



Chief Medical Officer's Annual Report 2014-15



REALISTIC MEDICINE



Letter to doctors from the Chief Medical Officer for Scotland



Dear Colleagues,

I am pleased to present my first annual report, which arrives nine months after starting my post as Scotland's Chief Medical Officer; perhaps fitting for an obstetrician and gynaecologist, who continues to work in clinical practice. My report is written in two parts as I seek to engage with the medical profession across Scotland. In the first part I explore and ask for answers to important aspects of how medicine is practiced in this changing world and part 2 describes the health of our nation.

We are working in times of challenge in our NHS and I recognise how this impacts on your professional and personal lives. In this report I want to lay out some of these issues and begin a discussion on some of the fundamental principles of how we practise medicine today; how we, as doctors, can be hugely influential in improving care, reducing these pressures and ultimately being true to the values and ambitions we held when we were competing for those highly desired and limited places at medical school. The role of medical trainees and junior doctors is vital to sustaining the NHS in Scotland and building a profession to meet the challenges of the future. Medicine remains a highly respected profession, and though many regard their chosen vocation as an extremely fulfilling career, some doctors are disillusioned, unhappy and feel undervalued in their work.

I believe that the profession, with doctors as collaborative leaders, as in so much of our history, can influence and be a driver for change. The clinical voice of the highly trained experts in all specialties and across all aspects of medical care is extremely important in our National Health Service in Scotland.

I realise that many of you will have insufficient time to read yet another document which lands in your inbox or on your desk. I ask you to dip in to this report and read the chapters that interest you, contact me to agree or disagree with the content, use the data and graphs as evidence to celebrate the successes we have achieved in the NHS in Scotland or as levers to drive improvement where this is possible. Data too has influence, especially when combined with the narrative of your everyday experience.

I want to engage in a conversation with clinicians on the following questions:

- How can we further reduce the burden and harm that patients experience from over-investigation and overtreatment?
- How can we reduce unwarranted variation in clinical practice to achieve optimal outcomes for patients?
- How can we ensure value for public money and prevent waste?
- How can people (as patients) and professionals combine their expertise to share clinical decisions that focus on outcomes that matter to individuals?
- How can we work to improve further the patient-doctor relationship?
- How can we better identify and manage clinical risk?
- How can all doctors release their creativity and become innovators improving outcomes for people they provide care for?

A handwritten signature in black ink that reads "Catherine Calderwood".

Dr Catherine Calderwood, MA Cantab FRCOG FRCP Edin
Chief Medical Officer for Scotland

I'd really welcome your opinion. If you have feedback I can be reached at:

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www.surveymonkey.co.uk/r/LMDCMWM

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Introduction

It is a huge privilege as Chief Medical Officer to:

- provide a **clinical voice** – shaping the direction of Scotland's future health policies and its approach to healthcare and public health;
- **lead medical and public health professionals** in driving forward improvements to ensure a health service fit to meet the challenges of the future;
- **inspire young people to enter the medical and public health sphere;**
- **provide trusted clinical advice on professional standards and guidelines on behalf of the Scottish Government; and**
- **provide independent advice to Scottish Ministers.**

The Scottish Government has laid out its vision for 2020 so that everyone is able to live longer healthier lives at home, or in a homely setting. We strive to deliver safe, effective, person-centred care and all clinicians should be empowered to lead changes in the way we design and deliver care with the people who use our services.

The Audit Scotland report NHS in Scotland 2015 (<http://www.audit-scotland.gov.uk/report/nhs-in-scotland-2015>) published in October presents us with a clear challenge to change the way services are delivered in order to continue to provide high-quality care.

To put that challenge in context, the NHS is the largest employer in Europe. In Scotland the NHS serves 5.2 million people. In terms of the medical profession, it employs 4,918 GPs across 987 GP practices; 4,902 consultants and 5,656 medical trainees. There are also 43,237 nurses and midwives and a total NHSScotland workforce of 165,000.

This report is divided into two sections. The first section addresses the issue of "Realistic Medicine" and explores the challenges that face us as doctors today. I hope this will encourage more conversations with and between doctors about the way we practice.

The second section is our report card which presents the surveillance data on the health of our nation. This report contains a summary of the data and you can find the full document at www.gov.scot/cmoannualreport201415part2. We can interpret these trends to inform how we continuously improve our management of health and disease.

Acknowledgements

I would like to thank my colleagues for their input into this report.

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Executive Summary

Through "Realistic Medicine" can we ...?

- Build a personalised approach to care
- Change our style to shared decision-making
- Reduce unnecessary variation in practice and outcomes
- Reduce harm and waste
- Manage risk better
- Become improvers and innovators

The Added Value of Doctors in a Complex System

Current models of healthcare services are stretched and do not always suit patients, their carers or the aspirations of the workforce. High profile failures in care have emphasised the importance of good clinical leadership which is clearly linked to good patient care. Strong clinical leadership is arguably the single most effective means of preventing similar failings occurring in the future.

Realism in Healthcare

Doctors generally choose less treatment for themselves than they provide for their patients.

In striving to provide relief from disability, illness and death, modern medicine may have overreached itself and is now causing hidden harm – or at best providing some care that is of lesser value.

We must deliver healthcare that focuses on true value to the patient. Waste in healthcare should be assessed not in terms of what might be thrown away, but in interventions that don't add value for patients. This includes avoiding unwarranted variation in clinical practice and resultant outcomes.

Evidence-based guidelines developed for people with single diseases should not necessarily be extrapolated to the management of patients with multiple conditions, given the possibility that this may result in over-treatment and over-complex medication regimes.

We as clinicians have a duty to ensure that we are able to acknowledge our powerlessness at times, and ensure that a difficulty on our part in accepting the inevitable does not adversely affect the patient's experience of death.

Sharing Decision-making and Informing Consent: People and Professionals Combining their Expertise

"The single biggest problem with communication is the illusion that it has taken place."

George Bernard Shaw

We need to change the outdated "doctor knows best" culture to one where both parties can combine their expertise and be more comfortable in sharing the power and responsibility of decision-making. It requires system and organisational change to promote the required attitudes, roles and skills.

Such system change is articulated in models such as the House of Care, which provides a useful representation of the components, all of which are required, to place collaborative, relational decision-making and planning at the heart of our system.



Scotland's House of Care

Shared decision-making is not a one-way transmission of information about options and risks from the professional to their patient. It is a two-way relational process of helping people to reflect on, and express, their preferences based on their unique circumstances, expectations, beliefs and values. Simple approaches can readily be implemented within consultations to improve communication by avoiding jargon, and checking understanding, using techniques such as Teach Back.

Doctors and the Management of Clinical Risk

Managing risk in healthcare is a universal challenge for doctors and other professionals. Doctors tread a difficult path, with the expectation that they will make robust decisions balanced against criticisms of being overly paternalistic.

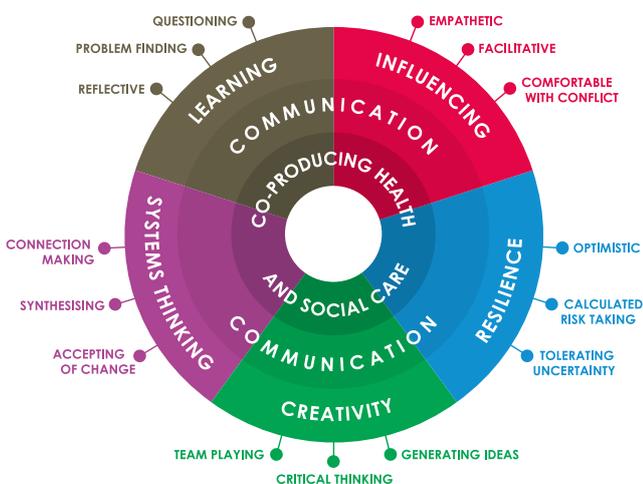
There is risk associated with every clinical decision, whether it is to do something, or do nothing. Beyond risk factors identified by statistical analysis there is no substitute for clinical experience. An early sign in burn out of doctors is their reduced ability to tolerate the anxiety of making risky decisions.

Good risk management is also dependent on communication of risk with other services.

Changing our Practice to Support Improvement

Scotland's medical staff, working with all our colleagues in health and social care, continue to be at the forefront of the wide range of improvements in the safety, effectiveness and quality of care and treatment within our National Health Service.

Improvements in the quality of care are often dependent upon having the right conditions in place – positive relationships with colleagues, a learning culture and an understanding of tried and tested ways of implementing change in complex systems.



From Lucas, B & Nacer, H. (2015). *The habits of an improver. Thinking about learning for improvement in healthcare.* London: The Health Foundation. P.8.

We should be focusing completely and relentlessly on what matters most to the people who look to us for care, support and treatment.

Translation of Medical Research into Routine Clinical Practice

The translation of research findings into clinical practice has transformed healthcare. It is a cornerstone of modern evidence-based medicine and of an advanced healthcare system. However, the route to translation can be challenging: high costs, scarce funds, shortages in key research infrastructure, capacity or capabilities, slow and incomplete recruitment to trials are amongst the potential barriers to the progress of translational research studies. Medical research and development can follow ill-defined and circuitous paths before being taken up into improved patient care.

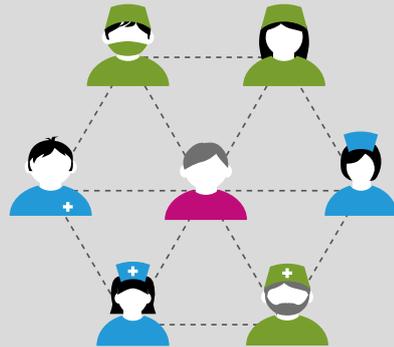
REALISTIC MEDICINE

CAN WE:



CHANGE OUR STYLE TO
SHARED DECISION-MAKING?

BUILD A **PERSONALISED**
APPROACH TO CARE?



**REDUCE HARM
AND WASTE?**



REDUCE **UNNECESSARY
VARIATION** IN PRACTICE
AND OUTCOMES?

MANAGE RISK BETTER?



**BECOME IMPROVERS
AND INNOVATORS?**

CHAPTER 1

The Added Value of Doctors in a Complex System

Doctors work in a complex system which, in these demanding times, is under pressure to change. Scotland has an increasingly aging population and a growing number of people who live with multiple and complex conditions. The subsequent increase in demand for services in an age of austerity requires us to achieve more through better use of resources.

Audit Scotland has called for a fundamental change in the way NHSScotland delivers services to cope with these increasing demands and has challenged us to increase the pace of change. Drivers for change will be and should be the needs and expectations of people who use our services. Services must adapt to the way in which people with multiple, complex and frequently changing conditions require to access care and support.

Current models of healthcare services are stretched and do not always suit the patients, their carers or the aspirations of the workforce. Delivering person centred and integrated healthcare with other agencies, statutory and non-statutory, is a challenge in the current configuration of our health and social care services.

In addition, our health services have tended to focus on urgent care rather than the early detection and even prevention of illness. Erasmus observed in the 1500s that "prevention is better than cure".

The training of doctors has been mainly in a traditional model of care with patients reliant on healthcare professionals for information, diagnosis and referral, and with interventions decided mainly by healthcare professionals.

The future model of care is one with an empowered patient in a shared decision-making partnership with the clinician. There needs to be co-creation of care packages that include prevention and rapid access to services when required. The growth of supported self-management is a key priority, as this allows patients to regain control of their own health. Healthcare now needs to extend far beyond the classical settings of hospitals, GP practices, and hospices and reach more effectively into a person's own home and community. However, the expectation in the minds of many of our population remains that care should be hospital based, when the evidence tells us that this is not always the optimal location.



Professor Sir Lewis Ritchie, in his independent review of the Primary Care Out of Hours Service in Scotland, has begun to lay the foundations for an approach that will provide consistent urgent and emergency care that is sustainable throughout Scotland. The demand for urgent care is increasing, and many of the approaches recommended in his review are equally applicable when providing care during daytime, so that increasingly care will be given by well led multi-disciplinary and multi-sectorial teams in community settings. As we move to reform the approach to delivering primary care and orientate towards a community-led health service, these new models of care will be further developed in test sites across the country, and in both rural and urban environments.

The morale of some doctors is low and there is reported erosion of professional status. Although we must adapt to the needs of a changing system it is important for us as a profession to recognise and build on our added value throughout healthcare. The practice of medicine is not a pure science. It is a discipline with the concerns of people at its heart and therefore requires integrity, ethics and knowledge.

Medicine is a vocation. Communication and compassion are at the core of doctors' work. Developing these professional skills is an essential part of the development of an individual clinician, which adds to the ethical value of his/her work.

High profile failures in care have emphasised the importance of good clinical leadership which is clearly linked to good patient care. Strong leadership would have made significant differences to care

and to outcomes. The lack of this leadership from clinicians, managers and within governance systems was arguably the single biggest contributor to poor outcomes and experiences.

Doctors continue to have an integral role in leading and facilitating the multi-disciplinary team. However, we need better distributed leadership in teams where different individual team members may take on leadership roles, depending on the task being tackled and their individual expertise and experience. We need collaborative leadership, working across the traditional role and organisational boundaries, for the best interests of patients rather than the promotion or furthering of single aims or areas, and to promote the development of other professions to ensure a holistic approach. Well trained health and social care workers, nurses, allied healthcare professionals, physician's assistants, pharmacists, community members and patients themselves have clear roles in providing services. Doctors have seen some of the work traditionally undertaken by the medical profession very successfully delivered by other trained healthcare professionals. This up skilling of others requires us to further adapt and redefine our role, so that we continue to provide our care where it will have greatest impact.

“There is no better person to improve the role of doctors than doctors themselves. This is why I want to start a conversation among doctors about changing healthcare.”

Dr Catherine Calderwood

CHAPTER 2

Realism in Healthcare

This chapter outlines the various concerns that have arisen with regard to modern medicine over the last five to 10 years and how clinicians might address these issues. At its heart, the concern has been that in striving to provide relief from disability, illness and death, modern medicine may have overreached itself and is now causing hidden harm – or at best providing some care that is of lesser value. But the problem has gone beyond that into what may not really be considered illness, to the medicalisation of common life experiences.

Jacob Bigelow, Professor of Surgery in Harvard until his death in 1890, was famous for a number of reasons. He wrote and disseminated information about the first uses of inhalational anaesthesia in the United States, encouraging its spread. Less famously, he also wrote “the amount of death and disease suffered by mankind would have been less if all disease were left to itself”. For much of history, his view was largely accurate: for centuries doctors had treated seriously ill people with purges, with bleeding, with leeches and with poultices of doubtful sterility. Despite the direct experience suggesting that the treatments offered no value, society had sought out treatment and advice from doctors driven more by hope than experience and struggling to accept the inevitable limitations of our short lives.

From around the beginning of the twentieth century, science gradually and incrementally discovered more of the biochemical and physiological aspects of disease and treatment, gradually more and more treatments were developed. In the United Kingdom a very significant advance was made by Dr Austin Belford-Hill, who pioneered the use of Randomised Controlled Trials (RCTs) in his work on streptomycin in the treatment of tuberculosis. This was the first example of applying rigorous and repeatable experimentation to establish the effectiveness of treatment. It was followed by an increase in proliferation of RCTs which helped establish the effectiveness of many treatments in use today, as well as dismissing a great number to history. The dawning of the age of evidence based medicine followed with considerable energy devoted to standardising healthcare based on evidence derived from these trials. It is easy to understand this progress and to assume that all treatment now offered is likely to be effective and unlikely to cause much harm. Unfortunately, this is not universally the case. This chapter will lay out the reasons why we should continue to remain curious about the overall effectiveness of modern medicine and why we should re-calibrate our approach to medicine in many settings. It has been argued that evidence-based guidelines developed for people with single diseases should not

necessarily be extrapolated to the management of patients with multiple conditions, given the possibility that this may result in over-treatment and over-complex medication regimes. This is a common problem for patients as our population becomes increasingly elderly and accumulates ever more long-term chronic conditions. This is not to suggest that guidelines for single conditions should not be used, because currently we have little evidence for what should replace them. There is, however, a need to balance this with the risks inherent in the resulting complex treatment regimens where less appropriate polypharmacy itself may cause harm and hospital admission.

However, doctors need support in choosing, with their patients, not to apply evidence based guidelines: the strength of guidelines can make doctors feel unable to deviate from them, driven by feelings of peer pressure, assumed patient demand, concern about litigation and an understandable, emotional need to “do something” in the face of long-term conditions.

Since 2004 the GP contract has introduced a Quality and Outcomes Framework, incentivised by performance related pay, encouraging doctors to use evidence based guidelines, mostly developed for people with single diseases to treat patients who very often have multiple conditions. This has coincided with an aging population and older patients who have accumulated multiple, long term conditions. The widespread use of guidelines has contributed to the massively increasing volume of medication taken by the population each year. Twenty per cent of the adult population in Scotland is taking more than five medications every day. With the increasing complexity of multiple drug regimes come the inevitable loss of uptake, increased potential for interactions and side effects, and a significant increase in the risk of unintended harm, such as falls, confusion and hospital admission.



There is evidence that doctors tend to underestimate the frequency and impact of side effects from treatment and fail to understand the total “treatment burden” that may be forced upon patients. This may involve complex medication regimes, multiple side effects (for which other medications may be required) and specialist and generalist follow-up appointments. It is argued that it will be in the better interests of patients for intelligent, patient-centred use of evidence-based guidelines, a reduction of over-literal interpretation of evidence, and support for doctors who provide a skilled and generalist view using their clinical judgement to advise patients and then make shared decisions on realistic goals and treatment options.

While evidence-based guidelines will continue to inform the management of people with complex, interrelated conditions, we must acknowledge that a focus on biochemical and physiological outcomes alone may frequently fail to support people to achieve their own realistic and holistic goals; asking “What matters to you?” becomes one of the fundamental questions underpinning the discussion with patients.

In 2012, the King’s Fund produced a challenging paper entitled “Patient’s Preferences Matter”. This collated a great number of studies that showed across a wide range of specialties and settings that:

1. Doctors often fail to take into consideration patient preferences in suggesting and providing treatment. Treatment that does not coincide with the patient’s preferences may ultimately be wasteful (in that it

doesn’t provide value for them). This can be seen in the use of heroic, complex and uncomfortable treatments as a patient approaches the end of life. It also appears to be demonstrable in many more settings.

2. Patients tend to choose less treatment when they are provided with greater detail of the impact, potential benefits and harms of a proposed intervention.
3. Doctors generally choose less treatment for themselves than they provide for their patients.
4. Despite our beliefs that treatment is based on evidence, the complexity of presentations possible means that 30-45% of care is not based on available evidence – partially a reflection of gaps in available evidence, and partially a reflection of the impossibility for clinicians in keeping up with the increasing volumes of guidance.

These conclusions are followed by discussion of variation in treatment and investigation rates: it is well known there is considerable variation between geographical areas that is not related to measurable patient need – and the strong suggestion from the paper is that the supply of treatments is determined by variation in doctors views far more than any differences in disease prevalence, or patient preferences in different populations. This observation – mirrored in the “NHS Atlas of Healthcare” produced by the NHS in England – suggests that a proportion of medical care may be prompted by “supplier induced demand”; healthcare that is provided in excess of patient/population potential to benefit, that is driven by a range of factors including legitimately held medical views, pressures from the manufacturers of medicines or equipment, perceived risk of litigation, and patient expectation in populations where treatment levels are high.

There has been an increasing trend to treat or intervene to address risk (rather than symptomatic illness). This can greatly improve outcomes – as seen in careful management of diabetes in pregnancy – but it can also result in large numbers of the population taking medicines, or undergoing screening, when they would never themselves have developed the condition in question. Increased use of medical approaches to reduce risk may result in less implementation of strategies for lifestyle changes, or treatment being provided to older patients who will not live long enough

to derive the potential benefits, and, of course, will cause direct harm in a small number of cases – as well as producing the psychological adjustments that occur when a patient is labelled as having a disease. While the reduction in heart disease rates can be attributed to the use of primary prevention with statins, and better control of hypertension and diabetes, trends show that the fall in heart disease rates pre-dated widespread use of these treatments, and has continued at the same rate as before. One explanation may be that the majority of the decrease has come about from the improvement of lifestyles and environment.

In an era when we have constrained resources, this overuse of medical interventions is of serious concern: It is certain that it co-exists with undertreatment of patients who might benefit, and the intensity with which modern medicine can consume resources, may mean that society is less able to progress improvements in poverty, education, housing and environmental factors that may more simply (and with less side effects) produce significant benefits in both life experience and the incidence of diseases.

Possibly of greater concern is the issue of “heroic” medicine when we are faced with the likelihood of death. A study in the United States asked relatives to assess the quality of death that had been experienced by their relatives. Using matched data it was possible to calculate the cost of treatment in the last six months of that patient’s life. The results showed that there was an inverse correlation between the quality experience of death and the resources used. What does this suggest? Overall there is a thread that the intensity of treatment did not result in better outcomes, and reduced the quality of some lives of the patients who were dying.

This should not prompt a trend towards therapeutic nihilism – but suggests that much greater consideration needs to be given to recognising the progression of disease to a point where death is inevitable, and greater care taken to communicate effectively to patients and their relatives in order to help them make appropriate choices. While it is easy to assume that patients and relatives will cling to treatments that may prolong life, and easier still to avoid the emotionally challenging acknowledgement of the ultimate futility of treatment in the face of advanced disease, we owe it to our patients to give honest assessments of prognosis, and clearer descriptions of the likelihood of benefit from treatments that will often be invasive, unpleasant, toxic and occasionally cause death.

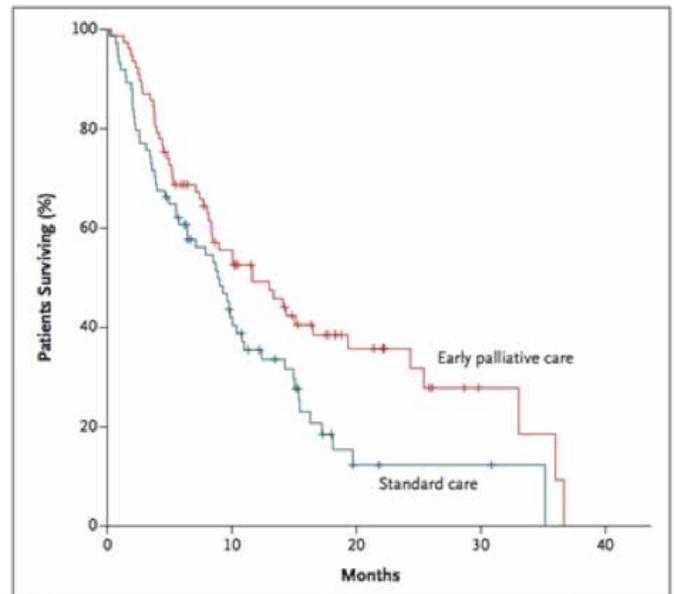


Figure 1: From Early Palliative Care for Patients with Metastatic Non-Small Cell Lung Cancer. New England Journal of Medicine.

Atul Gawande spoke passionately of this issue in the 2015 Reith Lectures, and in his book “Being Mortal”: He describes a study in patients with stage 4 lung cancer: half were given conventional chemotherapy, and comparable patients were assigned to a hospice at home programme, which focus strongly on symptom control, and achieving patient-focused goals that related to social interactions and enjoyment of life. Survival in the group treated with hospice at home care was better than those given conventional treatment – and it is certain that their experience of the last few months of life was more rewarding, and, more under their control. Atul Gawande powerfully speaks of the importance of asking the simple – but emotionally difficult – questions of “What do you understand about your illness at the moment?”, “What matters most to you thinking about the future?” and “What would good look like?”. He shows that an integrity and honesty in initiating these conversations, and ensuring that the patient has both the time and confidence to make their own fully informed decisions, results in a better experience of the remaining time, and less regret for patients and their relatives. It doesn’t mean that no patients choose aggressive treatment – but it does allow patients to feel in control, and to allow an honesty of communication that acknowledges the approach of death, and the emergence of the priorities that mean most to the patient. Many doctors are adept at pursuing this approach, but many are not: we as clinicians have a duty to ensure that we are able to acknowledge our powerlessness at times, and ensure that a difficulty on our part in accepting the inevitable does not reduce the patient’s experience of death.

The four principles of prudent healthcare

Public and professionals are **EQUAL PARTNERS** through **CO-PRODUCTION**

CARE FOR those with the greatest health need **FIRST**

Do only **WHAT IS NEEDED** and do **NO HARM**

Reduce **INAPPROPRIATE VARIATION** through **EVIDENCE-BASED** approaches

For further information visit www.prudenthealthcare.wales

Llywodraeth Cymru Welsh Government GIG Cymru NHS WALES

This section has highlighted some of the important emerging challenges to modern medicine. What action, if any, should we as clinicians take? Perhaps we should follow the example of the “Prudent Healthcare” movement in Wales – an initiative to ensure that healthcare that focuses on true value to the patient is delivered. Waste in healthcare should be assessed not in terms of what might be thrown away, but in interventions that don’t add value for patients. Ultimately, this is a topic for a widespread debate amongst clinicians and the population which we serve, but the outcomes might be:

- More research to establish the additional benefits of medicines in the older patient, especially those who are already on multiple medications.
- Increased attempts to support individual and population lifestyle changes, avoiding a rush to intervene where a lesser intervention might suffice.
- Understanding that treatment of risk must be carefully thought through. Aiming to treat with a probability of benefit should be more prevalent than treating with a possibility of benefit.
- Standardising process where appropriate to get the best results, but allowing variation where this is a result of patients expressing their preferences.
- Clinicians should expect to be questioned if their practice varies from others, and be prepared to offer justification for the variation.
- Above all, we must continue to involve patients more and more in their treatment, understanding that they must be fully informed on their illness and prognosis, and the risks and benefits of their possible managements.

The National Clinical Strategy will be published later this year and will provide a guide to further address these complex issues. The “Creating a

Healthier Scotland” national conversation started in August 2015 and will be continuing this year. This engagement with the people of Scotland over the future of our health and social care services will be instrumental in shaping care.

This is a difficult subject. We have moved far from Bigelow’s assertion that overall clinicians would be better not to have intervened, but we must remain alert to the possibility that we may be over-treating patients to their detriment. Experience shows that this may be best achieved by honest, open and full discussion with patients.

REDUCE HARM AND WASTE?

REDUCE UNNECESSARY VARIATION IN PRACTICE AND OUTCOMES?

CHAPTER 3

Sharing Decision-making and Informing Consent: People and Professionals Combining their Expertise

This chapter examines the future challenge in healthcare of helping people and professionals to be more involved in developing shared or partnership decisions. It explains the need to leave behind the outdated “doctor knows best” culture to one where both parties can combine their expertise and be more comfortable in sharing the power and responsibility of decision-making. It requires system and organisational change to promote the required attitudes, roles and skills. We highlight examples of policy and practice in Scotland that are supporting this change.

Time for Change?

On 1 October 1999 in Bellshill Hospital, Lanarkshire, Nadine Montgomery gave birth to a baby boy who subsequently developed severe disabilities. This was due to a traumatic vaginal delivery as a result of shoulder dystocia. In March of this year, the Supreme Court, in a landmark ruling, awarded substantial damages to Mrs Montgomery and her son. The case was unique in that the medical decision-making and management of her obstetrician was not inappropriate or negligent. The basis of the claim was that Mrs Montgomery had not been fully informed and involved in that decision-making. Had she been so, she argued, she would have stated a strong preference to have her baby delivered by caesarean section.

With the volume and complexity of information we are increasingly asked to consider, shared decision-making represents huge challenges for all of us. When we account for the time constraints that professionals and their patients have together, it is no surprise we have evolved a system and culture which favours “doctor knows best” or medical paternalism. Here the balance of decision-making power within the professional patient relationship is shifted more heavily onto the clinician to decide in the best interest of the individual. Meanwhile people often happily cede control and entrust themselves into the hands of their professionals.

However, the Montgomery ruling now sets a legal precedent that this “parental” approach is insufficient and there is an imperative for a system and values change that rebalances decision-making power, where the expertise of professionals is valued equally to the expertise that people have about themselves. This shift can be challenging for both people and their professionals.

This imbalance in the relationship can be seen most markedly in the parts of our society where need is often greatest, particularly patients living with the highest degrees of socio-economic deprivation, leading

to the perpetuation of health inequalities. Empowering these patients may be our greatest challenge, as they have traditionally often not engaged with the care service until further on in their illness journey. They can often be less confident and articulate when it does come to expressing their needs.

This contrasts with patients who are prepared to engage early with care services in order to ensure that their health needs are met. On occasion this can generate what is effectively more demand than need and further contribute to health inequalities. The “worried well” consuming resources while the “unworried unwell” do not come forward.

The Montgomery case took place 16 years ago and we could argue that the system has moved on. However, there are numerous examples of referrals to the Scottish Public Services Ombudsman (SPSO) and medico-legal process when individuals have had insufficient information, communication or understanding.

Studies have also indicated a significant proportion of people wish to be more involved in decisions about their care than they are currently allowed to be. These show that when people are more involved in decisions, they are more likely to adhere to treatment, less likely to suffer the consequences of over-investigation and over-treatment and be more satisfied with their outcomes and relationship with their professionals. Doctors often recommend end of life treatments and interventions that they would reject for themselves. This implies a lot of decision-making is based on unclarified assumptions and expectations.

Informed Consent

The goal of shared decision-making is to reach an agreed decision or state of mutual consent. A literal definition of consent, “feeling with”, is derived from the Latin *Con* – with and *Sensere* – to feel. It is where each party feels the others’ acceptance and agreement to

participate. The Consent Form represents a legally signed record of that agreement and is required for most interventions and procedures.

Obtaining consent before a procedure is commonly a professional-centred process done by practitioners to patients. In the time limited setting of busy clinical practice it can be a rushed responsibility of the most junior staff member, just before the procedure, when the individual is not at their most empowered. Obtaining a signature of informed consent is insufficient as it is not an endorsement that an individual may have received enough information or that it has been heard and understood. It provides no clarification that true shared decision-making has been achieved. Indeed evidence suggests that oral and printed communication is often of a complexity that exceeds people's reading skills (functional literacy) and ability to make sense of it (health literacy). People often hide their lack of understanding and clinicians frequently overestimate people's abilities. As George Bernard-Shaw famously stated:

"The single biggest problem with communication is the illusion that it has taken place."

Furthermore, shared decision-making is not a one-way transmission of information about options and risks from the professional to their patient. It is a two-way

relational process of helping people to reflect on, and express, their preferences based on their unique circumstances, expectations, beliefs and values. This can be a challenging communication process and individuals will equally need reassurance that their professional has understood them. Finally, and crucially, people need help to evaluate the medical options in the light of their preferences in order for both parties to agree on the best course of action.

There is a caveat in that people vary to the extent they wish to be involved in making decisions. Certainly it can only really take place when people have full decision-making capacity which might not apply for people with cognitive, learning or severe mental health difficulties. Similarly in emergency situations, where fear, pain and distress exist, professionals need to reach an agreement as to the extent their individual patient is willing and able to collaborate in decision-making. Many may be put off by low health literacy (poor understanding, confidence, knowledge and skills) which should be addressed by offering more time and support.

Because of the limitations of traditional informed consent procedures, some have advocated moving to a more person centred process of "request for treatment". This requires the person to record, in their own words, why they want a particular treatment, what they expect it to achieve and what their understanding is of the risks and limitations. It



promotes the notion that decisions should be informed and considered before people request treatment. It highlights any lack of decision-making competency, unrealistic expectations or misunderstanding that needs to be addressed. The practitioner can then be sufficiently reassured before they agree to that request. Recommendations to replace informed consent with request for treatment features in the recent Scottish Cosmetic Interventions Expert Group Report.

Policy Landscape

Things were perhaps different in 1999, cultural attitudes have evolved, along with policies, guidelines and professional codes. Patients and carers are increasingly knowledgeable, confident and expect to share decisions. The role of community and third sector organisations and charities, for example the ALLIANCE (which is the national third sector intermediary for a range of health and social care organisations) have been instrumental in championing policies, meaningful information, advice, advocacy and support for people to be in the driving seat of their care. Modern media and the internet have made medical knowledge accessible and have provided opportunities for hosting online communities for peer support.

In 2012 Scottish Government published The Charter of Patient Rights and Responsibilities a key thread of which is around Communication and Participation: the right to be informed and involved in decisions about healthcare and services. It chimes with 2008 GMC Guidance on consent: www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp.

“Fundamental to the doctor and patient relationship is the requirement that a patient with capacity to decide should be informed about the treatment options open to him or her; the risks and benefits of each option; and be supported to make their choice about which treatment best meets their needs.”

Many professional bodies such as Royal Colleges have produced updated guidance on consent and shared decision-making.

Public information sources such as NHS Inform are encouraging people to play an active role in decision-making by making them aware of their rights regarding consent and promoting “It’s OK to Ask” to

ensure people get the most out of their healthcare appointments.

There are rising expectations and perhaps, to a degree, health consumerism. Faced with increased access to almost every other aspect of life it might not be unreasonable for patients to expect the same ease of access to healthcare professionals, both electronically and face-to-face. This expectation may be in addition to the existing access arrangements – NHS 24, A&E, NHS Inform, out of hours GP services.

There are 4.1 million outpatient appointments in Scotland per year, of which 2.7 million are follow up appointments. Might it be appropriate in some specialties for outpatient appointments to be tailored to more immediate access when the person has symptoms/needs to be seen rather than “routine follow up” arrangements? The Scottish Government Delivering Outpatient Integration Together (DOIT) team is working to streamline outpatient visits and is keen to have input from interested clinicians.

Shared decision-making is core to the safety, effectiveness and person-centredness of care and therefore resonates with Scotland’s Healthcare Quality ambition. The person centred portfolio in Scottish Government is driving and supporting policies and quality improvements that help reshape health and care through the lens of people using services. For example, people with low health literacy face many barriers to shared decision-making. Low health literacy is a key determinant of poor health outcomes and a significant cause of health inequality. In response to this, Scottish Government produced “Making it Easy” which set out key actions to help NHSScotland rise to the challenge of responding to people’s health literacy needs.

Changing Practice

Despite favourable policies, implementing shared decision-making in practice is problematic given the constraints of delivering healthcare. This may be particularly difficult in hospital settings where professionals and people may have little previous knowledge of each other. In part it needs to be addressed by pragmatic solutions that can dovetail into existing practice, but it also needs considerable organisational and whole systems change to support what is a fundamental shift in the relationship between people and professionals. At its core, it involves making those short and precious interactions

that professionals and people have together, as productive as possible. This involves thinking outside of the consultation to prepare both parties beforehand and augmenting the process afterwards.

Simple approaches can readily be implemented within consultations to improve communication by avoiding jargon, and checking understanding, using techniques such as Teach Back. Teach Back involves a person paraphrasing, in their own language, what they have understood. It is a simple, yet powerful, method to screen for misunderstanding. NHS Tayside, are exploring how Teach Back can be routinely applied to informed consent procedures.

There is a great opportunity to build on existing tools and develop new innovations to support shared decision-making out with the consultation. Important approaches include:

- **Personalised information sharing** so that a person can have in advance, and reflect on, the same information that their professional has about them. The challenge is to provide this information in formats that are meaningful. IT developments such as shared medical records and patient portals (e.g. My Diabetes, My Way and Renal Patient View) can aid this process. It should also be helpful for people to provide personal information about themselves that they wish to share with their professional in advance.
- **Shared decision aids** are widely available for many conditions to help people explore their preferences with their professionals and find options that best match those preferences. However, they can be difficult for some and people may need help to use them.
- **Information tailored to need:** Written information has often proved disappointing, either because there is too much or challenges those with poorer reading skills. We need to look beyond relying exclusively on patient information leaflets. **Digital technology** now makes it feasible to provide information in more engaging, multimedia formats to enhance people's confidence and skills in sharing decisions.
- **Written summary or audio recording:** People can find it difficult to remember or interpret what has been discussed and it is helpful to leave with a record of their encounter. Professionals may find it challenging to have their consultations recorded but can take comfort that it can be highly valued by their patients.

A pragmatic example of how practice can be re-configured to enhance shared decision-making is illustrated by the Navigator Project (see below).

The Navigator Project at the Western General Hospital in Edinburgh set out to improve shared decision-making about treatment options for men diagnosed with early prostate cancer. They met with a "navigator" who helped explore what was important for them in terms of quality of life, life expectancy, acceptability of side effects etc. They then shared meaningful and tailored information. When they met with the specialist, both were able to have a more productive conversation about the choices they faced. They were then given an audio recording of that consultation so that they could replay it at home, perhaps with their family. Interestingly the study showed that those people who took part in Navigation opted for less invasive treatment and, at follow up, had less regret about the decisions they had made compared with those who received usual care. There are plans to develop an online tool to augment the navigation process.

Catering for this new type of relationship that our empowered "Google generation" has with those that deliver health and care, is one of our biggest challenges. We will need to create system and organisational change to embrace and promote it, mindful that those who are the least empowered will need the greatest help to flourish.

Such system change is articulated in models such as the House of Care (see Figure 2), which provides a useful representation of the components, all of which are required, to place collaborative, relational decision-making and planning at the heart of our system. Integrating these components into practice will take time but early progress is being made in Scotland with those adopting this approach with people living with long term conditions. A key initial phase of this is in developing the skills and values that healthcare professionals require for shared decision-making.



Figure 2: Scotland's House of Care

Finally, different groups whether they are nurses, pharmacists, allied health professionals, doctors, or in social, community or voluntary care have different skills, approaches and resources that can help and empower people to be fully involved in decisions. There are great opportunities to integrate this skill mix and share learning to enhance shared decision-making.

Conclusion

The traditional "doctor knows best" approach to decision-making has proved inadequate and there is now a cultural and legal expectation on both professionals and people to collaborate in partnership decisions. This sets all of us a challenge as to how we design and develop health and care services so that it brings out the best of the expertise of people and their professionals. There is a great potential to harness the support of friends and families, as well as the resources in local and online communities to help inform decisions. It will also require us to make healthcare simpler and more engaging so that it is responsive, particularly to those with the greatest health literacy needs and those with the least support. Professionals will need to develop the personal capabilities, within an organisational system, that helps them to communicate with and support people to make the decisions that are right for them. Decisions that help them live well, and indeed die well, on their own terms.



CHAPTER 4

Doctors and the Management of Clinical Risk

This section looks at doctors' management of clinical risk, its challenges and ways we can improve.

What is Clinical Risk?

A clinical risk is the chance of an adverse outcome resulting from clinical investigation, treatment or patient care. (National Patient Safety Agency: May 2007 report www.npsa.nhs.uk)

Weighing Up Risk in Decision-making

Managing risk in healthcare is a universal challenge for doctors and other professionals. This is because it is inherent in every clinical decision and because no risk assessment tool or process can ever be 100% accurate. Expectations can be very high, believing that if a perfect outcome is not achieved then blame should be apportioned. Doctors tread a difficult path, with the expectation that they will make decisions balanced against criticisms of being overly paternalistic.

In the stressful environment of illness and suffering it can be comforting to project an omnipotent and benevolent identity on a doctor who can then be counted upon "to make it alright". However, regardless of the skills, wisdom and abilities of any doctor there are situations where the outcome is bad. This could be side effects or failure of a procedure or treatment or advancement of disease. The effect of this is seldom

acceptance that it is not possible to mitigate against all bad outcomes but instead to apportion blame. Mistakes and incompetence, of course, do occur and these do need systems to mitigate them. At the point of decision, a patient has to trust the doctor to be working to their benefit and have confidence in their ability, knowledge and experience.

Standards of behaviour and sanctions for breaching these exist, whether they are through the professional regulation of doctors by the General Medical Council or other bodies such as the Colleges. (GMC: Good Medical Practice 2013 - Duties of a doctor)

Managing risk is an inherent part of a doctor's role. The breadth of their training and knowledge allows the management of complexity required to best plot the course of a patient's care and treatment through assessment, investigation and treatment. This can be rewarding when things go well for the patient but can also be stressful when the doctor realises that they are often making "judgement calls" where a decision is based not just on following an algorithm with a clear evidence base but also on "gut feeling" resulting from the application of wisdom rather than knowledge. An early sign in burn out of doctors is their reduced ability to tolerate the anxiety of making risky decisions.



The Importance of Positive Risk Taking

Everyone understands that everyday life contains risk and we all make positive decisions to expose ourselves to it. Our recreational lives are full of this. We choose to pursue certain sports with a degree of danger like skiing. We choose to travel on holiday to exotic and potentially risky destinations where gastrointestinal upsets, insect bites or other more serious risks await. The reason we take these risks is because the potential benefits of the choice outweigh, in our minds, the potential adverse consequences. Just as in healthcare decisions, our risk assessment is based on a combination of factual knowledge, experience and expectation. Avoidance raises anxiety rather than reduces it and it is psychologically healthy to stimulate and empower ourselves by taking some risks.

There are situations in healthcare where risk taking can be positive too. The decision to not admit to hospital or to a care home may be perceived as a risk, especially when there is a different expectation or pressure from patients and their carers. However, if we are to support more people to remain independent for longer at home or in the community we have to admit to hospital only those for whom there will be benefit and where there is no appropriate community alternative.

Similarly, the decision to discharge carries a degree of risk and again may be resisted by some patients and their carers. However, the advantages of keeping a patient in an inpatient bed have to be weighed up against the risks to that patient. The risks associated with being in hospital need to be recognised. Some are obvious and measurable like hospital acquired infections. Some are less obvious like increasing dependency or dislocation from home, family and

society. Older people experience functional decline as early as 72 hours after admission and are more likely to have an episode of delirium or infection.

There is also a wider service and societal impact from using resources inappropriately, preventing their use by others when they need it or driving an inappropriate increase in acute capacity at the expense of chronic care and support.

There is risk associated with every clinical decision whether it is to do something, or do nothing. Apparent therapeutic inaction may be frustrating or confusing for patients unless clear explanation is given. It can be tempting as a doctor to manage a patient's expectations and anxieties by prescribing or ordering an investigation when a better course of action is to do nothing beyond simple support and waiting.

Public concern about the steady risk in antidepressant use (www.nhs.uk/news/2013/07/July/Pages/Prozac-claim-as-antidepressant-use-soars.aspx) is based on the theory that these medications are being unsuitably prescribed rather than there being a true increase in depression presentations and prevalence. The reality is that antidepressants are an effective treatment for depression and some other conditions. The increase is prescribing mirrors increased awareness and treatment. However, people presenting acutely unhappy to doctors are not best helped by antidepressants. Their prescription may make the patient feel that their suffering has been validated and may fulfil their expectations that the reason for their unhappiness is disease based and therefore treatable. However an inappropriate prescription can cause problematic side effects and imply a diagnosis that is not accurate. The antidepressant "treatment" may then



prevent the patient seeking more effective solutions to their mood state such as exercise or socialisation. This also does disservice to the effective use of antidepressants which for some people are lifesaving.

How Can Risk Best be Managed?

Effective clinical risk management requires first and foremost an understanding by public, providers and policy makers that good outcomes are not guaranteed despite the best efforts of people and systems. This does not mean that all bad outcomes should be accepted. Avoidable risks should be identified and when bad outcomes occur in relation to these investigations, learning and action should occur to reduce the probability of such an outcome occurring again. Healthcare providers use clinical governance machinery to manage avoidable risk and Healthcare Improvement Scotland have an important national role in improving service quality and patient safety. The Scottish Patient Safety Programmes have delivered significant improvements in safety across a range of specialities through a collaborative approach to identifying and actioning opportunities for service improvement.

Risk assessment is a challenging skill. Across medicine, efforts have been made to apply a scientific approach to what is often an intuitive process, with varying degrees of success. The Prevention of Falls Programme identified significant risk factors that help predict which falls require additional, more specialist interventions to avoid future poor outcomes like fractures. The simple recognition that identifying and targeting people with poor bone health and cognitive impairment could mitigate future fracture risk is a good example of using scientific evidence base to modify risk assessment.

More contentious has been the management of risk in psychiatry. Creation of psychiatric risk assessment tools for general use has been criticised by clinicians. Significant incident/adverse event reviews have consistently shown that these risk assessments only work when they are translated into dynamic risk management plans effectively communicated between people and agencies. As simple lists of tick boxes they are ineffective. Research by the National Confidential Inquiry into Homicides and Suicides in people with mental illness has identified organisational factors that significantly affect suicide risk. This is an important illustration that the factors affecting risk are often beyond the direct patient – clinician relationship and that consequent outcomes are dependent on systems

as well as people. In Scotland, Healthcare Improvement Scotland is taking forward work to translate the understanding of these organisational factors into the “Reducing suicide risk – discussion framework” document for teams to use.

Beyond risk factors identified by statistical analysis there is no substitute for clinical experience. This is best gained by direct exposure to decision-making, initially supported and supervised. Good medical training requires this. Some decision-making that doctors traditionally did, is now being done by other disciplines. It is important that doctors are not de-skilled in this remodelling of service provision. It is also important that the other disciplines doing risk assessment and making decisions on the basis of it are appropriately supervised and supported.

Good risk management is also dependent on communication of risk with other services. Lessons learned from mental health significant incident/ adverse event reviews commonly find failings in the communication of risk between organisations. Issues of patient confidentiality are often cited as being the obstruction to communication, however, this should not be the case. Guidance is given by the GMC. www.gmc-uk.org/15__Risk_Management_Framework.pdf_56300660.pdf.

Doctors should always remain open to seeking the opinion of others in clinical risk assessment. Second opinions can be invaluable, as can discussion with peers. Other disciplines can bring an important alternative view on a situation and decision-making is often best shared through discussion. This is particularly relevant in the delivery of integrated services where social workers have an important insight, especially in relation to vulnerable adult and child protection issues, not to mention housing and employment.



CHAPTER 5

Changing Our Practice to Support Improvement

Scotland's medical staff, working with colleagues in health and social care, continue to be at the forefront of the wide range of improvements in the safety, effectiveness and quality of care and treatment that are being made within our National Health Service. Hundreds of doctors across the country have fulfilled a range of vital roles in making the changes and testing ideas on how to ensure that everyone in Scotland receives the highest quality of care possible – leading teams, encouraging junior medical staff to test their improvement ideas and emphasising the importance of time for learning and reflection amidst the demands of clinical practice.

Improvements in the quality of care are often dependent upon having the right conditions in place – positive relationships with colleagues, a learning culture and an understanding of tried and tested ways of implementing change in complex systems.

For several years, doctors have been the driving force behind quality monitoring work such as the Scottish Intensive Care Society Audit Group system – a system that is now being used to inform and design ways that routine data like these can be used to design routine quality monitoring and improvement systems across the country. Data are very powerful and important influencers. Surgeons and other clinicians have participated in the thousands of surgical safety “pauses” that take place across the country every week – collectively contributing to reductions in surgical mortality.

Through the Scottish Patient Safety Programme doctors of all grades and a wide range of specialties have changed the way they think about practice in respect of sepsis – more people than ever before are receiving timely antibiotics when sepsis is suspected, undoubtedly contributing to the 20% reductions in mortality from sepsis that have been observed. These improvements have been made possible through the engagement and enthusiasm of clinicians who have been willing to review the harms occurring within their teams and systems, consider learning from colleagues and then test ways of implementing this within their teams for every person that receives care from them in the future. It is this complete focus on design and the reliable delivery of care processes that has been at the heart of the significant improvements in quality and safety across the country.

The emphasis on using data to support discussions and learning in clinical teams, already an established approach within general medical practice, has been seen most strongly this past year through the work on measuring the safety culture of almost 950 general practices. Data that can be used for GPs and their practice colleagues for reflection, learning and

consideration of how team-working can support improvements in the safety and quality of care.

The importance of taking time to talk with other members of the team about the quality, safety and flow of people through healthcare systems has been reflected in the safety huddles that are now taking place – as well as through the advice given to directors and senior managers by medical staff as part of the leadership walkrounds.

Doctors who are supported to engage with broader organisational perspectives and have opportunities to discuss issues and problems within their work are likely to find it easier to identify and implement quality improvements. A team culture focused on valuing doctors and providing support is essential and something that every member of the medical profession has a responsibility to nurture.

The literature that shows a relationship between organisational performance and the quality of clinical leadership emphasises the importance of ensuring that the work of doctors is aligned to strategic priorities and organisational goals. This is just as much the responsibility of doctors as their colleagues working in management. This will in turn influence and shape organisational culture and build positive working relationships with the wider team.

Doctors working on improvements need to be clear what the aim of the work is and be clear that they have the knowledge and skills to deliver this.

Medical staff meeting with patients and families where they have concerns or have been dissatisfied with the quality of care is an essential component of a learning culture – and must continue to be a prominent element of our approach to feedback and complaints. Clinicians can significantly influence the approach taken within teams – building on relationships with patients, their families and carers and taking early action when it is becoming clear that someone has cause for concern or complaint.

A recent article in the Harvard Business Review by Giona and Staats, focused on the reasons that organisations don't learn, has some useful insights that can be applied to the way we approach quality and systems improvement. They suggest that deeply ingrained human tendencies can interfere with strategic aspirations to become a learning organisation.

There is greater recognition that medical staff are not immune from the human factors that impinge upon performance, but there can still sometimes be a tendency to forget that doctors have the same fears as everyone else and that sometimes behaviours need to be more supportive of learning, reflection and change. A growth mindset has been shown to be important – emphasising a recognition of the potential that exists for continuous learning and improvement, not taking the view that the capacity for change and learning is fixed by some genetic predetermination.

We must all demonstrate through our actions that we are committed to ensuring that everyone has the opportunity to grow through challenge and opportunity for continuous learning. Clinical leaders need to challenge their own thinking and ask themselves whether they have a growth mindset. This will mean an enhanced awareness of opportunity for self improvement, more engagement with complexity and a greater persistence in the face of obstacles.

Time for reflection and personal commitment to "pause before action" can be very difficult for clinicians. However, reactive modes with no time for reflection are energy depleting and ultimately ineffective. Although it can be counter-intuitive to think that taking more breaks increases productivity, there is compelling evidence that achieving a balance of more frequent breaks and restoration leads to greater productivity. These are important areas that can

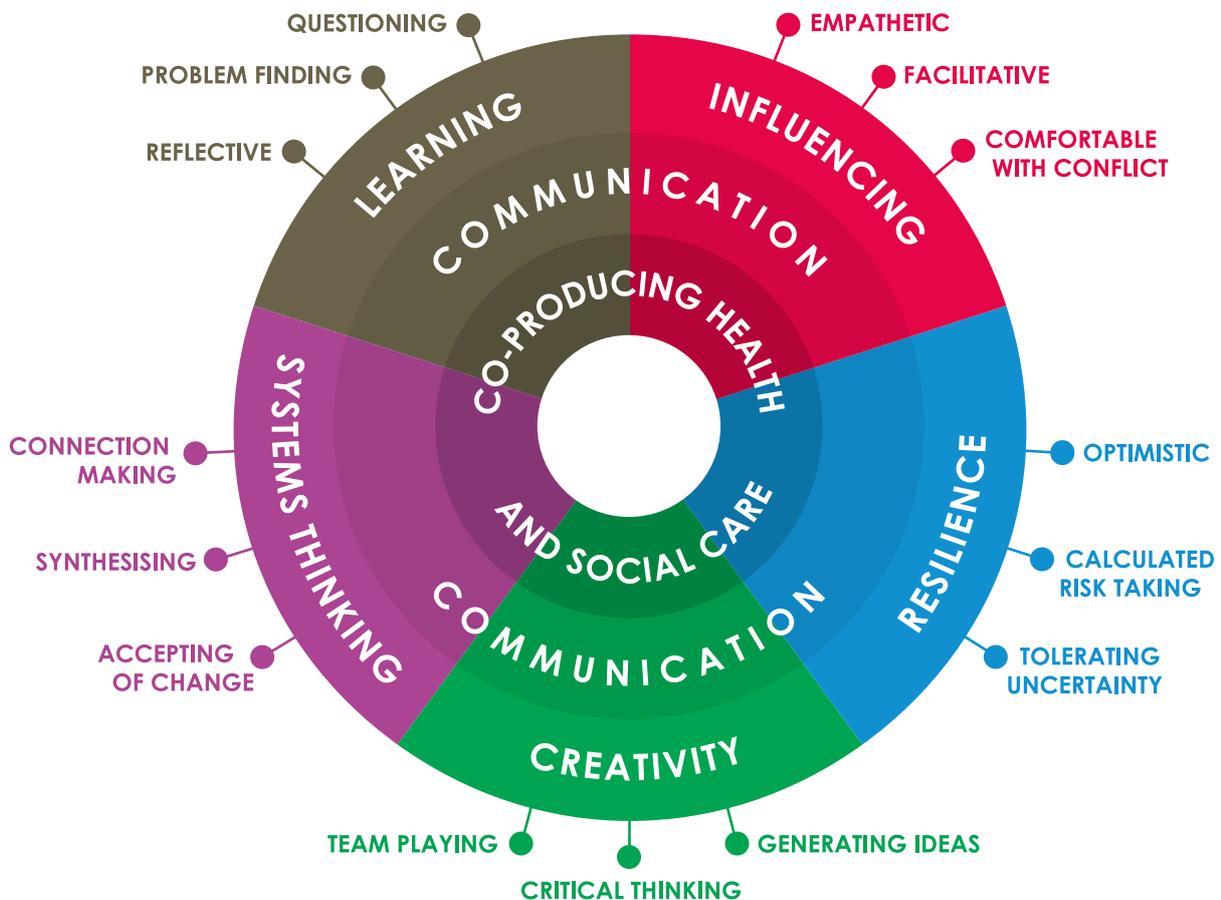


Figure 3: From Lucas, B & Nacer, H. (2015). The habits of an improver. Thinking about learning for improvement in healthcare. London: The Health Foundation. P.8.

contribute to feelings of personal control and mastery in the workplace – both of which can protect against burnout.

Junior medical staff have reported that they often have ideas on how improvements might be made, though have little opportunity to implement them. This is changing as NHS Boards have enhanced their understanding and capacity of how to support a more widespread emphasis on quality improvement capacity and capability. It is increasingly being recognised that the development of a range of improvement science skills, although necessary is unlikely to be sufficient to create the sort of widespread learning culture we want to see in Scotland.

The Health Foundation recognise the importance of reflection, communication and collaboration as the basis for the development of “habits” that will help shape future activity. Their recent paper on this issue states that “The science of improvement and the art, craft and practices of improving quality require us all to change our habits.” It has been suggested that these habits should be the primary outcomes of all learning activities, and that conversations about learning for improvement capability can be helpfully framed through the lens of five desirable improvement habits – learning, influencing, resilience, creativity and systems thinking. Each of these have “sub-habits” defined and outlined. They are habits that we could all benefit from reviewing – identifying the ones we have already acquired, considering how they might be best applied within our work and deciding how we might begin to develop new habits to support our collective work on quality and systems improvement. Communication is central to all improvement habits and sub-habits. (see Figure 3.)

Conclusion

Scotland’s medical staff have been at the forefront of identifying, testing and implementing changes that have seen world-leading changes in the safety of care and treatment within NHSScotland. Quality monitoring systems have demonstrated the ways in which data collected at the point of care can be used to identify test of change, to make connections and prompt questions in support of improvement. Resilience in the face of rising demand, critical thinking and challenge of the status quo have been valued across multi-disciplinary teams. Medical staff lead and participate in hundreds of empathetic and facilitative conversations with patients, families and colleagues. The habits of improvement are in action across hospitals, clinics and care settings every day. The medical profession in Scotland is in a strong position to lead and contribute to the challenges of delivering safe, effective and person-centred care in the future. There is still much to do though – not everyone has developed the habits of improvement; and some may have habits that don’t positively contribute to the learning and improvement culture that is vital to an engaged workforce and continuous improvements in quality.

What habits would you like to cultivate to develop, sustain and spread a learning and improvement culture across the country?



CHAPTER 6

Translation of Medical Research into Routine Clinical Practice

The translation of research findings into clinical practice has transformed healthcare. It is a cornerstone of modern evidence-based medicine and of an advanced healthcare system. However, the route to translation can be challenging; high costs, scarce funds, shortages in key research infrastructure, capacity or capabilities, slow and incomplete recruitment to trials are amongst the potential barriers to the progress of translational research studies. Medical research and development can follow ill-defined and circuitous paths before being taken up into improved patient care.

Over the last decade or so considerable attention has been given to understanding the process better, recognising it is often slow and the advantages of rapid translation of research are considerable. Hence, there is widespread interest in identifying opportunities to shorten translational pathways for the earlier realisation of research benefits to patients, the health service and wider society. Reaping the benefits of advancements in biomedical science including the development of precision medicine, and the care needs of an increasingly multi-morbid population are likely to drive changes to shorten translational pathways.

Translational Lag Time

Estimates, based on analyses of the later impact of medical research conducted during the 1970s to 1990s, suggest the average time for medical research to become embedded into clinical practice may have been around two decades. The considerable duration of this lag is not due only to the time to devise, undertake and report research studies or the nature of research, which often produces outcomes needing further investigation to be understood more fully. It can take time for a body of research evidence to accrue that is considered to be sufficiently well-developed to be applied into clinical practice. Rarely, for example, are conclusions about the safety and clinical and cost effectiveness of an intervention based on a single study. There can also be other factors at play in the journey from invention to application.

Translational Lags and the Return on Investment in Medical Research

Economic analyses of UK medical research have found returns from investment in different disease areas to be substantial in terms of health gain and economic benefit. In the area of cardiovascular disease (CVD), for example, it was estimated that UK public and charitable investments in research may produce an annual rate of return of around 39% (about 9% in health gain from new interventions and about 30% direct returns to the UK economy) or expressed differently: for every £1 of investment in CVD research, benefits equivalent to earning 39p per year *in perpetuity* may be produced. However, these analyses revealed such estimates were very sensitive to the lag between the time of research investment and when the eventual health benefits from research are accrued. The CVD estimate above was based on a lag of 17 years but when this was extended to 25 years the annual rate of return in terms of health gain, for example, dropped to 5.6% and conversely when the lag was shortened to 10 years it rose to 13.4%.

Translational Pathways

Understanding translational pathways to identifying potential opportunities to reduce avoidable time lags has become a major pre-occupation of health research funders, regulators, the life sciences industry and the research community in general.



Figure 4: A critical path for translation of medical research into clinical practice. Taken from Cooksey (2006) A review of UK health research funding.

In the UK, the process of translation of medical research and associated lags were considered in detail in 2006 in the influential Cooksey review. This investigated how the potential of UK health research to benefit patients, the NHS and the wider healthcare economy could be optimised. The review defined a critical path for the process of translating medical research into healthcare improvement with a number of discrete stages. Beginning with basic research, through pre-clinical development and then clinical testing into health technology assessment, demonstration and finally implementation of research findings into practice (see Figure 4).

Cooksey also identified two “translational gaps” – points of failure along the critical path where moving promising research further forward into application can be impeded. The first gap related to a failure in the development of ideas from basic or early stage research that could be applied into clinical practice. The second gap related to a failure to implement into clinical practice new healthcare approaches or interventions developed from those ideas. These gaps were considered to be the result of cultural, institutional and financial barriers that could be addressed in part by: greater prioritisation of health research funding (particularly to support medicines and therapies for unmet health needs); greater coordination between research funders with funding directed to supporting promising leads across the translational gaps (for example to support health technology assessment); and a culture in the NHS more supportive of clinical research.

Research funders responded to address these gaps. In Scotland for example, the Chief Scientist Office (CSO) focused its research grants towards the “Cooksey gaps” and created NHS Research Scotland – a partnership between CSO and the Health Boards – to agree and implement national clinical research policies and provide a supportive and efficient environment in Scotland for clinical research in the NHS. Nevertheless, translation remains challenging and continues to receive considerable attention. More recent analysis has represented it as a series of key milestones along a number of different research-based and non-research-based tracks (see Figure 5). In an idealised drug development scenario, this pathway begins in the discovery track with a biological target and series of compounds that can act on that target identified, that are taken through a programme of pre-clinical testing to establish the mechanism of action with the most promising candidate(s) tested in animal models to examine the effect on disease

and potential for toxicity. In the human research and review track, the safety and efficacy of the best candidate identified from the pre-clinical programme is assessed in a series of clinical trials which when the data are combined and synthesised provide robust evidence of safety and efficacy. In the non-research tracks, the synthesised evidence supports the market authorisation for use in patients by a medicine regulator and, together with economic evidence, a positive recommendation by guideline developers for adoption in the health service for the indicated group of patients. The drug is then supplied and used routinely in the health service.

However, progress along these tracks is often incremental and iterative. For example, in case studies of the route to translation along these tracks of the antihypertensive drug, amlodipine, and the antipsychotic drug, olanzapine, the translational timelines from discovery research to routine UK use of these drugs was judged to be 23 and 20 years duration, respectively. Inspection of the timelines, revealed potential avoidable lags of years between different clinical trial phases, between the completion of clinical trials and syntheses of the findings, and between regulatory approval of the drugs and policy statements on their use in the NHS and then their actual use in routine clinical practice. Thus, these timelines in these cases might have been appreciably shortened.



Figure 5: Research and non-research based tracks of development of a medical intervention with key milestones. The blue arrow represents the direction of the innovation process and the green arrow represents time. Based on Hanney *et al.*



Improving Translation

Refinements to current process around the discovery research, human research and research review tracks to generate greater efficiencies in translation have been suggested recently with five key areas where there is scope for improvement identified:

1. Better prioritisation of research by defining research questions of relevance and importance to users of research and for which there is an established need based on systematic reviews of the existing evidence.
2. Improved design, conduct and analysis of research studies so that they produce high quality, reproducible research results with a low likelihood of bias.
3. Research appraisal, regulation and management processes that support efficient and robust approval process to ensure high quality relevant research is funded with minimal delays in approval and administration times.
4. Better provision of information about studies underway and on all studies that have been completed, including those that produced negative results, so the complete existing evidence

base can be established thereby enhancing evidence assessment and synthesis and reducing unnecessary replication of research.

5. Better reporting of research study methods and findings in order that the findings can be understood and used by others with confidence in an accurate and meaningful way.

While much of the responsibility for improvement in these areas lies with the research community and health research funders and regulators, the wider clinical and patient communities can play important and active roles. Patients, carers and clinicians can become actively involved in research prioritisation. Through initiatives such as the James Lind Alliance these groups can systematically identify and prioritise important uncertainties about treatments, that could be answered by research. In this way, the research agenda cannot be pushed forward by the research community and research funders but also pulled through by users who may be the eventual potential beneficiaries of research. Greater patient (and user) involvement in research design and conduct has been advocated and patient and public involvement in research funding decisions is now widespread.

Reducing avoidable lags in the later non-research tracks is also currently under much scrutiny, notably through the UK Government Accelerated Access Review. This aims to speed up patient access to innovative drugs, devices and diagnostics by looking at how processes may be accelerated in three key areas: assessment of safety and efficacy; health economic assessment and re-imbursement; and uptake by the NHS. The review is part-way through but an interim report published recently has set out a number of guiding principles for development including: greater patient involvement, early identification of emerging products offering the most patient benefit, and supporting innovation along the translational pathway and in the NHS.

Responding to These Challenges

The conventional translational model with average lags of two decades is unsustainable and the demand for new translational models favouring more rapid realisation of patient and health service benefits and economic returns is growing. With advances in genomics and informatics driving better understanding of the molecular basis of diseases, the research opportunities to develop new therapeutics (or repurpose existing ones) and diagnostics to stratify patients to guide treatment (precision medicine) will increase. Combined with innovative clinical trial designs that allow more flexible methods to accumulate safety and efficacy data, the challenge, as predicted by the Accelerated Access Review, will be systems that can evaluate, select and adopt effective and cost effective innovations more quickly.

Scotland has made great strides in addressing this challenge. In terms of study start-up, NHS Research Scotland (NRS) has significantly removed the bureaucracy associated with commencing multi-centre

studies. With generic study issues now being considered once for the whole country, as opposed to being revisited at every site as was previously the case, there has been a significant reduction in the time taken to approve studies. The introduction of a single cost and contract negotiation for the whole country has further increased efficiency and made Scotland a popular destination for commercial trials.

But addressing this part of the process in isolation will not deliver the improvements required for an efficient 21st century health service. For that reason CSO has been working with our Scottish universities with a view to joining up early stage innovative research with later stage clinical testing. Taking a holistic view of the product development pathway is essential if time wasting delays are to be avoided, and patients are to have earlier access to novel treatments.

A good example is the development of a Scottish precision medicine ecosystem, pulling together the academic excellence of our universities with the clinical expertise of NRS, creating a joined up portal through which a single contract – spanning early development work through to clinical evaluation – can be made.

This model developed for research has the scope for wider application. As reported above, the Interim Report of the Accelerated Access Review (AAR) also outlines the need for a coherent and joined-up innovation infrastructure from research to procurement. The Innovation Cluster approach being adopted in Scotland aims to facilitate this move towards a simpler and clearer pathway through the innovation landscape. Initiatives such as the Cluster's work on Open Innovation and a Small Business Research initiative (SBRI) call in diabetes (co-funded by Scottish Government and Scottish Enterprise) are good examples of work in this area.

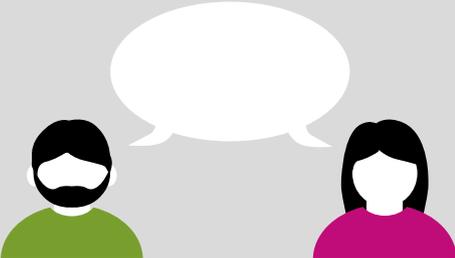
Conclusion

I am glad to have had this opportunity to use my first report to address the challenges of "Realistic Medicine." I believe that the profession, with doctors as collaborative leaders, as in so much of our history, can influence and be a driver for change.

I hope that you will engage with me on the issues raised in this report and use the infographic as an aid for discussion.

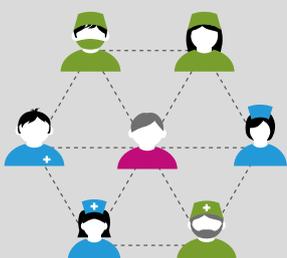
REALISTIC MEDICINE

CAN WE:



CHANGE OUR STYLE TO
SHARED DECISION-MAKING?

BUILD A **PERSONALISED**
APPROACH TO CARE?



**REDUCE HARM
AND WASTE?**



REDUCE **UNNECESSARY
VARIATION** IN PRACTICE
AND OUTCOMES?

MANAGE RISK BETTER?



**BECOME IMPROVERS
AND INNOVATORS?**

I'd really welcome your opinion. If you have feedback I can be reached at:
Email: cmo@gov.scot Phone: 0131 244 2379

You can also interact with me on twitter.com/CathCalderwood1
and via my blog blogs.scotland.gov.uk/cmo/
and via [in](https://www.linkedin.com/in/catherine-calderwood-691979108) at www.linkedin.com/in/catherine-calderwood-691979108 or complete my survey
www.surveymonkey.co.uk/r/LMDCMWM



The Health of the Nation – Executive Summary

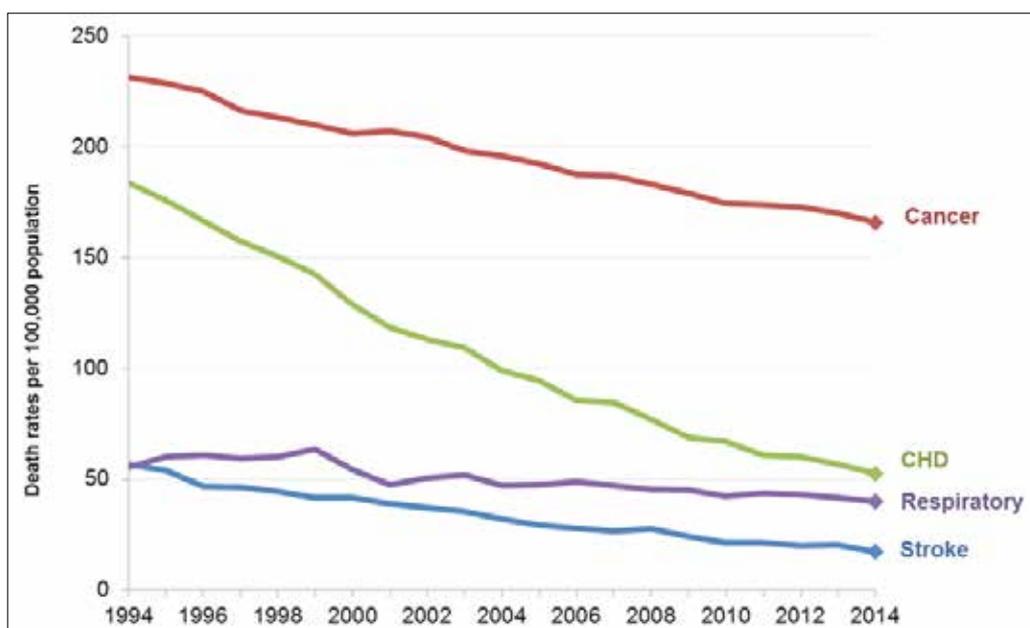
This is an Executive Summary containing highlights of the Health of the Nation report. The data and graphs are evidence of both the successes we have already achieved in Scotland and the areas where we need to drive further improvement.

The full report can be found at www.gov.scot/cmooannualreport201415part2.

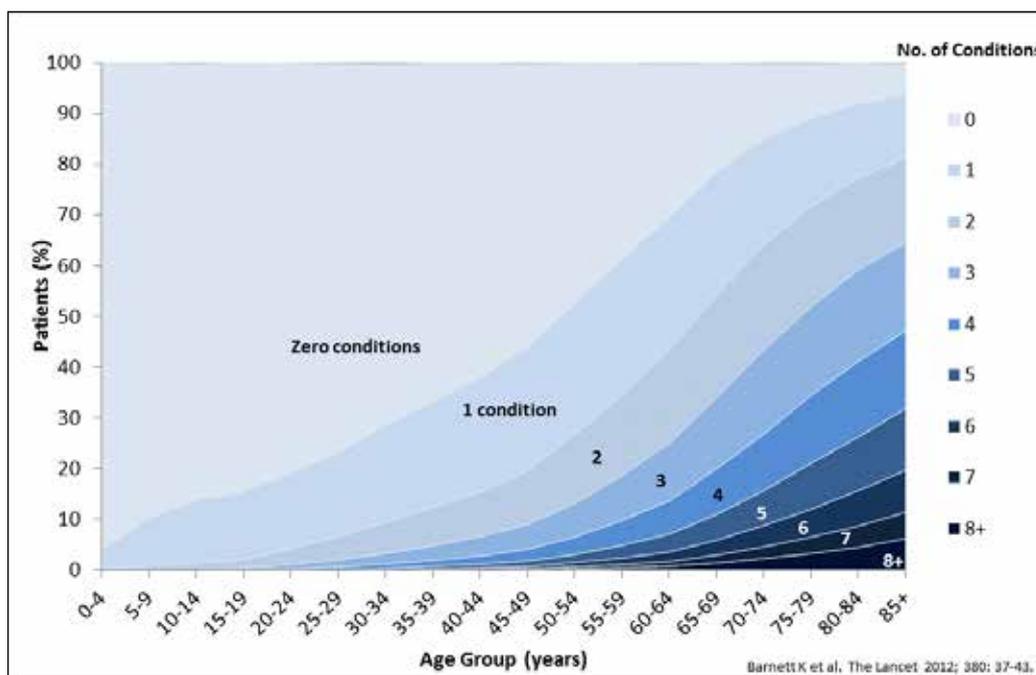
Health Improvement:

Premature mortality has reduced substantially in recent years, down 38% since 1994.

Death rates (<75y) per 100,000 population by selected causes, Scotland 1994-2014

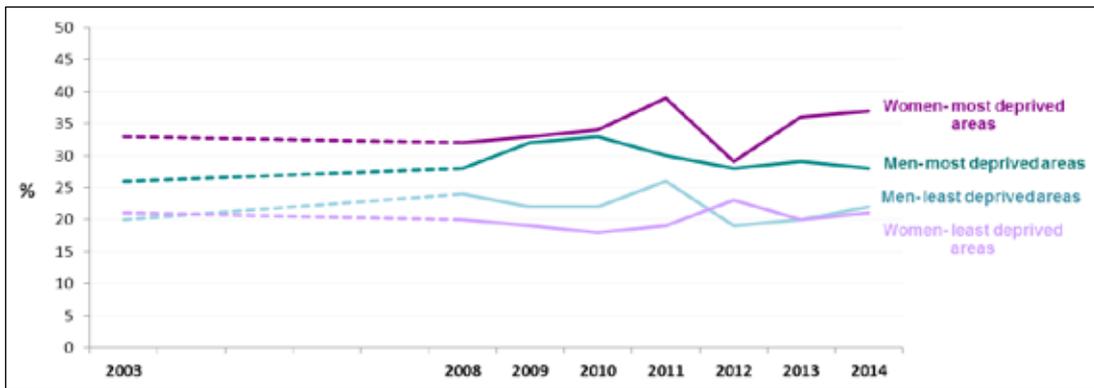


Multimorbidity. The Scottish Health Survey shows that 46% of adults (aged 16 and over) have at least one long-term condition. There are more people in Scotland with multimorbidity below 65 years than above.



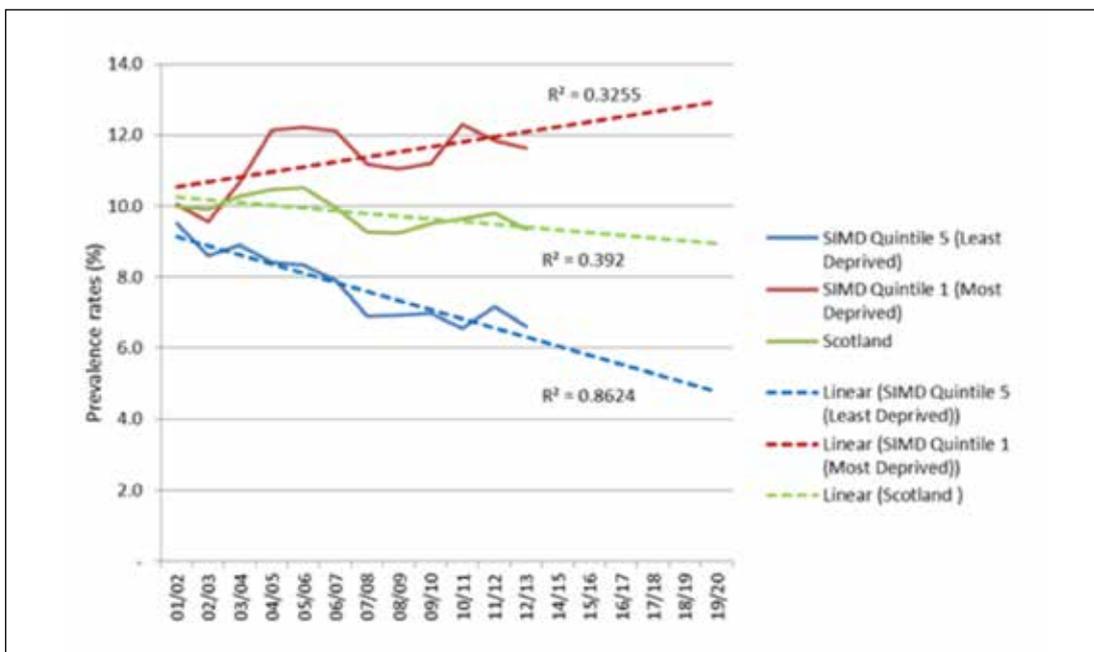
Obesity. The Scottish Health Survey (SHeS) 2014 found that almost two-thirds of adults (65%) in Scotland were overweight or obese (Body Mass Index (BMI) > or = 25), with 28% classified as obese (BMI > or = 30). In addition, around one in six (17%) of children were at risk of obesity, with a further 14% at risk of overweight. There has been a significant increase in the proportion of adults aged 16 to 64 categorised as obese, from 17% in 1995 to 27% in 2014, although the level has remained fairly constant since 2008. Women have higher rates of obesity than men (29% compared to 26% in 2014) with obesity rates highest in areas of greater deprivation. This pattern is particularly marked among women with women in the most deprived quintile in 2014 having obesity rates 16 percentage points higher than women in the least deprived quintile.

Obesity rates (adults) by gender and deprivation, Scotland 2003-2014



Children from the most deprived areas are more likely to be overweight or obese than to those from the least deprived areas.

The Projected Prevalence of Obesity in Primary 1 Children in Scotland for Scottish Index of Multiple Deprivation Quintiles 1 & 5 compared to Scotland as a whole: school years 2001/02 to 2019/20



Poor diet continues to be a major driver of the obesity epidemic. The Supporting Healthy Choices (SHC) framework outlines the Scottish Government and the Food Standards Scotland ambition to work collaboratively with partners to improve Scotland's diet and tackle health inequalities.

Four core principles of SHC:

- Put children's health first in food-related decisions
- Rebalance promotional activities to significantly shift the balance towards healthier choices
- Support consumers and communities with education and information
- Formulate healthier products and menus across retail and out of home catering

Physical activity. There is strong scientific evidence that sufficient, regular physical activity is beneficial for the health of body and mind.

This infographic was developed from the UK Chief Medical Officers' 2011 Physical Activity Guidelines. It is designed for use by healthcare professionals but has been well received by many others and shared widely using social media.

In 2014, 63% of adults in Scotland met the guidelines on moderate or vigorous physical activity (MVPA) of at least 150 minutes of moderate, or 75 minutes' vigorous activity, or an equivalent combination of the two, per week. This figure has not changed significantly in the 2012-2014 period. Men are more likely to meet the physical activity guidelines than women (68% v 59% in 2014). Activity levels are significantly associated with age, with adherence in 2014 highest among adults aged 25-34 (79%), and steadily declining with increasing age, with the lowest proportion found among adults aged 75 and over (26%).

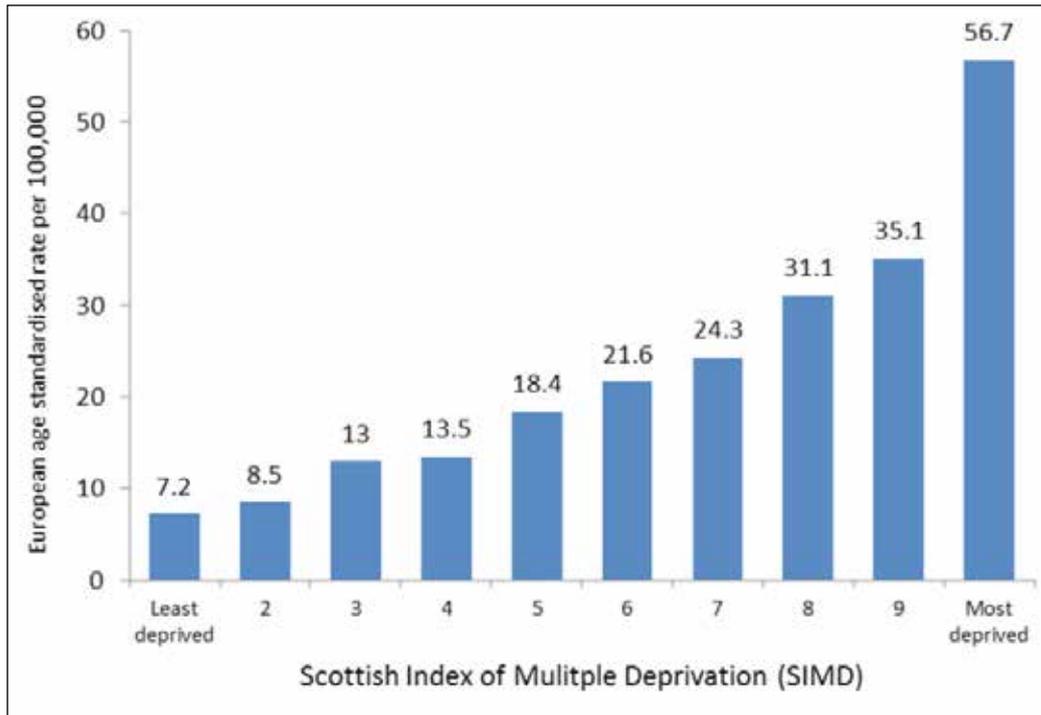


Alcohol continues to cause significant harm in Scotland. The scale of the problem is clear but the most recent data paints a mixed picture: consumption relatively stable, alcohol-related deaths up for the second year running and hospital admissions continuing to fall. There are clear links between alcohol and social deprivation. The UK CMOs' new consultation on guidelines for lower risk alcohol consumption were launched in January 2016.

The main recommendations are that men and women are advised not to regularly drink more than 14 units a week; to spread drinking over three or more days if drinking as much as 14 units a week; and there is no safe amount of alcohol that can be drunk during pregnancy.

<https://consultations.dh.gov.uk/alcohol/uk-cmo-guidelines-review>

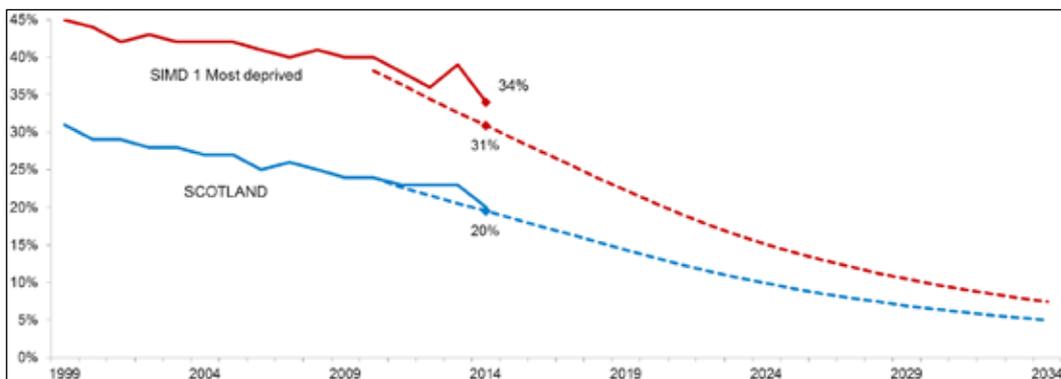
Alcohol-related deaths by deprivation decile, Scotland 2014



Smoking is the leading preventable cause of ill-health and premature death in Scotland, with half of all regular cigarette smokers estimated to die prematurely as a result of smoking. Smoking is associated with around a fifth of all deaths, and around 128,000 hospital admissions, per year in Scotland.

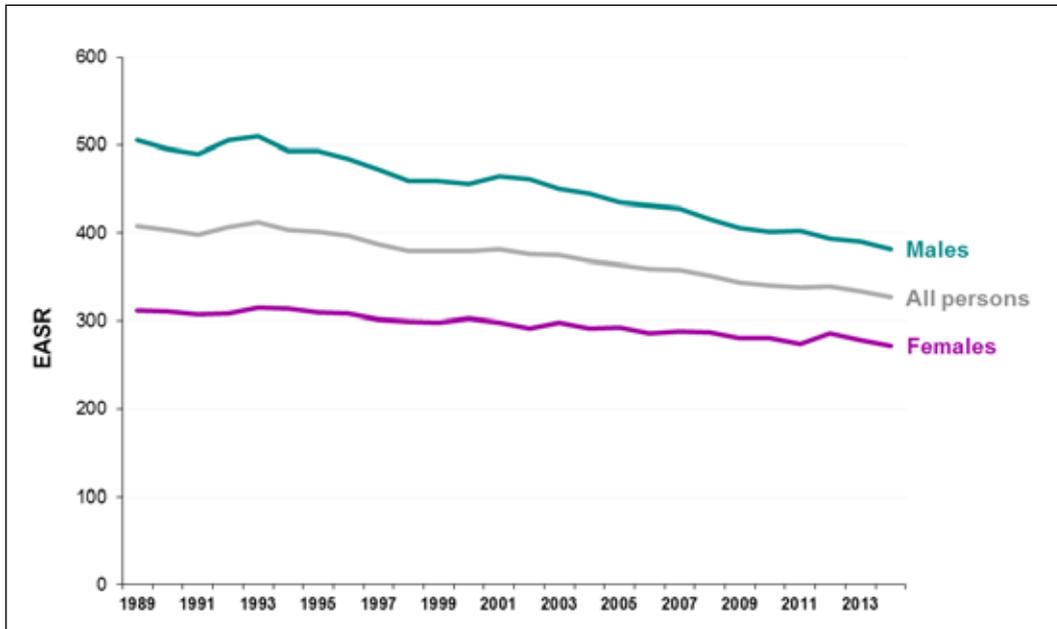
The decline in 2014 brings smoking prevalence in line with our projections towards the 2034 policy target (smoking prevalence of 5% or less by 2034). However, as with many other lifestyle factors significant inequalities remain: in the 20% most deprived areas 34% of adults smoke, compared to 9% in the least deprived areas.

Smoking prevalence: 1999-2014 and Projected smoking prevalence towards 2034 target¹



Cancer. Age-standardised cancer mortality rates have decreased by 20% since 1989, with a greater fall in males than in females (24% and 13% decrease, respectively). Cancers of the lung (4,117), colorectum (1,525), breast (976), prostate (906) and oesophagus (850) were responsible for more than half of the deaths from cancer in Scotland in 2014.

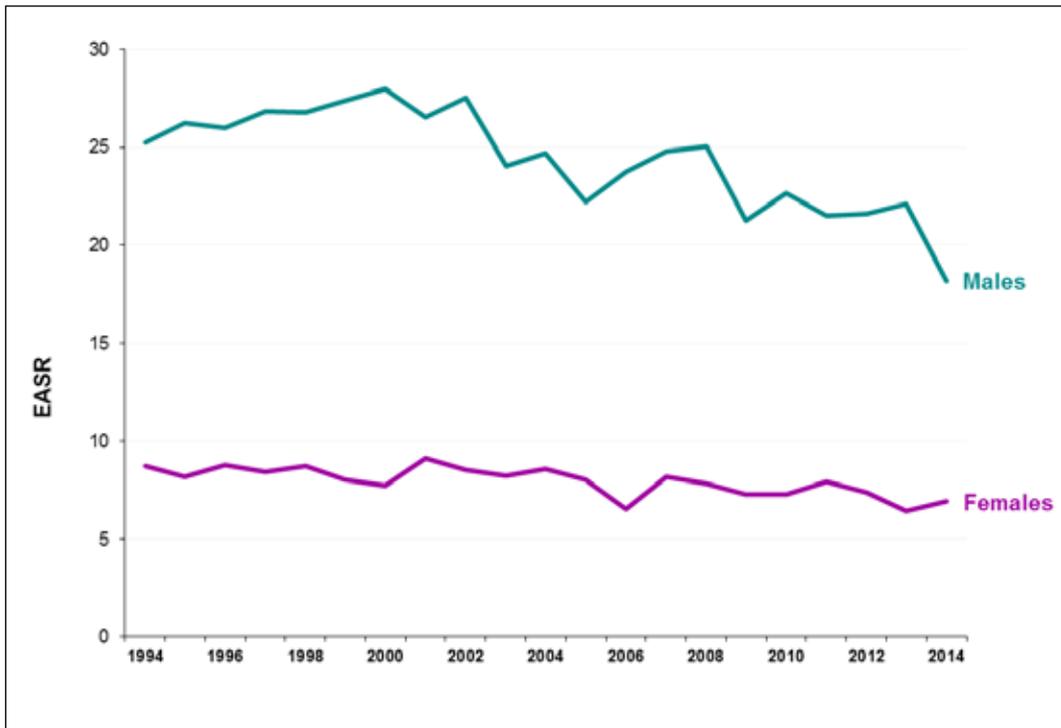
**Cancer mortality rates, Scotland 1989-2014 (excluding non-melanoma skin cancer)
 European Age Standardised Rate (EASR) per 100,000 population**



Mental health is one of the top public health challenges as measured by prevalence, burden of disease and disability, with around one in three people estimated to be affected by mental illness in any one year. In 2012-13, 26% of adults in the most deprived areas had a below average Warwick-Edinburgh Mental Wellbeing Scale score, compared to 6% of adults in the least deprived areas. The inequality gap has widened in recent years.

Suicide. There has been a 17.8% reduction in the suicide rate in Scotland over the period 2000-04 to 2010-2014, with the number of deaths by suicide in Scotland in 2014 the lowest in a single year since 1977.

Suicide rates, Scotland 1994-2014, European Age Standardised Rate (EASR) per 100,000 population



Communicable Diseases:

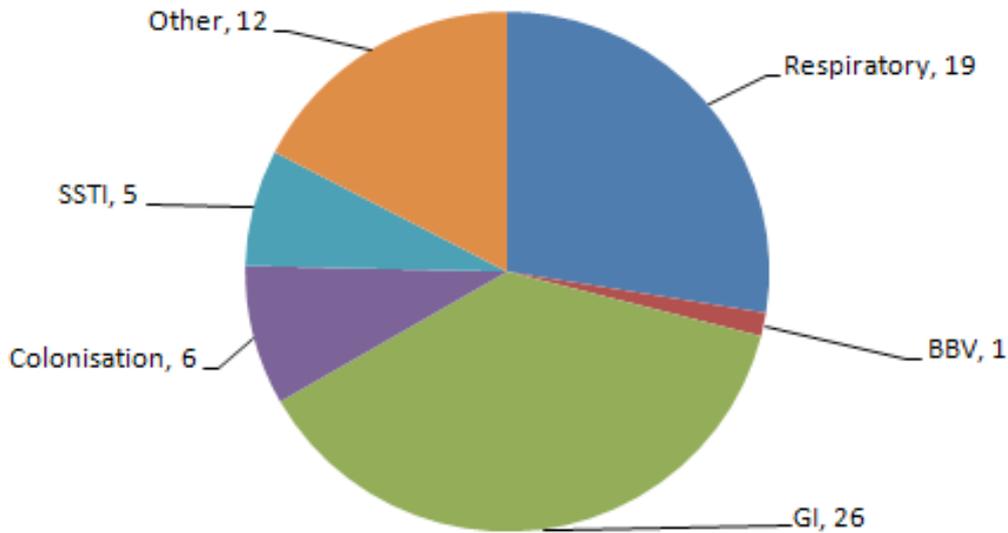
Vaccination

Since the beginning of 2014, immunisation programme developments include:

- Offering seasonal flu vaccine to all children from age two years to the end of primary school;
- Introducing vaccination against Meningococcal B disease for infants;
- Expanding protection against meningococcal disease for adolescents with introduction of ACWY vaccine for those aged 14-18 years and new university entrants;
- Continuing with the phased catch-up programme for herpes zoster (shingles) vaccine for those aged 70-79 years.

Healthcare associated infections continue to represent a threat to safe care.

Types of HAI outbreaks and incidents (n=69) reported to HPS, January 2014 to September 2015.



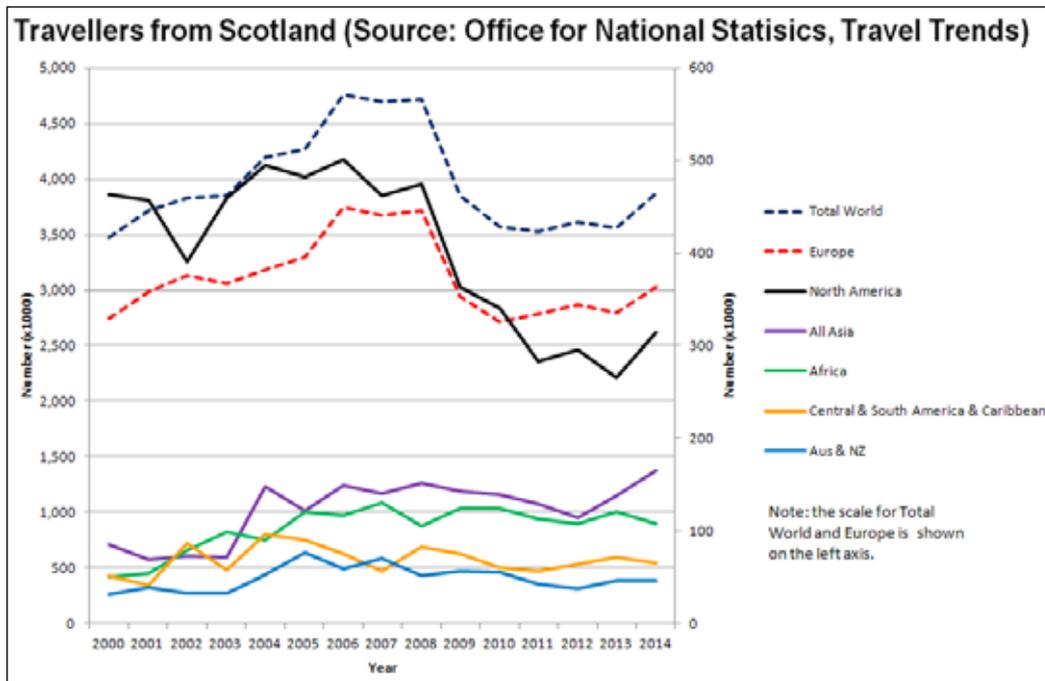
Norovirus outbreaks continue to be the most common cause of ward closures within NHS Boards.

Antimicrobial resistance. There is growing concern about antimicrobial resistance. Multidrug resistance among Gram-negative organisms continues to be a major threat to public health and patient safety. Established in 2015, the Control of Antimicrobial Resistance in Scotland team in HPS is leading Scotland's strategic response to control of antimicrobial resistance.

Blood-borne viruses. In the first quarter of 2015, over 400 individuals commenced treatment for chronic Hepatitis C virus infection, almost three-quarters of whom were being treated with a sofosbuvir-containing regimen.

5,000 people are estimated to be diagnosed and living with HIV in Scotland. An estimated further 1,600, however, remain undiagnosed. The first licensed HIV self-testing kits, based on a finger prick blood sample, went on sale at the end of April 2015.

Travel and surveillance of imported infections. In 2014 the Travel and International Health team (TIHT) of HPS continued to carry out surveillance of travel-related infectious disease imported in Scotland, surveillance of outbreaks and incidents abroad, in particular by supporting the risk assessment for the 2014 Commonwealth Games, and also playing a central role the Scottish public health response to the Ebola outbreak in West Africa.



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