



ROLE OF RESEARCH AND DEVELOPMENT ORGANISATION IN HEALTH CARE

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ABSTRACT

This review article provides a condensed research finding during the last two decades on the role of R&D in health care organizations. It is important that organizations work out strategies relevant for marketing to enhance their own R&D activities. Implementation of R&D systems is directly related with productivity, if it reflects dual embodiment of efficiency. The bodies of literature have been almost unanimous of the needs of QA for R&D. Despite the needs, QA in R&D have been rarely discussed due to the difficulties of defining, measuring, and managing R&D quality. QI forms an important part of their competitive strategy. QMS have been successfully designed and implemented for manufacturing and service functions. Embedding dedicated research positions within healthcare settings is a potential strategy to build allied health research capacity. Stronger research culture appears to be associated with benefits to patients, staff and the organization. Research investment in the health workforce could increase research productivity of the health workforce. In addition, investment in clinical research could lead to positive health outcomes. It is important to provide support for initiatives directed at the health workforce to increase a research culture in health services. Explorations are required for research networks and schemes to promote the engagement of clinicians and managers in research. Detailed observational research focusing on research engagement within organizations would build up an understanding of mechanisms. It is well recognized that research can play an integral role in the delivery of safe, effective, efficient, patient-centered, accessible and timely health care. Research in allied health can assist in minimizing overuse, underuse and misuse of precious health care services. The gap between implementers and researchers of QI had hampered the degree and speed of change needed to reduce avoidable suffering and harm in health care. The implementation of quality elements in research and development is a hot issue. There are still problems and misunderstandings on how to apply QA in research and development.

KEYWORDS: R&D, Healthcare, QA, QI, QMS.

RESEARCH AND DEVELOPMENT

The implementation of quality elements in research and development is a hot issue, still under discussion and development. In recent years much progress have been made in the development of effective proposals. However there are still problems and misunderstandings on how to apply quality assurance [QA] in research and development (R&D). These issues could be solved mainly by the application of formal standards for QA in R&D. It is important to demonstrate benefits of implementing quality elements in R&D and then work out detailed suggestions for addressing the most important issues without hampering the flexibility and creativity of R&D.^[1]

Organizations should work out strategies relevant for marketing to enhance their own R&D strategies; such as reliability of companies on “sourcing-in” R&D facilities and “think-tank” events. Regardless of the study and of the country, cash flow and profitability always positively influenced R&D expenditure, while sales and firm size did not. However, handling R&D determinants should require caution. It seems critical that implementation of R&D systems is directly related with productivity, if it reflects dual embodiment of efficiency and effectiveness. Scrutinizing the determinants of R&D expenditures emphasizes significant factors that are worth to highlight when planning an R&D investment strategy. Although there is no receipt fitting every situation, health care plan

makers may find relevant data in a systematic way in creating an initial implementation framework.^[2]

The body of literature has been almost unanimous for the needs in QA for R&D. Despite the needs, QA in R&D have been rarely discussed due to the difficulties of defining, measuring, and managing R&D quality. Even some guidelines or standards have been suggested to deal with quality management; there is a lack of research dealing with the concrete framework for QA for R&D. It is important to develop a framework for QA for R&D. The conceptual framework of Development of a QA frame work for Research and Development [R&DQASS] consists of four dimensions: managements of organizational level, project level, process level and outcome level. The role, characteristics, and detailed activities of each dimension must be explained in detail. Following on the conceptual framework of R&DQASS, it is essential to provide QA procedures which should be conducted prior to, during, and after the R&D projects. The suggested framework is expected to provide the meaningful implication for the QA managers by providing the role and characteristics of key dimensions which are critical to the QA for R&D.^[3]

Quality in R&D work has become increasingly important as companies commit themselves to Quality Improvement (QI) programs in all areas of their activity. QI forms an important part of their competitive strategy. Quality management systems [QMS] have been successfully designed and implemented for manufacturing and service functions; but so far the quality principles and systems have been difficult to translate in to R&D function. It is important to have quality concepts, terms, systems and critical factors for successful implementation. Brief case histories must be used to highlight particular approaches to implementation. Then, introduce a new, versatile method for evaluating the capabilities of an R&D organization in terms of Total Quality Management (TQM).^[4]

Role of Allied Health Services

Embedding dedicated research positions within healthcare settings is a potential strategy to build allied health research capacity, with different health care organizations investing in such positions. The majority of studies reported the research positions to provide academic support to individual clinicians and their teams, while developing their own research projects. Other studies reported support for research capacity building at a service and organizational level. Positive changes from these research positions were reported via increased individual research skills and participation and research outputs, improvements in research culture, attitudes and team and organisational skills levels. Emerging evidence suggests that research positions embedded within healthcare settings could influence individual and team based research skills and research participation of Allied Health Professionals (AHP). Future researches are needed to further investigate the

sustainability of changes that could arise from research positions and what mechanisms of the positions have the greatest impact. Healthcare managers should consider how to support potential components of the research position roles identified in the literature, as well as consider evaluating their impact on research capacity, cultural and attitudinal changes of AHP staff in addition to traditional research metrics.^[5]

Three studies evaluated the effect of specific interventions focused on the health workforce. All studies reported a positive association between research activity and organizational performance. Improved organizational performance included lower patient mortality rates, higher levels of patient satisfaction, reduced staff turnover, improved staff satisfaction and improved organizational efficiency. These studies have concluded that stronger research culture appears to be associated with benefits to patients, staff and the organization. Research investment in the health workforce can increase research productivity of the health workforce. In addition, investment in clinical research can lead to positive health outcomes. However, it is not known whether a positive research culture among the health workforce is associated with improved organizational performance. Review of the literature provides evidence that a positive research culture and interventions directed at the health workforce are associated with patient, staff and organizational benefits. For health service managers and policy makers, it is important to provide support for initiatives directed at the health workforce to increase a research culture in health services. However, because association does not imply causation, managers need to interpret the results with caution and evaluate the effect of any initiatives to increase the research culture of the health workforce on the performance of their organization.^[6]

It is important to conduct a theoretically and empirically grounded synthesis to map and explore plausible mechanisms through which research engagement might improve health services performance. The evidence that research engagement improves health-care performance was less strong than anticipated. There is also evidence that organizations in which the research function is fully integrated into the organizational structure out-perform other organizations that pay less formal heed to research and its outputs. The focused and wider reviews identified the diversity in the mechanisms through which research engagement might improve health care: there are many circumstances and mechanisms at work, more than one mechanism is often operative, and the evidence available for each one is limited. Drawing on the focused and wider reviews, it is suggested that when clinicians and health-care organizations engage in research there is likelihood of a positive impact on health-care performance. Organizations that have deliberately integrated the research function into organizational structures demonstrate how research engagement can, among other factors, contribute to improved health-care

performance. Further explorations are required of research networks and schemes to promote the engagement of clinicians and managers in research. Detailed observational research focusing on research engagement within organizations would build up an understanding of mechanisms.^[7]

Role of Health Professionals

Research is a major driver of health care improvement and evidence-based practice is becoming the foundation of health care delivery. For health professions to develop within emerging models of health care delivery, it would seem imperative to develop and monitor the research capacity and evidence-based literacy of the health care workforce. The 2011 survey findings indicate podiatrists have similarly low research capacity skill levels to those reported in the allied health literature. The 2012 survey, compared to the 2011 survey, suggests podiatrists perceived higher skills and support to initiate research in 2012. This improvement coincided with the implementation of research capacity building strategies.^[8]

Although 158 Speech Language Pathologists (SLPs) responded to the survey, complete data were available for only 137. Respondents were more confident and experienced with basic research tasks and less confident and experienced with complex research tasks. For most tasks, SLPs displayed higher levels of interest in the task than confidence and experience. Research engagement was predicted by highest qualification obtained, current job classification level and overall interest in research. Respondents generally reported levels of interest in research higher than their confidence and experience, with many respondents reporting limited experience in most research tasks. Therefore SLPs have potential to benefit from research capacity building activities to increase their research skills in order to meet organizational research engagement objectives. However, these findings must be interpreted with the caveats that a relatively low response rate occurred and participants were recruited from a single state-wide health service, and therefore may not be representative of the wider SLP workforce.^[9]

Role of Stakeholders

An initiative was implemented using a research capacity-building framework developed from a review of the literature and stakeholder consultations. The framework included leadership and governance, support to researchers and translation of evidence into practice and was contextualized to public health environments. There were several phases of implementation. An evaluation of the preliminary phase of establishing research positions and research activity should be conducted and several successes of the capacity-building strategies should be identified. These successes [e.g. solid partnerships with universities] must be incorporated as future concerns, such as sustainability of the initiative in a tighter fiscal context.^[10]

Small grants must be provided to facilitate the development of new work, help create new, multidisciplinary groupings and support junior researchers. Of the various schemes discussed, the research initiation grants and workshop awards appear to have been particularly valuable. Second, appoint cohorts of PhD students to pursue four-year training programmes' [rather than the traditional three years], during which they could receive individualized research training and development opportunities with an emphasis on both multidisciplinary and Health science research (HSR) training and generic skills training, as well as pursuing their own research projects. Third, improving research training opportunities by developing networks for research staff at various stages in their careers and organizing workshops and courses in HSR subjects, and for generic skills training. The premature closure of the Health Service Research Center may prevent from fully evaluating these initiatives and, arguably, their real value will not be apparent for some years.^[11]

Implementation Strategies

The field of implementation research is growing, but it is not well understood despite the need for better research to inform decisions about health policies, programmes', and practices. Studies focus the context and factors affecting implementation, the key audiences for the research, implementation outcome variables that describe various aspects of how implementation occurs, and the study of implementation strategies that support the delivery of health services, programmes, and policies. Use of research question as the basis for selecting among the wide range of qualitative, quantitative, and mixed methods that can be applied in implementation research, along with brief descriptions of methods specifically suitable for implementation research. Expanding the use of well designed implementation research should contribute to more effective public health and clinical policies and programmes.^[12]

The use of research evidence to facilitate improvements in healthcare quality continues to be a topic widely debated by scholars and practitioners. The concept of 'knowledge mobilization' has been developed, with strategies to help bridge this gap. These strategies include the development of "a culture of partnership between academic researchers and decision-makers to assist in strengthening the development of policy, practice and social innovation, or the co-production of knowledge". It is based on the premise that knowledge that is collected and created 'on the ground', through daily interaction and negotiation with practitioners, managers and service users, will provide better insight into the issues affecting these stakeholders, be more relevant to the local context and will, therefore, be more easily incorporated into changes in practice.^[13]

Factors altering Research in Healthcare

Process through which research is applied involves many factors, some of which are amenable to influence by

researchers. Within these constraints, multiple pathways can drive research use; no one of these is likely to perform better in all circumstances. Successful uptake is more likely when these pathways cause findings to be converted into messages meaningful to policy makers. Various intermediaries play an important role in creating effective pathways, while users also can influence them. The pathways that are open up too often are unexplored "black box" that mediates between health services research and its use by policy makers. Such pathways can help stakeholders to bridge different perspectives in ways that strengthen the possibility that effective research will be supported and used.^[14]

Despite 40 years of research into evidence-based policy [EBP] and a continued drive from both policymakers and researchers to increase research uptake, barriers to the use of evidence are persistently identified in the literature. Rather than asking how research evidence could be made more influential and academicians should aim to understand what influences and constitutes policy, and produce more critically and theoretically informed studies of decision-making. The main assumptions made by EBP researchers are to explore the implications of doing so, and propose new directions for EBP research, and health policy.^[15]

Economic evaluations are a set of outcomes and health services research methods to inform the debate about the rising cost of health care and include cost-of-illness studies and cost-effectiveness research. Cost-effectiveness research is the comparative analysis of two or more alternative interventions in terms of their health and economic consequences, whose results are expressed as an incremental cost-effectiveness ratio, the ratio of differences in cost between a pair of medical interventions to the differences in the corresponding health effects. These research methods are particularly important to neurological diseases with debilitating natural histories, long-term courses, and a growing number of exciting, yet costly, treatment options available. The results of economic evaluations of neurological conditions influence resource allocation decisions, help set reimbursement rates, estimate future healthcare expenses, and improve the quality and efficiency of delivering neurological care. For these research methods to achieve their potential, continued methodological advances within the field are needed, as well as a more systematic integration of these methods into mainstream research to address critical questions regarding the health and well-being of patients with neurological illness.^[16]

Health care stakeholders often lack sufficient information on these outcomes to make well-informed decisions. Health services approaches such as comparative effectiveness research, patient-centered outcomes research, and health economics assessments are some ways to evaluate value. The evidence generated from such studies directly informs decision making and

health policy. Rehabilitation of professionals have a great opportunity to increase their engagement in describing, evaluating, delivering, and disseminating high-value care, but there are several barriers they need to consider to be most successful. Embracing health services research best practices is essential for advancing appropriate rehabilitation practice, research, and policy and for addressing challenges to implementing high-value care.^[17]

For most countries, each of the Research Capacity Building (RCB) domains from Cooke's framework was a high priority. In about half of the countries, domain specific activities happened prior to Personal Health Investment Today (PHIT). During PHIT, specific RCB activities varied across countries. Many common challenges for RCB, such as adequate resources and local and international institutional support were not identified as major challenges for these projects. Overall recommendations are for funders to provide adequate and flexible funding for RCB activities and for institutions to offer a spectrum of RCB activities to enable continued growth, provide adequate mentorship for trainees and systematically monitor RCB activities.^[18]

Realizing the health-related sustainable development goals [SDGs] requires integrated action on system-wide challenges. To address gaps in health service delivery, we need evidence on which government agencies, research institutions, donors and civil society can act. Unless research is relevant to specific health systems, the evidence that it generates can be dismissed by policymakers. For example, there is plenty of evidence for the effectiveness of standard interventions to prevent maternal and child deaths, but countries vary widely in the degree to which these interventions have been implemented.^[19]

Mortality reductions must be estimated from a research-funding strategy focusing primarily on developing technology compared with one that also focused on delivery and utilization 97% of grants were for developing new technologies, which could reduce child mortality by 22%. This reduction is one third of what could be achieved if existing technologies were fully utilized. There is a serious discrepancy between current research and the research needed to save children's lives. In addition to increased research on the efficacy of treatment, there is an even greater need for increased research on delivery and use of technology.^[20]

Evidence Based practices

Evidence-based practice aims to achieve better health outcomes in the community. It relies on high quality research to inform policy and practice; however research in Primary Health Centers (PHC) continues to lag behind that of other medical professions. The literature suggests that research capacity building [RCB] functions across four levels; individual, team, organization and external

environment. Many RCB interventions are aimed at an individual or team level, yet evidence indicates that many barriers to RCB occur at an organizational or external environment level. Senior managers from a large healthcare organization should identify the barriers and enablers to RCB. It is important to build allied health [AH] research capacity at an organizational level from a senior managers' perspective. The dominant themes indicate that the organization plays an integral role in building AH research capacity and is the critical link in creating synergy across the four levels of RCB. The organization can achieve this by incorporating research into its core business with a whole of organization approach including its mission, vision and strategic planning. Critical success factors include: developing a co-ordinated and multidisciplinary approach to attain critical mass of research-active AH and enhance learning and development; support from senior managers demonstrated through structures, processes and systems designed to facilitate research; forming partnerships to increase collaboration and sharing of resources and knowledge; and establishing an internal framework to promote recognition for research and career path opportunities. Four key themes have been proposed. Whole of organization approach; structures, processes and systems; partnerships and collaboration; and dedicated research centers, units and positions. These themes form the foundation of a model which can be applied to assist in achieving synergy across the four levels of RCB, overcome barriers and create an environment that supports and facilitates research development in AH.^[21]

Role of Allied Health Professionals

General practitioners and other PHCPs are often the first point of contact for patients requiring health care. Identifying, understanding and linking current evidence to best practice can be challenging and requires at least a basic understanding of research principles and methodologies. However, not all PHCPs are trained in research or have research experience. A small grant and mentoring scheme through a University Department can effectively enhance research skills, confidence, output, and interest in research of PHCPs.^[22]

It is paramount to consider the level and content of qualifying professional training and the recruitment of staff to universities primarily as social work educators. Any developmental and/or remedial work undertaken has to address historical influences and, at the same time, be responsive to changes that are taking place within social work as both profession and discipline within the wider context of the social sciences. Drawing on theories of organizational learning, must concludes that any strategy must address staff development issues for academics and practitioners to facilitate the creation of vibrant learning communities across academic and practice settings.^[23]

Individual AHPs are more likely to report being motivated to do research by intrinsic factors such as a

strong interest in research. Barriers they identified to research are more likely to be extrinsic factors such as workload and lack of time. AHPs identified some additional factors that impact on their research capacity than those reported in the literature, such as a desire to keep at the "cutting edge" and a lack of exposure to research. Some of the factors influencing individuals to do research were different to those influencing teams. It is important to have motivated AHPs individuals and teams to conduct research by increased skills training, infrastructure, and quarantined time is likely to produce better outcomes for research capacity building investment.^[24]

Trainees in laboratory medicine must develop skills in laboratory management. Guidelines should be detailed for laboratory staff in training and directors are responsible for staff development and professional bodies wishing to generate material appropriate to their needs. The syllabus should delineates the knowledge base required and must include laboratory planning and organization, control of operations, methodology and instrumentation, data management and statistics, financial management, clinical use of tests, communication, personnel management, training and R&D. Methods for achievement of the skills required must also be suggested. International Federation of Clinical Chemistry [IFCC] reference materials will be very useful.^[25]

The U.S. Department of Health and Human Services [HHS] developed a set of federal standards for protecting the privacy of personal health information under the Health Insurance Portability and Accountability Act of 1996 [HIPAA]. The HIPAA Privacy Rule set forth detailed regulations regarding the types of uses and disclosures of individuals' personally identifiable health information—called "protected health information"—permitted by "covered entities" [health plans, health care clearinghouses, and health care providers who transmit information in electronic form in connection with transactions for which HHS has adopted standards under HIPAA]. A major goal of the HIPAA Privacy Rule is to ensure that individuals' health information is properly protected while allowing the flow of information needed to promote high-quality health care. The HIPAA Privacy Rule also set out requirements for the conduct of health research.^[26]

The importance of QI & QA

The gap between implementers and researchers of QI had hampered the degree and speed of change needed to reduce avoidable suffering and harm in health care. Underlying causes of this gap include differences in goals and incentives, preferred methodologies, level and types of evidence prioritized and targeted audiences. The Salzburg Global Seminar on 'Better Health Care brought together researchers, policy makers, funders, implementers, evaluators from low-, middle- and high-income countries to explore how to increase the impact

of QI. The outcome of this seminar has described some of the reasons for this gap and offer suggestions to better bridge the chasm between researchers and implementers. Effectively bridging this gap can increase the generalizability of QI interventions; accelerate the spread of effective approaches while also strengthening the local work of implementers. Increasing the effectiveness of research and work in the field will support the knowledge translation needed to achieve quality Universal Health Coverage [UHC] and the Sustainable Development Goals [SDG].^[27]

The implementation of QA for research laboratories will enable all fields of research and development to be judged impartially. There are no specific standards for research laboratories but where possible, existing standards can be adapted. The first approach is to consider research as a logical extension of testing, and should be assumed that testing standards can be applied methodically to each step in a research project. The second advocates a flexible approach, with research-specific criteria for assessing quality. The general quality management approach, encompassed by the ISO 9000 series of standards with the emphasis on customer satisfaction and 'fitness for purpose', is suitable for implementing QA in research laboratories.^[28]

It is mandatory for sponsors of clinical trials and contract research organizations alike to establish, manage and monitor their quality control [QC] and QA systems and their integral standard operating procedures (SOPs) and other quality documents to provide high-quality products and services to fully satisfy customer needs and expectations. QA systems together constitute the key quality systems. QC and QA are parts of quality management. QC is focused on fulfilling quality requirements, whereas QA is focused on providing confidence that quality requirements are fulfilled. The quality systems [QS] must be commensurate with the company business objectives and business model. Top management commitment and its active involvement are critical in order to ensure at all times the adequacy, suitability, effectiveness and efficiency of the QS. Effective and efficient QS can promote timely registration of drugs by eliminating waste and the need for rework with overall financial and social benefits to the Company.^[29]

The regulatory requirements, quality assessment programs, compliance issues, and general administrative responsibilities of laboratory directors have significantly increased over the past decade. As a result of these clinical service demands, the academic aspects of the profession and the time to participate in research have seemingly suffered. For instance, fewer clinical laboratory physicians and scientists are publishing in top journals such as *Clinical Chemistry*, where currently only approximately 35% of original reports have a first or last author associated with a laboratory medicine or

pathology department. Similar disturbing changes are currently happening in other parts of the world.^[30]

The results from many Lab Information Management System (LIMS) studies have shown a low conformity [30%] with LIS8-A, with no difference between teaching and private hospitals. The Analysis of Variance [ANOVA] revealed that in terms of conformity with the LIS8-A standard, there was a significant difference between the systems produced by different vendors. According to the results, a Kowsar system showed more than 57% conformity in the three groups of information component which showed a better conformity to the standard, compared to the other systems. Some studies have indicated that none of the LIMSs had a good conformity to the standard. It seems that system providers did not pay sufficient attention to many of the information components required by the standards when designing and developing their systems. It was suggested that standards from certified organizations and institutions should be followed in the design and development process of health information systems.^[31]

CONCLUSIONS

Research plays a significant role in any organization and it will drive towards better results outcome based on the company set goals. Many studies done in the past have predicted research and development activities as the pillars of setting up goals to achieve the growth of organization. Health care improvements also found to grow at a faster rate. Studies done in the past two decades have emphasized the role of all stakeholders from the bottom level employee to the top level CEO. Improvements will be further accelerated if allied health care professionals, nurses and all those involved in patient care play significant role. A well setup Hospital should have research and development section to monitor, update and suggest new methods that could be applied to improve patient satisfaction. These activities are also important for industries and other organizations to improve customer's satisfaction. The contents of this review article will be very useful for undertaking many dimensional research activities based on the need in each area of an organization.

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