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SHORT COMMUNICATION

INTEGRATING RESEARCH INTO CLINICAL CARE: A WINDOW OF OPPORTUNITY

Farrah Pervaiz, Imtiaz Ahmed Chaudhry, Sabeen Khurshid Zaidi, Safdar Abbas, Syed Muhammad Imran Majeed

Armed Forces Institute of Cardiology (AFIC)/ National Institute of Heart Diseases (NIHD) Rawalpindi Pakistan

ABSTRACT

Introducing a research and development program into a tertiary care cardiac setting can be challenging. Some primary factors to consider are the possible effects on the current clinical schedule, equipment and personnel resources required to support the research projects. More importantly, how can an organization successfully complete reliable and accurate research projects? This study describes our experience of establishing a R&D unit within our clinical setting.

Our primary emphasis was providing an integrated research environment through delegated research staff and resources. The first accomplishment was establishing 40 disease specific registry databases in all the relevant specialties. The data generated from these registries helped develop key performance indicators, conduct clinical audits, clinical trial, surveys and quality improvement initiatives, enhanced quality of care and improved patient outcomes. Furthermore, this useful and organized information led to the publication of 74 original articles in two years. Restructuring of Institutional Ethical Review Board (IERB) was done according to ICH and GCP guidelines to protect the rights, safety and well-being of all the humans involved in a clinical trials and research studies.

The major hurdles during the implementation process were the lack of a common vision for health research, coordination of research activities, dedicated budget for research and inconsistency in using evidence as the basis of policies, programmes and global standards. We expect that obstacles such as these can be overcome by improving the quality, impact and inclusiveness of research and development practices.

Keywords: Cardiac, Clinical research, Organization.

Evidence-based decision-making has been actively promoted at all levels of the health discipline and it's considered as a necessary step in the direction of improving the health of the population. Current studies have shown that developing countries possess the highest burden of infectious, communicable & non-communicable diseases, maternal and child morbidity and mortality. Presently, a mismatch has been found between this increased burden of disease and the technical and human capacity of the developing countries to use existing knowledge and to generate new knowledge to battle these diseases and health issues. An international commission has argued that strengthening research capacity is one of the most powerful, cost-effective, and sustainable means of advancing health and development[1]. As a key element of capacity building, countries must also address issues related to the enabling environment, in particular: leadership, career structure, critical mass, infrastructure, information access and interfaces between research producers and users. The accomplishment of efforts to build capacity in developing countries will ultimately depend on political will and credibility, adequate financing, and a responsive capacity-building plan that is based on a thorough situational analysis of the resources needed for health research and the inequities and gaps in health care. Greater national and international investment in capacity building in developing countries has the greatest potential for securing dynamic and agile knowledge systems that can deliver better health and equity, now and in the future[2,3].

Armed Forces Institute of Cardiology and National Institute of Heart Diseases (AFIC-NIHD) is one of the country's finest hospitals, and has a proud heritage of serving the country for more than 35 years. This modern, 250 bedded state-of-the-art tertiary

Correspondence: Dr Farrah Pervaiz, Director Research and Development, AFIC/ NIHD, Rawalpindi Pakistan
Email: farrahpervaiz@gmail.com

care cardiac centre is located in the heart of Rawalpindi, the twin city of the federal capital, Islamabad. AFIC-NIHD has the credit to be serving a large population of the upper Punjab, the federal capital and Khyber Pakhtunkhwa province, Azad Kashmir and referred cases from the Armed Forces Hospitals from all over the country.

With presence of highly qualified specialists, a progressive and active residency training programs in cardiology, cardiac surgery and cardiac anaesthesia, AFIC-NIHD has gained the status of a model hospital in the country. However, research related activities were lacking as they should have been in a modern clinical institution.

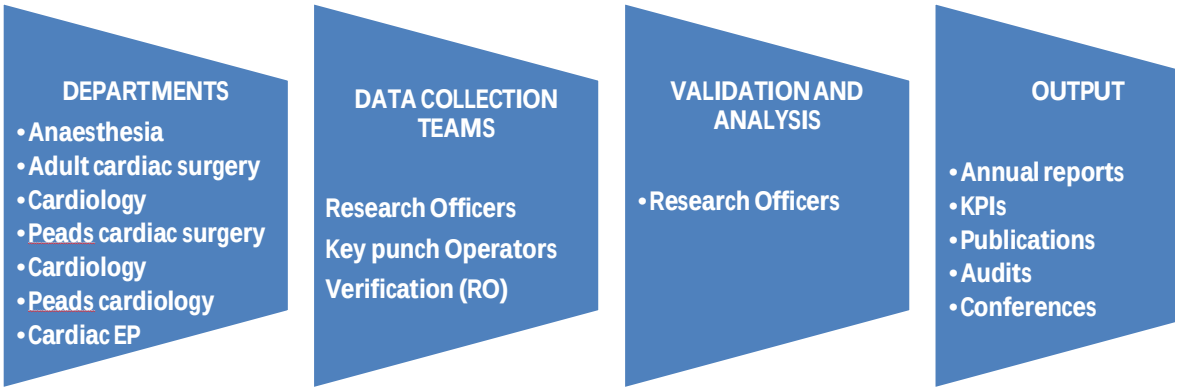

Figure-1: Conceptual framework for data collection & management.

Introducing a research and development program into a tertiary care cardiac setting can be challenging. Some primary factors to consider are the probable effects on the current clinical schedule, equipment and personnel resources required to support the research projects. More importantly, how can an organization successfully complete reliable and accurate research projects? This study describes our experience of establishing a R&D unit within our clinical setting. Our primary emphasis was providing an integrated research environment through delegated research staff and resources. A situational analysis regarding research related activities was carried out in 2013 at our institution and gaps were identified, which formed the basis of developing a research and development unit to keep up the pace at national and international level in providing the new knowledge needed to improve health across the population. Findings revealed that although colossal data was being generated, it had not been systematically organized to be used as purposeful scientific information. Furthermore, there was inadequate staffing for the organization, collection and analysis of this enormous data being generated. There was a huge gap in skills & knowledge pertaining to research methodology. However there were a limited number of scientific articles and publications due to the individual efforts by the clinicians to publish their scientific work. The Institutional review board was nonfunctional and ineffective. Unified vision and approach towards cardiovascular research activities was clearly missing at all organizational levels.

Figure-2: Research domains at FIC&NIHD.

The research and development department at our institution was established with the

objective to better utilize the rich research potential of clinical information collected on patients during their visit to AFIC&NIHD; to support the growth and delivery of faster, easier quality research within the organization and to facilitate set up and delivery of individual research projects of the clinicians within the institution.

After having identified the challenges, the immediate need was to setup a team of dedicated research workers who would act as an interface and support and coordinate with the specialists and clinicians, enabling them in systematic collection of data and research projects.

The first milestone achieved was establishing 40 disease specific registry databases in all the relevant specialties. A disease registry enables the provider to ensure that all their patients are getting proper care, track the progress of high-risk patients, identify the need for follow-up services, increase quality of care and improve patient outcomes, empower patients to take an active role in their treatment and coordinate care and identify gaps[4]. The data generated from these registries helped develop key performance indicators, conduct clinical audits, clinical trial, epidemiological surveys and quality improvement initiatives, enhanced quality of care and improved patient outcomes.

Medical research and its publication constitute a dignified cause. Being health care professionals, it is indeed our obligation to share professional experience with other colleagues who could employ these for the benefit and better care of the patients. Research has become even more important in this era of evidence based medicine where safe and effective therapies are best guided by the latest available best peer review literature[5].

Research with human subjects shall be guided by three general ethical principles: respect for persons, beneficence and justice. These principles and the rules that may be derived from them shall form the analytical framework for determining whether and how research with human subjects may be conducted. Researchers must respect and protect the rights and privacy and welfare of individuals recruited for and participating in research[6]. The International Council on Harmonisation (ICH) defines an institutional review board (IRB) as a group formally designated to protect the rights, safety and well-being of humans involved in a clinical trial by reviewing all aspects of the trial and approving its activation[7,8].

Figure-3: WHO Strategy on research for health.

In order to make clinical research more ethical and according to International Council on Harmonisation (ICH) and Good Clinical Practice (GCP guidelines) the restructuring of an Institutional Ethical Review Board (IERB) was mandatory. As a part of capacity building

workshops were arranged to enhance the skills of clinicians, specialists, trainees and research associates in research methodology, statistical analysis and bibliography.

As a result of these efforts, just in a short period of two years we were able to publish 74 articles in the form of two supplements in collaboration with Pakistan Armed Forces Medical Journal. The innovative R&D project included a telemedicine program, which enabled the provision of specialized medical care, services and treatment to the peripheral health facilities.

International collaboration in health research is a valuable mechanism for advancing knowledge and strengthening research capacity. It makes modern research tools available to institutions and countries that would not normally be able to provide them from their own resources. Cross-border multicentre studies have proved valuable for identifying risk factors, testing hypotheses generated in one locality at other sites, and developing and testing appropriate, cost-effective technologies[9]. Recognizing the potential value of such collaborative projects, the institution was enrolled into international post marketing phase IV clinical trials in cooperation with multinational companies.

A number of hurdles were identified during the implementation process, including the lack of a common vision for health research, the lack of coordination of research activities, the lack of a dedicated budget to support research, and inconsistency in using evidence as the basis of policies, programmes, and global norms and standards. The expectation is that obstacles such as these can be overcome by improving the quality, impact and inclusiveness of research practices. AFIC&NIHD projects & programmes will be supported by the best available research evidence, and related research activities will be conducted in accordance with a code of good research practice.

The future strategy of the organisation should be focused and in line with WHO strategy for research on health for improving health and health equity, as well as economic development[10].

- Actions for achieving our organization goal include:
- Developing a code of good research practice for AFIC&NIHD staff and improving staff competence in research;
- Strengthening ethical standards and peer review, using evidence to develop guidelines, and reviewing existing policies in the light of new evidence;
- Reviewing arrangements for working with partners, and seeking partners from all sectors that impact on research for health;
- Convening consultations to identify the priorities and funding for research on health;
- Improving communication on research and on the global trends and strategies
- Keeping abreast of developments in knowledge management, keeping in touch with the global research community and raising resources to support the strategy
- Develop an evaluation framework that will enable the elements of the research strategy to be monitored and the impact of implementation to be evaluated.
- To ensure that the strategy is successfully implemented, the organization will need to improve strategic and operational efficiency across its research activities.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

AUTHORS CONTRIBUTION

Farrah Pervaiz, Imtiaz Ahmed Chaudhry, manuscript writing, analysis and data interpretation , Sabeen Khurshid Zaidi, Safdar Abbas, Syed Muhammd Imran Majeed, supervision and substantial, guideline in manuscript

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