

## **Applying mixed methods research to a cost-benefit analysis**

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### **Abstract**

**Purpose:** This paper applies mixed methods research to analyse the costs and benefits of conducting sponsored clinical drug trials in a publicly funded New Zealand hospital.

**Design:** The research design incorporates mixed methodology and mixed methods. The costs and benefits of clinical drug trials are quantified

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using data from a retrospective case-control study. Qualitative focus groups, interviews and semi-structured surveys are used to explore the costs and benefits as perceived by stakeholders.

**Findings:** Our mixed methods research design enables the analysis of three layers; societal, organisational and personal. Each of these layers reveals different perspectives on sponsored clinical drug trials and the related costs and benefits within a New Zealand public hospital.

**Value:** This paper provides guidance for investigators seeking ways to use both quantitative and qualitative methods to enhance their understanding of research problems.

**Keywords:** mixed methods, stakeholder analysis, cost benefit analysis, multilevel methods, triangulation, clinical trials

**Classification code:** I1, H75.

**Key Words:** mixed methods, research paradigms, triangulation, research design innovations

## **i. Introduction**

Clinical drug trials are the most reliable way to assess the efficacy and safety of health interventions (Jull, *et al.*, 2005). They provide information for national treatment guidelines on patient management and are required for the approval and registration of new medicines. The evaluation of new pharmaceutical products through clinical drug trials plays an important role in modern evidence-based medical practice. Clinical drug trials follow laboratory testing in cell and animal studies

and occur in four distinct phases. Phase I trials are the first experiments using a new drug in humans and normally involve healthy participants. These studies are designed to determine how the drug interacts with the human body. They examine the effectiveness of and any side effects associated with the new drug. Information from Phase I studies is used to design Phase II trials. Phase II trials evaluate how well the new drug works and continue to test the safety of the new drug in a larger group of patient volunteers. Phase III studies assess the effectiveness of a new drug as compared with treatments currently being used. Researchers select participants randomly for either a drug trial group or a placebo control group. As these trials involve large numbers of participants and normally occur over a number of years, the costs are higher than earlier trials in this sequence. Phase IV trials are undertaken after a new drug has been approved for use on humans. Researchers continue to gather information about the drug's long term risks or benefits and possible new uses. Data may also be gathered on how the new drug interacts with other medications (Researched Medicines Industry Association of New Zealand, <http://www.rmianz.co.nz>)

New Zealand has an integrated public health system with twenty-one health boards and eighty-five public hospitals. Publicly funded health care accounts for eighty percent of all health spending. Private spending such as patient copayments for general practitioner visits, prescriptions or insurance, accounts for the remainder (New Zealand Treasury, 2009). Hospital treatment is provided free of charge at public hospitals. This makes the New Zealand health system different from many other countries that conduct clinical trials. In New Zealand, pharmaceutical

companies have to rely on publicly funded hospitals to gain access to participants and to have a 'locality' that is equipped to do clinical drug trials. Where an independent hospital is involved in the trials, the research is separated from the sponsoring company and is therefore seen to be less likely to be biased. There has been little independent research on the benefits of clinical drug trials to New Zealanders. In one of the few New Zealand studies, Watson (2006) highlights what he feels are the benefits of conducting clinical drug trials within New Zealand. Although his is a report based on secondary data, and the study commissioned by Pfizer Pharmaceuticals, it is the first of its kind based on New Zealand data and it raises some ideas that are worthy of further investigation. Watson suggests that sponsored clinical drug trials could have an important role in New Zealand's health system by providing the potential to contribute to reducing costs for New Zealand health boards, retaining and developing a pool of internationally recognised New Zealand researchers and sustaining New Zealand's clinical research infrastructure while at the same time allowing New Zealanders timely access to new drugs.

Nevertheless the growth of sponsored clinical drug trials has created fears that sponsorship arrangements may lead to too much interference in the research process. Angell (2008) asserts that since the 1900s pharmaceutical companies have insisted on more control of their clinical trials to the point that now '*in some multicentre trials, authors may not even have access to all of their own data*' (p 1069). She is concerned that competition for clinical trial contracts has applied pressure on

research centres *'to accept Drug Company terms that would once have been unthinkable'* (p1070).

The New Zealand Medical Journal published the first recorded New Zealand clinical drug trial in 1955 (Neal, *et al.*, 1996). This marked the beginning of a growth phase in clinical research in New Zealand according to Jull, *et al.*, (2005) who reviewed trials between 1998 and 2003. Their findings showed that the majority of ethics applications came from the Auckland and Canterbury regions and that most of these applications were for phase III trials involving pharmacological agents. Fifty percent of trials were in the fields of cancer, cardiovascular disease, and respiratory disease. Ethics approval was sought for 665 clinical drug trials over this six year period and the number of trials conducted each year was relatively consistent (1998, 118 trials; 1999, 91 trials; 2000, 103 trials; 2001, 104 trials; 2002, 108 trials; 2003, 141 trials). The Centre for Clinical Research and Effective Practice (CCRep) is a trust that manages trials for Counties Manukau District Health Board (CMDHB). Using data from the Australian and New Zealand clinical trials registry CMDHB identified the source of sponsorship for randomised clinical trials (RCT) in Australia, New Zealand, and CCRep (Counties Manukau District Health Board, 2009). Their results are shown in table 1.

The pharmaceutical industry sponsors eighty-five percent of CCRep's trials which is higher than the average for New Zealand (fifty-three percent) and Australia (fifty percent). While no one has investigated the impact of such a high percentage of clinical drug trials being sponsored

by the pharmaceutical industry, concerns have been expressed at the ‘*excess dependence*’ on sponsored clinical trials within CMDHB (Counties Manukau District Health Board, 2009, p. 6). However the nature and costs of such dependence is not known.

Dr Stuart Ryan, General Manager at CCRep has concerns about the recording of costs, ‘Overhead calculations for agencies that provide full cost funding of research have largely been guess work when it comes to District Health Boards’ (Stuart Ryan, personal communication Aug 1, 2008). CMDHB projects that the numbers of patients participating in pharmaceutical industry-sponsored studies will increase by twenty-five percent per year in the future (Counties Manukau District Health Board, 2009). Table 2 reflects this impact on participant numbers. CMDHB is anticipating that by 2012 it will have 3,851 or 11.1 percent of all of its outpatients enrolled in sponsored clinical drug trials. In 2015 the percentage of outpatients participating in sponsored clinical trials is expected to increase to fifteen percent (Ryan, 2009).

The clinical trials cost benefit analysis (CTCBA) referred to in this paper is a large mixed methodology collaborative case study. It involves a retrospective case-control study of the health outcomes associated with participation in sponsored clinical drug trials at CCRep and a PhD research project entitled ‘*A cost-benefit analysis of conducting sponsored clinical trials in a publicly funded New Zealand hospital*’ (see figure 1). The PhD component combines qualitative and quantitative methods; (1) a qualitative study of the perceived costs and benefits of drug trials and (2) a quantified cost benefit analysis based on the case control study. The

studies will be contrasted to give new insights into the costs and benefits of conducting clinical drug trials.

The CTCBA is an analysis of the costs and benefits of conducting sponsored clinical trials in a publicly-funded hospital. The costs and benefits related to these trials involve a range of stake-holders and several layers of analysis. The appropriate method for each of these layers differs according to the layer and stakeholder concerned. Underlying the research question are nine specific objectives.

The first seven objectives are to establish the costs and benefits of sponsored clinical drug trials as perceived by:

1. participants involved in clinical trials;
2. participants family and care-givers;
3. management and the multidisciplinary team;
4. researchers;
5. the larger South Auckland community;
6. government decision makers; and
7. pharmaceutical companies.

The eighth objective quantifies the costs and benefits to the Centre for Clinical Research and Effective Practice (CCRep) and Counties Manukau District Health Board (CMDHB). The ninth objective seeks to bring the above eight objectives together by identifying the similarities and differences across eight objectives.

## **ii. Stakeholder Groups and Layers of Analysis**

Publically funded institutions have a responsibility to consider stakeholders in their actions. CMDHB regards stakeholder involvement as important and has as one of its objectives *'to exhibit a sense of social*

*responsibility by having regard to the interests of the people to whom it provides, or for whom it arranges the provision of services'* ([http://www.cmdhb.org.nz/About\\_CMDHB/Overview/objectives-functions.htm](http://www.cmdhb.org.nz/About_CMDHB/Overview/objectives-functions.htm)). Although we have identified the stakeholder groups that are influenced by the clinical drug trials being conducted within the CMDHB, little information is available on the costs and benefits related to the trials. In particular there is little information about how these stakeholder groups perceive the balance between the costs and benefits of clinical drug trials and the relative values that they represent. A brief description of each stakeholder group follows.

#### ***International Community***

The information gained from clinical drug trials around the world feeds into the international knowledge base. Zycher, *et al.*, (2008) identified the interdependence of public and private sector contributions to the discovery of new drugs. They suggest that public and private-sector drug research complement each other and are equally necessary for new drug development. The balance between public and private contributions varies from country to country.

#### ***The New Zealand Community***

The benefits of clinical research vary among countries because societal values vary from country to country (Buxton, *et al.*, 2004). This variation justifies local research. Watson (2006) suggests that New Zealand has a competitive advantage over some other countries that undertake clinical research, but he maintains that the number of sponsored trials has been limited by government policy on the regulation of medicines, which has

in turn limited the willingness of pharmaceutical companies to conduct trials in New Zealand.

New Zealand has a highly regulated pharmaceuticals market (Watson, 2006). The Government is the primary funder of pharmaceuticals through a process administered by the Pharmaceutical Management Agency (PHARMAC). The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) manages the pre-market approval system for pharmaceuticals. Medsafe and PHARMAC work independently (<http://www.medsafe.govt.nz/other/about.asp>). Events such as the much-publicised debate over the subsidisation of Herceptin for early stage HER2+ breast cancer have highlighted tensions between PHARMAC and the major international pharmaceutical companies. The pharmaceutical companies are concerned about the restrictive nature of PHARMAC policies. Sage and Jellie sum up the impact this may have on central government policy (2003 p1):

*The challenge for the Government is to find an appropriate way to balance the very tangible cost of drug procurement against the less tangible cost (but potentially huge benefit) of encouraging research and development within New Zealand.*

### ***The Pharmaceutical Industry***

The pharmaceutical industry in New Zealand is small and dominated by internationally owned companies. The industry employed 596 people in New Zealand in 2004 (Watson, 2006). Conducting clinical drug trials is the final stage in the development of new pharmaceutical products and involves high financial risk and considerable resources for the sponsoring pharmaceutical companies (Murphy and Topel, 1998). Most

pharmaceutical companies have a department that is dedicated to conducting clinical drug trials and they usually employ a director of clinical research as well as clinical research associates and managers to liaise with local clinical research centres (Watson, 2006).

### ***Health Boards***

A few clinical research centres are attached to Health Board hospitals and function with a mixture of government grants and commercially sponsored contracts. One such research centre is CCRep, which facilitates sponsored clinical research for CMDHB. CCRep recruits participants from patients being treated by health professionals within the Health Board system. The costs and benefits of allowing pharmaceutical companies access to patients in New Zealand publicly funded hospitals has not been documented.

### ***Health Board Staff Members and Researchers***

Health board staff members and researchers are required for successful trial outcomes. Scheifele (1997) suggests that trial experiences can vary. On the positive side, a researcher engaged in a good trial might experience an academically stimulating research project, with researcher participation and involvement in all phases, a sensible budget, rapid release of results and opportunities for robust publication. Scheifele warns however that this is not always the case. Negative experiences when working with pharmaceutical companies include boring and non-challenging assignments, lack of opportunities for researcher input, highly restrictive enrolment requirements, and delays in beginning the project and in releasing results. As found within previous stakeholder

layers the experience of staff and researchers in New Zealand has not been well documented.

### ***The Trial Participants***

These are people who volunteer to have the new drugs trialed on them. Reichert and Milne (2002) indicate that the number of participants required increases between trial phases. They say Phase I trials, have 20 – 100 participants. Phase II trials have 100 – 500 participants. Phase III trials have 1 000 – 3 000 participants and Phase IV trials can involve thousands of participants. In the current highly competitive pharmaceutical industry environment, with new drugs often showing only incremental advances on existing drugs, larger patient numbers are needed to demonstrate a benefit which has resulted in pharmaceutical companies spending more on recruitment for clinical trials (Collier, 2009).

### ***The Family and Caregivers***

Of all the stakeholder groups identified in this paper the family and caregivers is the group of which the least is known. They provide emotional support for trial participants and often provide the necessary transport between trial appointments. Family members are generally happy for the trial participant to enrol in a clinical trial (Williams, *et al.*, 2006) White (2004) used multi-professional focus groups, patient and relative interviews and questionnaires to canvas trial perceptions from one hundred and one palliative care patients and 100 relatives. She found strong support for trials from both patients and their relatives. White suggests that clinical trials are more likely to be successful if the views of patients and their relatives are considered during trial development.

The key stakeholder groups identified above resolve into three layers based on emerging common group characteristics: (1) the societal layer which includes the international community and the New Zealand community, (2) the organisational layer which incorporates the Health Boards and the pharmaceutical companies and (3) the personal layer including researchers and health board staff, trial participants and their family and caregivers. Figure 2 depicts these layers.

Stakeholder groups represented in each of the layers identify costs and benefits in different ways from those in the other layers. Within the societal layer perceptions of costs and benefits may be filtered by stakeholders' political and social opinions particularly their views on free market policies versus government regulation. Within the organisational layer, stakeholders may perceive costs and benefits in terms of their influence on organisational functions: finance, human resources, operations, marketing and public relations and knowledge management. Finally within the personal layer stakeholders may perceive costs and benefits as contributing to the psycho-social, cognitive, physical and behavioural needs of individuals.

The next section of this paper illustrates research design choices followed by an illustration of how they were made in the CTCBA research project. It provides an overview of mixed methods research highlighting worldview, methodology, research design and method. For the purposes of this paper, we define the above terms as follows: (1) a worldview is a belief about what knowledge is and how it is constructed (Morgan, 2007); (2) methodology is an '*analysis of the assumptions,*

*principles, and procedures in a particular approach to inquiry*' (Schwandt, 2001, p161). (3) research design is a '*procedure for collecting, analysing, interpreting and reporting data in research studies*' (Creswell and Plano Clark, 2007, p58) and (4) methods are the tools and techniques used to gather data.

### **iii. The Methodology**

Researchers have historically opted for either a positivist worldview, associated with quantitative methods or a constructivist worldview associated with qualitative methods (Doyle, *et al.*, 2009). Pragmatism, a third worldview (Morgan 2006, Creswell and Plano Clark 2007), uses abductive reasoning (Morgan 2007) which refers to the way in which the researcher moves between inductive and deductive reasoning. By using abductive reasoning '*the inductive results from a qualitative approach can serve as inputs to the deductive goals of a quantitative approach, and vice versa*' (Morgan, 2006 p72). The pragmatic researcher also moves between subjectivity and objectivity which Morgan labels '*intersubjectivity*'. Morgan argues that it is impossible to act in a state of '*complete objectivity*' and that it is equally hard to establish a state of '*complete subjectivity*'; therefore the researcher should move freely along the objectivity – subjectivity continuum.

Methodology provides justification for the methods of a research project (Carter and Little, 2007 p1318).

Although researchers have traditionally chosen between qualitative or quantitative methodologies, they are now considering mixed methods research as an option. Doyle, *et al.*, (2009) suggest this is a response to

the limitations experienced using singular methods and the greater acceptance of mixed methods research by the academic community.

Creswell and Plano Clark (2007 p5) define mixed methods research as:

*a research design with philosophical assumptions as well as methods of enquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis of data and the mixture of qualitative and quantitative approaches in many phases of the research process. As a method, it focuses on collecting, analysing, and mixing both quantitative and qualitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone.*

Greene, *et al.*, (1989) present five advantages of using mixed methods research: (1) initiation—discovering fresh perspectives through paradoxes and apparent contradictions; (2) triangulation—testing the convergence or validity of results; (3) complementarity—elaboration, enhancement, illustration and clarification of results; (4) development—using the results from the first methods to inform, design and implement the second method; and (5) expansion—extending the breadth or scope of the project. Quantitative research methods provide the hard data required for evidence based medicine while qualitative research methods provide useful in-depth knowledge concerning the perceptions, beliefs and values of those involved (Alonso-Coello, *et al.*, 2009).

Creswell and Plano Clark (2007) identify four situations in which mixed methods research should be the preferred research methodology. These

include when: (1) either a quantitative or qualitative study is inadequate in itself to address the research problem; (2) there is a need to enhance a study with an additional source of data, i.e. a quantitative study enhances a qualitative study or a qualitative study enhances a quantitative study; (3) there is a need to explain the quantitative results; and (4) there is a need to explore qualitatively before undertaking a quantitative study. As this paper unfolds we will illustrate how these characteristics are met.

One reason that mixed methods research is used increasingly in the health industry is that it allows the complex questions frequently asked in this industry to be addressed. For example, using mixed methods research to answer questions about healthcare outcomes allows the consideration of multiple perspectives (Twinn, 2003). Giddings (2006) gives a second reason for the increased use of mixed methods research in the health industry. He asserts that mixed methods research is attracting more research funding as increasingly funding bodies encourage collaborative research projects with nursing, medical and paramedical professionals using a variety of methods. . With medicine traditionally associated with quantitative research and nursing with qualitative research, the interdisciplinary research team can utilise the strengths of mixed methods research (Doyle, *et al.*, 2009). Finally, mixed methods research meets the needs of multiple and diverse stakeholders for a project including those who need hard data for their decision-making and those who wish to understand better the feelings of the participants. Greene (2005, p209) observes mixed methods research: '*offers greater*

*possibilities than a single method approach for responding to decision-makers agenda, as well as to the interests of other legitimate stakeholders*'. The next step in the research process is the research design.

#### **iv. Mixed Methods Research Design Options**

A research design provides a strategy or blueprint that specifies the methods and procedures used for collecting and analysing data. The idea of mixing research methods is relatively recent, though the number of designs incorporating mixed methods research is growing (see for example; Creswell, 2003, DePoy and Gitlin, 1994, Morgan, 1997). A researcher makes three key decisions when designing a mixed methods study (Creswell and Plano Clark, 2007): timing, weighting and mixing. The decision tree for mixed method design appears in figure 3.

The timing decision is concerned with the timing of the stages, and whether qualitative and quantitative approaches will be used concurrently or sequentially (Creswell and Plano Clark, 2007).

A concurrent design allows results from the quantitative phase to be further explored in the qualitative phase and vice versa. This two way interaction is not possible in a sequential design in which the researcher completes one phase before the starting the next. Nevertheless following a review of forty-eight mixed methods research studies O'Cathain, *et al.*, (2007) found that within the field of health research sixty percent of studies were sequential.

The second decision is the weighting decision, which focuses on the status of qualitative versus quantitative methods. The way in which the

weighting is determined and the weights themselves have strong design and resource implications. The weighting influences the complexity and sophistication of the procedure used for each method (Creswell and Plano Clark, 2007). If both methods have equal weighting the study will require more resources (Creswell, 2003). There are several possible approaches to when, where and how quantitative and qualitative phases should be weighted. Possibilities include weighting phases according to their division in the research design, the time taken to undertake each phase, the quantity of data generated by each phase or the relative importance given to each type of result (Hall and Howard, 2008). The interpretation we adopt is the priority or relative importance given to each phase in answering the research questions (Morgan, 1998; Creswell and Plano Clark, 2007).

The third decision is the mixing decision which determines how the quantitative and qualitative sets of data will be explicitly related. Bazeley (2009) considers this analytical aspect of mixed methods research is underdeveloped and requires further conceptualisation and breakthroughs in techniques. Mixed methods research is distinguished from multiple methods research by the mixing of the data sets (Creswell and Plano Clark, 2007). Creswell and Plano Clark (2007) suggest three mixing options: (1) Merging - joining the two sets of data to form a combined set of data at the final interpretation or analysis stage, (2) Embedding - using one set of data to answer the primary question and the second set of data to answer a lesser or secondary question. Embedding begins early in the research design stage and produces results which show both data sets and (3) Connecting – joining one set of data with another set of data between

phases and exploring the data sets in the final analysis. Bazeley (2009) investigates strategies for mixing data specifically through analysis rather than simply as a conclusion to analysis. She calls this process 'integration' and identifies 11 ways in which this can be achieved. Table 3 shows these approaches. The CBCBA involves an intensive case analysis. Our data collection is one case (CMDHB) and collects data from a variety of sources. We consider the integration of our qualitative and quantitative data to be successful when they are '*mutually illuminating, thereby producing findings that are greater than the sum of the parts*' (Woolley, 2009 p. 7).

Creswell and Plano Clark (2007) developed a typology of mixed method designs that identifies four types of design: (1) triangulation (RD1), (2) embedded (RD2), (3) explanatory (RD3) and (4) exploratory (RD 4). These design choices are numbered 1-4 from left to right of figure 4. The triangulation design of mixed method research brings together the strengths of both quantitative and qualitative methods allowing results to be compared. It allows the reviewing and analysing of evidence from multiple sources as a base for a study's findings (Erlandson, *et al.*, 1993) and provides opportunities to confirm or corroborate the qualitative results with the quantitative findings (Creswell and Plano Clark, 2007). Triangulation occurs when the qualitative and quantitative phases are given equal weighting and are used concurrently. The term "triangulation" can be confusing in mixed-method research as it may refer either to data collection procedures or to research design (Tucci, 2007). Triangulation is the most frequently used design (Doyle, *et al.*, 2009).

Figure 4 shows four models of triangulation design: (1) the convergence model where integration occurs during the interpretation phase, (2) the data transformation model where quantitative and qualitative data are collected concurrently before being transformed either by quantifying the qualitative data or by qualifying the quantitative results, (3) the quantitative model, where qualitative techniques are added to quantitative, such as the adding of open ended questions at the end of a survey and (4) the multi-level model is when the focus of the study is on a system and different methods are used to address the different levels within the system.

The embedded design has one dominant data set while the other data set provides a secondary or supportive role (Doyle, *et al.*, 2009). When the researcher uses an embedded experimental model he or she gives priority to the quantitative data, and the qualitative data set is subservient. In contrast, an embedded correlational model reflects dominant qualitative data and the researcher adds quantitative data to help explain the outcomes. The skills and experience of the researcher, the research goals or the target audience may influence the selection of an embedded design. For example, if the target audience is unaccustomed to or unaccepting of either a qualitative or quantitative approach then their preferred approach can be given greater weighting (Creswell and Plano Clark, 2007).

The third design type is the explanatory design. This design comprises two sequential phases, beginning with the quantitative phase followed by the qualitative phase, which aims to explain or enhance the quantitative

results (Creswell and Plano Clark, 2007). There are two models of explanatory design: (1) the follow-up explanatory model, where the researcher uses qualitative techniques to explain specific quantitative findings, such as unexpected results, outliers or differences between groups and (2) the participant selection model where the quantitative phase is initially used to identify and purposefully select participants for a follow-up in-depth qualitative study (Doyle, *et al.*, 2009).

The qualitative phase of the exploratory design helps in the development of the quantitative phase. Again there are two models for an exploratory design: (1) the instrument development model which is used for developing and testing quantitative instruments based on their qualitative results (2) the taxonomy developmental model which is used when the qualitative element is used for developing a taxonomy or to develop an emerging theory - the quantitative element then adds more detail to the qualitative results.

This may mean that one or several methods represent each research approach. In well designed mixed methods research the specific research questions, the data collection and the ways in which evidence is interpreted complement one another. In addition, as each method has its own limitations or imperfections these are compensated for by using a mixture of methods (Brewer and Hunter, 1989). Hoffman (2009) asserts that communicative preferences explain why research methods that are optimal for some participants, shut down meaningful participation for others and suggests that research methods should be selected according to the communication preference of the participant not the researcher (Hoffman, 2009 p 10)

*While there are important advantages and disadvantages (for the researcher) associated with the use of different types of research methods within the same study, I will point out that if the object of the game is to stimulate participation in the research; using a variety of methods that corresponds to the communicative preferences of our potential participants, may be a better starting point than our own communicative preferences.*

#### **v. CTCBA Research Design**

Although we initially considered a single research approach for the CTCBA we rejected it because neither a qualitative nor a quantitative methodology used individually is likely to answer our research questions. We found that most research designs in the literature used a single approach which we saw as a disadvantage. Our review of methodology in the literature was similar to those of Edwards *et al.*, (1998) who undertook a review on attitudes of patients, the general public, and healthcare professionals to clinical trials. Of the 61 studies that they found, 54 used quantitative methods and eight used qualitative ones (one study used both). We found examples of research designs that were limited by their narrow focus. This problem was evident in both qualitative and quantitative studies. In one study LaFleur *et al.*, (2004) reviewed the study protocols and dispensing data for clinical drug trials in one unit over two years. Revenue generated and drug cost avoidance was calculated. Although they found evidence that substantial drug cost avoidance can be achieved through clinical trial participation, the scope

of the study was too narrow and did not take into account the costs associated with this gain.

One research design uses comparisons of hospital wide outcomes. Using a large sample of 174 062 patients treated at 494 hospitals, Majumdar *et al.*, (2008) conducted a quantitative comparative study between hospitals conducting clinical drug trials on patients with acute coronary syndrome with non-clinical trial hospitals. They found that although on average, the clinical trial hospitals enrolled less than three percent of their acute coronary syndrome patients into trials the improvements to patient care and mortality rates were significant and evident across both participating and non-participating patients. In addition, they found increasing the number of patient enrolments in the clinical drug trials lowered the mortality rates recorded. This research design however, did not take into account the possibility that hospitals that have a lower mortality rate may simply be more inclined to participate in clinical drug trials

There have been a large number of quantitative case match control studies which focus on clinical trial costs (Goldman *et al.*, 2001). In one study Fireman *et al.*, (2000) investigated the direct costs of medical care for participants enrolled in cancer trials for 135 case matched participants over a one year period. Their results showed a ten percent higher mean cost for trial participants over their case matched controls. Case match control is a useful way to compare trial and standardised treatments however a clear assessment of the trial cannot be made without evaluating a range of stakeholder views, without whose co-operation the trial could not take place.

A different approach to assessing the non-treatment time and costs of clinical trials was used by Emanuel *et al.*, (2003). A mock phase III clinical trial involving twenty patients and a twelve month trial period was used to estimate the time and costs of thirteen identified trial activities. On request participants from twenty-one sites provided time estimates for the mock trial first on the assumption it was a government sponsored and then on the assumption it was an industry sponsored trial. Time estimates were then translated into costs. Resulting ranges were large 1512 to 13319 hours for government sponsored and 1735 to 15699 hours for industry sponsored trials. The representatives at the sites may have over- or underestimated the time required for each activity (Emanuel *et al.*, 2003). As the authors suggest detailed time-motion studies provide a more accurate description of time involved.

With complex intertwining issues surrounding the costs and benefits to a number of stakeholder groups (trial participants, caregivers, researchers, staff, pharmaceutical companies and government decision makers), mixed methods research is the appropriate choice for the CTCBA. Using a pragmatic worldview that is both problem centred and practice oriented we focus on our research objectives and use methods that are likely to ensure achievement of our objectives. We collected qualitative data through structured interviews, focus groups and surveys. We opted for a single case study site to conduct our research. The quantitative data are patient-level Health Information New Zealand and administrative data for ADVANCE (ADVANCE Management Committee, 2001) and ONTARGET (ONTARGET/ TRANSCEND Investigators, 2004) trials and case matched controls. The data include medical record number and

diagnostic related group (DRG) code, CCRep profit and loss statements records, trial protocols and data from a trial health outcome co-study. We regard the freely flowing thinking of a pragmatic worldview to be beneficial to the CTCBA, because the quantitative data analysis requires a degree of objectivity while the qualitative analysis requires a greater amount of subjectivity. We are therefore able to move freely along the objectivity – subjectivity continuum. The design allows the systematic measurement of a wide range of costs and benefits and presents them in a way that helps health care users and decision-makers form a better judgement (Drummond *et al.*, 2005)

We intend to give equal priority to both qualitative and quantitative phases in conducting the CTCBA project because we value each phase equally in addressing the research questions. We therefore seek a balance between the presentation of qualitative perceptions and quantitative metrics. Hall and Howard (2008) developed three key principles that influence the choice of design for the CTCBA: (1) qualitative and quantitative methods interact synergistically (this means that their combined effect should exceed the sum of their individual effects in terms of information and insights). (2) The outcomes of the qualitative and the quantitative methods carry equal value. (3) Selection of the methods that provide the greatest opportunities within the research design. There are some research questions in the CTCBA that are better suited to a qualitative approach (research objectives 1-7) while objective 8 is best answered using a quantitative approach and objective 9 is a mixed research question which brings the study together. Debates abound in the literature over which perspective evaluations in health care

should take (Drummond *et al.*, 2005). Having a mixed method approach provided opportunities to take a societal perspective in the qualitative analysis and a more focussed Health Board perspective in the quantitative analysis.

The design most suited to the CTCBA is a multi-level research model variation of the triangulation design. Doyle *et al.*, describe the use of a multi-level model:

*The multi-level research model variation of the triangulation design is used when the focus of the study is on a system and different methods are used to address the different levels. For example, qualitative methodology may be used to ascertain the views of nurse managers on a particular issue, and this is compared with a survey of staff nurses' views (2009, p 181).*

Multilevel designs are used in hierarchically organised systems in which one level of analysis is nested within another (Teddie and Tashakkori 2009). For example, in the CTCBA study caregiver groups are nested within participant groups which are within CCRep which is within CMDHB. CMDHB in turn is within the New Zealand political system which is within New Zealand society. The New Zealand society also contains the pharmaceutical industry. This organised collection of collaborating stakeholder groups creates a system to accomplish the overall goal of conducting drug trials. We choose a concurrent design for the CTCBA to allow for corroboration between findings (see figure 5). We employ an analytic strategy in which qualitative and quantitative techniques were used at different levels of aggregation to answer our interrelated research objectives. Several links were made between the

data sets. We found the qualitative data alerted us to weaknesses in the accounting data used for the quantitative phase, for example a research nurse talked of completing many of her work-tasks at home and outside of the recorded work hours used in the quantitative part of the study. She found it easier to contact her trial participants in the evenings. The design allows adjustments to be made to the quantified data to accommodate this information.

A concurrent design allows costs and benefits identified in the quantitative phase to be explored further in the qualitative phase and vice versa. This two-way interaction is important and it cannot be achieved in a sequential design in which one phase is completed before the other has begun. The design uses triangulation at two levels: (1) triangulation occurs when a number of qualitative methods are used to gather data, which are then analysed concurrently; and (2) triangulation occurs when quantitative data are analysed with qualitative data. We base the CTCBA design on a successful design used by Johnstone (2004) to explore the adoption of new surgical technology in a health-care setting. She specifically asks 'what are top managers' assumptions about, and expectations of, their hospitals' investments in new surgical artifacts?' The questions that Johnstone addresses are sufficiently similar to those in our study to warrant the adaptation of her design. We merge the data in the interpretation stage of the study when we address objective nine. This is consistent with the previous design choice of equally weighting the data sets and is in contrast to embedding and connecting which are more closely linked to a single or dominantly weighted design.

The research process begins with the identification of a broad research problem, which is translated into a number of research questions. The identification of the worldview and the development of the methodology occur next as described previously in this section. Using a pragmatic perspective, as shown in figure 5, we determine what analyses are needed to meet our research objectives. This influences the development of the study design and method selection (cell 1), which provides a guide (cells 2 to 13) for the interactive, circular process of data collection, data analysis, and design review that follows until saturation is reached and no new information emerges (Lincoln and Gubra, 1985). We analyse the data using inductive and/or deductive reasoning (cells 4, 5, 6 and 7). We then use a qualitative phase used to gather information from a number of participant groups. Mixed methods research allows for a wide range of data to be considered and therefore provides opportunities for triangulation (cells 6, 7 and 9) which involves reviewing and analysing evidence from multiple sources (Cresswell, 1994). We merge the qualitative and quantitative data to provide an analysis of the research problem at multiple levels. We provide loops for reflection and further review of the literature (cells, 10, 11 and 12). One example of using this loop revealed concerns about ethical issues within clinical trials which could be compared with views from emerging literature. We reach conclusions using the merged data and a cost benefit analysis constructed for the quantitative (cell 8) and qualitative (cell 13) data. This data informs our final combined discussion and conclusions (cell 14). Table 4 shows the specific objectives, data collection methods and participants of the study.

We consider different methods for each participant group to allow for communicative preferences. Following consultation at the design stage of the CTCBA some participants indicated a strong preference for one method over another. In particular the pharmaceutical company representatives citing busy schedules were not keen to participate in focus groups but were willing to participate in interviews. This was also the case with most politicians. A participant who was involved in conducting clinical trials was happy to complete a survey but declined to be part of an interview or focus group, again citing time constraints. Although we did not initially intend to conduct telephone interviews a few trial participants telephoned and offered to answer questions and discuss their perceptions of the trial verbally rather than completing the survey form received in the mail.

We ask the same questions of each stakeholder group irrespective of the data collection method used to facilitate a comparison of their responses. This uncovers of differing perceptions - for example, health board staff felt that trial participants gained the most benefit from the new treatment drugs being offered whereas trial participants identified the additional care and attention as the greatest benefit. We also observe that the views of researchers differ from those of trial participants - although many researchers who were surveyed believe that New Zealand studies are needed to obtain drug registration in New Zealand, interviews with managers from Medsafe and PHARMAC reveal that New Zealand data are not required for this purpose.

## **vi. The Results**

Bryman (2007) identifies a range of challenges to the successful integration of mixed methods results, including the tendency for qualitative and quantitative results to be written for different audiences, the frequent availability of quantitative data before qualitative findings (owing to the time needed to conduct qualitative studies), and the barriers presented by journals that favour either qualitative or quantitative research respectively. One solution is to analyse and present the results of the various phases in mixed methods research separately. This solution can result in missed opportunities to capitalise on the potential that mixing methods can bring (Hall and Howard, 2008). Stange et al. (2006) suggest that where qualitative and quantitative findings are complex, results should be published in separate qualitative and quantitative forms as well as in a mixed methods form. Hall and Howard (2008) support the presentation of individual and mixed-paradigm results suggesting that there should be no expectation that the two types of results ‘*will confirm, support, or cancel out one another (we are not in search of a single truth) but rather that multiple perspectives are provided on one subject*’ (p 254). A pragmatic model suggests the results should be presented in a way that best suits the situation and intended audience. We intend therefore to present the qualitative and quantitative results for the CTCBA as standalone manuscripts and also to analyse and present combined results.

## **vii. Conclusion**

This paper presents a review of the literature that informed our decision to adopt mixed methods research in a current research project. We

illustrate the steps we took in developing our study with specific examples and provided a conceptual model of our research design, which is a triangulation mixed methods design. The design employs a mixed method, mixed methodology approach to analyse both qualitative and quantitative data. The quantitative phase of the design draws data from a retrospective case-control study establishes the costs and benefits of clinical drug trials. Concurrent with this data collection, qualitative focus groups, interviews and semi-structured surveys are used to explore the costs and benefits as perceived by decision makers, pharmaceutical company representatives, staff participants and caregivers. We collect both quantitative and qualitative data to bring together the strengths of both forms of research to compare, validate and corroborate results. Our research design enables the analysis of three key layers; societal, organisational and personal. Each of these layers reveals different perspectives on sponsored clinical drug trials and indicates the advantages of using mixed methods research.

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### **Personal Communications**

Ryan, S., 2008, "Overhead calculations will provide value to CCRep, CMDHB, the Ministry of Health (MOH) and the Health Research Council" Personal communication between Lynette Murphy and Dr Stuart Ryan, General Manager CCRep, Aug 1, 2008).

**Table 1: Source of sponsorship of active RCT at Australian and New Zealand sites in January 2008. (Source: Counties Manukau District Health Board, 2009, p. 6)**

	Australian studies	New Zealand studies	CCRep studies
Government and Charitable agencies	75 (32%)	20 (39%)	5 (11%)
University collaboration	42 (18%)	4 (8%)	2 (4%)
Pharmaceutical Industry	117 (50%)	27 (53%)	39 (85%)
Total Randomised Controlled Trials	234	51	46

**Table 2: Projected number of participants in CMDHB pharmaceutical industry sponsored studies to 2012 (Source: Adapted from Counties Manukau District Health Board, 2009, p. 16)**

	2009	2010	2011	2012
Participants	1,971	2,464	3,081	3,851
Participants as proportion of outpatient attendances	6.6%	7.8%	9.3%	11.1%

**Table 3: Strategies for integrating data (Source: Bazeley 2009 p 205)**

1. Intensive case analysis
2. Employment of the results from analysis of one form of data in approaching the analysis of another form of data
3. Synthesis of data generated from a variety of sources, for further joint interpretation
4. Comparison of coded or thematic qualitative data across groups defined by categorical or scaled variables (matched, where possible, on an individual basis)
5. Pattern analysis using matrices
6. Conversion of qualitative to quantitative coding to allow for descriptive, inferential, or exploratory statistical analysis
7. Conversion of quantitative data into narrative form, most often for profiling
8. Creation of blended variables to facilitate further analysis
9. Extreme and negative case analysis
10. Inherently mixed data analysis, where a single source gives rise to both qualitative and quantitative information, such as in some forms of social network analysis
11. Often flexible, iterative analyses involving multiple, sequenced phases where the conduct of each phase arises out of or draws on the analysis of the preceding phase



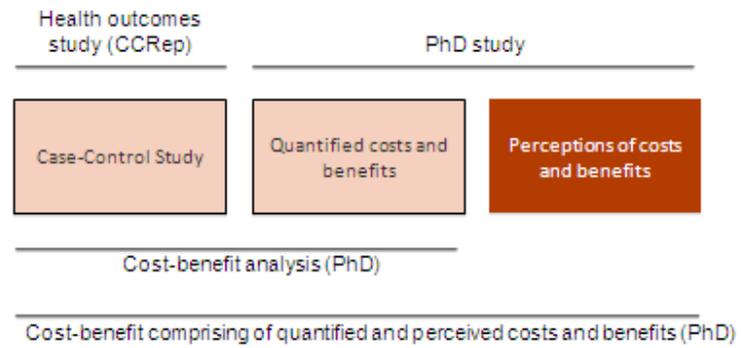
**Table 4: Specific objectives, research methods and participants of CTCBA study**

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Objective	Method	Participants
<b>1: To establish the cost and benefit of clinical drug trials as perceived by participants involved in clinical trials.</b>	Focus groups Individual surveys Telephone interviews	Purposive sampling will draw from two hundred and fifty two participants who were enrolled in either the ADVANCE or ON TARGET CCRep studies
<b>2: To establish the cost and benefit of clinical drug trials as perceived by participants family and caregivers</b>	Focus groups Individual surveys	Trial participants will be asked to invite family and caregivers to be part of focus groups or to complete surveys
<b>3: To establish the cost and benefit of clinical drug trials as perceived by management and the multidisciplinary team.</b>	Individual Surveys	Invitation to CMDHB management; doctors; nurses; pharmacists; dieticians and physiotherapists on hospital intranet.
<b>4: To establish the cost and benefit of clinical drug trials as perceived by researchers</b>	Semi-structured Interviews Individual Surveys	Purposeful sampling and invitation on hospital intranet
<b>5: To establish the cost and benefit of clinical drug trials as perceived by the larger South Auckland community</b>	Semi-structured Interviews Surveys	Purposeful sampling of South Auckland community including individuals, cultural groups and health related organisations
<b>6: To establish the cost and benefit of clinical drug trials as perceived by government and decision makers.</b>	Semi-structured Interviews	Purposeful sampling of government politicians and decision makers including central and local government politicians, elected health board members as well as members of the government organisations; Medsafe and PHARMAC
<b>7: To establish the cost and benefit of clinical drug trials as perceived by pharmaceutical companies.</b>	Semi-structured Interviews Individual surveys	The Researched Medicines Industry Association of New Zealand will be asked to supply a purposeful sample to meet this objective.
<b>8: To establish the cost of clinical drug trials to CCRep and CMDHB</b>	<b>Analysis of quantitative data</b> <b>accounting data</b> Retrospective case-control comparison	Currently reported monthly budget Retrospective case-control comparison
<b>9: To bring the above eight objectives together by identifying the similarities and differences across these levels of analysis.</b>	<b>Analysis using NVivo 8<sup>3</sup></b>	All

<sup>3</sup> NVivo 8 software is licensed to QSR International Pty Ltd.

**Figure 1: Relationship between the CTCBA studies being conducted (adapted from Ryan 2009 p14)**



**Figure 2: Layers of Analysis in the CTCBA**

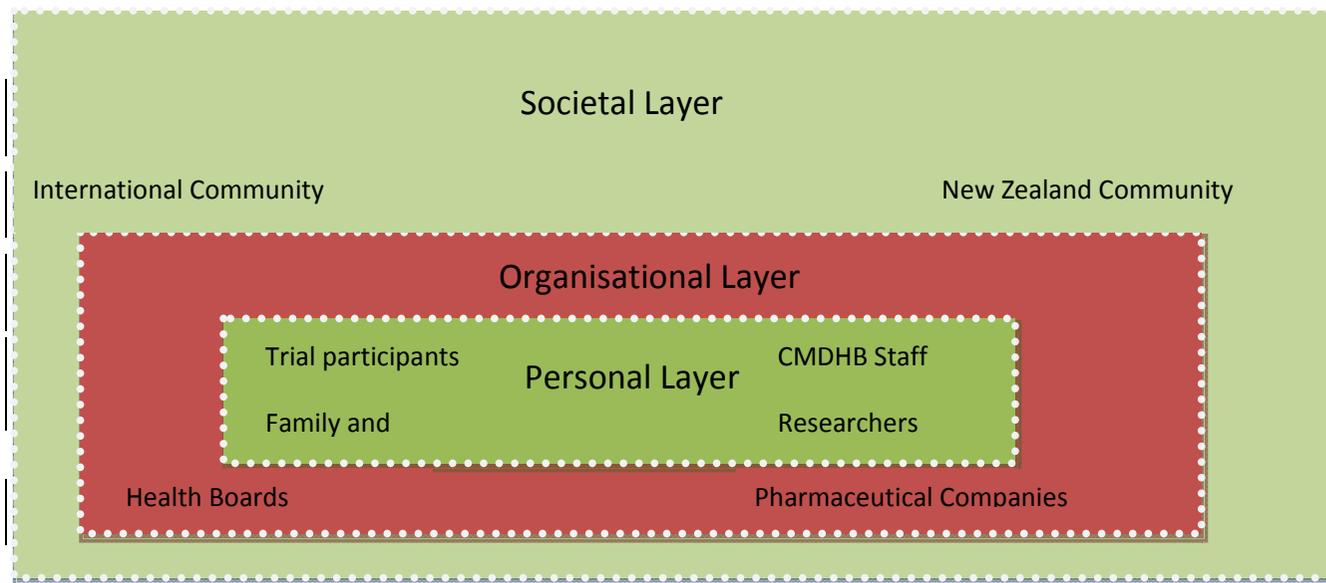
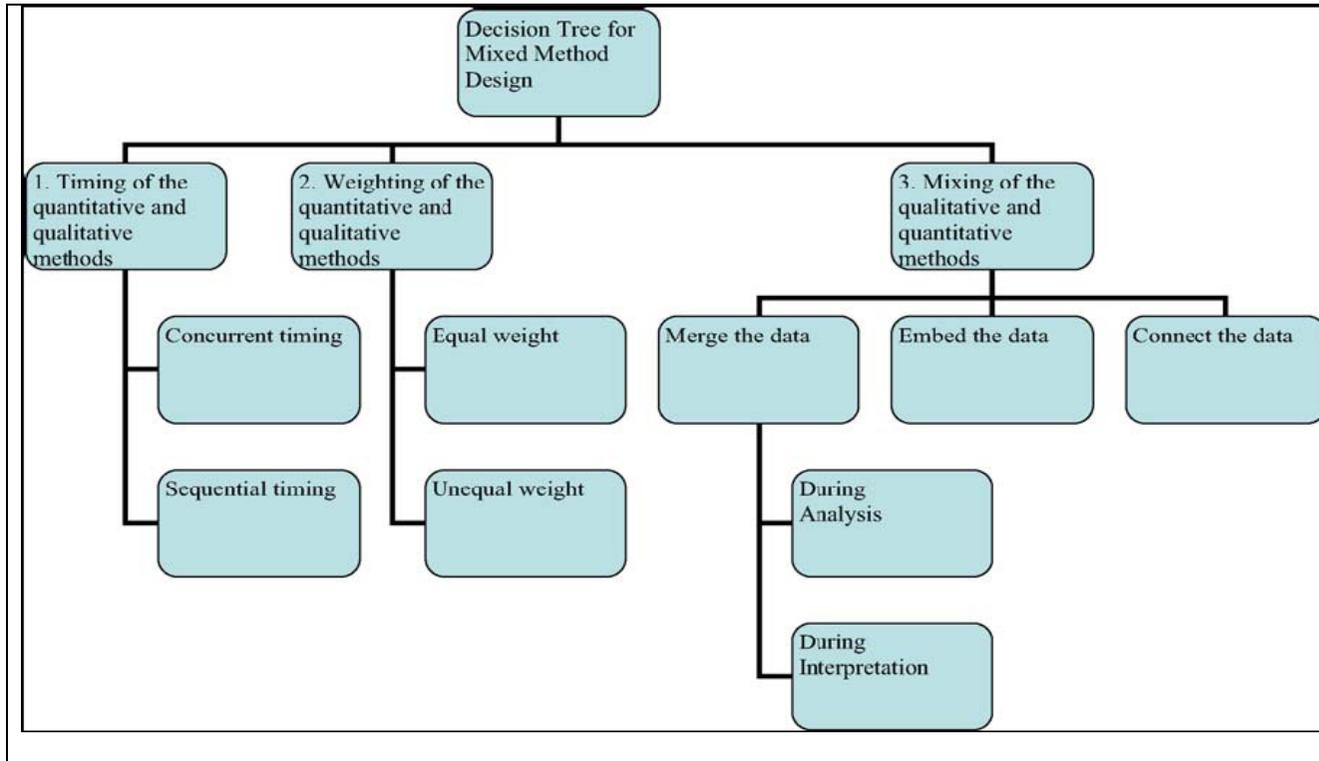
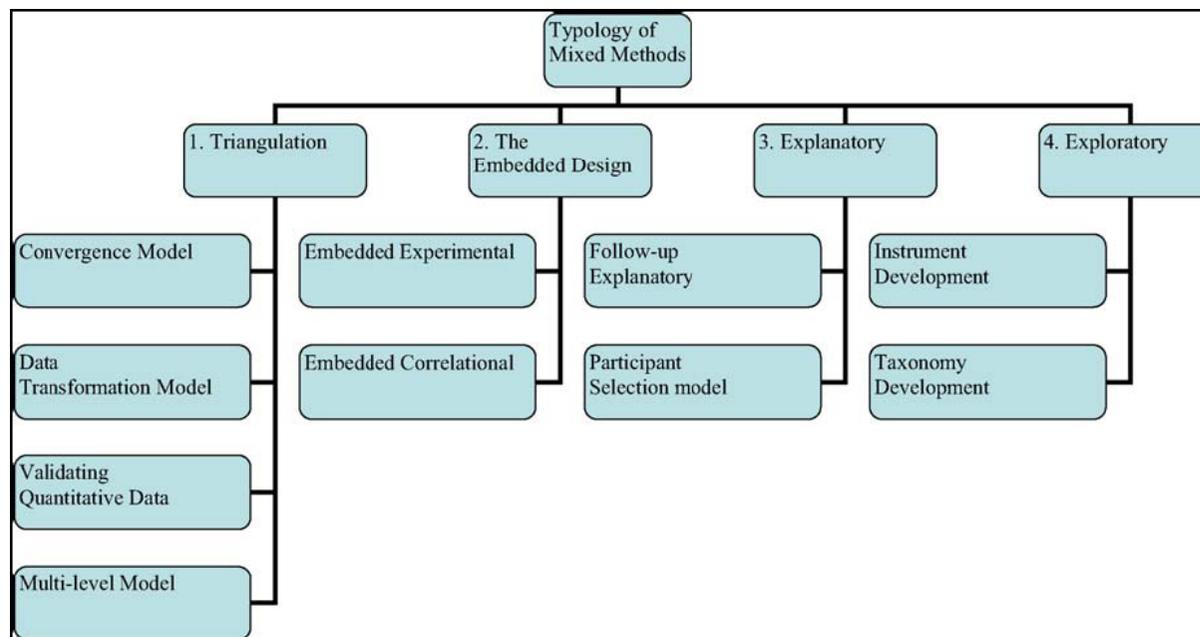


Figure 3: Decision tree for mixed method design based on Creswell 2003. Source: Doyle, et al., (2009).



**Figure 4: Creswell and Plano Clark's typology of mixed method research design Source: Brady and Byrne (2009).**



**Figure 5: Overview of research design**

