CHAPTER III

METHODOLOGY AND APPROACHES TO RESEARCHING ORGANISATIONS

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3.1. Introduction

The previous chapter has presented an introduction to the theoretical frameworks that can be applied to the study of organisations. Many of the studies discussed within the organisational literature raise methodological issues relevant to the study of organisations in general. The purpose of this chapter is to describe the methodological issues and develop a strategy that addresses these issues as related to academic medical research centres and the relevance of the methodology to answering the research questions raised in chapter one.

3.2. Methodological issues

Organisational theories are generally rooted in the sociological literature and are drawn from both theoretical and empirical research (Dunkerley, 1972). Organisational research methods frequently resemble the study techniques of the social sciences especially the field survey and data are regularly analysed using sociological dissertation (Ackroyd & Hughes, 1992; Bausell, 1991; Bryman, 1992; Clegg, 1990; Dunkerley, 1972; Perrow, 1967). The development of organisational theories also involves empirical research, conducted so as to test the propounded theoretical ideas and to test propositions (Merton, 1968; Popper, 1968). Methods adopted by researchers in the
organisational and sociological arenas include normative, interpretive, critical and
dialogic nature (Deetz, 1996) and occasionally case studies, comparative methodologies,
participant observation, grounded theory and cognitive mapping (Dean, 1994; Glaser,

However, there has been an increasing trend toward the use of empiricism in
social sciences, including organisational research (Brinberg, 1985). Earlier, organisational
analysis was largely concentrated on the description of actual organisations and their
administrative practices and on the development and testing of normative prescriptions
deduced from a few basic assumptions. Lately, major management research
programmes (Blau & Schoenherr, 1971; Blau, 1965; Hall, 1977, 1981; Lawrence &
Lorsch, 1967; Pugh, 1990; Woodward, 1965) are employing systematic and comparative
methods to study the relationships between organisational structure, function, and
environmental context of organisations. Some analyses have compared the structural
features of organisations (Georgopoulos, 1986; Gerwin, 1981; Powell, 1991; Schimpff &
Rapoport, 1997), while others have done so in relation to their external environments
(Johnston, 1976; McCaskey, 1976; Osborn & Hunt, 1976; Ouchi, 1974). The major
purpose for this approach is to measure the degree of variation in organisational
structures and to establish the conditions of such variation (Blau, 1965). In this way, a
systematic approach is useful for comparing organisational environments and structures
in order to observe relationships.
Pugh (1968) states that when organisations compared are very deviant in dimensions then the postulates related to the variation would be of limited use. However, systematic comparative analyses are used to establish general principles about organisations (Jackson, 1978) and to categorize organisational characteristics (Blau, 1965; Perrow, 1967; Udy, 1965).

Organisational researchers mostly search channels of formal structure and then relay these to environmental factors.

Case study methods are frequently employed to generate in-depth descriptions of an organisation. Single case studies are intensive assessments of one organisation or work group, which often involves the collection of longitudinal data and assessments along a number of variables. This method may utilise a variety of data collection techniques, including document analysis, secondary sources, observations, participant observation, survey questionnaires and interviews. Documents that may be analysed include financial reports and official communications, such as the organisation's website. Access to organisations for the purpose of observation, document analysis and staff interviews is dependent on organisational policies with respect to research and the nature of the organisation's formal communications.

While case studies might collect some quantitative data, most of the data is collected using interviews, observations, document analysis and anecdotal information.
and analysed using descriptive techniques. The data collection process for case studies relies strongly on the observational and interview skills of the researcher. So while a case study approach might provide a descriptive analysis of one or two organisations in detail, the generalisability of the findings might be quite limited (Kilmann, Pondy, & Slevin, 1976b; Shaffir, 1991; Vidich, 1992; Yin, 1994). In fact, a major criticism of classical case study design is that they provide little or no basis for the comparison of observations between organisations (Bryman, 1992; Burrell & Morgan, 1979; Frankfort-Nachmias & Nachmias, 1992; Kervin, 1992).

Researchers who employ case study methodologies justify this approach by substantiating that the size, nature, hierarchy and complexity of many organisations prohibit the in-depth analysis of more than one or two (Ackroyd & Hughes, 1992; Fischer & Sirianni, 1994).

Case studies have also been criticised for their lack of measurability and objectivity since the small sample sizes in most case studies do not allow for a statistical treatment of similarities and differences between organisations. This lack of statistical rigour further reduces the ability to generalise research findings from case studies to the wider population of organisations.

Thus, while a case study method is frequently employed to collect in-depth data, the scope or breadth of single case studies might be limited. However, case studies have
been described as an effective method for gathering information and generating hypotheses, particularly when the research questions are exploratory in nature (Jackson, 1978; Yin, 1994).

Many case studies reported in the organisational literature are focused on only one or two organisations. These studies involve the collection of longitudinal and observational data that is rich in context, interaction and depth.

In studies of hospital staff, Strauss (1994) employed both formal and informal interviewing techniques. The formal technique used an interview guide that permitted some scope to the flow and direction of the interview. However, these authors found that informal interviewing was a more productive means of data collection than the formal interview process in which some hospital staff were reluctant to participate. The researchers' offices were located within the hospital, which enabled not only participant-observation and document analysis, but also provided opportunities for informal and unstructured interactions and interviews with staff.

The most commonly used tool for generating broader, quantitative data in social and organisational research is the survey questionnaire. Surveys have limitations with respect to how the survey population is constructed, the nature of the survey sample and the response rate. The comparability of survey responses, especially in inter-organisational research, might be limited, though, particularly if the organisational
contexts of the respondents are too dissimilar to provide a meaningful aggregation and interpretation of responses (Fischer, 1994; Perrow, 1967).

Organisational research uses both quantitative and qualitative methods for collecting and analysing data. The context and scope of the research questions dictate the choice of methodologies and techniques employed. Qualitative methods could be employed as well to offset these limitations and to provide both in-depth data and a broader context for the interpretation and analysis of quantitative data. These are expected to be contributing factors in how clinical research is managed in AMCs, yet which may not be adequately or efficiently identified using broader enumerative techniques.

3.3. Methodological strategy

As an exploratory study, the research questions posed in chapter one are not aimed at establishing causality, but rather at identifying patterns and suggesting hypotheses for further research. This study has therefore adopted a methodological strategy involving multiple data collection methods and sources. This strategy expands the breadth and scope of study by including primary enumerative and secondary archival data from as many AMCs as practicable, in order to improve comparability and hence identify patterns of structure and environment. This strategy is also intended to generate in-depth data on incidents and histories through the use of archival data and
informant interviews. Therefore, data pertaining to the incidents and histories of clinical research management in AMCs has been collected mainly through secondary sources.

The design for this study incorporates data from a variety of sources and employs both quantitative and qualitative methods over a period of three years.

The following table summarises the relationships that identifies the stages used as the principal focus, exploratory focus and confirmatory focus for each of the research questions:

1. **What is the contemporary context of clinical research in AMCs?**
2. **What are the formal structures and mechanisms that enable clinical research management in AMCs?**
3. **What are the informal structures and mechanisms that enable clinical research management in AMCs?**

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Category</th>
<th>Secondary Data</th>
<th>Survey Questionnaire</th>
<th>Interview</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Research Question 1</td>
<td>Principal focus</td>
<td>Confirmatory focus</td>
<td>Confirmatory focus</td>
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<tr>
<td>2</td>
<td>Research Question</td>
<td>Exploratory focus</td>
<td>Principal focus</td>
<td>Confirmatory focus</td>
</tr>
</tbody>
</table>
The first stage of study was focused on the first research question: What is the contemporary context of clinical research in AMCs? The methodological aim in the first phase of this study is to collect archival data in order to describe the historical and environmental context of clinical research in AMCs. The first phase also involved the compilation of histories and incidents derived from secondary sources. These data provided material for the development of case studies related to the experiences of individual organisations. In addition, these data were analysed to determine organisational comparability and for describing emergent patterns or constructs that provided a foundation for the enumerative approach required for the second research question.

Stage one was also intended as a means to identify a vigorous survey sample for stages two and three. A study of AMCs in the researcher's Kerala environment yielded only a very small sample.

The methodology employed in stage two of this study explored the patterns and assumptions derived from stage one and were focused primarily on addressing the
second research question: What are the formal structures and mechanisms that enable clinical research management in AMCs?

This phase utilized a survey questionnaire distributed to the sample population identified during the first stage. The purpose of the questionnaire was to collect data related to the scope and scale of clinical research activity and to describe the formal structures and means employed in managing these activities. Through the use of open-ended questions, the survey instrument also collected qualitative data through questions that probe the informal structures and means employed by different AMCs.

As described earlier, the validity of survey data could be limited by a low response rate. It must be recognised, however, that the individuals in the selected sample might be too busy to participate, regardless of their interest in the subject. The strategies adopted for extenuating the risk of a low response rate in this study include the identification of a vigorous survey sample of key individuals by means of the first stage of research, the development of a suitable yet brief questionnaire, reminders, and incentives.

While it is important to observe the differences among the participating AMCs, the methods of enquiry needed to employ comparable terms and phrases, such as roles and position titles, to which respondents from all AMCs could relate.
Data collected in the second stage of this study were expected to contribute to the first and third research questions as well. In the case of the first question, the data collected in stage two might be confirmatory to the data collected in stage one. In the case of the third research question, the strategy involves the collection of qualitative data in the form of responses to exploratory, open-ended questions in the survey questionnaire. Survey respondents were encouraged to a discussion for sharing comments and feedback on the survey results. From this discussion group participants were shortlisted for the final interview stage of this study.

Stage three of this study was focused on the third research question: What are the informal structures and mechanisms that enable clinical research management in AMCs?

The literature suggested that informal organisational structures may be difficult to detect and quantify as they are not usually documented or articulated, and perhaps may be unique to an organisation. The methodological strategy in this phase was to generate qualitative data related to informal structures and professional issues through the use of both open-ended questions in the survey questionnaire and semi-structured in-depth interviews. The purpose of this last phase was to probe more deeply into the survey responses and to explore emergent issues relevant to the research questions.
To summarize, a case study approach was employed to assemble these data to identify similarities and differences in both context and structure. These points of comparison between formal structures and clinical research management processes identified in stage one supported in the development of the survey instrument as well as the sample population. In stage two the survey instrument collected data that facilitated broad comparisons of formal structures and management processes. By using exploratory questions with open-ended responses, the survey questionnaire also explored the strategies and issues related to structures and processes. The analysis of these data added to the third research question by identifying informal organisational structures related to clinical research management. This study therefore employed a combination of qualitative and quantitative data. Moreover, the data collected using these multiple methods added to the breadth and depth of the results and their analysis.

The methodology adopted in the current research may be reiterated as below.

3.4. **Statement of the problem**

Clinical research is a complex activity and one for which demand is increasing as new therapeutic agents and devices are presented for human testing. It is important that AMCs understand their clinical research management processes in order to maximise the potential for improving health outcomes and for generating revenue while
minimising the associated risks, which requires in-depth research to generate a suitable organisational structure for AMCs.

This led to the three fundamental research questions.

1. What is the contemporary context of clinical research in AMCs?
2. What are the formal structures and mechanisms that enable clinical research management in AMCs?
3. What are the informal structures and mechanisms that enable clinical research management in AMCs?

These research questions were translated into the following objectives.

3.5. Objectives of the study

The objective of this study was to explore the organisation and management of clinical research in Academic Medical Centres through

1. Study of existing literature on Organisation and Organisational Structure
2. Analysis of the roles, functioning, and relationship among the various roles of Clinical Research in Academic Medical Centres
3. Elucidation of the interrelationships among the roles and available Organisational Structures, and
4. Suggestion of a suitable structure for Academic Medical Centres

3.6. Data Collection

The researcher has used both primary and secondary data in the present study.
3.6. 1. **Primary Data**

Source: Executives and research personnel in Academic Medical Centres in the study area

Method: Scheduled Interview and Questionnaire are proposed to be utilized

3.6. 2. **Secondary Data**

Source: Existing literature from Internal sources of the sample units, research publications, and public documents.

3.7. **Survey Instrument Development**

A survey questionnaire methodology was chosen for several reasons. Firstly, surveys have the advantage of relative ease and speed of both participation and analysis. This was considered an important advantage for maximising the sample size. Secondly, the correlation between sample size and cost of administration is lower than other methods of data collection (Dillman, 1999). Thirdly, the survey instrument is capable of collecting both quantitative and qualitative data to allow multiple analytical approaches. This was considered important for eliciting responses that could be explored in further depth during the interview phase. However, the response rates of survey questionnaires may be limited by practicalities such as the typically heavy workloads of individuals managing complex activities in complex organisations. These
demands were expected to limit the amount of time available for participation in the
survey, and required that the survey instrument have a minimal impact on participants' time. In order to maximise the ease and speed of participation, care was taken to ensure that the time required to complete the survey instrument did not exceed 30 minutes, with the option to participate further through an on-line discussion forum and the interviews. However, the brevity of the instrument needs to be balanced by the need to maximise the quality and depth of the data. The survey was therefore designed to group the themes and types of questions used. Each part of the survey was prefaced with the purpose of each question. A combination of both closed and open-ended questions were used. The open-ended responses were expected to collect exploratory data with respect to the third research question and to follow further avenues of enquiry through the on-line discussion forum and in-depth interviews in phase three.

This study employed multi stage stratified random Sampling method to select participants typical of those having roles or positions in clinical research management at AMCs in Kerala.

Given that the vast majority of this population was identified through web-based sources, a web-based survey, in addition to a paper-based survey, was considered to interrogate the entire population. On-line survey methods were also considered to be cost-efficient for data collection by reducing or eliminating the costs of paper, printing, postage and data entry. Electronic surveys have also been shown to reduce errors
resulting from data handling during collection, processing and analysis (Dillman, 1999). However, considering the limited geographical area, online method was not adopted for the present study.

The survey instrument comprised of four parts.

The first part focused on variables at the macro-organisational level, particularly the formal organisational structures, tasks and processes for clinical research management. These sections of the questionnaire collect demographic data such as country, age and volume and types of research conducted. Other demographic questions included the respondent's position title, educational background, the type of organisation they work for (e.g. hospital or university) and the number of years they had been in that position. As it was anticipated that the target sample would include respondents with varied clinical, academic and/or administrative roles, the percentage of time devoted to research management tasks was also queried.

In part two, the primary purpose of the questions was to determine the volume of commercially sponsored studies undertaken relative to publicly or institutionally funded research, as this could have an effect on responses concerning the management tasks covered in part three of the survey. Respondents were also asked whether clinical research is explicitly recognised by their organisation as an important activity, testing
the traditional notion that AMCs embrace research as part of their organisational
mission.

The purpose of the questions in part three was to generate a data construct that
could be translated into diagrammatic representations of the formal clinical research
management structures in the AMCs.

In part 3(a), respondents were asked to list up to ten position titles for individuals
responsible for clinical research management decisions in their organisation, and the
percentage of time devoted to this role. The rationale behind this was that some
positions in clinical research management might include a number of roles. For example,
the dean of a medical faculty may only spend a few hours a week on research
management tasks. In order to understand the flow of decision-making authority in
clinical research management, respondents were also asked to identify the institutional
and reporting relationships between positions. The responses to these questions
enabled the reconstruction of formal organisational structures for clinical research
management, which are presented diagrammatically in appendix D.

In part 3(b) respondents were asked questions regarding the AMCs top three
positions of importance in the approval, tracking and accountability for clinical research.
These questions were used in order to extend and validate the positions and tasks
identified in 3(a), and also to pinpoint 'ultimate' institutional responsibility. That is, to
find out which organisation in the AMC was the locus of authority and control with respect to clinical research management.

In part 3(c) participants were presented with a list of ten clinical research management tasks and asked to assign a relevant position title to each task. The purpose of these questions was to refine and validate the responses from parts 3(a) and 3(b) as well as to introduce the tasks that would be presented again in part four of the survey.

<p>| Table 3.2 |</p>
<table>
<thead>
<tr>
<th>List of Clinical Research Management Tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processing applications for approval of clinical research (other than ethical review)</td>
</tr>
<tr>
<td>Budgeting of projects</td>
</tr>
<tr>
<td>Approving research project contracts</td>
</tr>
<tr>
<td>Granting final approval for projects</td>
</tr>
<tr>
<td>Daily project management</td>
</tr>
</tbody>
</table>
The list of clinical research management tasks, presented above, was compiled from the findings from data collected in review of literature phase of the research and the researcher's professional experience.

The literature review and the data collected in earlier phases of this study indicate that many AMCs have undergone significant structural change in recent years. To test whether there had been recent structural changes in clinical research management, question 3(d) examined the length of time that current management processes had been used and what, if any changes to those structures or processes were anticipated. Open-ended response opportunities were used to explore respondents' perceptions of the factors that drive these changes and the likely impact of these changes on clinical research management. The responses to these open-ended questions were expected to extend the depth of the closed-question responses and provide additional information that could be explored through the on-line discussion forum and in-depth interviews.

In order to validate the tasks involved in clinical research management, part four of the survey focused on variables and issues at the micro-organisational level, such as
the importance and effectiveness of task activities, key success factors and perceptions of the overall effectiveness of clinical research management.

To collect these data, questions 4(a) and 4(b) employed a ‘Five Point Likert Rating Scale’. In question 4(a), respondents were asked to rate their organisation's effectiveness in the ten tasks as either poor, fair, good, very good, or excellent. In question 4(b) the respondent rated the importance of each task as either not important, somewhat important, neutral (neither important nor unimportant), moderately important, or very important.

In the last questions of part four, respondents were asked to identify what they perceived to be critical success factors in the management of clinical research in their organisations. Open-ended questions were employed to elicit information regarding informal relationships and processes that might otherwise remain invisible in the structured responses. Finally, respondents were asked to make and justify a judgement concerning their organisation's overall effectiveness in managing clinical research. In other words, on what basis does their organisation achieve or not achieve its goals in this respect? With that cue, it was expected that the respondent would identify structures and mechanisms, whether formal or informal.

Prior to its distribution, the survey instrument was put through three levels of testing. The first involved pre-testing the paper-version of the survey instrument by a
group of two clinicians and two administrators involved in the management of clinical research in a public hospital in Kerala. As a result of the feedback obtained, refinements were made to the relative positions of closed question response options in order to improve ease of use and the overall user experience.

3.8. Interview methodology

A combined approach, involving both a survey and personal interviews, was adopted after consideration of practicalities such as accessing subjects, administering the questionnaire in several countries and ease of data analysis. The interviews provide another tool for collecting qualitative data, which is expected to assist in the interpretation of emergent patterns in the questionnaire data.

The objective of the interviews was to elicit information to substantiate and elaborate the responses to the survey questionnaire. The interview guide specifically sought to expand on the relationship between hospitals and universities in the management of clinical research by prompting interviewees to describe details of both the formal and informal structures that their organisations used (or didn't use) to manage this complex relationship. In particular, the relationships between professionals and management, as well as factors that respondents felt are critical for the effective management of clinical research, were explored and questioned in detail.

The items of the interview guide are summarised below:
1. Is your employing institution a university, hospital or health system?

2. How long have you been involved in the management of clinical research at this institution?

3. How would you describe the overall governance of this institution?

4. If there is more than one, does any one institution primarily manage clinical research?

5. What is the overall process for managing clinical research at your institution?

6. How is the effectiveness of this management evaluated? (How often, by whom, what criteria?)

7. Describe the effect of the following factors on clinical research management:
   a. Increase in pharmaceuticals presented for clinical trials
   b. Regulatory requirements
   c. Availability of research time for clinicians

8. What other factors do you think impact on clinical research management?

9. What do you feel are the critical success factors for clinical research management?

The interviews were structured only to the extent that the nine questions of the interview guide provided a focus of discussion during the interview. All interviews were conducted by the researcher, after perusing the survey questionnaire, and they lasted up to one hour. The interviewees received and approved the notes taken during the interview and were offered the opportunity to edit and expand on these notes. The
interview methodology had the advantage of presenting, reformulating and probing the answers to questions or details of issues of interest and importance in real-time.

3.9. Sampling

3.9.1. Area: Kerala State of India

3.9.2. Unit: Executives and research personnel in Academic Medical Centres in Kerala.

3.9.3. Size: All Executives and 20 percentage of the total number of Research Personnel employed in three of the Academic Medical Research Centre in the study area (one government owned research centre, one government aided research centre, and one private owned research centre) were considered as sample respondents for the present research.

3.9.4. Method: Multi Stage Stratified Random sampling method was adopted for the choice of research personnel.

Table 3.3

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Organisation</th>
<th>Executives</th>
<th>Research Staff</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Central government owned</td>
<td>5</td>
<td>16</td>
<td>21</td>
</tr>
<tr>
<td>2</td>
<td>State government owned</td>
<td>3</td>
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<td>10</td>
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<tr>
<td>3</td>
<td>Private owned</td>
<td>4</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>12</td>
<td>35</td>
<td>47</td>
</tr>
</tbody>
</table>

3.10. Tools for Analysis
3.10.1. *Elementary*: Tabulation, Percentages, and Diagrammatic Presentations

3.10.2. *Higher Level*: Correlation Analysis and Test of Significance were found sufficient to realise the objectives and answer the research questions.

3.11. **Limitations of the study**

3.11.1. *Procedural*: The study was limited to the research design and data collection

3.11.2. *Temporal*: The study was limited to a period of two calendar years 2012 and 2013

3.11.3. *Analytical*: The limitation of the statistical tools influenced the inferences utilized in the present research.

3.11.4. *Geographical*: The study was limited to Kerala State of India