CHAPTER IV

ANALYSIS OF SECONDARY DATA

4.1. Introduction

4.2. First Research question

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4.5. Summary
4.1. Introduction

This phase of research has contributed findings from secondary data collected from AMCs that can be applied to the research questions presented in chapter one.

4.2. First Research question

The first research question asks:

What is the contemporary context of clinical research in AMCs?

As described in chapter one the AMCs in the present study have all endured similar changes in their operating environments. These changes include economic
constraints, restructured health systems, increased competition for funding, an increased number of clinical trial protocols on offer and increased regulatory demands in respect to the conduct of clinical research. Within many of these AMCs, the internal pressures impacting on clinical research management are also similar: internal restructuring, lack of clinical time for research, increased demands for accountability, pressure to commercialise research findings and the promotion of research to inform evidence-based clinical practice.

These findings indicate that the environment, or context in which AMCs and clinical research operate has been dynamic in recent years and suggest that these conditions might have implications for AMC structures, policies and procedures with respect to clinical research.

The literature on organisational theory presented in earlier chapter suggests that the environment in which AMCs and clinical research operate might impact on the formal structures and mechanisms employed in the management of clinical research.

4.3. Second Research question

The second research question asks:
What are the formal structures and mechanisms that enable clinical research management in AMCs?

The data from this phase of research suggest that AMCs have responded to this by either establishing or strengthening their clinical research management infrastructure. AMCs tend to be comprised of multiple professional bureaucracies, usually involving a hospital and a university. In some cases a research institute has been established by the AMC to manage their clinical research missions.

In general, there is evidence of increased centralisation, formalisation and standardisation of clinical research management in AMCs, either within the hospital or university or within a research institute. The centralisation of these functions has been supported by arguments that the standardisation and formalisation of structures, policies and procedures for clinical research management will minimise organisational risks and improve the quality of research. Moreover, some AMCs have clearly identified such an infrastructure for clinical research management as a competitive advantage for attracting revenue from commercial clinical trials and for managing organisational risk.

There are differences, though, in how AMCs have responded structurally to common environmental challenges. Some AMCs have merged, changed their positioning and actively promote their clinical research facilities and services. Where the health system is not wholly government funded, while the management of clinical
research has largely been the domain of the universities, some AMCs have established research institutes to take on this role, although in most instances the university is a major if not sole shareholder of the research institute.

In some AMCs, however, clinical research usually takes place in publicly funded hospitals. In this situation, the government, or the government's purchaser of health services, is faced with the potential of cross-subsidisation of clinical research by public healthcare dollars. For managers operating health services in an environment of severe financial scrutiny and constraint the prospect of revenue meant for delivery health services being diverted for research may be perceived as an inappropriate use of that revenue. In these AMCs a uniform approach has been taken to establishing clinical research management infrastructure within the hospitals. This approach includes the use of funding incentives from the government.

This suggests that the public or private nature does not necessarily determine how clinical research activities are managed in its AMCs.

4.4. Third Research question

The third research question asks:
What are the informal structures and mechanisms that enable clinical research management in AMCs?

The literature suggests that matrix organisations and professional bureaucracies can be difficult to manage and that these difficulties arise through the departmentalisation as well as the presence of a professional culture, which guards its professional and academic autonomy. These types of organisations have an inherent need to address their structural and functional complexity by employing informal structures such as liaison roles or devices in order to maintain co-ordination and control.

However, the findings from this phase of research provide scant information with regard to the informal structures and mechanisms of clinical research management. There are indicators to suggest that AMCs experience a dichotomy – doctors as professional and executives as managerial viewpoints. The tensions between professionals and management may explain the lower than expected uptake by hospitals of R&D funding incentives for research management infrastructure. Indeed, the general increase in managerialism in AMCs, prompted by the changing context, cost containment and restructuring, may contribute to distrust and tension between professionals and managers in AMCs. For these reasons it is expected that more information would emerge regarding the informal organisational structures that are predicted in the literature of organisational theory.
The data from this phase indicate that the five basic constructs of the context for AMCs and clinical research hold in the case of all AMCs. The exception is the AMC funded by Government, where these data do not support the fifth construct, which is increased competition for clinical research contracts. Data to support this construct for this nature emerged in the survey or interview phases.

In addition to informing the research questions, this review of background data also identified specific clinical research management activities that were operationalised in the survey instrument. These activities include risk, financial and human resource management. In the following chapter, the background data from phase one is used in a survey instrument to collect data from respondents.

4.5. Summary

In this part, the researcher has analysed three categories of research questions namely First, second and third.