Barriers to Implementation of Clinical Research in the State of Qatar: A Managerial Perspective

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Abstract:

Clinical research helps in improving patient care and quality of life through translation of findings from basic research (laboratory based) into actual benefit to patients. The huge advancements in the field of clinical research are accompanied by increase in demand for infrastructure, funding and regulations to ensure the safe conduct of research. There are many barriers faced by researchers around the world that affect the initiation and progress of their clinical research projects and eventually lead to wastage of effort and resources. Many studies in literature assessed these barriers from the researchers' perspective. Nevertheless, the aim of this study was to identify the barriers as seen by research managers in Qatar. The study also had a retrospective aspect where the database of funded projects was analyzed for frequency of suspensions and terminations and if they were related to the identified barriers. Five research managers from different research institutions in Qatar were interviewed for their opinion about the barriers to conducting clinical research in Qatar. The interviews were recorded, transcribed and a thematic analysis model was applied to generate common themes. The major barriers identified could be categorized into four major themes – scientific / professional, financial, administrative and regulatory. A retrospective analysis of the grants awarded to Hamad Medical Corporation (HMC) confirmed that most reasons for the suspensions and terminations were related to these barriers. We believe that this study provided very important insight into the barriers faced by researchers in Qatar. The outcomes will be communicated to the policy makers in Qatar to focus on addressing these issues for a better utilization of the available resources and infrastructure to support clinical research in Qatar. The study also paves the way for a future study where barriers will be assessed by the researchers.

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Dedications:

To my beloved Mother and Father,

Siblings, nephews and nieces,

My belated but long awaited inspiration,

Old and new friends,

Everyone who believed in me,

Sincerely for you all,

Thank you.

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Introduction

Research is defined as "*creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies and understandings. This could include synthesis and analysis of previous research to the extent that it leads to new and creative outcomes."*(Western Sydney University, 2018). It reflects the human nature of exploring and finding answers to different existential, physical and metaphysical phenomena however in a more systematic and creative way that streamlines their effort towards a specific or practical aim or objective. Over the past decades, countries have realized the importance of Research and Development (R&D) which in turn resulted in huge investments from governments and business corporations into different fields like health, psychology, technology, energy and other vital elements of R&D. The outcome of these investments positively impacted the lives of millions, if not billions, around the world but are these outcomes really equitable compared to the invested money, time and effort? Are these R&D initiatives really benefitting from the actual investments or is there a "sieve-off" effect in the process where significant portion of these financial and non-financial investments are "apprehended" due to barriers in the system?

The answer to these questions might vary from one system to another, one sector to another, one country to another, however it only varies in the number or severity of these barriers. This is because, generally speaking, there is no "perfect research system" in the world but each system has its unique pros and cons whether from the legislative or executive perspective.

Background and Literature Review

Biomedical Research is one of the fields where countries invest heavily to improve the health of living individuals. These investments mainly aim at Research Capacity Building (RCB) that augments sustainable and fertile research systems to yield the expected outcomes. There are different approaches to RCB that could be initiated at institutional, state and national levels. Examples of such approaches are funding opportunities, training and development, building facilities and adopting national programs to implement the recommendations of different research projects (Pager et al., 2012).

According to the World Health Organization (WHO) report in 2017, Gross Domestic R&D (GERD) expenditure on health as percent of total GERD ranged between 9% and 18% across different WHO regions (WHO, 2018). However there are no studies or reports on the actual outcome of these huge investments in this sector over the past years. A recent official report (Battelle, 2013) issued by the authorities in the State of Qatar forecasts spending around 2.8% of its Gross Domestic Product (GDP) for R&D purposes – which is a huge investment, considering the fact that Qatar has one of the highest GDPs in the world (The World Bank, 2018). Later surveys about the R&D in Qatar reported that the actual spending as of 2015 was estimated around 0.5% of the national GDP, which was a massive 800 million US Dollars (MDPS, 2017).

Biomedical Research in Qatar started to be more organized in the mid-90s through a scientific committee at the National Care provider – Hamad Medical Corporation (HMC). Hamad Medical Corporation is the largest secondary and tertiary care

provider in Qatar (HMC, 2018). The committee evolved into a research center that specializes in research administration and support for all research across HMC and its nine hospitals. Being the largest clinical care provider, bulk of clinical research takes place at HMC, however there are other stakeholders in the Qatari clinical research ecosystem like Qatar University, Sidra Medicine, Weil Cornell Medicine Qatar and Primary Health Care Corporation. All these stakeholders including HMC fall under the umbrella of the Ministry of Public Health when it comes to national governance of the clinical research in Qatar.

HMC research center currently has its own funding opportunities on a routine as well as competitive basis that is open to HMC researchers and their collaborators. Another important source of funding is the Qatar National Research Fund (QNRF), which is the national research funding agency that funds research grants aligned with the Qatar National Research Strategy (QNRF, 2018).

QNRF has different funding programs that cater different levels of researchers ranging from Undergraduates to post-doctoral scientists and senior researchers. These funding program cycles are launched annually with minor changes to address the changing research priorities within Qatar and the region. Over the past years, HMC has received more than $70 million in funding through different QNRF funding programs. The major funded areas include diabetes and metabolic disorders, cancer, Cardiovascular diseases and public health.

However, like many other research systems around the world, there are barriers to implement clinical research in Qatar smoothly and efficiently that have been

observed over the past years. In this research study, our focus was barriers to implementation of clinical research which means the actual conduct of research or execution of research projects by researchers.

The existence of barriers to implement research – or clinical research to be specific – has been reported in quite a few studies in the literature. A systematic review identified four barriers to implementation of trials in Trauma surgery (Perry et al., 2014). One of these barriers was the surgeons' beliefs regarding the trial methodologies and absence of "equipoise" within the surgeon. Equipoise usually means a balance or counter balance of something but in this case, it means the surgeon's favoring opinion of one treatment over another and this in itself is a barrier for the surgeon to participate in research. The review also explored other barriers like disease barriers, process barriers and patient barriers. They concluded that even if high quality research was performed, there could be other barriers that hinder the transformation of this knowledge into clinical practice. Another extensive review assessed different barriers that are specific to the conduct of Randomized Clinical Trials (RCTs) (Duley et al., 2008).They identified seven barriers that were common to independently conducted RCTs. The first barrier was lack of funding for large trials and the high cost for setting up of low-cost trials. Large trials require huge funding and it becomes challenging for independent trials that are not sponsored commercially to secure these funds due to scarcity of available opportunities. In most cases, funding organizations are disease specific and do not accommodate all the major public health domains that do not fit their profiles. Other funding organizations are very competitive and the review process are so extensive and prolonged that affects the implementation of these trials. On the other hand,

low-cost clinical trials also require high cost for setting up sometimes almost equivalent to the cost of the actual trial itself. This is due to the increased complexity in the regulatory requirements of these trials that involve submission to different review and ethics committees and each committee requires a substantial review fee. Other regulatory requirements also require set up fees like storage spaces, offices, binders, annual reviews etc. Another issue related to lack of funding is inadequate infrastructure and facilities for conducting large trials. This has led to a new trend where trials are being conducted in low and middle income countries due to the relatively low setup and running costs compared to high income countries. Such trials may not produce the required results mainly if the research questions are not relevant to the target population in these countries. The second barrier identified in the review was complexity of the regulations preceding recruitment into the trial. The main issues underlying here are the multiple committees involved in review of clinical trials, the amount of time and effort to address the concerns of each committee, contract negotiations and the additional regulations for research involving drugs (IND review). The third barrier was excessive monitoring for adherence to the trial protocol. They discussed how applying the same standards for trials involving new drugs and trial testing a generic drug already in the market was adding stringent burden to the trial setup and lack of alternative methods for monitoring. An interesting aspect also discussed here was their suggestion to study the carbon footprint of monitoring i.e., the carbon emissions for each monitoring trip. The fourth barrier focused on the complexity of the trial procedures itself like the long consent forms, recruitment, complex reporting requirements and multiple protocol amendments for each minor revision. The fifth and sixth barriers were related to conservative interpretations of privacy

laws and lack of training and education about trial methodology. The last barrier assessed in the review was the lack of evidence on conducting trials and how common procedures for all trials – regardless of their research question – was not the ideal approach to tackle this issue. “Invisible” barriers to clinical trials have been studied with respect to opening of oncology trials in a single research network at Vanderbilt, USA (Dilts & Sandler, 2006). A comparison study was done to outline the possible differences between 2 diverse settings - a University Medical Center (VICC) and community-based oncology network (VICCAN). Mapping of existing processes for opening an oncology clinical trial and timing analysis for time required was performed. The process was broken down further into different steps like preparation of documents, discussion with team/ department, budgeting and final preparation for initiation of the trial. There was no significant difference in the process maps of both settings with regards to the number of steps, however, the number of committees/ individuals involved in the VICCAN were much less than VICC (almost 5 times less). Nevertheless, the timing analysis showed that actual time taken to open a trial did not differ much in both settings. A deeper analysis of the underlying reasons to these delays showed that the maximum time consuming step was the grants and contracts and not the IRB or scientific review – contrary to the usual belief among investigators. The study also had a unique finding that a good number of opened trials had poor accrual rates which raises concerns about “wasted efforts” at the different review stages for poorly planned trials. A short article describing the outcome of discussions by a working group convened by FDA and Duke University to identify barriers to conducting large RCTs stressed that these trials must be simple – financially and design wise (Eapen et al., 2017). FDA’s initiatives in this regard were described further that included two guidance

documents and a new rule regarding reporting of unexpected adverse events. The article also called for close collaborations between researchers and clinicians towards a health system that represents bench to bed research models.

There are quite few studies that covered the barriers from the researchers' perspective. Faculty members of Birjand University of Medical Sciences in Iran identified financial, organizational-managerial barriers and professional barriers as the most significant barrier to research (Ehtesham et al., 2017). Other barriers reported in this cross sectional study included facilities, individual and scientific barriers. A cross sectional observational study was conducted on Allied Health Professionals (AHP) teams in Australia to evaluate the motivators and barriers to research in these teams (Wenke et al., 2017). The survey tool used was the Research Capacity and Culture tool (RCC) which is a validated questionnaire that measures 3 domains of research capacity – organization, team and individual (Holden et al., 2012). Six major barriers were identified by the AHP team members including lack of time, clinical workload, lack of funds, poor administrative support and shortage of support staff. However, there was no significant correlation between the reported barriers and the research activity of these teams in terms of funding received, approved proposals and research output. On the other hand, there was stronger association between motivators like career development, job satisfaction, skills development etc. with the research output and higher funding received. Research barriers were also identified by experts attending educational seminars in Mazandaran University of Medical Sciences in Iran (Ataee et al., 2015). A survey questionnaire with 2 parts related to individual characteristics and personal/ organizational barriers was distributed to the attendees of these seminars

between 2007 and 2009. Among the individual barriers the most common barriers were lack of time and motivation. As for the organizational barriers, the most significant were research conducted by authorities, lack of funding and research. In another study, radiologic technologists registered with the American Registry of Radiologic Technologists (ARRT) were surveyed about perceived needs and barriers to research (Fauber & Legg, 2004). The survey also includes questions about their opinion regarding professional emphasis on research. Reported barriers included training, access to equipped facilities, funds and support personnel. Around 80% of the respondents agreed on the lack of available time for research and the priority of research in their practice. However they also had a positive attitude towards research as they agreed about its importance for professional growth.

Barriers to involvement of front clinicians were also identified in a cross-sectional study among clinical members of the American Society for Marital and Family Therapy (Sandberg et al., 2002). The study team mailed the clinicians requesting the participation of their clients in a hypothetical research project and asked the clinicians if they would be willing or not to participate in such a project and what could be changed to persuade them into participation. They were also asked about what could make the research more applicable to their practice. For the first couple of questions, the responses were analyzed and further coded into 4 categories – time/ money restraints, outside limitations like restrictions from employers, client concerns like confidentiality or risks and ambiguity regarding their role in the proposed study. As for the third question, the responses were again analyzed and further coded into another 4 categories – time/ convenience, relevance to their

discipline, personal/ professional barriers e.g. lack of support groups and design and presentation of the study. The authors suggested that clinicians must be involved in the conceptualization and design of studies to ensure relevance to their discipline. It was also suggested that clinicians must be compensated for their extra time and effort in these projects. Collaborations between academics and clinicians were also encouraged to overcome most of these barriers.

The topic has been addressed from the students' perspectives as well at Taibah Medical College in the Kingdom of Saudi Arabia (Noorelahi et al., 2015). A cross sectional survey was conducted among older medical students and included demographics, attitude towards research, practices and barriers to participate or conduct research. The respondents identified four major barriers like absence of adequate facilities, lack of interest by the faculty and guides as the main barriers to conduct of research, in addition to unavailability of patients. However, there was a positive overall attitude among the medical students towards research. The researchers also reported that lack of facilities and sample patients would be addressed soon after the (under-construction) facilities at their university would be up and running. Another research study elaborated on the bridges and barriers to integrated interdisciplinary research among graduate students (Nielson-Pincus et al., 2007). The study involved series of workshop exercises involving graduate researchers and identified three themes of bridges and barriers – individual, disciplinary and programmatic. Each theme had distinct categories with underlying issues and respective bridges to these issues. Individual barriers included vision, dedication and problem solving skills as the main categories. Four categories of disciplinary issues were idiosyncracies, scales and units, models and frameworks

and focal themes. At the programmatic level, the three categories were framework, mentoring and training/ resources.

On the other side of barriers to research implementation, there are other barriers to Research Utilization (RU). These barriers apprehend the implementation of research findings into actual practice, policies or programs that would benefit the target populations. Numerous studies were conducted to study barriers to RU in different settings (Kajermo et al., 2000 and Lyons et al., 2011).

Implementation research is the scientific study of processes used to implement health policies and programs by addressing challenges through real time application of gained knowledge through systematic methods (Theobald et al., 2018). It aims at identifying the strengths and weaknesses of the current system and different ways to improve implementation and maximize utilization of the available resources. WHO has recently adopted this initiative for many of its programs including disease eradication, enhancing service delivery through management improvement and empowering beneficiaries (WHO, 2013). The topic has also been discussed by Peters et al., 2013 who encouraged mixed methods of qualitative and quantitative studies as best means of implementation research.

Almost all studies regarding barriers to implementation of clinical research available in literature and described above are either review papers or studies that assess barriers from the researchers' perspectives. However published work on a similar topic from the perspective of research managers and executives is scarce. One study assessed the barriers to execution of cancer clinical trials from both

perspectives – researchers and managers. A cross sectional survey of oncologists together with semi-structured interviews of oncology leaders was conducted in a cancer research network under National Cancer Institute (NCI) (Somkin et al., 2005). The overall attitude of oncologists towards supplying support for research trials was positive. Barriers were classified into large, somewhat large and not barrier. Lack of support staff and dedicated time for research were the most frequently reported large barriers whereas majority of the oncologists did not see funding as a barrier. As for the infrastructural support, the majority of them agreed that the medical school education did not prepare them adequately to conduct research and the clinical oncology program did not help much either. However, they acknowledged the support from the local research department, fellow physicians and data managers in their organizations. There were also issues regarding identification of potential participants in the trials were lack of support from the organizational staff and resources was raised. As for the oncology research managers/ leaders, they were interviewed about issues related to finance and resources. Most believed in the importance of trials with least (negative) cost effect to actual patient care. Other leaders discussed about better communication within the network and with NCI and more involvement in the design of the trials. Overall, the study showed the different perspectives of oncologists in comparison to the leaders on how to conduct clinical trials. While oncologists bemoaned lack of support staff and time for research, leaders had a different perspective of the barriers to ensure that the costs of additional tests and protocols were controlled and that conduct of research trials must not affect the access of patients to their usual medical care.

Another component of this study was to retrospectively review the records of the grants received by HMC from QNRF and track the suspended/ terminated studies with the reasons for these setbacks. Since the funded grants are closely monitored by QNRF through periodic reports and site visits, they are subject to grace periods, suspensions and even terminations in extreme cases. These decisions are based on the assessment of the progress reports submitted by the Lead Principal Investigator (LPI) and site visits by QNRF project managers. These managers share their concerns with the LPI or in some cases raise it directly to the QNRF review committee for a decision in this regard. The decision is communicated to the Authorized Research Office Representative (AROR) of the awardee institution in a letter outlining the reasons for suspension or termination. The letter usually dictates the required actions to revoke the suspension or appeal the termination decision. However, suspensions and terminations can also be initiated by the AROR of the awardee institution. This could happen due to institutional findings, administrative issues or arising of unfavorable conditions that would affect the conduct of the research grant at that time. The final decision is always subject to QNRF's review and approval. Suspensions are provided for a maximum of 90 days after which the project gets terminated by default, unless further extension is granted on exceptional grounds. On the other hand, there are 2 types of terminations – for convenience and for cause. The first can be initiated by either party and is applied for obvious reasons stated in the master agreement whereas the latter is initiated by QNRF alone. It is always the duty of the awardee research office to communicate these decisions to the sub-awardees, if any. The main reason for reviewing these records was to extract information about the frequency of suspensions and terminations in the awarded projects to HMC and also identify the

main reasons for these adverse decisions by QNRF. The reasons would then be classified into categories and these categories would be compared to the themes/ categories generated from the analysis of the interviews to confirm the existence of the barriers identified by the managers in their interviews. Since the routine proposals managed at the research center are not scrutinized as thoroughly as the QNRF projects, it was ideal to select QNRF awarded projects for this descriptive analysis.

Rationale of the study

No other studies in literature, to the best of our knowledge, have assessed barriers to conduct clinical research in any setting from the managers' perspective. Hence this study was the first study in the region and possibly the world to identify these barriers from a new perspective. We believed that by doing so, we would not only identify barriers but possibly identify any gaps with regards to funding availability or resource management in the viewpoint of the researchers and managers. Elimination of such gaps would promote a more productive research culture as the targets would be clear to both sides of the equation in a research ecosystem. This would help not only in enhancing the conduct of clinical research but also in better utilization of this knowledge thereby contributing positively to the RCB initiatives in Qatar. The findings of this study would also help streamline efforts across all stakeholders and all levels thus contributing to better exploitation of the available research infrastructure and funding in generating the expected research output.

Research Questions

The questions that were expected to be answered at the end of the study are as follows:

1) What are the barriers to conducting clinical research in Qatar as seen by research managers?
2) What are the barriers to conducting clinical research in Qatar as reviewed in the existing QNRF funded grants?
3) How are these barriers affecting the implementation of clinical research in Qatar?
4) Are these barriers specific to the Qatari research systems?
5) What is being done to overcome these barriers?
6) How are funded grants affected by these barriers?

Specific Aims

Specific Aim 1: To identify the barriers to implementation of clinical research in Qatar from the research managers' perspective.

Specific Aim 2: To retrospectively assess the recurrence of suspensions/ terminations in the QNRF funded projects to HMC and the reasons for these setbacks

Methodology

Design

This is a pragmatic study that involves mixed methods approach. Firslty and due to scarcity of knowledge in literature about the managerial perspective of this topic, an interpretivist research model appeared to be the best approach for implementing this study since it includes an iterative process of interpreting the data and outcomes for the interviews and the qualitative analysis performed. On the other hand the positivist approach is also used in relation to the quantitative analysis, which deals with retrospective data that the researcher has no influence on.

There was no hypothesis as such but rather a tentative theory based on the literature review. The pragmatic model is also considered ideal for mixed design studies (Williamson and Johanson, 2018). Hence our study design was observational cross sectional and retrospective, including mixed design with both qualitative and quantitative components. The study had 2 parts:

Qualitative study: The first aim of the proposed study comprised of face to face semi-structured interviews with the research managers and executives of different stakeholders in the research community in Qatar. The key personnel to be interviewed were identified through their known profile in Qatar since the research ecosystem is relatively small considering the small geographical size of the country. These key personnel were contacted through email with an invitation to participate in this research study (See Appendix 3). The email also included an information sheet (See Appendix 1) with all the required details of this study that would be of importance to them as participants and the interview method. The participants were

asked to sign a consent form after reading the information sheet (See Appendix 2). They were also informed through the sheet that their interviews will be audio recorded and transcribed anonymously for the purpose of thematic analysis later. Confidentiality was assured and the interviews were scheduled according to their convenience. The interview guides were semi structured constituting of open-ended questions prepared by the research team after extensive literature reviews and inputs from experts in the field (See Appendix 4). The questions included background information about the participants (age, education and role), their experience in clinical research, to describe the research support in Qatar in general and specifically in their institutions, how much funding is used efficiently, research space and time allocations, research barriers and what solutions were suggested or taken. The discussions were moderated in English as a preferred mode of communication since all the managers had their higher education in English.

Participants

The interviews included the following personnel that represent the clinical research community in Qatar:

- HMC
- Ministry of Public Health
- Sidra Medicine
- Weill Cornell Medicine Qatar
- Qatar National Research Fund

Four managers were in the age group 50 to 60 years, one above 60 and one below 50 years. Except for one, all managers had educational backgrounds that included

both clinical and administrative degrees with sufficient experience in both fields as well. Two of them were still practicing clinicians while others focused on management only. One manager was relatively new to the clinical research ecosystem in Qatar and joined almost a year back but all other managers had at least 4 years of experience in the clinical research management in Qatar.

Each interview lasted for 30-45 minutes and the interviewees were asked questions about the clinical research environment in Qatar, strengths and weaknesses, barriers to successful implementation and proposed solutions.

Quantitative Study: A retrospective observational review of the QNRF funded grants to HMC was done for the second aim of the study. The information is available on the QNRF database that is accessible by the research office at HMC. Further investigation of the project specific folders was done to ensure that the right reasons for the suspension or termination were captured. The range of review included all studies awarded to HMC from the first cycle until the ninth cycle. The latter awarded cycles are relatively new and started as recent as last year hence there are no issues with any of them yet.

A separate data sheet was created with the number of awarded grants per cycle, number of suspensions per study and per cycle, terminations and reasons for the suspensions and terminations.

Ethical Considerations

Approvals were obtained from the relevant committees at Kingston University London and Hamad Medical Corporation since the study was being conducted in Qatar (See Appendix 5). All participants were presented with an information sheet along with the invitation email and consent form before starting the interview. The information sheet clearly described the goals of the study, assurance regarding confidentiality and that participation was voluntary giving them the option to withdraw at any point. They were also given the freedom of not answering any question that they were not comfortable with. However, none of the participants declined any question during the interview. A debrief sheet was also provided to each participant at the end of the interview (See Appendix 6).

The recordings and transcriptions were stored on the researcher's personal laptop in a password protected file that only the Researcher has access to. The transcriptions were anonymized by removing any reference to the name or place of work of the interviewee by replacing these identifiers with study specific codes once the final version of the transcription was verified (See Appendix 7). Only the anonymized transcriptions were stored for analysis.

The study was conducted in full conformance with principles of the "Declaration of Helsinki", Good Clinical Practice (GCP) and within the laws and regulations of MoPH in Qatar. The data that was shared with the Mentor at Kingston University London was in accordance with the UK Data Protection Act (2018).

Statistical Analysis

The study explored the different barriers to implementation of clinical research in Qatar. The data gathered from the participants' interviews was transcribed and then analyzed thematically using the following steps (Braun & Clarke, 2006):

1. Transcribe verbal interviews into verbatim transcripts.
2. Read through the transcripts to quality check them against the original verbal interviews.
3. Generate initial codes from the transcripts making sure to code for potential themes or patterns, remembering that individual data can be coded many times.
4. Search for themes in the initial coding, grouping codes together under broader themes. Some codes will become central themes, while others will be allocated to sub-themes or remain codes within a theme or sub-theme.
5. Review and refine themes to ensure that there is sufficient data to support them and if not seek to combine themes under an over-arching theme. Understand how each of the final themes links and work together with each other; understanding partnerships and causal relationships between them.
6. In case interview constitutes of data that does not come under the suggested themes we will build up new themes accordingly.
7. Define and refine the theme names by reviewing the data collated behind each theme name and where necessary adjust the name to accurately reflect the data.

For the quantitative part, descriptive statistics such as frequency and percentages for collected data were performed in the form of number of QNRF projects per year,

number of suspensions or terminations per project and per cycle and the reasons for these.

Results

Qualitative Study:

Five managers were interviewed for this part of the study. After transcribing the interviews (See Appendix 7), the thematic analysis model explained above was applied. Barriers from each interview were identified, listed, coded and grouped into sub themes and further condensed into four main themes. These themes included all the barriers identified in the interviews (See Table 1 for summary of these barriers according to themes and sub-themes).

Professional/ Scientific Barriers

There were mainly three categories or sub-themes under this theme that were grouped into one.

The first one was ***training*** that includes lack of proper training for clinical researchers and the administrative staff and its underlying issues. The second sub-theme was ***population*** – both researchers and research subjects – were transient and hence creating or retaining a critical mass of clinical researchers on the long term was not possible. The third sub-theme was the ***personal barriers for researchers*** like lack of protected time, clear assignment of roles and the ambivalent vision for research in the country.

Five out of six managers interviewed agreed that there was no protected time for clinicians and this was the main professional barrier. ***Lack of protected time*** had other implications that hindered self-development of clinicians as researchers:

"…the issue of lack of protected time for researchers because it is a real problem where the clinicians are expected to provide research output and spend time conducting research but at the same time expected not to compromise their clinical duties, which is of course their main duty as clinicians." (Manager 1)

"…there is a group of clinicians who are extremely busy and they are good at research and want to it but they don't have protected time." (Manager 2)

"…we are getting people who are more passionate about research itself but the problem with that is that they are clinically busy so they cannot really focus on doing research." (Manager 3)

"Physicians are very keen and interested in conducting research however there is no protected time for them to conduct research. Places like PHCC and HMC don't provide protected time to their physicians for doing research. Therefore, it does affect their ability to submit and work on these proposals." (Manager 4)

"The clinicians have so many beautiful ideas and they are sincere to make it happen but they do not have time and I cant blame them because their first job is the clinical service." (Manager 5)

The same majority also identified ***lack of research specific education and training*** as a barrier to conduct clinical research in Qatar. The reasons they mentioned were absence of sustainable training programs and induction training for the researchers when they join an institution in Qatar:

"There is a lot of education and training that needs to be done in terms of what clinical research looks like, how they are reported, SAEs, AEs, pathways that can be harmonized." (Manager 3)

"There has to be a very well-established training and education program to keep reminding a clinician about the ethics of research." (Manager 4)

"…most of the them are trained to be clinicians and not researchers. In the modern medical degrees, a lot of research component is included within the education and it's the approach in getting knowledge that gives them research experience. Such systems give the freedom of being creative in doing things in a new way not done by someone earlier because each one of us has their own unique way of thinking and applying. In the US, no matter where you come from, you need to complete a rigorous training before you start any research even when you move from one state to another. I wish we had something similar here in Qatar and if we have it now, I am not sure about its quality." (Manager 5)

Three managers also highlighted the issue of the importance of scientists and research support who would complement the role of clinicians in conducting clinical research studies. These resources are limited when it comes to clinical research support groups like coordinators, nurses and academic scientists:

"…from the point of quality of research being done, there is huge enthusiasm for research but I think we are yet to have a proper critical mass of really experienced researchers" (Manager 1)

"…So clinical research teams are not doctors who see patients but instead trained to do and support research while in HMC I don't think we provide that to our researchers… In my opinion I think the PI needs to spend more time doing the science than spending time on the operational part that is handled by other trained personnel like CROs. To be more efficient as an organization, we need to have our own core group of support that could be tapped into by different researchers." (Manager 2)

"Because the clinicians collaborate with scientists who take care of all the writing, designing and submissions and clinicians are only recruiting the subjects." (Manager 5)

One manager stated a very important problem that could be a deciding factor for clinical trials with long term follow up or longitudinal studies - transient population. Since Qatar is a country where expatriate population is very high, it becomes challenging to retain a recruited participant for a longer duration:

"…the population here is mostly transient and expatriate. It is therefore hard to have long term clinical trials because their jobs may not be secure to allow long term follow up." (Manager 3)

Managers also called for clear distinguishing between the roles of clinicians and clinician scientists based on their contracts and responsibilities:

"The biggest challenge here, and I believe it's not specific to HMC, is that the majority of the academic health systems find it difficult to distinguish between clinicians, clinical scientists and clinical research teams." (Manager 2)

"Everybody's job description must have outlined portion for clinical duties, research, teaching and administration. If this happens then research will become a part of their job and if it's their job then they will more likely do it better." (Manager 3)

Administrative Barriers

Processes, management and governance were the sub-themes identified here.

Processes includes operational and logistical issues like hiring, procurements,

maintenance and sustenance of resources. Lack of a focused strategic vision, leadership stability and communication were all grouped under ***management***. The third sub-theme, ***governance***, includes issues like data access and institutional framework.

The issues regarding ***processes and operational barriers*** at the institutional level like hiring and managing research were commonly discussed. In some cases, these procedures were described as repulsive while others said it added to the already existing problems:

"One of the issues is the mismatch between operational, capital and manpower expenses. What we see within AHS-MRC is the same what HMC experiences every year. We have a number of posts that are not occupied and hence we have programs and funds unutilized because of that. Last year we had developed a bid for a clinical trials unit and we were assigned a huge operational expense but then no posts were approved so we ended up handing back the operational expense which would imply that we didn't need it but the truth is that we needed the posts to use it." (Manager 1)

"The biggest challenge is the previously, and still, existing systems which are repulsive to conduct research at HMC. That translates into challenges in recruitment, procurement and career planning for researchers, recognition of research achievements – all these are not conducive to research at HMC." (Manager 2)

"These are all operational issues and if you have the right manager who ensures that all obstacles are removed, there will be progress. So, it's not about the funds you have but about how it is managed and how you have the right person in the right seat based on their qualifications and skills. In most cases here, there is a mismatch where we place the right person in the wrong seat." (Manager 6)

Lack of governance structure or their weak implementation was discussed by two managers. They had the view that strong governance system was either absent or misunderstood and hence not effectively implemented:

"Another important barrier is the research governance and by governance I don't mean the policies as such because the policies are very well drafted but then the personnel allocated to ensure proper implementation of these policies and guidelines is just not sufficient. We don't have enough hospital research officers or clinical monitors for having the site initiation visits or monitoring of ongoing research

projects. We need to be pro-active in avoiding compliance issues but the available research personnel only allow us to be reactive to a certain limit." (Manager 1)

"There is lack of understanding of the governance roles because the management depends on the feedback of the "violators" to review the performance of the governance officers." (Manager 6)

Three managers mentioned that one of the major barriers to design and implement clinical research in Qatar was the ***limited epidemiological data and the difficulty in accessing it***. The issue was not new, according to them, however limited steps were taken to address it:

"…we must seriously consider having a national research data registry that could provide real and reliable data to the researchers in Qatar and collaborators who wish to implement studies here. The problem currently is that we don't have reliable statistics about the patient population or the clinical burden of different diseases in Qatar and this is critical." (Manager 1)

"Initially, the system here was very conservative when it comes to data access because there was no Cerner available and any access for data needed many stages of approval. To go around this, the researchers used data from outside Qatar, which could sometimes be unreliable, to build their proposals and this is not right. Lack of epidemiological studies relevant to Qatar was a very big challenge. Even after we started having studies, there were issues with access to the data from these studies." (Manager 5)

"Not a single health institution in Qatar uses prescriptive analytics in healthcare which means that we are using basic analytics for the billions of dollars invested in the top-notch facilities. If we run those analytics and generate massive data, this would then cause experts from Harvard and MIT to come and work here because we would be sitting on a gold mine of research data." (Manager 6)

Absence of centralized leadership for research management and hence the absence of long-term strategic investments was also identified in a couple of interviews. Unclear KPIs and measures that would otherwise help in the strategic planning were also stated as a barrier:

"Qatar could do better than compared to other places because in places where there are regular elections, programs are encouraged for short terms but then the political system here is more stable and can plan for the long term." (Manager 1)

"I honestly believe there is a major gap in understanding our KPIs and how do we measure this return on investment" (Manager 6)

"Here we see a lot of redundant work but no focused areas... We have to define our trajectory, mission, vision to be fitting into the needs of the country. We have all of these things in paper but not in the reality." (Manager 6)

"The only thing missing for research across Qatar is proper management and oversight. I am referring to the overall cross-institutional strategic management of the research pot…The right question that I would like to answer is what does it take Qatar and my institution in particular to be an elite. I believe it's just the last mile – the leadership." (Manager 6)

Financial Barriers

Most issues identified in this theme were categorized under ***funding*** and ***infrastructure***.

Funding included both sides of the spectrum as some managers opined that the funding pot for research was not sufficient while others believed that research was generously funded but poorly managed. There were also concerns about the high costs of research related services and returns on the funds invested in research. There were other issues related to poor infrastructure like absence of core support facilities, lack of research space, and optimum utilization of the available physical resources.

All managers identified ***infrastructure*** as one of the barriers for clinical research but some referred to human infrastructure while others to space and other facilities:

"*Lack of personnel is again an issue if we are aiming to implement clinical trials because the available staff and expertise is good enough to support the clinical service but not research trials… We also have issues for research space to accommodate the different research trials happening across HMC."* (Manager 1)

"The footprint for research is small compared to the size of the organization. Another challenge is that the research space is scattered all over the organization in different buildings and facilities" (Manager 2)

"When we do a study at a clinic, the rooms change frequently and we can't have a stable environment to do it. Most countries have clinical research center geared up with nurses and it is done in a slick way." (Manager 3)

"Most of the hospitals such as HMC and Sidra are in the process of developing their infrastructure to build clinical research units however there are lots of barriers when it comes to budget, human capacity etc. so the progress in this area is very slow." (Manager 4)

Few managers listed ***funding or restrictions on use of current funding*** as a barrier. Three of them agreed that there was a gap in the reality and the expected outcomes based on the financial investment in research while another manager had concerns about the restrictions by the funding agencies on using the granted funds when it comes to re-allocation of costs, carry over etc.:

"There could be a 5-year plan to transform HMC into an academic health system with research at its core but this needs a lot of work that the higher management and senior clinicians fail to see this gap… One of the main issues that we face for funding in general is being underspent but then this has other reasons. For example, if we budget for a clinical trial but then the team is not able to recruit the required personnel due to the stringent procedures, the outcome is underspending but this does not reflect the true picture because the underspending was due to these barriers. The financial status in the country is now more stringent and hence any investment needs outcomes to justify it to the management." (Manager 1)

"…there is a gap in the expectation about what that fund could be translated into or what output could be produced through that investment… The expectation is high, the investment is significant however the means of meeting those expectations when it comes to having the right programs and right support services needed to implement to reach those outcomes are not properly in place." (Manager 2)

"We have a limited funding because when there is cap, you can't answer all the questions your research was exploring... Similarly, when there is a budget cutdown from the awarded grants by the funding agency, they can't do that for clinical research because it is not like basic science where you can adjust to budget revisions by doing less experiments." (Manager 3)

Two managers mentioned a couple of issues related to ***funding*** which could be specific to Qatar. One was the relatively high costs for carrying out animal experiments compared to costs for similar experiments outside Qatar while the other was about cost of recruiting qualified personnel for funded projects:

"if you are hiring a post-Doc, then you need to pay for their housing, education, leaves etc. in addition to their salary so a post-doc in the US might cost you 60,000 dollars but here it is around 200,000!" (Manager 3)

"Also, the cost is unusually high compared to the cost of performing the work outside and I am not sure about the reasons behind this." (Manager 5)

Any investment, including that on research, needs to have some outcomes to be reported against the invested funds. This matter was discussed by three managers who believed it is important to measure and report the return on these investments to show efficient spending of the allocated budgets:

"The other issue that we should be able to prove that we are effectively spending what we receive… we have to also be ready for a time where the higher management could change so we must have this data to convince anyone who would take over then." (Manager 1)

"However, when we look at the funders, they have to report somewhere higher about the outputs of this funding. Outputs can be publications, new IP and all that but science does not always produce these outputs, not right away at least." (Manager 3)

"When it comes to return on investments, we need to understand how much we are getting out of the generous spending. I honestly believe there is a major gap in understanding our KPIs and how do we measure this return on investment." (Manager 6)

Indirect Costs (IDC) associated with funded projects were discussed by two managers who believed that these costs required more assessment regarding its applicability to the system here and the best way of managing these costs:

"However, I don't see how this could be applied in the system in Qatar and hence there should be better ways to manage the IDC to be used more effectively." (Manager 1)

"the IDC until recently was being used for non-research purposes. It is very unfortunate that it was used for supporting other departments not involved in research but this is slowly changing now. The concept of "chopping off" funds for non-research purposes must be stopped and we must pursue better utilization of these funds into research purposes." (Manager 2)

Regulatory Barriers

Legal framework and ***Institutional Review Boards (IRBs)*** were the main sub-themes under regulatory barriers.

Managers expressed concerns about the lack of ***legal framework*** to support research in the country and most laws were either criminal or civil but no clear path as such for research related matters. The policies at the highest level also required refining as many policies were "imported" and did not cater the needs of the research environment in Qatar. Managers also seconded the negative feedback they receive from their researchers about inconsistency in the submission process for different IRBs at each institution and how each IRB had their own set of conditions, which were at times conflicting with conditions of a collaborator's IRB. Hence, ***regulatory barriers*** were identified at the national and institutional level.

For the ***legal framework***, two managers discussed that it required extensive work to be conducive for the clinical research, although it was developed recently. There were concerns that the adopted framework was not totally suitable for the clinical research environment in Qatar:

"Again, this takes us back to the American system being replicated here but unlike here, they have many startups or sponsors for research projects and researchers are actively holding shares or promoting these companies." (Manager 3)

"There is not much maturity in the legal system for research. As of today, I don't see any legal framework for research. We reviewed a draft a couple of years back but I am not sure if it was implemented but then it is important before we release millions of dollars that we have a legal background to support it. We started building this when we are almost ten years into awarding funds and that too was partially built on a trial and error basis by looking at the US system if it's doable in Qatar to apply the same." (Manager 5)

When it comes to ***IRBs***, four managers were adamant that the processes for IRB review and approval must be regulated and unified to avoid duplication, reduce burden and save time for actual research activities:

"One of the things that frustrate researchers in Qatar is that they have to apply to multiple IRBs if they want to have a collaborative research. One of the things I am proposing to the working groups is that we develop a reliance agreement for the whole country where then one IRB approval would cover all institutions." (Manager 1)

"It is very challenging as every institution has their own guidelines, rules, paperwork, way of doing things and pathways for reporting." (Manager 3)

"I see some of the research institutions are placing a lot of barriers under the name of regulations and I really believe that IRB committees decisions and review process should be in place for two main purposes. First, for human subject's protection and the second to help the PI's by reducing the burden of regulations." (Manager 4)

"That created a lot of challenges to the investigators because after going through long phases of review and evaluation, most of them face difficulties with the IRB approvals." (Manager 5)

There were also regulatory issues specific to Qatar that were described by one of the managers regarding the ***legal system for criminal liability*** and the regulatory systems for clinical trial drug imports:

"Another major barrier for undertaking clinical research in Qatar is the current legal setup where any person, if potentially harmed in a research study, can take criminal action against the study PI. This means that the PI would be immediately imprisoned until the investigation is completed and heavily fined if actually charged." (Manager 1)

"There are no clear regulations from the higher authorities about the import of these drugs for research purpose and basically the decision for import is taken on an ad-hoc basis." (Manager 1)

Table 1: Summary of the research barriers including themes and sub-themes according to managerials interviews.

	Barriers: Themes	Barriers: Sub-themes	Examples
1	**Professional/ Scientific**	Training	• Research specific training • Monitoring
		Population	• Absence of critical mass of researcers • Central support cores • Transient population • Retention of trained personnel
		Personal barriers for researchers	• Clear pathways for clinician scientist • Protected time • Distinguish between roles • Recognition
2	**Administrative**	Processes	• Administrative setbacks • Endless requirements • Too many steps involved causing delays
		Management	• Lack of a focused strategic vision • Leadership stability • Communication
		Governance	• Data access obstacles • Lack of institutional policies

			• Inconsistency
3	**Financial Barriers**	Funding	• Overspending and underspending • High cost compared to other systems
		Infrastructure	• Core support facilities • Lack of research space • Optimum utilization of the available physical resources.
4	**Regulatory Barriers**	Legal framework	• Most laws are either criminal or civil • Imported policies not suitable for Qatar
		Institutional Review Boards (IRBs)	• Inconsistency in requirements • Too many IRBs given the limited number of institutions

Quantitative Study:

Eighty-one proposals were awarded to HMC by QNRF from cycles 1 to 9 during the years 2007 until 2016 as the main awardee (Table 2), out of which 45 proposals (55.6%) are already completed and 26 proposals (32.1%) are still active. Out of the total, 26 (32.1%) projects were awarded directly to Lead PIs from HMC whereas the remaining projects had HMC PI as the Co-Lead PI. In all cases the main awardee is always HMC, however only the LPI has the access to submit progress reports to QNRF.

Suspensions: The awarded projects received a total of 53 suspensions (including repeated suspensions for the same projects) with some projects being suspended for up to 4 times during their lifetime. The number of terminated projects for the same duration was nine (11%). On the other hand, there were 40 (48.7%) studies without any suspensions or terminations out of which 15 (37.5%) are still ongoing while the remaining 25 studies (62.5%) are successfully completed and closed.

The most frequent reasons for suspensions were non-renewal of ethical approval (N: 23; 43.3%) followed by delay in submission of the progress reports to QNRF which occurred 16 times out of the total 53 times.

Table 2: Awarded proposals per cycle

QNRF cycle	No of projects
NPRP 01	5 (6.20%)
NPRP 02	3 (3.70%)
NPRP 03	8 (9.90%)
NPRP 04	14 (17.30%)
NPRP 05	15 (18.50%)
NPRP 06	10 (12.30%)
NPRP 07	19 (23.50%)
NPRP 08	4 (3.70%)
NPRP 09	4 (4.90%)
Total	**81 (100%)**

Other reasons included slow research project progress (4/53: 7.5%), deviation from the research protocol (2/53: 3.8%), transfer to HMC (2/53: 3.8), departure of LPI and change of LPI (3/53: 5.7%); LPI not reachable (1/53: 1.9%), administrative issues (2/53: 3.8%). There was also a mix of multiple reasons for suspensions as listed in table 3. Tabe 3 also identify whether the LPI was from inside Qatar or outside Qatar in each suspended project. When the reason of termination included a reason related to ethical issues, the LPI is most probably from inside Qatar, while when it is related to reporting delays and progress of the project the LPI is mostly from outside Qatar (Table 3).

Table 3: Reasons for suspensions

Reasons of suspensions	Number	%	LPI Inside Qatar	LPI Outside Qatar
No suspension	46	56.8	20 (43.5%)	26 (56.5%)
Delay in progress report submission	5	6.2	1 (20%)	4 (80%)
Change of LPI affiliation	1	1.2	0	1 (100%)
Slow progress	1	1.2	0 (0%)	1 (100%)
Expiry of ethical approval	15	18.5	1 (100%)	0 (0%)
Deviation in the study	1	1.2	0 (0%)	1 (100%)
Ethical concerns	1	1.2	1 (100%)	0 (0%)
Transfer to HMC	2	2.5	0 (0%)	2 (100%)
Multiple reasons (Ethical expiry and Slow progress)	1	1.2	0 (0%)	1 (100%)
Multiple reasons (Delay in report submission and expiry of ethical approval)	4	4.9	0 (0%)	4 (100%)
Multiple reasons (Ethical concerns and change in PI)	1	1.2	1 (100%)	0 (0%)
Multiple reasons (delay in report, ethical expiry and administration issues)	2	2.5	1 (50%)	1 (50%)
Multiple reasons (ethical expiry and departure of LPI)	1	1.2	1 (100%)	0 (0%)
Total	**81**	**100.0**		

Suspensions are sometimes repeated for the same project in the same cycle as illustrated in figure 1.

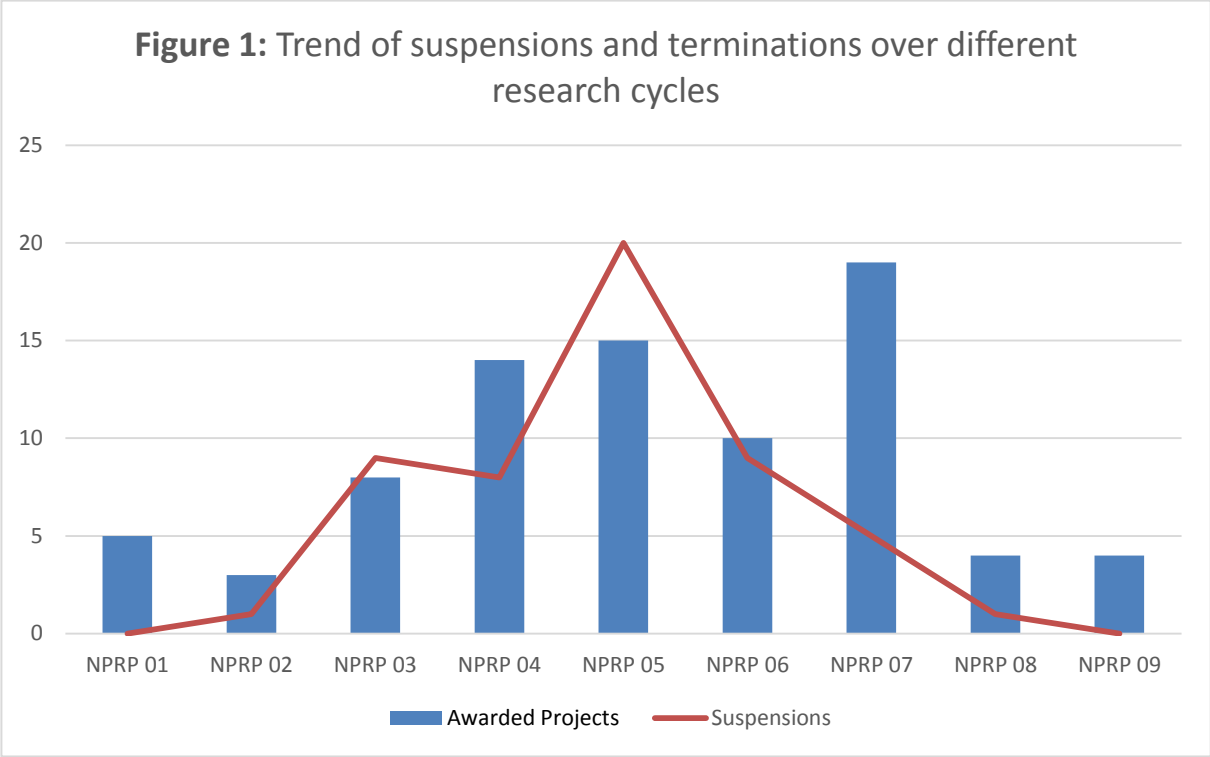

Figure 1: Trend of suspensions and terminations over different research cycles

Terminations: Nine projects out of the 81 were terminated (11.11%) for different reasons including disagreement between the PIs (N: 3; 33.3%), departure of LPI (old or second (N: 2; 22.2%) and other administrative issues (ethics, progress of the project or suspension requirements not addressed) (N: 4; 44.4%) (Table 4). Table 4 also identifies whether the LPI was from inside Qatar or outside Qatar in each terminated project. When the reason of termination was related to administrative issues the LPI is most probably from inside Qatar while when it is related to disagreement between PIs or the content of the project it is amongst LPIs outside Qatar.

Table 4: Reasons for terminations

Reasons for termination	Number	%	LPI Inside Qatar	LPI Outside Qatar
Disagreement between PIs	3	33.3	0 (0%)	3 (100%)
Departure of 2nd LPI without handover	1	11.1	1 (100%)	0 (0%)
Departure of old LPI	1	11.1	1 (100%)	0 (0%)
Ethical concerns	1	11.1	1 (100%)	0 (0%)
Administrative barriers	1	11.1	1 (100%)	0 (0%)
Slow progress	1	11.1	0 (0%)	1 (100%)
Suspension requirements not addressed	1	11.1	0 (0%)	1 (100%)
Total	**9**	**100.0**		

Discussion

This study investigated research barriers in Qatar using two methods, qualitative through interviews with research managers and quantitative by looking into existing research grants and investigating reasons for terminations and suspensions. Firstly, we will discuss these barriers from a managerial perspective and then from existing grants.

Research barriers in Qatar from a managerial perspective:

There were a number of barriers identified in the interviews, however many of them were not surprising as they are more or less similar to the barrier themes reported by researchers in other studies (Duley et al., 2008; Dilts & Sandler, 2006; Ehtesham et al., 2017; Ataee et al., 2015) but sometimes different in the actual content and suggested solutions. On mapping, they are condensed into 4 major categories or themes (Figure 2):

Figure 2: Thematic presentation of identified barriers

There were two major barriers that were common in all interviews – ***protected time and infrastructure***. The research setup at HMC is unique wherein clinicians are contracted for clinical service and that is what their service contracts mainly focus on, however since the hospital's focus for academic transformation; research is being considered for their promotions, annual appraisals, and budget requirements and so on. Even with all these efforts, not much has been done for securing protected time for clinicians interested in research. Almost all clinicians are undertaking research apart from their actual clinical duties, administrative and teaching duties. This poses the main barrier for conducting clinical research because it requires a lot of time and effort before, during and after execution of the research study. Lack of proper allocated time also affects the quality of the research because high quality research requires quality time for planning and implementing. However, managers have assured that this is being addressed at the highest levels to make it happen in the best possible way that would ensure continuity of the clinical service and allowing clinicians to undertake research for improving the quality of care provided to their patients.

Infrastructure is another major barrier that was commonly identified by all managers, however each interpreted in a different way. Research space for clinical research appeared to be an immediate requirement since most studies suffered setbacks because of space. Issues related to appropriate rooms for consenting, equipment, research clinics and offices could all be traced to lack of appropriate space – mainly in the hospitals where the research occurs. There seemed to be a consensus among all managers in this regard as they received feedback from

researchers at their institutions about this issue quite a few times. Lack of space is also an issue when equipment is procured through research grants because although funding is available, there is no space to accommodate this equipment within the facility or they run into administrative barriers which are inter-related with the infrastructure issues. Another infrastructure that appears to be limited is human, in the form of clinical research support groups. Such groups include clinical research coordinators, research nurses, scientists, biostatisticians and technical writers. Research institutions usually invest in one or more core groups for research support which are utilized across more than one department within the organization. The funding is generated through the grants to sustain these core group while the institution also taps in some of the resources as and when required. These groups are missing in the research institution in Qatar. All research related tasks are carried by the same individuals who are also covering the clinical service and hence the quality of the research is compromised as the teams cannot work to their full potential in this case. One manager had a view that a modest investment in these groups would have a direct impact on the quality of the research and the expected outcomes from the ongoing research projects. Another issue that could be linked to infrastructure as well are the high cost for research compared to other systems around the world. The managers said this could be due to the fact that the research culture was still developing and any project included costs for other "indirect expenses" like for example when you hire a post-doctoral scholar, all his utility bills, rents etc. are inclusive in the budgeted salary which increases the salary to a very high rate. Other developed countries provide discounted residence for such temporary staff at a reduced rate and hence the salary is decreased significantly. The cost of living in the country is undoubtfully high too. The recent

political embargo that the country is facing by the neighboring countries since June 2017 has also had its effect on research expenses as now the materials, equipment and even travel has to be re-routed through other countries which adds to the actual cost significantly (BBC, 2019).

The other barrier reported frequently in most interviews was the ***research mentoring and training***. HMC clinician researchers were mostly educated and trained to be clinicians and not clinician scientists or clinical researchers. This could be attributed to the fact that good number of medical schools still follow the traditional teaching methods where you are taught to apply what you learn unlike the modern schools that depend mostly on research methods for teaching which build up the creativity and give them indirect training for clinical research after graduation. Hence most of the clinician researchers we have are self-motivated and self-educated when it comes to research. Again, since there is no protected time, there is only a certain level up to which they can get involved and apply what they learn. There are no identified pathways for identifying young clinicians with research enthusiasm and mentor them all the way from their early career until they are established researchers. Again, this does not require huge investment but only proper leadership that channels their enthusiasm into professional multidisciplinary career where they can excel as clinicians and researchers. However, these clinician scientists would also require protected time, startup funds and facilities to accommodate their research. Because of the transient nature of the country's workforce, including clinicians, there are many senior clinician scientists who are hired at institutions in Qatar but they are not providing any mentoring or training to develop the local research community and eventually everything halts once they

leave the country and there is no human legacy to carry forward what they started. Hence it would be ideal to have compulsory training tasks assigned to the senior researchers to nurture local research scientists and share their experience to help develop a critical mass of clinician scientists in Qatar.

Inconsistencies in IRB processes at different institutions and ***absence of a legal framework for research*** were also identified by most managers. The legal framework includes policies and procedures that govern research, outcomes, Intellectual Properties, import of clinical trial drugs or devices and financial indemnity. One of the major issues related to legal framework was that there was no law governing clinical research in Qatar as of now, though many drafts were reviewed by institutions over different time periods, but none came into existence. The current draft was not very positive either, according to one of the managers. If applied, the law would mean that any research participant claiming to be harmed in a research project, would then be able to complain against the LPI under the criminal law which means immediate imprisonment of the PI until all investigations are completed to prove or deny any misconduct. The application of such a law would put an end to the clinical research in Qatar because the researchers would feel unsecure about anything that could go wrong because it might ruin their career, even if they proved innocent eventually. Researchers had also relayed their frustrations to the managers about the difficulty in obtaining IRB approvals for clinical research because of the inconsistencies in the requirements and processes at each institution and hence having collaborative projects was becoming challenging rather than encouraging with the current systems.

One of the interesting findings in this study was that few managers felt that there was a “gap” in the expected outcomes from the current investment and the current reality. They said that although the investment is significant, ***the absence of conducive systems at all levels*** was a main barrier to achieve what the State (government) and the community expected. They also said that the timelines were unrealistic too compared to the effort required to build these systems and start working through them.

However, the managers did confirm that this “gap” and all other barriers identified in their interviews was not something unheard of and the higher officials were aware of the issues since these were discussed in many of the high-level meetings that they attend. There were solutions being implemented to address all these barriers in an effective and strategic manner.

Research barriers in Qatar from existing grants (observational retrospective study):

Discussing the quantitative study, HMC has received a large number of grants through QNRF’s flagship funding program – the NPRP. However, the management of these proposals apparently was not very easy and went through many hiccups. The number of suspensions is relatively high compared to the number of awarded grants at the average of 0.65 per proposal which hints that proposals are more likely to face a suspension during their lifetime for one reason or the other. The number of proposals in the endangered zone is slightly higher than the ones in the safe zone but not a significant difference. It goes without saying that a research office for a reputed institution like HMC must maintain a far better record than the

current to reflect a better image to other stakeholders and the funding agency as well.

A closer look into the numbers reveals a trend of suspensions and terminations over different cycles as illustrated in figure 1. The number of suspensions started increasing in cycle 3 and peaked at cycle 5 where it exceeds the number of awarded projects. This means that the same proposal would receive multiple suspensions.

However, coming to the reasons behind the increase in suspensions, this was a transition stage for QNRF as a funding agency and HMC as a research office. As for QNRF, they gained further experience from the first 3 cycles and hence decided to transform the way grants are managed by launching their online grant management system – Qgrants. Until then, all progress reports and other requirements were communicated through emails and even hard copies sent to QNRF offices. With the launch of the system, there was a confusion about the tracking of the reports as some LPIs continued sending offline reports and denying to accept the fact that submissions were online now. As such, QNRF would not hesitate to issue suspensions for any project with a delayed report. The system is electronically timed and hence any report that misses the deadline raises a red flag at the award administration team and they would prompt a suspension notice immediately. However, the system was not much user friendly at all times and had its own cons that QNRF would consistently work on improving them. As for the transition at HMC research office, there were many changes in the research office personnel and turnovers that would often make it difficult to keep track of the grants

progress. The focal point of contact, AROR, had changed around 3 times in these 3 years without a proper handover to the successor. Absence of an electronic monitoring tool at the research office added up to these problems as manual tracking for bulk of these projects in a timely manner was challenging for a single person to handle.

Results also showed that the most frequent reasons for suspension were non-renewal or delayed renewal of ethics approval and delays in progress report submission. As for the delays in progress reports, part of the problem has been explained in the above paragraph. The other main factor that contributed to these delays was the Lead PIs that were external to HMC and Qatar. To enable RCB in Qatar through collaborations with established researchers abroad, QNRF allowed Lead PIs from outside Qatar to submit proposals to obtain funding through its programs, however there was a condition to have a Co-Lead PI from an institution within Qatar. The problem was that the access to progress reports and other communications was solely granted to the Lead PI without any role for the Co-Lead PI in the process. Hence in case of delays or approaching deadlines, it would become extremely difficult to reach out to the external Lead PIs as the only method would be emails. This was not very effective as the research office would be under the risk of suspension or even losing the grant if the Lead PI would not be reachable in this case. Many of these suspensions would have been avoided should the Co-Lead PI would have access to the same channel as contacting the local PI is much easier and effective. The issue was raised with QNRF in many meetings until they finally changed their rules to prohibit any Lead PI from outside Qatar to submit a project under their name. However, they were still allowed to

collaborate with Lead PIs submitting from the institutions based in Qatar. Unfortunately these changes were applied only from cycle 9 onwards, however a quick look at Figure 1 shows zero suspensions in that cycle where the projects are already in their final year. On the other hand, looking at other reasons for suspensions, we can see that there are no differences between LPIs inside or outside Qatar especially when the reasons are related to institutional issues such as ethical approvals.

Coming to the ethics approval, we have to start first by highlighting the fact that research – or clinical research specifically – is a relatively new concept in Qatar and the region compared to advanced research systems in Asia, Europe and the Americas. Hence the clinical research governance has been through transformations to find the ideal framework for the Qatari research system. However, everything comes with a cost and hence the cost of these transformations was changes in the IRB review and administration system in more than one institution across Qatar. The Ministry of Public Health guidelines for clinical research were also published not long ago. At HMC, the ethics committee was a small committee that would meet on a weekly basis and decide on the proposals being submitted by HMC researchers. Since the funding was very restricted, the volume and the nature of submitted studies would be at that level too hence the need for sub-specialty reviews or external opinion was very rare. However, with the changes in the research policies and the increased funds for research, the need for an advanced ethics review became evident. Hence HMC decided to partner up with Weill Cornell Medicine Qatar (WCMQ) to establish a joint ethics board where HMC would benefit from WCMQ's expertise and vice versa.

The joint ethics board was administratively managed by representatives from both institutions. The committee did start off well but unfortunately could not keep up with the load of proposals being submitted for review. At one point, the waiting time for an initial review of a proposal by the committee reached to more than 3 months. There were also other issues with the electronic submission system used for the ethics review and the majority of the researchers in both institutions were not happy about it. Hence these delays are reflected in the number of suspensions as some studies would be pending review at the committee and the PI being helpless about it. Eventually the joint ethics board was dismantled and a new Institutional Review Board (IRB) was set up for HMC alone. This was a relief for researchers at HMC but again came at its own cost because the new IRB decided to suspend all studies until these were resubmitted per the new guidelines for review and approval. This added up further to the suspensions received at that time period. However this issue is now resolved and the improvement can be noticed from cycle 7 onward.

Terminations were not very frequent for HMC grants. Only nine grants were terminated and looking further into the reasons for termination, there was nothing unusual. In most cases, termination was invoked due to departure of the LPI from the awardee institution. QNRF rules allow handover of the project to qualified researchers within the same institution, however where the original Lead PI decides to leave the institution due to disputes with the administration, unfortunately they use the grant as a “revenge” and decide not to sign on the handover documents. QNRF requires that the handover must be signed by the original Lead PI. Eventually the grant is terminated. There was also one incident where there was a

disagreement between the Lead PI and the Co-Lead PI and HMC had to initiate the termination in this case.

If we compare the outcomes of the qualitative and quantitative studies, the issues identified in the quantitative fit within the themes of the barriers. For example, lack of appropriate management systems falls under administrative barriers, shortage in personnel under financial barriers and absence of IRB approvals is due to the complications in the IRB systems which is a regulatory barrier. Even for cases where terminations were due to non-response or disagreement between PIs, it falls under professional barriers because if the researcher was aware of his roles and responsibilities as a Lead PI, they would adopt a constructive approach to resolve matters rather than choosing the hard way that has negative consequences.

Future Implications:

The topic of this study is of great interest at a time where no previous study has explored these barriers, especially in the state of Qatar. The outcomes of this study will be disseminated through publication and relevant conferences and symposiums. The results will also be communicated separately to the higher authorities involved in decision making for research related matters. The results of the study will help policy makers and research authorities and institutions to look into solutions to overcome these barriers. The study has clarified the overall research barriers as well as specific ones (through themes and sub-themes, see table 1) and thus will help policy makers and research institutions to rectify these barriers by looking at specific examples and real world data results directly from research managers who mostly have clinical and administrative experience.

Nevertheless, one of the most important outcomes of this study is that it will lay a strong foundation for the next phase of the study that involves exploring the barriers from the researchers' perspective and analyse these perspectives for any gaps to be addressed or efforts to be streamlined for both – researchers and managers. The policy makers will then have a full picture about the research ecosystem in Qatar.

Conclusion

This research study had several positive outcomes. We were successful in identifying the barriers to implementation of clinical research. Categorizing these barriers into the themes described in the results and discussion section will help to focus on those areas to tackle these barriers and streamline the processes at all levels. The study also identified other barriers that are unique to the Qatari research environment. The outcomes could be generalized to clinical research setting in other counterparts in the Arab world where the research environment is more or less the same as Qatar.

To the best of our knowledge, this study is the first in the world that addresses the managerial perspective of the barriers to conduct of clinical research. It also paves the way for future research in this field. The results will be communicated to the policy makers in the Qatari Research Leadership to provide them with real-time feedback of the current situation thereby helping them direct their efforts to prioritize tackling these issues in an efficient manner. It is evident from the interviews that the leadership is already aware of these barriers and massive efforts are being directed towards addressing these issues at the highest level.

Limitation

One of the limitations of the study is that it focuses on the research managers and executives perspectives' only, hence the generated data is limited but of high quality. However, we also included data from existing grants where we looked at ongoing research from different perspectives. Also, the current study lays a strong foundation for pursuing further research that could include the researchers in the clinical research environment in Qatar.

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Appendices

Appendix 1: Participant Information Sheet

Appendix 2: Participant Informed Consent Form

Appendix 3: Participant Invitation Email

Appendix 4: Semi structured interview guide

Appendix 5: Ethics Approval

Appendix 6: Participant Debriefing Form

Appendix 7: Transcriptions of the interviews

Appendix 1

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مؤسسة حمد الطبية
Hamad Medical Corporation
HEALTH · EDUCATION · RESEARCH صحة · تعليم · بحوث

PARTICIPANT INFORMATION SHEET

Dear Participant,

You are invited to participate in Project title:

"Barriers to Implementation of Clinical Research in Qatar: A Managerial Perspective"

Name of Principal Investigator: Saad Al Tamimi, Hamad Medical Corporation

This research study is being conducted among the research managers in Qatar to identify the barriers to implementing clinical research in Qatar from the research managers' perspective. Clinical research is generously funded however it is important to know if the current systems are supportive enough for these funds to be utilized in an optimum manner. The study will include research managers of the key stakeholders in the clinical research community in State of Qatar.

The research has received a favourable ethical opinion from the Research Ethics Committee of the Faculty of Business and Social Sciences at Kingston University London. The study has also been approved by the IRB at HMC.

You are invited to take part in a face to face interview. The interview will be audio-recorded for transcription purpose. You will be asked questions about the clinical research environment in Qatar, strengths and weaknesses, barriers to successful implementation and proposed solutions.

Your participation in this research is completely voluntary. You can stop the interview at any time or choose not to answer any question.

The interview is expected to take 30-45 minutes of your time and no further interaction will be required after the interview.

There are no direct benefits to you by taking part in the research. However, I believe that your experience with the research environment in Qatar will be of great value to this research study. Identifying and categorizing these barriers will help to focus efforts on those areas and streamline the processes at all levels. The study might also identify other barriers that are unique to the Qatari research environment.

There is no risk to participate in this study. The interviews will be confidential, and the transcriptions will be anonymized. The audio-recordings will be destroyed once the transcription is completed and verified.

You have the right of knowing the results of this study at the end of it.

If you have questions or concerns, or if you think the research has hurt you, talk to the research team: Saad Al Tamimi, Tel: 55909086 and sabdullah5@hamad.qa or Prof Muthanna Samara at M.Samara@kingston.ac.uk

If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team, please contact:

- HMC research office at Tel: 44392440 or research@hamad.qa

If you wish to complain about any aspect of how you have been treated in this research, please contact Professor Jill Schofield who is the Dean of the Faculty of Business and Social Sciences at Kingston University London. Professor Schofield's contact details are as follows:
Dean's Office, Faculty of Business and Social Sciences
Kingston University London, Penrhyn Road, Kingston upon Thames KT1 2EE.
Email: j.schofield@kingston.ac.uk
Tel: 020 8417 9000 ext. 65229'.

Appendix 2

Informed Consent for "*Barriers to Implementation of Clinical Research in Qatar: A Managerial Perspective***"**

Please tick the appropriate boxes	**Yes**	**No**

1. Taking part in the study

I have read and understood the study information dated **[**30/Jan/2019**]**, or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐	☐
I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	☐	☐
I understand that taking part in the study involves a face to face interview about the clinical research environment in Qatar that will be audio-recorded for transcription purpose. The recording will be destroyed once the transcription is completed and verified.	☐	☐

2. Use of the information in the study

I understand that information I provide will be used for the thesis of the PI's degree and could be published later however the publication will not include any identifiers or information that could disclose my identity.	☐	☐
I understand that personal information collected about me that can identify me, such as my name or where I live, will not be shared beyond the study team.	☐	☐
I agree that my information can be quoted in research outputs.	☐	☐

3. Signatures

_____	_____	_____
Name of participant [IN CAPITALS]	Signature	Date

I have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

_____	_____	_____
Name of researcher [IN CAPITALS]	Signature	Date

4. Study contact details for further information

- Saad Al Tamimi, Tel: 55909086 and sabdullah5@hamad.qa
- Prof Muthanna Samara at M.Samara@kingston.ac.uk

Appendix 3

Invitation Email

Dear Participant,

I am a Master's student at Kingston University London and I am conducting a research study titled *"Barriers to Implementation of Clinical Research in Qatar: A Managerial Perspective"*. The study will include research managers of the key stakeholders in the clinical research community in the State of Qatar.

As part of this study, I am seeking to conduct interviews with research managers and executives in the clinical research community in Qatar. I am approaching you because of your experience as a research manager/ executive for past years in funding/ managing clinical research in Qatar. This research study has received a favorable ethical opinion from the Ethics Committee of the Faculty of Business and Social Sciences at Kingston University London and Medical Research Center - HMC.

Together with your help I hope to gather insights into how these barriers could be identified and tackled. Your experience and understanding of these issues would make an invaluable contribution.

You will be asked questions about the clinical research environment in Qatar, strengths and weaknesses, barriers to successful implementation and proposed solutions.
The individual interviews will take place in person and are expected to take approximately 30-45 minutes. Please read the attached Participant Information Sheet and let me know if you are willing to participate by replying to this email.

In case you agree to participate in this study, please provide a suitable time and location for this interview at your convenience.

Please let me know if you have any further queries about this research study. I will be glad to address any concerns in this regard.

I look forward to receiving your positive response.

Regards

Saad

Appendix 4

Semi structured interview guide

1) Educational background:

   a. Clinical

   b. Administrative

   c. Both

2) Age:

   a. 40-50

   b. 50-60

   c. Above 60

3) Could you tell me about your role as a _____?

4) What is your experience with clinical research/ management?

   a. How many years?

   b. What aspects?

5) How would you describe the support provided by the State of Qatar for clinical research?

6) What about the support within your institution and its contribution in this regard? (programs, protected time, training)

7) Do you believe that the funding allocated for clinical research is being used effectively? How is this captured/ monitored?

8) Does your institution provide dedicated facilities for research? (labs, offices, storage)

9) What do you think motivates or demotivates researchers within your institution?

10) How would you describe the overall attitude of the clinical researchers within your organization?

11) How frequent are research related issues discussed or policies revised within your institution?

12) Do you think that there are any barriers specific to your organization?

   a. For each barrier mentioned can you explain whether there are any steps taken to try and solve it?

   b. If yes, what are the steps?

      i. Was it successful?

      ii. If not, why?

c. If no, why?

13) Do you think that there are any barriers specific to the State of Qatar only?

14) Are there any other barriers that we didn't discuss in this interview that you would like to add?

15) What is in your view would be the solution to overcome these barriers?

a. Barrier 1:

b. Barrier 2:

c. Barrier 3:

d. Barrier 4:

e. Barrier 5:

f. Barrier 6:

g. Barrier 7:

h. Barrier 8:

i. Barrier 9:

j. Barrier 10:

Appendix 5

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19 February 2019

Mr Saad Mohammed Abdullah Shahbal
MSc Student
Department of Psychology
School of Psychology, Criminology and Sociology
Faculty of Business and Social Sciences
Kingston University

Dear Saad

Barriers to Implementation of Clinical Research in Qatar: A Managerial Perspective

To confirm that you ethics application 1819CHA1 entitled: 'Barriers to Implementation of Clinical Research in Qatar: A Managerial Perspective' received a favourable opinion from the Deputy Chair on behalf of the Faculty of Business and Social Sciences Research Ethics Committee on 14 February 2019.

Yours sincerely

Emma Finch
Research Operations Manager
Clerk of the Faculty Research Ethics Committee
Faculty of Business and Social Sciences
Kingston University

Appendix 6

Barriers to Implementation of Clinical Research in Qatar: A Managerial Perspective

Participant Debrief Sheet

Thank you for participating in the face to face interview. The information you provided is very valuable for the purpose of our research and we are grateful for your contribution. We hope that you have found it interesting and have not been upset by any of the topics discussed.

However, if you have found any part of this experience to be distressing and you wish to speak to one of the researchers, please contact:

- Saad Al Tamimi, Tel: 55909086 and sabdullah5@hamad.qa
- Prof Muthanna Samara at M.Samara@kingston.ac.uk

If you have questions about your rights as a volunteer, or you want to talk to someone outside the research team, please contact:

- HMC research office at Tel 44392440 or email: research@hamad.qa

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Appendix 7

Manager 1

**** The interviewee is welcomed to the interview and briefed about the study ****

Educational Background: Both

Age: Above 60

Saad:
Could you please tell me about your role as an Institutional Research officer at your institution?

Manager 1:
My role has a number of components. As Institutional Research officer, I am responsible for research governance across my institution. In practical terms, it means I have the executive responsibility of the Medical Research Center (MRC) and its activities. The second half of my role is the Executive role at the Academic Health System (AHS) and program development. We are bringing partners across Qatar into a unified academic health system.

Saad:
Could you elaborate more on your experience in management of research?

Manager 1:
I have been a clinical scientist myself. I began research in 1987 and finished my high degree in 1991. Since then I have been a clinician scientist. I have been Prof of Medicine and held 2 chairs through British Health Foundation. The chair position comes with acute administrative responsibilities. I was also the Dean of Medical School. These roles had activities related to research administration and governance.

Saad:
You have been in Qatar for almost 9 months now so how would you describe the support for clinical research in Qatar?

Manager 1:
It is indeed an evolving culture and there is huge encouragement for research. Through the funding available by the MRC, support is being provided through grants, training and infrastructure. The state is also providing funding indirectly through other channels and some oversight through the Ministry.

There are issues in terms of doing clinical research that we have to overcome before we are a mature research system. The first is, from the point of quality of research being done, there is huge enthusiasm for research but I think we are yet to have a proper critical mass of really experienced researchers. That is important if we want to achieve good quality research. Part of this is achieved by bringing together parties across Qatar so we can

strengthen basic science input to increase the level of clinical interaction. The issue here is not only the creation of this mass of researchers but also planning for the legacy that benefits our institution. It wouldn't be effective again if we bring in researchers from abroad who would then initiate and publish research and then everything is over the moment they leave our institution. Hence, we should ensure that the local talent is built within this culture through training and mentoring such that the process continues all along. There should also be a clear pathway for identifying the young clinicians with interest in research such that they are guided from their final stages of medical school and mentored and trained as researchers and when they return here, they are given appropriate time allocation for research and clinical commitments. They must also be given proper access to the research facilities across Qatar. This also brings us to the issue of lack of protected time for researchers because it is a real problem where the clinicians are expected to provide research output and spend time conducting research but at the same time expected not to compromise their clinical duties, which is of course their main duty as clinicians here.

I have suggested to the higher management that we must seriously consider having a national research data registry that could provide real and reliable data to the researchers in Qatar and collaborators who wish to implement studies here. The problem currently is that we don't have reliable statistics about the patient population or the clinical burden of different diseases in Qatar and this is critical. The task is huge but if we are allowed to use the budget we have for the current year, I believe this is doable and if done as planned, it will be like a national treasure for researchers and Ministry for planning.

Another important barrier is the research governance and by governance I don't mean the policies as such because the policies are very well drafted but then the personnel allocated to ensure proper implementation of these policies and guidelines is just not sufficient. We don't have enough hospital research officers or clinical monitors for having the site initiation visits or monitoring of ongoing research projects. We need to be pro-active in avoiding compliance issues but the available research personnel only allow us to be reactive to a certain limit.

Lack of personnel is again an issue if we are aiming to implement clinical trials because the available staff and expertise is good enough to support the clinical service but not research trials. We need trained research support staff like nurses, technicians, trial coordinators etc. to support clinical trials. I believe that we are one step far away from this and all we need is a modest investment to increase our human capital and we can overcome these issues.

We also have issues for research space to accommodate the different research trials happening across our institution. The Translational Research Institute (TRI) would solve all these space issues but that won't happen until the next 5 years or so. In the meantime, we requested extra floors in the Medical City and expecting to receive this space soon.

There are barriers in the regulatory system for trials involving new drugs and devices. This sometimes delays import or is discouraging for sponsors to implement trials in this setting.

Personally, I don't think that the load of the trials we receive is large enough to call for revising the regulations but instead I suggested that we use the support from external bodies like Medicine Health and Research Agency (MHRA) at the UK. The MHRA would then be responsible to train the relevant personnel at Qatar and also review the import requests that we receive and provide approvals accordingly. This would be more feasible cost and effort-wise.
Financial indemnity for research is another barrier that I believe has to be highlighted here. So far, this wasn't seen a priority in the research setting here but since the insurance scheme is going to be applied soon, this barrier has to be looked into seriously. Research costs cannot be factored into the service costs. There are no clear-cut policies in the costing as well as we notice that the judgement is based on personal relations or individual relations rather than dependent on policies that would apply equally to all research studies. Hence there is an immediate need for it.
Another major barrier for undertaking clinical research in Qatar is the current legal setup where any person, if potentially harmed in a research study, can take criminal action against the study PI. This means that the PI would be immediately imprisoned until the investigation is completed and heavily fined if actually charged. This shouldn't be the case unless if real case of deliberate harm by the PI is proved. The public would usually take the criminal route because the course of action is much quicker than the civil route. This poses a great threat to the PI because any case of potential harm or adverse event in a research study could end their career as a physician and hence the stakes are very high here.

These are the most important barriers the way I see them in the Qatari system.

Saad:
Thank you for listing the barriers. If we talk about the funding, it is generously funded but then do you think that the allocated funds are fully utilized for research or there are other factors that hold funding or "sieve-off" the funding at different levels?

Manager 1:
Yes of course there are barriers. One of the main issues that we face for funding in general is being underspent but then this has other reasons. For example, if we budget for a clinical trial but then the team is not able to recruit the required personnel due to the stringent procedures, the outcome is underspending but this does not reflect the true picture because the underspending was due to these barriers. The financial status in the country is now more stringent and hence any investment needs outcomes to justify it to the management. As I mentioned, the costs of the lab tests and other research procedures are not controlled through clearly defined policies but depend on personal judgements. This needs to be addressed sooner than later to measure the actual costs of research and charging them against the relevant accounts.

Also, there is the issue of indirect cost (IDC) that needs to be addressed by our institution on how this has to be allocated or utilized. In UK for example, the indirect cost is used to cover the actual costs for the additional research tests and procedures and hence they charge indirect costs for these grants. These research costs are also covered through a central account that is fed in through the central government and then the universities

recuperate into this account. This is necessary in that system because for the universities teaching makes money and research loses so they have to compensate. However, I don't see how this could be applied in the system in Qatar and hence there should be better ways to manage the IDC to be used more effectively.

Saad:
How would you describe the overall attitude of the clinicians at our institution towards research?

Manager 1:
I would say that there is great interest in doing research but then the practically of it is not possible. There is no protected time for the researchers and if we are looking for top quality research, then it's not something that could be done a couple of hours after duty. I think there is a strong case to identify good researchers and give them protected time to be able to do research because the issue is that we either pay them additional amounts for undertaking research or provide them protected time. On the other hand, QNRF's view is that they are paying for the time but not the salary of the researchers and I understand their argument too. The prevalent view among researchers is that if you are not going to pay me or give me protected time then why would they do research.

Saad:
What do you think motivates or demotivates clinical researchers at our institution?

Manager 1:
The motivation is that it adds variety to their job because in the end we are all trained to be clinicians. Being 10 to 15 years in the job as a consultant, apart from the joy of helping people of course, there is a routine in the daily work we do. Hence research adds variety to the job which in turn increases job satisfaction I believe. For many other, publishing and presenting their researchers adds prestige to their identity. Hence for the substantial minority undertaking research here, I would say that there is high enthusiasm but also some sort of unhappiness that it is unrecognized by the institution in terms of protected time or salary.

Saad:
So, these are the things that would demotivate them?

Manager 1:
I think for some of them but for some other it doesn't. There are some people who are so driven that they will do research in the little time they have no matter how busy they are.

Saad:
Coming to the policies, how do you think your institution's policy framework supports clinical research?

Manager 1:
I think AHS-MRC have pretty well-defined policies that stand up to scrutiny but I think the strategy of developing it could be improved. As far as we are concerned, I think - though not deliberate – there is a disconnection between the reality and what is expected. If we are willing to say that we are a world class academic health system undertaking research, when it comes to the crunch in difficult times, from the clinical service, research is inevitable taken as a back burner. I don't say that in a critical way though. So, if we say it this way then research will always take the second place because there is always a clinical issue that would be a priority. Yet we know by looking at other organizations that do prioritize research that they get better clinical outcomes. So, it's a case of short-term challenges against the long-term impact of having an academic health system and how you change that balance. Qatar could do better than compared to other places because in places where there are regular elections, programs are encouraged for short terms but then the political system here is more stable and can plan for the long term. I personally believe that it's time for doing that now because I understand why the academic agenda stalled around in 2015 due to the financial cuts but then it can't be cut off forever. At the moment, and I'm not being critical, but I understand that there is more rhetoric than reality. The government here is not working on a research strategy and we are currently feeding into the health aspects of it. I would like to see a central funding for the AHS because at the moment our institution bears all the costs and hence it is seen as an internal matter and not national. There could be a 5-year plan to transform ourselves into an academic health system with research at its core but this needs a lot of work that the higher management and senior clinicians fail to see this gap. For politicians, maybe we have not done a good job proving to them what an academic system could do to help with improving the system and hence we needed to show value for money invested. In business, it makes sense that the growth 5 years from now would depend on the value for money invested and the same is true for health. We have to demonstrate that we have robust systems in place to show them how the money is spent.

Long answer to your question, I think more centrally there is more skepticism about importance of research in most sections of the corporation and externally and among politicians. Although they like to use the rhetoric on websites, I am not sure they are fully committed and we have a job to make sure that they are committed.

Saad:
If we take the business mentality of the politicians, then they would argue that they allotted a certain sum of money when in crisis and we managed fine with it so why would they have to increase now? We would need strong justifications for that.

Manager 1:
Yes, I wouldn't disagree with this. The other issue that we should be able to prove that we are effectively spending what we receive. For example, if we fully spent this year's budget on a national data capture system, we would be able to show the legacy we created from this expenditure. I believe that this national system will not only serve the researchers but also for informing health policy going forward. Once we start doing these things, people will start getting convinced that money is being well spent. My understanding when I came

here was that this never happened before and all it mattered was that the allocated funding was being spent in a "good way". Probably it wasn't asked earlier because money was easier back then but its tighter now and we have moved to a new era where we have to compete with other agendas. In a way, we have to also be ready for a time where the higher management could change so we must have this data to convince anyone who would take over then.

Saad:
Do you think that the policies and guidelines at your institution would motivate or demotivate clinical researchers?

Manager 1:
I think they are complex and none of the researchers know all the policies inside out – we are not expecting that from them. That's why the hospital research officers and clinical monitors are important because we need people in the ground who can educate the clinicians and ensure that the policies are instituted. The sentiment of the policies is very crucial and we have to make sure that if they want to do research then they go by it but we can't hold them totally accountable. My slight worry here is the research law that the Ministry is proposing and that is why I was trying to hold it down because it removes institutional responsibility and holds the investigator responsible. In that case, majority of ongoing research would stop with negative consequences. Ultimately our job becomes to train and support clinical researchers to ensure that they are compliant with the rules and regulations and if someone breaches them then clearly it has to be addressed. The issue remains though if the breach was done in good faith or if someone systematically and deliberately breached patient safety and if they have then they should face the consequences. However, for a one-off case where it was done in good faith, then we would have done our part in avoiding all that.

Saad:
The barriers that you listed earlier in the interview, are they specific to your institution?

Manager 1:
I would say across Qatar. I think many of the same would apply but the research done in Primary Health Care is relatively low risk but then Sidra would have similar issues to ours. The issues become more severe with higher risks involved.

Saad:
Are the barriers specific to Qatar? Or would you say it's similar to other systems you have worked in previously?

Manager 1:
I don't think all of them because some of them are different. For example, UK is very bureaucratic country and very rigid when it comes to applying rules. If you combine a rule applying mentality with thousands of rules to be applied, you end up with inertia to progress. Part of the problem for UK is that European Union believes in lot of rules and churns out thousands of rules every year. Large parts of the EU however treat these rules

in the manner how they should be, as a guidance rather than rules. The UK however embraces them and there is an army of people to apply these but if you read them, nothing actually would happen if you apply them. This is not specific to health only but all other sectors like business, communication etc. So, we (in Qatar) are not unique. I got a grant from the National funding body during my time in Aberdeen but then I moved to Norwich by the time it was awarded. It took me 3 years to move these approvals and the grant from Aberdeen to Norwich. The grant was finished by the time we got the approvals and we had to request a no-cost extension which was only for a fraction of the actual duration and the science was old too. So many of these problems here (in Qatar) are not unique. Investigators think it's terrible and so we have to resolve it but it's not unique. I would say that what other countries have had is much longer time to put sophisticated systems in place because they have been here longer so I see that we should take the best of these systems and adapt them to our needs here, like the regulatory structures for drugs. Qatar's development in this field is very recent maybe around 30 years so it's not possible to move from one stage to another very quickly as some would expect.

Saad:

Lets go back to the barriers you identified in this interview. I will name them and perhaps you could let me know what is being done or already done to overcome that barrier.

Barrier	Steps taken to solve
Critical mass of clinical researchers	I think we made a little progress through the clinical institutes but then the numbers are still small. I did a search of H-index of researchers around our institution and if we consider that an H-index of 30 would take you roughly to the international level, we have got only 5. We lack the strong mass of researchers across our institution to mentor the really enthusiastic people. I think we need at least 20 and if we look at the number of consultants that we employ every year we can surely do that. But then legacy is important because we can't have them for 3-4 years and then leave without any forward plan.
Mentoring and Training	Part of their role has to be mentoring and the other part of mentoring is not only developing the current senior people but also creating a pathway for clinician scientist. This involves Medical education, ourselves and other partners. One of the things I am waiting for is appointing my deputy and part of their responsibility that they will take on is the legacy issue. We are working to create a pathway for the Qataris to become clinician scientists in future.

Protected Time	I've raised it with the higher management who are sympathetic. I also have an upcoming presentation later this year and I will raise it again. The proposed solution would be that we agree a percentage FTE across the institution that would be devoted for protected research time. Then we would ask executives of the facilities to identify individuals based on the quality and quantity of research who would benefit from this. It should be for people who are or have the potential to be serious researchers.
Governance issues	I have fought very hard to have the HROs and monitors. I had meetings with HR and expect later this week to have more posts approved for MRC.
Policies	They would be tweaked and refined but I don't think we can simply further because there will always be a mismatch between what JCI would expect and a clinician would prefer. So, in order to meet JCI requirements they have to be detailed but then our job is to make life easier for the researchers.
Facilities and infrastructure	We are in the middle of preparing a bid for a clinical research facility. This would be for 2 floors at one of the buildings at the medical city.
Modest Investment in personnel	One of the issues is the mismatch between operational, capital and manpower expenses. What we see within AHS-MRC is the same what our institution experiences every year. We have a number of posts that are not occupied and hence we have programs and funds unutilized because of that. Last year we had developed a bid for a clinical trials unit and we were assigned a huge operational expense but then no posts were approved so we ended up handing back the operational expense which would imply that we didn't need it but the truth is that we needed the posts to use it. The major investment is posts and once we have that we can effectively use the money and demonstrate why we would need more money.

Financial Indemnity	It has been through Legal review and comments are being addressed. It will be back then to procurement for final sign off and we hope to happen in the next month. It will only cover our institution.
Reliance agreements	One of the things that frustrate researchers in Qatar is that they have to apply to multiple IRBs if they want to have a collaborative research. One of the things I am proposing to the working groups is that we develop a reliance agreement for the whole country where then one IRB approval would cover all institutions.
Regulatory systems	MHRA had 2 calls and we need further discussions to see how much it would cost and the scope of work.
Legal system for criminal liability	We are setting meetings with key stakeholders to try lobbying against the new law.

Saad:
Are there any other barriers that we may have missed in the interview?

Manager 1:
No, I think those are the most important ones there.

Saad:
Anything else you would like to add relevant to this topic?

Manager 1:
To give you some context, what I did was that I calculated what proportion of the NHS budget is spent on research and development compared to Qatar. They spend 3 to 4 times (on a percentage basis) to what is spent in Qatar and most of that is spent on manpower.

Saad:
What percentage of that is exactly going to manpower?

Manager 1:
That would be about 70% of the total expense on R&D so like I said, critical mass of researchers is the most important requirement. That includes researchers, research nurses, infrastructure, training schemes, pathways and the clinical trial units.

**** The interview is concluded by thanking the interviewee ****

Manager 2

**** The interviewee is welcomed to the interview and briefed about the study ****

Educational Background: Both

Age: Between 50 and 60

Saad:
Could you please tell me about your role as the Executive Director of Research at your institution?

Manager 2:
As the Executive Director of Research, I am supposed to oversee all the research activities at our institution in general and that includes governance, funding, monitoring, auditing, training, reporting and involving heavily in shaping the research strategy at our institution.

Saad:
How many years have you been involved in this role?

Manager 2:
For more than five years since 2013.

Saad:
How would you describe the overall support for clinical research by the government in State of Qatar?

Manager 2:
There is an overall interest and goodwill to support research by the government. There is significant investment through availability of funds. However, from the government perspective, there is a gap in the expectation about what that fund could be translated into or what output could be produced through that investment. The expectation of the outcome of this investment is unrealistic and therefore this gap is widened. The expectation is high, the investment is significant however the means of meeting those expectations when it comes to having the right programs and right support services needed to implement to reach those outcomes are not properly in place. Also, the timeline for deliverables is not realistic. In my opinion, this reflects some immaturity in the system. It's not unheard of, obviously, the ecosystem of research in Qatar is developing as we speak and typically it takes a couple of decades for such systems to develop and take the required shape. Five years ago, when I took over the research department here, things were much worse than now and I expect that in the next 5-10 years things will be more robust and developed. As you know I am departing this position soon and my successor will build on the current success. The major challenge in the past 5 years is the expectation from the investment which was significant but just enough to meet these expectations while the perception of the government is otherwise. The problem is that they did not see the outcome of this investment and this because the expectation was unrealistic on one

hand and secondly the means to transform this investment into outcomes wasn't robust and well-structured or as coordinated as it should have been.

Saad:
Then how would you describe the support for clinical research within your institution?

Manager 2:
I think what I just explained applies to here as well however our institution itself had and continues to have its own set of challenges. If we look back a decade, we were not an academic health system but only a teaching hospital. We had residents and fellows come in for training and education but that itself isn't enough to transform into an academic system. The research part was added later but even then, it was just a hobby or an option added to the mix. It was only recently that we adopted the tripod of research, education and health and things started to shape up since then. Firstly, we transformed into an academic health system with all the challenges that comes with that. As you know, any clinical research requires massive infrastructure to do proper research. People were doing clinical research at our institution in the past and continue doing but in an amateur way so bringing a new system was a great challenge. We are not a simple organization but a massive and complex organization which is unfortunately largely centralized. So, any challenge implementable to any other domain in the organization is also applicable to research, in addition to the set of challenges that are peculiar to research. Research is not looked at by its recipients as a necessity but a luxury and hence does not get enough attention. That said, and with the implementation of the new strategy and systems, significant investment has been allocated for research including funding and support from top leadership. The biggest challenge is the previously, and still, existing systems which are repulsive to conduct research at our institution. That translates into challenges in recruitment, procurement and career planning for researchers, recognition of research achievements – all these are not conducive to research here. However, things have improved and we tried to advocate for research agenda at our institution at different levels.

Saad:
How would you describe the infrastructure provided for clinical research at your institution?

Manager 2:
I don't think its adequate. The amount of research you expect from a big organization like our institution and so diverse when it comes to the patient population must be much more than what is currently allocated. The footprint for research is small compared to the size of the organization. Another challenge is that the research space is scattered all over the organization in different buildings and facilities and that is not much helpful because when it comes to clinical research, there must be a close link to the clinical areas. The newer buildings have a small space allocation for research like the Ambulatory Care Center and the Qatar Rehabilitation Institute have areas dedicated for clinical research. I think those are good start and I personally believe that a decentralized hub and spoke model for

clinical trial units is the most suitable for us because of the diversity of the disease and patient population we manage.

Saad:
When we look at the funding, and I believe you have received grants from QNRF as well, usually you are awarded a certain sum of money but do you think that this money is being utilized fully or is it being used for purposes other than actual research costs? Do you think there is a sieve off effect in this process?

Manager 2:
At our institution, the concept of Indirect costs (IDC) is not fully understood. In general, IDCs are used in any given academic system to pour back into the system by buying time for researchers or allocating more resources in certain areas or centralized support funds. Here, the IDC until recently was being used for non-research purposes. It is very unfortunate that it was used for supporting other departments not involved in research but this is slowly changing now. The concept of "chopping off" funds for non-research purposes must be stopped and we must pursue better utilization of these funds into research purposes.

Saad:
How would you describe the overall attitude of clinicians towards research?

Manager 2:
I think it is mixed. Obviously when there is a funding opportunity to do what you like you jump on board but when it becomes too challenging people start to have second thoughts. I think we moved through different stages of no funds to very easy access of funds to a securitized level of funds and this is healthy, I think. As research advocates, we need to look into the challenges faced by those who hop on board for sake of research and try resolving if its related to training then we provide better training and if related to support teams then we provide them that too. The biggest challenge here, and I believe it's not specific to our institution, is that the majority of the academic health systems find it difficult to distinguish between clinicians, clinical scientists and clinical research teams. So clinical research teams are not doctors who see patients but instead trained to do and support research while here I don't think we provide that to our researchers. We expect them to do everything by themselves in addition to their actual duties. Even if we free their team, they would still not be qualified to do that because it's not their job and they are not trained to do that. I think we need to allocate some funds so that they could then hire these support team members. For example if you allocate 100,000 USD for a project, a good portion has to be spent on bringing in qualified support team members doing things that the clinicians wouldn't do like IRB follow up, progress reports etc. so it is the PIs job to ensure that these are up to the required levels but then not actually not having to doing it themselves. This is not a realistic expectation from a basic clinician. In my opinion I think the PI needs to spend more time doing the science than spending time on the operational part that is handled by other trained personnel like CROs. To be more efficient as an organization, we need to have our own core group of support that could be tapped into by

different researchers. The model of a central office to support all researchers was something I always supported but I was hit by a wall of challenges like policies and procedures not conducive to research support. I believe we need a central office with qualified CRCs, nurses, legal negotiators and so one who can provide full support to clinical researchers to be good and up to par when it comes to research governance. The IDC we talked about earlier could be used to support this central pool and researchers can pay for the time of these Central support staff from their research grants.

Saad:
If we look further into the clinician's perspectives, what do you think motivates or demotivates them to do research?

Manager 2:
Most of the clinicians like to do research because it is challenging and challenge in medicine is always exciting and if they are able to do it without much trouble then that is good enough an incentive. The other motivation is the unique and diverse patient population at our institution which is attractive to do research and try to answer some of the scientific questions that are out there. In addition to that funding sources are very attractive – MRC, QNRF and pharma. Also, the vision of our institution and the country to support research is very attractive too. I think QNRF and many of its programs are a really good thing that happened to the Qatari research ecosystem.

As for the challenges, the first is the perception of the importance of research at the management level needs a lot of work. Clinicians who are doing research do not feel rewarded or recognized for doing research. Unfortunately, on the contrary, some of them are looked at that they are doing nothing because they are doing research and this is very damaging. The second biggest challenge is allocation of time. Not all clinicians are very busy as some of them do have time to do research however there is a group of clinicians who are extremely busy and they are good at research and want to it but they don't have protected time. The third challenge is the cumbersome processes we have for research approval, monitoring and reporting. We need to do a better job at this because we are still bureaucratic and need to be more efficient. Most, if not all, investigators do not like the IRB requirements in general but on the other hand they try to satisfy them. So, we, as administration, need to be more supportive and flexible and willing to revise our process to make it more conducive and attractive to the clinician researchers.

Saad:
Looking at the regulatory framework for research in Qatar, do you think that the policies are developed enough to support research? Mainly for the clinical trials that involve importing new drugs or investigational devices?

Manager 2:
I think it's difficult to do clinical trials in Qatar because the regulatory frameworks are unfortunately imported from different places and put in one pot. It is very unfortunate that the regulatory framework imports all the difficulties of each system and combines

them all into one framework. There are also some of the regulatory issues that are not built on much science and evidence.

Saad:
Going back to the barriers you listed, I will start listing them again and you may propose solutions to these barriers, in your opinion.

Barrier	Steps taken to resolve
Importance of research to clinicians	Research advocacy and education efforts are ongoing. We could still do more.
Repulsive admin systems	A lot of effort has gone into that but in vain. More persistence and resilience is required.
Infrastructure	Research leads are now more involved in planning of facilities. The Translational Research Institute (TRI) project is brought to life again so hopefully we will have a good research center. There are good efforts to advocate for research space and facilities in the new projects.
Lack of available trained research personnel and retention	Some efforts started with HR but again we were sidelined due to other priorities at HR. We have to continue persistence and resilience.
Differentiation between clinician, clinician scientist and clinical research teams	Part of it is education and we need more research mentors at different departments.
Protected Time	We raised it to the higher management but no progress so far. The solution is to keep persisting and resilience.

Saad:
Are there any other barriers you could think of that we did not discuss earlier?

Manager 2:
I think what we are going through is a natural process for a system trying to achieve milestones in development. We will take some time and things will happen as long as we don't give up and be resilient and we don't prematurely detour from doing this. I think there is a good umbrella that has been formed called the National Academic Advisory Board and areas of research are being prioritized. I think we are in the right track and we will achieve s long as the leadership keeps the vision and we don't give up.

Saad:
You had a large part of your education and training outside Qatar and also many interactions during your professional experience as a researcher. Do you think that these barriers are specific to Qatar or is it similar in other systems elsewhere?

Manager 2:
It is not unique to Qatar for sure. Trying to work in a hospital transforming to an academic health system is not unique to here. Academics think alike and non-academics think alike. Our system is trying to establish itself and there are more established systems around the world but when comparing ourselves to any developing system, we are ahead of them. One of the reasons why we are ahead is that we allocated huge funds and that brings in lot of resources. Unfortunately, the funds have been allocated but the systems are not fully developed so there is spillage. Improper utilization of funds will not lead us to where we want. Some of the systems I have evaluated have the right set of regulations and operations but lack funds – we are the other way around. Some of the more mature systems, their challenge is not operational but how to secure more funding and then use that fund to achieve better outcomes. This is like the difference between minor and major leagues. We are at the beginning of the minor league and not in the major league. I believe it is healthy to look at ourselves as a developing system in the minor league and one thing I learnt from this experience is that you can call yourself whatever you want but people will see whatever they see. You can say you are the best in the world but if you aren't and the people are not seeing it, they will tell what they see.

Saad:
Do you have any further information that you think will benefit the topic of my research?

Manager 2:
I think if you encompass what I said in a systematic way, it will give a whole picture.

**** The interview is concluded by thanking the interviewee ****

Manager 3

**** The interviewee is welcomed to the interview and briefed about the study ****

Educational Background: Both

Age: 50 to 60

Saad:
Could you please tell me about your role as a research lead?

Manager 3:
I am the assistant dean for clinical research at our institution and also run the clinical research core. At the core, we run and support clinical research across Qatar particularly in collaboration with other institutions.

Saad:
How many years have you been in this role?

Manager 3:
Almost six years now.

Saad:
What aspects of this role have you been involved in?

Manager 3:
When I first arrived, there was no infrastructure for clinical research at our institution or the country so we setup the infrastructure from beginning including equipment, personnel, SOPs, policies etc. necessary to conduct good clinical research. So, I have been involved in all aspects of setting up clinical research from the ground up – from having nothing to become a good organization for conducting clinical trials.

Saad:
And I believe you have been successful so far in doing that?

Manager 3:
There are challenges in the country. We are considered one of the successful groups but there are challenges obviously. We have succeeded in the infrastructure that we set up.

Saad:
How would you describe the support for clinical research from the government of Qatar?

Manager 3:
The Ministry of Public Health (MOPH) has guidelines for human and animal research. There guidelines are based in the American system and that is the main support provided. Apart from that there are individual institutions with their own structures and governance like

IRBs, DSMBs and so on. The support has been mainly to set the framework of how we do research however just setting the framework isn't sufficient. To succeed, they should develop pathways on how to implement the framework and how the institutions should work together. Unfortunately, and I am being honest here, the approach has been that clinical research is "bad" to do. The idea is that who is doing clinical research is doing something dangerous or difficult. To stop this danger, more regulations have to be in place whereas actually these regulations are stopping people from doing good things. There needs to be a balance for things to succeed and right now I think that balance isn't there.

Saad:
How would you describe the support for clinical research within your institution?

Manager 3:
Within the institution the support for clinical research obviously it is a medical school with teaching and hence it supports clinical research however it is the way the institution has developed. When they started there was a big emphasis on basic research and hence the clinical research is like a new kid around the block who is always trying to do extra things. The institution is catching up with the need to do more clinical research.

Saad:
How would describe the funding at the national and institutional level for clinical research?

Manager 3:
Qatar is not a poor country, that's a given. It has given money to solve problems through clinical research however the grants system is not designed for clinical research and particularly clinical trials. We have a limited funding because when there is cap, you can't answer all the questions your research was exploring but that is not possible in 800,000 or 1 million. Similarly, when there is a budget cutdown from the awarded grants by the funding agency, they can't do that for clinical research because it is not like basic science where you can adjust to budget revisions by doing less experiments. However, in clinical research, when you have to recruit 1000 patients then there is a specific cost required to reach that target and revisions are not serving the purpose here. There is impatience about spending and getting outcomes but the reality on the ground for the investigators is that they have to get all approvals from different IRBs and different hurdles that they have to go through and the funder is frustrated because they think you are not doing but it's not the investigator's fault here. The process of funding now is that I should have all the approvals in place to be able to start using my funding and if I didn't then they go punitive on the investigators. To make that happen, every institution has to agree to expedite the approval process within that time frame. Another barrier that we faced is that we have a grant with the money in place and approvals from two IRBs but then someone at MOPH is not happy about it so they decide to stop everything and we have to re-do the approval process again. The problem is that when we came back with the required revisions to our IRB, they requested further changes and doing research is getting more difficult now. These approaches are not conducive to doing research. Another thing done in Qatar is that you need to have your CRF stamped – which is a working document that should be allowed to change or re-arrange to be suitable to the way you are collecting your data. If its

stamped once and you change one sentence, you have to re-stamp the whole document again by both IRBs. The other issue is conflict of interest that has to be submitted repeatedly to all IRBs and annually for each PI and each project. This could be avoided by just having an annual COI general to all projects or an indefinite COI where the PI is only required to report it in case of any change in his status. I am not against declaring COI but it should be only as and when required. Again, this takes us back to the American system being replicated here but unlike here, they have many startups or sponsors for research projects and researchers are actively holding shares or promoting these companies.

Saad:
How would you describe the regulatory framework when it comes to the policies and guidelines governing clinical research?

Manager 3:
It is very challenging as every institution has their own guidelines, rules, paperwork, way of doing things and pathways for reporting.

Saad:
Why is this inconsistency happening, even when all of them are under one regulatory umbrella?

Manager 3:
It is not actually regulated. We need someone who really understands clinical research at the Ministry to be able to harmonize processes. This requires expertise, flexible mind, planning and understanding of the clinical research environment in Qatar. The idea is to facilitate while maintaining subject safety so this balance should be maintained and for that you need someone who does clinical research. Then the IRBs could be harmonized to follow one standard procedure and paperwork.

Saad:
Or would you rather advocate for a national IRB?

Manager 3:
The problem with the national IRB is that if its run by the Ministry then it gets bogged down and things get delayed. I think institutions should be able to decide whether their investigators are good enough to do research, the facilities required and so on and the institutions should be powerful enough to do that. If a national IRB is independent of the ministry, again it's a committee and it requires individuals, managing personnel, funding etc. I can see other countries in the GCC where the national IRB isn't succeeding and getting bogged down because the committee is formed by people who don't know what they are doing.

Saad:
How would you describe the overall attitude of clinicians towards research?

Manager 3:
The problems here are very similar to elsewhere. People do research to get it on their CVs, promotion, bigger pay, prestige but the reason they should be doing research is that they have a question that they need to answer about their patient cohort or they want to change clinical practice of how we do things. Attitude wise, clinicians are very open to doing research but looking at the history, research meant extra money in the pocket but that's not happening anymore so the people who did it for money are not doing much now. Hence, we are getting people who are more passionate about research itself but the problem with that is that they are clinically busy so they cannot really focus on doing research. One potential is going back to the UK model where you buy clinicians time for doing research hence you charge, for example, 20% of their time to the grant and somebody else is brought in to do their clinical time while they have time to do research instead. That will really help everything. Everybody's job description must have outlined portion for clinical duties, research, teaching and administration. If this happens then research will become a part of their job and if it's their job then they will more likely do it better.

Saad:
In the course of this conversation, you mentioned few barriers like multiple IRBs, funding limitations by QNRF, COI declaration. Can you mention some other barriers to conducting clinical research in Qatar?

Manager 3:
Organizational competition. Qatar is a wealthy country but the population of Qatar is small and the number of Qatari researchers is even smaller. People involved in clinical research come from different resource limited countries and have different agendas. As soon as they come, they think that they have to fight and hold on to the resources and look better than the other institution so one needs to do more collaborative work. We have to work together because when there is institutional competition, then money gets wasted and things don't progress but this is happening less now.

The other barriers in clinical research is the patient population because the population here is mostly transient and expatriate. It is therefore hard to have long term clinical trials because their jobs may not be secure to allow long term follow up. The other challenge is that when we started reporting (unrelated) adverse events, some IRBs are shocked to see that because they think something bad is happening. Most of the studies here are fairly simple and hence this concept of seeing SAEs being reported is not very developed. There is a lot of education and training that needs to be done in terms of what clinical research looks like, how they are reported, SAEs, AEs, pathways that can be harmonized.

I started this conversation some time ago to harmonize pathways with HMC as a start but it was blocked at various levels because people don't want to work together.

Saad:
What about the infrastructure?

Manager 3:
It is not well developed else we wouldn't be having this conversation in a temporary office. Big clinical organization should have better infrastructure when it comes to policies, guidelines.

There is also the barrier of lack of space. When we do a study at a clinic, the rooms change frequently and we can't have a stable environment to do it. Most countries have clinical research center geared up with nurses and it is done in a slick way. I don't know why Qatar does not have a good diabetes research, for example, since it is the biggest health problem here.

Saad:
Why do you think this is not happening?

Manager 3:
I think this depends on the leadership. Many countries in the world count on the advisors and depending who the advisor is, at that time, it changes how things work. In US and UK, there are companies, lobbying senators and things like that so Qatar is going through the same because the government wants to do the best for their people but they can only go on with certain levels of advice. We should be allowed to make mistakes and learn from them. If we look at countries with thousands of years of history, they made all the mistakes. It's a part of developing and it's not easy to have everything at one place in one go. Things can happen faster here, it's not that they don't want to do it.

Saad:
Talking about funds, let's say that you are awarded a million dollar project by QNRF, do you think that the funded amount is being effectively used for research or is there a wastage or sieve off effect in using those funds?

Manager 3:
There are specific issues with being in Qatar. For example, if you are hiring a post-Doc, then you need to pay for their housing, education, leaves etc. in addition to their salary so a post-doc in the US might cost you 60,000 dollars but here it is around 200,000! The cost of hiring personnel here is much higher here than elsewhere. If you have a grant with limited funding, then the post-doc takes most of that budget and nothing is left for consumables and other items.

Saad:
So, the barriers you mentioned, are these specific to Qatar?

Manager 3:
Some are specific and some are not. The specific ones are stability for example, as we don't have people long enough who can change things. Qatar is advanced compared to other GCC countries. It is amazing to have QNRF unlike any other country but the problem is that money was given at times when the infrastructure wasn't there so the money could have been wasted back then. Because of this wastage, the management system has

become so rigid that we can't do anything now with the money. In the UK, when you are awarded a grant, we have the flexibility of moving money around and go to where science leads us but here, we can't do that. We are stuck as we have to do exactly what we said we will and of don't we are punished by points, suspensions etc. Science does not develop like that but instead we have something that develops into something else that might lead us to a new direction. It is good, if the PIs are good project managers only.

Saad:
Do you think there is any gap between the investments and the expected outcomes by the State when it comes to funding?

Manager 3:
Absolutely. However, when we look at the funders, they have to report somewhere higher about the outputs of this funding. Outputs can be publications, new IP and all that but science does not always produce these outputs, not right away at least. For example, it's not realistic to expect papers out of undergraduate funding projects. The other thing introduced is the co-funding that could be managed differently. If an institution wants to co-fund ten million dollars, they put in the same pot as QNRF specifying the priorities and the funds come from one place. There is no need for multiple co-funding applications and agreements as it happens now.

Saad:
I will now list all the barriers you identified and you may propose some solutions to these barriers.

Barrier	Proposed Solution
Multiple IRBs	Reliance agreements among IRBs, Harmonized pathways and paperwork, Reporting
Funding limitations	Reduce wastage. For example, anything that can't be done in Qatar is immediately outsourced rather than building capacity to do that work within Qatar.
(Transient) Patient population	There is nothing much we can do about that. When we design the study, we over estimate dropout. Also, we avoid the extended holiday season including Ramadan and summer vacation specifically when the study involves a drug that could raise safety concerns. It is easier to do short term studies in this case.
Organizational skills	Harmonization is the way and avoiding duplication of efforts.
Education for researchers	It could happen at the organizational and individual levels. We are trying to set up courses but it always comes with

	experience. There must be flexibility in the system to allow people learn by making (limited) mistakes and learning from them.
Protected Time	I believe our institution has the funds to do that. We could identify young talents interested in research and clinical practice to buy their time for doing more research and have pathways for career development as clinician scientists.
Infrastructure	Unless the organization decides what they want to do and how they are going to do, it won't happen. There is a need for a building for clinical research.

Saad:
You mentioned in the beginning of this conversation that people think that doing research is a bad thing or people do it for fun. Where do these perceptions come from?

Manager 3:
Because there have been errors on research but there are errors in clinical service too. There are errors in doing everything, even bus driving. There must be systems to reduce these errors but then we don't look at people as bad or doing something for their own benefit. People do research because they are passionate about patient care. If patient care improves, that is a very good thing. For example, one of my studies on diabetes had a very positive outcome where 91% of the people who were diabetic are not diabetic anymore. This could impact more thousands of people. Papers are good but there are people who do it just to improve the life of their patients. Sadly, there are people who do it for other reasons as well like money or fame. The responsibilities ate research are not only clinical but involve research aspects as well. These are enormous responsibilities especially when you are doing research with safety implications. It is burdensome because if you are clinician you work for fixed hours unlike research where you might get called at the middle of the night because of someone having an adverse event related to your research study. It is much more stressful and complicated.

Saad:
Do you think that the outcomes we've had from the ongoing and completed studies are translated into clinical care for the patients as treatments or national programs?

Manager 3:
Let's look at QNRF for example. In the earlier themes, a project would get funded for a disease that is rarely seen in Qatar but just because the submitting PI is a renowned researcher in the world. Recently the calls are more focused to the country's needs and the same needs to happen with other institutions. Also, we have to fund studies that will have impact and avoid duplication of studies already done many times elsewhere. Scientifically each department needs to identify their priority areas not because it is attractive but because it is important to the community in Qatar.

The issue of generating publications but not making to patient practice is happening everywhere else too but there is something called rapid deployment. The Ministry has to look at some studies and decide to rapidly deploy them into practice rather than waiting for more evidence like the study I told you about earlier in this interview. Rapid deployment of these outcomes will change things.

Saad:
With all the mentioned barriers, how would you rate the readiness of the system to conduct clinical research?

Manager 3:
This is a difficult question. If by research, you just mean collecting of questionnaire data and blood samples then it's a ten but for clinical trials it's probably five or six out of ten.

**** The interview is concluded by thanking the interviewee ****

Manager 4

**** The interviewee is welcomed to the interview and briefed about the study ****

Educational Background: Both

Age: Between 50 and 60

Saad:
Could you please tell me about your role in the Research leadership in Qatar?

Manager 4:
I am the manager for department of research at our institution. Our function is to develop national regulations and policies that govern ethical conduct of research on Qatar. Consequently, we have developed a number of policies and regulations that have been posted on our website.

Saad:
How would you describe the support for clinical research in State of Qatar?

Manager 4:
Qatar has a very ambitious vision when it comes to research in general and clinical research in particular. So, when it comes to clinical research, there are a number of clinical research projects going on currently mainly at Hamad Medical Corporation as the primary hub for patient care in Qatar. To fulfill the regulatory requirement for the conduct of research, we have developed a number of policies. We have protection of human subjects involved in research and it is adopted from the 45 Code of Regulation 46 of the US regulation. The policy itself mainly addresses the function of the IRB committee, review conduct, review types and the elements of informed consent. We also developed policy for the conduct of clinical trials and its adopting ICH-GCP guidelines.

Saad:
Is there any clinical research going on within your institution?

Manager 4:
Not within the institution itself because we are a regulatory body however research takes place at hospital setting like HMC, private hospitals, academic research institutions located within Qatar Foundation.

Saad:
How would you describe the funding support provided by the State of Qatar for clinical research?

Manager 4:
There is a single funding organization which is the Qatar National Research Fund (QNRF). The fund is distributed on a competitive basis and each researcher/ institution submit their

proposal to QNRF and they will send it to external reviewers. Each proposal is valued according to its purpose and how it is addressing one of the national research priorities. It is a very competitive procedure but we can guess what is the result because the fund distribution is among four pillars – health, ICT, Social sciences and Energy. The majority fund goes to Qatar University as a national university followed by Texas A&M- Qatar and the remaining to WCMQ, HMC etc.

Saad:
Do you think that the funding allocated for clinical research is sufficient in this case?

Manager 4:
There isn't enough fund allocated to clinical research because Qatar is not that advanced un submission of clinical trial proposals. So far, we manage only phase 2, phase 3 and of course phase 4 trials however phase 1 trials where there is a new investigational drug or a device are very few, almost rare. Therefore, there isn't a chance for QNRF to fund these proposals.

Saad
What about the facilities and infrastructure for clinical research?

Manager 4:
Most of the hospitals such as HMC and Sidra are in the process of developing their infrastructure to build clinical research units however there are lots of barriers when it comes to budget, human capacity etc. so the progress in this area is very slow.

Saad:
How would you describe the overall attitude of clinicians towards clinical research in Qatar?

Manager 4:
Physicians are very keen and interested in conducting research however there is no protected time for them to conduct research. Places like PHCC and HMC don't provide protected time to their physicians for doing research. Therefore, it does affect their ability to submit and work on these proposals. Also, there is always problem of hiring personnel to assist physicians in their research endeavor. There are very strong barriers on dealing with HR to hire part time research coordinators, CROs etc. so it is hard for clinicians in Qatar to practice research.

Saad:
Despite of all the barriers, we still see clinicians undertake research so what do you think motivates them to do that?

Manager 4:
Clinicians will always be interested in having their names in the publications. Also, they really like to help their patients. Research is always a tool to provide their patients new

treatment, new diagnostic methods or prevention from diseases hence it gives them good feeling to conduct research. It is important for their professional growth.

Saad:
How would you describe the perception that some clinicians have of their fellow clinician-researchers that they are doing it as a "luxury"? Or maybe compromising clinical service to do research?

Manager 4:
This can happen in advanced countries like the US where the clinicians are actually away from their clinics for a certain period in order to do research. However, in Qatar we are not at this stage yet and clinicians have to work full time to see their patients along with doing research so I don't think it is a luxury in this case.

Saad:
You mentioned that the policies and regulations have been revised recently. How frequent do these revisions happen?

Manager 4:
We understand that there are always new things happening when it comes to protection of human subjects and policy making so we are always keen to look at international standards for best clinical practice. We look at the most recent regulations at US, UK, Canada just to make sure that procedures for human subject protection are in place, well updated and recently we introduced new consents applicable to all stem cell and genomic research in Qatar. We are always in the process of updating our policies to add anything new and relevant. Also, to gain public trust, we need to ensure that their rights are being well maintained.

The revisions are hence, as and when needed, and the process for policies development and regulation has to be approved Qatar National Research Ethics Committee. It a national committee that was issued by the Minister of Public Health. The main task of this committee is to review the policies and regulations and ask us to update them to address any controversial research issues that may arise in any institution like incidental finding in genetic research for example. It is the governance body that approves national policies and regulations.

Saad:
From previous interviews, there were comments regarding submission to multiple IRBs and concerns that Qatar, due to its relatively smaller geographical size, should have a single national IRB. Being the regulatory department, why do you think are these inconsistencies in the work of these committees? And could a national IRB solve this?

Manager 4:
We did a very good job in developing a systematic model for the registration of IRB committees and providing assurance to these IRBs to adhere to the terms and functions stated in our policies and regulations. Having multiple IRBs is a normal situation as seen in

many developed countries that conduct human research. However, considering the size of Qatar, it is true that a national central IRB committee can do the job and save a lot of time and effort. We wanted to empower the local institutional IRBs in doing their job in protecting its own patients as it comes to protection of the subjects within a hospital like HMC or Sidra for example. The matter of having a single IRB has been discussed many times. It is in the pipeline to develop and was submitted to the Minister's office however there was no budget for it. We would like that local institutions contribute to that budget and efforts could be articulated to build this national committee because the members for that committee will be from those institutions like HMC, Sidra, WCMQ etc. We have many experienced IRB members in those committees and I don't see any obstacles in initiating the central IRB except the budget required for this project.

Saad:
Going back to the funding, do you think that the funding allocated by the State of Qatar for clinical research is being effectively utilized or us there a wastage occurring at any level?

Manager 4:
Duplication of research topics and following anything done elsewhere and doing that same on Qatari population claiming that its new because the population is different is really a waste of time and effort. QNRF should do a better job in avoiding these duplications and follow up throughout the process if a project is progressing well. I believe the one or two reports are not good enough for the evaluation. They should have the power to terminate such proposals if not progressing within the timeframe. I think they lack the number of staffs who can meticulously monitor the research activities and its outcome and translate the outcomes into better use at the national and institutional level. This is a huge gap that the funding body is not following through. When it comes to institutional funds, there should be a very efficient mechanism to look into the submitted proposals and outcomes and if it's going to improve the prevention, diagnosis and treatment of certain diseases or not. We are coming to the point that a lot of money is being spent but the MOPH is not seeing any tangible outcomes that will improve patient's lives or help us in policy making.

Saad:
Do you think there is a gap between the expectation from the investment in research and the outcomes in reality?

Manager 4:
Qatar has invested massively into research and there has been a tangible growth when it comes to building the human capacity over the last ten years. The MOPH did an assessment of the research activity in Qatar and we saw that the number of researchers has grown exponentially. The same applies to the publications and citation index which shows how efficient the outcomes and publications are. Qatar is becoming a very advanced place above other regional countries. However, there is still room for further progress and growth.

Saad:
You mentioned few barriers during the interview like protected time, funding, infrastructure, administrative barriers like hiring personnel. Are there any other barriers that you think are faced by clinical research in Qatar?

Manager 4:
I see some of the research institutions are placing a lot of barriers under the name of regulations and I really believe that IRB committees decisions and review process should be in place for two main purposes. First, for human subjects' protection and the second to help the PI's by reducing the burden of regulations. Qatar should be a hub for international clinical trials. The fund should be provided to build infrastructure like clinical trial units and to hire staff to help putting Qatar in a better place for clinical trials. I believe Qatar can take a lead in the region with all the systems and support we have in this field. Many pharma companies approach Qatar for phase 2 and 3 because of the established system we have here. When it comes to hiring staff, this and other administrative barriers should be addressed within the institution itself and I believe that the management should be the focal point of contact with the authorities to request more budget for personnel, infrastructure etc.

Saad:
Do you think that the outcomes of the research projects are being translated into clinical care or national programs that would help disseminate information to the public?

Manager 4:
As I said there is a gap in the area of translating research outcomes from bench side to patient side. There is a huge gap in finding outcomes from the submitted or funded proposals and trials. Everybody is working in their own corner without really connecting the dots of the beneficial research that is going on. I think the funding body plays a huge role in making that connection. The research institutions should reach out to the MOPH to inform them about the outcomes of their projects that could help improve the patient care or changes in the national policies.

Saad:
Is this not happening at all or happening at a limited scale?

Manager 4:
It is not happening at all right now. There is a recent attention towards this but there is no defined mechanism on conducting this process.

Saad:
How would you describe the readiness of the system in undertaking clinical research?

Manager 4:
There has to be a very well-established training and education program to keep reminding a clinician about the ethics of research. We have the CITI training which is a very basic training for physicians who conduct research however it is really the institutional

responsibility to have a very well-established training program and to have a record of these being provided to the investigators. They have to ensure that the investigators are well trained and transfer this knowledge to their teams and ensure every personnel in their team understands the regulations.

Saad:
Is there anything else that you would like to add relevant to the topic that my research is addressing?

Manager 4:
I think we need a lot of research needs to be conducted similar to the one you are doing now to continue assessing the current framework and matrix of clinical research in Qatar. Not only clinical research but also for social and behavioral research too. We need to assess the conduct of the research activities and how to transform the outcomes into policy making and patient care. Such research provides evidence-based data that will help institutions and governments to formulate better policies.

**** The interview is concluded by thanking the interviewee ****

Manager 5

**** The interviewee is welcomed to the interview and briefed about the study ****

Educational Background: Both

Age: Between 50 and 60

Saad:
Could you please tell me about your role in the clinical research leadership in Qatar?

Manager 5:
I am involved in both phases - pre-award and post-award for grants at our institution. In the pre-award, I do the initial reading, identifying key words, assigning reviewers, similarity checks and the screening process. We receive the short-listed proposals that go through the programmatic review and my role here is more influential because I am a voting member. In this review we go through the nitty gritty details to ensure that the idea will be feasible in Qatar because the reviewers are usually external and not aware of the environment here. The scientific reviewers look into the science and the novelty while we look at the duplications, feasibility, performance of the team and other factors. For the post-award of funded projects, my contact would be every six months for reviewing the progress report and releasing the installments. We identify the progress and weaknesses (if any) even if overlooked by the Lead PI to ensure compliance with our policies and guidelines.

Saad:
How would you describe the support for clinical research in Qatar?

Manager 5:
In general, I think it's amazing compared to my background in the United States where the financial aspect was very challenging when it comes to getting thousands of dollars while here, they are very generous at all levels. This is from the financial aspect. From the legal perspective, I think it is the challenging part because it a nascent research culture. There is not much maturity in the legal system for research. As of today, I don't see any legal framework for research. We reviewed a draft a couple of years back but I am not sure if it was implemented but then it is important before we release millions of dollars that we have a legal background to support it. We started building this when we are almost ten years into awarding funds and that too was partially built on a trial and error basis by looking at the US system if it's doable in Qatar to apply the same. This means that there was no homework because it there was a background work done, there would have been an evaluation of the policies for their feasibility in Qatar before even releasing them. That created a lot of challenges to the investigators because after going through long phases of review and evaluation, most of them face difficulties with the IRB approvals. I see that it's not their problem alone because the proposals have been through the Research Office (RO) before reaching the review stage and hence the RO is aware of the ethical requirements needed initially and the expected load. All these things have to be assessed

before submission but usually this does not happen and the proposals then have to wait for six months to get the IRB approvals. Even for expedited review it takes a couple of weeks while actually it should be done in 48-72 hours because sometimes clinical trials involving patient safety can't wait that long. We need this interactive culture that is well equipped. Coming from Stanford University which is a very well-established clinical research facility, what I faced here was that there were no ethical committees that were well equipped with DSMBs for example. I had to specify for each awarded project that required DSMB and I think they would have gone ahead without it if I didn't do that. I recommended many times to have the IRB submissions prior to the QNRF application and many institutions in US do that because this would save a lot of time for the investigators and the reviewers. If this happens, then everything will be already in place if the project is awarded and they can start immediately without further delays. I think this will be a very good step if we want to improve this aspect.

Another issue is the infrastructure. For example, the vivarium at Qatar University (QU). The promise was to be functional by 2014 but as of now it does not accept all the animals that were promised initially for research. So, what happens is that when we receive the proposal for evaluation, the investigator says that the animal work will be done at QU vivarium but later after awarding, their application to QU gets rejected because they don't have that specific type of animal required for the research. Eventually the investigator changes the whole plan and decides to do the animal work outside which defeats our purpose of building research capacity within Qatar. So, we lose the value of helping the Qatari research culture and the money because its going outside Qatar. I think if we look at the millions of dollars that are being diverted to outside Qatar because of this limitation, then the management of the vivarium might need to reconsider their decision about the list of animals that they provide and extend it further. Also, the cost is unusually high compared to the cost of performing the work outside and I am not sure about the reasons behind this. It could be due to the current embargo that Qatar is facing from its neighboring countries but still it shouldn't be this high.

Also, there is the issue of access to data. For researchers being able to submit a project, they need to have some preliminary data about the population and the disease prevalence. Initially, the system here was very conservative when it comes to data access because there was no Cerner available and any access for data needed many stages of approval. To go around this, the researchers used data from outside Qatar, which could sometimes be unreliable, to build their proposals and this is not right. Lack of epidemiological studies relevant to Qatar was a very big challenge. Even after we started having studies, there were issues with access to the data from these studies. Currently with Cerner and Qatar Biobank there is a lot of improvement in this regard. The quantity of accumulated data is massive to make it a reliable source.

Saad:
And how would you describe the support from your institution for clinical research?

Manager 5:
Our role is a mediator but not a problem solver. However, we are able to identify the challenges if we get a glimpse of it and link them to the solution. For example, the first issue I raised when I came here was having access to data from private and public hospitals because having the public hospitals data alone would not be representative of Qatar because as you know most Qataris depend on the private hospitals. This issue is still ongoing however with Cerner, I hope they link it with the private hospitals and then access to data would be simpler and wider. We go through these kinds of difficulties and keep the as lessons learnt to take opportunity and raise it in any meetings to improve these issues. However, things are going forward but slowly and I think they could go faster with some sincere efforts and devotion to resolve these issues because time is precious and other countries are developing quickly in improving the health of their populations. The challenges are sometimes beyond the capacity of the researchers and as a funding agency we sometimes communicate with stakeholders through meetings and events but then our communication is limited to certain issues only as we cannot intrude ourselves in details or internal institutional issues. We try our best but then we cannot promise to resolve everything.

Saad:
How would you describe the funding for clinical research in Qatar?

Manager 5:
As mentioned earlier, the funding is generous but identifying the priorities needs more work. We didn't get any tangible outcomes like we didn't solve the diabetes issues; we didn't even come up with a new biomarker and this takes years to happen. As you know, drugs take 12-15 years until they make it to the market shelves. We started in 2007 and we haven't reached there yet, assuming that we have something discovered something promising in 2007 however there is progress. We started from zero and with all my due respect to the research happening in different institutions, it's not really focused the way we wanted to focus on Qatar. What we see in these institutions is that the researchers are working based on personal interests and their research background so the contribution to the research in Qatar is limited in this case. Of course, there are common denominators when it comes to common knowledge and skills but excelling in research requires focus for long years to make a difference. I hope we have a tangible outcome within next 5-10 years but as of today, it's too early to say did a difference with the funding spent. We are generously funding the priorities which are defined based on data generated over the years and relied on the MOPH data however we don't have many epidemiological studies in Qatar which is something very challenging to identify weaknesses and gap analysis. I think we did very well, given the limited resources we have and tried to fill all the gaps. This year, for example, we expanded the limits and widened the topics so we hope to receive more applications.

Saad:
Going back to what you said about tangible outcomes, there have been views by other managers that the expectations that the funders have from their "modest" investments are unrealistic. Would you support this statement?

Manager 5:
Well it depends on how big is your dream because if you are determined to make a difference, then you will regardless of how much you have. You have to be creative. From where I come from, we have been through difficult times as a country where we burnt tires to make bags and move on. Need is the mother of inventions and God gave us this creativity and mind to adapt and excel with the little we have. I believe many of them are spoilt to the extent that they just need fresh money coming every time so they don't need much effort to be creative and trying to get the most of what they have. If you have a dream worth 3 million dollars but you have only one million dollars, you will adjust it in a way to make the most of what you have in hand and then build a case for getting the additional funding or maybe divide your dream into phases. If you show that your proof of concept is promising, I guarantee you that we will fund the remaining stages of your project. We have been very generous initially and we didn't make much out of it. We understand that there were challenges but the promises that we got were very disappointing eventually. There was the exceptional grant that was awarded for five million dollars but then the results were not as expected because they faced many challenges related to cultural issues that could have been avoided if this was taken into consideration during the design stage. The challenges faced by this project is one of the main reasons why we introduced the programmatic review after the scientific review to ensure feasibility of implementation in Qatar. We have other exceptional grants with similar funding and we hope to have some outcomes out of them in future.

Saad:
How would you describe the attitude of clinicians towards clinical research in Qatar?

Manager 5:
God be with them, given the limited time they have! Since day one, I have been advocating for protected and since HMC is the teaching hospital for WCMQ and QU, this is very important. In other parts of the world, people usually kill themselves to go to teaching hospitals to get more time for research. There must be a minimum set protected time for research, around 20%, because you will never progress without research. Unfortunately, in HMC there is no protected time. The clinicians have so many beautiful ideas and they are sincere to make it happen but they do not have time and I canty blame them because their first job is the clinical service. Hence an increase in manpower is required to have at least 20-40% of protected time for research. Without having quality protected time for research, I cannot blame them that much for not performing better. I don't see much also because most of the them are trained to be clinicians and not researchers. In the modern medical degrees, a lot of research component is included within the education and it's the approach in getting knowledge that gives them research experience. Such systems give the freedom of being creative in doing things in a new way not done by someone earlier because each one of us has their own unique way of thinking and applying. In the US, no matter where you come from, you need to complete a rigorous training before you start any research even when you move from one state to another. I wish we had something similar here in Qatar and if we have it now, I am not sure about its quality. I think everyone should complete a training to be qualified as a clinician scientist.

Saad:
Most of the trainings you mentioned are for the post-award aspects of research projects but what about training to write research projects and grants?

Manager 5:
Yes, definitely it is required because sometimes even whole reviewing I come across proposals that are poor even grammatically and this affects the quality. However, it's not much different in US but they have technical writers in each department or institution who are responsible for writing grants or reviewing written proposals for further tweaking and fine tuning to make it appealing to the reviewers because the way of presenting an idea is very important to get funding. Hence as a scientist you would then focus on the idea and leave the writing and these details to the technical writers.

Saad:
Even with all the barriers you mentioned, we can still see a lot of proposals submitted by clinicians. How would you explain that?

Manager 5:
Because the clinicians collaborate with scientists who take care of all the writing, designing and submissions and clinicians are only recruiting the subjects. There is no significant intellectual input by these clinicians into the research. Again, if the clinicians had time, then they would have better ideas and outcomes by looking into the data they have from their patients or ongoing research. Sometimes they forgot even to renew the ethics and other important things that we have to remind them about.

Saad:
When we look at the regulatory framework and the policies that we have for importing drugs or new devices, for example, how would you describe its readiness?

Manager 5:
We might not be ready but then this does not mean that we don't have the potential. Qatar has a potential however I am not sure how focused we are to reach this level. Given the time we started, nobody grows this fast specially when it comes to science, we are challenging people who have been in the field for more than a century. Hence, we cannot compare them with a system (here) that is hardly 30 years old. If we think reasonably, I think we are doing well looking at when we started. We can do better of course but it's just that we need more sincere efforts in doing this for Qatar. That is the thing I feel is missing here because I see people do it for different purposes but it's different when you write or do something while believing in it. This can be noticed even in resubmitted proposals where we can feel how much sincere the investigator was in addressing the comments or if they did just for the sake of showing that they did their part by simply resubmitting. It requires really hard work to ensure that the money is being awarded to the right people because it's not easy to tell who deserves what. In order to be fair, we have to evaluate and reconsider and reconsider and reconsider at different levels until a final decision is reached. We did export a lot of science and knowledge to the world

thousands of years ago and we have the capacity to do that even now. It's just the confidence and sincerity that is lacking. For example, when I moved to the US, I could not be a scientist from day one although I am an experienced physician. The concept here is that if you get a grant then that's it - you are a king - but elsewhere in the world this will make you realize that there is so much to do to achieve more. Hence, I would encourage the Human Resource (HR) departments to accept only those graduates, mainly Qataris, who have worked a couple of years in those systems after graduation so that they have practical experience on how research systems function. If they work, then they have to complete a full training on the guidelines of research which will add to their experience. I think having this strong foundation is very important to realize that these systems are controlled by a set of guidelines and policies and not lose to individual controls. We hope to have a regional or national control agency like the FDA in future and also having the recently established pharma company in Qatar is a good start in this direction. We also need to have the regulations for safety and intellectual property of these imports or exports because it is a huge responsibility. So, we have the potential and we are taking it one step at a time because we can't leap in science.

Saad:
You have mentioned few barriers in the course of this interview like maturity of the legal system, infrastructure, data access, lack of epidemiological studies, protected time and training. Are there any other barriers that you wish to add?

Manager 5:
I wish I could meet all the investigators here and ask them to open their hearts and be more appreciative to what Qatar has given them so that when they give back, they give it from their heart, not for the job. Trust me no matter how much you get in your salary it can never pay you back the time and effort and health that you lose in reading and reviewing research papers or writing them. However, the most rewarding part is when you make a difference in someone's life and you leave a scientific legacy of your own. I think that the researchers should work with this mentality that they will leave behind a science that will benefit the patients and the future generations. I don't see this now unfortunately, there could be but very few I guess however when we reach to that level, we will definitely make a difference. After 10 years of investment, we have the money, a fairly good infrastructure, partially developed legal framework but the only think we need is sincere efforts.

Saad:
Do you think that the outcomes of these projects throughout the previous years have been successfully transformed into patient care or national programs?

Manager 5:
It depends on the areas where we invested. For example, we didn't invest much in infectious diseases or reproductive health because the priority was always to diabetes, cancer and genetic diseases like autism. We got tangible outcomes, for example, in prevalence of autism. For the first time now, we know how many children are suffering from autism and this should have been done years ago. Once you know the size of the

problem, it is easier to act upon it and address it scientifically and cost-effectively. I think it's too early to assess if we have made any difference or not because we just started and most of the projects are ongoing but I can see that we are on the right track. We know the problem now so we can act on it but how long does it take to make a difference depends on our sincerity and intentions. The intentions are good and Allah says that good intentions are always rewarded. Sidra is also a good addition to the clinical research and we have high expectation from them as well. However as of today, all what we have is mostly data but no drug or device that we can say is made in Qatar. This is not a weakness at all because as I said, we are in the early stages because the average timeline to reach is 12-15 years and we barely started ten years back. We highlighted the gaps and need to work on them but so far, we are in the right track. We have many great researchers who we can rely on since they are already trained rather than wasting resources on training them here – of course the case is different for Qataris where training is necessary to build local capacity.

Saad:
Do you have anything else that you think could add to the topic that I am researching?

Manager 5:
I would just pray for you to make it happen. It is a very nice concept and right to the point and something that was supposed to happen long ago. I hope you continue your PhD to cover the researcher's aspect and compliment both views on the barriers. Your research may improve the whole system and I pray it does. We need to change many things in the system and it has to be evidence based and your study is what will make it evidence based.

**** The interview is concluded by thanking the interviewee ****

Manager 6

**** The interviewee is welcomed to the interview and briefed about the study ****

Educational Background: Administrative

Age: Less than 50

Saad:
Could you please tell me about your role in the clinical research leadership at your institution?

Manager 6:
My role is in the research governance and operations. It entails basically the management of research operations in terms of operation sides including financials, procurements, services, managing day to day activities of the labs and regulatory aspects of the biosafety committee. Recently there has been a restructuring and all of this is renamed to research services. The research services now include the governance, contracts, regulatory and grant management.

Saad:
How many years have you been in this role?

Manager 6:
I have been in that role for about 3 years.

Saad:
How would you describe the support for clinical research in Qatar?

Manager 6:
The support in general, compared to my last 23 years in US before joining here, is very generous in terms of resources, finances, equipment, supplies, facilities – it's all A++ and top notch in these terms.

When it comes to the regulatory side, it's very primitive and in the beginning of its formation and a lot of work needs to be done for research on human subjects and clinical trials. I think there is a gap in a lot of regulatory and governance requirements. The MOPH research department has been very active and tried to engage us in forming these regulations and understating how to manage massive patient data, bio-samples, biobanks etc. but I think there is a lot to go to be worldwide benchmarked.

When it comes to return on investments, we need to understand how much we are getting out of the generous spending. I honestly believe there is a major gap in understanding our KPIs and how do we measure this return on investment – is it just number of publications? Or translation to bed side and how it impacted patient care? There are types of researches that are directly related to the patient care and mostly found in the academic hospitals and

tie the bench to bed so that connection has to be made. In my humble opinion as an operations manager, I think this gap exists and the link is not there. There are many discussions about innovations, personalized medicine and millions are invested into it but the tangible outcomes are missing. It could be just the beginning but there is a lot that could be done to expedite that path mainly from the operations and regulatory perspective. We don't need to reinvent the wheel as we can simply build on the processes of other systems and start from there instead of reinventing everything from scratch. To summarize research in Qatar, and not Sidra specifically, it's like you bought spare parts of a Ferrari but then they are only parts. So, if I want to go downtown, I need a car that will take me there not the spare parts but then you have to look how you can assemble the parts into a super car. Depreciation of medical and research equipment is 20% per annum compared to 10% in other industries so are we fast enough to utilize the investments we made or is the plan to keep pouring more and more into latest equipment without actual utilization. It is a dilemma worldwide on how to get return on investment but in developed countries it is brought back in the form of start-ups, venture capital, biotechnical industry where you discover a technology or a drug that pumps millions or even billions back into the system. It takes 18 years to develop a medication and put it on the shelves but once it does it generates billions. They have a history of doing that in the developed countries and they have many in the pipeline so every year something new is in the market that generates billions.

Here we see a lot of redundant work but no focused areas. We cannot be good in everything; no institution is good in everything. We have to define our trajectory, mission, vision to be fitting into the needs of the country. We have all of these things in paper but not in the reality. We have to incentive institutions to be aligned with the country's vision and focus for research. Research in country has been going on for at least 10 to 15 years now but when is the real assessment of where it's going? There should be a benchmarking every 10 years at least of where we are going when it comes to research outcomes and areas of focus. There has to be a single body at the country level that does these assessments. Right now, we are working as silos with redundant equipment, redundant budgets, redundant contracts but then the spending should be based on a long-term strategy. For example, if we look at the investment in the infrastructure like highways, sewage systems etc., these are long term investments because they will last for at least 100-120 years. Likewise, if we look at research, there are areas that take you on the long run. There are infrastructures that you can use today and after 100 years but there are other infrastructures that you can "flash" or "firework" now but then it's a very costly short-term investment.

The problem with the leadership here is that we have the best scientists but appointed as strategists but then they don't fit in this role. The best physicians not necessarily be the best managers of a hospital because a physician who is good in medicine only is different than a physician who has studied management. This dilemma exists not only in Qatar but elsewhere in the world that technical people when promoted into leadership without actual training for that post will eventually create disasters or move in a very slow pace until they learn by doing.
(a side discussion about MORALE curve)

So, it's not about the work someone is doing or the funding they get because given the size of Qatar, we can't afford to work in silos but instead as one focused system.

Saad:
I think this is possible given the geographical size of Qatar and the fact that all institutions are under a single regulatory authority.

Manager 6:
Yes, but this is where we differentiate good leaders and bad leaders. I use the example of a street in Jordan where there are 8 shops side to side selling falafel but only one of these 8 shops will have customers lined up until midnight. The raw material is same but the way you deal with it makes all the difference. So, we can have the best equipment, best researchers and best facilities but if we have a paper mentality to manage these, then that is a problem. Not a single health institution in Qatar uses prescriptive analytics in healthcare which means that we are using basic analytics for the billions of dollars invested in the top-notch facilities. If we run those analytics and generate massive data, this would then cause experts from Harvard and MIT to come and work here because we would be sitting on a gold mine of research data. The Qatar Genome Project is a good example for this concept because having this data is the next billion-dollar medication. We have to be clear on the management of this asset whether we do it by scientists or business innovators.

Saad:
You referred to the significant funding that is being invested but then there are other opinions that the expected outcomes from this funding is not realistic. How would you see that?

Manager 6:
No that is not true. If you visit a lab in NIH, it is merely a booth and 50 people share one piece of equipment so you can't compare it with here. If you talk about salaries, we have the highest else they wouldn't be here. So, I can guarantee you it's not the salaries or the science – then what's missing? If the question would be how to attract scientists then I would agree to some extent but not funding because there is enough money for research but then the question is if you are building an infrastructure or a flashy firework like I said before.

Saad:
I have been through all the clinical research institutions in Qatar as a part of this study. I am not sure how things are managed at your institution but other institutions have a budget for research but then there are several obstacles in using that fund so its not used.

Manager 6:
This takes us back to the same question about who is managing – scientists or managers. These are all operational issues and if you have the right manager who ensures that all obstacles are removed, there will be progress. So, it's not about the funds you have but about how it is managed and how you have the right person in the right seat based on

their qualifications and skills. In most cases here, there is a mismatch where we place the right person in the wrong seat. When an institution fires 500 people and I am about to hire 500 people every 2 years, then there is something fundamentally wrong in the management system. Is it a silo called HR? Or the scientists? Or the management? There should be someone to look at all these silos together to make a smart decision. Sometimes you need to invest money to save money but here that is difficult to convince them with this idea of investment to save. There are millions of papers written on how to manage when an economy is down or a company is suffering financially – it's not something new to be studied. Having been in so many institutions in my career, I can tell you. The only thing missing for research across Qatar is proper management and oversight. Here, I am referring to the overall cross-institutional strategic management of the research pot.

Saad:
How would you describe the overall attitude of clinicians towards research at your institution?

Manager 6:
If you remember the morale curve we discussed earlier, I would say that 60% are disengaged because of all the barriers and obstacles and the 40% are still continuing because I would say they are positive thinkers.

Saad:
Don't you think that this percentage of the disengaged researchers would then become a barrier/ burden to the system?

Manager 6:
Only if we leave them that way but if the leadership is working closely with them to ensure they are re-engaged, then they won't become a barrier. Again, there are many studies about inexpensive efforts that could increase employee morale across hospitals but then if the leaders are not going to listen or understand these problems, then it will lead to problems. This dilemma is worldwide – I am the boss I know everything. The first thing they need to realize is that they don't know everything because it is the front liners who know the problems and hence, they need to be engaged in the decision-making process and the strategic management of the institution. I can see that when it comes to the scientists and researcher, we are bringing in top notch quality but then the people who run the operations for these scientists are not very high level. So, we need restructuring but restructuring not necessarily means removing the people but investing in them by further training and coaching. Hence, they need to realize that world class scientists or clinicians do not really make the best managers, unless they have been trained for that role.

Saad:
So, talking about the barriers, you mentioned one of them is the management?

Manager 6:
No, it's not the management actually but the leadership. Management means you give them a list of tasks to complete and they will do it. We have very good managers around

here. Leaders need to identify the ecosystem, strengths, weaknesses and how people from country A and B should be treated differently based on their individual characters. There are books and studies on emotional intelligence in management and how to create an organizational culture. It's not about putting values on the wall or website but about how they are implemented and practiced in the organization.

Saad:
Let's start listing other barriers to conduct clinical research in Qatar.

Barriers	Discussion
Regulations	Regulations are primitive and need a lot of development
No clear KPIs	No clear KPIs or benchmarks, universal mission and vision, alignment to that mission and vision, unstable leadership to support the mission and vision.
Lack of measures	No balance score cards or added value
Data management	Absence of data retention, use and management
Leadership	All barriers and obstacles are traced back to leadership
Operational barriers	HR and finance related issues
Lack of understanding of governance roles	The management depends on the feedback of the "violators" to review the performance of the governance officers. Instead of measuring the number of tickets, violations stopped and corrective actions, they will measure the satisfaction of the violators against the officer.

Saad:
When you said about the frequently changing management, is it something specific to here or have you seen this during your professional experience outside?

Manager 6:
I started the health care systems engineering department which was only one of the 5 in the whole US and by the time I left there were 20 institutions applying the same concept across the US. Here, I have been trying to convince them for the last 5 years with no success at all although I can confidently tell you that the entire country does not have a single health care engineer doing something as of now. So, going back to your question, institutions do change their strategies but they do that in a systematic way. The university where I was used to be a pure engineering college that has nothing to do with healthcare but they changed their strategy systematically to include healthcare engineering through our department. Now, after 5 years since I left them, they have a vice president for health management and a whole department for health. So, these changes are a system of checks and balances and not a one-man decision. It does involve risk but then it's a well calculated

risk. For example, Warren buffet had a company and its manager decided to invest $300 million into a venture which eventually failed. Warren then call this manager to his office and the latter believes that it is the end of his journey in this position but instead warren asks him about his future plans for new programs. Surprised and shocked, the manager tell warren that he was expecting to be fired and Warren tells him "didn't you take all the precautions before starting the venture?". Warren replies that" as long as we learn the lessons from this, we are in the business of taking risks." This manager gets so motivated and committed that he created the one billion industry that contributed to most of Warren Buffets wealth. So, investing or taking a risk is not a bad thing but as long as its well calculated.

Saad:
When benchmarking, do you think that we should benchmark ourselves with the elite or be realistic and match with someone on a moderate level?

Manager 6:
Well if you are spending similar to the elite, equip more than the elite, supply more than the elite and you have open cheque but then expect less than the elite then, with all due respect, something is wrong. We should always set the vision to the stars so that even if we don't reach there, we still reach somewhere high but if your target is to benchmark with middle east, you will end up even less than that. The question that I should be asking you is "what is missing for us to reach there?" and you will not find an answer because we have everything including scientists, equipment, safe environment and diverse research subjects. In the beginning there could be some problems but then why do I have to set on this long path when I can use a super expedited path by learning from what others have already done so far. So, going back, it always traces back to the leadership.

Saad:
How do you see the translation of the research outcomes into patient service or national programs?

Manager 6:
For patients, it is similar to the politicians who have to show them actual spending as infrastructure like roads, bridges, services etc. but if they are building bridges to nowhere, the public will not favor them in the next elections. In the spectrum of research, you have basic at one end and the clinical trials and studies like surveys of the other. The strategic question here is on what side of this spectrum should we focus? Is it academic research which usually generates papers and add to the international literature or the clinical part where the actual translational and clinical research is happening? That is the right question and I am not the person to answer it but I would love to see it touch the patients. When you come to Sidra, it is supposed to be a facility where you can do all the fancy stuff for which you otherwise pay millions of dollars outside for your patients every year.

Saad:
Taking into consideration the barriers you identified and the positive aspects of the system, how would you describe the readiness of the system here for clinical research?

Manager 6:
I think it's not the right question to ask. The right question that I would like to answer is what does it take Qatar and my institution in particular to be an elite. I believe it's just the last mile – the leadership.

Saad:
Why is it the last mile and not the first?

Manager 6:
Because we have all the other elements like scientists, fund and infrastructure. We have the parts of the Ferrari, we know its name, we have the manual, we know how it could be assembled and all we lack is the person who has the right skills to assemble these parts and make it run. So, it's been a long mile but it's the last mile.

**** The interview is concluded by thanking the interviewee ****