Lindsay, Sharon

From:

Simpson, Paul

Sent:

18 October 2004 23:14

To:

Gowdy, Clive

Cc:

Hamilton, Andrew; Maguire, Philip

Subject:

FW: Investigating Deaths in Hospital in Northern Ireland

Clive,

Ref our discussion today about the Lucie Crawford case, you will want to see the attached report. Its conclusions, at pp34-36, are particularly relevant, and may come up in the UTV programme. Are we in a position, if asked, to say how we intend to respond to the report, by way of guidance?

----Original Message-----

From:

McMahon, Denis 15 October 2004 1:41

Sent: To:

Simpson, Paul; Hamilton, Andrew; Campbell, Dr Henrietta; Sullivan, Dean

Subject:

FW: Investigating Deaths in Hospital in Northern Ireland

Colleagues

ught you might have a particular interest in this.

Denis

----Original Message-----

From:

Floyd, Lisa

Sent:

13 October 2004 09:48

To:

Alison Annett; Alison Farr; Anne McCormill; Anne McGlade; Bride Harkin; Donna Allen; Elaine Williamson; Evan Bates; Heather Ellis; Hugh Mills; Jillian Bradley; Joan Peden; Judith Shaw; Linda Gordon; Lynda Gordon; Lynn Lappin; Manus Doherty; Michael

Gormley; Michelle Lemon; Nuala Sheerin; Seamus Trainor; Suzane McCartney; Thomas Dempster

Cc:

Weir, Roberta; Love, Stewart; Anne Mcglade (amcglade amcglade); Basten Anne; Bridget O'Rawe (Bridget O'Rawe);

Camplisson, Seamus; Claire Armstrong; Cullen Caroline; Ed McClean (Ed McClean); Frances Rolston

(frolstonbruce Gordon); McGonigle Jenny (M. Gormley's sec); McKelvey, Siobhan; McMahon, Denis; McWhirter, Liz

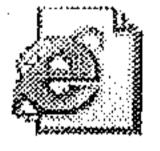
Subject:

Investigating Deaths in Hospital in Northern Ireland

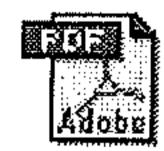
Dear all

"Investigating Deaths in Hospital in Northern Ireland - does the system comply with the ECHR?" published by NIHCR:

Copy of press release and of Dr Tony McGleenan's Discussion Paper attached for information.



Northern Ireland Human Rights ...



Hospital_Deaths_Se pt04.pdf

Stewart

INVESTIGATING DEATHS IN HOSPITAL IN NORTHERN IRELAND

DOES THE SYSTEM COMPLY WITH THE EUROPEAN CONVENTION ON HUMAN RIGHTS?

By TONY McGLEENAN

September 2004 ISBN 1 903681 47 2

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NORTHERN
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HUMAN
RIGHTS
COMMISSION

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FOREWORD

The Northern Ireland Human Rights Commission is pleased to be able to put into the public domain this report prepared for the Commission by Professor Tony McGleenan who is also a practising barrister. The report forms part of a larger body of work which the Commission is undertaking in the area of death investigations. We are conscious that deaths in hospital are but one category of deaths which need, at times, to be investigated. The mechanisms needed to satisfy Article 2 of the European Convention on Human Rights, now part of the law of Northern Ireland by virtue of the Human Rights Act 1998, may differ from those needed in relation to other categories of deaths.

We are keen to publicise this report at this time in order to stimulate debate around this important topic. In the wake of the terrible activities of Dr Harold Shipman and the recent reviews of the law concerning inquests in England, Wales and Northern Ireland, we feel the time is right to consider what, if any, measures need to be taken to ensure that deaths in hospital are properly reviewed. The Commission has also received a number of complaints from individuals concerning alleged medical negligence in hospitals and this report is one method by which the Commission is attempting to address those individuals' concerns.

The jurisprudence of the European Court of Human Rights is not yet fully developed in this context and the Commission would welcome comments on this report in order to assist it when deciding how to take further the recommendations it contains. In particular we would welcome views on the practicability of the recommendation that the circumstances of every death in hospital should be subjected to independent review.

Prof Brice Dickson Chief Commissioner

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THE AUTHOR

In 1994 *Dr Tony McGleenan* was appointed to the post of Lecturer in Jurisprudence at the Queen's University of Belfast and became Senior Lecturer in Law in 2000. He was appointed Professor of Law at the University of Ulster in 2002. He has published widely in legal and medical journals. Dr McGleenan is currently a member of the Northern Ireland Mental Health Review and the Irish Council of Bioethics.

After studying at the King's Inns in Dublin, Dr McGleenan was called to both the Bar of the Republic of Ireland and the Bar of Northern Ireland. He now combines a part-time academic appointment at the University of Ulster with practice at the Bar in the fields of public law, human rights and employment law. Dr McGleenan was selected this year for the Crown Civil Panel, a list of barristers who may represent public authorities in actions taken against the government.

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1. INTRODUCTION

- 1.1. Sudden and unexpected death arising from surgical or medical intervention can leave the family of the deceased with many unanswered questions. In particular, there may be a demand for information about the circumstances surrounding the death in order to determine how and why it occurred. Similarly, hospitals and healthcare trusts have an interest in understanding the systemic or individual causes of such a fatality and, where appropriate, in implementing measures to prevent a recurrence. Developments in human rights law coincide with these interests of relatives and healthcare professionals in that the law may now impose procedural obligations on public authorities under Article 2 of the European Convention on Human Rights to ensure that deaths in hospital are adequately investigated.
- 1.2. In 2003 a total of 14,462 people died in Northern Ireland. Of these, 7,464 died in hospitals, 3,042 died in nursing homes and 58 died in psychiatric hospitals. In the financial year 2001-02, of the 7,372 deaths occurring in hospitals in Northern Ireland, 436 deaths occurred within 30 days of a surgical procedure. The Northern Ireland Court Service in its consultation paper for the redesign of the Coroners Service stated that a total of 3,563 deaths were reported to the Coroner in Northern Ireland in 2002 and a total of 230 inquests were held. This data shows that, of the deaths which occur annually in Northern Ireland in healthcare settings, only a small proportion result in a full coronial inquest. In considering the question of overall compliance with Article 2 of the Convention it would seem reasonable to enquire of the 7,500 or so deaths which occur in hospitals in Northern Ireland each year how many result in:
 - (i) a hospital post mortem
 - (ii) a coroner's post mortem
 - (iii) a coroner's inquest.

¹ For an argument that all deaths in surgery should be subjected to forensic and statistical analysis see de Leval, M. 'Facing up to surgical deaths'. *British Medical Journal*, February 2004, 328: 361-362.

² Source: Northern Ireland Statistics and Research Agency. For the figures between 1994 and 2003 see Appendix 1, below.

³ National Confidential Enquiry into Perioperative Deaths, London, 2003 (available at www.ncepod.org.uk). The report also contains data for 2000-2001. In that period there were 399 such deaths recorded (see Appendix 2, below).

⁴ Northern Ireland Court Service. *The Coroners Service for Northern Ireland: Proposals for Administrative Redesign*, 2004 (available at www.courtsni.gov.uk).

1.3. This study examines the obligations which are imposed on public authorities to investigate healthcare fatalities as a consequence of the implementation of the Human Rights Act 1998. It considers whether public authorities may be required to conduct a form of investigation into deaths occurring after 2 October 2000 which is compliant with Article 2 of the European Convention on Human Rights. It also considers the existing mechanisms which are implemented following a healthcare fatality and evaluates whether such mechanisms, considered singly or as a whole, comply with the requirements of the Convention. Finally, this study identifies deficiencies in the current procedures for investigating healthcare fatalities and makes a number of remedial recommendations.

The ruling of the House of Lords in *In re McKerr* [2004] UKHL 12 has settled the question of whether there is any similar obligation relating to deaths which occurred before the implementation of the Human Rights Act on 2 October 2000. In this regard the House of Lords determined that the Act did not impose any retrospective obligations upon public authorities to investigate deaths which occurred before 2 October 2000.

2. ARTICLE 2 OBLIGATIONS: THE LEGAL BACKGROUND

2.1. Article 2 of the European Convention on Human Rights provides that:

"Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction for a crime for which this penalty is provided by law."

This provision imposes on member states a substantive obligation not to take life without justification and also to establish a framework of laws, precautions, procedures and means of enforcement which will protect life. It may not be immediately clear how Article 2 could impose any particular obligations upon healthcare providers in the event of a death in hospital. The Article 2 obligation may be breached, however, where the state does not have in place an adequate means of ensuring that life is not lost. The question which therefore arises is whether there is currently in place an effective system of ensuring that life is protected in hospital settings.

2.2. The jurisprudence of the European Court of Human Rights in Strasbourg has also developed an adjectival or procedural obligation which is appended to the substantive Article 2 right. This was described by Lord Bingham in *Middleton* as:

"a procedural obligation to initiate an effective public investigation by an independent official body into any death occurring in circumstances in which at appears that one or other of the foregoing substantive obligations has been, or may have been, violated and it appears that agents of the state are, or may be, in some way implicated."

The structure of the Human Rights Act 1998 imposes these particular obligations upon public authorities.⁸ Do healthcare providers constitute public authorities? There

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⁶ R (Middleton) v West Somerset Coroner [2004] 2 WLR 800 at 803.

Ibid.

⁸ Section 6(1) of the Human Rights Act 1998 provides that: "It is unlawful for a public authority to act in a way which is incompatible with a Convention right". A public authority is stated in section 6(3) to include, for the purposes of the Act, "any person certain of whose functions are functions of a public nature".

would seem to be little scope for disputing that they meet the section 6(3) definition. Notably, in the recent case of Glass v United Kingdom⁹ the European Court of Human Rights (ECtHR) observed that the United Kingdom government did not dispute that the hospital trust involved was a public authority.

The nature of the Article 2 procedural obligation was outlined by the ECtHR in 2.3. Jordan v United Kingdom (2001) at paragraph 105:

> "to secure the effective implementation of the domestic laws which protect the right to life and, in those cases involving State agents or bodies, to ensure their accountability for deaths occurring under their responsibility. What form of investigation will achieve those purposes may vary in different circumstances. However, whatever mode is employed, the authorities must act of their own motion, once the matter has come to their attention. They cannot leave it to the initiative of the next of kin either to lodge a formal complaint or to take responsibility for the conduct of any investigative procedures."

The essence of a *Jordan* compliant investigation has been determined as prompt, effective, independent inquiry with a sufficient element of public scrutiny and adequate involvement of the next of kin. The question which arises is whether Article 2 rights are engaged where death occurs in hospital. If they are, are the adjectival obligations of Article 2 adequately discharged by the state?

- In the recent decision of the House of Lords in Amin v Home Secretary Lord 2.4. Bingham examined the Strasbourg jurisprudence relating to Article 2 and outlined a series of propositions. These were that:
 - There should be some form of effective official investigation when individuals (i) have been killed as a result of the use of force by, amongst others, agents of the state.

Glass v United Kingdom (61827/00; 9 March 2004).

Amin v Home Secretary [2003] 3 WLR 1169.

- (ii) Where state agents have used lethal force the facts relating to the killing are likely to be largely within the knowledge of the state. Therefore it is essential that such a fatality is subject to some form of open and objective oversight.
- (iii) Where the facts are largely or wholly within the knowledge of state authorities there is an onus on the state to provide a satisfactory and convincing explanation of how the death or injury occurred.
- (iv) The obligation to ensure that there is some form of effective official investigation when individuals have been killed as a result of the use of force is not confined to cases where it is apparent that the killing was caused by agents of the state.
- (v) Where an investigation is required the state authorities must act of their own motion once they are aware of the matter.¹¹
- (vi) An effective investigation must be capable of leading to a determination of whether the force used was or was not justified in the circumstances.
- (vii) An effective investigation will generally require practical independence and a lack of hierarchical or institutional connection.
- (viii) There must be a sufficient element of public scrutiny.
- (ix) The next-of-kin of the victim must be involved to the extent necessary to safeguard his or her legitimate interests.
- (x) There must be proper procedures to ensure the accountability of agents of the state so as to maintain public confidence and allay legitimate concerns which arise from the use of lethal force.

This concise formulation of the principles, distilled from a range of ECtHR decisions, invites consideration of their applicability in cases of healthcare fatality. If such applicability can be established then the overall investigative approach adopted by the state in cases of healthcare fatality must be measured against these core principles.

2.5. It can be argued that where a death occurs in hospital the facts relating to that death are largely, if not wholly, within the knowledge of the public authorities involved. Consequently, just as in lethal force cases, it is essential that such a death is subjected to some form of open and objective scrutiny. Further, following *Amin*, it will be

See *Jordan* at para.105: "They cannot leave it to the next-of-kin either to lodge a formal complaint or to take responsibility for the conduct of any investigative procedure".

incumbent upon the state to provide a satisfactory and convincing explanation of how the death occurred. The jurisprudence arising out of Article 2 clearly indicates that the state authorities should act of their own initiative when a healthcare fatality occurs. It can be argued, therefore, that the investigation into a hospital death should not be contingent upon action or complaint by the next of kin of the deceased. The recent case law also provides guidance as to the nature of an appropriate open and objective investigation. It must be independent, non-hierarchical and should not have any institutional connection with the healthcare facility which is the subject of the investigation. The investigative process must be transparent to the public and must appropriately involve the next-of-kin of the deceased. Finally, there should be some accountability nexus between the investigative processes in order to ensure that systemic or individual failings are addressed in an appropriate and effective manner.

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3. IS ARTICLE 2 ENGAGED IN HOSPITAL FATALITIES?

- 3.1. The jurisprudence which developed the concept of adjectival Article 2 rights emerged from cases where there had been use of lethal force by state agents. More recently the ECtHR has considered whether Article 2 obligations extend beyond this to situations where the death in question has been caused by someone other than a state agent. In *Ulku Ekinci v Turkey* the Court held that the adjectival protections of Article 2 "requires by implication that there should be some form of effective official investigation where individuals have been killed as a result of the use of force. The obligation is not confined to cases where it has been established that the killing was caused by an agent of the state".
- 3.2. The question at the centre of this study is whether Article 2 rights are engaged in cases where death has occurred following a surgical or medical procedure. The ECtHR has examined this issue in a number of recent cases. It was addressed by the Court in *Erikson v Italy*. The applicant complained that the Italian legal system had failed to appropriately investigate and prosecute a doctor following an allegation of criminal negligence in the treatment of an elderly patient. The ECtHR rejected the application but stated:

"the positive obligations a State has to protect life under Article 2 of the Convention include the requirement for hospitals to have regulations for the protection of their patients' lives and also the obligation to establish an effective judicial system for establishing the cause of a death which occurs in hospital and any liability on the part of the medical practitioners concerned."

The debate with regard to hospital fatalities centres on the procedural obligation to investigate deaths appropriately. While there may be cases where the substantive Article 2 right can be infringed in a hospital setting this is likely to be a rare occurrence.

¹² McCann v United Kingdom [1996] EHRR 97.

¹³ Ulku Ekinci v Turkey (16 July 2002).

¹⁴ Erikson v Italy (37900/97; 26 October 1999).

3.3. In *Powell v United Kingdom*,¹⁵ the ECtHR held that, while there was a distinction to be made in terms of substantive Article 2 rights between deaths in hospital and deaths which have, allegedly, been directly caused by the state, that did not extend necessarily to the adjectival Article 2 rights. The Court stated:

"The court considers that the procedural obligation as described cannot be confined to circumstances in which an individual has lost his life as a result of an act of violence. In its opinion and with reference to the facts of the instant case, the obligation at issue extends to the need for an effective independent system for establishing the cause of death of an individual under the care and responsibility of a health professional and any liability on the part of the latter."

The *Powell* judgment appears to suggest that Article 2 is engaged in cases of healthcare related fatality.

3.4. The engagement issue was further considered by the ECtHR in *Sieminska v Poland*. In that case the Court held that:

"In particular, the positive obligations a State has to protect life under Article 2 of the Convention include the requirement for hospitals to have regulations for the protection of their patients' lives and also the obligation to establish an effective judicial system for establishing the cause of a death which occurs in hospital and any liability on the part of the medical practitioners concerned. The procedural element contained in Article 2 of the Convention imposes the minimum requirement that where a State or its agents potentially bear responsibility for loss of life, the events in question should be subject to an effective investigation or scrutiny which enables the facts to become known to the public, and in particular to the relatives of any victims."

¹⁶ Sieminska v Poland (37602/97; 29 March 2001).

¹⁵ Powell v United Kingdom (45305/99; 4 May 2000).

In Calvelli v Italy¹⁷ the ECtHR examined the principles outlined above from the Jordan case (para. 2.3, above) and stated:

> "Those principles apply in the public health sphere too. The aforementioned positive obligations therefore require States to make regulations compelling hospitals, whether public or private, to adopt appropriate measures for the protection of patients' lives. They also require an effective independent judicial system to be set up so that the cause of death of patients in the care of the medical profession, whether in the public or private sector, can be determined and those responsible made accountable."

The Court determined that Article 2 was applicable and went on to assess the adequacy of the state response to the facts of the case, ultimately holding that there had been no violation of Article 2.

The issue of Article 2 engagement has also been the subject of an Administrative 3.6. Court decision in England. In Khan v Secretary of State for Health¹⁸ the parents of a three year old child who had died as a result of a potassium overdose administered while she was undergoing chemotherapy for lymphoma contended that they had a right under Article 2 to an effective independent investigation. Silber J considered the recent Strasbourg authorities and concluded that an adjectival duty to investigate the death of the child was imposed by Article 2. He went on to state that:

> "in cases where a patient dies in hospital, the adjectival obligation of the state is satisfied where the state has an effective independent system to ascertain the cause of death and has established an effective judicial system to establish the responsibility of the professionals and to obtain civil redress."

It is apparent from these authorities that Article 2 is engaged in cases where deaths have occurred during medical or surgical treatment. In effect, this means that there is an obligation upon the state (not necessarily the hospital or trust alone) to ensure that

Calvelli v Italy (32967/96; 17 January 2002).
 Khan v Secretary of State for Health [2003] 4 All ER 1239.

healthcare fatalities are investigated in a manner consistent with the Article 2 obligations.

3.7. In Northern Ireland, the High Court recently granted leave in a judicial review application challenging a coroner's refusal to hold an inquest in circumstances where the applicant alleged surgical negligence in the period immediately preceding her husband's death. The applicant had argued that Article 2 was engaged in the circumstances of her husband's death. The coroner had exercised his discretion not to hold an inquest having acquired an expert report into the death. The deceased's wife sought to restrain the certification of the death and to compel the coroner to hold a full inquest. The High Court accepted that there was at least an arguable case that Article 2 was engaged in a case of this type.

¹⁹ Re Bernadette Magill (October 2003, unreported).

4. CURRENT PROVISION FOR INVESTIGATION OF HEALTHCARE FATALITIES

- 4.1. When a death occurs which is, or is suspected to be, related to the provision of healthcare then a range of internal and external investigative procedures may currently apply. These include:
 - (i) Internal clinical audit.
 - (ii) Investigation by hospital Chief Executive or medical director.
 - (iii) Report to National Confidential Enquiry into Perioperative Deaths (NCEPOD).
 - (iv) Hospital post mortem.
 - (v) Coroner's post mortem.
 - (vi) Coroner's inquest.
 - (vii) GMC investigation.
 - (viii) Civil litigation.
 - (ix) Complaint to the Ombudsman.

The likelihood of an investigation is greater in cases of surgical death than in cases where it is alleged that wrongful administration of medication may have caused the death. Unexpected "medical" deaths can raise fewer suspicions of negligent treatment among family members than unexpected surgical deaths. Where there is no complaint from family members, or where the doctor or surgeon in question is confident that the treatment afforded will not be subjected to professional criticism, then only a minimal level of investigation may take place into the death. The level of scrutiny of a healthcare fatality would appear to be contingent, at least in part, on the initiative of the deceased's family and the attitude of the healthcare professionals involved. This, in itself, raises questions about Article 2 compliance, given that the state ought to act of its own motion rather than waiting for relatives to initiate the process.

4.2. These weaknesses have been identified by the Department of Health in England and Wales. In 2000 the Department published a report entitled *An Organisation with a*

Memory which had been drafted by an expert group examining the effectiveness of reporting and investigating adverse events in the NHS. This report found that:

"There are no universally accepted criteria for identifying the occurrences or outcomes of healthcare that should constitute a basis for recording or reporting poor quality. Neither does the NHS have a single comprehensive system of gathering data to enable service failure to be recognised."²⁰

Further, the Department found that there was no standardised approach to investigating serious incidents at any level and that existing systems did not facilitate learning across the NHS as a whole. The difficulties were compounded by the fact that the existence of a "blame culture" acted as a disincentive to the candid reporting of "near misses" which might have helped avoid the occurrence of actual adverse outcomes. The Report recommended that a mandatory reporting scheme be introduced for adverse healthcare events and specified near misses and that a confidential process be developed to facilitate healthcare professionals in making such reports. No such scheme has yet been implemented in Northern Ireland.

4.3. There are arguments within the medical profession about the appropriate approach to adopt to healthcare fatalities. A recent editorial in the British Medical Journal argues that each surgical death should be subjected to detailed forensic and statistical analysis.²¹ De Leval argues that:

"People and organisations that manage potentially hazardous operations successfully are aware of the potential path of failures and develop sensitive strategies that forestall these possibilities. The purpose of a forensic analysis is not only to search for errors or adverse events but also to identify weaknesses of the systems and help develop designs and process modifications that overcome them. Failures can occur without errors; lack of errors does not mean success: 'If nothing goes wrong, is everything all right?'"

Department of Health. An Organisation with a Memory: Learning from Adverse Events in the NHS, 2000. Available at www.npsa.nhs.uk/admin/publications/docs/org.pdf. See para. 4.9.

de Leval, M. 'Facing up to surgical deaths'. British Medical Journal, February 2004, 328: 361-362.

There is clearly a body of opinion within the medical profession which contends that there are sound clinical reasons for ensuring that a coherent investigative process is instituted in response to every healthcare fatality.²² The content of that investigative process may be the subject of debate. A requirement to have a post mortem in the event of every hospital fatality may raise genuine resource concerns. Similarly, such an approach may conflict with religious or cultural sensibilities, or indeed, in Northern Ireland, the practice of ensuring that funerals take place within three days of the death. However, there may be alternatives to a post mortem investigation if, for example, in the case of a hospital fatality there was a requirement for the clinical notes and records (including the nursing notes) to be secured and scrutinised, where appropriate, by an expert independent assessor. The Luce Review²³ recommended the creation of the new post of Statutory Medical Assessor to improve liaison between the Coroners Service and the public healthcare system. The Statutory Medical Assessor could play an important role in ensuring that healthcare fatalities are investigated in accordance with Article 2 obligations.

The obligation to ensure that there is an Article 2 compliant investigation following a 4.4. death is one which rests on the state rather than on individual public authorities.²⁴ In the case of *Powell v United Kingdom*,²⁵ the death resulted from negligence in hospital. No inquest was held but a hospital committee investigation and a police investigation were carried out. The health authority admitted liability and the proceedings were settled. The Court found that in these circumstances, given that the family did not bring proceedings against the individual doctors, as they could have done, the procedural obligations were discharged. Powell indicates that in order to determine whether the state is, in fact, discharging the Article 2 adjectival obligations it is necessary to consider the composite pattern of possible investigative mechanisms outlined above. Does this regime of investigation adequately discharge the Article 2 obligations and, if not, what modifications might be introduced to ensure that the

²² White, S. 'Death on the Table'. *Anaesthesia*, 2003, 58:6. Goldstone, A.R., Callaghan, C.J., Mackay, J., Charman, S., and Nashet, S. 'Should surgeons take a break after an intraoperative death? Attitude survey and outcome evaluation'. British Medical Journal, February 2004, 328: 379-0. Poloniecki, J., Sismanidis, C., Bland, M., Jones, P. 'Retrospective cohort study of false alarm rates associated with a series of heart operations: the case for hospital mortality monitoring groups'. British Medical Journal, February 2004, 328: 375-0.

²³ Death Certification and Investigation in England, Wales and Northern Ireland, The Report of a Fundamental Review. Cm 5831, 2003.

See dicta of Kerr J in Re Jordan [2002] NIQB 7.
 Powell v United Kingdom (45305/99; 4 May 2000).

requirements of the Convention are met? In order to provide some view of the adequacy of investigations in the event of deaths it is necessary to consider each of the possible investigative mechanisms against the principles outlined in paragraph 2.4, above. This does, however, highlight a particular difficulty for the various public authorities involved. If the overall obligation to hold an Article 2 compliant investigation rests upon the state, how are individual public authorities to know whether they independently have discharged the burden placed upon them by Article 2? The reality which public authorities face is that when aggrieved relatives raise complaints about a hospital fatality they tend not to direct their criticisms at the state in general but rather challenge the actions of the individual public authorities and individual healthcare professionals.

Clinical audit. Audit was introduced into the National Health Service as a 4.5. consequence of reforms in 1989. Prior to these reforms the medical profession in the United Kingdom was largely autonomous. Doctors were subject only to self-regulation through the Royal Colleges and the General Medical Council. The publication of Working for Patients in 1989 introduced the concept of regular and systematic audit to the practice of medicine.²⁶ Clinical audit involves scrutiny of all aspects of the provision of clinical care including that provided by nursing and paramedical staff. The effectiveness of clinical audit as a quality assurance mechanism has, however, been challenged. A detailed review of clinical audit published in 1994 found that, while there was extensive audit activity within the NHS, the quality, coherence and effectiveness of the audit programmes were highly variable.²⁷ Criticisms of clinical audit have suggested that audit meetings are inadequately attended, infrequently organised and characterised by a hierarchical approach and deference to senior clinical opinions. Does clinical audit satisfy the requirements of Article 2? An evident weakness with relying on clinical audit meetings as a means of ensuring that the state has discharged its obligations under Article 2 is the fact that audit is, necessarily, an institutionally situated process. It therefore lacks the appropriate degree of independence from the authority under investigation. Clinical audit occurs within the healthcare domain. There is no role for

²⁶ Working for Patients. (Cm 555) London, HMSO, 1989.

Walshe, K. and Coles, J. Evaluating Audit in the NHS: A Review of Initiatives. London, CASPE Research, 1993.

the next-of-kin of a deceased person at a clinical audit meeting. Clinical audit is essentially a quality assurance tool and therefore lacks the necessary transparency required for Article 2 compliance.

- 4.6. Referral to Chief Executive. Where a fatality has occurred in hospital a common practice in many trusts is referral to the Chief Executive, who will then establish an internal review. Typically the matter in question will be reviewed by a team of three people often chaired by the Chief Executive and commonly involving a senior doctor or medical director and a senior nursing officer or nursing director. The internal review team may afford the medical staff involved in the incident an opportunity to make oral and written representations. In some instances the internal review may commission an expert report based on the clinical notes and records. The advantage of the internal review chaired by the Chief Executive is that it can act promptly with direct access to the personnel involved and to the available documentation. However, there is a clear institutional connection and a hierarchical structure involved in this process. Consequently, it is at odds with one of the core Article 2 requirements identified in Amin.
- NCEPOD. Since 1987 the National Confidential Enquiry into Peri-Operative Death 4.7. has collected data on all deaths occurring in hospital within 30 days of a surgical procedure performed by a surgeon or gynaecologist. The methodology used required that a local reporter in each hospital in the United Kingdom, usually histopathologists, reported data on deaths in their hospital to the centralised database held by NCEPOD. However, since 2001 the remit of NCEPOD was extended to include all medical deaths, deaths in primary care and "near misses". This led to a greater than ten-fold increase in the numbers of cases reported, from 20,000 per annum in 2002 to 260,000 in 2003. This increase in workload has led, unfortunately, to the withdrawal of this comprehensive reporting system. From 1 April 2004 NCEPOD no longer collects routine data on in-patient deaths. NCEPOD reports have addressed issues relating to appropriate follow-up procedures in the event of a medically related death. The 2002 report recommended that continuity of care should continue after death, with direct interaction between pathologists and clinical teams to ensure that appropriate lessons are learned from a fatality. NCEPOD recommended that morbidity and mortality

²⁸ Kerrison, S., Packwood, T. and Buxton, M. Medical Audit: Taking Stock. London, King's Fund, 1993.

reviews should be conducted in all hospitals by both surgeons and anaesthetists.²⁹ While NCEPOD provides an important mechanism for oversight of systemic failings related to deaths, its demise means that this important dimension of state supervision of healthcare fatalities has been removed.³⁰

4.8. Hospital post mortem. A hospital post mortem is carried out at the request of either the hospital or the family. The purpose of the hospital post mortem is to gain a fuller understanding of the patient's illness and the cause of death. Hospital post mortems differ from coroner's post mortems in that the consent of family members is required before a hospital post mortem can take place. Where a post mortem is not requested by relatives, and where the doctor does not consider that such an examination is necessary in the circumstances to establish the cause of death, then certification of the death can occur without any causal investigation. This has been identified as a major shortcoming by Dame Janet Smith's Inquiry into the deaths caused by Dr Harold Shipman. There is no general statutory duty upon a doctor to report a death to the coroner. Where the documentation is completed appropriately there is no further check or verification of the authenticity and veracity of the information provided. In her Third Report for the Shipman Inquiry, Dame Janet Smith observed that:

"It follows that the present system depends almost entirely on the good faith and judgement of the doctor who signs the MCCD [medical certificate of the cause of death] or decides that the case should be reported to the coroner. It also depends on the courage and independence of doctors, for the system places upon them some responsibility to police their colleagues, for example by refusing to certify a death which may have been contributed to by some misconduct, lack of care or medical error on the part of a professional colleague. It may not be easy for a junior member of the clinical team

Where a death occurs perioperatively the Royal College of Surgeons has a peer review emergency response team which can investigate surgical deaths.

Smith, Dame Janet. Death Certification and the Investigation of Death by Coroners. Third Report. The Shipman Inquiry. Cm 5854, 2003.

²⁹ National Confidential Enquiry into Perioperative Deaths. *Functioning as a Team*, 2002; Mayor, S. 'Poor team work is killing patients'. *British Medical Journal*, November 2002, 325: 1129.

³² Coroners Act (Northern Ireland) 1959. Section 7 provides that a medical practitioner must notify the coroner of the facts and circumstances surrounding a death where he or she has reason to believe that the deceased died, directly or indirectly, as a result of violence, misadventure or unfair means, through negligence or malpractice, from any cause other than natural illness or disease for which he or she had been seen and treated by a doctor within the last 28 days.

responsible for the care of the deceased to withstand the expectation that s/he will certify the cause of death, rather than report the case to the coroner for investigation."³³

In cases where the death in hospital occurs after a surgical intervention the discretion to report the matter to the coroner may lie with relatively junior members of medical staff. When a decision is taken not to report the matter to the coroner, and the medical certificate does not arouse any concern with the Registrar of Deaths, then no investigation will take place unless a complaint is made by a third party to the coroner. A coroner does not have jurisdiction to investigate a death which is not reported to him or her. This raises particular concerns with regard to Article 2 compliance. If a doctor elects to certify the death without referring the matter to the coroner, then in the absence of any further analysis directed by the Registrar of Deaths and any complaint by the next-of-kin, there will be no further investigation into the circumstances surrounding the death.³⁴

4.9. Coroner's post mortem. In Northern Ireland approximately 14,500 deaths are recorded per annum. Of those deaths, about one quarter are referred to the coroner in the first instance. In 2002 coroner's post mortems were ordered in 8.8% of those deaths. The Luce Review observed that this figure was low compared with England and Wales, where post mortems were conducted in 23% of deaths. Only 1.3% of the total number of deaths in Northern Ireland results in a full coronial inquest. A coroner's post mortem is carried out under the terms of the Coroners Act (Northern Ireland) 1959 and the Coroners (Practice and Procedure) Rules (Northern Ireland) 1963. Where a death occurs during surgery or within 24 hours of an operation, the normal working practice in Northern Ireland is that the coroner is informed immediately. There is no statutory requirement that this be done. Typically the contact with the coroner will be made by a relatively junior member of the medical staff. Once informed of such a death the coroner has discretion to order a post

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³³ *Ibid* at 5.26.

Dame Janet Smith notes in her Third Report on the Shipman deaths that Registrars, who are not medically trained, will not necessarily look behind the cause of death cited on the death certificate.

Northern Ireland Court Service. *The Coroners Service of Northern Ireland: Proposals for Administrative Redesign*, 2004. Annex C of this consultation document records that in 2002 some 3,563 deaths were reported to the coroners in Northern Ireland. Of those cases only 230 resulted in a full inquest.

³⁶ Luce, T. et al. Death Certification and Investigation in England, Wales and Northern Ireland, The Report of a Fundamental Review. Cm 5831. HMSO, 2003, p.19.

mortem or to issue a death certificate. A post mortem ordered by the coroner will be conducted by the State Pathologist (or Assistant State Pathologist). Where the death in question occurs in a hospital setting more than 24 hours after a surgical intervention then the discretion to hold a post mortem rests with the clinician and is subject to the consent of the deceased's family. In the event that a hospital post mortem is held the report may be provided to the coroner at a future date. These hospital post mortems are conducted by consultant pathologists at the Department of Pathology at the Royal Group of Hospitals in Belfast.

There are three main situations where a death will be referred to the coroner. First, in a case of sudden or unexpected death. Second, where a person has been ill but where the doctor confirming death is not certain why the death happened at that particular time. Third, a coroner's post mortem will be held where the death is the result of an industrial disease, accident or unusual circumstance. This third category includes cases where death follows a surgical procedure. But the fact that a coroner's post mortem takes place does not mean that there will, in fact, be an inquest.³⁷ The significance of this is that in cases where no coronial inquest takes place the only right which family members have in relation to the death investigation process is the right to see a copy of the post mortem report or to have a doctor represent them at the post mortem. Once the post mortem is completed in this category of cases the investigation effectively ends. The current system affords the post mortem a particular significance in the process. However, it is at least arguable that in some cases a post mortem will be less informative than an expert examination of clinical notes and records in cases where a death has occurred in hospital. The post mortem may quite readily disclose a cause of death which will, in many cases, draw the investigation to a close. Independent examination of the clinical notes and records, including the often more extensive nursing notes, would provide a more significant insight into the circumstances surrounding the care provided to the deceased prior to death. This raises obvious resource concerns. If all deaths which occur in hospital are to be subjected to a preliminary investigation by an independent assessor, this will inevitably require a considerable investment of resources. It could be argued that this

³⁷ Coroners Act (Northern Ireland) 1959, s.28(2). "If as a result of such post mortem examination as aforesaid the coroner is satisfied that an inquest is unnecessary, he shall send to the registrar of deaths whose duty it is by

level of scrutiny would be unnecessary in the many cases of death by "natural" causes which occur in hospital. The investigation of notes and records could, for example, be confined to those deaths which occur within a defined time period after a surgical intervention. However, this might exclude scrutiny of those controversial "medical" deaths which have resulted from systemic or individual clinical errors. A comprehensive system of securing and scrutinising notes and records prior to release of the body for burial or cremation also raises practical concerns, particularly given the funereal traditions in Northern Ireland. While such a system would ensure compliance with Article 2 and serve the public interest by identifying and preventing systemic failures, there will inevitably be competing claims on the public purse. If such an approach is to meet the Article 2 requirement of effectiveness then it must be appropriately resourced.

4.11. *Coroner's inquest*. The inquest is an inquisitorial court proceeding which is held in public for the purpose of determining the facts relating to the death. The coronial system in Northern Ireland was examined as part of the Luce Review of coronial and death certification systems.³⁸ In general terms the review recommended that in cases where Article 2 was engaged the inquest should, in principle, be the main forum for the investigation, in conjunction with other appropriate state investigation processes. The Luce Review found that:

"since the coroner's investigation and the inquest are generic mechanisms for investigating deaths it would be sensible to regard the inquest as the process most convenient and apt for the generality of Article 2 cases unless in a particular case there were good reasons for choosing another one. In current language the inquest should be the 'default' process for hearing Article 2 cases, in conjunction with other processes where necessary."

4.12. The coroner has a wide discretion as to the scope of an investigation into a death in Northern Ireland. Also, under section 13 of the Coroners Act (Northern Ireland) 1959

law to register the death a certificate under his hand stating the cause of death as disclosed by the report of the post mortem examination".

³⁸ Luce, T. et al. Death Certification and Investigation in England, Wales and Northern Ireland, The Report of a Fundamental Review. Cm 5831. HMSO, 2003.

the coroner has a discretion as to whether or not an inquest should be held at all.

Where a death in hospital is reported to the coroner the following courses of action are available:

- (i) the coroner may permit the registration of the death after initial inquiries but without conducting a post mortem examination;³⁹
- (ii) the coroner may order a post mortem examination and having been satisfied with the cause of death in the post mortem report conclude that an inquest is not necessary;⁴⁰
- (iii) the coroner may proceed to hold an inquest whether or not a post mortem examination has been conducted.⁴¹

In the context of the Article 2 obligations which may rest upon the coroner this wide margin of discretion may be somewhat problematic. How should the coroner exercise this discretion in order to comply with Article 2 of the Convention? The Shipman Inquiry suggests that there is wide variability in practice between individual coroners in England and Wales. One wonders whether there is in practice between individual coroners in Northern Ireland. The question of how coronial discretion should be exercised with regard to the holding of inquests has been the subject of a Court of Appeal ruling in England. In the case of R (Touche) v HM Coroner for Inner North London⁴² the coroner had refused to hold an inquest into the death of a 29-year-old woman who had just given birth to twins, developed high blood pressure and died of a brain haemorrhage shortly afterwards. Simon Brown LJ considered the question of whether, when a death takes place in hospital and a failure to provide "routine" treatment is a cause of death, that death is "unnatural". If such deaths are deemed to be unnatural then the coroner ought to hold an inquest. The Court of Appeal considered that the coroner should consider whether there is reasonable cause to suspect that the death was at least partly contributed to by neglect and thereby

³⁹ See section 23 of the Coroners Act (Northern Ireland) 1959 and Schedule 3 Form 14 of the Coroners (Practice and Procedure) Rules 1963. In 2002, 1,355 cases reported to the Coroner fell into this category. See also Northern Ireland Court Service. *The Coroners Service of Northern Ireland: Proposals for Administrative Redesign*, 2004. See also Leckey, J. and Greer, D. *Coroners' Law and Practice in Northern Ireland*. SLS, 1998, p.94.

Section 28 of the Coroners Act (Northern Ireland) 1959 and Schedule 3 Form 17 of the 1963 Rules. In 2002 the Northern Ireland coroners held post mortems but no inquest in 1,295 reported deaths.

⁴¹ *Ibid.* 230 inquests were held under the Form 21 procedure in 2002. ⁴² *R (Touche) v HM Coroner for Inner North London* [2001] 3 WLR 140.

unnatural.⁴³ However, the court also found that in cases which fall outside this category but where there is a wholly unexpected death from natural causes which would not have occurred but for some culpable human failure then the coroner should hold an inquest.⁴⁴ It has been suggested that this judgment provides a framework which would facilitate coroners in ensuring that they comply with Article 2 in the exercise of their discretion. Establishing an appropriate framework for the exercise of the discretion to hold an inquest is a significant issue in Northern Ireland. The position adopted by the state would appear to be that the coroner's inquest is now the default mechanism for Article 2 compliance. The decision whether or not to hold such an inquest can assume, therefore, pivotal importance in determining whether or not there has been compliance with the Article 2 obligations.

- 4.13. A further problem with coronial procedures operated in Northern Ireland is the lack of transparency. Where a death is reported to a coroner but no post mortem or inquest is ordered, the family members have no direct access to the person making the report. They do not have any automatic right to see the report or any response to it and they do not have access to the documents which record the findings of the coroner. Where a death is reported and a post mortem is ordered, but an inquest is not held, the family members have no direct access to the investigative process other than the right to be represented by a doctor when the post mortem is carried out. In Northern Ireland in 2002, only 6.5% of deaths reported to the coroner resulted in a full inquest. The other 93.5% were subject to what the Luce Review described as "a serious defect". 45
- 4.14. The voluntary body, Action for Victims of Medical Accidents (AVMA), in a submission to the Luce Review argued that consideration should be given to mandatory inquests for certain categories of medical death. However, the Review stopped short of proposing such mandatory public inquests. It did, however, recommend a specific duty to report deaths in which "lack of care, defective treatment, or adverse reaction to prescribed medicine may have played a part, or unexpected deaths during or after medical or surgical treatment". The Luce Review acknowledged that inquests will not occur in all such cases but noted that where there

⁴³ *Ibid.* see para.34.

⁴⁴ *Ibid.* see paras.43-47.

⁴⁵ Luce Review, p.75.

is a likelihood of uncovering important system defects or general risks which are not already known, an inquest should be held. The Luce Review also recommended the creation of Statutory Medical Assessors who will oversee and accredit hospital arrangements for death certification thereby ensuring that there is a proper mechanism for reporting deaths to the coroner.⁴⁷ The Review recommended that in Northern Ireland coroner's officers should be appointed to carry out investigative functions and that these officers should support the Statutory Medical Assessors.⁴⁸

- 4.15. The verdicts available to a coroner at an inquest are notably restrictive. Under the Coroners Act (Northern Ireland) 1959 the inquest should return a finding indicating who the deceased was and determining how, when and where he or she came by their death. The scope of the verdict available at an inquest has clearly taken on a new importance given that these inquests are to be the default Article 2 investigation into the death. The Coroners (Practice and Procedure) (Amendment) Rules (Northern Ireland) 1980 restricted the "findings" available at an inquest to ensure that one of only five possible forms of words could be recorded as a finding. Significantly, an inquest in Northern Ireland is precluded from recording a verdict of "unlawful killing". This is a substantial restriction which may not be compliant with the Article 2 procedural obligations. The question of what constitutes and Article 2 compliant verdict has recently been considered by the House of Lords in *R* (Middleton) v West Somerset Coroner. Lord Bingham considered three questions:
 - (i) What, if anything, does the Convention require of a properly conducted official investigation into a death involving, or possibly involving, a violation of Article 2?
 - (ii) Does the regime for holding inquests meet the requirement of the Convention?

Luce Review, p.129 at para.21.

⁴⁷ The Luce Review recommends that the Statutory Medical Assessor should help the coroner in the handling of cases needing circumstantial investigation of medical issues and improve the choice and suitability of medical and other medical/scientific investigations.

⁴⁸ There is no reference to the Statutory Medical Assessor in the Proposal for Administrative Design of the Coroners Service for Northern Ireland issued by the Northern Ireland Court Service in 2004.

⁴⁹ Coroners Act (Northern Ireland) 1959, s.31: "Where all the members of a jury at an inquest are agreed they shall give... their verdict setting forth, so far as such particulars have been proved to them, who the deceased person was and how, when and where he came to his death". See also rule 15 of the 1963 Rules.

⁵⁰ See Leckey and Greer, note 39 above, at 11.03 and n.10. ⁵¹ *R (Middleton) v West Somerset Coroner* [2004] 2 WLR 800.

- (iii) If not, can the current regime governing the conduct of inquests in England and Wales be revised so as to do so, and if so how?
- In response to the first question Lord Bingham found that an uninformative jury verdict will be unlikely to meet one of the purposes of an Article 2 investigation, which is to ensure that "those who have lost their relative may at least have the satisfaction of knowing that lessons learned from his death may save the lives of others." Lord Bingham also found that, while cases where use of lethal force by the state was involved were of the utmost seriousness, "a systemic failure to protect human life may call for an investigation which may be no less important and perhaps even more complex." The question of whether the existing system of coroner's inquests adequately met the requirements of Article 2 was answered in the negative. The House of Lords considered that the shortcomings with regard to Article 2 could be addressed by interpreting the relevant legislation in such a way that the question of "how" the deceased came by his or her death was to be interpreted as meaning "by what means and in what circumstances."⁵² Lord Bingham referred with approval to the approach adopted under the Fatal Accident and Sudden Death Inquiry (Scotland) Act 1976, where the sheriff is required, under section 6, to have regard to where and when the death took place, the cause or causes of such death, the defects in the system which contributed to the death and any other factors which are relevant to the circumstances of the death. He also referred to the practice adopted by coroners of making a report to appropriate bodies where they consider that such action should be taken to prevent a recurrence of further fatalities, adding:

"the procedural obligation under Article 2 will be most effectively discharged if the coroner announces publicly not only his intention to report any matter but also the substance of the report, neutrally expressed, which he intends to make."

4.17. The coronial power to report a matter to a relevant authority remains in Northern Ireland. Under the original 1963 Rules a coroner was permitted to make a recommendation "designed to prevent the recurrence of fatalities similar to that in

⁵² *Ibid.* para.35.

respect of which the inquest is being held".⁵³ This approach can be particularly significant in healthcare fatalities where a death may have resulted from a systemic failure with, or without, individual error. A report highlighting the systemic problem could, therefore, ensure that life is protected in future similar cases. This is, of course, the thrust of much of the Strasbourg jurisprudence on the purpose of the adjectival Article 2 rights. However, the power to make such recommendations was removed in the 1980 amendments to the Coroners Rules. It was replaced with rule 23(2), which provides that:

"A coroner who believes that action should be taken to prevent the occurrence of fatalities similar to that in respect of which the inquest is being held may announce at the inquest that he is reporting the matter to the person or authority who may have power to take such action and report the matter accordingly."

This power is external to the inquest procedure and is significantly weaker than the original rule 16 power. The coroner can make a report to an authority such as the GMC but there is no obligation on the GMC to take any action or even to issue a reply. The rule 23(2) procedure falls short of the need to ensure that life is protected through the removal of systemic errors which have caused death.

4.18. Under the present system the coroner has an investigative role and a judicial role. A coroner will have to exercise discretion in determining the scope of the investigation which should take place with regard to any particular death. Where a death is reported by a doctor who satisfies the coroner as to the medical cause of death then the coroner may determine that there is no need for any further investigation. However, where a coroner determines that a post mortem and an inquest are required, the coroner will assume a judicial role of presiding over that inquest. This combination of roles is problematic and could be resolved by ensuring that the investigative functions relating to Article 2 inquiries are conducted by an expert or

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This appeared in a proviso to Rule 16 of the 1963 rules. See Leckey and Greer, note 39 above, at 11.19. Rule 16 remains controversial and provides that "Neither the coroner not the jury shall express any opinion on questions of criminal and civil liability..."

group of experts independently of the coroner who would continue to discharge the judicial role.

- GMC investigation. Under Rule 23(2) of the 1963 Rules a coroner in Northern Ireland can make a report to the General Medical Council if he is concerned that negligence may have played a part in the death of the deceased. Of those cases where a fatality in hospital is followed by a coroner's inquest in Northern Ireland it is not known how many result in a referral to the General Medical Council. Similarly, of those cases which are referred to the General Medical Council it is difficult to determine how many result in some specific finding of fault and corrective recommendations. The possibility of an investigation by the GMC does open a potential channel of accountability with regard to healthcare fatalities. However, the accountability mechanisms within the General Medical Council's procedure have, themselves, been the subject of considerable criticism. The GMC procedure remains a form of self-regulation. Doctors consider the actions of other doctors against a standard of professional conduct. A significant weakness of this procedure is the absence of scrutiny of systemic failure. There is no requirement upon a body like the GMC to report findings back to a coroner who has referred the matter in the first instance.
- 4.20. *Civil litigation*. It is of course open to a bereaved person to seek redress by way of civil litigation where a relative has died in hospital care. Does such an approach satisfy the requirements of Article 2? It has been held in *Jordan*⁵⁴ and in *Wright*⁵⁵ that the fact that an individual is entitled to pursue a remedy for damages through the civil courts does not, of itself, discharge the state's procedural obligations under Article 2. In Northern Ireland clinical negligence claims have resulted in payments of over £37 million pounds in the five years to 2003.⁵⁶ While cases which have involved death will not have resulted in major expenditure of public funds, the failure to identify systemic failings through appropriate investigation of hospital deaths may have resulted in avoidable medical accidents which will have contributed to the overall pattern of clinical negligence claims in the jurisdiction. Where a death has occurred

⁵⁴ Para.141.

⁵⁵ R (on the application of Wright) v Secretary of State for the Home Department [2001] EWCA Admin 520, at para.61.

See written answer to Iris Robinson MP. *Hansard*, 16 March 2004 col.259W. For further details see Appendix 3, below.

in hospital the deceased's family may not be aware that there has been possible negligence and may not consider initiating such a claim. If the family do suspect that a breach of the appropriate standard of care has led to the death of their relative then there are a number of significant disincentives to pursuing a clinical negligence action. The success of any such case depends on expert witness reports and, if necessary, testimony. This investigation can be an expensive process. In order to commence an investigation into a bereavement a solicitor may require to be placed in funds to acquire the expert report. If legal aid is not available, the cost of the investigation phase of a clinical negligence claim may prove to be prohibitive. The financial outlay involved in initiating such a claim must also be balanced against the potential award of damages if successful. Perhaps more importantly, if relatives of a deceased do pursue a remedy by way of a negligence action this may not lead to a resolution of the factual issues relating to the death nor will it necessarily lead to the identification of systemic or individual errors and appropriate remedial action. In cases where there has been a clear medical or surgical error leading to death then the hospital trust involved has a strong incentive to admit liability at an early stage. The action will then either be settled in negotiations between the parties or will proceed as a "quantum only" action before the court (i.e. a dispute only about the amount of compensation to be awarded). An admission of liability will usually preclude any effective investigation into the circumstances surrounding death. A further shortcoming of clinical negligence actions as a means of discharging Article 2 obligations is that the litigation will not necessarily establish who was accountable for the fatal incident. In this jurisdiction clinical negligence actions are often brought against the hospital trust without naming individual clinicians as defendants. While the actions of those individual clinicians will ultimately form the basis of the claim, the plaintiffs will seek to make the trust accountable for the actions of their employees. In certain cases where liability is admitted and the case settled against the trust, there will be no determination or accountability for the clinical error which actually caused the death. Frequently, a condition of the settlement of the action will be a confidentiality clause preventing the Plaintiff revealing details about the case. The Department of Health, Social Services and Public Safety in Northern Ireland has advised the various trust legal advisors to desist from including such clauses in financial settlements. However, there is anecdotal evidence to suggest that the practice continues. In certain circumstances a hospital fatality may result in a

prosecution for manslaughter. Such "medical" manslaughter cases have become more prominent since the ruling of the House of Lords in *Adomako*. ⁵⁷ However, such prosecutions suffer from similar defects to those outlined in civil actions. The bringing of a criminal prosecution for a hospital death will not necessarily result in an Article 2 compliant investigation into the cause of death. ⁵⁸

4.21. *Complaint to the Ombudsman*. There has been a Commissioner for Complaints (or Ombudsman) in Northern Ireland since 1969. The jurisdiction of the Ombudsman was extended in 1997 to include the investigation of complaints into the work of doctors, dentists, pharmacists and opticians.⁵⁹ The Ombudsman does have power to investigate the administrative actions of healthcare trusts and boards as well as the clinical judgment of individual doctors. However, the system is complaint-driven and therefore does not necessarily meet the requirements of Article 2. A complainant will ordinarily be expected to have exhausted the internal Health Service Complaints Procedure before the Ombudsman will become involved. The Ombudsman will not consider complaints which appear to raise allegations of clinical negligence as these matters will be subject to the jurisdiction of the courts. In addition, the Ombudsman will decline to investigate complaints about matters which have taken place more than 12 months previously.

⁵⁹ Commissioner for Complaints (Amendment) (Northern Ireland) Order 1997.

⁵⁷ R v Adomako [1994] QB 302. The House of Lords found that the level of negligence required in such cases is significantly higher than that which applies in civil actions. In cases of this type it will be for the jury determine whether the negligence is so gross that it requires the imposition of a "criminal" sanction. This rather tautologous test can result in convictions in cases where there is incompetence but no subjective wrongdoing on the part of the clinician.

⁵⁸ See, for example, Ferner, R.E. 'Medication errors that have led to manslaughter charges'. *British Medical Journal*, November 2000, 321: 1212-1216. Dyer, C. 'Surgeons cleared of manslaughter after removing wrong kidney'. *British Medical Journal*, July 2002, 325: 9.

5. CONCLUSIONS

- 5.1. Article 2 requires the state to ensure that, where a death occurs in hospital, the circumstances surrounding that death are subject to open, objective, and independent scrutiny. Further, the state is required to ensure that scrutiny mechanisms are implemented as a consequence of the fact of that death and are not contingent upon any action on the part of bereaved family members. The investigation into a hospital death must be conducted independently of the hospital and must seek to determine the facts surrounding the death and the existence of any individual or systemic errors which contributed to it. The present collection of arrangements for investigating hospital deaths does not meet this standard. In particular, the following shortcomings can be identified:
 - (i) there is no automatic requirement for an investigation into a death in hospital;
 - (ii) clinical audit mechanisms are insufficiently independent to provide an appropriate level of scrutiny;
 - (iii) internal reviews and referrals to the Chief Executives of trusts are insufficiently independent to provide the appropriate level of scrutiny;
 - (iv) the system of death certification can conceal the presence of individual or systemic errors which have contributed to the death;
 - (v) where the death has occurred during or after a surgical procedure there is no mandatory requirement to report that death to the coroner;
 - (vi) the decision as to whether a surgical death should be reported to the coroner can be made by junior members of the medical team;
 - (vii) where a death is reported to the coroner the coroner retains a wide discretion as to whether there should be a post mortem;
 - (viii) a coroner's post mortem can take place and a report be provided by the State Pathologist without scrutiny of the clinical notes and records by an independent expert in the field;
 - (ix) the coroner has a wide discretion with regard to whether an inquest is held in a particular case;
 - (x) the coroner can decide not to hold an inquest on the basis of the completion of a post mortem report alone;
 - (xi) the coroner is currently required to combine an investigative role with regard to the preparation of an inquest and a judicial role in the holding of the inquest;

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- (xii) the restrictive nature of the verdicts available at an inquest can preclude a full investigation of the circumstances surrounding how the deceased died;
- (xiii) the coroner does not have the power to make a recommendation to prevent a recurrence of the circumstances which caused the death;
- (xiv) where a report is made to a professional healthcare body such as the General Medical Council there is no requirement for the professional body to address the matter and report back to the coroner;
- (xv) the clinical negligence system will not necessarily afford a mechanism for an open and objective evaluation of the circumstances surrounding the death; in cases where there has been clear systemic or individual error the clinical negligence system is more likely to conceal than to reveal such errors.
- 5.2. Some of these shortcomings may be addressed by the Government in light of the findings of the Luce Review and the Shipman Inquiry. Steps worthy of serious consideration include the following:
 - (i) the State should clearly acknowledge that Article 2 procedural obligations apply where a death occurs in hospital;
 - (ii) the State should give clear guidance as to which mechanisms discharge the Article 2 procedural obligation to investigate deaths in hospital;
 - (iii) deaths in hospital should be reported as a matter of course to an investigative body charged with discharging the Article 2 obligations;
 - (iv) each death in hospital should be subjected to an independent review at which, in the first instance, all hospital notes and records relating to the deceased are copied for examination by an appropriately qualified external scrutineer as soon as is practicable;⁶⁰
 - (v) where, as a result of scrutinising the clinical notes and records, the independent reviewer has reason to believe that the death may have been the result of negligence, culpable individual error or systemic failure a post mortem should take place and an inquest should be mandatory;

⁶⁰ In practice this function could be discharged by a "coroner's officer" as recommended by the Luce Review. The records could be photocopied and taken to the coroner's office where they could be examined by the Statutory Medical Assessor on the next working day. A less onerous system which involved, for example, scrutiny of the notes and records following a surgical death, would be less burdensome but would not address the problematic issue of appropriately investigating "medical" deaths.

- (vi) any discretion as to whether a post mortem should be ordered, whether clinical notes and records should be scrutinised and whether a full inquest hearing should be ordered, should be outlined in regulations to ensure uniformity of application;
- (vii) the question of whether an inquest takes place should not be contingent only on the outcome of a post mortem;
- (viii) the verdicts available at an inquest should be expanded to permit an examination of how the deceased came to die and the circumstances surrounding that death;
- (ix) there should be a clear mechanism whereby systemic errors identified in the Article 2 investigation or inquest can be reported directly to the Department of Health, Social Services and Public Safety, with a specified period in which a response should be issued;
- (x) given the potential complexities of healthcare fatalities and the fact that an inquest finding may reflect on the outcome of any civil litigation, consideration should be given to providing legal aid support for the family of the deceased at inquest proceedings;
- (xi) where an inquest has found that an individual error has led to a death in hospital there should be an automatic reporting requirement to the professional conduct mechanisms of the appropriate medical registration body.
- 5.3. The rationale underpinning the Strasbourg jurisprudence which developed the Article 2 procedural obligations was presumably the need to ensure that a state could take action to prevent a repetition of the circumstances which led to the loss of life.

 Unexpected deaths in healthcare may be the result of systemic or individual failings. There is a clear need for an investigative mechanism which adequately and appropriately addresses the circumstances surrounding these deaths. The Article 2 jurisprudence imposes an obligation upon the state to establish investigative procedures which will address that need. In light of the obvious shortcomings of the current mechanisms for investigating healthcare fatalities in Northern Ireland, and the financial and emotional cost of avoidable healthcare fatalities, that obligation has become an urgent imperative.

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APPENDIX 1

Ireland Statistical Research Agency: The number of deaths registered each year by place of death, 1994-2003 Northern

	1994	1995	1996	1997	1998	6661	2000	2001	2002	2003
										2007
Psychiatric Hospitals	139	121	88	63	104	79	104	73	17	28
								7	11	000
Other Hospitals	7321	7519	7533	7284	7747	7604	7439	7715	7370	7161
								7410	77101	†0†/
Nursing Homes	2777	2992	3049	3052	3187	3473	3150	3042	3053	30.42
								7100		7100
All Other Places	4877	4678	4548	4572	4455	4507	4210	4233	4114	3808
									1 7 7 1	0000
Total	15114	15310	15218	14971	14993	15663	14903	14513	14586	14467

CC3-CC1 - C39

APPENDIX 2

Confidential Enquiry into Perioperative Deaths (2003): Reported Deaths in Northern Ireland Hos National

Hospital	2001/02	2000/01
3		
Altnagelvin Hospitals Health and Social Services Trust	20	12
Belfast City Hospital Health & Social Services Trust	99	58
Causeway Health & Social Services Trust		
Craigavon Area Hospital Trust	30	43
Down Lisburn Health & Social Services Trust	25	23
Green Park Healthcare Trust	9	4
Mater Hospital Health & Social Services Trust	25	30
Newry & Mourne Health & Social Services Trust	26	30
Royal Group of Hospitals Health & Social Services Trust	119	106
Sperrin Lakeland Health & Social Care Trust	19	6
Ulster Community & Hospitals Trust	91	55
United Hospitals Health & Social Services Trust	12	18

APPENDIX 3

Clinical negligence cases pending in Northern Ireland Trusts, January 2004

Number of Cases pending	216	3.7	273	06	15	191	145	14	53	19	103	118		6	482	6	112	220	291
Hospital	Altnagelvin Hospitals HSS Trust	Armagh and Dungannon HSS Trust	Belfast City Hospital Trust	Causeway HSS Trust	Craigavon and Banbridge Community HSS Trust	Craigavon Area Hospital Trust	Down Lisburn HSS Trust	Foyle HSS Trust	Green Park HSS Trust	Homefirst Community HSS Trust	Mater Hospital HSS Trust	Newry and Mourne HSS Trust	M Ambulance Service HSS Trust	North and West Belfast HSS Trust	Royal Group of Hospitals HSS Trust	South and East Belfast HSS Trust	Sperrin Lakeland HSS Trust	United Hospitals HSS Trust	Ulster Community and Hospitals Trust

Northern Ireland Human Rights Commission

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Press Releases

HUMAN RIGHTS COMMISSION PUBLISHES DISCUSSION PAPER ON INVESTIGATING DEATHS IN HOSPITAL

Tuesday 21 September 2004

The Northern Ireland Human Rights Commission today published a paper on the human rights issues associated with investigating deaths in hospital. Whilst the paper sits within broader research being carried out by the Commission into how deaths are investigated in Northern Ireland, the Commission recognises that health care has not yet benefited from the level of debate which has proven so worthwhile in other contexts of death investigation. The Commission hopes that this report will act as a catalyst for further detailed public debate which will inform its future work on this area.

'Investigating Deaths in Hospital' was written on behalf of the Commission by Professor Tony McGleenan, who is a practising barrister and professor of law at the University of Ulster. The report looks at the principles arising from a range of decisions by the European Court of Human Rights (some specifically in respect of deaths in healthcare facilities) and concludes that effective systems to comply with Article 2 of the European Convention on Human Rights – the right to life – are not adequately in place in Northern Ireland.

Professor McGleenan highlights current failings in the system for investigating deaths in hospitals, including the following:

- there is no automatic requirement for an investigation into a death in hospital;
- internal reviews carried out by Health and Social Services Trusts are insufficiently independent and thorough;
- there is no mandatory requirement to report a death during or after surgery to the coroner; and
- the coroner does not have the power to make a recommendation to prevent a recurrence of the circumstances which caused the death.

Speaking today, Professor McGleenan said:

"The State needs to advise clearly on how the Article 2 obligation to protect life should be discharged by hospitals and other public authorities."

The report considers improvements that might be made to our current death investigation systems,

such as an independent review of each death in hospital with access to all patient notes and records.

Professor Brice Dickson, Chief Commissioner, said:

"The Northern Ireland Human Rights Commission is monitoring decisions of the European Court of Human Rights relating to deaths in the health care system. The implementation of Article 2 procedures in the investigation of such deaths is a topic on which further discussion is needed. We hope through this report, to stimulate informed debate on the future practice and procedure in this area of law, which is due for considerable change."/BLOCKQUOTE>
Notes to Editors:

- 1. Professor McGleenan is available for interviews between 12.00pm and 2.00pm on Tuesday 21 September. For interview arrangements, contact Nadia Downing on 028 9024 3987 or 07818 008442.
- 2. 'Investigating Deaths in Hospital' was written by Professor Tony McGleenan, who is a practising barrister and Professor of Law at the University of Ulster. His work has been published widely in legal and medical journals. The paper has been published by the Commission for discussion and its conclusions are attached, below.
- 3. In 2003 the Government published its review into the coroner system, including post mortems and inquests, in England, Wales and Northern Ireland. The report (also known as the Luce Review) is called Death Certification and Investigation in England, Wales and Northern Ireland The Report of a Fundamental Review.
- 4. The Northern Ireland Human Rights Commission was established in March 1999 by the Northern Ireland Act 1998. It aims to promote and protect human rights in Northern Ireland. The Commission has the power to conduct investigations and to provide advice on the compatibility of law, policy and practice with human rights in Northern Ireland.

Conclusions of Professor McGleenan's paper

Article 2 of the European Convention on Human Rights requires the state to ensure that, where a death occurs, the circumstances surrounding that death are subject to open, objective, and independent scrutiny. Further, the state is required to ensure that scrutiny mechanisms are implemented as a consequence of the fact of that death and are not contingent upon any action on the part of bereaved family members. The investigation into a hospital death must be conducted independently of the hospital and must seek to determine the facts surrounding the death and the existence of any individual or systemic errors which contributed to it. The present collection of arrangements for investigating hospital deaths does not meet this standard. In particular, the following shortcomings can be identified:

- (i) there is no automatic requirement for an investigation into a death in hospital;
- (ii) clinical audit mechanisms are insufficiently independent to provide an appropriate level of scrutiny;

- (iii) internal reviews and referrals to the Chief Executives of Health and Social Services Trusts are insufficiently independent to provide the appropriate level of scrutiny;
- (iv) the system of death certification can conceal the presence of individual or systemic errors which have contributed to the death;
- (v) where the death has occurred during or after a surgical procedure there is no mandatory requirement to report that death to the coroner;
- (vi) the decision as to whether a surgical death should be reported to the coroner can be made by junior members of the medical team;
- (vii) where a death is reported to the coroner the coroner retains a wide discretion as to whether there should be a post mortem;
- (viii) a coroner's post mortem can take place and a report be provided by the State Pathologist without scrutiny of the clinical notes and records by an independent expert in the field;
- (ix) the coroner has a wide discretion with regard to whether an inquest is held in a particular case;
- (x) the coroner can decide not to hold an inquest on the basis of the completion of a post mortem report alone;
- (xi) the coroner is currently required to combine an investigative role with regard to the preparation of an inquest and a judicial role in the holding of the inquest;
- (xii) the restrictive nature of the verdicts available at an inquest can preclude a full investigation of the circumstances surrounding how the deceased died;
- (xiii) the coroner does not have the power to make a recommendation to prevent a recurrence of the circumstances which caused the death;
- (xiv) where a report is made to a professional healthcare body such as the General Medical Council there is no requirement for the professional body to address the matter and report back to the coroner;
- (xv) the clinical negligence system will not necessarily afford a mechanism for an open and objective evaluation of the circumstances surrounding the death; in cases where there has been clear systemic or individual error the clinical negligence system is more likely to conceal than to reveal such errors.

- Some of these shortcomings may be addressed by the Government in light of the findings of the Luce Review and the Shipman Inquiry. Steps worthy of serious consideration include the following:
- (i) the State should clearly acknowledge that Article 2 procedural obligations apply where a death occurs in hospital;
- (ii) the State should give clear guidance as to which mechanisms discharge the Article 2 procedural obligation to investigate deaths in hospital;
- (iii) deaths in hospital should be reported as a matter of course to an investigative body charged with discharging the Article 2 obligations;
- (iv) each death in hospital should be subjected to an independent review at which, in the first instance, all hospital notes and records relating to the deceased are copied for examination by an appropriately qualified external scrutineer as soon as is practicable;
- (v) where, as a result of scrutinising the clinical notes and records, the independent reviewer has reason to believe that the death may have been the result of negligence, culpable individual error or systemic failure a post mortem should take place and an inquest should be mandatory;
- (vi) any discretion as to whether a post mortem should be ordered, whether clinical notes and records should be scrutinised and whether a full inquest hearing should be ordered, should be outlined in regulations to ensure uniformity of application;
- (vii) the question of whether an inquest takes place should not be contingent only on the outcome of a post mortem;
- (viii) the verdicts available at an inquest should be expanded to permit an examination of how the deceased came to die and the circumstances surrounding that death;
- (ix) there should be a clear mechanism whereby systemic errors identified in the Article 2 investigation or inquest can be reported directly to the Department of Health, Social Services and Public Safety, with a specified period in which a response should be issued;
- (x) given the potential complexities of healthcare fatalities and the fact that an inquest finding may reflect on the outcome of any civil litigation, consideration should be given to providing legal aid support for the family of the deceased at inquest proceedings;

(xi) where an inquest has found that an individual error has led to a death in hospital there should be an automatic reporting requirement to the professional conduct mechanisms of the appropriate medical registration body.

The rationale underpinning the Strasbourg jurisprudence which developed the Article 2 procedural obligations was presumably the need to ensure that a state could take action to prevent a repetition of the circumstances which led to the loss of life. Unexpected deaths in healthcare may be the result of systemic or individual failings. There is a clear need for an investigative mechanism which adequately and appropriately addresses the circumstances surrounding these deaths. The Article 2 jurisprudence imposes an obligation upon the state to establish investigative procedures which will address that need. In light of the obvious shortcomings of the current mechanisms for investigating healthcare fatalities in Northern Ireland, and the financial and emotional cost of avoidable healthcare fatalities, that obligation has become an urgent imperative.

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