* Most recent year for which information is available # Average of several years + Extrapolated from the best-developed Regional system

(from *An Organisation With a Memory,* DOH, 2000)

In summary, every year it has been found that approximately:

- 400 people die or are seriously injured in adverse events involving medical devices;
- nearly 10,000 people are reported to have experienced serious adverse reactions to drugs;
- around 1,150 people who have been in recent contact with mental health services commit suicide;
- nearly 28,000 written complaints are made about aspects of clinical treatment in hospitals;
- the NHS pays out around £400 million a year settlement of clinical negligence claims, and has a potential liability of around £2.4 billion for existing and expected claims;
- hospital acquired infections – around 15% of which may be avoidable – are estimated to cost the NHS nearly £1 billion.

However, current NHS reporting and information systems provide us with a patchy and incomplete picture of the scale and nature of the problem of serious failures in health care.

Results of a recent UK pilot study in hospitalised patients found that adverse events:

- occur in around 10% of admissions – or at a rate in excess of 850,000 a year;
- cost the service an estimated £2 billion a year in additional hospital stays alone, without taking any account of human or wider economic costs.

(Vincent et al, BMJ 2001; 322: 517-519)

b. Is the number of medical accidents increasing?

The estimated totals (see above) are high, however, since medical accidents have not been systematically documented until this year, whether or not they are actually increasing or have always been high, or, in fact, an accumulation of errors from past years, is impossible to ascertain. In recognition of the need for more information in this area, a new government organisation - the National Patient Safety Agency (NPSA) - has been established which will not only allow for the dissemination of information on medical accidents and adverse events, but also allow for the accurate assessment of trends. All NHS Trusts and staff are now required to

report medical accidents and adverse events to the NPSA who then have the responsibility of assessing cause, action for the prevention of future similar incidents, and distribution of this information to all trusts and health care organisations.

Based on the recent publicity given to a number of incidents of medical accidents, error, negligence, unethical practice and criminal behaviour (Bristol Heart enquiry, Harold Shipman, Alder Hey etc.), there *appears* to have been an increase in medical accidents. When evaluating each of these incidents in turn, however, it is evident that each had been ongoing for many, many years before being brought to light. One could conclude, therefore, that this appearance of an increase, in reality is an artifact of heightened public, professional, management and government awareness of the fallibility of health care providers and health care organizations. This has led to many questioning, rather than simply accepting, the standard of care, traditional practices, and the treatment provided by the health service.

It is also possible that the vast expansion of medical knowledge and technology that has taken place over the past decade may also contribute to the error rate.

With regard to medical equipment, a variety of technology is now incorporated into any one piece of equipment. This can lead to greater consistency for the majority of patients, but in the event of malfunction, which may go unnoticed by those providing service, the consequences can be considerable. It is virtually impossible, despite much testing, to predict every situation that might occur and therefore, when new equipment is introduced, it is possible for errors/failure to occur a number of times, before the cause/means of prevention is understood. One such type of error is cited in *'Clinical Risk Management'*, where failure of the x-ray/radiotherapy equipment to recognize a certain combination of inputs resulted in the death of a patient being treated for cancer. Technology also has the ability to lull individuals into a false sense of security and unless error prevention measures are developed and religiously adhered to, errors can result.

Similarly, even though extensive testing is carried out on new drugs, it will not always be possible to predict adverse effects. Again central notification of adverse effects is vital to limit the harm done.

There will always be a learning curve whether in terms of individual learning, diffusion of information, and in the development and improvement of technology. The goal for all health care services and providers, as well as the government, should be to provide the means of speeding up this learning curve process. Possible methods for this include providing accessible databases on evidenced based medicine such as the Cochrane Library, central accumulation and dissemination of error knowledge and prevention as is hoped the NPSA will do, standardized protocols based on best practice/evidence, etc.

c. How much is the budget for those studies and research activities?

Within the UK, there are various bodies that fund studies and research activities. These range from the Department of Health and the Department of Trade and Industry who fund large amounts, to the research funded by Trusts or charities which are carried out on a much smaller, local scale and/or are disease specific.

Trusts: Most Trusts stated that they had no budget allocated for study and/or research into the causes and prevention of medical accidents/errors (60%). Some declined to answer this question (20%) and a further 20% had money allocated for this purpose, typically to be applied ad hoc for individuals that wanted to go to courses or conferences. One Trust funded a full time researcher (£30,000 budget) to carry out research into medication errors.

Medical Defence Union (MDU): They had no budget as such, however, their work indirectly includes the causes and prevention of medical accidents/errors. They compile information and data on medical accidents/errors and then provide training for and disseminate information to their members with regard to high-risk areas and frequently repeated adverse events.

Government: The Department of Trade and Industry funds the Medical Research Council, the main government agency responsible for research into the causes of and treatments for disease. The annual budget is £351.9 million (1999-2000).

The Department of Health invests approximately £500 million per year in total on research and development. Their goal is to fund research to support policy and the delivery of effective practice in the National Health Service (NHS). Their budget is channelled in a variety of ways. They fund the Policy Research Programme to support their work on policy development and evaluation in public health, health services and social care, to ensure that policy is based on reliable evidence of needs and of what works best to meet those needs.

They manage the National Health Service Research and Development funding. This supports research and development vital to improvements in medicine and health of relevance to the National Health Service. It is typically undertaken in hospitals, general practice and other health care settings. The Department of Health pays for the service support but not the treatment costs of the research. This research is often funded by other bodies, as well, such as research councils and charities.

In addition, it funds research into identifying NHS needs and research undertaken by non-Departmental public bodies. There are also various ad hoc research budgets held by Departmental policy branches.

d. Is the status of medical errors understood well in your country?

The understanding of medical errors has developed in the UK over the past 5-10 years and the government has introduced reforms aimed at improving the quality of care and more recently, the consistency and safety of care (see section B.1.). On a service level, audit has become well established and is understood by most Trusts and both clinical and non-clinical service providers. This is still one of the major routes by which medical errors, among other things, are communicated to 'front-line' individuals.

With the high levels of media publicity that medical errors have generated, the move from simple audit to laying blame on individuals became much more common place, both from a Trust perspective as well as from a public perspective. In 1998

the government introduced the concept of Clinical Governance, giving responsibility to management for the clinicians working within their Trust. There is some evidence, however, that Clinical Governance has not had much impact on improving the care provided, and it may have simply provided additional people to be held responsible should error occur (unpublished work by Sarah Atkinson).

Finally, there is a definite trend, promoted by the medical profession and others, that doctors do not work in isolation, and that junior doctors, especially, have very little say as to what they do and how they do it. This has led to an understanding that system errors, both direct and latent play a very large role in the number of adverse events that occur and that without addressing system errors, blaming individual practitioners will do little to correct the problems. This has led to the promotion of a 'no-blame' culture by the government and others. (There was some evidence from the Trusts that we interviewed that this was a key part of their own risk management strategies.) The purpose of a 'no-blame' culture is to promote openness in the airing of incidents and 'near-misses' so that corrections can be made to protect patients in the future. It is recognised that only a tiny minority of adverse events occur from malicious intent or negligence and the vast majority have much more complex causes, many of which could be prevented by changing the system. For example, the syringe ports for spinal medication and intravenous medication are the same and so there is potential for lethal accidents to occur, as, in fact, they did, over 11 times in the UK. A safer system is now being sought whereby the ports are different so faulty administration would not be possible. There is evidence that to promote this concept so that it effectively reaches patients, positive action from management is still needed. Management must provide channels of communication for front line staff to feed back to management, areas that require system change in order to protect patients from adverse events. With the establishment of the NPSA, formal routes of information gathering will be taking place and the concept of system error is likely to play a key role in the prevention of adverse events in the future.

2. Public concern for medical accidents/errors

a. To what extent are medical accidents/errors getting public concern in your country?

Medical accidents/errors is very, very topical in the UK. A quantitative analysis of the number of articles in The Times Newspaper (London) found that from January 2000 to July 2001, there were 33 articles that specifically referred to medical error. Three of these articles defended the actions of doctors and presented an alternative viewpoint to the recent adverse media; 20 of these articles portrayed the medical profession and the health service in a very negative light; and 5 were neutral. Five of the articles were found in the law section and were medico-legal articles. One particularly interesting article, which highlights the interest that the legal profession has in the health profession and in adverse events in particular, is Lord Woolf's inaugural speech printed in the January 17, 2001 edition of *The Times*. In his speech, he implies that the courts will both have and be using more powers to make decisions with regard to negligence and appropriate care by the medical profession.

The medical profession is also putting much effort and time into the discussion with numerous articles in the BMJ, and even a whole issue, dedicated to the discussion of risk management and adverse events (see bibliography). The articles in the BMJ were not simply defending the medical profession or refuting claims by the media, but appear to be a concerted effort by the medical profession to assess the extent of medical error and to discuss and research ways in which error can be reduced.

The government has shown much interest culminating in papers such as *Organisation With A Memory* and *Supporting Doctors, Protecting Patients.* Both doctors and managers are putting a great deal of effort into protecting patients. I think because people are more aware of it, it is rather like a snowball effect.

An MDU representative states that:

> 'it is too early to tell if any of the quality initiatives introduced have had any real impact on patient safety. The NHS is a bit of a beast and everything takes a long time. A claim is usually made at least 18 months after the event and it takes another 18 months to 2 years to settle. So what we are seeing now is from some years ago and it will be a while into the future before we are able to truly assess whether all this concern and hype has made a difference.'

b. Is the number of lawsuit against medical accident increasing?

Answers to this question were sought from a number of sources, including individual Trusts, the MDU, and the Department of Health. (Published documents are included in the Bibliography.) The consensus of opinion on this is that the numbers of lawsuits have been increasing dramatically over the past 5 years, but, although still increasing, have started to tail off as the effects of legal reforms are being felt. Lord Woolf states in his inaugural lecture in the new Provosts Lecture Series, held by University College, London, that there is an increase of more than 30% in the number of complaints made to the General Medical Council. He states that the number has risen from 3000 in 1999 to a predicted 4,300 in 2000, and that even 'the future of the GMC itself has been called into question'.

Of the trusts that responded to this question, one said no, claims had not increased; most said yes, the claims had increased, with one giving figures that were up by just over 1/3 from 1994. Some trusts made it clear that although the absolute numbers had increased, this was not due to an increase in incidents occurring, but rather due to a greater public and professional awareness of the problem. It was stated that they believed the real problems to be reduced, implying that many more patients could have claimed in the past, that had not, and that the increase in claims was not a reflection of error prevention failure. In other words, they believed they were getting better at error prevention, even though the claims were increasing. One trust stated that the number of open cases had fallen from 70 in 1996 to around 40 currently, but that this drop was due to a clearing of the backlog rather than a reduction in claims. The number of new claims per year varied from 16 to 25 with no clear trend emerging over the past 5 years.

The Medical Defence Union (MDU) states that there has been an increase in both claims and indemnity payments over the last 5 years, but state that this is a reflection of a number of variables and does not necessarily indicate an increase in medical accidents/incidents. Some variables cited include:

- a rise in litigation culture
- a change in law that allows lawyers to charge clients only if they are successful
- changes in the discount rate resulting in higher payouts, i.e., the discount rate used to be 3 % but is now 2 ½ % and therefore damages that need to be generated automatically must increase by ½ %

The MDU also states that even though the number of claims has increased dramatically over the past 5 years, this has started to level off and they believe the Wolfe reforms to be responsible for this. Lawyers must now provide a better work up of cases before litigation can commence and so the frivolous claims are eliminated and more valid claims are settled.

The Association of Litigation and Risk Managers (ALARM) imply that there is an increase in claims, but state that it is hard to be certain about the significance of this as it has become easier for claims and complaints to be made. In addition, the high cost being quoted for the cost of claims should also be interpreted with caution for a number of reasons. They state that since the state has taken responsibility for all of the indemnity attributable to the NHS, the reporting of cases centrally has meant that for the first time the aggregate liability for the NHS is being measured. They also believe that the financial systems used and the methodology for valuing cases is flawed. They state that the mechanisms of cash management used result in double counting, i.e., by Trust and Health Authority and contingency reserves must be held for all cases regardless of merit. In addition, they believe that the rapidly rising costs may be an artifact of starting CNST from scratch in 1995. At that time it was anticipated that costs would rise for about 7 years before settling into their long term pattern. This was on the basis that cases (especially big ones such as birth asphyxia) would take 2 years to emerge and then a further 6 to settle. Other reforms such as the introduction of the solicitors panel by the NHSLA has meant that the number of law firms employed by the NHS has dropped from 89 in 1996 to less than 20 currently. This has made the disposition and disposal of cases quicker with the result that settlements in any given year have increased as the backlog falls.

c. Is the industry interested in patient safety?

Yes, there is clear evidence for this as seen by the numerous articles in the BMJ (see bibliography) and as discussed in section E2.

3. Impact of IOM report

Is a report from the Institute of Medicine in the U.S., "To Err is Human", published in November 2000 known in your country? And if so, did it have influence?

A representative from the Government stated that extensive research was conducted into patient safety as part of the process of establishing the National Patient Safety Agency. 'To Err is Human: Building a Safer Health System' was read as part of that research and the report is referenced in both *'An Organization With A Memory'* and *'Building A Safer NHS for Patients'*.

A surprising number of trusts (60%) had not heard of the US Institute of Medicine report 'To Err is Human'. Some declined to answer (20%) and a further 20% had heard of it and read it. They stated that they were not using it specifically to bring about change, but rather, they were using the UK report *'An Organisation With A Memory'* from the Department of Health, and were implementing the recommendations in that document.

The opinion of the MDU representative was that the report 'To Err is Human' was based on outdated, possibly questionable studies, including the Harvard study done in 1980, and that there are more recent studies, including a very recent one by Charles Vincent and his group at University College London, that should be incorporated in any analysis of medical error and risk management. He believed that there has been a general progression in the direction of risk management and patient safety for a number of years in the UK, culminating in the new government National Patient Safety Agency. 'To Err is Human' may well have been utilized, but was not necessarily the primary instigator.

B. Action by Stakeholders

1. Government action toward medical accidents/errors and patient safety

Is there a governmental policy especially for medical accidents?

If there is, please describe the policy including the historical development of the policy.

In recent years there has been increasing concern over the quality of care provided within the NHS. Although serious problems in the quality of health care are uncommon in proportion to the high volume of very good care provided, when they do occur they can have devastating consequences for individuals and their families. Stories about very poor care regularly hit the headlines.

There was a concerted drive during the 1990s to develop risk assessment and risk management systems within the NHS. This work was initially focused on reducing litigation risks and subsequently on the reduction of financial risks. More recently there have been moves to encourage a broader focus on adverse events, rather than simply on litigation.

In December 1997, the Government published a White Paper *The New NHS: Modern, Dependable*, which set out a ten year modernisation strategy for the NHS. One of the main aims of the proposals set out in the White Paper is to bring about a major improvement in the quality of clinical care delivered to patients in the NHS.

Following on from *The new NHS* White Paper, the consultation document *A First Class Service: Quality in the new NHS* set out an approach to NHS quality improvement, comprising:

- Clear national quality standards: set by a new National Institute for Clinical Excellence (NICE) and National Service Frameworks (NSFs)
- Clinical governance, i.e. a framework through which NHS organisations have been given a formal responsibility for continuously improving the quality of their services
- Strong monitoring mechanisms: a new statutory Commission for Health Improvement, an NHS Performance Assessment Framework and a national survey of NHS patient and user experience.

The introduction of local systems of clinical governance is particularly relevant to the development of NHS organisations' predisposition to learn from failures. The three main components of local clinical governance arrangements are:

- clear arrangements for accountability and reporting, with ultimate Board level responsibility for arrangements to assure and improve quality;
- a coherent programme of quality improvement activity; and
- **risk management processes, including mechanisms for detecting and dealing with poor professional performance.**

In February 1999 an expert committee was established 'to examine the extent to which the National Health Service and its constituent organisations have the capability to learn from untoward incidents and service failures so that similar occurrences are avoided in the future. To draw conclusions and make recommendations.'

From this group *An Organisation With A Memory* was published in May 2000. A number of systems already present within the NHS for learning from adverse health care events were noted:

- Incident reporting systems (e.g. local risk reporting systems in NHS Trusts and other bodies, untoward incident schemes run in NHS regions, reporting of adverse reaction to medicines and medical devices).
- Systems designed to investigate or respond to instances of poor quality care (e.g. litigation for alleged medical negligence, the NHS complaints procedure, cases referred to the Health Services Commissioner, Coroner's cases).
- On-going studies on a national basis which aim to identify poor outcomes and avoidable factors in certain specific fields of health care (in particular the confidential enquiries into peri-operative death, maternal mortality, stillbirth and infant deaths, homicides and suicides by mentally ill people).

- Periodic external studies and reviews (e.g. the national Value for Money studies conducted by the Audit Commission
- Spontaneous reporting outside normal channels by individual members of staff
- Health service and public health statistics

Incident reporting systems

The Clinical Negligence Scheme for Trusts (CNST) was established in 1995 and almost all NHS Trusts are members. It requires, as a condition of discounted premium, the development of clinical incident reporting systems for compliance with its risk management standards.

Historically incident reporting has been rather haphazard. Today, although the great majority of NHS Trusts have some form of incident reporting system in place, there is substantial variation in the coverage and sophistication of these systems:

- a fifth do not have reporting systems covering the whole organisation
- less than half provide specific training on risk management or incident reporting
- less than a third provide guidance to staff on what to report
- a third do not require clinicians to report unexpected operational complications or unexpected events
- rates of reporting vary widely

(Dineen, M. and Walsh, K. 'Incident reporting in the NHS'. *Health Care Risk Report* March 1999)

Reporting of adverse reactions to drugs

The Medicines Control Agency (MCA) administers a single system – the 'Yellow Card' scheme – for reporting adverse drug reactions (ADRs) in England, Scotland and Wales. Reporters of suspected ADRs are doctors, dentists, coroners and hospital pharmacists. Reports are received directly from them and from pharmaceutical companies relating to the drugs for which they hold Marketing Authorisations. The scheme is voluntary for health professional, whereas Marketing Authorisations holders are required to report serious ADRs to the MCA within 15 days of notification.

Reporting of adverse incidents involving medical devices

Adverse incidents involving medical devices are reported to the Medical Devices Agency (MDA). Information is logged on a central database and incidents are assigned a level of investigation depending on the risks involved. Outcomes of investigations are subject to a formal review. Patterns or clusters of incidents can

then be identified, subjected to further risk assessment procedures and investigated where necessary. When an incident reveals a device-related safety problem the MDA produces a Hazard or Safety Notice for distribution.

Complaints

A single NHS complaints system was introduced in 1996 for hospitals, community health services and family health services. Complaints to NHS organisations are first addressed by local services, with the aim of resolving the issue (often informally) as quickly as possible. Unresolved complaints are subject to further review which may result in consideration by an Independent Review Panel. The panel will investigate the complaint and produce a written report, which may make comments and recommendations about the circumstances of the complaint and the need for service improvements.

If complainants are not satisfied with the response from the NHS, they may refer the matter to the Health Service Commissioner. The Health Care Commissioner publishes an annual overview and more detailed six-monthly reports on complaint investigations, which may contain recommendations for changes in practice.

Litigation

There are currently no systematic analyses of the litigation data on hospital cases held by the NHS Litigation Authority. In primary care the medical defence organisations such as the Medical Defence Union and Medical Protection Society (which provide cover against negligence for individual practitioners in primary care and in private practice) maintain their own databases of claims and publish illustrative case-histories as an aid to learning among their members.

Confidential inquiries

Four National Confidential Inquiries operate in the NHS:

- the Confidential Enquiry into Maternal Deaths (deaths of women during pregnancy or within one year of childbirth)
- the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) (stillbirths and infant deaths)
- the Confidential Enquiry into Peri-Operative Deaths (NCEPOD) (hospital deaths within 30 days of surgery)
- the Confidential Inquiry into Suicides and Homicides by People with Mental Illness (suicides within one year of contact with mental health services and homicides involving people who have been in contact with mental health services at any time)

Key features of the confidential enquiries:

- Aim to identify all deaths in a specific category

- Confidential reporting (i.e. patient, staff and hospital not identified in reports)
- Multidisciplinary review of deaths to discover avoidable factors
- Results published in periodic reports
- Key themes identified and recommendations made for improvement
- No mandatory compliance with recommendations
- No systematic monitoring of uptake of recommendations

Other external reviews

The Audit Commission conducts 'Value for Money' studies in the NHS. These reviews are concerned with service quality, but they tend to focus on the generality – for example on 'sub-optimal' care – rather than adverse incidents *per se*;

The professional regulatory bodies, such as the General Medical Council, deal with issues of individual professional performance.

Medical Royal College visits from time to time highlight concerns about the quality and safety of care provided in a particular unit;

The Commission for Health Improvement will have a key role both in the detection of poor quality systems, through its reviews of local clinical governance arrangements, and in the scrutiny of specific adverse incidents through its 'troubleshooting' work.

Inquiries

Although they are not a mechanism for systematic information gathering, inquiries of one kind or another are an area in which the NHS invests considerable resources in an effort to learn from failures.

Recent examples of external inquiries include:

- Bristol Royal Infirmary Inquiry into the deaths of a number of children following heart surgery
- The inquiry into the retention of children's organs after post-mortem at Alder Hey hospital
- The enquiry into the case of Dr Harold Shipman, the general practitioner convicted of murdering 15 of his patients.

Internal inquiries (with or without external advisers) are used in the majority of serious incidents within the NHS.

However, it was felt that these sources of information give a very incomplete picture

of the size and nature of the problem of service failure and adverse events in the NHS. It was noted:

- There were no universally accepted criteria relating to error, adverse events and patient safety
- There is no single focal point for NHS information on adverse events, and at present it is spread across nearly 1,000 different organisations

The NHS has no reliable way of identifying serious lapses of standards of care, analysing them systematically, learning from them and introducing change which sticks so as to prevent similar events from recurring.

In April 2001, *Building a Safer NHS for Patients,* was published. This set out the government's plans for promoting patient safety following the publication of the report *An Organisation with a Memory.* The fundamental approach being to establish a system which ensures that lessons from adverse events in one locality are learnt across the NHS as a whole.

With a new emphasis on system error as opposed to individual error, the report describes a new national reporting system for learning that includes:

- establishing agreed definitions of adverse events and near misses for the purposes of logging and reporting them within the NHS (moving gradually to agreed international standards); detailed guidance for organisations, staff and patients will be issued and pilot sites activated;
- formalising a minimum data set for adverse events and near misses
- producing a standardised format for reporting
- building expertise within the NHS in root cause analysis
- ensuring that information from all other major existing adverse event reporting systems (e.g. medical devices, reactions to medicines, complaints to the Health Service Commissioner) are fed into the new system
- promoting a culture of reporting and patient safety within NHS organisations, building on the transformation already under way as part of the clinical governance initiative

Central to the implementation of the new reporting system is the creation of the *National Patient Safety Agency*, which will be established as an independent agency within the NHS. The primary purpose of the body will be to implement, operate and oversee all aspects of this new national system in all sectors of the NHS and therefore improve patient safety by reducing the risk of harm through error. It will:

- Collect and analyse information on adverse events from local NHS organisations, NHS staff, and patients and carers;

- Assimilate other safety-related information from a variety of existing reporting systems and other sources in this country and abroad

- Learn lessons and ensure that they are fed back into practice, service organisation and delivery;

- Where risks are identified, produce solutions to prevent harm, specify national goals and establish mechanisms to track progress.

Although it has been recognised that analysis of failures needs to look at root causes, not just in terms of human error, there are rare instances where the central problem is poor performance by an individual. In November 1999 a consultation paper *Supporting Doctors, Protecting Patients* was published. This contained a wide range of measures to ensure that poor clinical performance was prevented, recognised early and resolved more effectively so that patients received a greater deal of protection from poor practitioners than they had in the past. In future if a problem with a consultant, general practitioner or other grade of doctor cannot be evaluated or resolved locally, or is particularly serious, a referral will be made to the new National Clinical Assessment Authority (NCAA). Expert teams from the NCAA will aim to identify the underlying causes of clinical failings and devise an appropriate solution to be implemented by the NHS Trust or health authority that employs the doctor. Educational and training solutions will be used where possible to resolve problems with a doctor's practice. Some serious problems will also be referred to the General Medical Council. There will be occasions when the investigation of an individual practitioner's performance will reveal wider service problems in the organisation concerned - if the NCAA finds a problematic service it will notify the Commission for Health Improvement which may follow through with its own investigation.

2. Action by other stakeholders

Is there a policy by provider association, medical doctor, nurse, or hospital?

All the trusts that responded had policy for dealing with medical accidents/incidents and/or for protecting patient safety. Monitoring and enforcing compliance seemed to vary, however, with some stating that staff were 'required to follow Trust policies and procedures'; others saying that 'the policy was something staff are required to read as part of induction'; others mentioned 'Accident Reporting Procedure document' and 'the Trust's protocol for reporting and investigating "Unusual Occurrences", with the onus on the individual to report the incident to the Ward Manager. One Trust stated that individual clinicians received a 'regular review in a no blame culture' as part of their appraisal process, and that the same was done for service reviews of department/service directorates.

3. Action by patients, patient groups or representatives

Do patients, patient groups or representatives have a strong influence on governmental or health care professionals' activities for medical error prevention?

Yes. The recent scandals have attracted much publicity and patients and patients' families have achieved in getting numerous enquiries and much public support. Good examples of this are the Bristol enquiry, the Alder Hey organ scandal, the Harold Shipman scandal. Patients and patient groups have been very influential in the establishment of the NPSA.

4. Third Party Accreditation

With regard to quality, third party organization accredits and evaluates hospital performance in many countries. And in some cases, the organization rates/ benchmarks hospitals or health care institutions. Is there any such organization in your country?

A number of third party organizations evaluate Trusts, these include:

1) The Department of Health publishes NHS Performance Indicators annually. The most recent set (July 2000) contains 49 indicators at health authority level; 7 of these (the clinical indicators) were also published at the NHS Trust level. The next publication is due in the autumn and, for the first time, will include a full set of NHS trust indicators, clinical and non-clinical. Performance indicators are publicly available and placed on the Department's website.

The first set of NHS performance traffic lights will be issued to health authorities and NHS trusts in the summer. This will assess their performance during 2000-01 as green, yellow or red against a number of key indicators which were the subject of consultation with the NHS in January/February.

Poor performance does not result in the closure of the hospital. NHS bodies with a red traffic light will have to agree a recovery plan with the Department's regional office. They will then receive targeted support and assistance from the Modernisation Agency to address their areas of weakness and turn the poor performance round. They will be subject to more frequent inspections from the Commission for Health Improvement to ensure that satisfactory standards are being met.

In rare cases where poor performance is repeatedly not addressed, or is extremely serious in nature, the Government will be able to place the NHS body under an intervention order (as per the Health and Social Care Act 2001). This would allow for the replacement of Board members or for failing services to be provided by a third party.

2) The Commission for Health Improvement (CHI), established to help monitor, assure and improve the quality of NHS patient care by undertaking regular reviews of local organisations' clinical governance arrangements, reporting on them and helping the organization draw up action plans to address any necessary weaknesses. CHI also investigates serious service failures in the NHS. More information can be found at their website www.chi.nhs.uk.

3) The Clinical Negligence Scheme for Trusts. This is essentially a risk pooling

arrangement administered by the NHS Litigation Authority (basically a self-insurance scheme based on contributions from members). The scheme is voluntary but the vast majority of NHS organizations are members. Members pay reduced contributions if they comply with certain risk management standards (3 levels of compliance);

4) Controls Assurance; and

5) District and Internal audit.

C. Information System

1. Reporting system/ information system

Is there any nation wide reporting system for medical accidents, e.g. a reporting system in aviation industry or adverse event reporting system in Australia?

If there is,
a. Is it obligatory or voluntary?
b. b. Who collect data?
c. Who analyze the data?
d. Is there any legal protection for reported cases against lawsuit?

The National Patient Safety Agency will be established as a Special Health Authority in July 2001 and will progressively recruit its initial complement of staff over the remainder of this year. A Chair and up to 15 members will be appointed who in turn will appoint a Chief Executive. The NPSA will become operational at the end of the year.

The National Patient Safety Agency will run a national, independent mandatory reporting system for logging all failures, mistakes, errors and near-misses across the health service. For the first time it will introduce a streamlined approach to dealing with errors and mistakes and ensure that lessons are learnt and spread throughout the health service.

Information received by the NPSA will be confidential to the organisation. Detailed arrangements are currently being developed and will be taken forward by the new body once it has been established.

2. Complains from patients or their family

Is complaint data collected and analyzed? If so, how?

All Trusts had a complaints procedure, with some an individual, the 'Patient's Advisor', collects and analyses all complaints, with others it is a department that

handles all complaints; some used specific computer software to produce reports for further Clinical Governance Board Review, per NHS procedure, and Service Department action audit. Some specified that they produced quarterly reports, prepared and reviewed on a regular basis by a sub-group of the Trust Board with the maintenance of databases of complaints and changes that have been instituted as a result of investigations into the complaints. A number of trusts stated that they adhered to the national policy, i.e., acknowledging complaints in 2 working days and responding within 20 working days and if the complainant is unsatisfied, they can have their complaint further reviewed by a Trust convenor and the ombudsman.

The Department of Health states that there is an NHS complaints system in place which was introduced on 1 April 1996. It has common features for handling complaints to hospitals (including cases involving clinical judgement), community health services and family health services, covered by three main stages: local resolution, independent review, and health service ombudsman.

D. Legislation

a. With regard to a legal system, if an accident is not caused by someone's negligence or system error, we heard that there is a remedy for indemnification in some countries. Do you have the same system in your country as well?

The MDU representative stated as follows:

> 'There is not automatic indeminfication, no, but we provide indemnity for our members and the trust does the same. There is the public interest disclosure act 'whistleblower's charter' that protects people from consequences of whistle blowing, but these are more subtle consequences as the individual may or may not be involved. There is an ethical duty to report adverse events and events that risk patient safety as stated by the GMC. This whole area is currently being looked at. We have a blame culture and the government is trying to change it. This is the purpose of adverse event reporting, where the emphasis is that adverse events are systems errors not individuals who are to blame.'

b. Is there any compensation scheme for medical accidents/errors similar to a compensation scheme for side effect of drug?

Of the trusts that responded, 60% stated that they belonged to CNST (see above), 40% stated that they had no compensation scheme. Some trusts give ex-gratia payments to patients and their relatives when an adverse event has occurred, i.e., paying for the relatives traveling expenses and/or hotel costs if the event has resulted in a longer hospital stay.

The Department of Health states that discussions are currently underway around the possibility of no-fault compensation schemes but that no decisions have been

taken on this subject as yet.

The MDU described the current system as one where fault and causation must still be proved before damages can be awarded. The personal opinion of the representative was that it can sometimes be difficult to prove fault, particularly in some cases such as birth injuries, and that some people who deserve compensation don't receive it. The MDU provides indemnification to their members.

> 'As far as I am aware, there is no government scheme for this. There are compensation schemes for healthy volunteers involved in drug trials, where arrangements are made to compensate for adverse events and I think there have been compensations given for vaccine damage in the past, but this was based on one off decisions.'

E. Concept of Quality and Safety

1. Health care quality and medical error/accident

In the IOM report, "To Err is Human", there is a discussion that we have to take a measure against both health care quality and medical errors because they have the same root cause. Is this concept prevailing in your country?

Yes. UK government policy towards health care policy and medical errors is strongly linked. Central to *A First Class Service: Quality in the new NHS* (a document focussed on improving health care quality) is the development of clinical governance. One of the main components of clinical governance is risk management. (See B1 for more details).

2. Concept of patient safety

In the same report from IOM, the importance of a concept of patient safety is proposed against risk management to hospitals for litigation. Does a concept of patient safety prevail in your country?

There is a growing awareness that many adverse events in hospitals are preventable and often with an increase in cost effectiveness. It is now accepted that adverse events leading to lawsuits are only the tip of the iceberg, and that most adverse events while not resulting in litigation do increase the health care providers' costs. For example, hospital acquired infections often lead to longer hospital stays: action to minimise cross infection such as use of disposable gowns, isolation, prophylaxis, education on hand washing is reduces the incidence and is cost effective.

However, much of the drive for patient safety is coming from outside the industry such as from the government and patient action groups as a response to the perceived failure of the health industry to have sufficient concern for patient safety.

F. Risk Management at Hospital or Clinic level

1. Risk Manager

a. Is there an organization to train a risk manager in your country?

There are a number of institutions that provide training at a variety of levels. These include University College London (MSc in Clinical Risk Management), Southampton University (Dip/MSc in Risk Management, Kings Fund (part of Senior Management Training course)and Capsticks (PG Diploma in Risk Management). Additionally, all trusts in the NHS are required to have an in-house risk manager whose function is to provide training to staff and develop strategies for decreasing clinical risk within their trust.

b. Is there any post taking charge of medical error prevention such as risk manager in a hospital?

All Trusts are required to have a Risk Manager on their staff. (See below for how this fits into the general management structure.)

2. CQI (Continuous Quality Improvement) / Patient Safety

Do you have integrated managing unit in hospital for quality and medical error?

Of the trusts that responded, there was a variety of levels of integration between quality management and error management. The most common method of integration was where the Clinical Risk Manager was directly responsible to a Clinical Governance Coordinator or Clinical Governance Board, or to someone on the Board such as the Clinical Risk Director (60% of trusts). There were two other variations. The first was where Quality and Risk were separate departments but within the same directorate (20%) and the second was where the responsibility was held by one and the same person, i.e., the Clinical Risk Manager was also responsible for Quality and managed all complaints, litigation, research, governance and risk (20%).

3. Fail Safe and Fail Fault System

Is there any system of package for high risk areas in a hospital such as anesthesia, surgery, ICU, delivery, and emergency room?

There were a number of systems specific measures used for managing risk and safety in high risk departments, the majority of trusts stated that they used protocols for care extensively in high risk departments. Additional system specific measures which often applied to all areas, in addition to high risk, included protocols for consent as well as care, incident reporting systems, specialty specific triggers for incident reporting, adherence to risk management standards, regular/weekly review of all incidents or clinical near misses, the use of and review

of patient journeys in theatre, and regular audit. One Trust stated that there were individual approaches to managing risk and safety in high risk departments but that there was not a generally recognized formal system specific measures Trust wide nor NHS wide.

The Department of Health states that this will be an area that the NPSA will get involved in. High frequency/risk procedures will be identified and ways of preventing error will be developed by the NPSA on a continuous basis. An *Organisation with a Memory* identified 4 high-risk areas and set specific targets for action.

4. Specific Measure for High Frequency Risk Procedure

Specific measure has been developed to prevent medical errors such as medication error, transfusion error and falls.

Again, all had regular/weekly review of all incidents with some form of more detailed monitoring and/or more in-depth studies of serious issues such as falls, medication errors and transfusion errors. One trust stated that they used the 'Australian Risk Management System'.

Two trusts were more specific about these processes. One stating that

> ***'all incidents are analysed locally, and incidents which have caused concern are analysed in more depth. The analysis takes the form of a review of contributory factors, both latent and active conditions which contributed to the incident—any areas for change or recommendations made are expected to be implemented and this is subsequently reviewed by the risk management team and the clinical governance groups.'***

The second stating that

> ***'Falls are monitored by a working party; the Drug Incident Group meets monthly to review all drug incidents and analyse trends and make recommendations to prevent recurrence; we employ a Blood Transfusion Nurse Co-ordinator; and most specialties have their own regular governance meetings where incidents are reviewed.'***

5. Risk Analysis Method

What methods are generally employed to analyze risks associated with medical errors at health care institutions?

There were a number of different responses to this question. Some trusts stated that all incidents were catagorised and recorded on a database and then quarterly figures analysed by directorates; others that they had a complaints review procedure as part of their management output by their service directorate; others mentioned the use of protocols based on the Reason Model of incident investigation.

One stated that they had a formal risk assessment process used throughout the Trust based on a consequence and likelihood calculation to formulate a risk rating. Control measures are then implemented in order to eliminate/minimise risk. They then go on to state that further work is still needed to formulate a comprehensive list of risks for assessment.

One trust did not utilise any methods for analysing risk associated with medical error.

The Association of Litigation and Risk Managers recommend that all care pathways should contain a detailed risk assessment when they are constructed. They state that the most helpful way that they have found in determining risks to patients is to use the patient's journey through a health care procedure or service as a skeleton and then risk assessments can be attached to this 'journey' systematically.

Organisations other than Trusts also analyse data and provide feedback. The Medical Defence Union, for example, takes the data they have on claims and complaints and then they develop strategies out of that and give advice to their members concerning error minimisation and prevention. They try and target specific areas where they see high frequency adverse events. In primary care, this tends to involve delay in diagnosis and referral, and medication errors which together make up approximately 70% of settled claims. In the hospital high frequency adverse events tend to be performance based and varies with speciality and procedure. For example, areas that are more risky tend to be back surgery/injury in orthopaedics, post-operative infections, perforated viscus, creation of a fistula, or other incidents that reflect careless or poor performance.

The Clinical Negligence Scheme for Trusts (CNST) provides criteria for their member trusts to adhere to. These criteria help to reduce risk. Various levels are attainable, with each higher level reflecting a greater level of compliance and presumably, safety.

The Department of Health require that Trusts carry out local root cause analysis of any adverse events. However, the NPSA will be looking into the broader picture and identify high risk procedures and trends. Guidance will then be issued to Trusts as required.

6. Education and Training for Employee

a. Is there any training course for employees in a hospital?

All trusts stated that education on patient safety/quality awareness was included as part of the induction process for new employees with most stating that they had annual clinical and non-clinical up-dates. The extent of this training appeared to be variable, however, with some trusts stating that it was simply 'discussed' or 'on the agenda' of a one day induction for medical staff. Others ran a series of mandatory refresher courses and/or speciality specific multi-disciplinary training on risk, complaints, litigation and clinical governance.

b. Is there any hospital or clinic which develops educational tools and/or