problems faced at patient level, healthcare worker level (shortages), hospital administration level, directorate level, political level

8. Why you are not able to implement the certain set of activities given under National patient safety implementation framework in your healthcare facility?
   Probe questions: probe what are the problems in implementing each of the activities found to be not implemented in the healthcare facility (during process evaluation) in the following list: NQAS standards, separate checklist/SOP for patient safety, anonymous patient safety reporting system, separate patient groups for discussing the patient safety related policy making in the institute, separate patient safety surveillance system, training the healthcare workers on patient safety, HICC, CSSD, BMW committee, hand hygiene programme, kayakalp certification, safe surgical care, safe obstetric care, safe injection, medication safety, blood safety, medical device safety, patient safety research
   - probe at different levels, problems faced at patient level (patient cooperation/non-adherence to guidelines/ignorance/lack of awareness), healthcare worker level (lack of human resources/compliance to guidelines/lack of awareness), hospital administration level (lack of infrastructure/lack of standard guidelines/policies), directorate level, political level

E. Suggestions/solutions to overcome the challenges in implementation of NPSIF (NEXT DAY):

9. Can you give any suggestions to overcome the challenges you are facing in the implementation of patient safety related activities in your institute?
   Probe questions: probe against each of the challenges listed by the participants to question number 7 & 8;
   - probe at different levels, problems faced at patient level, healthcare worker level, hospital administration level, directorate level, political level

10. Is there anything else you would like to tell us about your experiences or your views on how to best implement the patient safety framework in public health facilities? If so, please tell us what that is.

This is the end of the interview. Thank you for your time!

Interviewer & notetaker: please tell us more about the interview *while the audio recorder is still on:*

1. Was the participant nervous or calm? Did they seem comfortable answering the questions?

2. What is your impression about how honest the participant was with their answers?

3. Is there anything else about the interview that would be good to note?

APPENDIX – 5: INFORMED CONSENT FORM FOR PATIENTS

Process evaluation and Implementation Challenges of National Patient Safety Implementation Framework in Selected Public Healthcare Facilities in Tamil Nadu – A Mixed Method Study

Informed Consent form for health care providers in health facilities

Introduction

I am _____, working at the ESIC Medical College and PGIMSR, Chennai. I have been given the assignment to understand appropriate use of antibiotics in public health facilities in Tamil Nadu. I intend to collect this information from patients in various health facilities in Tamil Nadu and submit a report with recommendations to improve the patient safety practices in public health facilities.

Purpose of the research

In spite of availability of several data management systems, there has been little to no documentation of the errors, HCAIs, negligence or adverse events occurring to the patients during their hospitalization. To address these challenges, Ministry of Health and Family Welfare (MoHFW) has introduced the "National Patient Safety Implementation Framework" to ensure the patient safety at different levels of healthcare delivery system in both public and private facilities. However, there is a need to evaluate the proper implementation of the patient safety practices mentioned in the framework across the public healthcare facilities. Tamil Nadu is one of the best performing states in terms of health indicators and healthcare delivery in India. It is also important to know whether the state is better performing in terms of its patient safety practices and good quality service delivery. Hence, we will do the process evaluation of National patient safety implementation framework across the public healthcare facilities in Tamil Nadu. We will also try to explore the challenges in implementation of this framework and suggestions to overcome the same through qualitative interviews.

Type of Research Intervention

This research will involve examining your hospital case sheet for details of your disease, course in hospital, tests taken, diagnosis, and your feedback about the patient safety practices using a questionnaire.

Participant selection

In order to understand the patient safety practices, we have to do an examination of a random sample of case sheets of patients admitted in the hospital at the time of the research. You have been randomly selected to participate.

Voluntary Participation

Participation in this study is completely voluntary. Irrespective of whether you participate in the study or not, you will continue to receive the same treatment as before.

Procedures and Protocol

If you consent to participate in this study, we will carefully study your case record. We will be interviewing you to obtain the information and feedback about your recent visit or stay in the health facility. We will not be interfering with the treatment that you are currently receiving and will not be performing any additional tests or procedures on you.

During the research, we will not require to interact with you frequently. We will meet you once, explain the study and get your consent. Then we will review your case records and note the important points. With that, the study will be completed.

Risks

As we will be using your case sheet to extract information regarding your illness, there is a small risk of breach of confidentiality of your medical information. We will try our level best to protect your confidentiality and will ensure that we do not keep the case sheet for too long so that we not disturb the treatment that you are receiving.

Benefits

You are unlikely to receive any direct benefits from participating in this study. However, knowledge gained from your data will help to improve the patient safety practices and reduce the harms for future patients.

Confidentiality

Information obtained from you during this study will be kept confidential. While extracting information from your case sheet, we will not collect your name and other personal identifying information. The data will be collected in encrypted and password protected software which will be accessible only to the researchers.

Sharing the Results

The findings of this research will be shared with the Tamil Nadu health system in order to help them improve the patient safety practices in the public health facilities. However, while sharing the findings, we will protect your confidentiality.

Who to Contact

If you have any doubts or questions related to this study, you may contact the principal investigator, Yuvaraj Krishnamoorthy (+91 9551892665).

This proposal has been reviewed and approved by Institutional Ethics Committee, ESIC Medical College and PGIMSR, KK Nagar, Chennai, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact Vijayaprasad Gopichandran, Member Secretary, Institutional Ethics Committee, ESIC Medical College and PGIMSR, KK Nagar, Chennai.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the procedures to be followed in the study.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

APPENDIX – 6: INFORMED CONSENT FORM FOR HEALTHCARE PROVIDERS

Process evaluation and Implementation Challenges of National Patient Safety Implementation Framework in Selected Public Healthcare Facilities in Tamil Nadu – A Mixed Method Study

Informed Consent form for health care providers in health facilities

PART I: Information Sheet

Introduction

I am _____, working at the ESIC Medical College and PGIMSR, Chennai. I have been given the assignment to understand patient safety practices in public health facilities in Tamil Nadu. I intend to collect this information from health care providers (medical superintendent / resident medical officers / nursing superintendents / doctors / nurses) in various health facilities in Tamil Nadu and submit a report with recommendations to improve the patient safety in public health facilities.

Purpose of the research

In spite of availability of several data management systems, there has been little to no documentation of the errors, HCAIs, negligence or adverse events occurring to the patients during their hospitalization. To address these challenges, Ministry of Health and Family Welfare (MoHFW) has introduced the "National Patient Safety Implementation Framework" to ensure the patient safety at different levels of healthcare delivery system in both public and private facilities. However, there is a need to evaluate the proper implementation of the patient safety practices mentioned in the framework across the public healthcare facilities. Tamil Nadu is one of the best performing states in terms of health indicators and healthcare delivery in India. It is also important to know whether the state is better performing in terms of its patient safety practices and good quality service delivery. Hence, we will do the process evaluation of National patient safety implementation framework across the public healthcare facilities in Tamil Nadu. We will also try to explore the challenges in implementation of this framework and suggestions to overcome the same through qualitative interviews.

Type of Research

This research will involve interviewing you with a few questions to understand patient safety in your hospital.

Participant selection

To understand the patient safety aspect in the state, we have sampled a few health facilities. Your health facility has been sampled and you are invited to participate in this study from your health facility.

Procedures and Protocol

If you consent to participate in this study, we will conduct a detailed interview with you. During this interview we will ask you specific questions regarding various aspects of patient safety like safe injection practices, safe surgical care, obstetric care, blood transfusion, organ donation, waste management, healthcare associated infections and research. We will be audio recording the interviews. Then we will transcribe these interviews and analyze them. The total duration of the interview is not likely to be more than 30 mins.

Risks

As we will be conducting an interview for about 30 minutes, we may be briefly interrupting your work. We will ensure that we fix up the most convenient time for the interview so that we don't hamper your routine work. We will carefully protect your confidentiality and will not reveal sensitive information revealed by you during the interview.

Benefits

You are unlikely to receive any direct benefits from participating in this study. However, knowledge gained from your data will help plan better the safety practices for future patients.

Confidentiality

Information obtained from you during this study will be kept confidential. The data will be collected in encrypted and password protected software which will be accessible only to the researchers.

Sharing the Results

The findings of this research will be shared with the Tamil Nadu health system in order to help them improve the patient safety aspect in the public health facilities. However, while sharing the findings, we will protect your confidentiality.

Who to Contact

If you have any doubts or questions related to this study, you may contact the principal investigator, Yuvaraj Krishnamoorthy (+91 9551892665).

This proposal has been reviewed and approved by Institutional Ethics Committee, ESIC Medical College and PGIMSR, KK Nagar, Chennai, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact Vijayaprasad Gopichandran, Member Secretary, Institutional Ethics Committee, ESIC Medical College and PGIMSR, KK Nagar, Chennai.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the procedures to be followed in the study.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

APPENDIX – 7: ETHICAL APPROVAL CERTIFICATE

ESIC Medical College and PGIMSR
(Ministry of Labour & Employment, Govt. of India)
Ashok Pillar Road, K. K. Nagar, Chennai-600 078.

INSTITUTIONAL ETHICS COMMITTEE

सत्यमेव जयते

Office : 044- 24748959
Fax : 044- 24742825

Email : iec.esic.kkn@gmail.com
Website: http://esic.nic.in

The Institutional Ethics Committee met on 04.05.2021 online between 2 PM and 4 PM. The below mentioned proposal was considered in this meeting of the committee.

The following is the decision of the Institutional Ethics Committee.

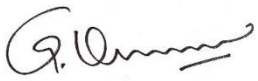
IEC No.	IEC/2021/1/12
Research Proposal Title	**Process evaluation and Implementation Challenges of National Patient Safety Implementation Framework in Selected Public Healthcare Facilities in Tamil Nadu – A Mixed Method Study**
Name of the Principal Investigator	Dr. Yuvaraj K
Name of the Co-Investigator	Dr. Deivasigamani Kuberan, Dr. Devidas Tondare, Dr. Anuradha R, Dr. Aruna B Patil, Dr. Kala M, Dr. Vijayaprasad G, Dr. Venmathi Elangovan
Department	Community Medicine
Name and Address of the Institution	ESIC Medical College & PGIMSR, KK Nagar, Chennai 600078
Type of Review	Full Board Review
Documents Reviewed	Revised research proposal dated 15.05.2021 Indicators Checklist dated 15.05.2021 Informed Consent form in English dated 15.05.2021
Decision of the IEC	Approved
Period of validity of the approval	15.05.2021 to 14.05.2022

The IEC gave the following recommendations:

a. Very important and relevant study. Well written proposal.
b. Share the final instruments and the informed consent form with the IEC.
c. Make sure you obtain administrative permissions from the govt as well as from the participating health facilities.
d. The rationale for using HDI for sampling the districts is flawed. It uses development as an indicator. Why should development be a criterion for assessing patient safety? Patient safety must be followed irrespective of development status of the district. Revise the sampling strategy.

The proposal and related documents were revised and resubmitted to the IEC. It was reviewed by expedited review process and the IEC has decided to approve the project.

A fresh IEC application must be filed in case of any change of study procedure, site or investigator. This IEC approval is only for the period mentioned above. Final report of the research must be submitted to the IEC on completion of the study. Members of IEC have right to monitor the study at any point with prior intimation.



Member Secretary
IEC, ESIC MC and PGIMSR, Chennai

Date: 15.05.2021
Place: Chennai 600078