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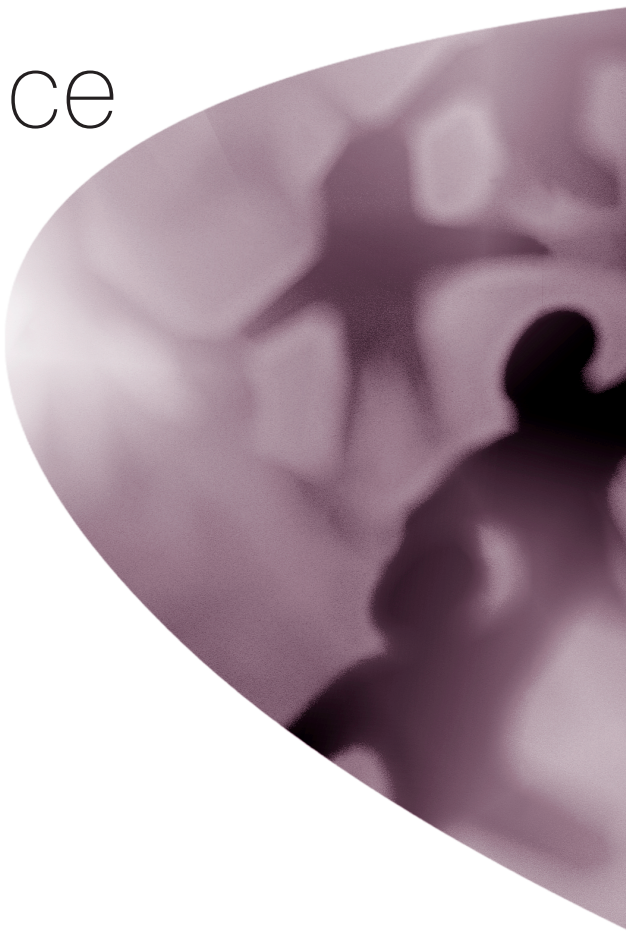
20th anniversary commemorative issue: quality then, quality now



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News and views

Edited by Jo Lamb-White

World Health Organisation

WHO and Sanofi-Aventis expand programme to fight neglected tropical diseases

Keywords Public health, Health equality, Partnership working

The World Health Organization (WHO) is expanding its program to fight some of the most neglected tropical diseases that destroy the lives and health of poor people. This expansion is possible thanks to a renewed collaboration with Sanofi-Aventis, which has agreed to donate medicines and financial support worth US$25 million over five years to WHO.

This collaboration builds on a previous agreement between WHO and Aventis (now Sanofi-Aventis) to prevent deaths due to sleeping sickness. Since 2001, this work has saved the lives of an estimated 110 000 people who would otherwise have died from sleeping sickness, a disease spread by the bite of the tsetse fly which is fatal if not treated.

"This project shows the power of collaboration to make a positive difference in the lives of poor people", said Dr Anders Nordström, WHO Acting Director-General. "By actively seeking out people who show the early symptoms of these diseases, we can ensure that they get the treatment they need before their symptoms worsen."

Under the new agreement, Sanofi-Aventis will donate $5 million of drugs to treat sleeping sickness and a further US$20 million in financial support for the control of neglected tropical diseases.

As well as sleeping sickness (also known as human African trypanosomiasis), the new project will also address:

(1) leishmaniasis;

(2) Buruli ulcer; and

(3) Chagas disease.

All four diseases are among the most neglected in the world. The people who suffer from them are almost all poor inhabitants of remote, rural areas.

The new project will take a common approach to detecting, preventing and treating these four diseases. The key to all four is to actively seek out people who show early symptoms of the diseases. By identifying them early, people can be given effective treatment before the symptoms worsen.

"The excellent results obtained by working together with WHO to combat sleeping sickness make us very confident that the same approach will produce similar results in other diseases", said M. Jean-François Dehecq, President and CEO of Sanofi-Aventis. "With this new programme, we hope to contribute to saving many more lives and we are proud to be one of the major WHO collaborators to fight neglected tropical diseases."

For more information: www.who.int

Americas

USA

AHCA: today's nursing home quality summit next step toward advancing seniors' access to highest quality long-term care services

Keywords Partnership working, Quality Improvement initiatives, Long term care

The American Health Care Association (AHCA) said that the unprecedented gathering with a wide range of participating stakeholders at a "Nursing Home Quality Summit" held in our nation's capital represents the next logical step toward ensuring America's nursing home residents have access to the highest quality long term care and services. Keynote addresses by the Administrator of the Centers for Medicare and Medicaid Services (CMS) Mark McClellan; Co-Chairs of the National Commission for Quality Long-Term Care former Senator Bob Kerrey and former Speaker of the House Newt Gingrich; Governor Haley Barbour (R-MS); and Senator Charles Grassley (R-IA) underscore the importance of stakeholders from both the public and private sectors working together to advance quality in long term care.

Bruce Yarwood, President and CEO of AHCA stated that the AHCA is proud to be a leader in the coalition effort and the quality summit because it helps place the profession's "Quality First" principles into action, and also helps to set the stage for advancing on a variety of fronts. The overall objective of ensuring the USA's nursing home residents have increasing access to the highest quality long-term care and services.

The summit, convened by a coalition of healthcare providers, caregivers, medical and quality improvement experts, government leaders, consumers and others, launches a new, voluntary, two-year Advancing Excellence in America's Nursing Homes campaign, which will help create greater awareness of quality care improvement efforts already underway, and report on the progress of providers' quality improvement efforts.

Yarwood said the new quality campaign will build on and complement the work of existing quality initiatives including Quality First, the Nursing Home Quality Initiative (NHQI), and the culture change movement. Overall, he said, the effort is designed to help boost the public trust in nursing home care by focusing on transparent accountability, with facilities monitoring both clinical quality goals and organizational improvement goals that focus on resident and family satisfaction and employee retention.

The AHCA President and CEO also praised outgoing CMS Administrator Mark McClellan, who addressed the Quality Summit. "Mark McClellan has been a key driving force behind ensuring the government and profession-wide quality improvement initiatives in which we participate are effective vehicles for improving the quality of care and quality of life for frail, vulnerable and disabled Americans", Yarwood said. "We commend him for his excellent service and stewardship at CMS."

In addition to AHCA, the other founding stakeholders of the Advancing Excellence in America's Nursing Homes campaign are the Alliance for Quality Nursing Home Care; American Association of Homes and Services for the Aging (AAHSA); American Association of Nurse Assessment Coordinators (AANAC); American College of Health Care Administrators (ACHCA); American Medical Directors Association (AMDA); The

Commonwealth Fund; The Evangelical Lutheran Good Samaritan Society; National Association of Health Care Assistants (NAHCA); National Citizen's Coalition for Nursing Home Reform (NCCNHR); The National Commission for Quality Long-Term Care and the Centers for Medicare & Medicaid Services (CMS) and its Quality Improvement Organization (QIOs) contractors.

For more information: www.ahca.org

The Disease Control and Prevention (CDC) recommends routine, voluntary HIV screening in health care settings: new recommendations designed to increase early diagnosis of HIV infection as a pathway to improved treatment and prevention

Keywords Public health, Patient information, Healthcare interventions

The US Centers for Disease Control and Prevention (CDC) have published new recommendations for health care providers that are designed to make voluntary HIV screening a routine part of medical care for all patients aged 13 to 64. The recommendations aim to simplify the HIV testing process in health care settings and increase early HIV diagnosis among the estimated more than 250,000 HIV-positive Americans who are unaware of their infection. The recommendations also include new measures to improve diagnosis among pregnant women and further reduce mother-to-child HIV transmission. The Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings were published in CDC's *Morbidity and Mortality Weekly Report* (MMWR).

Increasing the proportion of people who know their HIV status is an essential component of comprehensive HIV treatment and prevention efforts in the USA. Early diagnosis is critical in order for people with HIV to receive life-extending therapy. However, nearly 40 percent of individuals diagnosed with HIV are diagnosed within one year of infection progressing to AIDS, when it may be too late for them to fully benefit from treatment. Additionally, studies show that most people who learn they are infected take steps to protect their partners, while people who are unaware of their infection are estimated to account for between 50 percent and 70 percent of new sexually transmitted HIV infections.

"We urgently need new approaches to reach the quarter-million Americans with HIV who do not realize they are infected", said Dr Julie L. Gerberding, CDC director. "People with HIV have a right to know that they are infected so they can seek treatment and take steps to protect themselves and their partners."

The new recommendations address HIV screening in health care settings only, and do not apply to non-clinical settings such as community centers or outreach programs. They replace CDC's 1993 recommendations on testing in acute care hospitals and update the portions of CDC's 2001 recommendations on HIV counseling, testing, and referral that apply to health care settings.

The new recommendations are designed to overcome several barriers that hindered implementation of the earlier recommendations, which called for HIV testing for patients in health care settings with high HIV prevalence (above 1 percent) and for all high-risk individuals. Implementation of these recommendations was difficult because many health care facilities do not have information on HIV prevalence, and many providers report that they do not have sufficient time to conduct risk assessments.

Physicians also report that the processes related to separate, written consent and pre-test counseling for HIV testing have posed significant barriers. In surveys and in consultations held by CDC, health care providers consistently reported these time-consuming processes were not feasible in emergency rooms and other busy health care settings.

The goal is to ensure that everyone who receives medical care also has the opportunity to learn if they are infected with HIV. These new recommendations will make routine HIV screening feasible in busy medical settings where it previously was impractical. Making the HIV test a normal part of care for all Americans is also an important step toward removing the stigma still associated with testing.

CDC's recommendations were developed over a three-year period with extensive input from health care providers, public health experts, community-based organizations, and advocates nationwide. Major components of the new recommendations include:

- *HIV screening for all patients, regardless of risk*. Despite prior CDC recommendations for routine testing for high-risk individuals and for all patients in settings with high HIV prevalence, many patients with unrecognized HIV infection access health care but are never tested for HIV. To normalize HIV screening as a routine part of medical care, the revised recommendations advise that all patients aged 13-64 be screened.
- *Voluntary, "opt-out" approach*. CDC's recommendations strongly emphasize that HIV testing must be voluntary and undertaken only with the patient's knowledge. The recommendations advise that patients be specifically informed that HIV testing is part of routine care and have the opportunity to decline testing. Before making this decision, patients should be provided basic information about HIV and the meanings of positive and negative test results, and should have the opportunity to ask questions.
- *Simplified testing procedures*. To overcome the most significant barriers to testing in health care settings, the recommendations advise that pre-test counseling and separate, written consent for HIV testing should no longer be required. Consent for HIV testing can be incorporated into general consent for medical care. Regarding counseling, the recommendations underscore the need to ensure that patients who test positive for HIV are provided prevention counseling and linked to ongoing care. Additionally, CDC continues to encourage prevention counseling for all patients where feasible, especially when the health care visit is related to substance abuse, sexual health, family planning, or comprehensive health assessments.
- *Enhanced screening for pregnant women*. Existing CDC recommendations for routine prenatal HIV screening have already contributed to remarkable success in preventing mother-to-child HIV transmission in the USA. The estimated number of infants born with HIV declined from a peak of approximately 1,650 in 1991 to fewer than 240 each year today. The new recommendations are intended to help reduce this number even further. They state that repeat HIV testing should be provided in the third trimester not only for women at high risk for HIV, as current recommendations advise, but also for women in areas with high HIV prevalence among women of childbearing age or in facilities with at least one HIV diagnosis per 1,000 pregnant women screened. They also specify that a rapid HIV test should be used during labor for all women whose HIV status remains unknown at the time of delivery.

These recommendations are one of many steps that CDC, in conjunction with multiple private and public sector partners, is taking to increase HIV testing in health care settings. CDC will issue additional guidance for health care providers in early 2007, which will provide examples of model approaches and practical tools for implementation in various types of health care settings. CDC is also working with other federal government agencies to ensure that people diagnosed with HIV have access to care.

CDC continues to support the full range of HIV prevention interventions needed to reduce HIV infections in the USA, including comprehensive interventions for both HIV-infected and high-risk individuals. As part of these efforts, CDC believes it is essential to reach everyone with the opportunity to learn whether they are infected with HIV. These recommendations are designed to maximize opportunities for early diagnosis in health care settings, but must be supplemented with innovative approaches to expand testing in community settings and ensure linkages to prevention and care.

For more information: www.cdc.gov/od/oc/

Canada

Health Canada announces $8.1 million for NurseOne Portal: cutting edge tool another step to improving health care

Keywords Resource management, Healthcare information, Quality improvement

The Honourable Tony Clement, Minister of Health, announced federal funding of $8.1 million over six years to launch and maintain the NurseOne web portal, a tool of particular importance for the recruitment and retention of nurses in First Nations and Inuit communities. Minister Clement made this announcement following a meeting with the Board of Directors of the Canadian Nurses Association (CNA), in Ottawa.

NurseOne is a bilingual portal that has been in development by the CNA since 2002 and contains a wealth of health information for the Canadian public and for all nurses across Canada. This portal allows nurses to obtain timely, easily accessible information on all aspects of health care – from public health alerts, to consultations with experts and health specialists, to best practices. In short, it gives nurses many new tools to better treat their patients and improve their professional skills.

Minister Clement stated that NurseOne will certainly empower nurses everywhere in Canada, but particularly those working in rural, isolated and First Nations and Inuit communities. This portal will provide nurses with quick access to reliable resources, enable them to improve quality of care and will assist in reducing wait-times. This investment will serve as an important contributor to the advancement of the professional practice and development of Canada's front-line health providers – nurses.

NurseOne is a significant tool that will provide access to quality, up-to-date health information to support the 250,000 plus nurses working in urban, rural and remote parts of the country to deliver effective, evidence-based care, the President of the Canadian Nurses Association stated. The investment supports nurses in caring for their patients, families and communities, managing their careers and connecting with colleagues and experts with the click of a mouse. In addition, NurseOne supports employers in recruiting and retaining nurses.

Health Canada had previously contributed $3.98 million to the Canadian Nurses Association to develop this Portal which was introduced at the Canadian Nurses Association Biennial Convention in Saskatoon on June 19, 2006.

For more information: www.hc-sc.gc.ca

Far East and Australasia

Australia

Health spending grows 10 percent to $87 billion

Keywords Healthcare expenditure, Private healthcare spending

Health expenditure in Australia was $87.3 billion in 2004-2005, according to a new report by the Australian Institute of Health and Welfare.

Head of the Institute's Expenditure and Economics Unit, Mr John Goss, said that total growth since 2003-2004 was about 10 percent, or 6 percent adjusted for inflation and that average health services expenditure was up $361 per person to $4,319.

The report, *Health Expenditure Australia 2004-05*, shows that as a proportion of gross domestic product (GDP), expenditure on health increased to 9.8 percent, up from 9.4 percent in 2003-04 and 8.1 percent in 1994-1995.

Australia's health expenditure to GDP ratio is comparable to Canada, Austria and Norway. It is more than the UK and New Zealand, and considerably lower than the USA which in 2004 was 15.3 percent of GDP.

The areas of health expenditure that showed relatively high increase were public health (14 percent), medical services (13 percent), ambulance services (12 percent), community health (11 percent), research (10 percent) and high-level residential care (10 percent).

These six areas accounted for close to 40 percent of the health spending increase between 2003-2004 and 2004-2005.

The report showed the majority of health spending was funded by governments (68 percent) with the Australian Government contributing 46 percent. State, territory and local governments contributed 23 percent, and the non-government sector funded 32 percent.

The relative share of funding for public hospitals has been changing over the past decade. Between 1994-95 and 2004-05, the Australian Government share of public hospital funding decreased from 47.6 percent to 44.2 percent, while the state and territory government share of public hospital funding increased from 43.3 percent to 48.0 percent.

Hospitals represented the largest area of health expenditure in 2004-2005 (33 percent of the total). Public hospitals accounted for $22.1 billion and private hospitals $6.9 billion. The private hospital share of hospital expenditure increased in the last decade from 21 percent of hospital expenditure in 1994-95 to 24 percent in 2004-2005.

Private health insurance funding of $5.7 billion was mainly spent on private hospital services (48 percent), dental services (12 percent), administration (10 percent) and medical services (10 percent).

For more information: www.aihw.gov.au

New Zealand

Māori health providers celebrate with Whānau Ora Awards

Keywords Innovation, Quality, Leadership

The passion and professionalism of top Māori health providers will be on show with the Manatū Hauora and Te Matarau 2006 Whānau Ora Awards.

a total of 20 Whānau Ora Award finalists showcase their initiatives and celebrate their achievements at Wellington Town Hall, said Māori Health Directorate Service Development Manager Kathy Grace.

ManatŪ Hauora is thrilled to be hosting the event that celebrates Māori health initiatives and promotes successful *whānau ora* models of service delivery. Displays are open to the public.

The inaugural Whānau Ora Awards in 2004 were a huge celebration of excellence and achievement by individuals and organizations in the Māori health and disability sector.

Anticipation and excitement were now building ahead of this year's event – the second Whānau Ora Awards, said Ms Grace. It has been exciting seeing the ongoing passion and professional development of Māori health providers over the past ten years, and the Whānau Ora Awards showcase and celebrate this.

They have come a long way – with accreditation, staff training and development and quality standards while at the same time maintaining the whānau ora vision. The awards have attracted interest from small, medium and large Māori health providers.

The judging panel was very impressed by the high quality of the entries and the wide range of health services delivered by Māori health providers (mental health, disability, residential, immunization, healthy eating, GP/PHO service and many more).

The judging criteria for the finalists was based on three guiding principles: innovation; quality; and leadership.

The vision for Whānau Ora was firmly established in 2002 in *He Korowai Oranga*, the Māori Health Strategy. It reoriented the whole Māori health sector towards wellness and wholeness. This led to the sector taking a leadership role across the whole of government and its agencies in their approach to ongoing health and disability service delivery.

The overall aim of He Korowai Oranga is Whānau Ora: Māori families supported to achieve their maximum health and wellbeing.

For more information: www.moh.govt.nz

Europe, Middle East and Africa

UK

Audit Commission reveals use of resources judgements for NHS bodies

Keywords Resource management, Performance measurement, Local improvement

The Audit Commission publishes for the first time judgements that show how well or how poorly individual National Health Service (NHS) trusts and primary care trusts (PCTs) are managing and using their financial resources.

The Auditors' Local Evaluation (ALE) gives a rating on the use of resources at 538 NHS organisations for 2005/06. On a scale of 1 to 4, the ALE rates performance over five areas: financial reporting, financial management, financial standing, internal control, and value for money.

The overall ALE score forms a use of resources score, which is part of the Healthcare Commission's Annual Health Check for NHS trusts and PCTs. Detailed use of resources scores for each organisation and the main national findings are published (12 October) in the Audit Commission's briefing, *Auditors' Local Evaluation 2005/06 – Summary Results*.

Among the key findings of the first evaluation is that 61 per cent of NHS bodies demonstrated adequate or more than adequate use of their resources. But only two trusts, both of which have become NHS foundation trusts, demonstrated strong performance.

The majority of NHS bodies have shown adequate or more than adequate performance in the areas of financial reporting, financial management, internal control and value for money.

A total of 39 per cent of bodies are judged inadequate in their overall ALE performance, reflecting the number of NHS bodies that failed to achieve financial balance in 2005/2006. This part of the evaluation, called financial standing, is the area of poorest performance, where 35 per cent of NHS trusts and 38 per cent of PCTs were assessed as inadequate.

Steve Bundred, chief executive of the Audit Commission, stated that the Auditors' Local Evaluation had identified strengths and weaknesses in the use of resources of individual NHS bodies and across the whole NHS. Most were meeting minimum requirements but it was disappointing that more NHS organizations are not in the top two categories. The auditors had pinpointed the individual areas that most need improvement to ensure each NHS body achieves better use of their resources. A small minority of organizations need to make significant progress across the board. Individual NHS trusts and PCTs will receive their own assessment of where their weaknesses or strengths may lie and how they can improve to achieve better value for money for patients and taxpayers.

Some examples of the ALE findings are that:

- Of NHS bodies, 61 per cent demonstrated adequate or more than adequate performance in their overall use of resources.
- A total of 210 of the 538 NHS bodies failed to meet minimum requirements and therefore were assessed as having inadequate performance (in other words, they had scored 1 in financial standing, financial management or value for money, or in some cases a combination of these).
- The performance of mental health trusts, learning disability and specialist trusts was better than that of acute trusts and PCTs, and this is consistent across the five categories assessed.

Each NHS trust and PCT will receive an ALE summary report and auditors will use each NHS organization's results to help identify local improvements. The 2005/2006 judgments will also be a yardstick for progress against a further ALE assessment in 2006/2007.

Note: the Audit Commission is an independent body responsible for ensuring that public money is spent economically, efficiently and effectively, to achieve high-quality local services for the public. The remit covers around 11,000 bodies in England, which

between them spend more than £180 billion of public money each year. The work covers local government, health, housing, community safety and fire and rescue services. As an independent watchdog, it provides important information on the quality of public services. As a driving force for improvement in those services, it provides practical recommendations and spreads best practice. As an independent auditor, the commission ensures that public services are good value for money and that public money is properly spent.

For more information: www.audit-commission.gov.uk

Health Challenge England launch event October 2006

Keywords Partnership working, Healthcare needs assessment, Public health

Public Health Minister, Caroline Flint and the Deputy Chief Medical Officer (DCMO), Fiona Adshead were joined in October 2006 by Prime Minister Tony Blair at the launch of Health Challenge England.

The launch, held at Leyton Orient Score Complex in east London, marked the first of a series of local workshops for local community leaders, businesses, charitable and voluntary organizations and health professionals. The aim of the workshop was to examine ways in which all sectors of society can work together to address local health needs.

This is a new opportunity for local communities to take forward a social marketing approach, putting people in the driving seat to make the changes they need to lead healthier lives.

After an introduction to the event, the 50 participants from Tower Hamlets took part in a social marketing workshop, the first in a series of local Small Change, Big Difference events that will be rolled out across the country over the coming months.

Launched in April of this year by the PM and Caroline Flint, the Small Change, Big Difference initiative encourages people to make small, but achievable positive changes to their lifestyle that have the potential to reap significant benefits.

The Leyton event focused on childhood obesity, and it is hoped that the attendees, with their cross community experience and insight, will identify specific hurdles that their community may face when tackling this issue.

Two publications were also launched at the event:

(1) *Health Challenge England – Next Steps for Choosing Health*, which sets out the successes achieved since the launch of the Choosing Health White Paper in 2004.

(2) *Health Profile of England*, which shows the impact of the public health improvements that have been made, and the continuing problems.

"Since we published our *Choosing Health* White Paper in 2004 we have begun to build up a clear idea of what works to improve the health in those areas of the country that face the most serious problems," said Public Health Minister Caroline Flint.

"Working closely with a range of stakeholders from the health, commercial and voluntary sectors we have found out more about why people don't make healthy choices. Only by knowing this can we be more effective in tackling obesity and targeting the right services to the right people".

The Health Foundation calls for more support to help NHS trusts improve quality and safety

Keywords NHS performance, Benchmarking, Quality Training and Development

More than half of the NHS trusts in England need to improve either the quality of their services or their financial management, new figures released by the Healthcare Commission show. The Annual Health Check, which combines hospital self-assessments with patient reports, financial and quality data, aims to provide a more accurate picture of NHS performance than the previous, much-criticised "star ratings" system.

The Commission ranked 60 percent of trusts as either "fair" or "weak" for quality of services, while 84 percent were ranked fair or weak for financial management. Eight trusts received the bottom ranking of weak on both quality of service and financial management. All trusts given at least one weak rating will now need to put action plans in place within 30 days, setting out how they will improve.

The Health Foundation's chief executive Stephen Thornton stated that the report provides a useful snapshot of NHS performance and welcomed the tougher, more robust system which replaces the outdated star ratings. Without benchmarking the NHS cannot make improvements to the quality of care provided.

However, the Foundation also called for more support and training to help Trusts improve the quality and safety of their services. Improving the quality of patient care is hard to do and from experience it takes a long time. Few trusts can do it on their own, and more support and training in quality and safety improvement is needed for NHS professionals.

As an example it is known that patient safety rates dramatically improve when hospital staff and visitors wash their hands more frequently. Actually making this happen in all hospitals requires a sustained change in working practices to guarantee it will happen reliably every time. Staff will find it difficult to interpret performance data such as the Healthcare Commission's report. They need support to use it locally to improve the care they deliver to patients.

Ireland

Health sectoral plan sets out clear commencement dates for new disability entitlements

Keywords Access and equity, Needs assessment, Disability entitlements

The Tánaiste and Minister for Health and Children, Mary Harney, TD, welcomed the launch of the Health Sectoral Plan on Disability which was published along with the plans of five other departments.

The Sectoral Plan clearly sets out the actions which the Department of Health and Children, the HSE and 27 statutory bodies will take to meet their obligations under the Disability Act 2005.

The Tánaiste stated that the Sectoral Plan represented a commitment at all levels of the health service to improve access and equity of service for people with disabilities. It was an important opportunity to ensure that the needs of people with disabilities are considered in all health policy and service planning.

The main elements of the Sectoral Plan set out in detail the arrangements proposed for implementing Part 2 of the Disability Act, 2005.

Under the Act, persons with a disability will be entitled to an assessment of needs and a formal statement of services which are to be provided. There is also an independent appeals system.

Part 2 of the Disability Act will commence for children with a disability aged under 5 years with effect from 1 June 2007. In simple terms, parents of these children will now have the right to get, not only an assessment of the child's needs, but also a clearly worked out plan from the Health Service Executive for the provision of services. And if the plan is in any way deficient the parents have a right to appeal.

Part 2 will be commenced in respect of children aged five to 18 in tandem with the implementation of the Education for Persons with Special Educational Needs Act 2004.

The Act will be extended to adults as soon as possible but no later than the end of 2011. Services for adults and children will continue to be enhanced progressively over the next number of years. The HSE will promote the practice of assessment of individual needs and the provision of service statements for all service users, as capacity permits.

The Tánaiste said: "Plans without resources are of questionable value but the commitment of the government in this area is clear. Across government we are spending €3.3 billion this year alone on services for persons with disabilities. In the Department of Health alone we have already spent €285 million since publication of the National Disability Strategy and we will be spending an additional €720 million between 2006 and 2009."

Finland

Finns have heavy health agenda ahead

Keywords Health inequalities, Nutrition and physical activity, Advanced therapies

In addition to promoting "Health in all Policies", the Finnish Presidency is expected to hammer out political agreements on Health programme 2007-2013, medical devices and advanced therapies.

The Finnish EU presidency's overall objective in health policy is to promote the principle of Health in All Policies, as health is largely determined by factors outside the domain of health care and policies other than health have direct effects on health determinants. The "Health in All Policies" approach is also meant to contribute to horizontal EU policies, such as the Lisbon strategy, and have positive effects on national economies through higher productivity and labour participation.

Accordingly, the main health policy event during the Finnish Presidency, a high-level expert conference on Health in All Policies, took place in September 2006. A book on Health in All Policies was published to serve as background material for the conference, which will consist of plenary sessions and thematic workshops on specific topics related to, for example, health inequalities, nutrition and physical activity, alcohol policies, and mental health and public policies.

The main EU legislative proposals on the table during the second half of the 2006 are the Health programme 2007-2013, the revision of legislation on medical devices and a proposal for a Directive on advanced therapies; on all of which the Council is expected to reach a political agreement.

The Commission will also publish a communication on EU alcohol strategy, which will aim to reduce the health and social harm due to alcohol consumption.

For more information: www.euractiv.com

European Union

Patient mobility: Commission to launch public consultation on EU framework for health services

Keywords High-quality and efficient healthcare services, Free movement of healthcare services, Patient rights

The European Commission September 2006 decided to launch a public consultation on how to ensure legal certainty regarding cross-border health services under Community law, and to support cooperation between the health systems of the member states. The consultation will be based on a Communication to be drawn up by European Health and Consumer Protection Commissioner Markos Kyprianou setting out ideas for an EU framework for safe, high-quality and efficient healthcare services, reflecting the outcome of the orientation debate held by the Commission. The first step will be a consultation on issues such as: the conditions according to which cross-border health care must be authorized and paid for, and the provision of information to patients about treatments available in other member states; which health authority is responsible for supervising cross-border health care in different circumstances; responsibility for any harm caused by healthcare and compensation; patient rights; and supporting health systems through European co-operation. On the basis of responses to this consultation, any formal Commission proposals will follow in 2007.

The healthcare that patients need is sometimes best provided in another EU country. The European Court of Justice has ruled that patients have rights to cross-border care under Community law, but there are uncertainties about what this means in practice. A clear, practical framework is needed to enable patients to and those who pay for, provide and regulate health services to take advantage of cross-border healthcare where that is the best solution. This will also help to unlock huge potential for European cooperation to help improve efficiency and effectiveness of all EU health systems, whilst respecting national responsibility for their organisation and financing.

Patient mobility – background

Discussions about free movement of healthcare services, and in particular "patient mobility", were prompted in 1998 after judgments of the European Court of Justice in the cases of Mr Kohll and Mr Decker, both Luxembourg nationals, regarding direct application of EU Treaty articles on free movement to the reimbursement of health services provided abroad. In its rulings, the Court made it clear that health services are subject to Treaty provisions on the free movement of services. Measures making reimbursement of costs incurred in another member state subject to prior authorization are thus barriers to freedom to provide services, although such barriers may be justified by overriding reasons of general interest.

In the 2003 report of the High Level Reflection Process on patient mobility and healthcare developments in the European Union, health ministers and other stakeholders invited the Commission to explore how legal certainty could be

improved following the Court of Justice jurisprudence concerning the right of patients to benefit from medical treatment in another member state.

The Commission's proposal for a directive on services in the internal market at the start of 2004 therefore included provisions codifying the rulings of the Court of Justice in applying free movement principles to health services. This approach, however, was not accepted by Parliament and Council, and the Commission therefore undertook to explore how best to develop a separate specific initiative on health services.

Providing legal certainty

The main objective of an initiative in this area would be to provide clarity and certainty regarding the application of Treaty provisions on free movement to health services following the Court of Justice rulings, including the necessary clarity on medical, regulatory and administrative issues. This could cover issues such as the following:

- The terms and conditions according to which health care in another member state must be authorized and paid for, and the provision of information to patients about treatments available in other member states.
- Which health authority is responsible for supervising cross-border health care in different circumstances, and ensuring continuity of care.
- Responsibility for any harm caused in cross-border healthcare and compensation arising from such harm.
- Common elements of patient rights.
- Support to cooperation between health systems.

In addition, a range of specific areas where the economies of scale of coordinated action between all member states could bring added value to national health systems have been identified, in particular through the work of the High Level Group on health services and medical care. These include:

- European networks of centers of reference;
- collaboration on assessment of new health technologies;
- providing a basis for sharing best practice through comparable data and indicators; and
- better methods for evaluating the impact of new proposals on health systems.

Following the debate in the College of Commissioners, the Commission will launch a public consultation on these issues based on a Commission Communication, seeking input from the member states, the European Parliament and other stakeholders such as patients and health professionals, as well as purchasers and providers of care, with a view to bringing forward specific proposals in 2007.

For more information: http://europa.eu

Recent publications

Please note that unless expressly stated, these are not reviews of titles given. They are descriptions of the books, based on information provided by the publishers.

Solution-focused Nursing – Rethinking Practice

Margaret McAllister
Palgrave Macmillan
ISBN 1 40394 627 2
Keywords Managing change, Quality frameworks, Patient centred care

This book discusses an innovative approach to nursing practice. Solution-focused nursing is a practical philosophy which emphasises change at three levels: the client, nursing and society. It teaches three important principles: to be cautious of dominant paradigms, to focus not only on problems but solutions too, and to work with and for clients rather than on them. Solution-Focused Nursing challenges common assumptions about care and provides a framework for nursing that is not just technical, but psychosocial too.

Contents include:

(1) *Part one: principles of solution focused nursing*:
- "An introduction to solution focused nursing", M. McAllister.
- "Cultural roots and new developments in nursing", M. Clinton.
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(2) *Part two: contexts of nursing care*:
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Child and Adolescent Mental Health Nursing

Edited by Tim McDougall

Blackwell Publishing
ISBN 1 40512 801 1
Keywords Healthcare skills and competencies, Evidence based healthcare

All nurses share a responsibility to promote the mental health and mental wellbeing of children and young people in the context of recent developments including the National Service Framework for Children, Young People and Maternity Services.

Child and Adolescent Mental Health Nursing equips nurses with the essential skills and competencies needed when working with this important group of people. It explores best practice in a variety of settings and addresses issues such as eating disorders, self-harm, ADHD, learning disabilities, forensic mental health issues and misuse of drugs and alcohol in children and young people, as well as child protection, clinical governance and legal requirements.

Child and Adolescent Mental Health Nursing enables nurses working in CAMHS to provide a high quality, evidence-based service to all children and young people with mental health problems and disorders, ensuring effective assessment, treatment and support, for them and their families. It is essential reading for all nurses working with children and young people, particularly those working in specialist child and adolescent mental health settings.

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- "Nursing children and adolescents who are aggressive or violent: a psychological approach".
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- "Ten practical tips for nursing children and young people with mental health problems".

Supporting Self Care in Primary Care

Ruth Chambers, Gill Wakley and Alison Blenkinsopp
Radcliffe Publishing
ISBN 1 84619 070 3
Foreword by David Colin-Thomé, National Clinical Director for Primary Care, Part-time GP, and Honorary Visiting Professor, Manchester Centre for Healthcare Management, Manchester University
Keywords Interactive professional learning and development, Healthcare promotion

Designed around the Department of Health's Working in Partnership Programme, this book is full of easy-to-implement advice for everyday use, promoting a positive approach to self care and demonstrating how smoothly it can be introduced and undertaken.

Supporting Self Care in Primary Care encourages interactive professional learning and development, both individually and within a team, and highlights the importance and benefits of self care in the workplace. It is a self-contained text with tools and illustrative examples to aid comprehension, and includes a complementary web resource containing further tools and a training package.

All healthcare professionals involved in commissioning or providing primary care to patients will find this practical guide invaluable, as will healthcare managers and health promotion specialists.

"Self care is about people's attitudes and lifestyle, as well as what they can do to take care of themselves when they have a health problem. Supporting self care is about increasing people's confidence and self-esteem, enabling them to take decisions about the sensible care of their health and avoiding triggering health problems. Although many people are already practising self care to some extent, there is a great deal more that they can do." (Ruth Chambers, Gill Wakley and Alison Blenkinsopp, in the Preface).

Contents are:

- "Supporting self care".
- "What we know about the practice and impact of self care".
- "Getting organised for supporting self care as a PCT".
- "Getting organised for supporting self care as a general practice team".
- "Getting organised for supporting self care as a practitioner".
- "Supporting self care in a pharmacy team".
- "Seeing the patient's perspective".
- "Managing change".
- "Completing the cycle – evaluation".
- "Illustrative patient pathways to self care".

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20th anniversary commemorative issue: quality then, quality now

Editors
Keith Hurst and Kay Downey-Ennis

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Editorial

An auspicious and sad occasion

To mark two sentinel events – publication of Volume 20 Number 1, and Robin Gourlay's retirement (founding editor in 1988 and later Editor in Chief), we review and republish some of the articles in Volume 1.1 and match them to manuscripts on similar topics 20 years later. We also asked one of Robin's close friends, Professor Roger Dyson, to write a testimonial, which he did with his usual eloquence and humour. It is with great sadness, however, that we report Roger's unexpected and untimely death only a few weeks after Roger completed the commission. Readers, I am sure, would have joined us when we sent our condolences to Roger's family through Robin and Janet.

Hannu Vuori's article in Volume 1 Number 1, as readers will see from its republication in Volume 20 Number 1, firmly grasped the QA implementation nettle. In a slightly offbeat piece, the author, a WHO R&D stalwart, underlined most issues facing QA managers, practitioners and academics – challenges that he felt were likely to invoke a gamut of responses, ranging from employee hostility to the QA manager's pleasure of knowingly making a difference to healthcare services. The article turned out to be prophetic – the importance that commissioners would eventually attach to quality assured health and social care services; and the statutory clinical governance arrangements implemented in the UK following serious breaches of patient-practitioner trust such as the murders committed by Harold Shipman and Beverly Allet. Hannu also bemoaned the thin data sets necessary for supporting QA workers before going on to recommend some approaches. Twenty years later, we publish Elizabeth Murray's and Rodney McAdam's exploration of pharmaceutical QA theory and practice, and one that clearly shows how much road has been travelled in 20 years. They examine pharmacy industry quality management systems (QMS) and underline patient safety versus profit motive, hence the industry's careful regulatory systems. Clearly, there is an overlap and repetition between in-house, mandatory and rigorous pharma QMSs and voluntarily adoption of a standardised, international QMS such as ISO 900:2000. Nevertheless, two important sidelines emerge from their article – the educational value of comparing QMSs; and how one accreditation system can learn from the other.

Jim Dummer's article on health service performance and productivity never left managers' agenda during the 20 years since publication. Indeed, productivity has experienced a resurgence in 2006 with the launch of several productive time initiatives (doing more with same resources) in the UK. Clearly, Jim's article isn't out-of-place in issue 20.1 even though the language has changed slightly. For example, he underlines the association between cost savings and QA – a stitch-in-time – saves-nine managerial approach. Jim also explored the shift from outputs to outcomes; once again, a hot topic in the twenty-first century NHS, although output is now called a target-driven culture. We parallel Jim's article with Jaakko Kujala and his Finish

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colleagues' report. Kujala *et al.*'s project is elegant. They take a fairly simple notion – improving operating theatre throughput. Simplicity, however, is counterbalanced with the number of confounding variables needing (but not easily) control (led), such as the patient's readiness for surgery at short notice. Consequently, they develop and test a sophisticated simulation model that incorporates empirically determined operating theatre data. Using what-if scenarios, they are able to highlight the factors that explain variation in open-heart surgery throughput and suggest ways of improving operating theatre efficiency and effectiveness. Equally elegant are their recommendations – although some would say it is blindingly obvious, but it is always good to see recommendations underpinned by strong data and robust inferential statistics. For example, simply extending the theatre day's length, while shortening the working week from five to four days is good way of reducing "down time".

Steve Wright's article in Volume 1 Number 1 described a relatively new nursing practice concept in the 1980s – nursing development units (NDUs). These units had several purposes, not least: increasing nursing autonomy, flattening the professions' hierarchy and introducing primary nursing, where individual patients were cared for by a small nursing team. These were radical departures from traditional nursing that preceded NDUs, epitomised by task centredness (one nurse completes the same job for all patients – a production line in short). Nursing development units aimed to improve job satisfaction, nursing recruitment and retention, and most of all the quality of nursing in the so-called Cinderella services such as care of the elderly. Over the ensuing 20 years, many NDUs were established, accredited and monitored, and the NDU network is strong. The NDUs' radical approach spawned other, autonomous nursing projects. Most expand and extend nursing roles. Consequently, it's a great pleasure to pair Steve's article from 20 years past with a recent one from a former *IJHCQA* editor, Sue Jackson and her colleague Gillian Morgan. Sue, as readers may recall, has a special interest and expertise in EFQM – knowledge that she and Gillian use effectively. Their case study – minimising the impact of coronary heart disease (CHD) on a particularly prone and vulnerable population using a nurse-led team, is well crafted. A bonus is the way the authors apply EFQM, notably RADAR, to increase the project's success. So, not only can readers learn about the CHD project's journey but also understand more about EFQM. Also, the case study is a lesson in mutual trust, collaboration and the alternating light and heavy hand-on-the-tiller approach required by senior managers and leaders. The importance of generating baseline data and realistic, short and long-term output and outcome targets is double-underlined. Reporting is honest – their warts-and-all description pulls no punches. Nevertheless, the article bristles with sound theoretical and practical guidance.

Finally, we turn to another article showing considerable foresight. The report by van Everdingen and colleagues has all the hallmarks of modern evidence-based care protocols. Their evaluation of blood transfusion policy guidelines was based on a systematic review of the literature and Delphi technique for added credibility. Twenty years on, Laurence Leigh and his colleagues take one step back from transfusion policy and describe good practice for attracting and retaining donors. The authors suggest their publication is unique. If not, then at least it is an intriguing insight into blood donor perceptions, donor care and recipient safety. This article also includes sound and

practical advice. The authors focus on universities as a good place to attract donors and run blood drives. They apply marketing theory to explain behaviours, perceptions and recommend best practice. Readers also are given an intriguing account into some bizarre perceptions held by donors and non-donors, and also ethical issues surrounding donation. These matters are handled sensitively by the researchers and authors.

Twenty years on, 133 issues, approximately 665 articles and 3.4 million words later, typified by the high-quality and fascinating material published and re-published in Volume 20 Number 1, represents a marvellous testimonial to Robin Gourlay's vision and hard work.

Well done Robin! All the *IJHCQA* staff wish you a long, happy and well-deserved retirement. Here's to the next 20 years!

Keith Hurst

To echo Keith's words above, I would like to congratulate Robin on a successful 20 years with *IJHCQA*, and a well-deserved retirement! Robin's vision for the journal has helped to steer it to the place it now occupies – a leading peer-reviewed journal in the healthcare field. Robin has been ably assisted throughout his tenure as Editor by a number of co-editors; most recently, Keith Hurst. Keith has now taken over as Editor-in-Chief, with Kay Downey Ennis as Co-Editor – an excellent team who will, I am sure, drive the journal forwards over the coming years.

We would love to receive feedback on this commemorative issue, so please feel free to get in touch with Keith, Kay or myself at any time.

Vicky Williams
Publisher

A tribute to Robin Gourlay

I am delighted to contribute to this recognition of Robin's career and achievements. We first met and started work together in 1969 at the Nuffield Centre, Leeds University. Thereafter, for over 30 years, there was not a year when we did not share joint teaching programmes for NHS personnel or professional organisations. When we began, the NHS was experiencing its first industrial relations difficulties with organised labour and the culture shock was profound. Many senior managers found it almost impossible to come to terms with the idea of strike action "against sick patients" and even with the requirements of the 1971 Industrial Relations Act. The national ancillary staff industrial action of 1972 was an intense crisis of philosophy and direction for managers and many did not survive the 1974 Reorganisation. Robin and I had a strong, shared academic interest in how the NHS might respond to this challenge, but we approached it from very different academic disciplines, applying different analytical reference frames. We were first brought together into a team-teaching environment; an innovative idea at the time, as "conflicting solutions to the challenge"! Instead, over a number of years, through case study research, publication and teaching, we hammered out a joint approach to industrial relations management and conflict resolution that was to influence NHS management over the next 30 years.

Robin was the principal publicist and main author of our team and when he went to the Wessex Region as Personnel Officer in the mid-1970s, he gained the direct personal experience of applying a new and innovative approach to industrial relations management that gained him great "street cred" among the very insular mafia that was then the NHS senior management. His most popular and successful publication in this field was undoubtedly the *Negotiations for Managers* book, which went through several editions and over 20 years, sold 11,500 copies! It educated and informed a generation of senior managers, not to mention many trade union officers and shop stewards. Crucially, through teaching and writing, Robin gave senior managers a framework within which to respond to the industrial relations experience of the 1970s.

It is easy in today's world to regard this particular management skill as just one ordinary tool in the armoury, but what was achieved has to be seen in context. One laundry manageress, who had promised that her staff would cross the picket lines, locked herself in a cupboard and drank herself paralytic for three days in succession because no staff member came to work. One hospital administrator cancelled most patient discharges for four weeks and organised patients into work groups having locked out his ancillary staff for striking. When they wanted to return, he refused and would not let them back until the national strike was officially over – after which Ministers quietly ensured his removal from office. Many made unofficial deals to keep basic services running and there was a real terror that when the strike was over "heads would roll" because of unauthorised expenditure. When it was over, very senior managers in one Region were found to have tried to falsify records to hide these unofficial deals and were dismissed. It was against this background, against the guerrilla warfare of the mid-1970s and the conflict of 1979, that *Negotiations for Managers* had such an influence on management thinking.

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It is also a great tribute to Robin's ability and resilience that when this type of industrial action was virtually laid to rest after the two big union defeats in 1979 and 1982, his work and teaching increased with great popular demand. A new edition of *Negotiations for Managers* appeared alongside a number of new linked, specialist, books and their relevance to the management challenges of the Thatcher years remained undimmed. In particular, the development of clinical management directorates, with a first generation of senior consultant directors, substantially expanded the call for Robin's work and expertise and this demand continued throughout most of the 1990s as medical involvement in management continued to grow. This occurred despite the fact that by the mid-1980s there were many new academic specialists and despite the arrival of external management consultants marketing their wares to the NHS. Many shamelessly plagiarised Robin's work, but then, imitation was the sincerest form of flattery!

Robin taught managers how to communicate more effectively with their staff. He taught them how to identify their long-term negotiating objectives, how to stay calm and focussed under pressure, and how to secure the right negotiating outcome. The fact that occasional teaching examples came from the domestic family environment gave participating males some useful personal spin-offs, although we all felt some sympathy for his wife Janet as a lifetime guinea pig of Robin's negotiating experiments!

I find from my old diaries that for over 30 years Robin and I worked together on at least 140 joint programmes, the majority of which were two-day seminars. He was a delight to work with as a colleague; always well-prepared, always consistent and great fun as a teaching partner. This was despite the fact that he always played the straight man of the duo. Any readers who may have attended one of these programmes will remember his great patience as I kept butting in, or missing my cue. I look back on this aspect of my career and remember the enormous pleasure I felt when working with Robin and how much I valued his friendship.

The regular fan mail we received is now no more, but one or two come to mind. One man was ecstatic because after years of trying, he had finally persuaded his wife to go on a holiday to the USA. A radiologist reported that he had persuaded the secretary not to eat her lunch immediately outside the reporting room. But the more unusual ones tended to come from the era of industrial conflict. "When the night duty union steward summons us back at 03.00 hrs, our team no longer gets up and goes to the hospital to meet him". Another letter explained that "I am very pleased to say that our local negotiations have succeeded and senior managers no longer have to carry the foul linen to the transport lorry every time the laundry staff withdraws their services". If readers think these examples bizarre then they should remember the context. In 1979 Jamie Morris, the union convenor at the Westminster Hospital, managed to summon the Secretary of State, the Minister, the Permanent Secretary and a bevy of senior civil servants to the hospital in the middle of the night to hear his complaints under threat of strike action! After the 1979 debacle, Robin was a major contributor as he helped to rebuild management confidence and restore a sense of proper management purpose, which had been badly eroded through the 1970s, and I am grateful to have the chance to record this.

Roger Dyson

Introducing quality assurance: an exercise in audacity

Hannu Vuori
World Health Organisation, Regional Office for Europe

Abstract

Purpose – The purpose of the paper is to examine commitment to quality assurance within health authorities.

Design/methodology/approach – The paper discusses approaches to achieving the requisite changes, including what to change and how to increase readiness for change; motives for change, where to start and prerequisites for change.

Findings – The paper finds that health authorities have a tendency to look at quality assurance as a professional luxury which deals with the subtleties of care rather than with its essence and that a strategy for change is needed.

Originality/value – The paper provides useful information on the development of quality assurance in health care.

Keywords Health services, Quality assurance

Paper type Conceptual paper

The first oyster

Brave was the man who ate the first oyster and likewise, probably, is anyone who tries to introduce quality assurance for the first time into a country or an institution. In many European countries the obstacles often seem insurmountable. Three key groups – the health authorities, the health professionals and the consumers of health services – have to be convinced that quality assurance is needed, possible and beneficial. In the best instance, these groups are indifferent, in the worst, hostile.

The health authorities may sincerely believe that quality assurance is not needed. They consider it an American invention, not appropriate for Europe. They believe that in their relatively small countries with society-controlled education of health professionals and strict licensing requirements for health care institutions and professionals, the quality of care is of a rather even and universally high level. Although they accept that "rotten apples" may exist, these are rare, highly visible and they believe can easily be dealt with without a quality assurance system.

Even when the health authorities believe that the quality of care varies too much, they may not be aware of the existence of effective methods to detect poor quality care. Finally, they may doubt whether quality assurance – assuming the existence of effective, reliable and valid methods – indeed benefits health care as a whole. They have a tendency to look at quality assurance as a professional luxury which deals with

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The opinions expressed are those of the author and not necessarily those of the World Health Organisation.

the subtleties of care rather than with its essence. They may also fear that quality assurance makes care more expensive.

The health professionals, particularly the physicians, are a proud breed, convinced of their high professional and ethical standards. Any suggestion that the quality of their professional activities can vary so much as to need quality assurance may be taken as an insult.

Their training and socialisation into the profession may contribute to a negative attitude to quality assurance; medical education emphasises independent judgement; modern medical practice is characterised by narrow specialisation. Only those with equivalent specialised knowledge are presumed to be able to judge one's work. Whatever, such judgements should not be made publicly but internally by peers. A quality assurance system introduced from the outside and by an outsider is thus easily an anathema to the physicians; it conjures up an image of "big brother".

The consumers do not usually know that it is possible to assess the quality of care. Even when they are aware, they often lack yardsticks against which to compare it. In many European countries, they often take the quality of care for granted. They may also more easily than their American sisters and brothers accept variation and concomitant poor quality as an inalienable characteristic of all human activities.

The situation is, however, changing: the health authorities are demanding value for money; the health professionals are beginning to see quality assurance both as an ethical obligation and as a means of competing with other providers of care; the consumers have been taught to be quality conscious not only when buying household utensils and cars but also when receiving health care. A few years ago, a WHO survey concluded that there is a great amount of interest, a considerable number of research activities and some pilot programmes, but very few activities that could be called quality assurance. The lack of cross-fertilisation among research, policy making, and practice is conspicuous (Vuori, 1982).

Quality assurance means change

In spite of the promising signs, the oyster is still hard to swallow.

In most European countries and health care institutions, quality assurance is a new thing. To market a new thing, one needs a clear strategy. The essence of the strategy is the introduction of change. Consequently, the theories and methods related to planned change are relevant. In planning the change strategy, useful information can be found in literature on organisation development, systems analysis, adult learning and organisational sociology and psychology (Jessee, 1981).

The key elements in planned change are the identification and demonstration of a need, assessment of readiness and capability to change and a change strategy.

Demonstrate a need for change

Things are not likely to change unless the main actors feel that the current situation is unsatisfactory. In the case of quality assurance, the best way to do this is to demonstrate that there is variation. Usually even a cursory look at existing routine statistics will suffice: the average length of stay between different hospitals varies; one surgeon performs twice as many hysterectomies as another in the same hospital;

maternal mortality significantly differs between the regions; some physicians seem to be able to arrive at a diagnosis on the basis of only half of the laboratory tests and X-rays that another needs, etc.

Such variations can often be explained by virtue of differences in population base, case mix and severity of the health problems. It does, however, arouse curiosity and sometimes leads to the posing of the question of whether this could have something to do with the quality of care. To answer this question, more rigorous and time-consuming studies may be needed to analyse the extent, nature and cause of the problem. But the seed has been sown which may result in the acceptance of quality assurance as a possible solution to the problem.

Assess the readiness for change

Change is usually resisted. To overcome this inertia, energy is needed on the part of both the change agent and of those whose activities will be affected by the change. A useful formula to determine readiness and capability for change is:

$$C = (ABD) > X$$

where C = change; A = level of dissatisfaction with the status quo; B = clear or understood desired state; and D = practical initial steps. For a change to be possible and for commitment to occur, there has to be sufficient dissatisfaction with the current state of affairs to mobilise energy towards change. There has also to be a clear idea of what the state of affairs would be if and when the change was successful and what practical first steps need to be taken towards achieving the desired state (Beckhard, 1975).

An analysis pinpointing which of these conditions does not exist will suggest where emphasis should be put in the change strategy.

A strategy for change

The strategy is comprised of answers to certain key questions, such as what to change; how to increase readiness for change; motives for change; where to start; and prerequisites for successful change. The strategy has to give justifiable unequivocal answers. A previous situation analysis, consisting of an identification of the problem and required changes and of an assessment of the readiness for change, usually provides some of the answers. The remainder may depend on the health and socio-economic system of a given country as well as on the prevailing political climate. A pluralistic approach is essential; no single approach can be recommended for all countries and institutions.

What to change and how to increase readiness for change

A situation analysis points to whether it is attitudes (if so, whose attitudes), behaviour, knowledge and understanding, organisation, or ways of work that need to be changed.

An analysis of the readiness and capability for change [$C = (ABD) > X$] can suggest whether one should concentrate on heightening the awareness of the undesirability of current situation, i.e., *"A"*; it can specify the desired state of affairs,

i.e., *"B";* clearly spelling out what needs to be done and how this can be accomplished, i.e., *"D",* or alleviate the fears related to the costs of the suggested activities, i.e., *"X"*.

All of these aspects may need to be covered but their relative importance depends, not only on the situation, but on the target group which one wishes to influence. Useful questions to be put to identify the target groups are: who are the decision makers; who are the people with "clout"; which individuals are most committed to improving the quality of care; who can be depended upon for support; who are the people most likely to oppose a change and what are their arguments; and who are the people who can follow the changes through?

Motives for change

When selling quality assurance to different target groups, one may need to highlight different motives. The authorities and administrators are probably most interested in the social motives, i.e., in the accountability to the society for funds spent to buy health services. The consumers probably emphasise safety. The health care providers, in turn, are likely to be motivated by professional factors such as the desire to be self-correcting and self-regulating, and altruistic motives (World Health Organisation, 1985a).

While it may be completely legitimate to use different motives for different target groups, as they are all valid, one has, however, to be honest. The failure of the American PSRO system can, at least partly, be attributed to the fact that it was sold using different motives: the politicians bought it as a cost-containment mechanism, the health care providers were told that it was a quality assurance mechanism. It is also very important for the change agent to be clear and honest about his own role and motives. Perhaps the most important decision in this respect is whether to be an advocate or a methodologist. Although the temptation to be an advocate, almost a missionary, may be great it may be wiser to leave this role to a key individual in the system who has enough clout to see to it that suggested changes are carried out.

Where to start

In some cases, the top management of the system may be the most appropriate initial target. By starting at the top one may, however, run the risk of establishing a quality control system despised by those whose activities are being controlled rather than a quality assurance system supported by everybody. In any case, the quality assurance activities will have to be legitimated through the explicit approval of the top management.

In other cases, a pilot project may be an effective method to convince everyone that it can be done and that it will yield results.

In some systems, it may be possible to find a sub-system, such as a laboratory or radiology department, which is particularly amenable to introducing quality assurance. Again, in other cases, all concerned may agree that there is a part of the system running on thin ice, i.e. a sub-system which has obvious problems. This would then be a logical starting point. The reward system may be a useful target, particularly when one aims at changing attitude. Finally, one may first wish to create a critical mass requesting change. Such activities are often aimed at the consumers. While consumer support may be essential for the wide acceptance of quality assurance,

consumer orientated activities may entail the risk of turning quality assurance into a populist or political concern.

Prerequisites for change

The above-mentioned WHO study (Vuori, 1982) stated the prerequisites as follows: for the development of quality assurance there must exist a clearly expressed political will. The research community has to pick up leads from this political will and from the health care practices to clarify the concept of quality, to identify factors influencing the quality of health services, and to develop methodologically sound quality assurance methods. The education system has to transmit the knowledge and skills thus gained to the practitioners. It would be advantageous if the practitioners themselves were responsible for implementing the programmes. Finally, the experiences gained in practice have to be fed back to the decision-making process, research and education.

Remember – you have got a friend

A few years ago, a big American bank used to advertise: "Remember – you have a friend at Chase Manhattan." Those implementing quality assurance in Europe also have a friend that they may not have been aware of – the Regional Office for Europe of the World Health Organisation.

The member states of the European region have approved, as a part of their overall health policy goals, a target which requests all member states to build, by 1990, an effective mechanism for ensuring quality of patient care within their health care systems (World Health Organisation, 1985b). Thus both WHO and the member states have not only a green light but an obligation to develop quality assurance. For those active in quality assurance this target is indeed a powerful support.

The WHO's role in the achievement of this target is to assist the member states. The main components of this assistance are: introduction of the concept in countries where it is not known or accepted; development of methods for quality assurance; identification and analysis of ways of organising quality assurance; training for quality assurance; and evaluation of the achievements. So far, the conceptual and methodological issues in quality assurance (Vuori, 1982), principles of introduction of quality assurance (World Health Organisation, 1985a), training for quality assurance (World Health Organisation, 1986) in nursing (World Health Organisation, 1984) and nursing homes (Chambers, submitted for publication) have been dealt with. In addition, training courses in quality assurance have been organised. WHO also sponsors the publication of a European quality assurance newsletter by the Dutch Institute for Quality Assurance in hospitals.

Thus, when developing your quality assurance activities, do remember – you have a friend in WHO.

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A comparative analysis of quality management standards for contract research organisations in clinical trials

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Abstract

Purpose – This article compares and contrasts the main quality standards in the highly regulated pharmaceutical industry with specific focus on Good Clinical Practice (GCP), the standard for designing, conducting, recording and reporting clinical trials involving human participants.

Design/methodology/approach – Comparison is made to ISO quality standards, which can be applied to all industries and types of organisation. The study is then narrowed to that of contract research organisations (CROs) involved in the conduct of clinical trials.

Findings – The paper concludes that the ISO 9000 series of quality standards can act as a company-wide framework for quality management within such organisations by helping to direct quality efforts on a long-term basis without any loss of compliance.

Originality/value – This study is valuable because comparative analysis in this domain is uncommon.

Keywords Pharmaceuticals industry, Product trials, Quality management, Best practice, Standards, Northern Ireland

Paper type Research paper

Introduction

Clinical trials are conducted as part of the drug development and approval process, which is highly regulated. Quality management values have always been central to the industry's success. This article examines pharmaceutical standards including Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP). (A glossary of acronyms used in this article can be found in the Appendix.) Conflicting quality philosophies are investigated before we look at the application of the ISO 9000 standard in the context of contract research organisations (CROs) by comparing ISO and GCP criteria. Finally, industry developments are surveyed by highlighting recent trends towards systems and process control and ISO influences throughout the industry with recommendations being made on implementing quality management practices.

Good practices (GxP)

The International Conference on Harmonisation (ICH) GCP document (referred to as GCP) is:

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> [...] an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

Together with other pharmaceutical "good practices" it is now known as a "GxP". Such standards include Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Distribution Practice (GDP). Baxendale (2004) states:

> [...] the GxPs are statutory requirements imposed on specific industries, generated by governments, with the input of industry and other bodies, but nonetheless minimum requirements for operation in those industries.

Unlike the ISO family of standards, which are voluntary, pharmaceutical good practices are mandatory (see Table I).

GCP is a specialist standard for the "clinical" portion of drug trials; other portions include computer-modelling, laboratory, animal testing and post-marketing studies. As such, the standard can be vague in relation to long-term organisational quality management. It is made up of eight sections that outline GCP principles and requirements for ethics committees, investigators (e.g. hospitals, research units

	GMP	GLP	GCP
History	Established in 1970s. Attainment is the responsibility of senior managers – participation and commitment of staff in all departments and levels, including suppliers is required	Based on the Organisation for Economic Cooperation and Development model for testing chemicals (1981). Legislated in UK in 1997	Harmonised in 1996. Industry shift from QC to QA. Continual improvement is embedded through monitoring, audit and non-compliance correction. Legislated in UK in 2004
Quality management synopsis	"To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of Quality Assurance (QA) incorporating Good Manufacturing Practice (GMP) and thus Quality Control (QC). It should be fully documented and its effectiveness monitored" (GMP, 2004)	"'Quality Assurance Programme': a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with the principles of good laboratory practice" (HMSO, 1999)	"Systems with procedures that assure the quality of every aspect of the trial should be implemented" (EMEA, 1995, 2.13)
Application	Manufacture of medicinal products (including investigational medicinal products used in clinical trials)	Test facilities conducting regulatory studies undertaken to demonstrate the health or environmental safety of new chemical or biological substances	Design, conduct, recording and reporting of clinical trials

Table I.
GxPs/quality management

and investigators), sponsors (usually pharmaceutical companies) and study protocols (documents describing the design and organisation of the trial). In addition to the medical and ethical principles, the following general "quality" concepts are central:

- *Quality management*. Clinical trials should be conducted. . .that are consistent with GCP (EMEA, 1995, 2.1). Systems with procedures that assure the quality of every aspect of the trial should be implemented (ICH GCP 2.13). Investigational products should be manufactured, handled, and stored in accordance with applicable GMP (EMEA, 1995, 2.12).
- *Risk/benefit analysis*. A trial should only be initiated and continued if the anticipated benefits justify the risks (EMEA, 1995, 2.2).
- Specifications: Clinical trials should be . . . described in a clear, detailed protocol (EMEA, 1995, 2.5). Investigational products should be used in accordance with the approved protocol (EMEA, 1995, 2.12)
- *Training*. Each individual conducting a trial should be qualified by education, training, and experience to perform his or her respective tasks (EMEA, 1995, 2.7).
- *Documentation*. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification (EMEA, 1995, 2.10).

GCP background

The pharmaceutical industry is global and clinical trials are conducted on all continents. Developed in the mid-1990s, the ICH GCP guidance document (EMEA, 1995) aimed to harmonise differences recognised between the three main drug producing regions (USA, Japan and Europe). However, variation continued across European nations and therefore two Directives were launched in recent years in an effort to harmonise standards further. Importantly, all trials must still comply with ICH GCP standards as noted by the following extracts:

> The principles of GCP and detailed guidelines in line with those principles shall be adopted and, if necessary, revised to take account of technical and scientific progress . . . (European Commission, 2005a, Article 1, Scope 3).

> The International Conference on Harmonisation (ICH) reached a consensus in 1995 to provide a harmonised approach for Good Clinical Practice. The consensus paper should be taken into account (European Commission, 2005b).

The 2005/28/EC Directive makes inspection mandatory across Europe and extends the trend towards systems and process control:

> These procedures shall include modalities for examining both the study management procedures and the conditions under which clinical trials are planned, performed, monitored and recorded, as well as follow-up measures (European Commission, 2005b, Article 26).

Quality philosophies

The GCP approach is still relatively new compared to GMP and other quality standards. It does not define what is meant by a quality management system

(QMS) and perhaps because of this, quality assurance (QA) systems may be based on the implementation of standard operating procedures (SOPs). Tielemans (2004) notes:

> SOPs are an important part of a quality system, but a collection of SOPs does not equal a quality system.

The GCP method is, however, strongly rooted in modern quality management theory. This is demonstrated through a full comparison with ISO 9001:2000 (see Table II). Meanwhile, Gittelson (1996) writes that although such GxPs, including GCP, recognise the importance of process control, they are:

> [. . .] too narrowly construed to provide universal guidance to the development of a quality assurance assessment plan for all the systems and subsystems involved in the conduct of regulated clinical and non-clinical research.

Although ISO accreditation may not be typical within organisations conducting the clinical portion of drug trials, clients often expect research staff to follow such standards in relation to training and resource management. This is now more crucial in 2006 following the introduction of mandatory inspection noted earlier. In fact Sweeney (1994) suggested:

> Incorporating the ISO requirements into quality assurance systems creates an opportunity to provide a better product within a well-defined quality management framework.

The clinical research standards framework is indeed much wider than GCP. For example, there are countless ICH documents, EU and US industry guidance, and in the UK there are guidelines produced by the Association of the British Pharmaceutical Industry (ABPI). This is not an exhaustive or fixed list as noted by the recent introduction of 2005/28/EC in April 2005. With such a variety of standards making up the compliance framework, it is important to assess whether these offer a common or conflicting view of what is meant by quality management. For example in GCP, QA personnel are expected to be operationally independent by providing advice, but being careful not to make decisions for the operational group. In GMP, QA staff are expected to set standards and it is the quality control (QC) personnel who are independent. In fact where GCP is concerned, Visschedijk-Brinkman (2004) writes:

> QC is not a job, but part of the job responsibilities of each employee.

Therefore, this is the opposite of Oakland's (2004) theory that many quality approaches talk the same language, but just use different dialects. In this instance, the clinical and manufacturing practices appear to use the same dialects but vary in scope (see Table III).

Russell (2004) affirms:

> These codes [GCP and GMP] are different [. . .] with different ideas and philosophies.

He explains that in clinical trials, which are often project-based experiments that:

> [. . .] there is not the continuity to allow trending [i.e. establish predictive patterns] or the time to build up experience and knowledge about the process.

ICH GCP (CPMP/ICH/135/95) ICH Topic E6	ISO 9001:2000(E)
Introduction An international ethical and scientific *quality standard* for designing, conducting, recording and reporting trials that involve the participation of human subjects	International *Standard for Quality* Management Systems 1.1 This International Standard specifies requirements for a quality management system where an organisation a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements
Introduction This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.	1.2. Application All requirements of this International Standard are generic and are intended to be applicable to all organisations, regardless of type, size and product provided
Framework: Sponsor CRO Investigator Subjects Regulatory Authority Ethics committee	3. Terms and Definitions Supplier Organisation Customer
2. Principles of ICH GCP 2.1 Clinical trials should be conducted in accordance with the ethical principles … Declaration of Helsinki, … GCP and the appropriate regulatory requirement(s)	7.2.1 The organisation shall determine c) statutory and regulatory requirements related to the product 7.3.2 These inputs shall include b) applicable statutory and regulatory requirements
2.6 A trial should be conducted in compliance with the protocol	7.2.1 The organisation shall determine a) requirements specified by the customer, including delivery and post-delivery activities
1.44 Protocol A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial	
2.8 Each individual involved in conducting a trial should be qualified by education, *training,* and experience to perform his or her respective task(s)	6.2.1 Personnel performing work effecting product quality shall be competent on the basis of appropriate education, *training,* skills and experience
2.10 All clinical information shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification (4.9, 5.5.4)	4.2.4 Control of Documents: Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records
2.13 *Systems* with procedures that assure the *quality* of every aspect of the trial should be implemented	4.1 The organisation shall establish, implement and maintain a *Quality Management System* and continually improve its effectiveness in accordance with the requirements of this International Standard
3.1.3 The IEC should consider the qualifications of the investigator … by a CV and any other relevant documentation	6.2.2 The organisation shall e) maintain appropriate records of education, training, skills and experience
3.3.7 Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IEC approval	8.3 The organisation shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery
4.5.2 The investigator should not implement any *deviation* from, or changes of the protocol without agreement by the sponsor and review and documented approval/ favourable opinion …	7.5.2 The organisation shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring and assessment. This includes any processes where *deficiencies* become apparent only after the product is in use or the service has been delivered
4.5.4 The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/ IEC approval/favourable opinion	

Table II.
GCP/ ISO comparison

(*continued*)

ICH GCP (CPMP/ICH/135/95) ICH Topic E6	ISO 9001:2000(E)
4.1.1 The investigator should be qualified by education, training and experience …	5.5.1 Top management shall ensure that responsibilities and authorities are defined and communicated within the organisation
4.1.5 The investigator should maintain a *list of appropriately qualified persons* to whom the investigator has delegated significant trial-related duties	6.2 *Human Resources*
4.2.3 The investigator should have available an adequate number of qualified staff …	6.2.1 Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience
4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions	6.2.2 The organisation shall a) determine the necessary competence for personnel performing work affecting product quality b) provide training or take other actions to satisfy these needs d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives e) maintain appropriate records of education, training, skills and experience
5.18.4 Monitor's Responsibilities n) Informing the investigator of any CRF entry error, omission, or illegibility. The monitor shall ensure that appropriate corrections, additions, or detections are made, dated, explained (if necessary), and initialled by the investigator or by a member of the investigator's trial staff who is authorised to initial CRF changes for the investigator. The authorisation should be documented	7.2.3 *Customer Communication* The organisation shall determine and implement effective arrangements for communicating with customers in relation to: a) product information b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints
4.4 Communication with the IEC 4.5	8.5.2 *Corrective Action* The organisation shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered
Compliance with Protocol 4.5.1 The investigator/ institution should conduct the trial in compliance with the protocol agreed by the sponsor and, if required, by the regulatory authorities and which was given approval/favourable opinion by the IRB/ IEC	8.3 Control of nonconforming product Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained
4.11 Safety Reporting	8.3 b) by authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
4.12 Premature Termination or Suspension of a Trial	7.3.7 *Control of* design and development *changes* The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered
4.5.2 The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and review and documented approval/favourable opinion …	7.2.2 Where product requirements are changed, the organisation shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements
4.5.3 The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol	
4.5.4 As soon as possible, the implemented deviation or change, the reasons for it, and if appropriate the proposed *protocol amendments* should be submitted: to the IRB/ IEC … the sponsor … the regulatory authority	
4.8 Informed Consent of Trial Subjects	
4.8.2 The written informed consent form and any other written information to be provided to subjects should be revised whenever important *new information* becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information should receive the IRB/IEC's approval/ favourable opinion in advance of use	
5.13.5 If significant *formulation changes* are made in the investigational or comparator product(s) during the course of clinical development, the results of any additional studies of formulated product(s) needed to assess whether changes would significantly alter the PK profile of the product should be available prior to use of the new formulation in clinical trials	
1.45 *Protocol Amendment* A written description of change(s) to or formal clarification of a protocol	

(*continued*)

Table II.

ICH GCP (CPMP/ICH/135/95) ICH Topic E6	ISO 9001:2000(E)
4.2 *Adequate Resources* 4.2.3 The investigator should have … adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely 4.6.4 The investigational product(s) should be stored as specified by the sponsor (see 5.13.2 and 5.14.3) and in accordance with applicable regulatory requirement(s)	6.3 *Infrastructure* The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities 6.4 Work Environment The organisation shall determine and manage the work environment needed to achieve conformity to product requirements
4.9 *Records and Reports* 4.9.1 The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports	4.2.4 *Control of Records* Records shall remain legible, readily identifiable and retrievable
4.9.4 The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial … The investigator/institution should take measures to prevent accidental or premature destruction of the documents	6.3 Infrastructure The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements 7.5.5 Preservation of the product The organisation shall preserve the conformity of product during internal processing and delivery to the intended destination
4.9.6 The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution 5.6.3 The sponsor should obtain the investigator's/ institution's agreement: 5.2.2 Any trial-related duty and function that is transferred to an assumed by a CRO are retained by the sponsor	7.2.3 Customer Communication The organisation shall determine and implement effective arrangements for communicating with customers in relation to b) … contracts …
5.1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs	4.1 The organisation shall establish, document, implement and maintain quality management systems and continually improve its effectiveness in accordance with the requirements of this International Standard
5.2.1 A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control	4.2.1 The quality management system, documentation shall include c) documented procedures
5.1.3 QC should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly	7.1 Planning of product realisation In planning product realisation, the organisation shall determine the following, as appropriate: a) quality objectives and requirements of the product c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance 8.1 Measurement, analysis and improvement
5.1.4 Agreements, made by the sponsor with the investigator/ institution and any other parties involved with the clinical trial, should be in writing, as part of the protocol or in a separate agreement 5.2.3 Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor	7.2.1 Determinations of requirements related to the product The organisation shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities b) requirements not stated by the customer but necessary for specified or intended use, where known
5.2.3 Any trial-related *duties and functions not specifically transferred* to and assumed by a CRO are retained by the sponsor 5.7 Allocation of Duties and Functions Prior to initiating a trial, the sponsor should define, establish, and allocate all trial-related duties and functions	7.2.2 Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organisation before acceptance 4.1 Where an organisation chooses to outsource any process that affects product conformity with requirements, the organisation shall ensure control over such process. Control of such *outsourced processes* shall be identified within the quality management system

Table II.

(*continued*)

ICH GCP (CPMP/ICH/135/95) ICH Topic E6	ISO 9001:2000(E)
5.4 *Trial Design* 5.4.1 The sponsor should utilise qualified individuals (e.g. bio-statisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRFs and planning the analyses to analysing and preparing interim and final clinical trial reports 5.4.2 For further guidance: Clinical Trial Protocol and Protocol Amendment(s), the ICH Guideline for Structure and Content of Clinical Study Reports, and other appropriate ICH guidance on trial design, protocol and conduct	7.3 *Design & Development* 7.3.1 The organisation shall plan and control the design and development of product. The organisation shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility 7.3.2 Design and development inputs These inputs shall include c) applicable statutory and regulatory requirements
5.5.3 When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should: a) Ensure and document that the electronic data processing system(s) conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation) f) Maintain adequate backup of the data	6.3 Infrastructure The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable b) process equipment (both hardware and software)
5.5.5 The sponsor should use an unambiguous subject identification code that allows identification of all data and observations with processed data 5.13.1 The sponsor should ensure that the investigational product(s) is characterised as appropriate to the stage of development of the product(s), is manufactured in accordance with any applicable GMP, and is coded and labelled in a manner that protects the blind, if applicable 5.13.4 In blinded trial, the coding system for the investigational product(s) should include a mechanism that permits rapid identification of the product(s) in case of medical emergency, but does not permit undetectable breaks of the blinding	7.5.3 Identification and traceability Where appropriate, the organisation shall identify the product by suitable means throughout product realisation
5.6.2 Before entering an agreement with an investigator/ institution to conduct a trial, the sponsor should provide the investigator/institution(s) with the protocol and an up-to-date Investigator's Brochure, and should provide sufficient time for the investigator/ institution to review the protocol and information provided	7.2.2 Review requirements related to the product The organisation shall review the requirements related to the product. This review shall be conducted prior to the organisation's commitment to supply a product to the customer
5.10 Notification/submission to a Regulatory Authority Before initiating the clinical trial(s), the sponsor and the investigator, if required by the applicable regulatory requirement(s) should submit any required application(s) to the appropriate authority(ies) for review, acceptance, and/or permission (as required by the applicable regulatory requirement(s)) to begin the trial(s)	8.2.4 Monitoring and Measurement of product Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by the relevant authority and, where applicable, by the customer
5.12 Information on Investigational Product(s) 5.12.2 The sponsor should update the Investigator's Brochure as significant new information becomes available	7.2.2 Where product requirements are changed the organisation shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements
5.13 Manufacturing, Packaging, Labelling, and Coding Investigational Product(s) 5.13.1 The sponsor should ensure that the investigational product(s) is characterised as appropriate to the stage of development of the product(s), is manufactured in accordance with any applicable GMP, and is coded and labelled in a manner that protects the blind, if applicable 5.13.2 The sponsor should determine, for the investigational product(s) acceptable storage temperatures, storage conditions (e.g. protection from light) 5.13.3 The investigational product(s) should be packaged to prevent contamination and unacceptable deterioration during transport and storage	7.5.5 Preservation of product The organisation shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection 7.6 Control of monitoring and measuring devices The organisation shall determine the monitoring and measurement to be undertaken
5.14 Supply and Handling Investigational Product(s) 5.14.1 The sponsor is responsible for supplying the investigator(s)/institution(s) with investigational product(s) Documents are no longer needed (4.9.4, 5.5.12)	7.5.4 Customer Property The organisation shall exercise care with customer property while it is under the organisation's control or being used by the organisation

(*continued*)

Table II.

ICH GCP (CPMP/ICH/135/95) ICH Topic E6	ISO 9001:2000(E)
5.15 Records Access 5.15.1 The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) provide direct access to source data/ documents for trial-monitoring, audits, IRB/IEC review, and regulatory inspection 5.6.3 The sponsor should obtain the investigator(s)/ institution(s) agreement: to retain the trial related essential documents until the sponsor informs the investigator these	
5.18 Monitoring 5.18.4 Monitor's Responsibilities a) acting as the main line of communication between the sponsor and the investigator 8.3.11 Relevant communications other than site visits – letters – meeting reports – notes of telephone calls	7.2.3 Customer Communication The organisation shall determine and implement effective arrangements for communicating with customers
5.18.4 Monitor's Responsibilities b) verifying that the investigator has adequate qualifications and resources and remain adequate throughout the trial period, that facilities, including laboratories, equipment, and staff, are adequate to safely and properly conduct the trial	7.6 Control of monitoring and measuring devices Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national standards; where no such standards exist, the basis used for calibration or verification shall be recorded 4.1 Where an organisation chooses to outsource any process that affects product conformity with requirements, the organisation shall ensure control over such process. Control of such outsourced processes shall be identified within the quality management system
5.18.4 Monitor's Responsibilities n) Informing the investigator of any CRF entry error, omission, or illegibility. The monitor shall ensure that appropriate corrections, additions, or detections are made, dated, explained (if necessary), and initialled by the investigator or by a member of the investigator's trial staff who is authorised to initial CRF changes for the investigator q) communicating deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations	8.3 Control of nonconforming product The organisation shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity 8.5.2 Corrective Action The organisation shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered 8.5.3 Preventive action The organisation shall determine the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems
5.18.6 *Monitoring Report* Reports should include a summary of what the monitor reviewed and the monitor's statements concerning the significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken and/or actions recommended to secure compliance	8.2.1 Customer Satisfaction As one of the measurements of the performance of the quality management system, the organisation shall monitor information relating to *customer perception* as to whether the organisation has met requirements
5.19 Audit 5.19.1 Purpose The purpose of a sponsor's *audit*, which is independent of and separate from routine monitoring or quality control functions, should be to evaluate trial conduct and compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements	8.2.2 Internal audit The organisation shall conduct *internal audits* at planned intervals to determine whether the quality management system a) conforms to planned arrangements (see 7.1), to the requirements of the International standard and to the quality management system requirements established by the organisation, and b) is effectively implemented and maintained
5.19.2 Selection and Qualification of Auditors The sponsor should appoint individuals, who are independent of the clinical trials/ systems, to conduct audits	8.2.2 Internal audit Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work

Table II.

(*continued*)

ICH GCP (CPMP/ICH/135/95) ICH Topic E6	ISO 9001:2000(E)
5.19.3 Auditing Procedures The sponsor should ensure that the auditing of clinical trials/ systems is conducted in accordance with the sponsor's written procedures on what to audit, how to audit, the frequency of audits, and the form and content of audits reports	8.2.2 Internal audit An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure
5.20 *Non-compliance* 5.20.1 Non-compliance with the protocol, SOPs, GCP, and/or applicable regulatory requirement(s) by an investigator/ institution, or by member(s) of the sponsor's staff should lead to prompt action by the sponsor to secure compliance	8.3 *Control of nonconforming product* The organisation shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity
6 Clinical Trial Protocol and Protocol Amendment(s) 1.44 Protocol *A document that describes the objective(s), design, methodology*, statistical considerations and *organisation of a trial*	7 Product realisation 7.1 Planning of product realisation 7.2.1 *Determination of requirements related to the product* The organisation shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities
6.1 General Information The contents of the protocol should generally include the following topics 6.15 Publication Policy 7 Investigator's Brochure 7.2 General Considerations	7.5.4 Customer property The organisation shall exercise care with customer property while it is under the organisation's control or being used by the organisation. The organisation shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product
7.2.2 Confidentiality Statement The sponsor may wish to include a statement instructing the investigator/ recipients to treat the IB as a confidential document for the sole information and use of the investigator's team and IRB/IEC	
8 Essential Documents 8.1 Introduction These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with standards of Good Clinical Practice and with all applicable regulatory requirements	4.2.4 Control of Records Records shall be established and maintained to provide evidence to requirements and of the effective operation of the quality management system

Table II.

Furthermore, he suggests that QA is not only about preventing things from going wrong in GMP, but also checking for compliance in GCP.

The GCP/GMP Quality Assessment and Improvement Comparison (Table III) highlights some of the differences that support Russell's (2004) view that "continuity and trends are more difficult to measure and manage" in clinical trials where specifications and processes are often a one-off. As GMP has a long-term focus, it includes such language as regular review, re-validation, monitoring effectiveness and periodically assessed. In GCP, specifically early drug development, clinical trial's project-nature does not always provide time for these activities. However, the terms "amendment" and "revision" are used. The need for continual improvement is, therefore, recognised in relation to study protocols as new information becomes available, for example. Overall, our comparison illustrates that quality improvement is central to both GCP and GMP, however, much more guidance is provided for the latter standard.

CROs and ISO

Now that the GxPs have been examined in relation to quality management, the focus turns specifically to the ISO series of quality standards and contract research

Table III.
GCP/GMP quality assessment and improvement comparison

Quality factors	GCP	GMP
Timeframes	Project-based, campaign style, short term, e.g. proof of concept	Long term, remote start and end points
Quality management/approaches	*QA: Compliance*	*QA: Prevention – covers all matters that influence the quality of the product*
	5.19.2 Individuals who are independent	*QC: Independent*
	QC: Responsibility of people carrying out the work – operational techniques and activities. Built-in to operational activities	2.3 The heads of production and quality control must be independent from each other.
	1.47 Quality Control: The operational techniques and activities undertaken within the quality assurance system to verify the requirements for quality of the trial-related activities have been fulfilled	Chapter 6 The independence of quality control from production is considered fundamental to the satisfactory operation of quality control
	5.1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly	
	Audit – Purpose	Chapter 9 Self-inspection
	5.19.1 To evaluate trial conduct and compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements	Self inspections should be conducted in order to monitor the implementation and compliance with GMP principles and to propose necessary corrective measures
Continual improvement	1.3 Amendment (amend as you go along)	Change control, no change without approval
		Consistency
	5.20.1 Non-compliance … should lead to prompt action to secure compliance	5.24 Processes and procedures should undergo periodic critical re-validation to ensure that they remain capable of achieving the intended results
	7.1 The investigators brochure should be reviewed at least annually and revised as necessary. More frequent revision may be appropriate depending on the stage of development and the generation of relevant new information	8.15 The effectiveness for the arrangements for recalls should be evaluated from time to time
Processes	*Flexibility needed*	Chapter 1 (1.3 ii) critical steps of manufacturing processes and significant changes to the process are validated
	Early stages of research/processes change as you go along due to experimental nature, e.g.	
	7.1 It is expected that the type and extent of information available will vary with the stage of development	5.23 Significant amendments to the manufacturing process, including any change in equipment or materials, which may affect product quality and/or the reproducibility of the process, should be validated
SOPs	1.55 Detailed, written instructions to achieve uniformity of the performance of a specific function. Try to keep open/ flexible to cover all eventualities	1.3 (iv) instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided 4.1 Procedures give directions for performing certain operations

(*continued*)

Table III.

Quality factors	GCP	GMP
Complaints/quality defects	4.5.2 The investigator should not implement any deviation from, or changes of the protocol 4.5.3 The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol 4.9.2 Data reported on the CRF … should be consistent with the sources documents or the discrepancies explained 5.18.6 Monitoring Report c) Reports should include … monitor's statements concerning significant findings/facts, deviations and deficiencies … 5.20.1 Non-compliance with the protocol, SOPs, GCP and/or applicable regulatory requirements by an investigator/institution, or by members of the sponsor's staff should lead to prompt action by the sponsor to secure compliance	1.3 (vi) any significant deviations are fully recorded and investigated (x) complaints about marketed products are examined, the cause of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent recurrence 1.4 (iv) records are made…which demonstrate that all the required…inspecting procedures were actually carried out. Any deviations are fully recorded and investigated (vi) records are made of the results of inspection . . .an assessment of deviations from specified procedures 4.26 There should be written procedures and the associated records of actions taken or conclusions reached, where appropriate for: complaints 5.15 Any deviation from instructions or procedures should be avoided as far as possible. If a deviation occurs, it should be approved in writing by a competent person, with the involvement of the Quality Control Department when appropriate 5.20 Measures to prevent cross-contamination and their effectiveness should be checked periodically according to set instructions 8.1 A person should be designated responsible for handling complaints and deciding the measure to be taken 8.2 There should be written procedures describing the action to be taken 8.5 All the decisions and measures taken as a results of a complaint should be recorded and referenced
Trending	5.20.2 If the monitoring and/ or auditing identifies serious and/ or persistent non-compliance on the part of an investigator/ institution, the sponsor should terminate the investigator's/institution's participation in the trial.	Chapter 1 Quality Management: system of quality assurance – its effectiveness monitored 1.2 (ix) there is a procedure for self-inspection and/or quality audit which regularly appraises the effectiveness and applicability of the quality assurance system 1.3 (i) all manufacturing processes are … systematically reviewed 2.9 Continuing training should be given, and its practical effectiveness should be periodically assessed 8.6 Complaints records should be reviewed regularly for any indication of specific or recurring problems requiring attention and possibly the recall of [marketed] products

organisations (CROs). Unlike many other manufacturing and service industries, where ISO accreditation is viewed as a necessity, the pharma industry based its success on strict compliance with appropriate GxPs. It is already highly regulated and quality management has always been seen as integral to drug development and patient safety. However, Sweeney (1994) outlines why ISO principles are relevant to organisations involved in the conduct of clinical trials. He discusses how:

> [. . .] from the perspective of a CRO [. . .] inspected by many clients [. . .] while each individual company may not seek all of the requirements of ISO 9001 [. . .] the collective requirements of the different sponsors add up to a close equivalent of ISO 9001.

ISO/GCP comparison

Sweeney's (1994) demonstrates how contract review, document control and corrective action are central to both ISO and GCP. For example, ISO outlines the need for document control, as documents must be approved before use. The GCP method, expresses the same need regarding SOPs, protocols, informed consent forms (ICFs) and investigator's brochures (IBs). Measurement, Analysis and Improvement are also important to both; GCP advocates the amendment process, for regulatory applications and documents, while ISO focuses on corrective and preventative actions. The ISO principles can be compared to clinical trial requirements:

- *Focus on your customers*. Customers include study sponsors, regulators and patients.
- *Provide leadership*. Sponsors take overall responsibility for the trial. Investigators are responsible for trial conduct at the site.
- *Involve your people*. Training is important – all staff involved must be adequately informed.
- *Use a process approach*. Trial processes include consent, randomisation and data processes.
- *Take a systems approach*. Quality assurance and quality control systems are advocated.
- *Encourage continual improvement*. Amendments and annual reporting are central themes.
- *Get the facts before you decide*. Risk/ benefit analysis is encouraged throughout.
- *Work with your suppliers*. CROs are often used by sponsors to carry out trial functions.

Table II, a ICH:GCP/ISO line-by-line comparison demonstrates that:

> [. . .] implementing ISO 9001 in a clinical research environment doesn't involve drastic changes in the operational work. Strict compliance with GCP goes a long way towards working according to general quality system standards (Tielemans, 2004).

There are clear training, handling deviations/deficiencies, qualifications, compliance, managing change, resources, records/reports, outsourcing, audit and customer requirements parallels. Sweeney (1994) concludes:

> Incorporating the ISO requirements into quality assurance systems creates an opportunity to provide a better product within a well-defined quality management framework.

Furthermore, Schnurr *et al.* (2005) states:

> [...] adapting a widely acknowledged system like ISO 9001 [...] demonstrates [an organisation's] accredited commitment to consistent quality.

Industry developments

The industry regulators have been examined to ascertain whether ISO 9000 standards are relevant for clinical trials. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) is currently aiming for ISO 9001 registration for all operational activities. To date, the Agency's Inspection and Standards Division and Enforcement and Intelligence Group have such a fully documented quality management system. It must also be noted that all Inspectors (including GMP and GCP) are ISO certified auditors. The European Medicines Agency (EMEA, 2004) describes its quality system as:

> An integrated quality management system to continually improve effectiveness in line with the requirements of ISO 9001:2000, the regulatory framework, the framework financial regulation and the staff regulations.

Meanwhile the US authority, the Food and Drugs Administration (FDA) has experience mapping its activities according to ISO 9001:2000 elements, which ensures that its systems contain the necessary essentials. A risk management task force found in 1999:

> [...] that, overall, although some elements of FDA's quality control system could more closely comply with the proposed ISO framework, the key elements of the ISO QA/QC system are in place and are regularly followed (US Department of Health and Human Services, FDA, 1999).

Furthermore, in 1996 the ISO 9001:1994 standard was compared to GMPs and quality system regulations. In a question and answer document relating to medical device quality systems and ISO, the FDA wrote:

> It is easier and less confusing for industry to develop a quality system if the quality system requirements of various countries are similar (ISO, 2000).

Quality auditing

In the clinical trials arena, site qualification audits and regulatory inspections include facility tours, interviews with representatives from all departments, examining document control systems, training and outsource management. Such activities are similar to ISO certification audits. Sweeney (1994) notes:

> A regulatory authority [...] wants to see how a company is structured, how responsibilities are defined, and how the organisation functions [...] to see quality built into a process and not tested in after the event.

When ICH GCP (EMEA, 1995) was developed in 1995/1996, it had been proposed that auditing guidelines were issued. This proposition was not pursued, but a working group composed of senior auditors from pharmaceutical companies and CROs published a guidance document on GCP audits (ENGAGE, 1997). However, this document has now been updated to reflect new trends in quality management. For example, definitions from ISO 19011:2002 (ISO, 2002) have been incorporated into the new guideline, which was recently published in the *International Journal of Pharmaceutical Medicine* (Cheetham, 2005). This update was necessary as:

> [...] many independent Quality Management departments have now been active for ten or more years and there has been a resultant increase in experience and expertise in the area of Good Clinical Practice (GCP) compliance auditing.

Furthermore Cheetham (2005) states:

> [...] new International Organisation for Standardisation (ISO) Guidelines, the 9000:2000 series, have been published in which there has been a trend away from a system based on quality standards to one based on quality management.

This trend has also been reflected by the British Association for Research Quality Assurance (BARQA) who, in 2005, amended their objectives by removing the term "quality assurance", and replacing it with "quality and compliance". Quality assurance means different things to different people as discussed in the GCP/GMP comparison, while "quality and compliance" are central to all the GxPs, and incorporate both QC and QA.

Conclusions and recommendations

Pharmaceutical quality standards have been compared and contrasted, and in the arena of project-based clinical trials, adopting the internationally recognised ISO series of standards could offer consistency to CROs conducting project-based activities. By directing quality efforts on a long-term basis, ISO 9001:2000 could act as a company-wide framework for quality management without any loss of compliance. The pharma industry is highly regulated and its quality management values are already firmly rooted. However, the conflicting philosophies of GMP and GCP, for example, may be rationalised under the ISO umbrella. There has been a move away from "quality assurance" to "quality management" in recent years and other industry developments demonstrate ISO influences in relation to drug development. The GCP audit guideline (Cheetham, 2005) update and implementation of mandatory clinical trials inspections based on system and process review, mean that an organisational approach to quality is vital. The ISO system would not involve radical changes for a CRO, but the costs and benefits should be examined closely before embarking on such campaigns. The GCP standard alone may be narrow in focus, but the range of standards and compliance framework under which trials are conducted, already ensures patient safety. Perhaps ISO could be used as a gap analysis tool, as demonstrated by the FDA (US Department of Health and Human Services, FDA, 1999). By comparing an organisation's quality management system against the ISO standard, it may be possible to identify missing elements. It remains, however, whether CROs follow the MHRA's lead and opt for full ISO implementation.

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Appendix. Glossary

ABPI	Association of the British Pharmaceutical Industry.
BARQA	British Association for Research Quality Assurance.
CRF	Case report form.
CRO	Contract Research Organisation.
EMEA	European Medicines Agency.
FDA	Food and Drugs Administration.
GCP	Good clinical practice.
GDP	Good distribution Practice.
GLP	Good Laboratory practice.
GMP	Good manufacturing practice.
GxP	Good practices.
IB	Investigators brochure.
ICF	Informed consent form.
ICH	International Conference on Harmonisation.
IEC	Independent Ethics Committee.
IRB	Institutional Review Board.

ISO	International Standards Organisation.
MHRA	Medicines and Healthcare Products Regulatory Agency.
QA	Quality assurance.
QC	Quality control.
SOP	Standard operating procedure.

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Health care performance and accountability

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Abstract

Purpose – The purpose of the paper is to examine health care performance and accountability.

Design/methodology/approach – A strategic view of how quality assurance fits into other initiatives aimed at bringing about improvements in health care is offered in the paper.

Findings – The paper finds that the task of defining the way in which health care can be most efficiently and effectively delivered is the concern of all health care staff. Aims, should be clarified, performance criteria and measures agreed on and, wherever possible and appropriate standards set up. Management also has the responsibility of ensuring the consistency and coherence of the many different activities that contribute to the aim of good health care.

Originality/value – The paper provides useful information on the planning and performance of quality assurance in health care.

Keywords Health services, Quality assurance, Performance management, Management accountability

Paper type Viewpoint

Introduction

The growing interest in all aspects of health care performance both among those who provide care and among the public at large is finding expression in many different ways. The wider public debate is being conducted in highly charged and generally simplified terms in the press and elsewhere, though the proposition underlying the discussion is by now well known, if not always kept in view: infinite demand and finite resources require careful consideration of priorities.

It is at the next stage of debate, when questions of means and ends are raised, that controversy begins. If the public concern is focused on service limits and shortages this is understandable; as is the oft-heard corollary that the solution lies in more resources. Consumers are well placed to see the simple connection between input and output, and in some instances that is indeed the only analysis necessary to understand a service shortfall.

Health service workers, especially those at the sharper end of service delivery, also have a keen and of course more sophisticated appreciation of the adequacy of available resources. They have responded well, though perhaps with diminishing appetite, to calls for greater efficiency, usually expressed in terms of higher output for a given input, or in saving in one programme in order to pay for advance in another. It is partly reaction to the effects of resource shortfalls and the pressures of cost saving that have heightened interest in the quality of health care, and especially in the definition and measuring of outcome.

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This interest is reflected in many different initiatives to measure performance or to set standards. There is, though, an evident danger in this rich diversity of activity. It is that different views of what constitutes good performance or quality will lead to conflicting objectives and diverging policy aims. Management particularly needs to be aware of this danger and to take steps now to see that the potential value of this new awareness is not dissipated.

Equally, there are strong reasons for ensuring consistency between performance and planning; a conjunction which is generally missing from current organisational models. These issues are discussed in the remainder of this article and an approach is proposed which could help to avoid such problems and reap the full value of the burgeoning interest in performance.

Planning and performance – the need for a unified approach

The National Health Service was primarily concerned with inputs for the first 30 years of its existence. Planning to replace a largely Victorian (or earlier) legacy of buildings to build up the skilled staffing and to provide equitable levels of and access to health care were the necessary preoccupations of the Service until the late 1970s.

Concern for efficiency began to emerge in the 1960s as work study and operational research were applied to health service processes. Looking at outcomes has been until recently a more sporadic activity, featuring morbidity or mortality reviews for example, but not generally linked in any way to the management or overall assessment of the efficacy of health care.

As interest in all aspects of health care performance begins to grow there is a need to ensure that all activity aimed at demonstrating the efficiency or effectiveness of the Service is brought into account at an appropriate level in building up the complete picture of health care delivery in a unit or health district. Management therefore needs to identify systems and channels that will ensure that planning and performance activity flow from common service policies and are directed at securing or supporting consistent and agreed service aims.

Models of planning in the health service are generally represented as closed cycles where the plan begets feedback, is modified in consequence and the cycle is renewed. Performance activity appears to be developing according to a similar "closed-loop" model, or perhaps worse as a series of unrelated closed loops each representing one aspect of performance enquiry.

Planning and performance are elements of an operational process which is better represented by a continuous wave (see Figure 1).

The operational consequences and value of integrating the activities of planning and performance are demonstrated in the final section of this article.

In search of performance

The search for ways to improve the performance of health services has resulted in a number of initiatives most of which have been designed to respond to particular aspects of the operation and delivery of health care ranging from straight value for money surveys through cost saving programmes to the pursuit of indicators of efficiency and output.

The Rayner Scrutiny programme selected specified subjects in each of which current practice was examined in detail and alternative, more cost effective, modes of operation proposed. The competitive tendering programmes have had a similar orientation, with the major benefit being seen as providing the required service at

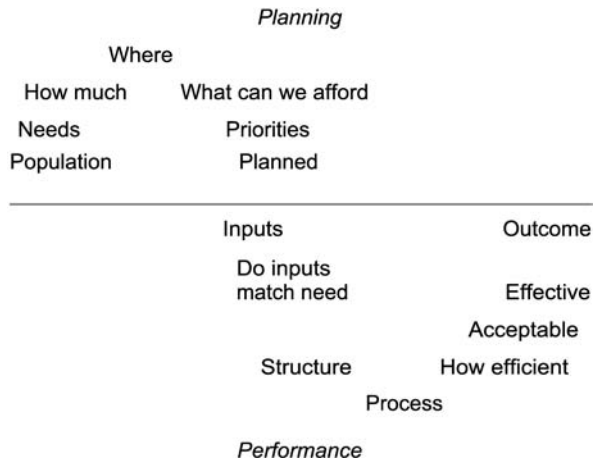

Figure 1.
Planning and performance

lower cost. There is though a more enduring benefit of both these programmes which has not been widely recognised. In order to propose changes to existing systems and procedures or to describe the required operation for competitive tenderers it is necessary to draw up a detailed specification of the task to be undertaken, the objective to be achieved and the standard to be met. What more specific mapping of the route to an efficient service could any manager wish for? Cost improvement programmes have similarly focused attention on doing more for the same (or less) money, but have also helped to encourage the understanding that it is necessary for redundant or ineffective services to give way to new.

The construction of performance indicators has now reached the status of a cottage industry. As indicators proliferate in ever more ingenious combinations the need to give thought to the questions they can most usefully address becomes urgent. There is no doubt though that used appropriately, and preferably in combination with other analytical modes, they are a useful addition to the performance review diagnostic kit.

The quest for outcome – quality assurance

Moving the performance debate towards a concern for outcome has considerable attraction for most health care providers. It offers the opportunity of a client-centred approach, distanced from the narrow concern for cost savings. The theme has come to be represented by the term quality assurance, under which banner a great and growing variety of activity concerned with many aspects of and approaches to health care delivery is now taking place. In the Wessex Region the 1987 Regional Plan contained the Regional Health Authority's (RHA) first working definition of quality assurance:

> Quality Assurance is agreeing standards of care and service to be provided and assuring those standards by regular measurement of performance and initiating appropriate change where this is indicated.

The first *Wessex Regional Plan for Quality Assurance* was published in July 1987. It offered an extended definition of the concept which took account of the resource constraints within which a service must operate and acknowledgement the importance of identifying the action required to remedy problems affecting the quality of service. Unlike the earlier definition it did not restrict the process to the production of service

criteria and standards but recognised the possibility of a variety of approaches to evaluating health care.

Quality assurance is a process which provides for the systematic evaluation of health care taking account of the views of the recipient of services in order to:

- assess and demonstrate the output and outcomes of such services;
- show they are being delivered within the resources available and meet agreed standards where these have been set; and
- identify the action required to remedy problems affecting the quality of service.

The first District Quality Assurance Plans in Wessex were completed by November 1987. They address, through programmes of different size and composition, the issues of effective health care activity. In most cases there is a declared wish to start assessing outcome, while recognising the difficulty in many cases of pinning down tangible criteria and measures of effectiveness.

In most health authorities quality assurance managers have been appointed and there is no doubt that they have been the wellspring of the expanding interest in performance issues. But it is important to assert that performance, and especially a concern for quality, must be the direct responsibility of all involved in managing or delivering health care. This can best be achieved by an approach which recognises the many facets of good performance, all of which will need to be related if truly efficient and effective services are to be provided.

Achieving coherence in planning and performance activity

There is thus a growing web of performance related initiatives, the products of which need to be drawn together, at an appropriate point, to provide a coherent overall picture of health service performance. The consistency of the relationship between this and planning decisions and directions needs also to be demonstrated in the same context.

The problem is however that "web" is an inappropriate analogy for what in many places is becoming a tangled skein of activities. Management now needs to establish a framework within which all these approaches can be related and deployed in a more coherent, way to develop a consistent statement of what business we are in and how well we are doing in it. Excellence in performance – providing a service of high quality – lies in all of the aspects of service operation and delivery which these various techniques separately address.

Following Donabedian three dimensions of a health care system are now generally identified, all of which need to be considered when evaluating performance. They are:

(1) *Input (or structure)*. The resources of people, skills, money, buildings, equipment and organisation needed to provide a given service.

(2) *Process*. The systems and activities through which inputs are brought to bear operationally in the provision of care, leading to a measurable amount (or output) of health care provision.

(3) *Outcome*. The observed or measured effect of health care and treatment on individuals or populations.

Most of the techniques or performance initiatives touched on above address issues of process with tentative forays in the direction of outcome. Input tends to be left on one side, perhaps on the basis that we have spent long enough thinking about it and indeed

have a whole planning system devoted to its continued nourishment. Indeed one product of planning which tends to be forgotten once buildings are commissioned is the carefully detailed operational policies which have guided design and commissioning. These should be kept up-to-date as the definitive statement of the resource and organisational policy for the operation of the services to be provided in the facility – an essential prerequisite to the consideration of service standards for example.

An integrated planning and performance framework

The task of defining the way in which health care can be most efficiently and effectively delivered is the concern of all health care staff. It rests on the ability to clarify aims, to agree performance criteria and measures and, wherever possible and appropriate, to set up standards. Management's task is sometimes to define the steps to that goal and always to encourage and support work in this territory. Management also has the responsibility of ensuring the consistency and coherence of the many different activities that contribute to the aim of good health care.

The framework set out in Table I identifies the elements of a complete planning and performance statement. It is not in itself an instrument for reviewing or measuring

Dimension	What is needed	Some information sources	Present position
1. Departmental or functional	Statement of mission and objectives		The current position against each of these five elements should be set out here and updated as appropriate
2. Inputs	Staff Buildings Equipment Money	National and regional guidance Professional colleges Planning brief for new departments NHS building notes	Details of projects and other work should be recorded and indicators, targets, performance criteria, measures, standards, etc. detailed as are agreed
3. Process	Range, scale and form of service. Statements of "how much" often expressed as ratios across reltaing patients seen, admitted treated, etc. to facilities staff, costs, population	National and regional performance indicators Korner and other information	Reporting mechanisms should be identified and a process for agreeing any action clearly established
4. Outcome	Performance criteria, measures and standards Systems for reviewing outcome against these Index of consumer satisfaction tested by questionnaire, interview, etc.	Korner and other information Professional leterature and research	
5. Achieving change	Systems for reporting results of monitoring and review		

Table I.
Planning and performance statement

anything, but suggests a way by which general or departmental managers can relate all activity concerned with the scale, scope, efficiency and effectiveness of a health care service or function.

As performance and quality assurance programmes multiply there will be an increasing need to draw together the many strands of this activity in a systematic way, not least to ensure that problems and needs identified through these processes are taken up by management and health authorities. Only if this happens will the present fashion for performance and the pursuit of quality have an enduring impact on health care.

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Cardiac surgery productivity and throughput improvements

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Abstract

Purpose – The high variability in cardiac surgery length – is one of the main challenges for staff managing productivity. This study aims to evaluate the impact of six interventions on open-heart surgery operating theatre productivity.

Design/methodology/approach – A discrete operating theatre event simulation model with empirical operation time input data from 2,603 patients is used to evaluate the effect that these process interventions have on the surgery output and overtime work. A linear regression model was used to get operation time forecasts for surgery scheduling while it also could be used to explain operation time.

Findings – A forecasting model based on the linear regression of variables available before the surgery explains 46 per cent operating time variance. The main factors influencing operation length were type of operation, redoing the operation and the head surgeon. Reduction of changeover time between surgeries by inducing anaesthesia outside an operating theatre and by reducing slack time at the end of day after a second surgery have the strongest effects on surgery output and productivity. A more accurate operation time forecast did not have any effect on output, although improved operation time forecast did decrease overtime work.

Research limitations/implications – A reduction in the operation time itself is not studied in this article. However, the forecasting model can also be applied to discover which factors are most significant in explaining variation in the length of open-heart surgery.

Practical implications – The challenge in scheduling two open-heart surgeries in one day can be partly resolved by increasing the length of the day, decreasing the time between two surgeries or by improving patient scheduling procedures so that two short surgeries can be paired.

Originality/value – A linear regression model is created in the paper to increase the accuracy of operation time forecasting and to identify factors that have the most influence on operation time. A simulation model is used to analyse the impact of improved surgical length forecasting and five selected process interventions on productivity in cardiac surgery.

Keywords Productivity rate, Heart, Surgery, Health services, Finland

Paper type Research paper

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Introduction

Healthcare providers in both the public and private sectors are facing increasing pressure to improve their cost efficiency and productivity. While process improvements in the healthcare sector have often been driven by the development of

medical technology, the increasing cost of new technological solutions has lead to applying operations management techniques developed for industrial and service processes. Meyer's (2004) literature review shows that, on average, operating theatres operate at only 68 per cent of capacity. This is a rather low capacity utilisation rate, especially when combined with the cost associated with the long wait times for surgical procedures in many countries (OECD, 2001), emphasises the importance of improving management practices in operating rooms. Our primary objective is to analyse the effect that six different process interventions have on the productivity of operating theatres performing open-heart surgery. However, effectively scheduling open-heart surgery is complicated owing to the high variability and inaccurate procedure time estimates. There is a high variability in the length of cardiac surgery and combined with a four and half hour average duration, it makes scheduling two surgeries during a normal eight-hour workday difficult. Having just one surgery a day results in low productivity. Thus, our second objective is to develop a model for estimating the length of procedures. We also consider whether increased estimation accuracy can improve operating room productivity. First, we review literature on management practices applied to improve operating room productivity. We further focus on how estimating procedure times influence operating room productivity. Second, we derive concrete research questions from the objectives and discuss the method. Third, we created a linear regression model to determine how accurately procedure times can be forecast. Fourth, we estimate the implication of more accurate procedure time estimates and five other process interventions on operating room productivity using a discrete event simulation model. Finally, the theoretical and managerial implications of our findings are discussed.

Improving operating room productivity

One productivity definition is the ratio of a volume measure of output to a volume of input (OECD, 2001). According Schmenner (2004), service process productivity is dependent both on the throughput time and variability in the time it takes for various tasks to be completed. In the operating room, with a fixed number of tables and personnel reserved for a specific specialty in a given time period, productivity can be measured as a throughput volume. Two ways to increase operating room productivity, therefore, are to speed up the actual operation times or improve operating room utilisation rate by minimising idle time. In this paper, we focus only on how to improve operating room utilisation rate by slashing unproductive idle time. The importance of effective management and scheduling of operating theatres is demonstrated by the number of studies focusing on analysing operating room performance from an operations management point of view. In the following, key findings from these studies are classified by the three ways that are used to improve operating room performance: resource allocation for different specialties, optimal scheduling of surgeries and design and coordination of operating room activities. All are used to increase the operational efficiency of the daily use of operating theatres.

Resource allocation

An operating theatre is often a shared resource used by many specialties. Resource allocation concerns operating theatre time allocation procedures, which are used to advance reservation and dynamic changes in allocated blocks of time for each specialty

or surgical group (Dexter and Macario, 1996). Forecasting a surgical group's total hours is important for effective operating theatre utilisation (Dexter *et al.*, 1999a). Operating room productivity also depends on the allocation of other resources required in the overall care process. For example, Akkerman and Knip's (2004) research focuses on the allocation of hospital and intensive care beds required for pre- and post-operative care for cardiac surgery and which may limit its throughput thus reducing operating room productivity.

Optimal scheduling

The focus on patient optimal scheduling is to effectively use all of the available time. One of the key issues concerns how to schedule elective procedures, when the same operating theatres must take other patients (Gerchak *et al.*, 1996). Efficient operating theatre scheduling is further complicated by the inherent surgical procedure variability, which decreases operating theatre utilisation (Tyler *et al.*, 2003; Buchanan and Wilson, 1996). An accurate modelling of time distribution as well as accurate estimation of procedure times have been recognised as important factors in effective planning and scheduling systems (Spangler *et al.*, 2004; May *et al.*, 2000). If operating room schedules are not fixed for the day; for example., changes can be made the day of surgery then operating room productivity can be increased through the effective re-scheduling of surgery (Dexter *et al.*, 2004). When optimising operating room cost efficiency, both capacity utilisation during regular working hours and overtime hours, which means extra labour cost, must be taken account (Dexter, 2003). Weiss (1990) introduces a model for estimating start times for each surgery, which takes into account the idle time cost and cost related to surgeons performing the surgery. However, it should be noted that productivity is measured as physical resources required to produce one unit of output, which does not take the price into account. Karvonen *et al.* (2004) propose a change in the queuing system for coronary artery bypass graft (CABG) from a single to a two-queue system, which they claim increases productivity by 40 per cent. However, their solution – that two surgeries lasting less than four hours can be scheduled for the same day. In order actually to implement their suggestion, one needs to be able to perform such a partitioning. Karvonen *et al.* (2004) assumed that operation times can be accurately forecast before the surgery, but this key assumption cannot be substantiated. Unfortunately, the accurate estimation of procedure time proves to be a difficult task. Macario and Dexter (1999) found that using historical procedure time data are an ineffective strategy for accurately estimating surgical times. Buchanan and Wilson (1996) propose that there is a correlation between individual surgeons and the average length for a specific procedure, but according Zhou *et al.* (1999) the use of historical data from the previous year, an analysis of the same procedure type preformed by the same surgeon, do not lead to satisfactory results.

Designing and co-ordinating operating room activities

Karvonen *et al.* (2004) propose that reducing changeover time leads to significant productivity improvements for open-heart surgery, because it would allow two open-heart surgeries to be performed during regular working hours. Sieber and Leibundgut (2002) discuss how separate induction rooms can minimise changeover time between two procedures. Torkki *et al.* (2006) demonstrate that performing

anaesthesia outside the operating theatre for trauma patients can significantly reduce patient throughput time with constant resources, thus leading to an increase in productivity. Cayirli and Veral (2003) outpatient scheduling review presents several factors that can influence operating room efficiency. They include characteristics of the arrival process, lateness, doctors' interruptions, queue discipline and service times.

Research question and method

Kuopio University Hospital (KUH) is responsible for treating severe illnesses that call for special expertise and technology in the hospital district of Northern Savo, Finland. The hospital district population is about 860000. The average yearly number of invasive cardiology procedures is 1,700 and the average number of open-heart surgeries is about 1,000. In 2003, KUH started a development project to increase the quality and efficiency of the coronary disease care processes. One focus was to increase productivity in the operating theatre, which was identified as a resource that limited open-heart surgery throughput. The hospital was not able to meet medically recommended waiting times for cardiac surgeries. For example, unstable angina pectoris patients are forced to wait six days for CABG surgery after an angiogram. Additionally, KUH offers coronary bypass surgeries for external hospital districts and it is loosing patients to its competitors. Improving coronary bypass surgery productivity, therefore, would directly increase hospital turnover and profitability.

The specific features of open-heart surgery shape our research objective, as the length of open-heart surgery tends to be so long that accommodating more than one surgery in an eight-hour working day is a challenge. On the other hand, productivity remains low when there is no more than one surgery per working day. Research in operating room management has not focused on improving the productivity on cardiac surgery. Our main research question, therefore, addresses that gap in the existing research and the second research question addresses the challenge of estimating open-heart operation times:

(1) *How can in open-heart surgery productivity be increased?* We suggest some concrete proposals, such as increasing workday length, more overtime and shorter setup times between surgeries, which could lead to productivity improvements. These are tested with a discrete-event simulation open-heart surgery patient process model. Discrete-event simulation enables the evaluation of alternative productivity improvement proposals while maintaining the dynamic nature of the open-heart surgery patient queue. One such proposal, accurate procedure time estimates, was not found in the literature and estimates need to be developed in order make reasonable and achievable schedules in the simulation model

(2) *Can a satisfactory model be constructed for forecasting open-heart operation times?* We screen potential factors that could influence open-heart surgery operation times and then use such significant factors to develop a linear regression model for predicting operation times. Input data for developing both the operation time forecasting and simulation models were the actual data of all the 2,613 open-heart surgeries performed at KUH during 2001-2003. Ten cases, where the operation time according database records was null, negative or excessively long (more than 20 hours) were excluded from the analysis making the total number of cases included in the analysis 2603.

Forecasting model for operation times

The average overall open-heart surgery operating theatre time was more than four hours, with the actual operation taking 3.21 hours (Table I). Because operation time is a key component in the overall operating theatre use, a forecast model is created only for operation times. However, it should be noted that for a simulation model, both operation and total surgery times are needed.

An essential step in a practical scheduling model is a realistic and reasonably accurate forecasting model for predicting open-heart operation times. The existing "forecast" available in the KUH data system explained only 11 per cent ($R^2 = 0.11$) of the operation time variability. The actual operation time was also, on average, 27 per cent less than we forecast.

Variable classification and screening

Our data included a number of potential explanatory variables for the observed operation time. The total number of potential variables in the operation data was 64 – roughly classified into:

- Demographic, like patient origins, age or weight (six variables).
- Personal and medical records, for example, the number of previous procedures, smoking/non-smoking or New York Hearth Association (NYHA) classification (40 variables).
- Operation variables: start date and time, operating room, surgical team members (ten variables), diagnoses and planned operations (16 variables).

Each variable was screened using a one-way analysis of variance (ANOVA) procedure in order to find whether a particular variable should be included in the forecasting model. Those variables that explained less than 1 per cent of the total variability, even though significant, were excluded. Also, three variables that explained 1-2 per cent of the variability were excluded because complicated transformation to an ordinal scale was required. There were, however, no standard times for surgeries; therefore, the operation time variable for forecasting had to be created, based on the number of operations and average time of each surgery. A linear regression model was constructed in order to forecast the operation time. A bonus of using a regression model is that it will also reveal what factors influence the operation's duration, i.e. open-heart surgery productivity – factors that managers can influence.

Open-heart operation time model

The linear regression model with patient serial number and those 15 variables that passed the ANOVA screening procedure explained 46 per cent of the variation in the

Table I.
Operating theatre time usage for open-heart surgeries in KUH

Reporting stage	Start	Room ready	Anaesthesia start	Operation	Anaesthesia end	End	Total
Duration h:mm	0:01	0:24	0:27	3:21	0:16	0:00	4:31
Share %	0.5	9.0	10.1	74.3	6.1	0.0	100.0
Standard deviation h:mm	0:03	0:21	0:22	1:21	0:35	0:01	1:22

data ($R^2 = 0.462$) while the rest remains unexplained. Nevertheless, the overall model is statistically highly significant (see Table II).

As patient serial number also measures the location of surgery date in the data, it can be used to measure productivity improvement over time. It has an overall effect of 14.9 minutes over the three-year range; that is, a five minute productivity improvement each year. The skills or perhaps more appropriately the speed of the heart surgeon has an effect of 55.3 minutes; i.e. the fastest group of surgeons is almost an hour quicker than the slowest group. A rather interesting finding was that when additional surgeries were performed, after normal working hours for piecework pay, they were on average 20 minutes faster. However, it remains open as to whether those surgeries were selected based on additional forecasting knowledge on operation times not used in the regression model, or if it was just that the surgery team was motivated to work faster.

Simulation model for evaluating production improvement proposals

A discrete event simulation model was created to capture the most important elements of the operating theatre scheduling system in the case study organisation (Figure 1).

ExpertFi™ software was used to fit operation time distribution to all of its 22 build-in distributions. The hypotheses that the operation time data were drawn from any of the distributions could be rejected based on Chi- square test even at the $p < 0.01$ level. Therefore, in the model, the operating time is randomly assigned from the historical patient data.

In the simulation the emergency patient weekly arrivals are modelled by a Poisson distribution with mean 7.15. Based on the Equal-width Chi-square test on three-year weekly emergency arrivals, the Poisson-model cannot be rejected ($p = 0.532$, df = 13). These weekly emergency arrivals are randomly assigned to a weekday. Two operating

Variable	Coefficient	Range	Effect (minutes)	*p*-value	Significance
Intercept	−49.57			0.07	***
Patient serial number	−0.01	2,727	−14.9	0.02	***
AGE	6.32	2	12.6	0.11	***
Redo operation	64.30	1	64.3	1.65E-17	***
Queue priority	−2.81	4	−11.3	0.52	*
NYHA classification	6.32	2	12.6	3.28	NS
Abnormal EKG rhythm	2.24	1	2.2	65.34	NS
Indication for angiogram valve disease	−1.34	1	−1.3	70.67	***
Mitral valve regurgitation	7.70	1	7.7	0.86	NS
Aortic valve regurgitation	−3.34	1	−3.3	33.06	NS
Diagnosis number (IDC-10)	−2.65	2	−5.3	46.69	***
Head surgeon	27.66	2	55.3	8.25E-70	***
Piecework pay	19.69	1	19.7	3.04E-10	***
Preoperative lung disease	19.88	1	19.9	2.42E-05	NS
Preoperative anticoagulation	−2.99	1	−3.0	48.28	***
Annuloaortic ectacia	39.89	1	39.9	0.02	***
Operation forecast	1.06	505	533.9	1.63E-160	

Table II.
Linear regression model for open-heart surgery operation time

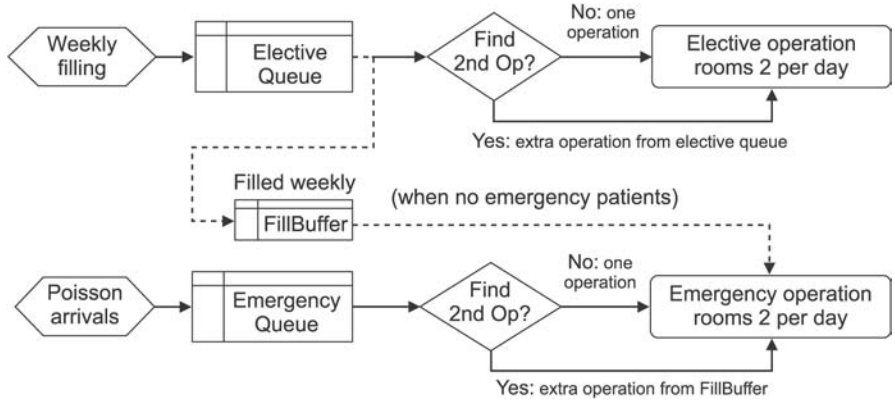

Figure 1.
Simulation model for scheduling open-heart surgeries

rooms are reserved for emergency patients and in case there is temporary lack of capacity, patients are placed in an emergency patient queue.

With average of 7.15 weekly emergency arrivals, there is a considerable average overcapacity in the emergency surgery. The emergency surgery overcapacity is supplemented by a specific safeguard called a fillbuffer, which allows patients from an elective queue to be called at short notice. The patients in the fillbuffer can be called in at one-day notice and it is topped-up weekly from the elective queue. For each emergency surgery, fillbuffer is also checked for the possibility of a second surgery during the day. A second surgery can be scheduled only if the forecasted operation times for first and second surgery, combined with idle time between surgeries and margin at the end of workday, are less than the length of a work day.

It is assumed that available supply of elective patients is larger than operating capacity. Elective patient arrivals are modelled so that they fill the elective queue up to the maximum queue limit. Operating time and priority are randomised based on historical patient data. Priority controls the time a patient may wait in the queue; when the maximum queuing time is reached, the patient is then moved to the front of the queue. Operation planning is done weekly for the two operating rooms according to the patient priority. For each scheduled patient, a check is preformed to see whether there is another patient in the elective queue whose surgery can also be performed that day.

Experimental design for simulation

The time it takes for the simulation model to reach a steady-state was evaluated using Welch's method (Robinson, 2004) with ten replications and a seven-day moving average. The model reaches a steady state rather fast, after the third simulation week or so. In the experimental design, to be on the safe side, a simulation warm-up period of 100 days was used to reach the steady state. Full factorial design with five replications was used to capture all the main and interaction effects of two responses: patient volume and overtime worked. In addition, for understanding the improvement potential, the average idle time was calculated. Production improvement factors and values were selected based on a literature review and a discussion of what is practical

to implement in the case study organisation. The following factor values were included in the design:

- *Slack*. The time margin used when accepting a second surgery or to avoid overtime work. Its values are 0 min or 60 min.
- *Forecast accuracy of the operation time*. A low value is a forecast based on linear regression. High value models about 50 per cent improvement in forecast accuracy. It is calculated using the following formula: 0.75 * linear regression forecast + 0.25 * true value.
- *Induction*. Anaesthesia induction is done outside the operating theatre which moves anaesthesia and room ready times offline (see Table I).
- *Four-day week*. Staff moved to a four-day-week. The 390 min. Friday workday is allocated to other days.
- *Fillbuffer*. This is the weekly amount of patients waiting to be called into surgery at very short notice. Its values are 3 and 10.
- *Queue length*. This is all elective patients waiting for a surgery. Its values are 50 and 150.

Simulation results

All the main effects and the most important interaction effects that are statistically significant ($p > 0.99$) are presented in Table III, while Figure 2 shows the results of surgery output. The induction of anaesthesia outside the operating room and the shorter slack time both increase surgical output by 166 patients a year. Additionally, they have a positive interaction effect, which further increases the output by 55 patients. Forecast improvements have no effect on output, because scheduling a second surgery is based only on forecast operation time while its accuracy is indirectly reflected by the slack variable. A larger fillbuffer increases emergency operating rooms output by 61 patients. It also has positive interaction effect on induction and slack, because it becomes more likely that a patient can be called in from the fillbuffer in cases of shorter emergency surgery. A longer elective queue has a small positive effect on the output of elective operating rooms, owing to the increased number of patients selected for the second elective surgery.

The production improvement factors and values used in the simulation had, in practice, only slight effects on overtime work. In Figure 3, the effects on overtime are presented as minutes per day per operating room. Increasing slack has the largest influence on overtime, but its value is only −2.1 minutes. Surprisingly, improved forecasting had a small effect on overtime. The most likely cause is the generous slack time values after surgery. The statistically significant increased other factors come mainly as a by-product of increased output; for example, having a second surgery in the day, which, all things being equal, increases, as one might expect, the probability of overtime work.

Model validation

The conceptual model validity was assessed by KUH doctors, who also participated in the project. Their view was that the conceptual model and approach appeared valid for evaluating productivity improvements. Assessing validity through comparison to actual KUH performance is not clear-cut, however, because the model does not aim to

Factors	Response		Output components					
	Idle time	Over time	Output	ELE1	ELE2	EME1	EME2	EME_BF
Main effects								
Overall average	127.1	6.0	1283.1	495.2	242.4	372.3	53.5	119.7
4-day	−10.9 [a]	1.1 [a]	65.8 [a]	−52.3	106.6	−2.4	14.9	−0.9
Fillbuffer	−19.9 [a]	0.4 [a]	86.0 [a]	0	−12.3	1.6	39.6	57.0
ForecImpr	−1.4 [a]	−1.8 [a]	6.3 [a]	0	4.3	−2.1	2.4	1.6
Induction	−22.8 [a]	1.9 [a]	202.2 [a]	0	147.7	0.2	64.6	−10.3
Queue	−10.7 [a]	0.5 [a]	48.5 [a]	0	34.3	−0.3	18.0	−3.5
Slack	36.0 [a]	−5.2 [a]	−195.8 [a]	0	−145.8	−0.7	−59.3	9.9
Interaction effects								
4-day + Fillbuffer	−1.3 [a]	0.0	5.1 [a]	0	−3.0	0.9	4.8	2.4
4-day + ForecImpr	−0.5 [a]	−0.2 [a]	0.1	0	−0.4	0.3	0.3	−0.2
4-day + Induction	5.7 [a]	−0.7 [a]	−8.0	0	−15.7	−0.8	8.9	−0.4
4-day + Queue	1.5 [a]	−0.1	−5.7 [a]	0	−0.4	2.1	−7.4	−0.1
4-day + Slack	−1.9 [a]	−0.4 [a]	9.7 [a]	0	16.7	−0.7	−8.4	2.1
Fillbuffer + ForecImpr	−0.2	−0.2 [a]	1.4	0	0.0	−1.0	1.0	1.5
Fillbuffer + Induction	−6.9 [a]	0.4 [a]	34.2 [a]	0	−0.3	0.3	24.3	9.8
Fillbuffer + Queue	−1.3 [a]	−0.1	5.2 [a]	0	0.1	0.9	1.3	2.9
Fillbuffer + Slack	6.6 [a]	−0.2 [a]	−33.5 [a]	0	−1.3	−1.0	−23.0	−8.3
ForecImpr + Induction	−0.2	−0.6 [a]	0.6	0	0.6	0.6	−0.3	−0.3
ForecImpr + Queue	0.5	−0.3 [a]	−0.5	0	0.3	−0.7	0.0	0.0
ForecImpr + Slack	1.1 [a]	1.0 [a]	0.2	0	0.1	0.6	−0.1	−0.3
Induction + Queue	1.4 [a]	0.1	2.3	0	−4.8	0.8	8.8	−2.5
Induction + Slack	−0.1	−1.2 [a]	−37.0	0	−14.6	−0.4	−27.1	5.1
Queue + Slack	1.0 [a]	−0.7 [a]	−7.9 [a]	0	−2.9	0.0	−6.5	1.5

Notes: [a] Ten replications of three-year runs; Productivity improvement factors' effects on the productivity measures i.e. responses. The statistical significance of each factor on each response at $p = 0.99$ level based on a full factorial design; Output is also divided to its components: ELE1 (1st elective); ELE2 (2nd elective); EME1 (emergency); EME2 (elective from fillbuffer. operated in emergency room as a 2nd patient after the emergency patient); EME_FB (elective from fillbuffer that is operated when emergency patient queue is empty)

Table III.

exactly replicate existing situations and because historical performance is not available in comparable basis. First, actual variation in the amount of operating tables was excluded from the model. This includes, for example, summer reductions. Second, slack and fillbuffer values applied to KUH cannot be explicitly numerically determined. The KUH slack estimate was 60 minutes. Fillbuffer, i.e. the number of patients called on short notice, was merely said to be uncommon. The patient queue length also varied in actual operation (for example, owing to holidays), while in the model it was fixed. Third, overtime and idle time data were not reliable and direct comparisons were not possible. However, for idle time, a surrogate measure was used in the period between ending and start time of an overtime surgery performed in the same room. Of the 461 data pairs, the average time between two surgeries was 2.25 hours. This can be considered as the idle time, although it does not give an indication of the amount of days without any surgery, and on the other hand, it is likely to overestimate the idle time because of the selection of short surgery and/or empty rooms for overtime

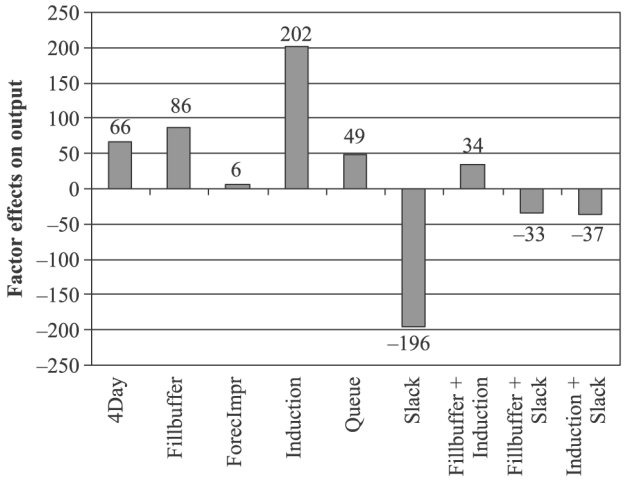

Figure 2.
Main effects and important interaction effects on surgery output (yearly output)

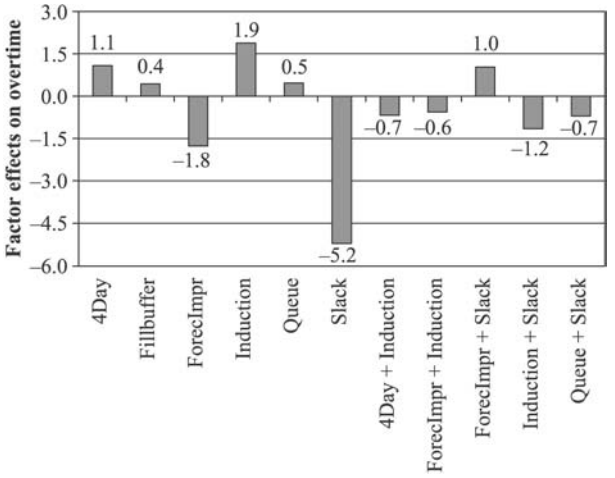

Figure 3.
Main effects and most important interaction effects on overtime response (minutes per day and per operating room)

surgeries. For output, the surrogate validation metric is the amount of 2nd surgeries in the same operating room per day. In the data, there were 1906 surgeries assessed to have started during regular working hours. Of these 130 (7 per cent) were 2nd surgeries. The simulation model results for idle time and percentage of 2nd surgeries with factor values that either correspond or were judged closest to past conditions (slack: 60 min.; forecast accuracy: no improvement; induction: no; four-day week: no; fillbuffer: 10; queue length: 150) are shown in Table IV.

Table IV indicates that confidence can be put to model results and the model appears valid for assessing the means to improve productivity.

Conclusions and recommendations

Surgery volume and overtime work were selected as output variables because they have a direct impact on productivity. The effect of idle time on productivity depends on how idle resources can be allocated for other work. For example, a surgeon may allocate idle time for patient visits. However, in the case study organisation, there was agreement that production improvement methods should not lead to significant use of overtime. As a result, the effects on overtime were minor as compared to the effects on surgery output. If any of the production improvement methods have positive effects on surgery volume then productivity should increase. Reducing changeover time between surgeries by the inducing anaesthesia outside the operating theatre and by reducing the slack time at the end of day after a second surgery have the strongest effects on surgery output and productivity. The area that shows the greatest potential is reducing slack time, because it does not involve any investment. The drawback is the increased overtime. On average, however, overtime is only 0.89 per cent of the total working time. Our research confirms Dexter *et al.*'s (1999b) claim that improving forecast accuracy does not directly lead to large increases in operating room utilisation. Better forecasting accuracy has an indirect effect by enabling slack time reductions without increasing overtime.

Increasing the fillbuffer has a considerable positive effect on surgical output in rooms dedicated to emergency surgeries. If more patients willing to be called for surgery at short notice, as was the situation in the case study hospital, then longer fillbuffers is a cost effective way to increase output. Also, an increasing queue length for elective patients has a positive effect on productivity, but needs balancing with additional costs, decreased quality of care and the potential loss of market share related to long waiting times. A four-day work week increases workday length. It makes it possible to schedule the second elective surgery on most days, which compensates missing Friday surgical sessions and increases the total output without any additional resources.

Our results demonstrate that although the length of open-heart surgery, as well as difficulties forecasting operation times, decreases operating theatre productivity, cost-effective methods to considerably improve productivity exist. The challenge in scheduling two open-heart surgeries in one day can be partly resolved by increasing the working day length and decreasing the time between two surgeries or by improving patient scheduling procedures so that two short surgeries can be paired. However, the improvement potential is significantly less than proposed in previous research (Karvonen *et al.* 2004). Nevertheless, there is much potential for productivity improvement. The average idle time for operating theatres fully dedicated to open-heart surgeries across the experimental design was 33 per cent. One method for decreasing idle time is to have more flexible working hours or arrangements, in which an operating theatre and surgical team can be effectively used for minor surgeries. Changes that lead to increased productivity are difficult to implement without the

Table IV.
Simulation model validation with 99 per cent confidence interval for model results

	Idle time	Percentage of 2nd surgeries
Simulation model results	2 h 34 ± 1.2 min.	6.8 ± 0.3
KUH actual	2 h 15 min.	7.1

proper incentives, however. Motivating surgical teams to accept flexible working time and to decrease the average operating time are important factors to consider when designing payment systems. Payment systems should be designed to account for surgery volumes and types of surgeries.

A forecasting model based on the linear regression of variables available before the surgery explains 46 per cent of the operating time variation. It confirms previous research findings that there is a correlation between surgeon and average operating time, which unfortunately does not lead to an accurate forecasting model (Zhou *et al.*, 1999; Buchanan and Wilson, 1996; Macario and Dexter, 1999). Owing to our simulation design, improved accuracy decreased overtime, but it did not influence surgical output. Further research on forecasting accuracy, overtime work and how surgery output are related could be fruitful.

We have not studied a reduction in the operation time itself. However, the forecasting model can be applied to discover which factors are most significant in explaining variation in the length of open-heart surgery. We propose that further research should be done concerning why the head surgeon's role and piecework pay have such an important effect on surgery length. The forecast model, and the simulation results, created discussion and enabled the evaluation of the impact of concrete improvement proposals without testing them in practice. Based on our results and the experience gained from this research project, the case study organisation is looking for alternative methods for improving its forecast model, e.g. Bayesian and other simulation models could be integrated with existing information systems and be used to plan and schedule open-heart surgery.

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Developing nursing: the contribution to quality

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Abstract

Purpose – The paper aims to examine the concept of a nurse development unit and its impact on the quality of nursing practice.

Design/methodology/approach – The study uses the Nurse Development Unit at Tameside as an example and the implications for both the patients and nurses are explored.

Findings – The paper finds that initial assessments of the Unit and its impact on quality assurance have been very positive, with great emphasis being placed on the patient as a consumer of the quality provided.

Originality/value – The paper provides useful information on the development of quality assurance in nursing.

Keywords Nursing, Quality assurance, United Kingdom

Paper type Case study

Nurses remain the biggest single group of professional employees in health care. In both hospital and community, they are one of the few sectors to provide round-the-clock service. As such, what nurses do, and how well they do it, is probably the biggest single factor that directly affects the quality of care the patient or client receives (HMSO, 1979).

Currently, nursing is beset by severe recruitment problems, which are likely to get worse when the "demographic time bomb" (UKCCN, 1986) explodes. Traditionally nursing has attracted the majority of its recruits from 17/18-year-old school leavers, predominantly female. With around 35,000 nurses each year leaving the profession, nursing has had to take almost 10 per cent of these females leaving school (about 450,000) each year to replace the loss.

By the 1990s the end of the effects of the post-war baby boom will mean only about 250,000 school leavers will be in this category. Even if nursing still gets 10 per cent of these (and evidence (UKCCN, 1986) is accumulating that nursing is being perceived as a less and less attractive occupation), then this represents a significant shortfall.

By any stretch of the imagination, an exit of over 30,000 nurses each year represents an enormous loss to the profession, to the NHS and to society as a whole. While efforts are rightly promoted to maintain the current intakes (encouraging more men into

Copies of various documents relating to the Nursing Development Unit, including its annual report, standards, papers, nursing philosophy, etc., can be purchased from the Nursing Development Unit.

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nursing, increasing nurses' pay), there is much evidence to suggest (Dean, 1987; MacKay, 1988) that nurses do not leave nursing (or are reluctant to enter it) because of economic factors alone.

If nursing is to play its full part in the overall high quality of the patients' care, then nursing itself must become a high quality, stable workforce. While the professional organisations and the Government are currently embroiled in issues over pay, there are matters to which nurses and their managers should be concurrently addressing themselves. They are fields of activity which can have as much effect on nursing recruitment and retention, and the subsequent quality of care delivered, as well as matters of pay.

Two primary areas of concern require action. First, there is a need to tackle the climate in which nurses work – to move away from the traditional, hierarchical styles of management and produce a more open, professional approach which encourages nurses to develop and to learn, and which motivates them, by being cared for and encouraged, to new enthusiasm, energy and skill at work.

Second, nursing practice itself needs to be developed, so that nurses can fulfil their desires for patient-centred practice. To do this he or she needs opportunities to try out different ways of organising nursing and to apply new knowledge to practice. In fulfilling the patients' needs, the nurse fulfils her own. The two are inextricably linked. MacKay's (1988) survey indicates that nurses leave nursing because they cannot deliver the standard of care they wish, as much as for reasons of poor pay or conditions. High quality care emerges when high quality nurses have the knowledge, skills and freedom to nurse, in an environment which nourishes and supports them.

Those in management positions who do not perceive this are doomed to failure in their own roles. Efforts to save money by restricting nursing will, in the long term, prove counter-productive if a climate for care is not produced which makes nurses feel supported and encouraged. Such a crisis has already emerged in many health authorities where managers have adopted an insensitive approach in their efforts to cut costs. Nurses become angry, militant and demotivated. Often what such managers have done, is to replace one dogmatic and autocratic system (the old nursing hierarchy) with another (the new "cost effective" managerialism).

The situation is made worse in sectors which have historically been of low status in nursing (although this is changing) such as services for the elderly or mentally ill.

A nursing development unit

Understanding that nurse recruitment and retention was intimately linked with conditions of practice, Tameside created its first "Nursing Development Unit" (NDU) in 1986. While a complex set of aims was drawn up (see the Appendix), the thrust of the whole unit was to produce a "pincer" movement to tackle nursing, that is, develop both nurses and nursing.

While pay matters related to nursing motivation are largely out of local hands, there is much that individual units can achieve. In the Tameside instance, the NDU, was the culmination of over five years of groundwork in transforming the Care of the Elderly (Wright, 1983, 1989, 1985a, b, 1986a; Wright and Reader, 1986), which has now been well documented.

Many health authorities have attempted to tackle the problems through various strategies. What marks the NDU as different is a planned approach of not one but

many intertwining factors – a deliberate attempt through a network of nursing activities – to promote nursing (in this case specifically the elderly) as valuable and worthwhile. The "network" point is crucial, since no one item (i.e. increasing pay, or supporting a few nurses in advanced education) will produce the breadth of results that is desired (Vogt *et al.*, 1983).

Tameside General Hospital is a typical "bread and butter" hospital, situated in an ordinary town on the outskirts of the big city. It is surrounded by other health authorities competing for recruitment, yet has little to offer in the way of glamorous facilities. Much of the care of the elderly takes place in old "work-house" buildings. Given these factors, and that the setting chosen for the NDU was a "Cinderella" site, i.e. geriatric services, then what has been achieved must be viewed as even more exceptional. A situation such as this, which in any health authority, would have been difficult to staff, now has a waiting list of potential recruits and a low turnover, sickness and absenteeism rate. These features among others are tangible evidence that the approach being adopted actually produces results.

The network

A multiple variety of strategies being adopted within the NDU appears to be the deciding factor. A full explanation of each of the elements is beyond the scope of this paper and Figure 1 summarises the main points.

Towards professional practice

One area of significant activity has been the development of primary nursing, a highly developed form of accountability and control over care of individual patients by individual nurses (Manthey, 1980; Hegyvary, 1985). Not to be confused with primary health care, "primary nursing" involves one nurse having total responsibility for the care of a small group of patients during the whole of their stay in hospital. This is a radical departure from more traditional task-centred or team efforts at care.

It has profound implications for the way nursing is organised at ward level and for the roles of the nurses and other disciplines involved. There is no doubt that primary nursing has developed as a major force in nursing in recent years (Wright, 1987a; Pearson, 1987) and the NDU along with similar settings has led the way in this field. Certainly one of the overwhelming factors in favour of primary nursing is the enhanced commitment, motivation and enjoyment it brings to professional nurses in their work, evidence for which (Wills, 1988) has recently accumulated in the wards of the NDU where primary nursing has been successfully developed.

Quality assurance

Another principle area of activity of the NDU has been developing quality assurance tools. Work begun several years ago identified four principle areas of consideration (Wright, 1986b) as shown in Figure 2.

The work in all these fields is still continuing, but it is true that quality assurance forms a key role in the overall strategy in the NDU. This is not only for the benefit of nurses, to know how well (or not, as the case may be) they are doing, but also to provide evidence that the direction of the NDU is correct and that money is being spent wisely and productively.

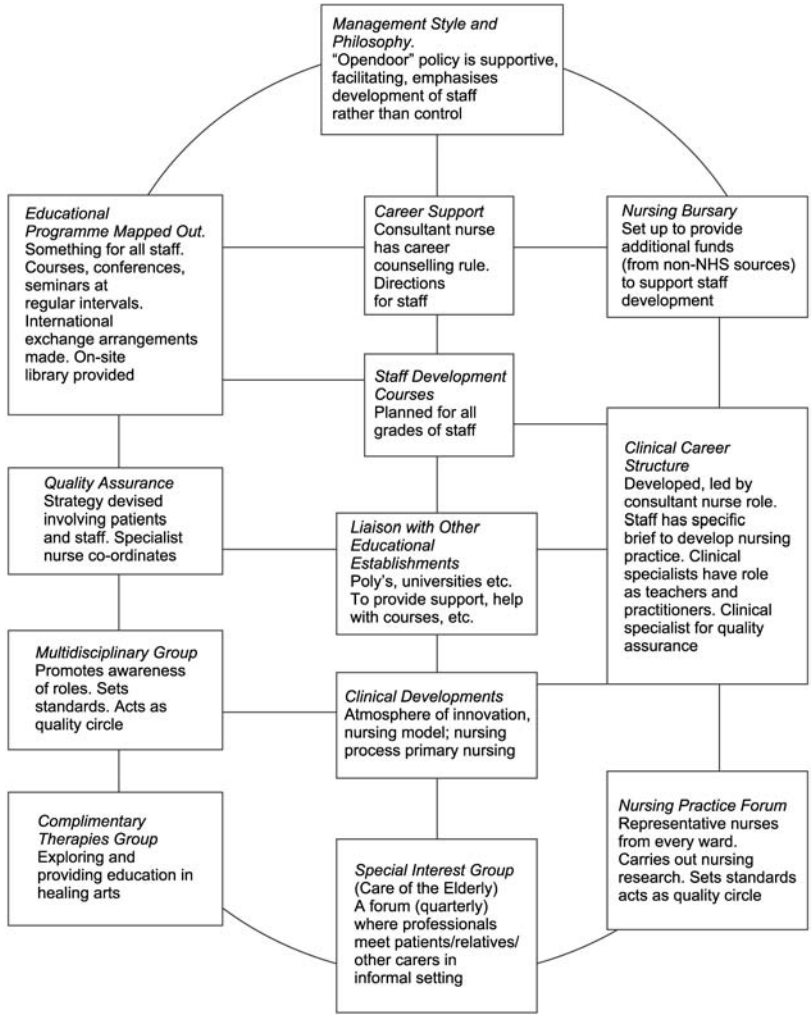

Figure 1.
The network

Initial assessments have proved highly positive (Wright, 1987b), while the early work done on quality assurance techniques clearly identified the need for a highly skilled nurse at unit level to sustain the effort. The complexities of quality assurance are beyond the abilities and workload of most clinical nurses, and while they must be involved to the maximum, a key person is needed to monitor and co-ordinate the whole activity.

In this instance, a clinical specialist was appointed to provide the expertise and support needed at clinical level. She liaises closely with the chief nursing officer/assistant-general manager and assistant unit general manager to co-ordinate quality assurance techniques within part of the overall Unit and District policy. Great emphasis is placed on patient or "consumer" involvement in quality measurement. Questionnaires are used, but the results of them for patients can often be less than

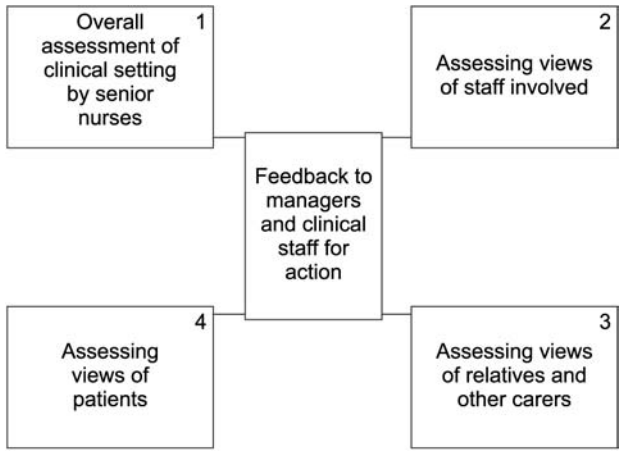

Figure 2.
Quality assurance

revealing. Patients are notoriously unwilling or unable to comment critically on the care they received (Wright, 1987b; Hall, 1966). A significant role of the clinical specialist in this area, is to follow selected patients and relatives through into the community for in-depth interviews and appraisals of care.

Working with the consultant nurse and senior managers this role is also instrumental in developing quality circles and setting up training schemes for circle leaders.

With nursing beset by its current difficulties, to talk of "developing" or of "quality assurance" may seem like pie-in-the-sky to many onlookers. However, nursing itself and the managers who support it must meet the challenge of these ideas, for much can be achieved at the small unit level that does not depend on the great decisions of government. The quality of nursing can be challenged and improved, when nurses themselves are a part of that challenge and improvement.

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Appendix

Nursing Development Unit – aims

(1) To enhance the development and status of nursing the elderly as a speciality in its own right.

(2) To promote excellence in nursing practice with the elderly.

(3) To continue the development of a nursing model for the elderly.

(4) To promote nursing practices which produce individualised nursing.

(5) To provide a climate for nursing the elderly in which learning and ideas flourish, in which research is conducted and findings applied, and in which our knowledge and experiences are disseminated to other nurses.

(6) To motivate nurses to remain in the Unit and the speciality by providing professional development for all, with careers advice, educational plans and financial assistance.

(7) To provide opportunities for nurses who have left to return to nursing, and to develop excellence in their practice and commitment to remain in nursing.

(8) To develop a clinical career structure which permits those nurses prepared to commit themselves to the Unit and the speciality to enhance both their status and remuneration, while at the same time remaining in clinical roles.

(9) To identify the desired standards of nursing care required by the elderly and to test, through the development of a variety of quality assurance methods, that these standards are being achieved.

(10) To promote the full contribution of nursing to the multi-disciplinary team to produce high standards of care for the elderly.

Objectives

Many developments are already under way to make these goals a reality, while other aspects have yet to be launched. Our target year for the achievement has been set at 1990. Current and future activities include:

(1) *Nursing practice*:

- Continued work in the development of the already published nursing model.
- Initial work on primary nursing has already been undertaken on two wards.

- A care planning system has been implemented, and is now being expanded with the development of core care plans.
- Sharing of care planning and evaluation with patients and relatives is also in progress, and to be expanded with two pilot schemes already completed.
- Plans have been drawn up to develop contacts between nurses in community and in hospital.
- The exploration of themes of partnership with patients, advocacy and patients' rights has already begun. Increasing involvement of relatives and patients in their own care through teaching and information giving is a priority.
- A Nursing Practice Forum, to cover all wards and departments, has been set up to examine and make explicit the desired nursing standards, and explore different methods of assessing achievement of these standards.
- Liaison with local organisations concerned with the elderly and the media to promote awareness of nursing practice at Tameside and develop health education programmes, e.g. health groups, "extend" teaching.

(2) *Nursing organisation and development*:

- A variety of nursing roles are envisaged to produce a clinical career structure for nurses with appropriately increased salary and status, whilst remaining ward based.
- The first and second of these roles are already in post – being the consultant nurse and the specialist nurse in continence promotion. Others are envisaged for quality assurance, research, staff support and so on. All these roles are set at varying levels of grading, and yet all have direct clinical accountability at ward level.
- We are actively pursuing additional ways of rewarding nursing excellence, apart from expanding roles, where given objectives and standards are achieved.
- Quality assurance questionnaires and assessments have been developed for nurses, relatives and patients. A pilot scheme on this has been completed.
- The "consultant nurse" is a clinical role which has been established to promote staff development, research awareness and application and innovations in clinical nursing.

(3) *Nursing education*:

- The Nursing Development Unit Bursary has been set up to provide funding for continued professional development of all nursing staff. We have already received many donations and have numerous projects and activities in the pipeline to keep money coming in.
- Links have been set up with local colleges, polytechnics and the Continuing Nurse Education Project, for students to make use of our facilities, and to enable our nurses to make better use of the professional development opportunities on offer by these institutions.
- International links have been set up with the Emory University Hospital of Atlanta, Georgia, USA, to provide facilities for an annual exchange of nurses. Nurses, funded by the Bursary, will be able to "swap" countries for two to three weeks to pursue projects, research, attend conferences and other courses of study. The first course in this exchange system will visit Tameside in July 1987.
- Regular study sessions are planned related to the theme of the elderly. These will vary from conferences lasting one or more days (the first of these took place in May 1987) to monthly seminars, workshops and case conferences.

(4) *Nursing research*:

- The Nursing Practice Forum has expanded its activities initially from a small group, to a unit-wide organisation. Representative nurses from every setting, both days and nights, attend the forum, disseminate research findings, help to implement findings and carry out projects themselves.
- The Unit has offered facilities to other bodies to conduct research here, including students from the educational institutions and the international exchange students.
- A number of research projects have already been identified and are currently in progress.
- An annual research day is planned when researchers and project workers will present their findings. These and other activities of the NDU will be documented and publication encouraged.

About the author
Stephen G. Wright was a Consultant Nurse of the Nursing Development Unit (Care of the Elderly), Tameside General Hospital, Ashton under Lyne, Lancashire at the time of writing this article.

Change of heart

How a team of North Kirklees Primary Care Trust clinicians used performance management principles to improve coronary heart disease services

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Abstract

Purpose – North Kirklees, an urban area in the East of England, known to have a 6.8 per cent incidence of Coronary Heart Disease (CHD), embarked on a nurse-led CHD primary prevention service in order to improve residents' health. This paper seeks to investigate this serice.

Design/methodology/approach – Keen to utilise the principles of performance management, the team applied the European Foundation for Quality Management (EFQM) Excellence Model RADAR logic believing that it would strengthen their "results orientation". This paper investigates the results.

Findings – Using RADAR, the team identified baseline data for CHD health indicators. The teams were then equipped to set targets for continuous improvement, thereby increasing their potential to progress local residents' health. The case-study findings enable others to adopt a similar approach in their pursuit of excellence.

Research limitations/implications – The CHD Primary Prevention team focused only on performance results in the first instance and did not look at other EFQM Excellence Model results areas.

Originality/value – The paper describes an original case study into how nurses applied RADAR, which gives insight into the team's experiences during their 18-month journey.

Keywords Primary care, Heart, Diseases, England, European Foundation for Quality Management, Quality standards

Paper type Case study

Introduction

North Kirklees Primary Care Trust (NKPCT) came into being April 2002. as a National Health Service organisation situated in England's North East. The Primary Care Trust (PCT) provides primary and community health care via approximately 80 general practitioners (GPs) and 350 health professionals including nurses, speech and language therapists, occupational therapists, and podiatrists. In addition to providing primary care, the PCT uses part of its £198 million budget to commission secondary care services for 178,000 people. North Kirklees is mainly urban with some areas suffering considerable disadvantage and deprivation. Death and morbidity rates are higher in these deprived areas. Moreover, two of the PCT's ten electoral wards appear in the top 10 per cent of England's most deprived localities. Three other deprived areas are just outside the 10 per cent band. Particular health problems include high death rates from:

The authors acknowledge the efforts of Chris McLean (Professional Development Leader), Samantha Thompson (CHD Leader), Sue Senior (Dedicated Nurse for Data Analysis and Dissemination) and the CHDPPS team for their steadfast efforts in the pursuit of excellence.

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- heart disease;
- strokes;
- chronic lung disease; and
- high incidences of diabetes mellitus.

Of the population, 20 per cent have an ethnic minority background and so the risk of an increased incidence of coronary heart disease (CHD) and diabetes mellitus is greater (North Kirklees Primary Care Trust, 2003). It was against this backdrop that the PCT embraced the Department of Health's National Service Framework (NSF) for Coronary Heart Disease recommendations (Department of Health, 2000), as it felt prioritising this area of healthcare could have a significant impact on the local population's health.

National Service Framework for CHD

The March 2000 National Service Framework (NSF) set out a ten-year plan containing national standards, broader milestones and specific targets for improving service provision, quality and to reduce the number of CHD deaths. Because the national incidence of CHD was 4.2 per cent at the time, compared to the local incidence 6.8 per cent, NKPCT became particularly interested in NSF Standard 4:

> GPs and primary health care teams should offer appropriate advice and treatment to all symptom free people at significant risk of cardio-vascular disease in order to reduce their risks.

Moreover, a Healthcare Commission NSF Report *Getting to the Heart of Coronary Heart Disease in England: A Review of Progress towards National Standards* (Commission for Healthcare Audit and Inspection, 2004) stated that 268,000 UK people suffer heart attacks each year, with 1.5 million men and 1.2 million women living with CHD. The highest death rates from CHD are found in the English North East (including, North Kirklees), North West, Yorkshire and Humberside. During April 2003 and June 2004 the Healthcare Commission undertook a review of the NSF (Commission for Healthcare Audit and Inspection, 2004) in order to assess progress nationally. The review found that:

> [. . .] few communities or PCTs have developed strategies for tackling risk factors in all four of the key risk areas. Services provided vary considerably and are often [. . .] small scale [. . .] In many areas much, also needs to be done to target services at those most at risk of developing CHD.

Contrary to the Healthcare Commission findings, NKPCT had been addressing CHD risk for some time and had won a regional modernisation award for its efforts. It is because of this uniqueness and recognition that the authors describe their experiences for a wider audience. It is anticipated that our case study will encourage and support others embarking on a similar journey.

CHD prevention services

Before deciding how to meet the conditions laid down in the NSF standard, the PCT's staff undertook an assessment during 2003 to determine a clear baseline. The exercise showed that some general practices were incorporating aspects of primary prevention in their work. However, contrary to NSF Standard 4, there were service inconsistencies

and variations. To address this imbalance, NKPCT staff developed and implemented a nurse-led PCT-wide CHD prevention service. The first step was preparing and submitting a business case to the PCT's Governance Board during the 2003/2004 fiscal year. As a result, PCT managers allocated approximately £250,000 over a period of three years for establishing and maintaining a CHD Primary Prevention Service (CHDPPS). Once funding was secured, the CHD programme leaders, including a general practitioner with particular interest in CHD, the PCT's professional development manager and the CHD nurse leader, put the plan into action in April 2004 including recruiting a team of nurses to provide the service. Securing a financial footing was not the only thing to influence the new CHD programme. Around that time the PCT appointed a new senior manager to drive this and similar performance management projects. It was, therefore, decided to explore if the new CHDPPS service could benefit from the new performance manager's knowledge and skills. During a scoping meeting, the Performance Management Team (PMT) explained that often during an initiative's implementation phase, healthcare personnel concentrated on new service processes and leave no time to determine accurately what "impact" they want. In order words, a new initiative's "desired results" were not likely to move beyond a broad conception (Jackson, 2001). Healthcare personnel often express aims like "we want to make things better for patients" or "we want to improve the health of patients", but rarely do they identify the measures that demonstrate they have achieved their aims. The CHDPPS team seemed to be in this position, which is unsatisfactory when the team was spending £250,000 of public money and striving to improve CHD prevention services, which affect a significant number of North Kirklees people. If the aim of an initiative or service change is to make things better then teams need to be clear about what they are working towards and also need to set up systems to measure progress. Otherwise they will have no baseline or objective measure of the impact they have made at any time during the implementation or consolidation phases (Jackson *et al.*, 2005). To help CHDPPS team members understand this message, the PMT members explained the RADAR logic, an approach that stems from the European Foundation for Quality Management Excellence Model, otherwise known as the EFQM Excellence Model (EFQM, 2003). This approach enables teams to achieve outcomes for which they are striving. The CHDPPS team had no doubts that they wanted to be successful and knew what was at stake when establishing an innovative service that was to challenge existing practices and demonstrate continuous improvement. So they decided to adopt RADAR. From that moment, strong links were developed with the PMT at the PCT, who provided support. These interventions seemed to secure a continuous improvement strategy.

Applying RADAR

Before the team could take the first step they had to understand the EFQM Excellence Model and in particular the RADAR logic (EFQM, 2003):

> The EFQM Excellence Model is a "non-prescriptive framework that recognises there are many approaches to achieving sustainable excellence" (EFQM, 2003) "Non-prescriptive" in this sense means that there is no one-way of achieving excellence, as many approaches will attain similar outcomes because they are applied in different cultural, economic and social contexts.

Underpinning the EFQM Excellence Model are eight fundamental concepts:

(1) results orientation;
(2) customer focus;
(3) leadership and constancy of purpose;
(4) management by processes and facts;
(5) people development and involvement;
(6) continuous learning, innovation and improvement;
(7) partnership and development; and
(8) corporate social responsibility.

The order of which do not reflect any particular significance (EFQM, 2003). The EFQM Excellence Model is based on nine criteria, five enablers (describing how things are done in the organisation) and four results (describing what is achieved by the enablers). The five enablers are:

(1) leadership;
(2) people;
(3) policy and strategy;
(4) partnerships and resources; and
(5) processes.

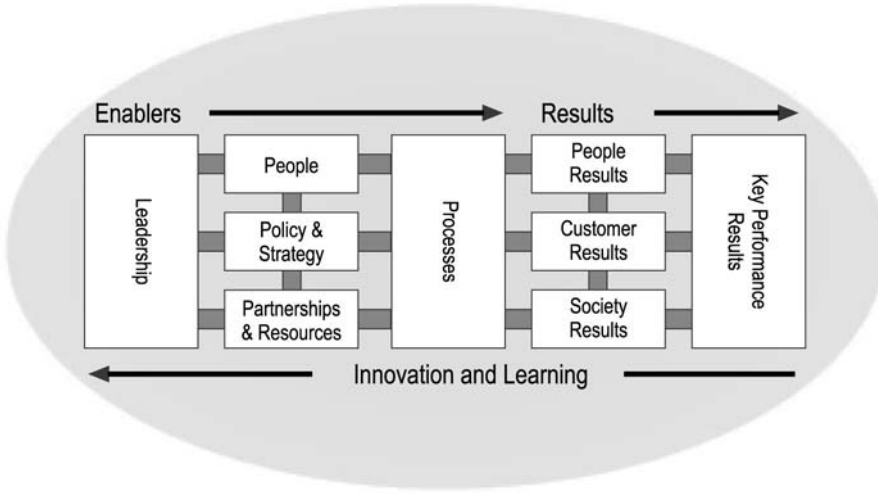
The four results areas, on the other hand, are:

(1) people;
(2) customers;
(3) society; and
(4) key performance.

The EFQM Excellence Model is diagrammatically represented in Figure 1 as nine boxes. Each box depicts one of Model's self-assessment criteria. Each EFQM Excellence Model criterion contains sub-criteria (32 in the whole Model), to which an organisation applies self-assessment, thereby working towards excellence.

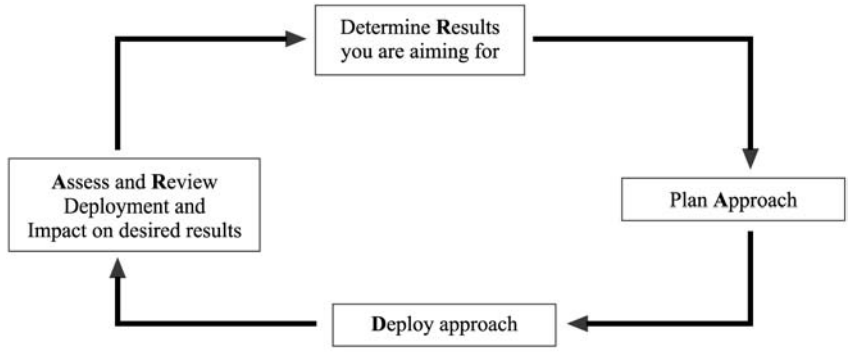
At the heart of the EFQM Excellence Model lies a logic known as RADAR – a mnemonic for results, approach, deployment, assessment and review (see Figure 2). In order to fulfil RADAR's requirements, an organisation, team and/or individual needs to:

- Determine the results they are aiming for as part of the overall policy and strategy.
- Plan and develop an integrated approach or set of approaches that are believed to achieve the proposed results; i.e., develop a new policy or protocol, or plan a change to a service.
- Deploy the approach(es) in a systematic way so that full integration is achieved i.e., undertaking all the necessary tasks to ensure that everyone follows the policy.
- Assess and review the approach(es) by monitoring and analysing deployment.



Source: EFQM (2003)

Figure 1.
The EFQM Excellence Model



Source: EFQM (2003)

Figure 2.
The RADAR logic

That is, was it fully implemented or did only a few people follow the new policy? Identifying what was achieved by the organisation is important, so what differences were made to the organisation, team and/or individual desired results?

Once aware of this information, the team realised that in order to use RADAR effectively, they had to be clear about what they were setting out to achieve. Consequently, the first thing was to identify specific results that would demonstrate progress.

What the CHD team wanted to do (determining results)

During a workshop facilitated by the PMT, the CHDPPS group, now 17 (12 full-time CHD primary prevention nurses and two leaders, brainstormed, prioritised and agreed the service's result topics, to:

(1) Reduce the CHD mortality rate.
(2) Increase the percentage of patients with:
    - normal body mass index (BMI);
    - reduced BMI;
    - blood cholesterol level < 5 mmols;
    - reduced blood cholesterol;
    - blood pressure (BP) of 140/90 or below;
    - reduced BP; and
    - taking moderate physical activity.

All the above were for local residents found to be at CHD risk. Early estimations from the Public Health team identified that approximately 26 per cent of NKPCT adult residents were CHD "at risk". That is, having a CHD risk greater than 15 per cent (British Cardiac Society, 1998). Once these results areas were agreed, the CHDPPS team recognised the importance of determining a starting point as soon as the service was set up. In terms of RADAR, this meant collecting and analysing data relating to the above results areas as soon as the nurses began to see patients. As a consequence, this important aspect of the initiative had to be built into the planning and deployment stages.

What we wanted to do (planning the approach)

The plan was for CHDPPS to be a nurse-led service supported by general practiioners. Each general practice surgery agrees to the guidelines in the CHD 2nd Edition Pack, a protocol produced by NKPCT and the local acute trust. The Pack was designed for identifying, treating and following-up patients at risk. The Pack clearly stated that people at high risk (over 30 per cent chance of developing CHD) should be targeted first and that people at lower risk (15 per cent chance) should be treated as resources allow. This approach was felt to help practice staff achieve NSF Standard 4. It was agreed, therefore, that the CHDPPS would:

- Identify patients at CHD risk.
- Invite these patients to attend an initial and then annual face-to-face consultations with a CHD primary prevention nurse.
- Agree an evidence-based lifestyle modification plan with the patient.
- Monitor progress on meeting patients' individual needs that reflected best practice.

The service was to be provided in general practices so that:

- Patients could gain access via their normal (primary healthcare) route.
- Primary prevention nurses could more easily undertake the risk scoring assessments by interrogating GP practice records and/or databases.

With the plan clearly stated, the team could move into the initiative's deployment (implementation) stage.

Deploying (implementing) the planned approach

Deploying the plan started before RADAR was applied. Each surgery had been given the choice whether they wanted their own practice nurse or a PCT employed nurse to run the surgery's Primary Prevention CHD Clinic. This enabled general practice staff to direct how the PCT-driven initiative was to be put into effect. It also facilitated stronger working links between the general practice staff and the PCT. The practices' decisions meant that seven PCT nurses were employed and ten practice nurses agreed to increase their working hours so that they could dedicate time to the initiative. This allowed all 32 North Kirklees general practices to have devoted nurses employed to deliver CHD Primary Prevention. The dedicated nurse time allocated to each general practice reflected their particular population. Each practice nurse held the CHD Diploma qualification and each PCT employed nurse had a credible secondary care clinical background in cardiac nursing. Given these disparate backgrounds and the value of sharing learning, the PCT along with local cardiologists and other experts in the field, designed a month-long study programme for each nurse. This took place before any nurse saw patients at risk of CHD. Besides the clinical training, the team also received training in the RADAR logic and immediately began to apply the latter.

During the deployment stage, the nurses began to explore how they would find the patients "at high risk" of CHD. Initially they came up with a manual system for interrogating general practice registers but later with the help of Information Department staff, a risk-scoring tool was developed that was compatible with almost every clinical system in the PCT area. This breakthrough enabled general practices to have their entire registered population risk scored for CHD, thereby finding the target audience for primary prevention quickly and efficiently. Once categorised at risk, patients were invited to their surgery to have a risk assessment undertaken by the nurse. The invitation to the "Healthy Living Clinic", the name given to the nurses' consultation sessions, was either by telephone or letter. During face-to-face consultation with the nurse, the patient would have a cardiac risk assessment done and be involved in designing an individual, realistic plan of care to help him or her achieve the desired lifestyle modifications for enhancing health and life. Subsequent follow-up appointments were agreed based upon need and availability.

The nurses used the Prochaska and Diclemente (1986) Change Cycle to assess patients' motivation to alter their lifestyles. It was felt vital that once patients were empowered to change their lives, the nurses would be there to support them and give additional advice and information. Consequently, follow-up visits were arranged based on need. The service offered smoking cessation, weight management, blood pressure recording and alcohol-reduction monitoring. Moreover, some patients were identified as being clinically suitable for statin, aspirin and/or anti-hypertensive medicines and so the nurses ensured that patients were prescribed the appropriate medication. In applying RADAR, it became evident that measures were needed in order to determine medical therapy and other interventions, and so throughout the deployment stage, data were collected at the time of patient assessment.

Assessment

In order to assess progress objectively towards the original aims of making things better for patients and improving their health, a data collection tool was jointly developed by the primary prevention team and the PMT. The tool was purposely

simplistic and took up little nurse time. Completing the data collection proforma merely involved placing a mark on a score sheet each time the nurse undertook an initial or annual patient assessment. The score sheet was divided into two elements relating to:

(1) Deployment of the initiative i.e., the number of risk assessments undertaken, and the number of people prescribed medication.

(2) Desired results i.e., the per centage of people who had a blood pressure $\leq 140/90$ or who had a normal BMI (see Figure 3).

At the beginning of each month, nurses sent their completed score sheets to the PMT who entered data into a spreadsheet. The PM team staff then analysed and presented the findings to CHDPPS leaders, who in turn fed back to nurses each month. Once in receipt of the performance data, the CHDPPS team were in a position to learn more about their service and take steps to demonstrate continuous improvement through the process known as review.

Findings

Between September 2004 and July 2005, 2,173 patients underwent an initial risk assessment. The numerical findings below, therefore, relate to that total number of patients. The findings from the assessment forms have been segmented to reflect RADAR's review elements. The EFQM Excellence Model assessment and review process requires:

- excellent organisations;
- teams and/or individuals to show they have used clear measures;
- that they have learned from those measures; and
- they can demonstrate continuous improvement.

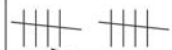
Deployment measure	**Target**	**Performance**	**Comments**	**Who/when**
Number of people who had a CHD risk assessment			These are **first full** assessments and subsequent **annual full** assessments only	Primary CHD Prevention Nurse / 1st of each month
Results measure	**Target**	**Performance**	**Comments**	**Who/when**
% of patients whose BMI is normal			Normal BMI is: 18.5–25 kg/m^2	Primary CHD Prevention Nurse / 1st of each month
% of patients whose Blood Pressure is 140/90 or below				Primary CHD Prevention Nurse / 1st of each month

Figure 3.
Example of the data collection proforma completed by a primary CHD prevention nurse

Further findings from this initiative relate to the implementation process and the experiences along the way. Therefore, in addition to the numerical data, this article also contains key findings from the start of the journey up until October 2005, which have been separated into data management, patient views and practitioners' experiences.

Reviewing deployment

In terms of reviewing deployment, the team could see that on a monthly basis that they were providing risk assessments to more and more patients (see Figure 4). Moreover, they could explain the reasons why performance dipped in some months, which EFQM recognises as good practice (EFQM, 2003). That is, fewer patients were seen over the holiday periods and at times when nurse vacancies arose. The PM team explained to the CHDPPS nurses that an example of demonstrating continuous improvement in this area would be to reduce the time taken to recruit, train and induct a new nurse into the service. Consequently, the number of risk assessments was not adversely affected when a nurse left the team.

The deployment review also showed that for patients attending an assessment between September 2004 and July 2005:

- 20-30 per cent smoked;
- 14-24 per cent took appropriately prescribed statins;
- 10-20 per cent ingested appropriately prescribed aspirin; and
- 31-57 per cent were on an appropriately prescribed anti-hypertensive medication.

Reviewing desired results

Results between September 2004 and July 2005 showed that the average percentage of patients to have a/taking:

- normal BMI, ranged from 24 per cent to 38 per cent;
- cholesterol level of 5 mmol/L or below, ranged from 21 per cent to 33 per cent;
- blood pressure of 140/90 or below, ranged from 30 per cent to 52 per cent; and
- regular moderate exercise, ranged from 34 per cent to 44 per cent.

Figure 4.
Monthly increases in risk assessments

The CHD mortality rate was falling locally (see Figure 5), and of course cannot be attributed to the CHDPPS, but the figures provide a baseline for future interpretation of the impact the CHDPPS has made.

Data management

During the initial workshops when the CHDPPS team was brainstorming the "results areas", the PMT encouraged the primary prevention service (PPS) to consider four perspectives:

(1) health gain;
(2) patients' views;
(3) team views; and
(4) financial performance.

Preliminary measures were identified for all four outcomes. However, it was soon recognised that collecting data was too time consuming and so a decision was made to start with health gain before moving incrementally into the other areas as time and experience allowed. To facilitate data collection, the PMT designed an assessment pro-forma – not the ideal situation as it would have been better for the CHDPPS team to own the pro-forma. Nevertheless, the PMT recognised that ownership of this kind takes time. Indeed, it was five months before the CHD leader suggested changes to the pro-forma, and asked if it would be possible for her to make them. This sense of ownership was a major breakthrough in the RADAR process. Data collection was sporadic at first – only five general practices returned data during September 2004. Efforts by the CHD leaders improved this to 23 practices for October; 29 for November and the full 32 by December 2004. Moreover, the return date also improved, in some cases, from two months late to 100 per cent returned within seven days of each month end. Another issue was the confusion that arose about what information should be included on the data collection pro-forma. At first, nurses thought that each face-to-face consultation needed to be recorded but soon realised that this would not be informative. Hence, it was agreed to only record data for initial and annual risk assessments. Consequently, the data collection tool was amended to include this new guidance. Initially the PMT processed all data and returned the findings to the CHD leaders, who in turn, disseminated the results among the CHD Primary Prevention nurses. Initially, the CHD leaders asked the PMT for an explanation of what the figures meant and their next RADAR logic steps. Approximately ten months into the

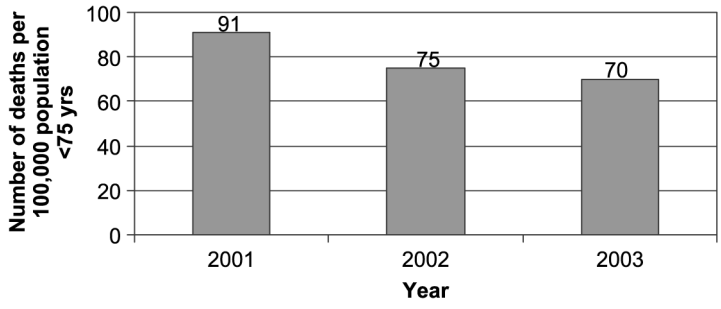


Figure 5.
NKPCT mortality rates for CHD

initiative, the CHD team identified a nurse to process and analyse the data. This was another breakthrough towards process and outcome ownership. Further help from the PMT – amending the spreadsheet meant that the percentage calculations were done automatically requiring less time to produce monthly findings. In July 2005, the CHDPPS team announced that they were ready to collect consumer views and so took the necessary steps to prepare a "patient survey". By October 2005, the survey was ready to be distributed.

Patient views

The scheme was not advertised because the nurses felt this would create a "worried well" deluge. Prior to formally collecting the patients' views, nurses made a number of observations. Many patients invited to the Healthy Living Clinic were sceptical because the scheme was new. Nevertheless, the first few patients became excellent ambassadors for the service and the word spread rapidly. Subsequently, the service began to advertise more widely, and nurses started attending local health awareness days and answering health-related questions from the local population. Consequently, patients said they "felt listened to". Each patient had a 30-minute appointment slot, which some expressed was longer than they had experienced previously for discussing healthy lifestyles. After the initial nurse consultation, the majority of the patients felt it was a "wonderful idea" and "why hadn't it been done before". Other comments included:

> It's so obvious, almost like an apple a day keeps the doctor away, except you [the nurse] tell me five portions of fruit or vegetables a day will keep him away.
>
> I never thought something as simple as cutting out salt could lower my BP.
>
> I am amazed and pleased, thank you.
>
> I didn't think I would be able to stay off the beer, but I did and I lost weight. It was knowing I was seeing you each week.
>
> The new early morning clinic is better, I don't miss work.

The team's experiences

Not all CHDPPS team members' experiences have been good. There have been some anxieties along the way. Their lack of understanding of RADAR caused concern. The CHDPPS team felt it was the PCT manager's way of monitoring what they were doing and how hard they were working. The team members also felt that applying RADAR stopped them doing what they were there to do; i.e. "see patients". This frustrated the team, as they wanted to start caring for patients rather than be sat in workshops undertaking conceptual exercises. However, it was crucial that they identified the results areas first otherwise demonstrating progress towards their aims would be severely compromised. Failing to determine results and establish a data collection system rendered the whole initiative devoid of a known starting point from which to demonstrate continuous improvement. Unlike the programme's leaders, nurses did not warm to RADAR. It took approximately 16 months for the whole team to feel comfortable applying RADAR, although some members were "on board" much sooner

than others. Quotations that demonstrate and/or explain these experiences during the journey include:

> As nurses, we were more used to treating patients and promoting health than looking at desired outcomes, targets and achievement. However, our common aim was to optimise patients' health and to prove we were making a difference. So with that thought in mind we decided to give the RADAR logic a go. The doubt we had about RADAR, was that it would be a number crunching exercise, so the PCT [managers] would be able to see how many patients we were seeing, not results like lowering of BP or cholesterol. As a new service, we were concerned about being a worthwhile resource and we thought if we didn't meet expectations, then the team would be disbanded. However, after much work from the Performance Management Team and their continued visible faith in the service, the nurses started to warm to the RADAR logic.

> The nurses felt that their activity wasn't reflected in the RADAR logic collection tool. They felt that their follow-up interventions, such as blood pressure monitoring, should be recorded, because at this stage we felt we were being judged on activity and numbers seen, not on results. We felt this additional paperwork, time and effort into plotting future goals, was deflecting our energies away from what we wanted to achieve. Much reassurance was needed from the PM team, saying even if the figures were zero, the team was still learning and that was the most important thing for the time being.

> After the initial slow start, the team has gone from strength to strength. We had lots of successes, particularly in weight loss and management, which in turn had a knock- on effect in lowering blood pressure.

> When we first started submitting the performance data, some of the team were not receiving monthly feedback, this was due to some not having e-mail access or good e-mail access. This problem has now been resolved by sending out the feedback as e-mail or in the post.

The CHDPPS team felt it was crucial to the service that they received regular feedback as it boosted their commitment to RADAR and most importantly, helped the members to retain service ownership and its subsequent development. The team had frequent meetings to ensure that the data collection tool evolved alongside the service and therefore reflected not only current thinking but also the team's greater insight into their long-term goals. Experience showed it was hard initially for the team to set targets and they knew that practising good performance management involved setting clear targets. They did not know where to start, and what targets to set. The key message from the PMT was that baseline data were needed before appropriate targets could be set. Moreover, the team recommended not setting sights too high as after the initial success and related euphoria, unrealistic goals are unmet, which can de-motivate. This in mind, three targets were set during July 2005 for attainment in September 2006:

(1) 30 per cent of patients should have a normal BMI;

(2) 41 per cent of patients – a blood pressure of 140/90 or below; and

(3) 37 per cent of patients to be undertaking moderate physical activity.

Workload targets were not set.

Discussion (change of heart)

The new service not only involved changing the physical condition of the patients' hearts, but also their minds. The CHDPPS team members, in relation to this new service and its approach towards demonstrating continuous improvement, have also been changed. The PMT worked tirelessly to get the message across – that performance management makes a positive contribution to health services, and that it is vital for learning which interventions are effective and vice versa. No team should fear trying something new and be anxious about failing to achieve what they wanted to. Instead, they should embrace learning and be inspired to keep trying new things until they find what works. The CHDPPS team did just that – they moved from a team threatened by performance management to one liberated by it.

Evidence demonstrating our journey comes from the team's request initially not to segment data by each general practice. They did not want their individual efforts compared, and yet 18 months later, when designing the patient survey, they requested a nurse-based analysis. They wanted to learn from best practice within the team - an amazing change of heart, which clearly reflected the nurses' confidence in themselves, the team within which they worked and their leadership approach. A change of heart also occurred within the PMT. Initially, it was suggested that the CHDPPS identify its results areas at the business case submission stage, rather than when recruitment began. However, identifying the key results areas with the newly recruited team felt right, because it enabled the whole team to get involved in the process by determining what they wanted to achieve. Brainstorming results and prioritising them took approximately five hours during two workshops, which included many explanations of RADAR by the PMT. As recommended by Jackson (2001), a variety of healthcare examples were explained in order to help nurses understand the logic. At that early stage, RADAR was not fully understood by the majority of the team including the leaders. However, the leaders trusted the PMT and were willing to take what they saw as "a leap of faith". Without the leaders' constancy of purpose, the CHDPPS team would not have attained their successes. This confirms the work of Melan (1998) who showed that quality programmes without effective leadership would fail. The RADAR logic is so well embedded that a CHDPPS nurse inputs data, analysis them and feeds back the results to the team explaining how well they are doing in relation to their targets. The lead CHD nurse, who was originally sceptical about the process, now uses RADAR naturally.

The Professional Development Manager has moved on and is leading another PCT initiative. The Senior Performance Manager (SPM) facilitator's expertise was crucial for success in this instance. During one meeting, when the SPM was unavailable, queries arose that reflected concerns about using RADAR. For instance CHD team members were apprehensive that RADAR was designed to capture how hard each member worked. Also, they felt that their interventions would reduce referrals to secondary care, when on reflection, they realised this may not be the case. Despite the leaders providing reassurance, the team were not receptive, and they wanted assurances from the SPM. Reliance on the SPM at the initial stages of implementing RADAR was not desirable, but given the SPM's expertise, maybe it was understandable and proved beneficial in the long term. That is, the SPM worked world-wide helping healthcare managers and practitioners apply the EFQM Excellence Model and has been the UK representative on the EFQM Health Sector Group, and has

published widely on the subject. Jackson *et al.* (2005) noted that implementing RADAR could be frustrating so facilitators and leaders must be prepared for addressing emerging issues.

This case study clearly demonstrates that leaders and facilitators also need to work closely with managers and practitioners until the major team concerns have been addressed. The team members discovered that it could take more than one invitation to persuade patients to visit the Healthy Living Clinic. In some instances, the patient was asymptomatic and therefore did not see a need for a consultation with a health professional, or there was a language barrier that needed to be overcome before the patient understood the initiative. Once patients attended the clinic, nurses noticed that patients were keen to see their clinical results and that this motivated patients to make lifestyle changes. The team learned that they needed to evolve in order to fulfil patients' needs. So a patient's suggestion that a web site was appropriate was followed. Currently, the team is making the web site more visual and user-friendly. Moreover, a message or query board, where each nurse will take a turn answering posted items, is planned. Once up-and-running, the team will canvass patients' views and suggestions for improvement. A significant success was submitting an application for a West Yorkshire Modernisation Award and winning first prize in the category "Improving public health by promoting healthy living and preventing disease". The submission explained the RADAR logic and the approach taken by the team. This was a vital step for changing the hearts of the team where RADAR was concerned. External recognition and realisation that they were not being monitored on how hard they worked all helped the team to focus on improvement rather than on their fears and insecurities. Since its inception, the team has begun to appreciate that it has much expertise to share and that it can play a significant role promoting healthy messages associated with reducing CHD incidence. Team members are growing in confidence and are keen to work towards the targets that have been set. Hence, instead of fearing targets they are driven by them. One concern is that the scheme has become known as "Doing RADAR" rather than providing CHD Primary Prevention. Nevertheless, the PMT recognised that the journey towards success is ongoing and that this is one change of heart that has yet to be secured.

Eighteen months may seem a long time to embed RADAR in today's "quick fix" environment and yet the journey could not have been any quicker. Fully understanding RADAR came with applying it rather than learning about it in a workshop. Moreover, baseline data were needed before improvement targets could be agreed. It was nine months (from the data collection phase) before the team was confident that their data provided a robust foundation. It also took time before the CHD team recognised that the leaders and PMT's motives were about continuous improvement and not finding fault. Jackson (2001) maintains that it is the journey's direction that matters not the speed, something with which the CHDPPS and the PMT now agree. Sustainable change takes time and is linked to hearts and minds as much as structure and process.

Regarding the remaining organisation, PCT leaders warmed more to RADAR than all the EFQM Excellence Model. The PCT was a new organisation and did not have any trend data for the Model's nine criteria. Neither did it have the resources to train and facilitate such an undertaking. Instead, the senior PCT team decided to set foundations for using the whole EFQM Excellence Model at a later date. The promotion of a "results orientation" and the use of RADAR for achieving corporate

objectives, therefore, are more likely. The CHDPPS team's success has provided evidence for enhancing and spearheading that journey. Moreover, there is a "buzz" in the organisation for using performance management tools for demonstrating continuous improvement. In short, there is a better understanding of the difference between processes and results. Consequently, when developing organisational policies, teams are required to identify the results areas on which new policies affect. In turn, managers and practitioners need to undertake assessment and review in order to learn whether they have made a positive difference or not.

Conclusion

There is no doubt that applying RADAR to clinical developments adds value. In particular, the CHD team developed as much enthusiasm for service impact (results areas) as they did for the process. Consequently, they are equipped with baseline data and information processes to demonstrate continuous improvement through target setting. Others in a similar situation should note that the journey was not hurdle-free and that it took approximately 18 months before the CHDPPS team accepted RADAR. Nevertheless, the team's outlook and approach to their work has matured. They have the confidence to compare performance and learn from the best within their team, rather than being intimidated by outcome measurement. In short, this change of heart among clinicians had a positive impact on patients' change of heart. One characteristic that enhanced the project's success was leadership constancy, a fundamental EFQM Excellence Model concept. If the leaders were not steadfast in their message – that applying RADAR was about demonstrating continuous improvement and learning then engaging the team in the change process might not have happened. Leadership constancy was achieved by an experienced facilitator, who also provided practical support in the form data collection, entry, analysis and reporting. A further significant factor was submitting an application for a local award. External recognition was a clear message that RADAR was a sound approach, and proved to be a well-timed boost for the team. Other helpful features included involving team members from the start while ensuring that the data collection system was sensitive to other demands on the clinical team. Trying to the rush the team, or cut corners would not have been conducive to sustainable change. It is also important to have a clear vision – one that evolves over time, so that change is continuous rather than short-lived. Clearly, the CHD team have risen to a challenge. Moreover, they continue to grow and develop for the benefit of North Kirklees' residents.

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Blood transfusion policy in Dutch hospitals

J.J.E. van Everdingen, N.S. Klazinga and A.F. Casparie

Abstract

Purpose – The paper aims to investigate the quality in health care with regard to the blood transfusion policy in Dutch hospitals.

Design/methodology/approach – The value of an approach to good standards of health care practice, based on Consensus Development Conferences is analysed in the paper in the context of blood transfusion policies.

Findings – The paper finds that the Consensus Development Conference on transfusion policy had a substantial impact on daily practice of care in Dutch hospitals.

Originality/value – The paper provides useful information on maintenance of good health care standard with regard to blood transfusions in Dutch hospitals.

Keywords Blood transfusions, Quality assurance, Hospitals, The Netherlands

Paper type Research paper

Introduction

In The Netherlands, Consensus Development Conferences (CDC) are organised by the National Organisation for Quality Assurance in Hospitals (CBO). CBO is an independent organisation founded in 1979 by the Medical Specialists' Organisation and the Medical Association of Hospital Directors. Its purpose is to stimulate and guide quality assurance activities in hospitals.

One of the elements of quality assurance is the establishment of criteria for good health-care delivery. During the implementation of a quality assurance programme in hospitals, CBO became aware of the physicians' need for national guidelines concerning a number of medical topics. This led CBO to start a consensus development programme (CDC) in 1982. Up to 1987, 22 CDCs have been held. Details of the CDC procedure employed, the choice of topics, and the differences between our approach and those of other countries have been described elsewhere (*Nederlands Tijdschrift voor Geneeskunde*, 1983; Casparie and van Everdingen, 1985). One of the distinctive characteristics of CDC in The Netherlands is that they have originated in the field of quality assurance rather than in the field of technology assessment. Besides assessment of guidelines and criteria for quality assurance during a CDC, the importance of the implementation of the conclusions in the daily practice of care must also be recognised. We therefore conducted an evaluation of our first CDC on blood transfusion policy (Casparie *et al.*, 1987) to assess the effect of this CDC on the daily practice of care and on the quality assurance activities in Dutch hospitals. The results

The authors are indebted to the many hospitals that made available the results of their quality assurance studies and especially to Dr R.B. Dinkelaar and Dr Yvonne Bally for their contribution to the analysis of the data of two studies (Figures 1 and 2).

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of an analysis of these studies were presented at the Third International Symposium on Quality Assurance in Health Care held in Paris in November 1986 (van Everdingen *et al.*, 1986), and are discussed in this article.

CDC on blood transfusion policy

The first CDC was held in 1982 in The Netherlands and addressed the topics of blood-ordering and transfusion policies in hospitals (Casparie *et al.*, 1987). Transfusion therapy was considered a costly and frequently applied form of treatment with potential risks and complications.

Many hospitals did not have well-defined guidelines for a number of aspects of their transfusion policy. These were the main reasons for the choice of this policy as a topic for consensus development.

A working committee consisting of 12 experts prepared statements concerning good health-care delivery with respect to blood transfusion therapy. During the conference on 9 October 1982 the members of this committee gave short presentations and defended the statements before an audience. The conference was attended by 320 participants, mainly internists, heads of bloodbanks, clinical chemists, surgeons and anaesthesiologists. The final consensus text was formulated by the working committee a few weeks after the meeting. This text was composed of the statements agreed on in the public discussion, together with explanatory remarks. The statements were published in the national medical journal (*Nederlands Tijdschrift voor Geneeskunde*, 1983).

Elements of the blood transfusion policy on which explicit recommendations were made in the consensus text included:

- identification of the blood samples;
- double testing of the cross-match technique for missed compatibilities;
- type and screen strategy and registration of irregular antibodies against red blood cells;
- use of standardised ordering lists for the use of blood in surgery;
- proportion of whole blood versus red-cell concentrates;
- quality aspects of red-cell concentrates;
- cross-match/transfusion ratio;
- indications for use of blood and blood products;
- administration of blood to the patient;
- blood transfusion reactions; and
- transfusion committee in hospitals.

Evaluation of CDC: methodology

The evaluation took the form of a survey combined with interviews and an analysis of peer review studies. Three years after the conference a questionnaire was filled in by the heads of the Dutch bloodbanks (number = 22). The annual reports of the bloodbanks between 1981 and 1986 supplied quantitative data. A structured interview comprising 56 questions was held with a representative sample of heads of hospital

haematological laboratories (57 out of 183). After the conference a quality assurance study on blood-transfusion policy was performed in 17 of the 183 Dutch hospitals.

Evaluation of CDC: results

Questionnaire sent to 22 heads of bloodbanks

Of the 20 directors, 19 had attended the conference. All but one of them had arranged discussions of the text with the hospitals in their region. A total of 16 directors had established guidelines for transfusion policy that were consistent with the consensus text.

Interview with 57 heads of haematological laboratories

All but two of the respondents were aware of the existence of the consensus text and 32 (63 per cent) had attended the meeting. In 36 (66 per cent) of the hospitals, the consensus text was discussed and transfusion policy was modified to some extent. These changes primarily concerned the increased use of erythrocyte concentrates, the introduction of the "type and screen" strategy, and the installation of a transfusion committee. Only eight (5 per cent) hospitals could give a synopsis of data concerning the transfusion reactions.

Quality assurance studies

In 17 hospitals, representing 9 per cent of all acute-care hospitals in The Netherlands, a formal quality assurance study was performed after the CDC.

Table I shows the elements of the consensus statements that were subjects of a peer review study and also the results of the study. For two of the mentioned topics, i.e., the preservation of blood and policy on outdated blood, no recommendations were made at the conference.

Table II gives a summary of the characteristics of the 17 quality assurance studies. In seven studies explicit criteria were formulated in advance and in the other ten the criteria had an implicit character, but both types of criteria were consistent with the consensus text. In two studies data collection failed because of inadequate co-operation in filling in of the forms as requested for these studies. Of the remaining 15 investigations, the results of four show that practice in transfusion policy satisfied the criteria but in the other 11, changes in physician behaviour or procedures with respect to blood-transfusion policy appeared to be necessary. In seven cases a re-evaluation was performed and in four this was done annually. These studies dealt with the cross-match/transfusion ratio, the proportion of the whole blood versus erythrocyte concentrates, and policy on outdated blood and blood products. Five studies showed improvement in blood-transfusion policy, one study showed no changes and in one case blood transfusion was found to be worse than in the year before.

Two studies will be discussed in more detail. In hospital A a quality assurance study on the indications for transfusion was performed in 1986. Retrospective analysis of 100 medical records showed no differences in blood-ordering patterns for men and women when the baseline haemoglobin concentration was taken as indication for transfusion (Figure 1).

The results were not altered by exclusion from the analysis of data on patients with complicating factors such as active bleeding, angina pectoris or poor general condition, (selected category in Figure 1). Thus, the physiological differences among and

Topics	Consensus guidelines	Main results
Identification of blood samples	Each hospital should formulate strict rules for the identification of patients' blood samples	983 samples: 280: birth date missing 3: family name missing
Registration of irregular antibodies against red blood cells	The finding of irregular antibodies in a patient's blood should at least be recorded in the following places: – in the records of the blood transfusion laboratory – in the report sent by the laboratory to the specialist – in the medical file – in the letter to the general practitioner after discharge – on the patient's blood-group card	78 samples: Mentioned on patient's blood-group label in 70 cases Not mentioned in medical record in eight cases Mentioned to the general practitioner in only four cases
Use of blood-order list	Use of a maximum surgical blood-order schedule in combination with a "type and screen" procedure for elective surgery is advocated	Number of cross/match tests reduced from 750 to 500 monthly
Proportion of whole blood versus erythrocyte concentrate used	In all cases requiring transfusion because of a shortage of erythrocytes (anaemia, blood loss) red blood cells should be used instead of whole blood	Percentage taken by erythrocyte concentrates 85.3 in 1983; 82.5 in 1984; 87.0 in 1985
Cross-match/transfusion ratio	Efficient use of blood can be promoted by calculation of the cross-match/transfusion ratio	Percentages: 1.68 in 1983; 1.72 in 1984; 1.74 in 1985
Preservation of blood	No consensus guidelines available	48-hour supply available for 96 per cent of all blood-groups
Out-dated blood	No consensus guidelines available	Percentages: 5.2 in 1983; 3.7 in 1984; 3.9 in 1985

Table I.
Overview of 17 quality assurance studies on blood transfusion policy

Step in the procedure	n =	Remarks
Selection of topic	17	
Assessment of criteria	17	Explicit in 7, implicit in 10
Collection of data	15	
Introduction of changes	11	Not neccessary in 4
Re-evaluation	7	Improvement in 5

Table II.
Progress of 17 quality assurance studies in Dutch hospitals along the different steps of the audit-cycle

adaptations made by women, whose red cell mass is on average lower than men's, do not seem to have been taken into account, the quality assurance committee issued recommendations. The investigation was repeated in 1987.

In hospital B a pre-operative blood-order list was introduced in 1983. Until then it had been customary to cross-match two units of blood for each operation. For elective

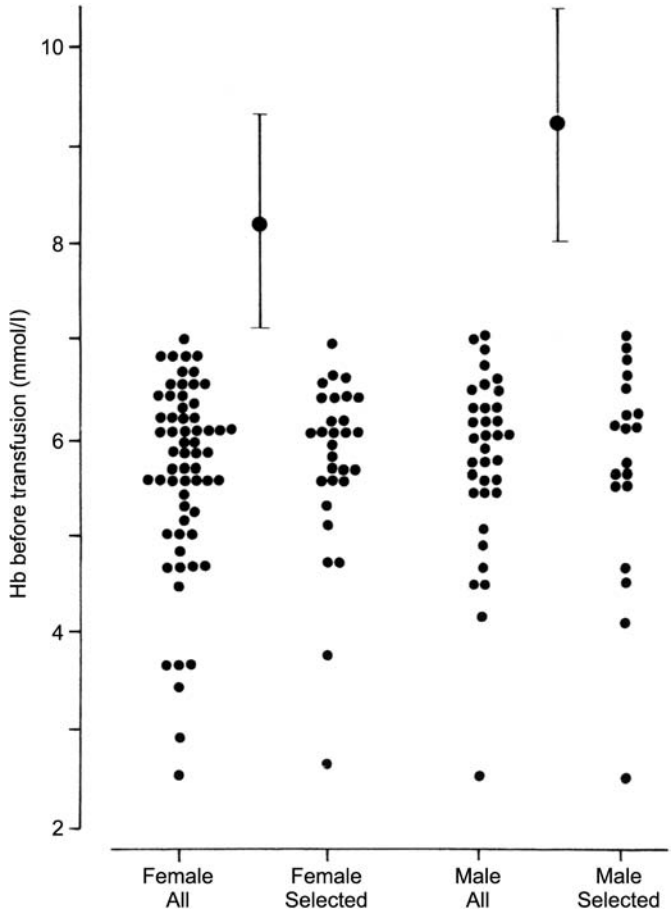

Figure 1.
A retrospective analysis of 100 medical records in blood-ordering pattern for men and women when the base-line haemoglobin concentration was taken as an indication for transfusion in hospital A

surgical procedures a list was produced starting with the number of cross-match units of blood that should be held in stock before the operation. In addition to the routine investigation to detect the presence of irregular antibodies against red cells in the patient's serum, pre-operative blood-group typing was performed. The introduction of this blood-order strategy has reduced the number of cross-match tests by 3,000 a year (Figure 2). In the four years since the introduction of this schedule, no problems have arisen as to the availability of cross-matched blood when urgently needed.

Discussion

Assessment of guidelines and criteria for good health care is not sufficient for adequate improvement of the practice of care. Implementation of these guidelines in daily practice, and thus effective improvement of care, must be the ultimate goal. Systematic evaluations of the effect of CDCs on the practice of medical care have not been published yet, but some preliminary results from various countries that conduct CDCs were recently presented at the Third Annual Meeting of the

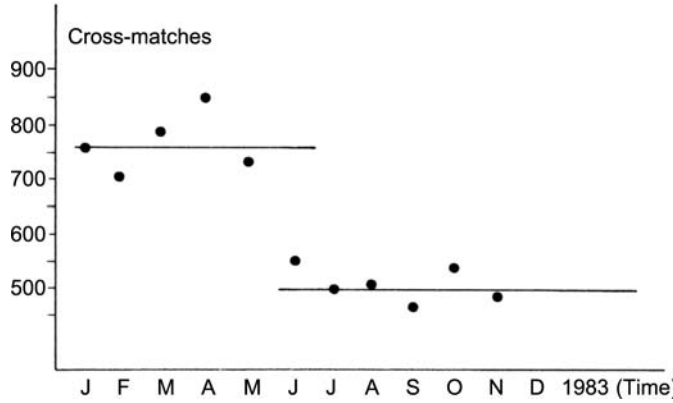

Figure 2.
The number of cross-matches in hospital B before and after the introduction of a blood-order strategy in May 1983

International Society of Technology Assessment in Health Care in Rotterdam (Calltorp, 1987; Hill, 1987; Kanouse and Jacobi, 1987; Klazinga *et al.*, 1987; Lomas *et al.*, 1987). That a CDC can have an impact is suggested by a recent study done in the USA, where the trial of labour after a previous caesarean delivery, as advocated in the NIH consensus statement, increased almost fourfold from 2.1 per cent in 1979 to 8.0 per cent in 1984.

For our CDC method we have chosen a procedure with two group processes. The first of these group processes is embodied in meetings by a committee of experts who will convene six to ten times until agreement is reached. The second process will occur during the conference and take the form of open discussion between the experts and the physicians and other health-care workers involved in that area of care, all of whom can influence the final consensus text. The experts are chosen in consultation with their specialist organisation, and we assume that their prestige will increase the credibility of the consensus development process.

The announcement of a conference is sent to all physicians and health-care workers involved, and the conferences are attended by a substantial proportion of them (100-1,000 participants. The final consensus text is published in the national medical journal and is given large-scale distribution by the CBO. We think that our procedure ensures that the final consensus statements have a solid basis and will be accepted by the medical profession. These expectations were confirmed by the finding that the text of the CDC on blood-transfusion therapy was widely known and had been discussed in almost all hospitals in The Netherlands. Furthermore, guidelines and criteria had been adopted by the transfusion committees where necessary. In hospitals where transfusion policy was chosen as a topic for audit, the criteria applied were in agreement with the consensus statements. Thus, these guidelines can be considered to be of practical value.

In only four of the 15 completed quality assurance studies did the current practice of care satisfy the criteria. Five out of seven re-evaluation studies showed improvement.

Although other factors such as Aids and budgeting of hospitals undoubtedly also influenced blood-transfusion policy in The Netherlands, our findings suggest that the CDC on transfusion policy had a substantial impact on the daily practice of care.

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Marketing blood drives to students: a case study

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Abstract

Purpose – The aim of this paper is to motivate blood donation among international students and demonstrate the applicability of marketing techniques in the health care sector.

Design/methodology/approach – The paper uses a combination of focus groups and a questionnaire-based survey.

Findings – The paper finds that donors primarily find gratification from their altruistic acts through awareness of their contribution to saving lives. Receiving information on how each individual donation is used is seen as a powerful means of reinforcement. Practical benefits such as receiving free blood test information are also useful motivators, while communicating the professionalism of the blood collection techniques are important for reassuring the minority of prospective donors who expressed fears about possible risks associated with blood donation.

Research limitations/implications – Since this was a small-scale study among Hungarian and international students in Budapest, further research is necessary to validate its results among other demographic groups.

Practical implications – Findings were reported to the International Federation of Red Cross and Red Crescent Societies in Hungary in order to increase blood donations among students in Hungary. Subject to validation through further research, applying recommended approaches in different countries and other demographic groups is suggested.

Originality/value – This is the first research paper on motivation toward blood donation among international students and offers new and practical suggestions for increasing their level of participation in blood drives.

Keywords Blood transfusions, Hungary, Marketing strategy, Student

Paper type Case study

Introduction

Blood, indispensable to life, is becoming ever more important in health care today – not least donor and recipient safety. A crucial element in ensuring safety is to know as much as possible about the source of donated blood and to do this a source of voluntary, regular non-paid blood donation is recognized as a critical factor in quality blood service delivery. One of the major contributors to the worldwide blood supply (more than 75 million units of blood) is the International Federation of Red Cross and Red Crescent Societies (IFRC), which supplies 30 percent. The IFRC represent, for many people, an institution where blood is donated to save lives, confident that it will be properly managed. With the largest humanitarian network of volunteers, IFRC has considerable experience handling volunteer retention, motivation and support. But, in order to supply blood that meets the growing demand, it is necessary to increase the willingness of the population to donate.

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The aim of this research project was to increase the number of IFRC Hungarian blood donors. The study was part of an MBA program at the Central European University in Budapest. One objective was to find the most effective approach to recruiting blood donors at Budapest Universities, which have a large and international student population. Our approach was based on the idea that international student bodies could be an ideal base for spreading the blood donation habit not just in Hungary, but also in other countries. We believe that universities are a good source of donors since if people start to donate blood regularly while young they may keep the habit for the rest of their lives. We believe also that regular donors are a good medium for attracting and persuading others to become new donors. Other advantages of universities, as a setting for "blood drives", are the number of prospective donors gathered in one place and the large number of other voluntary activities taking place there that make such events easier to organize successfully and the fact that highly educated people are more likely to become donors (Eurobarometer, 1995). Certainly, "blood drives" – a commonly observed feature of university life in both North America and Europe tends to confirm these views.

Literature review

Applying marketing theory to the problem of blood donation has a long history that predates public awareness of AIDS as a complicating factor. Knight (1983) discussed the issue in the context of the UK National Blood Transfusion Service (NBTS). He found that the NBTS had a good public image and that there was a high awareness of the need for blood donations. Even if there was considerable "latent guilt" about not giving blood, a "cost" was perceived in terms of physical discomfort to the donor. Andaleeb and Basu (1995) reviewed US research into the relationship between demographic variables and blood donation. They and other authors attempted to predict donor status largely on the basis of demographic characteristics such as marital status, occupation, income, race and religion (Bettinghaus and Milkovich, 1975; Condie and Maxwell, 1970; Oswalt, 1977). Although demographic variables were useful for identifying and segmenting potential donors, they found that these factors alone could not provide adequate insight into the reasons why people do or do not donate blood. Subsequent research tried to incorporate a variety of personality traits as alternate predictors of blood donation behavior (Lemmens *et al.*, 2005; Burnett, 1982; Condie *et al.*, 1976). Andaleeb and Basu's (1995) model included three attitudinal variables:

(1) trust in the blood bank;

(2) specific fears of health risks associated with the act of blood donation; and

(3) general fears.

Their results showed that it is the propensity to take risks that has the greatest ability to differentiate a donor from a non-donor. Gender had the second highest discriminatory power, with men being more likely to donate than women. Gender was followed closely in explanatory power by the perception of health risks associated with donation and respondents' trust in blood banks. An increase in trust and a reduction in perceived health risk each served to enhance the chance of donation. Finally, they found that older people were more likely to donate. Consequently, Nonis *et al.* (1996) looked at US college students' blood donation behavior. They concluded, unlike Andaleeb and Basu (1995), that there was no significant difference between

donors and non-donors in terms of perceived risks associated with donation. They argued that incorporating risk-reducing information into promotional material may not be helpful. Indeed doing this may be counter-productive since such messages may act as a reminder of these risks. Forming and maintaining blood donation habits were important, however, and required different marketing approaches. While incentives in terms of gifts, etc., had little impact on new potential donors, they appeared to work as a means of maintaining the flow of donations among existing donors. They concluded that a segmented marketing approach was likely to be the most effective.

The US Food and Drug Administration (FDA, 2000) found a consensus on many key points reached by successful blood centers. They concluded that successful programs draw on expertise in customer relations, advertising, public relations, and marketing. Staff exhibited a culture of innovation and hard work while at the same time encouraging and thanking donors. Donor recognition is an important component of a successful program. However, recognition does not generally mean providing incentives or gifts to donors, it means acknowledging donors' altruistic contribution at each donation. Special recognition of regular donors at milestones in their career, such as a public thank you for multi-gallon donors at a celebration dinner, can be valuable. Successful advertising campaigns should be emotionally-oriented rather than practical appeals; for example, just showing pictures of empty blood shelves is not effective (FDA, 2000). Service managers should put a human face on the transfusion recipient and the donor. While advertising increases awareness, it does not automatically generate more donors. To put a donor in the chair, he or she should be asked directly – preferably one-on-one. Despite evidence that incentives discourage long-term repeat donations, most recruiters seem reluctant to give them up. Some "incentives," such as T-shirts, fulfill a second function – free advertising. Despite these success factors, donors, themselves, primarily do not want incentives – just recognition (FDA, 2000).

Europe-wide data on the issue of blood donation have been gathered a number of times, most recently in 2002 (Eurobarometer, 1995, 2003). These surveys examined the level of awareness of certain basic facts concerning blood donations and people's donation behavior. While awareness tends to be quite high (around 70 percent), only 30 percent of Europeans donated; and of the remainder who had never given blood, only 39 percent had considered doing so. A majority thought that those who donate blood "should not receive anything – should give just for the sake of giving". Donors were found among all demographic groups with a slightly lower frequency among the under 25 and over 55 age groups. Higher levels of education and greater affluence also tended to be associated with blood donation (Eurobarometer, 1995). For non-donors, among the main reasons for not giving blood, apart from poor health and medical advice, was a fear of contracting HIV/AIDS during the donation process. About 70 percent of Europeans, on the other hand, said that HIV/AIDS made them worry about the safety of the donated blood they might receive during transfusion (Eurobarometer, 1995). Clearly, HIV/AIDS is a major issue for blood transfusion services. Consequently, blood donation procedures are covered by a EU directive (European Union, 2004), which lays down standards of quality and safety for human tissues and cells intended for human applications.

The best source of current attitudes towards blood donation is currently the internet. For example, "Is refusal to donate blood immoral?" was a discussion hosted at Samizdata (2003). Most respondents disagreed while some argued that the frequently cited ethical taboo against the sale "body parts" has no moral justification. Following classical economics, they argued that a free market for blood, just like a free market for

food, would match supply and demand more efficiently without any need for moral suasion. Indeed, some accused blood banks of subsequently selling freely blood donated to private hospitals – a practice they felt offended the charitable motivation behind the gift. Nonetheless, most contributors accepted and supported the current voluntary donation system as it is generally practiced in Europe and the USA. They confirmed the value of non-financial rewards, such as public recognition through celebration events for frequent donors, etc. Additionally, some argued that even if there is no moral objection to governments paying blood donors then taxpayer-supported health services provided better value for money if they obtained their supplies at no cost.

Discussing general health-related issues, one contributor suggested that frequent blood donations might be bad for you, since they "cut into" your body's life-time capacity to regenerate itself. This view is contradicted by van Jaarsveld and Pool (2002), who argued that blood donation is actually beneficial to health. Apart from the value of the compulsory blood pressure and pulse checks that are required prior to donation, preliminary research studies found that giving blood could decrease the likeliness of having a heart attack or other cardiac problems. The authors suggested that blood loss helps the body get rid of excessive iron, which is thought to contribute to heart disease. In December 2003, evidence came to light in the UK that a blood donor may have transmitted variant Creutzfeldt-Jakob Disease (vCJD) through blood transfusion (National Blood Service, 2004). Tests to identify vCJD in donated blood had already been introduced in 2001 and at that time the National Blood Service worried that subjecting donors to a CJD test might cut the number of UK blood donors by as much as 50 percent (BBC, 2001). While screening for possible exposure to CJD is now also mandatory in North America and Europe, the feared impact on donation behavior has not occurred either in the UK or elsewhere. Creutzfeldt-Jakob Disease did not figure in the Internet-based discussions of blood donation discussed above, which implies a non-issue.

Research aims and exploratory procedures

Our literature review suggests that increasing the supply of blood donors, particularly given the overwhelming preference for donations to remain free, is not easy. While there is some evidence for non-donation being associated with specific fears associated with pain, catching AIDS, etc., it seems to be more associated with general inertia rather than specific objections. Increasing blood supplies seemed likely to be more a question of finding strategies for overcoming inertia rather than adopting a radical new approach. To find such strategies, we aimed to identify ways of:

- Fostering IFRC activities and providing new approaches for attracting blood donors at Hungarian universities.
- Educating new blood donors among foreign students to spread the blood donation habit to other countries.

We had few specific a priori ideas about how to do this. In order to develop proposals for increasing the effectiveness of blood donation drives at universities and to explore the main fields of concern about blood donations, we organized two focus groups among students in the target population. These groups consisted of male and female MBA students at Budapest's Central European Business School. Because of the sensitivity of some issues concerning AIDS and sexual behavior, the male and female

groups were interviewed separately to explore their orientation towards blood donation and potential motivations and concerns. About a third of each group had been donors in the past (similar to the Europe-wide percentage reported by the Eurobarometer (2003) research). The main conclusions were in line with the US and European studies discussed above. Donors tended to do so through a combination of convenience factors, such as a blood drive organized at their school or university, and feelings of altruism; they were also likely to respond to an appeal related to specific blood shortages. Non-donors tended to be afraid of needles, seeing blood and possible unpleasant feelings afterwards. Some justified their decision by saying that they had a common blood type that was not in great demand. Respondents generally felt that donors should be approached directly; advertising alone was not felt to help. In fact they said that students are particularly resistant to media advertising and more likely to want to ask questions to obtain information before donating; something that can be done easily using a direct approach during on-campus blood drives. Organizing blood-drives at universities was said to be effective because people do not want to waste time searching for and travelling to the next available donation session at a distant location. Respondents also felt that efforts to inform people about the value of being a donor should start as early as possible and that universities were seen as the "last chance" to educate people as donors. This view is reinforced by the Eurobarometer (2003), cited above, which found that blood donation is more prevalent among more educated groups.

Only one participant had donated blood at a Hungarian Red Cross event and was a regular donor in his home country. Lack of information about where and when to donate blood, the language barrier and concerns about local safety standards were the reasons most frequently given by other respondents for not donating in Hungary. The possibility of offering donors free mandatory blood tests was also discussed and seemed an important issue. The majority of participants knew that donated blood is tested, but only few of them knew that the Red Cross could send these tests results to them at no cost. This increased their interest in testing and they made suggestions about procedures that should be used. For example, prospective donors should be asked if they want to receive their blood test results. Most felt that if tests were positive, donors who had asked for their results should then be asked by letter to go to their doctor for confirmatory tests. In the case of a positive HIV test, however, most respondents felt that a different procedure should be followed given the danger of the potentially lethal consequences to the donor and to others. In this instance, they felt that blood drive organizers had a duty to ask the donor to contact blood transfusion service staff and recommend confirmatory tests even if the donor had not previously asked to receive test results. Doing this might of course raise ethical and legal issues that the groups did not discuss, but these procedures would of course have to be carefully considered before implementation.

The quantitative survey

There are about 90,000 students in Budapest – 60,000 in the largest four universities chosen for the quantitative survey:

- Budapest University of Technology and Economics (15,859 students in academic year 1999-2000);
- Szent István University, Budapest – Veterinary Science (about 24,000 students);

- Loránd Eötvös University of Liberal Arts and Sciences Budapest (about 12,000 students); and
- Corvinius University of Budapest, University of Economic Sciences and Public Administration, Budapest (about 17,000 students).

Based on the results of our qualitative research, the quantitative research questionnaire covered four main areas:

(1) personal information (three questions);
(2) awareness (two questions);
(3) blood donation (five questions); and
(4) reasons to give/not to give blood (six questions).

The questionnaire was available in both English and Hungarian (respondents were approximately evenly divided between Hungarian and international students). The total number of respondents was 130 (62 male, 58 female). Of these, 27 percent had donated blood; the majority were not regular donors - 84 percent had donated less than five times. Since this was an exploratory study, the responses were gathered through convenience sampling during a small number of visits to the university campuses. We developed our questionnaire from the focus group discussions (see the Appendix, Figure A1). However, we did not test its reliability and validity. While the authors admit that these conditions may raise questions concerning the study, we believe that these methodological limitations are not sufficient to prevent us from reporting the results for what they are; small-scale exploratory research designed to offer practical help to those formulating policy in relation to a particular situation. In view of these limitations, however, any generalizations that we draw from our study have to be treated tentatively. Notwithstanding these restrictions, it should be noted that the percentage of donors in the sample was broadly in line with other more sophisticated studies of blood donation behavior, such as the Eurobarometer (1995, 2003) studies discussed above. Also, in common with other studies (Nonis *et al.*, 1996, Andaleeb and Basu, 1995), blood donation was more common among the males than females in our sample (34 percent and 22 percent) respectively. However, this difference was not statistically significant (Chi-square $= 0.13$, $p = 0.71$). Observation of these characteristics in our sample, however, gave us some confidence in their representativeness.

Findings

Most respondents felt that hospitals were the most convenient place to give blood, followed by "an event organized by the Red Cross at our university". As might be expected, awareness about the need for blood and the length of time it can be stored before use was low. Most (97 percent) of the respondents did not know how much blood is needed yearly in Hungary, while 91 percent did not know how much time blood can be stored. Reasons for making (or not making) blood donations fell into three groups:

(1) social or moral;
(2) personal health; and
(3) fears.

Among donors, the most commonly cited reason was "to do a good thing for the community" (52 percent) followed by "feeling of saving peoples" lives" (47 percent).

Among non-donors, common motivations were "because I never knew where I should go and when" (23 percent) and "because I never thought of it" (20 percent). Donors felt that others should donate for the same altruistic reasons and thought that the most likely way they could be persuaded to donate would be if they were able "to get information when my blood has saved a life" (62 percent) followed by "to know that there is an urgent need of blood" (59 percent) and "to know what my blood will be used for" (50 percent). Respondents could choose up to three answers to these questions so totals may exceed 100 percent.

The most important health-related reason given by donors and non-donors alike was "if everyone donates blood, I can get blood when I need it" (33 percent) followed by "to have own blood before an operation" (18 percent). Only 7 percent said their main reason for not donating blood was "because of the danger of HIV infection". Most of the non-donors offered other reasons (50 percent of which were medically related: body weight, iron levels, fainting and other illnesses). Over half the respondents (56 percent) knew that specific tests were done on donated blood. Preferred test results received free (79 percent), official document with their blood type (63 percent) and HCV (a test for Hepatitis C) (54 percent). Indeed, receiving these and other blood test results, such as blood sugar levels, were methods for encouraging non-donors to donate that received most support. The main fear-related reasons for not giving blood were: "because I am afraid of needles" (23 percent) and "because I think it is very unpleasant" (20 percent). Clearly there were also groundless fears related to the use of dirty needles since the most important reason cited in this category to encourage people to donate blood is "to see that the needles are unused" (14 percent). We also looked the differences between the attitudes of donors and non-donors in relation to these issues. However, splitting the data between these groups and using chi-squared tests on their responses to each question did not yield any statistically significant differences.

Discussion and recommendations

The challenge facing "blood drive" organizers everywhere can be summarized as the "three R's" - Recruitment, Retention and Reward. Regarding recruitment, one of the major problems that emerged is the low level of awareness among students about general facts concerning blood donation. This might be a result of either a lack of interest in the community or limited information available about the Red Cross" blood service activity. Advertising, public relations and other communication activities, such as partnerships with popular sports teams, may have a role to play but more effort is required to get people to donate blood for the first time. This is one of the most difficult parts in the recruiting process since there are many obstacles that recruiters have to overcome in order to enroll new donors. These obstacles can be overcome by:

- Attracting, convincing and helping potential donors take the first step.
- Red Cross staff should make sure that they have the right program set-up.
- Staff members should be well prepared and exhibit a culture of hard work and innovation and provide timely information.
- From our data, we found that the biggest concern when it comes to giving blood were needle and safety fears. Therefore, staff members should explain these steps carefully.

- Staff should patient and professional in order to build trust and then emphasize the importance of each individual's donation by informing donors of all the different ways in which their donations can be used to save lives.

The last point is important. Our study indicated that donors appreciate recognition of their desire to save lives by knowing how and when their donated blood is used. For example, perhaps it would be possible to attach a pre-addressed postcard to each donation that could be mailed to the donor from the hospital at the moment it is taken from storage. The fact that donated blood is often "separated" and then used for purposes other than traditional transfusions represents a difficulty, however. Nevertheless, we still think that an honest and clear explanation of the value of whatever health-care service donated blood is facilitating still achieves our aim of providing donors with an important and timely reinforcement of the value of their gift to the community. Another important and perhaps underestimated issue is promising donors free blood tests. Particular interest was shown in receiving the test results for HIV (subject perhaps to the precautions suggested above).

Findings from the Eurobarometer research, as well as our focus groups, suggest that generic advertising does not encourage students or "well-educated" people to donate blood. It is most important, therefore, that Red Cross staff provide clear and concise information about their activities, processes and procedures regarding blood donation, and the specific use of donated blood. Given that our research indicated that the majority of donors (86 percent) have given blood no more that five times, it is clear that retention is also a challenge. In order to address retention, we recommend that Red Cross staff should build a donor database and subject to their agreement, share it with other Red Cross organizations in the countries from where foreign donors travel. This would enable service staff to send information about opportunities to give blood within their own area. Events that offer recognition to donors who have reached particular milestones in their donation career are also another strategy. Given that regular donors tend to provide quantity and quality blood, conversion of the infrequent donor into a regular one through retention activities is crucially important.

While blood donors often donate for the first time because of convenient circumstances, if they do not have similar experiences again then they tend not to make a repeat donation. While the proportion of donors among the student population was near the average found in other studies, we were surprised how few regular donors were. This may perhaps be explained by their participation in an event organized by their universities, perhaps for reasons of convenience and conformity to peer behavior. On the other hand, donors who give more often and are used to the habit tend to maintain the practice even if they move to other places. Blood donations should, therefore, be held at regular intervals at participating universities – perhaps corresponding to the two to three-month interval before an individual donor is normally permitted to donate again so that the maximum number of students gets into "the blood donation habit." While our findings show that donors are not primarily looking for monetary rewards, some privileges like being offered discounts for health checks, might be valuable at least in countries that do not have "free" healthcare. While events organized in recognition of milestones in a regular donor's career may not be appropriate in the rapidly changing student community, other token rewards such as parties, raffles etc., may have some value. While respondents said that T-shirts, caps and badges etc. are not important, they have secondary functions such as creating "buzz" around each event.

Convincing international students to donate blood in Hungary represents a particular challenge because of the language barrier. This may be, even subconsciously, an obstacle for people who are thinking about donating blood, especially the first time. Trust was an important issue in blood donations to emerge in both the focus groups and literature and experience shows that donors may not trust people with whom they can't converse. For this reason, staff sent to carry out blood donation drives at universities with foreign students, should ideally have a basic knowledge of English and be familiar with information material written in English since this is the most common second language among international students.

As with research into other groups, we conclude that general advertising has only a limited role to play in stimulating donations. Instead, students preferred detailed information about the blood donation process, stating especially the need and the applications for donated blood. The IFRC should inform students about the different blood elements and their applications as well as about what happens with unused blood. Special emphasis should be put on information about bloods' storage life which, when used for surgery, is normally five weeks (TSO, 2001); i.e. significantly less than the minimum period allowed between donations. Other important information relates to safety regulations and health facts about blood donation. This applies not only to international students but also to Hungarian ones who expressed concerns about the safety standards. Some would rather donate blood in countries (like Germany) they associate with higher safety standards. This reassurance should be done in a low-key but professional manner so as not to raise safety concerns unnecessarily. Those who wish to know should be able to find out easily that needles are used once only and are taken out of their anti-bacterial packing in front of the each donor. They should also be informed that personnel dealing with the blood donation process are healthcare professionals and that donors are covered by insurance for any accidents, however unlikely, occurring during the blood donation process.

Blood drive information could be posted on university intranets or made available through poster campaigns shortly before the blood drive. University classes could also be held in connection with blood donation drives. A wide range of topics is possible covering almost every subject, although clearly too much exposure may be counter-productive. For example, lectures in medical and veterinary classes on blood storage and the applications of its different elements as well as demonstrations of the techniques used to carry out blood tests could be used. Discussions about the social incentives and social responsibility involved in blood donation could be included in ethics, philosophy or related classes. Marketing classes could analyze IFRC marketing campaigns and different tools used. Language classes could translate the advertisements and information materials. All such parallel activities help to raise the visibility of university-based blood drives and, hopefully, increase participation.

Conclusion

The idea of using marketing techniques to help promote desirable social behavior is not new. However, we believe much more can be done to assist health-care sectors to benefit from this approach. Our small-scale study suggest some practical ways in which this can be done by helping to ensure an adequate and risk-free flow of blood donations. While further research would be necessary to be certain, we believe our recommendations for recruiting, rewarding and retaining donors among the international student population in Hungary will prove valid, perhaps with some adaptation to meet local conditions, in other contexts. Our recommendations certainly provide pointers for achieving these

aims among other demographic groups and in other countries. We are confident that our work will be beneficial to the IFRC, as well as other groups whose quest is to spread the blood donation habit in Hungary and elsewhere.

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Appendix

1. What is your nationality?.....

=> ***If the answer is Hungarian please go to question 4.***

2. Which of the following languages are you more familiar with than English?

Arabic	☐	Chinese	☐
French	☐	German	☐
Spanish	☐	Russian	☐
Other	☐	None	☐

=> If other then please tell us which: .....

3. Have you ever donated blood in your home country?

Yes ☐ No ☐

=> ***If the answer is No, please go to question 8.***

4. Have you ever donated blood in Hungary?

Yes ☐ No ☐

=> ***If you are Hungarian and the answer is Yes then please go to question 6.***

=> ***If you are Hungarian and the answer is No then please go to question 8.***

5. If you have donated blood in your home country, but not in Hungary, why?

a. because of the language barrier ☐
b. I didn't know where and when ☐
c. I donated blood at home to help people in my country ☐
d. I am afraid that their safety standards are too low ☐
e. other reasons ☐

=> If other, please tell us which: .....

6. How many times have you donated blood?

a. 1-5 times ☐
b. 6-10 times ☐
c. more than 10 times ☐
d. regularly ☐

7. What was your reason for donating blood? (max. 3 answers)

a. to have own blood before an operation ☐
b. to get access to free tests such as the HIV test ☐
c. to receive social benefit, such as praises from friends or others ☐
d. to have the feeling of saving peoples lives ☐
e. to do a good thing for the community ☐
f. if everyone donates blood, I can get blood when I need it ☐
g. other reasons ☐

=> If other, please tell us which: .....

=> ***Please go to question 9.***

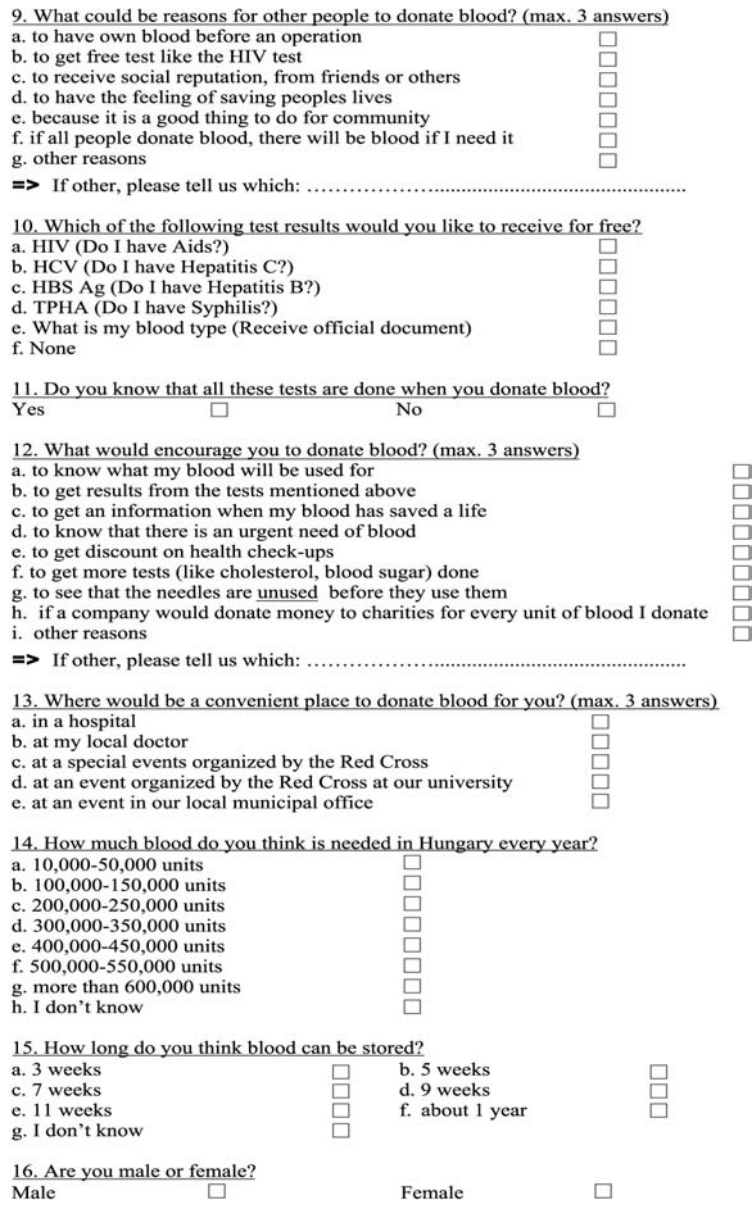
8) Why have you never given blood? (max. 3 answers)

a. because I never thought of it ☐
b. because I never knew where I should go and when ☐
c. because I do not have time for donating blood ☐
d. because I think it is very unpleasant ☐
e. because I am afraid of needles ☐
f. because I think it can harm me/my body ☐
g. because of the danger of HIV infection ☐
h. other reasons ☐

=> If other, please tell us which: .....

(*continued*)

Figure A1.
The questionnaire



9. What could be reasons for other people to donate blood? (max. 3 answers)
a. to have own blood before an operation ☐
b. to get free test like the HIV test ☐
c. to receive social reputation, from friends or others ☐
d. to have the feeling of saving peoples lives ☐
e. because it is a good thing to do for community ☐
f. if all people donate blood, there will be blood if I need it ☐
g. other reasons ☐
=> If other, please tell us which: …….....

10. Which of the following test results would you like to receive for free?
a. HIV (Do I have Aids?) ☐
b. HCV (Do I have Hepatitis C?) ☐
c. HBS Ag (Do I have Hepatitis B?) ☐
d. TPHA (Do I have Syphilis?) ☐
e. What is my blood type (Receive official document) ☐
f. None ☐

11. Do you know that all these tests are done when you donate blood?
Yes ☐ No ☐

12. What would encourage you to donate blood? (max. 3 answers)
a. to know what my blood will be used for ☐
b. to get results from the tests mentioned above ☐
c. to get an information when my blood has saved a life ☐
d. to know that there is an urgent need of blood ☐
e. to get discount on health check-ups ☐
f. to get more tests (like cholesterol, blood sugar) done ☐
g. to see that the needles are unused before they use them ☐
h. if a company would donate money to charities for every unit of blood I donate ☐
i. other reasons ☐
=> If other, please tell us which: …….....

13. Where would be a convenient place to donate blood for you? (max. 3 answers)
a. in a hospital ☐
b. at my local doctor ☐
c. at a special events organized by the Red Cross ☐
d. at an event organized by the Red Cross at our university ☐
e. at an event in our local municipal office ☐

14. How much blood do you think is needed in Hungary every year?
a. 10,000-50,000 units ☐
b. 100,000-150,000 units ☐
c. 200,000-250,000 units ☐
d. 300,000-350,000 units ☐
e. 400,000-450,000 units ☐
f. 500,000-550,000 units ☐
g. more than 600,000 units ☐
h. I don't know ☐

15. How long do you think blood can be stored?
a. 3 weeks ☐ b. 5 weeks ☐
c. 7 weeks ☐ d. 9 weeks ☐
e. 11 weeks ☐ f. about 1 year ☐
g. I don't know ☐

16. Are you male or female?
Male ☐ Female ☐

Figure A1.

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Note from the publisher

Emerald at 40

This year Emerald Group Publishing Limited celebrates its 40th Anniversary. As anyone with more than two score years under their belt (or approaching it) will know, 40 represents a milestone. It marks a point at which we have, or we are supposed to have, come to terms with the world and reached a good understanding of what we want from life. And for those of a more contemplative persuasion, it prompts us to reflect on our earlier years and how we got to where we are.

It is perhaps not so different for a company. In many ways, to reach the age of 40 for an organisation is quite an achievement. Emerald's own history began in 1967 with the acquisition of one journal, *Management Decision*. The company was begun as a part-time enterprise by a group of senior management academics from Bradford Management Centre. The decision to found the company, known as MCB University Press until 2001, was made due to a general dissatisfaction with the opportunities to publish in management and the limited international publishing distribution outlets at this time. Through the creation and development of the journals, not only was this particular goal achieved, but also the foundations of a successful business were laid. By 1970 the first full-time employee was appointed and by 1975 there were five members of staff on the pay roll. In 1981, there were 20 members of staff and three years later the company had grown to a size that meant we had to move to larger premises – one half of the current site at 62 Toller Lane.

Through the 1990s Emerald came of age. In 1990 the first marketing database was introduced and several years later we acquired a number of engineering journals to add to our increasing portfolio of management titles. The IT revolution also began to impact on the publishing and content delivery processes during this period. Writing in 2007, it seems hard to remember a time when information was not available at the click of a button and articles were not written and supplied in electronic format – and yet it was only 11 years ago that Emerald launched the online digital collection of articles as a database. The move was seen as pioneering and helped to shape the future of the company thereafter. The name of the database was Emerald (the Electronic Management Research Library Database) and in 2001 we adopted this name for the company.

So, how does Emerald look in 2007? Emerald has grown into an important journal publisher on the world stage. The company now publishes over 150 journals and we have more than 160 members of staff. Emerald has always stressed the importance of internationality and relevance to practice in its publishing philosophy. These two principles remain the cornerstones of our editorial objective. The link between the organisation and academe that was so crucial in the foundation of the company continues to influence corporate thinking; we uphold the principle of theory into practice.

Emerald also continues to carry the tag of an innovative company. Through our professionalism and focus on building strong networks with our various communities, we have launched and developed initiatives such as the Literati Network for our

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authors and a dedicated web site for managers. These innovations and many more, help to set us apart from other publishers. For this reason, we feel confident in stating that we are the world's leading publisher of management journals and databases. It is important to us that we continue to strengthen the links with our readers and authors and to encourage research that is relevant across the globe. In more recent history we have, for example, awarded research grants in Africa, China and India. We also opened offices in China and India in 2006, adding to our existing offices in Australia, Malaysia, Japan and the USA.

We would like to thank the editors, editorial advisory board members, authors, advisers, colleagues and contacts who, for the past 40 years, have contributed to the success of Emerald. We look forward to working with you for many years to come.

Rebecca Marsh
Director of Editorial and Production