

Development and implementation of ZED-YOG quality module: *Niyantrita Madhumeha Bharata* skill development initiatives

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ABSTRACT

Background: Government initiatives and schemes for global healthcare improvement require efficient implementation which can transform the quality standards. We redefined the purview of Good Laboratory Practices (GLP) in the basic research investigations in order to create a benchmark of quality standards for conducting translational research.

Methods: We propose *Zero effect-Zero defect Youth Oriented GLP (ZED-YOG)* as a management tool for funding agencies to monitor data generated in labs funded by them.

Summary: This strategy can not only promote enhanced data scrutiny, validation but also health awareness.

Key message: YOG will ensure the communication of audited research data generated from publically funded national agencies

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Introduction

In the twenty-first century, the global healthcare management has been transformed through policy reforms and innovative technological interventions. A qualitative and quantitative assessment of clinical research and laboratory settings is crucial as their decisions influence the critical care of patients. Data fabrication, falsification of research data, authorship disputes are among the prime cause of research misconduct reported throughout the world, not only in biological sciences but also in other scientific disciplines [1]. Human errors have brought down million dollar Mars mission in the past as a result of failure in checks and regulations [2]. Similarly, recent stem cell research related incidents of misconduct have contributed to a change in society's opinion regarding science and its harmful effects. This necessitates applicability of quality module and quality assurance in order to ensure the credibility of processes, services, management, research and health care. Similarly, establishing the quality driven research facilities will ensure a competitive translational research among faculty driven research projects [3]. Various institutions have implemented or mandated one or other regulatory norms including Good Laboratory Practices (GLP), International Organization for Standardization (ISO), National Accreditation Board for Testing and Calibration (NABL), National Accreditation Board for Hospitals & Healthcare Providers (NABH) etc. for specific healthcare sectors. However, there are no mandatory policies for implementation of quality standards in the

basic research as well as national public health initiatives for improved public health and research practices.

GLP was developed by Organisation for Economic Co-operation and Development (OECD) to regulate clinical trial and pharmaceutical studies but not the basic research. The Neuroscience Research Lab (NRL), PGIMER, Chandigarh, India transformed the quality management system to regulate the basic research laboratory based on requirements of day to day research conducts. Therefore, GLP was introduced in 2008 for creating a scaffold for quality management. GLP was later redefined by this group for implementation in the basic research investigations without diluting the core principles of GLP or research. It fulfilled the needs of research functioning as well as the needs of research personnel for their professional and personal development alike.

In the under-developed and developing countries, various government flagship initiatives have been launched but systems of data monitoring is lacking. There is also dearth of compliance to quality standards in the public funded government initiatives involving massive human research and epidemiological data. The major two national initiatives focusing global health were International Yoga day (Global wellness) and Niyantrita Madhumeha Bharat (Diabetes control movement). Another national initiative, Zero effect zero defect (ZED) was a recent implementation of Government of India which focuses on error free manufacturing capabilities with minimal environmental impact. ZED was proposed as the effective to change the dynamics of economy by focusing on manufacturing as an engine to sustained growth.

We, therefore, sought to acquire processes involved in implementing ZED scheme with integration towards Quality driven skill development and empowerment of youth in the Government of India's (GOI) yoga-based intervention initiatives. We propose the term ZED-YOG (Zero effect zero defect -Youth Oriented GLP) which inspires propagation of the integration of youth driven implementation of quality standards in the management of these government programmes by mandatory integration of Yoga research activities in offices and healthcare organizations.

We discuss our effort to align the Government of India's initiatives with existing quality management research systems in order to provide an organized and successful outcome of the initiatives. Government of India has launched three significant initiatives which were implemented to transform the gamut of Health and manufacturing sectors in India. We mobilized and channelized the youth to complete two mega programs of GOI through ideologically similar ZED programme. This has been accomplished through existing GLP module of the NRL, importantly, by training more than 100 student in this maiden effort. These students were trained by the experienced lab personnel with expressed purpose of skill and leadership development. We emphasized the documentation of minimal error rate, penetrence of standardized yoga protocols in work place, periodic monitoring through digitization efforts defined as zero defect. In line with ZED effect in the "Make in INDIA" concept of manufacturing sector, the research sector could also be driven by ZED policy. Simultaneously, NRL's community outreach programme, encouraged by Government's Swachh Bharat Abhiyan (cleanliness drive) was also linked to the camps. Yoga camp activities were followed by Swachh Bharat activity at the camp site. We define this to be "Zero Effect" as the biomedical waste generated at camp sites is safely disposed according to the standard biomedical waste segregation protocol.

Prime Minister of India, Narendra Modi asked the world leaders to adopt an International Yoga Day, emphasising changing lifestyle as means to lead healthy life advocating policies for climate change. Addressing the 193-member UN General Assembly in United Nations, Prime Minister Modi said "Let us work towards adopting an International Yoga Day," Noting that Yoga is "an invaluable gift of our ancient tradition", he said: "It is not about exercise but to discover the sense of oneness with yourself, the world and the nature." "Yoga embodies unity of mind and body; thought and action; restraint and fulfilment; harmony between man and nature; a holistic approach to health and well being," he said, adding "By changing our lifestyle and creating consciousness, it can help us deal with climate change." During the 2nd International day of yoga (21st June 2016) held at Chandigarh, The Indian Prime Minister gave a clarion call to all Yoga institutions to focus this year, on taking up several programs to promote yoga for Diabetes. NRL took to the call and analysed the effects of Yoga protocol on biochemical, anthropometric and molecular changes in persons practising Yoga, and integrating it with ongoing research projects. Niyantrita Madhumeha Bharata

(NMB) is an ambitious national project for controlling Diabetes through yoga intervention. National Diabetes Control Program (NDCP) routed through Central Council of Research in Yoga and Naturopathy, New Delhi, and implemented by the Indian Yoga Association (IYA) (IYA is an association that has members from all major traditional yoga *paramparas* of the country). NRL took up the project and has analysed the results from the 3-month intervention on prediabetic and diabetics screened from house to house survey in North India.

This paper discusses the methodology adopted to carry out the NMB programme to enhance the credibility, back-traceability of the data obtained from a facility following GLP quality module. We integrated two different concepts ZED and YOG (Youth Oriented GLP) for seamless implementation of the abovesaid program.

Methods

Yoga protocol for NMB

Quality Council of India, in coordination with AYUSH, Government of India, developed yoga protocol for pan-India diabetes control. More than 9000 individuals were selected pan-India for participation based on the IDRS score. We focused on North Indian region (Chandigarh) for implementing NMB initiative.

Orientation to Yoga Instructors

Orientation classes were provided to all Yoga volunteers for diabetes management (YVDMs) regarding the NMB program and different phases of entire regimen. Methods of administering the questionnaire were explained along with demonstration of measurements of anthropometric variables and precautions. Orientation class regarding hands on training of screening procedures with mock drill of screening session was carried out.

YOG (Youth Oriented GLP) Module

Basic research investigations and procedures are dynamic in nature and need several rounds of modifications. Therefore, sustainability of the module was maintained by continuously improving this module through student-oriented protocols. One of our improvisations was to regulate and improve the functioning of basic research investigations through digital processes. We digitalised the procedures for GLP compliance, human resource skill development, environment safety, Intelligence, Emotional, Spiritual Quotient (IQ/EQ/SQ) of researchers, communication skill development, Security of research data and premises, economic viability and productivity which were helpful to formulate new policy changes for better regulations in this field.

Methods of Identifications of the Problem

The responsibilities for all the activities such as policy making, administrative, documentation and testing etc. were distributed among the staff. The problems in all respects were identified by the concerned staff in that activity and document

in the deviation sheet. It was ensured that the Study Director was kept informed and the concerned steps were taken to implement data capturing sheets called the Data Recording Sheets (DRS). There was a three tier Problem Identification System involved in the study, at each level of staff personnel:

- Study Director
- QA Personnel
- Technical Staff/ In-life observer

Policy

Measures for corrective actions were formulated when non-conforming work or departures from policies and procedures in the management system or technical operations were identified. Responsibilities for the actions were centred around the in-life observer who was responsible for maintenance, calibration, breakdown reporting/documentation for individual instruments. For procedural/technical errors, the experimenter was responsible for reporting

and documentation. The QA personnel reported this to the Management and any deviation or amendments in the protocols was finalized after thorough discussion between experimenter, QA personnel and the Management.

Adherence of national initiatives to the Quality module in NRL as “Zero defect Policy”

Master Schedule

Each research staff mandatorily proposed a weekly plan of the work to be completed in a month to plan the entire month. Master schedule was to be submitted to Quality Assurance (QA) cell before the beginning of the month. Master schedule of NMB camps were also prepared as per Figure 1. QA reviewed the progress of the research and technical staff at the end of the month through one to one interaction. Students prepared a draft in the Microsoft word document and mailed it to the Quality Assurance personnel to reduce the paper work. Master schedules were kept in a format by QA personnel in an electronic format.

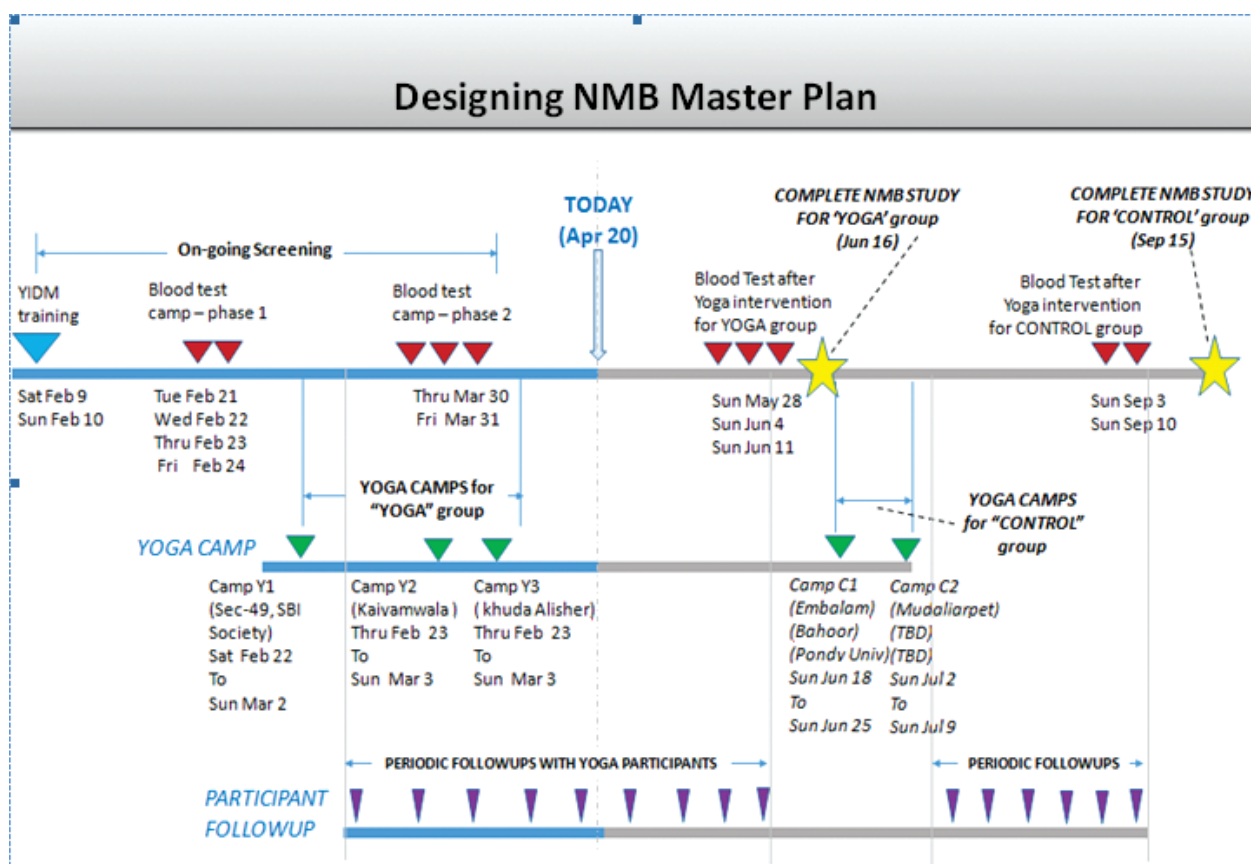


Fig. 1: Master Schedule of date wise NMB Camps.

Standard Operating Procedures (SOPs)

Experimental and administrative procedures performed in the laboratory adhered to the corresponding SOPs in order to streamline lab experiments and related procedures including

purchase procedures, cleanliness drive, publication of Annals of Neurosciences (PubMed indexed Journal published from the lab), project writing, grant writing, thesis writing etc.

Using similar quality modules, SOPs were developed to streamline entire NMB yoga camps as explained in Figure 2.

Standard Operating Protocol (SOP)

NMB Camps

Neuroscience Research Lab, PGIMER, Chandigarh-India

Niyantrit Madhumeha Bharat (NMB) is the Yoga initiative from AYUSH and SVYASA for controlling diabetes in India via Yoga. Under NMB, blood testing camp to check diabetes were carried out across India. This protocol represents the structure of management to handle the blood testing camps.

The whole camp activities were divided into following activities which was done in serial order:

1. **Token Distribution:** Token number is distributed to people coming to manage crowd and chaos.
2. **Master Coding:** Each person is assigned with a unique master code which is exclusive for him only and this code is written on all the forms and vials in which blood is collected.
3. **Registration Form:** Registration form filled for each person by indicating master code on top of the form.
4. **SRL Form:** SRL form is filled for each person by indicating master code on top of the form.
5. **Height/Weight/Waist Circumference/Hip Circumference:** measurements are taken by using weighing machine and measuring tapes. After that write that on form.
6. **Blood Pressure:** measure and write on form.
7. **Blood Sampling:** Blood sample taken by SRL team.
8. **Glucose Drink:** Glucose is given to prediabetic person only. Diabetic person should take regular food
9. **Form Filling:** Detailed Neuropsychology form is filled after person give the blood sample
10. **Photography/Crowed Management/Swachh Bharat:** These activities are keep running with other activities during camp.

Fig. 2: Standard Operating Protocol of NMB camp.

Data Recording sheet (DRS)

To minimize the procedural errors, DRS were formulated along with SOPs for the real time monitoring. This was prepared in consultation with Study director and consisted of the columns for identification of SOP, along-with control of the document through Quality Assurance (QA) cell. DRS was issued only at the time of conducting the experiment and re-submitted to the QA after attestation from the Study Director. Data recording sheets were followed in all procedures of NMB data analysis.

Quality Assurance Review

Independent review of infrastructure and facility-based QA audit was carried out once in a month. Study based QA

review encompassed the review of the work planned by the research scholars as per their master schedule. Deviations from the master schedule were documented and carried forward for the next month. Independent verification of experiments was carried out to check the compliance to SOP. QA review sheets were prepared in the Microsoft word document.

Log Sheet and Log Books

The log sheets and log books maintained for the entire chemical, refrigerated reagents and all sophisticated instruments are used for documenting usage. These are useful for troubleshooting not only the technical problems but also in ensuing timely re-ordering reagents.

Checklist Based Management

Checklists were developed to ensure the completeness of the task assigned to students which compensate for the human limitations. Checklists were formulated for all the academic or administrative lab procedures including, synopsis preparation and its approval through Dean Doctoral Committee (DDC), presentation of the progress of research through Doctoral Committee (DC), PhD viva, grant writing, seminar presentation, human and animal ethical clearance, visa application for travelling for conferences, manuscript writing etc. Checklists were stored in the common domain of the lab networking system. Thus, it could be used among the closed user group for guidance without having the need to approach a senior/Study Director. This created a system dependent guidance system for the trainees for implementation with respect to NMB project execution.

VPN based servers for digital data accessibility and storage

Server based virtual private network (VPN) in the secured network is installed in the Neuroscience Research Lab for the storage, security and remote accessibility of research data. Usually, in industries or IT sectors the server-based access and storage are available; however, introducing it to basic research facility in a Medical Institute is challenging. The server spaces were utilized to import the data obtained from NMB camps. Server domain was allocated to each student and staff to store the confidential research data. Only study director was authorised to access all domains. Besides having personal drive, every computer was allocated with official user domain among closed user group where research data is fed in the form of SOP, DRS and master schedule. This domain represented a personal and common drive in which research data could be accessed in a secure fashion by the study director in order to restrict the access of intellectual property and common administrative procedures, respectively. Network security system, through firewall, was created as a barrier across internal network. Another network was geared up to provide security of confidential research data that protects the server against various threats from public networks. Remote access through virtual private network provided secured access to data from anywhere through internet and ensured safety of lab assets by real time surveillance.

Real Time Monitoring (CCTV)

NRL was kept under the surveillance of CCTV camera and real time monitoring was enabled through VPN system. It acted as a deterrent for any unforeseen security lapse thus it also provided a secure environment to the female members of the lab and monitoring of the research activity in lab.

Master Coding of Individuals And Samples

Participants were provided a unique code according to the ongoing GLP led quality management system of NRL. This maintained confidentiality of participants, data blinding and

management of the crowd. Samples obtained were coded for blinding and kept according to the existing quality standards. Data was digitised through new team under the supervision of experienced personnel.

Personal Discussion and Lab Meeting

A day was allocated to every student for personal discussions regarding the research problems, progress and purchases with the study director. Every experimental and purchase procedure was structured into indent, benchmark checking, and assessment of log sheets maintained to see the previous purchase.

Administrative documents

(Log books, Log sheets, Inventory sheets, temperature sheets)

Inventory Sheets and Master inventory

Lab reagents, Kits and glassware were kept in various shelves and refrigerators. These inventories and their management were distributed among students who looked after the exchange of material. Inventories were submitted monthly to QA, who prepared a master inventory. Master inventory was used to check the location and available stock of any chemical or kits. Quarterly, the hardcopy of the inventory sheets was updated with freshly updated quantity of the stock. To reduce the paper burden on this task, the quarterly review of inventory was carried out and electronic records of the inventories were sent by the students to the QA and Master inventory was maintained by the QA personnel.

Zero Effect Supporting Initiatives

Bio Medical Waste Management

Rigorous biomedical waste management training was provided to the students with periodic orientations to the trainees. Biomedical waste was segregated in four different polybags. Black containers were used for general waste, Yellow containers for soiled infected waste, Blue containers involved sharps and red containers included plastic wastes.

Printer/Paper Usage

Printers were linked to each computer/Laptop in the NRL. Printer log was monitored for each research personnel in order to save resources.

Swachha Bharat Abhiyaan (Clean India Mission)

Zero effect programme was also encouraged by Swachha Bharat Abhiyaan (SB) led by Neuroscience Research Lab. Volunteers from the NRL devoted two hours each week for continuation of cleanliness drive continuously for 203 weeks till date. The activities were also submitted to government portal Mygov.in and propagated through Facebook and WhatsApp groups. Government officials from scientific, academic and social backgrounds were mailed and chal-

lenged to propagate the cleanliness drive further in an ice bucket challenge mode.

Educational Programmes

Scientific symposiums were carried out to disseminate the importance and challenges in implementing quality standards. Research projects and thesis works were connected to quality assurance programme in order to orient the researchers about implementation of quality standards. These trained researchers further oriented the yoga teachers and volunteers of NMB national initiative for integration of quality parameters in the execution of NMB. Researchers were oriented to adopt the quality parameters from experts in the field.

Validation of NMB Data

Entire set of NMB documents and data were validated by trained personnel. Each participant was telephonically identified, excel files were cross checked for manual errors in digital entries and the statistical data was also validated by an independent investigator.

Results

In 2014, Quality Council of India (QCI), recognized NRL for D. L. Shah National award for "Redefining Quality standards in basic research investigations by broadening the purview of Good Laboratory Practices (GLP)" under research

category. In 2016, Quality council of India again recognized this effort and awarded the NRL for "Digital Research Lab for Enhancing Capability: Towards Skill Development and Community Outreach". For the first time, this award was constituted to create a special category to accommodate the unique initiative.

Financial and tangible benefits of the quality module

The research chemicals upto the scale of microlitres were laboriously documented for as per daily use. Purchasing time was streamlined through availability of chemicals and correspondingly documented in the log sheets. Experiment wise documentations ensured auditability of experiments. Digital scrutiny encouraged improvements in the purchase and accounting procedures. Intra and Inter laboratory auditing of various grants were carried out to ensure auditability.

Storage and Security of the research Data

Large data saving capacity makes this server unique in the basic research settings. Server automatically updates the storage capacity after one year. Thus, the data can be extracted from the server within this time-frame. Server is also used as a data backup device. The security of crucial research data, which is a requirement in the basic research settings, is stored under the control of firewall which disables any possible hackers efficiently. Network layout plan is described in figure 3.

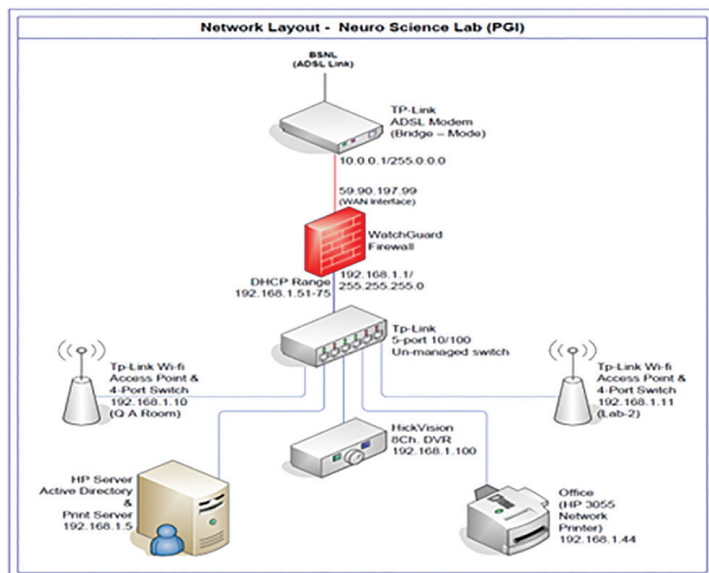
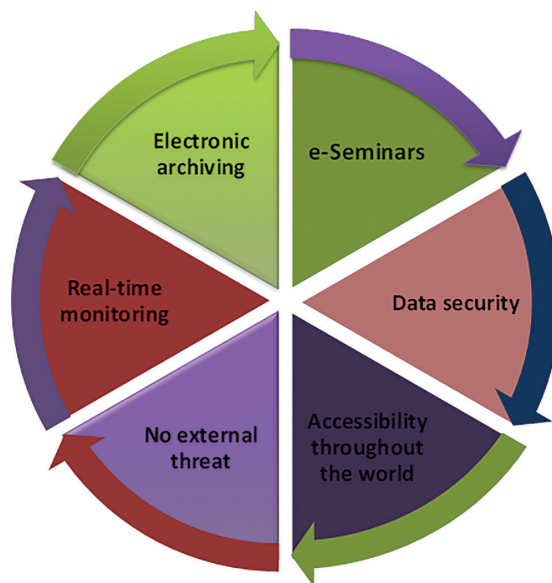


Fig. 3: VPN based Network layout plan.



The Server based networking system encourages controlled utilization of papers as it keeps the log of printer usage for each personnel. In this way the system is kept environ-

ment friendly as it is important in the smooth functioning and saves time. NRL became the first entity to finish 100 hours of SB in India. It trained youth to participate in the "Swachha

Bharat Activities” through the camps NMB and International Yoga Day. After each of such camps, the completion youth driven *Swachhata Abhiyaan* were carried out for orientation of staff towards ZED-YOG.

NRL Social networking

NRL team enhanced its efficiency through WhatsApp group chats. Professional guidance’s, suggestions, sharing ideas and instructions were facilitated through the WhatsApp group. It reduced the communication gap between the study director and other research staff. NRL’s activities, achievements, future programmes are projected through a separate Facebook page. Implementation of quality module has increased the credibility of data published through the scientific fraternity. Benefits of such quality module in various research areas is depicted in Figure 4.



Fig. 4: Benefits of ZED-YOG quality module.

Discussion

The student/youth driven GLP module enhanced the reproducibility of data and error reporting of research data and internalised the quality system in research practices, thereby facilitating a higher sincerity of purpose for research in Medical Institutes in India (paper in communication). It also sought to bridge the credibility chasm that exists between data generated from India and that from the West, because of which the best research from India is rarely published in top Journals. The implementation of this module has led to enhanced visibility in the research. Research papers written from NRL provide sufficient data which shows that this quality module has improved the quality of data generated [4–6].

The redefined GLP system encourages goal driven, self proposed monthly master schedule map of activities in

coordination with the study director, using the combination of SOPs, DRSs and master schedule applicable for various research projects. The Quality Assurance (QA) unit in NRL conducts periodical audit of the progress, compliance and reproducibility of experiments. The data generated filed in a defined format using a mandatory raw book, master code, calibrated instruments (with IQ, OQ, PQ), log sheets with continuously regulated infrastructure and room environment provides the necessary back up for data retrieval. The data and samples which are archived in defined shelves or freezers, as the case may be, can be seamlessly used for future experiments saving precious resources. The current system is rare in any research settings specifically in the medical institutions. In view of the increasing government participation for global health programs, the implementation, backed by quality standards, is necessary. Ideological integration of governments quality module, ZED and our youth oriented GLP (YOG), provides a robust organizational system for success of science policy implementations in govt funded research labs. Manufacturing & Design capabilities, Quality/Environment/Safety assurance systems, People development and engagement systems, Standardization and measurement systems for quality and environment, Learning and improvement systems, Legal compliances are the key features of ZED which are being integrated with the GLP core principles.

SOPs facilitate the robustness of the system and enhances productivity of students and staffs thus reducing the scope of errors. It also results in internalising the quality principles in the youth. More than 100 volunteers working in various streams have been trained to work in a ZED-YOG fashion by adapting the NRL module of GLP and minimizing medical waste through Swachha Bharat Activity. The scientific analysis of the samples obtained from International Yoga Day (IYD) and Niyantrita Madhumeha Bharata Abhiyaan (NMB) camps were similarly evaluated according to the existing quality management system developed by NRL. Successful implementation of government programmes such as IYD and NMB camps generated crucial authenticated data backed by Quality standards thus, necessitating implementation of quality standards in all government programs.

Conclusion

Modified GLP module has been found to be effective to safeguard the accountability, back traceability of the research data and management of human resources. NRL strives to create a module which can be emulate by other basic research facilities in India. New policies can be formulated for the basic research settings using the quality module. ZED-YOG has capacity to develop a new generation of basic scientists striving towards quality-oriented environment with effective research output. The national initiatives with focus on global health research standards can consider adopting the ZED-YOG protocol in their work places.

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Conflict of interest

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