

**Recruiting ethical expertise: the roles of  
Lay and Expert members in NHS  
Research Ethics Committees**

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**Presented for examination of Professional  
Doctorate in Health Studies in 2014**

# DECLARATION

This work has not been submitted in substance for any other degree or award at this or any other university or place of learning, nor is being submitted concurrently in candidature for any degree or other award.

Signed J. Hapeta..... (candidate) Date 26.6.13.....

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This thesis is being submitted in partial fulfilment of the requirements for the degree of **DHS**

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This thesis is the result of my own independent work/investigation, except where otherwise stated.

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Julie Hapeshi  
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## Summary

Drawing on the classification of expertise developed by Collins and Evans, this study explores the expertises held by members of NHS Research Ethics Committees (RECs) and how they differ from the ones described by the regulations.

The study used Q methodology followed by ten semi-structured interviews with *Lay* and *Expert* REC members. The results show that committee members see themselves as part of a team, with individual members making different contributions to a collective task. Viewing REC members in this way allows their different expertises to be formally recognised and leads to the creation of two new membership categories, specialist and generalist, based on these expertises.

Specialists have expertises such as statistics and pharmacy that are required by the current legislation and which would be present on recruitment. Generalists possess the other expertises needed by the committee but which not required by statute. These include the clinical expertises possessed by healthcare professionals and the other professional expertises – legal, academic, IT and so on – that are typically found amongst those currently classed as *Lay* members. All REC members, be they specialist or generalist, would also be trained in the ethical and regulatory expertises required to deliver an ethical review.

Emphasising how all REC members, whether specialist or generalise, have expertises that contribute to the ethical review enables recruitment activities to focus on the skills needed by the committee rather than current concerns with population demographics. This provides a solution to many of the recruitment issues identified by participants. In particular, it enables the replacement of skills on a 'like for like' basis using clearly defined person specifications. Not only would such a process comply with the Nolan principles it be more likely to maintain the integrity and function of the committee regardless of personnel changes.

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## Table of abbreviations

AIDS	Acquired Immuno-deficiency Syndrome
BSE	Bovine Spongiform Encephalopathy
CE	Contributory Expertise
CT	Clinical Trial
CHC	Community Health Council
CIOMS	Council for International Organizations of Medical Sciences
COREC	Central Office for Research Ethics Committees
DH	Department of Health
DHSS	Department of Health and Social Security
DTI	Department of Industry
EUCTD	European Clinical Trials Directive
GAfREC	Governance Arrangements for Research Ethics Committees
GMC	General Medical Council
HIV	Human Immunodeficiency Virus
HRA	Health Research Authority
HSG	Health Service Guidance
IE	Interactional Expertise
IRB	Independent Review Board
LINKs	Local Involvement Networks
MHRA	Medicines and Health Related Products Regulatory Agency
MREC	Multi-centre Research Ethics committee
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NPSA	National Patient Safety Agency
NRES	National Research Ethics Service
PA	Patient's Association
PSA	Professional Standards Authority
RCP	Royal College of Physicians
REC	Research Ethics Committees
SHA	Strategic Health Authority
SI	Statutory Instrument
SW	South-west
UK	United Kingdom
UKECA	United Kingdom Ethics Committee Authority
WHO	World Health Organisation
WMA	World Medical Association



# Chapter 1 - Introduction

Research that involves the testing of medicines on humans is subject to strict legislative controls via the European Clinical Trials Directive 2001/20/EC (EUCTD), which was enacted into UK law as the Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031)<sup>1</sup>. The United Kingdom Ethics Committee Authority (UKECA) was created as a requirement of this legislation and mandated to establish ethics committees for the UK, with the National Health Service Research Ethics Committees (NHS RECs) constituted to review studies that fell within the jurisdiction of S.I. 1031 (2004). Although NHS RECs review a wide range of studies, not all of which involve medicines, this study will focus on their role in the review of trials which fall within the EUCTD and which are governed by the Medicines for Human Use (Clinical Trials) Regulations 2004. This is because the current structure of RECs was created to fulfil these regulations.

The governance arrangements for research ethics committees were harmonised across the UK in 2011 and published as Governance Arrangements for Research Ethics Committees (GAfREC) (DH, 2011<sup>2</sup>). This guidance was up-dated to reflect the European Clinical Trials Regulations that came into place in 2004 and clarified where ethical review was required by both UK legislation and the policies of the UK Health departments. It also stipulated where NHS REC review was no longer required, such as research involving NHS staff, anonymised data or tissue samples (GAfREC, 2011, p10) These arrangements specify the composition and function of all NHS RECs and apply

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<sup>1</sup> The EUCTD has been repealed in April 2014 but the current arrangements will apply until 2016. It is unlikely this will change the constitution of NHS RECs

<sup>2</sup> The document was amended to correct a missing paragraph that was added as 2.3.8A but the publication reference was unchanged (HRA, 2012).

to all research that involves patients treated by or under contract with the NHS regardless of the study design or methods used (DH, 2011, p2). These guidelines enable the regulations to be put into operation and mean that all studies falling under GAfREC (DH, 2011) need approval from an NHS REC. This, in turn, makes research ethics committees, and their members, crucial gatekeepers in the process of gaining access to patients.

In implementing the EUCTD, the main driver for the legislation and the subsequent policies is to ensure the safe delivery of research involving medicines. This is reflected in the EUCTD definition of a research ethics committee as

*“an independent body in a Member State, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent;”*

(EU Clinical Trial Regulations 2001 article 2 Definitions).

In the UK, the composition, membership and functioning of these committees are set out in GAfREC (2011, p17) but where the law specifies other criteria (e.g. for membership, composition or attendance) these are further clarified in a note provided by the National Research Ethics Service (NRES 2009; see Appendix 1). This explanatory note gives guidance on the interpretation of the membership requirements for recognised RECs<sup>3</sup> as set out in Schedule 2 to the Medicines for Human Use (Clinical Trials Regulations) 2004 and provides basic guidance on how membership categories should be interpreted.

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<sup>3</sup> Recognised RECs are those that are mandated to review clinical trials involving medicines.

Of particular significance in this context is the distinction between *Lay* and *Expert*<sup>4</sup>committee members. *Expert* members are typically ‘registered health professionals’ but the category also includes some non-medical experts, such as statisticians and pharmacists. *Lay* members are those members who are not categorised as *Experts* and are further sub-divided into two categories: *Lay* and *Lay plus*. The former includes health care professionals after they have been retired for five years, board members and clinical research staff but does not include doctors or dentists who continue to be classed as *experts* even after retirement. *Lay plus* members have no healthcare experience, are not researchers in healthcare, or board members of healthcare organisations. This further differentiation was to fulfil the requirement to have a minimum number of members who were not connected to healthcare organisations (NRES 2009, p7). There are currently sixty-nine NHS RECs in England with over 1200 volunteer members (HRA, 2013c, p3). Not all of the committees are authorised to review studies falling within the regulations but all meet monthly and have up to eighteen members of whom one third should be *Lay*. It is further stipulated that of *Lay* members one half of *Lay* members must be *Lay plus*.

The inclusion of *Lay* and *Expert* members to some extent mirrors the distinction between registrant and non-registrant members found in other contexts. For example, the General Medical Council (GMC, 2014) has lay members. This situation is mirrored across other bodies that fall under the Professional Standards Authority (PSA) and the PSA board (PSA, 2014). However, there are also some interesting differences between these regulatory bodies and NHS RECs. GMC lay members are often recruited because

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<sup>4</sup> *Lay*, *Lay Plus* and *Expert* in italics always refers to the REC membership categories



of their expertise in some relevant professional field, hold director level posts or are Members of Parliament. In contrast, no such restrictions apply on the recruitment of *Lay* members to RECs, which is much more inclusive.

As with other regulatory bodies, recruitment to RECs is expected to be Nolan complicate. In practice, however, the data presented later shows that this is not the case and that part of the reason for this lies in the ways in which the membership categories are defined.

Recruitment of members is expected to be by “open” advertisement and interview to comply with the principles to provide standards for public life set out in the Nolan report (1995). These standards include selflessness, integrity, objectivity, accountability, openness, honesty and leadership and have become known as the seven principles of public life. The implications of this guidance for recruitment to NHS RECs will be discussed later.

Drawing on the experiences and expertise of these three groups, *Expert, Lay and Lay plus*, NHS RECs are expected to “harmonise public and professional opinion in reaching decisions about proposed research” GAfREC (DH, 2011, p20). The mixed membership of the Committee is integral to its work as it provides the variety of perspectives needed to provide the wide-ranging scrutiny implied in the GAfREC guidance (DH, 2011).

## The research problem

It is perhaps easier to begin by stating what the problem is not: the problem is not that Research Ethics Committees fail to provide adequate scrutiny of research proposals or that they fail to protect the interests of patients. Rather the problem is to explain how these heterogeneous groups are able to work together and, given this understanding, how best to ensure that they continue to do so. In particular, what kinds of expertise(s) do REC members need in order to perform their role and are these expertises actively selected for at recruitment, promoted via formal training or simply developed informally through participation in the work of the committee?

The need for some greater clarity on the characteristics and qualities of REC members is hinted at in the variety of terms used to describe them. For example:

- The EUCTD distinguishes between ‘healthcare professionals’ and ‘non-medical’ opinion
- GAfREC distinguishes between ‘public’ and ‘professional’ opinion
- REC recruitment guidelines distinguish between *Expert*, *Lay* and *Lay-plus*

In addition, none of the definitions clearly distinguishes between patients i.e. service users with in-depth experience of particular clinical domains and the wider public i.e. lay citizens with no more than everyday experiences of healthcare professionals (Staley, 2013, p1).

This ambiguity matters because recruitment to RECs should follow principles set out in the Nolan report (1995). Implementing these guidelines means that recruitment should

be open and fair, that vacancies are publicly advertised, and that potential candidates should be required to complete an application form and be interviewed so that the selection process is transparent. The starting point for this process is a clear specification of the task applicants are being asked to perform and, crucially, the skills or expertise they are expected to bring to that role. The current recruitment guidelines for England, Wales and Scotland seek to fill vacancies by category, with information relating to skills being derived from this but information relating to the skills is not explicit,

*Centre Managers should identify the number of current and potential vacancies in the next six months, identifying the relevant committees and type of member (Expert, Lay or Lay plus). A list of vacancies and required skills is compiled, giving consideration to any equality data collected from previous campaigns*  
(NRES, 2013, p4).

The starting point for this thesis is, therefore, the extent to which the labels – *Expert*, *Lay* and *Lay-plus* – and the required skills associated with each succeed in capturing the expertises needed to deliver the function. There is already some research evidence that suggests the labels do not fit well with committees in practice and that it is often difficult to distinguish between *Lay* and *Expert* members (Dyer, 2004, p342). More important, however, is the way that ‘expert’ is associated with healthcare professionals, whilst ‘lay’ retains its everyday meaning of ‘without specialist expertise’. This masks the diversity of expertises needed in a typical REC and does not support the recruitment of members with non-medical skills that are relevant to the ethical review. Or, to put the problem slightly differently, the idea being explored in this thesis is that REC committees work despite the current recruitment practices rather than because of them.

In seeking to develop a more descriptively accurate typology for this distribution of expertise I start from the assumption that RECs contain a wide range of expertises, some of which belong to healthcare professionals and some of which do not. This, in turn, suggests the need for a more general theory of expertise that does not define expertise in terms of its substantive content. Collins and Evans' work (2007, p13) provides a framework for analysing expertise based on the experiences of the individual and the kinds of tacit knowledge these give rise to. Thus, for example, some experiences are widely shared, with the result that the expertise they give rise to is more or less ubiquitous. In contrast, other experiences are more esoteric and give rise to expertises that need to be more proactively recruited and/or developed through bespoke training.

Applying this approach to the different skills used by REC members provides the starting point for identifying the various expertises REC members have as individuals and as groups. This, in turn, informs recommendations for improving the recruitment process by distinguishing between those skills that are shared by all members and those that are more unique or specialist. One consequence of this is that the definitions of both *Lay* and *Expert* members currently in use are shown to be inadequate.

In the case of *Expert* members, the focus on registered healthcare professional status as a defining characteristic is challenged and an alternative category of 'specialist' proposed to recognise those members of the REC who are recruited because they have a specific expertise (e.g. in statistics). In the case of *Lay* members, the contrast is no longer with healthcare professionals but with the specialist category. This leads to a more positive definition of a 'generalist' role in which a range of more or less ubiquitous

skills (as opposed to the absence of registered HPC status) are either recruited for directly or developed through training.

## **Structure of the Thesis**

The thesis makes this argument as follows. The literature review (Chapter Two) examines the various roles that the public and patients have played in health care decision-making and highlights how RECs both draw on this rhetoric whilst also differing in important ways in terms of their constitution and role. Chapter two also includes an exposition of Collins and Evans' (2007) theory of expertise, paying particular attention to the difference between ubiquitous and specialist expertises. The review of the literature concludes with a formal statement of the research questions.

Chapter Three summarises the methods used to address these research questions. The first is Q methodology where a Q sort was used to map participants' understandings of the contributions that *Lay* members make to the work of the REC. The outcome of the Q sort was then further explored using semi-structured interviews with serving REC members.

The following two chapters present the results and discuss their implications for the recruitment of REC members. The data analysis and interpretation are presented in chapter four. Although the Q sort identified several factors, the most important one – in the sense of explaining the most variance – was one in which the distinction GAfREC documents make between *Lay* and *Expert* members plays no part. Instead, the REC is

seen as a team with each member making a distinct but valuable contribution. The robustness of these factors is confirmed in the interviews.

The discussion, implications and recommendations for practice are described in chapter five. The discussion identifies the different kinds of expertises and, drawing on Collins and Evans' work, discusses how they can be developed and shared. It is at this point that the distinction between Specialist and Generalist committee members is formally introduced and its implications for recruitment and training examined. The final chapter provides some reflections on the use of Q methodology and a concluding summary of the main elements of the argument.

## Chapter 2 – Literature Review

### Introduction

This chapter describes the literature that has been reviewed in three key areas relevant to this study with particular focus on:

- I The role of public involvement (mainly in health care) considering its strengths and weaknesses. This includes a history of the Lay role to provide context to the role of the lay public in health care decision-making and NHS research. It will also consider how the use of the terms *Lay* and *Expert* are used to define membership roles.
- II An account of the history and development of NHS RECs where this relates to the current legislation, policy and practice of committees, including a consideration of the role and method of recruitment of members.
- III An analysis of literature on expertise, both specialist and lay, leading to the use of the framework described by Collins and Evans (2007, p14) to understand the development and distribution of ubiquitous and specialist expertises amongst REC members

### Public Involvement in Health Care – a policy imperative

The involvement of service users, carers and the lay public in various aspects of the business of the NHS has been actively encouraged through a number of NHS policies over a period of years (DH, 2000, 2001a, 2001b, 2006). There are also legal and regulatory imperatives that mean that NHS organisations have to engage with patients and the public (Health and Social Care Act, DH 2008). Against a background of low turnout in national elections, and in spite of ever-changing involvement initiatives, the idea of involving the public and patients appears to have been accepted as an

inherently good thing to do. Although this is a key government policy, and there are a number of examples of public participation in a variety of public, private and charitable sectors, participation is not without its problems. Notably there is a lack of clarity as to exactly what public involvement means in health care; who should be involved and how it should work in practice (Florin and Dixon, 2004, p159; Harrison *et al.* 2002, p63).

It could be argued that it was the creation of the Patients' Association in 1963 by Helen Hodgson, a part-time teacher, and five others following concerns regarding informed consent into clinical trials that pioneered public involvement (Mold, 2013, p239).

However, the public involvement initiative as a more formal policy has developed predominantly since the inception of the Community Health Councils (CHCs) in 1974 (DHSS, 1974). Patient and public involvement has spread into other areas of the health care system, including research, in the last twenty years. The contribution of patients and the public to the design of new research projects is considered to provide a key opportunity to influence the study in terms of formulating meaningful research question and informing relevant outcomes (Boote *et al* 2010). This involvement can also extend to information for participants and consent processes, which inevitably overlap with the remit of NHS REC members. However, regardless of the limited evidence base patient and public involvement is now considered to be good practice and has significant support (Boote, *et al* 2013, p2, Evans, 2013, p2).

The first structured attempt at public participation in the NHS was the creation of the CHCs in 1974 (DHSS, 1974). The Department of Health and Social Security (DHSS) created the CHCs to provide an independent view of the operation of the Health Service



in the area it served and to give advice to members of the public who wished to complain. It was assumed that CHC members would provide the lay view of what was required in terms of health care in order to improve the health of the local population. The CHCs also provided a mechanism for external review of the workings of hospitals, commenting on annual plans and proposed changes to service provision. CHC members even had the right to inspect NHS premises without notice. In the early days of NHS RECs, the CHCs were also a common source for *Lay* members (DHSS 1975).

Although the statutory rights and responsibilities of the CHCs were abolished in 2003 amid criticisms of variable practice and limited diversity (Tritter and McCallum 2006, p158), they certainly shaped public involvement in the modern NHS. Each of the successor organisations to the CHCs has enjoyed similar rights but not always the same degree of independence or effectiveness. This has resulted in regular changes to the mechanisms for lay input in recent years and a number of new initiatives (DH 2012a, p4).

This started with a requirement for a Patients' Forum to be created in every NHS Trust in order to review and monitor performance (The Patients' Forums [Functions] Regulations 2003, SI 2123). The role of the Forums was to be independent of the NHS and their procedures focussed on broader public representation rather than acting simply as patients' representatives for complaints as the CHCs had done (Hogg, 2007, p130). This latter role was taken over by the Patient Advice and Liaison Service, which was created as part of the NHS Plan (DH, 2000). This indicated a move to a wider view of the community that went beyond the patient. However, less than two years later new

arrangements were announced as the Forums were criticised for being “too close to the organisations they were meant to be monitoring” (Times, April 15<sup>th</sup> 2006, p19), leading to a lower level of independence and scrutiny than was expected.

In 2008 Local Involvement Networks (LINks) replaced the Forums as the new independent voice of the local community of service users, carers and interested members of the public. LINks were networks of patients and the public from across the voluntary sector and community organisations. They were created to support the increased requirement for public involvement in the provision, commissioning and scrutiny of local health and social care services but the debate continued as to who they actually represented and what their role was (Nathan *et al.* 2010, p273). Just two years after their creation, LINks were replaced by HealthWatch, with the Department of Health justifying their decision as follows:

*Some LINks, despite their best efforts, have struggled to be truly representative of their communities, often lacking diversity and failing to engage with all sections of society (DH, 2012a, p4).*

*The current system of patient and public involvement in publicly funded health and social care is inaccessible and fragmented, has been constrained by a lack of real power, and – despite two attempts at reform in the past decade – is not providing the strong and constructive voice that is needed (DH, 2012a, p6).*

The new organisations, created in 2012, called Local Healthwatch committees, provide information and views on health care services to a national body called Healthwatch England. This change was as a result of the Health and Social Care Act (DH, 2012b) but it only applied to England and different provision for this function was made in the devolved nations.

Healthwatch England is a statutory committee of the Care Quality Commission, which has a clear role in the scrutiny of health and social care services, but each Local Healthwatch committee is accountable to the local authority that creates it. The change was intended to improve the coordination, responsiveness and accountability of service commissioning ensuring that services met the needs of patients, carers and the public (DH, 2012a, p12). Although the role of Healthwatch England is published and the criteria for members set out in a structured member role profile (DH, 2012c), there is limited detail of the skills required, no published person specification and no mention of 'lay members' or 'public participation'. Instead there is a focus on independence from the NHS and the need to use a collective voice to improve services. Interestingly, the criteria for members of Healthwatch England include 'high level skills' such as 'managing organisational performance at board level' and 'experience of risk management and strategic thinking' which are not skills that would be commonly found in public members. It is too early to know if they will succeed where other initiatives have failed.

It is widely accepted that despite the numerous policies to increase patient and public involvement in NHS decision-making little has changed in practice (Pickard *et al.*, 2002, p197; Rhodes and Nocon, 1998, p73; Alborz *et al.*, 2002, p22). Heller (2003, p159) reviews the development of participation and power sharing in modern organisations and notes that this was an area filled with optimism with little evidence to support it. However, Church *et al.* (2002, p25) suggest that members of the public do play an important part in health care decision-making. Tritter and McCallum (2006, p164) have a view that lay members can provide a form of user expertise that gives alternative

perspectives to counter-balance those of healthcare professional committee members. Lay members also play a significant role in the regulation of professions with many regulatory bodies having lay or non-registrant members (PSA, 2014).

The use of ambiguous terms relating to participation and involvement and poor methodological approaches to evaluation are cited as reasons for lack of evidence in this area (Evans 2013, p3). What research there is, however, suggests that there are legitimate questions about the balance of costs and benefits of public participation, as it requires significant investment to get it right and there is little information on actual costs. Although the costs of over £1m for the Patient and Public Involvement process associated with the Government White Paper, “Your Health, Your Care, Your Say” have been criticised as wasteful, there are others who argue that this remains an under resourced activity (El Ansari and Andersson, 2011, p51). Other methods of involvement, such as Citizen’s Juries, have also been noted to be costly, not only financially but also in terms of time, people and skills (Pickard, 1998, p243, Buckinghamshire Citizen’s Jury Learning Outcomes Report, 2011, p17). Regardless of the downsides of public involvement the desire for increasing public participation continues unabated, which is to be expected when it is considered that the main reasons for this initiative are improving accountability and patient-focussed care.

### **The NHS – an organisation with a ‘democratic deficit’?**

The increasing involvement of the lay public in executive functions has arisen from dissatisfaction with traditional methods of decision-making and a lack of accountability, especially when choices are difficult (Syrett, 2006, p871). The need for more involvement has arisen from a system in which services were developed and run based

on the professionals' ideas of what would 'be best' for patients. This has led to a view of the NHS as a service with a 'democratic deficit' leading the NHS towards a process of deliberative democracy aimed at improving the legitimacy of decision-making and priority setting (Syrett, 2006, p872). It has been suggested that involving the public in decision-making is an attempt to 'cure the ills of democracy' (Weeks, 2000, p360). Although the many definitions of deliberative democracy may not be in perfect agreement, they do concur that the decision-making process should involve discussion of all viewpoints without the prior exclusion of any factors (Pellizzoni, 2001, p60). This is important because NHS public consultation events often present the options for consideration rather than all of the possibilities (House of Commons, 2007, p77, Rayner, 2003, p165). The presentation of pre-selected options rather than the full spectrum of possibilities provides a distillation of viewpoints and removes the opportunity for a full debate. This stance does not sit comfortably with the ideas of deliberative democracy. For any consultation to be genuine there needs to be a real possibility of influencing the outcome (Litva *et al*, 2002, p1831).

Cooke (2000, p947) provides five arguments in favour of deliberative democracy, which have some resonance with the desire to improve public participation in the planning of health care services. These include: the development of community power; education; fairness; improvement in the quality of public decision-making; and the achievement of some similarities with political policy makers. This adds weight to the idea that patient and public involvement should be a partnership between patients and healthcare providers, rather than simply information sharing and consultation about the decisions that are already made. Deliberation should, therefore, be 'an unconstrained exchange'

of reasoned arguments that leads to modification of preferences not based on the customary summary items (Cooke, 2000 p948).

However, Syrett (2006, p894) cautions that deliberative decision-making is not a panacea for resolving difficult areas of health care decision-making and public deliberation rarely results in a consensus view. Nevertheless, changes in legislation following the Health and Social Care Act (DH, 2008) made it compulsory for health and social care organisations to consult with patients and their carers when changes and developments to services are planned so the process of public involvement is likely to stay for a while at least. This, in turn, means that questions about the process of involving the public, how the role of the patient / public is defined in the process or who the patient or public representative is considered to be will remain salient for the foreseeable future.

### **User Involvement or public consultation - who should represent who?**

It is easy to understand that patients are likely to be able to make judgments based on their experience and understanding of their condition and that this may result in different aspirations and thoughts about health outcomes than may otherwise be considered. Dyer (2004, p339) suggested that increasing patient participation in health care has shifted decision-making and led to the development of a more patient-centered approach in which patients and members of the public are invited to make decisions that historically were within professional domains (mostly those of doctors). Thus, members of the public are now involved in many areas of decision-making, including the regulatory and governance arrangements of professional bodies such as the General

Medical Council, the Nursing and Midwifery Council and other regulatory bodies such as the Human Fertilisation and Embryology Authority.

Hogg and Williamson (2001, p3) offer a number of reasons why the involvement of lay members is desirable. These include improved transparency and legitimacy in decision-making and the contribution of additional skills in domains including law, finance and the media. This approach is used in publicly funded organisations to legitimise their decisions and typically takes one of two forms: working with professionals to reach a mutually agreed position or simply agreeing decisions that would have been made anyway. Callaghan and Wistow (2006, p2290) suggest that it is the structure of the NHS that limits public involvement, forcing it into mainly advisory roles in selected areas. The weakness of the advisory role is that advice need not be heeded even though it is sought (McLaughlin, 2006, 1398).

Martin (2007, p36) identifies a number of failings in how public involvement works in practice. These include poor recruitment and selection processes, difficult power relationships between professionals and the lay members, and the use of involvement as a mechanism for 'rubber stamping' decisions. The description of what is required from lay members is often vague, typically asking for no more than 'experience of health services' (Martin, 2007, p49). This lack of clarity is not unusual and seems to be a recurring feature in many instances where public involvement is required (Hogg, 2007, p134). For example, it is not clear whether this needs to be first-hand experience or experience by proxy, i.e. as a carer. The current DH initiative for securing the views of the patients on the healthcare provider where they have recently received in-patient

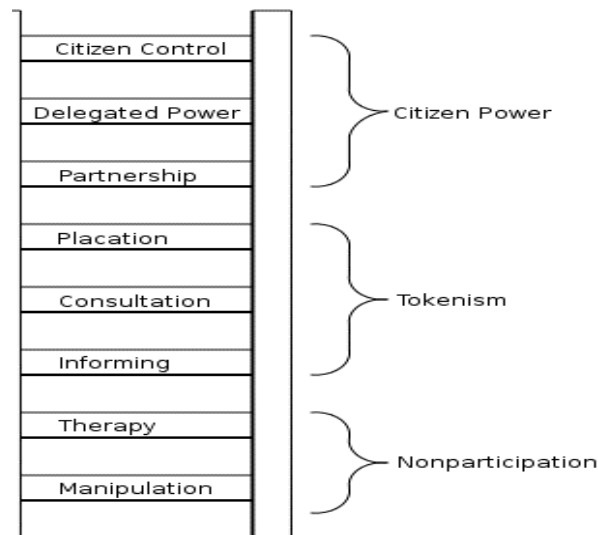
care is called the 'Friends and Family test' (DH, 2013). This became mandatory for NHS organisations on April 1<sup>st</sup> 2013 and seems to take patient experience one-step further by creating a more consumer focus of healthcare provision by asking patients if they would recommend their local healthcare provider to members of their family. This reflects a growing desire to publicly account for the patient experience and indicates the value of patient input and has been recently extended to include the views of the NHS staff on their respective organisations.

This variety in models of involvement contributes to some of the confusion over whether the purpose is 'user involvement' or 'public consultation'. Harrison and Mort (1998, p60) offer definitions of user involvement and public consultation to enable differentiation between involving the public as either patients or interested members of the public. They suggest that public consultation is a method of seeking the views of a broad range of the public in a local area, whereas user involvement is the way of involving organised groups of service users in the planning and management of health care. The level of engagement can affect the degree of involvement.

As a model of engagement, Arnstein's Ladder of Citizen Participation (Figure 1) is widely used, though it has also been criticised as being a poor indicator of the quality of involvement (Salomon, 2000, p47) and for its failure to acknowledge the diverse knowledge and experience of health professionals and lay people (Tritter and McCallum, 2005, p156). Nevertheless, it usefully illustrates that some forms of public participation are little more than public relation exercises with the sole purpose of imparting information and winning hearts and minds. At another level, public



participation allows for comments and criticisms to be voiced but no real contribution to the decision-making process leading to cynicism (Litva, *et al* (2002, p1831). This illustrates that there is limited real participation until there is a genuine partnership, which allows shared decision-making.



**Figure 1. Ladder of Citizen Participation (Arnstein, 1969)**

Martin (2007, p36) also strongly suggests that if involvement is used instead of consultation it will be narrow and tokenistic. However, according to Arnstein even consultation remains inadequate. Regardless of this view it may be that consultation is more pertinent in a health care setting because service users tend to see things from the particular perspective of their own needs and experiences. It is important for patients to be able to say what is important to them and their contributions are often insightful, providing a valuable but alternative view and broader context to the usual NHS organisational perspective. However, Evans and Kotchetkova (2009, p639) observed that in their deliberations patients were often allowed to hold the 'moral high

ground' and set the terms of the debate because it was felt that patients would have a better understanding of what it was really like to experience a certain condition. Lay people were considered by patients to be easily influenced by the media and consequently ill informed (Evans and Kotchetkova, 2009, 639). Two key issues seem to be whether patients or service users have different views to those of the general public and which is preferable: the 'informed' or the 'representative' representative (Callaghan and Wistow 2006, p2293).

One of the main problems seems to be that the terms 'patient' and 'public' are used interchangeably in the selection process of lay members, when they almost certainly have different influences and agendas and indeed different roles to play in the participation process (Staley, 2013, p2).

### **Recruitment, roles and representation.**

If it is simply the experience of patients that is important in decisions relating to health care organisation and delivery then it is likely that this will require a type of expertise gained from using services rather than from formal training. Litva *et al* (2002, p1827) suggest four broad types of representation, which include, elected representation, advocacy by experts such as health care professionals, random samples of citizens, and special interest groups. The elected and advocacy representatives are already playing roles in health care decision making by virtue of their professional roles but the roles of the other two groups, in particular those who are not part of health interest groups, are less defined. Lay members are often characterised not by what skills they need to enable them to perform in the role, but by an assumption that they do not need (or have) any specialist skills at all. However, if it is the contribution of the public to the

delivery of health care that is required then this will also require a local view of how a service would be best delivered or an ability to consider the view of a patient who uses the service under review. There is little empirical research to support which of these different roles is preferred, what skills they need, how they should be recruited or the lines of accountability (Hogg and Williamson 2001, p3).

The DH (2003, p50) suggests that organised groups, such as user groups or support groups are better able to represent the views of patients than *ad hoc* individuals with a health condition.

*Unrepresentative of who or what? Patients and members of the public bring their own experiences to the debate. Unless they are speaking on behalf of a patient group or an established forum they are rarely able to represent the collective views of others. (DH, 2003, p50)*

Issues around representation have become a key criticism of patient and public involvement (Hogg, 2007, p134; Callaghan and Wistow, 2006, p2290; Litva *et al*, 2002, p1827; Tritter and McCallum, 2006, p164). Based on the view of the DH described above, there are likely to be instances where the views of the public or patients are sought from individuals who are unlikely to represent anyone's view but their own. The idea of individuals being able to represent communities or groups may therefore be an aspiration on the part of the policy makers rather than a realistic possibility. If individuals can only ever represent themselves, it probably does not matter too much that the terms public and patients appear to be used inter-changeably. However, this creates additional confusion about the purpose of involvement and who should be involved.

Regardless of the criticisms and concerns, patient and public involvement remains a key policy in many countries across the developed world (Martin, 2007, p35). To meet the policy requirements in the UK, the number of lay members appointed to NHS committees has steadily increased but, regardless of the 'job title', it is inconceivable that all lay roles will have the same requirements in terms of skills and/or expertise. This use of the term 'Lay' member as a 'catch all' is therefore neither desirable nor accurate. Instead, as Thornton (2006, p2454) suggests, commonly used words to describe patient involvement should be "used with precision".

To be clear, it is not the use of members of the public that is being questioned here. Hogg and Williamson (2001, p3) suggest a variety of reasons why lay members may be recruited to committees. Apart from providing a scrutiny or legitimacy role they may bring complementary skills such as legal and financial not held by other committee members. These sorts of skills, which are 'not formally required but useful', seem to be a fortuitous gain to committees with lay members and more consideration should be given to how far these skills form a critical part of the committee's role.

Concerns have been expressed that generally in NHS practice the lay role is not based on role descriptions but is formed largely by the personality of lay members themselves (McGregor and McCray, 2011, p395). There have been particular concerns about the possible elitism in the recruitment process, where self-selection favours better off groups (Church *et al.*, 2002, p17). Furthermore it may be that it is the process of appointing lay members that controls or limits participation by other groups leading to lack of diversity amongst lay members. It has also been suggested that the participation

by lay members who are appointed by Government or local public bodies is more controlled and limited than those who self-select but this may be due to the type of lay representatives who are selected to these committees (Hogg and Williamson, 2001, p3). Other practical issues such as where involvement opportunities are advertised, timing of meetings, time commitments and lack of clarity of what is expected in the role all affect who will apply and who is able to participate.

Due to the diversity of the roles and the variety of purposes and functions of committees that require lay representation within their membership, it is difficult to imagine a situation where a 'one size fits all' role description would help to improve the clarity of the lay role. However, it may be possible to develop a description of the core skills required by a lay member regardless of the committee's function, which could then be supplemented by the additional skills or specialist functions required by the individual committee. This could only be accomplished by a carefully considered assessment of the role and the skills required to function in that role. This is at odds with the idea of Citizen's juries or legal juries that comprise members of the public chosen at random without any reference to skills or expertise. These situations assume that the required expertise is ubiquitous and any new knowledge required by the juries is acquired during the trial<sup>5</sup>. Some doubt was cast on this bastion of British justice in a recent court case where the judge dismissed the jury because the nature of their questions raised concerns as to their ability to function (Rajan, 2013, p14).

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<sup>5</sup> The exception being complex financial and fraud cases which are often conducted without juries as they are deemed too complex.

## Legitimising decisions

Regardless of the increases in public involvement, whether it is effective in decision-making and priority setting remains a contentious issue. It could be argued that the reason the public are involved in the process of health care decision-making is to legitimise the harsh decisions that need to be made and protect from the 'professional' groups involved in the decision-making process. In many respects, difficult decisions in health care are no different to other difficult political decisions, which are dealt with through the normal democratic processes. This method of prioritising health care using robust democratic processes may be the least unsatisfactory way of deciding what treatments to provide, to whom. If this is the case then there needs to be a transparent mechanism for selecting those representing the public and a clear description about the role they are required to undertake, which is not always currently the case. A code of practice launched by the Chief Scientific Officer in 2000 (Department of Trade and Industry [DTI] 2000) demanded more public involvement in areas of risk assessment. It particularly recognised the need to generate public trust in areas of scientific uncertainty (DTI, 2000, p53). The Secretary of State at the time, Stephen Byers, also acknowledged that decisions with ethical and sociological implications needed wider discussion that should involve the public in order,

*...to ensure that membership of a committee reflects both its remit and the degree of public concern in the area. This includes the need to draw on the best available expertise covering all the relevant disciplines and at least the main viewpoints where the issue is contentious. The guidance states that where committees are to consider wider issues there is a need to consider the background of Lay members, and how they will be involved (DTI, 2000, p53.)*

The DTI policy statement recognised that the public need to be involved in the debate but that membership of the committees and the role of members needs to be carefully

considered. Lay members may need to have confidence in debating scientific issues and the experts may need to develop new skills to enable this to happen.

The use of lay participation to legitimise expert decisions is not without its problems and requires a level of understanding that may not be widely present. Nearly three decades ago a report from the Royal Society (Bodmer, 1985, p11) suggested that the public would be more supportive of science and scientists if they had a better understanding of science. There were calls for jargon-free, intelligible summaries in the media to improve public engagement in technological developments (Bodmer, 1985, p24). Sturgis and Allum (2004, p57) are critical of this 'Deficit Model' of public understanding of science in which the public are considered to be unnecessarily concerned with developments in technology due to a lack of full understanding. Rayner (2003, p164) considers that all forms of public participation lead to improved decision-making through transparency.

Jones *et al* (2008 p20) observed that a lay presence on professional committees provided a social context for the debates and would therefore go some way to improving the transparency alluded to by Rayner. Some of the involvement of lay members of scientific committees followed the then Government's false reassurances on the Bovine Spongiform Encephalopathy (BSE)<sup>6</sup> issue. Attempts by the Wellcome Trust to reduce public fears of innovative technologies (especially gene modifying techniques) by developing a more informed public seemed to backfire, and the increased knowledge in the lay public allowed them to be even more critical and mistrusting of experts (Brown and Webster, 2004, p113).

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<sup>6</sup> BSE is a fatal neurological condition caused by eating contaminated meat.

## **NHS Research Ethics Committees**

Research on humans has a long history and there have been many notable instances where research has been conducted in circumstances without the participants giving their consent and their well-being has not always been a priority for researchers (Hazelgrove, 2002, p119). Ethics is the branch of philosophy that considers what is right and wrong using a set of moral values or standards. Research ethics is the application of the same principles to research studies and the interaction of researchers with their participants. The basic ethical principles commonly considered are autonomy, justice, beneficence and non-maleficence. These principles aim to respect the human right of freedom to choose for themselves ensuring researchers act in a fair way, helping and not harming others (Schüklenk 2000, p971). As described in the Belmont report (1978) these principles translate into ethics committee practice as informed consent, including consideration of the quality of the information provided and whether participation is voluntary. They also give a framework for the assessment of the risks associated with taking part in the study, the fairness of the recruitment process and are used in the training of REC members (Eckstein 2011, p129).

There were significant developments in ethical codes of conduct for research after the Nuremberg Trials. The Nuremberg Code (1949) provided a set of ethical principles for the conduct of research on humans, which were translated into an ethical framework for the conduct of research on humans by the World Medical Association (WMA) in 1964 as the first version of the Declaration of Helsinki. The Declaration of Helsinki has been periodically revised and the most recent version (7<sup>th</sup> version) was adopted in October 2013 (WMA, 2013). It still forms the basis for most debates about research ethics and



decision-making related to research involving human subjects. However, it was not pivotal in changing medical practice in Britain where medical paternalism with regard to research ethics was dominant (Hazelgove, 2002, p110). Changes to the system came later, in the 1960s, with rising government and public concerns following the thalidomide tragedy, in which numerous babies were born with phocomelia (absent limbs) after their mothers had taken the drug to quell morning sickness during their pregnancies. The death in 1953, of a serviceman involved in research at Porton Down, a Ministry of Defence research establishment further highlighted the risks associated with human experiments (Hazelgrove, 2002, p128, Evans, 2004).

The Royal College of Physicians (RCP) led the development of committees to review human experiments, publishing a report in 1967 entitled *Report of the Committee on the Supervision of the Ethics of Clinical Investigations in Institutions* (RCP 1967). This endorsed the principles of the Declaration of Helsinki and recommended that committees were established to independently review studies. There was no formal guidance on membership or operational guidance for the committees but it was suggested that it would be the responsibility of the respective organisation's management committees to have over-sight of the process. It also recommended that this was a role for an approved group of doctors.

At the same time there was increasing pressure from the Patient's Association as the up-take of the RCP recommendations gathered momentum (Hedgecoe, 2009, p344). By 1971 a survey by the DH indicated that 187 institutions (out of 238) had an ethics committee although they did not have *Lay* members. It was only following the

publication of a Health Service Circular by the Department of Health and Social Security in June 1975 (DHSS, 1975) that it was indicated that a Lay member should be included in their membership and that they should be recruited from one of the (recently formed) Community Health Councils.

The Department of Health published its first guidance in 1975 followed by 'The Red Book' as it was affectionately known in 1991 (DH, 1991, Health Service Guidance circular (HSG (91) 5), which gave NHS Research Ethics Committees (NHS RECs) operational procedures by which to function. At that time NHS RECs were constituted as committees of the District Health Authorities who had the responsibility for their function, management and governance.

The REC system was becoming complicated, and in 1997, committees were created to review studies taking place in four or more NHS sites to simplify the process of approving multi-centre research (DH, 1997). The Multi-centre RECs, or MRECs as they were known maintained the same membership structure of the local committees with a mixture of *Lay* and *Expert* members. More direct DH control of NHS RECs came in 2000 with the creation of the Central Office for Research Ethics Committees (COREC). This was created as an over-arching body to manage and develop the NHS Research Ethics system and to implement the changes required as a result of impending European legislation by which clinical trials involving medicines needed to be regulated. In 2007, COREC was replaced by the National Research Ethics Service (NRES), which continues to manage both the infrastructure of the research ethics service and the

committees themselves. NRES moved from the National Patient Safety Agency (NPSA) to the newly created Health Research Authority (HRA) in December 2011.

As medical practitioners lead most research that involves medicines and falls under the EUCTD their practice is an important requirement and a key focus here. The Hippocratic Oath followed by doctors suggests they should never do deliberate harm to anyone for anyone else's interest and this is reflected in many codes of professional conduct. All doctors have to be registered with the United Kingdom (UK) General Medical Council (GMC) to be able to practice in the UK and must follow the Good Medical Practice Guidance for Doctors (GMC, 2009) otherwise their registration is at risk. This guidance states that “patients must be able to trust doctors with their lives and health” and in the case of research they must “put the protection of the participant first” (GMC, 2009, p. 30).

It is not difficult to see why it was deemed necessary for the NHS to have formally constituted research ethics committees to over-see research involving patients. In spite of clear professional codes for the conduct of research involving humans, the paternalistic attitude of the medical profession generated much disquiet. A suggestion by Bradford Hill in 1963 (Foster, 2001, p143) a respected epidemiologist, that most patients would not be able to understand the research that they were being asked to take part in thus negating the need for consent was likened to the German Concentration camps (Hedgecoe, 2009, p334). Attitudes, such as this, reinforced the perceived need to protect patients from doctors and have been attributed to the instigation of ethics committees (Foster, 2001, p145).

There are now many examples where the lay contribution or public involvement in the assessment of risk has become the norm, both within and outside the health care arena (Jones, *et al.* 2008, p2). However, there are also criticisms about the lack of clarity around the definition of the term 'lay' and what the role involves (Hogg and Williamson, 2001, p1). In the case of NHS RECs, *Lay* members are not recruited because of their status as patients or to represent anyone else's views but their own; they are simply denoted as an "other" member to be contrasted with the *Experts* (SI 1031, 2004, p45). In addition to this, NHS RECs are not advisory; they have a clear place in the regulatory approval of clinical trials as set out in Medicines for Human Use (Clinical Trials) Regulations 2004. The lack of a requirement to represent other associated with this position makes this *Lay* role very different to a number of others.

It is not clear whether the current enthusiasm for *Lay* involvement is linked with a general rise in suspicion and doubt about the quality of scientific evidence, an inherent need to know more about how *Experts* make decisions or simply a move to a more consumerist approach to health care (Horlick-Jones, 1998, p84; DTI, 2000, p50; McGregor and McCray, 2011, p396). Regardless of the reason behind this, the *Lay* role in NHS RECs has some significant history behind it.

Dyer (2004, p346) suggests that in the past it was the clinician's expertise that was valued but now the involvement of the *Lay* member is needed to help create public trust. When considering NHS RECs, it is not clear whether the public view is needed to provide an alternative view to the health care professional who is the 'expert', or to provide alternative skills in for example, critical reading, project management or law. It

could be argued that the *Experts* are better placed to understand the impact of research on patients as they have a greater insight into their pains and sufferings than *Lay* members who have no clinical expertise. *Lay* members provide expertise in 'every day' life, a view that is grounded in the reality of their everyday life, but not necessarily, the everyday reality of the patient. The potential for effective representation seems to rely on the ability of the lay member to understand who and what they are representing (Hogg and Williamson, 2001, p4). This could work in areas where the issues are narrow or focussed or on a single condition but in the case of NHS RECs a multiplicity of conditions or groups need to be represented. It is therefore highly unlikely that full representation can be achieved, and this supports the view of patients who often feel that their views cannot be adequately expressed by members of the public who have no experience of their particular condition (Evans and Kotchetkova, 2009, p636). Considering all these aspects suggests that *Lay* members of ethics committees do not represent the patient's view but, instead, perhaps represent the view of a non-patient population bringing other expertise to the debate.

Both Parker (2008, p31) and Dyer (2004, p346) assert that RECs need to be viewed from a political perspective to understand what the composition of their membership should be. Parker (2008, p31) argues that the REC is the political mechanism by which medical research is socialised and legitimised and *Lay* members are the way of achieving this. Public involvement in NHS RECs is not the same as involvement in the planning or delivery of healthcare in as much as it is not about resource allocation and *Lay* members are not expected to represent anyone's views but their own (DH, 2011, p20).

## **Ethics Committees – selection, recruitment and public representation**

GAfREC (DH, 2011) clearly sets out the membership requirements for NHS RECs and these were reinforced by a more recent statement from NRES (2013) which made it a requirement that one third of members of the committee should be *Lay*.

*“At least one-third of the members must be ‘Lay’. Lay members are people whose main personal or professional interest is not in a research area. The remainder of the committee are Expert members, who are specialists including doctors, other healthcare professionals and academics.*

*Membership can also include a category known as ‘Lay plus’. This category excludes anyone who has been involved in clinical research other than as a participant.*

*REC members often have the sort of experience, which will be useful in scrutinising the ethical aspects of a research proposal. For example, they might be patients, members of the public, nurses, GPs, hospital doctors, statisticians, pharmacists and academics, as well as people with specific ethical expertise gained through a legal, philosophical or theological background.*

*REC members receive special training in ethical review and have the chance to debate challenging issues” (NRES 2013)*

The differentiation of *Lay* and *Lay Plus* was to satisfy the Medicines for Human Use (Clinical Trials) Regulations 2004 for RECs giving opinions on medicinal trials. Under these regulations a *Lay* member is anyone who is not a health care professional as defined by the Health Care Professions Registration Regulations (see CT Regulations - membership of ethics committees Version 4.1 dated July 2009, Appendix 1). *Lay* members may include board members and directors of NHS trusts and other staff such as clinical psychologists who are not currently covered under the registration of healthcare professionals’ regulations. *Lay* members may also be non-medical professionals, such as nurses, who have not been on the Health Care Professions’ register for any period in the last 5 years. This extends the concept of *lay* as a category and assumes that retired non-medical staff lose their healthcare status and become

able to question the ethics of a study from a *lay* perspective after five years. This presents a confused model for categorising members.

It is known that NHS RECs are representative of the general population in terms of ethnicity (predominantly white British) but none of the committees' age profiles match regional or national census data (HRA, 2013a, unpublished report). *Lay* members are also middle class, educated, articulate and often retired (McGregor and McCray 2011, p396) making them older than their *Expert* colleagues. The time commitment required from members may also serve to attract those who are retired or not in full time work or retired. Although expenses are paid to *Lay* members this can be a minefield of bureaucracy for those in receipt of state benefits. This may further exclude some members of the public and deter some service users from coming forward as *Lay* members (INVOLVE, 2008, p19). A more recent survey by Simons *et al.*, (2009, p6) found that 84% of the *Lay* members who responded were educated to degree level (50% to postgraduate level) compared with 20% of the population of England and Wales as reported in the 2001 Census. Sengupta and Lo (2003, p3) observed a similar demographic profile in their study of American Institutional Review Boards (IRBs) with 81% female and 72% with graduate or professional degrees. As such, serious questions have been raised as to how RECs can realistically meet the standards for accreditation that require committees to have a,

*balanced membership as regards age, sex, ethnic minorities and disabilities*  
(Goodman (2004 p199)).

### **An additional problem**

The recruitment and selection of NHS REC members, including *Lay* members, is expected to conform to the standards set for public life (Nolan 1995). However, like

many public committees, recruitment is often by word of mouth, personal recommendation and without advertising or formal vetting (Udale, 2006, p60). Staley (2013, p1) argues that the *Lay* role requires greater clarity to improve recruitment and increase the diversity of the committee.

Although the REC Member Recruitment Policy (HRA, 2013b) indicates that there are “two distinct person specifications one for a *Lay* member and one for an *Expert* member”, the essential and desirable requirements for *Lay* and *Expert* members are very similar and may contribute to this lack of perceived differences observed between *Lay* and *Expert* members (Table 1). The only obvious difference in the description of qualities (not even skills) is experience of conducting research as a desirable quality for *Expert* members. Therefore, if Dr X had not done any research, but had been a carer or user of the NHS, there is no difference at all.



**Table 1. The essential and desirable qualities of lay and expert members of NHS RECs (HRA, 2013b).**

<b>Essential qualities of <i>Lay</i> members</b>	<b>Essential qualities of <i>Expert</i> members</b>
<p>Have a strong personal commitment to the interests of research participants who take part (or are asked to) in health care research.</p> <p>Have a strong personal commitment to ensuring the highest standards for health care research.</p> <p>Be able to read, understand and analyse complex issues from research proposals and weigh up conflicting opinions</p> <p>Be able to take an objective stance, looking at a situation from different perspectives.</p> <p>Be a good communicator with a practical approach and the confidence to voice their opinions.</p> <p>Be able to discuss issues with people who may not agree with them including being able to influence and listen to the views of others from a range of backgrounds.</p> <p>Be committed to the public service values of accountability, probity, openness and equality of opportunity.</p> <p>Be able to demonstrate an ability to contribute to the work of the REC.</p> <p>Be available monthly (approximately 11 meetings per year) to attend at least two-thirds of the REC meetings, which could include virtual or face-to-face proportionate review sub committee meetings.</p> <p>Understand the requirement for confidentiality in issues faced by a REC</p> <p>Be willing to undertake a degree of training to equip themselves to carry out the role of REC member.</p> <p>Be IT literate to allow some work to be carried out by email.</p>	<p>Have a strong personal commitment to the interests of research participants who take part (or are asked to) in health care research.</p> <p>Have a strong personal commitment to ensuring the highest standards for health care research.</p> <p>Be able to read, understand and analyse complex issues from research proposals and weigh up conflicting opinions</p> <p>Be able to take an objective stance, looking at a situation from different perspectives.</p> <p>Be a good communicator with a practical approach and the confidence to voice their opinions.</p> <p>Be able to discuss issues with people who may not agree with them including being able to influence and listen to the views of others from a range of backgrounds.</p> <p>Be committed to the public service values of accountability, probity, openness and equality of opportunity.</p> <p>Be able to demonstrate an ability to contribute to the work of the REC.</p> <p>Be available monthly (approximately 11 meetings per year) to attend at least two-thirds of the REC meetings, which could include virtual or face-to-face proportionate review sub committee meetings.</p> <p>Understand the requirement for confidentiality in issues faced by a REC</p> <p>Be willing to undertake a degree of training to equip themselves to carry out the role of REC member.</p> <p>Be IT literate to allow some work to be carried out by email</p>
<b>Desirable qualities of <i>Lay</i> members</b>	<b>Desirable qualities of <i>Expert</i> members</b>
<p>Have experience as a carer or as a user of the NHS</p> <p>Live in, or close to, the geographical area served by the NRES Committee</p>	<p>Have experience of conducting research projects.</p> <p>Live in, or close to, the geographical area served by the NRES Committee</p>

## Defining the lay contribution

The difference between *Lay* and *Expert* members is effectively created, albeit in slightly different ways, from the descriptions and definitions in the various legislation and operational guidance to NHS RECs (NRES, 2009). It is the presence or absence of a professional registration that is the crucial, differentiating factor. It appears, therefore, that the key difference between *Lay* and *Expert* members is in the area of their primary expertise, as GAfREC (DH, 2011, p21) states that lay members primary professional interest is not related to patient care. This is a dichotomy based on healthcare professional (predominantly medical) versus non-healthcare professional (non-medical) rather than expert versus non-expert as the names given to the membership categories suggest. This gives rise to further questions relating to expertise required for the role and assumes that the only expertises that are relevant to ethical review are those linked to healthcare professional status.

In March 2007 the National Patient Safety Agency<sup>7</sup> (NPSA) held a workshop to explore a common understanding of research ethics across communities, patients and RECs (NPSA, 2007a, p1). The report of the workshop illustrated a number of concerns regarding the current definition of *Lay* member, the method of recruitment and the unrepresentative nature of the *Lay* membership. A strong view was expressed that the current membership of committees was too narrow but there was also recognition that complete demographic representation was not realistic.

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<sup>7</sup> The National Patient Safety Agency was at this time the parent organisation to the National Research Ethics Service

The notion of representing communities was discussed, but how this might be achieved was not resolved. Some of the issues raised related to a perception that the *Lay* member role was intended for the “great and the good” and that measures to broaden the membership, promote equal opportunities for *Lay* members and not to deter any number of applicants are likely to have a limited effect. The need to broaden recruitment by advertising vacancies and the provision of training were discussed. The training provided may be an important factor in developing *Lay* members ability to contribute to the work of the committee (Sengupta and Lo, 2003, p9), but could be broadened to cover diversity issues and the political, social and clinical implications of research in healthcare (NPSA, 2007a, p8).

Attendees at the workshop also agreed that there was a general lack of awareness about NHS Research Ethics Committees amongst the wider public, which could be improved by some promotion of their work including the importance of research ethics and the *Lay* member’s role on the committee. This could be promulgated throughout schools, colleges of further education and universities to generate interest and awareness amongst younger age groups. Publicity should be placed in public places such as libraries and doctor’s surgeries and advertisements for members should be placed in a wider range of media to attract a more diverse group of members (NPSA 2007a, p3).

It was considered that the *Lay* member’s role was to provide a ‘common-sense’ perspective in the ethics debate (NPSA, 2007a, p2). Interestingly although many *Lay* members were retired professionals, they felt that *Lay* members were less protective of

participants in research studies than their *Expert* colleagues. Instead, *Lay* members preferred to give research participants the choice as to whether they took part in research and felt that it was important to provide participants with the information needed to make that decision. It was considered that a key role for *Lay* members was to ensure that research participants do receive clearly written information. This may appear to be simply a form of 'user testing' but understanding what they are being expected to do as research participants is a key tenet of informed consent.

This view is not limited to NHS RECs but was also found in a study of American IRBs by Sengupta and Lo (2003, p8). They interviewed 32 *Lay* members from 11 IRBs and the participants described their key role as one of representation of the public view and to simplify the information to participants. There seems to be some assumption that this is a key aspect of the *Lay* role because only they would have the skills to undertake it, suggesting a limited repertoire of skills required but also that other members could not undertake this because they are experts and have specialist medical knowledge.

Ethics committees are not required to undertake a scientific review of the protocol and training is not provided to enable members to carry out this function. Under the Research Governance Framework (DH 2005a) this is the role of sponsor. Rawbone (2007, p2) thought that ethics committee members could not be expected to assess the ethics of a research study without the capacity to understand the science behind it. This is predicated on the view that poor science is in itself unethical. The World Health Organisation / Council for International Organizations of Medical Sciences

(WHO/CIOMS) guidelines (2002) describe recommendations for Ethics Committee membership that state that:

*National or local ethical review committees should be so composed as to be able to provide complete and adequate review of the research proposals submitted to them. It is generally presumed that their membership should include physicians, scientists and other professionals such as nurses, lawyers, ethicists and clergy, as well as Lay persons qualified to represent the cultural and moral values of the community and to ensure that the rights of the research subjects will be respected. They should include both men and women. When uneducated or illiterate persons form the focus of a study they should also be considered for membership or invited to be represented and have their views expressed.*

*A number of members should be replaced periodically with the aim of blending the advantages of experience with those of fresh perspectives.*

*A national or local ethical review committee responsible for reviewing and approving proposals for externally sponsored research should have among its members or consultants persons who are thoroughly familiar with the customs and traditions of the population or community concerned and sensitive to issues of human dignity (WHO/CIOMS, 2002, Guideline 2).*

This implies that the committee has the expertise to consider the ethical issues of any study submitted to them for review with the option to invite additional comment from others when required. However, it does not specify what these expertises might include and suggests that lay members would only represent 'cultural and moral' values of the community and ensure rights are protected.

A number of authors have put forward differing ways of describing lay and expert members based on their contributions in other similar settings. Rawbone (2007, p1) suggests that to enable a proper assessment of the science and ethics in NHS RECs it would be preferable if there were two categories of *Lay* member; specialist lay and lay generalist and two categories of expert member; technical specialist and scientist / academic. The specialist lay member would be selected from a group of potential

participants of the research under review and the generalist lay member should be from the wider population. This could be considered to be another way of distinguishing between patients and the public. The technical generalist category described by Rawbone (2007, p1) as those who have technical skills that would cross a number of projects also cuts across the *lay / expert* distinction in GAfREC (DH, 2011). This would include lawyers and ethicists but also statisticians and pharmacists. Healthcare professionals would never be classed as *Lay* members regardless of whether they were still registered or not, unlike the current arrangements.

Similarly, Schutz (1964, p120) describes the distribution of knowledge according to people's experiences using the terms the 'man on the street', 'the citizen who aims to be well informed' and 'the expert'. The expert is described as someone whose "judgements are not mere guesswork or loose suppositions".

From their observations of lay members in various NHS committee settings, Hogg and Williamson (2001, p5) describe three types of lay member but in a very different way to Rawbone (2007). They categorise them using the areas of their key allegiances and motivation for being a lay member. These include "dominant" ("professional supporter"), "challenging interests" ("managerial supporter") and "repressed interests" ("patient supporter"). They make the point that as part of the recruitment process these standpoints need to be considered to enable the right sort of appointment to be made. These categories are more political views or attitudes than skills and although assessing them might be possible determining the quota for each could prove problematic.

Jones *et al.* (2008, p45) suggest that lay members should be able to cope with a range of technical subjects, communicate well and be confident enough to challenge experts. These attributes need not be exclusively those of lay members but could be expected of both lay and expert members alike. Zimbardo and Ebbesen (1970, p17) suggest that the ability to be a credible communicator is dependent on expertise and trustworthiness while Shanteau *et al.* (2002, p257) found that common traits were found in different expert groups. These included self-confidence, creativity, perceptiveness, communication skills and stress tolerance. They argued that if it was possible to measure these traits then it might be possible to form the profile of a generic expert. However, developing tests to measure some of these traits and at what level to set the norms for different professional groups proved too complex. In addition, there was concern as to the extent that these traits might also be present in non-experts creating a test that was not suitably discriminating.

Although it would be reasonable to assume that an expert would be able to use their knowledge and expertise to refine their judgement to account for subtle variations in information. It was also noted that non-experts could do so too. However, non-experts based their decisions on different factors, such as skills derived from their 'everyday' lives or through 'on the job' experiential learning (Horlick-Jones, *et al.*; 2007, p97). Dyer (2004, p347) observes that Lay members of NHS RECs often use their working knowledge of the REC operating procedures to confirm rather than challenge the views of the professionals and this leaves them with no clear role as *Lay members per se*. If *Lay* members are to maintain their identity they need to be given a clear description of the role they are there to perform and there should be clear specification of what exactly

is required from them. *Lay* contributions can be made in a multitude of ways but much time can be wasted and trust lost if roles are not clear (Dyer 2004, p347).

### **Tenure, training and team influences**

Training of lay members can be contentious. There have been criticisms that the induction of new members and training could be strengthened. (NPSA, 2007a, p8).

Suggestions for additional training for all members did not focus on research ethics *per se* but on topics such as diversity and awareness of the political, social and clinical implications of research. It was also suggested that confidence building, and communication skills that would enable *Lay* members to perform better in meetings.

Improved training may seem to be ideal but there may also be a downside to this, too.

Hogg and Williamson (2001, p4) argue that lay people lose their lay status as they become more trained whilst Nancarrow *et al.* (2004, p20) suggest that training, although perceived as essential, has the potential to reduce the ability of the layperson to contribute in a *Lay* role by encouraging conformity amongst committee members. So, although the giving of additional information makes them more able to contribute it may change the lay perspective. Training coupled with experience could lead to the development of expertise in ethics committee practices, which will be explored in the study.

Dyer (2004, p340) describes the experiential expert as someone who becomes an expert by the experience gained from being a member of a group. This leads to a thorny issue where *Lay* members are recruited to be without specialist knowledge but are then trained for the role and then criticised for knowing too much to be useful as *Lay* members. Epstein (1995, p417) describes a situation whereby patients with AIDS



became activists and campaigners for the faster adoption of new treatments and improved study designs for researching new medicines to treat HIV / AIDS. Their development of expertise in this condition and the design of clinical trials to test new therapies was paramount in highlighting the complexities of their plight and they eventually became accepted as 'experts' in their field. The more expert in HIV / AIDS they became and the more influence they had, the further they moved from the 'grass roots' of the patient groups they had created.

Although committee members are unlikely to become expert in the same way that the AIDS activists did, it is not unreasonable to speculate that *Lay* and *Expert* members of NHS RECs may become more similar as a result of the training provided through joint induction programmes and shared committee experience. The length of time spent practicing as a committee member enables *Lay* and *Expert* members to apply the training they have received into practice. It would be expected that behaviours would be modified or changed by education, expertise developed as a result of practice and improvement of skills by consolidation of theory and practice. It is not clear what happens to *Lay* members (or *Experts* for that matter) once they become trained and whether they retain their original perspectives. It is worth considering whether it may be possible for *Lay* members' level of ethics committee expertise to get in the way of their ability to provide a lay perspective and if so, whether the role should be redefined, the training modified or the tenure on the committee reduced to reflect this. Observation of committees has suggested that distinguishing between *Lay* and *Expert* members can sometimes be difficult (Dyer, 2004, p342). This may be as a result of training but it may

also be because many *Lay* members are retired healthcare professionals or that *Expert* members can be 'lay' with respect to applications outside their own specialism.

Time spent as a committee member may enhance expertise in the practices of the group but it may also be a factor in the modification of an individual committee member's behaviour to conform to the group. This may be more prominent in *Lay* members as they are the 'outsiders' in the group where the majority is from the medical and health care professions. This may in turn impact on how the *Lay* member performs in their role (Hogg and Williamson, 2001, p4) developing increased confidence as a result of familiarity with other committee members and the committee processes.

Access to training opportunities provides a firm basis for decision-making and the development of the expertises required for committee practice. These aspects are all linked to length of tenure and time to develop skills through practice. The length of tenure on any one NHS REC is up to five years and this may be further extended to a maximum of ten years after which members (both *Lay* and *Expert*) can move to another committee where they can serve another ten-year term if they so wish. With no limit to the number of terms that can be served, there is no effective end to the time spent as a research ethics committee member. The length of tenure increases the opportunity for the development of expertise through training and practice.

Ericsson (2006, p685) described work by Bryan and Harter in 1987 where they claimed that over ten years was required to become an expert. If it is assumed that performance improves as experience is gained (Ericsson, 2006, p685) then length of tenure might be an important factor in determining whether *Lay* members become more like the *Expert*

members of the committee by dint of their experience, but what about *Expert* members? There seems to be an unspoken assumption that *Expert* members are unchanged by length of experience and tenure on the committee based on the idea that they are expert already in REC practice. This might be the case if clinical experience and education provide all the relevant expertise and *Expert* members thus arrive fully formed and ready to function as an *Expert* in ethics committee practice. It is also possible that none of these factors influence expertise and that *Lay* members are merely established members of society and can be compared with a Justice of the Peace or another senior figure familiar with committee work. In these cases a REC meeting once a month does little to change their expertise.

The effects of social influence on groups have been recognised for over fifty years (Abrahams and Hogg, 2006, p5) and it is possible that this mechanism changes the behaviour of *Lay* members by group pressure is a possible contributing factor. Kiesler and Kiesler (1970, p11) note that conformity is not a personality trait but it is a change in behaviour that results from a real or perceived pressure from a group. They also report the need to conform with the rest of the group or committee may be a result of real or implied group pressure, which may force some committee members to attempt to fulfil the expectations of others because they care what others think of them. However, there may be other psychological factors, which influence the behaviour of committee members including the need to conform to the group. Davis (1969, p21) in his descriptions of group performance suggests that the members' social behaviour depends on experience; and that behavioural cues are taken from observing others. Training, experience and an improved understanding of the role may improve

committee members' confidence in their own abilities and reduce the likelihood of this occurring.

Goodman (2004, p199) expresses concerns that the drive for 'a balanced membership' of NHS RECs is a sign of their move 'to become another part of the professional accountability business' and suggests that achieving representativeness amongst volunteers is unlikely. REC members paint a different picture, however, stressing the importance of the role of the *Lay* member (Dyer, 2004, p343). They described themselves as 'independent' and felt that they were there to represent the views of the 'man on the Clapham omnibus'<sup>8</sup> a way by which lay representation has been commonly framed.

## **Expertise**

The dictionary definition of an expert is "one who has special skill or knowledge, a specialist" (Webster, 1998, p447) and goes on to say that experts are skilful as a result of practice. Shanteau *et al.* (2002, p253) suggest that in any study of expertise it is vital to be able to identify who is an expert but that this is not simple. Identifying experts when it is possible to test against a 'gold standard', is straight forward, but there is not always a right answer to judge against and, in some cases, the decisions made by novices are no less accurate or easier to identify than those made by experts (Ericsson, 2006, p684).

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<sup>8</sup> "The man on the Clapham omnibus" is a term taken from the English legal system and was deemed to be reasonably educated and intelligent but non-specialist person, against whom the conduct of the defendant could be measured especially in negligence cases (Brewer, 1999, p739).

The difficulty of identifying experts makes the use of the distinction between *lay* and *expert* members within the NHS REC membership categories more complicated than it might first appear. As defined by the legislation relating to medicinal trials (Medicines for Human Use [Clinical Trials] Regulations 2004: Membership of Research Ethics Committees section 4.1), the terms pay little attention to exactly what the members might contribute to the ethical debate but, instead, refer mainly to healthcare professional or non-healthcare professional allegiances. In order to understand what the two groups created by this classification bring to the work of RECs, it is necessary to consider the knowledge held by both experts and lay people.

### **Lay beliefs, knowledge and expertise**

The nature and extent of the knowledge held by lay people is a controversial topic. On the one hand Freund and McGuire (1991, p180) consider that lay people do not possess a “specialised body of knowledge” and Arksey (1998, p95) notes that scientific knowledge is often considered to be superior to lay knowledge. More recently, Prior (2003, p44) has questioned the valorisation of lay knowledge within medical sociology, arguing that the tendency to see lay people as “multi-skilled and knowledgeable”, without any acknowledgement of the limitations, is misleading. Instead, he criticises the drift from ‘lay beliefs’ to ‘lay knowledge’ in academic writing and argues that many patients are not experts on the complexities of their diseases, what causes them or how they are managed.

On the other hand, there are a number of scholars who argue the opposite case, suggesting that lay citizens can have sophisticated and well informed opinions and who have coined the term ‘lay expert’ to emphasis the equality between lay and scientific

knowledge (e.g. Brown, 1995; Wynne, 1992; Arksey, 1998; Irwin, 2001; Popay and Williams, 1996; Epstein, 1995; Kerr, *et al*; 2007). Summarising this research, Horlick-Jones et al (2007, p. 83) suggest that there is no consensus on this, with divided opinions across a range of literature debating the relative merits of lay and expert knowledge.

Those arguing for the expertise of lay people typically question the assumption that lay knowledge is inferior and that lay people lack the ability to contribute to complex decisions (Popay and Williams, 1996, 761). The experience of Cumbrian sheep farmers (Wynne, 1992, p287) is a clear example of how non-scientists can have sophisticated knowledge and, as Popay and Williams (1996, p766) argue, more consideration needs to be given to the contributions that different forms of knowledge can make to decisions. They assert that there is a “borderland” between science and lay opinion that needs to be understood. More radically, McClean and Shaw (2005, p730) consider the concept of knowledge as a continuum, suggesting,

*“lay and expert knowledge cannot adequately be conceptualised as two distinctly different types of knowledge”.*

The efforts to bridge the gap between lay and expert knowledge are well illustrated by the debate about the ‘Deficit Model’ (Sturgis and Allum, 2004). According to critics of the Deficit Model, public concerns about science were mistakenly understood as resulting from public ignorance, with the implication that they could be addressed by increasing public knowledge of the relevant science. In contrast, seeing citizens as informed suggests that public concerns have other sources, such as lack of trust in experts and the institutions they represent and that more knowledge may not lead to more support

(Lidskog, 2008, p82). For this reason, Jones, *et al* (2008, p18) consider it important to move beyond the deficit model, where only the technical knowledge of scientists is valued, and recognise that the concerns of lay people should not be dismissed or marginalised by the presumption that they are unfounded. This means it is essential that public participation is not seen as a way of persuading the public to accept difficult decisions but as a way of enabling alternative perspectives to be articulated.

Jasanoff (2003, p398) suggests that wider participation and public engagement facilitate the dissemination of knowledge and enable the critical supervision that allows experts to be challenged. Funtowicz and Ravetz (1993, p752) liken this to a form of peer review. They assert that new approaches are needed to widen what is considered to be the 'expert group' and this is especially important when scientific results are used to inform policy changes. Funtowicz and Ravetz (1993, p752) describe an "extended peer community", involving people who may have first-hand experience of a condition, problem or location and compare it to a professional peer reviewing process. This reviewing structure is not dissimilar to the one used by the National Institute for Health and Care Excellence (NICE) where all its guidance is reviewed by experts and lay reviewers (NICE, 2011).

Despite these noble aspirations, it is not always clear how these diverse knowledges, experiences and power relationships interact. Brown (1995, p37) highlights a lack of clarity around the differences in the social construction of medical knowledge as opposed to illness. He suggests that the former deals with professional beliefs in healthcare settings rather than the experience of illness. Kelly and Field (1996, p242)

assert that expert and lay descriptions of illness simply provide “bench marks” by which conditions can be described but it is not clear whether the social construction of illness influences the ethical review of studies by *lay* members. Since *lay* members of NHS RECs are not expected to be patients or have biomedical knowledge it is not clear where their experience fits within the various descriptions of lay expertise.

This is important since in the context of NHS RECs the *Expert* role is largely linked to healthcare professional status with the affiliations of the *Lay* role less clear. This distinction is used in the context of on-going debates about whose views are more important, whether expert knowledge and expertise reigns supreme, or whether lay knowledge has the same status (Irwin 2001, p3). In the case of RECs, these concerns translate into questions about the skills or expertise that *Lay* members bring to the committee and the synergy between *Lay* and *Expert* members.

### **Complementary skills**

The vast majority of those classed as *Experts* in NHS RECs are healthcare professionals, with the remainder selected on the basis of a non-medical expertise such as statistics. Helman (2001, p4) suggests that the impact of medical culture has an important influence in the description of disease, while medicine’s a unique set of “sub-professions”, all of which have their own cultures to control and knowledge and expertise to protect, makes it substantially different to other professions (Helman, 2001, p61). This protection can manifest itself in the use of jargon, which is employed to “distance” non- experts (Kerr, 2007, p390).



Parker (2008, p32) emphasises the importance of *Lay* member being from outside the medical profession and hence independent of the medical viewpoint. There is some evidence that the lay public utilise a number of different experiences to enable them to come to complex decisions and that they use a wider range of factors in their decision-making than experts by including factors that matter to them in their personal lives (Horlick-Jones *et al.*, 2007, p84). Evans and Collins (2007, p610) point out that although specialist experts use their knowledge to respond in given circumstances their expertise is usually focused in a narrow field. Including both *expert* and *lay* members in a decision can, therefore, broaden the view of the committee whilst maintaining an 'overlap between common sense and scientific rationality' (Horlick-Jones *et al.* 2007, p84). Popay *et al* (1998, p640) describe how lay knowledge differs from expert knowledge, in particular, considering lay knowledge as a fair challenge and equal but different to experts. These views would suggest a clear but complementary role for *Lay* members and an important reason for seeking membership across professional and lay communities.

However, Parker (2008, p32) expresses concerns that *Lay* members' views may be swayed by the *Experts*, which would make their decisions less independent than they might otherwise be. In his view, the *Expert* member defines the medical view and represents the clinical interests of research, and this combines with the *Lay* members' views to form the ethical review. It is interesting to consider that neither *Lay* members of RECs nor non-executive directors of trust boards are required to have an in depth knowledge of the delivery of health care. Nor do they need to be regular or experienced users of NHS services. On the other hand, they often bring skills and expertise from

other areas including Higher Education, professional services, industry or business, even though these are not explicitly identified as useful in the recruitment process. In addition, they bring the ability to comprehend complex information presented in meeting papers (and other documents) enabling them to provide a critical review of the information presented.

Although the term 'lay' is often used to differentiate public members of committees from professional or trained members, Jones *et al.* (2008, p46) observe that the term is often used to distinguish between those with scientific knowledge and those without.

However, the term fails to recognise that lay members may have expertise of their own, either professional or academic (or both). For example, both the HIV AIDS activists described by Epstein (1995) and the Cumbrian sheep farmers described by Wynne (1992), are often referred to as "lay". These groups either developed or possessed specific expertises to challenge those who were considered "experts" demonstrating the importance of different expertises. Hogg and Williamson (2001, p3) suggest that the term 'lay' is a

*blunt recognition of the demographic and cultural differences between groups and individuals. The term 'health professional' covers a wide range of ability, knowledge and socio-economic attributes; the term 'Lay' covers an even wider range.*

Hogg and Williamson highlight how lay members are commonly defined by the skills they do not have rather than by the skills they bring and the contribution they can make. They also report how health care professionals consider educated lay members unrepresentative of the 'public' view. All of which indicates that the current vocabulary used to describe "lay and "expert" contributions is inadequate and misleading.

It is generally considered that as lay members become more knowledgeable and skilled in their role, they function differently and become less useful as lay members (Nancarrow *et al.*, 2004, p20). It would seem, therefore that *Lay* members who are both educated and trained are less likely to be demographically representative. On the other hand, they are therefore more likely to bring other expertises such as legal or critical reviewing which are useful to the function of the role and delivering the committees goals. *Lay* members of NHS RECs require a number of skills that are not gained through training and it is doubtful that these are found in large numbers of people. This suggests that *Lay* members of RECs should be recruited by focussing on particular skills, and this requires a clear understanding of the different kinds of expertise required.

### **The Lay / Expert divide**

One factor that might explain why it is difficult to distinguish *Lay* members of NHS RECs from *Experts*, is that once *Lay* members have been trained and have served for a short while on a REC they become socialised into a committee role. The convergence of *Expert* and *Lay* roles through the development of the required expertises for the committee to fulfil its role makes *lay* qualities difficult to observe, as they are no longer distinct. This form of 'going native' in a predominantly medical environment may lead to a point when a *Lay* member might no longer be sufficiently 'lay' and their attitudes may be changed by their desire for conformity within the group. What is not clear is whether the *Lay* members lean towards the medical model or whether all members, both *Expert* and *Lay* become socialised into a new, shared ethics committee practice. This could be a manifestation of 'group think' or simply an example where following shared rules leads to the same answer. Nancarrow *et al.* (2004, p19) observed that, over time and with some training, patient representatives in their study became advocates for the

professionals rather than the patients they were supposed to be representing. This suggests a shift away from the key purpose of patient representation, and although there is some feeling that *Lay* members are less paternalistic in their review of research (NPSA, 2007a, p2), it is not clear whether this demonstrates sympathies with researchers or with *Expert* REC members. Familiarisation seems to be a real issue and the development of knowledge, shared values and priorities, all of which serve to make their decision-making similar.

From her observation of NHS Research Ethics Committees, Dyer (2004, p340) reports that there it is often hard to distinguish between *Lay* and *Expert* members. There may be several reasons for this. The *Lay* members are mostly well-educated, professional people who are recognised as not being representative of the wider population. The key difference between them and the *Expert* members is the lack of a health care background or professional training in a healthcare related area. *Lay* people are assumed to bring the norms and values of the community they represent whereas *Expert* members namely registered health care professionals, have belief systems that are linked to their professional training and practice (Ong and Hooper, 2006, p219) and the need to achieve the standards required for professional registration. However, professional behaviours such as reading professional journals and continuing professional education are not confined to healthcare professionals so other professionals may share similar behaviours.

The problem is exacerbated by inconsistency within NHS REC criteria. For example, a nurse is an expert when practicing but becomes a *Lay* member once they have been

retired for five years. This seems to assume that some professional groups lose their professional values once they cease to be professionally registered whereas for others, namely doctors, this is not the case. It may be that the classification of *Lay* members is not especially well defined but neither is that for *Experts*. In addition, there are other groups that are classed as *Lay* members under the NRES definitions including lawyers, ethicists, sociologists and the clergy all of whom could be classed as “experts” in some other classification. This group of experts contribute a higher level of expertise than the *Lay* title credits them with (Emmerich, 2009, p11).

The real issue may be that there is an assumption that the medical and ethical perspectives are inextricably linked so any consensus agreement on the part of *Lay* members suggests that their ability to contribute as *Lay* members has been compromised. If however, the REC is seeking to collectively apply general ethical guidelines to all studies, then consensus is appropriate as the standards are supposed to be shared. It may be that *Lay* members need to become ‘non-certified experts’ in healthcare research ethics committee practice and in order to function they familiarise themselves with the jargon and the knowledge of *Expert* members to make themselves heard. Accepting this does not affect their ability to contribute as *Lay* members but it may lead to their contribution to be identified as something different.

### **(Re)defining expertise**

Although there are a number of ways by which experts can be identified, none is perfect. Shanteau *et al.* (2002, p254) suggest that although certification of expertise is a reasonably reliable measure of expertise (at least at the time of certification) it is not a measure of competence. Experience can be a measure of expertise though it is

possibly a better measure of seniority. The use of peer groups to identify experts in their field seems to be a robust measure but the ‘popularity effect’, as Shanteau *et al.* (2002, p255) describe it, can be a big influence on who is inside and who is outside the group, and may have no direct bearing on their expertise.

Defining expertise is not easy but Collins and Evans’ (2007, p13) Periodic Table of Expertises provides a helpful framework to explore expertises (Table 2). The theory is based on a sociological model of knowledge in which the acquisition of tacit knowledge is a central a feature of all expertises. As tacit knowledge can only be acquired by socialisation in the relevant social group, the model maps how different kinds of social interaction lead to different kinds of expertise.

**Table 2. Periodic Table of Expertises**

UBIQUITOUS EXPERTISES					
Dispositions				Interactive ability Reflective ability	
Specialist Expertises	Ubiquitous tacit knowledge			Specialist tacit knowledge	
	Beer-mat knowledge	Popular understanding	Primary source knowledge	Interactional expertise	Contributory expertise
				polimorphic mimeomorphic	
Meta-Expertises	External (transmuted expertises)			Internal (non-transmuted expertises)	
	Ubiquitous Discrimination	Local Discrimination	Technical Connoisseurship	Downward Discrimination	Referred Expertise
Meta-Criteria	Credentials		Experience		Track record

(Collins and Evans, 2007, p14)

The model starts with the ubiquitous expertises of everyday life – the ability to speak a natural language and so on – as these are the foundation upon which all other expertises are built. The model describes other facets that contribute to expertise such as dispositions, which are personal qualities that describe an individual’s linguistic or analytic tendencies. Specialist expertises are skills that are not ubiquitous and range from skills that might be possessed by many (e.g. driving a car) to those skills that only a few possess (e.g. cardiac surgeon), with higher levels of expertise relating closely to education and training with other experts. Meta-expertises are the expertises about expertise that are used to judge others; such judgements may use ubiquitous expertises about character or demeanour or draw on some expertise in the domain. Thus, for example, technical connoisseurs, like wine connoisseurs, are knowledgeable about an area but are not practicing experts in the field (i.e. connoisseurs are skilled consumers rather than skilled producers). Finally, meta-criteria are the mechanisms for checking expertise by outsiders, such as credentials, experience and track record. These are largely criterion-based assessment and certification and probably the area of most familiarity.

Although there are a number of different aspects of the model, the expertises of interest in this study are ubiquitous expertises and the specialist expertises that Collins and Evans (2002, p254) and (2007, p621) and Collins (2004, p127) call Interactional Expertise (IE) and Contributory Expertise (CE). Ubiquitous expertises are those that allow members of society to exist within it and cover a wide range of everyday interactions and experiences. They include those expertises that are learnt without an

understanding of how the learning occurs, such as in the case of learning native language, and are often not recognised as being expertises (Collins 2013).

Turning to the specialist expertises, there is an important distinction between those that are based solely on ubiquitous expertises and which do not, therefore, require interaction with the specialist community and those that include the specialist tacit knowledge of the expert community and for which interaction with domain experts is essential. Specialist expertises based on ubiquitous skills are derived from explicit forms of knowledge, with the three categories (beer mat knowledge, popular understanding, and primary source knowledge) reflecting increasingly sophisticated outputs with primary source knowledge being the knowledge gained from reading information from the relevant literature. Crucially, however, even reading the professional literature does not provide the skills needed to reach the highest levels of expertise. Instead, to develop Interactional Expertise and Contributory Expertise, it is necessary to interact with domain experts as this is the only way in which the specialist tacit knowledge of the expert group can be acquired. In this model, contributory expertise denotes when

*“a person has both the conceptual and practical expertise held by the group, whereas someone with interactional expertise possesses only the former”*

Collins and Evans (2007, p621)

Contributory expertise is therefore being able to converse fluently in a specialist domain and being able to contribute to it. This is achieved when a person has mastered the practices of a domain that enables them to contribute. In contrast, interactional expertise is a level of expertise developed when people are exposed to the language and culture of experts that allows them to interact linguistically but not contribute to the practice of the domain. It is a level of expertise that is gained from prolonged interaction



with the expert community and use of the language of the relevant specialism (Collins and Evans 2007, p32).

Interactional expertise allows people to converse and function as expert decision-makers but not as practitioners. It is not a halfway house between expert and non-expert but a position whereby the individual has developed knowledge in a subject area and the language that is linked to it. It forms a specific type of expertise acquired over a long period of time. It is the recognition of the development of this form of expertise that has led to a call by Dyer (2004, p340) for a review into the ways in which expertise is defined and used in practical terms and with particular reference to lay expertise. However, interactional expertise cannot develop in a vacuum and as part of the developmental process needs contributory expertise to be present.

When considering NHS RECs within Collins and Evans' framework, expertise seems to fall into three key domains:

- Ubiquitous expertises of every day ethics that is possessed by everyone by virtue of living in a complex society;
- Primary Source Knowledge and interactional expertise in aspects of medical science gained from reading applications, attending meetings and participating in discussions about research studies. Although *Lay* members may learn more about medicine, equally, *Expert* members may learn from the specialist expertises of *Lay* members as well.

- Contributory expertise gained from member's own jobs in specialist areas plus shared expertise in research ethics committee practice gained through training and practice of ethical review.

## **The Proposed Research**

All of these issues and considerations pose significant issues for the theory and practice of lay involvement. Regardless of the possible difficulties in establishing clear credentials and role descriptions for lay members Lidskog (2008, p83) is still supportive of the lay / expert divide. He suggests that the use of the lay label denotes a group of citizens who give up their leisure time to contest experts and give alternative viewpoints. There may be an argument for the development of the role of an expert lay member function that recognises the expertise that lay members can develop through their experience as committee members and removes the need to strive to find the perfect mix of lay and expert on public sector committees. If the status of the lay representative is questionable due to the development of interactional or contributory expertises that relate to the function of the committee then perhaps it is better to acknowledge it and work with it so that the function of the committee can benefit from this wider knowledge. This research project will explore these issues through an examination of the role of *Lay* members of NHS RECs. Using the Periodic Table of Expertises (Collins and Evans, 2007, p13) this study will:

- a. Describe how the *Lay* role is understood by REC members and their perception of the *Lay* role's function within the committee.
- b. Explore whether the expertises within the committee are different to the ones described by the regulations.

- c. Show how recognising the range of expertises within RECs can inform the re-naming of membership categories, clarify recruitment practices and improve training of members.

# Chapter 3 - Methodology

## Introduction

This chapter describes the methods used in this study. A multi-strategy study (Bryman, 2004, p464) was designed employing Q-methodology and semi-structured, face-to-face interviews. The proposed study was to explore what the members of NHS RECs believed to be the role of *Lay* members including whether the recruitment process, training and length of time spent as a *Lay* committee member influenced the expertises within the committee. This would allow a review of which interactional or contributory expertises affect the role and functions of the members of NHS RECs.

However, the measurement of beliefs and attitudes is not an easy task (Cross, 2005, p208) because there are often significant problems in clearly defining what is to be measured (Brown, 1980, p3). A number of alternative methods were considered for this study, which included the possible creation of scales or questionnaires such as Likert or Thurston scales or using Semantic Differentials. These methods were rejected as options because the development of a conventional attitudinal scale could be influenced by the researcher's views (de Graaf & van Exel, 2008-9) and these approaches require identification of the 'right answer' in order to create the scales.

It was decided that the most appropriate method for this study was Q-methodology because it is a technique that includes both operational and psychometric principles that enable the systematic measurement of an individual's point of view or a subjective perspective (McKeown and Thomas, 1988, p5). Each of the other methods has its own merits but as Cross (2005, p208) points out, a number of researchers have identified

that attitudes are context dependent. As Q methodology is a method of measuring both views and their context it seemed an appropriate one to use. The data provide a number of factors, which reveal possible conceptualisations of the *Lay* role in NHS RECs. Although often mistaken for a quantitative method, Stenner *et al.* (2007, p216) emphasise that Q-methodology is a qualitative method where the participants are asked to sort a set of descriptive statements, pictures or even single words to form a point of view. It is the analysis that allows for the effective recognition of patterns of similarly placed statements and outliers and it is this aspect that sometimes creates confusion and causes Q-methodology to be mistaken with quantitative methods.

## **What is Q? Why Q?**

William Stephenson, a psychologist and physicist, first described the technique called Q-methodology in a letter to Nature (Stephenson, 1935) and later more substantially in a book (Stephenson, 1953). He differentiated his method of correlating persons rather than tests on them, from the 'standard' correlation method of Pearson (*r* methodology) by calling it Q methodology.

This methodology is a modified rank ordering procedure where statements are sorted and then ordered into a forced distribution by the participants. The significance of the statements is therefore defined from the point of view of the person conducting the sort and not by the researcher. It differs from a rating scale in as much as a rating scale has the 'right answers' contained in it, which relate to an operational definition (Brown, 1980, p195). In spite of the subjectivity in the technique it is the use of conventional statistical analysis techniques such as factor analysis and correlation that provide a systematic

approach to the measurement of subjectivity. Subjectivity in this case is defined as “a person’s point of view on any matter of personal or social importance” (McKeown and Thomas, 1998, p7).

In addition to this, the nature of the process of sorting the statements allows them to be considered individually and compared with each other. This gives the added dimension of context with the comparison of one statement with the others: this is created by the process of sorting and by describing the relative position of the statement in the Q-sort. This is a feature of Q methodology, which is not seen in other questionnaire or scale methods. The sorting of the statements allows each one to be given a relative importance value and therefore there are no ‘right’ or ‘wrong’ answers to a Q-sort.

Brouwer (1999, p35) commented that,

*subjective tastes, feeling and opinions are most fruitfully studied when respondents are encouraged to order a good sample of items from one and the same domain of subjective interest (instead of replying to single questions).*

There is much to commend this methodology but unfortunately, as Brown, (1980, p181) points out, a key issue with Q-methodology is that there is no single, detailed description of the method to follow. This lack of guidance has resulted in the development of a technique based on Stephenson's principles but with multiple interpretations and applications. As a result of this lack of methodological definition, studies using Q-methodology are as diverse in their utilisation of the method as they are in the subject matter they investigate.

These include studies of health beliefs, decision-making, consumer experience and political beliefs. They vary immensely in the method of creating the statements, the

number of statements used, the number of participants, administration of the Q-sort and even the analysis of the data. Table 3 illustrates some of the studies reviewed and shows a wide variation in the size of usable sorts (P), number of statements (Q) and the method of administration. The number statements range from 24-80 and the number of participants varied from small (4 participants) to medium (40), from large (98) to very large numbers (180 participants) and the method has also been utilised in single case studies.

**Table 3. A summary of a sample of studies using Q methodology showing the variation in the size of the P and Q samples and method of administration.**

Author (s)	Subject area	P Sample (usable sorts)	No. of items	Method of administration
Brown, 1996	Consumer experience (Health)	1*	24	Supervised
Corr <i>et al.</i> , 2005	Consumer experience (Health)	16 (16)	32	Supervised
Eccleston <i>et al.</i> , 1997	Health beliefs	98 (60)	80	Postal
Kozlowski & Cottle, 1993	Conceptions of privacy	40 (40)	60	Supervised
Spurgeon <i>et al.</i> , 2012	Patient experience	23(23)	39	Supervised
Thompson <i>et al.</i> , 2005	Decision-making	180 (122)	67	Postal
Valenta <i>et al.</i> , 1997	Health Care Informatics	59(51)	30	Postal
Young, 2006	Partner violence	4 (4)	45	Supervised

*\*one person was asked to repeat the same sort but under different instructions.*

Van Exel and de Gaaf (2005) describe five key steps to conducting a study using this methodology and it is this framework that will be used to describe these steps, as they relate to this project:

1. Definition of the concourse, or framing of the question by selecting the material from which to derive the questions
2. Development of the Q-sample
3. Selection of the P-sample
4. Q-sorting
5. Analysis and interpretation

### **Definition of the Concourse: framing the questions**

A critical aspect of the process is the creation of the concourse or range of possible statements that are used in the Q-sort but Brown (1980, p186) suggests that the selection of statements remains,

*more an art than a science, although there are scientific principles that can be called upon for guidance*

Although the choice of statements in the concourse might sometimes appear arbitrary and without structure there are scientific principles in Q-methodology, which ensure representativeness in the concourse (statements). These include statements that are constructed for their relevance to the subject area and the analysis is based on the observed variance of different factors. All of these are based on Fisher's principles of experimental design including randomisation, replication and control (Stephenson, 1953, p76).

Q-sorts can be either naturalistic or 'ready-made' and this differentiation relates to the derivation of the statements used for the Q-sort. A naturalistic Q-sort may use statements taken from interviews or written narratives from potential participants, or



from secondary source data, newspapers or other communications. Whereas 'ready-made' Q-sorts have statements taken from rating scales, other Q-sorts or interview data from other studies in the same field but external to the study participants (quasi-naturalistic). The Q-sort can be structured or unstructured, with a structured Q-sort using statements to promote theory testing and possibly including hypothetical considerations in the statements (MacKeown and Thomas, 1988, p28). This approach can be used both deductively and inductively.

An unstructured Q-sort includes items presumed to be relevant to the question but these are chosen without any attempt to explore in any detail related areas of interest and therefore may lack breadth of coverage of the subject area. An assessment of whether the sort includes all relevant areas (a sort of face validity) is made but there is always a risk of bias of not including or over including statements on some aspects. Validation of the statements comes from the participants and their positioning of the statements in the Q-sort.

The statements for this study were created from a detailed review of the literature and DH policy documents. The main texts that contributed to the creation of the Q-sort statements were the areas of public involvement in healthcare, legislation, policy and practice relating to NHS Research Ethics Committees and the development of expertise using the model described by Collins and Evans (2007, p13). This was supplemented by a documentary review of key texts and policy documents relating to recruitment, roles and responsibilities and training of NHS REC members.

An alternative approach would have been to create a naturalistic Q-sort by undertaking interviews with NHS REC members but this was discounted as an option to avoid any bias in the creation of statements from members' viewpoints, which may not reflect the current position.

### **Development of the Q-sample**

Given the significant amount of literature and policy material already available the creation of a structured, naturalistic Q-sort was not difficult. The number of statements in the Q-sort usually ranges between 40-80, in this case the original number of statements (50) was revised, reviewed and reduced until 42 statements were finalised (there were 43 statements at the pilot stage but one statement was removed due to similarity with another). The 42 statements made up the structured, naturalistic Q-sort and comprised statements that allowed both *Lay* and *Expert* members to consider aspects of the role and functions of the *Lay* members and the context in which they operate. The final number of statements was decided upon once the range of aspects that needed to be covered in the concourse had been included making the Q-sort as representative of the issues as possible. A full list of the statements can be found in Appendix 2. It is important to note that even a small number of statements allows for a large number of permutations of the sort since this is calculated as a factorial of the number of items in the sort; in this study the number of possible permutations is 42 factorial ( $42! = 1.405 \times 10^{51}$ ).

### **Piloting**

The Q-sort, the demographic questionnaire and instructions were piloted with the chair and the vice chair (one *Expert* and one *Lay plus* member) from the local research ethics

committee linked to the researcher's place of work. They were chosen because the committee had been identified for closure and members of this committee had already been excluded from the project due to their relationship with the researcher. Following the piloting of the Q-sort and the demographic questionnaire a number of minor changes were made. These included some clarification of the instructions to participants; a merging of two statements with similar meanings, which removed an additional 43<sup>rd</sup> statement, and modification of the wording of two other statements to clarify their meaning. Comments were also sought on the process of completing the Q-sort, for example whether the instructions were clear enough to make the sorting simple and straightforward and how long it took to complete the exercise. The two participants who piloted the tool felt that it was time consuming but nevertheless worthwhile and estimated that the time for completion of the task was around 30-45 minutes. This information was added to the accompanying instructions.

## **Materials**

Research packs were created that could be given to potential participants via the REC coordinators. The packs contained an introductory letter with the instructions for the REC coordinator (Appendix 3) and the initial contact letter to the participants in the Q-sort (Appendix 4). The 42 statements to complete the Q-sort were prepared as randomly numbered, individual cards and placed, in order, in a small brown envelope. There is some suggestion that the statements should be randomly ordered due to any effects of ordering or grouping of the statements (Thomas and Watson, 2002, p145). For this study the statements were supplied in a standard order. The Q-sort instructions (Appendix 5), the sort grid (Figure 2), the demographic questionnaire and a reply card to indicate willingness to be approached for interview (see Appendices 6 and 7) and two

prepaid return envelopes addressed to the work address of the researcher were also included. This allowed the participants to return their completed Q-sorts directly to the researcher without other committee members or the coordinator being aware of their participation in the project. The use of separate envelopes also maintained the anonymity of the Q-sort respondents who indicated a willingness to be interviewed. The participants were asked to return the results of their Q-sort within 2-3 weeks. Although help to complete the Q-sort was offered in the accompanying letter if the need arose no one requested it. No reminders were sent.

### **Selection of the P-sample**

This methodology does not rely on large numbers of participants and is not especially affected by poor response rates (Valenta *et al.*, 1997) since it is not the number of participants that is of interest but the similarity of their Q-sorts. Participants are normally selected from a population who have been identified as being able to define a factor and have a clear opinion of the question being asked (Brown, 1980, p194). Therefore the sample is not randomly selected but purposively chosen for their ability to give a view of the subject under investigation. Bouwer (1999, p35) suggests that the P-sample is usually smaller than the number of statements in the Q-sort but does not expand on why this should be; however, it is only necessary to have sufficient participants to establish that a factor exists (de Graaf and van Exel, 2008-9, p75). The proportion of the population that belongs to one factor or another is not matter for Q methodology it is the differing views of the *Lay* role within the committee that are of interest.

## **Participants**

A total of 64 members, eight from each of the eight NHS Research Ethics Committees from the South West Strategic Health Authority domain (SW SHA) were approached via their committee administrators. As the operation of RECs is nationally determined it was not anticipated that the committees in the South West would be materially different to any others. What is important with Q-methodology is that participants are selected because of their ability to provide a view (Stainton Rogers, 2008, p182). This gave a self-selected sample of *Lay* and *Expert* members from the eight committees. This number allowed for an adequate number of Q-sorts for analysis even if the number returned was low. The inclusion and exclusion criteria were kept simple because of the reliance on the REC coordinator to determine eligibility and minimise exclusions.

## **Inclusion criteria**

- A current member of an NHS Research Ethics committee in the SW SHA.
- A committee member for at least six months.

## **Exclusion criteria**

There were no exclusion criteria.

## **Sample size**

No formal sample size calculation was performed. Unlike R methodology where large samples of participants are tested on fewer variables, in Q-methodology it is expected that the subjects have the status of variables and the sample is the number of items in the Q-sort. The sample size is related to the distribution of the sort so when the distribution of the sort is from -4 to +4 or -5 to +5, between 30-60 samples (statements) are used (Thomas and Watson, 2002, p142). Brown (1980, p260) suggests that 40-60

participants would be ample and often fewer will suffice but ideally there should be at least two sorts defining each factor.

The original plan was to approach six members from each of the nine committees (54 potential participants) in the south west NHS region but the closure of one committee in the region led to a change of plan and eight members from eight committees were approached (64 potential participants). It was felt that reducing the potential sample to 48 might reduce the available data if the number of responses was low. Increasing the number of potential participants to 64 was agreed as a reasonable stance with the academic supervisor and adequate for the project.

## **Recruitment**

The Area Manager for the SW SHA committees agreed that the REC coordinators could cooperate with this project and distribute the research packs to REC members at their next committee meeting. The REC coordinator's contact details, which are publicly available from the National Research Ethics Service (NRES) website, were used to contact the REC coordinators and the initial contact was made by a collective email to the coordinators for each of the committees in the SW SHA area.

After checking the dates of the next committee meetings, large envelopes containing eight research packs were posted to the coordinators of all eight NHS Research Ethics Committees in the south west of England in readiness for their next meeting. The packs were posted as close to the meeting date as possible to prevent them from being lost or forgotten. The REC coordinator was asked to give out the packs to approximately equal numbers of *Lay* and *Expert* committee members who were interested in taking part. The

committee coordinators were asked to return any undistributed packs so that some indication of pack distribution could be made. This was not universal with sporadic returns of a few packs, except in the case of one committee, which returned all eight Q-sort packs, unused without any explanation.

**The respondents**

Twenty-five Q-sorts were returned from REC members representing all membership categories and most age groups. The respondent’s demographic characteristics, including membership category, length of tenure, view on adequacy of training and age group (see Table four) were used to describe those respondents whose Q-sorts exemplified factors and for further interpretation once the factors had been defined.

**Table 4. A summary of the demographical information of the Q-sort respondents.**

Membership category* and gender	Age group	Number in group
Female <i>Experts</i>	41-50	3
	51-60	3
	61-70	2
Male <i>Experts</i>	51-60	2
Female <i>Lay</i>	18-30	1
	61-70	2*
	71-80	1
Male <i>Lay</i>	51-60	1
	61-70	1
Female <i>Lay plus</i>	51-60	5
	71-80	1
Male <i>Lay plus</i>	31-40	1
	51-60	1
	61-70	1

\*Includes one Q-sort that was returned without the grid to denote the positioning of the statements. Although data was completed on the reasons for choosing the statements at the extremes the Q-sort was not usable.

There was no obvious pattern in the demographics of the participants whose sorts exemplified the different factors and these data are described in more detail in the description of each factor in the next chapter.

## **Q-sorting process**

The information letter to the participants that was included in the Q-sort pack told them that the task would take between 30-45 minutes. They were advised to sit at a table, as it would be easier to set out the score sheet and then start the process of the sort. They were asked to sort the statements based on their thoughts and views of the role and functions of *Lay* members of NHS RECs. The first stage was to sort the statement cards (into three piles: one for statements they agreed with, one for statements they disagreed with and a pile for those statements that were either not relevant or they felt ambivalent about. The number of statement cards in each pile is then counted and recorded on the relevant boxes on the score sheet. This information is used to give an idea of the kurtosis of the distribution of the Q-sort.

The next stage was to start placing the statement cards (Appendix 2) onto the scoring framework (Figure 2). This resembles an inverted, quasi-normal distribution, with nine boxes across the top with scores from +4 to -4 and zero as the mid-point. This framework allowed for the statements to be scored. The next stage was for participants to select from the pile of statements that they agreed with and identify the two statements that they agreed with most. These two statements were then placed in the two boxes on the top right hand side of the grid on the score sheet (column nine). The next step was to find the next three statements that they most agreed with and place



them under the column marked '8'. This procedure was continued until all of the cards in the agree pile had been placed.

A similar process is then followed for the cards in the disagree pile. The two statements they most disagreed with are placed in the top left hand column under the number one, the next three statements in column 2 and so on until all the 'disagree' statements had been placed.

The cards from the remaining pile of statements that participants neither agreed nor disagreed with were distributed in the remaining squares. Once all of the cards were placed participants were encouraged to review the positions of the cards and to continue to change the positions of any of the statements within the framework, until they were happy with the relative positions of the statements. Once they were content with the position of the statements they were asked to write down the reasons why they had chosen the two statements that they had strongly agreed with and the two that they had strongly disagreed with. Analysis of the reasons for placing the statements at the extremes, where feelings were strongest, formed an important aspect in the interpretation of factors and in the formulation of the interview schedule. Finally, they were instructed to complete the grid by writing down the number of the statement in the corresponding box to mark the position of the statement in the Q-sort and return it with the demographic questionnaire, in the pre-paid envelope. It is these relative positions of the statements that are entered into the analytical software and are unique to the analysis of the Q-sort.

	1	2	3	4	5	6	7	8	9
agree									
Not relevant									
disagree									

**Figure 2. Example of the Q-sort grid**

There is some debate whether the preferred method of administration of a Q-sort is in a face-to-face setting and that it is not especially suitable for postal administration. Van Exel and de Graaf. (2005, p8) suggest that they would only administer a Q-sort by post if there were no alternative. The main reasons cited for the preference for face-to-face administration relate to the complexity of the task and the opportunity for probing responses within the Q-sort. Comparisons of findings from studies administered in both ways showed no real differences in findings (van Exel, 2005, p7). The geographical spread of NHS REC committees across the south west of England would have made anything other than postal administration difficult to manage in practical terms and it was reasonably anticipated that the members of RECs would have the intellectual capacity to complete the task. One pack was returned with a note saying that it was 'too complicated' to complete and one other was not correctly completed.

The Q-sort was accompanied by a short questionnaire to collect demographic data (Appendix 6), which were used to provide context to the Q-sort. The questionnaire gathered data on type of membership, gender, age group and length of tenure on their current committee; total duration of REC membership and whether they felt that the amount of training they had been given was sufficient. It was considered that training and duration of tenure could be important aspects in the participant's familiarity with the role and also in the possible development of expertise. These data items were therefore added to the demographic questionnaire.

## **Q-sort analysis and interpretation**

The data from the Q-sort were analysed using PQ-method software that is freely available on the Internet (Schmolck, 2013). The software runs under Windows and is limited to a maximum of 299 sorts and 200 statements. The maximum number of factors that can be extracted as part of the analysis is eight. This study has 24 usable sorts with 42 statements and six factors were identified.

## **Data entry and analysis**

The data were entered into the PQ-method software. The software had to be prepared by entering the wording of the statements in the same order that they are numbered in the sort. The text space available to describe each statement is limited to 60 characters. After the statements are entered into the software the position of the individual statement on the grid from each sort is entered column by column, separated by commas. The software has a built in checking mechanism that identifies whether the same value has been entered twice or if data are missing from any point in the grid. Once data from all the sorts are entered analysis can begin.

The analysis of the Q-sort data gives an overview of the different ways in which REC members perceive the *Lay* role and this is expressed through their ordering of the statements. The analysis of the data by the specialist software looks for similarities and differences in the placing of statements on the grid by participants and this allows the relative importance or strength of the statement to be established between the sorts. It is this degree of similarity that is calculated using eigenvalues and the total variance associated with each factor indicates how much of the data are accounted for by each factor. The level of agreement (or disagreement) between views of the respondents and any groupings of Q-sorts there might be in the data are identified using a factor analysis technique. This process searches for Q-sorts that have similar positioning of statements within them (factor array) and identifies any respondents whose views define the sort and the degree to which each sort contributes to the definition of the factor.

The Q-sorts are therefore the variables and the factors represent groupings of respondents who have expressed similar viewpoints through their Q-sort and not by membership group. The factors that emerge are linked with an eigenvalue, which is the amount of variance explained by each factor. The factors were selected using an accepted convention (Brown, 1980, p222) whereby only factors with an eigenvalue above one were utilised in the analysis. The variance for each factor is measured by the eigenvalue, which is calculated by the sum of its squared factor loadings and a value of 1.0 or more is considered important. The software allows for the factors to be rotated either manually or using the varimax rotation technique which is incorporated into the software ensuring the best 'fit' of the data into factors. The automatic varimax rotation was used for this study. A list of factor loadings is produced that identifies the defining

sorts within each factor. The relative contribution of each sort to the definition of the factor can be established by calculating the weighted score of each defining sort using the formula  $W=f/(1-f^2)$  where  $W$ =weight and  $f$ =factor loading. This procedure helps to define which sorts are important to the overall analysis.

### **Defining and describing the factors**

Stainton Rogers (2008, p191) suggested that it is important to note that the factors emerge from the data as a result of the sorting. They are not pre-determined and can be influenced by the position of the researcher. This will be considered more fully in the discussion of the method at the end of the thesis. The relative contribution each factor makes to explain the total variance in the data is germane to considering which factors are most important but these are not the only aspects to consider when defining the factors. In this study there were a total of 5 main steps:

- I In addition to the eigenvalues, the factors were all defined by a minimum of two sorts (Brown 1980, p222). Using this rule, a factor matrix of six factors was identified which had two or more defining sorts for each factor. This matrix accounted for a total of 74% of the total variance with Factor one accounting for almost 4 times more of the variance than the next most important factor.
- II A review of the factor array for each factor. This is a composite sort derived from all the sorts that defined that particular factor and is calculated by the average score for each statement in that factor. This sort does not necessarily represent the view of any one respondent but represents a 'best fit' of the data. The factor arrays can be found in Appendix 12.
- III A review of the z-scores of the statements for each factor was also taken from the analysis. In Factors three, five and six the ordering of the statements did not reflect the grid that was used in the sorting of the statements. Where z-score values were tied it allowed for more accurate placing of the statement, for example there is an

additional statement in a column than the sorting grid indicated. This was a particular issue in Factors three and six (see Appendix 12, Figures 6 and 9).

- IV An analysis of the statements positioned at the extreme ends of the sort, i.e. those scoring -4, -3, +3 and +4 were reviewed along with the qualitative descriptions illustrating the reasons for respondents choosing the positioning of these statements. This follows a method described by De Graf and Van Excel (2008, p77) and Stainton Rogers (2008, p188) who suggested that careful assessment of these statements forms an important aspect of the analysis of the Q-sort. These statements and the reasons for their selection formed an important role in the naming of the factors.
- V Factor interpretation was also aided by grounding the data with reference to the literature and by comments made by participants completing the sort following a framework suggested by Stainton Rogers (2008, p188). This was achieved by semi-structured interviews with ten individuals. Their interview data was used to further describe the Q-sort factors and contributed to the naming of the factors

## **Interviews**

The primary aim of the interviews was to clarify any issues raised by the Q-sort, in particular areas where the responses were incongruous, and to explore in more detail any emerging issues from the data. It has been suggested by Brown (1980, p200) that individual interviews with participants should follow immediately after they have completed the Q-sort. The main purpose of the interviews is usually to explore in more depth the reasons for the positioning of the statements on the grid of their Q-sort. For this study it was decided to use the interviews to explore any potentially conflicting aspects observed in the idealised Q-sort and the comments that respondents had included on their response sheets. It is for this reason that it was important to interview participants who had completed the Q sort.

The interviews in this study were not seen as purely an attempt to triangulate the findings from the Q-sort. Bloor (1978, p548) suggests caution in the area of respondent validation using triangulation techniques. The interviews in this study were not an attempt to validate the findings from the Q-sort. Instead, the interview data were used to provide context to and explanations for the reasons for selecting the position of the statements in the Q-sorts. This gave the opportunity to explore further the areas emerging from the analysis of the Q-sort data and to seek further explanation where responses appeared to conflict with each other.

An interview guide (Appendix 8) was created following a preliminary analysis of the Q-sort data. It involved consideration of the positive and negative statements from the defining sorts for each factor and the reasons that were given by respondents for choosing them. Also, the significant items at the extremes of the scales (those scoring +4, +3 and -4, -3) that emerged from the idealised Q-sort were considered. The interviews allowed further exploration of where the relative positions of statements in the sorts appeared to conflict with each other or the free text comments giving the reasons for positioning statements in the sort needed further exploration.

### **Selecting participants for interview**

At the time of receiving the research pack the participants were asked to indicate, by return of a separate postcard (Appendix 7), their willingness to take part in an individual interview to explore the Q-sort findings in more depth. The return of the postcard was separate from the Q-sort, which enabled the participant's Q-sort responses to remain anonymous. Up to ten individual interviews were planned with approximately equal numbers of *Lay* and *Expert* members.

It was considered that ten interviews would be a reasonable sample and as this represented over a third of the Q-sort respondents it would provide adequate additional data to clarify or explore any particular issues arising from the Q-sort data. It was proposed that if expressions of interest in being interviewed were received from more than ten participants; the names would then be selected for interview at random, simply being drawn from a hat.

Sixteen expressions of interest were received and their names were listed in order of receipt of their response. Numbers corresponding to the respondent's position on the list were placed in a 'hat' and drawn to indicate the order that they would be approached. The remaining names were held in abeyance, as a reserve list, in case of attrition. One person who agreed to be interviewed had to cancel their appointment and then withdrew, requesting that another person be approached. Another participant cancelled their interview due to bad weather. In the first case, the next person on the list was then contacted; in the other case, data were used from the pilot interview rather than try to rearrange another one.

The first interview was intended to pilot the interview guide but since this was unchanged after the pilot interview, the data from this interview were included in the analysis and only nine additional interviews were conducted. It was intended that the interviews would be conducted with approximately five *Lay* and five *Expert* members. However, an oversight in the information requested on the postcard that potential interviewees returned to indicate their willingness to be contacted meant that this information was omitted. Fortunately, those selected for interview were actually divided reasonably evenly between the membership groups. Interviews were conducted with



four *Expert* members and six *Lay* (two previously employed by the NHS employees including retired nurses and four who had never been NHS employees).

The interviews were arranged by direct contact with the potential participants who had returned their postcard expressing an interest in the interview phase of the study. They were contacted by email or telephone in the order that they had been 'pulled from the hat' and the interview details were confirmed by a letter attached to an email (Appendix 9). The interviews were conducted at a mutually convenient time and venue. This required a moderate amount of travel across the south west of England and on the whole the interviews were either held in the participant's home (4) or place of work (2) or in a meeting room at the researcher's office (2). One interview was held in a local library and one in a supermarket coffee shop. The latter was not the planned location but the venue had to be hastily rearranged after the participant realised that due to security restrictions in their place of work audiotaping was not permitted. This created some difficulties with background noise on the recording making transcription slightly difficult but the data were still usable.

The purpose of the interview was explained again prior to taking written consent by reminding participants of the content of the initial information letter that was included in the research pack. Written consent was obtained at the time of the interview and included permission to audiotape the interview and use illustrative quotations where appropriate. Two copies of the consent form (Appendix 10) were signed allowing the participants to keep one and the researcher retained the other.

All of the interviews were digitally recorded and fully transcribed, including most non-words and hesitations. Using a modified framework for the analysis described by Hycner (1985) the first step of the analysis involved extracting key themes in response to each of the questions in the interview schedule that were relevant to the research question. Many of these headings form the basis of the reporting of the results. General and unique themes were identified from each of the interviews and then linked back into the six factors identified in the Q-sort.

Once the interviews were completed the additional respondents who had expressed an interest were sent a letter politely declining their offer to be interviewed (Appendix 11). They were thanked for their interest but it was explained that, as there had been a high response, which had resulted in too many participants and they would not be required for interview.

## **Research Ethics and Governance**

According to the Governance arrangements for NHS RECs (DH, 2001b) this project did not require ethical review by an NHS REC, this was confirmed by contacting the National Research Ethics Service Queries line. However due to the potentially sensitive nature of a project involving NHS REC members it was advised that an application should be made.

As part of the NHS research governance arrangements all research in the NHS has to have an identified sponsor. The role of the sponsor is to assure the quality of the project and that the protocol is adhered to. It is usual that in the instance of student projects

that supervision would fulfil this obligation and approval was gained from Cardiff University to act as sponsor for this project.

Following NHS REC approval, approval was sought from the research lead at the SW SHA and from the NRES regional manager to approach committees. No approach to research participants was made until these approvals had been confirmed.

The data protection arrangements for the project that were approved as part of the ethical review required that all person identifiable information such as signed consent forms and cards with contact details for potential interviewees were stored in a locked drawer. Compliance with this requirement was achieved by storing all person identifiable information in the researcher's office in her place of work.

The data collection proceeded as planned and the data were analysed as described. The next chapter describes the analysis and a full interpretation of the data.

## Chapter 4 – Data analysis and interpretation

### Introduction

Using Q sort methodology described in the previous chapter, members of NHS RECs were asked to construct their view of the role of *Lay* members. The Q-sort statements were constructed from a review of the literature and policy documents covering two related areas: the role of *Lay* members in NHS RECs; and the role of patient and public involvement in the NHS more generally. The Q-sort data reveal how members of NHS RECs understand the role of *Lay* members based on their experience as members of RECs. Although the focus of this study was on the role of *Lay* members, the dichotomous nature of the *Lay* and *Expert* categories means that some corresponding descriptions of the roles played by *Expert* members also emerged during the course of the analysis.

### An overview of the factors

The patterns observed in different Q sort groups form factor arrays that, in turn, characterise the six factors identified (see Appendix 12, Figures 4-9). The analysis software also allows the relative importance of each statement to be compared between the different sorts (see Appendix 13). It is the degree of similarity in the way the statements are ordered, which is calculated using eigenvalues, that measures the total variance explained by each factor. The factor eigenvalues and variances can be seen in Table 5.

**Table 5. The factor names, their eigenvalues and variances.**

<b>Factor no.</b>	<b>Factor Description</b>	<b>Eigenvalue</b>	<b>Variance %</b>
<b>One</b>	<i>Lay members are part of the REC team</i>	9.47	39
<b>Two</b>	<i>Lay members are skilled and not representative</i>	2.41	10
<b>Three</b>	<i>Lay members are the voice of the ordinary people</i>	1.71	7
<b>Four</b>	<i>Lay members have the same role as experts</i>	1.48	6
<b>Five</b>	<i>Lay members in the traditional REC role</i>	1.29	5
<b>Six</b>	<i>Lay members are complementary to the <i>Experts</i></i>	1.17	5

As described previously, the naming of the factors is an interpretive process that includes an analysis of the positioning of the statements that characterise them. Particular significance is given to the statements at the extremes of the factor arrays (i.e. statements scoring +4, +3, - 4 or -3). The reasons given by the respondents for the positioning of statements at the ends of the grid are central to the more detailed explanation of the factors even if their particular sort is not a defining one.

Six factors emerged from the data. Following an overview of the findings each factor is described in detail using the following structure,

1. A summary description of the factor, including the demographics of the respondents whose sorts defined it
2. A review of the statements at the extremes of the factor array

3. An interpretation of the factor, including the derivation of the titles and, where appropriate, a broader discussion of how the issues raised by the position of Q-sort statements relate to the interview data.

The factors provide a description of the *Lay* role within NHS RECs from the perspective of the respondents. Some of the emerging issues revealed tensions and contradictions in the way the *Lay* role is considered. The implications of these and recommendations for future practice are discussed in the next chapter.

Of the six factors, Factor one, *Lay members are part of the REC team*, was by far the most important, accounting for 39% of the total variance. Given the number of possible variations in the ordering of the 42 statements (42 factorial or  $1.405 \times 10^{51}$ ) it is notable that nearly 40% of the variance of the data are reflected in this one factor, more than the sum of the variances for all of the other factors combined.

By contrast, the next most important factor accounted for 10% of the variance. Factor two, *Lay members are skilled and not representative*, suggests that *Lay* members are not demographically representative of the wider population. This raised a number of issues relating not just to expertise but also to the recruitment and selection procedures, including the advertising of vacancies. Factor three, *Lay members are the voice of the ordinary people* and Factor four, *Lay members have the same role as Experts*, are less significant statistically, accounting for 7% and 6% of the variance respectively.

Nevertheless, they do describe interesting aspects of the *Lay* role including an advocacy role (Factor three) and highlight the lack of differences between *Lay* and *Expert* members (Factor four). Factors five and six are the least important, statistically,

with each explaining less than 5% of the variance in the data. Factor five describes the *Lay* role as a balancing role that does not change over time in spite of training and experience. More importantly, this factor suggests that *Lay* members cannot become experts in their own right and it is the one that mostly closely reflects the qualities of the *Lay* member as described by the HRA (see Table 1, p36). For this reason, this factor has the title *Lay members in the traditional REC role*. Factor six suggests that *Lay members are complementary to the Experts*, describing a role with a key function to assure the quality of information to participants.

Where different factors have similarities in the placing of the statements in the factor arrays then there may be correlations between factors. The relevant significant value for any correlation is calculated by  $2.58(1/\sqrt{n})$  where  $n$  is the number of statements in the Q-sort; a value above 0.4 is significant in this study. Some of the factors correlated with a significant factor loading at  $p < 0.01$  level shown in Table 6. The highest correlation is between Factors three and four (0.73), with additional strong correlations observed between Factors one, two, four and six. It is also worth noting that Factor five, *Lay members in the traditional REC role*, does not correlate with any of the other factors.

The demographic information about the respondents is not intended to provide a way of establishing associations between them and the factors but to give information about the respondents who defined them. Most of the factors were defined by the views from a combination of membership categories, with varied lengths of tenure and views on the adequacy of their training. There were, however, two interesting exceptions worth noting: Factor three, *Lay members are the voice of ordinary people*, was only defined by

Lay members and Factor four, *Lay members have the same role as experts*, was only defined by *Experts*.

**Table 6. Factor correlations – relationships between the factor scores**

Factor	<i>Lay members are part of the REC team</i>	<i>Lay members are Skilled and not representative</i>	<i>Lay members are the voice of ordinary people</i>	<i>Lay members have the same role as Experts.</i>	<i>Lay members in the traditional role.</i>	<i>Lay members are complementary to the Experts.</i>
1	1.00	<b>0.42</b>	-0.05	<b>0.52</b>	0.36	<b>0.53</b>
2	<b>0.42</b>	1.00	-0.18	0.28	0.30	<b>0.51</b>
3	-0.05	-0.18	1.00	<b>0.73</b>	0.01	-0.14
4	<b>0.52</b>	0.28	<b>0.73</b>	1.00	0.09	<b>0.43</b>
5	0.36	0.30	0.01	0.09	1.00	0.36
6	<b>0.53</b>	<b>0.51</b>	-0.14	<b>0.43</b>	0.36	1.00

*Data in bold indicate significant correlations*

### **Uniformly held views of the *lay* role**

As described in the methods, a score is created by each statement's position in the Q-sort using specialist software. The rank statement totals (Appendix 13) illustrate the positioning for each statement as it is scored in each factor from their placements in the factor arrays. The ranks assigned to each statement across the rows allow an overview of the relative ranks for statements across the factors whereas the rank scores in the columns indicate the ranks of statements within the factors.

This scoring also helps to identify certain statements that are uniformly placed in the grid regardless of the factor with which they are associated as shown in Table 7. This



similarity suggests that irrespective of the description of the *Lay* role given by each factor, there are some uniformly held views of the *Lay* role.

**Table 7. Shows statement scores for those indicating uniformly held views**

Factor → Statement ↓	<i>Lay</i> members are part of the REC team	<i>Lay</i> members are Skilled and not representative	<i>Lay</i> members are the voice of ordinary people	<i>Lay</i> members have the same role as <i>Experts</i> .	<i>Lay</i> members in the traditional role.	<i>Lay</i> members are complementary to the <i>Experts</i> .
<b>Mostly Positive statements</b>						
2. Training is vital for lay members	+1	+2	+1	+1	+4	+2
17. Lay members are essential to balance the views of the committee	+3	+3	+3	+2	+3	+2
7. Lay members can bring a set of expert skills of their own, e.g. legal, financial etc	+3	+4	-2	+4	+3	+4
<b>Mostly Negative statements</b>						
15. The ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a lay member	-2	-1	-2	-1	-2	-4
36. Lay members do not need to be trained	-2	-2	-1	-2	-2	-3
21. The value of lay members ability to give a lay perspective diminishes over time	-3	-2	0	-2	-2	-1

There were three largely positive statements and three negative statements where this was observed and merit further discussion. The most consistently positive scoring statement was statement 17, (*Lay members are essential to balance the views of the committee*), scoring +3 or +2 on all factors. One interviewee emphasised the need to balance the *Expert* role is important in allowing the perspective of the patient to be assessed.

*I'm not sure the two ethics committees I've been on have been balanced as such because the power of the medics I think prevails, unless you do have an ex-*

*medical person<sup>9</sup> with a different opinion who is Lay and then perhaps people take notice, but like I've said before my view is that they're (Lay members) there to balance in terms of allowing the effect of the patients or the client come through*  
(Pilot interview, female *Expert* member)

Statement 7, (*Lay members can bring a set of Expert skills of their own for example, legal, financial, etc.*), is the most consistently, highly rated, positive statement, scoring +4 or +3 on all factors, except in Factor three, (*Lay members are the voice of ordinary people*). In this factor it had a negative score (-2), suggesting that although not important in the framing of this statement, was important in the sense that it denies that *Lay* members have expertise. Statement 2, (*training is vital for Lay members*), also scores positively across all of the factors illustrating that training is considered to be necessary for the role regardless of the overall view of the role. Although a uniformly positive statement, it scores most highly in Factor 5 (*Lay members in the traditional role*) and this will be discussed in more detail later in the explanation of the factor.

There were two statements where the scoring was negative across all factors, indicating disagreement with the statements and a third where the scores were mostly negative. There was universal disagreement with statements 15 and 36 (*the ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a Lay member* and *Lay members do not need to be trained*). The third statement, (*value of Lay member's ability to give a Lay perspective did not diminish over time, number 21*), scored negatively across all but one of the factors suggesting that *Lay* members retain a perspective that is different to *Experts* and the concept of lay-ness is not lost. This was

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<sup>9</sup> This may be the case but doctors are the only *expert* group that maintain their *expert* status post retirement.

Factor three (*Lay members are the voice of ordinary people*), where it scored zero, indicating ambivalence to the idea expressed.

The description of the factors that follows begins by focussing on the placing of statements that are factor specific. Where this raises more general issues, these are explored using the comments provided by Q-sort respondents as explanations about the placing of statements at the extremes and quotations from the interview data. Given the ways in which some factors correlate, there is inevitably some overlap where the same statements feature in other factors and where the statements feature as uniformly held views.

## **The Factors explained**

### **Factor one - *Lay members are part of the REC team***

Four Q-sorts that were all completed by women defined this factor. They were from mixed membership categories, including two *Experts*, one *Lay* and one *Lay plus* with ages across most categories from 51-80. Although the *Lay plus* member had spent more than five years as a member she was the only one defining this sort who did not feel that she had received sufficient training, with the rest of the respondents feeling adequately trained. Q-sort number 7, which was completed by an *Expert*, contributes the greatest weight to this factor (Table 8).

**Table 8. The demographics of the respondents whose Q-sorts defined Factor one.**

Defining Sorts	Factor Loadings	Weighted Average	Demographics				
			Type of Member	Gender	Age group	Tenure more or less than 5 years	Training sufficient
7	0.8	10.08	<i>Expert</i>	Female	61-70	>5	Yes
11	0.72	6.8	<i>Lay</i>	Female	71-80	Not given	Yes
22	0.65	5.13	<i>Lay plus</i>	Female	51-60	>5	No
18	0.59	4.05	<i>Expert</i>	Female	51-60	<5	Yes

Factor one has a number of positive and negative statements that define it as shown in Table 9.

**Table 9. Defining statements for Factor 1 - lay members as part of the REC team**

Statement number	Statement	Grid Position
14	Lay members have the same role and responsibilities as the professional members	+4
28	Being accepted as a fully functioning member of the committee is vital to performance	+4
7	Lay members can bring a set of expert skills of their own, e.g. legal, financial etc	+3
17	Lay members are essential to balance the views of the committee	+3
24	Lay members need to be able to challenge the views of the professional members	+3
12	The role of lay members is different to that of their professional colleagues	-3
19	Lay members are only there to safe guard the public interest	-3
21	The value of lay members ability to give a lay perspective diminishes over time	-3
4	Lay member's primary role is to ensure that subjects are able to give informed consent.	-4
40	Lay members are only there to legitimise 'committee's decisions	-4

The highest, positively ranked statements scoring +4, were 14 and 28. They were ranked higher in this factor than any of the factors. Statement 14 described *Lay* members as having the same role and responsibilities as their *Expert* colleagues, suggesting an equality of position and shared purpose. Statement 28, says that “*being accepted as a fully functioning member of the committee is vital to performance*”. The positive scoring of this statement is suggestive of a need to “fit in”. Taken together, these two positive statements suggest that *Lay* and *Expert* members contribute equally to the work of the committee. By looking at the other statements, however, we can also see that these contributions may take different forms when considering the ways the uniformly held statements define the *Lay* role. For example, both statements 7 (*Lay members bring expert skills of their own, e.g. legal, financial*) and 17 (*Lay members are essential to balance the committee*) both scored +3, as did statement 24 (*Lay members need to be able to challenge the views of the professional members*). This leads to a summary of Factor one as a committee that works together as a team, bringing different skills but with equal weight to the ethical review.

However, the discourse of Factor one, (*Lay members are part of the REC team*), then problematises the use of *Lay* and *Expert* to define REC members. It suggests that *Lay* members bring a set of skills, such as legal, project management or financial, that is similar in that they are professionally based. These skills are complimentary to the *Expert* members and they have the confidence to use them to contribute to the same ultimate goal, the ethical review. All of which makes the use of the term “lay” a strange choice in this situation,

*It's a funny term, I think, I think it's, I think you do need to have people who have knowledge from different backgrounds but I don't think necessarily they are either*

*Lay or health or professionals really, it's sort of, in a way, there's a list of attributes that the committee have to have, and in a way you need to say he's good at that, she's good at that,* (Interview 4, female, Expert member).

There was a strong view from the interview data and explanations of why statement 14 was placed where it was on Q sort grid that the *Lay* role was not different; it was simply that the role was carried out using a non-clinical perspective:

*All members of a REC have the same role, i.e. to protect participants. Lay and professional members simply bring different skills and experience to the discussion.* (Q sort 8, female, Lay plus member, 51-60).

This could denote the key distinction, i.e. with roles the same but some skills and expertise being shared and others different. One of the shared skills was considered to be an analytical approach to reading applications and one of the *Lay* members in their interview suggested,

*Yeah, I'm not quite sure if I would describe it as different skills and think we've got different viewpoints than perhaps the Expert members...um, in terms of skills, I'd say, if, I can only think about me really and how I sort of approach it, but the skill that I bring to it from work, from what I used to do at work, I suppose, is being, being analytical and sort of being able to read quite a long document and pick out relevant points really, um, but I'm not sure that's necessarily different from the professional members.* (Interview 1, female Lay plus member).

Their different approaches were explored in the interviews, one of the questions in the interview schedule asked; *if Lay members have the same role and responsibilities but use different skills and expertise to do the job, how do the skills differ?* There was some reflection on medical skills but acknowledgement of the value of others, too.

*Well they've got a different background, they haven't got a medical background, less medical knowledge but they've got some knowledge of other areas of life. I was an (gives profession)*

*Right (JH)*

*So that's interesting because a lot of computer things come up so I'm, so I was in computers for thirty years...so this particular skill's been useful plus the fact that I've been part of a big organisation for, you know, fifty years.*

*(Interview 5, male, Lay plus member).*

The use of skills from outside of healthcare illustrates the different expertises required by RECs and how *Lay* members may have specialist expertises in domains that are useful in the ethical review. For example, one *Expert* member in her interview commented how one *Lay* member in her committee brought a business perspective to her review of the application,

*but then we've got another person who runs their own business and she's got a very much strong business head and looks at it in a completely different way again and she focuses on things like the indemnity issue or the, or the money involved or the um you know the things that other users might not think about.*

*(Interview 7, female, Expert member)*

Those interviewed also recognised that although the backgrounds of *Lay* members differ enormously they possess the core skills in literacy and critical reading expected of all professionals. It was reported that some also have a vast knowledge of the health service gained from prior employment or work in occupations linked to research or health care. It is not uncommon for *Lay* members to be retired university professors with expertise in research methods and statistics, which are useful skills when reviewing applications to the ethics committees. *Expert* members share similar professional core skills with varied clinical or health care expertises.

The different backgrounds of *Lay* members do bring a set of general and specialist skills including critical appraisal, as well as more research specific specialist skills such as statistics. Some of this is a function of the recruitment process whereby fairly homogeneous groups of educated professionals are recruited. They use skills acquired from their working roles such as an idea of 'process' or the expected behaviour within a committee and identifying salient points from reading long documents. One interviewee commented that her training in the legal profession had made her,

*prepared to read documents no matter how thick they are*  
(Interview 9, female, *Lay plus* member).

The structure of the committee allows members with specialist expertise to play to their strengths. They are able to use specialist expertises developed during the course of their work and which are recognised by other REC members as useful in the ethical review. Collins and Evans (2007, p64) suggest that expertise can be applied; that is where reasonable judgements can be made based on expertise taken from another field. It was identified in the interviews that legal expertise, project management and risk assessment were amongst a number of other skills that added to the ethical review and these were unlikely to be provided by the *Experts* and were skills that were not sought as part of the recruitment process. It was recognised during the interviews that *Lay* members brought skills to the committee and that these were overwhelmingly more likely to be evident as a result of their education and employment backgrounds than due to the training provided for the role,

*Lay members often have had a professional career outside of healthcare and contribute knowledge and opinion drawn from that career. They are able to articulate their views on proposals and can evaluate the worth of research to the public.*  
(Q sort 6, female, *Expert* member, 41-50).



## Different (but equal) contributions

The idea of different (but equal) contributions was reinforced by one of the interviewees:

*...everybody can bring something and the whole idea of an ethics committee is to have a broad, rounded um group of people...from different backgrounds, different ages and different expertise, you need obviously people with clinical expertise, 'cause you, your participants will probably be patients, then you need other types of expertise at different times...but you don't need it all the time...but it doesn't mean to say that because, you know, I mean, because you work for a large multinational car manufacturer you're not an Expert*

(Interview 2, female, Lay member).

It is not clear whether these are aspects of the role that are associated with the ubiquitous expertises of every-day life or with the kinds of specialist expertise (legal, financial) that are highlighted in the Q-sort statement. Thus, for example, working for a large multi-national car manufacturer could be taken to imply a robust common sense or some more specific skills relating to project management, IT or managing people.

The other positively scoring statement that defines this factor is statement 24 (*Lay members need to be able to challenge the views of the professional members*). As Schutz (1962, p120) suggests, members of a group do not necessarily take their view of the world for granted or accept it without challenge. The high, positive score for statement 24, indicates that a degree of confidence and assertiveness is required by Lay members as they are expected to challenge the views of other committee members. Jones *et al.* (2008, p26) identified this function as the 'challenge function', which they assert leads to better decision-making by the committee. The importance and nature of Lay members 'challenging professionals' was explored further in the interviews.

## Using 'the challenge function'

The interviewees were asked *if a Lay member's role is to challenge the views of Experts and researchers, bringing balance to the committee, how does this affect the function of the committee*. There were three main themes in the responses to this interview question which link to Factor one (*Lay members are part of the REC team*). Firstly, the interview data supported the Q-sort data, with the notion of challenging views and opinions seen as important in both sets of data. The interview data added some additional depth, however, and made it clear that the challenge function was not restricted to *Lay* members. Instead, it would be more accurate to say that the responsibility falls on all members – *Lay* or *Expert* – with everyone expected to challenge when necessary.

Secondly, one respondent said that there was no real issue with *Lay* members challenging researchers. Since the researchers were unlikely to know the background of *Lay* members they would not see them as having different roles anyway. This may be due, in part, to the fact the most members have professional backgrounds and are familiar with the behaviours and processes expected in committees. Suggesting that it is difficult to tell the difference between a medic and lawyer, for example, as members know how to ask questions politely and have the social skills to do so. Therefore 'being a professional' swamps disciplinary differences in this context. It was also noted that some committees used a process for the questioning of researchers by submitting questions via the REC chair. This way the source of the question to the researcher would not be known.

Thirdly, regardless of their background, it emerged that the *Lay* members were felt to have more subtle ways to challenge the thinking of the *Experts* and this did not require any particular specialist expertise. The main method used by *Lay* members to ‘challenge’ views and to ask searching questions was called asking what they termed “daft questions”. One *Lay* plus member stated,

*asking daft questions was my function*

(Interview 9, female, *Lay* plus member).

This can be accomplished through admitting (or feigning) an absence of expertise in order to ask what they perceived to be ‘daft questions’. This could be seen to be the part in the team that the *Lay* member plays by opening up the discussion for others. “Daft questions” are the sort of questions that *Lay* members feel empowered to ask because they would not be expected to know the answer anyway. This enables them to challenge *Expert* members (and researchers) by encouraging them to look at things differently.

*Um, I think one of the joys really of Lay members is that they come from very different backgrounds and some of them are completely Lay and some of them are sort of quasi-lay um and none of them with NHS knowledge and others are professional, have worked in the NHS in a sort of non-professional way who have quite a lot of knowledge um, but the other thing, one of the skills that they have is just looking at it from a completely different perspective.*

(Interview 4, female, *Expert* member).

This alternative view helps to subtly challenge established ways of thinking and ways of doing things. By asking “daft questions”, *Lay* members could open-up issues that *Experts* take for granted and fail to challenge because of that.

*...the Lay member will say “can we just go back to the beginning, what exactly do you mean... by X,Y,Z? Followed by a sort of stunned silence but that, that to me, is where the Lay members come into their own because the Experts could never admit that they don’t understand.*

(Interview 2, female, *Lay* member).

This mechanism for challenging the *Experts* was also seen to be a way of allowing the patient's perspective through and of 'balancing the views of medical science'. In this sense, it could be an example of a ubiquitous expertise whereby *Lay* members use experience of 'every day' ethics to ask the questions. There was, however, some concern that *Lay* members did not always fulfil this role, with some interviewees claiming that that some *Lay* members were more inclined to agree with what others said.

*We've got two very young Lay members one of them quite recently done a degree in ethics and another one is quite young so they would not you know, I think they would tend not to disagree with what, what other people say*

(Interview 3, female, *Lay* member).

These views concur with Parker (2008, p32) who expressed similar concerns that certain *Lay* members' decision-making may be swayed by the views of *Experts* and supported the view that there was at least some medical dominance in the committee. This will be discussed in more in Factor three (*Lay members are the voice of the ordinary people*).

### **Managing the Old Boys' Network**

The negatively scoring statements in Factor one, (*Lay members are part of the REC team*), suggested that there was no recognition of a distinctive *Lay* member function in those areas where lay contributions are usually made (Hogg and Williamson, 2001, p3) such as: safe guarding the public interest (statement 19, scoring -3), ensuring that subjects can give informed consent (statement 4, scoring -4) or "legitimising" committee decisions (statement 40, scoring -4). However, the reason for one of the Q sort

respondent's positioning of statement 17 at +4 (*Lay members are essential to balance the views of the committee*) suggested something more serious,

*Lay members stop a real or perceived 'old boy's network' developing where doctors approve research by other doctors in the belief that as fellow professionals they will behave ethically*

(Q-sort 8, female, *Lay plus* member aged 51-60).

The idea of preventing the formation of an "old boys' network" and acting as "scrutineers<sup>10</sup>" was highlighted in two of the Q-sort responses, which were suggestive of a legitimising or governance function. This contradicted the disagreement with statement 40 (*Lay members are only there to 'legitimise' committees decisions*) scoring -4. This statement also scored -4 on Factors one and six indicating a strong disagreement with this function by those whose Q sorts defined these factors. One of the Q sort respondents gave their reason for disagreeing with statement 40 as,

*I see no philosophical, organisational, regulatory or practical evidence to support this statement. It would require extraordinarily inept chairmanship to cause this to seem to be true.* (Q sort 23, male *Lay plus* member, aged 51-60).

Another commented,

*This may be the view of some "clinical" professionals who can be patronising towards Lay members.* (Q sort 3, female, *Expert* member, aged 61-70).

There are numerous examples in the literature linking lay involvement with the need to legitimise professional decision-making (including Callaghan and Wistow, 2006, Harrison and Mort, 1998, Jones, *et al* 2008, Pickard, 1998). Interestingly neither the responses to the Q-sort or the emerging themes from the interviews were supportive of this view.

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<sup>10</sup> This was assumed to be scrutiniser.

*Legitimise just sounds as though you're rubber-stamping it and I've never thought that at all.*  
(Interview 9, female *Lay plus* member).

There was a sense of needing to defend the real role rather than the notion of the role simply requiring the members to “tick the box”. The mechanisms for legitimating decisions such as voting in cases of disagreements were also considered ineffective. Two respondents were of the opinion that although voting decisions were rare it would be impossible for *Lay* members to be able to over-rule an *Expert*-led decision because only one third of the committee is made up of *Lay* members. Another commented that they did not feel that *Lay* members had a scrutiny role but conceded that the research community may view them differently.

*They don't have that at all. I believe that some of the, the professional, clinical research community view Lay members like that (in a scrutiny role)*

*Right, that's interesting (JH)*

*Um and that they, you know, how could Lay members possibly question what they have been doing...because they've been doing it for years, so I would see that, that perspective has come from researchers*

*Right (JH)*

*That would be my view having had a few arrogant, rude researchers come to our committee...who've talked to all of us as if we're complete plonkers*

(Interview 2, female, *Lay* member).

However, in two interviews it was also suggested that there was a more favourable review for researchers when a committee member knew them, which may give the impression of an “old boys’ network” and *Expert* members were especially more supportive of their own professional groups.

*A senior person made an application with what appeared to be a flaw... (I) didn't want to upset the medical members but eventually the application was turned down ...but the suggestion was that he was so eminent he was beyond question. But it had a conceptual flaw that even I could see...suggests the system works. But the Experts had to confirm that the decision was right.*

(Interview 9, female, *Lay plus* member).

Hedgecoe (2012, p668) considered this as a form of “local knowledge” that plays an important role in the way RECs make decisions which has now disappeared for a number of researchers with the closure of their local committees. Jones *et al.* (2008, p42) found that policy makers and scientific advisory committee members considered that the inclusion of lay members renewed public confidence in their work. Lay members were felt to improve communication, transparency and the provision of advice that has social context. It was also considered that they,

*... bring complementary forms of expertise to the committee table*  
(Jones *et al.*, 2008, p42).

In addition, this factor considered that the *Lay* role is not different to that of *Experts* (statement 12, scored –3) in the sense that they both have to review the ethics of research (collectively) by individually contributing different skills. This can be analogous to a football team, with all members playing football but with some defenders and some in attack; the team would not function if all played as goalkeepers.

There was also disagreement with the view that the *Lay* members’ ability to give a lay perspective diminished over time (statement 21, scored –3). Although it might be considered that training or length of tenure would influence the *Lay* perspective, i.e. through practical application of the skills used in the work of the committee, this factor shows this was not considered to be the case.

There was a low importance placed on the statements relating to training (statements 2 and 3 rated +1 and –1, respectively). It is interesting to see the ambivalence about the idea that practical experience is more useful than formal training (statement 11, scoring

0). The overall indication that training is not considered to be an important aspect in the development of the role by those who defined this factor may be due to their view that a certain amount of expertise relevant to the role is already present. As one interviewee described,

*yeah I suppose our committee might be quite a brand new one because we've got some, some retired academics on, on it and one was a retired professional chemist. Whenever there was any project involving any chemistry or, I mean he's particularly interested in spectroscopy as well so anything that involved that kind of technology including MRI as well and, and CT scans and things like that, he would then focus on the techniques they use in the study and because of his interest*

*so not the average Lay member (JH)*

*no and we've got another one who is not an average Lay member because he's a retired statistician so he's very tempted to start to pull apart what the analysis is and what the sample size calculation was and things like that*

*Mmm which is no longer the remit of the committee anyway (JH)*

*I know it's not but only this week you know [he] sent me an email about a particular application and he's querying the, the sample size on it and actually how they calculate it so you know again it's people bringing their own experience to the committee. (Interview 7, female, Expert member).*

The findings of a survey of NHS REC Lay members conducted in 2008 found that 78% of the respondents felt that they brought a professional perspective to their committee (Simons *et al.*, 2009, p8). The majority (73%) of these professional perspectives were gained from their experience in the education or health and social care sectors. The HRA / NRES training programmes are not tailored to account for this pre-existing knowledge and the skills required by members are not explicitly described (Table 1, p36) either at recruitment or from the training. The importance of training for the role emerges more fully linked with in Factor five, *Lay members in the traditional role*, and is discussed in detail in the description of this factor.



## **Risk of team pressure**

The predominant view emerging from the data suggests that the committee functions as a team with members contributing different skills. Being accepted, as a part of the team, is important to the committee's function with statement 28, *being accepted as a fully functioning member is vital to the performance of the committee*, (scoring +4). However, there are risks, and one of the Q sort respondents acknowledged that,

*The committee needs to work as a whole unit with each member respecting the perspectives and views of the others. "Misfits" are often ostracised and can be undervalued, so they leave.* (Q sort 6, female, Expert member 41-50).

It is known that being accepted into a group may require subtle behaviour changes or modifications on the part of members to enhance their 'belonging' (Kiesler and Kiesler, 1970, p11). This social identity approach summarised by Abrahams and Hogg (2006, p5) emerged over half a century ago and creates a level of conformity that may not be entirely desirable. Hogg (2001, p6) suggests that lay members who are most likely to support the views of professionals are more likely to be recruited. Although there was no particular evidence of this, eight of the ten interviewees were recruited by "word of mouth" or direct approaches by friends or colleagues. It could be argued that these recruitment strategies could inadvertently support a desire to recruit members who are perceived to be more likely to "fit in", potentially reinforcing the need to ensure conformity rather than efficacy.

## **Factor two - Lay members are skilled and not representative**

The question of representativeness of the wider society is a high priority in the policy statements (DH, 2011, p20) and defines the second most important factor from the Q-

sort data. It focuses on the representativeness of *Lay* members (or in many cases lack of it) and whether this is something worth striving for.

Four Q-sorts define this factor. The respondents completing the sorts were two *Experts*, one male and one female, one female *Lay* and one female *Lay plus*. The *Lay plus* respondent had been a committee member for less than five years and felt that she had not received sufficient training whereas the others who had been members for more than 5 years were happy with the level of training they had received. The Q-sort from the *Lay plus* member contributed most weight to the definition of the factor (Table 10).

**Table 10. The demographics of the respondents whose Q-sorts defined Factor two.**

Defining Sorts	Factor Loadings	Weighted average	Demographics				
			Type of Member	Gender	Age group	Tenure more or less than 5 years	Training sufficient
14	0.81	10.12	<i>Lay plus</i>	Female	51-60	<5	No
6	0.67	5.32	<i>Expert</i>	Female	41-50	>5	Yes
10	0.66	7.83	<i>Expert</i>	Male	51-60	>5	Yes
2	0.57	3.74	<i>Lay</i>	Female	61-70	>5	Yes

One statement scored more highly on this factor than any other: *Lay members are not representative of the population as a whole* (statement 5 scoring +4). It is this statement that defines the factor. One of the Q sort responses suggested that,

*They most certainly are not (representative). They cannot be due to the level of literacy and educational need required, a sad, but true fact. A large portion of the population could not read let alone understand half of the words!*  
(Q sort 14, female, *Lay plus*, 51-60).

Another commented,

*None of our Lay members are representative of the general population; they have specialist skills, just not medical.* (Q sort 4, female, Expert, 41-50).

Negative scores indicate where participants disagreed with the statements. The two statements which scored -4 on this factor, suggesting strong disagreement that *anyone, regardless of their educational background could be an effective Lay member of an NHS Research Ethics Committee and that Lay members do not need to be trained* (see Table 11).

**Table 11. Defining statements for Factor 2 - Lay members are skilled and not representative**

Statement number	Statement	Position
5	Lay members are not representative of the population as a whole	+4
7	Lay members can bring a set of expert skills of their own, e.g. legal, financial etc	+4
17	Lay members are essential to balance the views of the committee	+3
24	Lay members need to be able to challenge the views of the professional members	+3
37	The key role for Lay members is to make sure that the information to participants is understandable	+3
4	Lay member's primary role is to ensure that subjects are able to give informed consent.	-3
29	It is only members without any connection to the NHS who can represent the public view	-3
35	Lay members can never be as knowledgeable as professional members	-3
23	Anyone, regardless of their educational background, could be an effective lay member	-4
36	Lay members do not need to be trained	-4

As in Factor one, statement 7, (*they bring a set of Expert skills of their own such as legal or financial, etc.*) scored highly positively (+4). This suggests that REC members recognise that Lay members are more likely to possess a high general level of

education and to bring professionally based skills such as legal or financial, that are not explicitly demanded by the person specification.

This view of *Lay* members is also consistent with research evidence showing that *Lay* members of NHS RECs are more likely than the general population to have a higher level of educational attainment, social standing and post graduate degrees (Simons, 2009, p6), all of which can be linked to the development of particular types of expertise such as substantive knowledge gained from degree level education.

Factor two (*Lay members are skilled and not representative*) captures this view but in accepting the need for a higher than average level of educational requirement it also raises the question of whether the membership can be demographically representative. The whole notion of representativeness is not a simple one and as Church *et al.* (2002, p16) suggest,

*Representation usually considers some combination of social position, professional status, and linguistic or ethnic background. Each is subject to bias.*

There was certainly a general recognition in this factor that *Lay* members are unlikely to be representative of the population and did not necessarily need to be independent of the NHS to enable them to represent the public view (statement 29, scored -3). Thus, Factor two describes *Lay* members as skilled and educated, as members in their own right, as not representing any organisation or interest group, and certainly not representative of the general population. From the distribution of the factor array for Factor two (Appendix 12, Figure 5) it is also interesting to note the negative score for (and therefore disagreement with) statement number 35, (*Lay members can never be as knowledgeable as Expert members, scoring -3*). A view is emerging of *Lay* members

who are already educated beyond the average and for whom, experience and training will more than adequately equip them for their role.

One obvious consequence of this over-representation is that achieving diverse and demographically representative committees will be difficult. If RECs can only 'appoint' members who apply, and these are unlikely to be from a diverse population, then there is going to be a problem with demographic representativeness. One interviewee, when asked about the drive by NRES to improve equality and diversity in RECs commented that there is little point making a fuss about it,

*That's completely, it's nonsense, it's political correctness gone bonkers really...I don't think it matters, it would be, it would be, in a way if you look at the research that's done, that's not representative of the general population*  
(Interview 4, female, *Expert* member).

Any focus on equality and diversity may not be a critical issue and as this interviewee points out, research is not conducted on a specific population demographic. The desire to have a membership, and in particular a *Lay* membership, that is demographically representative seems to cloud the need to consider the expertises or the ability to do the job. A committee with the correct mix of expertises would be a more reliable way of reviewing research making the committee better placed to conduct an ethical review than a demographically diverse one.

### **Factor three – *Lay* members are the voice of the ordinary people**

Factor three describes the *Lay* role as providing a 'voice' for the public and the need for this may be linked to the dominance (perceived or otherwise) of healthcare professionals, principally doctors, in research. The need to provide an independent view

was certainly behind the creation of research ethics committees but the inclusion of *Lay* members came later. So this is a discourse that positions the *Lay* members in terms of governance and accountability i.e. it is about the role of *Lay* members as a means of keeping *Experts* in check. One of the Q-sort responses suggested that,

*Professionals need to be challenged, many live outside the 'real' world*  
(Q sort 21, male, *Lay* member 51-60).

The Q-sort factors provide actors' descriptions of the world as they see it and Factor three describes an independent scrutiny role reflecting the qualities of a personal commitment to the interest of patients and public service values. The two Q-sorts defining this factor produced a dichotomous factor (one with a negative factor loading and one positive). This provides a polarised view: on the one hand, an active advocacy role; on the other, a more passively permissive one. The factor was defined by two Q-sorts, one positively by a female, *Lay plus* member and negatively by a male, *Lay* member. Both were in the age range 51-60 with less than five years committee experience. The female respondent did not feel sufficiently trained but the male did and the positive sort contributed twice as much weight to the factor definition as the negative one (Table 12).

**Table 12. The demographics of the respondents whose Q-sorts defined Factor three.**

Defining Sorts	Factor Loadings	Weighted Average	Demographics				
			Type of Member	Gender	Age group	Tenure more or less than 5 years	Training sufficient
15	0.81	9.98	<i>Lay plus</i>	Female	51-60	<5	No
21	-0.66	-4.95	<i>Lay</i>	Male	51-60	<5	Yes

The positive statements that define the factor seem to idealise *Lay* members as advocates and protectors of the public interest. They need to make sure that the information for participants is understandable (statement 37, scored +4), that they protect the public interest (statement 19, scored +3) and balance the views of the committee (statement 17, scored +3). To perform this task they need to be able to “see” the bigger picture’ (statement 27, scored +4). All these positive statements scored higher on this factor than any others. In contrast to the previous factor, those defining this statement considered *Lay* members to be representative of the population as a whole (statement 5, scoring –3) and that *Lay* members can represent the views of the public (statement 22, scoring –3). In addition statement 14, *Lay members have the same role and responsibilities as the professional members* scored +3. The defining statements for Factor 3 are found in Table 13.

**Table 13. The statements defining Factor 3 - Lay members as the voice of the ordinary people**

Statement number	Statement	Position
27	Lay members need to be able to ‘see’ the bigger picture to make informed decisions	+4
37	The key role for Lay members is to make sure that the information to participants is understandable	+4
14	Lay members have the same role and responsibilities as the professional members	+3
17	Lay members are essential to balance the views of the committee	+3
19	Lay members are only there to safe guard the public interest	+3
5	Lay members are not representative of the population as a whole	-3
16	There is a hierarchy of membership led by the professional members	-3
22	Lay members can only represent their own views, not those of the wider public	-3
24	Lay members need to be able to challenge the views of the professional members	-4
25	Lay members need to be able to challenge the views of researchers	-4

There was disagreement with statement 24 (*Lay members need to be able to challenge the views of the professional members*) and statement 25 (*Lay members need to be able to challenge the views of researchers*) which both scored -4. This suggests that challenging researchers and *Experts* is not considered part of the *Lay* role. This negative scoring is contrary to all of the other factors where these statements scored positively.

Within this factor *Lay* members are seen to be representing the patient's point of view, ensuring the information presented to research participants is understandable (statement 37, scoring +4). Interestingly, the interview data revealed that representing the patient's view was not solely the province of the *Lay* members with *Experts* having the ability to represent the patients' view, too. That said there was definitely a feeling in the interviews that *Lay* members were better at it possibly because their non-clinical backgrounds allow for a different perspective.

*So, I probably look at it more from the point of view of the patient and less about the medicine that's being researched.*

*Right! (JH)*

*Compared to the doctors or, you know, the other healthcare people on the committee, I think.*

*Do you think that doctors aren't very good at looking at it from the patient's point of view? (JH)*

*I think that some are and some aren't (laughs) I think it varies. I think it varies on the sort of, how they view things, um, how much research they have done themselves (Interview 1, female, Lay plus member).*

If the *Expert* members have recruited patients into research studies they will have a greater understanding of the issues relating to this. It may also be linked to individual's ability to be reflective on their practice or experiences though Collins and Evans (2007,



p39) note that the ability is taught in some disciplines as part of their contributory expertise.

This type of governance and accountability function is not an expert function but more of an oversight role. This suggests that the presence of *Lay* members on the committee has political motives, linked to limiting professional autonomy and increasing public accountability. One of the Q-sort respondents noted,

*It's quite important to remember how ethics committees came about, why we need committees rather than a set of rules to make decisions, and the perspectives of health professionals, companies and care providers*  
(Q-sort 10, male, *Expert* member, 51-60).

This level of mistrust and suspicion was observed in several other responses, including one who went as far to say,

*Lay members ensure that the REC decision is not just a medics 'cook up' and are seen to fulfil that role, and are appreciated by medics for it*  
(Q-sort 12, male *Lay* member, 61-70).

Although, respondents used the phrase 'balancing the committee'; it may be what they are actually referring to is not unlike the 'grit in the oyster': an irritation in the committee that improves the decision-making. *Lay* members thus provide an important, alternative view but without the need to challenge the views of either researchers or professional members (which may account for the negatively scoring of statements 24 and 25, both of which score -4).

This may also be an issue created because the research questions and protocols for medicinal trials are, on the whole, medically framed, and this feeds into every other discussion or debate. There was also a sense that doctors were the only experts, and

although not the official discourse, the medical role did emerge as such in the data. This view has the potential to devalue the other *Experts* as listed by NRES (2009), see Appendix 1. There was a vague notion of something more sinister linked to the domination of medicine and the need to minimise any sense of crony-ism. It had been suggested by the NPSA that *Lay* members

*stopped RECs from becoming clinical clubs* (NPSA, 2007, p2).

Although the explicit presence of a membership hierarchy was denied in this factor with respondents disagreeing with statement 16, *there is a hierarchy of membership led by the professional members*, which scored –3, this was contradicted in the interviews where it was recognised that *Expert* members needed to be medical. This suggests a subtle under-current of medical dominance remains, as implied by two of the interviewees who commented,

*well I think there's only ever been one committee member who I never heard say anything, but they were an Expert...a nurse, so the confidence thing really only, we don't need to make the assumption it's going to be Lay members that lack the confidence its, that also about the professional hierarchies and nurses not feeling confident when there's a bunch of medics around because it's been bashed into us*  
(Pilot interview, female, *Expert* member).

and

*..taking everybodys' views into account and listening to what the committee feels rather than what one just rather very loud, dominant generally male medical person might think*  
(Interviewee 4, female, *Expert* member).

This view of medical dominance has been expressed for decades and was a key driver for the creation of NHS RECs nearly fifty years ago (Hedgecoe, 2009, p338). It is a view that is reflected in these data and is also borne out by Parker (2008, p32). He expressed concern that it is the *Expert* member who defines the medical viewpoint and

this is linked to the interests of clinical research rather than the ethical issues. One of the interviewees commented:

I think um there's more tolerance for different types of research now, so maybe that has kind of flattened out that hierarchy slightly, I still think the medics gain control um because you can do more damage with medical research I think to the individual...but they would always have the upper hand or control of ethics committees I think (Pilot interview, female, *Expert* member).

It may be that this deference to medicine arises due to its privileged status, though doctors are not the only healthcare professionals in the *Expert* category. Alternatively, the same phenomenon might be interpreted as meaning that the *Experts* would be better placed to understand the impact of the research on the patient and the risks involved more related to individual skills as illustrated by the quote below.

*do you think there are some things that, that the Lay members are better at spotting than the Experts? (JH)*

*I suppose it depends what background the Experts have, because I mean, there's a huge breathe of knowledge within, the Experts themselves as well and ... so, me as a nurse have a different, have a very different background than a consultant physician has really, so I suppose, I suppose the Lay and perhaps the sort of patient orientated professional members are very good at the patient, you know, sort of seeing the points of views as how would I feel, so I think that's how I would feel in that position, so I think that's why they, you know, one of their, one of their strengths. (Interview 4, female, *Expert* member).*

Green, (2007, p9) likens this role to that of a non-executive director, who plays a full part in the debate and brings relevant experience to the table but is independent of the organisation. Although non-executive members are not lay members, as such, they are recruited to the management boards of organisations for the skills they can contribute an independent viewpoint. This independence of view is in distinct contrast with Factor four, which describes *Lay* and *Expert* members in a homogeneous role, which is not to "legitimise" the decisions of *Experts*.

## Factor four – *Lay* members have the same role as experts

This is a minor factor accounting for 6% of the variance. It is the only factor defined solely by sorts completed by female, *Expert* members (Table 14). One was in the 51-60 age group with less than five years' experience and a view that she had received insufficient training, the other was aged 61-70, had more than five years' experience and was happy with her level of training. The Q-sort completed by the older, more experienced member contributed more weight to defining this factor.

**Table 14. The demographics of the respondents whose Q-sorts defined Factor four.**

Defining Sorts	Factor Loadings	Weighted Average	Demographics				
			Type of Member	Gender	Age group	Tenure more or less than 5 years	Training sufficient
3	0.74	10.07	Expert	Female	61-70	>5	Yes
9	0.72	9.21	Expert	Female	51-60	<5	No

The defining statements for this factor strongly agree that *Lay* members have equal weight in the committee debate / decisions (statement 6, scoring +4) and refute the idea that *Lay* member's role is different to that of their *Expert* colleagues (statement 12, scoring -4) or that they are there to legitimise the committee's decisions (statement 40, scoring -4), see Table 15.

**Table 15. Defining statements for Factor 4 – Lay members have the same role as experts**

Statement number	Statement	Grid Position
6	Lay and professional members have equal weight in committee debate / discussion	+4
7	Lay members can bring a set of expert skills of their own, e.g. legal, financial etc	+4
10	There comes a point where it is difficult to identify an experienced lay members from their professional colleagues	+3
14	Lay members have the same role and responsibilities as the professional members	+3
34	'Life experience' is the most important qualification for lay members	+3
1	Lay members need to be able to understand the science behind the research to be able contribute effectively to REC meetings	-3
35	Lay members can never be as knowledgeable as professional members	-3
39	Lay members find it difficult to contribute to the ethical debate about studies involving complex diseases or illnesses	-3
12	The role of lay members is different to that of their professional colleagues	-4
40	Lay members are only there to 'legitimise' committee's decisions	-4

One of the positive statements defining this factor, *Lay members can bring a set of Expert skills of their own, e.g. legal, financial etc*, (statement 7, scoring +4) was previously highlighted as one statements that constructed a universal view of the *Lay* role. Statement 14, *Lay members have the same role and responsibilities as professional members* (scoring +3) and statement 10, *there comes a point where it is difficult to identify an experienced Lay member from their professional colleagues* (scoring +3) start to indicate that gives *Lay* members equal status in the ethical review but with different skills. This was reinforced by the ranking of the statements, *the distinction between Lay and professional members would not be clear to outside observers* (statement 30, scoring +2) and that *the lay / expert divide is a false dichotomy when it comes to research ethics committees* (statement 32, scoring +2).

Although not high scoring statements, these positively scoring statements, are noteworthy in this context because they do not feature prominently in any other factors.

Those defining the factor disagreed with the idea that *Lay members can never be as knowledgeable as professional members* (statement 35, scoring -3) and also disagreed with statements 1 and 39, both of which relate to the need for *Lay* members to understand more complex issues surrounding research or science (*Lay members need to be able to understand the science behind the research to be able to contribute effectively in REC meetings*, and *Lay members find it difficult to contribute to the ethical debate about studies involving complex diseases or illnesses*, both scoring -3). It is this aspect that will be explored in more detail since this lack of difference between *Lay* and *Expert* members highlights the mismatch between the official discourse and the experiences described in the data. There is a clear recognition, in agreement with Dyer (2004, p342) that *there comes a point where it is difficult to distinguish an experienced Lay member from their professional colleagues* (statement 10, scoring +3)

This is conceptually problematic in the current environment where expertise in the form of a health care professional qualification is the important discriminating factor in the differentiation between *Lay* and *Expert* members. There is certainly a difference between various members' experiences but the current use of the terms *Lay* and *Expert* does not adequately capture this. If the role of the ethics committee members is truly homogeneous it would not be clear where the boundaries between what *Lay* and *Expert* role might be and this is how participants described their experience. As one of the interviewees said,

I can hardly tell you know, the people in (name of committee), I don't know, I can't really tell who is a clinician and who is not and on our side there really isn't any feeling...that you're one or the other (Interview 3, female, *Lay plus* member).

A degree of homogeneity in the role may not be problematic providing there is a good mix of relevant skills though this does run counter to what Jones, *et al.* (2008, p25) identify the value in 'the real lay member' who is not an expert in anything. However, Jones *et al.*, (2008, p45) also suggest that it is desirable for lay members to be able to cope with a range of technical subjects and be sufficiently confident in their understanding to be able to challenge expert members which also suggests skills that may be out of the ordinary. The need for *Lay* members to understand complex studies and science in the REC setting was explored further in the interviews.

### **Do lay members need to understand the science behind the research?**

There was disagreement in Factor four with the statement that *Lay members need to be able to understand the science behind the research to be able to contribute effectively in REC meetings* (statement 1, scoring -3). This disagreement was mirrored, to some extent, across all the factors, except in Factor 5 where there was some ambivalence (statement 1, scoring 0).

The views were mixed regarding the need for *Lay* members to have a basic understanding of science (or at least to know where to find the information they lacked). It was felt to be good, if not essential, to be able to understand

*I think you need a bit of an understanding of the science because in the patient information sheet we should be able to understand in that shouldn't you, it should be explained in that...what you're doing...and if you can't understand that then you perhaps need to look again after they explain it but I'm an Expert but have to say sometimes I struggle to understand the science...so being an Expert or a Lay*

*member is sort of irrelevant isn't it...because um some of the concepts that I am familiar with, I know within the committee others that might not be*  
(Interview 8, female, *Expert* member).

It was also considered by one *Lay* member to be an idea to go and look it up and she said,

*I mean I haven't got a science background at all, I didn't even do a science O Level for various reasons but I usually find that if I look up the medical, medical jargon you know, through Google or something. I can get the science to the point that I can understand enough to know what the research is about and I normally haven't come to the wrong conclusion...* (Interview 1, female *Lay plus* member).

The interviews suggest a more optimistic view than a survey of *Lay* REC members (Simons *et al.*, 2009, p16), which reported that one area in which they experienced difficulties was in the understanding of the language that was used in application forms. Emmerich (2009, p9) argued that RECs need to have the 'appropriate' expertise to understand the proposal to be able to review it. Rawbone (2007, p 2) also reflects this requirement suggesting that, without the ability to understand the science, *Lay* members cannot assess the ethical implications of the research for the participants. Although this comes from the view that poor scientific research is unethical scientific review should already have been undertaken before submission to the REC, as it is the responsibility of the research sponsor. It is difficult to ignore the need to understand the project to assess whether it is ethical or not. All researchers do have to submit plain English summaries as part of their application but the participants raised concerns that if the *Lay* members could not understand the study from the plain English lay summary or the participant information sheet then this would be a serious issue. The interviewees felt that this situation is more likely caused by poor communication on the part of the researchers than the *Lay* members' ability to understand the science.



Although it was recognised that *the technical aspects associated with certain projects do confuse Lay members*, this was not a problem unique to *Lay* members. It was also encountered by *Experts*, too, where the narrowness of some fields of contributory expertise amongst the *Experts* lead to them also having difficulty when considering complex studies from outside their own field of specialist practice. This suggests that there are problems in highly specialist areas where there may not be any contributory expertise within the committee in the clinical area or methodology under review. To counter this concern, there was a defensive view taken in some of the interviews and the point was well made that it was not considered to be standard REC practice to review the scientific aspects of a study.

All of those interviewed recognised that there were issues associated with the review of complex studies. However, the main issue was felt to be less to do with understanding the science but more to do with the communication of the project by the researcher. This is a genuine ethical issue as informed consent is needed from participants and if the aims and nature of the study are not explained clearly then this cannot be achieved and the study cannot be classed as 'ethical'. The levels of poor communication of the study's intentions affected *Lay* and *Expert* members equally and the *expert* versus *lay* divide was not the issue here as it was unrealistic to expect that everyone could be familiar with everything.

There were mixed feelings as to whether a basic understanding of science was really the issue with a number of interviewees expressing the view that this was not quite as it seemed. There was a consensus amongst those interviewed that the committee as a

whole was likely to have two main problems with studies linked to complexity and clarity. Studies, which have a number of component parts, make them technically more difficult (often more so than those that involve basic laboratory science) but this is compounded where applications lacked clarity. It was usually expected that when researchers attend the committee to respond to questions on their projects that they should be able to explain studies involving complex science and answer questions. This would place the understanding of science at a level where the ability to seek out information from independent sources to enhance understanding and the capacity to utilise that information would seem to be an important skill. This is an expertise, which would relate to primary source knowledge as described in Collins and Evans (2007) model.

### **Factor five - *Lay* members in the traditional REC role**

Factor 5 is another statistically minor factor and is the only factor that does not correlate with any of the others (Table five). It is defined by two male respondents, one a *Lay* member and the other an *Expert*, with the Q-sort completed by the *Expert* member contributing more weight to defining the factor (Table 16). The factor array for this factor can be found in (Appendix 12, Figure 8).

**Table 16. The demographics of the respondents whose Q-sorts defined Factor five.**

Defining Sorts	Factor Loadings	Weighted Average	Demographics				
			Type of Member	Gender	Age group	Tenure more or less than 5 years	Training sufficient
17	0.8	9.99	Expert	Male	51-60	>5	No
12	0.73	7.16	Lay	Male	61-70	>5	No

Interestingly, although each respondent had five years or more experience neither felt that they had been sufficiently trained. It is not possible to connect their perceived lack of training with defining this factor since there is at least one other factor with a defining Q-sort where the respondent cited lack of training in spite of being a committee member for more than five years. However, it is notable that many of the highly scoring statements in this factor (see Table 17) relate either positively (or negatively in the alternatively worded statement) to training.

**Table 17. Defining statements for Factor 5 – The *Lay* members in the traditional REC role**

Statement number	Statement	Position
2	Training is vital for lay members	+4
7	Lay members can bring a set of expert skills of their own, e.g. legal, financial etc	+4
17	Lay members are essential to balance the views of the committee	+3
24	Lay members need to be able to challenge the views of the professional members	+3
34	'Life experience' is the most important qualification for lay members	+3
3	Lay members can be over-trained	-3
13	Lay members can become experts in their own right	-3
30	The distinction between lay and professional members would not be clear to outside observers.	-3
23	Anyone, regardless of their educational background, could be an effective lay member	-4
36	Lay members do not need to be trained	-4

The positively scoring statements, 7 and 17 are uniformly held views of the *Lay* role as previously discussed (see Table 7). They highlight that *Lay* members balance the committee (statement 17, scoring +3), can contribute skills from their employment, (statement 7, scoring +4), and recognise the “challenge function” with statement 24

scoring +3. The other key positive statement indicates that *'life experience' is the most important qualification for Lay members* (statement 34, scoring +3). This appears to contradict the negatively scored statement 23, (*anyone regardless of their educational background could be an effective Lay member* scoring -4). However, both of these statements reflect factual information about the *Lay* membership; namely that it is both older and more educated than the general population, combining both education and life experience.

A key feature in this factor is the role of training and the high scores awarded to the statements that reflect this. *Training is vital to Lay members* (statement 2, scoring +4) and conversely *Lay members do not need to be trained* (statement 36, scoring -4) and *Lay members can be over trained* (statement 3, scoring -3). These scores may be related to the respondents' views on their own training experiences but from the data overall, training was considered to be an important issue, not just for *Lay* members, but also for all members:

*Training is as vital for Lay members as it is for anyone on the committee! Some Lay members could be recruited completely 'green' and would need to know what it's all about*  
(Q sort 17, Expert, male 51-60).

*Training is essential to understand the legal and regulatory requirements (this is needed for non-Lay members too!) and to discuss common ethical problems in research.*  
(Q sort 8, Lay plus, female, 51-60).

It may be that the description of *Lay* members in Factor five largely reflects the role as conventionally described because training and length of tenure have not influenced the viewpoint of those defining it. Most interestingly, this factor did not accept that *Lay members can become Experts in their own right* (statement 13, scoring -3) or that *the*

*distinction between Lay and professional members would not be clear to outside observers* (statement 30, scoring –3). This suggests a view that once a *Lay* member, always a *Lay* member, and that there is no progression or development within the role. One of respondents whose sort exemplified this factor described his reason for disagreeing with statement 13 (*Lay members can become experts in their own right, scoring -4*), as follows:

*I don't think that Lay members can become Experts in their own right. An Expert in what? It's not as if they have a particular role that they can develop, such as a clinician or a statistician, for example. The trouble is that Experts see themselves as "consumers" or "users" as well – and they are sometimes, but not vice versa.*  
(Q sort 17, *Expert*, male, 51-60).

This might seem strange given the largely professional background of the *Lay* membership and that the length of tenure for the position on the committee can be up to ten years (interestingly the respondents defining this sort have both served more than five years as members). It would be reasonable to expect some development within the role to occur during this time either through training or practice but this factor gives a view of *Lay* members who remain unchanged by their experience or training. Their role is considered to be in balancing the committee and challenging *Experts* using skills that they bring with them from professions outside of the NHS.

### **Factor six – *Lay* members are complementary to the *experts***

Factor six considered that *Lay* members contributed skills that are complementary to those of the *Experts*. Four Q-sorts define this factor (Table 18). Three female *Expert* members and one male *Lay plus* member completed the sorts. All respondents, except

one of the *Expert* females, have less than 5 year's committee experience but all felt adequately trained. The factor array for Factor six is in (Appendix 12, Figure 9).

**Table 18. The demographics of the respondents whose Q-sorts defined Factor six.**

Defining Sorts	Factor Loadings	Weighted Average	Demographics				
			Type of Member	Gender	Age group	Tenure more or less than 5 years	Training sufficient
5	0.72	9.75	Expert	Female	41-50	>5	Yes
19	0.72	9.75	Expert	Female	51-60	<5	Yes
20	0.71	9.17	Lay plus	Male	31-40	<5	Yes
4	0.65	7.35	Expert	Female	41-50	<5	Yes

This factor correlated with Factors one, two and four and this is reflected by the number of statements that feature highly across all three factors. Two of the statements that scored highly have already featured in the uniformly held views (statements 7 and 17, scoring +4 and +3, respectively). One of the highly negative statements, *Lay members are only there to 'legitimise' the committee decisions* (statement 40, scoring -4) is also found in Factors one and four. The summary of statements that define this factor can be found in Table 19.

**Table 19. Defining statements for Factor 6 – Lay members are complementary to the experts**

Statement number	Statement	Position
6	Lay and professional members have equal weight in committee debate / discussion	+4
7	Lay members can bring a set of expert skills of their own, e.g. legal, financial etc	+4
12	The role of lay members is different to that of their professional colleagues	+3
17	Lay members are essential to balance the views of the committee	+3
24	Lay members need to be able to challenge the views of the professional members	+3
19	Lay members are only there to safe guard the public interest	-3
31	Lay members have different values to professional members	-3
36	Lay members do not need to be trained	-3
15	The ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a lay member	-4
40	Lay members are only there to 'legitimise' committee's decisions	-4

One of the key defining statements does not feature strongly or positively in any other factor is statement 12, (*the role of Lay members is different to that of their professional colleagues*) scored +3. This is in distinct contrast to the statement's negative score in Factor 4, (*Lay member's role is the same as the Experts*) where it scored -4.

## Lay experts

Factor six suggests a *Lay* role that is complementary to the *Experts* with the positive statements confirming that the *Lay* role is equal in weight but relies on different skills to the *Expert* members. Jones, *et al.* (2008, p24) describe lay members as 'complementary experts' and make a distinction between scientific and non-scientific experts. One of the interviewees commented,

*I think it's very hard because they say lay members do become expert members because you've got to have a certain expertise to be able to contribute really. So*

*you've got to learn a certain amount before you can, sort of take part fully really*  
(Interview 1, female, Lay plus member).

Although this stops short of explicitly suggesting that Lay members could be considered to be contributory experts in REC practice they acknowledge that a level of expertise is required to fulfil the role. According to another interviewee their expertise in ethical review does not need to be linked to a health care profession,

*...there to review the ethics of the study, it doesn't matter what your background, whether professional or Lay, you can have an opinion on the ethics of the study, which is entirely different to any legal aspects or technical aspects of the study.*

*Do you think that there is a sort of umbrella role of ethical review? (JH)*

*Yes! There can be your professional expertise and your review as a Lay person, putting yourself in the place of the participant.*

(Interview 2, female Lay member).

Another prominent statement in this factor was statement 15; *the ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a Lay member*. Although this statement scored negatively across all the factors, it scored more negatively on this factor than any of the others (scoring -4). However, the negative feelings towards jargon expressed in the positioning of statement 15 were not entirely borne out in the interviews, which produced mixed and sometimes even contradictory responses.

## **Views on using jargon as the language of experts**

The issue of jargon was more complex than initially anticipated and on further investigation largely related to effective communication rather than an intentional attempt to exclude anyone.

*We should all (researchers and REC members) ensure that we converse effectively and reduce jargon to a minimum.* (Q sort 5, Expert, female, 41-50).



The interviewees were asked “*does the use of healthcare jargon improve acceptance of lay members by the committee?*” The responses fell into three key areas; it helps to know, it should not happen and it creates misunderstandings. The findings from three areas will be further expanded.

### **It helps to know**

There were mixed views from the interviews but half of the interviewees felt that it was helpful to know jargon, that they could make a better contribution once they understood it and it might even improve confidence (usually in others but not them personally). The problems caused by jargon were not considered to be restricted to *Lay* members and when asked if *Lay* members used jargon, as one of the interviewees explained:

*Yes they do (use jargon), 'cos I get annoyed having to explain things to them (other Lay members) being another Lay person but I have the benefit of having typed these words for many, many years. So yes, you know, I think people do get a bit irritated when they don't understand the jargon and they need to understand the jargon, it does help because, well you've got to have, mind you've always got to have certain things in plain English...and if there's a professional who can explain it, good. But often there quite often isn't...and it, it, it differs from specialist to specialist so you know, other specialists will need to have things explained to them...you know if a person can pick up a bit of the jargon it is “ah”, it probably helps a bit*  
(Interview 3, female, *Lay plus* member).

However, it was felt to be even more important to understand the committee processes or simply how things are done,

*it always helps knowing the jargon but more important to understand the structural stuff – not really jargon, just how things are done*  
(Interview 6, male, *Lay plus* member).

### **It should not happen**

Others were not so positive about the use of jargon and felt that its use was inexcusable

*I don't think that's required at all really, I think that's sort of ah, I mean, I think, well perhaps that was, is, is in some committees, but I think that, if you use any*

*language whether it's grammar or whether it's science or whether it's healthcare jargon...um for the exclusion of other people so that they don't understand, I think that's, you know, a very poor...way of running a committee...it's plain bad manners* (Interview 4, female, *Expert* member).

The problem seems to be that there is not one single set of jargon that characterises the committee and it is not just jargon that was considered to be bad but also acronyms and abbreviations. It seems that the REC may even have a set of jargon of its own. One *Expert* member excused *Lay* members' use of jargon by saying,

*But sometimes I don't think they can help it (using jargon)...because they're so socialised into the committee um so they, they're using the terminology sometimes without realising it and that's what happens isn't it?* (Pilot interview, female, *Expert* member).

### **It creates issues of (mis) understanding**

Although these issues were not confined to the *Lay* members, there was recognition that the *Expert* members and researchers used jargon and not everyone understood what was being said. This may be more connected with understanding the science than to ethics but it potentially creates a communication issue and a need to trust others in the committee,

*you can't use jargon in an area you don't understand...I don't always understand what the medics are talking about but am happy with their jargon – I don't have the expertise to copy it* (Interview 9, female *Lay plus* member).

Although one *Expert* member felt that the use of jargon made the *Lay* members more confident she also noted a negative element, suggesting a lack of full understanding in some circumstances,

*... I think they would, they would gain more confidence...as well, although some can become a right pain in the arse um because they use it inappropriately, think they've grasped it but absolutely really don't...they don't have a hold on it at all and misunderstood what it means* (pilot interview, female, *Expert* member).

The use of jargon seems to have exposed some ambiguity about what “jargon” actually is or means. A possible explanation is that there is no single, recognised set of jargon as there are a number of domains related to REC expertises. It is likely that there is a level of REC specific jargon that is shared by all members but also many more specialist areas in which jargon was not shared. Couple this with the normative commitment to clear communication and this may well explain why this was the topic that generated least consistency of viewpoints in the interviews.

Jargon also has implications for interactional expertise (Collins *et al.*, 2006, p3). The more *Lay* members develop expertise in these areas, e.g. REC practice, healthcare and research design, the more adept they are likely to become at using jargon. This is the language linked to these skills thus sounding like *Experts*. Although there is a set of jargon, which is generic to the NHS, there is also a large body of subject or discipline specific jargon that is not always familiar even to *Experts* if it is from outside of their discipline. This would make it less likely that either the *Expert* or the *Lay* members could ever become fully conversant in all the NHS and clinical jargons that appear before a typical NHS REC.

## **What does this tell us?**

The Q sort data indicates that there are six different discourses describing the *Lay* role, where all except one, express some form of team work with the most dominant discourse/factor is Factor one, *Lay members as part of the REC team*. The view of the REC as a team challenges the *lay / expert divide* and demonstrates that the qualities

sought in the recruitment process (HRA, 2013b) are not adequate to describe the expertises required to perform the job.

The data also provide other insights regarding specific features of REC practice including the use of the challenge function, problems of representativeness, the relevance of understanding science versus ethics and ambiguous views on jargon. The data also highlight other issues questioning current recruitment and training strategies of all REC members.

# Chapter 5 - Discussion

## Introduction

The chapter will examine what conceptualising REC members based on their expertise and their contributions to the committee means for their recruitment and training. In particular, any attempt to recruit members based on the expertises required to do the job must consider the issues around recruitment that were raised in Factor two, *Lay members are skilled and not representative*. The argument made here is that recruitment would be improved by replacing the implicit democracy of the equality and diversity agenda and its unattainable notion of a 'representative' committee with a clear description of the expertises required to do the job. I therefore propose a selection process that is consistent with Nolan principles but which is guided by the skills/expertise required by the REC as a group rather than any criteria relating to notions of demographic representativeness.

This chapter begins by discussing the implications of considering the REC, as a team as described in Factor one, *Lay members are part of the REC team*, which is the predominant finding from the Q-sort. It will also provide a review of the expertises that are required for the team to function. It will then consider the problems with the current system, including the recruitment process and training that affect the expertises within the committee. Finally, it will make recommendations for new role descriptions and the changes required to implement a system rooted in expertise.

## The REC team

The dominant factor that emerged from the data described in the previous chapter characterises the REC as a team with members bringing different skills to the

committee. The data also describe other critical elements of the *Lay* role (and in a number of instances also the *Expert* role) that need to be considered to allow the committee to function efficiently and effectively. This includes the need for a clear mechanism for identifying the expertises required and a transparent process by which to recruit members who can bring them into the team.

The committee relies on a set of skills from its members (*Lay* and *Expert*) that are important to its function and this should be reflected in clear person specifications. These descriptions of the role and the skills required could be used to support the recruitment process, to identify skills that need to be replaced when members leave, and to develop a training programme that reflects the expertises required to function as a REC member. Under the current arrangements committees seem to function regardless of the fact that this is not the case.

The National Research Ethics Service sets out a description of the essential and desirable qualities described for both *Lay* and *Expert* members (HRA, 2013b, see Table 1, p36). However, many of these are personal attributes or characteristics rather than expertises, for example, a strong personal commitment to the work of the committee. All of the essential attributes described are the same for *Lay* and *Expert* members. The only exception is one difference in the desirable criteria, where experience in conducting research is included for *Expert* members and experience of the NHS as a patient or a carer for the *Lay* member. Given this, it is not difficult to see why committee members see their role as being the same regardless of which membership category they fall into.

Even so, NRES recognises that REC members need to come from a variety of backgrounds, as indicated by the following, they just do not actively recruit for them:

*REC members often have the sort of experience, which will be useful in scrutinising the ethical aspects of a research proposal. For example, they might be patients, members of the public, nurses, GPs, hospital doctors, statisticians, pharmacists and academics, as well as people with specific ethical expertise gained through a legal, philosophical or theological background.*

NRES (2013).

The number of different backgrounds suggested by NRES can be translated into a set of contributory expertises, which will be found in those currently defined as *Lay* as well as those defined as *Experts*. These contributory expertises will include the medical and clinical expertises already recognised by the existing classification but supplemented by currently un-recognised expertises identified by REC members as important. These included, for example, areas such as chemistry, data protection, law, customer service, project management, theology, social research methods and so on. To the extent that all these different skills are necessary for the REC team to function effectively then it is vital that the recruitment process enables them to be identified and selected.

Recruiting a diverse set of contributory expertises also creates the potential for REC members to develop a range of interactional expertises. Using the model defined by Collins and Evans (2007, p14) shown in Table two, (p56), it can be assumed that there is the potential to for any individual REC member to develop interactional expertise in any area where another member holds contributory expertise. This includes areas represented by *Experts* but also in the areas of non-medical expertise represented by *Lay* members. In other words, this potential for interactional expertise to develop exists for both *Lay* and *Expert* members.

## **REC Expertises**

The primary finding from the Q-sort is that the REC functions as a team using various expertises. Based on the data it is possible to distinguish between ubiquitous, interactional and contributory expertises, which can be summarised as follows.

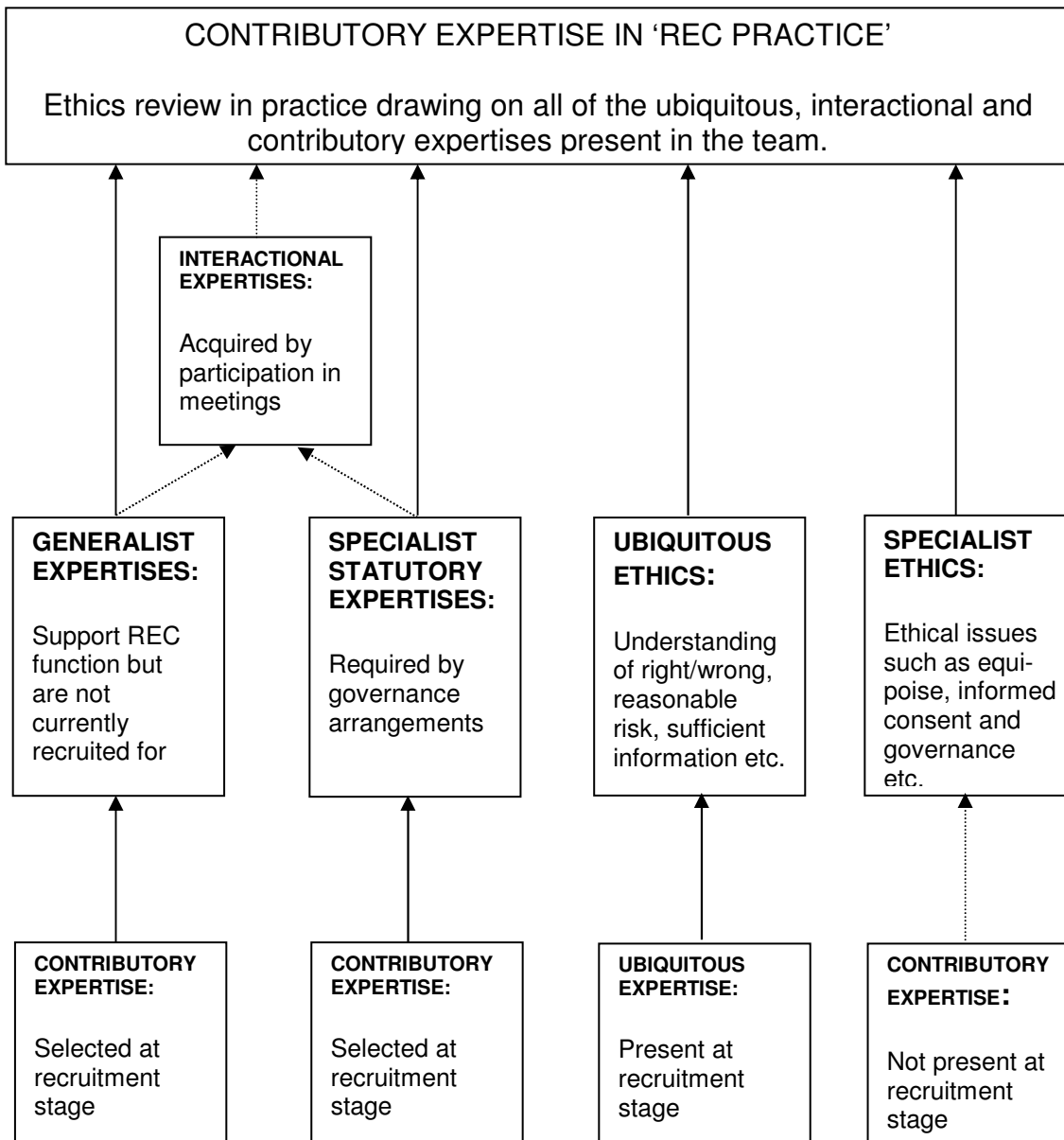
First, all members will join the committee with ubiquitous expertise in every-day ethics. This will include a common moral understanding of what constitutes right and wrong as well as widely shared ideas about acceptable risk, reasonable rewards and what counts as 'undue pressure'. In addition, all members of the committee acquire the more specialist ethical expertise that is necessary for the specific task of ethical review. This expertise, which is currently developed via an introductory training day, participation in meetings and mandatory annual training events, includes: key aspects of the DH Research Governance Framework (DH 2005a); the role of the REC within these governance structures; and key moral issues in research including understanding of equipoise and informed consent.

In addition, there are the various contributory expertises that the individual committee members bring to the REC, which can be divided into two sorts: specialist or statutory expertises and generalist expertises. Specialist statutory expertises are those provided by committee members who are specifically recruited to meet the regulatory and governance requirements for ethical review of medicinal trials (e.g. Medicines for Human Use Act (2004); NRES, 2009). In contrast, the generalist expertises are those supplied by the other committee members and which provide the skills needed to



support the REC function more generally. These would include the medical and clinical skills already recognised but also domains of expertise that are not currently recruited for, such as information governance.

Taken together this analysis leads to the two insights. The first is that the REC shares a new contributory expertise in ethical review that is created by this combination of individual expertise. This contributory expertise is what I have termed REC practice and it forms the collective knowledge that individual REC members are socialised into when they join the Committee. As such, it is this new, shared, contributory expertise that defines the work of the REC. Secondly, by examining what is required to sustain this collective expertise, we see that distinguishing between those who provide the specialist statutory expertises and those who provide the generalist expertises would enable a more refined approach to both recruitment and training.



**Figure 3. Specialist expertises, generalist expertises and ethical expertises the REC team**

This analysis is summarised in Figure 3, where the expertises needed for a REC to function fall into four main areas, two of which can be actively recruited for, one of which should be present in all applicants and the fourth of which is provided by training. These expertises are now examined in more detail, starting with ubiquitous expertise in ethics.

### **Ubiquitous ethical expertise.**

The idea of a ubiquitous expertise can be counter-intuitive. This is reflected in Q-sort Factors three and five, which describe *Lay* members in a stereotypical way, i.e. without expertise or any possibility of developing it. Both these factors are minor, however, each explaining only 5% of the overall variance. *Lay* members are described by these factors as a group who, regardless of their background, training and length of tenure on the committee remain unchanged in anyway. This could be because the respondents forming this opinion see research ethics committee practice as something, which anyone can do, and not therefore a 'proper' expertise. In contrast, medical practice, which is both esoteric and elite, is seen as deserving the accolade of expertise.

If, however, social interactions are seen as requiring skills that have to be learnt then the idea of ubiquitous expertises does make sense. What is more, such expertises would need to include things like "moral sensibility and political discrimination" (Collins and Evans, 2007, p16), making ubiquitous expertise a necessary requirement of all REC members, including both those currently classified as *Lay* and *Expert*. Seen this way, the view of the *Lay* member as someone without a specialist contributory expertise would be correct, as there is no link between ethics committee practice with any particular contributory expertise. Conceptualised in this way, the main impact of the *Lay* role is to provide 'a voice' for the public – though conceptualised as a 'consumer' or 'user' rather than 'patient' or 'citizen'. This is in keeping with the consumer-led culture that is developing to balance the power of the experts in a number of regulatory models including RECs, the Nursing and Midwifery Council and the General Medical Council (Legood, 2005, p136). This 'voice' provides a more authentic view on what members of

the public might be prepared to accept in the name of research their views on informed consent and indeed their willingness to participate in studies.

It should also be stressed that this scrutiny role is important. Like the jury in a trial, the *Lay member's* presence is only partly symbolic; it does fulfil a real purpose too by providing independent scrutiny. It is described as an alternative, but complementary view (Factor three, *Lay members are the voice of the ordinary people* and Factor six, *Lay members are complementary to the Experts*) with *Lay members* performing a real function as independent observers. To do this, however, requires accepting the notion of ubiquitous expertise and the assumption that everyone knows what is right and wrong by using experiences of everyday life.

### **Specialist Ethical Expertise**

Ubiquitous expertises are not enough, however. The review of research proposals requires skills that are not found in the general population including, for example, an understanding of moral issues such as informed consent and equipoise and some familiarity with the procedures and standards of research governance. As such knowledge is specific to the work of RECs it is not something that can reasonably be expected to be present at recruitment but is something that must be developed through training and practice as a committee member.

Training is, therefore, a key feature of inducting new members into the role. It helps to improve the understanding of the context of the ethical review and the criteria to be applied when assessing projects. McGee *et al.* (2006) audited REC members' perceptions of their training needs and members indicated the key topics in which

training was required. These included the responsibilities of the REC, the principles of ethical review and aspects of consent including research with vulnerable groups. As part of this study they were also asked to identify whether their prior experience had helped them as a REC member. More than half of the respondents identified their roles as health care professionals, involvement in committee work or research as key experiences, suggesting that many REC members start with some kind of specialist expertise.

There were mixed views regarding training from the data. Some respondents felt adequately trained after short periods of time whilst others felt their training was insufficient even after five years as members. Given that all members are expected to attend an introductory training course followed by annual training this was unexpected. There was also a mixed but generally positive emphasis on the importance of training from the Q-sort data reflecting its value to the function of the committee. If the training provided is critical for the members to function in the role, this would suggest there is a contributory expertise in REC practice that *Lay* and *Expert* members develop.

*..both Lay and professional members need training in what is currently considered to be a matter of ethics. Confidentiality, laws on tissues sampling and many other matters have entered the ethical debate...*

(Q-sort 1, female, *Lay plus*, aged 71-80).

*Without training you wouldn't know what you were supposed to be looking at or doing! You'd be a totally ineffective committee member*

(Q-sort 3, female *Lay member*, aged 61-70).

*Training is essential to understand the legal and regulatory requirements (this is needed for non-Lay members too) and to discuss common ethical problems in research.*

(Q-sort 8, female, *Lay plus*, aged 51-60).

As more specialist ethical expertise is developed through a structured training programme and 'on the job' experience the expertise will be self-sustaining as it is transmitted to new committee members through their participation in the work of the committee. In this way, contributory expertise in REC practice becomes the shared expertise that enables agreements to be reached whilst new Committee members and research projects provide the stimulus for reflecting on this expertise and allowing it to develop and change over time.

The practical implication of this is that, although some will join the committee with the specialist ethical expertise that is relevant to ethical review, this is by no means necessary. Moreover, selecting for such skills at recruitment would be counter-productive, as it would reduce the diversity of other skills available to the committee. Instead, the development of contributory expertise in REC practice is something that should be developed on the job via training and through the work of the committee. Attending such training provides an important socialisation mechanism that helps committee members develop the skills necessary needed. In addition, by not assuming any previous expertise in research ethics, this approach would also have the advantage of opening up membership to a wider group of people. Instead, it is only ubiquitous expertises and other contributory expertises that members bring with them from their everyday and professional lives that should be the subject of recruitment and selection.

### **Contributory Expertises: Specialist and generalist experts**

A shared view of the *Lay* member's role was that they helped to balance the committee by bringing a set of expert skills of their own. This view was particularly strong in Factor one, which was summed up by the title *Lay members are part of the REC team*. The

crucial insight is that *Lay* members do this work by bringing a number of skills and expertises in domains that are not currently identified during the recruitment process but which are still important to the committee's function. These include skills from a multitude of professions including law, teaching and engineering. It was also identified that *Lay* members used these skills when challenging the views of the *Experts*.

Jones *et al.* (2008, p25) concluded that a real lay member in a committee is someone who is not an expert in that field but who nevertheless still forms an important part of the committee's function. One of the key areas identified in Factor one was that *Lay* members needed to be accepted as part of the team to be fully functional. However, this seemed to be more linked to recruiting the "right" people rather than a divide within the membership groups and what was important was that members were seen to have the same role and responsibilities in the ethical review of research projects.

*Lay members and professional members make up a whole team – with all points of view respected. All roles and responsibilities are the same as for Expert members*  
(Q-sort response, female, *Lay* member, 61-70).

It would seem that members rely on skills that they already possess to undertake the ethical review and that *Lay* members brought to the committee transferable skills from their personal careers. This caused blurring of the *Lay / Expert* divide and recognition that the labels used by NRES do not reflect the experience of members.

*I think those that are deemed to be Expert are those that are employed by the Trust<sup>11</sup>...however I've got the list of who are Lay and who aren't, being retired doesn't mean they're any less of an Expert...some of the Lay people are actually retired statisticians so their skills are way and above anybody else because nobody, none of the Experts are statisticians...and so their expertise is absolutely invaluable so there is no way any of us would see them as being*

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<sup>11</sup> Suggesting employed by an NHS organisation, as is the case of most of the health care professional members.

*less... and especially, although I'm supposed to be Expert in psychiatry I'm not as much an Expert in my category as they are in theirs and they are Lay but they are actually retired...so like the doctors (academics) they're called Lay but you can't call a doctor a Lay member just because they're retired...so in our committee actually everybody has a profession that relates in some degree to health<sup>12</sup>*  
(Interview 8, female, Expert member).

The important point, here, is that the 'key members' discussed above do not actually map onto the *Expert / Lay* categories as described by NRES. So the skills these *Lay* members bring to the committee (that are seemingly so critical) would not be explicitly sought at the point of recruitment and are, therefore, only present in the committee by chance.

*Yeah I think it has to have all these different viewpoints otherwise the chemist is going to miss the indemnity thing and the business person is going to miss the chemistry and the stats...and they admit to that and they say I don't know any of those statistics or chemistry or physics or...or methodology but I do know how to understand how a patient information sheet can be written and how you can get things across*  
(Interview 7, male, Expert member).

Another observed how the committee functioned differently if key members were absent.

*I don't think we would have (the right skills), if we lost the statisticians and if the statistician and um there's a pharmacist for example and the, the research design bloke...um and if we didn't have those who look at things differently from the rest of us...um I think we would be a poorer committee.*  
(Interview 8, female, Expert member).

When asked who actually fulfilled the *Lay* role there was a suggestion that it is *Lay* members who were key when looking at projects from the point of view of the participant although this role was not restricted to them,

*well I think we have one Lay member who is a management consultant and she does look at things much more as the un-informed individual even though she's a very clever, a very skilled women, she looks at it from the point of view of*

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<sup>12</sup> All previously registered health care professionals (except for medical doctors) revert to lay members after a period of 5 years retirement.



*somebody who, who would just be coming to this...member of the public, so perhaps she comes up with things a little bit more about um how it presented her, how it looks but I think all of us, there's an oncologist and she looks at things also from the point of view of the man on the street rather than an Expert so it's, and there's me who gets very pedantic about how things are presented, nothing to do with ethics* (Interview 8, female, Expert member).

Training was not considered to be an important feature in the description of Factor one and the data reinforces the idea that the skills being identified are those derived from work or life and not from the training undertaken. Given the wealth of skills that members bring to the committee it is likely that by using these skills they are able to function reasonably well even before they have received any training and developed contributory expertises in REC practice.

Indeed, although one interviewee initially supported distinguishing between *Lay* and *Expert* members on the basis of clinical and non-clinical backgrounds, he also conceded that this was inconsistent as, even under the current arrangements, the *Expert* category includes non-clinical professionals such as statisticians. What he goes on to describe is more suggestive of the development of a shared contributory expertise in ethics committee practice:

*Good idea to have a spread of skills and experience but this is flawed because Lay members get quite used to the jargon and how to go about things even though they don't gain clinical expertise. The clinical person doesn't know any more than the lay person* (Interview 6, male, Lay plus member).

## **Interactional Expertises**

Interactional expertise is expertise in the language of a domain that is acquired through interaction with contributory experts in that domain. As RECs are populated by individuals with contributory expertises in a wide range of fields, it would not be

surprising if, as a result of being on the committee, individuals began to develop interactional expertise in at least some of these fields. This would include *Lay* members developing expertise in some aspects of medical science but it would also include *Expert* members developing interactional expertise in the domains where *Lay* members have specialist expertise as well as *Expert* members developing interactional expertise in medical specialisms outside their own domain of practice. As Collins and Evans (2007) state,

*“interactional expertise provides a bridge between the rest of us and full-blown, physically engaged Experts” (p.77).*

Thus, although, members will join the committee with different levels and types of expertise depending on their backgrounds, through their work on the committee they will do more than develop contributory expertise in REC practice. As a result of reading research applications, protocols and summaries, many will develop the equivalent of primary source knowledge in some areas of medical research. In addition, where the same topic is discussed in detail and over many meetings, and where contributory experts are present, then the opportunity also exists for the other REC members, whether they be *Lay* or *Expert*, to develop interactional expertises in these domains. When talking about a member with contributory expertise on their committee one *Lay* member commented:

*I think you do learn from other people's knowledge. We've got a lecturer from (local university) who teaches social science research and I think we've all learnt quite a lot about qualitative research from her. Including the doctors, or also the doctors should I say.* (Interview 1, female *Lay plus* member).

It was also noted that there were difficulties when the members who possessed key skills were not at the meeting or had left the committee and were not immediately

replaced. These seem to be key areas where interactional expertise may be used to as a short-term substitute for the specialist skills necessary for ethical review during absences of particular members but new contributory expertise would be needed eventually. Of course, where the missing contributory expert was necessary to meet the requirements of the clinical trials' legislation then any deputy or replacement would need the appropriate qualifications (i.e. to be a genuine contributory expert)<sup>13</sup>.

## **Summary**

The current use of the terms *Expert* and *Lay* to define REC members is unhelpful because the terms do not reflect the expertises found in each group. The current recruitment process relies on a single description of the *Lay* (and *Expert*) member's role without any consideration of the diversity of skills the committee might require or what individuals might bring. As a result, none of the current methods of recruiting new members would enable a committee to fill a vacancy with a specific contributory expertise, as the essential and desirable qualities are not sufficiently detailed.

## **Recruitment and representativeness – limitations of the current system**

In some ways, the issues that emerged from the data have also been recognised by the Department of Health. The Report of the DH Ad hoc review of the operation of NHS RECs in 2005 stated:

*The current membership is drawn in general from a relatively narrow spectrum of society, members tending to be professional in background and from an older age group. We do not have evidence of ethnic mix but doubt that RECs overall reflect the mix of the communities that make up our society.*

(Department of Health, 2005).

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<sup>13</sup> Not all committees review clinical trials involving medicines to which this legislation relates. In these cases some of the specialist expertises would not be mandatory.

The data (Factor two, *Lay members are skilled and not representative*) resonated with this view and there was general agreement amongst participants that the committees are not representative of the population they serve in terms of age, gender, race, disability or socio-economic standing. In contrast to the DH, however, the evidence from the interviews was that this was not considered to be an important target and some expressed incredulity that this could realistically be achieved across a committee with only eighteen members. Over half of the interviewees expressed some resignation about this issue and considered the lack of representativeness to be inevitable given the systems that are in place to recruit members. There was also some acceptance within the data that the current situation was neither good nor ideal but the ideal of achieving adequate representation was seen as unrealistic.

*one of the reasons we're not representative is that recruitment has been restricted to internally in hospitals and that by NRES, the other is the um often the timings of committees ah the other is people who have benefits and so on um although you don't get paid to attend, you have to commit to attend therefore you could not be available for work so your benefits could be reduced, so we're never going to get to that aspect and I don't know how necessarily, um its quite right to have or to have, to always say to have somebody from every aspect of life on every committee* (Interview 2, female Lay plus member).

In fact, there was general criticism about the recruitment process by the majority of those interviewed. The poor process was further compounded by a lack of public awareness of the role and limited advertising of committee vacancies. This led to an acknowledgement that members were recruited by personal contact from one out-going member to another. As one interviewee put it:

*Recruitment process is bad – they virtually ask the people they know* (Interview 6, male, Lay plus member).

These views reflected those of Updale (2006, p60) and the whole process of advertising was not seen to be particularly successful. When questioned about the recruitment process, one said:

*...there are (recruitment processes) but how just sort of putting in an advert and hoping someone's going to apply probably going to get the people you don't necessarily want, the sort of mouthy, self-opinionated, high up...*

(Interview 4, female, *Expert* member).

All interviewees were asked how they were recruited to their committee. Eight of those interviewed had never applied for the 'job' but had been approached by other members to join the committee. One interviewee said,

*don't know how many Lay members have been recruited, to be honest, I think you know, a lot have been recruited from people they know or who know someone, you know, or who have contact with someone*

(Interview 1, female *Lay plus* member).

She went on to say she was not sure how much advertising went on and acknowledged that a REC is quite a hard thing to recruit to. There was some conflation of the issues of how not following Nolan principles for public life affects the principles of representativeness or diversity and the effect that lack of applicants might have.

Criticism of the recruitment process extended to the fact that vacancies are often not advertised in areas where a reasonably diverse population might see them. Others suggested that the diversity of the membership is limited by the mechanism of the ethical review process itself, with those with sight and hearing impairments excluded due to the way the meetings are conducted and the application paperwork circulated. Indeed, several members commented how, since a recent reorganisation had merged their committee with another, they now met via a video link from two different locations

and this made it very difficult for to hear what was being said, with the result that several members had left the committee. <sup>14</sup>

Recruitment was not the only factor affecting diversity. Another issue related to the time commitment required. This included the timing of the meetings, which meant that membership of the committee mainly fell to the retired or those not in full-time work. One *Lay* member, who was working full time, said that his employer allowed time for 'public service' activity and although time off for meetings was allowed they were no longer allowed time off for training which had to be done during their own time. Using their annual leave entitlement for this activity made membership of the committee a less attractive proposition and may exclude them. The time to read the papers before the meeting, which often required several hours, also had to be done outside of the working day, in their own time. The ability or desire to commit this amount of time for each meeting and to stay up-to-date with current regulations would be not possible or desirable for everyone and may not be sustainable and attendance could not be compelled due to the voluntary nature of the membership (Saunders, 2002, p536).

It was also recognised that the membership of the committees is largely governed by who might volunteer and *Lay* members are not usually recruited for their skills but for their willingness to commit their time to read the vast quantity of paperwork and to attend the meetings. On this basis, it was felt to be

*a nice voluntary job to do, sort of as a retirement thing because it makes your brain work, it's quite a challenge to read all the projects and to get to grips with them and stuff...* (Interview 1, female *Lay plus* member).

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<sup>14</sup> This committee has since closed in the national rationalisation of the number of committees.

Due to the amount of paperwork and complex reading it requires members to be well-educated and even a good basic level of education was not considered to be enough.

All this raises questions about how representative of the wider population a REC can be in demographic terms. If it takes skills and training and a high level of general education to function as a *Lay* member this suggests that the level of desired diversity could only ever be an aspiration. But does this matter? In the case of RECs, *Lay* members are not expected to represent anyone but themselves (DH, 2011, p20) which suggests that NHS RECs do not fall into the normal model of NHS patient and public involvement which largely centres around empowering patients and improving patient choice (Tritter and McCullum, 2006, p158) and in which democratic notions of representation are important. That said, however, there were some interviewees who felt that although they could not possibly represent everyone, they could do more than simply represent themselves:

*I think if you're a person like the brigadier who was able to represent people who held, you know had command in the past or me I'd been able to represent patients who've come with queries you know, if you're that sort of person you can represent them better than they could represent other people in their own group*  
(Interview 3, female, *Lay* member).

There were some suggestion that the participants in the research studies they were reviewing were not especially diverse so may be it did not matter too much that those reviewing the studies were not diverse either. However, although participants within a single study might be homogeneous, this certainly is not true for the range of studies a typical REC considers. This means that the committee has to represent a heterogeneous range of participants, even if they do not all take part in a single study leaving this as an unconvincing post hoc rationalisation of existing practice.

## Improving the System

The mix of members, both *Lay* and *Expert* was considered to bring different skills and improve decision-making (interviewee 1). This was brought into sharp focus by any change in the membership of a committee in which skills were lost and not replaced on a like for like basis. One of the interviewees even felt that replacing members by 'word of mouth' could be a good method of recruitment,

*In a way, you got a far better make up of committee than, than the sort of more slightly open, everyone can join*

*The Nolan principles approach? (JH)*

*Yeah, you can get a very disparate group of very Expert but unlinked and not terribly useful members* (Interview 4, female, *Expert* member).

This view leads to the idea of the committee where individuals contribute to the same overarching goal but who use different skills to meet the needs of the ethical review. Although some shared essential qualities of committee members are explicit (Table 1, p36) the specific skills required for the role are not clearly described, making the recruitment of REC members very different to the normal recruitment process.

It was clear from the analysis of Q sort data and the interview transcripts that the official mechanism for recruiting members neither promotes nor supports the need to replace skills. In fact it can act against it because it does not explicitly identify the skills that need to be replaced. This loss of skills poses a risk to the function of the committee even if, in practice, it is mitigated by informal recruitment strategies in which REC members actively seeking suitable replacements when vacancies arise.

In practice, the system works because these generic qualities are being supplemented by informal rules of 'baton passing' in which current or out-going members recommend



suitable replacements as a way of ensuring essential skills such as information governance, project management and legal expertise are replaced. This ensures that people with certain (not-formally-required-but-useful) skills are replaced with others who also have similar skills even though the current system does not formally recruit for skills outside of the *Expert* membership group.

It has been suggested that the demographic representativeness of the membership could be widened by improvements to the recruitment process (NRES 2013, p3). Unfortunately, it is difficult to envisage how simply improving the openness of the recruitment process would provide the committee with the skills required by the team. If recruiting the necessary skills was desirable this would still require the vague descriptions of *Expert* and *Lay* qualities currently available to be replaced with a clearer, more detailed description of the skills needed. The recruitment of *Lay* (and *Expert*) members for the skills they bring to the table is good for the committee's function but this would need more consideration at the recruitment stage and some clarity on exactly what the most important skills might be. The provision of some clarity of the skills and expertises required could then feed into the training plans to develop other the contributory expertises.

*Lay* members on NHS RECs are already known to be more educated than the average person and, more often than not, possess contributory expertise in some professional domain. The potential for the development of expertise by those who already possess practical intelligence and tacit knowledge are well described (Cianciola *et al*; 2006, p623) and this increases their receptiveness to learning and development. If recruitment

to the committee were to be based on the skills required for the role rather than a notion of demographic representativeness, then one problem would solve the other. In other words, determining the role definition using clearer definitions of expertise would resolve the recruitment problem providing a Nolan-compliant process and strengthening the ability to replace expertises in the committee.

## **The role of training in an expertise-based model**

The respondents were in no doubt that training was a key factor in the development of the skills necessary to do the job. Other studies (Davis, 1969, Nancarrow *et al.*, 2004) have argued that too much training in the skills required for the task is a problem, as it changes values or beliefs, and makes *Lay* members too knowledgeable. This was not viewed as an issue in this study, however:

*Training does not tell people what to think or what values to hold, but draws out abilities to assess and appraise in previously unfamiliar territory. Training and education demystify and enhance the performance of Lay members*  
(Q-sort 23, male, *Lay* plus member, aged 51-60).

This view seems closer to that of Dreyfus, whose model of Skills Acquisition (Dreyfus, 1981, p14) describes how novices need rules to follow until they become confident and skilled. At this point they are able to see a wider perspective and are able to make decisions without conscious recourse to the rules. Competence and proficiency follow until the status of expert is reached but this is not a fixed status, it is something that is continually built on, in a similar way to continuing professional development. A competent practitioner moves from rule-driven practice to a more intuitive way of working (Benner, 2004, p190), which may be another factor in the development of expertise.

Although training was seen to be universally important to developing the required skills for ethical review in both *Lay* and *Expert* members with statement 2, (*training is vital for Lay members*) scoring positively across all factors and supported by data from the interviews, there was some scepticism as to whether it was necessary to specifically identify experts in ethics as committee members. Schicktanz, *et al* (2012, p129) observe an expansion in ethics experts but also note that “ethics” combines social roles and practical functions, suggesting that the public contribution is important. Emmerich (2009, p11), on the other hand, argues that the lack of recognition of the academic ethicist as an *Expert* member on NHS RECs is strange; especially considering that new committee members all undergo training in research ethics as part of the induction programme. There was some feeling that skills in ethics were not really required at all and it is worth noting that in America, committees under taking ethical review are called Institutional Review Boards (IRBs) not Research Ethics Committees.

*Can there be an Expert in ethics? Many committees don't have ethicists on them  
No they don't (JH)*

*I don't know if it would be necessary, I think you need skills and knowledge, if you had things like advocacy you may need a higher degree of expertise but not for the stuff that we're doing, not for research, a knowledge and interest is useful but not expertise*  
(Interview 8, female *Expert* member).

There was also some disagreement as to what the training programme should include and even whether some of the skills required could be acquired by training. Many of the comments about training reflected the concept of functioning as a team with not all members needing the same skills. For example, there was a recognition that members brought transferable skills from their ‘day jobs’ and it was not necessary to waste time training everyone in areas such as how to contribute in a meeting or how to critically read the meeting papers.

*Need to link training to the 'day job' – not everybody needs to be trained to the same level. Some need to take the lead on certain aspects.*

(Interview 2, female, *Expert* member).

In several of the interviews it was recognised that expertise in research methods or statistics was not necessarily required for every member given that it would be expected that these skills would be present in other members.

*Committee members need to specialise, committee as a whole, so that at least someone is trained in everything. Key skills, critical analysis, putting over your own point of view. The committee as a team with everyone contributing something.*

(Interview 6, male, *Lay plus* member).

Regardless of these differences, however, there was strong and widespread agreement that training should be a joint activity, which is currently the norm.

## **The current arrangements – what needs to change?**

The recruitment to any position, whether paid or voluntary, usually relies on a clear description of the responsibilities of the role and the essential and desirable skills required. The current recruitment process for members of ethics committees partially fulfils these criteria but assumes that there are clearly defined roles for both *Lay* members and *Expert* members. With the exception of certain *Expert* members, such as pharmacists and statisticians who are required by the regulations, the discourse of the members who were participants in this study suggests otherwise.

Factor one was the most important factor in the analysis of the Q-sort accounting for four-times more of the variance than any of the other factors. It describes the committee as a team with *Lay* members as an integral part of it. O'Reilly *et al.* (2009, p251) also described the REC as a team. Their review of the correspondence from the NHS RECs to researchers describing the committee's decision suggested that the committee

functioned as a 'collective unit'. By using third person terms such as 'the committee' they reinforced the collaborative nature of the ethical review. This presentation of a shared view was also seen as a mechanism for asserting authority and accountability.

The Q sort data also shows that *Lay members* are seen as bringing essential skills to the committee, skills which they already possess as a result of their pre-existing education, training or experience and which include critical reading, skills from legal training or social research to name a few. The committee benefits from this experience, which enhances its function, but these are skills that are not expressly recognised in the recruitment process. The ability of the system to recruit members (*Lay* and *Expert*) as part of a team is not helped by lack of clarity in the recruitment process about the expertise required. There was also acknowledgement that the skill gap created when certain members of the committee are absent or resign was detrimental to committee's function. This was also linked to training the rest of the committee to be less dependent on particular individuals in order that the group might be able to function better in these instances:

*Occasionally, very, very occasionally when there isn't a statistician there um people will recognise that between us we don't really have enough statistical information – so a bit of statistical training would actually be quite helpful. At (previous committee) we had a very strict rule where we always had a pharmacist of one or another and usually a statistician and again one would deputise for another I've been on a committee since where we just don't have a statistician and it makes life a bit difficult, I think... in the sense that you, perhaps we, perhaps we could be making better decisions if we have a statistician on board.*

(Interview 9, Female *Lay plus* member).

The idea of members deputising for each other is not practical in the long term as interactional expertise can only be developed through continuous interaction with the relevant contributory experts. More seriously, such arrangements are not permitted by

the legislation if the contributory expertise in question is in one of the specific domains required. This makes some *Experts'* domains more important than others since they are only replaceable by those who have contributory expertise and the right credentials.

## **Recommendations for change**

One option could be that committee members are all recruited and employed so that the ethical review of research proposals becomes a paid role. This would ensure that the role definition, recruitment, and person selection would follow usual employment practices and such a move has been considered;

*We believe that the totally voluntary system of RECs may not be sustainable and, indeed, may no longer be appropriate. It is likely that it inhibits applications for membership by sections of society that should be better represented.*

(DH 2005b, p14).

In fact, the concept of paid regulators is not unheard of in the world of research. The Medicines and Health Care Products Regulatory Agency (MHRA) employs a large number of inspectors who are employed to assess compliance with the Clinical Trials Regulations in research active organisations such as NHS Trusts and Pharmaceutical companies. In fact, there was also some support for professional, paid committees within the interviews, where it was seen as a means of improving consistency both between and within committees and of creating more transparency in recruitment. One interviewee suggested that some of the issues in the committee could be improved with a paid system,

*....is a product of the way we don't have a tight structure of professional ethics committees we have a looser structure of country ethics committees...it would be more credible to have a National approach to a type of ethical governance, but we don't...*

(Interview 6, male, Lay plus member).

On the other hand, others saw professionalised committees as a step too far for NHS RECs, with the concept of paid members undermining the idea that *Lay* members are recruited for the alternative and independent perspective they bring to the committee's deliberation:

*You would start getting some not...corruption but bias and drug companies interfering and that sort of thing*

*And where would the Lay members fit in to that sort of set up? (JH)*

*I don't know, they would get gradually de-lay-ed I think (laughter)...no Layman would do it fulltime if that suddenly caught on...so you're into a paid situation...and then the Layman is sort of ah um not wanting to upset the employer they might get fired, so this kills the whole aspect of it*

(Interview 5, male, *Lay plus* member).

Dawson, (2005, p435) reinforces this view, that people would be unlikely to want to do the 'job' full time and that research participants would not trust an ethical review conducted by people paid to do it. She suggests that this process would compromise the independence of the ethical review.

In the absence of proceeding along a "paid" committee route, the findings from the data lead to two options, both of which would maintain the voluntary nature of the current system whilst helping it to work more effectively. The first would be to ensure a consistent approach to the definition of the terms *Lay* and *Expert* in the context of RECs and to ensure that *Lay* members are both representative and truly lay (i.e. without any contributory expertise in domains that support ethical review). This option is an improbable choice, as the use of the terms *Lay* and *Expert*, even if *Expert* is expanded to include non-clinical expertises, do not adequately define the roles and, more importantly, the new definition of *Lay* member would place an even greater premium on achieving full demographic representation.

The second, more realistic, option would be to identify what is working well in spite of the current role descriptions and recruitment strategies and then amend the systems and processes to enable them to support these practices. The categorisation of expertises suggested in Figure 3, and the subsequent identification of generalist and specialist groups, would achieve this outcome by enabling a more rigorous approach to both recruitment and training. Adopting such an approach would require accepting that achieving demographic representativeness across the membership is not only unlikely but also unnecessary. The National Research Ethics Service strives to make *Lay* membership more inclusive but has recognised that this is problematic (DH, 2005). Perhaps it is time to recognise that there are always likely to be some groups of people excluded from being members due to the high general educational requirement, inconvenient meeting times and incompatibilities with work and other time commitments such as childcare, to highlight a few reasons and there are likely to be many more. Although, it seems counter-intuitive to focus on expertise as a key tenet for the fair and open recruitment of REC members it would eliminate unnecessary efforts to achieve the unachievable and move towards a system that would target skills that are required to achieve an appropriate balance in the committee's function. By focussing on the expertise to do the job, recruitment can target those skills in a more open and transparent way but a decent job specification is needed first.

Recruiting on the basis of specific expertises would force the recognition that, despite their lack of demographic diversity, *Lay* members bring a wide range of important skills to the committee that render the terms *Lay* and *Expert*, as used by NRES, unhelpful. Creating a recruitment process that makes being a *Lay* member as accessible as



possible but recognises that demographic representativeness is unlikely to be achieved could save much time and angst. A comment from the Q-sort indicates the view that,

*Membership is always going to be difficult, for among others, those with low educational attainment, those who are inarticulate, those with caring responsibilities, full-time employment, chronically ill, drug addicts, etc*

(Q-sort response, male, *Expert* member, aged 51-61).

Instead, it is known that *Lay* members of NHS RECs are very similar to their *Expert* colleagues and all are well educated compared to the population overall (NRES, 2007).

*None of our Lay members are representative of the general population; they have specialist skills, just not medical*

(Q-sort 4, female, *Expert* member, aged 41-50).

*Lay members often have had a professional career outside of healthcare and contribute knowledge and opinion drawn from that career. They are able to articulate their views on proposals and can evaluate worth of research to the public*

(Q-sort 6, female, *Expert* member, aged 41-50).

The current recruitment process of *Lay* members (or indeed the *Expert* members) does not reflect this. It also does not support the concept of being a member of a team and nor does it acknowledge that all members are experts in research ethics committee practice. This was the most important finding from the Q-sort data but translating it into practice requires detailed role descriptions for the individuals and the committee as well as a recruitment system that complies with the Nolan principles. A fair and open recruitment process supported by a clear role description linked to the expertises required would provide a structured process for recruitment. This would link the need to replace skills within the team rather than a 'hit and miss' approach which is more likely to leave the committee lacking in the expertise it needs to function. It may even improve diversity amongst the expert domains.

When one of the interviewees was asked whether it would be better if NRES were to produce a generic person specification for committee members as the current specification for *Lay* members looks almost the same as the one for *Experts*, she felt that,

*Without differentiating between the two (membership categories) however, you do need to have a good weighting of people with specialist knowledge.*

*Which would come down to each committee as vacancies became available? (JH)*

*It would, it would, you know if you need somebody with clinical expertise then that's what you would go for,*

*May be you would have a generic job description? (JH)*

*Exactly, and something that could be more specific"*

(Interview 2, female, *Lay* member).

Jones *et al.* (2008, p46) observe that use of the term 'lay' does not adequately reflect lay members' many talents and could be potentially misleading or unhelpful. As already suggested, by removing the terms *lay* and *expert* that are used to define the roles and replacing them with terms that are more descriptive of the backgrounds or skills of members would be a step forward; for example, clinical and non-clinical members, NHS staff and non-NHS staff or as proposed even more simply specialist and generalist. The system would also be much simpler if the terms *Lay* and *Expert* were removed from the role descriptions and recruitment driven by the skills that are actually required for the committee's function. The basis of these descriptions is provided in Figure 3, which identifies the areas of expertise that are present in all RECs and which can be summarised as:

- Ubiquitous ethical expertise acquired through everyday life experiences
- Specialist ethical expertise: contributory expertises in domains relating to REC practice such as critical reading, research ethics, etc, that all REC members would be expected to develop through training and participation in the meetings

- Statutory contributory expertise: contributory expertise in domains that are required by legislation such as statistics, pharmacology etc.
- Generalist contributory expertise: contributory expertise in areas that are currently recognised (e.g. medicine, healthcare) and those not currently recognised (e.g. legislation, legal training, research methods, theology, etc.)
- Interactional expertise: interactional expertises acquired through interaction with other committee members

Starting from this categorisation would provide clear role descriptions for REC members and make identifying the requirements for each role much simpler. The use of these role descriptions would also support the recruitment process and make it easier to identify the skills that would be lost from the committee when members left or their tenure expired.

## **Summary**

This chapter summarises the expertises within the NHS REC across all current membership groups. Whilst acknowledging the members necessary to meet the current Clinical Trial regulations are clearly specialist, contributory experts the data also show that there are other contributory expertises in the REC. These include a shared contributory expertise in REC practice and the individual contributory expertises of REC members that are important to the committee's function but which are not formally sought in the recruitment process. Recognising the diversity of expertises enables the creation of new membership categories that more clearly reflect the distribution of expertise and lay the foundation for improved, Nolan-compliant recruitment practices for NHS RECs.

# **Chapter 6 - Reflections on the methods and summary of main findings**

## **Introduction**

This chapter provides a reflection on the use of Q methodology from the perspectives of those interviewed and from the researcher who was using an unfamiliar method for primary data collection. There is also reflection on the practical issues of conducting a Q sort as a postal exercise and the possible effects the recruitment process may have had on recruitment of participants. There are also comments on the research process including the problems encountered with obtaining the necessary governance approvals for the study from the NHS REC system.

This chapter concludes with a summary and reflection on the use of Collins and Evans (2007) model, The Periodic Table of Expertises and its contribution to the main findings and recommendations.

## **Using Q methodology: the participants' views**

All the participants who were interviewed were asked at the start of the interview how they managed the Q-sort. No one had ever done anything like it before or had even come across it but on the whole the respondents seemed to manage the process although some said that it was not a particularly easy thing to do. The sorting process needed a lot of thought, was considered to be 'fiddly and time consuming' and one participant felt that there ought to be a better way of getting the same information. Many found the whole prioritisation exercise difficult as there were too many things that were important though one person felt that this was especially the case with the items in the

middle of the grid. They felt that the first stage of putting statements into 3 groups was fine, but one person said that the wording in the statements made them feel uneasy at times. There were comments relating to concerns regarding their ability to replicate their sorts and that they may have eventually contradicted themselves. One person felt that she could not guarantee that the statements would actually be in the same position, questioning the reproducibility of the sort.

In practical terms, one person commented that she had found it difficult due to her poor eyesight, and at least two participants commented on the potential for the sort to be disrupted by wind, fans or pets. More positively several people actually said that they had enjoyed completing it and did not find it particularly troublesome to do. Many of these comments concur with other reports of the problems associated with completing Q-sorts (Walker, *et al.*, 1998, p24).

### **Using Q methodology: the researcher's view**

On reflection using Q methodology, which was unfamiliar prior to this project, was not easy. Although there are numerous papers describing the use of this methodology there is a distinct lack of an agreed process or even standard, clear instructions of 'how to do it' and this made the process feel uncertain and confusing. Each subsequent reading of key texts has revealed subtleties in the method that I had previously missed and points that I have only realised the relevance of once my data were collected. The comments by experts are largely reassuring in that the flexibility of the method is quite forgiving and minor variations in its execution probably do not affect the quality of the data or the conclusions to the study.

The literature searching and development of the concourse was a lengthy process and I was always aware that my experience as a former *Expert* committee member could influence the presentation of the statements. The use of two REC members to informally pilot the instructions and comment on the Q-sort statements was an important step to ensure the feasibility of the method and gave confidence in the face validity of the statements.

There were questions raised around the completeness of the Q-set by reviewers. Watts and Stenner (2005, p75) suggest that realistically the Q-set can never be complete but providing it contains 'a representative condensation of information' then it is the ordering of the statements as presented to the participant that generates the data. This is a reassuring view and Thomas and Watson (2002, p143) suggest that the respondents will have made the best choices with the statements presented to them.

One of the key advantages was the ability to generate the statements from what was known and said about the subject and not from my personal views. This allowed those creating the Q-sorts to reflect their view of the published discourse of the committees and the *Lay* role. The method also allowed for the expression of complex views, personal interaction and for participants to think about issues they might not have considered previously. This might have led participants to consider conflicting or incompatible positions and their relationships to each other as in real life but the recording of the reasons for the positioning of statements allowed this to be captured and reflected upon in the analysis. As Stainton Rogers (2008, p191) suggest, it is important to note that the factors emerge from the data as a result of the sorting. They

are not pre-determined and cannot be influenced by the position of the researcher. As the study progressed I became more reassured that my previous role, some five years previously, as a REC member had little or no influence. The topic guide for the interview phase was derived from the Q-sort data and not my personal experience. The discussions that took place in the interviews reassured me that any influence that might have arisen from my REC experience was probably minimal. The interviews themselves allowed for expansion of the views from the Q-sort, reducing the need for interpretation by me.

What appeared at face value to be a simple method for obtaining the views of a small sample of participants proved to require a complex process of analysis using unfamiliar software and analysis techniques. I had envisaged that the software to analyse the Q-sort data would provide more direction for the interpretation of the emerging factors. This was more of a journey of discovery than ever I had expected but nevertheless an informative one.

## **The research process**

It took a while to obtain a definitive decision on whether this project required ethical review by an NHS REC. There was some confusion at the National Research Ethics Service (NRES) queries line and following referral to the policy advisor at NRES it was finally agreed that the project was outside of the requirements of GAFREC but the advice was that an application might be sensible given the sensitivity of the subject matter. Therefore an application was made and approval subsequently granted.

When questionnaires are distributed via a third party, it is not possible to know how many made it past the gatekeeper. Although response rates, as such, were less of an issue with Q methodology, I would have preferred to mail the packs directly to members without having to go via the committee coordinator. The method used made it difficult to calculate the response rate for the Q-sort due to the lack of absolute certainty how many Q sort packs were distributed to potential participants. Sixty-four packs were sent out and twenty-five returned by respondents but eight were returned from one committee without any being distributed. It would be a reasonable guess that of the remaining 31 not all of them would have reached their intended destination.

An alternative method of distribution would have required another step in the consent process and access to the names of individuals to whom I could have sent study packs. This would have complicated the process unnecessarily and would have been difficult in terms of the Data Protection requirements. It would have also afforded less anonymity to the respondents who, at least this way, could respond freely. Keeping the Q-sort responses distinct from the interview data was also important in this respect, as it may have reduced participants' willingness to be interviewed.

As noted in the Method chapter, the expression of interest cards for the interview phase did not ask participants to indicate their membership category. The information for them to say whether they were *Lay*, *Expert* or *Lay plus* had been omitted from the card. This meant that purposive sampling based on membership category was not possible. Luckily, this did not make much difference (but could have done) and almost equal numbers were chosen at random from the list of those who responded.



However, it became obvious during the interview phase that a number of members were not clear to which membership category they belonged, whether they were *Lay* or *Lay plus* members. As previously described *Lay plus* was additional membership category that was added in 2004 to satisfy the requirement to further differentiate *Lay* members into non-clinical NHS members and those who were from outside of the NHS (see explanatory note from NRES in Appendix 1). It is therefore likely that some of the *Lay* members' should be in the '*Lay plus*' category. One of the interviewees even commented

*So um I, I, they're now having another category that's Lay plus um I'm not really sure what this is ...* (Interview 2, female, *lay* member).

Many of the studies that had used Q-sort had explored with participants the rationale for where they had placed statements in their sorts. This was not possible in this study as the sorts were returned anonymously. This was a deliberate choice since I was concerned that there might be an element of social desirability in responses if participants thought they could be identified or a possible adverse effect on response rates.

The original plan was to approach no more than six members from each of nine committees in the southwest of England (REC committees usually have an average of 18 members). However, this was affected by a phase of planned closures of committees, which started across England, including the southwest, just around the time that the application to the NHS REC was being finalised. This reduction in the number of committees meant approaching a larger number of members from each committee to ensure an adequate number of responses. It was anticipated that this

might have affected return rates of the Q-sort data. It was pleasing that a high proportion of those returning the Q-sort also opted into the interview phase of the study.

## **Use of the Periodic Table of Expertises**

As already discussed, lay expertise is complex and lay members use arguments that experts do not consider and which are drawn from other experiences and training (Horlick-Jones, 2004, p110). In addition, there are a number of factors that intuitively feel that they should have an influence on the development of expertise. These include general level of education, time spent in the role and the characteristics highlighted by Shanteau (2002, p257) such as communication skills, self-confidence and credibility. There is no evidence that Collins and Evans' framework (2007, p14) for describing expertises as shown in the Periodic Table of Expertises (Table 2) considers how some of these wider influences might affect the development of expertise and in particular interactional expertise. In the case of NHS RECs the effects of training and duration of tenure were considered to be important in the development of expertises but time is not a dimension in the model.

The potential to develop interactional or contributory expertise is an important consideration when involving the public in NHS RECs and other settings. As Dyer (2004, p339) suggests, the participation of the public in NHS decision-making has become accepted, almost without question, as a good thing to do. It has become the panacea for ensuring fair process, open-ness and integrity in public services. There is no doubt that 'lay involvement' offers an additional dimension to decision-making in many settings but there is a risk that over time other expertises related to relevant to the

role will develop and this might effectively change the *Lay* (and *Expert*) contributions. Nancarrow *et al.* (2004, p20) considered that the only way to manage this issue would be to make sure that any user involvement activity was explicitly time limited. The current tenure for REC members on one committee is ten years but they are not precluded from transferring to another committee, thus transferring the skills already gained.

The original assumption in this project was that interactional expertise may feature as a factor in the lack of differentiation between *Lay* and *Expert* members and may influence their function in the committee. It was also presumed that the development of interactional expertise would only occur in one direction, from *Expert* to *Lay*. This assumption has been modified as a result of the data collected. The model of expertises in NHS RECs that has emerged is more complex than first thought, with interactional expertise going in both ways, in members considered to be *Expert* and *Lay*, with diverse contributory expertises represented by individual members, and a shared contributory expertise in REC practice present in all members.

In spite of some limitations, the Periodic Table of Expertises created by Collins and Evans (2007, p14) has given a useful framework for the study. It has provided a structure to enable the expertises in NHS RECs to be described and has helped to illustrate that the current nomenclature for the categories of members does not make much sense. This study has focussed on the specialist expertises in the model and has not considered the areas of meta-expertises or meta-criteria that complete the model. Some of these aspects were less relevant to the argument in this context as the study

had not set out to explore the expertises of individual members or to compare them. There is no single, formal qualification for REC members and members' track record was not scrutinised in the study. It seems implausible that *Lay members* of NHS RECS could be described as ordinary citizens with only ubiquitous expertise therefore the consideration of interactional and contributory expertise is important in reviewing the membership categories.

## **Summary of the main findings**

The primary function of the REC is to identify any ethical concerns associated with a research project (Hunter 2007, p24) and there are clear regulatory functions associated with NHS REC's role. These are defined by the Governance Arrangements for Research Ethics Committees (DH 2011) and the current legislation (Medicines for Human Use [Clinical Trials] Regulations 2004). This legislation and operational guidance informs the structure of the membership and the roles of *Lay* and *Expert* members.

## **NHS REC members view of the *Lay* role**

The data from the Q-sort, reinforced by the descriptions from the interviews, describe several views of the *Lay* role. However, interestingly (and importantly) the 'official' discourse of the *Lay* role within the committee is only a minor one. The findings support the view that *Lay* members are part of the REC team but suggest that the term *lay* is unhelpful. In particular, it fails to recognise the expertises that lay members bring to the committee as described by Hogg and Williamson (2001, p3) and suggests that the lay-expert dichotomy serves no practical purpose. It is not recognised by the majority of members and makes the terms *lay* and *expert* inappropriate when defining the

membership categories. For example, it does not properly describe their functions, their contribution to the committee or assist in the recruitment of new members.

The data describe several views of how the current holders of the *Lay* role function within the ethics committee structure. The predominant view is that *Lay* members form part of the REC 'team'. They use different skills that are complementary to *Expert* members and which they bring with them from their current or previous employment and/or other 'life experiences'. These are the skills that allow *Lay* members to make similar contributions to the decision-making process as *Expert* members. Crucially these skills are not acknowledged as part of the recruitment process and are therefore not recruited for. Nevertheless these expertises are important to the function of the committee. The discourse of the committee as a team challenges the standard view of both the *Lay* and *Expert* roles and leads to a new way of categorising members. However, to recruit *Lay* (or *Expert*) members considering the skills required would necessitate a recruitment process that uses an explicit description of the expertises in the relevant domains required for the role.

### **Recommendations for recruitment, roles and representation**

According to Martin (2007, p36) one of the key failings in public involvement is the recruitment process. The data in this study suggest that the processes for recruitment, including a clear idea of the expertises required, are not in place to support the function of the committee. This is largely because the expertises are not defined. Important, but practical changes are necessary to support the recruitment of all members in two key areas. Firstly, there need to be role descriptions (individual and collective) based on the specific expertises required to conduct an ethical review. This can be achieved by

mapping the skills for the team using the information in Figure 3 (on page 141). Secondly, this would provide clarity for succession planning by providing adequate replacement of skills, which may otherwise be lost due to turnover of members. Although committees currently deliver the required ethical review implementing these changes would improve their ability to function consistently and effectively. The proposed changes are not particularly major or onerous and there is experience that can be gained from other similar settings where lay members are used in scientific committees such as the National Institute for Health and Clinical Excellence or the Human Fertilization and Embryology Authority.

With a little effort a refined membership structure could be put in place to enable committees to be formally developed as a team with skills spread amongst members. This thesis maps the skills that are required, identifying the areas of expertise that are necessary and enabling clear descriptions of the requirements for the roles within the team. If committees were developed as teams and functioned as such it would enable the recruitment to vacant positions to be based on the skills required to replace those lost by a vacancy, for example a generalist with a particular background (e.g. social science) or a specialist with a specific contributory expertise (e.g. statistics). This recognises that expertises in some domains may be found in non-NHS staff and these may be more important than demographic representativeness.

The lack of demographic representativeness of RECs is considered to be something that could be improved (DH, 2005). A change away from demographic representativeness brings other gains and the emphasis on demographic

representativeness would be replaced by a focus on the skills, expertise and function of the whole committee as a team. The current system is incompatible with the need to ensure that the committee has the expertises required to function. Clear expressions of the expertise required in the relevant domains which are cognisant of the current legal requirements coupled with a recruitment procedure that follows the principles set out by the Nolan report (1995) would be a perfect place to start.

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# Appendices

## Appendix 1. Membership of RECs required by the clinical trial regulations (NRES 2009)

### Experts

Hospital doctors  
Medical academics  
GPs  
Psychiatrists  
Dentists  
Nurses and midwives  
Pharmacists  
Other currently registered health care professionals  
Previously registered doctors/dentists  
Clinical research data managers  
Clinical research statisticians  
Any other person with professional qualifications or experience of conducting clinical research <sup>(1)</sup>

### Lay

Previously registered health care professionals (other than doctors/dentists)  
Board members and directors of Trusts, Health Boards, SHAs, etc <sup>(2)</sup>  
Research managers and administrators at pharmaceutical companies or other clinical research bodies, e.g. project managers, CRAs, monitors, trials unit managers <sup>(2)</sup>  
Research secretaries (if involved in management of clinical trials) <sup>(2)</sup>

### Lay+

Members of the general public  
Social care professionals  
Sociologists  
Statisticians with no clinical trials experience  
Academic ethicists  
Lawyers  
Chaplains  
NHS administrative, technical and support staff (not involved in management of clinical trials)

(1) The *'conduct of, or use of statistics in, clinical research'* is not defined in the Regulations. The guidance from NRES is that 'clinical research' should be interpreted comprehensively for this purpose, and includes any research involving: interventions, procedures, tests or analyses undertaken as part of the diagnosis, treatment or care of patients in the clinical setting, including monitoring and follow-up tests or analyses to evaluate the safety or efficacy of methods of diagnosis, treatment or care of patients in the clinical setting, including quality of life outcomes tests or analyses to develop new methods of diagnosis, treatment or care of patients in the clinical setting.

(2) In practice, potential conflicts of interest would need to be taken into account by the appointing authority before such persons could be appointed as members of an ethics committee, but this is a separate issue from the classification of membership as expert/lay/lay plus

## Appendix 2. Q-sort items

<p>1. Lay members need to be able to understand the science behind the research to be able contribute effectively to REC meetings</p>	<p>2. Training is vital for lay members</p>	<p>3. Lay members can be over-trained</p>	<p>4. Lay member's primary role is to ensure that subjects are able to give informed consent.</p>	<p>5. Lay members are not representative of the population as a whole</p>	<p>6. Lay and professional members have equal weight in committee debate / discussion</p>	<p>7. Lay members can bring a set of expert skills of their own, e.g. legal, financial etc</p>
<p>8. A good level of education is essential to being effective in the role of lay member</p>	<p>9. Expertise develops with time</p>	<p>10. There comes a point where it is difficult to identify an experienced lay members from their professional colleagues</p>	<p>11. Practical experience is more useful than formal training</p>	<p>12. The role of lay members is different to that of their professional colleagues</p>	<p>13. Lay members can become experts in their own right</p>	<p>14. Lay members have the same role and responsibilities as the professional members</p>
<p>15. The ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a lay member</p>	<p>16. There is a hierarchy of membership led by the professional members</p>	<p>17. Lay members are essential to balance the views of the committee</p>	<p>18. Lay members change their ethical perspectives over time</p>	<p>19. Lay members are only there to safe guard the public interest</p>	<p>20. The user perspective can only be obtained through lay members views</p>	<p>21. The value of lay members ability to give a lay perspective diminishes over time</p>

<p><b>22.</b> Lay members can only represent their own views, not those of the wider public</p>	<p><b>23.</b> Anyone, regardless of their educational background, could be an effective lay member</p>	<p><b>24.</b> Lay members need to be able to challenge the views of the professional members</p>	<p><b>25.</b> Lay members need to be able to challenge the views of researchers</p>	<p><b>26.</b> Lay members are more likely to feel accepted as committee members once they can speak the same language as the professionals.</p>	<p><b>27.</b> Lay members need to be able to 'see' the bigger picture to make informed decisions</p>	<p><b>28.</b> Being accepted as a fully functioning member of the committee is vital to performance</p>
<p><b>29.</b> It is only members without any connection to the NHS who can represent the public view</p>	<p><b>30.</b> The distinction between lay and professional members would not be clear to outside observers.</p>	<p><b>31.</b> Lay members have different values to professional members</p>	<p><b>32.</b> The distinction between lay and professionals is a false dichotomy when it comes to research ethics</p>	<p><b>33.</b> Personal credibility is important for lay members if they are to be taken seriously</p>	<p><b>34.</b> 'Life experience' is the most important qualification for lay members</p>	<p><b>35.</b> Lay members can never be as knowledgeable as professional members</p>
<p><b>36.</b> Lay members do not need to be trained</p>	<p><b>37.</b> The key role for Lay members is to make sure that the information to participants is understandable</p>	<p><b>38.</b> Lay members find it difficult to contribute to the ethical debate on studies using complex methods.</p>	<p><b>39.</b> Lay members find it difficult to contribute to the ethical debate about studies involving complex diseases or illnesses</p>	<p><b>40.</b> Lay members are only there to 'legitimise' committee's decisions</p>	<p><b>41.</b> A 5-year tenure is long enough for lay members to serve on a committee.</p>	<p><b>42.</b> Most lay members have some connection with the NHS</p>

## Appendix 3. Introductory letter to REC coordinators

Address for correspondence  
Gloucestershire RDSU  
Leadon House  
Gloucestershire Royal Hospital  
Great Western Road  
Gloucester  
GL1 3NN

To: REC Coordinators in the South West SHA area

May 2009

Dear

***At the next meeting of your ethics committee please could you take a few moments to ask your members if they would be willing to take part in this study?***

My name is Julie Hapeshi and I am currently studying for a Professional Doctorate in Health at Cardiff University. I have been a member of an NHS Research Ethics Committee (NHS REC) for a number of years and during my time as a committee member I have observed how lay members develop a level of expertise that makes them difficult to tell apart from their professional counter-parts. When I realised that, from the literature, I am not the only person to have observed this, I chose to explore this further for my professional doctorate thesis.

To conduct this piece of research I do need your help; but hopefully what's required will not be too onerous!

All that you need to do is to give out one of the eight study packs to a mixture of lay or lay plus and professional members who have been members of an ethics committee for at least six months (roughly four of each would be good but not essential). They need not have been members of your committee for all of that time; they may have come from another committee elsewhere.

If, once they have read the information in more detail, they do not want to take part in the study; I have asked them to return the pack to you so that it can be passed onto another member. They do not need to give a reason why they have decided not to take part as I will have no knowledge of who you have approached. If you are unable to find 8 willing members, please could you return the unused packs to me so that I can canvass other committees for their help?

Although this project was deemed by the National Research Ethics Service Queries line to be outside of the Governance Arrangements for Research Ethics Committees, I chose to submit my project for NHS REC review because of the nature of the project (*REC ref:09/H0104/2*)

Thank you for taking the time to read this letter.

Yours sincerely

Julie Hapeshi



## Appendix 4. Introductory letter to participants

Address for correspondence  
Gloucestershire RDSU  
Leadon House  
Gloucestershire Royal Hospital  
Great Western Road  
Gloucester  
GL1 3NN

Dear REC members

My name is Julie Hapeshi and I am currently studying for a Professional Doctorate in Health at Cardiff University. I have been a member of an NHS Research Ethics Committee (NHS REC) for a number of years and during my time as a committee member I have observed how lay members develop a level of expertise that makes them difficult to tell apart from their professional counter-parts. When I realised that, from the literature, I am not the only person to have observed this, I chose to explore this further for my professional doctorate thesis.

Some evidence exists that it is possible to develop a substantial level of expertise by basic training and 'socialisation' in the area and this makes experts and non-experts difficult to distinguish. It has been argued that it is the immersion in the culture and language of the area in question that creates a particular type of expertise called interactional expertise. This study will explore how both lay and professional REC members across the southwest consider the role of lay members. This will be done using a special questionnaire called a Q-sort.

If you do not want to take part in the study please return your pack to your REC co-ordinator so that it can be passed onto another member. You do not need to give a reason and I will have no knowledge of who has been approached.

If you do decide to participate in the study, the study pack will contain all that you need including the instructions on how to complete the Q-sort and the question cards. The Q-sort is likely to take around 30 – 45 mins and it would be helpful if you could return the Q-sort responses within the next 2 - 3 weeks. If you require any special help to complete the Q-sort, please contact me directly and I will do my best to help.

I would also like to ask some participants in the Q-sort to consider taking part in a short face-to-face interview to explore further the key findings of the Q-sort. If you would be willing to take part in a short interview please return the postcard from the pack with your details and I will contact you to arrange a mutually convenient time to meet with you.

Participation in the Q-sort will be completely anonymous to me as the researcher and if you decide to participate in the interview phase then your response to the Q-sort will not be linked to your interview.

Although this project was deemed by the National Research Ethics Service Queries line to be outside of the Governance Arrangements for Research Ethics Committees, I chose to submit my project for NHS REC review because of the nature of the project.  
Thank you for taking the time to read this letter.

Yours sincerely  
Julie Hapeshi

## Appendix 5. Q-sort instructions

### Instructions to Q-sort questionnaire about lay members of NHS Ethics committees

These instructions will guide you through the survey step by step. Please read each step to the end before you start carrying it out.

1. Take the cards provided and the score sheet and sit at a table. Lay down the score sheet in front of you. All 42 cards in the deck contain a statement about lay members of ethics committees. The numbers on the cards (from 1 to 42) have been assigned to the cards randomly and are only relevant for the administration of your response. You will need to rank-order these statements from your own point of view considering the question: 'To what extent do you agree with the following statements.'
2. This study is about lay members of NHS Research Ethics committees. I am interested in **your thoughts about their role and functions**.
3. Read the 42 statements carefully and split them up into three piles: a pile for statements you tend to disagree with, a pile for cards you tend to agree with, and a pile for cards you neither agree nor disagree with, or that you feel are not relevant or applicable. Please use the three boxes 'AGREE', 'NEUTRAL OR NOT RELEVANT' and 'DISAGREE' at the bottom left of the score sheet. Just to be clear, we are interested in your point of view. Therefore, there are no right or wrong answers. When you have finished laying down the cards in these three boxes on the score sheet, count the number of cards in each pile and write down this number in the corresponding box. Please check whether the numbers you entered in the three boxes add up to 42.
4. Take the cards from the 'AGREE' pile and read them again. Select the two statements that *most agree* with your view of lay members of NHS RECs and place them in the two last boxes on the right of the score sheet, below the '9' (it does not matter which one goes on top or below).

Next, from the remaining cards in the deck, select the three statements you *most agree* with and place them in the three boxes below the '8'. Follow this procedure for all cards from the 'AGREE' pile.

5. Now take the cards from the 'DISAGREE' pile and read them again. Just like before, select the two statements you *most disagree* with your view of lay members of NHS RECs and place them in the two last boxes on the left of the score sheet, below the '1'. Follow this procedure for all cards from the 'DISAGREE' pile.
6. Finally, take the remaining cards and read them again. Arrange the cards in the remaining open boxes of the score sheet.
7. When you have placed all cards on the score sheet, please go over your distribution once more and shift cards if you want to.
8. Please explain why you *agree most* with the two statements you have placed below the '9'.

---

Card no.: ... :

Card no.: ... :

---

9. Please explain why you *disagree most* with the two statements you have placed below the '1'.

---

Card no.: ... :

Card no.: ... :

---

10. When you are finished, please write down the number of the cards in the boxes on the score sheet that you placed them on.

Please return this sheet, the score sheet and the cards to Julie Hapeshi in the envelope provided.

If you are volunteering to participate in the follow-up interview, please return the post card separately from your questionnaire response to ensure that your responses remain anonymous

## Appendix 6. Demographic questionnaire

This is a short questionnaire to collect some information about you to give the Q-sort some context.

1. Using the National Research Ethics Service definitions are you:  
Please tick one only

*A lay member? – any member who is not a professional member is by definition a lay member. This includes previously registered Health care professionals (except for doctors and dentists), chairs, members or directors of any health care body.*

*A Professional member? – are a currently registered health care professional or a professional with a qualification related to the conduct of clinical trials, statistics or is a previously registered medical practitioner or dentist*

*A Lay plus member? – a person who has never been a health care professional, never been involved in the conduct of clinical research and never been a chair, member or director of any healthcare body.*

2. Are you

male

female

3. Please indicate your age category, tick one option:

18 - 30

31 - 40

41 - 50

51 - 60

61 - 70

71 - 80

over 80

4. How long have you been a member of this NHS Research Ethics committee?

Years..... Months.....

5. If you have been a member of more than one committee please give your total time as a member.

Years..... Months..... not applicable

6. Have you attended training to help you perform your role as a REC member?

Yes, too much

Yes, enough

Yes, some but not enough

None

Thank you for completing this questionnaire, please return it in the envelope provided with your Q-sort responses to:

Julie Hapeshi, Gloucestershire R&D Unit, Leadon House, Great Western Road, Gloucester, GL1 3NN

## Appendix 7. Postcard template expressing an interest in the interview phase.

**Please return postcard in the envelope provided**

### **Interactional Expertise in Lay Members of NHS RECs**

I would be happy to be contacted for you to arrange to interview me for your project. My contact details are below:

Name	
Address	
Postcode	
Contact telephone number	
Email	

## Appendix 8. Interview guide

Thank you for completing the Q-Sort which was the first phase of the project and agreeing to be interviewed for the second phase.

The interview will pick up on some of the issues that have arisen from the analysis of the Q-sort data and I hope will take no more than an hour.

If during the interview you want to take a break, or stop completely please just tell me and I will stop the questions and the tape recorder.

Do you want to ask me any questions?

Are you happy to sign the consent form and to proceed with the interview?

→Can you tell me a little about your ethics committee 'career'? For example, how did you become a REC member? How many committees have you been a member of? For how long? In what capacity?

→Moving on, I wonder if you could tell me how you got on with actually doing the Q-Sort?

→Did you have any particular problems with it?

I would now like to go on to explore with you some of the key findings from the Q-Sort.

→One of the key themes that arose was that respondents felt that lay members have the same role and responsibilities as their professional colleagues but use different skills and expertise to do the job.

→I wonder if you might be able to tell me how lay members' skills differ.

→What do we mean by expertise?

Training was a key factor from the Q-Sort.

→If skills already differ, should training be the same or different?

→Who should set the training agenda?

→What should the training programme include?

→Anything else?

It was also suggested that lay members' role was to challenge the views of not only the professional members but also researchers with the idea of bringing balance to the committee a key factor.

→How do you think that the role of the lay member contributes to balancing the decisions of the committee?



→How does this affect the function of the committee?

→There was strong disagreement that lay members were not part of the committee simply to legitimise the committee's decision-making. However, there was a suggestion that lay members had a role as 'scrutineers' in the committee.

→What do you feel about this assertion?

There was a feeling that lay members were not representative but that there were justifiable reasons for this.

→What are your views on this?

There were a few conflicting responses that I would like to explore. You might be able to help me explain how this has happened

→Lay members struggle to understand complex studies but they don't need to be able to understand the science

→Lay members don't need to be able to understand or converse in healthcare jargon but are more likely to be accepted by the committee once they can

## Appendix 9. Letter confirming interview

**Address for  
correspondence**

Gloucestershire RDSU  
Leadon House  
Gloucestershire Royal  
Hospital  
Great Western Road  
Gloucester  
GL1 3NN

Date

Dear

**Does the development of expertise make lay members of NHS Research Ethics Committees too much like professionals?**

Thank you for returning the postcard indicating your interest in taking part in a short interview about the role and functions of lay members of NHS Research Ethics committees.

Following our recent email /telephone contact I can confirm that I will meet you to conduct the interview on *day – month – year* at *venue name*.

When we meet I will ask you to sign a consent form and will request your permission to tape record the interview so that I can transcribe the interview verbatim. I will give you a copy of the consent form to keep.

I look forward to meeting you. If in the meantime you need to contact me please call me on 08454 22546 or email [Julie.hapeshi@glos.nhs.uk](mailto:Julie.hapeshi@glos.nhs.uk).

Yours sincerely

Julie Hapeshi  
Professional Doctorate Student

## Appendix 10. Consent form

### CONSENT FORM

**Title of Project: Does the development of expertise make lay members of NHS Research Ethics Committees too much like professionals?**

Name of Researcher: Julie Hapeshi, Professional doctorate Student, Cardiff University

Please initial box:

1. I confirm that I have read and understand the information sheet dated .....   
for the above study.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my human or legal rights being affected
3. I agree to the interview being audio recorded and transcribed
4. I understand that although illustrative quotes may be used I will not be identified in any transcript or any future publication
5. I agree to take part in the above study

Name of participant

Date

Signature

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Name of person taking consent

Date

Signature

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

1 copy for participant, 1 copy for researcher.

## Appendix 11. Letter to those not selected for interview

Address for correspondence  
Gloucestershire RDSU  
Leadon House  
Gloucestershire Royal  
Hospital  
Great Western Road  
Gloucester  
GL1 3NN

February 9<sup>th</sup> 2010

Dear

Thank you for your interest in taking part in the interview phase of my professional doctorate project, *'Does the development of expertise make lay members of NHS Research Ethics Committees too much like professionals?'*

I have received such an overwhelming response to my requests for interview participants that I will not be able to interview everyone who has expressed an interest. To ensure that participants were selected fairly I have used a randomisation process and unfortunately you were not selected.

Thank you once again for your interest in my project. A summary of the findings will be made available to you through your committee coordinator in due course (towards the end of 2010).

Yours sincerely

Julie Hapeshi  
Prof. Doctorate Research Student

## Appendix 12. Q-sort Factors exemplifying sorts

-4	-3	-2	-1	0	1	2	3	4
4. Lay member's primary role is to ensure that subjects are able to give informed consent.	12. The role of lay members is different to that of their professional colleagues	1. Lay members need to be able to understand the science behind the research to be able contribute effectively to REC meetings	3. Lay members can be over-trained	5. Lay members are not representative of the population as a whole	2. Training is vital for lay members	6. Lay and professional members have equal weight in committee debate / discussion	7. Lay members can bring a set of expert skills of their own, e.g. legal, financial etc	14. Lay members have the same role and responsibilities as the professional members
40. Lay members are only there to 'legitimise' committee's decisions	19. Lay members are only there to safe guard the public interest	15. The ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a lay member	16. There is a hierarchy of membership led by the professional members	10. There comes a point where it is difficult to identify an experienced lay members from their professional colleagues	23. Anyone, regardless of their educational background, could be an effective lay member	8. A good level of education is essential to being effective in the role of lay member	17. Lay members are essential to balance the views of the committee	28. Being accepted as a fully functioning member of the committee is vital to performance
	21. The value of lay members ability to give a lay perspective diminishes over time	18. Lay members change their ethical perspectives over time	20. The user perspective can only be obtained through lay members views	11. Practical experience is more useful than formal training	27. Lay members need to be able to 'see' the bigger picture to make informed decisions	9. Expertise develops with time	24. Lay members need to be able to challenge the views of the professional members	
		26. Lay members are more likely to feel accepted as committee members once they can speak the same language as the professionals.	29. It is only members without any connection to the NHS who can represent the public view	13. Lay members can become experts in their own right	30. The distinction between lay and professional members would not be clear to outside observers.	22. Lay members can only represent their own views, not those of the wider public		
		31. Lay members have different values to professional members	32. The distinction between lay and professionals is a false dichotomy when it comes to research ethics	33. Personal credibility is important for lay members if they are to be taken seriously	38. Lay members find it difficult to contribute to the ethical debate on studies using complex methods.	25. Lay members need to be able to challenge the views of researchers		
			35. Lay members can never be as knowledgeable as professional members	34. Life experience 'is the most important qualification for lay members	39. Lay members find it difficult to contribute to the ethical debate about studies involving complex diseases or illnesses			
			36. Lay members do not need to be trained	37. The key role for Lay members is to make sure that the information to participants is understandable	42. Most lay members have some connection with the NHS			
				41. A 5-year tenure is long enough for lay members to serve on a committee.				

**Figure 4. Exemplifying sort for Factor one – lay members as part of a team**

-4	-3	-2	-1	0	1	2	3	4
23. Anyone, regardless of their educational background, could be an effective lay member	4. Lay member's primary role is to ensure that subjects are able to give informed consent	1. Lay members need to be able to understand the science behind the research to be able to contribute effectively to REC meetings	6. Lay and professional members have equal weight in committee debate / discussion	3. Lay members can be over-trained	8. A good level of education is essential to being effective in the role of lay member	2. Training is vital for lay members	17. Lay members are essential to balance the views of the committee	5. Lay members are not representative of the population as a whole
36. Lay members do not need to be trained	29. It is only members without any connection to the NHS who can represent the public view	20. The user perspective can only be obtained through lay members views	10. There comes a point where it is difficult to identify an experienced lay members from their professional colleagues	11. Practical experience is more useful than formal training	16. There is a hierarchy of membership led by the professional members	8. A good level of education is essential to being effective in the role of lay member	24. Lay members need to be able to challenge the views of the professional members	7. Lay members can bring a set of expert skills of their own, e.g. legal, financial etc
	35. Lay members can never be as knowledgeable as professional members	21. The value of lay members ability to give a lay perspective diminishes over time	14. Lay members have the same role and responsibilities as the professional members	18. Lay members change their ethical perspectives over time	25. Lay members need to be able to challenge the views of researchers	12. The role of lay members is different to that of their professional colleagues	37. The key role for Lay members is to make sure that the information to participants is understandable	
		22. Lay members can only represent their own views, not those of the wider public	15. The ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a lay member	19. Lay members are only there to safe guard the public interest	27. Lay members need to be able to 'see' the bigger picture to make informed decisions	13. Lay members can become experts in their own right		
		31. Lay members have different values to professional members	30. The distinction between lay and professional members would not be clear to outside observers	26. Lay members are more likely to feel accepted as committee members once they can speak the same language as the professionals.	32. The distinction between lay and professionals is a false dichotomy when it comes to research ethics	28. Being accepted as a fully functioning member of the committee is vital to performance		
			39. Lay members find it difficult to contribute to the ethical debate about studies involving complex diseases or illnesses	34. Life experience 'is the most important qualification for lay members	33. Personal credibility is important for lay members if they are to be taken seriously			
			41. A 5-year tenure is long enough for lay members to serve on a committee.	38. Lay members find it difficult to contribute to the ethical debate on studies using complex methods	42. Most lay members have some connection with the NHS			
				40. Lay members are only there to 'legitimise' committee's decisions				

**Figure 5: Exemplifying sort for Factor two – Lay members are skilled but they are not representative.**

-4	-3	-2	-1	0	1	2	3	4
24. Lay members need to be able to challenge the views of the professional members	5. Lay members are not representative of the population as a whole	7. Lay members can bring a set of expert skills of their own, e.g. legal, financial etc	1. Lay members need to be able to understand the science behind the research to be able contribute effectively to REC meetings	11. Practical experience is more useful than formal training	2. Training is vital for lay members	4. Lay member's primary role is to ensure that subjects are able to give informed consent.	14. Lay members have the same role and responsibilities as the professional members	27. Lay members need to be able to 'see' the bigger picture to make informed decisions
25. Lay members need to be able to challenge the views of researchers	16. There is a hierarchy of membership led by the professional members	*10. There comes a point where it is difficult to identify an experienced lay members from their professional colleagues	3. Lay members can be over-trained	18. Lay members change their ethical perspectives over time	28. Being accepted as a fully functioning member of the committee is vital to performance	6. Lay and professional members have equal weight in committee debate / discussion	17. Lay members are essential to balance the views of the committee	37. The key role for Lay members is to make sure that the information to participants is understandable
	22. Lay members can only represent their own views, not those of the wider public	12. The role of lay members is different to that of their professional colleagues	8. A good level of education is essential to being effective in the role of lay member	20. The user perspective can only be obtained through lay members views	29. It is only members without any connection to the NHS who can represent the public view	23. Anyone, regardless of their educational background, could be an effective lay member	19. Lay members are only there to safe guard the public interest	
		*13. Lay members can become experts in their own right	9. Expertise develops with time	21. The value of lay members ability to give a lay perspective diminishes over time	35. Lay members can never be as knowledgeable as professional members	34. Life experience 'is the most important qualification for lay members		
		15. The ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a lay member	31. Lay members have different values to professional members	26. Lay members are more likely to feel accepted as committee members once they can speak the same language as the professionals.	39. Lay members find it difficult to contribute to the ethical debate about studies involving complex diseases or illnesses	38. Lay members find it difficult to contribute to the ethical debate on studies using complex methods.		
		30. The distinction between lay and professional members would not be clear to outside observers.	36. Lay members do not need to be trained	32. The distinction between lay and professionals is a false dichotomy when it comes to research ethics	40. Lay members are only there to 'legitimise' committee's decisions			
			<b>*statements 10 &amp; 13 have tied z-scores which have altered the pattern</b>	33. Personal credibility is important for lay members if they are to be taken seriously	42. Most lay members have some connection with the NHS			
				41. A 5-year tenure is long enough for lay members to serve on a committee.				

**Figure 6. Exemplifying sort for factor three - Lay members as the voice of the ordinary people**

-4	-3	-2	-1	0	1	2	3	4
12. The role of lay members is different to that of their professional colleagues	1. Lay members need to be able to understand the science behind the research to be able contribute effectively to REC meetings	18. Lay members change their ethical perspectives over time	11. Practical experience is more useful than formal training	5. Lay members are not representative of the population as a whole	2. Training is vital for lay members	17. Lay members are essential to balance the views of the committee	10. There comes a point where it is difficult to identify an experienced lay members from their professional colleagues	6. Lay and professional members have equal weight in committee debate / discussion
40. Lay members are only there to legitimise 'committee's decisions	35. Lay members can never be as knowledgeable as professional members	21. The value of lay members ability to give a lay perspective diminishes over time	15. The ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a lay member	8. A good level of education is essential to being effective in the role of lay member	3. Lay members can be over-trained	30. The distinction between lay and professional members would not be clear to outside observers.	14. Lay members have the same role and responsibilities as the professional members	7. Lay members can bring a set of expert skills of their own, e.g. legal, financial etc
	39. Lay members find it difficult to contribute to the ethical debate about studies involving complex diseases or illnesses	22. Lay members can only represent their own views, not those of the wider public	20. The user perspective can only be obtained through lay members views	16. There is a hierarchy of membership led by the professional members	4. Lay member's primary role is to ensure that subjects are able to give informed consent.	32. The distinction between lay and professionals is a false dichotomy when it comes to research ethics	34. Life experience 'is the most important qualification for lay members	
		31. Lay members have different values to professional members	26. Lay members are more likely to feel accepted as committee members once they can speak the same language as the professionals.	19. Lay members are only there to safe guard the public interest	9. Expertise develops with time	33. Personal credibility is important for lay members if they are to be taken seriously		
		38. Lay members find it difficult to contribute to the ethical debate on studies using complex methods.	27. Lay members need to be able to 'see' the bigger picture to make informed decisions	23. Anyone, regardless of their educational background, could be an effective lay member	13. Lay members can become experts in their own right	42. Most lay members have some connection with the NHS		
			29. It is only members without any connection to the NHS who can represent the public view	24. Lay members need to be able to challenge the views of the professional members	25. Lay members need to be able to challenge the views of researchers			
			36. Lay members do not need to be trained	28. Being accepted as a fully functioning member of the committee is vital to performance	37. The key role for Lay members is to make sure that the information to participants is understandable			
				41. A 5-year tenure is long enough for lay members to serve on a committee.				

**Figure 7: Exemplifying sort for factor four – lay members in the same role as experts**



-4	-3	-2	-1	0	1	2	3	4
23. Anyone, regardless of their educational background, could be an effective lay member	3. Lay members can be over-trained	10. There comes a point where it is difficult to identify an experienced lay members from their professional colleagues	12. The role of lay members is different to that of their professional colleagues	1. Lay members need to be able to understand the science behind the research to be able contribute effectively to REC meetings	6. Lay and professional members have equal weight in committee debate / discussion	8. A good level of education is essential to being effective in the role of lay member	17. Lay members are essential to balance the views of the committee	2. Training is vital for lay members
36. Lay members do not need to be trained	13. Lay members can become experts in their own right	15*. The ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a lay member	16. There is a hierarchy of membership led by the professional members	4. Lay member's primary role is to ensure that subjects are able to give informed consent	9. Expertise develops with time	11. Practical experience is more useful than formal training	24. Lay members need to be able to challenge the views of the professional members	7. Lay members can bring a set of expert skills of their own, e.g. legal, financial etc
	30. The distinction between lay and professional members would not be clear to outside observers.	19. Lay members are only there to safe guard the public interest	26. Lay members are more likely to feel accepted as committee members once they can speak the same language as the professionals.	5. Lay members are not representative of the population as a whole	18. Lay members change their ethical perspectives over time	29. It is only members without any connection to the NHS who can represent the public view	34. Life experience 'is the most important qualification for lay members	
		21*. The value of lay members ability to give a lay perspective diminishes over time	28. Being accepted as a fully functioning member of the committee is vital to performance	14. Lay members have the same role and responsibilities as the professional members	25. Lay members need to be able to challenge the views of researchers	31. Lay members have different values to professional members		
		37. The key role for Lay members is to make sure that the information to participants is understandable	32. The distinction between lay and professionals is a false dichotomy when it comes to research ethics	20. The user perspective can only be obtained through lay members views	27. Lay members need to be able to 'see' the bigger picture to make informed decisions	38. Lay members find it difficult to contribute to the ethical debate on studies using complex methods.		
		42. Most lay members have some connection with the NHS	41. A 5-year tenure is long enough for lay members to serve on a committee.	22. Lay members can only represent their own views, not those of the wider public	33. Personal credibility is important for lay members if they are to be taken seriously			
			<b>*Statements 15 &amp; 21 have tied z-scores which have altered the pattern of the distribution</b>	39. Lay members find it difficult to contribute to the ethical debate about studies involving complex diseases or illnesses	35. Lay members can never be as knowledgeable as professional members			
				40. Lay members are only there to legitimise' committee's decisions				

**Figure 8: Exemplifying sort for factor five - a traditional view of lay members**

-4	-3	-2	-1	0	1	2	3	4
15. The ability to understand and converse in healthcare jargon is crucial to being able to effectively perform as a lay member	19. Lay members are only there to safe guard the public interest	1. Lay members need to be able to understand the science behind the research to be able contribute effectively to REC meetings.	14. Lay members have the same role and responsibilities as the professional members	8. A good level of education is essential to being effective in the role of lay member	4. Lay member's primary role is to ensure that subjects are able to give informed consent.	2. Training is vital for lay members	12. The role of lay members is different to that of their professional colleagues	6. Lay and professional members have equal weight in committee debate / discussion
40. Lay members are only there to legitimise' committee's decisions	31. Lay members have different values to professional members	3. Lay members can be over-trained	*21. The value of lay members ability to give a lay perspective diminishes over time	10. There comes a point where it is difficult to identify an experienced lay members from their professional colleagues	5. Lay members are not representative of the population as a whole	9. Expertise develops with time	17. Lay members are essential to balance the views of the committee	7. Lay members can bring a set of expert skills of their own, e.g. legal, financial etc
	36. Lay members do not need to be trained	16. There is a hierarchy of membership led by the professional members	*26. Lay members are more likely to feel accepted as committee members once they can speak the same language as the professionals.	18. Lay members change their ethical perspectives over time	11. Practical experience is more useful than formal training	13. Lay members can become experts in their own right	24. Lay members need to be able to challenge the views of the professional members	
		20. The user perspective can only be obtained through lay members views	27. Lay members need to be able to 'see' the bigger picture to make informed decisions	22. Lay members can only represent their own views, not those of the wider public	33. Personal credibility is important for lay members if they are to be taken seriously	23. Anyone, regardless of their educational background, could be an effective lay member		
		39. Lay members find it difficult to contribute to the ethical debate about studies involving complex diseases or illnesses	28. Being accepted as a fully functioning member of the committee is vital to performance	30. The distinction between lay and professional members would not be clear to outside observers	37. The key role for Lay members is to make sure that the information to participants is understandable	25. Lay members need to be able to challenge the views of researchers		
		*Statements 26 & 27 have tied z-scores this has altered the pattern of the distribution	29. It is only members without any connection to the NHS who can represent the public view	35. Lay members can never be as knowledgeable as professional members	41. A 5-year tenure is long enough for lay members to serve on a committee.			
			32. The distinction between lay and professionals is a false dichotomy when it comes to research ethics	38. Lay members find it difficult to contribute to the ethical debate on studies using complex methods.				
			34. 'Life experience' is the most important qualification for lay members	42. Most lay members have some connection with the NHS				

**Figure 9. Exemplifying sort for factor six – lay members' skills complement the experts**

## Appendix 13. The rank statement totals for each statement for each Q-sort factor.

Factor → Statement no. ↓	Lay members as part of a team	Lay members are skilled but not representative	Lay members are the voice of ordinary people	Lay members role is the same as experts	A traditional view of lay members as described by NRES	Lay members skills complement the experts
1 <sup>D</sup>	-2	-2	-1	-3	0 <sup>C</sup>	-2
2 <sup>B*</sup>	1	2	1	1	4 <sup>E</sup>	2
3	-1	0	-1	1	-3	-2
4	-4 <sup>D</sup>	-3	2	1	0	1
5	0	4	-3	0	0	1
6	2	-1	2	4	1	4
7 <sup>*</sup>	3	4	-2 <sup>D</sup>	4	3	4
8	2	2	-1 <sup>D</sup>	0	2	0
9	2	1	-1 <sup>D</sup>	1	1	2
10	0	-1	-2	3 <sup>E</sup>	-2	0
11	0	0	0	-1 <sup>D</sup>	2	1
12	-3	2	-2	-4 <sup>D</sup>	-1	3
13	0	2	-2	1	-3	2
14	4 <sup>E</sup>	-1	3	3	0	-1
15 <sup>A*</sup>	-2	-1	-2	-1	-2	-4 <sup>D</sup>
16	-1	1	-3	0	-1	-2
17 <sup>B*</sup>	3	3	3	2	3	3
18	-2	0	0	-2	1	0
19	-3	0	3	0	-2	-3
20	-1	-2	0	-1	0	-2
21 <sup>A*</sup>	-3	-2	0 <sup>C</sup>	-2	-2	-1
22	2	-2	-3	-2	0	0
23	1	-4 <sup>D</sup>	2	0	-4 <sup>D</sup>	2
24	3	3	-4 <sup>D</sup>	0	3	3
25	2	1	-4 <sup>D</sup>	1	1	2
26	-2	0	0	-1	-1	-1
27	1	1	4	-1	1	-1
28	4	2	1	0	-1	-1
29	-1	-3	1	-1	2	-1

Factor → Statement no. ↓	Lay members as part of a team	Lay members are skilled but not representative	Lay members are the voice of ordinary people	Lay members role is the same as experts	A traditional view of lay members as described by NRES	Lay members skills complement the experts
30	1	-1	-2	2	-3	0
31 <sup>D</sup>	-2	-2	-1	-2	2 <sup>E</sup>	-3
32	-1	1	0	2	-1	-1
33	0	1	0	2	1	1
34	0	0	2	3 <sup>E</sup>	3 <sup>E</sup>	-1
35	-1	-3	1	-3	1	0
36 <sup>A*</sup>	-1	-4	-1	-1	-4	-3
37	0	3	4	1	-2 <sup>D</sup>	1
38	1	0	2	-2 <sup>D</sup>	2	0
39	1	-1	1	-3	0	-2
40	-4	0	1	-4	0	-4
41	0	-1	0	0	-1	1
42	1	1	1	2	-2 <sup>D</sup>	0

\* Statements denoting uniformly held views of the *Lay* role

<sup>A</sup> all negative	<sup>B</sup> all positive	<sup>C</sup> only neutral	<sup>D</sup> only negative	<sup>E</sup> only positive
---------------------------	---------------------------	---------------------------	----------------------------	----------------------------

Contrary to ranks on other factors		Key positions for statements within factors	
---------------------------------------	--	--	--

Statements in cells with heavier borders are contrary to the rankings of that statement compared with its rank in the other factors; for example, statement 1 scores negatively on all factors except for factor 5 where it scores 0. Those highlighted grey indicate key positions for those statements within the factor. This can also be seen in factor 5 where statement 2 scores +4 but the same statement scores 1 or 2 on other the factors.