Workshop C22: Learning from the Mid-Staffordshire Case in the English NHS

10th December 2013

Institute for Healthcare Improvement
25th Annual National Forum on Quality Improvement in Health Care

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and

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@donberwick

The overall aim of this session is to show how a public inquiry into the problems of care at one English hospital (Mid Staffs) led to an improvement in the system for regulation and monitoring of hospital care in the English NHS.
Aims and timing of the session:

- Describe how the problems at Mid Staffs arose
- Identify the early signs of similar problems in other healthcare systems
- Identify ways of developing early warning systems from data analysis, patient and staff feedback and surveys and timely inspections and investigations
- First 30 minutes - Brian Jarman will cover how Mid Staffs problems arose and developing early warning systems
- Second 30 minutes – Don Berwick will cover “a promise to learn – a commitment to act: improving the safety of patients in England.”
- Final 15 minutes – questions (also interrupt earlier)

Mid Staffs hospital is in Stafford
Stafford, England, population 63,681

Abbots Bromley – the Horn Dance

About the Horn Dance

The Abbots Bromley Horn Dance, performed at the Barthelmy Fair in August 1226, is one of the few ritual rural customs to survive the passage of time. Today the Horn Dance, which takes place annually on Waakes Monday, offers a fascinating day out attracting visitors from all over the world.

After collecting the horns from the church at eight o’clock in the morning, the Horn Dancers comprising six Deer-men, a Fool, Hobby Horse, Bowman and Maid Marian, perform their dance to music provided by a melodian player at locations throughout the village and its surrounding farms and pubs. A walk of about 10 miles (or 16 kilometres).
The Holly Bush Inn, Salt Village, Stafford is one of England’s oldest pubs, dating back to Charles II

History of the Hollybush

SALT VILLAGE

The village of Salt stands on the south bank of the river Trent, between Sandon and Weston. It was listed in the Doomsday book (1086) as "Selt" and recorded as having “land for four ploughs,... a mill, twelve acres of meadow and four of wood”, Sels in Old English meaning "a salt pit or salt works". It probably originates from the Saxon period, owing its existence to a sheltered position and proximity to water, Trent meaning “the flooding river” from the Celtic name "the trespasser”. There seems to be no written evidence of salt workings within the parish but it is likely that there were in the early days of settlement as salt has been

The Ancient High House in Stafford main street is an Elizabethan town house dating from 1594
Before Mid Staffs - Bristol Inquiry 2001

1. Paediatric cardiac surgery at Bristol poor for 10 years.
2. Mortality in children <1, open heart surgery, was 29%.
3. External investigation found Bristol under-resourced.
4. Changes led to mortality reduction to 3% in 3 years.
5. Patient group + media pressure led to a public inquiry.
6. Department of Health accepted that it was ultimately responsible, with the Secretary of State for Health, for having a system for quality audit in the NHS
7. Bristol Inquiry concluded the Department of Health was unable to respond to an issue of quality of care.

Bristol Inquiry: number of concerns per year about Paediatric Cardiac Surgery 1986 to 1994

- 1986 ‘it is no secret that their surgical service is regarded as being at the bottom of the UK league for quality’. CMO Wales expressed concerns to the CMO of England
- New anesthetist, Dr Bolsin, expressed repeated concerns - 1989 to 1995 both locally and nationally
- 1987 BBC Wales TV ‘Heart Surgery - 2nd class Service’
- Article in Daily Telegraph, 5/4/1995
- External on-site inspection 1995 led to big improvement
The Bristol Inquiry conclusions

- “The prevailing ethos of the time was that such matters should be resolved locally. There seemed to be no alternative means of responding to clinical problems.”
- “The DoH [Department of Health], for historical and structural reasons, was simply unable adequately to respond when an issue of the quality of care was being raised.”
- “We conclude, therefore, that the DoH stood back from involvement in the quality of clinical care. It had not created systems to detect or act on problems of clinical care, other than by referring them back to the district or hospital concerned.”

Bristol: data were available from 1990

“From the start of the 1990s a national database existed at the Department of Health (the Hospital Episode Statistics database) which among other things held information about deaths in hospital. It was not recognised as a valuable tool for analysing the performance of hospitals. It is now, belatedly.”

Main Government initiatives post-Bristol

2. Set up the National Patient Safety Agency (NPSA) to record adverse events in hospitals.
3. CHI was abolished in 2004 and replaced by Healthcare Commission (HCC), which depended on inaccurate self-reporting, but investigated Mid Staffs 2008-9.
4. HCC was abolished in 2009 and replaced by the Care Quality Commission (CQC), which decided not to investigate poor clinical care [as did Health & Safety Executive].
5. NPSA acknowledged significant under-reporting so was abolished and functions incorporated into the CQC.

25 organisations involved in regulation from 2004 - responsibility is diffused and not clearly owned

- Healthcare Commission (CQC from April 2009)
- Strategic Health Authority -responsible for performance management of trusts
- Monitor – financial regulator but ? of quality of care
- Primary Care Trust – ‘World Class Commissioning’
- Parliamentary and Health Service Ombudsman
- Patient support (PPIF, LINk, POhWER), the oversight and scrutiny committees, the NHSLA, the GMC, the NMC, the Health & Safety Executive (HSE), National Confidential Inquiry into Patient Outcome and Death (NCPOD), National Patient Safety Agency (NPSA), Patients Association, the deaneries responsible for training graduate doctors, the PMETB, the universities responsible for training nurses, the relevant unions, the Royal Colleges, the coroner.
Imperial College and Dr Foster 2000

1. Unit formed at Imperial College to analyse death rates.
2. A company (Dr Foster) was formed to publish data, do monthly analyses, train hospital staff, develop website.
3. Used the Hospital Standardised Mortality Ratio (HSMR), SMRs for diagnoses and patient-level data.
4. Also mortality alerts for diagnoses & procedures when adjusted death rate double national (‘signal’ at 1:1000 false alarm rate – continuous quality improvement).
5. In 2007 started sending monthly mortality alerts to CEOs of hospitals and copying them to regulator Healthcare Commission (led to Mid Staffs investigation).
6. Data used for (a) detecting possible problems and (b) monitoring improvement initiatives.

Methodology of HSMR calculations

Data used - Hospital Episode Statistics (HES)
Electronic record of every inpatient or day case episode of patient care in every NHS (public) hospital
14 million records a year
300 fields of information including
- Patient details such as age, sex, address
- Diagnosis using ICD10
- Procedures using OPCS4
- Admission method
- Discharge method
Case-mix adjustment model for HSMR and for each diagnosis and procedure group

Adjusts for

- age
- sex
- elective status
- socio-economic deprivation
- diagnosis subgroups (3 digit ICD10) or procedure subgroups
- co-morbidity – Charlson index
- number of prior emergency admissions
- palliative care
- year
- month of admission
- source of admission

HSMRs - Mid Staffordshire NHS Hospitals Trust

Mortality (in-hospital) | Diagnoses - HSMR
Healthcare Commission
first report 18/03/2008
### Measuring hospital performance: Mortality rates

This table shows standardised mortality ratios for NHS acute trusts in England. Trusts are listed alphabetically and by low, average and high mortality ratio. Trusts are determined high or low if they fall outside 99.8 per cent (3 sigma) control limits on a funnel plot.

**TRUST LOW MORTALITY**

<table>
<thead>
<tr>
<th>Trust Name</th>
<th>Three-Year Mortality</th>
<th>Three-Year 95% Confidence Interval</th>
<th>One-Year Mortality</th>
<th>One-Year 95% Confidence Interval</th>
<th>Percentage Change (%)</th>
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**DATA EXPLAINED**

**Mortality indicators explained**

**One-year mortality**

The adjusted Hospital Standardised Mortality Ratio (HSMR) for 2005/06.

**One-year confidence intervals**

The lower and upper confidence intervals give year-to-year variations in the expected number of deaths for 2005/06.

**Three-year mortality**

The adjusted Hospital Standardised mortality ratio (HSMR) for 2003/06 for the conditions that lead to 86 per cent of deaths. 120 shows 20 per cent more deaths than expected. 80 represents 20 per cent fewer deaths than expected from Hospital Episode Statistics (HES) and NHS-Wide Cleaning Services (NWCS).

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### Monthly alerts sent to hospitals: Example diagnosis = Acute MI

**Hospitals NHS Foundation Trust**

- **Diagnosis:** Acute myocardial infarction
- **Date year:**
- **Mortality (inHospital):**
- **Diagnoses:** Acute myocardial infarction
- **CISM/GM Statistic:** 0.74 (average)
- **CISM/GM Statistic:** 5.7
- **Note:** 0.4%
Anonymised version of a monthly alert letter
Sent to trust Chief Executive (copied to the CQC)

The healthcare Commission decision to investigate Mid Staffs

Nigel Ellis, Head of Investigations at the Healthcare Commission, statement to the Inquiry, para 97, 9 May 2011

"The concerns from local patients obviously added significantly to our level of concern about the Trust but it is important to clarify that these concerns were raised with us after the mortality alerts had caused HCC to contact the Trust. These letters, important though they were, were not the initial prompt for the Investigation."
Other warnings about Mid Staffs

- **Loss of star rating** – In 2004, the Commission for Health Improvement (CHI) re-rated the Trust, and it went from a three star trust to zero stars.
- **Peer reviews** – Peer reviews, including the Cancer Peer Review in 2005, the Care of Critically Ill and Critically Injured Children’s Peer Review in 2006, and a follow up of the Children’s Peer Review. Each raised questions about management capability.
- **Surveys** – The HCC commissioned annual surveys of staff and patient opinion conducted by the Picker Institute. The results of the survey taken for the previous year were published in about April the following year. The 2007 inpatient survey, while identifying many areas in which the Trust did well or performed satisfactorily, in several areas rated the Trust as being in the worst performing 20% in the country.
- **Whistleblowing** – It is clear that a staff nurse’s report in 2007 made a serious and substantial allegation about the leadership of A&E - known to the Royal College of Nursing (RCN) because of its involvement with the personnel involved.
- **Royal College of Surgeons** report in January 2007 – The RCS reached critical conclusions about the operation and management of the Trust’s surgical department, which it described as “dysfunctional”. The report itself was known at the time only to the Trust and the relevant staff, and the Royal College. It showed a state of affairs which would have been expected to cause serious concern to the public, and any regulator, if known to them.
- **Trust’s financial recovery plan** and the associated staff cuts – Savings in staff costs were being made in an organisation which was already identified as having serious problems in delivering a service of adequate quality, and complying with minimum standards.

Main flaws in the regulatory system

1. In 2009 the CQC decided not to investigate clinical quality of care. Francis said: as the HSE doesn’t cover healthcare cases this “has led to a particularly unsatisfactory situation when placed alongside the CQC’s inability to investigate individual cases. This has led to a regulatory gap that needs to be closed.”
2. In 2004 the Independent Review Panels for unresolved patients’ complaints about hospitals were abolished. In 2011/12 only 0.27% of ~14,000 written hospital complaints were formally investigated by Ombudsman.
3. **Whistleblowers** “At present, if you whistleblow, you will be dismissed—it’s as simple as that! . . . Once doctors are dismissed, it is virtually impossible to find employment back in the NHS.”
The 2008 IHI report to Ara Darzi

• “The NHS has developed a widespread culture more of fear and compliance, than of learning, innovation and enthusiastic participation in improvement.”
• “Virtually everyone in the system is looking up (to satisfy an inspector or manager) rather than looking out (to satisfy patients and families)”
• “managers ‘look up, not out.’ ”
• “We were struck by the virtual absence of mention of patients and families in the overwhelming majority of our conversations, whether we were discussing aims and ambition for improvement, ideas for improvement, measurement of progress, or any other topic relevant to quality.”

The events at Mid Staffs in 2007

1. Pressure to increase the number of Foundation trusts.
2. March the SHA put Mid Staffs forward for FT status.
3. April Mid Staffs HSMR published as 127 (27% high).
4. April first of 4 mortality alerts sent to CEO of Mid Staffs.
5. May Birmingham University asked to examine HSMRs.
6. June Department of Health not told of high HSMR.
8. Nov Healthcare Commission decide to investigate Mid Staffs because of the number of mortality alerts.
10. HCC investigated Mid staffs 2008/9 – appalling care.
Mid Staffs HSMR data – 2005/09. 68,647 admissions
3820 deaths, 3355 expected deaths. HSMR 114 (110-118)

68,647 adms 3820 deaths, 3355 expected deaths. HSMR 114 (110-118)
2724 admissions 80 deaths, 40.7 expected deaths. SMR 196 (156-244)

Difficulties mentioned during the Mid Staffs inquiry by the three Regulators’ Chairmen:

1. Ian Kennedy, Chair of the Healthcare Commission, stated:
   “The engagement of the Department of Health was one of interest… quality of the care provided by the NHS was not part of their agenda.”

2. Barbara Young, Chair of the CQC, stated:
   “The reason the government didn’t like tough reports was because they were running the services that were being reported upon.”

3. William Moyes, Chair of Monitor, stated:
   “The culture of the NHS, particularly the hospital sector, I would say, is not to embarrass the minister.”

- Comment by the Minister (Sec of State, Health) Andy Burnham:
  “The impression of us all was that we would just, you know, constantly do what was meant to be the thing that Number 10 wanted or that we were all, you know, unthinkingly piling this stuff through. We weren’t.”
### Actions after the Francis report on Mid Staffs was published on 6 February 2013

1. Feb 2013 Robert Francis, CQ Mid Staffs Inquiry report.
2. Feb 2013 Prime Minister asked Medical Director of NHS Sir Bruce Keogh to investigate 14 high death rate trusts.
3. July 2013 Keogh Mortality Review published. Found all 14 trusts had problems and action plans made for each.
4. SoS, Health put 11 of 14 trusts into special measures (10 of the 11 had significantly high HSMRs from 2007).
5. Chief Inspectors for Hospitals, General Practice and Social Care appointed.
6. CQC Chair, CEO and most of the Board were changed.
7. CQC started thorough inspections using trained, professional investigators.

### The Keogh Mortality review 2013

- Firstly, we gathered and conducted detailed analysis of a vast array of hard data and soft intelligence held by many different parts of the system. This helped identify key lines of enquiry for the review teams, allowing them to ask penetrating questions during their site visits and to focus in on areas of most concern.
- Secondly, we used multidisciplinary review teams to conduct planned and unannounced site visits. These teams, around 15-20 strong, were composed of patient and lay representatives, senior clinicians, junior doctors, student nurses and senior managers. The diverse make-up of these teams was key to getting under the skin of the organisations.
- Thirdly, these review teams placed huge value on the insight they could gain from listening to staff and patients as well as to those who represented the interests of the local population, including local clinical commissioning groups and Members of Parliament. Unconstrained by a rigid set of tick box criteria, the use of patient and staff focus groups was probably the single most powerful aspect of the review process and ensured that a cultural assessment, not just a technical assessment, could be made.
- Finally, once the teams had completed their reviews, we convened a meeting of all involved statutory parties - a Risk Summit - to agree with each trust a coordinated plan of action and support to accelerate improvement.
Other changes since Francis report in 2013

1. The Parliamentary Health Service Ombudsman has called for improvements in the way hospital complaints are handled and said that she will formally investigate a much higher proportion of patient complaints.

2. There is an intention to abolish the widespread so-called gagging clauses that undermine the culture and transparency of the NHS.

3. November 2013 - Department of Health accepted 281 of Francis' 290 recommendations though not (a) to criminalise untruthful statements to commissioners and regulators made by healthcare professionals; (b) to merge the CQC and Monitor; and (c) to register or develop standards for healthcare support workers.

The future after Mid staffs and Francis

1. My hope is that continuous learning and improvement, the use of monthly mortality alerts, adjusted death rates and other data, regular patient and staff feedback, skilled hospital investigations, and development of a culture without blame, denial or fear of acting in the best interests of patients will lead to a safe NHS.

2. Don Berwick was asked to study the various accounts of Mid Staffordshire, as well as the recommendations of Robert Francis and others, to distil for Government and the NHS the lessons learned, and to specify the changes that are needed. His August 2013 report made recommendations for the way forward.
Workshop C22: Learning from the Mid-Staffordshire Case in the English NHS

A PROMISE TO LEARN – A COMMITMENT TO ACT: IMPROVING THE SAFETY OF PATIENTS IN ENGLAND

December 10, 2013
IHI National Forum on Quality Improvement in Health Care
Orlando, FL

Donald M. Berwick, MD

The Francis Report - March 2013
Background of Mid-Staffordshire

- 2004-2009 – High Hospital Standardized Mortality Rates
- Many complaints from staff, patients, and families
- Investigation began in 2009
- The Francis Report – March 2013
  - Many were harmed
  - Signals ignored
  - Basic care standards were violated
- David Cameron, PM, announced “Zero Harm” goal
- Committee – Berwick Chair
- The Keogh Report – 14 high HSMR hospitals
- Report: August 6, 2013

Mid Staffs: Operations on the jejunum – sent July 2007
Mid Staffs: Aortic, peripheral, and visceral artery aneurysms – sent Aug 2007

Mortality (in-hospital) | Aortic, peripheral, and visceral artery aneurysms

Date of discharge

Mid Staffs coding of palliative care vs HSMR

% Discharged alive

England % deaths coded as palliative care

Mid Staffordshire NHS Foundation Trust (RJD) % deaths coded as palliative care

HSMR Mid Staffordshire NHS Foundation Trust
The Problems

1. Patient safety problems exist throughout the NHS.
2. NHS staff are not to blame.
3. Incorrect priorities do damage.
4. Warning signals abounded and were not heeded.
5. Responsibility is diffused and therefore not clearly owned.
6. Improvement requires a system of support.
7. Fear is toxic to both safety and improvement.
The Solutions

1. Recognize with clarity and courage the need for **wide systemic change**.
2. **Abandon blame** as a tool.
3. Reassert the primacy of **working with patients and carers** to set and achieve health care goals.
4. Use quantitative targets with **caution**.
5. Recognize that **transparency** is essential.
6. Ensure **responsibility** for functions related to safety & improvement are vested clearly and simply.
7. Give the people of the NHS career-long help to **learn, master and apply** modern methods for quality control, quality improvement and quality planning.
8. Make sure **pride and joy** in work, not fear, infuse the NHS.

Culture will trump **rules, standards, and control strategies** every single time.

A safer NHS will depend far more on **major cultural change** than on a new regulatory regime.
Quality for the NHS

- **Safety**: Avoiding harm from the care that is intended to help
- **Effectiveness**: Aligning care with science and ensuring efficiency
- **Patient-experience**: Including patient-centeredness, timeliness and equity

Recommendation Categories

I. The Overarching Goal
II. Leadership
III. Patient and Public Involvement
IV. Staff
V. Training and Capacity-Building
VI. Measurement and Transparency
VII. Structures
VIII. Enforcement
IX. Moving Forward
I. The Overarching Goal

- The NHS should continually and forever reduce patient harm by embracing wholeheartedly an ethic of learning.

II. Leadership

- All leaders concerned with NHS healthcare – political, regulatory, governance, executive, clinical and advocacy – should place quality of care and patient safety at the top of their priorities for investment, inquiry, improvement, regular reporting, encouragement and support.

- Who are the leaders?
  - All staff and leaders of NHS-funded organizations
  - All leaders and managers of NHS-funded organisations
  - NHS England
  - Leadership bodies of NHS-funded organisations
  - Prime Minister and Government
  - Local Government Association
III. Patient and Public Involvement

- Patients and their carers should be present, powerful and involved at all levels of healthcare organizations from wards to the boards of Trusts.

IV. Staff

- Government, Health Education England and NHS England should assure that sufficient staff are available to meet the NHS's needs now and in the future.
- Healthcare organizations should ensure that staff are present in appropriate numbers to provide safe care at all times and are well-supported.
V. Training and Capacity-Building

- Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all health care professionals, including managers and executives.

- The NHS should become a learning organization. Its leaders should create and support the capability for learning, and therefore change, at scale, within the NHS.
  - Collaborative Improvement Networks
Mortality Rates from Circulatory Disease – Progress Against a Target

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Source: NCHOD


- Germany
- United Kingdom
- United States
- Australia
- France

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Mortality from Conditions Considered Amenable to Healthcare
England, 1993 - 2006

Deaths per 100,000 population (DSR)

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</table>

Source: NCHOD

International Mortality from Conditions Considered Amenable to Healthcare (1997/98 - 2002/03)

<table>
<thead>
<tr>
<th>Country</th>
<th>% decrease 1997/98-2002/03</th>
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<tbody>
<tr>
<td>France</td>
<td>14.5%</td>
</tr>
<tr>
<td>Australia</td>
<td>19.3%</td>
</tr>
<tr>
<td>Canada</td>
<td>13.5%</td>
</tr>
<tr>
<td>Germany</td>
<td>15.1%</td>
</tr>
<tr>
<td>United States</td>
<td>4.3%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>20.8%</td>
</tr>
</tbody>
</table>

Source: Nolte and McKee, 2008
VI. Measurement and Transparency

• Transparency should be complete, timely and unequivocal. All non-personal data on quality and safety, whether assembled by government, organizations, or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the public.

• All organizations should seek out the patient and carer voice as an essential asset in monitoring the safety and quality of care.

VII. Structures

• Supervisory and regulatory systems should be simple and clear. They should avoid diffusion of responsibility. They should be respectful of the goodwill and sound intention of the vast majority of staff. All incentives should point in the same direction.
VIII. Enforcement

• We support responsive regulation of organizations, with a hierarchy of responses. Recourse to criminal sanctions should be extremely rare, and should function primarily as a deterrent to willful or reckless neglect or mistreatment.

IX. Moving Forward

1. **Place** the quality of patient care, especially patient safety, above all other aims.
2. **Engage, empower, and hear** patients and carers throughout the entire system and at all times.
3. **Foster** whole-heartedly the growth and development of all staff, including their ability and support to improve the processes in which they work.
4. **Embrace** transparency unequivocally and everywhere, in the service of accountability, trust, and the growth of knowledge.
Major Media Interest on August 6

- Mandatory Staffing Ratios
- Criminal Sanctions
- A “Duty of “Candor”
- How Many Other “Mid-Staffordshires”?
- How Can We Trust the Leaders?

The NHS in England can become the safest health care system in the world.

That will require unified will, optimism, investment, and change.

Everyone can and should help.
And, it will require a culture firmly rooted in continual improvement.

Rules, standards, regulations, and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning.
For Government and NHS England Leaders:

- State and restate the primacy of safety and quality as aims of the NHS: Assure prompt response to and investigation of early warning signals of serious problems, and, when needed, assure remedy.
- Support investment in the improvement capability of the NHS.
- Lead with a vision. Avoid the rhetoric of blame. Rely on pride, not fear.
- Reduce the complexity of the regulatory system, and insist on total cooperation among regulators. If they do not cooperate, restructure them.

For NHS Organization Leaders and Boards:

- Listen to and involve patients and carers in every organizational process and at every step in their care.
- Monitor the quality and safety of care constantly, including variation within the organization.
- Respond directly, openly, faithfully, and rapidly to safety alerts, early warning systems, and complaints from patients and staff. Welcome all of these.
- Embrace complete transparency.
- Train and support all staff all the time to improve the processes of care.
- Join multi-organizational collaboratives – networks – in which teams can learn from and teach each other.
- Use evidence-based tools to ensure adequate staffing levels.
For System Regulators:

- Simplify, clarify, and align your requests and demands from the care system, to reduce waste and allow them to focus on the most important aims.
- Cooperate fully and seamlessly with each other.

For Professional Regulators and Educators:

- Assure the capacity and involvement of professionals as participants, teammates, and leaders in the continual improvement of the systems of care in which they work.
- Embrace complete transparency.
<table>
<thead>
<tr>
<th>For NHS Staff and Clinicians:</th>
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<tbody>
<tr>
<td>• Participate actively in the improvement of systems of care.</td>
</tr>
<tr>
<td>• Acquire the skills to do so.</td>
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<tr>
<td>• Speak up when things go wrong.</td>
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<tr>
<td>• Involve patients as active partners and co-producers in their own care.</td>
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<table>
<thead>
<tr>
<th>For Patients and Carers:</th>
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<tbody>
<tr>
<td>• As far as you are able, become active partners in your healthcare and always expect to be treated as such by those providing your healthcare.</td>
</tr>
<tr>
<td>• Speak up about what you see – right and wrong. You have extraordinarily valuable information on the basis of which to make the NHS better.</td>
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