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QUALITY, RISK AND CONTROL IN HEALTH CARE

'With better governance a key issue in the NHS boardroom, this book provides a comprehensive underpinning to future developments.'

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'This book provides a much needed integration of different streams in the quality movement, examining the need and methods for control and accountability as well as the continuous improvement approach.'

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'This excellent book is both informative and challenging…[it] helps us work our way through the contradictory and often inconsistent health maze that is bound by quality, risk, control, governance, trust, regulation, private activity, accountability, assurance and outcome.'

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This book explores the concepts of trust, control and risk management as key components of organizational accountability in the public sector. It explores how the concept of risk management has been introduced into the public sector and how this has impacted on the definition of governance in the National Health Service. It also addresses the concept of controls assurance by placing it in the context of developments both in local health care management and central government.

Key questions that are addressed include:

- How can devolved public sector organizations be held accountable?
- What is the relationship between risk, control and governance?
- How do private sector ideas about governance translate into the provision of public health services?

Quality, Risk and Control in Health Care is essential reading for health policy makers, health practitioners and professionals, as well as students and academics in the fields of health policy, health services management, social policy and public policy.

Ellie Scrivens is Professor of Health Policy at Keele University and Director of the Health Care Standards Unit for the Department of Health which advises the Department of Health and NHS on standards development and use.

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For Justine, Kester, David and Gill

Foreword

At the heart of the debate about the delivery of health care in Britain – as in other countries – lies a fundamental challenge. Is it possible to devise a system of governance for the health care system which can reconcile seemingly contradictory policy objectives: the achievement of national policy objectives and standards of quality, on the one hand, and freedom for the managers and professionals responsible for delivery freedom to devise local solutions to local problems? How best can we strike a balance between regulatory over-kill and anarchic diversity, between protecting ourselves against risk and squeezing out innovation and exploration?

These are some of the concerns that shape Ellie Scrivens' book, an important contribution not only to the current debate about the NHS but also to the wider health care organisational literature. In it she explores some of the key issues involved. Most centrally, she addresses the question of how control over quality and performance should be exercised: whether any national system of external review should look at outputs, outcomes, processes, behaviour or the internal systems of control of the organisations being reviewed. Which in turn leads to a discussion of how standards should be written, of the role of inspectorates in enforcing them and of what the currency and lines of accountability should be.

All this is much-trawled ground, by myself among others (which is no doubt why I was asked to write this foreword). But the book also introduces and explores new dimensions. It explores the flow of ideas about governance from the private to the public sector. It documents the role and potentials of audit. It provides a history, informed by Professor Scrivens' own participation in the process, of the Department of Health's controls assurance programme designed to provide a governance structure for the boards of NHS trusts.

So the book passes what is my test for an interesting contribution to debate. It provides not only reassurance (Professor Scrivens has clearly read everything there is to be read) but also provides surprises (Professor Scrivens introduces a reader like myself to new ideas). While I am not sure that I share the author's commitments to notions of self-regulation based on risk assessment, I am quite sure that I will be able to argue about these and other questions in a much more informed way as a result of reading the book.

Rudolf Klein

Preface

For many years there has existed a popular view that management is unnecessary in health care. Doctors and nurses left to their own devices are able to provide the best health care. However, there is no universal agreement on the definition of 'best'. In our western-style democratic society, we are concerned equally with ensuring that decisions are taken in ways that conform to our values which, in turn, defines what we mean by good treatment. Recent events such as the retention of children's organs at Alder Hey Hospital demonstrate that doctors and other health care professionals may not share public values about what is perceived as good practice. Therefore, in order to address our concerns about what we mean by best health care, we have to address not only issues of clinical practice but also the issues of governance, decision making and better management processes – to ensure the organizations are able to deliver what we are asking of them. In short, we are seeking a process of 'New Governance', which will enable us to receive health care in the way we want it, putting our values – as patient and funder of health care – at the centre of decision making in health care.

The ideas underpinning New Governance in health services have their genesis in a number of different areas. It has long been recognized that any producer or employer can, through their production processes, cause harm to their staff, customers or society at large. Health services are as open to criticism as any organization that they can create pollution, or that they can damage staff through accidents. Protection from pollution and harm to staff are provided for in legislation, which applies as much to health care organizations as it does to any other employer or producer. Boards of NHS organizations are expected to follow legal requirements to ensure they are good employers and protectors of their local communities. Health care organizations deal with large amounts of public money, and are expected to protect themselves against risk of fraud and impropriety. Health care organizations are expected to deliver on government's promises to provide improved health care delivery, which requires a broader and more strategic assessment of risk associated with the management of their organizations. In addition, health care organizations face some specific risks. The very nature of health care means that patients can be put at risk by health care interventions and the risks associated with these are now recognized and health services are expected to deal with them. Almost every activity provided by a health care organization or its staff in dealing with the public entails a risk to patient health and safety, and health care managers are required to ensure that patients are afforded protection from harm wherever possible.

It was not until the 1970s that quality became applied to health care – often as an antidote to the overpowering emphasis on cost reduction and efficiency. All health care systems can spend more money than is made available to them. Advances in technology and people's desire for higher and higher quality of life have meant that there will always be more demand for health care than can be afforded. As health care systems expanded to cover more demand, pressures arose to reduce the expenditure on individual clinical procedures. There was a growing emphasis on cost reduction, creating a perceived trade-off between cost and quality of services. In addition, new technologies require increasing numbers of highly skilled people which, in turn, increases the complexity of the task of the management of health care, thus requiring new management skills. Hospitals with hundreds of beds employ thousands of people, to make sure that patients are well cared for. These range from doctors and nurses and people with other clinical skills, all increasingly highly trained and specialized to use the sophisticated equipment available; catering staff to make sure food is provided properly to help healing and health; cleaners to ensure a clean environment; estate managers to keep the buildings and equipment in proper order; and many others. Health care systems may spend over 70 per cent of their income on staff. Every patient uses the services of large numbers of people from doctors and nurses, to cleaners, porters, managers and finance experts. Ensuring that every one of these people is able to contribute to a service that is not only what patients want, but in a way that matches the personal and professional aspirations of staff, is a challenging task.

Between 2000 and 2004 I have had the privilege of being the Director of the Controls Assurance Support Unit, tasked with the role of supporting the NHS to introduce a standardized system of internal control across all NHS organizations. This was a unique opportunity to take part in a national experiment of vast scale. The NHS employs nearly one million people and uses over 800 organizations to deliver health care to the population of England. It is a national organization which has to provide care of an equivalent quality to each person who uses it and co-ordinate all the necessary organizational functions to ensure each individual receives the best possible care. Part of my role was to evaluate the impact of the controls assurance project. As a Professor of Health Policy, I found it necessary to review the origins of the concept of controls assurance and to place it in the wider context of developments taking place in the regulation of private businesses. I had to review developments in the professions of internal and external audit and also to examine recent government policy which influenced the development of controls assurance. I wanted to place controls assurance in the context of the wider developments taking place in the running not only of health services, but of central government, particularly the growing emphasis on devolution of power to local organizations. The government had decentralized power to a large number of independent agencies which, rather than improving the quality of health care

or reducing bureaucracy were, in my opinion, doing little for quality and escalating bureaucracy. This book is the product of this extensive review.

In trying to explain the history and the recent policy developments, I have been forced to review a large number of documents. I was struck by the significance of many of these in developing the current views about governance in organizations and its relationship with internal control. I wanted to convey the significance of these writings to the current structures and policies. Therefore, I have included quotations to demonstrate the inter-relationship between these ideas which I hope, in the context of this topic, enhance rather than detract from the story.

However, the analysis revealed, as did my own personal experience, that although the controls assurance initiative introduced by the Department of Health was far ahead of its time in recognizing the need for a standardized approach to internal control, which would provide much needed public accountability for the actions of organizations, the approach was complicated and made more so by the array of different central initiatives to control the NHS. The introduction of the policy-creating, independent Foundation Trusts, believed to be fundamental to the improvement of quality and the progress of modernizing the National Health Service, would be seriously undermined if the confusion at the centre about the nature and the purpose of controls were not removed. In 2004, the unit of which I am Director changed its name to the Health Care Standards support unit, to provide support to the new Department of Health initiative on standards. I believe, based on my own research into the impact of standards on health care, that the recent emphasis on standards is an opportunity to develop further accountability for the quality of health care.

This book examines the arguments, debates and decisions that have been taken to create the governance infrastructure which allows these new developments to occur. It is predominantly concerned with the UK experience, as the UK has always had its own approach to the governance of business and this has impacted on assumptions about the governance of public sector services. In addition, due to the period of time upon which the subject matter focuses, this book is also a review of government policy at the turn of the twenty-first century. In some respects, the UK has been a pathfinder for other countries in that its experience of managing a national health service, and its approach to regulating private business have provided different models from those adopted in other countries. This book examines the changes that have been occurring in central government and local health care management resulting in the opportunity for 'New Governance' to occur. The book examines the issues in controlling the provision of health care and the new opportunities for thinking about the monitoring and management of health services. To do this it has been necessary to examine the arguments for changing our approach to the provision of health care and to ascertain how we want to manage health care in the new millennium.

Chapter One provides a brief review of the dimensions of quality that form the basic elements of quality needed to assure the public that health services are meeting their expectations. It is based upon a lecture I gave in Cork at the invitation of the Office for Health Management in Ireland which from 2005 will be part of the Health Service Executive in Ireland. I am grateful to them for the opportunity to develop my thinking in this area. Chapter Two reviews issues in the provision of assurance and the relationship between risk and control that has emerged from the corporate governance literature. This is central to the development of assurance under the government policy of devolved management. A related component in the provision of assurance is the building of public trust in public services and, therefore, the relationship of trust to accountability is also examined. Different approaches to describing control are developed as a framework for examining the approaches to assurance and control, and the views of corporate governance that have emerged in the private sector and central government departments. Chapter Three examines the emergence of risk and control as central issues in the development of governance in the private sector, along with ideas of increased stakeholder involvement in the production of accountability. Chapter Four examines how ideas about regulation by central governments have changed and how the ideas of corporate governance from the private sector have been translated into central government for use in civil service departments. Chapter Five examines how the limitations of regulation, inspection and audit in the NHS have led to the further development of ideas about the need for improved corporate governance in the NHS, and how these, in turn, have led to the concept of standardizing controls across the national health service. Chapter Six examines the arguments for change in the present accountability and assurance arrangements (particularly considering the limitations of current models of audit and inspection) and develops the argument for a new model. Chapter Seven concludes with the arguments for a new model of governance to meet the specific needs generated by the desire to provide assurance on quality in health care under a policy of devolving management to individual health care organisations.

The conclusion of the book is that a multidimensional model of assurance is needed to deliver public accountability in health care in a devolved management system, which has to have as its main focus improving the trust of the public in the health services that exist to serve them. And I must point out that the views and any errors in this book are wholly my responsibility and are not those of the Department of Health.

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June 2004

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I should like to thank the very many people who have helped me to understand the complex issues now developing in the field of governance and internal control in health care. There are too many to list them individually. Almost everyone I have spoken to over the past four years has contributed to my thinking and understanding. But there are a few special thanks I should like to make. I am deeply indebted to the team at the Health Care Standards Unit, previously known as the Controls Assurance Support Unit. Mrs Kim Donovan started out this voyage of exploration with me as we puzzled our way through the changes in government policy. Dr Katherine Birch has helped to shed light on the developments in risk management in the NHS. Mrs Janice Goldstraw, Dr Kate Wilde and Mrs Sue Fawcett have helped me in the understanding of the impact of controls assurance and standards on the NHS. Mr Phil O'Rourke has been invaluable in providing technical input without which I could not have worked my way through the ever growing body of literature on risk and governance. And I should like to thank Mrs Hazel Swift, Miss Helen Newton and Mrs Pat Leadbeater who provided moral support and organized me.

I should also like to thank Mr Robert May from the Department of Health who first introduced me to controls assurance and the ideas underpinning it. His vision for controls assurance provided the opportunity to pilot an approach to standardizing approaches to risk management, in order to deliver improved accountability. More recently, I have worked with Mr Stephen Mackenney and Dr Paul Stanton from the Clinical Governance Support Unit who have provided me with insights into clinical governance and the workings of the Department of Health. I am also grateful to Mr Chris Butler of the Treasury Risk Support Unit who has helped me to understand the development of risk management in government policy. Any mistakes I have made in the explanation of the development of risk management in central government and other areas are entirely mine. The Audit Commission and the National Audit Office also provided me with ideas and insights and to them I am grateful.

But most of all, I should like to thank David Rogers and my two children Kester and Justine, whose patience and tolerance in dealing with the chaos ensuing from the documents used in writing this book has been endless. And I

apologize to Justine who wanted more pictures and larger letters so she and other little children could read it.

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June 2004

1 The search for good quality health care: establishing principles for control

Health services across the world are being reinvented. The National Health Service in England has embarked upon a massive set of changes, moving from a state run, highly bureaucratic system to one intended to be more innovative and more concerned about improving patient care. On 15 January 2002 the then Secretary of State, Alan Milburn, pronounced a new vision for the National Health Service.

> What we envisage is a fundamentally different sort of NHS. Not a state run structure, but a values based system, where greater diversity and devolution are underpinned by common standards and a common public service ethos.
>
> (Rt Hon Alan Milburn MP 2002)

This statement suggests a vision of a more organic health care system, based upon common values and recognized standards, which will permit diversity in its management and design while recognizing a central core of best clinical practice and a public service ethos. The challenge, therefore, is to move from a highly centralized system, which dictates an identical structure and functioning of all the organizations that make up the national health service, to a more organic health care system, which is able to adapt its structure and its processes to meet local and individual needs while at the same time recognizing common definitions of good quality and good clinical care.

This requires a change in thinking about the management of health care and changes in the way health services are run. There is a need to establish a new system of governance for health care that enables care to be delivered in ways that are meaningful to patients and to the public who pay for them. The main objective of health care is to achieve health outcomes, better health and wellbeing for individuals. However, it is generally agreed that to demonstrate that outcomes are achieved requires measurement, and methods of measurement are elusive, at least at present. Therefore, there has been a tendency for

health care organizations, and the governments who seek to control them, to look for processes that can be specified and to control the actions of the people who deliver health care. Quality is, therefore, frequently defined not in terms of the health of the patient, but in terms of the processes that contribute to care. The reliance on processes is not of itself a bad thing. Good processes are necessary to ensure that the right things happen, that the right drugs are given at the right time, that patients receive the right operation. Health care depends upon many complex processes which if wrongly undertaken, can result in unintended and often disastrous outcomes (Rt Hon Alan Milburn MP 2002). As a consequence the control of the people who administer care to patients became, in the past, the pre-occupation of those who control the quality of health care.

However, central control has not provided the incentives for innovation and the focus upon the patient (patient-centredness) that are required by modern patients and health care systems. The new values reflect more diverse and complex attitudes to quality, seeking to address the expectations of patients and the public rather than the expectations of those who provide health care. There is, therefore, a need to find new governance processes which can reflect these changed expectations for health care and ensure health services conform to wider societal expectations of the role of health services.

Health care has always been a major love of populations – it is not only the means to good health and long life, it is a symbol of democratic rights and citizenship, therefore, no-one should be denied the right to health and to a good quality of life. But this definition of access is relatively new. Beveridge, in outlining his social security plans for Britain post the Second World War, placed great emphasis on the need for a comprehensive health service (Sir William Beveridge 1942). Prevention was a key issue, though not for the reason often given today (i.e. the right to quality of life) but in order to afford the social security system he so desired.

> It is a logical corollary to the payment of high benefits in disability that determined efforts should be made by the State to reduce the number of cases for which benefit is needed. It is a logical corollary to the receipt of high benefit in disability that the individual should recognize the duty to be well and to cooperate in all steps which lead to the diagnosis of disease in early stages when it can be prevented.
>
> (Sir William Beveridge 1942 Para 426)

Today, satisfaction (particularly with regard to waiting times) with health care services is seen as an important indicator of how well a health care system serves its population. Long waiting lists have been thought to be the reason for an apparently high level of dissatisfaction and have been used to justify not only a governmental policy emphasis on reducing waiting times but also the

need for better understanding of the whole system and how patients move through the health care process (Houses of the Oireachtais 2002).

Beveridge was concerned that 'suitable hospital treatment [should be] available for every citizen and that recourse to it, at the earliest moment when it becomes desirable, is not delayed by any financial consideration' (Sir William Beveridge 1942). Today, delay in any shape or form is a prime consideration of access to health care. Equally, there is an awareness that different ethnic or social groups may have different experiences of health care through unconscious discrimination, and health systems are becoming aware of the need to address these issues. The approach to this varies as the impact of discrimination varies in different countries. In the United States, 42.6 million Americans are estimated to lack health insurance, many of whom are in racial and ethnic minorities (Health Resources and Services Administration 2000). In the UK, there is concern that religious practices may be overlooked by professionals who fail to appreciate the impact of these upon the ability of patients to use or gain benefit from health care (Department of Health 2000).

A second aspect of access is ensuring that everyone who needs health care gets the right services. This requires that special services are provided to meet the needs of particular groups in society. And recently, a third aspect has also become important. One of the major changes in our thinking about quality of health care came from an understanding that people's willingness to use health care depends upon their relationship with the health care system. Avedis Donabedian, the father of the concept of quality in health care, also included accessibility to be a highly subjective attribute. He felt that accessibility of care, the doctor-patient relationship and the 'amenities of care' greatly influence acceptability, legitimacy and equity in health services (Donabedian 1990). Therefore, when thinking about equity and fairness, we have to consider what is acceptable to people in terms of their personal value systems and their personal desires, as well as what might be considered, in objective terms, good for them.

Beveridge and indeed most commentators and social reformers of his time were not concerned with variability in clinical practice. Only relatively recently have differences been recognized, not only in the way that services are experienced by patients but also in the way they are delivered by individual clinicians and in the differential use of resources in treating conditions. These may be attributable to individual doctors having access to different training and information but differences in the management of waiting lists and other key indicators of access to health care have also been identified. It is postulated that something more complex than simply the differential skills of clinicians is causing the level of variation. Variations in the quality of health care are evident from studies, even in systems such as the NHS, which are intended to have (through high levels of central control) the same basic administrative, resource allocation and management approaches.