Health Research Authority

A PRELIMINARY EXPLORATION OF THE PERCEIVED RISKS AND BARRIERS TO ORGANISATIONS CONDUCTING RESEARCH

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BACKGROUND

It is expected that from late 2014, the Health Research Authority (HRA) will take over the responsibility for the Research Governance Framework (RGF). In preparation for this transfer of responsibility, there is UK-wide agreement that the HRA begins to review the principles on which the framework is based. Therefore, the HRA wishes to gain some preliminary insights from R&D community on how the RGF contributes to the delivery of good quality research and the perceptions they have of risks or barriers that are deterring them from being more research active. For example, which principles of research governance encourage active and which ones disrupt it. Likewise, what are enablers of good practice? Are they based on practice or explicit requirements?

This project was commissioned to deliver these preliminary insights and, based on these, make recommendations for next steps.

METHODOLOGY

Conversations based around the concept of grounded theory, i.e. no fixed assumption of areas, have been explored with 10 participants (the participants) from across a range of healthcare organisations who have broad experience of R&D governance (see Appendix 1). An initial list of questions (see Appendix 2) was extended using an iterative process as new themes emerged.

The scope for this project (see Appendix 3) was expanded in November to include a case study which looked at the setup and subsequent issues that emerged from a current Research for Patient Benefit (RfPB) project, which is struggling to meet its recruitment target. This provided context to the perceptions expressed during the conversations.

The case study was conducted under the remit of the RGF[1] through both document review and a series of conversations with the involved stakeholders to facilitate the identification of lessons learnt that can be shared with the wider R&D community.

[1] RGF section 1.8

PURPOSE

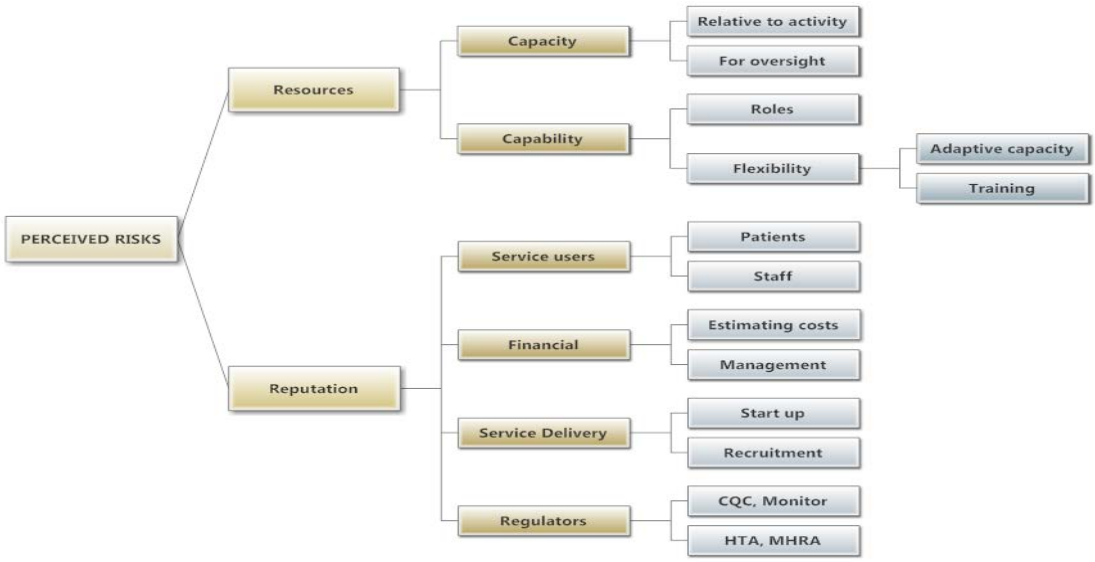
These conversations continue a process of engagement with the R&D community and serve as a scoping exercise to surface perceived risks that are deterring organisations from taking part in clinical research. These risks can then form the basis for further questions/discussions around the issue of Research Governance e.g. how does it influence day-to-day operations? What are the risks from it being interpreted inconsistently? Where are the common areas of misunderstanding and how could these be clarified?

The project has helped identify areas that are either ambiguous or absent in the current RGF which may be creating risks in relation to consistent service delivery. It has also begun conversations with the R&D community that may help to address, or at least characterise, some of the perceived risks/barriers identified.

PERCEIVED RISKS AND BARRIERS IDENTIFIED

Participants in the conversations spoke more about barriers that created risks than about risks themselves per se. Those risks that were mentioned fell broadly into two categories: reputational risk for the organisation and risk associated with maintaining and developing adequate resources for consistent service delivery of clinical research. These risks are summarised in figure 1.

Figure 1 Perceived Risks to Organisations when Conducting Clinical Research



These two risks are inextricably linked since reputation is threatened when an organisation is unable to deliver to its board, its research partners or its service users because they have inadequate levels of capacity and capability. In the prevailing financial austerity, organisations need greater caution before committing precious resources to research projects that may not meet recruitment targets since this will have accompanying financial burdens and reputational damage. Several of those who took part in the conversations highlighted the importance of R&D managers being more aware of the broader environment in healthcare within which research projects are conducted.

However, much of the conversations focused on barriers rather than actual risks. These risks or barriers have been summarised as themes in relation to the principles of research governance as outlined in the RGF.

THEMES FROM CONVERSATIONS AND THE CASE STUDY

Research Governance

Principles of Research Governance

Research governance, rather than either its principles or the RGF, was raised spontaneously by participants in the conversations. That said, through questions related to standards it was acknowledged that the Research Governance Framework remains central to the conduct of clinical research. The caveat to this apparent assertion being that increasingly the focus is on regulation driven by the perceived fear or risk of inspection. Indeed several participants in these conversations suggested that many inexperienced staff are

> "*scared of MHRA inspections*."

Interpretation of the RGF

From both the conversations and the case study, it would appear that research governance processes, rather than its principles, remain a key focus for R&D management and also National Institute of Health Research (NIHR) clinical research networks, although they are neither followed nor interpreted consistently. One participant questioned whether:

> *"the RGF is still the dominant paradigm in the R&D community?"*

A recurrent perception was that so much attention is being focused on Good Clinical Practice (GCP) to help secure more commercial work. One participant remarked that this

also had benefits particularly in relation to quality management:

> *"My main reference is the MHRA's Grey Guide – it covers quality management, provides relevant examples so is easy to use."*

Despite the RGF being a core standard in the NHS (RGF, p. ii), new starters learn about it primarily on-the-job as reflected by a comment from a participant who is involved actively in training:

> *"Few outside an R&D office would know what research governance is."*

Inexperienced staff trying to make sense of the relationship between GCP and the RGF may conclude that the latter is a subset of the former, as reflected by the taxonomy used on NIHR Clinical Research Network website (see fig 2) particularly as regular GCP training is now mandatory. This is even more confusing for those working on studies which do not involve Investigational Medicinal Products (IMPs).

Figure 2 RGF represented as a subset of GCP

(source: http://www.crncc.nihr.ac.uk/workforce_development)

The experience of the participants who took part in the conversations enabled them to pinpoint the main principles of the RGF. They were, however, less confident that new starters or inexperienced colleagues would be able to do likewise. To some extent this is to be expected since the RGF states

> "*Professional judgement is involved in the interpretation of this guidance. Quality in research depends on those responsible being appropriately qualified, with the skills and experience to use their professional judgement effectively in the delivery of dependable research.*"
>
> (RGF 2.1.2)

An inference that can be drawn from this statement is that the absence of the skills and experience which are prerequisites for professional judgement will lead to difficulties in the delivery of dependable research and thus pose a risk.

The participants concluded that for new starters research governance is more implicit than explicit as it is difficult to determine with any certainty what are the key principles of the RGF, even with reference to the document itself since it is contradictory and misleading. For example, it begins by stating that the RGF:

> *"outlines principles of good governance"*
>
> (RGF, p. ii)

However, it subsequently indicates that:

> *"The Annex lists detailed principles and requirements for different aspects of research governance."*
>
> (RGF 2.1.2)

Unfortunately, the principles of research governance are not mentioned explicitly anywhere within the Annex.

This picture is further complicated by the view of all the participants that

> *"ICH GCP is perceived by many to be law in the UK."*

Likewise, confusion arose within the case study regarding who needed GCP training, with local R&D management insisting that it was part of their:

> *"Governance checks in line with Good Clinical Practice, the Research Governance Framework and UK law."*

Standard Operating Procedures (SOPs)

These are not specifically referred to in the RGF and can cause confusion since as one participant suggested:

> *"the level and detail required varies with some being generic and others being tailored to a department within an organisation. Consequently, they can be isolated documents rather than part of a quality system."*

Sometimes it is not clear which SOPs need to be followed, by whom and when. Similarly, some trials are persisting with the use of so-called Trial specific SOPs when what is intended is a trial specific manual or procedures.

Again, such inconsistencies create misunderstandings which in turn can affect the service delivery and its oversight.

Terminology

Several key terms associated with effective oversight of research are used differently by funders, sponsors and NHS organisation studies hosting research. This is causing confusion with the risk that governance processes may not be applied consistently so that errors may be overlooked or remain unaddressed, particularly at the interface between different stakeholders.

For example, the oversight of projects may be suffering where the terms audit and monitoring are used either interchangeably or differently by stakeholders. This makes it difficult to determine the level of scrutiny that is being applied in practice and adds to the risks of either duplication of effort or issues identified not being shared between stakeholders and thus remaining unresolved.

Training

> *"Research management is knowledge work"*

This comment was linked to the need for recruiting staff with the appropriate competencies then ensuring that they received the training and guidance to nurture the skills required for knowledge work. Participants expressed concern that training focused almost exclusively on GCP and regulatory requirements much of which lacked relevance for non-CTIMPs. Such training does not provide the self awareness needed so, as one participant expressed:

> *"They need to know the limits of their knowledge and who to go to in that situation."*

GCP requires that each person involved in a clinical trial is qualified in terms of their education, training and experience. Certificates of attendance may satisfy this regulatory requirement[2] but they do little to develop skills related to effective research governance.

As one participant observed:

> "*GCP training just goes right over our heads.*"

Indeed, this subject-based approach to GCP training would seem at odds with the promotion of learning networks within the Research Governance Framework[3] through which R&D

[2] Only a regulatory requirement for studies involving investigational medicinal products

[3] RGF 4.15

personnel can share ideas and learn from one another's experience[4]. Active knowledge sharing was picked up as a key point by one participant since if one person runs into an issue

"*someone else will have already tackled it*"

It was also suggested that

"Training should be fit for purpose rather than fit in a box to be ticked."

Financial Restraint

Organisations are cautious amid the ongoing and significant cost containment in the NHS[5]. Consequently, perceptions of risk may well be heightened in relation to cost or resource intensive projects such as clinical research studies, particularly those which attract additional regulatory scrutiny.

The case study was initially hosted by an NHS organisation grappling with the additional requirements of the special measures imposed by Monitor[6] as a result of quality issues that were unrelated to R&D. It is reasonable to conclude that this additional pressure contributed to a proportion of issues arising from the host particularly in relation to the management of the grant for the study.

Views from larger, more research active centres highlighted that financial constraints were influencing operational strategies but they were less aware of the wider health environment in which there are also regulatory pressures, e.g. the Care Quality Commission (CQC) and Monitor.

Costs Associated with Clinical Research

The majority of the 10 participants in the conversations raised the issue of costs as being a significant risk when undertaking new clinical research projects. The concerns lay in the different interpretations, not least between NIHR Clinical Research Networks.

The biggest single cost is often Excess Treatment Costs (ETCs) which must be borne by the NHS organisations which host the research. Several participants commented that it is particularly difficult to determine these in relation to studies in the field of mental health. There were certainly issues in relation to ETCs for the case study which was conducted in the field of mental health. However many of these issues could have been addressed through early discussion, before submitting for funding, between the Chief Investigator, the lead NHS organisation and the lead Comprehensive Local Research Network (CLRN) – a

[4] Bowden (2004) piloted action learning sets to help new R&D managers but this was not continued.

[5] A Decade of Austerity, Nuffield Trust (2012)

[6] Monitor is the sector regulator for health services in England

requirement in England since April 2011.

From the conversations a concern was expressed several times that research is often delayed because commissioners want a level of transparency that can be difficult for researchers to gauge in relation to costs, particularly when they are dealing with multiple providers. A recent paper highlighted the apparent paradox whereby NHS organisations have been instructed by successive policy documents to fund ETCs in the continued absence of an agreed national scheme to manage them. The same paper offered a way forward for managing these costs more effectively by CLRNs addressing the concerns of both researchers and commissioners[7]. A similar approach for managing ETCs more effectively has been developed by Trent CLRN, the lead CLRN for the project in the case study.

Another participant indicated that many researchers have found themselves in limbo because NHS England's interim guidance enables Clinical Commissioning Groups (CCGs) to refuse payment of ETCs if they consider them poor use of resources or beyond their current budget.

The case study was set up during the transition to CCGs and found itself in the invidious position of having its ETCs refused on the basis of it being beyond the budget of the commissioning PCT involved.

NHS England have committed to refining its guidance in 2014, so that it explains how it will cover the ETCs associated with the NIHR portfolio studies.

For now, a remark from one of the participants sums up the concerns that prevail in England in relation to study costs:

> "*There seems to be many interpretations by different CLRNs in relation to [Study Support] costs so we get different messages from them than we get from Chief Investigators [in London]. Until this is resolved it's probably better to do fewer studies and have them properly funded*."

The Quality Research Culture (QRC)

The QRC envisaged in the 2005 Research Governance Framework (2.7) needs champions who are visible within the R&D community so remains implicit rather than explicit. The challenges facing the governance of research are, like many of those facing healthcare in the UK, primarily adaptive rather than technical. Adaptive challenges[8] require changes in the values and beliefs of the stakeholders involved whereas technical ones can be fixed with

[7] Westwood et al, Health Service Journal (8 August 2013)

[8] Adaptive challenges are discussed in the King's Fund report *Recent trends in leadership (2011)*

existing knowledge. Despite the significant streamlining of processes, e.g. the advent of IRAS, integrated research as a whole, like the concept of integrated care, remains elusive and thus frustrating to its users.

Stakeholders in research must learn more than just the governance and regulatory requirements if they are to work together more effectively, including with those in the broader healthcare environment. Several participants commented on this:

> *“R&D managers must get out and talk to people – they must actively facilitate the R&D process.”*

> *"We need to create or rekindle a culture of curiosity – R&D management can be an isolated role. Managers need to be pro-active. For example, look at business plans for their organisations and see how service improvements can be aligned with the NHS initiatives."*

> *"Good practice needs to be shared to promote an ethos of good research. One way to achieve this would be true credible champions drawn from, amongst others, large acute hospitals, universities and mental health."*

> *“Funders needed to change their language from cost to affordability and insist that grant applicants demonstrate such affordability by completing appropriate feasibility."*

Variability in capacity and capability of staff

The perception amongst participants was that there had been considerable movement of experienced staff from R&D departments to the NIHR networks and subsequently vice versa. Consequently, some R&D departments lacked an experienced cadre of staff at a time of much structural and procedural change. With sustained financial constraints across the NHS there is much uncertainty making it more difficult to recruit experienced staff so there may be a reluctance to take on major projects while resources are limited or inexperienced or both.

This situation can be exacerbated where different approaches to planning and project management are used by the sponsor or chief investigator and NHS organisations hosting research studies. This increases the likelihood of misunderstandings and conflicts in communication.

The clear and supportive management espoused in the RGF’s Quality Research Culture is needed to address such shortfalls in capability through ongoing guidance.

This was illustrated by one participant who indicated that in her unit training for trial coordinators focused on project management skills and learning to work within a team since:

> "*Communication is everything*"

Variability in R&D approval times

Perception amongst participants remains that there is wide variability across many projects. One researcher provided a current example of a range between 33 days and 349 days for approval, with suggestions that the 30 day target turnaround can be bypassed by delaying the submission[9]. This causes even more frustration when information on delays is not available. Again, a more collaborative approach between stakeholders would help alleviate such frustration or as highlighted by one participant:

> *"Communication is everything……We know we've made it when a site starts calling us back."*

The case study reinforced the importance of good collaboration by demonstrating the adverse consequences which occurred when a combination of NHS R&D departments, universities, NIHR clinical research networks, sponsors, funders and researchers failed to establish an agreed modus operandi at the outset of the study[10].

Collaboration – the missing ingredient?

The principles of Quality Research Culture in the RGF makes only passing reference to collaboration yet this was a key theme that ran throughout the case study and also the conversations with participants.

Different types of organisation span the healthcare system and these continue to change e.g. as the voices of patients and service users rightly coming to the fore. Levels of research activity vary between and within NHS trusts and also Higher Education Institutes.

Greater awareness is needed between stakeholders and individuals who work together on clinical studies that their collaborative efforts will be influenced by different organisational priorities and cultures. Consequently, different overlapping frames of reference exist for individuals: their role, their professional discipline, their employer, and their regional or national R&D partners – see figure 3.

[9] A view echoed in the literature from a few years ago e.g. Whitehead et al, 2011

[10] The NIHR feasibility process introduced in 2011 would have addressed these issues in the case study.

Figure 3 Cultural Frames of Reference for Personnel involved in R&D

Amidst the prevailing flux in healthcare, organisations with experienced staff and established ways of working can perceive additional risks from the delays of having to work through more recently formed bodies e.g. NIHR clinical research networks. Participants remarked that an honest broker, like an NIHR clinical research network, can seem superfluous since they do not need help with what they can already manage by themselves. However, the case study provided a persuasive argument that there are benefits to working through established national processes and networks since they ensure a common basis for both progress and the prompt resolution of any issues that may arise.

Where adaptive solutions are needed then an ethos of collaboration should be articulated openly with the active promotion of good practice by exemplars sharing their experiences. One participant noted that local champions can help facilitate process change or updates. However, it is important that these champions receive sufficient support since their employers may have local priorities that conflict with the national processes that they are helping to implement.

Oversight of Projects from Funding to Reporting

Participants in the conversations noted that risk management is often confused with risk

assessment – the former being an ongoing process that should be managed actively throughout the life of a project.

The oversight of projects, from inception through to their implementation and reporting, is another area that the study pinpointed as needing more attention. In particular, there is a need to ensure that where shortfalls in meeting responsibilities are detected they are resolved promptly rather than cascaded down across the other stakeholders (see fig 4).

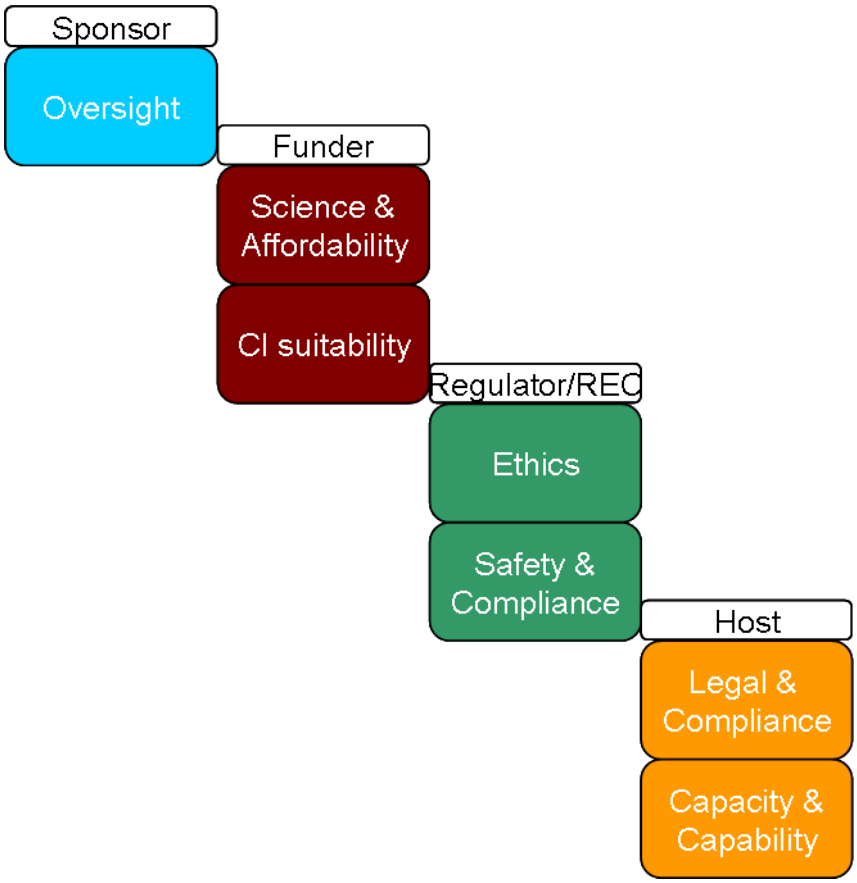


Figure 4 Cascade of Responsibilities

The study also illustrated the potential benefits of harmonising the approaches to oversight of projects, including terminology used, between funders, sponsors, ethics committees and R&D departments in NHS organisations so that there are a common set of standards. This would help remove the collection of disparate information whilst also improving governance. For example, clear expectations of project management structures and capabilities prior to funding would help mitigate the risk that inexperienced staff would be appointed to critical roles such as study coordinator.

Likewise, approaches to the oversight of R&D projects would benefit from plans with decisions trees and trigger points where actions are required. These would enable early corrective interventions for projects running into difficulty e.g. increases in the frequency and intensity of oversight.

Evidence suggests that when clinical research projects stall there is a genuine risk that recruitment will not recover.[11] In turn, such failing studies bring the risk that research funds will be dissipated without generalisable knowledge being obtained – the antithesis of the value for money that funders are held accountable for in the RGF (3.7.1). Likewise they can create financial risk to NHS organisations hosting research e.g. recruiting of a trial specific research nurse or co-ordinator, the funding for whom may be withdrawn. Therefore, more robust processes for resolving issues between stakeholders are required to ensure that most resources are devoted to research rather than dispute resolution. An alternative would be some form of mediation service between the parties to ensure a prompt resolution but this would depend on determining more accurately how frequently projects stall as a result of failure to resolve issues.

Commercially Sponsored Research

In theory, commercial studies should benefit from well written protocols and provision of study related files or templates for study management.

However, views from participants were mixed in relation to commercially sponsored studies. Views expressed included that:

> *"commercial trials seem attractive but requirements vary"*

> *"Trials often managed by Contract Research Organisations who have high turnover amongst monitors…..this can create confusion especially overzealous application of regulations including some which are not relevant in the UK*"

> *"There's a lot of pressure to take part…….we pulled out all the stops to get everything ready then the PIs refused to take part saying it was not in the interests of their patients."*

Despite the use of model agreements, participants remarked that negotiations with industry sponsors remain excessively time consuming.

[11] (2007) STEPS study

RECOMMENDATIONS

From the conversations with participants together with the case study, four recommendations can be supported, all of which relate to the diagram in the current Research Governance Framework (see fig 5). For many in the R&D community, this diagram fails to provide an accurate reflection of what is happening in practice. However, it does provide a useful starting point for making recommendations.

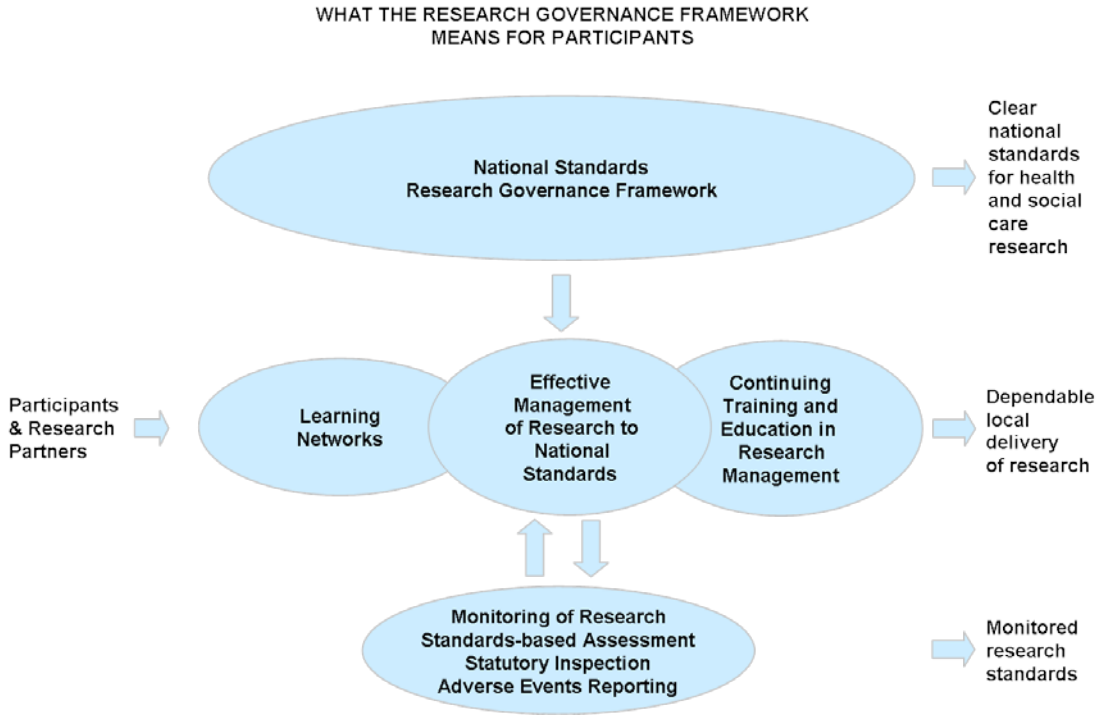


Figure 5 The RGF - Theory vs. Reality (based on Fig 1 in RGF 2005)

Clarify the Purpose of the Research Governance Framework

The purpose of the Research Governance Framework needs to be clarified i.e. it provides the overarching principles, rather than national standards and operational detail, which should be applied to all clinical research studies[12] conducted in England.

These principles need to be clearly articulated with consistent use of terminology which ensures their relevance to the collaborative efforts of all stakeholders. New starters

[12] as well as those in social care

presently have good reason to be befuddled since the principles are loosely described within the document and not readily available as a clear list, despite assurances that greater detail is provided in the Annex.

There needs to be consistency between what the RGF purports to represent and support and what it actually does in practice.

Define Principles for Interface Management Between Stakeholders

Clinical research is a collaborative enterprise and this needs to be reflected within research governance. The case study undertaken illustrated the problems that can arise when there are failures to manage issues effectively at the point of origin which result in them being cascaded down across other stakeholders. This situation needs to be resolved beginning with the definition of clear principles and/or expectations in relation to the main stakeholders: funders, sponsors, chief investigators, and NHS organisations hosting research.

Make the Quality Research Culture Explicit and Relevant to all Stakeholders

The Quality Research Culture remains intangible and inaccessible to many in the R&D community as evidenced by the case study and the preliminary conversations that have taken place during this project. Supportive management, especially for collaboration between organisations, needs to be made more explicit and relevant to all stakeholders including patients.

Ensuring adequate capability and capacity is inextricably linked to the provision of effective, open and supportive management. Again, principles of good practice should be defined rather than intertwined in any update to the Research Governance Framework.

The effective calculation of costs should be included under the umbrella of a Quality Research Culture since ensuring value for money may start with funders but is a responsibility for each person involved in the R&D enterprise. Exploration of how principles or standards could be created that support this ethos should be actively considered as evidenced by the recent case study.

Focus on Learning and Sharing Good Practice

10 years ago a pilot study looking at the value of action learning among R&D managers in

England took place[13]. This facilitated the RGF principle (4.15) of:

> *"opportunities for individuals and organisations to learn from one another."*

Presently, the learning networks described in the Research Governance Framework are more informal than formal and the extent to which they are promoted by the Department of Health is unclear. However, the principle (and benefits) of sharing of lessons learnt among sponsors, funders and researchers remains sound, as evidenced by the recent case study. Mechanisms to help support the lessons learnt process should be actively explored. Any future update to the Research Governance Framework should consider the inclusion of principles that promote effective collaboration, encourage care with financial resources and greater awareness of the wider environment within which clinical research is conducted.

GCP is understandably prescriptive so the Research Governance Framework has the opportunity to provide the guidance through which lessons that can be learnt from its implementation as well as from other applicable regulatory and governance processes. Consideration should be made of a suitable set of criteria for lessons learnt exercises which could then be incorporated into any future update of the Research Governance Framework.

This focus on learning from practice is consistent with initiatives elsewhere in healthcare in particular, the Berwick report (2013) in relation to improving patient safety: *A promise to learn – a commitment to act*.

David Montgomery

31st March 2014

[13] Boaden, M (2004) 'A Pilot Action Learning Set for NHS R&D Managers'

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APPENDIX 1 PARTICIPANTS IN CONVERSATIONS

NAME	ROLE	ORGANISATION
Dr Gill Dale	Director of Research Quality;	Joint R&D Office of South London and Maudsley NHS Foundation Trust and Institute of Psychiatry
Jenny Liebscher	R&D Governance and Delivery Manager	Joint R&D Office of South London and Maudsley NHS Foundation Trust and Institute of Psychiatry
Pauline Parker	R&D Manager	Mersey Care NHS Trust Prescot L34 1PJ
Dr Maria Palmer	Director	NHS R&D Forum
Ursula Bowler	Senior Trials Manager	NPEU Clinical Trials Unit University of Oxford OX3 7LF
Sarah Lawson	Head of IT and Information Security	NPEU Clinical Trials Unit University of Oxford OX3 7LF
Razia Meer Balloch	Quality Assurance Manager	Primary Care Clinical Sciences University of Birmingham B15 2TT
Maria Thornton	Research & Development and Innovation Lead	The Walton Centre NHS Foundation Trust

		L9 7LJ
Dave Watling	Research & Development and Innovation Manager	The Walton Centre NHS Foundation Trust Fazakerley L9 7LJ
Wendy Fisher	R&D consultant	Wendy Fisher Consulting Ltd

APPENDIX 2 OUTLINE OF POINTS USED FOR CONVERSATIONS

- Which research roles are you familiar with and what is your primary role?
- What type of organisation(s) do you work in or are familiar with?
- What guidance or reference documents (standards) are used in your role or the roles with which you are familiar?
- How do you or others you are associated with learn about these guidance or reference documents (standards)?
- Where can information on these guidance or reference documents (standards) be found?
- How do these guidance or reference documents (standards) help you most?
- How do these guidance or reference documents (standards) help you least?
- In your role or those you are familiar with, what tools are used?
- In your experience, how is the Research Governance Framework (RGF) perceived and/or used by researchers?
- What are the most helpful parts of RGF to your role and members of your research community?
- What are the least helpful parts of RGF to your role and members of your research community?
- How do you keep your staff up to date?
- What uses the most unplanned time?
- How has your portfolio of studies changed over past three years?

APPENDIX 3 EXPLORATION OF RISKS PROJECT

Scope

Within six months (by 31st March 2014), complete two related steps:

- Explore published data on perceived risks and/or barriers that are deterring or disrupting participation in research by institutions in the UK i.e. a literature search of the CINAHL and MEDLINE.

- Conduct a series of conversations with the research community and report on recurrent themes relating to perceived risks issues or which emerge from these.

These conversations will begin with a selection of experts who span a range of different research activities so each can provide a broad perspective. In addition, these conversations will help surface further lines of enquiry e.g. what guidance could be expanded or reinforced, what changes to existing guidance would help most and which ambiguities within Research Governance are causing the greatest confusion. They may also identify other parties with whom it would be helpful to have conversations as well as potential next steps for working with the research community to dispel confusion and tackle barriers.

Conversations with experienced practitioners operating in health research covered by the RGF will take place using a semi-structured outline – see appendix 2. This outline will be added to as themes emerge which would benefit from further exploration in subsequent conversations.

The initial Scope was revised in November to include a case study to explore lessons learnt using a live study which has stalled. This will help frame the themes emerging from the conversations by looking at the blockages that have occurred in an active research project. More specifically, whether the root causes of these blockages are governance/technical issues or the interactions with/interpretations of governance requirements and processes..

The case study is part of the Research Governance Framework's commitment to learn lessons in the interests of good practice as well as the need to share them with involved parties (see RGF 1.18[14] and 3.1.4). It should be emphasised that this case study is neither an investigation nor does it seek to resolve the issues identified.

[14] The framework aims to forestall poor performance, adverse incidents, research misconduct and fraud, and to ensure that lessons are learned and shared when poor practice is identified.

Planned Outputs

- Report summarising findings from conversations with R&D professional with recommendations for next steps.
  Date due: 7 March 2014.

- Report summarising results from literature search.
  Date due: 7 March 2014.

- Report summarising lessons learnt from case study with recommendations for further actions to be considered.
  Date due: 14 March 2014.

APPENDIX 4 GLOSSARY

ACRONYM	MEANING
CCG	Clinical Commissioning Group
CI	Chief Investigator
CLRN	Comprehensive Local Research Network
COPIC	COgnitive Behaviour Therapy for Pain In the Chest
CRN	Clinical Research Network
CTIMP	Clinical Trial of Investigational Medicinal Product
ETC	Excess Treatment Costs
GCP	Good Clinical Practice
HEI	Higher Education Institute
HRA	Health Research Authority
ICH	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute of Health Research
PI	Principal Investigator
RfPB	Research for Patient Benefit
RGF	Research Governance Framework
SOP	Standard Operating Procedure